UNIVERSIDAD PARA LA COOPERACION INTERNACIONAL
(UCI)

PROJECT MANAGEMENT PLAN FOR THE IMPLEMENTATION OF FOOD AND DRUG ADMINISTRATION (FDA) FOOD SAFETY REGULATIONS AT CHOO'S ENTERPRISES, BARBADOS

NADINE BENN-GREAVES

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Master in Project Management (MPM) Degree

Cristian Soto Vasquez

TUTOR

James Perez C
REVIEWER No.1

Sophia Crawford
REVIEWER No.2

Nadine Benn-Greaves
STUDENT

DEDICATION

This research project is dedicated to my mentors (Mr. Ralph Bizzy Williams, Susan Branker Greene, Raquel Lloyd) for giving me more than one reason to continue to strive for excellence; to my mother for nurturing me and helping to be who I am today and my dad, Cecil Benn, for being my support and vessel of wisdom. Also, to my very good friend and business partner Suzzette Roberts, thank you for pushing me even when I was down and wanted to give up. Above all, to my husband, my Lord and my Savior God, thank you for being my refuge and strength and helping me to see this project through to the end.

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ABBREVIATIONS AND ACRONYMS

CA	Corrective Action/s
CCPs	Critical Control Point
CGMPs	Current Good Manufacturing Practices
FDA	Food and Drug Administration
FGP	Final Graduation Project
FSMA	Food Safety Modernization Act
FSPC	Food Safety Preventive Controls
FSQ	Food Safety & Quality
GAPs	Good Agricultural Practices
GMPs	Good Manufacturing Practices*
HACCP	Hazard Analysis And Critical Control Points
ITTO	Inputs, Tools & Techniques and Outputs
NC	Non-conformances
PCQI	Preventive Controls Qualified Individual
PM	Project Management
PMBOK Guide	Project Management Body of Knowledge
PMI	Project Management Institute
SBA	Small Business Association
SMEs	Budding micro/small and medium enterprises/entrepreneurs
SOP	Standard Operation Procedures
TOR	Terms of Reference
WBS	Work Breakdown Schedule
YES	Youth Entrepreneurship Scheme

EXECUTIVE SUMMARY (ABSTRACT)

Choo's Enterprises Ltd. is a Barbadian owned company which is known for producing high quality food products, mainly herbs, spices, exotic spice blends, condiments, syrups, concentrates and sauces under the brand "Try It" and distributing bulk food items since 1983. They currently market these products to all segments of the retailing, catering and manufacturing trade in Barbados only, but since they are actively seeking to export their food products to the USA, they must first comply with Food and Drug Administration (FDA) food safety requirements and this requires the implementation of their international Food Safety Regulations. They therefore reached out to FSQ Solutions Inc. to assist with them with this project.

FSQ Solutions Inc. is a "small company established in response to the specific food safety, hygiene, and quality management needs of budding micro/small and medium enterprises/entrepreneurs (SMEs) in the food industry across Barbados" (FSQ Solutions Inc., 2011, p. 2). Since they have worked on several similar projects, Choo's Enterprises decided to solicit their services for this project.

The Managing Director of Choo's Enterprises Ltd. decided that in the absence of a Project Management Plan for this project, one was needed to enhance the success of this project. FSQ Solutions Inc. therefore worked on creating a Project Management Plan for the implementation of the FDA Food Safety Regulations at the facility with all the sections of the Project Management Plan along with all of the tools, techniques, and concepts needed using the standards set out by the PMBOK Guide.

Generally, the implementation of Food Safety systems fails due to the process being driven by manufacturing units rather than initiated by management. In addition, the implementation is usually done backwards, without the prerequisite training and support, and this can lead to several serious issues, such as: failure to identify hazards and CCPs correctly; inadequate provision of resources; poor management commitment and culture; poor quality data and information; poor understanding of the requirements; and poor training and technical leadership. In order to avoid these pitfalls, proper planning is required. Therefore, for better implementation and stability of such a system, the creation of a Project Management Plan is critical.

The general objective for this project was to create a Project Management Plan, using the standards set out by the PMBOK Guide, for the implementation of the FDA Food Safety Regulations at Choo's Enterprises. The specific objectives were to: create a project charter that formally sanctions the project and provides the project manager with the authority to apply organizational resources to the project activities; create a scope management plan to ensure that all works essential for the successful completion of the project are encompassed; create a schedule management plan to sustain the development and management of the project

schedule within the time constraints; create a cost management plan to define the processes for developing and estimating the project budget; develop a quality management plan to identify and manage the quality requirements for the project and the food products to ensure the results meet stakeholders' expectations; create a resource management plan to ensure that all the required human resources, facilities, equipment, materials, supplies and other resources needed are identified and the critical teams acquired and developed; craft a communication management plan to ensure the timely and effective communication to stakeholders of needs, status and other fundamental information; create a risk management plan to ascertain and scrutinize the risks to the successful completion of the project and develop plans to minimize the likelihood and severity of the risks; generate a procurement management plan to be used in attaining products, services or results required by the project, and build a stakeholder management plan to identify the people, groups or organizations that could impact the project and develop effective strategies for their engagement in order to support the project's timely and successful execution and within the approved constraints.

The methodology employed for this project involved sourcing information mainly from field observation, structured questionnaires, surveys/audits, interview schedules, notes, meeting minutes, internet communications and correspondence, as well as standards, especially the Guide to the Project Management Body of Knowledge (PMBOK® Guide) Sixth Edition, other books, official publications and library databases. The evaluation of data obtained was done using analytical statistical techniques from various tools such as templates and checklists for each process component in the planning process group of activities in order to develop the Project Management Plan.

In conclusion, FSQ Solutions did an exceptional job in managing the project and several scheduled meetings were held with the Project Manager and the selected project team members in order to develop the elements needed as part of the attainment of the objectives of the Project Management Plan. The methodologies and tools outlined in Section 3 of this FGP for the FDA Food Safety Regulations Implementation at Choo' s Enterprises were also used in the development process. The templates used in developing the deliverables by the team were adapted from the PMBOK® Guide and PMI database as well as the Lean Six Sigma Guide.

As a means of continuous improvement, it is recommended that FSQ Solutions, as a Project Manager, contract a team responsible for the review of documentation for legal reasons as a service to clients; provide services and training on the bidding, TOR, SOW and tendering process to assist clients in these aspects; invest in the tools required to complete quantitative risk analyses for all projects and have clients use the Project Management Guide or Framework to help direct the development of all project management tools. In addition, have full transparency when documents are updated in a timely fashion but disseminate to all respective personnel, including management, stakeholders and directors, so everyone will know the impact of the delays for various activities on the project's outcome and timelines.

1 INTRODUCTION

1.1. Background

FSQ (Food Safety and Quality) Solutions Inc. was founded in 2007 and is geared at providing support services, auditing and training in the areas of Food Safety Management (inclusive of HACCP, FSPC, GAPs and GMPs); Quality, Environmental and Entrepreneurship Management; Quality Assurance and Control; New Plant/Product Development and Continuous Product Improvement. They cater mainly to stakeholders in the food industry but also to other budding and existing entrepreneurs in various areas of business. They have received several awards, such as the Professional Services Sectorial Award by the Barbados Small Business Association (SBA) and the Youth Entrepreneurship Scheme (YES) Small Business Start-Up Award in 2011. The company has had the opportunity to work with several companies on various food-related projects and as such, Choo's Enterprises Ltd asked them to assist with the Project Management Plan for the Implementation of the Food and Drug Administration (FDA) Food Safety Regulations at their facility.

Choo's Enterprises Ltd. is a Barbadian owned company, which is known for producing high quality food products and distributing bulk food items since 1983. The main activity of the company is the manufacturing of herbs, spices, exotic spice blends, condiments, syrups, concentrates and sauces under the brand "Try It". They currently market these products to all segments of the retailing, catering and manufacturing trade in Barbados with the slogan "Try it, you will like it". The plant was previously located in Whitepark Road, in the heart of Bridgetown, the city of St. Michael, but due to plant expansion they now operate from a new location in the same city, under the new management of Mr. Edwin Choo, the Managing Director. Under his stewardship, Choo's Enterprises Ltd. acquired the company Windmill Products and commenced providing co-packing services for many other small businesses across the island.

1.2. Statement of the problem

As a food manufacturing company, Choo's Enterprises had never sought to export their food products or look into implementing a food safety system. They did not see the need for the aforementioned since they were satisfied with supplying only the local market. However, due to the economic situation in Barbados over the past few years, the need to increase profits due to a saturated market and the increasing monitoring of food safety practices within the company by local customers, they are actively seeking to export their food products to the United States of America (USA). In order to achieve this, they must first comply with Food and Drug Administration (FDA) Preventive Controls for Human Food (FSPC) regulation.

The regulation requires that certain activities must be completed by a "preventive controls qualified individual (PCQI)" who has "successfully completed training in the development and application of risk-based preventive controls" (FSPCA, 2019) and these activities are centered on the Current Good Manufacturing Practices (CGMPs), Hazard Analysis, and Risk-based Preventive Controls for Human Food. The intent of this regulation is to ensure safe manufacturing/processing, packing and holding of food products for human consumption in the United States. As a result, companies exporting to the USA must also have trained PCQIs who are trained to the "standardized curriculum" recognized by the FDA. This "standardized curriculum" was developed by the FSPCA and is taught only by Lead Instructors trained by the FSPCA.

Therefore, in the absence of a Project Management Plan for this project, FSQ Solutions Inc. will create all the sections of the Project Management Plan for the company, along with all of the tools, techniques, and concepts needed to assist them with the successful planning for the implementation and maintenance of the regulation, in order to meet the client's objectives.

1.3. Purpose

Generally, the implementation of Food Safety systems fails due to the process being driven by manufacturing units rather than initiated by corporate or management. In addition, the implementation is usually done backwards, without the prerequisite training and support, and this can lead to: failure to identify hazards and CCPs correctly; inadequate provision of resources; poor management commitment and culture; poor quality data and information; poor understanding of the requirements; and poor training and technical leadership. In order to avoid these pitfalls, proper planning is required. Therefore, for better implementation and stability of such a system, the creation of a Project Management Plan is needed. This would allow for an increase in the success of effective and efficient project execution, ensure proper process monitoring, controlling and closing, and continuous improvement and maintenance of the Food Safety System.

1.4. General Objective

To create a Project Management Plan using the standards set out by the PMBOK Guide, for the implementation of the Food and Drug Administration (FDA) Food Safety Regulations at Choo's Enterprises for the purpose of USA import compliance.

1.5. Specific objectives

1. To create a project charter that formally sanctions the project and provides the project manager with the authority to apply organizational resources to the project activities for the project management plan.

2. To build a stakeholder management plan to identify the people, groups or organizations that could impact positively on the project and develop strategies for effective stakeholder engagement in order to support the project's timely and successful execution.

3. To create a scope management plan to ensure that all works essential for the successful completion of the project are encompassed.

4. To create a schedule management plan to sustain the development and management of the project schedule within the time constraints outlined.

5. To create a cost management plan to define the processes for developing and estimating the project budget that ensures the project is completed within the approved budget constraints.

6. To develop a quality management plan to identify and manage the quality requirements for the project as well as the food products produced by Choo's Enterprises Ltd to ensure the results meet customers' and other stakeholders' expectations.

7. To create a resource management plan to ensure that all the required human resources, facilities, equipment, materials, supplies and other resources needed for project success are identified and the critical teams are acquired and developed.

8. To craft a communication management plan to ensure the timely and effective communication of the project needs, status and other fundamental information to its stakeholders.

9. To create a risk management plan to ascertain and scrutinize the risks to the successful completion of the project and develop plans to minimize the likelihood and severity of the risks.

10. To generate a procurement management plan to be used in attaining products, services or results required by the project.

2 THEORETICAL FRAMEWORK

2.1. Company/Enterprise Framework

2.1.1.1 Company/Enterprise Background

FSQ Solutions Inc. is a “small company established in response to the specific food safety, hygiene, and quality management needs of budding micro/small and medium enterprises/entrepreneurs (SMEs) in the food industry across Barbados” (FSQ Solutions Inc., 2011, p. 2). They have worked on several types of projects similar to this project, where they have successfully brought many SMEs from the initial stage of having no food standards in place to that of compliance to recognized international standards. Just like their past projects and for this project, their client’s needs are their main focus as they work with them to reflect who they are and what is important to them.

FSQ Solutions Inc. (2011) indicated that they usually “endeavor to make all projects attainable and this in turn leads to an environment that allows for clarity, focus, less apprehension and accomplishment for the clients” (p. 2). As a result, clients have often complimented them for their professionalism, the hands-on way in which they approach projects, their ability to share information based on their wealth of knowledge about food safety requirements compliance and their quest in supporting them to successfully attain the necessary information as quickly as possible.

FSQ Solutions Inc. was contracted to work on this project because of the aforementioned, but the Managing Director decided that a standard for project planning is needed. Therefore, to enhance the success of this project, a project management plan must be generated as a basis for the execution of the project.

2.1.1.2 Mission and Vision Statements

The mission of FSQ Solutions Inc. (2011) from inception has been to provide essential but superior technological support and training needed in the food sector for successful business sustainability. They pride themselves on consistent professional, personalized, timely and quality service, which caters to the individual needs of their clients. In addition, they use strong customer relations and hands-on user-friendly tools to complement the services provided in order to help their clients succeed at growing their business (FSQ Solutions Inc., 2011, p. 3).

In alignment with this mission, once they were contacted by Choo's Enterprises to submit a proposal for this opportunity via verbal communication of the Terms of Reference (TOR) for this project, they ensured that the company define the scope of work required and their respective stakeholder needs and responsibilities. FSQ Solutions Inc. met and communicated with the Office Manager of Choo's Enterprises on several occasions via virtual meetings and teleconferences in order to finalize a proposal which not only catered to their individual training and consultation needs but one that allows them to still continue production as a business.

Thus, their vision as a company is "to be the leading provider of the best technical support and training in the area of food safety, service and quality for the food sector throughout the region, while adding value to their customers' productive environment" (FSQ Solutions Inc., 2011, p. 3).

2.1.1.3 Organizational Structure

FSQ Solutions Inc. is a microenterprise comprising shareholders, directors and officers. They are staffed with three (3) permanent employees but as projects come on board, the team can increase to ten (10) with the use of contracted operational and project management team members for executing a project such as this (C. Griffith, personal communication, May 2019).

The current officers elected by the Board of Directors include the Managing Director, Vice President and Company Secretary where each post has a specific function and duty as they carry out the day-to-day activities of the business. The organizational structure (FSQ Solutions Inc., 2011, p. 4) for the company is depicted in Figure 2-1.

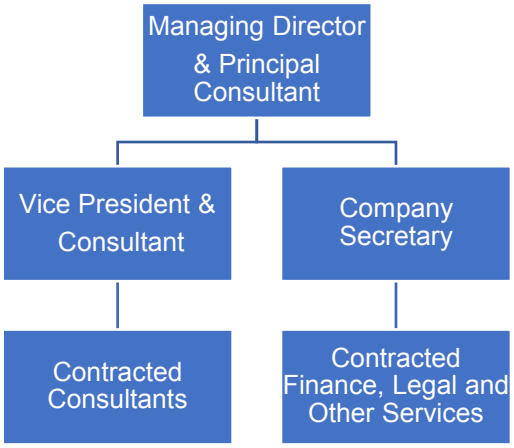

Figure 2-1 Organizational Structure

(Source: Reprinted from FSQ Solutions Inc. Business Plan, p. 5, FSQ Solutions Inc., 2011. Copyright 2011 by FSQ Solutions Inc. All rights reserved.)

According to C. Griffith (personal communication, May 2019), the shareholders own a share of stock in the corporation and play a very active role in overseeing who manages the business but they do not run the business or manage it in any way. They significantly affect the business by electing the Board of Directors and ensuring that they have a shared vision for the direction of the company and that the set policies are carried out as they oversee the activities of the business. The Managing Director carries the majority of the responsibility of the enforcement of corporate policy and feeds information upwards to the Board of Directors. The Vice President, who is also a Consultant for the business, fills in for the Managing Director in their absence while the Secretary maintains corporate records and books. The team ensure that they norm and storm before working with the clients to reflect what is important to them while ensuring consistent personalized, professional, timely and quality service.

2.1.1.4 Products Offered

FSQ Solutions Inc. (2011) is a “very dynamic company geared towards providing technical support services such as auditing, coaching, mentoring, and training” in the following areas:

- Food Safety Management Systems Development, Implementation and Maintenance
- Quality, Environmental and Entrepreneurship Management
- Quality Assurance and Control Implementation
- New Plant/Product Development
- Continuous Product Improvement

They also offer Root Cause Analysis for any problems being experienced in the area of food production, safety and quality (p. 3).

The company sees this project as an opportunity to provide the technical support services of auditing, mentoring, and training for the implementation of the Food and Drug Administration (FDA) Food Safety Regulations at Choo’s Enterprises, as well as coaching on how it can be successfully executed using a Project Management Plan based on the standards set out by the PMBOK Guide.

2.2. Project Management Concepts

2.2.1.1 Project

A project is defined as “a temporary endeavour undertaken to create a unique product, service, or result” (Project Management Institute, 2017, p. 4). This project is classifed as a unique combination project of several products, services and results based on the objectives desired and will be executed by a single individual. It has a definite beginning and ending but the products, services and results created will outlast the project.

For FSQ Solutions Inc., the implementation of the requirements of any specific food safety regulation or standard and its supporting elements results in the generation of a Food Safety System. For this project, the system being implemented must comply with the FDA Food Safety Modernization Act (FSMA) prevention- and risk-based food safety standards, and its supporting elements require comprehensive, science-based preventive controls. According to the Committee to Ensure Safe Food from Production to Consumption (1998), “the mission of an effective food safety system is to protect and improve the public health by ensuring that foods meet science-based safety standards through the integrated activities of the public and private sectors and the consumer”, as depicted in Figure 2-2.

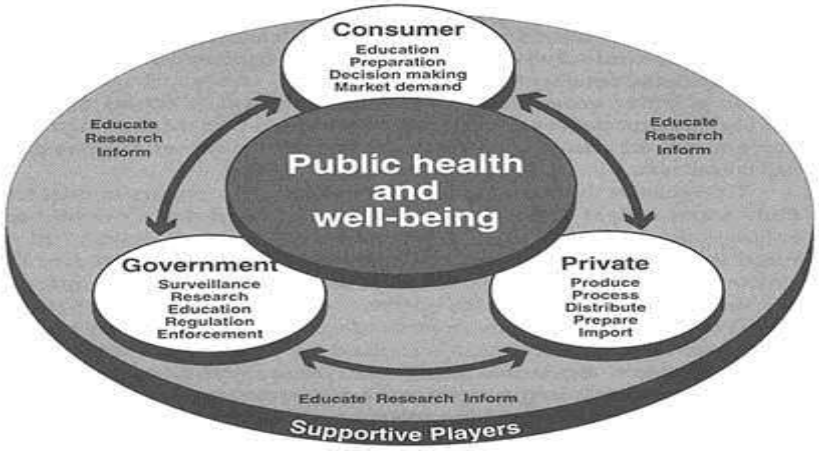

Figure 2-2 Attributes of an Effective Food Safety System
(Source: Reprinted from Committee to Ensure Safe Food From Production to Consumption 1998, National Academy of Sciences. Copyright 1998 by the National Academy of Sciences)

2.2.1.2 Project management

According to the PMBOK® Guide, “project management is the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements” (Project Management Institute, 2016, 2017, p. 10). The PMBOK® Guide contains the standard for managing most projects most of the time, across many types of industries, and includes proven traditional practices that are widely used for which organizations can develop the methodologies, policies, procedures, rules, tools, techniques and life cycles phases needed in project management (Project Management Institute, 2016, 2017, p. 2).

Therefore, the creation of a Project Management Plan for the implementation of the FDA Food Safety Regulations at Choo’s Enterprises will be managed as a project for the development of this Final Graduation Project (FGP) using the standards set out by the PMBOK Guide but the implementation will be managed as another project outside of this FGP. The project will be managed to meet the general and specific objectives in relation to time, cost and quality while taking into consideration the following:

- Organizational project fit, i.e. strategic goals, organizational culture and structure and who may affect, be affected by, or perceive themselves to be affected by a decision, activity, or outcome of the project.
- Over time how the project will evolve, i.e. the Project Life cycle.
- In order to successfully manage this project, what knowledge is required, i.e. the Project Knowledge Areas.

2.2.1.3 Project life cycle

The “series of phases that a project passes through from its initiation to its closure” is called the project Life Cycle, like that shown in Figure 2-3. It defines the transitional activities, work and resources involved in each phase from the beginning to the end of the project, and it may be one phase of the product life

cycle (Project Management Institute, 2017, p. 19). The phases of the product life cycle are shown in Figure 2-4.

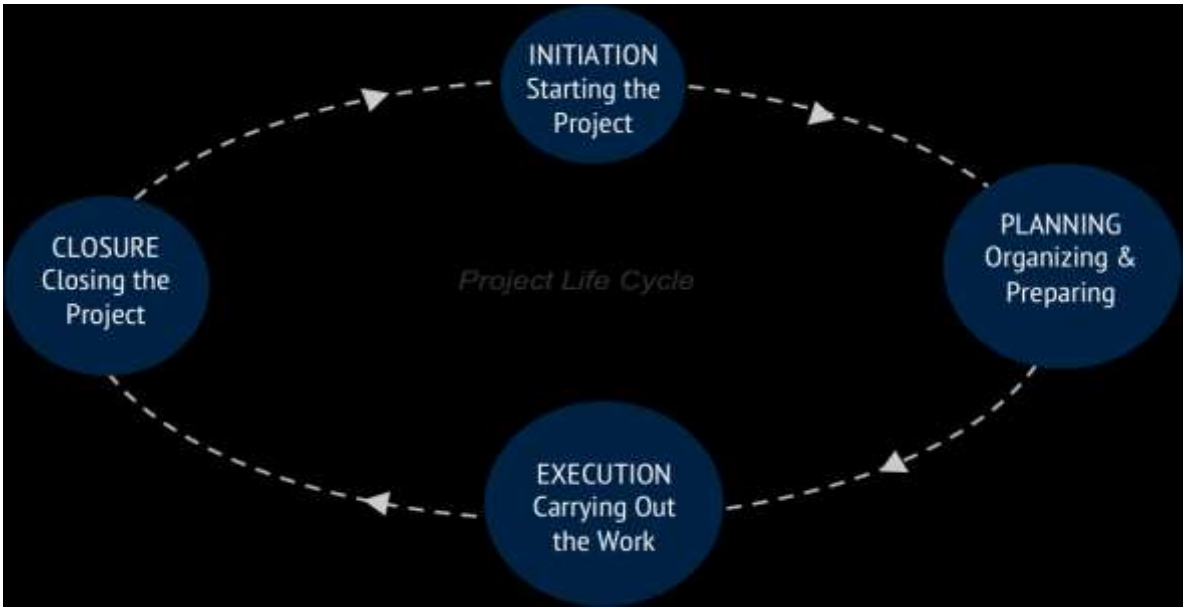

Figure 2-3 Project Life Cycle Phases.

(Source: Reprinted from Mavenlink - What is the Project Life Cycle (2019). Retrieved from https://www.mavenlink.com/resources/what-is-the-professional-services-project-life-cycle)

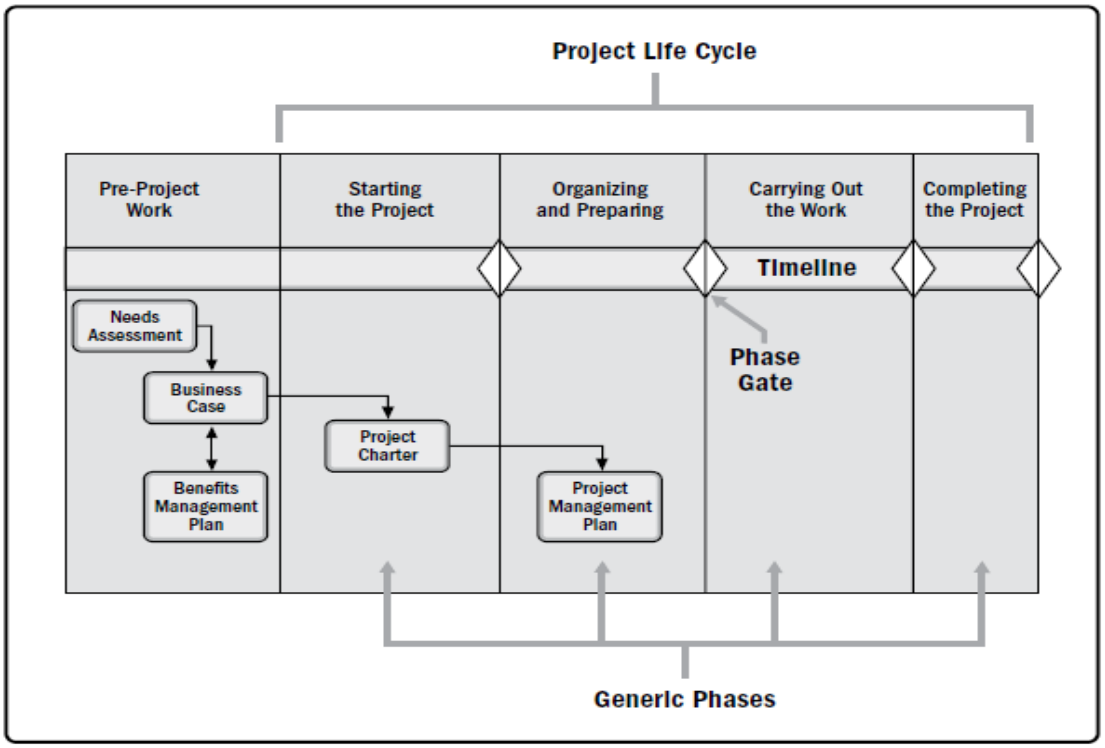

Figure 2-4 Typical Cost and Staffing Levels Across a Generic Project Life Cycle Structure.

(Source: Reprinted from PMBOK Guide (p. 30), Copyright 2017 by Project Management Institute, Inc. All rights reserved)

The life cycle of this project will move from the generic start to finish stages via different phases. However, within one phase you might go through all the Process Groups, or just some of them. This may vary widely based on the project but it is the basic structure for managing a project. The Project Management Institute indicated that a life cycle can be documented within a methodology and determined or shaped by the unique aspects of the organization, industry, or technology employed. Regardless of the specific work involved, the phases, whether sequential, iterative or overlapping, can be broken down by functional or partial objectives, intermediate results or deliverables, specific milestones within the overall scope of work, or financial availability but they are generally time bound, with a start and ending or control point (Project Management Institute 2017, p. 547-548).

2.2.1.4 Project management processes

The appropriate application and integration of logically grouped project management processes is how Project management is accomplished and these processes are categorized into five Process Groups (Project Management Institute, 2017, p. 23). These five Process Groups, as depicted in Figure 2-5, are Initiating, Planning, Executing, Monitoring and Controlling, and Closing; and these are further explained in Figure 2-6. The Process Group Interactions within a Phase or Project like this FGP is depicted in Figure 2-7.

Figure 2-5 Project Management Processes.

(Source: Reprinted from Demystifying the 5 Phases of Project Management. (2019). Smartsheet Inc. Retrieved from https://www.smartsheet.com/blog/demystifying-5-phases-project-management)

- **Initiating Process Group.** Those processes performed to define a new project or a new phase of an existing project by obtaining authorization to start the project or phase.
- **Planning Process Group.** Those processes required to establish the scope of the project, refine the objectives, and define the course of action required to attain the objectives that the project was undertaken to achieve.
- **Executing Process Group.** Those processes performed to complete the work defined in the project management plan to satisfy the project specifications.
- **Monitoring and Controlling Process Group.** Those processes required to track, review, and regulate the progress and performance of the project; identify any areas in which changes to the plan are required; and initiate the corresponding changes.
- **Closing Process Group.** Those processes performed to finalize all activities across all Process Groups to formally close the project or phase.

Figure 2-6 Project Management Processes Groups.
(Source: Reprinted from PMBOK Guide (p. 23), Copyright 2017 by Project Management Institute Inc. All rights reserved)

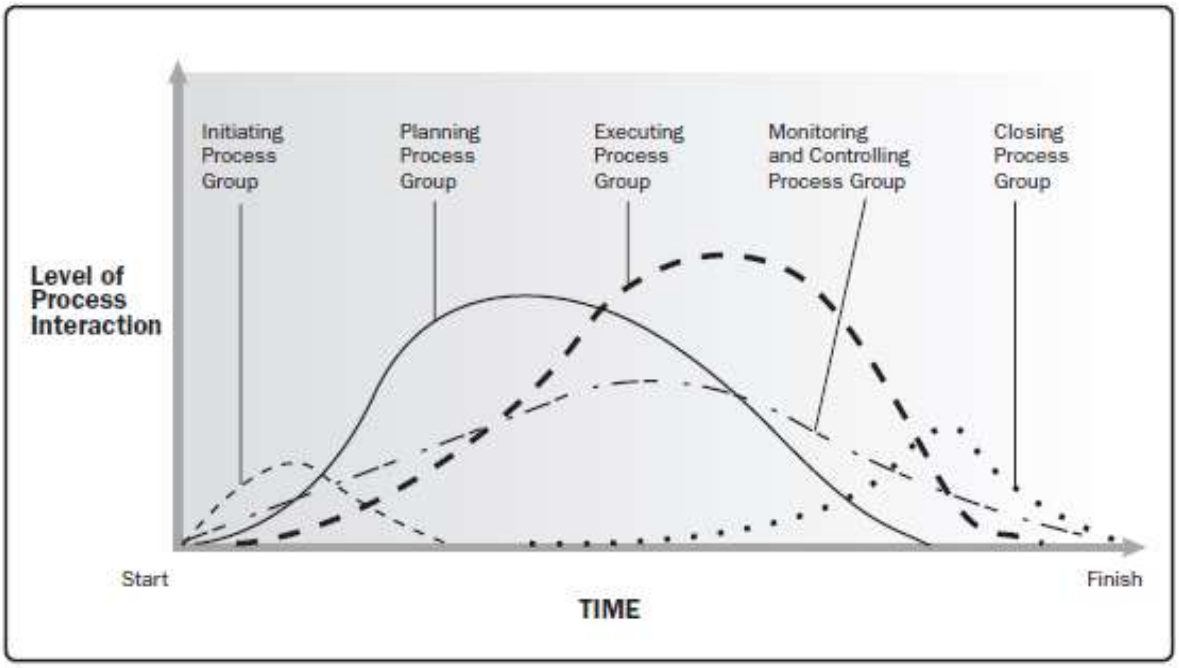

Figure 2-7 Process Group Interactions Within a Project or Phase.
(Source: Reprinted from PMBOK Guide (p. 555), Copyright 2017 by Project Management Institute Inc. All rights reserved)

The processes involved in initiating and planning a project will be used to develop this FGP while the initiation, planning, execution, monitoring and controlling, and closing phases (stages) will be used in the creation of the PM Plan.

This will consist of all the required documents for the initiating and planning processes as shown in Figure 2-8.

Knowledge Areas	Initiating Process Group	Planning Process Group
4. Project Integration Management	4.1 Develop Project Charter	4.2 Develop Project Management Plan
5. Project Scope Management		5.1 Plan Scope Management 5.2 Collect Requirements 5.3 Define Scope 5.4 Create WBS
6. Project Schedule Management		6.1 Plan Schedule Management 6.2 Define Activities 6.3 Sequence Activities 6.4 Estimate Activity Durations 6.5 Develop Schedule
7. Project Cost Management		7.1 Plan Cost Management 7.2 Estimate Costs 7.3 Determine Budget
8. Project Quality Management		8.1 Plan Quality Management
9. Project Resource Management		9.1 Plan Resource Management 9.2 Estimate Activity Resources
10. Project Communications Management		10.1 Plan Communications Management
11. Project Risk Management		11.1 Plan Risk Management 11.2 Identify Risks 11.3 Perform Qualitative Risk Analysis 11.4 Perform Quantitative Risk Analysis 11.5 Plan Risk Responses
12. Project Procurement Management		12.1 Plan Procurement Management
13. Project Stakeholder Management	13.1 Identify Stakeholders	13.2 Plan Stakeholder Engagement

Figure 2-8 Project Management Process Group and Knowledge Area Mapping
(Source: Reprinted from A PMBOK Guide (p. 25), Copyright 2017 by Project Management Institute Inc.)

During the initiation process, FSQ Solutions Inc. sought to define the project on a broader level after consultation with the Office Manager at Choo's Enterprise to determine if the project was feasible and should be undertaken. They created a project charter for the project that outlined the purpose and requirements of the project.

During the planning phase, the project management plan will be developed. This involves identifying the cost, quality, available resources, and a realistic timetable. The project management plan and project documents developed as outputs from this Process Group will explore all aspects of the scope, time, costs, quality, communications, human resources, risks, procurements, and stakeholder management as shown in Figure 2-9 (Project Management Institute, 2017, p. 566). The project plans will also include establishing baselines or performance measures using the scope, schedule and cost of the project. Roles and responsibilities will be clearly defined, so everyone involved knows what they are accountable for. In addition, the following documents will be developed ("Demystifying", 2019):

- Scope Statement – A document that clearly defines the business need, benefits of the project, objectives, deliverables, and key milestones. A scope statement may change during the project, but it should not be done without the approval of the project manager and the sponsor.

- Work Breakdown Schedule (WBS) – This is a visual representation that breaks down the scope of the project into manageable sections for the team.

- Milestones – High-level goals that need to be met throughout the project are identified and included in a Gantt chart.

- Gantt chart – A visual timeline that can be used to plan tasks and visualize a project's timeline.

- Communication Plan – This is of particular importance if the project involves external stakeholders. Develop the proper messaging around the project and create a schedule of when to communicate with team members based on deliverables and milestones.

- Risk Management Plan – Identify all foreseeable risks. Common risks include unrealistic time and cost estimates, customer review cycle, budget cuts, changing requirements, and lack of committed resources.

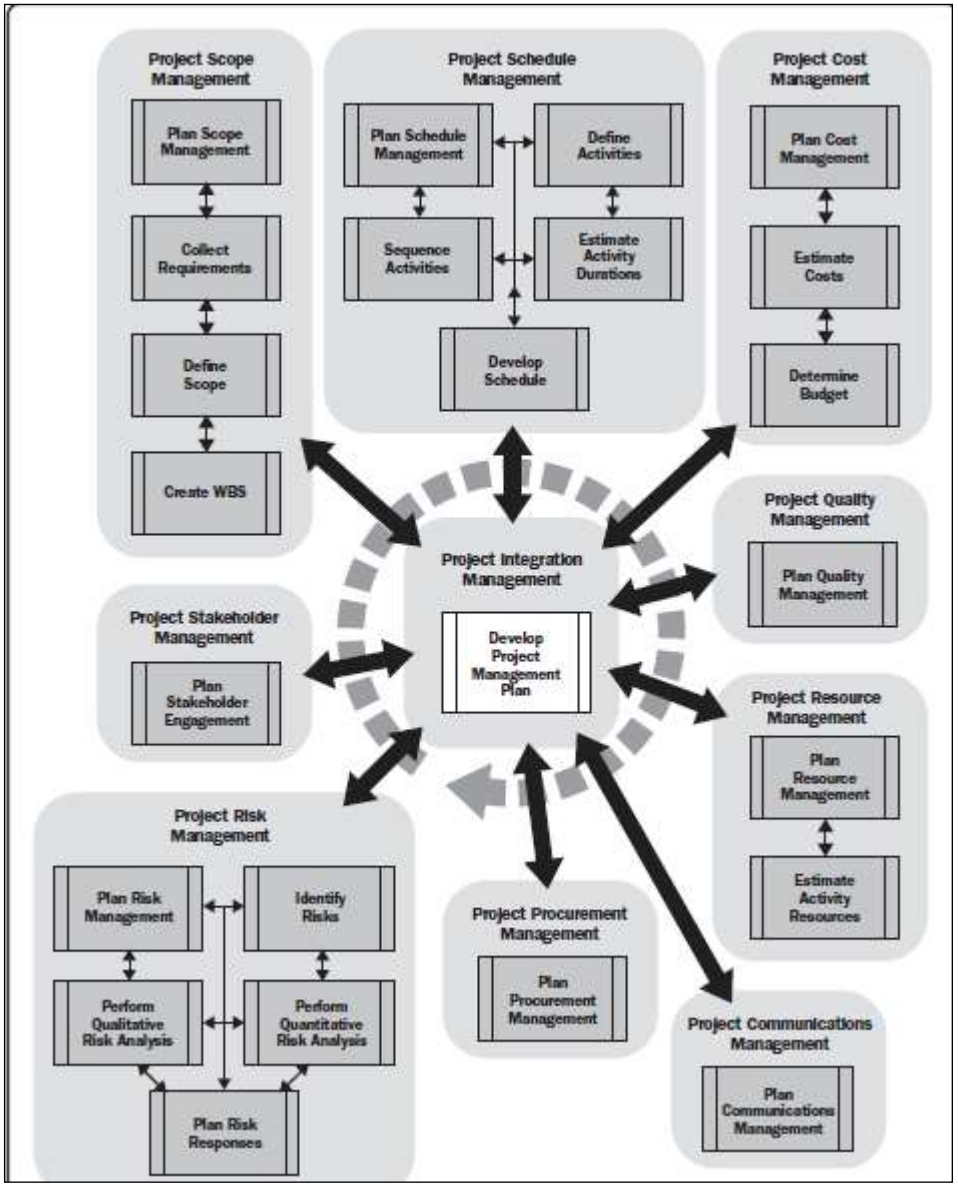

Figure 2-9 The Planning Process Group

(Source: Reprinted from A PMBOK Guide (p. 566), Copyright 2017 by Project Management Institute Inc.)

- Processes and Procedures - Processes and procedures for conducting project work include, but are not limited to the following:
    - Guidelines and criteria for tailoring the organization's set of standard processes and procedures to satisfy the specific needs of the project;
    - Specific organizational standards such as policies (e.g., human resource policies, health and safety policies, ethics policies, and project management policies), product and project life cycles, and quality policies and procedures (e.g., process audits, improvement targets, checklists, and standardized process definitions for use in the organization); and
    - Templates (e.g., risk statement templates, stakeholder register templates, and contract templates) (Project Management Institute, 2017, p. 40).

2.2.1.5 Project management knowledge areas

As outlined in the Project Management Institute PMBOK Guide (2017), all the project management processes outlined are grouped into ten separate Knowledge Areas, which are (p. 23):

- Project Integration Management
- Project Scope Management
- Project Schedule Management
- Project Cost Management
- Project Quality Management
- Project Resource Management
- Project Communications Management
- Project Risk Management
- Project Procurement Management
- Project Stakeholder Management

A Knowledge Area is an "identified area of project management defined by its knowledge requirements and described in terms of its component processes, practices, inputs, outputs, tools, and techniques" used frequently on most projects (Project Management Institute, 2017, p. 23).

2.2.1.6 Project Integration Management

Project Integration Management includes “the processes and activities to identify, define, combine, unify, and coordinate the various processes and project management activities within the Project Management Process Groups” (Project Management Institute, 2017, p. 71). Figure 2-10 presents an overview of the Inputs, Tools, Techniques and Outputs (ITTOs) for the discrete processes involved in Integration Management.

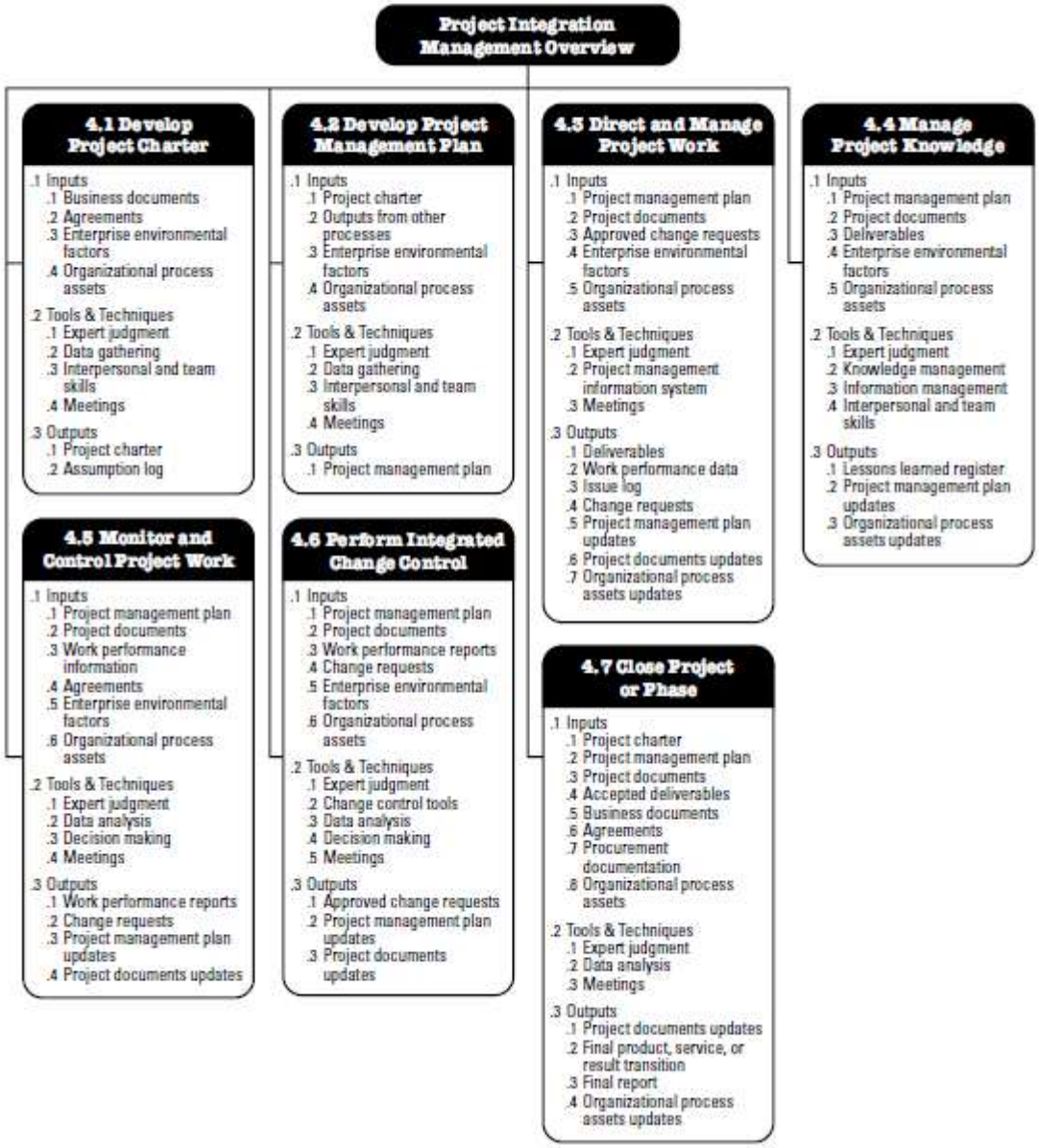

Figure 2-10 Project Integration Management Overview

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 71), Copyright 2017 by Project Management Institute Inc.)

As part of the Project Integration Management processes, FSQ Solutions Inc. will be developing a Project Charter and Project Management Plan for this project which will involve the “process of defining, repairing, and coordinating all subsidiary plans and integrating them into a comprehensive project management plan” (Project Management Institute, 2017, p. 64).

2.2.1.7 Project Scope Management

Project Scope Management includes “the processes required to ensure that the project includes all the work required, and only the work required, to complete the project successfully” (Project Management Institute, 2017, p. 130). Figure 2-11 gives an overview of the ITTOs for the Scope Management processes.

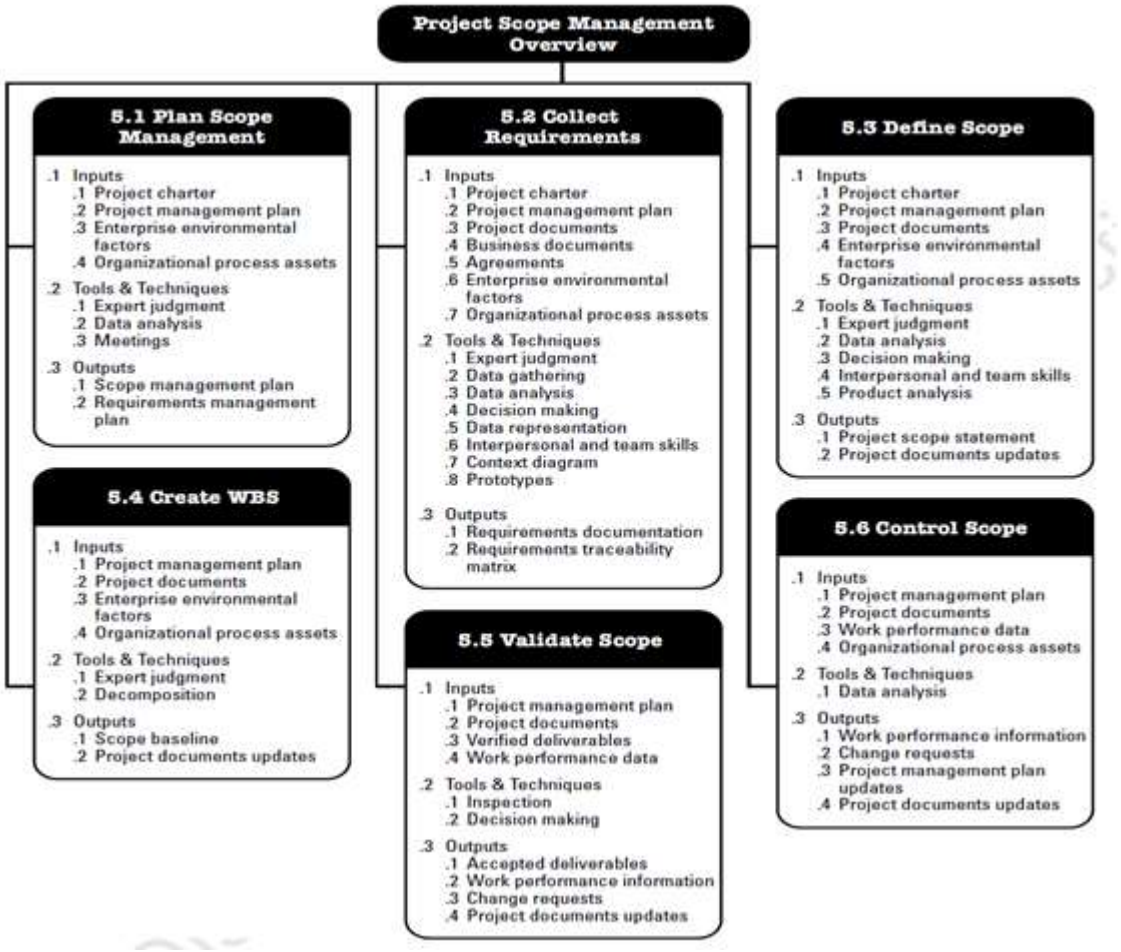

Figure 2-11 Project Scope Management Overview
(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 130), Copyright 2017 by Project Management Institute Inc.)

As part of the Project Scope Management processes, FSQ Solutions Inc. will be producing the following for this FGP:

- Planned Scope Management, i.e. creating a scope management plan that documents how the project scope will be defined, validated, and controlled.
- Collection of Requirements, i.e. determining, documenting, and managing stakeholder needs and requirements to meet project objectives.
- Defined Scope, i.e. developing a detailed description of the project and product.
- Work Breakdown Structure (WBS), i.e. subdividing project deliverables and project work into smaller, more manageable components.

2.2.1.8 Project Schedule Management

Project Schedule Management includes the processes required to manage the timely completion of the project (Project Management Institute, 2017, p. 173). The ITTOs for this process are shown in Figure 2-12 and FSQ Solutions Inc. will be executing the following for this FGP:

- Plan Schedule Management, i.e. process of establishing the policies, procedures, and documentation for planning, developing, managing, executing, and controlling the project schedule.

- Defining Activities, i.e. identifying and documenting the specific actions to be performed to produce the project deliverables.

- Sequencing Activities, i.e. identifying and documenting relationships among the project activities.

- Estimate Activity Durations, i.e. estimating the number of work periods needed to complete individual activities with estimated resources.

- Develop Schedule, i.e. analyzing activity sequences, durations, resource requirements, and schedule constraints to create the project schedule model.

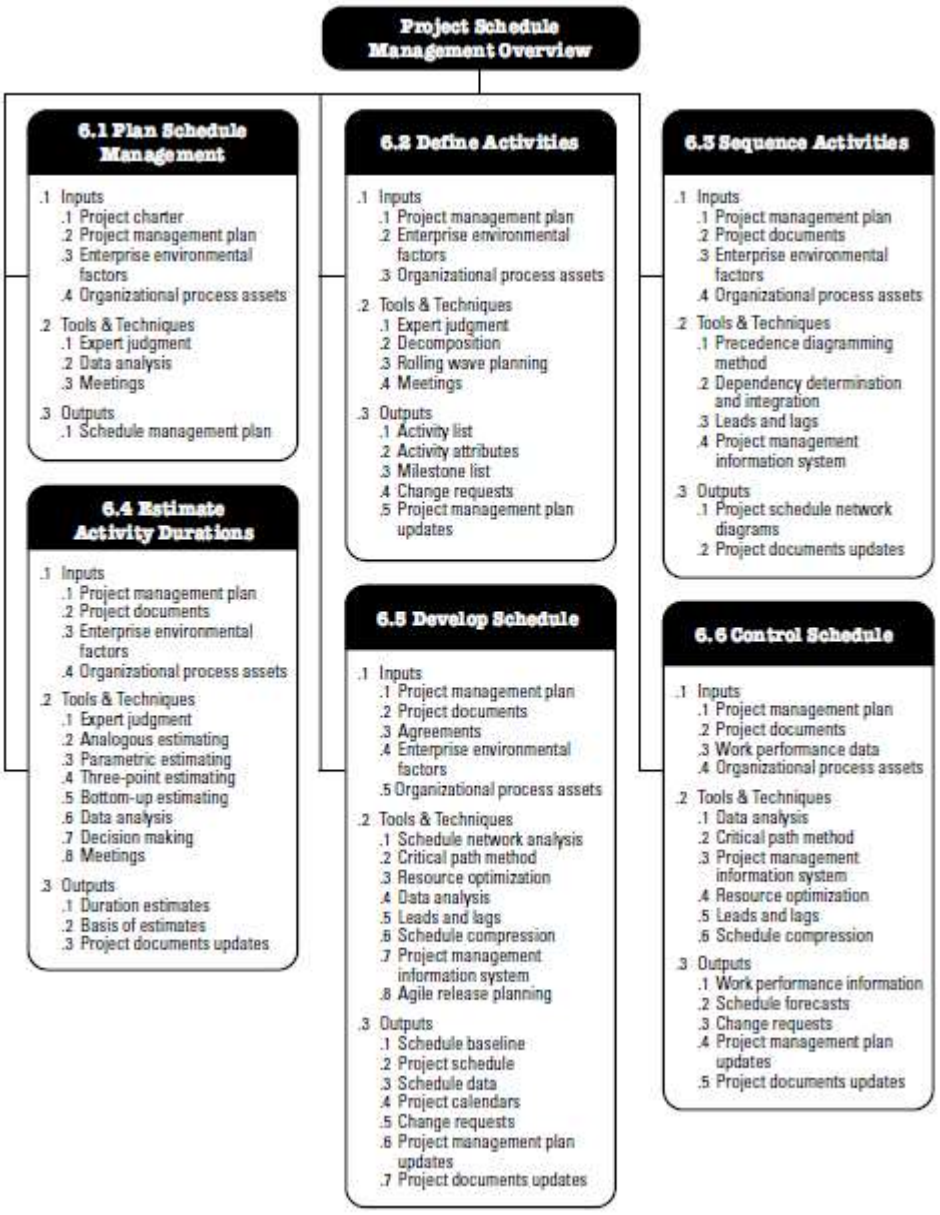

Figure 2-12 Project Schedule Management Overview.

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 174), Copyright 2017 by Project Management Institute Inc.)

2.2.1.9 Project Cost Management

Project Schedule Management includes the processes involved in planning, estimating, budgeting, financing, funding, managing, and controlling costs so that the project can be completed within the approved budget". Figure 2-13 provides an overview of the ITTOs for the Cost Management processes (Project Management Institute, 2017, p. 232).

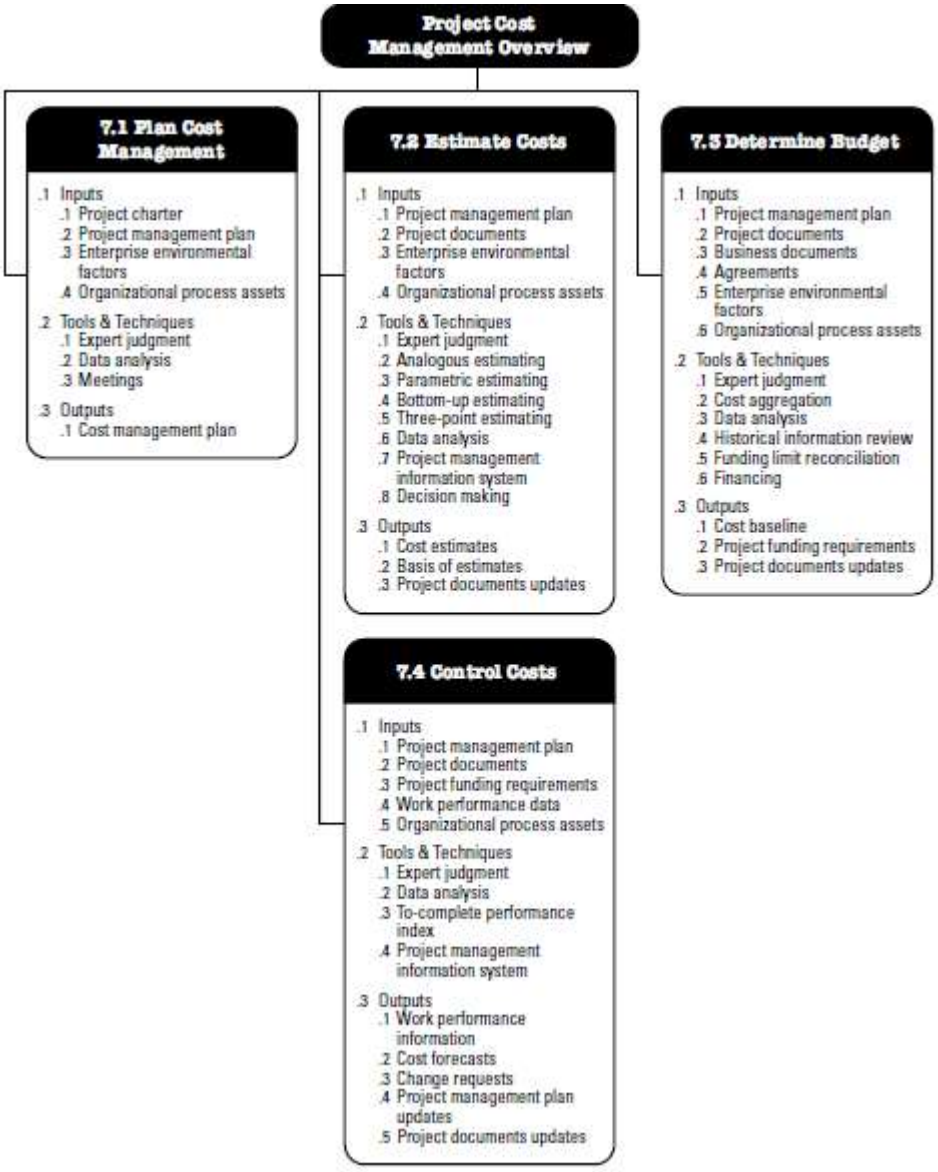

Figure 2-13 Project Cost Management Overview.

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 232), Copyright 2017 by Project Management Institute Inc.)

For this project, FSQ Solutions Inc. will be executing the following for the cost management planning phase:

- Planning Cost Management, i.e. establishing the policies, procedures, and documentation for planning, managing, expending, and controlling project costs.
- Estimating Costs, i.e. developing an approximation of the monetary resources needed to complete project activities.

- Determining the Budget, i.e. aggregating the estimated costs of individual activities or work packages to establish an authorized cost baseline.

2.2.1.10 Project Quality Management

Project Quality Management includes "the processes for incorporating the quality policies of the organization with regard to planning, managing and controlling the project and the product quality requirements in order to meet the needed objectives and support continuous process improvement activities" (Project Management Institute, 2017, p. 271).

According to Aized (as cited by Edward, 1968) 'quality' is defined as the "capacity of a product or service to satisfy the consumer requirements" (p. 220). Aized sums up quality as follows:

1. Quality is conforming to the standards and specifications of a product/service.

2. Quality is zero defects or meeting the specifications 100%.

3. Quality means that a product/service possesses the fitness for purpose of use based on its functions.

4. Quality is the ability of a product/service to meet the customer's needs and expectations.

5. Quality is assessed by the customer only, borne upon the critical features and characteristics of a product/service considered by the customer.

6. Quality is determined by the deviation of the measures of quality characteristics of a product.

7. Quality is customer satisfaction (Aized as cited by Edward, 1968).

The Quality Management process consists of several processes with inputs and outputs and Figure 2-14 delivers an overview of these ITTOs.

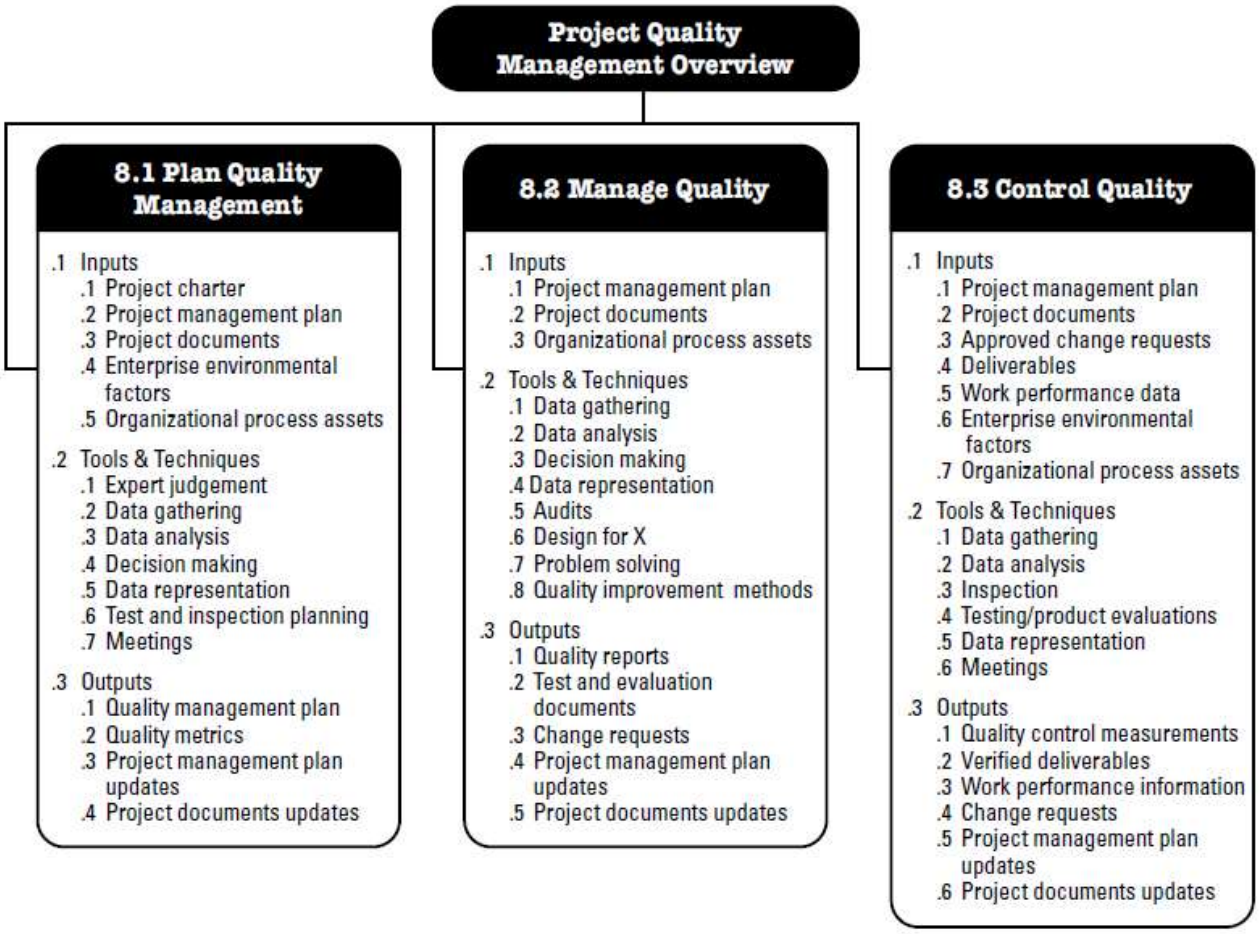

Figure 2-14 Project Quality Management Overview.

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 272), Copyright 2017 by Project Management Institute Inc.)

As cited in Juran (1974) “a quality management system can be divided into three stages: planning, controlling and improving”, as shown in Figure 2-15. According to Aized (2012) as cited in Harry (2000), Six Sigma represents a new, holistic, multidimensional systems approach to quality that replaces the form, fit and function specification of the past” (Aized, 2012, p. 225, p. 233). Six Sigma is more than just a process improvement program as it is based on concepts that focus on continuous quality improvements for achieving near perfection by restricting the number of possible defects to less than 3.4 defects per million utilizing several quality management tools (“Six Sigma”, 2019).

Figure 2-15 How to Implement Quality Project Management.

(Source: Ray, S. (2018) Project Quality Management – A Quick Guide. Retrieved from https://www.projectmanager.com/blog/project-quality-management-quick-guide.)

During this project, FSQ Solutions Inc. will be executing the Planning Quality Management process, which involves identifying quality requirements and/or standards for the project and its deliverables and documenting how the project will demonstrate compliance with quality requirements (Project Management Institute, 2017, p. 271). Six Sigma methodologies will be used in developing the standards for the project, as a measurement-based strategy for process improvement and increasing customer satisfaction.

2.2.1.11 Project Resource Management

Project Resource Management includes the “processes to identify, acquire and manage the resources required for the successful completion of the project” and the ITTOs for the processes involved are represented in Figure 2.2.16 (Project Management Institute, 2017, p. 307).

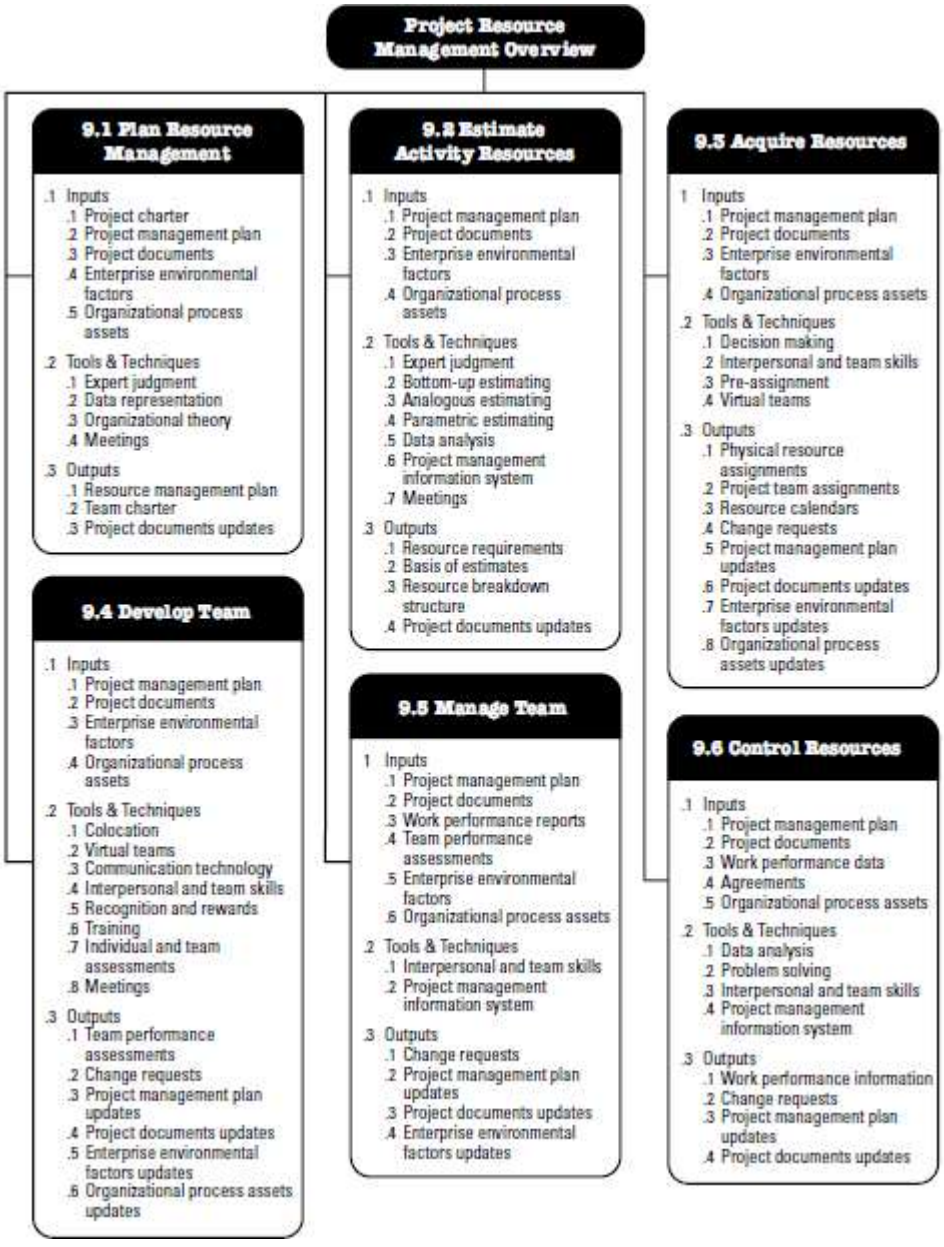

Figure 2-16 Project Resource Management Overview

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 308), Copyright 2017 by Project Management Institute Inc.)

During this project, FSQ Solutions Inc. will be executing the Planning Resources Management processes, which involves defining how to estimate, acquire, manage and utilize physical and team resources as well as the Estimate Activity Resources that involve estimating the team resources and the type and quantities of materials, equipment and supplies desired to accomplish the project deliverables.

In addition, for this project they will be presenting two (2) elements of the execution phase for this process that would have been completed, which are:

- Acquire Resources, i.e. obtaining team members, facilities, equipment, materials, supplies and other resources required for the project; as well as
- Develop Project Team, i.e. improving competencies, team member interaction, and team environment to enhance project performance (Project Management Institute, 2017, p. 307).

2.2.1.12 Project Communications Management

Project Communications Management includes “the processes essential to ensure the development of artifacts and the implementation of activities designed to achieve effective information exchange to meet the needs of the project and its stakeholders” (Project Management Institute, 2017, p. 359).

For FSQ Solutions Inc., communication is critical to the success of this project and therefore executing the Planning phase of this process is vital. This is often a common threat to implementation projects such as these and leads to problems such as delayed or no message transfer, not enough communication of information to the right audience, or stakeholders misunderstanding or misinterpreting the message communicated.

Therefore, for this project, FSQ Solutions Inc. will be executing the Planning Communications Management, which involves developing an appropriate approach and plan for project communications activities based on stakeholders’

information needs and project requirements, and available organizational assets (Project Management Institute, 2017, p. 359).

The ITTOs for the Project Communications Management processes are represented in Figure 2-17.

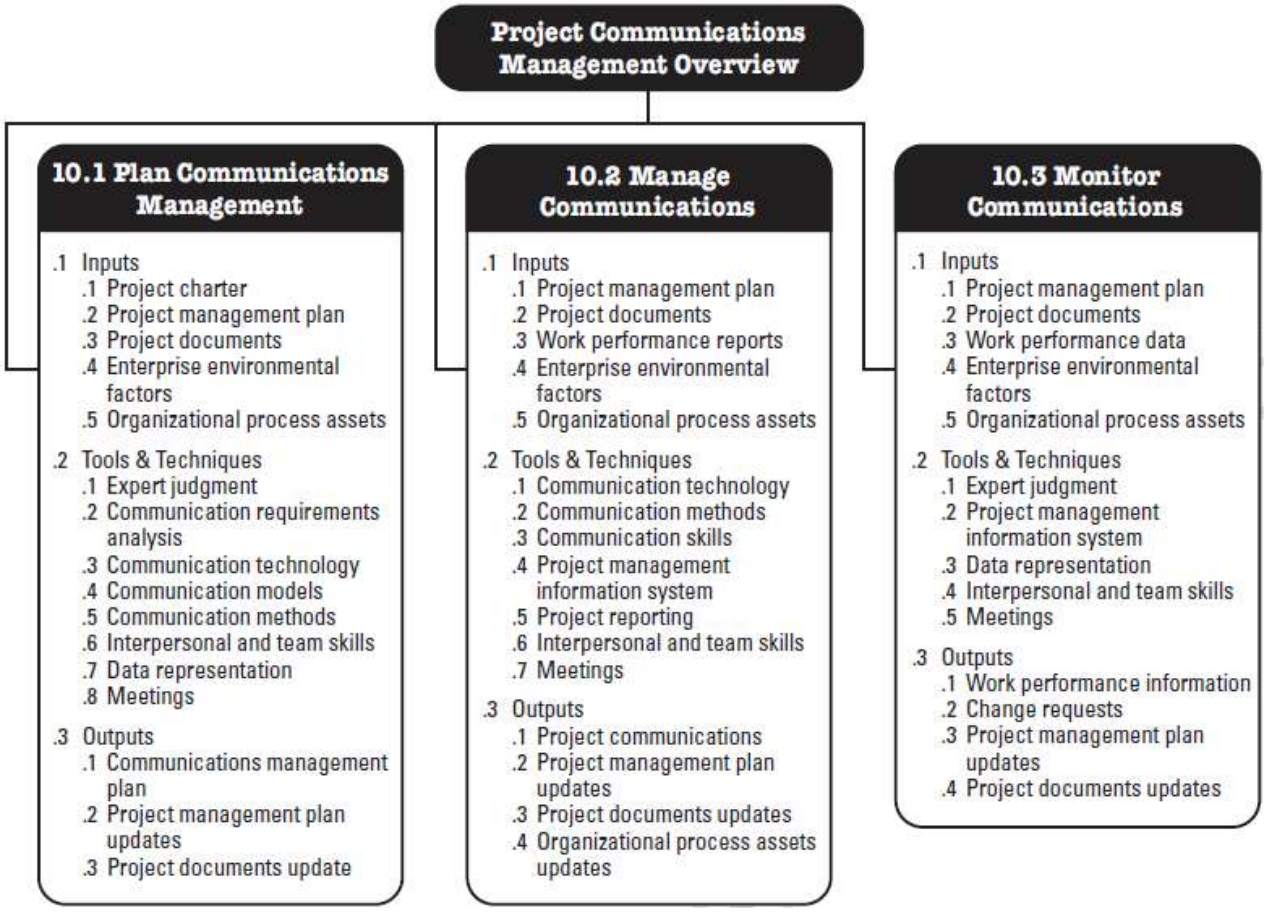

Figure 2-17 Project Communications Management Overview

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 360), Copyright 2017 by Project Management Institute Inc.)

2.2.1.13 Project Risk Management

The PMI PMBOK Guide establishes Project Risk Management as the “processes of conducting risk management planning, identification, analysis, response planning, response implementation and monitoring risk on a project” (Project

Management Institute, 2017, p. 395). The ITTOs for the Project Risk Management processes are represented in Figure 2-18.

Figure 2-18 Project Risk Management Overview

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 396), Copyright 2017 by Project Management Institute Inc.)

For this project, FSQ Solutions Inc. will be executing the following the risk management planning phase processes (Project Management Institute, 2017, p. 395):

- Plan Risk Management, i.e. defining how to conduct risk management activities for the project.

- Identify Risks, i.e. identifying individual risks and their sources of overall project risk and documenting their characteristics.

- Perform Qualitative Risk Analysis, i.e. prioritizing risks for further analysis or action by assessing and combining their probability of occurrence and impact.

- Perform Quantitative Risk Analysis, i.e. numerically analyzing the combined effect of identified individual project risks and other sources of project objectives uncertainty.

- Plan Risk Responses, i.e. developing options, selecting strategies and agreeing on actions to address project risk exposure and reduce threats to project objectives.

2.2.1.14 Project Procurement Management

The PMI PMBOK Guide establishes Project Procurement Management as the "processes necessary to purchase or acquire products, services, or results needed from outside the project team" (Project Management Institute, 2017, p. 459). The ITTOs for the related processes are represented in Figure 2-19.

For this project, FSQ Solutions will be executing the Planning Procurement Management, which involves developing documents related to project procurement decisions, the appropriate approach and the potential sellers identified.

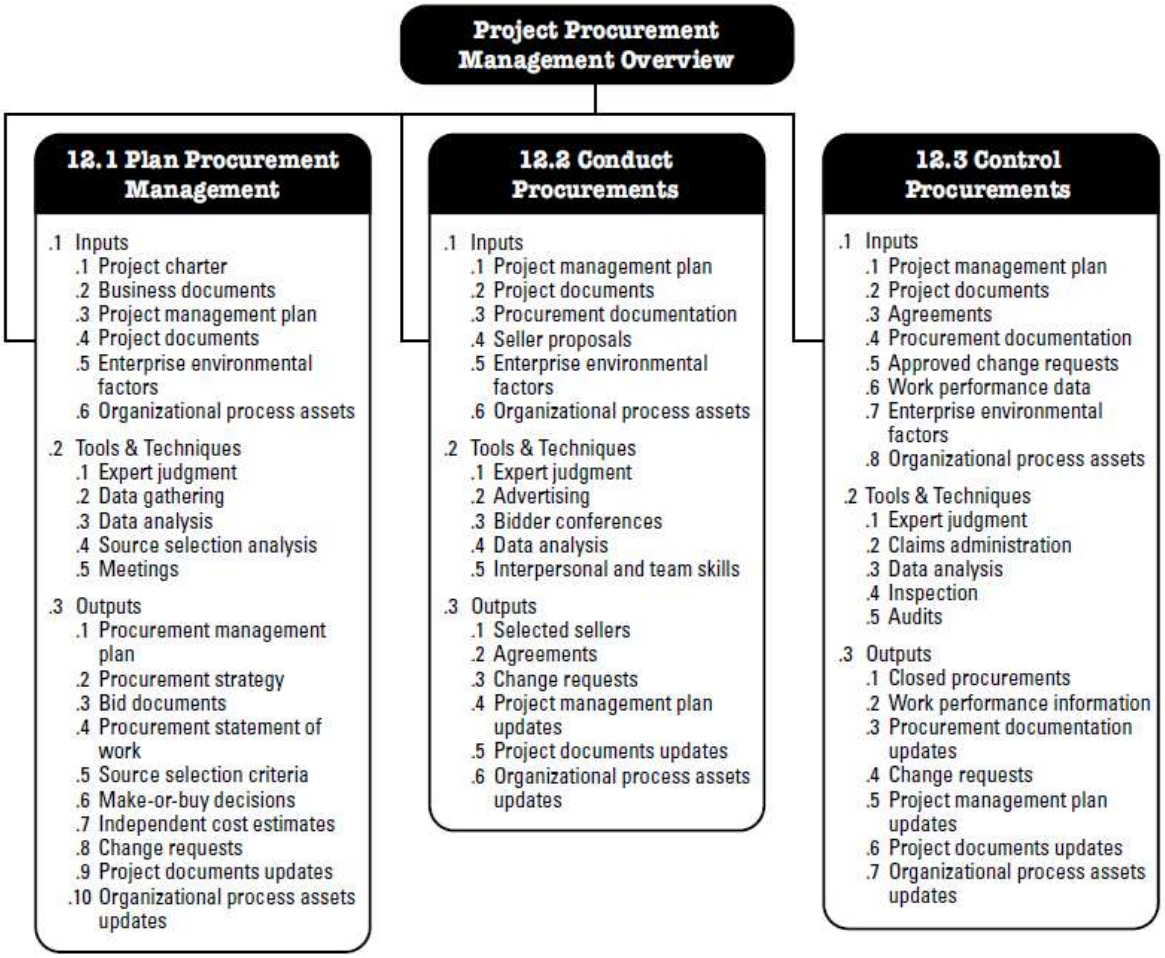

Figure 2-19 Project Procurement Management Overview

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 459), Copyright 2017 by Project Management Institute Inc.)

2.2.1.15 Project Stakeholder Management

Project Stakeholder Management as defined by the PMI PMBOK Guide is “the processes required to identify individuals, groups, or organizations that may affect, be affected by, or perceive itself to be affected by the project, to analyze stakeholder expectations and their impact on the project as well as to develop appropriate management strategies for effectively engaging them in project execution and decisions” (Project Management Institute, 2017, p. 503). The ITTOs for the related Stakeholder Management processes are shown in Figure 2-20.

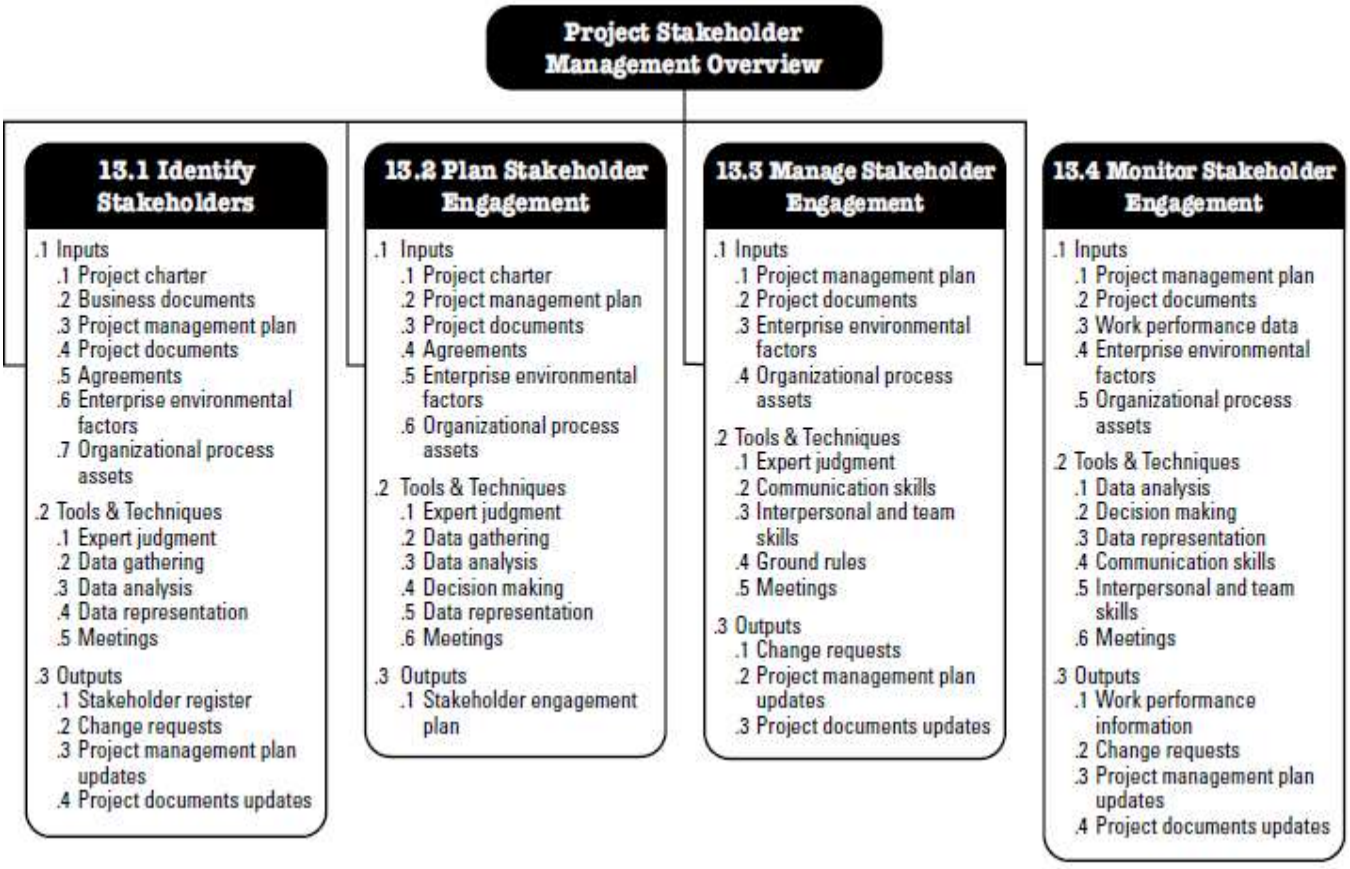

Figure 2-20 Project Stakeholder Management Overview.

(Source: Reprinted from A Guide to the Project Management Body of Knowledge PMBOK Guide (p. 504), Copyright 2017 by Project Management Institute Inc.)

For this project, FSQ Solutions will be executing the Identify Stakeholders and the Plan Stakeholders Management processes. This involves identifying project stakeholders, developing approaches to involve them based on their needs and expectations, and documenting and analyzing data on their interests, involvement, interdependences, influences and potential impact on the success of the project.

2.3. Other Applicable Concepts - Food Safety System Implementation

The planning phase of this project has to do with the development of a project management plan for the implementation of the FDA Food Safety Management System (FSMS). In order for this to be a success, the implementation strategy of such a Food Safety System must be taken into consideration. The activities that must be executed during planning for such a project, according to Timperley (2010), are as follows:

- Senior management prepares an organizational strategy based on customer and potential customer requirements.
- Senior management should communicate policies and responsibilities, including authority levels.
- A food safety team leader and a multi-disciplinary food safety team with all functions of the business represented should be appointed by senior management to develop the FSMS and they should be suitably competent.
- The system documentation should be developed based on a study by the HACCP team.
- Food safety policies and objectives, HACCP plans and associated documents, procedures, and records that ensure the safe manufacture of food products should be generated.
- Resources needed to implement, maintain, and improve the FSMS, including personnel, infrastructure, training, and work environment, should be considered and provided.
- This standard being used should be read and understood by key personnel followed by communication and training (Timperley, 2010).

For this FGP, FSQ Solutions will be considering the aforementioned as part of the project management plan while executing the planning phase of the project.

3 METHODOLOGICAL FRAMEWORK

According to the PMI PMBOK Guide, information is the organized or structured data, processed for a specific purpose to make it meaningful, valuable, and useful in specific contexts (Project Management Institute, 2017, p. 708). The facilities, processes, and procedures used to collect, store, and distribute information between project team members and stakeholders of information, whether in physical or electronic format, is very important to this process.

3.1. Information sources

An information source is the various media by which and where information is attained and recorded for use (“Unit 1”, 2019, p. 8).

3.1.1 Primary sources

Primary information sources are original materials on which other research is based and such data is collected through laboratory measurement, field observation, structured questionnaires, surveys, interviews (e.g., oral histories, telephone, e-mail), opinionnaires, schedules, audio recordings (e.g. radio or internet broadcasts), diaries, journals, notes, autobiographies and memoirs, internet communications (e.g. email, chat transcripts), journal articles describing original research or containing original analysis, letters, postcards, and other forms of correspondence, newspaper and magazine articles with eyewitness accounts, original reporting or analysis, original documents (i.e. birth certificates, wills, marriage licenses, trial transcripts), records of organizations, government agencies, and businesses (e.g. corporate reports, treaties, constitutions, census data, government documents), speeches, user manuals, etc. (Pandey, 2015, p. 69; “Unit 1”, 2019, p. 9). Information from primary sources is not translated by anyone else and has not been published elsewhere.

3.1.2 Secondary Sources

Secondary information sources are materials that describe or analyze primary sources of data and such data is collected from different technical publications such as manuals, handbooks, data sheets, and standards, books and journals, official publications of the Central government, state government and local bodies, biographical works, commentaries, criticisms, histories, magazine and newspaper articles (except eyewitness accounts, original reporting or analysis), books (other than fiction and autobiography), private data services and computer databases (Pandey, 2015, p. 69; “Unit 1”, 2019, p. 8). Information from secondary sources is repackaged, examined, restatement or interpretation of primary information that leads to primary sources (“Information”, 2019; “Unit 1”, 2019, p. 8).

A summary of the information sources as shown in Chart 1 defines the primary and secondary information sources used in the FGP. These are as follows:

- **Primary**: field observation, structured questionnaires, surveys/audits, interviews, schedules, notes, meeting minutes, internet communications and correspondence.
- **Secondary**: standards, books, official publications and library databases.

Chart 1 Information Sources

Objectives	Information sources	
	Primary	**Secondary**
1. To create a project charter that formally sanctions the project and provides the project manager with the authority to apply organizational resources to the project activities for the project management plan.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager.	PMBOK® Guide and PMI database
2. To create a scope management plan to ensure that all works essential for the successful completion of the project are encompassed.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager.	PMBOK® Guide and PMI database, standards
3. To create a schedule management plan to sustain the development and management of the project schedule within the time constraints outlined.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager.	PMBOK® Guide and PMI database, standards
4. To create a cost management plan to define the processes for developing and estimating the project budget that ensures the project is completed within the approved budget constraints.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager. Internet communications and correspondence.	PMBOK® Guide and PMI database, standards
5. To develop a quality management plan to identify the quality requirements for the project as well as their food products to ensure the results meet customers' and other stakeholders' expectations.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager. Surveys/audits, Field observation and structured questionnaires.	PMBOK® Guide and PMI database, standards, books, official publications.

6. To create a resource management plan to ensure that all the required human resources, facilities, equipment, materials, supplies and other resources needed for project success are identified and the critical teams are acquired and developed.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager. Surveys/audits, Field observation and structured questionnaires, correspondence.	PMBOK® Guide and PMI database, standards, books, official publications.
7. To craft a communication management plan to ensure the timely and effective communication of the project needs, status and other fundamental information to its stakeholders.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager. Internet communications and correspondence.	PMBOK® Guide and PMI database, standards, books, official publications.
8. To create a risk management plan to ascertain and scrutinize the risks to the successful completion of the project and develop plans to minimize the likelihood and severity of the risks.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager. Surveys/audits, Field observation and structured questionnaires.	PMBOK® Guide and PMI database, standards, books, official publications.
9. To generate a procurement management plan to be used in attaining products, services or results required by the project.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager.	PMBOK® Guide and PMI database.

10. To build a stakeholder management plan to identify the people, groups or organizations that could impact positively on the project and develop strategies for effective stakeholder engagement in order to support the project's timely and successful execution.	Meeting minutes, schedules and notes from interviews or meetings with stakeholders and the Project Manager. Internet communications and correspondence, questionnaires, surveys.	PMBOK® Guide and PMI database.

(Source: N. Benn-Greaves, FGP Author, June 2019)

3.2. Research Methods

According to Kothari (2004), research methods or techniques are the "approaches the researchers use in performing research operations to arrive at a solution for a given problem" (p. 8). The main types, methods and techniques for research are shown in Figure 3-1.

Type	*Methods*	*Techniques*
1. Library Research	(i) Analysis of historical records	Recording of notes, Content analysis, Tape and Film listening and analysis.
	(ii) Analysis of documents	Statistical compilations and manipulations, reference and abstract guides, contents analysis.
2. Field Research	(i) Non-participant direct observation	Observational behavioural scales, use of score cards, etc.
	(ii) Participant observation	Interactional recording, possible use of tape recorders, photo graphic techniques.
	(iii) Mass observation	Recording mass behaviour, interview using independent observers in public places.
	(iv) Mail questionnaire	Identification of social and economic background of respondents.
	(v) Opinionnaire	Use of attitude scales, projective techniques, use of sociometric scales.
	(vi) Personal interview	Interviewer uses a detailed schedule with open and closed questions.
	(vii) Focused interview	Interviewer focuses attention upon a given experience and its effects.
	(viii) Group interview	Small groups of respondents are interviewed simultaneously.
	(ix) Telephone survey	Used as a survey technique for information and for discerning opinion; may also be used as a follow up of questionnaire.
	(x) Case study and life history	Cross sectional collection of data for intensive analysis, longitudinal collection of data of intensive character.
3. Laboratory Research	Small group study of random behaviour, play and role analysis	Use of audio-visual recording devices, use of observers, etc.

Figure 3-1 Research Types, Methods and Techniques.

(Source: Reprinted Kothari, C. (2004). Research Methodology Methods and Techniques – Sixth Edition, New Delhi: New Age International Ltd, p. 7)

Each method can be put into the following three groups (Kothari, 2004, p. 8):

1. Collection of data: where the data already available are not sufficient to arrive at the required solution;
2. Using statistical techniques: used for establishing relationships between the data and the unknowns;
3. Evaluation of data: where methods are used to evaluate the accuracy of the results obtained.

Example:

3.2.1 Analytical methods - Research methods falling in the above stated last two groups are generally taken as the analytical tools of research (Kothari, 2004, p. 8). Data analysis involves both qualitative and quantitative activities.

3.2.1.1 Quantitative type - Research concerned with trying to quantify data and generalise results from a sample of the population of interest (MacDonald & Headlam, 2009).

3.2.1.2 Qualitative type - Research concerned with the quality of information acquired to gain an understanding of the underlying reasons and motivations for actions and provide insights into the setting of a problem to generate ideas and/or hypotheses (MacDonald & Headlam, 2009).

A summary of the research methods used in this FGP is shown in Chart 2.

Chart 2 Research methods

Objectives	**Research methods**
	Analytical Method
1. To create a project charter that formally sanctions the project and provides the project manager with the authority to apply organizational resources to the project activities for the project management plan.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.

2. To create a scope management plan to ensure that all works essential for the successful completion to the project are encompassed.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.
3. To create a schedule management plan to sustain the development and management of the project schedule within the time constraints outlined.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.
4. To create a cost management plan which outlines the processes for developing and estimating the project budget inorder to ensure project completion within the approved budget constraints.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicatedfor this objective in Chart #1.
5. To develop a quality management plan to identify the quality requirements for the project as well as their food products to ensure the results meet customers' and other stakeholders' expectations.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.
6. To create a resource management plan to ensure that all the required human resources, facilities, equipment, materials, supplies and other resources needed for project success are identified and the critical teams are acquired and developed.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.

7. To craft a communication management plan to ensure the timely and effective communication of the project needs, status and other fundamental information to its stakeholders.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.
8. To create a risk management plan to ascertain and scrutinize the risks to the successful completion of the project and develop plans to minimize the likelihood and severity of the risks.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.
9. To generate a procurement management plan to be used in attaining products, services or results required by the project.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.
10. To build a stakeholder management plan to identify the people, groups or organizations that could impact positively on the project and develop strategies for effective stakeholder engagement in order to support the project's timely and successful execution.	Evaluation of data and the use of statistical techniques if required of the primary and secondary sources indicated for this objective in Chart #1.

(Source: N. Benn-Greaves, FGP Author, June 2019)

3.3. Tools

Tools are tangible paraphernalia, such as a template or software program, used in performing an activity to produce a product or result (Project Management Institute, 2017, p. 725). These tools, illustrated in Figure 3-2, can be software automated or manually operated and are usually defined by the different features offered.

Figure 3-2 Features of Project Management Tools

(Source: Reprinted from Project Management Tools – Helping Aids of Project Managers. (2019). Retrieved from, (https://www.edureka.co/blog/project-management-tools/#pmtools.)

However, the tools used on this FGP are set out in Chart 3 and include the following (Project Management Institute, 2017 p. 86, 570, 699, 715; "PMP ITTO", 2019; Haughey, 2019):

- Management Plan template – Used to guide the development of the various management plans required and all its subsidiaries.
- Benchmarking – The comparison of actual or planned products, processes, and practices to those of comparable organizations to identify best practices, generate ideas for improvement, and provide a basis for measuring performance.
- Product analysis – Used to define scope and requires asking questions about a product and forming answers to describe the use, characteristics, and other relevant aspects.
- Project management information systems (PMIS) – Software that has the capability to help plan, organize, and adjust the sequence of the activities; insert the logical relationships, lead and lag values; and differentiate the different types of dependencies.

- Project Management Plan – Consists of the documents that describe how the project will be executed, monitored, controlled and closed.
- Gantt chart – Used throughout the project from planning through project closure and allows for tracking tasks, resources, deadlines and more. It also illustrates the Logic Network, which shows the sequence of activities in a project over time and which activity logically precedes or follows another activity.
- SIPOC diagram – A detailed process map that illustrates who the suppliers are, what are the inputs, what is the high-level process, what are the outputs produced, and who the customers are from the Voice of the Customer (VOC) data gathered.
- Gemba Walk Checklist – A checklist used during a "Gemba Walk"– to observe the organization's process, identify needs, problems and improvement ideas.
- Work Breakdown Structure (WBS) – Hierarchical decomposition of the deliverables needed to complete a project, which breaks the deliverables down into manageable work packages that can be scheduled, costed and have people assigned to them.
- Others – Audit templates, questionnaires, surveys.

Chart 3 Tools

Objectives	**Tools**
1. To create a project charter that formally sanctions the project and provides the project manager with the authority to apply organizational resources to the project activities for the project management plan.	- Project Charter Template

2. To create a scope management plan to ensure that all works essential for the successful completion of the project are encompassed.	- Scope Management Plan Template - Requirements Management Plan Template - Requirements Documentation Template - Requirements Traceability Matrix Template - Scope Baseline document with templates for Project Scope Statement, WBS, etc. - Questionnaire and Survey Templates
3. To create a schedule management plan to sustain the development and management of the project schedule within the time constraints outlined.	- Schedule Management Plan Template - Gantt Chart - Schedule Baseline and Data Template
4. To create a cost management plan to define the processes for developing and estimating the project budget that ensures the project is completed within the approved budget constraints.	- Cost Management Plan Template - Cost Estimates with Basis Template - Cost Baseline Template - Project Funding Requirements Template
5. To develop a quality management plan to identify the quality requirements for the project as well as their food products to ensure the results meet customers' and other stakeholders' expectations.	- Quality Management Plan Template with Quality Metrics - Audit Templates - Gemba Walk Checklist - SIPOC Diagram Templates - Benchmarking Templates - Product Analysis Templates

6. To create a resource management plan to ensure that all the required human resources, facilities, equipment, materials, supplies and other resources needed for project success are identified and the critical teams are acquired and developed.	- Resource Management Plan Template - Resource Requirements Template with Basis of Estimates - Resource Breakdown Structure Template - Responsibility Assignment (RAM) and Physical Resource Assignments Matrix - Resource Calendars - Project Team Charter and Assignments Template - Team Development and Assessment Templates
7. To craft a communication management plan to ensure the timely and effective communication of the project needs, status and other fundamental information to its stakeholders.	- Communications Management Plan Template - Communications Matrix - PMIS - Electronic Communications Management Tools
8. To create a risk management plan to ascertain and scrutinize the risks to the successful completion of the project and develop plans to minimize the likelihood and severity of the risks.	- Risk Management Plan Template - Risk Register Template - Risk Checklist with Root Cause - Risk Probability and Impact Assessment Matrix
9. To generate a procurement management plan to be used in attaining products, services or results required by the project.	- Procurement Management Plan Template - Procurement Strategy Template - Bid Documents Template - Procurement Statement of Work Template - Source Selection Criteria Template

10. To build a stakeholder management plan to identify the people, groups or organizations that could impact positively on the project and develop strategies for effective stakeholder engagement in order to support the project's timely and successful execution.	- Stakeholder Management Plan Template - Stakeholder Analysis Chart with Power/Interest Grid - Stakeholder Register Template - Stakeholder Engagement Assessment Matrix - Questionnaires, Surveys

(Source: N. Benn-Greaves, FGP Author, June 2019)

3.4. Assumptions and Constraints

According to the PMI PMBOK Guide, constraints are limiting factors that affect the execution of a project, program, portfolio, or process, while assumptions are factors in the planning process that are considered to be true, real, or certain, without proof or demonstration (Project Management Institute, 2017, p. 699, 701). The assumptions and constraints considered in the Final Graduation Project for each specific objective are set out in Chart 4.

Chart 4 Assumptions and Constraints

Objectives	Assumptions	Constraints
1. To create a project charter that formally sanctions the project and provides the project manager with the authority to apply organizational resources to the project activities for the project management plan.	The charter will be created and approved before all other subsidiary activities and documents. Sufficient enterprise environmental factors were taken into consideration during the charter development.	No organizational process assets were available for use and only one week was given to develop the charter.

2. To create a scope management plan to ensure that all works essential for the successful completion of the project are encompassed.	Sufficient enterprise environmental factors (EEF) have been taken into consideration for the scope management plan development and the company will provide enough information required to complete this process.	No organizational process assets were available for use and so it is not known how the quality aspects that impact the scope are implemented.
3. To create a schedule management plan to sustain the development and management of the project schedule within the time constraints outlined.	The Project Management Plan can be completed in the three (3) months allocated.	The three (3) months allocated to develop the Project Management Plan.
4. To create a cost management plan to define the processes for developing and estimating the project budget that ensures the project is completed within the approved budget constraints.	Sufficient EEFs have been taken into consideration prior to the cost management plan development and the budget created covers the major associated costs for the project.	The company may not have considered all the requirements and their associated costs to establish an overall budget as none was provided.
5. To develop a quality management plan to identify the quality requirements for the project as well as their food products to ensure the results meet customers' and other stakeholders' expectations.	Sufficient EEFs have been taken into consideration prior to the quality management plan development, to ensure that it will cover and meet all the quality standards as well as determine the criteria for success/failure.	No organizational process assets are available for this and in assigning responsibilities; it is unknown as to who would be overall in charge of the various functions.

6. To create a resource management plan to ensure that all the required human resources, facilities, equipment, materials, supplies and other resources needed for project success are identified and the critical teams are acquired and developed.	Sufficient EEFs have been taken into consideration for the resource management plan development to ensure that it will cover most of the resource needs for the project.	The company is working with a human resources constraint.
7. To craft a communication management plan to ensure the timely and effective communication of the project needs, status and other fundamental information to its stakeholders.	Sufficient EEFs have been taken into consideration for the development of the communications plan and senior management have communicated policies and responsibilities as well as authority levels and adequate stakeholder information.	The company may not be able to attain all information needed of all the various stakeholders for this project.
8. To create a risk management plan to ascertain and scrutinize the risks to the successful completion of the project and develop plans to minimize the likelihood and severity of the risks.	There is sufficient information required to adequately identify all the risks associated with the project, with all EEFs being considered.	Limited knowledge on the impact and severity of some risks may skew the analysis.

9. To generate a procurement management plan to be used in attaining products, services or results required by the project.	Sufficient EEFs have been taken into consideration for the development of the procurement management plan. Request for Proposal (RFP) for professional services and awarding the contract involves only senior management and not a lawyer.	No organizational process assets are available for this and some activities may have been executed before the prerequisite policies and standards would have been put in place.
10. To build a stakeholder management plan to identify the people, groups or organizations that could impact positively on the project and develop strategies for effective stakeholder engagement in order to support the project's timely and successful execution.	Sufficient EEFs have been taken into consideration for the development of the stakeholder management plan. This is inclusive of a comprehensive list of all stakeholders involved as well as a plan as to how to properly manage each.	The company may not be able to attain all the required information needed of all the various stakeholders for this project to properly manage each.

(Source: N. Benn-Greaves, FGP Author, June 2019)

3.5. Deliverables

A deliverable is defined as “any unique and verifiable product, result, or capability to perform a service that is required to be produced to complete a process, phase, or project” (Project Management Institute, 2012, p. 8). The deliverables for the Final Graduation Project for each specific objective are set out in Chart 5.

Chart 5 Deliverables

Objectives	Deliverables
1. To create a project charter that formally sanctions the project and provides the project manager with the authority to apply organizational resources to the project activities for the project management plan.	- Project Charter with Assumptions - Project Management Plan
2. To create a scope management plan to ensure that all works essential for the successfully completion of the project are encompassed.	- Scope Management Plan - Requirements Management Plan - Requirements Documentation - Requirements Traceability Matrix - Scope Baseline document with Project Scope Statement, WBS, etc.
3. To create a schedule management plan to sustain the development and management of the project schedule within the time constraints outlined.	- Schedule Management Plan - Activity List and Attributes - Milestone List - Schedule Baseline and Data - Project Schedule and Calendar with Duration Estimates via Gantt Chart - Project Schedule Network Diagram

4. To create a cost management plan to define the processes for developing and estimating the project budget that ensures the project is completed within the approved budget constraints.	- Cost Management Plan - Cost Estimates with Basis - Cost Baseline document - Project Funding Requirements
5. To develop a quality management plan to identify the quality requirements for the project as well as their food products to ensure the results meet customers' and other stakeholders' expectations.	- Quality Management Plan with Quality Metrics
6. To create a resource management plan to ensure that all the required human resources, facilities, equipment, materials, supplies and other resources needed for project success are identified and the critical teams are acquired and developed.	- Resource Management Plan - Resource Requirements with Basis of Estimates - Resource Breakdown Structure - Physical Resource Assignments - Resource Calendars - Project Team Charter and Assignments - Team Performance Assessments
7. To craft a communication management plan to ensure the timely and effective communication of the project needs, status and other fundamental information to its stakeholders.	- Communications Management Plan
8. To create a risk management plan to ascertain and scrutinize the risks to the successful completion of the project and develop plans to minimize the likelihood and severity of the risks.	- Risk Management Plan - Risk Register and Report

9. To generate a procurement management plan to be used in attaining products, services or results required by the project.	- Procurement Management Plan - Procurement Strategy - Bid Documents - Procurement Statement of Work - Source Selection Criteria
10. To build a stakeholder management plan to identify the people, groups or organizations that could impact positively on the project and develop strategies for effective stakeholder engagement in order to support the project's timely and successful execution.	- Stakeholder Register - Stakeholder Engagement Plan

(Source: N. Benn-Greaves, FGP Author, June 2019)

4 PROJECT DEVELOPMENTAL PLAN AND RESULTS

This section of the FGP describes the activities undertaken by the team to implement the tools and techniques in this project in order to develop the planned results and deliverables as per the objectives. The main tool used to generate the results was that of meeting and brainstorming along with several other communications between FSQ Solutions Inc. as the Project Manager and the selected project team members of Choo's Enterprises.

4.1. Project Integration Management

Several scheduled meetings were held with the Project Manager and the selected project team members in order to define the project charter and develop the Project Management Plan as part of the attainment of the objectives for this project. The templates used in developing the deliverables by the team were adapted from the PMBOK® Guide and PMI database as well as the Lean Six Sigma Guide. The results for the Integration management of this project as shown in Figures 4-1 through to 4-3 are follows:

- A-3 DMAIC Model – Results from the analysis of the current situation and problem at the company in order to generate the business case for the Project charter and the implementation plan for the solutions to the problem.

- Assumption Log – These are assumptions extracted from the Project Charter and applied to the entire project.

- Project Charter – This was generated by the team using the information from the A-3 DMAIC Model.

Since the Project Management Plan consists of various documents and this FGP is focused on the initiation and planning processes groups as described in Section 3.3 of this FGP, some of the documents were generated further in the project as per each knowledge area while others were not. However, the Project Management Plan and Project Documents as shown in Figure 4-4 summarize the

elements of the plan and the related project documents once all processes were accomplished.

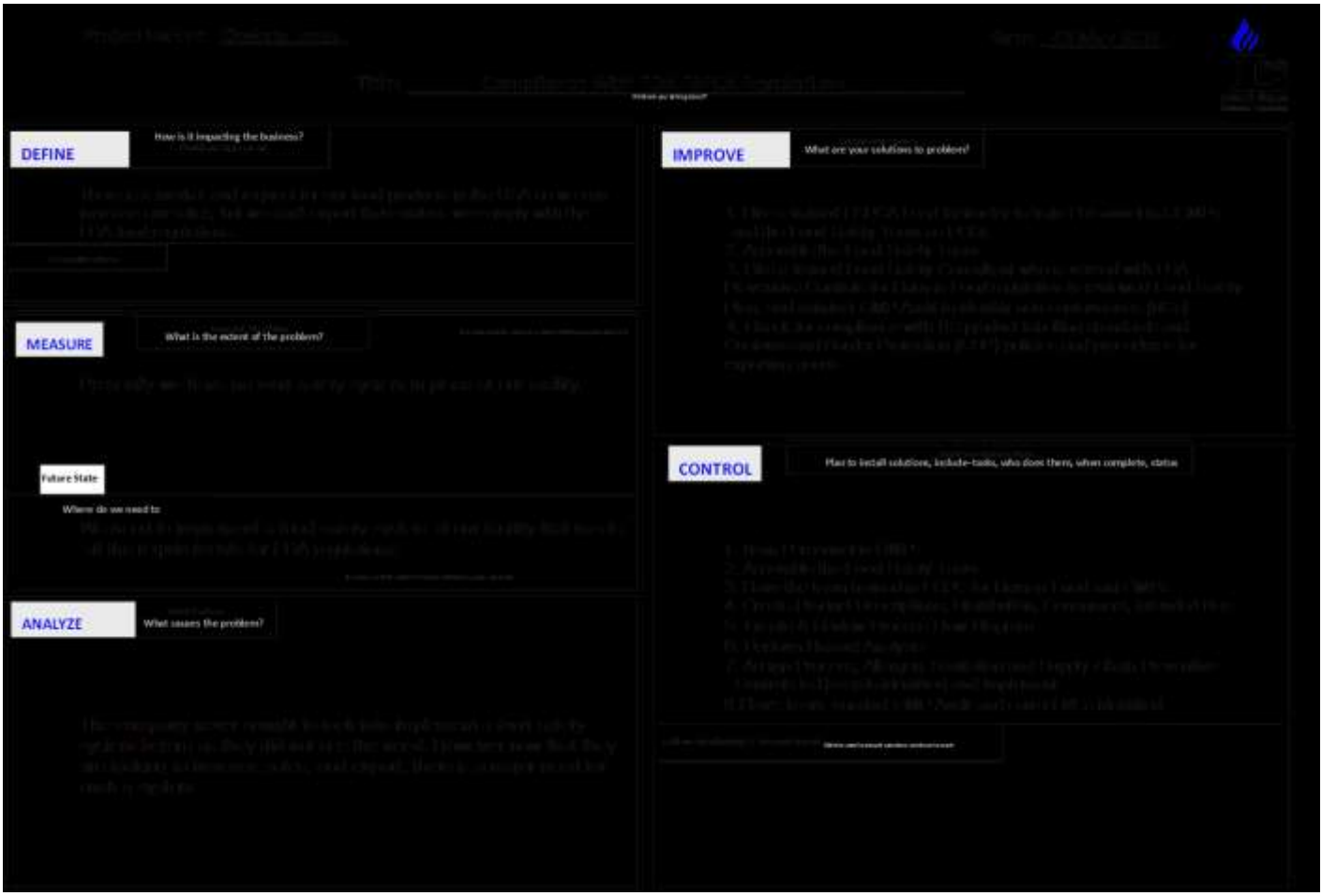

Figure 4-1 A-3 DMAIC Model for Choo's FDA Food Safety Regulations Implementation Project

(Source: C. Jones, Personal Communication, June 2019)

Assumptions Log

1. It is assumed that the project can be completed in four months by the team.
2. It is assumed that the company will provide all the resources needed to complete the project.
3. It is assumed that the company will provide all the required information needed to complete the various processes for the project.

Figure 4-2 Project Assumptions Log for the Implementation Project
(Source: C. Jones, Personal Communication, June 2019)

Project Name:	Food and Drug Administration (FDA) Food Safety Regulations Implementation
Project Manager:	FSQ Solutions Inc.
Customer/ Beneficiaries:	Distributors, Local, Regional and International Consumers, Staff and Shareholders of Choo's Enterprises
Project Sponsor:	Mr. Edwin Choo, Managing Director at Choo's Enterprises
Location	Choo's Enterprises, Bridgetown, BARBADOS

Business Case:

Currently most of Choo's sales come from the local market, which is very saturated and new sales are down significantly for the past 5 years. Their competitors are presently exporting to the USA.

They have distributors from the USA who would like to have their products and as a result, they have been losing out on this customer base for the past 2 years.

Therefore, complying with the FDA food regulations and exporting to the USA will allow them to capture customers in that market.

This could lead to:

- Moving from a one shift to a two or three shift operation
- Increased new customer sales and profit from increased production
- Increased access to other markets
- Increased customer retention since they are being audited more by their customers
- Food Safety and Quality improvement

Opportunity Statement:

Currently, 74% of the sales from Choo's come from the local market, which is very saturated, while 26% is from exports regionally. As a result, they have been losing out on the opportunity to gain more sales from the export market in the USA and UK.

By exporting some of their specialty products to the USA, they anticipate that they can grow their market share with an increase of sales by 18% above their original base. However, in order to export to the USA, they have to comply with the FDA food regulations before doing such.

Goal Statement:	**Project Scope:**
1. Effectively implement the activities centred on the FDA Preventive Controls for Human Food (FSPC) regulation such that they comply with Current Good Manufacturing Practices (CGMPs), Hazard Analysis, and Risk-based Preventive Controls for Human Food. 2. Hire a trained FSPCA Lead Instructor to train the established food safety team to the "standardized curriculum" recognized by the FDA and developed by the FSPCA, so they can be established as a "preventive controls qualified individual" (PCQI) as required by the FDA regulation.	In Scope: • Product Processing operations from receiving to distribution • Plant Personnel and Management Team • Support processes related to Processing operations • Premises • Product Specifications and labelling
Milestone Schedule:	**Team Selection:**
• Hire a trained FSPCA Lead Instructor to train Personnel in CGMPs and the Food Safety Team as PCQI (1 day) • Hire a trained Food Safety Consultant who is versed in FDA Preventive Controls for Human Food regulation to review Food Safety Plan (1 day) • Train Personnel in CGMPs and the specific staff as PCQIs for Food Safety Team (15 days) • Assemble a Food Safety Team who will be responsible for developing Food Safety Plan Components (25 days) • Develop Food Safety Plan Components: Product Descriptions, Process Flow Diagram and Process Description, Hazard Analysis and Process, Allergen, Sanitation and Supply-Chain Preventive Controls to Hazards identified (70 days) • Implement Monitoring and Corrective actions for Preventive Controls to Hazards identified and establish Verification and Validation procedures (5 days) • Have CGMP Audit conducted by the Food Safety Consultant and execute corrective actions for Non-conformances identified (2 days) • Check for compliance with US product labelling standards, CGMP and Preventive Controls for Human Food (5 days)	• Project Leader – Mrs. Cheketa Jones (Office Manager) • Process Owner Needed – Food Safety and QA Officer (To be Hired) • Team Members – Food Safety Team • Expertise – Food Safety Consultant, Project Manager from FSQ Solutions Inc.

Assumptions

- The project can be completed in five months by the team.
- The company will provide all the resources needed to complete the project.
- The company and its suppliers will provide all the required information needed to complete the various processes for the project.

Constraints

Constraints	Flexibility		
	Rigid	Relatively flexible	Flexible
Schedule: *Four months to complete the project*		X	
Cost: *Restricted budget for attaining the resources needed*	X		
Scope: *Restricted to the initiation and planning process of project*	X		

Preliminary risks

If the deliverables and activities assigned are not executed as required, this might delay the project.
If support from the organization is not forthcoming, this might impact the project plan and schedule.

Budget

- The budgeted amount of $32,000.00 BDS will constitute the financial resources needed to fully implement the project, inclusive of attaining the human and other resources required.

Figure 4-3 Project Charter for Choo's FDA Food Safety Regulations Implementation Project
(Source: C. Jones, Personal Communication, June 2019)

Project Management Plan	Project Documents	
1. Scope management plan	1. Activity attributes	19. Quality control measurements
2. Requirements management plan	2. Activity list	20. Quality metrics
3. Schedule management plan	3. Assumption log	21. Quality report
4. Cost management plan	4. Basis of estimates	22. Requirements documentation
5. Quality management plan	5. Change log	23. Requirements traceability matrix
6. Resource management plan	6. Cost estimates	24. Resource breakdown structure
7. Communications management plan	7. Cost forecasts	25. Resource calendars
8. Risk management plan	8. Duration estimates	26. Resource requirements
9. Procurement management plan	9. Issue log	27. Risk register
10. Stakeholder engagement plan	10. Lessons learned register	28. Risk report
11. Change management plan	11. Milestone list	29. Schedule data
12. Configuration management plan	12. Physical resource assignments	30. Schedule forecasts
13. Scope baseline	13. Project calendars	31. Stakeholder register
14. Schedule baseline	14. Project communications	32. Team charter
15. Cost baseline	15. Project schedule	33. Test and evaluation documents
16. Performance measurement baseline	16. Project schedule network diagram	
17. Project life cycle description	17. Project scope statement	
18. Development approach	18. Project team assignments	

Figure 4-4 Project Management Plan and Project Documents
(Source: Project Management Institute, 2017, p. 86)

4.2. Project Scope Management

The Project Manager and Food Safety Consultant, along with the Project Leader and Sponsor, met to discuss and further develop the project scope as presented in Figures 4-5 (Project Scope Statement) and 4-6 (Scope Verification Matrix) in order to define the Work Breakdown Structure in Figure 4-7 as part of the attainment of the objectives for this project. The work for each of the deliverables was subdivided using the decomposition method and this is presented in Figure 4-8 as a hierarchical breakdown. From this a work dictionary was generated, as shown in Figure 4-9. These all form part of the Scope Management Plan.

In addition, as part of the Requirements Management Plan, the team generated the Requirements Traceability Matrix as per Figure 4-10 using the Key Stakeholders Role and Responsibilities Chart (Section 4.9), which was developed prior to this process along with the Project Charter. The templates used in developing these deliverables were all adapted from the PMBOK® Guide and PMI database.

Project Scope Statement	
Project Scope Description	**Project Exclusions**
➢ Build and fully implement the food safety system centred on the FDA regulation for full compliance to their Current Good Manufacturing Practices (CGMPs), Hazard Analysis, and Risk-based Preventive Controls for Human Food, by September 30, 2019. This would include only products to be sold in the USA and their related processing operations from receiving to distribution, product specifications and labelling, the premises, plant personnel and Management Team, and any other support service related to the operations.	➢ Application process with FDA ➢ Products not being exported to the USA ➢ Execution PM Processes and their requirements
Project Deliverables	**Acceptance Criteria**
➢ Contracted FSPCA Lead Instructor and Food Safety Expert. ➢ Train Personnel in CGMPs and the specific staff as PCQIs for Food Safety Team. ➢ Quality, timely, and cost effective training which aligns with organizational project initiatives. ➢ A Food Safety Team headed by a Process owner who will develop the Food Safety Plan Components. ➢ Fully developed and implemented Food Safety Plan that is in total compliance with CGMP and supporting documentation.	➢ We must have 100 – 85 % Level of Compliance on Site audit. ➢ We must have zero Non-conformances' outstanding for the Desk audit. ➢ The system must be easily understood and with all System Elements in use.

Figure 4-5 Project Scope Statement
(Source: Project Team, Personal Communication, June 2019)

Scope Verification Matrix - (FDA) Food Safety Regulations Implementation Project

ID	Deliverable	High-Level Description	Organization		Contract		Priority			Status					Quality Assurance			Formal Sponsor Acceptance	
			Internal	External	Yes	No	Low	Medium	High	Active	Cancelled	Deferred	Added	Approved	Quality	Units (meters, pounds, etc.)	Specifications	Yes	No
1	Contract FSPCA Lead Instructor and Food Safety Expert	• Hire a trained FSPCA Lead Instructor to train Personnel in CGMPs and the Food Safety Team as PCQI as well as a Food Safety Consultant.	✓	x		✓			✓	✓					Level of Service and Delivery	Timelines Gaps	95% Confidence attainment for Timelines.	✓	
2	Staff Training	• Train Personnel in CGMPs and the specific staff as PCQIs for Food Safety Team .	x	✓	✓				✓	✓					Level of Service and Delivery	Timelines Gaps & Scores on Feedback form	95% Confidence attainment for Timelines. 100 – 75 % Score from Feedback.	✓	
3	Build Food Safety Team	• Assemble a Food Safety Team, have them Develop Food Safety Plan Components.	✓	x		✓			✓	✓					Level of Service and Delivery	Timelines Gaps	95% Confidence attainment for Timelines.	✓	
4	Build Food Safety Plan	• Develop, Product Descriptions, Process Flow Diagram and Process Description, Hazard Analysis and Process, Allergen, Sanitation and Supply-Chain Preventive Controls to Hazards identified	✓	x		✓			✓	✓					Level of Compliance	Number of non-conformances	0-5 of NC for Desk audit of the Plan	✓	
5	Validate FS Plan	• Implement Monitoring and Corrective actions for Preventive Controls to Hazards identified and establish Verification and Validation procedures	✓	✓	✓				✓	✓					Ease of Use of System Elements	Number of complaints	0-3 complaints maximum	✓	
6	Conduct Internal Audit	• Have CGMP Audit conducted by the Food Safety Consultant and execute corrective actions for Non-conformances identified.	✓	✓		✓		✓		✓					Level of Compliance, Correctness	FSPC Audit scoring and Number of non-conformances	100 – 86 % on Site audit	✓	
7	Validate Compliance	• Check for compliance with US product labelling standards CGMP and Preventive Controls for Human Food (5days)	x	✓		✓	✓			✓					Level of Compliance, Correctness	Number of non-conformances	0-5 of NC maximum	✓	
8																			

Figure 4-6 Scope Verification Matrix
(Source: Project Team, Personal Communication, June 2019)

WBS- FDA Food Safety Regulations Implementation Project																				
Level	**WBS Code**	**Element Name**	**Level**	**WBS Code**	**Element Name**	**Level**	**WBS Code**	**Element Name**	**Level**	**WBS Code**	**Element Name**	**Level**	**WBS Code**	**Element Name**	**Level**	**WBS Code**	**Element Name**	**Level**	**WBS Code**	**Element Name**
1	1	Contract FSPCA Lead Instructor and Food Safety Expert	1	2	Staff Training	1	3	Build Food Safety Team	1	4	Build Food Safety Plan	1	5	Validate FS Plan	1	6	Conduct Internal Audit	1	7	Validate Compliance
2	***1.1***	***Selection and Acceptance of Training Vendor Proposal***	2	***2.1***	***Training Preparation***	2	***3.1***	***Identify Team Members***	2	***4.1***	***Develop Product Descriptions***	2	***5.1***	***Confirm Implemented Monitoring, Corrective actions and Records for identified Hazards***	2	***6.1***	***Audit Preparation***	2	***7.1***	***Confirm Implemented Corrective actions and Records for identified Non-Conformances in Desk & Physical Audits.***
			3	**2.1.1**	**Training location preparation**	2	***3.2***	***Identify Process Owner***	2	***4.2***	***Develop Process Flow Diagram and Descriptions***	2	***5.2***	***Verification and Validation of procedures***	3	**6.1.1**	**Auditing Materials**	3	***7.2***	***Verification and Validation of CAs***
			4	2.1.1.1	Implement technical requirements	3	**3.2.1**	**Define Role and develop JD for process owner**	2	***4.3***	***Conduct and Develop Hazard Analysis for all Ingredients and Processes***				4	6.1.1.1	Review and customize materials for Audit			
			3	**2.1.2**	**Training Materials Preparation**	3	**3.2.2**	**Interview Candidates**	2	***4.4***	***Develop Process, Allergen, Sanitation and Supply-Chain Preventive Controls for Hazards identified***				3	6.1.1.2	Prepare Interview Questions for Auditees			
			4	2.1.2.1	Review and customize training materials for Presentation	3	**3.2.3**	**Select candidate and send them job offer**	2	***4.5***	***Develop supporting Food Safety Plan components***				4	**6.1.2**	**Finalize Schedule and Audit Team**			
			4	2.1.2.2	Prepare Participants Assessment & Practical exercises	3	**3.2.4**	**Candidates' acceptance of the offer & Commencement**	2	***4.6***	***Review of plan by Food Safety Expert***				2	6.1.2.1	Confirm Start date and Time, Audit Scope, Documentation requirements, Staff notifications, and number of host.			
			3	**2.1.3**	**Feedback Questionnaires Preparation**	2	***3.3***	***Define roles and responsibilities of the team and its members.***	3	**4.6.1**	**Write Audit Report**				3	***6.2***	***Audit***			
			4	2.1.3.1	Review and customize Feedback Questionnaires				3	**4.6.2**	**Distribute audit report & supplemental Corrective Action materials to Team leader/Mgmt.**				3	**6.2.1**	**Conduct Physical audit of the company, related Material(SOP & Records).**			
			3	**2.1.4**	**Finalize Schedule**										2	**6.2.2**	**Interview Staff**			
			4	2.1.4.1	Confirm Start date and Time, Room reservations, Technical requirements, Staff notifications and number of attendees, and Catering arrangements										3	***6.3***	***Audit Closeout***			
			2	***2.2***	***Training***										3	**6.3.1**	**Review Audit Results, and confirm any questions.**			
			3	**2.2.1**	**General staff & PCQI training sessions**										3	**6.3.2**	**Write Audit Report and score**			
			4	2.2.1.1	Train Participants in using Materials & Practical exercises											**6.3.3**	**Distribute audit report & supplemental Corrective Action materials to Team leader and Mgmt. Rep.**			
			4	2.2.1.2	Have Participants Conduct Assessment and Feedback Questionnaires															
			2	***2.3***	***Training Closeout***															
			3	**2.3.1**	**Review Participants Assessment & Score**															
			3	**2.3.2**	**Evaluate Feedback & tally Scores.**															
			3	**2.3.3**	**Distribute corrected assessments & supplemental training materials to staff**															

Figure 4-7 Work Breakdown Structure (WBS)
(Source: Project Team, Personal Communication, June 2019)

WBS DIAGRAM

PROJECT TITLE	FDA Food Safety Regulations Implementation	PROJECT FUNDING AGENT	Choo's Enterprises
PROJECT MANAGER	FSQ Solutions Inc.	DATE	Jun-19

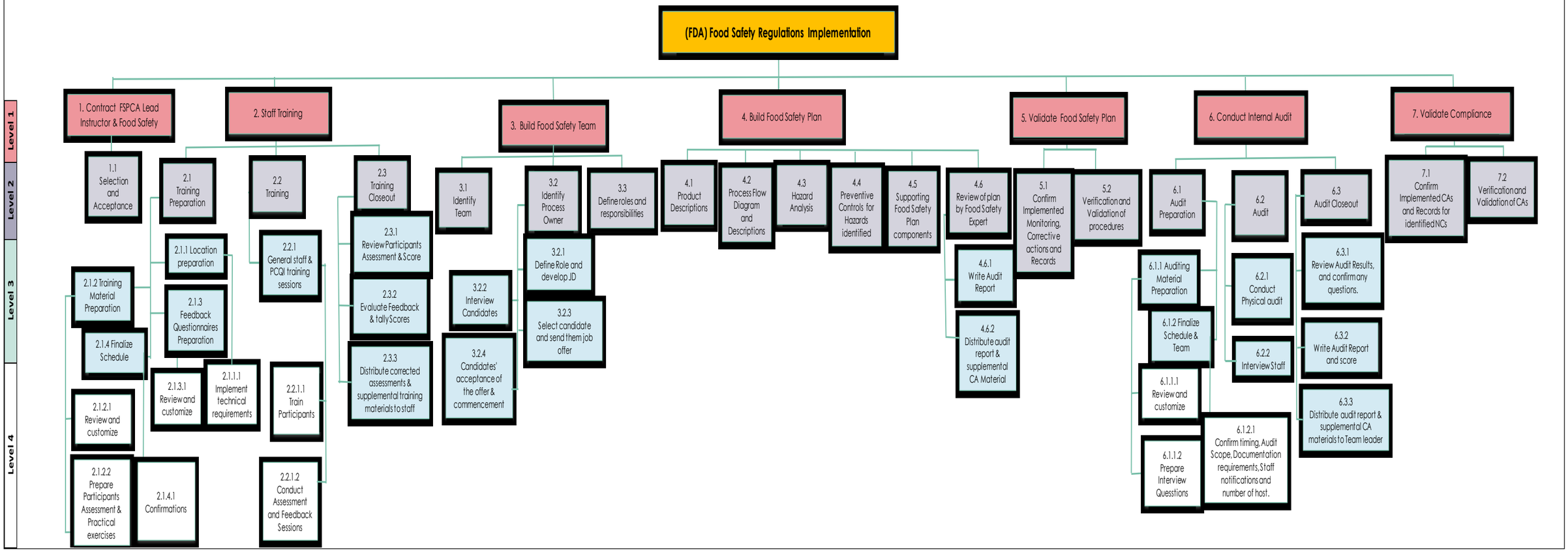

Figure 4-8 Hierarchical Breakdown of Work Breakdown Structure (WBS)
(Source: Project Team, Personal Communication, June 2019)

Requirements Traceability Matrix

Project Name: FDA Food Safety Regulations Implementation **Cost Center:**

Project Description: This project involves the building and full implementation of a food safety system centered on the FDA regulation, for full compliance to their Current Good Manufacturing Practices (CGMPs), Hazard Analysis, and Risk-based Preventive Controls for Human Food by September 30, 2019.

	ID	Requirements Description	Needs/Goals/Objectives Type *Business, Stakeholder, Product, Transition, Quality*	Project Owner	WBS Deliverables	Priority	*Due Date*	Status As of 21 June 2019
1.	B1	Contracting of a FSPCA Lead Instructor.	*Business*	Managing Director & Office Manager	Task 1.0.0	High	May 01, 2019	Completed
2.	B2	Contracting of a Food Safety Expert.	*Business*	Managing Director & Office Manager	Task 1.0.0	High	May 01, 2019	Completed
3.	B3	Time allocations for the Staff to that they can work on this project.	*Business*	Managing Director & Shareholders of Choo's	N/A	High	May 01 – Sept 30, 2019	In Progress
4.	B4	Financial allocations for the project which was adequately projected and allocated.	*Business*	Managing Director & Shareholders of Choo's	N/A	High	May 01 - Sept 30, 2019	In Progress
5.	B5	Adequate and timely resource allocations for the project.	*Business*	Managing Director & Shareholders of Choo's	N/A	High	May 01 - Sept 30, 2019	In Progress
6.	S1	Export products to the USA to increase market share and profitability.	*Stakeholder*	Managing Director & Shareholders of Choo's	N/A	High	Jan 01, 2020	To Commence
7.	S2	Improve current food safety system to meet FDA requirements.	*Stakeholder*	Managing Director & Shareholders of Choo's	Task 4.0.0 and Task 6.0.0	High	Sept 30, 2019	To Commence
8.	P1	Build a Food Safety Plan that meets FDA requirements.	*Product*	Food Safety Team	Task 4.0.0	High	Sept 30, 2019	To Commence
9.	P2	Validate Compliance Food Safety Plan to FDA regulations.	*Product*	Food Safety Expert	Task 7.0.0	High	Oct 30, 2019	To Commence
10.	T1	Training of the project team.	*Transition*	Project Manager & Principal Consultant	Task 2.0.0	High	May 30, 2019	Completed
11.	T2	Training of the general staff in CGMPs.	*Transition*	FSPCA Lead Instructor	Task 2.0.0	Medium	May 30, 2019	Completed
12.	T3	Training of the specific staff as PCQIs for the Food Safety Team.	*Transition*	FSPCA Lead Instructor	Task 2.0.0	High	May 30, 2019	Completed
13.	T4	Hiring a Food Safety and QA Officer.	*Transition*	Managing Director & Office Manager	Task 3.2.3	High	July 01, 2019	In Progress
14.	T5	Building a Food Safety Team.	*Transition*	Office Manager (Project Leader)	Task 3.0.0		July 01, 2019	In Progress
15.	T6	Training start date and time; room location, reservation and readiness with working technical equipment and adequate seating with tables; stationery requirements; Training, Assessment, Feedback and Auditing Materials; Staff notification of training, schedule and what is required of them; Catering arrangements and times; and the total number of attendees for each training session.	*Transition*	Office Manager	Task 2.1.4.1	High	May 06, 2019 and May 20, 2019	Completed

Figure 4-9 Requirements Traceability Matrix
(Source: Project Team, Personal Communication, June 2019)

WBS Dictionary	
Project Name: FDA Food Safety Regulations Implementation	Choo's Enterprises
Control Account ID: 20191001	
Work Package Name: Confirmations	
Work Breakdown Structure WBS ID: 2.1.4.1	
Responsible Organization: Choo's Enterprises Office Manager	
Work Package Deliverable Description: This involves the confirmation of the training start date and time; room location, reservation and readiness with working technical equipment and adequate seating with tables; stationery requirements; Staff notification of training , schedule and what is required of them; Catering arrangements and times; and the total number of attendees for each training session.	
Assumptions - Scope and objectives of the project have been adequately defined and outlined. - Financial allocations for this phase of this project has been adequately projected and funds allocated. - Resources are adequate for this phase. - Required information needed to complete the various processes for this phase of the project will be provided by the company - Minimal project delays so this phase can be completed on time for the project **Constraints** - Room size and position of some the equipment - Technical and engineering capabilities of staff preparing the room - Operating capability of instrumentation and devices.	
Quality Metrics: - Number of non-conformances observes Pre-Training. - # of complaints received during the training process. - Actual Timelines accomplished versus the planed timelines. - Feedback Questionnaire results and metrics attain.	
Resources Assigned: - Training room, and technical equipment(projector, pointer, etc) - FSPCA Lead Instructor - Seating with tables; - Staff and Caterer - Stationary	
Schedule Milestones: • Check works of technical equipment and adequate seating with tables; (2 hrs) • Check for adequacy of technical equipment and seating with tables(2 hrs) • Check for adequacy of stationary s (2 hrs) • Remind staff of training , schedule and what is required of them (1hr) • Check for the total number of attendees for each training session and confirm catering arrangements and times	
Approved by:____*C. Jones*_____ Date:_____28/June/2019_____	

Figure 4-10 Work Breakdown Structure (WBS) Dictionary
(Source: Project Team, Personal Communication, June 2019)

4.3. Project Schedule Management

Several scheduled meetings were held with the Project Manager and the selected project team members in order to define the project Schedule Management Plan as part the attainment of the objectives for this project. The templates used in developing the deliverables by the team were adapted from the PMBOK® Guide and PMI database. The results for the process generated the Activity and Milestone List as shown in Figures 4.11 and 4.12 respectively.

WBS	Activity Code	Activity Name	Duration/ Work days
1	100	Contract fspca lead instructor and food safety expert	3.00
1.1	150	***Selection and acceptance of training vendor proposal***	**3.00**
2	200	Staff training	20.00
2.1	250	***Training preparation***	**5.00**
2.1.1	300	**Training location preparation**	1.00
2.1.1.1	350	Implement technical requirements	1.00
2.1.2	400	**Training materials preparation**	2.00
2.1.2.1	450	Review and customize training materials for presentation	1.00
2.1.2.2	500	Prepare participants assessment and practical exercises	1.00
2.1.3	550	**Feedback questionnaires preparation**	1.00
2.1.3.1	600	Review and customize feedback questionnaires	1.00
2.1.4	650	**Finalize schedule**	1.00
2.1.4.1	700	Confirm start date and time, room reservations, technical requirements, staff notifications and number of attendees, and catering arrangements	1.00
2.2	710	***Training***	**10.00**
2.2.1	720	**General staff and pcqi training sessions**	10.00
2.2.1.1	730	Train participants in using materials & practical exercises	8.00

2.2.1.2	740	Have participants conduct assessment and feedback questionnaires	2.00
2.3	750	***Training closeout***	**5.00**
2.3.1	760	**Review participants assessment and score**	1.00
2.3.2	770	**Evaluate feedback and tally scores**	3.00
2.3.3	780	**Distribute corrected assessments and supplemental training materials to staff**	1.00
3	790	Build food safety team	**25.00**
3.1	800	***Identify team members***	3.00
3.2	850	***Identify process owner***	17.00
3.2.1	900	**Define role and develop job description for process owner (attain Managing Director approval)**	7.00
3.2.2	950	**Interview candidates**	3.00
3.2.3	1000	**Select candidate and send them job offer**	2.00
3.2.4	1050	**Candidates' acceptance of the offer and commencement**	5.00
3.3	1100	***Define roles and responsibilities of the team and its members***	5.00
4	1150	Build food safety plan	**50.00**
4.1	1280	***Develop product descriptions***	5.00
4.2	1290	***Develop process flow diagram and descriptions***	5.00
4.3	1300	***Conduct and develop hazard analysis for all ingredients and processes***	15.00
4.4	1310	***Develop process, allergen, sanitation and supply-chain preventive controls for hazards identified***	5.00
4.5	1320	***Develop supporting food safety plan components***	15.00
4.6	1340	***Review of plan by food safety expert***	5.00
4.6.1	1350	**Write audit report**	4.00
4.6.2	1160	**Distribute audit report and supplemental corrective action materials to team leader/mgmt**	1.00
5	1170	Validate fs plan	**6.00**
5.1	1180	***Confirm implemented monitoring, corrective actions and records for identified hazards***	1.00

5.2	1360	***Verification and validation of procedures***	5.00
6	1370	Conduct internal audit	**8.00**
6.1	1380	***Audit preparation***	2.00
6.1.1	1390	**Auditing materials**	2.00
6.1.1.1	1400	Review and customize materials for audit	1.00
6.1.1.2	1410	Prepare interview questions for auditees	1.00
6.1.2	1420	**Finalize schedule and audit team**	
6.1.2.1	1430	Confirm start date and time, audit scope, documentation requirements, staff notifications, and number of hosts	1.00
6.2	1440	***Audit***	2.00
6.2.1	1450	**Conduct physical audit of the company, related material (SOPsand records)**	1.00
6.2.2	1460	**Interview staff**	1.00
6.3	1480	***Audit closeout***	4.00
6.3.1	1490	**Review audit results and confirm any questions.**	1.00
6.3.2	1500	**Write audit report and score**	2.00
6.3.3	1470	**Distribute audit report and supplemental corrective action materials to team leader and mgmt. Rep.**	1.00
7	1510	***Validate compliance***	**5.00**
7.1	1560	***Confirm implemented corrective actions and records for identified non-conformances in desk and physical audits***	5.00
7.2	1590	***Verification and validation of cas***	1.00
		Total days	117.00
		Months	5

Figure 4-11 Activity List and Duration

(Source: Project Team, Personal Communication, June 2019)

		Name	Duration	Start	
1		**FDA Food Safety Regulation Implementation**	**111 days?**	**4/29/19 8:00 AM**	**9/30/**
2		**Contract a FSPCA Lead Instructor and Food Safety Expert**	**3 days?**	**4/29/19 8:00 AM**	**5/1/1**
3		Request Proposal for Training & Consultation Service from Vendor	2 days?	4/29/19 8:00 AM	4/30/
4		Selection and Acceptance of Proposal from Vendor	1 day?	5/1/19 8:00 AM	5/1/1
5		**Staff Training**	**17 days?**	**5/2/19 8:00 AM**	**5/24/**
6		**Training Preparation**	**3 days?**	**5/2/19 8:00 AM**	**5/6/1**
7		**Location Preparation**	**1 day?**	**5/3/19 8:00 AM**	**5/3/1**
8		Prepare room and implement technical requirements	1 day?	5/3/19 8:00 AM	5/3/1
9		**Training materials Preparation**	**2 days?**	**5/2/19 8:00 AM**	**5/3/1**
10		Review and customize training material for presentation	1 day?	5/2/19 8:00 AM	5/2/1
11		Prepare participants Assessment and Practical Exercises	1 day?	5/3/19 8:00 AM	5/3/1
12		**Prepare Feedback Questionnaires**	**1 day?**	**5/6/19 8:00 AM**	**5/6/1**
13		Review and customize Feedback Questionnaires	1 day?	5/6/19 8:00 AM	5/6/1
14		**Finalize Schedule with Choo's**	**1 day?**	**5/3/19 8:00 AM**	**5/3/1**
15		Confirm Start date and Time, Room reservations, Technical requirements, Staff notifications and number of atten..	1 day?	5/3/19 8:00 AM	5/3/1
16		**Training**	**15 days?**	**5/6/19 8:00 AM**	**5/24/**
17		**General staff & PCQI training sessions**	**10 days?**	**5/6/19 8:00 AM**	**5/17/**
18		Train Participants in using Materials & Practical exercises	8 days?	5/6/19 8:00 AM	5/15/
19		Have Participants Conduct Assessment and Feedback Questionnaires	2 days?	5/16/19 8:00 AM	5/17/
20		**Training Closeout**	**5 days?**	**5/20/19 8:00 AM**	**5/24/**
21		Review Participants Assessment & Score	1 day?	5/20/19 8:00 AM	5/20/
22		Evaluate Feedback & tally Scores.	3 days?	5/21/19 8:00 AM	5/23/
23		Distribute corrected assessments & supplemental training materials to staff	1 day?	5/24/19 8:00 AM	5/24/
24		**Build Food Safety Team**	**25 days?**	**5/27/19 8:00 AM**	**6/28/**
25		**Identify Team Members**	**3 days?**	**5/27/19 8:00 AM**	**5/29/**
26		Identify Team Members from Trained PCQIs	3 days?	5/27/19 8:00 AM	5/29/
27		**Identify Process Owner**	**17 days?**	**5/30/19 8:00 AM**	**6/21/**
28		Define Role & develop JD for process owner(Attain MD Approval)	7 days?	5/30/19 8:00 AM	6/7/1
29		Interview Candidates	3 days?	6/10/19 8:00 AM	6/12/
30		Select candidate and send them job offer	2 days?	6/13/19 8:00 AM	6/14/
31		Candidates' acceptance of the offer & Commencement	5 days?	6/17/19 8:00 AM	6/21/
32		**Define roles and responsibilities of the team and its members.**	**5 days?**	**6/24/19 8:00 AM**	**6/28/**
33		Define Team Members roles and responsibilities	5 days?	6/24/19 8:00 AM	6/28/
34		**Build Food Safety Plan**	**50 days?**	**7/1/19 8:00 AM**	**9/6/1**
35		**Build Components of Food Safety Plan**	**45 days?**	**7/1/19 8:00 AM**	**8/30/**
36		Develop Product Descriptions	5 days?	7/1/19 8:00 AM	7/5/1
37		Develop Process Flow Diagram and Descriptions	5 days?	7/8/19 8:00 AM	7/12/
38		Conduct and Develop Hazard Analysis for all Ingredients and Processes	15 days?	7/15/19 8:00 AM	8/2/1
39		Develop Process, Allergen, Sanitation and Supply-Chain Preventive Controls for Hazards Identified	5 days?	8/5/19 8:00 AM	8/9/1
40		Develop supporting Food Safety Plan components	15 days?	8/12/19 8:00 AM	8/30/
41		**Review of plan by Food Safety Expert**	**5 days?**	**9/2/19 8:00 AM**	**9/6/1**
42		Write Audit Report	4 days?	9/2/19 8:00 AM	9/5/1

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		Name	Duration	Start	Finish
43		Distribute audit report & supplemental Corrective Action materials to Team leader/Mgmt.	1 day?	9/6/19 8:00 AM	9/6/19 5:00 PM
44		**Validate Food Safety Plan**	**5 days?**	**9/9/19 8:00 AM**	**9/13/19 5:00 PM**
45		Confirm Implemented Monitoring, Corrective actions and Records for Identified Hazards	1 day?	9/9/19 8:00 AM	9/9/19 5:00 PM
46		Verification and Validation of procedures	5 days?	9/9/19 8:00 AM	9/13/19 5:00 PM
47		**Conduct Internal Audit**	**5 days?**	**9/16/19 8:00 AM**	**9/20/19 5:00 PM**
48		**Audit Preparation**	**2 days?**	**9/16/19 8:00 AM**	**9/17/19 5:00 PM**
49		**Auditing Materials**	**2 days?**	**9/16/19 8:00 AM**	**9/17/19 5:00 PM**
50		Review and customize materials for Audit	1 day?	9/16/19 8:00 AM	9/16/19 5:00 PM
51		Prepare Interview Questions for Auditees	1 day?	9/17/19 8:00 AM	9/17/19 5:00 PM
52		**Finalize Schedule and Audit Team**	**1 day?**	**9/17/19 8:00 AM**	**9/17/19 5:00 PM**
53		Confirm Start date and Time, Audit Scope, Documentation requirements, Staff notifications, and number of host.	1 day?	9/17/19 8:00 AM	9/17/19 5:00 PM
54		**Audit**	**1 day?**	**9/18/19 8:00 AM**	**9/18/19 5:00 PM**
55		Conduct Physical audit of the company, related Material(SOP & Records).	1 day?	9/18/19 8:00 AM	9/18/19 5:00 PM
56		Interview Staff	1 day?	9/18/19 8:00 AM	9/18/19 5:00 PM
57		**Audit Closeout**	**2 days?**	**9/19/19 8:00 AM**	**9/20/19 5:00 PM**
58		Review Audit Results, and confirm any questions.	1 day?	9/19/19 8:00 AM	9/19/19 5:00 PM
59		Write Audit Report and score	2 days?	9/19/19 8:00 AM	9/20/19 5:00 PM
60		Distribute audit report & supplemental Corrective Action materials to Team leader and Mgmt. Rep.	1 day?	9/20/19 8:00 AM	9/20/19 5:00 PM
61		**Validate Compliance**	**6 days?**	**9/23/19 8:00 AM**	**9/30/19 5:00 PM**
62		Confirm Implemented Corrective actions and Records for Identified Non-Conformances in Desk & Physical Audits.	5 days?	9/23/19 8:00 AM	9/27/19 5:00 PM
63		Verification and Validation of CAs	1 day?	9/30/19 8:00 AM	9/30/19 5:00 PM

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Figure 4-12 Activity and Milestone List
(Source: Project Team, Personal Communication, June 2019)

From the Activity and Milestone and Duration List, a Gantt chart showing the project sequence as shown in Figure 4-13, the Schedule Network as shown in Figures 4-15 and 4-16, along with the Project's Critical Tasks as shown in Figure 4-14 were developed by the team. The sequencing methodology used was from start to finish for the project with a 10% probability of the project exceeding the 5 months duration. As part of the process of identifying and estimating the resources needed to complete this project, Analogous Estimating was used by using previous project information for other similar projects by the Food Safety Expert.

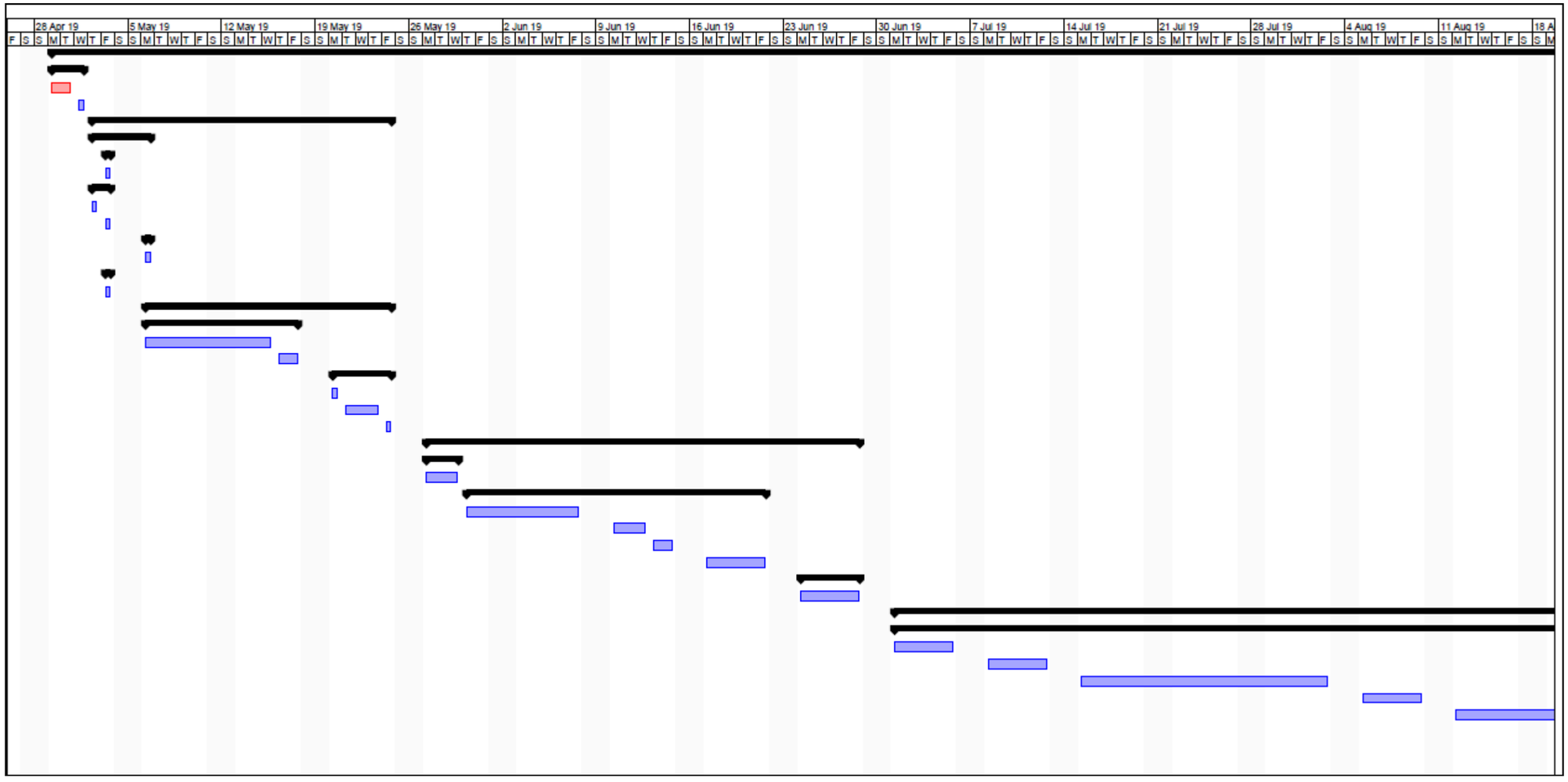


Figure 4-13 Project Gantt Chart Part 1

(Source: Project Team, Personal Communication, June 2019)

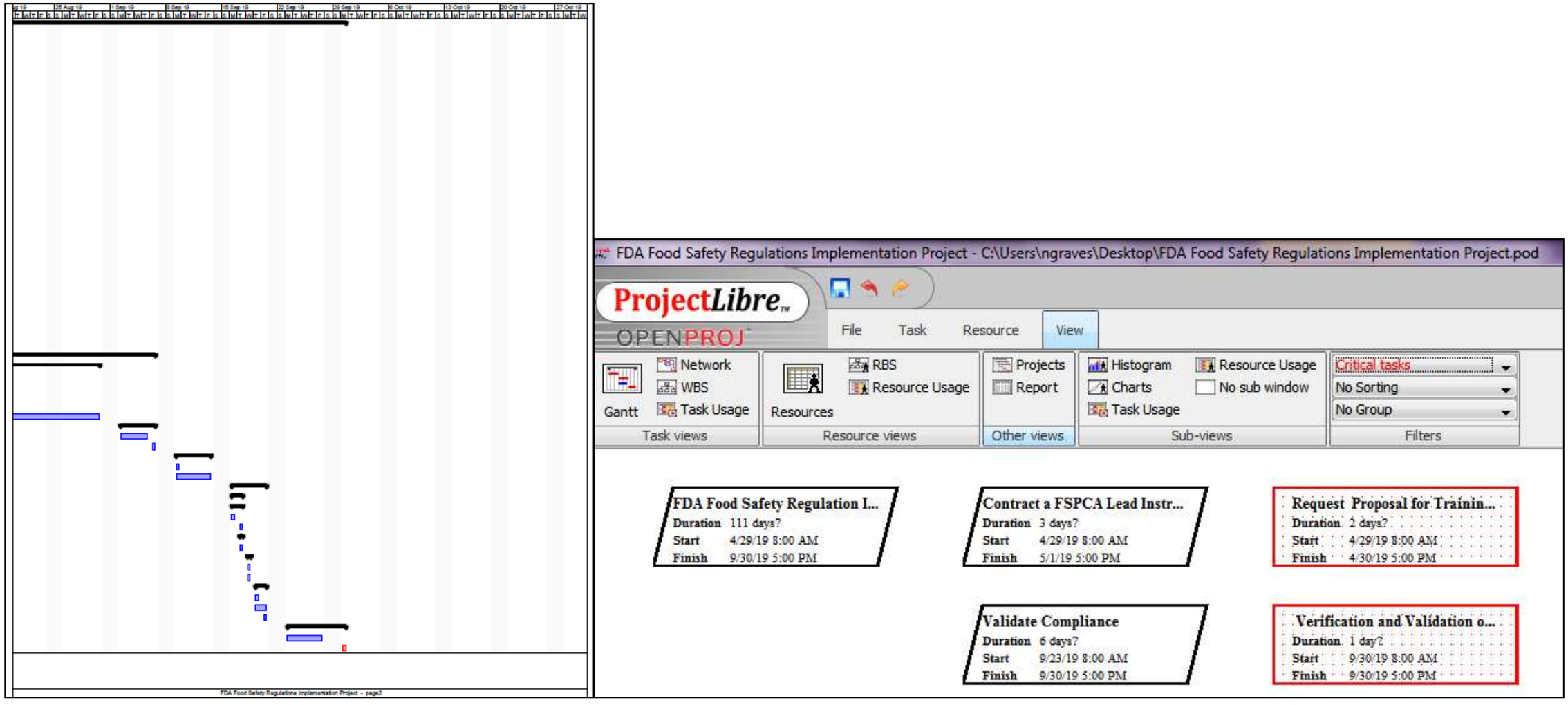


Figure 4-14 Project Gantt chart Part 2 and Project Critical Task

(Source: Project Team, Personal Communication, June 2019)

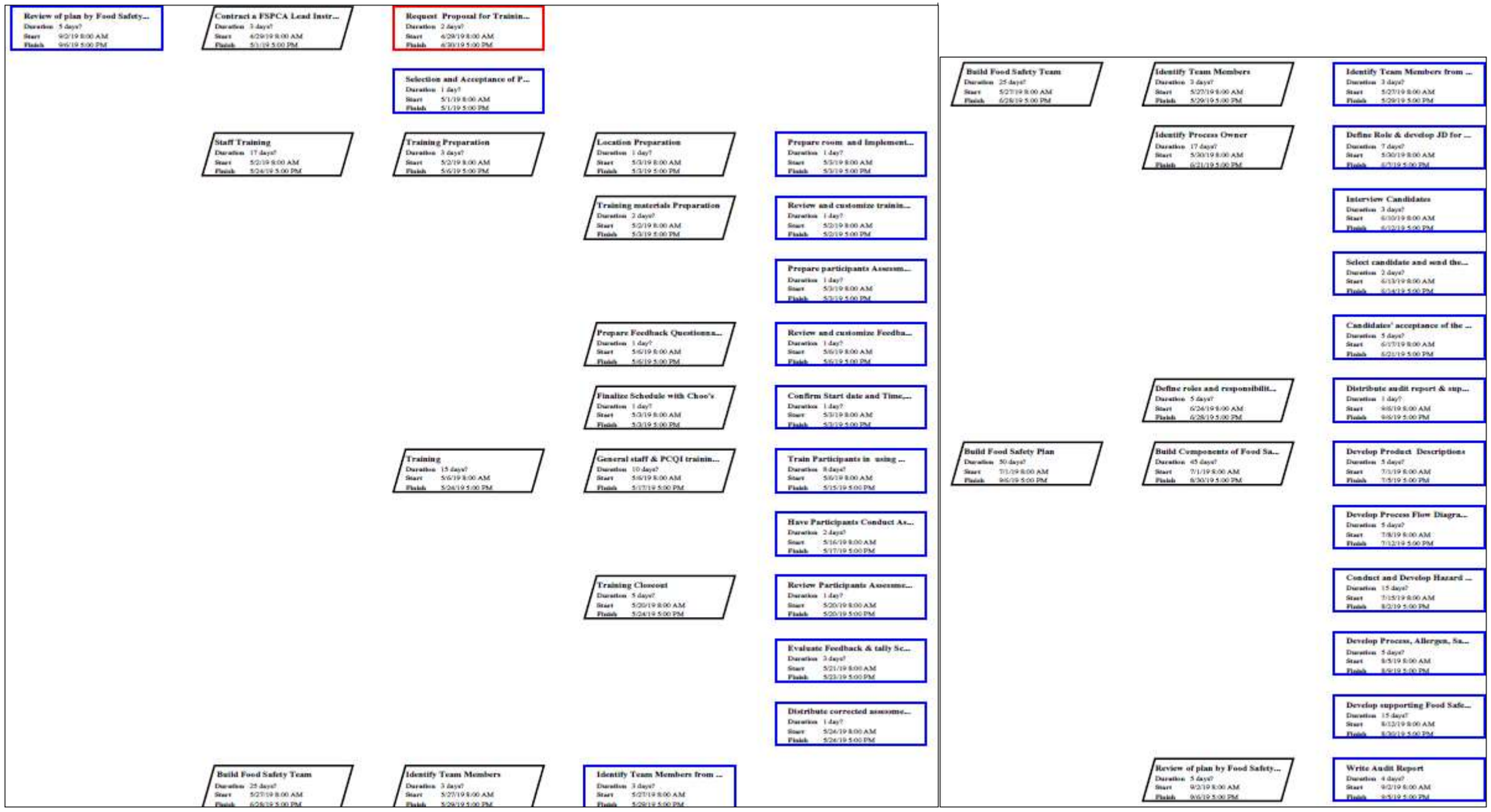


Figure 4-15 Project Gantt chart Part 2 and Project Critical Task

(Source: Project Team, Personal Communication, June 2019)

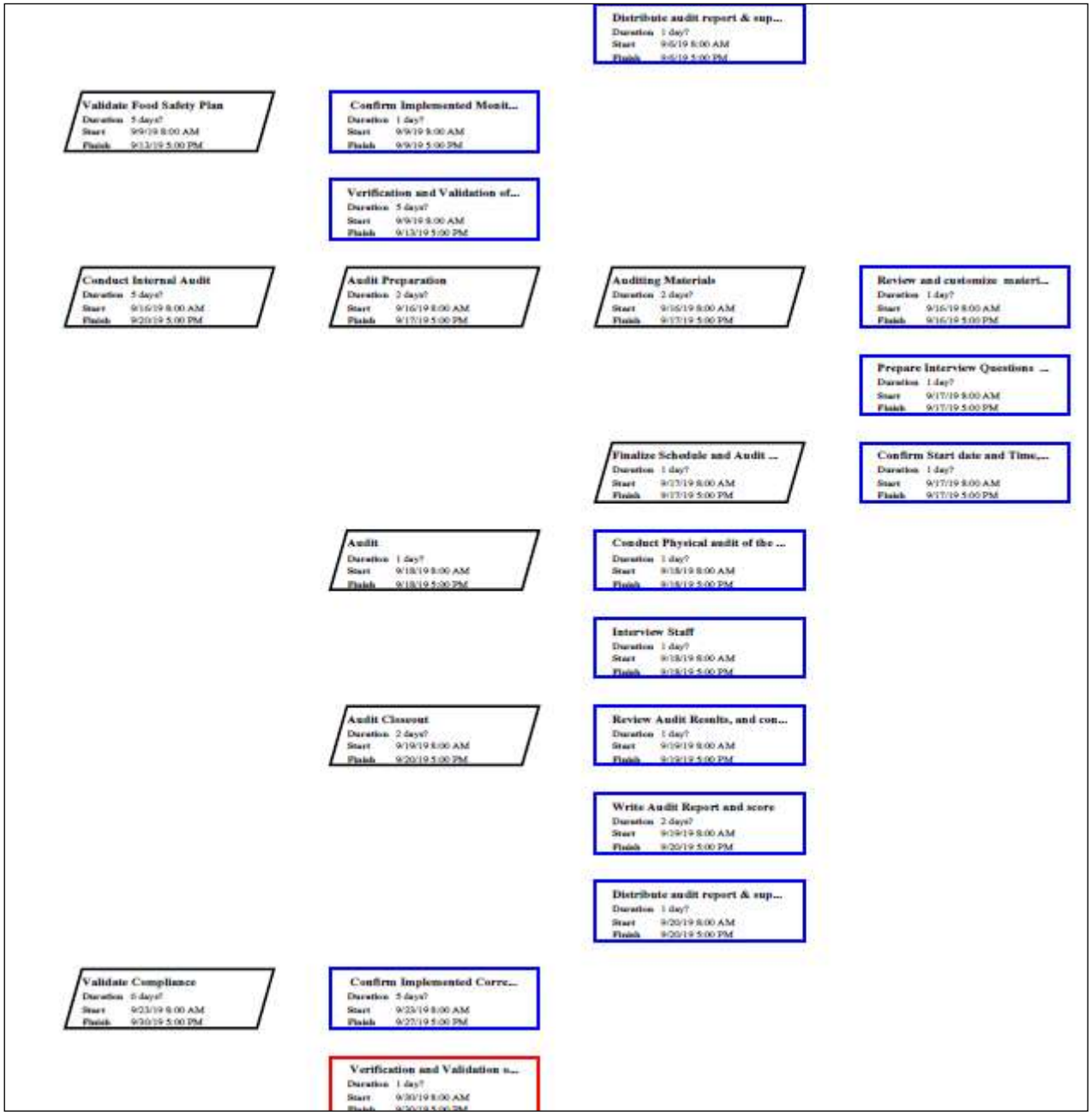


Figure 4-16 Project Gantt chart Part 2 and Project Critical Task

(Source: Project Team, Personal Communication, June 2019)

One of the tools used to execute and schedule such was the Responsibility Assignment Matrix (RAM), as shown in Figure 4-18. A cadre of knowledge and data was available from similar previous jobs and this was used to estimate cost, timeframe and responsibility assignment.

4.4. Project Cost Management

The Project Manager, along with the Project Leader and Sponsor, met to discuss and develop the project cost management. This was accomplished by using the Work and Requirements Breakdown Structure to specifically identify the costs associated with the requirements. The Cost Estimates with Basis was developed as presented in Figure 4-17 and a contingency reserve of 10% was applied to the Cost Baseline along with a Management Reserve of 3%.

WBS	Activity Code	Activity Name	Resources	Planned value (PV/$) as per schedule.
1	100	Contract FSPCA Lead Instructor and Food Safety Expert		
1.1	150	***Selection and Acceptance of Training Vendor Proposal***	Office Manager	
2	200	Staff Training	PCA Lead Instructor and Food Safety Expert	
2.1	250	***Training Preparation***		$500.00
2.1.1	300	**Training location preparation**		
2.1.1.1	350	Implement technical requirements	1 technician, 1 admin staff, 1 Caterer	$200.00
2.1.2	400	**Training Materials Preparation**		
2.1.2.1	450	Review and customize training materials for Presentation	Training materials, PCA Lead Instructor	
2.1.2.2	500	Prepare Participants' Assessment and Practical exercises	Participants' Assessment and Practical exercises, PCA Lead Instructor	
2.1.3	550	**Feedback Questionnaires Preparation**		
2.1.3.1	600	Review and customize Feedback Questionnaires	Feedback Questionnaires, PCA Lead Instructor	
2.1.4	650	**Finalize Schedule**		n/a
2.1.4.1	700	Confirm Start date and Time, Room reservations, Technical requirements, Staff notifications and number of attendees, and Catering arrangements	Team Leader	

2.2	710	***Training***		$6,000.00
2.2.1	720	**General staff and PCQI training sessions**	Engineer, Foreman, 2 laborers	
2.2.1.1	730	Train Participants in using Materials and Practical exercises	Training materials, Templates and Worksheets, PCA Lead Instructor	
2.2.1.2	740	Have Participants Conduct Assessment and Feedback Questionnaires	Assessment Forms, Feedback Questionnaires, PCA Lead Instructor	
2.3	750	***Training Closeout***		$500.00
2.3.1	760	**Review Participants' Assessment and Score**	Assessment Forms, PCA Lead Instructor	
2.3.2	770	**Evaluate Feedback and tally scores**	Feedback Questionnaires, PCA Lead Instructor	
2.3.3	780	**Distribute corrected assessments and supplemental training materials to staff**	PCA Lead Instructor, Office Manager	
3	790	Build Food Safety Team		
3.1	800	***Identify Team Members***	Office Manager	
3.2	850	***Identify Process Owner***		
3.2.1	900	**Define Role and develop JD for process owner**	Office Manager	
3.2.2	950	**Interview Candidates**	Office Manager, Food Safety Expert	$400.00
3.2.3	1000	**Select candidate and send them job offer**	Office Manager	
3.2.4	1050	**Candidates' acceptance of the offer and Commencement**	Candidate	$16,800.00
3.3	1100	***Define roles and responsibilities of the team and its members***	Project Team Leader	
4	1150	Build Food Safety Plan		
4.1	1280	***Develop Product Descriptions***	Food Safety Team, Templates	
4.2	1290	***Develop Process Flow Diagram and Descriptions***	Food Safety Team, Templates	
4.3	1300	***Conduct and Develop Hazard Analysis for all Ingredients and Processes***	Food Safety Team, Templates	
4.4	1310	***Develop Process, Allergen, Sanitation and Supply-Chain Preventive Controls for Hazards identified***	Food Safety Team, Templates	

4.5	1320	***Develop supporting Food Safety Plan components***	Food Safety Team, Templates	
4.6	1340	***Review of plan by Food Safety Expert***		$500.00
4.6.1	1350	**Write Audit Report**	Audit Report, Food Safety Expert	
4.6.2	1160	**Distribute audit report and supplemental Corrective Action materials to Team leader/Mgmt.**	Audit Report, Food Safety Expert, Office Manager	
5	1170	Validate FS Plan		$500.00
5.1	1180	***Confirm Implemented Monitoring, Corrective actions and Records for identified Hazards***	Audit templates, Food Safety Expert, Office Manager	
5.2	1360	***Verification and Validation of procedures***	Audit templates, Food Safety Expert, Office Manager	
6	1370	Conduct Internal Audit		
6.1	1380	***Audit Preparation***		$250.00
6.1.1	1390	**Auditing Materials**		
6.1.1.1	1400	Review and customize materials for Audit	Audit templates, Food Safety Expert	
6.1.1.2	1410	Prepare Interview Questions for Auditees	Audit templates, Food Safety Expert	
6.1.2	1420	**Finalize Schedule and Audit Team**		
6.1.2.1	1430	Confirm Start date and Time, Audit Scope, Documentation requirements, Staff notifications, and number of hosts	Food Safety Expert, Office Manager	
6.2	1440	***Audit***		$500.00
6.2.1	1450	**Conduct Physical audit of the company, related Material (SOP and Records)**	Audit templates, Food Safety Expert, Food Safety Team Members	
6.2.2	1460	**Interview Staff**	Audit templates, Food Safety Expert, Food Safety Team Members	
6.3	1480	***Audit Closeout***		$250.00
6.3.1	1490	**Review Audit Results and confirm any questions**	Audit templates, Food Safety Expert	
6.3.2	1500	**Write Audit Report and score**	Audit templates, Food Safety Expert	
6.3.3	1470	**Distribute audit report and supplemental Corrective Action materials to Team leader and Mgmt. Rep.**	Food Safety Expert, Office Manager	

7	1510	***Validate Compliance***		$600.00
7.1	1560	***Confirm Implemented Corrective actions and Records for identified Non-Conformances in Desk and Physical Audits.***	Audit templates, Food Safety Expert, Office Manager	
7.2	1590	***Verification and Validation of CAs***	Audit templates, Food Safety Expert, Office Manager	
			Cost Baseline	$ 27,000.00
			Contingency reserve equal to 10%	$ 29,700.00
			Management Reserve equal to 3%	$ 30,591.00

Figure 4-17 Cost Estimates

(Source: Project Team, Personal Communication, June 2019)

4.5. Project Quality Management

In order to fulfill the development of the Quality Management Plan for this project, interviews were conducted with stakeholders and the project team members, resulting in the generation of meeting minutes. This also involved the use of Six Sigma methodologies, FSPCA templates (Appendix 6: Facility Audit Checklist Template, Appendix 7: Food Safety Plan Template and Appendix 8 Food Safety Preventive Controls Verification Report Template) and the PMBOK® Guides as the catalyst for the plan, together with the application of the analytical research methodology when required. As part of the quality standards development for this project, a measurement-based strategy for process improvement and increasing customer satisfaction was used to ensure project success for the future as part of the lessons learned.

4.1.1 Project Quality Plan

During the execution of the Planning Quality Management process, the quality requirements and/or standards for the project and its deliverables were identified, as illustrated in Chart 6. An outline of how the project will demonstrate compliance with quality requirements is also shown in Charts 7-9.

Chart 6 Key Factors Related to Quality

Quality Factor	Factor Definition	Quality Objective
Level of Compliance	Assurance that a product or process is designed or done in accordance with a specific policy, procedure or standard.	Ensuring compliance of all aspects of FSPC and GMPs via records, food safety plans, procedures policies, processes, forms and checklists, work instructions, specifications and non-conformances.
Ease of Use of System Elements	Amount of effort required to learn, operate, prepare input for and interpret output from a process by the users/people interfacing with the process.	Ensure all documentation, forms, checklists, procedures, policies, plans, and/or work instructions needed for compliance to all aspects of FSPC and GMPs are easy to follow, understand and use.
Level of Service and Delivery	The desired results will be achieved within the required timeframe and acceptable by the client and the users.	Ensure the transition process to FSPC Food Code System Elements and GMP requirements is completed by October 15, 2019.
Correctness	The degree to which the data entered, generated and processed and the output from such is accurate and complete.	Ensuring, relevance, full documentation and effective implementation and use of all aspects of FSPC and GMPs, i.e. accuracy of records, food safety plans, policies, processes, forms and checklists, procedures, policies, plans, work instructions, specs and non-conformances.

(Source: Principal Consultant, FSQ Solutions, May 2019)

Chart 7 Metrics and Quality Baseline

Factor	Metrics	Metric definition	Expected Outcome/Result	Measurement Frequency	Responsibility
Level of Compliance	FSPC Audit scoring and the number of non-conformances	✓ Score received from the Principal Consultant during the Site audit post implementation. ✓ Number of non-conformances received during the desk audit post implementation.	100 – 86 % on Site audit 0-5 of NC for the Desk audit of the Plan	Once – Pre-Onsite Audit Once – Post-Onsite and Desk audit	Compliance Score – Principal Consultant External audits – Principal Consultant
Ease of Use of System Elements	Number of complaints	✓ # of complaints received during the transition process and 6 months thereafter.	0-3 complaints maximum received	Monthly – Internal Assessment	Project Manager and Lead
Level of Service and Delivery	Timeline Gaps Scores on Feedback form	✓ Actual Timelines accomplished versus the planed timelines. ✓ Questionnaire results and metrics attained.	95% Confidence attainment for Timelines. 100 – 75 % Score from Feedback.	Monthly – Internal Assessment	Project Manager and Lead
Correctness	FSPC Audit scoring and Number of NC	✓ Score received from the Principal Consultant during the Site audit post implementation. ✓ Number of non-conformances received during the Desk audit post implementation.	100 – 86 % on Site audit 0-5 of NC for the Desk audits, Both Internal and External	Once – External Post-Onsite and Desk audit Monthly – Internal Audit and reviews	Compliance Score and External Audit – Principal Consultant Internal Audit – A Member of the Project Team

(Source: Principal Consultant, FSQ Solutions, May 2019)

Chart 8 Quality Activities Matrix

Deliverable	Requirement	Manage and Control activities	Frequency	Responsible
Transition to FSPC should be such that it is smooth and with minimal stress.	Provision of all of the resources required to ensure everything is easy to follow, understand and use.	*Manage:* Audits and Data Analysis. Meetings *Control:* Root cause analysis	Monthly – Internal Audit Bi-Weekly – Meetings	Project Manager and Principal Consultant and Project Team
Attain full compliance to the FDA *Preventive Controls for Human Food* Regulation by October 15, 2019.	Provision of all of the required resources needed to ensure compliance in the required timeline	*Manage:* Graphical plot of actual Timelines against planned. *Control*: Checklist	Bi-Monthly – Internal Audit	Project Manager and Principal Consultant, Project Team, Managing Director, Shareholders.
Ensure full implementation of all of the elements of the Regulation and maintain such.	Using the FSPCA and FDA templates provided and ensuring correctness, relevance, full documentation and effective implementation and use of all aspects of FSPC and GMPs, i.e. accuracy of records, food safety plans, policies, processes, forms and checklists, procedures, policies, plans, work instructions, specifications and non-conformances (NC).	*Manage:* External and Internal Audits, Meetings, Virtual and on-Site consultations. *Control:* Checklist	Monthly – Internal Audit -1 External Pre-Onsite Audit -1 External Post-Onsite - 1 Desk audit Bi-Weekly- Meetings/ Virtual and on-Site consultations	Project Manager and Principal Consultant, Project Team, Staff, Senior Management
Easy documentation navigation and use – The System should be easily	Ensure all documentation, forms, checklists, procedures, policies, plans, work instructions needed for compliance to all aspects	*Manage:* Assessments *Control:*	Monthly – Internal Assessments	Project Manager and Principal Consultant, Project Team, Senior Management,

Deliverable	Requirement	Manage and Control activities	Frequency	Responsible
understood and followed by staff. The staff should be able to navigate the various documents, policies, processes and procedures with minimal stress.	of FSPC and GMPs are easy to follow, understand and use.	Surveys, Meetings and Questionnaires		Managing Director
Attain full compliance to the FDA *Preventive Controls for Human Food* Regulation	Conduct Pre- and post-implementation FSPC Audit with scoring and ensure minimal number of non-conformances attained.	*Manage:* External Audits *Control:* Checklist	One – External Pre and Post-Onsite and Desk Audit	Project Manager and Principal Consultant

(Source: Principal Consultant, FSQ Solutions, May 2019)

Chart 9 Continuous Improvement Plan

Process Description for the Closure of Non-conformances
1. Train the team on the tools used to assist with Non-conformances
2. Review entire system monthly for compliance and status of corrective action
3. Use tools such as Six Sigma and Fishbone to analyze and solve non-conformances
4. Close all minor Non-conformances within 30 days
5. Close all major Non-conformances within 15 days

(Source: Principal Consultant, FSQ Solutions, August 2019)

4.6. Project Resources Management

As part of the process of identifying and estimating the resources needed to complete this project, Analogous Estimating was employed by using previous project information for other similar projects from the Food Safety Expert. There was a great deal of knowledge and data available from similar previous jobs, which was used to estimate cost, timeframe and responsibility assignment. One of the tools used to execute and schedule such was the Responsibility Assignment Matrix (RAM), as shown in Figure 4-18, with the resource person/group assigned to each work package showing who was Responsible, Accountable, Consulting and Informing. This way, there was clear direction about who was in charge of what and what role each person/group has.

Responsibility Assignment Matrix - RACI Chart								
	Project Manager & Principal Consultant	FSPCA Lead Instructor and Food Safety Expert	Project Team:-	Managing Director	Senior Management	Staff	Shareholders	Suppliers & Customers
An executing agent for the project approved by Managing Director.	A	C	R	I	I	I	I	I
Provides technical support for the implementation of the project	R	R	R	A	C	C	I	C
Fund and approve the project along with being the resource person for the project	A	I	I	R	I	I	R	I
Hire a trained FSPCA Lead Instructor/Food Safety Consultant as well as Food Safety and QA Officer.	C	C	I	A	R	I	I	I
Train Personnel in CGMPs and the specific staff as PCQIs for Food Safety Team .	A	R	I	I	I	I	I	I
Develop Food Safety Plan Components	A	C	R	R	R	C	I	I
Implement Monitoring and Corrective actions for Preventive Controls to Hazards identified and establish Verification and Validation procedures. Execute corrective actions for Non-conformances identified	A	C	R	R	R	R	I	I
Conduct Internal Audit and Check for compliance	A	R	R	I	C	C	I	I
'R' Responsible								
'A' Accountable								
'C' Consult								
'I' Inform								

Figure 4-18 Responsibility Assignment Matrix

(Source: Principal Consultant, FSQ Solutions, June 2019)

As part of the process of identifying and estimating the resources needed to complete this project, the team outlined the Human Resource Needs as shown in Figure 4-19 and their scheduled required times as shown in Figure 4-20. In addition, the other types of resource requirements are outlined in Figure 4-21.

Resource Needs For Project Duration					
Resources	**May**	**June**	**July**	**August**	**September**
Project Manager and Principal Consultant	1	1	1	1	1
Procurement Specialist	0	0	1	1	1
Senior Management	5	5	5	5	5
FSPCA Lead Instructor and Food Safety Expert	1	1	1	1	1
Engineer	0	1	1	1	1
Administrative Officer Manager and Financial Specialist	1	1	1	1	1
PCQIs for Food Safety Team	10	10	10	10	6
Food Safety and QA Officer	1	1	1	1	1
Caterer	1	0	0	0	0

Figure 4-19 Human Resources Needs Matrix

(Source: Principal Consultant, FSQ Solutions, June 2019)

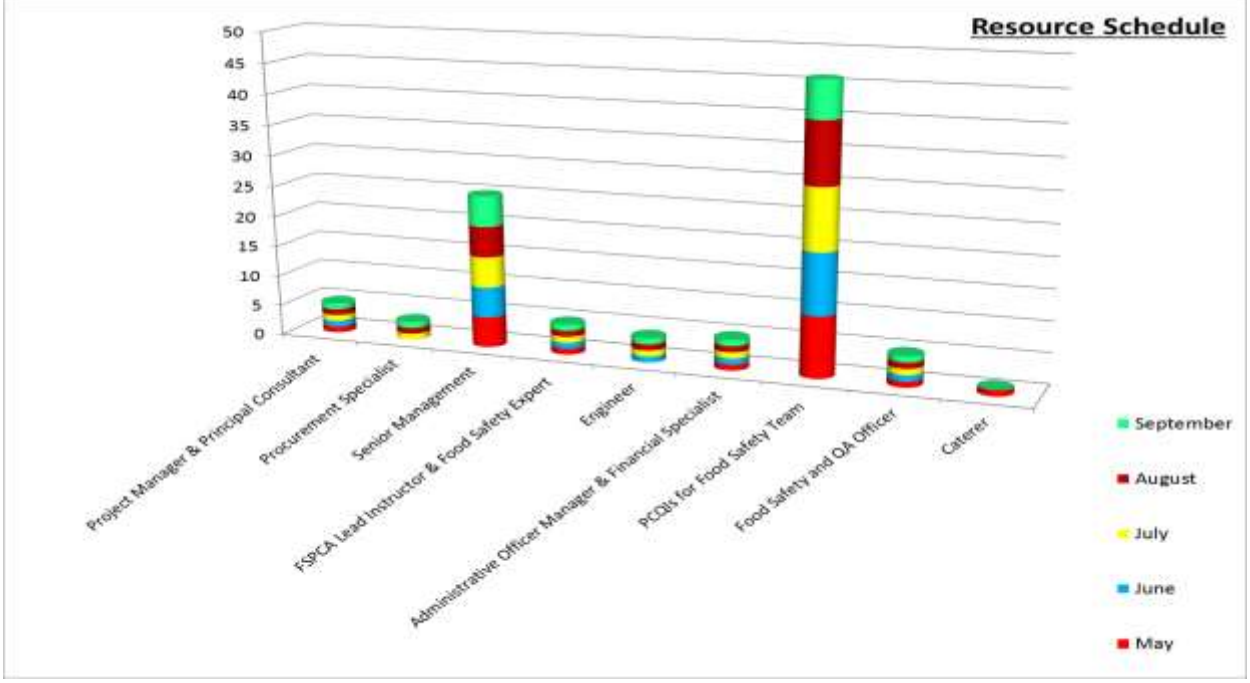


Figure 4-20 Human Resources Schedule

(Source: Principal Consultant, FSQ Solutions, June 2019)

RBS DIAGRAM

PROJECT TITLE	FDA Food Safety Regulations Implementation	PROJECT FUNDING AGENT	Choo's Enterprises
PROJECT MANAGER	FSQ Solutions Inc.	DATE	Jun-19

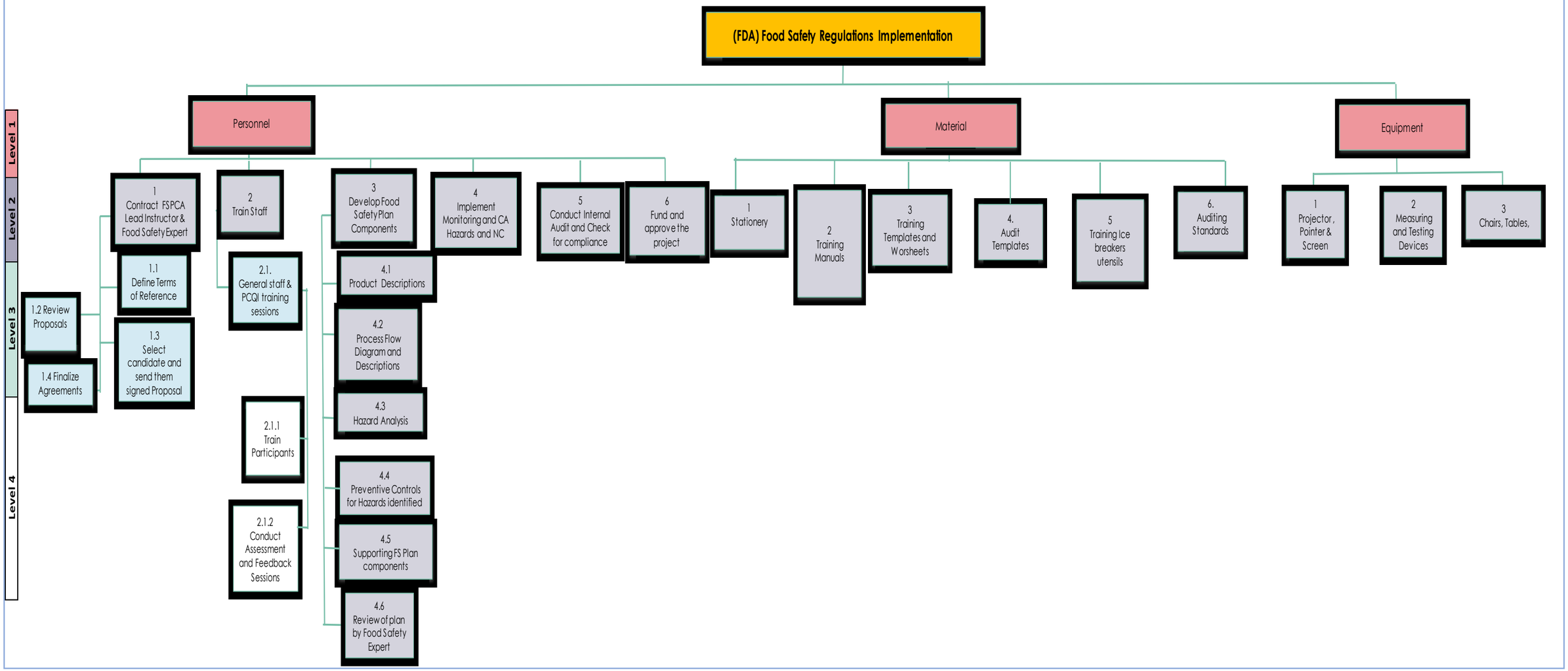


Figure 4-21 Resources Breakdown Structure

(Source: Principal Consultant, FSQ Solutions, June 2019)

The initial service contracting for the FSPCA Lead Instructor and Food Safety Expert was done by the Project Leader in order to commence the project. The process illustrated in Figure 4-21, was used in acquiring such resource personnel and ensuring that they had the skills, competencies and knowledge aligned with guaranteeing the quality of service, timing and financial budget needed to be accomplished. The Project Manager and the Food Safety Expert played a critical part in the hiring for the Food Safety and QA Officer Resource personnel in order to create an efficient and effective team. The team established clear roles and responsibilities as outlined in the job description in Figure 4-22.

JOB DESCRIPTION

Job Title:
Food Safety & Quality Assurance (QA) Compliance Officer

Department: Operations

Reports To: Operations Manager/Food Safety Plan Leader

Purpose and Scope of Job:

Be responsible for the planning, maintaining, coordinating, enforcement and monitoring of the company's Quality Assurance (QA) and Food Safety Systems to ensure compliance with customers and regulatory agencies, General assistance and support to the Food Safety Team, liaising with all departments ensuring safe practices are documented, implemented and conform to all established Food safety and Quality requirements and reasonable expectations of internal and external customers, To manage and monitor Quality Assurance and Food Safety Systems databases, conduct audits, training and maintain the necessary documentation to ensure the organization's compliance to the required standards to ensure certification and re-certification is always achieved. Assists in the performance of quality education, quality performance measurements and quality improvement directions, and To oversee corrective action/preventative action activities as required and be a major driver for effective cultural changes and improvement in manufacturing excellence across all parts of the facility.

Primary Responsibilities:

To include, but not be restricted to, the following duties:

- Provide general support and assistance to the Food Safety Team. Assist the Food Safety Team with
    a. Food Safety and Health monitoring activities.
    b. Food Safety and Health audits and produce reports and follow up any actions.
    c. Provide clerical support as needed
    d. Identification of need and preparation of risk assessments, compliance and training of staff
    e. Report and assist with correcting any unsanitary conditions in food storage areas as well as employee work areas
    f. Help develop, maintain, and update all records, manuals, training procedures, product specification records as pertain to food safety and quality control.
    g. Scheduling and assigning periodic audits with the audit team and ensuring that audits have been completed accurate and in a timely manner.

Figure 4-22 Sample Job Description
(Source: Principal Consultant, FSQ Solutions, June 2019)

Interviews with the various candidates were undertaken and the prime candidate selected. The candidate selected also needed to be someone who can interact well and quickly fit in with the internal environment and culture at Choo's Enterprises for good team dynamics.

As part of the training program conducted at Choo's Enterprises for the Food Safety Team, team building exercises were conducted to assist in developing the team dynamics. The activities were geared toward building trust, collaboration and cohesiveness to enhance the team spirit and culture within the group. The plan is for the team to have more sessions of this nature in the future and to effectively lead and manage the team, using Work Performance Reports and Team Performance Assessments as a way to monitor how each member is doing in relation to their team performance.

If any challenges are experienced with the team, the plan is to manage this by using a set of rules and polices created for this purpose. In addition, as part of the management of Control of Resources, the Project Manager will be:

- ✓ Monitoring resource expenditures.
- ✓ Identifying and dealing with resource shortages or surpluses in a timely manner.
- ✓ Ensuring that resources are used and released according to the plan and project needs.
- ✓ Informing all stakeholders of any issues which may arise concerning any relevant resources.
- ✓ Managing the actual changes as they occur with resources.

The project team plans on also utilizing the following techniques to control resources for this project: data analysis, problem solving, interpersonal and team skills and staff evaluations. If the need for additional resources occurs, the Project Manager will negotiate for such changes and ascertain the impact of such on associated costs, scope, schedule and quality.

4.7. Project Communications Management

In order to ensure effective and consistent communication throughout the entire project, the team decided that the following methods of communication will be used and continue to be used throughout as part of the Communications Management Plan. These different communication methods include:

- Email communications using email system/addresses for internal and external official communications
- Interactive communication via group chats on WhatsApp/Skype
- Formal reports to the Project Leader and Key Stakeholders outside the groups
- Bi-Weekly minuted meetings with the Project Team

Policies and procedures for communication were set out by the Project Manager since some of the more seamless, convenient and cost effective options for communication were being used for this project. These methods reduced the one location face-to-face meetings and utilized more face-to-face web meeting (Zoom, Skype), teleconference calls, video calls (WhatsApp), screen sharing and instant messaging (IM via Skype, WhatsApp), where key personnel would have a set time to interact or meet as a small group. These meetings assisted with managing the following:

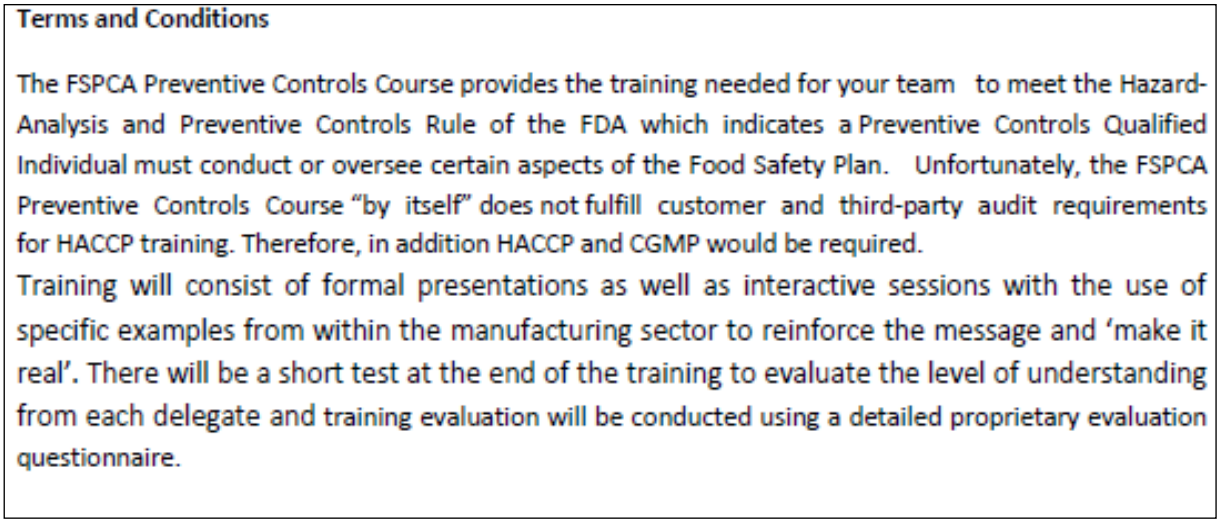
- ✓ Any updates on the project
- ✓ Identifying any issues and successes that have occurred within the project
- ✓ Mitigating any issues that may arise
- ✓ Prioritizing any goals or initiatives that may arise
- ✓ Providing stakeholders any information
- ✓ Any initiatives that may need to be executed or included and that may have been forgotten or might have arisen.

For key stakeholders outside of these communication channels, the Project Manager would be the one to focus on keeping main stakeholders informed about

the project's progress but using official channels where information is transmitted by official quarterly reports.

The management of information would be done by the secretary at FSQ Solutions via the popular Cloud Computing and Windows operating system. The system will be used to manage and ensure the information distributed to all the stakeholders is done successfully, in a timely manner and officially but also stored securely and easily retrievable. The main email tool used was that of Outlook, since all parties had an Outlook account and this also allowed the team to use the calendar option that would alert them when meetings have been set.

The FSPCA Lead Instructor and Food Safety Expert indicated that their official communication would be via email and "at the completion of each week a progress report will be submitted to Choo's Enterprises to track participants' participation and a final report will be handed over unless otherwise stated" (FSQ Solutions, Contract, May 2019).



Terms and Conditions

The FSPCA Preventive Controls Course provides the training needed for your team to meet the Hazard-Analysis and Preventive Controls Rule of the FDA which indicates a Preventive Controls Qualified Individual must conduct or oversee certain aspects of the Food Safety Plan. Unfortunately, the FSPCA Preventive Controls Course "by itself" does not fulfill customer and third-party audit requirements for HACCP training. Therefore, in addition HACCP and CGMP would be required.

Training will consist of formal presentations as well as interactive sessions with the use of specific examples from within the manufacturing sector to reinforce the message and 'make it real'. There will be a short test at the end of the training to evaluate the level of understanding from each delegate and training evaluation will be conducted using a detailed proprietary evaluation questionnaire.

Figure 4-23 Terms and Conditions for Food Safety Training
(Source: Project Team, Personal Communication, June 2019)

As shown in Figure 4-23, the main form of communication used during the training was that of formal presentations (Appendix 4: FSCPA Preventive Controls for Human Food Course Outline), interactive sessions with the staff and written evaluation questionnaires for feedback at the end (Appendix 5: Course Evaluation Questionnaire Template).

The project management team utilized the Project Manager Software program to generate a Gantt chart (Section 4.6) which tracked the project's milestones. During the bi-weekly meetings, the team will review this chart as a means of monitoring deadlines, major events, major dates and deliverables to ascertain whether milestones are being met and if so, whether they are within the set parameters. This will assist in highlighting any potential project bottlenecks which require management within the system. If such issues should occur, these will be logged using the Issues Log as depicted in Figure 4-24. These will then be prioritized and managed accordingly.

Issues Log - FDA Food Safety Regulations Implementation Project									
Level	**WBS Code**	**Element Name**	**Description**	**Reported by**	**Priority**	**Status**	**Reported Date**	**Date Resolved**	**Impact**
1	2	Staff Training	Confirm training dates and Time changes	***Project Leader***	High	***Addressed***	20-May-19	20-May-19	***Training session reorganized to accommodate change but no impact to the project.***
1	3	Build Food Safety Team	Candidates' acceptance of the offer but can't commence until 21st July 2019.	***Project Leader***	Critical	***Open***	21-Jun-19		***Potential delay in the project.***
1	4	Budget	Finances not available for further consultation until	***Project Leader***	Low	***In Progress***	30-Jun-19		***Potential delay in the project.***

Figure 4-24 Issues Log
(Source: Project Team, Personal Communication, June 2019)

As it pertains to information about the effectiveness of the communication activities, such will be tracked via the use of the main stakeholder engagement assessment matrix, as shown in Figure 4-25, which will indicate the current (C) and desired (D) level of engagement of each stakeholder.

Stakeholder	Level of Stakeholder Engagement				
	Unaware	Resistant	Neutral	Supportive	Leading
Project Manager & Principal Consultant					C
FSPCA Lead Instructor and Food Safety Expert					C
Project Team:- Office Manager, Food Safety & QA Officer, Food Safety Team			D	C	
Managing Director				DC	
Shareholders				CD	
Senior Management			D	C	
Staff		C	DC	DC	D
Suppliers & Customers	C			DC	

Figure 4-25 Stakeholder Engagement Matrix
(Source: Project Team, Personal Communication, June 2019)

The Project Communication Requirements were as identified in Chart 10.

Chart 10 Project Communication Requirements

Stakeholder Group	Characteristics	Communication Requirement	Information Needs
Project Manager and Principal Consultant	An executing agent for the project approved by the Managing Director.	Progress reports and communications from all stakeholder groups.	Project benefits, milestone achievements and issues experienced.
FSPCA Lead Instructor and Food Safety Expert	Provides technical support for the implementation of the project.	Communications from the project team and manager on the project and its progress.	Project benefits, milestone achievements and issues experienced
Project Team: Office Manager, Food Safety and QA Officer, Food Safety Team	An executing agent for the project approved by the Managing Director.	Broadcast capacity of the company to complete the project and maintain compliance.	Project progress, financial performance and goals achievement.
Managing Director	Financier and Resource person for the project.	Successful implementation of funded project.	Project progress, financial requirements, performance and goals achievement.
Senior Management and Staff	Most frequent users of the system.	Understand the how, when, why, what and frequency for compliance.	Project benefits and milestone achievements.
Shareholders	Financier and Approver for the project.	Successful implementation of funded project and when exportation profits will begin.	Project benefits and milestone achievements.
Suppliers and Customers	Beneficiary of the project.	Successful implementation and maintenance of compliance	Compliance results and assurance of continued business.

(Source: Principal Consultant, FSQ Solutions, June 2019)

4.8. Project Risk Management

In order to establish the Risk Management Plan for this project, the team met, brainstormed and generated the Risk Breakdown Structure shown in Figure 4-26, which highlights the individual project risks and their categorized sources. Since there is no way for one person to be aware of all the risks, asking only persons within the organization is usually not adequate. Therefore, the team sought to identify all possible risks by also asking experts outside of the organization in order to conduct a more complete risk analysis.

Level 0	Level 1- RBS	Level 2- RBS	Level 3- RBS	RBS Code
FDA Food Safety Regulations Implementation Project Risk	Technical Risk	Scope and Requirements Definitions	Requirements for the project changes or additional requirements are added to the scope.	T1.1
			The requirements for the project are not communicated clearly	T1.2
		Estimates, Assumptions & Constraints	The project requires more funds or resources than that which was approved or estimated for the project.	T1.3
		Technology & Technical Processes/ interfaces	Technical difficulties during training sessions or tools/materials not available	T1.4
			Training not understood by the team i.e. effective	T1.5
			Food Safety and QA Officer and the team has challenges developing the system.	T1.6
			Tools required to ensure conformance to the standard are not available/ not being supplied.	T1.7
			The development and improvement of components of food safety systems including food safety policies, food legislation, food inspection, laboratory analysis, epidemiological surveillance of food-borne diseases, monitoring systems for chemical and microbiological contamination in foods, take longer than anticipated or delay do to unforeseen challenges.	T1.8
		Performance	Staff have challenges executing components of the food safety systems.	T1.9
			Staff and Management do not adhere to the specifics of the regulation	T1.10
		Test & Acceptance	Verification and Validation of the system takes longer than anticipated.	T1.11
			Corrective action for any nonconformance not completed as required	T1.12
	Management Risk	Project, Program or Operations Management	Project Team did review contract terms before project commence	M2.1
			Food Safety and QA Officer unable to attend Training session	M2.2
			Food Safety and QA Officer commence work later than July	M2.3
			Food safety team unable to meet and execute duties as required	M2.4
			The storming stage of the Food Safety team development was longer than anticipated.	M2.5
		Communication & Information	Required information needed to complete the various processes for project is not being provided by the company contractors or its' suppliers.	M2.6
		Quality	The quality of work produce in relation to components of food safety systems does not met FDA regulations	M2.7
		Organization and Resourcing	FSPCA Lead Instructor/Food Safety Consultant not available to train as well as Food Safety and QA Officer was unavailable to commence work as required	M2.8
	Commercial Risk	Contractual terms & conditions	Contract terms and deliverable not met	C3.1
			There's no clause in consultant's contract to address if delays occur in relation to the established schedule or early termination.	C3.2
		Internal Procurement	Procurement process was not followed as required	C3.3
		Supplies & Vendors	Suppliers an Vendors did not meet terms and deliverables as required	C3.4
		Client/ customer	Client not satisfied with the work done as their request of a broad range of additional actions with no added cost were not completed	C3.5
	External Risk	Legislation	Legislation change during implementation period	E4.1
		Site/Facilities	Amenities on site not adequate for regulation compliance or in poor condition.	E4.2
		Environment	Amenities on site not adequate for regulation compliance or in poor condition.	E4.3

Figure 4-26 Risk Breakdown Structure
(Source: Project Team, Personal Communication, June 2019)

The team then assessed the probability and impact on time, cost and quality of the project objectives of each risk using the template highlighted in Figure 4-27.

			IMPACT ON PROJECT OBJECTIVES		
Scale	**Probability**	**Score**	**Time**	**Cost**	**Quality**
Very High	> 80 %	5	> 2 months	Major	Very significant impact on overall functionality
High	61 -80 %	4	1 - 2 months	Significant	Significant impact on overall functionality
Medium	41 -60 %	3	1 month	Medium	Some impact on key functionality
Low	21 -40 %	2	1 - 3 weeks	Small	Minor impact on overall functionality
Very Low	1 -20 %	1	< 1 week	Minor	Minor impact on Secondary functions
Nil	< 1%	0	No Change	No Change	No Change

Figure 4-27 Probability and Impact Matrix
(Source: Project Team, Personal Communication, June 2019)

For each risk identified, the team then identified the cause and effect and the impact, in order to determine the mitigation strategy/response to use along with identifying who will be responsible for its execution. An assessment of the cost of the impact on risks was also executed and this is shown in Figure 4-28. Even though the team used the Qualitative Risk Analysis strategy during their session to generate the required data, the team also decided to avoid and mitigate the risks as much as possible.

The plans for this project also include using a selected team to deal with any upcoming risk immediately to ensure mitigation strategies are implemented as required, as well to conduct re-analysis during the monitoring stage in the event that any new risks may come about that have not been considered in the plan. It must be noted that if support from the organization is not forthcoming to reduce or alleviate these risks, this could impact the project plan, schedule and cost.

RBS CODE	RISK	CAUSE	CONSEQUENCE	PROBABILITY	IMPACT	P x I	RESPONSE PLAN/ STRATEGY	OWNER	COST
T1.1	Requirements for the project changes or additional requirements are added to the scope.	The client decided to make changes to the project or Project Manager and team failed to be specific about all the terminology, and requirements so as to reduce allowance for additional request at no cost.	Scope Creep and cost overruns	1	5	5	Have regular meeting with stake holders and client to establish clear lines	Project Manager and Project Leader	$5,500.00
T1.2	The requirements for the project are not communicated clearly	Poor communication of the scope and requirements in the initial part of the project	Confusion and project delay	2	5	10	Have regular meeting with team and client to establish	Project Manager and Project Leader	$0.00
T1.3	The project requires more funds or resources than that which was approved or estimated for the project.	Difficulty in attaining all the resources needed to complete the project	Project delays & Cost overruns	4	5	20	Have regular meeting to establish clear lines and build	Project Manager and Project Leader	$5,000.00
T1.4	Technical difficulties during training sessions or tools/materials not available	Mechanical or operational glitches with that tools use or poor engineering/operational capabilities of staff during setup.	Participants loose focus during the training which affects learning.	3	3	9	Have technical team onboard to deal with this and a back up plan in place.	Project Leader	$0.00
T1.5	Training not understood by the team i.e. effective	Trainer failed to identify the learning styles of the participants and simulate knowledge to their level of understanding.	Participants loose focus during the training which affects learning.	3	5	15	Brief trainer on the learning levels of the staff and have the trainer test learning styles prior to training.	Trainer and Project Leader	$0.00
T1.6	Food Safety and QA Officer and the team has challenges developing the system.	Food Safety and QA Officer did not complete the training required or does not comprehend the training material.	Project delays & Cost overruns	2	5	10	Work closely with the Food Safety and QA Officer to	Trainer and Project Leader	$1,000.00
T1.7	Tools required to ensure conformance to the standard are not available/ not being supplied.	The project manager did not review this area thoroughly or sources challenges being experienced	Project delays	2	4	8	Have technical team onboard to deal with this and a back up	Project Leader & Sponsor	$0.00
T1.8	The development and improvement of components of food safety systems including food safety policies, food legislation, food inspection, laboratory analysis, epidemiological surveillance of food-borne diseases, monitoring systems for chemical and microbiological contamination in foods, take longer than anticipated or delay do to unforeseen challenges.	Delay do to unforeseen challenges internally or externally	Project delays & agency need to pay extra hours to the employees or for services required.	3	5	15	Have technical team onboard to deal with this and a back up plan in place.	Project Leader & Food Safety Expert and Project Sponsor	$3,000.00
T1.9	Staff have challenges executing components of the food safety systems.	The Food Safety Expert did not review the site thoroughly to identify such possibilities	Project delays & Food Safety Expert need to spend extra time auditing the system.	3	5	15	Have technical team onboard to deal with these challenges along with Food Safety Expert.	Project Leader & Team & Food Safety Expert	$5,000.00
T1.10	Staff and Management do not adhere to the specifics of the regulation	Lack of enforcement by Management Team	Project delays & agency need to pay extra hours to the employees or for services required.	3	5	15	Monitor and enforce adherence to the specifics of the regulation	Project Leader & Management Team	$4,000.00
T1.11	Verification and Validation of the system takes longer than anticipated.	Lack of enforcement by Management Team	Project delays & agency need to pay extra hours to the employees or for services required.	3	5	15	Monitor and enforce the need for execution.	Project Leader & Management Team	$5,000.00
T1.12	Corrective action for any nonconformance not completed as required	Lack of enforcement by Management Team	Project delays & agency need to pay extra hours to the employees or for services required.	3	4	12	Monitor and enforce the need for execution.	Project Leader & Management Team	$10,000.00
M2.1	Project Team did review contract terms before project commence	That project manager or leader didn't share the contract terms with the team.	Team confusion or lack of understanding.	1	1	1	Add this to a checklist to ensure it is executed.	Project Leader & Manager	$ -
M2.2	Food Safety and QA Officer unable to attend Training session	Food Safety and QA Officer has other pressing priorities or otherwise unavailable.	Project delays & agency need to pay extra for Training	5	2	10	Have an alternative training session for this Officer	Project Leader & Trainer	$ 1,000.00
M2.3	Food Safety and QA Officer commence work later than July	Food Safety and QA Officer has other pressing priorities or otherwise unavailable.	Project delays & agency need to pay extra for external Services.	5	2	10	Proceed with project plan until this Officer comes on board	Project Leader & Sponsor	$ 3,000.00
M2.4	Food safety team unable to meet and execute duties as required	Lack of enforcement by Project Leader & Process Owner	Project delays	2	4	8	Monitor and enforce the need for execution.	Project Leader & Manager	$ 5,000.00
M2.5	The storming stage of the Food Safety team development was longer than anticipated.	Lack of team development by Project Leader & Process Owner	Project delays	nil	nil	nil	Monitor and Counsel the team to reduce the timeline for this	Project Leader & Manager	$ 3,000.00
M2.6	Required information needed to complete the various processes for project is not being provided by the company contractors or its' suppliers.	Lack of enforcement by Project Leader & Process Owner	Project delays and agency need to pay extra for external Services.	1	3	3	Monitor and enforce the need for execution.	Project Leader & Sponsor	$ 1,000.00
M2.7	The quality of work produce in relation to components of food safety systems does not met FDA regulations	Lack of enforcement by Project Leader, Sponsor and Management Team	Project delays and agency need to pay extra for Services and for extra hours to the employees.	3	5	15	Monitor and enforce the need for quality in order to reduce reprocessing.	Project Leader & Management Team	$ 20,000.00
M2.8	FSPCA Lead Instructor/Food Safety Consultant not available to train.	Food Safety and QA Officer has other pressing priorities or otherwise unavailable.	Project delays and agency need to pay extra for procurement.	1	5	5	Attain alternative vendor as a back up.	Project Manager & Leader & Food Safety Consultant	$ 5,000.00
C3.1	Contract terms and deliverable not met	The project manager didn't review/ monitor the contract frequently enough.	Project delays & agency need to pay extra for services required.	3	5	15	Monitor and enforce quality prior to commencement and during project execution.	Project Manager & Leader & Food Safety Consultant	$1,000.00
C3.2	There's no clause in consultant's contract to address if delays occur in relation to the established schedule or early termination.	The project leader forgot to include such.	Project delays & agency need to pay extra for services required.	5	2	10	Attain an alternative plan in the event that such occurs.	Project Manager & Leader & Food Safety Consultant	$7,000.00
C3.3	Procurement process was not followed as required	The project leader did not have a written OP for this and to the staff were unaware of the protocol	Project delays	2	2	4	Monitor and enforce all OPs are followed during project	Project Manager & Leader	$0.00
C3.4	Suppliers and Vendors did not meet terms and deliverables as required	The project manager didn't review/ monitor the contract frequently enough.	Project delays & agency need to pay extra for services required.	3	4	12	Monitor and enforce compliance during project	Project Manager & Leader	$6,000.00
C3.5	Client not satisfied with the work done as their request of a broad range of additional actions with no added cost were not completed	That project team didn't discuss the quality of work required as part of the contract .	Project delays & agency need to pay extra for works to be redone.	1	3	3	Monitor and enforce quality prior to commencement and	Project Manager & Leader	$9,000.00
E4.1	Legislation change during implementation period	That project manager didn't monitor Legislation changes prior to implementation	Project delays & agency need to pay extra for works to be done.	1	3	3	monitor Legislation changes prior and during	Project Manager & Leader	$5,000.00
E4.2	Amenities on site not adequate for regulation compliance or in poor condition.	Lack of PM and Monitoring	Project delays & agency need to pay extra for works to be done.	3	2	6	Ensure PM and Monitoring	Project Manager, Leader , Sponsor & Mgt. Team	$15,000.00
E4.3	Amenities on site not adequate for regulation compliance or in poor condition.	Lack of PM and Monitoring	Project delays & agency need to pay extra for works to be done.	3	2	6	Ensure PM and Monitoring	Project Manager, Leader , Sponsor & Mgt. Team	$15,000.00

Figure 4-28 Qualitative Risk Analysis
(Source: Project Team, Personal Communication, June 2019)

4.9. Project Procurement Management

As part of the requirements in meeting specific objective nine (9), interviews with some of the major stakeholders, various vendors and candidates, along with team meetings, were used to produce the Project Procurement Management Plan.

Prior to the commencement of this project, several procurement activities took place. This included the hiring of the FSPCA Lead Instructor and Food Safety Expert. This did not include the use of Bid Documents, the tendering process and a written Procurement Statement of Work before a selection was made but the procurement strategy used was that of a verbal Procurement Statement of Work along with a Source Selection Criteria, shown in Chart 11.

Chart 11 Source Selection Criteria for FSPCA Lead Instructor and Food Safety Expert

Criteria	Service Provider Evidence	Criteria Met
Capability and Capacity	• Internationally Certified Food Scientist and a highly trained Food Technologist • Lead Trainer for FSPCA in Human Food	✓
Availability for required Delivery dates	• Training Services: Monday – Friday (Date to be determined) between the hours of 9 am and 4 pm • Provides technical support for the implementation of the project for the full five months duration	✓
Technical expertise and approach	• Certification and Experience in Project Management, Greenbelt Lean Six Sigma, Auditing SQF Systems and Quality Assurance and HACCP Food Safety and approach outline in TOR.	✓
Relevant Experience	• Braced with more than 15 years' experience in the area of Food Science and Technology • Worked at several different types of Food Manufacturing companies, both in Barbados and Trinidad	✓
Adequacy of proposed work plan and costing	• Training services for 2 weeks @ $125 per hour plus written report • On site Audit and virtual consulting services in document development at 10 hours @ $50 per hour and provision of supporting material – 1 month total	✓

(Source: Office Manager & Project Leader, Choo's Enterprises, May 2019)

Both the procurement Statement of Work and the Terms of Reference were written into the proposal and agreement by the FSPCA Lead Instructor and Food Safety Expert and these are shown in Figures 4-29 and 4-30.

FSQ SOLUTIONS

May 2nd, 2019

Attention: Ms. Chaketa Jones

Choo's Enterprises,
Eagle Hall,
Bridgetown, Barbados

Dear Ms. Jones

FSQ Solutions is pleased to provide you with training and consultancy services in the area of Food Safety for the newly established operations of agro-processing at Choo's Enterprises.

Understanding of Client Needs

FSQ understands that Choo's Enterprises requires expertise training in the following areas to support customer Food Safety Audits and export of products to the USA:-

- Good Manufacturing Practices(CGMPs),
- Hazard Analysis Critical Control Points(HACCP) and
- Hazard-Analysis and Food Safety Preventive Controls Rule (FSPCA) of the US Food and Drug Administration (FDA)

In order to fulfill these requests FSQ will need to have access to:

- A flip board with markers, projector, pointer, and screen.
- Internet access for videos and resource sites.
- Business site assess to conduct an onsite audit of the physical facilities and operational activities as needed.
- Business document assess to facilitate accurate development of the Food Safety Plans for the facilities and operational activities as needed.

In addition, consultation is required in the area of Food Safety document development for the company as required by:-

- US Food and Drug Administration (FDA) for CGMPs, HACCP and FSPCA

In order to fulfill these requests FSQ will need to have access to:

- Business site assess to conduct an onsite audit of the physical facilities and operational activities as needed
- Any necessary available documentation, records and any other objective evidence required for document development progress and completion for the company.

Figure 4-29 Statement of Work

(Source: FSPCA Lead Instructor and Food Safety Expert, FSQ Solutions, May 2019)

Terms and Conditions

The FSPCA Preventive Controls Course provides the training needed for your team to meet the Hazard-Analysis and Preventive Controls Rule of the FDA which indicates a Preventive Controls Qualified Individual must conduct or oversee certain aspects of the Food Safety Plan. Unfortunately, the FSPCA Preventive Controls Course "by itself" does not fulfill customer and third-party audit requirements for HACCP training. Therefore, in addition HACCP and CGMP would be required.

Training will consist of formal presentations as well as interactive sessions with the use of specific examples from within the manufacturing sector to reinforce the message and 'make it real'. There will be a short test at the end of the training to evaluate the level of understanding from each delegate and training evaluation will be conducted using a detailed proprietary evaluation questionnaire.

- Choo's Enterprises will provide break, lunch, venue for training, flip board with markers, projector, pointer, and screen and print all class work material required for the training.
- FSQ Solutions is prepared to provide HACCP and CGMP Course training services for (3-4) hours per session five days; Monday – Thursday (6 May – 9 May 2019) between the hours of 8:30am and 4:30pm for approximately 24 persons (Line staff).
- FSQ Solutions is prepared to provide FSPCA Preventive Controls Course & HACCP training services for (6) hours per the five days; Monday – Friday (Date to be determined) between the hours of 9:00am and 4:00pm for the for approximately 10 persons (Multidisciplinary Food Safety Team).
- FSQ Solutions is prepared to provide some virtual consulting services in document development and some supporting material to assist the selected team in this process. Times may vary and onsite validation may be required to confirm information documented.
- Participants must honor the set date and time and must be present at each session at all times in order to attain certification.
- At the completion of each week a progress report will be submitted to Choo's Enterprises to track participants' participation and a final report will be handed over unless otherwise stated. All documents will be submitted at the end of the project unless circumstances occur beyond the control of FSQ.

Figure 4-30 Terms of Reference

(Source: FSPCA Lead Instructor and Food Safety Expert, FSQ Solutions, May 2019)

The team, after meeting and discussion had taken place, decided that in order to improve the procurement process for future procurements, standards such as Statement of Work and the Terms of Reference would need to be established, along with other the strategies to be used. Since this skill set is not available in-house, a plan for establishing these processes was generated as shown in Figure 4-31.

PLAN PROCUREMENT PROCESS:				
	Procurement Requirements	**Plans for Procurement**	**Procurement Responsibility**	**Metrics to be use to Manage Contract/Activities**
OUTPUTS	Plan Procurement Management	All project activities to be performed are based on the WBS with very few requiring bidding activities, only local sourcing. This would require the development of a Statement of Work for these activities so the provider know what is required of them and a procurement strategy which will define the delivery method, contract types and procurement phases.	To be done by an external body.	Review documentation to ensure they include the detail requirements and the other recommendations. The team will review the project schedule, cost, quality and scope during meetings to be held weekly
	Source Selection Criteria	Develop criteria which is based on cost, delivery date, expertise, track record, qualifications, expertise in the provision of industry specific knowledge, and the stability of the vendor	To be done by an Internal body.	Sellers will be rated based on: ● Pricing ● Quality of work versus Proposed ● Activity/Delivery Schedule ● Payment Terms ● Reputation of Organization Arrangements of regular meetings with the vendors will be made along with tracking delivery progress, reviewing the ordered items against the approved product specifications, and making necessary changes to the procurement contract,
	Data Analysis	Formal evaluation of Agrrement, contracts and other legal documents	To be done by attorneys to ensure compliance with the law	Monitor Feedback time lines. The team will review the project schedule, cost, quality and scope during meetings to be held weekly

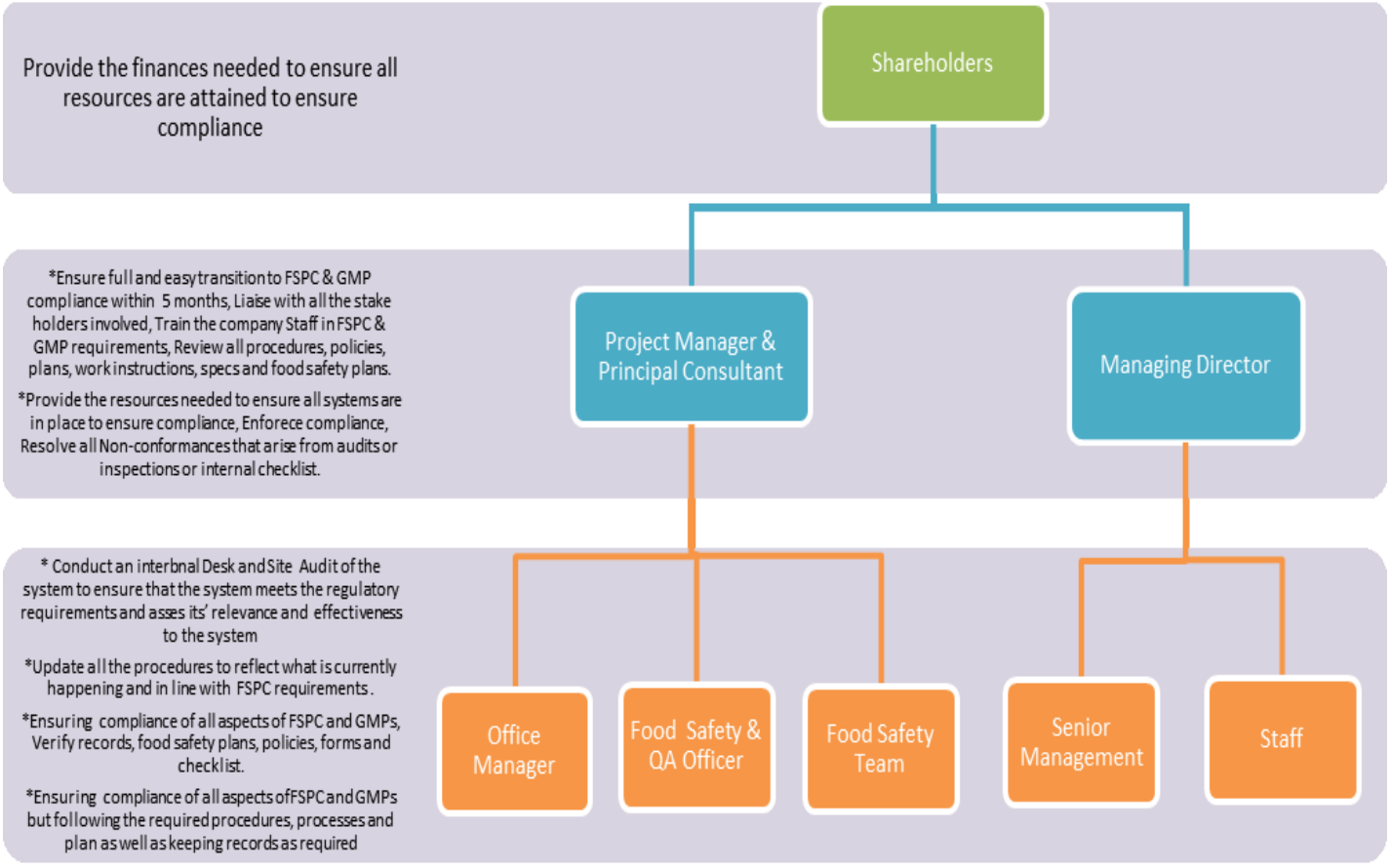
Figure 4-31 Planned Procurement Process

(Source: Project Team, Personal Communication, June 2019)

4.10. Project Stakeholder Management

In developing the Project Management Plan for the implementation of FDA Preventive Controls for Human Food regulation at Choo's Enterprises, a Project Quality Plan, specific objective ten (10), was the first process to be developed in the Project Quality Management knowledge area. This was accomplished using interviews with some of the major stakeholders, meeting minutes with project team members, feedback from the staff, and the PMBOK® Guide and PMI database as sources. The inputs, tools and techniques adapted from the PMBOK® Guide, along with the aforementioned, were then used as the catalyst for the Project Management Plan together with the application of the analytical research methodology. The initial lists of stakeholders are outlined in Figure 4-32, with their roles and responsibilities outlined in Chart 12 and the Stakeholder Power and Impact Matrix highlighted in Figure 4-33.

Figure 4-32 Roles and Responsibilities of Stakeholders



(Source: Principal Consultant, FSQ Solutions, June 2019)

Chart 12 Key Stakeholders Role and Responsibilities

Roles	Responsibilities
Project Manager and Principal Consultant Food Safety Expert and FSPCA Lead Instructor	✓ Ensure full and easy transition to FSPC and GMP compliance within the 5 months ✓ Liaise with all the stakeholders involved ✓ Train the company Staff in FSPC and GMP requirements ✓ Review all procedures, policies, plans, work instructions, specifications and food safety plans ✓ Conduct pre- and post-assessment Desk and Site Audit of the system to ensure that the system meets the regulatory requirements ✓ Provide scientific and expert advice where and when needed
Project Team: Office Manager, Food Safety and QA Officer, Food Safety Team	✓ Develop all aspects of the Food Safety System and Plan ✓ Update all the procedures to reflect what is currently happening and in line with FSPC requirements ✓ Ensuring compliance of all aspects of FSPC and GMPs, monitor and verify all records developed for the food safety system
Shareholders	✓ Provide the finances needed to ensure all resources needed are attained to ensure compliance
Managing Director	✓ Provide the resources needed to ensure all systems are in place to ensure compliance ✓ Enforce FSPC Compliance and ensure all Non-conformances are resolved that arise from audits or inspections or internal checklists
Senior Management	✓ Enforce FSPC Compliance, adequate monitoring, verification and record keeping ✓ Ensure all Non-conformances are resolved that arise from audits or inspections or internal checklists
Staff	✓ Ensuring compliance of all aspects of FSPC and GMPs by following the required procedures, processes and plans as well as generating all records as required.

(Source: Principal Consultant, FSQ Solutions, June 2019)

Stakeholder Register Matrix

Project Name	FDA Food Safety Regulations Implementation
Main Sponsor	Managing Director of Choo's

FDA Food Safety Regulations Implementation - Stakeholder Analysis

ID	Stakeholders	Functional Area	Roles - Responsibilities	Main Expectations	Major Requirements	Influence	Impact	Power/Interest Matrix (Low - High)		
						Low-Medium-High		Power	Interest	Justification/Explanation
1	Project Manager & Principal Consultant	Service Provider (PM Consultation)	- Liaise with all the stake holders involved - Oversight of project implementation and administration - Ensure full and easy transition to FSPC & GMP compliance within the 5 months	- Increased trade and economic growth - Full project completion in the required timeline with no scope creep.	- Design and plans are approved and accepted by project manager, leader and sponsor. -All permitting and clearances are obtained by project manager. -Signed contracts for works.	Medium	High	Medium	High	The Project Manager is dependent of the success of this project which demonstrates competency of him 'her to generate effective project management
2	Food Safety Expert & FSPCA Lead Instructor	Service Provider (Training & Consultation)	- Train the company staff in FSPC & GMP requirements, - Review all procedures, policies, plans, work instructions, specs and food safety plans. -- Conduct pre and post assessment Desk and Site	- Effective learning and comprehension - Full staff participation - Full project completion in the required timeline with no scope creep.	- Skill of training and influence	High	Medium	Low	High	The team is dependent of the success of this project which demonstrates learning and effective training and consultation.
3	Project Team:- Office Manager, Food Safety & QA Officer, Food Safety Team	Administration & Operations	-- Ensure oversight of project administration - Develop all aspects of the Food Safety System and Plan - Update all the procedures to reflect what is currently happening and in line with FSPC requirements - Ensuring compliance of all aspects of FSPC and	- adequate and clear communication of requirements -access to the required documentation - Full comprehension and development of the tools needed for compliance	- Adequate funding exist to support implementation accordance with standards - Approved Contracts and plans for acceptable and adequate implementation. - Provision of access to and adequate materials required. '- Increased trade and economic growth	High	High	High	High	The success or failure of this project lies with the Food Safety Team
4	Managing Director	Project Sponsor	- Approve funding and ensure oversight of project implementation - Provide the resources needed to ensure all systems are in place to ensure compliance, - Enforce FSPC Compliance and ensure all Non-conformances are resolve that arise from audits or inspections or internal checklist.	- Ensure Adequate funding exist to support implementation accordance with standards - Approves Contracts and plans for acceptable and adequate implementation. - Provide access to and adequate materials required. '- Increased trade and economic growth	- Managerial skills and experience. -- Understanding the benefits of the project to the company	High	High	High	High	The success or failure of this project lies with the Director
5	Shareholders	Financier	Provide the finances needed to ensure all resources needed are attained to ensure compliance	-Give full support to the process, influence the governance of the firm to meet objectives and goals with minimal risk. '- Increased trade and economic growth	- Communication and Financial Management skills - Interpersonal Skills	Low	Medium	Low	High	They represent the interest of the company but they are more interested in seeing a high Rate of return on their investments .
6	Senior Management	Service Provider (Air Services)	-- Enforce FSPC Compliance, adequate monitoring, verification and record keeping - Ensure all Non-conformances are resolve that arise from audits or inspections or internal checklist.	-Pass down the vision and implementation requirements along with feeding upwards the issues are tools needed for such - Fair and open communication to staff in all areas as well as monitoring with enforcement for compliance.	- Training in what is required of them - Auditing skills. - Interpersonal Skills	High	High	High	High	Senior Management is the driver of the implementation to ensure persons executing the processes are in compliance. The compliance cannot occur without their support which can make or break the implementation.
7	Staff	Operations	-- Ensuring compliance of all aspects of FSPC and GMPs by following the required procedures, processes and plan as well as generating all records as required	- Comply with required regulations/standards and practice GMPS, food monitoring and verify -- Follow all procedures, policies, plans, work instructions, specs and food safety plans	- Training, Supervision, guidance, required tools and monitoring for enforcement.	High	High	High	High	The staff are the persons executing the processes and are a part of the process compliance. The compliance cannot occur without their support which can make or break the implementation.
8	Suppliers & Customers	Service/Product Provider or Receiver	-Beneficiary of the project outcomes.	- Meet required regulations/standards.	- Compliance to company's request as a supplier and to FSPC regulations as food provider to customers	High	Medium	Low	High	They are interested in maintaining or doing business with Choo's but they cannot push for the company to implement the requirements

Figure 4-33 Stakeholder Power and Impact Matrix

(Source: Principal Consultant, FSQ Solutions, June 2019)

5 CONCLUSIONS

Several scheduled meetings were held with the Project Manager and the selected project team members in order to develop the elements needed as part of the attainment of the objectives of the Project Management Plan. The methodologies and tools outlined in Section 3 of this FGP for the FDA Food Safety Regulations Implementation at Choo' s Enterprises were also used in the development process. The templates used in developing the deliverables by the team were adapted from the PMBOK® Guide and PMI database as well as the Lean Six Sigma Guide.

1. The Project Charter was the first element developed as the deliverable for specific objective number one. This captured the Business case and opportunities and transformed them into project goals, scope, milestones team selection, constraints, risks, assumptions and project budget.

2. From the aforementioned, the project scope statement was generated as part of the Scope Management Plan. The further enhance the project deliverables; the Scope description, exclusions and acceptance criteria were developed. These, along with the Scope Verification Matrix, were used in order to define the Work Breakdown Structure where the work for each of the deliverables was subdivided using the decomposition method.

   In addition, as part of the Requirements Management Plan, the team generated the Requirements Traceability Matrix using the Key Stakeholders Role and Responsibilities Chart which was developed prior.

3. In order to attain the output for specific objective number three, the Schedule Management Plan was created along with the Activity List, Schedule Network Diagram, Milestone List, Resource Assignments table and Project Gantt chart. In order to ensure the project's completion within the specific time constraints, timelines were generated for each project activity.

4. The Cost Management Plan for objective number four required the use of a budget template to adequately develop the project budget and capture the cost management performance measures and documents, such as the Cost Baseline and the Project Funding Requirements.

5. During the execution of the Planning Quality Management process, the quality requirements and/or standards for the project and its deliverables were identified as part of the requirements for objective number five. Templates were used to demonstrate key Quality Factors, Quality Metrics and a Quality Activities Matrix along with a Continuous Improvement plan.

6. As part of the process of identifying and estimating the resources needed to complete the Resources Management Plan for objective number six, analogous estimating was utilized by using previous project information for other similar projects from the Food Safety Expert. One of the tools used to execute and schedule such was the Responsibility Assignment Matrix.

7. Objective number seven, the Project Communications Plan, was met by the generation of a Communications Requirements Matrix and looking at the level of stakeholder engagement. This involved using different communication methods with associated policies and procedures generated throughout the project. However, the main form of communication used during the training was that of formal presentations.

8. When generating, the Risk Management Plan for objective eight, the Risk Breakdown Structure highlighting the individual project risk and their categorized sources was used. The team sought to identify all possible risks by also asking experts outside of the organization in order to conduct a more complete risk analysis using a template. The team then assessed the probability and impact of each risk on time, cost and quality of the project objectives of each risk using the Probability-Impact template. The Risk Register engendered was developed using qualitative risk analysis.

9. As part of the process to meet the objectives for number nine, a Procurement Management Plan was created for future procurement processes since some of the project's procurement deliverables were done prior and without using the standard protocol. However, both the procurement Statement of Work and the Terms of Reference were written into the proposal and agreement by the Service Provider.

10. The Stakeholder Management Plan, developed for specific objective ten, was also developed using several templates. Such templates outlined the lists of stakeholders, their roles and responsibilities and the Stakeholder Power and Impact Matrix.

6 RECOMMENDATIONS

FSQ Solutions did an exceptional job in managing the project. However, the following is suggested for future improvement for the management of such a Project:

1. Contract a team responsible for the review of documentation for legal reasons as a service to clients.

2. Provide services and training on the bidding, TOR, SOW and tendering process to assist clients in these aspects.

3. Invest in the tools required to complete quantitative risk analyses for all projects.

4. Have clients use the Project Management Guide or Framework to help direct the development of all project management tools.

5. Have a team available who possess the experience and training necessary to save projects when mishaps happen.

6. Have full transparency when documents are updated in a timely fashion but disseminate to all respective personnel, including management, stakeholders and directors, so everyone will know the impact of the delays for various activities on the project's outcome and timelines.

7 BIBLIOGRAPHY

Aized T. (2012). *Total Quality Management and Six Sigma*. Croatia: InTech

Chand, S. (2019). *Project Management Tools – Helping Aids of Project Managers.* Retrieved from https://www.edureka.co/blog/project-management-tools/#pmtools

Committee to Ensure Safe Food from Production to Consumption - Institute of Medicine (US) and National Research Council (US). (1998). *Ensuring Safe Food: From Production to Consumption.* Washington (DC): National Academies Press (US). Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK209123/

Demystifying the 5 Phases of Project Management. (2019). *Smartsheet Inc*. Retrieved from https://www.smartsheet.com/blog/demystifying-5-phases-project-management

Edwards, C. D. (1968). *The Meaning of Quality*. Quality Progress; 36-39

FSPCA and Other Training (2019). *FAQ Food Safety Preventive Controls Alliance of* Illinois Institute of Technology. Retrieved from https://www.ifsh.iit.edu/fspca/faq/faq-category/fspca-and-other-training-faq

FSQ Solutions Inc. (2011). *FSQ Solutions Inc. Business Plan* - First Edition

Harry, M. (2000). *A New Definition Aims To Connect Quality Performance With Financial Performance*. Quality Progress 2000; 33(1) 64-66.

Haughey, D. (2019). *Project Management Tools*. Retrieved from https://www.projectsmart.co.uk/project-management-tools.php

Information Types & Characteristics. (2019). *Community College of Philadelphia*. Retrieved from http://infoliteracyccp.pbworks.com/f/infotypes.pdf

Juran, J. M. (1974). *Quality Control Handbook*. 3rd Ed. New York: McGraw-Hill;.

Kothari, C. (2004) *Research Methodology Methods and Techniques– Sixth Edition*, New Delhi: New Age International (P) Ltd.

MacDonald, S. & Headlam, N (2009). *Research Methods Handbook: Introductory Guide To Research Methods For Social Research*. Manchester: Centre for Local Economic Strategies (CLES).

Pandey, M & P. (2015) *Research Methodology: Tools And Techniques*. Romania: Bridge Center,

PMBOK Guide 6th Edition Knowledge Areas for Project Management (2019). *Process Groups and Processes - The Complete Guide.* PM Prepcast-OSP International LLC. Retrieved from https://www.project-management-prepcast.com/pmbok-knowledge-areas-and-pmi-process-groups

PMP ITTO Complete Guide (Inputs, Tools, Techniques & Outputs). (2019). *PM Prepcast*-OSP International LLC. Retrieved from https://www.project-management-prepcast.com/pmp-itto

Project Life Cycle Phases. (2019). *What is the Project Life Cycle.* Mavenlink. Retrieved from https://www.mavenlink.com/resources/what-is-the-professional-services-project-life-cycle

Project Management Institute. (2012). *The PMI Lexicon of Project Management Terms,* Project Management Institute, Inc., 2012.

Project Management Institute. (2016). *The PMI Lexicon of Project Management Terms,* Project Management Institute, Inc., 2016.

Project Management Institute. (2017). *A Guide to the Project Management Body of Knowledge, (PMBOK® Guide)* – Sixth Edition, Project Management Institute, Inc.,

Ray, S. (2018). *Project Quality Management – A Quick Guide* Retrieved from https://www.projectmanager.com/blog/project-quality-management-quick-guide

Six Sigma vs. Total Quality Management. (2019) Project Management Articles by Project-management.com. Retrieved from https://project-management.com/six-sigma-vs-total-quality-management/

Timperley S. (2010). *Start a Food Safety Management System.* Retrieved from https://www.foodqualityandsafety.com/article/start-a-food-safety-management-system/2/

Unit 1 Categories Of Information Sources. (2019). The Indira Gandhi National Open University (IGNOU). Retrieved From http://egyankosh.ac.in/bitstream/123456789/34948/1/Unit-1.pdf

8 REFERENCES FOR FIGURES

Figure 2-1 Organizational Structure FSQ Solutions Inc. (2011). *Reprinted from FSQ Solutions Inc. Business Plan*

Figure 2-2 Attributes of an Effective Food Safety System (1998). *Reprinted from Committee to Ensure Safe Food From Production to Consumption 1998, National Academy of Sciences*

Figure 2-3 Project Life Cycle Phases (2019). Reprinted from Mavenlink - https://www.mavenlink.com/resources/what-is-the-professional-services-project-life-cycle.

Figure 2-4 Typical Cost and Staffing Levels Across a Generic Project Life Cycle Structure (*2017). Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-5 Project Management Processes (2019). *Reprinted from Demystifying the 5 Phases of Project Management Smartsheet Inc.*

Figure 2-6 Project Management Processes Groups (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-7 Process Group Interactions Within a Project or Phase (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-8 Project Management Process Group and Knowledge Area Mapping Groups (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-9 The Planning Process Group Phase (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-10 Project Integration Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-11 Project Scope Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-12 Project Schedule Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-13 Project Cost Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-14 Project Quality Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-15 How to Implement Quality Project Management (2018). Source: Ray, S. Project Quality Management – A Quick Guide.

Figure 2-16 Project Resource Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-17 Project Communications Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-18 Project Risk Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-19 Project Procurement Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 2-20 Project Stakeholder Management Overview (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 3-1 Research Types, Methods and Techniques (2004). *Reprinted Kothari, C. Research Methodology Methods and Techniques– Sixth Edition.*

Figure 3-2 Features of Project Management Tools (2019) *Reprinted from Project Management Tools – Helping Aids of Project Managers*

Figure 4-1 A-3 DMAIC Model for Choo's FDA Food Safety Regulations Implementation Project (2019) *Source: C. Jones, Personal Communication.*

Figure 4-2 Project Assumptions Log for the Implementation Project (2019) *Source: C. Jones, Personal Communication.*

Figure 4-3 Project Charter for Choo's FDA Food Safety Regulations Implementation Project (2019) *Source: C. Jones, Personal Communication.*

Figure 4-4 Project Management Plan and Project Documents (2017). *Reprinted from PMBOK Guide by Project Management Institute, Inc.*

Figure 4-5 Project Scope Statement (2019) *Source: Project Team, Personal Communication.*

Figure 4-6 Scope Verification Matrix (2019) *Source: Project Team, Personal Communication.*

Figure 4-7 Work Breakdown Structure (WBS) (2019) *Source: Project Team, Personal Communication.*

Figure 4-8 Hierarchical Breakdown of Work Breakdown Structure (WBS) (2019) *Source: Project Team, Personal Communication.*

Figure 4-9 Requirements Traceability Matrix (2019) *Source: Project Team, Personal Communication.*

Figure 4-10 Work Breakdown Structure (WBS) Dictionary (2019) *Source: Project Team, Personal Communication.*

Figure 4-11 Activity List and Duration (2019) *Source: Project Team, Personal Communication.*

Figure 4-12 Activities and Milestone List (2019) *Source: Project Team, Personal Communication.*

Figure 4-13 Project Gantt Chart Part 1 (2019) *Source: Project Team, Personal Communication.*

Figure 4-14 Project Gantt chart Part 2 and Project Critical Task (2019) *Source: Project Team, Personal Communication.*

Figure 4-15 Project Network Diagram Part 1 (2019) *Source: Project Team, Personal Communication.*

Figure 4-16 Project Network Diagram Part 2 (2019) *Source: Project Team, Personal Communication.*

Figure 4-17 Cost Estimates (2019) *Source: Project Team, Personal Communication.*

Figure 4-18 Responsibility Assignment Matrix (2019) *Source: Principal Consultant, FSQ Solutions.*

Figure 4-19 Human Resources Needs Matrix (2019) *Source: Principal Consultant, FSQ Solutions.*

Figure 4-20 Human Resources Schedule (2019) *Source: Principal Consultant, FSQ Solutions.*

Figure 4-21 Resources Breakdown Structure (2019) *Source: Principal Consultant, FSQ Solutions.*

Figure 4-22 Sample Job Description (2019) *Source: Principal Consultant, FSQ Solutions.*

Figure 4-23 Terms and Conditions for Food Safety Training (2019) *Source: Project Team, Personal Communication.*

Figure 4-24 Issues Log (2019) *Source: Project Team, Personal Communication.*

Figure 4-25 Stakeholder Engagement Matrix (2019) *Source: Project Team, Personal Communication.*

Figure 4-26 Risk Breakdown Structure (2019) *Source: Project Team, Personal Communication.*

Figure 4-27 Probability and Impact Matrix (2019) *Source: Project Team, Personal Communication.*

Figure 4-28 Qualitative Risk Analysis (2019) *Source: Project Team, Personal Communication.*

Figure 4-29 Statement of Work (2019) *Source: FSPCA Lead Instructor and Food Safety Expert, FSQ Solutions*

Figure 4-30 Terms of Reference (2019) *Source: FSPCA Lead Instructor and Food Safety Expert, FSQ Solutions*

Figure 4-31 Planned Procurement Process (2019) *Source: Project Team, Personal Communication.*

Figure 4-32 Roles And Responsibilities of Stakeholders (2019) *Source: Principal Consultant, FSQ Solutions*

Figure 4-33 Stakeholder Power and Impact Matrix (2019) *Source: Principal Consultant, FSQ Solutions*

9 APPENDICES

Appendix 1: FGP Charter

PROJECT CHARTER Formalizes the project start and confers the project manager with the authority to assign company resources to the project activities. Benefits: it provides a clear start and well defined project boundaries.	
Date	**Project Name:**
13th May 2019	Project Management Plan for the Implementation of FDA Food Safety Regulations at Choo's Enterprises
Knowledge Areas / Processes	**Applicacion Area (Sector / Activity)**
Knowledge areas: Integration Management, Scope Management Schedule Management, Cost Management Quality Management, Resources Management, Communications Management Risk Management, Procurement Management Stakeholder Management. **Process groups:** *Integration* - Developing, *Scope* - Planning, Collecting, Define, Creating *Schedule* - Planning, Define, Sequence, Estimating *Cost* - Planning, Estimating, Determine *Quality* - Planning, *Resources* - Planning, Estimating, *Communications* - Planning *Risk* - Planning, Identifying, Performing, *Procurement* - Planning, Stakeholder - Identification, Planning	Food Manufacturing
Start date	**Finish date**
13th May 2019	13th Sept 2019
Project Objectives (general and specific)	
General objective: To create a Project Management Plan using the standard set out by the PMBOK Guide, for the implementation of the Food and Drug Administration (FDA) Food Safety Regulations at Choo's Enterprises for the purpose of USA import compliance. Specific objectives: 1. To create a project charter that formally sanctions the project and provide the project manager with the authority to apply organizational resources to the project activities for the project management plan. 2. To create a scope management plan to ensures that all works essential for the successfully completion to the project are encompassed. 3. To create a schedule management plan to sustain the development and management of the project schedule within the time constraints outlined. 4. To create a cost management plan to define the processes for developing and estimating the project budget that ensures the project is completed within the approved budget constraints.	

5. To develop a quality management plan to identify and manage the quality requirements for the project as well as their food products to ensure the results meet customers' and other stakeholders' expectations.

6. To create a resource management plan to ensure that all the required human resources, facilities, equipment, equipment, materials, supplies and other resources needed for project success are identified and the critical teams are acquired and developed.

7. To craft a communication management plan to ensure the timely and effective communication of the project needs, status and other fundamental information to its stakeholders.

8. To create a risk management plan to ascertain and scrutinize the risks to the successful completion of the project and develop plans to minimize the likelihood and severity of the risks.

9. To generate a procurement management plan to be used in attaining products, services or results required by the project.

10. To build a stakeholder management plan to identify the people, groups or organizations that could impact positively on the project and develop strategies for effective stakeholder engagement in order to support the project's timely and successful execution.

Project purpose or justification (merit and expected results)

As a food manufacturing company, Choo's Enterprises had never sought to look into implementing a food safety system before as they did not see the need since they were supplying their products to only the local market. However, since the current need to increase profits due to a saturated market and the increasing monitoring of food safety practices within the company by local customers, they are actively seeking to export their food products to the USA and Canada and meet customer's needs.
However, even though Choo's Enterprises goal is to export any of their food products to the USA and Canada, they first have to be in compliance with FDA Food Safety Regulations in order to do such.
The implementation of this international Food Safety Regulations would give them access to trade and markets regionally apart from USA and Canada, and also be able to meet the basic food safety requirements of their local customers. Additionally, it would enhance their marketing image and credibility, and allow for growth, increased profit and market share as well as customer retention.
Therefore, given their needs and the benefits of this project, the basis for creating a Project Management Plan for the implementation of FDA Food Safety Regulations within their facility is to increase the success of effective and efficient execution and ensure that proper monitoring, controlling and closing processes are done for continuous improvement and maintenance of the Food Safety System. During this project, the project manager will be developing the subsidiaries of the Project Management Plan to meet the time, cost, schedule, resources and quality constraints of and for Choo's Enterprises.

Description of Product or Service to be generated by the Project – Project final deliverables

The Project Management Plan for the implementation of the FDA Food Safety Regulations at Choo's Enterprises will be generated by this project and consist of all the required documents for a Project Management Plan and some methodologies.

Assumptions

It is assumed that the project can be completed in three months by one (1) person.
It is assumed that the company will allow for the Final Graduation Project (FGP) within the company.
It is assumed that the company will provide all the required information needed to complete the various processes for the Knowledge areas outlined.
It is assumed that the support from the tutor is fore coming and clear so as to avoid miscommunication and project delays.

Constraints

Time: Three months to complete the project and seminar to be completed in five (5) weeks.
Resources: One (1) person i.e. Project manager to complete the project.

Preliminary risks

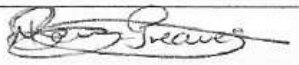
If the deliverables and activities assigned are not executed as required, this might delay the project and impact the final grade.
If support from the organization is not fore coming, this might delay the project execution and impact the project schedule.
If support from the tutor is not fore coming, this might delay the project execution and impact the project schedule.

Budget

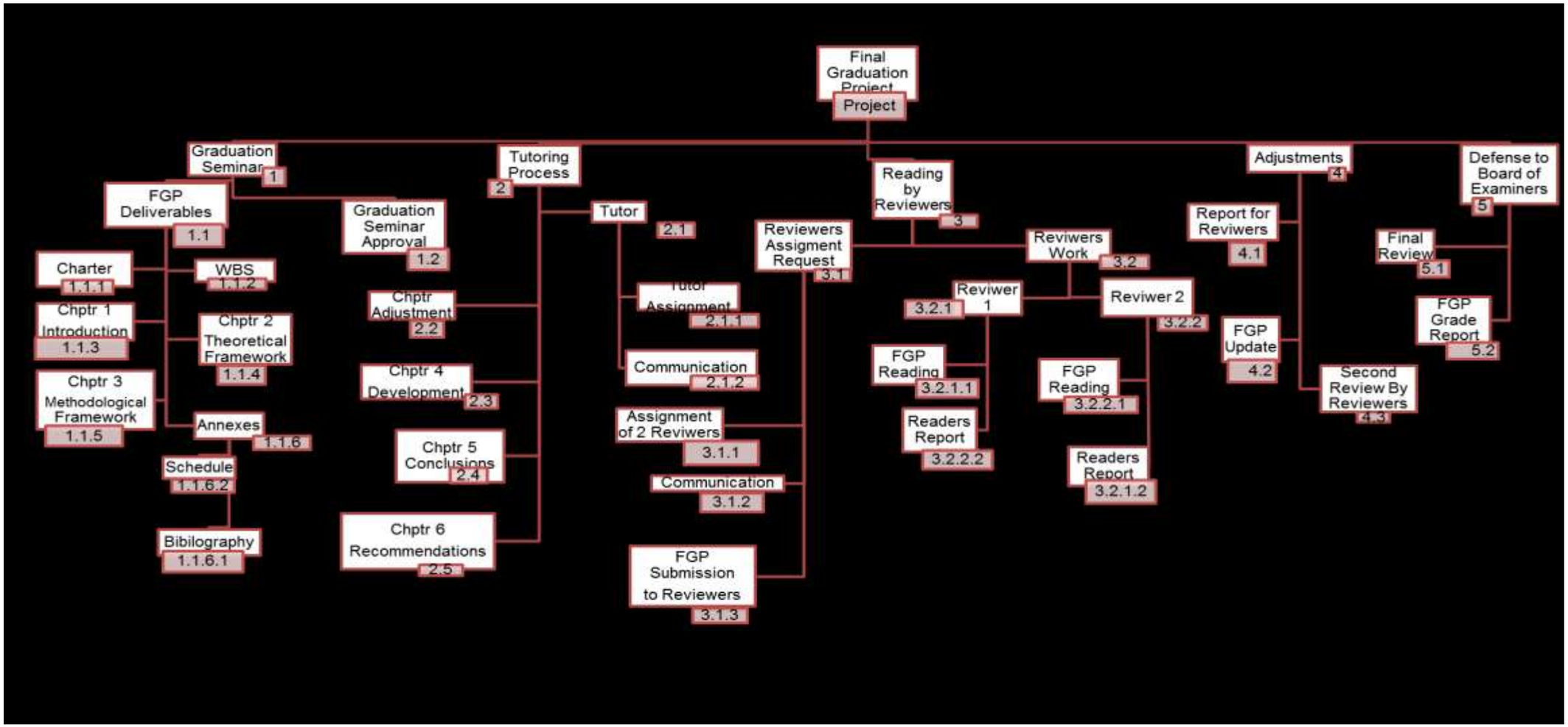
Budget will constitute of the financial resources needed to compile a hard copy of the Final Graduation Project and ship to the University in Costa Rica.

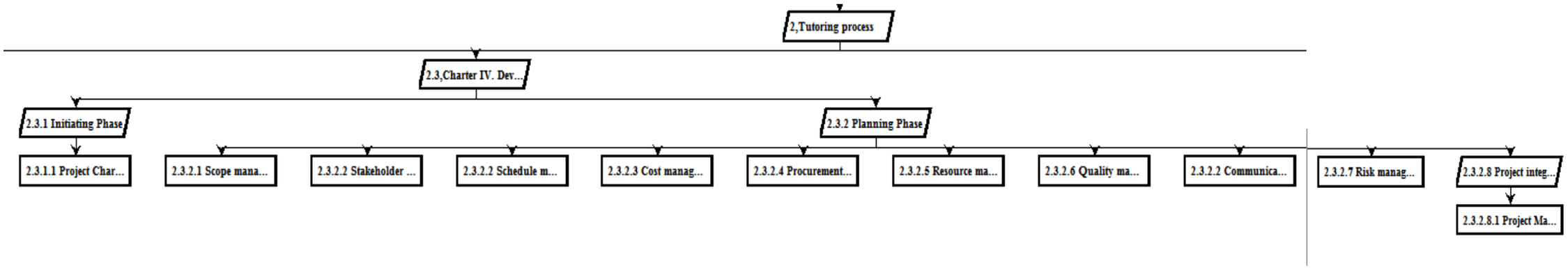
Milestones and dates

Milestone	Start date	End date
FGP Start	13th May 2019	13th May 2019
Project Charter	13th May 2019	17th May 2019
WBS	13th May 2019	17th May 2019
Chapter I. Introduction	20th May 2019	24th May 2019
FGP Schedule	20th May 2019	24th May 2019
Chapter II. Theoretical framework	27th May 2019	31st May 2019
Chapter III. Methodological framework	3rd June 2019	7th June 2019
Annexes -	13th June 2019	24th June 2019
Bibliography	13th June 2019	17th June 2019
Graduation Seminar approval,	10th June 2019	14th June 2019
Tutoring process	17th June 2019	13th Sept 2019
Tutor	17th June 2019	19th June 2019
Tutor assignment	17th June 2019	17th June 2019
Communication	18th June 2019	19th June 2019
Adjustments of previous chapters (If needed)	20th June 2019	26th June 2019
Charter IV. Development (Results)	27th June 2019	30th Aug 2019
Initiating Phase	27th June 2019	30th June 2019
1 Project Charter	27th June 2019	30th June 2019
Planning Phase	1st July 2019	29th Aug 2019
1 Scope management	1st July 2019	7th July 2019
2 Stakeholder Management	8th July 2019	14th July 2019
3 Schedule management	15th July 2019	21st July 2019
4 Cost management	20th July 2019	28th July 2019
5 Resource management	29th July 2019	4th Aug 2019
6 Procurement management	29th July 2019	4th Aug 2019
7 Quality management	5th Aug 2019	10th Aug 2019
8 Communications Management	11th Aug 2019	14th Aug 2019
9 Risk management	15th Aug 2019	19th Aug 2019
10 Project integration	19th Aug 2019	30th Aug 2019
10.1 Project Management Plan	19th Aug 2019	30th Aug 2019
Chapter V. Conclusions	2nd Sept 2019	6th Sept 2019
Chapter VI. Recommendations	9th Sept 2019	13th Sept 2019
Tutor approval	13th Sept 2019	13th Sept 2019
Reading by reviewers	23rd Sept 2019	4th Oct 2019
Adjustments	7th Oct 2019	1st Nov 2019
Presentation to Board of Examiners	4th Nov 2019	8th Nov 2019
FGP End	8th Nov 2019	8th Nov 2019

Relevant historical information	
Choo's Enterprise Ltd. is a Barbadian owned company which is known for producing high quality food products since 1983. The main activity of the company is manufacturing of herbs, spices, exotic spice blends, condiments, syrups, concentrates and sauces. These products are marketed to all segments of the retailing, catering and manufacturing trade in Barbados West Indies. The plant was previously located in White park Road, in the heart of the city of St. Michaels but now due to expansion, the plant is currently operating from a new location of Eagle Hall in the same city. There have been no similar efforts related to a project of this nature conducted prior.	
Stakeholders	
Direct stakeholders: • FGP Lecturer – Mr. Brenes • Tutor • Project Manager- Nadine Benn-Greaves Indirect stakeholders: • Academic Assistant • FGP Reviewers	
Project Manager: **Nadine Benn-Greaves**	**Signature:** 
Authorized by:	**Signature:**

Appendix 2: FGP WBS




2,Tutoring process
2.3,Charter IV. Dev...
2.3.1 Initiating Phase
2.3.1.1 Project Char...
2.3.2 Planning Phase
2.3.2.1 Scope mana...
2.3.2.2 Stakeholder ...
2.3.2.2 Schedule m...
2.3.2.3 Cost manag...
2.3.2.4 Procurement...
2.3.2.5 Resource ma...
2.3.2.6 Quality ma...
2.3.2.2 Communica...
2.3.2.7 Risk manag...
2.3.2.8 Project integ...
2.3.2.8.1 Project Ma...

Final Graduation Project Work Breakdown Structure
FGP Start
1,Graduation Seminar
1.1,Final Graduation Project (FGP) Deliverables
1.1.1, Project Charter
1.1.2,WBS
1.1.3,Chapter I. Introduction
1.1.4,Chapter II. Theoretical framework
1.1.5,Chapter III. Methodological framework
1.1.6,Annexes
1.1.6.1,Bibliography
1.1.6.2,Schedule
1.2,Graduation Seminar approval,
2,Tutoring process
2.1,Tutor
2.1.1,Tutor assigment
2.1.2,Communication
2.2,Adjustments of previous chapters (If needed)
2.3,Charter IV. Development (Results)
2.3.1 Initiating Phase
2.3.1.1 Project Charter
2.3.2 Planning Phase
2.3.2.1 Scope management
2.3.2.2 Stakeholder Management
2.3.2.3 Schedule management
2.3.2.4 Cost management
2.3.2.5 Resource management
2.3.2.6 management
2.3.2.7 Procurement Quality management
2.3.2.8 Communications Management
2.3.2.9 Risk management
2.3.2.10 Project integration
2.3.2.10.1 Project Management Plan
2.4,Chapter V. Conclusions
2.5,Chapter VI. Recommendations
2.6 Tutor approval
3,Reading by reviewers
3.1,Reviewers assignment request
3.1.1,Assigment of two reviewers
3.1.2,Communication
3.1.3,FGP submission to reviewers
3.2,Reviewers work
4,Adjustments
4.1,Report for reviewers
4.2,FGP update
4.3,Second review by reviewers
5,Presentation to Board of Examiners
5.1,Final review by board
5.2,FGP grade report
FGP End

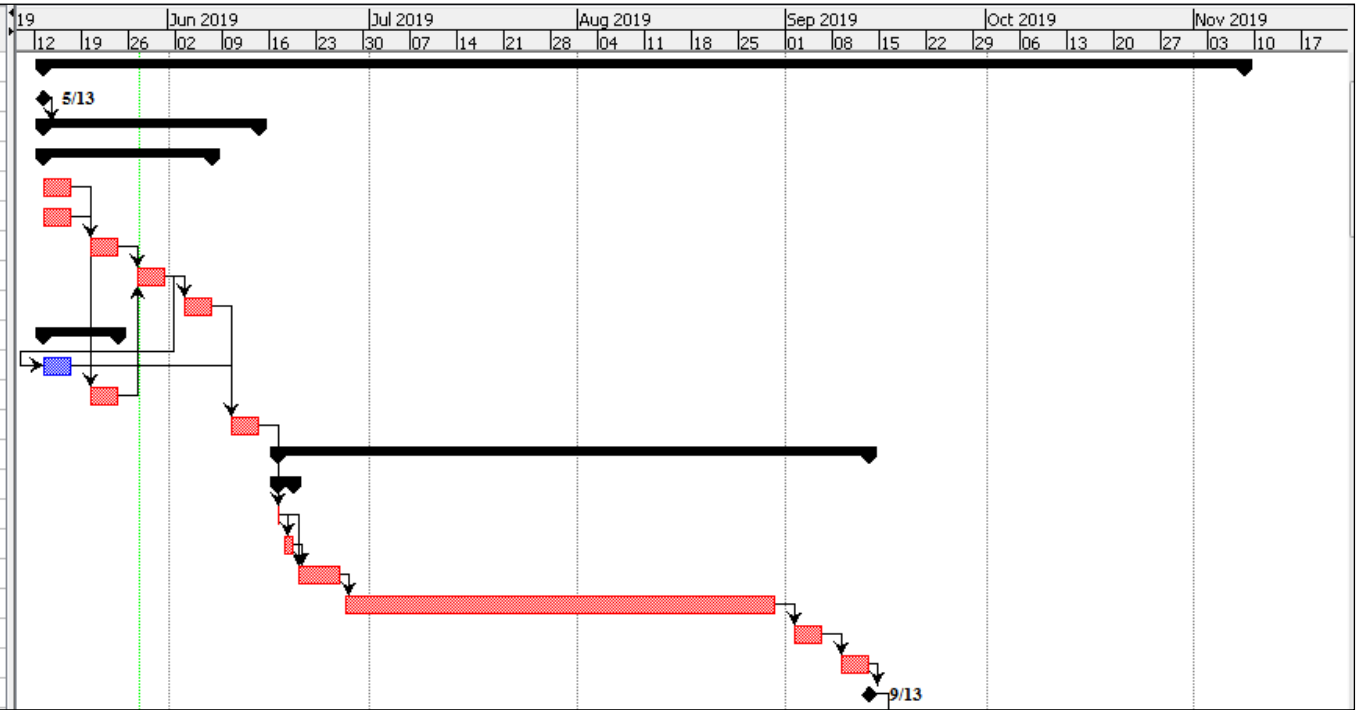
Appendix 3: FGP Schedule

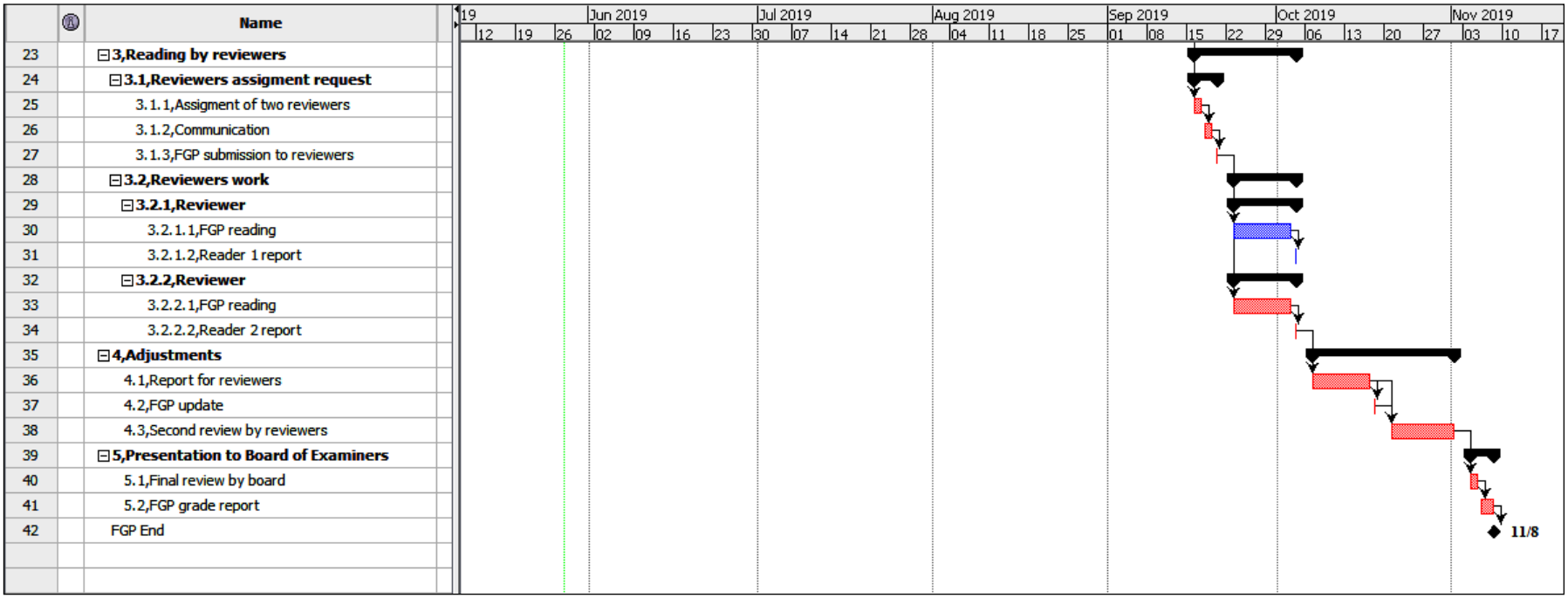
	Task Name	Duration	Start	Finish
1	**Final Graduation Project**	**130 days**	**May 13 '19**	**Nov 8 '19**
2	FGP Start	0 days	May 13 '19	May 13 '19
3	**1,Graduation Seminar**	**25 days**	**May 13 '19**	**Jun 14 '19**
14	**2,Tutoring process**	**65 days**	**Jun 17 '19**	**Sep 13 '19**
23	**3,Reading by reviewers**	**15 days**	**Sep 16 '19**	**Oct 4 '19**
35	**4,Adjustments**	**20 days**	**Oct 7 '19**	**Nov 1 '19**
39	**5,Presentation to Board of Examiners**	**5 days**	**Nov 4 '19**	**Nov 8 '19**
42	FGP End	0 days	Nov 8 '19	Nov 8 '19

		Name	Duration	Start	Finish	Predecessors
1		**Final Graduation Project**	**130 days**	**5/13/19 8:00 AM**	**11/8/19 5:00 PM**	
2		FGP Start	0 days	5/13/19 8:00 AM	5/13/19 8:00 AM	
3		**1,Graduation Seminar**	**25 days**	**5/13/19 8:00 AM**	**6/14/19 5:00 PM**	**2**
4		**1.1,FGP Deliverables**	**20 days**	**5/13/19 8:00 AM**	**6/7/19 5:00 PM**	
5		1.1.1,Charter	5 days	5/13/19 8:00 AM	5/17/19 5:00 PM	
6		1.1.2,WBS	5 days	5/13/19 8:00 AM	5/17/19 5:00 PM	
7		1.1.3,Chapter I. Introduction	5 days	5/20/19 8:00 AM	5/24/19 5:00 PM	5;6
8		1.1.4,Chapter II. Theoretical framework	5 days	5/27/19 8:00 AM	5/31/19 5:00 PM	7;12
9		1.1.5,Chapter III. Methodological framework	5 days	6/3/19 8:00 AM	6/7/19 5:00 PM	8
10		**1.1.6,Annexes**	**10 days**	**5/13/19 8:00 AM**	**5/24/19 5:00 PM**	
11		1.1.6.1,Bibliography	5 days	5/13/19 8:00 AM	5/17/19 5:00 PM	8
12		1.1.6.2,Schedule	5 days	5/20/19 8:00 AM	5/24/19 5:00 PM	6;5
13		1.2,Graduation Seminar approval,	5 days	6/10/19 8:00 AM	6/14/19 5:00 PM	9;11
14		**2,Tutoring process**	**65 days**	**6/17/19 8:00 AM**	**9/13/19 5:00 PM**	
15		**2.1,Tutor**	**3 days**	**6/17/19 8:00 AM**	**6/19/19 5:00 PM**	
16		2.1.1,Tutor assigment	1 day	6/17/19 8:00 AM	6/17/19 5:00 PM	13
17		2.1.2,Communication	2 days	6/18/19 8:00 AM	6/19/19 5:00 PM	16
18		2.2,Adjustments of previous chapters (if needed)	5 days	6/20/19 8:00 AM	6/26/19 5:00 PM	16;17
19		2.3,Charter IV. Development (Results)	47 days	6/27/19 8:00 AM	8/30/19 5:00 PM	18
20		2.4,Chapter V. Conclusions	5 days	9/2/19 8:00 AM	9/6/19 5:00 PM	19
21		2.5,Chapter VI. Recommendations	5 days	9/9/19 8:00 AM	9/13/19 5:00 PM	20
22		Tutor approval	0 days	9/13/19 5:00 PM	9/13/19 5:00 PM	21
23		**3,Reading by reviewers**	**15 days**	**9/16/19 8:00 AM**	**10/4/19 5:00 PM**	
24		**3.1,Reviewers assigment request**	**5 days**	**9/16/19 8:00 AM**	**9/20/19 5:00 PM**	
25		3.1.1,Assigment of two reviewers	2 days	9/16/19 8:00 AM	9/17/19 5:00 PM	22
26		3.1.2,Communication	2 days	9/18/19 8:00 AM	9/19/19 5:00 PM	25
27		3.1.3,FGP submission to reviewers	1 day	9/20/19 8:00 AM	9/20/19 5:00 PM	26
28		**3.2,Reviewers work**	**10 days**	**9/23/19 8:00 AM**	**10/4/19 5:00 PM**	
29		**3.2.1,Reviewer**	**10 days**	**9/23/19 8:00 AM**	**10/4/19 5:00 PM**	
30		3.2.1.1,FGP reading	9 days	9/23/19 8:00 AM	10/3/19 5:00 PM	27
31		3.2.1.2,Reader 1 report	1 day	10/4/19 8:00 AM	10/4/19 5:00 PM	30
32		**3.2.2,Reviewer**	**10 days**	**9/23/19 8:00 AM**	**10/4/19 5:00 PM**	
33		3.2.2.1,FGP reading	9 days	9/23/19 8:00 AM	10/3/19 5:00 PM	27
34		3.2.2.2,Reader 2 report	1 day	10/4/19 8:00 AM	10/4/19 5:00 PM	33
35		**4,Adjustments**	**20 days**	**10/7/19 8:00 AM**	**11/1/19 5:00 PM**	

		Name	Duration	Start	Finish	Predecessors
36		4.1,Report for reviewers	9 days	10/7/19 8:00 AM	10/17/19 5:00 PM	34
37		4.2,FGP update	1 day	10/18/19 8:00 AM	10/18/19 5:00 PM	36
38		4.3,Second review by reviewers	10 days	10/21/19 8:00 AM	11/1/19 5:00 PM	36,37
39		**5,Presentation to Board of Examiners**	**5 days**	**11/4/19 8:00 AM**	**11/8/19 5:00 PM**	
40		5.1,Final review by board	2 days	11/4/19 8:00 AM	11/5/19 5:00 PM	38
41		5.2,FGP grade report	3 days	11/6/19 8:00 AM	11/8/19 5:00 PM	40
42		FGP End	0 days	11/8/19 5:00 PM	11/8/19 5:00 PM	41

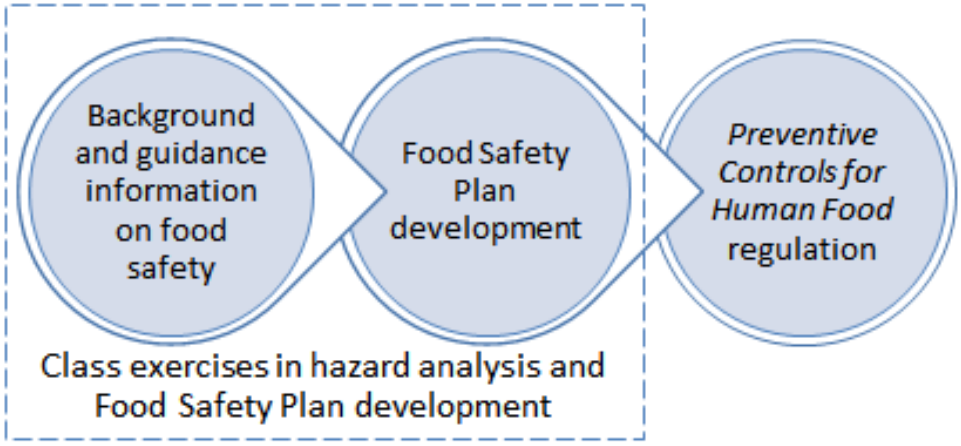
	Name
1	**Final Graduation Project**
2	FGP Start
3	**1,Graduation Seminar**
4	**1.1,FGP Deliverables**
5	1.1.1,Charter
6	1.1.2,WBS
7	1.1.3,Chapter I. Introduction
8	1.1.4,Chapter II. Theoretical framework
9	1.1.5,Chapter III. Methodological framework
10	**1.1.6,Annexes**
11	1.1.6.1,Bibliography
12	1.1.6.2,Schedule
13	1.2,Graduation Seminar approval,
14	**2,Tutoring process**
15	**2.1,Tutor**
16	2.1.1,Tutor assigment
17	2.1.2,Communication
18	2.2,Adjustments of previous chapters (If needed)
19	2.3,Charter IV. Development (Results)
20	2.4,Chapter V. Conclusions
21	2.5,Chapter VI. Recommendations
22	Tutor approval




Name
23 3,Reading by reviewers
24 3.1,Reviewers assigment request
25 3.1.1,Assigment of two reviewers
26 3.1.2,Communication
27 3.1.3,FGP submission to reviewers
28 3.2,Reviewers work
29 3.2.1,Reviewer
30 3.2.1.1,FGP reading
31 3.2.1.2,Reader 1 report
32 3.2.2,Reviewer
33 3.2.2.1,FGP reading
34 3.2.2.2,Reader 2 report
35 4,Adjustments
36 4.1,Report for reviewers
37 4.2,FGP update
38 4.3,Second review by reviewers
39 5,Presentation to Board of Examiners
40 5.1,Final review by board
41 5.2,FGP grade report
42 FGP End
19
Jun 2019
Jul 2019
Aug 2019
Sep 2019
Oct 2019
Nov 2019
12 19 26 02 09 16 23 30 07 14 21 28 04 11 18 25 01 08 15 22 29 06 13 20 27 03 10 17
11/8

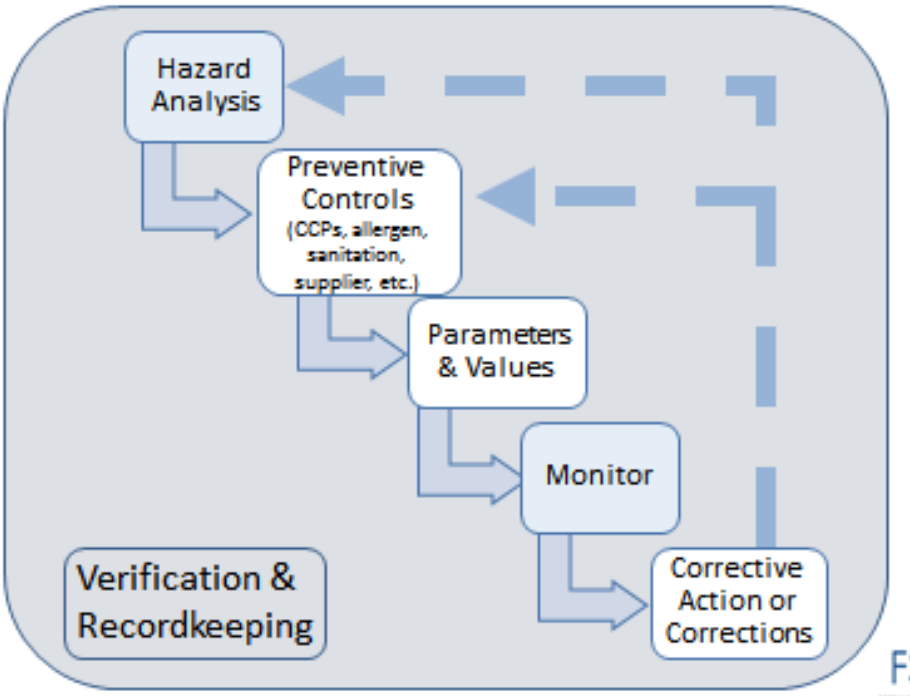
Appendix 4: FSCPA Preventive Controls For Human Food Course Outline

Course Format



Preventive Food Safety Systems

Preventive Controls Include More Than HACCP



Chapter 2—Food Safety Plan Overview Summary

- A written Food Safety Plan, specific to the facility, is required to include a hazard analysis
- When hazards requiring a preventive control are identified, the following are required, as appropriate:
  - Preventive controls
    - Process, food allergen, sanitation, supply-chain and others determined through the hazard analysis process
    - A recall plan
  - Implementation procedures
    - E.g., validation studies and monitoring, corrective actions and verification procedures
- The format is flexible

Appendix 5 Course Evaluation Questionnaire Template

Please address the following questions in each of the sections listed below. Your answers will provide valuable insight into how our courses are delivered and what quality control measures are needed to improve your learning experience.

Please use the following rating scale for sections one and two (section three has a separate key, indicated in the column heading):

1 = Unsatisfactory, 2 = Needs improvement, 3 = Satisfactory, 4 = Excellent, 5 = Exceptional.

Evaluation							
Section One	***Instructional Delivery***						
	1. Overall quality of classroom instruction.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	2. Professional behavior of instructors.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	3. Use of training aids (e.g. slides, handouts) provided by the instructors.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	4. Use of classroom equipment (e.g. projectors, computers) by the instructors.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	5. Course length.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	Comments or suggestions regarding instructional delivery:						
Section Two	***Instructional Effectiveness***						
	6. Instructor(s) was/were prepared to teach this course.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	7. Instructors' abilities to present the material clearly and at a reasonable pace.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	8. Instructor's abilities to interact with participants during the course.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	Comments or suggestions regarding the instructional effectiveness:						
Section Three	***Learning Effectiveness***						
		Strongly Disagree	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**	**Not Applicable**
	9. I will be able to apply the knowledge and skills learned in this course to develop a food safety plan.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	10. Course materials will be useful to me.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	11. My expectations were met.	1 ☐	2 ☐	3 ☐	4 ☐	5 ☐	N/A ☐
	Comments or suggestions regarding learning effectiveness:						
Section Four	***Course Summary***						
	12. What was the most valuable part of the course?						
	13. What was the least valuable part of the course?						
	14. Overall, how could this course be improved?						
	15. What other areas of instruction would you like FSPCA to offer in the future?						
	16. Please provide any additional comments and/or recommendations.						

Instructor: Mrs. Nadine Benn-Greaves

Appendix 6 Facility Audit Checklist Template

FACILITY AUDIT					
	Conducted By: Nadine Benn-Greaves			Date:	
	PART 117—CURRENT GOOD MANUFACTURING PRACTICE, HAZARD ANALYSIS, AND RISK–BASED PREVENTIVE CONTROLS FOR HUMAN FOOD (PCHF Rule)	**Aligns to Standard**	**Score**	**Description of Gaps and Actions to Align**	**Additional Comments**
	Subpart A—General Provisions				
	§117.4 Qualifications of individuals who manufacture, process, pack, or hold food.				
	(b) Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food. Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must: (1) Be a qualified individual as that term is defined in §117.3 (2) Receive training in the principles of food hygiene and food safety,				
	(c) Additional qualifications of supervisory personnel. Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.				
	§117.9 Records required for this subpart. (a) Records that document training required by §117.4(b)(2) must be established and maintained. (b) The records that must be established and maintained are subject to the requirements of subpart F of this part				
	Part 1: Personnel (117.10) 1.1				
1.1	Is there a written policy about employee reporting of an illness; open lesion, including boils; sores; infected wounds; or any other sort of wound or health issue that can cause contamination? Are workers with these reportable illnesses excluded from operation? Personnel must be instructed to report such health conditions to their supervisors.	☐	☐		
1.2	Policy on dress code- Wearing outer garments suitable to the operation in a manner that protects	☐	☐		
1.3	Policy on personal hygiene & personal cleanliness.	☐	☐		
1.4	Policy on when and where for eating, chewing gum, drinking beverages, use of smoking and tobacco and removing all unsecured jewelry.	☐	☐		

	(5) Maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition.	☐	☐		
	(6) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints.	☐	☐		
	(7) Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.	☐	☐		
1.5	Policy identifying items that can cause contamination of food, food-contact surface, or food packaging materials	☐	☐		
1.6	Training on proper food handling techniques and food protection principals is provided and documented. Washing hands thoroughly observed.	☐	☐		
1.7	Policies identify designated supervisory individual to ensure facility/personnel compliance.	☐	☐		
	Part 2: Plant and Grounds (117.20)				
2.1	Properly store equipment, maintain roads and parking lots, maintenance of areas around the plant are maintained to be free from litter, waste, uncut weeds, and standing water (proper drainage), so they do not become a source of filth or attract pests.	☐	☐		
2.2	Adequate space for equipment and storage of materials that maintenance, sanitation, and production of safe food can occur	☐	☐		
2.3	If storage occurs outside the plant, ensure adequate protection from pests or other contaminants.	☐	☐		
2.4	Plant size, construction and design (non porous) allow for cleaning, maintenance, prevention of contamination, and allows for employees to perform their duties without contamination occurring.	☐	☐		
	1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe food.	☐	☐		
	(2) Permit the taking of adequate precautions to reduce the potential for allergen cross-contact and for contamination of food, food-contact surfaces, or food-packaging materials with microorganisms, chemicals, filth, and other extraneous material.	☐	☐		

	3) Permit the taking of adequate precautions to protect food in installed outdoor bulk vessels by any effective means, including:(i) Using protective coverings.(ii) Controlling areas over and around the vessels to eliminate harborages for pests.(iii) Checking on a regular basis for pests and pest infestation.(iv) Skimming fermentation vessels, as necessary.	☐	☐		
	(4) Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and kept in good repair; that drip or condensate from fixtures, ducts and pipes does not contaminate food, food-contact surfaces, or food-packaging materials	☐	☐		
2.5	Light bulbs and glass are appropriately protected so as not to contaminate products (if broken) and provide adequate light for hand-washing, dressing and locker rooms and toilet rooms	☐	☐		
2.6	Ventilation and/or operate fans that minimize dust, odors, vapors, or cross-contact of allergens.	☐	☐		
	Provide, where necessary, adequate screening or other protection against pests.	☐	☐		
	Part 3: Sanitary Operations (117.35)				
3.1	A regular cleaning and sanitation program specifies cleaning practices and cleaning frequency for each area (inside and outside) of the facility. The program is monitored on a regular basis, with records of findings	☐	☐		
3.2	All equipment (both food-contact and non- food-contact surfaces) is cleaned on a scheduled basis with records kept and cleaned and sanitized equipment is stored to prevent contamination	☐	☐		
3.3	Cleaning compounds and sanitizing agents must be free of undesired microorganisms and are safe and adequate for the conditions of use.	☐	☐		
3.4	Toxic materials such as lubricants, laboratory testing agents, cleaning compounds, pesticides, insecticides, rodenticides, and non-feed products are identified, held, and stored in a manner that avoids food contamination	☐	☐		
3.5	Effective pest control program should be established. Use pesticides only in ways that will protect.	☐	☐		
3.6	Single-use paper supplies (paper cups or paper towels) are stored in appropriate containers and handled, dispensed, used and disposed of in a manner that prevents contamination	☐	☐		

3.7	d) Sanitation of food-contact surfaces. All food-contact surfaces, including utensils and food-contact surfaces of equipment, must be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of food.Store all cleaned and sanitized equipment in a manner and location to protect against allergen cross contact and food contamination.	☐	☐		
	1) Food-contact surfaces used for manufacturing/ processing, packing, or holding low-moisture food must be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they must, when necessary, be sanitized and thoroughly dried before subsequent use.	☐	☐		
	(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into food, all food- contact surfaces must be cleaned and sanitized before use and after any interruption during which the food- contact surfaces may have become contaminated. Where equipment and utensils are used in	☐	☐		
4	**Part 4: Sanitary Facilities and Controls (117.37)**				
4.1	Water supply is from potable, sanitary source. Steam added to food during processing must be chemical-free	☐	☐		
4.2	Appropriate water temperature and pressure is provided in areas where processing, cleaning and packaging of human foods occur	☐	☐		
4.3	Plumbing must be adequately sized, design, installed and maintained to carry the quantity of water required to convey sewage and liquid disposable waste. These substances should not contaminate the food, water supply, equipment or create an unsanitary condition	☐	☐		
4.4	Sewage treatment systems/septic system(s) are functioning properly with no evidence of leaks or run off	☐	☐		
4.5	Rubbish is managed so as to minimize odors and decrease the potential to attract and harbor pests	☐	☐		
4.6	Adequate floor drainage is located in areas where flooding-type cleaning or other normal operations release large quantities of water.	☐	☐		
4.7	Piping systems are functioning properly to prevent backflow and cross-connections.	☐	☐		
	(e) Hand-washing facilities. Each plant must provide hand-washing facilities designed to ensure that an employee's hands are not a source of contamination of food, food-contact surfaces, or food-packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature.	☐	☐		

4.8	All toilets/restrooms are accessible and clean. Facilities are equipped with hand washing options	☐	☐		
5	**Part 5: Equipment and Utensils (117.40)**				
5.1	All plant equipment, utensils, and adjacent spaces must be cleanable and properly installed and maintained.	☐	☐		
5.2	Equipment and utensils must be constructed and used so as not to allow adulterants into the food material	☐	☐		
5.3	Food-contact surfaces must resist corrosion and be made from non-toxic materials.	☐	☐		
5.4	Seams on food-contact surfaces must be constructed to discourage accumulation of materials and growth of microorganisms or harbor food allergens	☐	☐		
5.5	Equipment in the processing and handling area that is not in direct contact with food should be designed to be fully cleanable	☐	☐		
5.6	Holding, conveying, and manufacturing systems must be able to be cleaned and sanitized	☐	☐		
5.7	Freezers and cold storage units used for human food must be equipped with a temperature monitoring device that is placed to show the inside temperature of the compartment.	☐	☐		
5.8	Temperature measurement, control, and recording devices must be accurate and precise.	☐	☐		
5.9	(e) Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms must be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately within the compartment.				
	(f) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food must be accurate and precise and adequately maintained, and adequate in number for their designated uses				
	Compressed air or gases that are mechanically introduced into food or used to clean contact surfaces must be treated in such a way that they cannot contaminate the food or equipment				
6	**Part 6: Processes and Controls (117.80)**				
6.1	Adequate sanitation principles must govern all operations of manufacturing, processing, packing and holding of human food. These include receiving, inspecting, transporting, and segregating.	☐	☐		

6.2	Appropriate quality control operations must be employed to ensure food is suitable for human consumption (including food packing materials).	☐	☐		
6.3	Overall plant sanitation is supervised by one or more competent and well-trained individuals.	☐	☐		
6.4	Precautions should be made to prevent allergen cross contact and contamination from chemical, microbial, or extraneous materials to ensure no adulteration occurs.				
	(5) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination.				
	6) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination.				
6.5	Raw materials and ingredients must be inspected, handled, and stored in a manner that protects against microbial growth and allergen cross contact (e.g. remove soil, water is allergen or contamination free).	☐	☐		
6.6	Raw materials should be tested for microorganisms that could be harmful to humans or treat to ensure levels will not be harmful to humans.	☐	☐		
6.7	Raw materials and ingredients susceptible to contamination to aflatoxin, other natural toxins, pests, undesirable microorganisms, or extraneous materials must comply with FDA regulations for poisonous substance or defect action levels	☐	☐		
6.8	Raw materials must be held in bulk or containers designed to protect against cross-contact or contamination. This may include temperature, humidity, or a rework schedule		☐		
6.9	Frozen, liquid, or dry materials or ingredients should be kept in a manner to prevent altering of the current temperature state or contamination from allergens or other contaminates	☐	☐		
6.10	Equipment and utensils and food containers must be maintained in sanitized and cleaned	☐	☐		
6.11	All manufacturing, packaging, holding, or process must be done in an environment that minimizes microbial growth, allergen cross-contact and contamination	☐	☐		
6.12	Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated.	☐	☐		
6.13	Measures such as sterilizing, irradiating, pasteurizing, cooking, that are taken to destroy or prevent the growth of undesirable microorganisms must be validated	☐	☐		

6.14	Protective measures must be taken to protect work-in process, rework, and finished food to ensure protection against allergen cross-contact, contamination, and growth of undesirable microbes	☐	☐		
6.15	Equipment, containers, and utensils used to convey, hold, or store raw materials and other materials that protects against allergen cross-contact and against contamination	☐	☐		
6.16	Adequate measures must be taken to protect against the inclusion of metal or other extraneous materials in food	☐	☐		
6.17	Food, raw materials, and other ingredients that are adulterated must be disposed in a manner to protect against cross contamination, or reconditioned in a manner that has an effective method or re-examined to ensure no adulteration is concurring.	☐	☐		
6.18	Steps such as washing, peeling, trimming, filling, assembling, packaging, and other operational processes must be performed so as to protect food against allergen cross-contact and against contamination. Food must be protected from contaminants that may drip, drain, or be drawn into the food.	☐	☐		
6.19	Heat blanching, when required, must be effected by heating the food to the required temperature, holding for a required time, then rapid cooling or passing the food to subsequent manufacturing without delay.				
6.2	Batters, breading, sauces, gravies, dressings, dipping solutions, and other similar preparations that are held and used repeatedly over time must be treated in such a manner that they are protected against food contamination, and minimizing undesired microorganism growth.				
6.21	Food, such as dry mixes, nuts, etc. that relies principally on the control of aw for preventing undesirable microorganism growth must be processed to and maintained at a safe moisture level.	☐	☐		
6.22	Food, such as acid and acidified food, that relies principally on the control of pH for preventing growth of undesired microorganisms must be monitored and maintained at a pH of 4.6 or below.	☐	☐		
6.23	When ice comes in contact with food, it must be made from water that is safe and sanitary.				
	Part 7: Warehousing and Distribution (117.93)				
7.1	Food must be stored and transported under conditions that prevent contamination of the food as well as deterioration of the food and the container	☐	☐		

7.2	The food safety plan should include a protocol for evaluating and recording the material hauled in prior loads	☐	☐		
7.3	Document how stock is rotated.	☐	☐		
7.4	Finished product containers should be clearly labeled to identify contents and the presence of any allergens	☐	☐		
7.5	Products returned from distribution should be assessed for food safety and handled accordingly	☐	☐		
	Part 9: Defect Action Levels (117.110)				
9.1	The manufacturer processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.	☐	☐		
9.2	The mixing of food containing defects at levels that render the food and final product adulterated is not permitted.	☐	☐		

Additional Observations & Points for Improvement	
1	
2	
3	
4	
5	

Appendix 7 Food Safety Plan Template

PRODUCT(S):	Model Template	**PAGE 133 of 162**	
PLANT NAME:		**ISSUE DATE**	1/7/2017
ADDRESS:		**SUPERSEDES**	3/30/2016

Food Safety Plan
for
[Name of Food]

Developed by: _____[Name]_____ PCQI Date: _____
Approved by:_____[Signature]_____ Plant Manager Date: _____

This Food Safety Plan template is modeled after forms developed for the FSPCA Preventive Controls for Human Food curriculum, and can be modified to reflect the need of individual establishment needs. FSPCA has no input on individual establishment Food Safety Plans. **There is no standardized or mandated format for a Food Safety Plan**, but the information should be arranged in a progressive manner that clearly explains the thought process for the hazard analysis and the individual steps in the Food Safety Plan. Forms used for process preventive controls may be adapted for other types of preventive controls, but other formats are entirely acceptable if it works for your organization and contains all of the required information. The following forms are provided as examples. These worksheets can be copied for routine use, but if they are used for official use, they must include details that identify the commercial firm and related information.

The information in this example is for training purposes only and does not represent any specific operation. Processing steps may have been omitted or combined to facilitate its use for class exercises. **It is not complete and contains both required and optional information.** Because development of a Food Safety Plan is site specific, it is highly unlikely that this plan can be used in a specific facility without significant modification. Conditions and specifications used (e.g., validation information) are for illustrative purposes only and may not represent actual process conditions.

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Company Overview

[Provide a brief description of the company. Consider listing members of the food safety team, if you have one. Consider including a company organization chart and/or plant layout, if it helps explain the food safety plan]

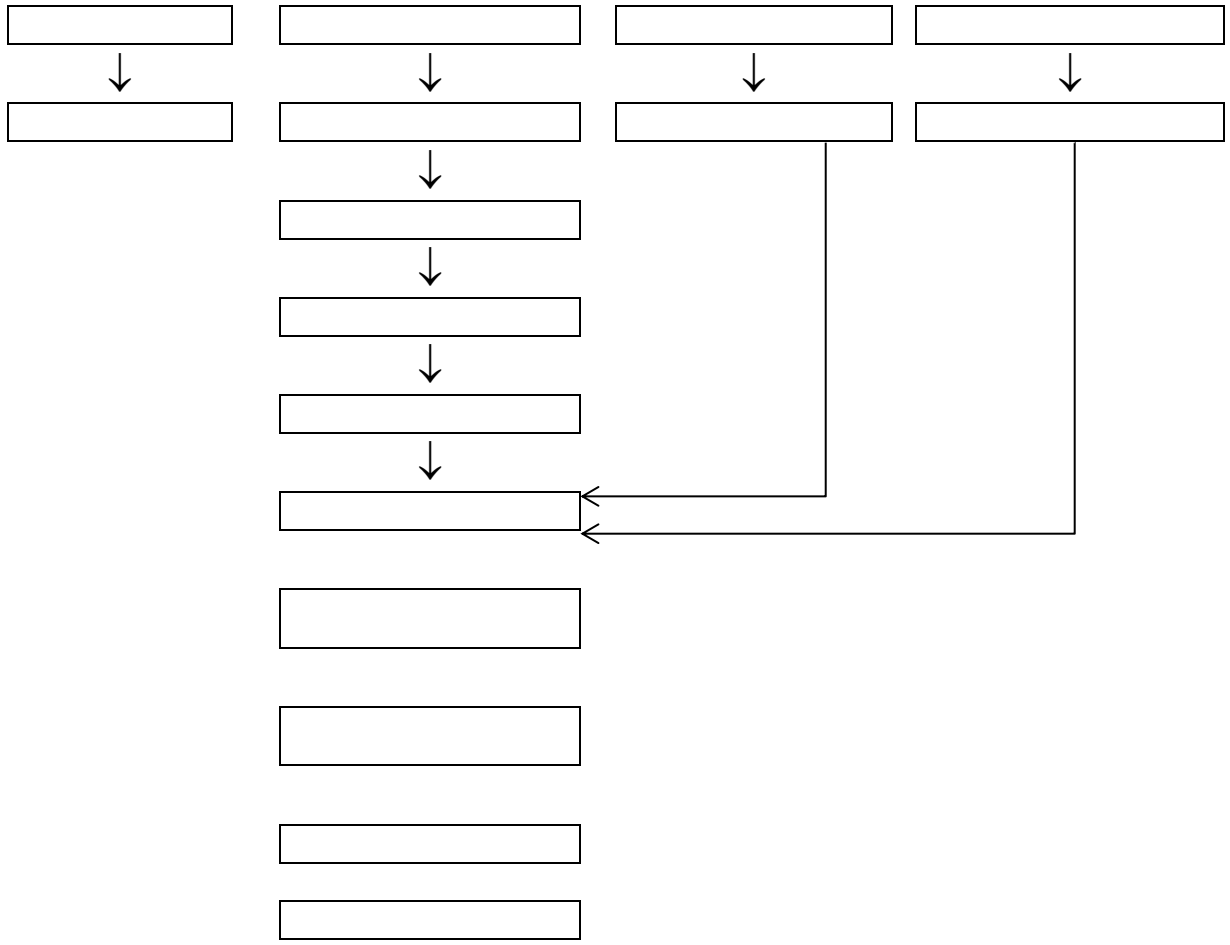
Product Description

Product Name(s)	
Product Description, including Important Food Safety Characteristics	
Ingredients	
Allergens	
Packaging Used	
Intended Use	
Intended Consumers	
Shelf Life*	
Labeling Instructions*	
Storage and Distribution*	

[*Provide information relevant to food safety]

Flow Diagram

[*A table format or other program can be used to develop a flow diagram for the product(s) covered in this food safety plan. "Insert Shapes" can be used to add arrows in Word documents.]*



Process Narrative

[*A text description of each step in the flow diagram can provide more food safety and/or control information than can be shown easily in the flow diagram and important.to understanding the process]*

Hazard Analysis

Hazard identification (column 2) considers known or reasonably foreseeable hazards (i.e., potential hazards) that may be present in the food because the hazard occurs naturally, the hazard may be unintentionally introduced, or the hazard may be intentionally introduced for economic gain.

B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens

C = Chemical hazards, including radiological hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives

P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							
	P							
	B							
	C							

(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step		(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
			Yes	No			Yes	No
	P							
	B							
	C							
	P							
	B							
	C							
	P							

Process Preventive Controls

Process Control Step	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

Food Allergen Ingredient Analysis

Raw Material Name	Supplier	Food Allergens in Ingredient Formulation								Allergens in Supplier's Precautionary Labeling
		Egg	**Milk**	**Soy**	**Wheat**	**Tree Nut** (market name)	**Peanut**	**Fish** (market name)	**Shellfish** (market name)	

Allergen Verification Listing

Product	Allergen Statement	Label Number

Allergen Scheduling and Cleaning Implications

Production Line Allergen Assessment

Product Name	Production Line	Intentional Allergens							
		Egg	**Milk**	**Soy**	**Wheat**	**Tree Nut** (market name)	**Peanut**	**Fish** (market name)	**Shellfish** (market name)

Scheduling Implications:
[*State the order in which products should be run to minimize allergen cross-contact. Consider adding when alternate production practices may be permitted, including approval for this, if you wish.*]

Allergen Cleaning Implications:
[Identify when cleaning to prevent allergen cross-contact is required]

Food Allergen Preventive Controls

Allergen Control Step	Hazard(s)	Criterion	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

Sanitation Preventive Controls

Cleaning and Sanitizing Procedure

Location	
Purpose	
Frequency	
Who	
Procedure	
Monitoring	
Corrections	
Records	
Verification activities	

Hygienic Zoning

[Insert simple facility layout, indicating flow of material to aid common understanding and visualization.]

Location	
Purpose	
Frequency	
Who	
Procedure	
Monitoring	
Corrections	
Records	
Verification activities	

Environmental Monitoring for Sanitation Control Verification

Purpose	
Sample identification	
Sampling procedure	
Laboratory	
Test conducted	
Interpretation of results	
Action of a negative result	
Corrective action for a positive result	

Supply-chain-applied Preventive Controls Program

Verification Procedures for Supply-Chain-Applied Control Ingredients

Ingredient 1:

Hazards requiring a supply-chain-applied control	
Preventive controls applied by the supplier	
Verification activities and procedures	
Records	

Ingredient 2:

Hazards requiring a supply-chain-applied control	
Preventive controls applied by the supplier	
Verification activities and procedures	
Records	

Approved Suppliers for Ingredients Requiring a Supply-chain-applied Control [this table is an alternative format to provide the information above]

Ingredient (requiring supply-chain-applied control)	**Approved Supplier**	**Hazard(s) requiring supply-chain-applied control**	**Date of Approval**	**Verification method**	**Verification records**

Receiving Procedure for Ingredients Requiring a Supply-chain-applied Control

[Document procedures used for receiving ingredients requiring a supply-chain-applied control.]

Recall Plan Template	
Company Information	
Company Name:	*What is the registered name of the company undertaking the recall?*
Address:	*Company's registered address?*
Business hours phone number:	*What is the business contact phone number during business hours?*
After hours phone number	*What is the business contact phone number after business hours?*
Email:	*What is the recall coordinator's email address?*
Business Website:	*What is the business website?*
Notifications	
Federal Department Notification:	*Have you contacted the FDA?* *□ Yes* *□ No*
Federal Dept. Contact Person:	*Who did you speak with at the FDA?*
State Department Notification:	*Have you contacted the state regulatory agency (Dept. of Ag & Markets, etc.)?* *□ Yes* *□ No*
State Dept. Contact Person:	*Who did you speak to with?*
Health Department Notification:	*Have you contacted the State Health Department?* *□ Yes* *□ No*
Health Dept. Contact Person:	*Who did you speak with?*
SQFI Notification:	*If you are certified through SQFI, have you contacted your CB? It is required to notify them within 24 hours of the recall.*
SQFI Contact Person:	*Who did you speak with?*
Company Recall Coordinator Contact	
Contact Name:	*What is the company recall coordinator's name?*
Contact Phone Number:	*What is the best contact number for this contact?*
Consumer Enquiries Contact	
Consumer Contact Name:	*Who can consumers contact for questions in relation to the recall? This can be a customer service line or a specific person.*
Contact Phone Number:	*What is the best contact number for the contact?*

Product Information	
Product Name:	*What is the name of the product as it appears on the packaging?*
Food Type:	*What food type is the product? Please specify category (bread, milk, etc.)*
Food Storage Category:	*What is the shelf stability of the product? (shelf stable, chilled, frozen)*
Type of Product Coding:	*What type of date marking appears on the product packaging?* *□ Use by...* *□ Best before...* *□ Other (please specify):*
Date on Packaging:	*What is the date or lot mark of the affected product? Please record exactly as it appears on the packaging. If there are multiple dates, please indicate each date.*
Lot Code:	*List all lot codes of affected product(s).*
Bar Code:	*If available, what is the bar code of the affected product(s)?*
Packaging dimensions:	*What are the dimensions of the product and/or packaging? Please indicate how may individual portions of a product are included in one package.*
Weight:	*What is the weight of the product?*
Description:	*What is the description of the product packaging (cardboard box, vacuum-sealed plastic, plastic tub, etc.)?*
Import:	*Has the product been imported?* *□ Yes. If so, from where?* *□ No*
Export:	*Has the product been exported?* *□ Yes. If so, to where?* *□ No*
Manufacturer Location:	*If you do not manufacture the product at the address listed on page 1, where is the product manufactured?*
Manufacturer Name:	*If you are not the manufacturer, what is the name of the product manufacturer?*
Manufacturer Address:	*What is the manufacturer's address?*
Supplier Information **Imported foods not purchased from the manufacturer*	
Supplier Name:	*If you did not purchase the imported product from the manufacturer, what is the business name of the company that you purchased the product from?*
Supplier Address:	*What is the supplier's company address?*

Product Distribution	
Recall Classification:	□ ***Class I*** *Dangerous or defective products that predictably could cause serious health problems or death. Examples include: food found to contain botulinum toxin, food with undeclared allergens, a label mix-up on a lifesaving drug.* □ ***Class II*** *Products that might cause a temporary health problem, or pose only a slight threat of a serious nature.* □ ***Class III*** *Products that are unlikely to cause any adverse health reaction, but that violate FDA labeling or manufacturing laws. Examples include: a minor container defect and lack of English labeling in a retail food*
Recall Level:	□ ***Consumer*** *Recovery of affected product from all points in the production and distribution network (retail stores, food service, wholesalers, online sales, etc.) as well as product already in the possession of the consumers.* □ ***Trade*** *Recovery of affected product where the product has not been available for direct purchase by the general public. This may include school, hospitals, prisons, restaurants, and other food service/catering businesses that sell and/or provide food for immediate consumption.* □ ***Consumer and Trade*** *Recall containing food products packaged for different markets (ie pints of ice cream for home consumption and bulk tubs of ice cream for use in a restaurant)*
Distribution Method:	*How was the affected product distributed?* □ *Direct to consumer (Please provide a list which contains contact details of consumers to whom you have directly sold the affected product)* □ *Direct to Food Service/Trade* □ *Wholesalers/Distribution Centers* □ *Retail Outlets* □ *Online (Please provide a list which contains contact details of consumers to whom you have directly sold the affected product)* □ *Other (Please specify):*
Distributors Notifications:	*Have the distributors been notified?* □ *Yes* □ *No* *It is required that you contact all distributors to whom you have sold the affected product. Documentation of this communication is required.*
Retailers:	*At what retail outlets is the affected product available for sale to the public?* *It is required that you contact all retail outlets to whom you have sold the affected product. Documentation of this communication is required.*
Manufactured Stock:	*How much affected product was manufactured?* *Quantity: _____* □ *Exactly* □ *Approximately* □ *Unknown*
Imported Stock:	*How much affected product was imported?*

Exported Stock:	*How much affected product was exported?* *Quantity: _____* □ *Exactly* □ *Approximately* □ *Unknown*
Warehoused Stock:	*How many units of affected product remain in the warehouse?* *Quantity: _____* □ *Exactly* □ *Approximately* □ *Unknown*
Time in marketplace:	*How long has the affected product been in the marketplace?*
In which states has the affected product been distributed and in what quantity?	
Has the product been exported outside the US?	
Exported countries and quantity?	
Recall Reason	
Description of the recall reason:	*What is the reason for the recall?* □ *Microbial (Pathogen, Viral, Standard Plate Count)* □ *Biotoxin (Aflatoxin, mycotoxin, histamines)* □ *Chemical contamination (Cleaning fluid, intentionally added)* □ *Foreign matter (Glass, metal, wood, etc.)* □ *No-compliant labeling (Incorrect instructions, etc.)* □ *Package tampering* □ *Faulty packaging* □ *Undeclared Allergens* □ *Other (Please specify):*
Recall reason specifics:	*Please detail specific recall reasons:* *(ie undeclared peanuts in a product, a packaging fault resulting in a choking hazard)*
Pathogen Notices:	*If one of the following reasons are the cause of your recall, the following statement may be used to communicate to the public:* □ *Pathogens* • *Listeria monocytogenes may cause illness in pregnant women and their unborn babies, children, the elderly, and the immuno-compromised.* • *Salmonella may cause illness in children, the elderly, and the immune-compromised.* • *E. coli may cause illness in children, the elderly, and the immune-compromised. While most people recover within a week, some develop a type of kidney failure called hemolytic uremic syndrome (HUS).* □ *Undeclared Allergens* • *Any consumers who have a _____ allergy or intolerance may have a reaction if the product is consumed.* □ *Faulty Packaging/Foreign Matter/Chemical Contamination* • *Food products containing _____ may cause illness or injury*

Advice to Consumers:	*What should consumers who have the affected product do?* *If one of the following reasons are the cause of your recall, the following statement may be used to communicate to the public:* *□ Pathogens* • *Consumers should not eat this product. Consumers who have consumed this product should seek medical advice.* *□ Undeclared Allergens* • *Consumers who have a _____ allergy or intolerance should not consume this product. Consumers who have consumed this product should seek medical advice.* *□ Faulty Packaging/Foreign Matter/Chemical Contamination* • *Consumers should not eat this product.*
Problem detection:	*How was the problem first detected?* *□ Consumer complaint* *□ Routine testing by company* *□ Routine testing by state agency* *□ Routine testing by federal agency*
Tests:	*Have any analytical tests been performed?* *□ Yes* *□ No*
Test Results:	*If yes, what were the results? (ie number of pathogens present)*
Illness Reports:	*Have there been any reported cases of illness/injury associated with this recall?* *□ Yes* *□ No*
Illness Reports Details:	*Describe the incidence of illness/injury.*
Recall Decision Responsible Party:	*Whose decision was it to recall the affected product?* *□ Company* *□ State Agency* *□ Federal Agency*
Product Disposal Statements:	*You **may** use statements like the following to reach different groups of stakeholders:* *□ Consumers* • *Return the product to the manufacturer for a refund/replacement.* *□ Retailers* • *Isolate affected product and destroy as per manufacturer recommendation OR Isolate and return to/pack for collection by the manufacturer/importer.* *□ Distribution Centers/Wholesalers* • *Isolate affected product and destroy as per manufacturer recommendation OR Isolate and return to/pack for collection by the manufacturer/importer* *□ Manufacturer/Importer* • *Isolate the affected product and destroy on site.* *Food which is subject to a recall must be separated from other food and clearly identified. Evidence is required to prove the destruction of the product.*

Product destruction/ reconditioning

- Provide a proposed method of destruction, if applicable.
- If the product is to be "reconditioned", explain how and where the reconditioning will take place. It is recommended that you provide details of the reconditioning plan to your local FDA District Recall Coordinator before implementation. All reconditioning must be conducted under any applicable GMPs.
- Describe how reconditioned product will be identified so it is not confused with recalled (pre-reconditioned) product.
- It is recommended that you contact your local FDA District Recall Coordinator prior to product destruction. FDA will review your proposed method of destruction and may choose to witness the destruction.
- You and your customers should keep adequate documentation of product destruction (and whether or not destruction was witnessed by an FDA investigator).
- Field corrections, like product relabeling, be performed by recalling firm representatives, or under their supervision and control. Contact your local FDA District Recall Coordinator prior to release of reconditioned goods.

Communication Plan	
Communication plan:	*Please indicate your means of communication (check all that apply):* □ *Costumer loyalty card database* □ *Media release* □ *Newspaper article/advertisement* □ *Radio/TV advertisement* □ *Social Media* □ *Business website* □ *Other (Please specify)*
Procedures: Please provide a complete list of media outlets and publications.	
Other Information	
Other information?	Is there any other information you would like to provide?

DRAFT Recall Notice

[Company Name] Voluntarily Recalls [insert summary info] Representing [X quantity] [--No Other Products Affected--]

Contact
Consumer:
1-xxx-xxx-xxx

Media Contact:
xxx-xxx-xxxx
FOR IMMEDIATE RELEASE – [date] – [Company name] is voluntarily recalling [X] Lot Codes of [COMPANY/BRAND name] [insert specific product name and description], representing [insert quantity]. [Insert reason for recall].
This action relates only to [COMPANY NAME] products with any of these Lot Codes printed on the package:

- **[insert lot codes]**

No other Lot Codes, or any other [COMPANY NAME] products, are involved in this action.
Only these specific lot codes are impacted. Customers are asked to remove all product with codes listed below out of distribution immediately. Customers may call the number listed or visit our website for instructions on what to do with the product.

PRODUCT **LOT CODE** **ITEM NO.**

[Company Name] [insert product name(s)] [insert product codes(s)] [insert item number(s)]

[Company Name] is conducting this voluntary recall because [insert product name(s)] [modify as necessary. We have not received any reports of illness associated with this product, but we are voluntarily recalling this product out of an abundance of caution.]
For more information or assistance, please contact us at 1-xxx-xxx-xxxx (Monday to Friday, 9:30 a.m. to 5 p.m. EST) or via our website at www.xxx.com

Information Templates for FDA Communication

PRODUCT INFORMATION:

Modify the "Product Description, Distribution, Consumers and Intended Use" form as needed to reflect only the product involved, including:

- Product name (including brand name and generic name)
- Product number/UPC or product identification
- Remove any names of products that are not involved in the recall

Assemble TWO COMPLETE SETS OF ALL labeling to the Local FDA District Recall Coordinator. Include:

- Product labeling (including ALL private labels)
- Individual package label
- Case label (photocopy acceptable)
- Package Inserts
- Directions for Use
- Promotional Material (if applicable)

CODES (Lot Identification Numbers):

- UPC code(s) involved: _____
- Lot number(s) involved: _____
- Lot numbers coding system: *Describe how to read your product code:* - _____
- Expected shelf life of product: _____

Recall Team

[Add, combine or delete rows to accommodate your operation]

Assignment	Person	Contact Information
Senior Operations Manager Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Publicity and Public Relations Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Sales & Marketing Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Scientific Advisor Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Logistics and Receiving Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Quality Assurance Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Accountant Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Attorney Alternate:		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
Administrative Support		Office: xxx-xxx-xxxx Mobile: xxx-xxx-xxxx Home: xxx-xxx-xxxx
FDA Recall Coordinator		Office: xxx-xxx-xxxx

Effectiveness Checks

Effectiveness checks by account – Consider filling in the Consignee's recall contact name and information to make it easier to contact them in the event of a recall.

Consignee	Recall contact		Date contacted	Method of contact				Date if response	Number of products returned or corrected
	Name	Contact info		Phone	Email	Fax	Letter		

Effectiveness check summary – to be provided to FDA periodically

Date of notification	Method of notification	Number of consignees notified	Number of consignees responding	Quantity of product on hand when notification received	Number of consignees not responding and action taken	Quantity accounted for	Estimated completion date

Appendix 8: Food Safety Preventive Controls Verification Report Template

Annual Food Safety System/HACCP Plan Verification Report (Verification Record)

	Date Task Completed	Signature of Person who Completed the Task
List of Food Safety/HACCP Team with individual responsibilities updated		
List of Product and Processes in place at facility		
Product Flow Diagrams updated		
Hazard Analysis Updated		
HACCP Plan updated		
Good Manufacturing Practices Plan updated		
Sanitation SOP/Prerequisite Program Plan updated		
Food Safety/HACCP Plan implemented		
Reviewer Signature	**Date of Annual Review**	

Company Name _____ Telephone Number _____

Address _____ Email/Website _____

Version/Date _____ Supersedes _____

Approved by (*print name*) _____ Title _____

Approval Signature _____ Date Signed _____

Appendix 9: Letter from Philologist

Melissa Alleyne
#122 Atlantic Shores
Christ Church
Barbados
TEL: 546-4634 (h) | 262-1723 (c)

December 20, 2019

To whom it may concern,

I write to confirm that I have edited the Final Graduation Project for Nadine Benn-Greaves, entitled "Project Management Plan for the Implementation of Food and Drug Administration (FDA) Food Safety Regulations at Choo's Enterprises, Barbados" and that it is ready for submission.

Regards,

Melissa Alleyne, BA (hons), MPhil (hons)