UNIVERSIDAD PARA LA COOPERACION INTERNACIONAL
(UCI)

DESIGN OF A CROSS-TRAINING PROGRAM FOR QUALITY PROCESS INSPECTORS AND QUALITY FINAL INSPECTORS ON A MEDICAL DEVICE INDUSTRY

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DEDICATION

I dedicate this Final Graduation project to my mother and the rest of my family, for nursing me with affection and love, as well as helping me achieve success in my life during these awful pandemic months.

My work and effort go to all families that lost their loved ones to Covid-19 and all healthcare providers fighting the virus, being a healthcare provider myself.

ACKNOWLEDGMENTS

I would like to thank God for his grace and the opportunity of completing this Final Graduation Project.

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ABBREVIATIONS AND ACRONYMS

- CEA: Controlled-Environment Areas
- DPMO: Defects per Million Opportunities
- FDA: Food and Drug Administration
- FGP: Final Graduation Project
- FTE: Full-time equivalent
- IGT: Image Guided Therapy
- ISO: International Organization for Standardization
- NCR: Non-Conformance Report
- PMBOK® Guide: Project Management Book of Knowledge
- PMI: Project Management Institute
- QC: Quality Control
- QFI: Quality Final Inspection
- QPI: Quality Product/Process Inspection
- QMS: Quality Management System
- RACI: Responsible, Accountable, Consulted, Informed
- SPC: Statistical Process Control
- SOP: Standard Operating Procedures
- SRC: Sleep and Respiratory Care
- SWOT: Strengths, Weaknesses, Opportunities and Threats
- TQM: Total Quality Management
- WI: Work Instruction

EXECUTIVE SUMMARY (ABSTRACT)

In a modern global marketplace, quality is a key competency which companies derive competitive advantage. Accomplishing quality is essential to competition in business, including medical device industries.

The meaning of quality in medical industries has developed over time to create maintainable sources of competitive benefits. A medical device industry will benefit most through concentrating on the key processes that provide their clients with quality products and services. Therefore, assuring quality management throughout the company and promoting staff members knowledge about quality standards and processes within the company is crucial for the organization success.

A medical device industry founded in 1891, has one of the main manufacturing plants for the assembly of medical devices in Costa Rica. The Corporation headquartered in Europe is formerly one of the largest electronics companies in the world, currently focused in the area of health technology, with other divisions being successfully divested.

New challenges faced by managers are addressed to improve organization's performance and future competition. To date, the organization does not always have available quality inspectors trained and competent on quality inspections for all products that the company manufactures. For this reason, in case of absenteeism of any nature, coverage is assured, and it can cause serious problems to metrics and product release.

The general objective of this Final Graduation Project (FGP) was to develop a Cross-Training Program for Quality Process Inspectors and Quality Final Inspectors to balance workforce on a medical device industry in Alajuela, Costa Rica. This Cross-Training Program design deals with what is quality, cost of quality, linking quality management system to organizational performance, its impact to an organization, its approaches of implementing the QMS (Quality Management System) and the quality journey.

The specific objectives were to perform a diagnosis of the Quality Management System at a medical device manufacturing plant in order to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs, to design a Training Program for Quality Process Inspectors at a medical device manufacturing plant that meets the needs of the Quality Management System and calibrate the Team´s capability and to plan a cross training among applicable areas of Quality Process Inspectors with identification of timing, costs, participants, logistics and methodology in order to have more inspectors trained on certain areas.

The methodology used for the development of this Cross-Training Program was analytical. The main sources used to gather information included interviews to the Company´s Quality Personnel (Inspector, Technicians and Managers) in order to understand the way Quality Inspectors are trained, the areas each one of them is trained on and the needed resources in order to provide them with a Cross-Training. A Guide to the Project Management Body of Knowledge (PMBOK® Guide) Sixth Edition was also used as a support source.

The diagnosis of the Quality Management System helped to determine the gaps that Quality Process Inspectors have in terms of training. Even though results

showed that certain Inspectors were already trained on different areas, it was identified that most of them don´t handle multiple certifications. Therefore, the need of a training made sense in order to maximize the use of the company resources and guarantee coverage when the resources report illness or take vacations. It was also concluded that the lack of multitasked inspectors currently impacts the ability of having one single inspector in-charge of multiple tasks such as performing an inspection of a lot or batch and releasing the same production order, which is costing more money and resources to the organization.

The design of a Training Program for Quality Process Inspectors helped to structure the main elements required to provide adequately trained resources for quality inspection activities and therefore assure the quality system is functioning properly. Thus, it was concluded that designing a Training Program to provide effectively trained and efficient resources will help decrease the current difficulties faced in terms of providing immediate coverage for unforeseen events such as resignations without notice or dismissals, maternity leaves, vacations and other long-term medical leaves. This will avoid denying vacation days requested by employees.

The cross training among applicable areas of Quality Process Inspectors considered the development of a model of a four-stage cross-training process to have more inspectors trained on certain areas and have them prepared in case of absenteeism of different natures. The training model was defined pairs between themselves and was designed based on areas that have affinity in terms of activities. It was concluded that having crossed trained resources throughout this cross-training model will also help provide quicker answers to manufacturing teams in the organization when requesting overtime for quality inspectors upon increases in production lines. Given these requests are usually made in real time, fast coordination is required and having on-site trained resources will avoid having to call inspectors to check availability and paying for their transportation to the manufacturing plant.

Based on these conclusions, Supervisory and Management Teams should consider a new revision of the SWOT Analysis performed in this Final Graduation Project in aims to understand additional gaps not related to cross-training needs. A mapping of all tasks is recommended to be performed as well as a definition of each area´s metrics. In addition, activity times need to be tracked in order to establish standard times so a standard work can be created for Quality Process Inspectors that can will help understand capacity of each inspector per area.

Further research is needed to regulate performance of Quality Inspectors through a periodic evaluation system that needs to be designed by Quality Supervisor that can improve performance of the resources. Finally, analyzing the leadership system for an average of 50 Quality Inspectors across 24/7 shifts and several areas is also recommended to Quality Management.

1. INTRODUCTION

1.1 Background

This Cross-Training Program will be executed at a medical device company in Alajuela, Costa Rica. The Corporation headquartered in Europe is formerly one of the largest electronics companies in the world, currently focused in the area of health technology, with other divisions being successfully divested.

The medical company was founded in 1891. It was once one of the largest electronic conglomerates in the world and currently employs around 74,000 people across 100 countries, including Costa Rica, where one the main manufacturing plants for the assembly of medical devices is located.

1.2 Statement of the problem

Medical Device companies that manufacture more than one product on their manufacturing plants, should always have available quality inspectors trained and competent on quality inspections for all products so in case of absenteeism of any nature, coverage is assured. The lack of a quality inspector that can release a product, can cause serious problems to metrics and product release.

To date, this medical device company reunites an average of 50 Quality Inspectors that specialize on different inspection tasks. Some of them are experts on good documentation practices, others specialize on quality tests and some others specialize on visual inspections. The problem the team of inspectors is currently struggling with, is the fact that not all of them are trained on all areas and tasks. This means that when an area is busy due to inventories and necessitates the support of more than the primary inspectors, the backup inspectors on-site watching other areas are not trained nor certified to complete the task. Medical leaves and unforeseen events are also situations in which quality inspectors need to be replaced immediately but given the lack of trained resources, finding a backup can take many hours and will require the time of locating this individual, waiting for a confirmation and the Company will often need to pay for transportation and extra hours.

1.3 Purpose

The purpose of the development of this Cross-Training Program is to provide adequately trained resources for quality inspection activities and therefore assure the quality system is functioning properly.

A quality system that has been implemented effectively and is monitored to identify and address problems is more likely to produce devices that function as intended and therefore the diagnosis of the Quality Management System will be vital in order to identify the gaps.

A primary purpose of the inspection is to determine whether management with executive responsibility ensures that an adequate and effective quality system has been established (defined, documented and implemented) at the firm. Because of this, inspectors should be crossed trained on all product inspections with a properly designed and carefully structured training with identification of timing, costs, participants, logistics and methodology.

Considering that safety is a risk management issue, and that optimum safety and performance of medical devices cooperation is required among all who are involved in the life span of a medical device, this project will provide a resulting robust team of quality inspectors for a medical device organization located in Alajuela, Costa Rica.

1.4 General objective

To design a cross-training program for quality process inspectors and quality final inspectors to balance workforce.

1.5 Specific objectives

- To perform a diagnosis of the Quality Management System at a medical device manufacturing plant in order to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs.

- To design a Training Program for Quality Process Inspectors at a medical device manufacturing plant to meet the needs of the Quality Management System and calibrate the team´s capability.

- To plan the logistics associated to the implementation of a cross training among applicable areas of Quality Process Inspectors to successfully train more inspectors on additional areas.

2. THEORETICAL FRAMEWORK

2.1 Company background

This medical device company is a leading health technology company focused on improving people's health and enabling better outcomes across the health continuum from healthy living and prevention, to diagnosis, treatment and home care.

The medical company leverages advanced technology and deep clinical and consumer insights to deliver integrated solutions. Headquartered in the Netherlands, the company is a leader in diagnostic imaging, image-guided therapy, patient monitoring and health informatics, as well as in consumer health and home care. It generated 2019 sales of EUR 19.5 billion and employs approximately 81,000 employees with sales and services in more than 100 countries around the world.

2.2 Mission and vision statements

2.2.1 Mission

We are teaming up with hospital and health systems to understand their needs, provide integrated solutions, and engage in multi-year cooperation to drive improvements in terms of patient outcomes, quality of care delivery and cost productivity. In this context, we are pioneering new business models that fit our customers’ needs better. These include Technology Managed Services, as well as Software as a Service and Product as a Service models. We have also started to take co-accountability for our customers’ patient outcomes and productivity. Going forward, we aim to expand our strong positions across the health continuum, extend our solutions capability to address our customers’ unmet needs, and so deliver the full benefits of data-enabled connected care.

2.2.2 Vision

We are striving to make the world healthier and more sustainable through innovation, with the goal of improving the lives of 3 billion people a year by 2030.

With our global reach, deep insights and leading innovations, we are uniquely positioned in ‘the last yard’ to consumers and care providers, delivering:

- Connected products and services supporting the health and well-being of people.
- Integrated modalities and clinical informatics to deliver definitive diagnosis.
- Real-time guidance and smart devices for minimally invasive interventions
- Connected therapeutic products and services for chronic care patients.
- Underpinning these solutions, and spanning the health continuum, our connected care and health informatics solutions enable us to:
- Connect patients and providers for more effective, coordinated, personalized care.
- Manage population health, leveraging real-time patient data and clinical analytics.

2.3 Organizational structure

The Executive Committee of the Medical Device Company operates under the chairmanship of the Chief Executive Officer and shares responsibility for the deployment of Philips' strategy and policies, and the achievement of its objectives and results.

Under Dutch Law, the Board of Management is accountable for the actions and decisions of the Executive Committee and has ultimate responsibility for the management and external reporting of Koninklijke Philips N.V. shown on Figure 1 and is answerable to shareholders at the Annual General Meeting of Shareholders.

Pursuant to the two-tier corporate structure, the Board of Management is accountable for its performance to a separate and independent Supervisory Board. The Supervisory Board supervises the policies of the executive management and the general course of affairs of Koninklijke Philips N.V. and advises the executive management thereon. The Supervisory Board, in the two-tier corporate structure under Dutch law, is a separate and independent corporate body. (Koninklijke Philips N.V., 2020).

Figure 1 Philips Group Structure. Source: (Philips website, 2020)

Figure 2 shows the organizational chart of the medical device company healthcare structure as it has been made publicly available on their website. The medical device company has a management structure in its Healthcare sector to improve performance and allow it to respond better to evolving customer demands in a changing health care landscape. In this model, the Healthcare business groups report directly to the company´s Chief Executive Officer.

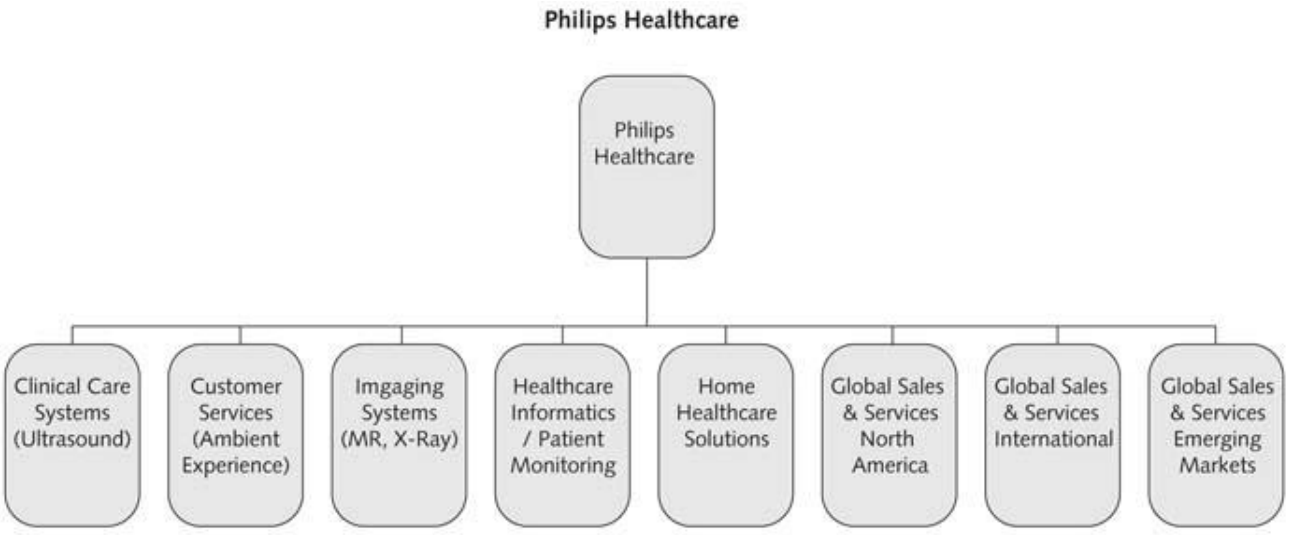


Figure 2 Philips Healthcare Structure. Source: (Philips website, 2020)

Discussions about maintenance and quality in medical device manufacturing industries help to understand that these two cannot be segregated from the production process. Although, maintenance and quality interact, models that relate them both have not been adequately developed in the literatures yet. Therefore, a broad interaction framework between inspection and maintenance is nowadays analyzed as illustrated in figure 3.

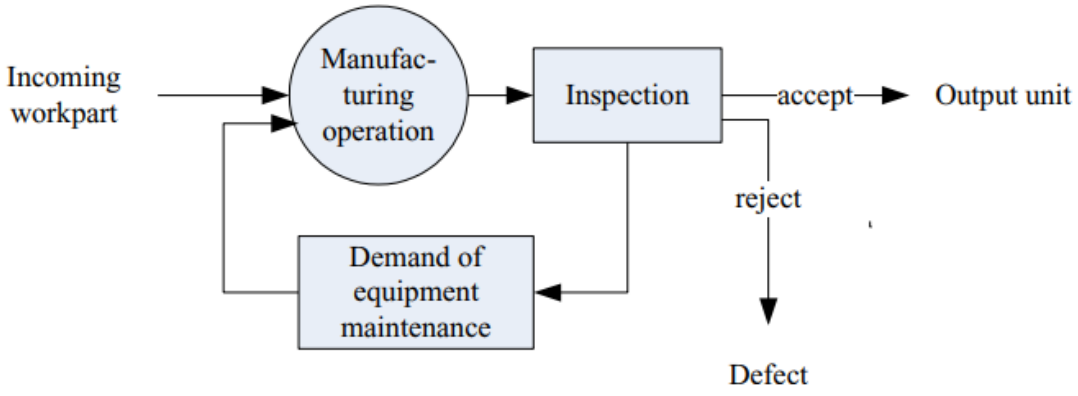


Figure 3 Framework of inspection and maintenance interaction in production system. Source: (Kurniati, 2015)

A single production system, machine or device conduct the manufacturing process to serve the final product. Inspection on quality of the product under a particular sampling plan may result rejection or acceptance of the lot product. The rejected lot may trigger for examination on manufacturing process or machine, and moreover, become a demand of equipment maintenance. Whenever proper maintenance policy apply, machines can be restored to their operational state following deterioration condition, then the product quality and process capability may improve.

It is proposed to medical device companies, three areas of structure, function and responsibilities of its organization, development and deployment of an appropriate regulatory strategy, the most efficient and compliant quality management system, and then to aggressively execute these actions needed to demonstrate product efficacy and safety under a corrective feedback system. Specific structures, functions and responsibilities for middle to executive management levels are needed to ensure that there is a seamless workflow in and around the components of the organizational structure shown on Figure 2.

A medical device company needs to have its organizational structure, functional roles and a comprehensive set of Standard Operating Procedures in place developed from their regulatory strategy and quality management system as seen in Figure 4. Their regulatory strategy and quality management system can be developed from a cross-functional structure of their organization which would co-ordinate the functional area talent focused on sharing the ‘Bigger Picture’ of long-term corporate goals. This approach of tying in structure, functional roles and SOPs with regulatory strategy and quality management systems has repeatedly proven effective in putting medical device companies on the ‘fast track’ for cost and risk reduction as well as championing the competitive advantage.

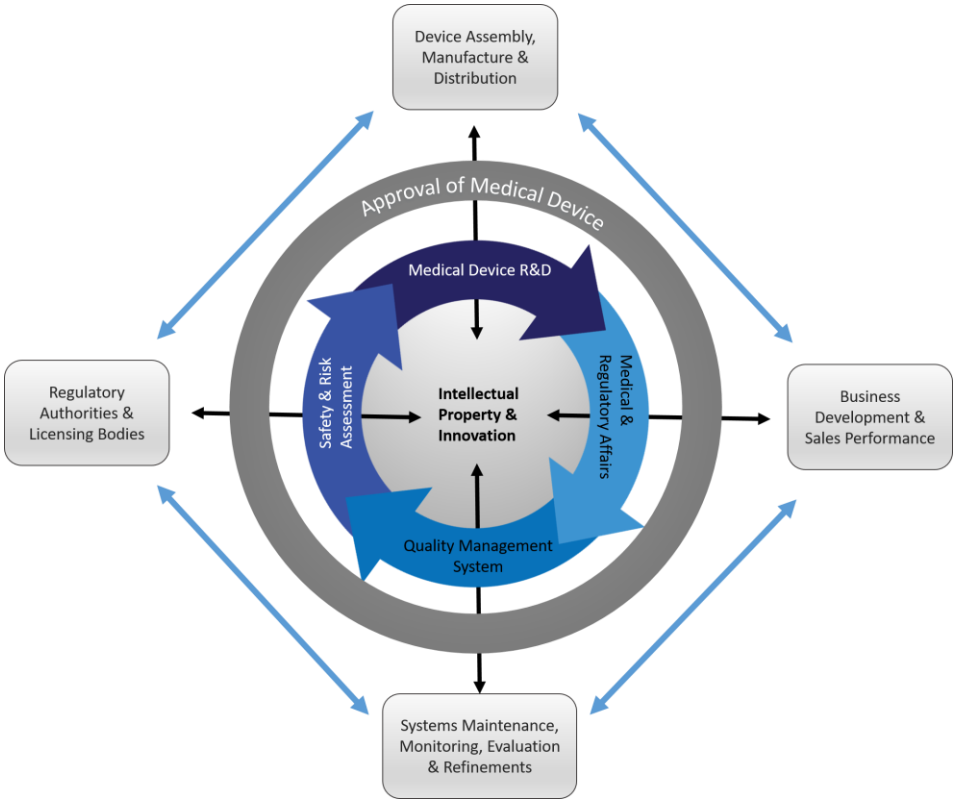


Figure 4 Organization Structure for Medical Device Industry. Source: (i3 Consult, 2018)

2.4 Products offered.

An emerging medical device business tends to focus their energy on product development and research. This is understandable because medical device founders are often first experienced innovators. As innovators, there's a natural affinity to maintain a continued focus on product development and maturation. Having a clear position and strategy is an important factor for attracting capital, which could further emphasize the importance of Research & Development, product development and market analysis.

This medical device industry focuses on the manufacturing of Image Guided Therapy devices as well as Sleep and Respiratory Care medical devices.

2.5 Project Management Concepts

2.5.1 Project

A project can be defined as “a temporary endeavor undertaken to create a unique product, service, or result” (PMI, p. 4, 2017).

For the purpose of this FGP, the project being undertaken is the development of a Cross-Training Program for quality process inspectors and quality final inspectors cross training on a medical device industry in Alajuela, Costa Rica.

2.5.2 Project management

Project management has evolved into a business process being used by companies all over the world to increase corporate value in many ways. For example, it can be used to efficiently deliver services, enhance customer satisfaction, and as a tool to embrace opportunities to expand services (Picariello, 2014).

The approach has been used for “thousands of years dating back to the Egyptian epoch” (Appopardi, n.d.). However, the discipline was not formally recognized until the 1950’s (Project Management, n.d.). Within every sector, the discipline of project management is integral to success. According to PMI, “ninety percent of global senior executives ranked project management methods as either critical or somewhat important to their ability to deliver successful projects and remain competitive” (PMI, p.142, 2017).

In the field of project management, different methodologies, like SCRUM, Agile, Waterfall, etc., “contain guiding processes for those who are doing project management” (Successful Projects, 2016). Although, each methodology has its advantages, they all agree that “every project management life cycle contains five steps: initiating, planning, execution, monitoring, and controlling & closure” (Picariello, 2015). After initiating the project, planning is seen as “the all-

important second step of any successful project management life cycle" (Picariello, 2015). A project's plan, depending on the project, can be simple or complex. However, in all cases, once completed, it results in a document that contains a fully developed project solution detailing the "steps necessary to meet the project's objectives". (Watt, 2014).

PMI's *PMBOK® Guide* is a globally recognized standard (Daley, 2013) that details how to initiate, plan, execute, monitor, and control and close a project. It can be used as a tool to ensure that all project management professionals are speaking the same language and understand the stages and role of the project. According to PMI, "project management is the application of knowledge, skills, tools, and techniques to project activities to meet the project requirements" (PMI, p. 8, 2017).

2.5.3 Project life cycle

A project life cycle is a "series of phases that a project passes through from its initiation to its closure". The project life cycle is a "natural progression" and the four main stages (phases) in a project life cycle are concept and approval, planning and preparation, executing work activities, and closing all project activities (Wilson, 2014). However, the PMBOK® Guide states that within each phase of a project life cycle, there are five process groups that interact with one another and "could be conducted within a phase".

2.5.4 Project Management Processes

Only the processes involved in initiating and planning a project will be used to develop a Cross-Training Program within the standards of the Project Management Institute for Quality Inspectors of a medical device industry in Alajuela, Costa Rica.

2.5.5 Project Management Knowledge areas

There are 47 project management processes identified in the PMBOK® Sixth

Edition that have been grouped into ten separate knowledge areas. Knowledge areas are vertical, while process groups as horizontal. PMI has divided the large field of project management into 10 more digestible parts and these are the core technical subject matter, which are necessary for effective project management. The ten knowledge areas of project management are as follows:

- **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”. (PMI, p.63, 2017).

- **Project Scope Management**: Project Scope Management is defined as the knowledge area that “includes the processes required to ensure that the project includes all the work required, and only the work required, to complete the project successfully”. (PMI, p. 130, 2017)

- **Project Schedule Management**: Project Time Management includes the processes required to manage the timely completion of the project. (PMI, p. 141, 2017).

- **Project Cost Management**: “Project Cost 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”. (PMI, p. 193, 2017).

- **Project Quality Management**: “Project Quality Management includes the processes and activities of the performing organization that determine quality policies, objectives, and responsibilities so that the project will satisfy the needs for which it was undertaken”. (PMI, p. 227, 2017).

- **Resource Management**: “Project Human Resource Management includes the processes that organize, manage, and lead the project team”. (PMI, p. 255, 2017).

- **Project Communications Management**: “Project Communications Management includes the processes that are required to ensure a timely and appropriate planning, collection, creation, distribution, storage, retrieval, management, control, monitoring, and the ultimate disposition of project information”. (PMI, p. 359, 2017).

- **Project Risk Management**: “Project Risk Management includes the processes of conducting risk management planning, identification, analysis, response planning, and controlling risk on a project”. (PMI, p. 309, 2017).

- **Project Procurement Management:** “Project Procurement Management includes the processes necessary to purchase or acquire products, services, or results needed from outside the project team” (PMI, p. 355, 2017).

- **Project Stakeholder Management:** “Project Stakeholder Management involves identification of stakeholders, analysis of their expectations and influences, development of appropriate strategies to work with the stakeholders and executing the process “. The Project Management Institute defines a stakeholder as “an individual, group, or organization that may affect, be affected by, or perceive itself to be affected by a decision, activity, or outcome of a project, program, or portfolio” (PMI, p.12, 2017).

2.6 Other applicable concepts

2.6.1 Total Quality Management

Total Quality Management describes a management approach to long-term success through customer satisfaction in which all members of an organization

participate in improving processes, products, services, and the culture in which they work. Total Quality Management (TQM) philosophy suggested the process control inspection along production line rather than final inspection only. This diversion keeps the inspection as an essential technique in quality assurance and does not reduce the necessity for inspection instead. Industrial experience shows that the manufacturer may monitor its process at every stage, the acceptance inspection for the final product and incoming raw materials inspection are still necessary (Montgomery, 2009).

2.6.2 Quality Management Systems

In managing quality, the focus is not only on quality of product and service itself. It is also on the means to achieve it. Thus, QMS (Quality Management System) uses management techniques and tools in quality assurance and control of processes to achieve consistent quality of products and services. Many definitions of quality can be found in the literature, QMS defines it as an effective system for integrating the quality development, quality maintenance and quality improvement efforts of the various groups in an organization so as to enable production and service at the most economical levels, which allows for full customer satisfaction. It is an integrative philosophy of management practice in an organization for continuous improvement of their product, services and processes. It capitalizes on the involvement of management, employees, suppliers, and its customers to meet or exceed customer satisfactions and expectations in several areas. Some of these areas are cross-functional product design, process management, supplier quality management, customer involvement, information and feedback, committed leadership, strategic planning, cross-functional training, and employee involvement. There are critical factors of quality management such as the role of management leadership and quality policy; training; process management; employee relations; product / service design; supplier quality management; the role of the quality department; and quality data and reporting. They also identified that managerial commitment to quality combines several functions as one of the vital

imperatives for the success of any quality improvement program. (Kim-Soon, 2012).

2.6.3 Inspections

According to ISO 2859-2:2020, an inspection is an activity such as measuring, examining, testing, or gauging one or more characteristics of a product and comparing the results with specified requirements in order to establish whether conformity is achieved for each characteristic.

The term inspection refers to the activity of checking products, whereas audit applies to analyzing manufacturing processes and/or systems. The quality inspector usually follows a pre-established checklist that is based on the product specifications. Inspected products can be the components used for production, semi-finished goods, or (most often) finished goods before shipment to a customer.

Inspections are performed at various times during the manufacturing process. Including inspection on raw materials and components from outside sources (incoming inspection), and final inspection on finished product to ensure the functional quality and the appearance of the product (outgoing inspection). (Kurniati, 2015).

Manufacturing product exhibits several quality characteristics. Quality inspection becomes a crucial way to verify product conformance to requirements. Under certain inspection procedures, we may identify whether the product quality conforms to specifications or not. If the product quality fails to conform, many possible reasons come include problems from the preceding manufacturing process (Kurniati, 2015). Performance of the manufacturing equipment is substantial to preserve the production process. The well-maintained equipment ensures the high-quality product. The roles and advantages of quality inspection has been well-addressed in literatures. The investigations on the inspection aspect, suggests a way to preserve better quality assurance.

2.6.4 Finished Goods

A finished product may exhibit several quality characteristics. Quality control (QC) techniques apply by inspecting and measuring the product quality characteristics using inspection equipment and some procedures. For single production system, the QC is applied into the output of the system. By comparing to the standard, the product can be identified whether conforms to requirements or fails, consider as accepted or rejected as well. Inspection provides useful information about the current demonstrated product quality. Then, any managerial decision made based on this information, which is concentrate more on the effort of product and process improvement program. Many procedures, especially for acceptance inspection, has been developed to conduct the inspection which technically effective and/or economically efficient. Consistent monitoring on quality will ensure that products meet the requirements defined by either the manufacturer's product design department or by customers (Kurniati, 2015).

2.6.5 Acceptance Inspection

The acceptance inspection is kind of middle bridge between 100% inspection and zero inspection, which has a primary advantage of fewer resources needed including money, labor, and time. Acceptance inspection provides decision rules for product acceptance determination based on sample taken from the lot product, well-known as acceptance sampling or sampling plan. Acceptance sampling is not a substitute for adequate process monitoring and control to reduce variability. Acceptance sampling does not estimate the lot quality, but sentence it, does not provides any direct form of quality control of a lot; nor use to control and systematically improve quality as process control yet do. Nevertheless, acceptance sampling still constitutes quality science. Moreover, acceptance sampling is a necessary defensive measure, instituted as a protective tool against the threat of quality deterioration and provides valuable feedback for process control. Acceptance sampling is an instrument for producer to quicken the process control. The most effective use of acceptance sampling is as an audit tool to ensure that

the output matches the requirement. When the statistical process control optimizes the capability of the process, the acceptance sampling prevents the nonconforming product to be pass and then delivered to the next process or the customer, a useful effort to maintain the product quality (Montgomery, 2009).

2.6.6 Training Framework

For the design of the cross-training plan it is required a training framework that will help as a guide as the training program is set up. Figure 5 presents a Training Program Framework Development, that establishes the 11 main phases in which the program should be developed.

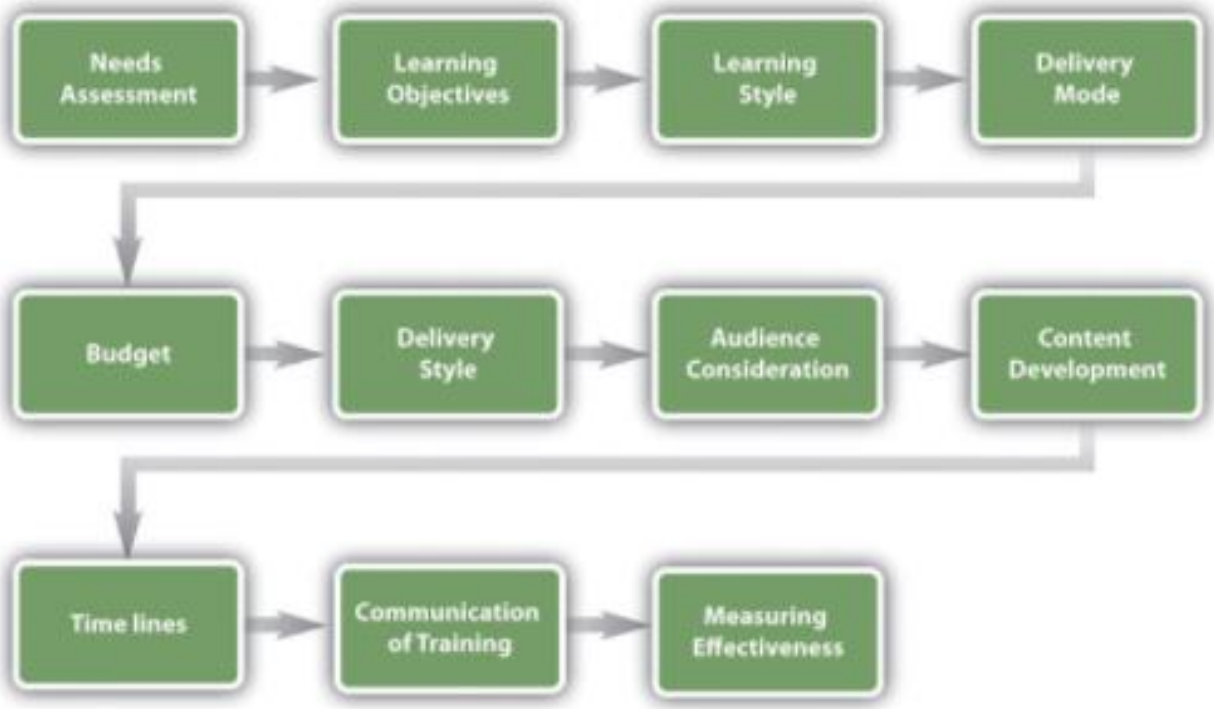


Figure 5 Training Program Framework Development. Source: (A. Barrantes, The author, 2020)

2.6.7 Needs assessment.

The first step in developing a training program is to determine what the organization needs in terms of training. There are three levels of training needs

assessment: organizational assessment, occupational (task) assessment, and individual assessment. (Kirkpatrick, 2006).

- **Organizational assessment.** In this type of needs assessment, skills, knowledge, and abilities a company needs to meet its strategic objectives can be determined. This type of assessment considers things such as changing demographics and technological trends. Overall, this type of assessment looks at how the organization as a whole can handle its weaknesses while promoting strengths.

- **Occupational (task) assessment.** This type of assessment looks at the specific tasks, skills knowledge, and abilities required to do jobs within the organization.

- **Individual assessment.** An individual assessment looks at the performance of an individual employee and determines what training should be accomplished for that individual.

2.6.8 Learning objective

This part of the framework development considers the learning objectives to be set in order to measure the training results.

2.6.9 Consideration of learning styles

This phase refers to establishing the learning styles of each training stage. Most individuals use more than one type of learning style, depending on what kinds of information they are processing. Recent research has shown that classifying people into learning styles may not be the best way to determine a style, and most people have a different style depending on the information being taught. (Kirkpatrick, 2006).

2.6.10 Delivery mode

Most training programs will include a variety of delivery methods. During this phase, a delivery mode will be determined; whether it will be virtual, in-person or both. When choosing a delivery mode, it is important to consider the audience and budget constrictions. (Kirkpatrick, 2006).

2.6.11 Budget

In the budget phase, the financial aspect will be analyzed in terms of much money needs to be spent on this training, if any. The type of training performed will depend greatly on the budget. Besides the actual cost of training, another cost consideration is people's time and overtime. (Kirkpatrick, 2006).

2.6.12 Delivery style

Delivery style refers to establishing if training will be self-paced, or instructor led, as well as any discussions and interactivity that can be developed in conjunction with the training. Many trainers implement online videos, podcasts, and other interactive media in their training sessions. This ensures different learning styles are met and also makes the training more interesting. (Kirkpatrick, 2006).

2.6.13 Audience

Defining the audience involves documenting who will be part of this training and if there is any mix of roles. In addition, it means understanding the job responsibilities of these individuals, and how the training program is relevant to their individual roles. (Kirkpatrick, 2006).

2.6.14 Content

The content is the delimitation of what needs to be taught and the way the information will be sequenced. Development of content usually requires a development of learning objectives and then a brief outline of the major topics that will be covered. With that outline, you can "fill in" the major topics with information.

Based on this information, you can develop modules or PowerPoint slides, activities, discussion questions, and other learning techniques. (Kirkpatrick, 2006).

2.6.15 Timelines

Developing a dependable training schedule allows for better communication to the staff, results in fewer communication issues surrounding training, and allows all employees to plan ahead in order to attend training. (Kirkpatrick, 2006).

2.6.16 Communication

Defining how employees will know the training is available to them is essential. A recommendation is to consider utilizing the company's e-mail, or even old-fashioned posters to communicate the training. Another option is to verbally communicate the training plan to them. (Kirkpatrick, 2006).

2.6.17 Measuring effectiveness of training

After training is completed, training objectives need to be revisited in order to understand if they were met. One model to measure effectiveness of training is the Kirkpatrick model (Kirkpatrick, 2006), developed in the 1950s. His model has four levels:

- Reaction: How did the participants react to the training program?
- Learning: To what extent did participants improve knowledge and skills?
- Behavior: Did behavior change as a result of the training?
- Results: What benefits to the organization resulted from the training?

3. METHODOLOGICAL FRAMEWORK

3.1 Information sources

According to the Concise Oxford English Dictionary, information is “facts or knowledge provided or learned” (Information, 2011, p. 729) and a source is “a place, person, or thing from which something originates” (Source, 2011, p. 1380). Therefore, it can be concluded that an information source is a place, person or thing from which facts or knowledge are provided or learned. There are many places for information to be obtained. One can use library sources, internet sources, organizational sources, government agencies as sources, pictorial sources, sources from bibliographies, a colleague or sometimes even one’s personal account as a source. Information sources can be printed or presented in an electronic format. Basically, it can be taken from almost anywhere. No matter where information originates from, there are only three types of information sources – primary, secondary, and tertiary (Schmidt, 2013). To develop the Final Graduation Project, primary and secondary sources will be used.

3.1.1 Primary sources

“A primary source is information taken directly from a person, event, location, or material at the point of the occurrence” (Schmidt, 2013, p. 62). For the development of the Final Graduation Project, the primary information sources that will be used are the interviews with the experts, such as Quality Managers and Quality Engineers.

3.1.2 Secondary sources

“A secondary source is information that a person provides after he or she has gotten the information from a primary source” (Schmidt, 2013, p. 62). In this case, the person providing the information did not participate in or is not furnishing first-hand knowledge about the incident. For the development of the Final Graduation

Project, secondary sources such as the PMBOK® Guide, library databases, and the PMI database will be used. Refer to Chart 1 for the list of primary and secondary sources used for each specific objective.

Chart 1 Information sources (Source: A. Barrantes, The Author, 2020)

Objectives	Information sources	
	Primary	**Secondary**
1. To perform a diagnosis of the Quality Management System at a medical device manufacturing plant in order to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs.	▪ Personal interview with Quality Manager (expert) from the Organization where the plan will be developed. ▪ Doc Control and Training Departments ▪ Quality Process Inspectors.	▪ PMBOK® Guide, 6th Edition ▪ PMI Database (online articles for PMI members).
2. To design a Training Program for Quality Process Inspectors at a medical device manufacturing plant that meets the needs of the Quality Management System and calibrate the Team´s capacity.	▪ Personal interview with Quality Manager (expert) from the Organization where the plan will be developed. ▪ Doc Control and Training Departments ▪ Quality Process Inspectors.	▪ PMBOK® Guide, 6th Edition ▪ PMI Database (online articles for PMI members). ▪ Websites.

Objectives	Information sources	
	Primary	**Secondary**
3. To plan the logistics associated to the implementation of a cross training among applicable areas of Quality Process Inspectors to successfully train more inspectors on additional areas.	▪ Personal interview with Quality Manager (expert) from the Organization where the plan will be developed. ▪ Doc Control and Training Departments ▪ Quality Process Inspectors.	▪ Websites.

3.2 Research methods

According to the Concise Oxford English Dictionary, research is defined as “the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions” (Research, 2011, p. 1222). The same source defines the word ‘method’ as “a particular procedure for accomplishing or approaching something” (Method, 2011, p. 899). Therefore, it is concluded that a research method is a procedure to establish facts and reach new conclusions.

3.2.1 Analytical method

The analytical research method sometimes referred to as the explanatory method “uses facts or information already available and analyze to make a critical evaluation” (Sridhar, 2008). With this research method, information from multiple sources will be examined and used to develop the deliverables of this project.

3.2.2 Interview method

A formal or informal approach to elicit information from stakeholders by talking to them directly. It is typically performed by asking prepared and spontaneous questions and recording the responses. Interviews are often conducted on an

individual basis between an interviewer and an interviewee but may involve multiple interviewers and/or multiple interviewees. Interviews should be conducted in an environment of trust and confidentiality to encourage honest and unbiased contributions. Within the PMBOK® Guide, interviews are one of the techniques used in the Initiating and Planning processed.

The research methods for each specific objective are indicated in Chart 2 below.

Chart 2 Research methods (Source: A. Barrantes, The Author, 2020)

Objectives	Research methods	
	Analytical Research	**Interview Method**
1. To perform a diagnosis of the Quality Management System at a medical device manufacturing plant in order to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs.	The analytical method will be employed by using facts or information from the sources identified to drive decision making when creating the project charter.	Interviews will be conducted as needed with experts such as Quality Process Inspectors, Quality Managers, Quality Supervisors and Quality Engineers.
2. To design a Training Program for Quality Process Inspectors at a medical device manufacturing plant to meet the needs of the Quality Management System and calibrate the Team´s capacity.	The analytical method will be employed by using facts or information from the sources in order to drive decision making when creating the documents which comprise the scope management plan.	Interviews will be conducted as needed with experts such as Quality Process Inspectors, Quality Managers, Quality Supervisors and Quality Engineers.

Objectives	Research methods	
	Analytical Research	**Interview Method**
3. To plan the logistics associated to the implementation of a cross training among applicable areas of Quality Process Inspectors to successfully train more inspectors on additional areas.	The analytical method will be employed by using information from the sources identified to drive decision making when creating the documents that will comprise the time management plan.	Interviews will be conducted as needed with experts such as Quality Process Inspectors, Quality Managers, Quality Supervisors and Quality Engineers.

3.3 Tools

According to PMI (2017), a tool is defined as “something tangible, such as a template or software program, used in performing an activity to produce a product or result”. Each tool used in the Final Graduation Project is described below and identified in Chart 3.

- Expert Judgement: Recommendations from Quality Assurance experts such as Quality Engineers and Quality Managers.
- Meetings: Meetings with former and current Quality Inspectors, Training Specialists as well as Manufacturing and Quality Operation Managers/Supervisors.
- Interviews: Interviews with Quality Inspectors and Quality Supervisors with the organization.
- Data gathering: Throughout a survey, SWOT, brainstorming, checklists, and interviews.

- Data Analysis: Including survey results analysis, SWOT Analysis, gap assessment.

- Microsoft Project: Scheduling, Gantt charts.

Chart 3 Tools (Source: A. Barrantes, The Author, 2020)

Objectives	Tools
1. To perform a diagnosis of the Quality Management System at a medical device manufacturing plant in order to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs.	▪ Expert Judgement. ▪ Meetings ▪ Interviews ▪ Data Gathering: Brainstorming, Checklists, Interviews ▪ Data Analysis: Alternatives Analysis, Document Analysis, Performance Reviews
2. To design a Training Program for Quality Process Inspectors at a medical device manufacturing plant that meets the needs of the Quality Management System and calibrate the Team´s capacity.	▪ Expert Judgement. ▪ Meetings. ▪ Data Analysis: Alternatives Analysis, Document Analysis, Performance Reviews.
3. To plan the logistics associated to the implementation of a cross training among applicable areas of Quality Process Inspectors to successfully train more inspectors on additional areas.	▪ Microsoft Project. ▪ Expert Judgement. ▪ Meetings. ▪ Data Analysis: Alternatives Analysis, Document Analysis, Performance Reviews.

3.4 Assumptions and constraints

PMI defines an assumption as “a factor in the planning process considered to be true, real, or uncertain, without proof or demonstration” (PMI, p. 699, 2017). It also defines a constraint as “a limiting factor that affects the execution of a project, program, portfolio, or process” (PMI, p. 701, 2017). The assumptions and constraints considered on the Final Graduation Project for each specific objective are set out in Chart 4 below.

Chart 4 Assumptions and constraints (Source: A. Barrantes, The Author 2020)

Objectives	Assumptions	Constrains
1. To perform a diagnosis of the Quality Management System at a medical device manufacturing plant in order to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs.	▪ Most Quality Inspectors can multitask on different areas.	▪ Release of New products that need to be part of the Quality Inspector Scope during the execution of the Training Program.
2. To design a Training Program for Quality Process Inspectors at a medical device manufacturing plant that meets the needs of the Quality Management System and calibrate the Team´s capacity.	▪ All the work required will be identified.	▪ Quality Process Inspectors need to comply with training while completing their daily tasks.

Objectives	Assumptions	Constrains
3. To plan the logistics associated to the implementation of a cross training among applicable areas of Quality Process Inspectors to successfully train more inspectors on additional areas.	▪ The time allocated for the development of the Cross-Training Plan is enough.	▪ The time allocated for the development of the project must not exceed 3 months.

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” (PMI, p. 704, 2017).

Chart 5 Deliverables (Source: A. Barrantes, The Author, 2020)

Objectives	Deliverables
1. To perform a diagnosis of the Quality Management System at a medical device manufacturing plant in order to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs.	▪ Diagnosis of the Quality Management System, which considers: Diagnostic survey to current Quality Product Inspectors, Diagnostic results, SWOT Analysis, Gap Analysis, Analysis of results).
2. To design a Training Program for Quality Process Inspectors at a medical device manufacturing plant that meets the needs of the Quality Management System and calibrate the Team´s capacity.	▪ Training Plan Structure ▪ Control and Monitoring

Objectives	Deliverables
3. To plan the logistics associated to the implementation of a cross training among applicable areas of Quality Process Inspectors to successfully train more inspectors on additional areas.	▪ Cross-training schedule. ▪ Roles & Responsibilities ▪ Cost Analysis of overtime required.

4. RESULTS

4.1 Diagnosis of the Quality Management System

The purpose of the survey was to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs.

4.1.1 Survey design

A diagnosis survey was designed by the author and applied via Google forms to 48 Quality Inspectors from the Quality Department of a Medical Device manufacturing company in Alajuela, Costa Rica. Refer to Appendix 4: Training Diagnostic Survey for Quality Product Inspectors and Quality Final Inspectors.

Because there were no traceable records of all the trainings taken by Quality Inspectors, then the need of designing the survey for themselves to clarify seemed to be a good option to understand the big picture. The Documentation Center from the organization holds current certifications, meaning that getting the information from them would have only helped to document their main/current role only but not additional trainings the Team has received in the past.

There are three sections in the survey that focus on the evaluation of competencies of employees on QPI and QFI positions in order to understand what they are trained on. Therefore, the objectives of the survey questions were to collect and trace the information of quality inspectors current work areas, additional training that lets them support other areas and finally, to understand if their contract is permanent or not.

4.1.2 Survey results

The survey was completed during the month of September 2020. Results were received on real time digitally as well.

In terms of current work areas and official roles that Quality Inspectors perform, Figure 6 presents a graph that helps identify the areas where most of the population of Quality Inspectors is located. Presently, QPI (Quality Product Inspectors) in the SRC (Sleep and Respiratory Care) area and the Java area is where most inspectors are located. This is due to demand because productivity in these areas has been increasing in 2020. The distribution is balanced according to the workload. However, in the event one Inspector is out due to vacation or illness, the need of coverage is required by someone certified in the same process.

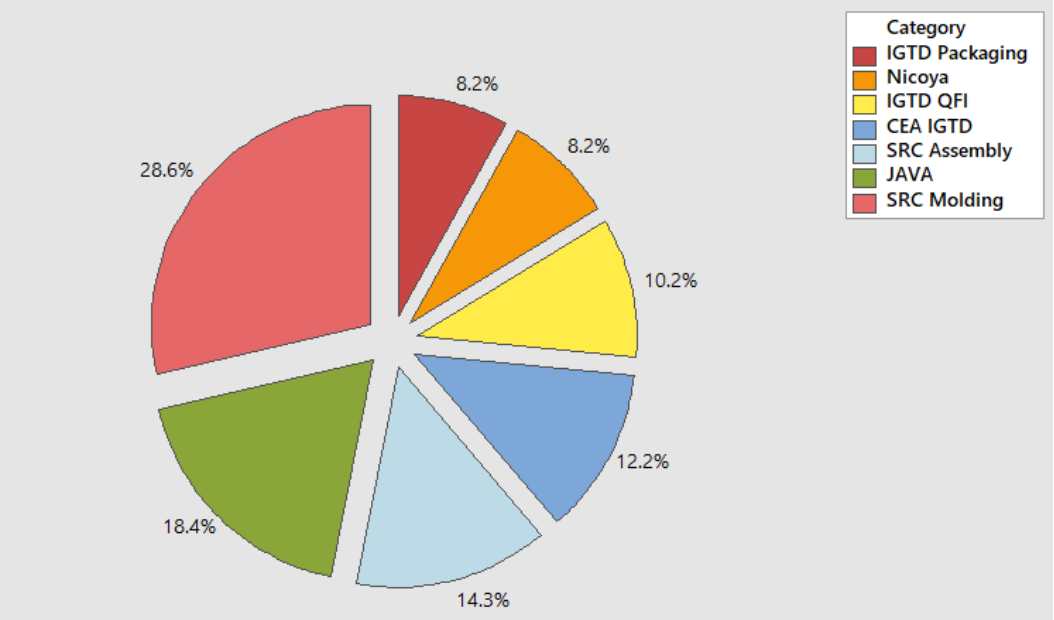


Figure 6 Distribution of Quality Inspector per area. Source: (A. Barrantes, The author, 2020)

The graph displayed on Figure 7 shows the global picture of additional certifications that Quality Inspectors currently hold. The results show the breakdown of certifications of the areas. This helped to organize the information on Chart 7 to visualize the individual situation of each Quality Process Inspector. The results show that Inspectors are trained on one main area, which is the one they execute inspections at. Most inspectors are lacking training on an additional area, different to the one they currently work at. This is not ideal because the organization wants them to expertise on at least an additional area, so they can cover absenteeism situations during overtime, for instance.

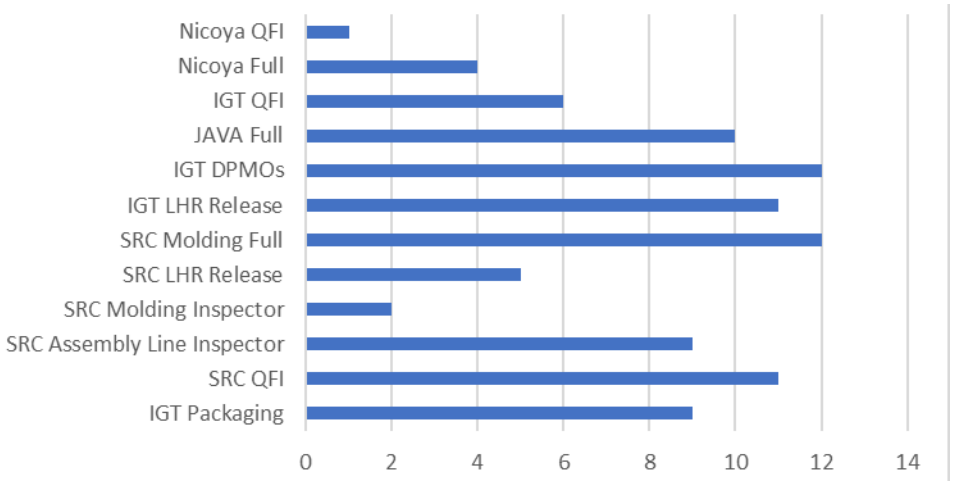


Figure 7 Additional Trainings/Certifications. Source: (A. Barrantes, The author, 2020)

The type of contract in the Quality Department is not always permanent as shown in Figure 8. Almost 25% of Quality Inspectors hold temporal contracts (contingent staff) and for most of them, receiving a permanent contract depends on positive-result oriented performance monitored for 3 to 6 months. It is important to consider these results in order to make sure that only FTE (full time employees) are considered in a cross-training plan. Contingent staff members that will become permanent (FTE), should be added to cross training plan(s) since they will stay permanent in the Quality Department.

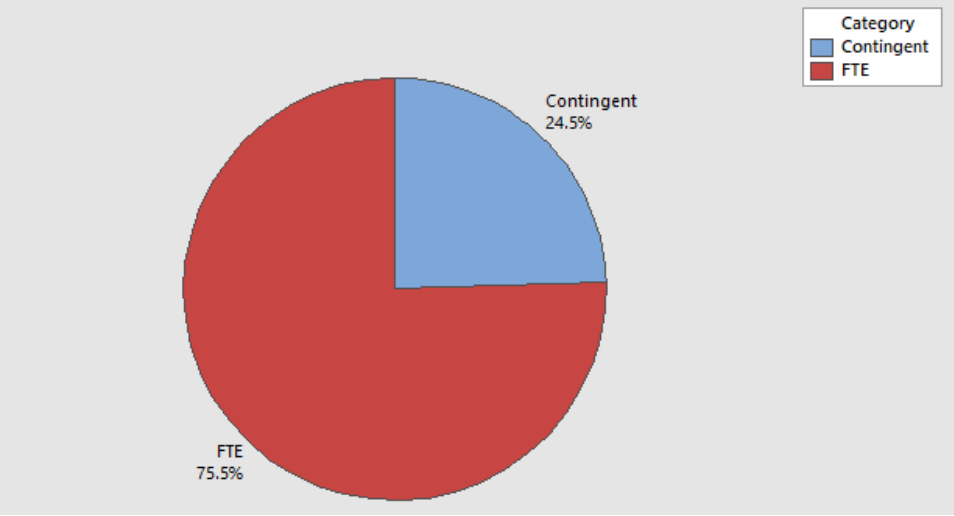


Figure 8 Quality Inspectors Contract Type. Source: (A. Barrantes, The author, 2020)

Based on the survey results, the below training matrix on Chart 6 was created in order to have a clear understanding of every single individual and the training certification each one of them holds. This table will be used as a tool during the completion of trainings in order to track the new certifications that the inspectors will receive throughout the cross-training period.

Chart 6 presents the current picture of Full Time Equivalents vs Contingent staff members. This data helps define which employees will be participating in the training, under the premise that only full-time employees will participate. Most contingent (temporal) staff will eventually finish their rotation in Quality and therefore will not be cross trained.

Chart 6 Current picture of Full Time Equivalents vs Contingent (Source: A. Barrantes, The Author, 2020)

		Shift							Totals	
		A	B	C	A1	A2	B1	B2	Contingent	FTE
IGTD	Catheters	3	2	1	0	0	0	0	3	3
	Wires									
	Packaging	0	0	0	1	1	1	1	0	4
SRC	Molding	0	0	0	4	4	4	3	5	10
	Assembly	4	3	0	0	0	0	0	3	4
JAVA	MS	0	1	0	2	2	2	2	5	4
	LoFlo									
	Capnostrack									
	Reusables									
	Detector									
	Source									
Nicoya		2	1	1	0	0	0	0	2	2
QFIs		0	0	0	1	2	1	1	1	4
									19	31

Chart 7 presents the current picture of Full Time Equivalents staff members with their names. During the development of this cross-training program, an analysis will be done together with the Quality Management Team in order to define if the team can potentially keep an average of eight additional FTEs, that will be selected from the list of contingent team members.

Chart 7 Current picture of Full Time Equivalents (Source: A. Barrantes, The Author, 2020)

		Shift							
		A	B	C	A1	A2	B1	B2	FTE
IGTD	Catheters	JOSE BARRERA/DANIELA CHASSOUL		MARIANA ARAYA					3
	Wires								
	Packaging				ANGELY LIZANO	MARIANA CARRILLO	KEYLIN BETANCOURTH	JASON MEJIA	4
SRC	Molding				MANFRED ALFARO	KERBY RAMIREZ/FRANCIS GARCIA/KIMBERLY ALFARO	NEMECY ARAYA/STEPHANIE ANGULO/JIMMY ARAYA	DANIELA MARTINEZ/WILSON RODRIGUEZ/JOSUE MIRANDA	10
	Assembly	ROSAURA MENDEZ/KAROL VINDAS	NAZARETH LOBO/KARINA VALVERDE						4
JAVA	MS				YAZDANY RODRIGUEZ	**DAYRA SANDOVAL**	RICARDO ALFARO	ALEXANDER MENDEZ	4
	LoFlo								
	Capnostrack								
	Reusables								
	Detector								
	Source								
Nicoya		MARIA VARGAS	KARINA AZOFEIFA						2
QFIs					CINTHIA GARCIA	JORYANELLA FONSECA	JOSELINE NUÑEZ	ADDRIANA AGUILAR	4

Chart 8 presents the projection for 2021 in terms of headcount for QPIs and QFIs for the medical device organization vs the current picture of permanent team members. In conversations with the Quality Manager currently overseeing this process, the forecast shows an increase of eight heads for the next year that will be a part of the cross-training plan.

Chart 8 Projection 2021 vs Actual FTE (Source: A. Barrantes, The Author, 2020)

Area	Current FTE 2020	FTE Projection 2021
CEA IGTD	3	4
IGTD Packaging	4	4
SRC Molding	10	12
SRC Assembly	4	7
Nicoya	2	4
Java	4	4
QFI	4	4
TOTAL	**31**	**39**

Training Matrix on Appendix 5 was created in order to have a clear understanding of every single individual and the training certification each one of the inspectors hold. This table will be used as a tool during the completion of trainings in order to track the new certifications that the inspectors will receive throughout the cross-training period.

4.1.3 SWOT Analysis

SWOT refers to strengths, weaknesses, opportunities, and threats. A SWOT analysis is a process where the management team identifies the internal and external factors that will affect a Team´s future performance. The company's strengths and weaknesses are the internal factors. Opportunities and threats deal with factors external to the company – environmental factors (Gürel, 2017).

In this case, a SWOT analysis was done as part of the overall planning process in which financial and operational goals are set for the near future and strategies are created to accomplish these goals, including the creation of a Cross Training Program.

Chart 9 shows the results of the SWOT Analysis performed. The valuable part of a SWOT Analysis is determining what story the four lists tell about the Quality Inspectors situation and how that helps to examine what actions are needed. In summary the basic assumption of this SWOT Analysis is that the organization must align certain internal activities with external realities to be successful.

This SWOT Analysis provided a framework for analyzing the company's context. It helped to focus on minimizing weaknesses such as the education limitations and taking the greatest possible advantage of opportunities available such as training within the 7 areas in order to optimize the resources.

As a result, considering external and internal factors is essential because they clarified the world in which this specific QMS unit operates, enabling it to get a

better envision for the desired future in terms of headcount and internal training strategies.

Chart 9 SWOT Analysis (Source: A. Barrantes, The Author, 2020)

Chart 10 represents the proposed strategies, taking the form of a matrix in which (Gürel, 2017):

- Strategies SO considers those strategies which leverages the organization's strengths and opportunities.
- Strategies WO includes those strategies which leverage weaknesses and opportunities to be impactful within the action plan.
- Strategies ST considers those strategies which build on the competences derive from strengths to overcome the threats.
- Strategies WT are those formulated to transform the weaknesses and threats to encourage successful outcomes for the action plan.

Chart 10 SWOT Strategies (Source: A. Barrantes, The Author, 2020)

	Strengths	**Weaknesses**
Opportunities	**Strategies SO** 1. Develop a cross-training plan within the seven areas in order to be prepared for unforeseen events such as sickness or strikes. To be addressed in the present Final Graduation Project. 2. Optimize current work methodologies. Addressed to Quality Managers. 3. Implement biweekly or monthly staff meeting. Addressed to Quality Supervisors.	**Strategies WO** 1. Designate leaders for each area that can provide support to the most unexperienced. Addressed to Quality Supervisors. 2. Create robust reporting system for data collection. Addressed to Quality Engineers. 3. Create internal trainings on Medical Industry Regulations. Addressed to Training Department.
Threats	**Strategies ST** 1. Create a performance evaluation system for Quality Inspectors. Addressed to Quality Supervisors. 2. Present career path plan for Quality Inspectors with the help of Human Resources. Addressed to Training Department. 3. Improve individual communication with inspectors through a periodic 1:1 meeting to listen to their recommendations, feedback and/or needs. Addressed to Quality Supervisors.	**Strategies WT** 1. Provide Quality Inspectors with technical courses such as Microsoft Office, English language, Quality Technician or Statistic courses. Addressed to Training Department. 2. Promote high school education within Quality Inspectors that do not hold a High School Degree. Addressed to Human Recourses. 3. Promote superior education (University) to Quality Inspectors that do hold high school degree. Addressed to Human Recourses.

4.1.4 Evaluation of Gaps

Upon the observation of the survey results and SWOT analysis of Quality Inspectors in a medical device manufacturing organization, several gaps were identified. Given the purpose of this Final Graduation Project is to focus on cross training, gaps are oriented towards training towards training necessities. Chart 11 describes the GAPs identified.

Chart 11 GAP identification (Source: A. Barrantes, The Author, 2020)

No.	GAPS	GOAL
1	The majority of Quality Inspectors are only specialists in their own work area.	Having Quality Inspectors certified on at least two areas.
2	Even though certain Quality Inspectors are already trained on different areas, it was identified that most of them don´t often perform these tasks, making them feel not comfortable of handling the task without a re training or refresher.	Having Quality Inspectors certified on an additional area different from their main one and execute these activities periodically.
3	Training in medical device in industry regulations is necessary. Poor information on Quality Systems is handled within the Team.	Contact the Training Department and design a training on applicable Medical Device Regulations and ISO such as EU MDR, ISO 13485-2016 and MDSAP.
4	Training refreshers are never performed within the Team.	Refresh procedures annually and involve all Quality Inspectors.
5	There is no definition on which areas cross trainings should be designed.	Define what the cross-training areas will be and who will be trained on what.
6	No contingency plan is documented for absenteeism situations. A flowchart with names, shifts, trained staff and contact information is necessary in order to understand who can cover an absent team member.	Creation of a flowchart with names, shifts, trained staff and contact information in order to understand who can cover an absent team member.

4.2 Design of a Training Program

Upon the analysis of the survey results, SWOT analysis and gap analysis in terms of training needs of Quality Inspectors in a medical device manufacturing organization it appears appropriate to make a decision on whether or not it makes sense to train all 46 Quality Inspectors in 12 different processes. 48 Inspectors took the initial survey but two of them did not have their contracts renewed as Quality Inspectors in the company.

During an interview with a Manufacturing Manager who used to manage the area a few months back, it was determined that Quality Inspectors should handle no more than 2 or 3 processes. In addition, the process should be trained, performed and refreshed with periodicity in order to ensure the Inspector is comfortable performing the task and is ready to move to these second or third expertise areas at any time.

4.2.1 Training Plan Structure

As described section 2.6.6, Training Framework, Chart 9 presents the Training Program Framework that serves as a starting point for training development.

4.2.1.1 Needs Assessment

QFI/QFI cross training is required among 7 areas, in various stages to balance workforce. Certifications as applicable by 4 stages in the below 7 defined areas:

- Java
- SRC Molding
- SRC Assembly
- Nicoya
- IGT Packaging
- IGT DPMO
- QFI (IGT, SRC, Nicoya and Java)

Figure 9 presents a diagram with the model of 4 Cross Training processes in which Quality Inspectors will be situated. Each process has been assigned a stage (1, 2,

3 and 4) and the areas of each stage were linked by affinity. This figure with areas that relate was designed as a baseline so that it can be used as reference when designing a cross-training program.

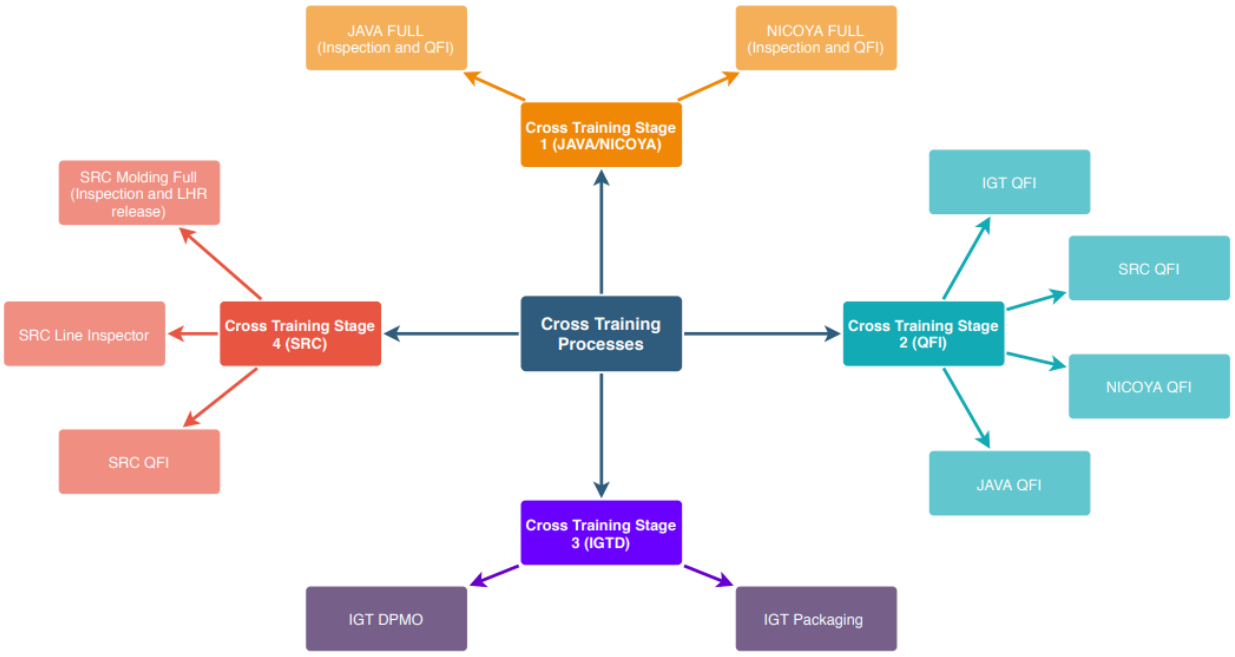


Figure 9 Cross Training Processes. Source: (A. Barrantes, The author, 2020)

The next step in the training process is to create a training framework that will help as a guide as the training program is set up.

- **Cross Training Stage 1** considers Java and Nicoya Quality Product Inspectors to Cross Train with each other. Java full time employees (FTEs)-QPIs will be assigned a pair in the Nicoya area (also an FTE) to cross train with.

- **Cross Training Stage 2** considers all FTEs-QFI Technicians that are already certified for final product release for 4 areas (Java, SRC, IGT and Nicoya). Nicoya will cross train with Java on stage 1, while SRC will cross

train with IGTD on Stage 2. IGT and SRC QFI Technicians will later cross train with both Nicoya and JAVA on final product release tasks only.

- **Cross Training Stage 3** considers all FTEs-QPIs certified on IGT Packaging to cross train with QPIs that currently perform audits and DPMO (Defects per Million Opportunities) testing on CEA (Controlled-Environment Areas).

- **Cross Training Stage 4** finally considers cross training among SRC QPIs. This means QPIs in the SRC Molding area to cross train with QPIs in the Assembly area, including final release activities. Simultaneously, during Stage 4, QPIs in the Assembly area will train internally in order to ensure they have both the QFI and the Inspection certification.

Chart 12 presents the training target dates for the 4 Cross Training Stages as well as the monitoring task the Project Manager will achieve. In addition, each stage holds the name and last name initials of responsible trainers and trainees.

Chart 12 Cross training stages (Source: A. Barrantes, The Author, 2020)

TASK	ASSIGNED TO	PROGRESS	START	END
Cross Training Stage 1				
DS and MV	Trainers	0%	3/1/21	7/30/21
AM and YM	Trainers	0%	3/1/21	7/30/21
AM and KS	Trainers	0%	3/1/21	7/30/21
KA and RA	Trainers	0%	3/1/21	7/30/21
Monitoring	Adriana Barrantes	0%	3/1/21	7/30/21
Cross Training Stage 2				
JF and KV	Trainers	0%	3/1/21	7/30/21
CG and RM	Trainers	0%	3/1/21	7/30/21
EA and DM	Trainers	0%	3/1/21	7/30/21
JN and KV	Trainers	0%	3/1/21	7/30/21
Monitoring	Adriana Barrantes	0%	3/1/21	7/30/21

TASK	ASSIGNED TO	PROGRESS	START	END
Cross Training Stage 3				
JM and IP	Trainers	0%	3/1/21	7/30/21
MC and JR	Trainers	0%	3/1/21	7/30/21
AL and JB	Trainers	0%	3/1/21	7/30/21
KB and SC	Trainers	0%	3/1/21	7/30/21
Monitoring	Adriana Barrantes	0%	3/1/21	7/30/21
Cross Training Stage 4				
MA/LV/SO and MS/RM	Adriana Barrantes	0%	3/1/21	7/30/21
JM/KA/FG and KV/DM	Adriana Barrantes	0%	3/1/21	7/30/21
KR/DM/WR and MR/KV	Adriana Barrantes	0%	3/1/21	7/30/21
SA/JA/NA and NL/KV	Adriana Barrantes	0%	3/1/21	7/30/21
Monitoring	Adriana Barrantes	0%	3/1/21	7/30/21

4.2.1.2 Learning objectives

Quality Final and Product Inspection Technicians have the responsibility to act as the last check point in terms of document and process inspection before the product is released. They work with different products manufactured in the plant. products.

Chart 13 details learning objectives for each area along with the Work Instructions based on the training areas in which trainees will need to be trained on. Due to confidentiality agreements, it was only possible to name the Work Instructions and Standard Operating Procedures, but contents were kept private.

Chart 13 Learning objectives and Work Instructions per area (Source: A. Barrantes, The Author, 2020)

Areas	Learning objectives	Work Instructions
QFI (Quality Final Inspection) IGTD (Image Guided Therapy Devices)	1. Training on Work Instructions on Standard Operating Procedures and Work Instructions so Quality Inspector is certified and can execute the tasks of releasing orders in the system from a Quality Final Inspector standpoint and creating Certificates of Conformances as per client´s request. 2. Shadowing on-the-job to confirm concepts are clear.	• WI- Certificate of Conformance • WI- Filling Out History Record • WI- Final Product Release Disposables - CR • WI- QFI Product Release in the ERP System - CR • WI- Quality Data Recording Requirements Clean • W- QA Final Release Capnography Sensors
- QPI (Quality Process Inspection) Packaging IGTD (Image Guided Therapy Devices)	1. Training on Work Instructions on Standard Operating Procedures and Work Instructions so Quality Inspector is certified and can execute the tasks of calculating lot samples, perform pouch peel as well as tip pull tests and document them accordingly. 2. Shadowing on-the-job to confirm concepts are clear.	• WI. Sampling Procedure • SOP, Control of Non-Conforming Product • WI- in process pouch & tray peel test • WI- Quality In Process Inspection

Areas	Learning objectives	Work Instructions
QPI (Quality Process Inspection) CEA (Controlled-Environment Areas) IGTD (Image Guided Therapy Devices)	1. Training on Work Instructions on Standard Operating Procedures and Work Instructions so Quality Inspector is certified and can execute the tasks of DPMO testing, assisting in NCR segregations and dispositions as well as executing pouch peel and tip pull tests. 2. Shadowing on-the-job to confirm concepts are clear.	• WI- Quality in Process Inspection • SOP, Control of Non-Conforming Product • WI- In Process Pouch & Tray Peel Test • SOP, Control of Non-Conforming Product
QPI (Quality Process Inspection) Nicoya (Pulse Oximeter Sensor Devices Inspection)	1. Training on Work Instructions on Standard Operating Procedures and Work Instructions so Quality Inspector is certified and can execute the tasks of DPMO testing for Oximeter Sensor Devices and releasing final orders. 2. Shadowing on-the-job to confirm concepts are clear.	• WI- QA Final Release, Pulse Oximeter Sensor • WI- Quality In Process Inspection

Areas	Learning objectives	Work Instructions
QPI (Quality Process Inspection) Java (Capnography Sensor Devices Inspection)	1. Training on Work Instructions on Standard Operating Procedures and Work Instructions so Quality Inspector is certified and can execute the tasks of Capnography Sensor Devices Inspection, DPMO testing and release of the finished goods. 2. Shadowing on-the-job to confirm concepts are clear.	• WI- QA Final Release Capnography Sensors • WI- Quality Assurance Inspection Capnography Sensors • WI- Quality In Process Inspection
QPI (Quality Product Inspection) SRC (Sleep and Respiratory Care Inspection of subassemblies) Molding	1. Training on Work Instructions on Standard Operating Procedures and Work Instructions so Quality Inspector is certified and can execute the tasks of machine inspections, NCR segregation and disposition as well as release of SRC subassemblies. 2. Shadowing on-the-job to confirm concepts are clear.	• WI- Sampling Procedure • WI- QA Final Inspection SRC • WI- Quality In Process Inspection

Areas	Learning objectives	Work Instructions
QPI (Quality Product Inspection) SRC (Sleep and Respiratory Care Devices Inspection of finished goods) Assembly	1. Training on Work Instructions on Standard Operating Procedures and Work Instructions so Quality Inspector is certified and can execute the tasks of line inspections, NCR segregation and disposition as well as release of SRC finished goods. 2. Shadowing on-the-job to confirm concepts are clear.	• WI- Production Order Execution on ERP System for Disposables • WI- Quality In Process Inspection

4.2.1.3 Learning Style

The nature of the training involves live training, on site (non-virtual or remote), in-person, on-the-job and requires coaching in terms of mentoring and shadowing.
Trainers will be recommended to work with visually appealing, animated and interactive lessons to keep trainees engaged.
Lessons can be redone for those who benefit from repetition to fully understand the concepts.

4.2.1.4 Budget

Certain extra hours (overtime) will be required. 4.3.4 details a more robust cost analysis.

4.2.1.5 Delivery Style

Written resources will be used in the form of Standard Operating Procedures, Manufacturing Process Instructions and Work Instructions. A trainer Quality Inspector will guide the trainee in real time.

4.2.1.6 Audience

Quality Process Inspectors and Quality Final Inspectors from seven business units or areas:

- Java, Capnography Sensor Devices Inspection
- SRC Molding, Sleep and Respiratory Care
- SRC Assembly, Sleep and Respiratory Care
- Nicoya, Pulse Oximeter Sensor Devices Inspection
- IGT Packaging, Image Guided Therapy
- IGT DPMO, Image Guided Therapy
- QFI IGTD, Image Guided Therapy

4.2.1.7 Content

Certifications as applicable by 4 stages defined: Java, SRC Molding, SRC Assembly, Nicoya, IGT Packaging, IGT DPMO, QFI (IGT, SRC, Nicoya and Java).

Existing Standard Operating Procedures and Work Instructions will be the official content trainees will be trained on.

4.2.1.8 Timeline

Training kick off will be March 2021 through the end of July 2021. During these five months, training sessions (stages 1 through 4) will be executed at the very same time given trainers and trainees are all different and areas (business units) are different as well so there will be no conflicts.

4.2.1.9 Communication

Both written and verbal communication for trainers and trainees of the Cross-Training Plan will be done. In-person and verbal communication will be essential in order to ensure there is full understanding of the project, responsibilities and timelines.

4.2.1.10 Measurement Method

Periodic Performance Evaluations that are held twice a year by the organization will help to measure the effectiveness of the Training.

4.2.2 Control and Monitoring

Appendix 5 presents the Individual Training Plan Sheet that Trainers and Trainees will fill out in order to track the progress of their training plan in terms of objectives met, description of activities, documents reviewed, date/time, responsible trainer, trainee and signatures. Participants will be presented with the document and an explanation on how to fill out the sheet so they have an opportunity to ask any questions they may have.

4.3 Cross Training Plan

To plan the logistics associated to the implementation of a cross training among applicable areas of Quality Process Inspectors, a cross-training schedule, a RACI chart, and a cost analysis were defined.

4.3.1 Cross Training Schedule

A total of 10 tasks were added to the timeline and each one holds a specific start/end date as well as a designed responsible role. Chart 14 displays a detailed timeline prior the project implementation on November 30th, 2021.

Chart 14 Implementation Detailed Timeline (Source: A. Barrantes, The Author, 2020)

Phase Tasks	Description	Start Date	End Date	Responsible Role
1. Implement Readiness Activities	Validate training pairs (participants) schedules have not changed and schedule a meeting with Quality Manager to inform project timelines.	Feb 15, 2021	Feb 16, 2021	Project Manager
2. Secure Training Facilities	Ensure there is trainee station available on each work area since this is an on-site, on-the-job training.	Feb 17, 2021	Feb 18, 2021	Project Manager
3. Print Session Materials	Including: Standard Operating Procedures, Work Instructions and Individual Training Plan Sheets.	Feb 19, 2021	Feb 20, 2021	Project Manager
4. Contact QPI-QFI Trainers	Verify if they have training certification or not. If not, this is a quick certification that can be requested from one day to another. This is a certification required for an inspector to be able to train someone in the organization.	Feb 21, 2021	Feb 22, 2021	Project Manager
5. Prepare QPI-QFI Trainers ("Train-the-Trainer" Sessions)	Contact the Training Department and have them assign the training certification (if any are missing).	Feb 23, 2021	Feb 24, 2021	Project Manager
6. Provide trainers with Training Schedule templates	Both written and verbal communication for trainers on how to fill out the Individual Training Plan Sheets.	Feb 25, 2021	Feb 26, 2021	Project Manager

Phase Tasks	Description	Start Date	End Date	Responsible Role
7. Communicate participants	Both written and verbal communication for trainers and trainees of the Cross-Training Plan.	Feb 27, 2021	Feb 28, 2021	Project Manager
8. Training Sessions (Stage 1-4)	Training sessions (stages 1 through 4) will be executed at the same time given trainers and trainees are all different and areas (business units) are different as well. Monitoring through Individual Training Plan Sheets.	Mar 1, 2021	Jul 30, 2021	Trainer(s) and Project Manager
9. Evaluate Training (Performance Evaluation)	Once cross trainings are completed, ensure certifications are uploaded on the official organization´s document control system.	Aug 1, 2021	Nov 30, 2021	Project Manager, Trainer(s), Supervisor.

Figure 10 displays all project phases documented on a Gantt chart that shows the progress percentage based on the start and end date for each task. Training sessions (stages 1 through 4) will be executed at the same time given trainers and trainees are all different and areas (business units) are different as well.

CROSS-TRAINING PROGRAM FOR QUALITY PROCESS INSPECTORS AND QUALITY FINAL INSPECTORS

Medical Device Company
Project Lead

Project Start: Mon, 2/15/2021
Display Week: 1

TASK	ASSIGNED TO	PROGRES $	START	END
Phases				
Implement Readiness Activities	Project Manager	0%	2/15/21	2/16/21
Secure Training Facilities	Project Manager	0%	2/17/21	2/18/21
Print Session Materials	Project Manager	0%	2/19/21	2/20/21
Contact QPI-QFI Trainers	Project Manager	0%	2/21/21	2/22/21
Prepare QPI-QFI Trainers ("Train-the-Trainer" Sessic	Project Manager	0%	2/23/21	2/24/21
Provide trainers with Training Schedule templates	Project Manager	0%	2/25/21	2/26/21
Communicate participants	Project Manager	0%	2/27/21	2/28/21
Training Sessions (Stage 1-4)	Trainers and PM	0%	3/1/21	7/30/21
Evaluate Training (Performance Evaluation)	Trainers, PM and Supervisor	0%	8/1/21	11/17/21

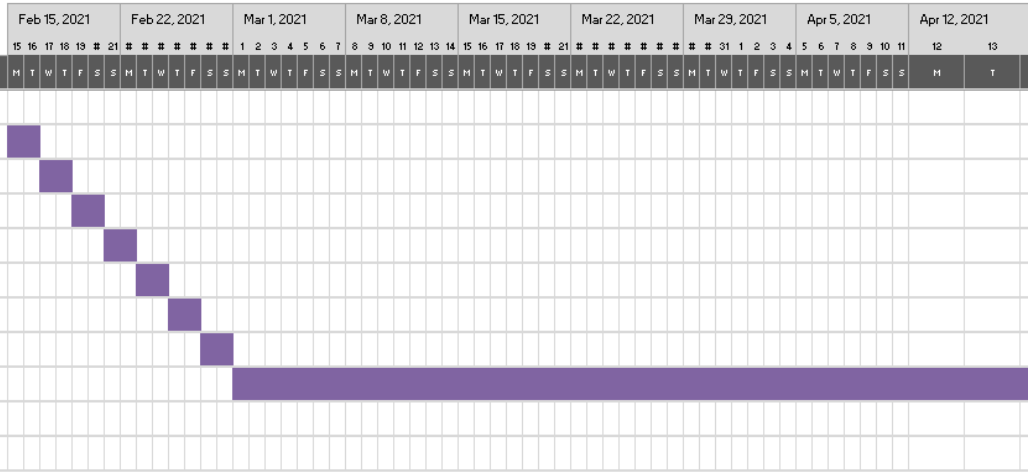


Figure 10 Implementation Detailed Timeline. Source: (A. Barrantes, The author, 2020)

4.3.2 Roles and responsibilities

A RACI matrix was developed to depict the functions or roles of the staff involved. RACI stands for Responsible, Accountable, Consulted, Informed. Each letter in the acronym represents a level of task responsibility. (Elhady, 2015).

- **Responsible:** This team member does the work to complete the task. Every task needs at least one Responsible party, but it's acceptable to assign more.
- **Accountable:** This person delegates work and is the last one to review the task or deliverable before it's deemed complete. On some tasks, the Responsible party may also serve as the Accountable one.
- **Consulted:** Every deliverable is strengthened by review and consultation from more than one team member. Consulted parties are typically the people who provide input based on either how it will impact their future project work or their domain of expertise on the deliverable itself.
- **Informed:** These team members simply need to be kept in the loop on project progress, rather than roped into the details of every deliverable.

Chart 15 maps the RACI Chart with specifications for Responsible (R), Accountable (A), Consulted (C) and Informed (I) stakeholders for each one of the main project phases: analysis, design, development, and implementation of the training plan.

Chart 15 RACI Chart (Source: A. Barrantes, The Author, 2020)

Project Phases	Project Manager	Trainees	Trainers	Quality Supervisor	Quality Manager
Implement Readiness Activities	R	I	I	A	I
Secure Training Facilities	A	I	R	A	I
Print Session Materials	R	I	I	A	I

Project Phases	Project Manager	Trainees	Trainers	Quality Supervisor	Quality Manager
Contact QPI-QFI Trainers	R	I	C	A	I
Prepare QPI-QFI Trainers ("Train-the-Trainer" Sessions)	R	I	A	A	I
Provide trainers with Training Schedule templates	R	I	A	A	I
Communicate participants	R	I	I	A	I
Training Sessions (Stage 1-4)	I	I	R	A	I
Evaluate Training (Performance Evaluation)	A	I	I	R	I

4.3.4 Cost Analysis

As far as cost analysis, it was defined that training times will be executed during slow times in the areas that will be identified by the Quality Supervisor. In addition, overtime will be also approved by Quality Supervisor in order to achieve target training dates. Overtime has been approved by Quality Manager and will be kept informed through over time monthly reports.

In average, a Quality Final or Process Inspector makes 3.0 USD for ordinary hour, meaning extra or over time is paid at 4.5 USD an hour. The expectation for the cross-training program is to have each Quality Inspector dedicate 3 hours a week during a 4-month period.

Chart 16 details the cost breakdown for the cross training. A total of 36 Quality Final and Process Inspectors will be part of the cross training and therefore, a total of 7776 USD will be required to cover the overtime. In addition, there is a cost of 50 USD for the material that will be printed out. Finally, the cost of the rest of the tasks

described in the Chart 16 were calculated with the rate per hour of the individual performing the activity. The grand total for the project is 8526 USD.

Chart 16 Cross training stages (Source: A. Barrantes, The Author, 2020)

Phase Tasks	Cost
1. Implement Readiness Activities (define cross training pairs)	USD 100
2. Secure Training Facilities	USD 50
3. Print Session Materials	USD 50
4. Contact QPI-QFI Trainers	USD 25
5. Prepare QPI-QFI Trainers ("Train-the-Trainer" Sessions)	USD 150
6. Provide trainers with Training Schedule templates	USD 25
7. Communicate participants	USD 100
8. Training Sessions (Stage 1-4)	USD 7,776
9. Evaluate Training (Performance Evaluation)	USD 250
TOTAL	**USD 8,526**

5. CONCLUSIONS

1. The diagnosis of the Quality Management System at a medical device manufacturing plant helped to determine the gaps that Quality Process Inspectors have in terms of training. Even though results showed that certain Quality Inspectors are already trained on different areas, it was identified that most of them don´t handle multiple certifications. Therefore, the need of a training became evident in order to maximize the use of the company resources and guarantee coverage.

   In addition, the diagnosis helped with the identification of the number of inspectors holding permanent and contingent contracts in order to define which employees would be participating of the project.

   It was also concluded that the lack of multitasked inspectors currently impacts the ability of having one single inspector in-charge of multiple tasks such as performing an inspection of a lot or batch and releasing the same production order, which is costing more money and resources to the organization.

2. The design of a Training Program for Quality Process Inspectors at a medical device manufacturing plant to meet the needs of the Quality Management System and calibrate the team´s capability helped to structure the main elements required to provide adequately trained resources for quality inspection activities and therefore assure the quality system is functioning properly.

   Thus, it was concluded that designing a Training Program to provide effectively trained and efficient resources will help decrease the current difficulties faced in terms of providing immediate coverage for unforeseen events such as resignations without notice or dismissals, maternity leaves,

vacations and other long-term medical leaves. This will avoid denying vacation days requested by employees.

3. The development of this Cross-Training Program will provide adequately trained resources to cover quality inspection activities of 7 areas of a manufacturing plant in Costa Rica.

   The cross training among applicable areas of Quality Process Inspectors considered the development of 4 stage cross-training process to have more inspectors trained on specific areas and have them prepared in case of absenteeism of different nature.

   It was defined to develop a cross training model in which Quality Inspectors will train in defined pairs between themselves. The 4-stage cross-training model was designed based on areas that have affinity in terms of activities and it can be concluded that during year 2021 no additional staff will be required, ensuring a cost saving for the Quality Department.

   It was concluded that having crossed trained resources throughout this cross-training model will also help provide quicker answers to manufacturing teams in the organization when requesting overtime for quality inspectors upon increases in production lines. Given these requests are usually made in real time, fast coordination is required and having on-site trained resources will avoid having to call inspectors to check availability and paying for their transportation to the manufacturing plant.

6. RECOMMENDATIONS

1. Based on the conclusions, Supervisory and Management Team should consider a new revision of the SWOT Analysis in aims of understanding additional gaps not related to cross-training needs. A mapping of all tasks needs to be performed. In addition, metrics of the area need to analyze, and times for each activity performed need to be tracked in order to calculate and then establish the standard times so a standard work can be created for Quality Process Inspectors.

2. Future studies performed by the area Quality Supervisor focused on better understanding the implications of the results previously mentioned, could lead to the design of a standard work that can will help understand capacity of each inspector per area. This recommendation is addressed to Quality Supervisors.

3. Further research is needed to regulate performance of Quality Inspectors through a periodic evaluation system that needs to be designed by Quality Supervisor that can improve performance of the resources and will help them create a career path within the company. There is already an annual performance in place in the organization; however, there are no monthly solid metrics to evaluate inspectors at the end of the year. This recommendation is addressed to Quality Supervisors.

4. Analyzing the leadership system for an average of 50 Quality Inspectors across 24/7 shifts and several areas is also recommended to Quality Management. A single Supervisor for this population may not be effective. Therefore, the designation of leaders per shift is an improvement opportunity that can be analyzed further. This recommendation is addressed to Quality Supervisors.

7. BIBLIOGRAPHY

Azzopardi, S. (n.d.). *THE EVOLUTION OF PROJECT MANAGEMENT*. Project Smart. Retrieved January 3, 2021, from https://www.projectsmart.co.uk/evolution-of-project-management.php

Elhady, A. & Abushama, H. (2015). RACI Scrum Model For Controlling of Change User Requirement In Software Projects*. International Journal of Application or Innovation in Engineering & Management*, *4*(1). 221-224. https://www.ijaiem.org/Volume4Issue1/IJAIEM-2015-02-01-73.pdf

Gürel, E. (2017). SWOT ANALYSIS: A THEORETICAL REVIEW. *Journal of International Social Research, 10(51),* 994-1006. https://doi.org/10.17719/jisr.2017.1832

Harned, B. (2019, September 16). *How to Clear Project Confusion with a RACI Chart [Template].* Retrieved January 3, 2021, from https://www.teamgantt.com/blog/raci-chart-definition-tips-and-example

ISO. (2020). *ISO 2859-2:2020.* https://www.iso.org/standard/64505.html

i3 Consult. (2019, January 21). *Case Study: Structure, Function, Roles and Responsibilities for a Small Cap Medical Device Company*. Retrieved January 3, 2021, from https://medium.com/@i3consult.com/case-study-structure-function-roles-and-responsibilities-for-a-small-cap-medical-device-company-d6a25231ceae

Kim-Soon, N. (2012). *Quality Management System and Practices.* http://doi.org/10.5772/36671

Koninklijke Philips N.V. (2015, February 24). Annual Report 2014. Retrieved January 3, 2021, from https://www.results.philips.com/publications/ar14/downloads/files/en/PhilipsFullAnnualReport2014_English.pdf?v=20210104173950

Koninklijke Philips N.V. (2021a). *Vision & misión.* Retrieved January 3, 2021, from https://www.philips.com/a-w/research/vision-and-mission.html

Koninklijke Philips N.V. (2021b). *About*. Retrieved January 3, 2021, from https://www.philips.com/a-w/research/vision-and-mission.html

Kirkpatrick, D. (2006). *Evaluating Training Programs* (3rd ed). Berrett-Koehler.

Kurniati, N., Yehb, R. & Lin, J. (2015). Quality inspection and maintenance: the framework of interaction. *Procedia Manufacturing, 4*(2015), 244 – 251. https://doi.org/10.1016/j.promfg.2015.11.038

Oxford University. (2011a). Information. In *Concise Oxford English Dictionary* (12 ed.). Oxford Press Inc.

Oxford University. (2011b). Source. In *Concise Oxford English Dictionary* (12 ed.). Oxford Press Inc.

Oxford University. (2011c). Research. In *Concise Oxford English Dictionary* (12 ed.). Oxford Press Inc.

Oxford University. (2011d). Method. In *Concise Oxford English Dictionary* (12 ed.). Oxford Press Inc.

Picariello, G. (2008, June 7). *The Top 10 Benefits of Project Management*. Bright Hub PM. Retrieved January 3, 2021, from https://www.brighthubpm.com/project-planning/2350-the-top-ten-benefits-of-project-management/

Project Management Institute. (2013). *A Guide to the Project Management Body of Knowledge: PMBOK® Guide* (Fifth Edition). Pensilvania: Project Management Institute, Inc.

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

Saylor Academy. (2012). *Human Resource Management*. Retrieved January 3, 2021, from https://saylordotorg.github.io/text_human-resource-management/index.html

8. APPENDICES

Appendix 1: FGP Charter

PROJECT CHARTER	
Date:	**Project Name:**
March 1st, 2020	Design of A Cross Training Program For Quality Process Inspectors And Quality Final Inspectors on A Medical Device Industry
Knowledge Areas / PM Processes:	**Application Area (Sector / Activity):**
Knowledge Areas: Project Integration Management, Project Scope Management, Project Time Management, Project Cost Management, Project Quality Management, Project Resource Management, Project Risk Management, Project Procurement Management, Project Communications Management, Project Stakeholder Management **PM Processes:** Initiating and Planning	Quality Management System
Project Start Date:	
March 1, 2020	November 22, 2020
Project Objectives (General and Specific):	
General Objetive • To design a cross-training program for quality process inspectors and quality final inspectors to balance workforce. **Specific objectives** • To perform a diagnosis of the Quality Management System at a medical device manufacturing plant in order to determine the gaps that Quality Process Inspectors have in terms of training in order to identify and address their training needs. • To design a Training Program for Quality Process Inspectors at a medical device manufacturing plant to meet the needs of the Quality Management System and calibrate the team´s capability. • To plan a cross training among applicable areas of Quality Process Inspectors with identification of timing, costs, participants, logistics and methodology to have more inspectors trained on certain areas.	

Project purpose or justification:

The purpose of the development of this Cross-Training Program is to provide adequately trained resources for quality inspection activities and therefore assure the quality system is functioning properly.

A quality system that has been implemented effectively and is monitored to identify and address problems is more likely to produce devices that function as intended and therefore the diagnosis of the Quality Management System will be vital in order to identify the gaps.

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

The project is expected to produce a Cross Training Program that would be used to provide adequately trained resources for quality inspection activities; assure the quality system is functioning properly; monitor the quality system; and make necessary adjustments.

Deliverables are:

1. Diagnosis of the Quality Management System
2. Training Program
3. Cross-training Plan

Assumptions:

Time and Resources: The project can be completed in three (3) months by one (1) person.

Constraints:

Time and Resources: The project can be completed in three (3) months by one (1) person (Project Manager).

Preliminary Risks:

1. If the schedule for milestone completion is not adhered to, the plan may not be completed in three (3) months.
2. If support from tutor is not prompt, the project management plan may not be completed in a timely manner.

Budget:

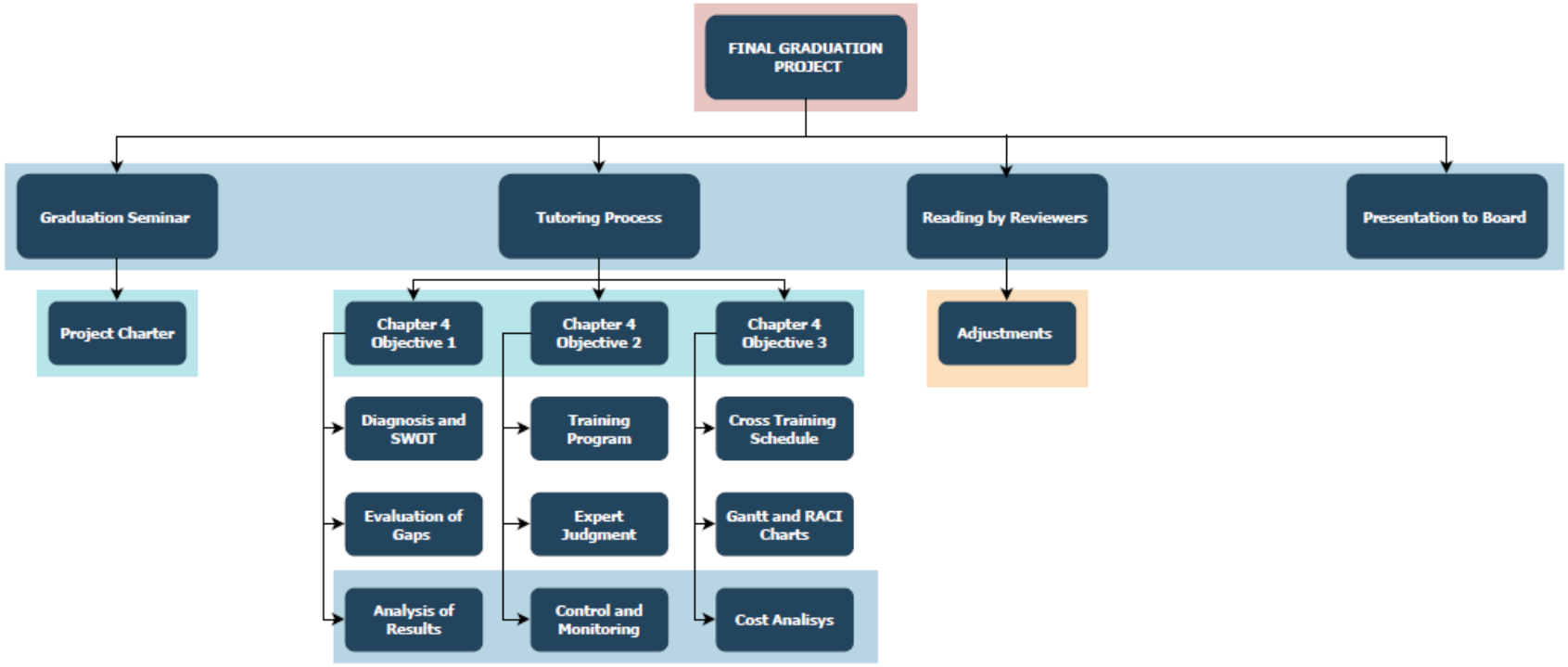
Budget will constitute of financial resources required to print the manual as well as the Final Graduation Project.

Milestones and dates:

Milestone	**Start date**	**End date**
Project Start	24 February 2020	24 February 2020
Project Charter	24 February 2020	1 March 2020
WBS	24 February 2020	1 March 2020
Chapter I: Introduction Chapter	2 March 2020	8 March 2020
FGP Schedule	2 March 2020	8 March 2020
Chapter II: Theoretical Framework	9 March 2020	15 March 2020
Chapter III: Methodological Framework	16 March 2020	22 March 2020
Executive Summary	16 March 2020	22 March 2020

Annexes - Bibliography, Indexes	16 March 2020	22 March 2020
Signed Charter - Approval	23 March 2020	29 March 2020
Tutoring	07 September 2020	6 December 2020
Previous Chapters Adjustments	07 September 2020	13 September 2020
Chapter IV: Development (Results)		
a. Objective I	14 September 2020	27 September 2020
b. Objective II	28 September 2020	11 October 2020
c. Objective III	12 October 2020	25 October 2020
Chapter V: Conclusions	26 October 2020	1 November 2020
Chapter VI: Recommendations	2 November 2020	8 November 2020
Tutor Approval	9 November 2020	15 November 2020
FGP Submission to Reviewers	16 November 2020	22 November 2020
Review	23 November 2020	29 November 2020
Adjustments	30 November 2020	6 December 2020
Presentation to Board	TBC	TBC
Relevant historical information		
This Cross-Training Program will be developed to be executed at a medical device company in Alajuela, Costa Rica. The Corporation headquartered in Europe is formerly one of the largest electronics companies in the world, currently focused in the area of health technology, with other divisions being successfully divested.		
Stakeholders:		
Direct stakeholders: FGP Advisor: Mr. Carlos Brenes FGP Tutor: Karolina Jiménez Medical Device Manufacturing Company Indirect stakeholders: Academic Assistant: Gabriela Zúñiga		
Approval:		
Project Manager: Adriana Barrantes	Signature:	
Authorized by:	Signature:	

Appendix 2: FGP WBS



Appendix 3: FGP Schedule

ID	Task Mode	Task Name	Duration	Start	Finish	Predecessors
1		**Project Start**	**1 day**	**Mon 24/02/20**	**Mon 24/02/20**	
2		Project Charter	6 days	Mon 24/02/20	Sun 01/03/20	
3		WBS	6 days	Mon 24/02/20	Sun 01/03/20	
4		**Chapter I: Introduction Chapter**	**6 days**	**Mon 02/03/20**	**Sun 08/03/20**	3,1
5		FGP Schedule	6 days	Mon 02/03/20	Sun 08/03/20	
6		Chapter II: Theoretical Framework	6 days	Mon 09/03/20	Sun 15/03/20	
7		**Chapter III: Methodogical Framework**	**7 days**	**Mon 16/03/20**	**Tue 24/03/20**	6
8		Executive Summary	6 days	Mon 16/03/20	Sun 22/03/20	
9		**Annexes - Bibliography, Indexes**	**7 days**	**Mon 16/03/20**	**Tue 24/03/20**	7
10		Signed Charter - Approval	6 days	Mon 23/03/20	Sun 29/03/20	
11		Tutoring	66 days	Mon 07/09/20	Sun 06/12/20	9
12		Previous Chapters Adjustments	6 days	Mon 07/09/20	Sun 13/09/20	
13		**Chapter IV: Development (Results)**				**11**
14		Objective I	14 days	Mon 14/09/20	Thu 01/10/20	
15		Objective II	11 days	Mon 28/09/20	Sun 11/10/20	
16		**Objective III**	**12 days**	**Mon 12/10/20**	**Tue 27/10/20**	**15**
17		Chapter V: Conclusions	6 days	Mon 26/10/20	Sun 01/11/20	
18		Chapter VI: Recommendations	6 days	Mon 02/11/20	Sun 08/11/20	
19		Tutor Approval	6 days	Mon 09/11/20	Sun 15/11/20	
20		FGP Submission to Reviewers	6 days	Mon 16/11/20	Sun 22/11/20	16
21		Review	6 days	Mon 23/11/20	Sun 29/11/20	
22		Adjustments	6 days	Mon 30/11/20	Sun 06/12/20	
23		Presentation to Board	5 days	TBC	TBC	

Appendix 4: Survey

Training Diagnostic Survey for Quality Product Inspectors and Quality Final Inspectors

The purpose of this form is to evaluate competencies of employees on QPI and QFI positions in order to understand what they are trained on.

Complete Name:

_____

Current Work Area:

- QFI
- QPI IGT CEA LHR Release
- QPI Packaging
- QPI JAVA
- QPI Nicoya
- QPI SRC Assembly
- QPI SRC Molding
- QPI IGT CEA DPMOs

Aside from your current official role, what other certifications do you hold that let you provide support in other areas?

- QFI
- QPI IGT CEA LHR Release
- QPI Packaging
- QPI JAVA
- QPI Nicoya
- QPI SRC Assembly
- QPI SRC Molding
- QPI IGT CEA DPMOs
- None

What kind of contract do you hold?

- Temporal
- Permanent

Appendix 5: Training Matrix

	IGT Packaging	SRC Assembly		SRC Molding			CEA IGTD		JAVA	IGTD QFI	Nicoya	
Quality Inspector	**IGT Packaging**	**SRC QFI**	**SRC Assembly Line Inspector**	**SRC Molding Inspector**	**SRC LHR Release**	**SRC Molding Full**	**IGT LHR Release**	**IGT DPMOs**	**JAVA Full**	**IGT QFI**	**Nicoya Full**	**Nicoya QFI**
Wilson Rodríguez Ponce	x		x			x		x				
Kimberly Alfaro Quirós						x						
Yessenia Cruz Solano									x			
Mariana Carrillo Sibaja	x							x				
Joryanella Fonseca		x			x					x		
Nemecy Araya Villegas	x					x	x					
Daniela Martínez Espinoza						x						
Cinthia García Valverde		x			x		x			x		
Lissy Villalobos Abarca						x						
Adriana Murillo Ugalde											x	
Jose Barrera Corea	x				x			x				

	IGT Packaging	SRC Assembly		SRC Molding			CEA IGTD		JAVA	IGTD QFI	Nicoya	
Quality Inspector	**IGT Packaging**	**SRC QFI**	**SRC Assembly Line Inspector**	**SRC Molding Inspector**	**SRC LHR Release**	**SRC Molding Full**	**IGT LHR Release**	**IGT DPMOs**	**JAVA Full**	**IGT QFI**	**Nicoya Full**	**Nicoya QFI**
Estefani Alfaro Rodríguez										x		x
Keilyn Segura Moreno											x	
María José Vargas Zumbado								x	x		x	
Heissel Arce Peralta									x			
Nazareth Lobo González			x									
Ixzayana Ponce Galeano							x					
Kerby José Ramírez Gutiérrez						x		x				
Sofía Obando Leitón						x						
Rosaura Méndez Carballo	x	x										
Madison Rodríguez			x									
Josué Miranda Castillo		x				x				x		
Manfred Alfaro Arce						x						
Karol Vindas Campos			x									

	IGT Packaging	SRC Assembly		SRC Molding			CEA IGTD		JAVA	IGTD QFI	Nicoya	
Quality Inspector	**IGT Packaging**	**SRC QFI**	**SRC Assembly Line Inspector**	**SRC Molding Inspector**	**SRC LHR Release**	**SRC Molding Full**	**IGT LHR Release**	**IGT DPMOs**	**JAVA Full**	**IGT QFI**	**Nicoya Full**	**Nicoya QFI**
Marianela Rodríguez Quesada									x			
Marianela Zumbado Rodríguez			x				x					
Jason Mejía Soto	x	x	x	x			x	x				
Silvia Elena Cruz Espinoza								x				
Jennifer Rodríguez Vega								x				
Stephanie Angulo Calvo		x	x			x						
Yariela Navarro Rodríguez									x			
María Soto Camacho			x									
Dayanna Montero Camacho		x										
Keilyn Betancourth Sandoval	x											
Johanna González Navarrete						x						
Yazdany		x			x		x	x	x		x	

	IGT Packaging	SRC Assembly		SRC Molding			CEA IGTD		JAVA	IGTD QFI	Nicoya	
Quality Inspector	**IGT Packaging**	**SRC QFI**	**SRC Assembly Line Inspector**	**SRC Molding Inspector**	**SRC LHR Release**	**SRC Molding Full**	**IGT LHR Release**	**IGT DPMOs**	**JAVA Full**	**IGT QFI**	**Nicoya Full**	**Nicoya QFI**
Rodríguez Molina												
Mariana Araya Sandoval							x	x				
Joseline Núñez Ceciliano		x			x					x		
Angely Lizano Chacón	x						x	x				
Alexander Méndez		x	x	x					x			
Jose Ricardo Alfaro							x		x			
Dayra Sandoval Martínez								x	x			
Adriana Pineda									x			
Adriana Matarrita						x						
Daniela Chassoul Duarte	x						x					
Adriana Aguilar		x					x			x		

Appendix 6: Individual Training Plan Sheet (QPI-QFI Cross-training 2021)

Training Area:	
Date/Time:	
Responsible Trainer:	

Objectives:	
Material needed:	
Trainee:	

Start and End Time	Description of activities	Documents reviewed	Trainee´s signature	Responsible Signature

Appendix 7: Philologist Credentials

Universidad Internacional de las Américas

Por haber cumplido con los requisitos reglamentarios
de la carrera respectiva se confiere a

ALVARADO MATA NATALIA
Céd.: 3-0503-0705

el grado académico de:

BACHILLERATO EN INGLES
con todos los derechos y deberes inherentes a tal grado.

Dado en San José de Costa Rica, en la sede de la Universidad
el día ***diecisiete de agosto de dos mil diecinueve***

CONESUP

Lic. Mario Sanabria Ramírez
Dirección Ejecutiva
CONESUP

Dr. Máximo Sequeira Alemán
Rector
UNIVERSIDAD

Inscrito Ministerio de Educación:
Código de la Universidad: 2 Asiento: 217709 Anotado Universidad: Tomo: 3 Folio: 15 Número: 9175

Appendix 8: Revision Dictum

San José, January 14, 2021

Universidad para La Cooperación Internacional (UCI)

To Whom It May Concern:

Natalia Alvarado Mata, identification number 305030705, Bachelor in English with a focus on translation, hereby states that the project titled: **DESIGN OF A CROSS-TRAINING PROGRAM FOR QUALITY PROCESS INSPECTORS AND QUALITY FINAL INSPECTORS ON A MEDICAL DEVICE INDUSTRY**, carried out by Adriana María Barrantes Gutiérrez, has been revised.

The project was carried out to obtain the **Master in Project Management (MPM)** Degree. Aspects such as paragraph form, language quirks in written language, orthography, punctuation, and other aspects related to syntax and grammar were inspected and proofread. Therefore, taking into account the changes that were made, the project is ready to be presented.

Sincerely,

Natalia Alvarado

Natalia Alvarado Mata
English Translator and Proofreader
natalia.alvarado@filologos.cr