TALLINN UNIVERSITY OF TECHNOLOGY

SCHOOL OF ENGINEERING

Department of Power Engineering and Mechatronics

Development of Quality Management System at Golden Pearl Cosmetics Pvt. Ltd

Kvaliteedijuhtimi sesüsteemi arendamine Golden Pearl Cosmetics Pvt.Ltd-s

MASTER THESIS

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Tallinn, 2020

AUTHOR'S DECLARATION

Hereby I declare that I have written this thesis independently.

No academic degree has been applied for based on this material. All works, major viewpoints and data of the other authors used in this thesis have been referenced.

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DEDICATION

I dedicate this work to my teachers and family and my beloved fiancé without their guidance and confidence in me; it was not possible to achieve this milestone in my life.

THESIS TASK

Student: Ahsan Mujtaba Bashir, 184515-MAHM

Study program: MAHM

Main specialty: Mechatronics

Supervisor(s): Andres Kiitam, Research Scientist

Consultants: Saad Naseer

Thesis topic:

(In English) Development of *Company Quality Management system at Golden Pearl Cosmetics Pvt Ltd*
(In Estonian) Kvaliteedijuhtimi sesüsteemi arendamine Golden Pearl Cosmetics Pvt.Ltd-s

Thesis main objectives:

- The objective is to implementation and development of Company Quality Management System *(*QMS, specified as a formalized system that documents practices, procedures, and accountabilities for completing quality policies and aims, complying with standard ISO 9001:2015)

Thesis tasks and time schedule:

No	Task description	Deadline
1.	Understanding of the QMS Requirements	31.12.2019
2.	Gap Analysis for QMS implementation	05.03.2020
3.	Implementation of QMS in the company	05.04.2020

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List of abbreviations and symbols

QMS	Quality Management System
ISO	International Standards Organization
GPC	Golden Pearl Cosmetics
IMS	Integrated Management System
TQM	Total Quality Management
IDEF9000	A Standard for Modeling Operating Business Processes with Links to ISO 9001
cGMP	current Good Manufacturing Practice
Q.C lab	Quality control laboratory
Emerald Insight®	Emerald is a scholarly publisher of journals and books
ISO 9001	The international standard that identifies requirements for a quality management system
Science Direct®	Science Direct database gives subscription-based access to a large database of scientific and medical research.
AVL	Approved Vendor List
VSC	Vendor Selection Criteria
OM	operations manager
PM	Purchasing Manage
ETA	Expected Time of Arrival
MR	Market Representatives

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Chapter 1

Introduction

1.1 Overview

In today's world, customers are demanding high-quality goods and services. Thus, the major challenge encountered by Golden Pearl Cosmetic (GPC) is to meet the exceeding customer requirements. The other purpose of delivering high-quality products and services is to keep the current customer as customer retention is one more significant challenge faced by organizations globally. Organizations need a system that assures required levels of quality of both manufactured goods and services offered to the customers through valuable planning and management. Various industries have established different practices to guarantee customer satisfaction and achieve competitive advantages.

The American Society of Quality identifies quality management as the application of quality management techniques and approaches in managing a procedure to enhance customer satisfaction with minimum resources while keep trying to improve the whole process. Quality of manufactured goods and services demanded by customers can only be delivered by boosting and maintaining quality performance. Customer satisfaction and trust can only be achieved by executing a Quality Management System (QMS) within the companies to facilitate quality control and improvement. However, not all organizations, whether small-sized or large-sized, have effectively implemented QMS for several reasons. In literature, quality management is based on the practices of big organizations. However, the key findings, lessons, and conclusions learned from these practices are equally applicable to all organizations (Boon and Ram, 1998). There are various unique QMS frameworks adopted that identify many requirements an organization must agree with to implement the QMS in their services. The applicability of these settings depends on present situations in the organizations reliant on whether they are already in place or needed to be there.

1.2. Background of Golden Pearl Cosmetics:

Golden Pearl Cosmetics is a private family-maintained business by Pakistani producer of Beauty & Skin caring products, which was established by Mr. Sheikh Abid Mehmood (Chairman Golden pearl Cosmetics) in 1997. Production operations initially started from Pakistan (Chichawatni), and recently a sizeable modern set-up is established in Lahore to manufacture a wide range of personal Skincare products. Golden Pearl Cosmetics) have independent laboratories like Q.C. lab, microbiological lab, and R&D lab fully provided with scientific equipment and qualified specialists. Q.C. lab manages analytical tests on raw materials as completed products using state of the art equipment like HPLC, U.V. (Spectrometry), and potentiometer. R&D lab is responsible for constancy testing of products using a pilot batch mixer and stability chamber. The microbiological lab is performing all the microbiological tests under controlled conditions in the HVAC system and BSL2 standard cabin.

1.3. Research Motivation

Many researchers, based on their knowledge and experiences, have suggested several conceptual frameworks that can be used by organizations for implementing QMS. However, very few theoretical frameworks have been analyzed and or applied practically. Many survey analyses have been done to study the effect and success of QMS implementation. Such studies give lessons learned from organizational practices that can be used by other organizations for developing and implementing QMS more successfully. Nonetheless, some have already started the implementation of quality systems, while others are uncertain about the application. Very few studies have described entire efforts of quality management projects from early planning to implementation. No comprehensive framework or QMS practices exist due to constant advancements, and changes are happening in today's world. The purpose of my master thesis is to develop an understanding of how quality management system working for Golden Pearl Cosmetics (GPC). This thesis addresses the Quality Management System (QMS) in the context of the ISO 9001 standard. The thesis's aim is to make a solid start that can help and provide support to the people in The Golden Pearl Cosmetics Pvt. Ltd towards better learning and development of the business and implementing the standards.

The Golden Pearl Cosmetics Pvt. Ltd faces challenges in measuring and monitoring the quality of their services. The second challenge is to implement a strong testing process and related new processes, functions, and policies. Therefore, the organization needs to develop a quality management system (QMS) to meet its clients' expectations, increase market

share, and improvement in processes.

1.4. Objectives:

The objective is to create and implement a QMS (specified as a formalized system that documents practices, procedures, and accountabilities for completing quality policies and aims, complying with standard ISO 9001:2015), which will allow the Golden Pearl Cosmetics PVT. Ltd. Pakistan".

1. To verify the personnel training and certification, as equipment calibration
2. CLSI quality control system for QC labs in GPC
3. To reduce the cost of quality appraisal by using automated statistical process control (SPC)
4. To facilitate better processes for measuring and monitoring cost on suppliers, source and receiving inspection and process audits
5. Bring together critical quality management processes like audit management, complaint handling, change control, and supplier quality management.

The result would help to uphold current Good Manufacturing Practice (cGMP) by automating quality procedures across the production process and provide visibility and compliance throughout the organization.

Chapter 2

Literature Review, Materials, and Methods

2.0. Literature Review

This Chapter covers the literature review. Currently, there is no definitive conclusion in the literature regarding the relation between quality management systems and organizational performance. Beyond that, a few studies analyze if the maturity level of quality management systems and processes affect organizational performance. Given these gaps, this paper shows a systematic literature review about quality management and organizational performance in the period between 2000 and 2020.

Some factors contribute to the generation of uncertainties and turbulence in the business environment. Among them, the elevated competition on the global market and the increasing demand for better products and services can be cited. Those factors are originated from pressures made by different products, the introduction of new products by competitors, quick technology innovation, shorter product life, unforeseen costumer changes, and advances in manufacturing and information management processes (Islam, M. M., Habes, E., Karim, A., & Syed Agil, S. O. B. (2016).

The first version of ISO 9001 was introduced in 1987 and focused on standardizing the activities of organizations through procedures. The second model, published in 1994, brought concern for defect prevention so that organizations monitor the product at all stages of the process, rather than just evaluating the finished product. The 2000 version introduced the concept of process management, making organizations manage their activities in an interconnected way to satisfy the requirements of their clients. This idea was reinforced in the 2008 version of the standard, which brought small changes to improve understanding of the needs. In 2015, the latest version of the measure was published, bringing the concept of risk management, assessment of the organizational context, and reinforcing leadership roles and responsibilities to achieve the organization's objectives (Ramphal, 2015).

Other aspects of being considered would be the time of the implementation of the certification and its scope. Besides that, the implementation of a QMS in a company can facilitate the implementation of parallel processes, which may lead to the management by the process, or formalize and certify the existent processes of the company. Hence, the

analysis of the relation between QMS and organizational performance can consider these two sub factors:

1. the maturity level of the QMS, and
2. the maturity level of the process management.

The adoption of ISO 9001 has shown to be a persistent and growing phenomenon in the market, embodying all sectors, types of business, and company sizes (Psomas & Kafetzopoulos, 2014). However, some authors diverge about the influence that the implementation of an ISO 9001-based QMS has on organizations' performance (Ilkay & Aslan, 2012; Psomas & Kafetzopoulos, 2014). Therefore, there is no amply accepted conclusion in the literature about the relation between ISO 9001 and organizational performance (Terziovski, Samson, & Dow, 1997; Ismyrlis & Moschidis, 2015).

According to Ismyrlis and Moschidis (2015), performance is related to the extent to which organizations reach their goals. Several authors suggest that such purposes should not only focus on financial gains but include operational and market issues that will support economic improvement (Psomas & Kafetzopoulos, 2014; Ismyrlis&, 2015; Psomas&Pantouvakis, 2015).

On the other hand, Psomas and Kafetzopoulos (2014) realized research with 140 Greek companies. They concluded that companies with ISO 9001 certification overcome companies that are not certified regarding product quality, customer satisfaction, and operational, market, and financial performances.

The studies identified in the literature do not allow a definitive conclusion about the relation between ISO 9001 implementation and organizational performance. It is noticeable that:

(1) some studies found a definite link between ISO 9001 and all performance dimensions – operational, market and economic-financial (Fonseca, L. M., &Domingues, J. P. (2018); Arumugam, V., Ooi, K. B., & Fong, T. C. (2018);

(2) others do not find the relation between ISO 9001, and none of those performance dimensions (Ilkay & Aslan, 2012; Sampaio, Saraiva, & Monteiro, 2012);

(3) and others found the relation between the ISO 9001 and just a few performance dimensions, such as (Yousefinezhadi, T., Mohamadi, E., Palangi, H. S., & Sari, A. A. (2015).; Feng, Hussain, T., Eskildsen, J. K., & Edgeman, R. (2018).; Wiengarten, F., Humphreys, P., Onofrei, G., &Fynes, B. (2017); Psomas, Pantouvakis, &Kafetzopoulos, 2013)

On the systematic literature review about this topic in the period from 2010 to 2020, Sfreddo, Vieira, Vidor, and Zin (2018) found only two studies approaching that relation

explicitly. In one of these studies (Tasleem, M., Khan, N., & Masood, S. A. 2016) related ISO 9001 with processes management using the IDEF9000 standard, also presenting a step-by-step implementation tool. The authors developed a case study to demonstrate that IDEF9000 meets all requirements of ISO 9001, also mapping and automating the processes, providing fulfillment of all mandatory phases of the process, and a better understanding of ISO 9001 for the involved people. In the second study, Lindlbauer, I., Schreyögg, J., & winter, V. (2016), should the Service Blueprinting as a tool for organizational process mapping, allowing the subsequent implementation of ISO 9001.

2.1. Materials and method

To get a clear understanding of the relation between ISO 9001 based QMS and organizational performance, a systematic literature review of the topic in the period from 2010 to 2020 was conducted, considering, in this period, different ISO 9001 editions, principles and requirements. This systematic review aimed to

1. Analyze the main characteristics of the developed research relating to QMS to organizational performances.
2. Verify if the QMS and process management maturity levels of the studied companies are analyzed, and which models are used to such analysis.
3. Check how the organizational performance was analyzed and which are the performance indicators considered.
4. Verify if QMS and processes management maturity levels are related to the organizations' performance; and
5. Identify the main research contributions and the gaps to be filled.

For this purpose, the terms' ISO 9001' and 'performance' are defined to search studies about QMS, processes management, and organizational performance in the databases Emerald Insight® and Science Direct®. Although the QMS concept is more comprehensive than ISO 9001, this term was chosen to limit the number of studies to be analyzed, enabling the systematic review.

The analysis method consisted of three rounds. The first analysis round sought to apply the inclusion and exclusion criteria, verifying if the searched articles explicitly contained the relation between ISO 9001 QMS and organizational performance.

From the analysis of each article purpose, it was possible to separate the studies into four groups:

1. To analyze the relation between ISO 9001 based QMS and organizational performance.
2. To investigate the link between QMS maturity level and organizational performance.
3. To identify the organizations perceived benefits about ISO 9001 implementation
4. To compare performances of ISO 9001 certified and not certified companies.

Eleven studies analyzed the relation between QMS maturity level and organizational performance. However, the authors used different models to evaluate the QMS maturity level, i.e., no specific model was identified.

1. Ataseven, Prajogo, and Nair (2014) and Aba, E. K., Badar, M. A., & Hayden, M. A. (2016), for instance, evaluated the degree of ISO 9001 internalization in the organizations. Heras, Marimon, and Casadesús (2011), on the other hand,
2. Sought to identify quality tools implementation levels.
3. Padma et al. (2008) and Ismyrlis and Moschidis (2015) used critical success factors, extracted from the literature, to evaluate maturity. These factors are based on TQM. Moreover,
4. Willar et al. (2015) and Novokmet and Rogošić (2017) assessed the implementation level of the eight ISO 9001 principles while,
5. Terziovski et al. (2003) aimed to evaluate the quality management culture in the organizations, involving resources provided for quality, quality conscience, benchmarking to improve quality, focus on customers, and use of excellence as a performance measure.

Regarding the performance evaluation, studies using predesigned models and studies with some indicators based on a literature review are identified.

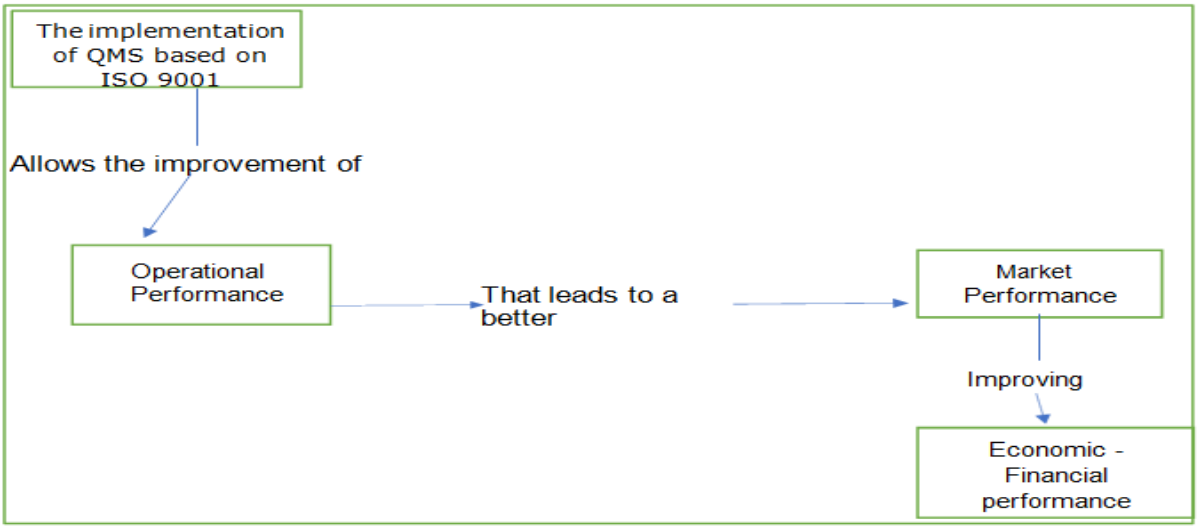


Figure 1-QMS-performance relation.

Figure 1. Shows the performance evaluation measures found in each one of the considered dimensions (operational, market, and economic-financial). The economic-financial performance includes indicators such as sales, sales by employee, exports, the price versus costs, profitability, and return on investments. On the other hand, market performance involves indicators such as market share, company's image, customer satisfaction and loyalty, customer complaint rate, and flexibility in negotiation with customers. The operational performance, in turn, is measured by productivity and costs, quality, and labor conditions.

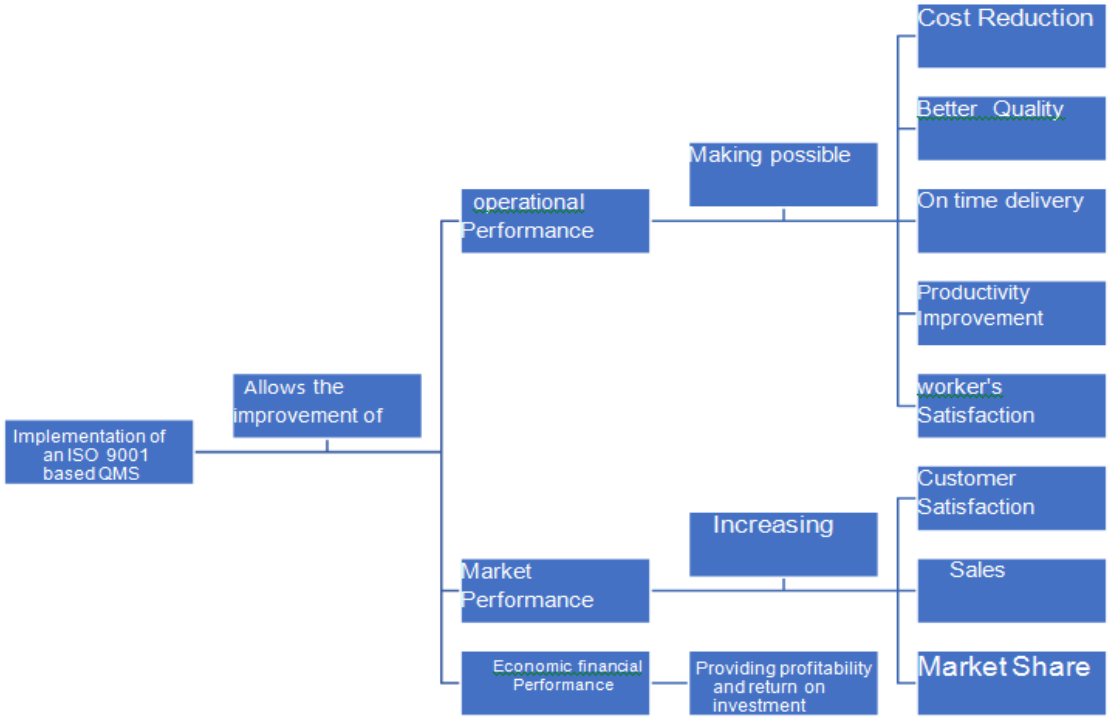


Figure 2- Relation among performance evaluation types

Considering the performance evaluation and measure cited by the authors and relating them with the three types of performance (operational, market, and economic-financial) considered in the present study, a conceptual map was developed for GPC.

The conceptual map presented in figure 2 serves as a starting point for future studies relating to ISO 9001 based QMS and organizational performance. This map also can be used as a reference to elaborate QMS performance evaluation models.

Based on these findings, it is possible to classify the articles according to the type of relation evidenced.

According to the literature review,

1. 30 of 57 analyzed articles (53%) found a positive relation between ISO 9001 and operational performance.
2. On the other hand, 12 studies (21%) did not find such ties, and the other 15 reviews (26%) did not analyze that relation.
3. It is also observed that 20 of 57 articles (35%) found a definite link between ISO 9001 and market performance.
4. However, 13 studies (23%) did not find such a relation, and 24 (42%) did not analyze that relation.
5. Finally, 15 of 57 analyzed articles (26%) found a positive relation between ISO 9001 and economic-financial performance. However, 21 studies (37%) did not find such a link, and the other 21 reviews (37%) did not analyze such a relation.

Based on these findings, it is possible to perceive that most studies indicate that ISO 9001 affects the organizations' operational and market performances. This cannot be said about the economic-financial performance once most of the studies did not find such a relation. However, taking into consideration that the economic-financial performance is a variable that depends on the market and operational achievements, it can infer that it also tends to be positive.

The results of this study give a practical orientation for the organizations, indicating which way the ISO 9001 certification can contribute to their performance improvement. In this sense, one of the identified aspects in most of the analyzed studies is that the increase of QMS maturity by ISO 9001 implementation tends to improve the organizations' operational and market performance, which indirectly will influence their economic-financial performance.

CHAPTER 3

RESEARCH METHODOLOGY

3. Research Method

The reason for this study is to propose a detailed framework of a QMS implementation for GPC with currently no-quality system capability. This framework facilitates a change of any organization from a no-quality system environment to an ISO 9001 QMS environment with marginal resources. The adaptability of this framework is described as a case study experience in chapter 5.

It discussed several reasons that affect QMS in GPC as barriers or critical success factors. The most widely considered barriers are lack of top management commitment, lack of resources, lack of expertise, and employee resistance.

However, in the production site, an effective quality management system would be very effective for the delivery of skincare products and high-quality test results in the lab. CLSI's quality management system standards would help in the labs with clear understanding and precise documents that would be helpful in the implementation of a quality management system. Our standards document recommendations, including management of laboratory documents, training sessions, competence assessments, laboratory design, and nonconforming event management. A detailed literature study was done to identify different frameworks and implementation strategies related to quality management practices. These frameworks are compared with each other to determine their applicability and impact. It is using the lessons learned from past studies in the literature to propose a detailed framework for GPC for achieving a successful transition to a quality system-oriented environment with a do-it-yourself approach.

Essential quality tools and data analysis techniques like charts are used, where possible. A Plan-Do-Check-Act (PDCA) approach was adopted to develop the QMS implementation framework to address the needs of the company. QC Lab has five phases of QMS implementation:

1. Plan
2. Define
3. Refine
4. Deploy, and
5. Improvement was proposed.

3.1. Quality Management Principles

QMS is defined as a management system used for managing a procedure to achieve maximum customer satisfaction at the least overall cost level to the organization while continuing to improve the process. As discussed in the literature, QMS implementation can be affected by either outer factors like customers and competitiveness or internal factors like organizations' aim is to enhance the quality of its current processes and culture within the company. ISO 9001:2015 standard states that the foundation of a QMS should be established based on eight quality principles (ISO 9001, 2015).

3.2. Process-based Approach

A process-based approach to QMS is proposed in ISO 9001 standard and defined as the application of a scheme of processes in an organization, combined with the identification and interactions of these processes. An organization's QMS adoption should start with identifying various processes and activities linked with each other. As shown in figure 3, QMS begins with customer processes, i.e., Customer requirements serve as an input to all the different methods and drive organizations' operations. Data in the form of customer requirements is directly fed to the product realization processes.

The data collected during these processes are then used to analyze the accomplishment of QMS using analysis, measurement, and development processes. These requirements for QMS linked to all these methods discussed in the next section. Results obtained from measurement and analysis procedures are then discussed in the management review meetings where management analyzes the situation and takes essential decisions related to the provision of resources if needed. These can be achieved by establishing resource management processes. Feedback can be obtained from the customers after delivery of Products and customer services, and consumer satisfaction levels are determined using measurement, improvement methods, and analysis.

Figure 3-Process-based Approach to Quality Management

3.3. ISO 9001: 2015 QMS Requirements

ISO 9001: 2015 standard facilitates QMS requirements in the form of eight different clauses that can be used to develop and implement a QMS. Figure 3 shows the process-based approach specified in the standard. Requirements of ISO 9001: 2015 standard are elaborated and provided in the form of gap analysis checklist

The first three clauses in the standard:

- Scope,
- Normative References and Terms, and
- Definitions,

Provide details and terms of the standard. However, the perspective of these clauses should also be considered.

1. Clause four is divided into two different sub-clauses. The provision stipulates overall obligations that every company should ponder. Clause 4.2 stipulates documentation requirements that can be established to manage QMS. Clause 4.2 is further split into clause 4.2.1 that stipulates info just about all-purpose documents in the form of quality manual, quality procedures, and quality records. Clause 4.2.2 provides explicit info about quality manual documentation. Likewise, clause 4.2.3 control of

documents and clause 4.2.4 control of records defines controls needed to manage quality-related documents like work instructions, forms, procedures, manuals.

2. Clause 5 offers obligations of top management of the company and further divided into clause 5.1 management commitment, clause 5.2-customer focus, clause 5.3-quality policy, clause 5.4 planning, clause 5.5 responsibilities& authority, and clause 5.6 management reviews.
3. Clause 6 is labeled as resource management and delivers requirements related to the provision of resources like human resources, infrastructure, and work environment.
4. Clause 7 is important clauses that divided into six sub-clauses. Clause 7.1 offers requirements related to the development of product realization, clause 7.2 offers requirements related to customer-related procedures, clause 7.3 stipulates requirements related to design and growth, clause 7.4 delivers necessities for purchasing processes, clause 7.5 offers requirements product, and service provision and clause 7.6 stipulates requirements needed for control of monitoring and measuring equipment.
5. Clause 8 is titled as analysis, measurement, and improvement is the last clause and is further split obsessed by clause 8.1 general, clause 8.2 delivering requirements for measurement and monitoring, clause 8.3 provides requirements desired for the control of the nonconforming product, clause 8.4 specifies about data analysis and clause 8.5 specifically providing instructions for improvement.

Quality Manual is labeled as the top-level document established by the top management of the company. It includes the Quality Policy, Quality Objectives, and, most importantly, any exclusions from the ISO 9001 requirements. It must be discussed with all the employees in the company.

3.4. PROPOSED FRAMEWORK

3.4.1. QMS Implementation for GPC

In this section, it has proposed a detailed framework for QMS implementation for the cosmetics industry. A step-by-step framework is intended to overcome or mitigate the barriers faced during QMS implementation, as discussed in the literature review. It has considered the significant obstacles and critical factors to implement successful QMS. It attempts to mitigate the effects of such barriers through our seven-step proposed framework for QMS development and implementation.

3.4.1.1. Step 1: Determine the Organizational Needs Do-it-yourself approach (PLAN)

The aim of this step is

(1) To identify the requirements of an organization with respect to quality systems. An organization should create a clear knowledge of QMS requirements and then compare them using a gap analysis tool to determine organizational needs.

(2) To overcome the barrier of a weak and incorrect knowledge of QMS requirements, it has offered a clause by clause clarification of the standard in the form of a gap analysis checklist in the table.

At this stage, an organization can evaluate the stronger areas within the organization using our comparison checklist. Other methods, like SWOT analysis, can also be performed. It proposes creating a quality improvement team of experienced employees and dividing the responsibilities for a quicker start.

3.4.1.2. Step 2: Develop QMS Infrastructure (PLAN)

In this step, it establishes the foundation of QMS, i.e., necessary procedures mandatory for efficient and effective implementation of QMS are defined as QMS infrastructure. Failed to handle these obligations will ultimately lead to the failure of QMS. These are corrective and preventive actions, internal audits, control of nonconformance and management commitment, control of documents and records. QMS for any company, irrespective of its nature and size, cannot perform without QMS infrastructure. It classifies QMS documentation under QMS infrastructure as follows:

1. Quality Manual and Quality Policy
2. Management Review Meetings
3. Control of QMS Documents
4. Control of QMS Records
5. Internal Quality Audits

At this moment, an organization should publish a quality management plan by launching a quality policy. A 'Quality Manual' is the document detailing the QMS of an organization. It comprises of quality objectives, quality policy, and other important information in it. 'Quality

policy' is defined as the top management's overall intentions and direction of an organization related to quality (ISO 9000, 2015). 'Quality objectives' are something aimed for or sought, compared to quality (ISO 9000, 2015). 'Management review 29 meetings' are actions commenced to determine the adequacy, suitability, and effectiveness of an organization's QMS to achieve established objectives. A non-fulfillment of a requirement is called a 'nonconformity' (ISO 9000, 2015).

3.4.1.3. Step 3: Develop QMS for Critically Substantial Process (PLAN)

The aim of this stage is to recognize the crucially important process within the organization, i.e., the method or functional area that possesses the highest risk in the non-fulfillment of customer requirements. This objective can be obtained by risk assessment on all the nonconforming findings in the gap analysis report. An organizational process or functional area possessing the ultimate risk can be labeled as critically essential for the organization.

(1) During this step, an organization must comply with all the non-conformances recognized in the gap analysis. The assessment of the scope of implementation is decided based on the risk evaluation presented on the gap analysis conclusions.
(2) Utilizing risk assessment, verify the effect of the gap findings, and set a priority for each of them. Dependent on the priority of reaction, initiate QMS only for a process or functional area with the highest priority level. Ultimately, nonconformance's that 30 possess the most top risks must be set on high-level priority.
(3) Create measurable quality objectives and develop QMS documentation necessary to prove and achieve these objectives.

3.4.1.4. Step 4: Implement QMS for slight a scope, determined in step 3 (DO)

The aim of this step is

(1) To apply the QMS design in the earlier stage. This execution must be restricted to the boundaries determined in step 3. Organizational changes occur during this stage.
(2) Process owners must ensure those process performers are trained on required changes and use of documentation.

(3) It is up to the management to make sure the availability of the needed resources, as needed, prior to introducing the implementation.

Keeping the procedure interactions in mind, training must be provided to process performers that will be affected due to the changes made.

3.4.1.5. Step 5: Maintain and advance the QMS (CHECK & ACT)

As soon as the implementation system has been achieved, QMS must be maintained to reap benefits. Organizations must devise a plan to successfully manage the QMS.

1. Regular client satisfaction levels must be measured for both internal and external customers.
2. QMS can also be retained using corrective and preventive action procedures, internal audits, and management review meetings.
3. Every nonconformance found during maintenance of QMS must be rectified before planning for QMS extension to other company processes.

Lessons learned through this stage should also be documented as a reference for potential development.

3.4.1.6. Step 6: Expand the QMS Scope

After ensuring the successful implementation of QMS for prior scope, QMS can be expanded to other areas, as needed. At this stage,

1. The risk assessment should be performed again to determine 31 of the most critical process and then develop processes to satisfy QMS requirements. Experiences realized during the earlier stages must be utilized to effectively expand the scope to improve implementation measures for the QMS expansion.

3.4.1.7. Step 7: Maintain and Improve the QMS

This step splits the same objective as step 5. The difference is that when the scope of QMS is maintained, obligations for QMS maintenance also increase. Therefore, organizations must react to the lessons learned during the QMS implementation phase for prior ranges and use it as feedback and valuable information to improve the implementation methods during the expansion of the QMS scope.

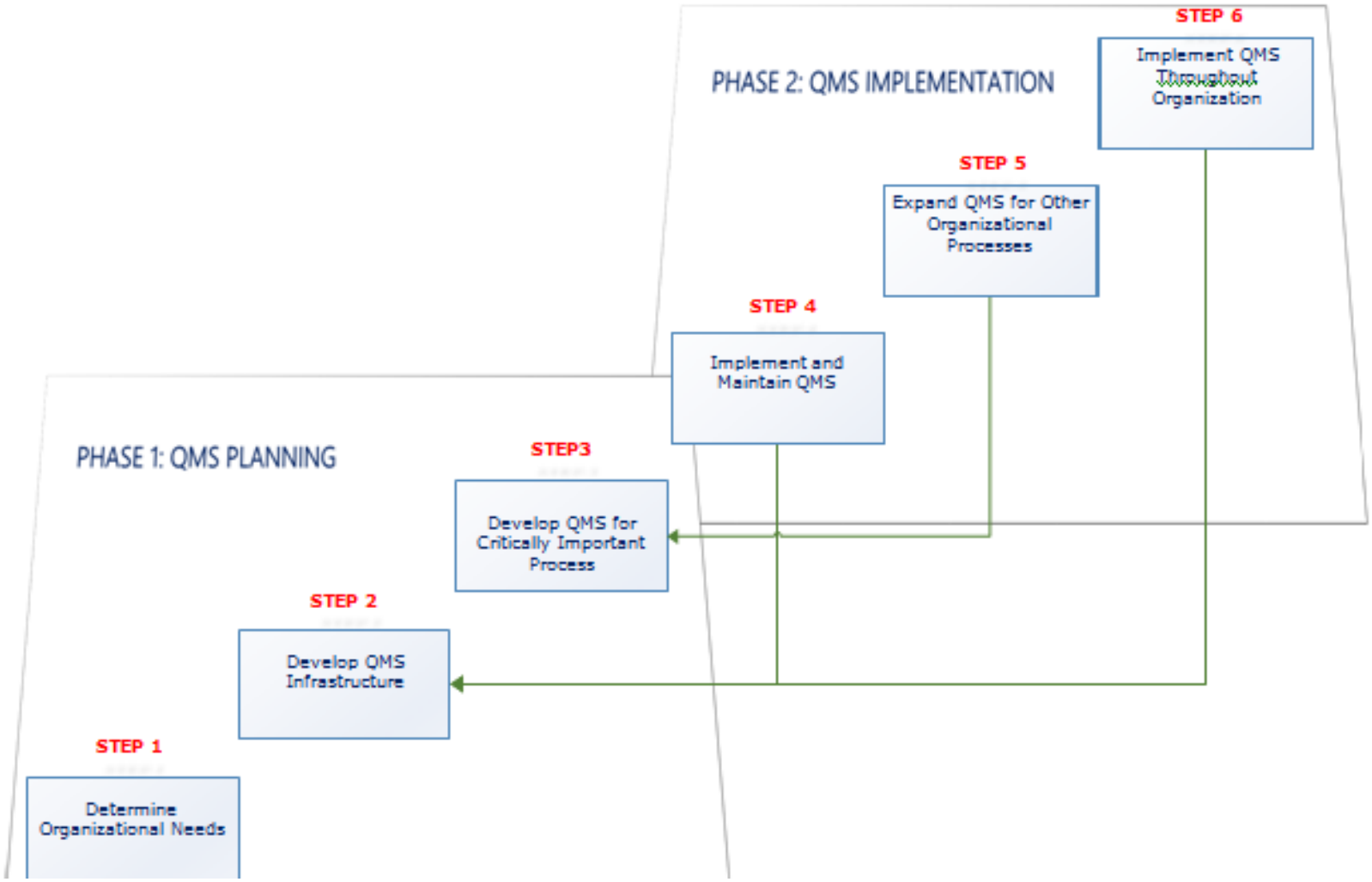


Figure 4-Proposed Framework for QMS Implementation

CHAPTER 4.

4.1. QMS Implementation for Golden Pearl Cosmetics

This section shows the implementation of the proposed framework in the GPC. The framework proposed in the prior section should be implemented by any organization regardless of its nature and size. The fundamental motivation for this study, though, was to guide businesses that want to transit to a QMS environment with limited resources.

4.1.1 About the company

The framework proposed was implemented in a cosmetics manufacturing company named GPC, located in CHICHAWATNI, Pakistan. This implementation program also facilitated the validation of our proposed model. GPC has been providing beauty products and more for skincare and cosmetics since 1997. The main products of the company are beauty cream and personal care products. Its manufacturing operations were initiated from Chichawatni, and now a sizeable modern set-up is established in Lahore to produce a wide variety of personal care products. The manufacturing facility of GPC is located on a 3-acre plot in Lahore Pakistan and has state of the art instruments and offices. GPC has laboratories like R&D lab, Q.C. lab, and microbiological lab equipped with modern scientific types of equipment and experts. Q.C. lab carries out analytical tests on raw materials as well as end products using state of the art machinery like U.V. (Spectrometry), HPLC, and potentiometer. R&D lab helps instability testing of manufactured products using the pilot batch mixer and stability chambers. GPC microbiological lab is used to perform all the microbiological tests under the controlled environment of the HVAC system and Biosafety labs standard cabin.

Experienced and qualified team of professionals in sales and marketing departments is operating in every city of Pakistan with the collaboration of technical and creative support. For effective, efficient, and convenient services to distributors and support of sale team, the zonal center is operational in major cities of Pakistan. To approach customers at the local level, distributors are working all over Pakistan. Devoted Export department to fulfill the international customer’s demands and has already launched distribution networks in many foreign countries.

Overall, the brand is getting a lot of success with its more products lined up like whitening soaps, scrubs, lotions, body sprays, facials, and anti-wrinkle formulas. GPC Beauty Cream

is one of the most used whitening beauty cream in Asia and particularly in Pakistan. Both men & women are using this cream. GPC's main product is skin whitening cream, which is made up of Carnauba Wax, Emulsifier, Kojic Acid Dipalmitate, Sunscreen Agents, Herbal Extracts, Bees Wax, Preservatives, and FD&C Colors. After knowing the ingredients, it is being observed that GPC cream is used for multi-purposes. It contains chemical ingredients than other skincare products, which decrease the possibilities of side effects.

GPC has supplied beauty products mainly in Pakistan but also other countries of the Asian region, etc. The company is growing rapidly and maintaining a reputation among its customers due to its ability and willingness to provide beauty products adjusting to its customer's demands. Most items are purchased from their vendors and machined to fulfill the customer's requirements. The raw material needed for skincare is manufactured to the specifications and assembled into products. Inventory related to the production of skincare products is taken from its vendors and stored at a separate warehouse (named warehouse 2, W2). Material is moved to the main warehouse (called warehouse 1, W1) for production procedures, as detailed on the production tickets. Material is moved between W1 and W2, separated only by a few blocks, by using trucks owned by the company. Sometimes products are directly shipped from vendors to the customer.

Logistics solutions offered by GPC operators allow for 24-hour transport of cosmetics to many points throughout the country, maintaining the required temperature conditions and tracking the route of cargo. It is a sign of the times; it is becoming increasingly crucial that many manufacturing companies already can trace products in the supply chain, the so-called traceability**.** This solution is very beneficial for businesses in any irregularities or damage because it enables them to reach a specific batch of products and withdraw it. It, therefore, facilitates a reaction, but only when a crisis has already occurred.

To facilitate investment and enter new markets, the optimization of the international supply chain, from supply to production centers, to the final distribution of finished products, is essential for success.

Among the service GPC offer to our clients of cosmetics, hygiene and beauty are included:

Services for the production line

1. Analysis of workflows and recommendations based on seasonality, suppliers' location, and the type and volume of supplies (whether ingredients, packaging, promotional items, etc.).

2. Organization and optimization of the national and international collections: thanks to the management of customs and fiscal representation service, the reliability of the flows, and continuous emergency services.
3. Intermediate storage with value-added services: quality control, preparation of orders, or post-production.

4.1.2. Services for the distribution of the final product

1. Inventory management and order picking.
2. Organization of continental and intercontinental deliveries.
3. Control channels of distribution: supermarkets, specialty shops, pharmacy, hairdressers, direct sales, spa 'duty-free' shops, outlets, etc.

4.1.3. Value-added services

1. Urgent and special transport.
2. Logistics solutions for promotional activities, the launch of new products, trade shows, etc.
3. Management of materials handling solutions.
4. Simplification of the administrative operations

Astoundingly though, the company does not have any data collection system established and relies only on the capability and knowledge of its employees to enable the supply of quality products and services to its customers. There was no standard in the R&D labs and Engineering department of GPC. Studies on quality management systems (QMS) show that all the quality relevant components within an integrated system are linked with the main framework set by the ISO 9000 series of standards. However, the idea of decreasing the variability through standardization and meanwhile looking for continual improvement in the system often seems paradoxical and is misinterpreted for R & D activities. But GPC is not even ISO certified and engaged in R & D functions. This area mainly focuses on bridging the gap between the principles of the quality management system and the requirements of quality assurance.

Due to Increase in the complexity and globalization of the competitive business environment has made the Engineering department and R & Das a competition. So, it is essential to have systematic processes for an R & D activity for the quality management system. Perhaps an activity constitutes a process or a set of methods / sub-processes. ISO 9001: 2000 and ISO 9001:2015 standard, which is a proper procedure driven quality management system, has a strong potential to manage and control the R & D quality very effectively. Thus R& D

managers have the extra edge to get total quality management (TQM) by implementing ISO QMS in their organizations.

Thus, quality levels and the effectiveness of its current processes cannot be evaluated. Lately, the company had experienced a higher rate of product returns and customer complaints. Replacements are provided to the customers without any quality analysis of the performance. It was mainly due to the lack of qualified personnel in the company. However, GPC was determined to react to decrease the rate of customer complaints and realized a need for external assistance.

4.2. Engineering and Laboratory Equipment List

The equipment required in cosmetics and skincare products manufacturing. Cosmetic products (including quasi-drugs) come in an overwhelming variety, and there is also a significant distinction in their color and smell. That is why production processes, manufacturing equipment, and other technologies are developing at a rapid rate with ongoing research on cosmetic products to make sure that the best quality products are produced. The major types of equipment are

1. Grinders
2. Dispersing emulsifying equipment,
3. Cooling equipment,
4. Mixers,
5. Molding equipment, and
6. Filling equipment.

The key reason for using grinders is not usually grinding; they are more often used to make the mixing process faster by breaking up the powder lumps. Mixing equipment can be divided mainly into the rotatory type and the fixed type. It is the container that rotates, and the various models that have been designed, including a tubular type, a cube-shaped type, a double cone type, a pyramid type, and a V-type. With the fixed type, the container is fixed, and a screw, ribbon, or other types of stirring apparatus revolves inside it.

The equipment required for production were

1. Milling color
2. 3-roll-mill
3. Hammer Mill
4. Big Jet Mixer
5. Cowels Dissolver
6. Horizontal bead mill

7. Sm KD ceramic bead mill
8. Dispax Reactor

Milling machines are calibrated and tested manually to ensure that they are checking registration marks, greyscale values, and color bars occasionally is calculated against the product specification and agreed on quality standards.

Horizontal bead mill confirmed the sealing property of a material to avoid the pollution of the product and to make sure the purity of the product. Horizontal bead mill is appropriate for high fitness grinding processes and the same high precision.

The DISPAX REACTOR is shear, three steps dispersing machines to produce delicate suspensions and micro-emulsions. Three rotor-stator combinations (generators) in a sequence produce a small dewdrop or particle size, with the minimum distribution.

4.2.1. HPLC LAB

High-performance liquid chromatography (HPLC) is a vital analytical method generally used to divide and quantify components of liquid samples. In this process, a solution (first phase) is pumped with a column that helps in the packing of small porous particles with a second phase connected to the surface. The different soluble of the sample components in the two phases cause the components to move through the column with various average velocities, thus produce separation of these components. The pumped solution is known as the mobile phase, while the phase in the column is called the stationary phase.

4.2.2. Microbiological Lab

1. Establishment of scientifically sound and proper specifications, sampling plans, standards, and test procedures designed to ensure that components product containers, in-process materials, labeling, closures, and products conform to suitable standards of identity, quality, strength, and purity.
2. Establishment of specifications, sampling plans, standards, and test procedures that are written, approved, justified Sampling, documented, and testing procedures that are used for: each lot, in-process materials, components, drug products.
3. Calibration at appropriate intervals of Instruments, Gauges, Apparatus, Recording devices, with written procedures.

4.2.3. HVAC

A well-selected and installed HVAC system can increase the comfort and productivity of occupants. However, a badly selected system will create problems for the facility executive, whether it is hot/cold call, indoor air quality issues, or any astronomical energy bills.

4.2.4. BSL 2 Lab cabinet

This document specifies requirements to establish and maintain a safe working environment in a BSL2 laboratory. Safety guidelines and requirements set forth to specify the role and responsibilities of the laboratory safety Engineer in ensuring that all employees take personal responsibility for

- Own safety at work, and
- Safety of others who can be affected by it.

BSL2 Cabinet services are essential for the care and must be available to meet the needs of all patients and the personnel responsible for the care of those working there, such services include:

4. Arrangement for examination requests.
5. Collection of samples
6. Transportation
7. Storage
8. Processing
9. Examination of skin samples
10. Subsequent interpretation
11. Reporting and advice

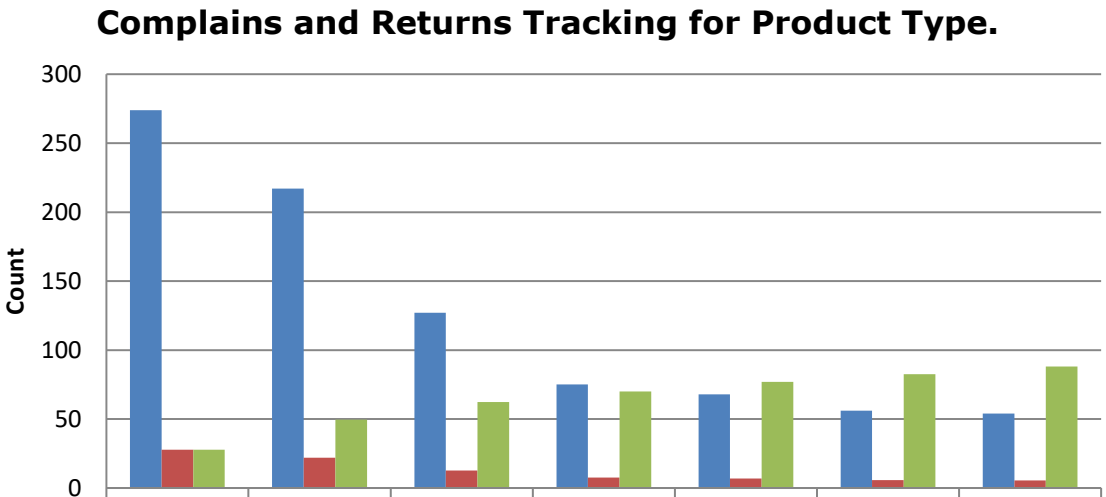
There should be a document stating results achieved or providing evidence of activities performed, and stored data can be used to,

4. Familiarize traceability and
5. To provide evidence of verification,
6. Preventive action, and
7. Corrective action.

Note 2 to entry: Generally, records need not be under revision control as per ISO 9000:2015, 3.8.10.

4.3. Analysis of Customer Complaints and Customer Returns

Due to the lack of any quality-related data, a simple return tracking system was formed to gather some data to study consumer returns. Critical information captured in the returns tracking was the type of product, return info, or cause of return and returns code. Due to the shortage of time commitment and employees, returns tracking responsibility was divided between customer service personnel and inventory specialist. Process flow maps are developed to better understand the working of organizational processes.



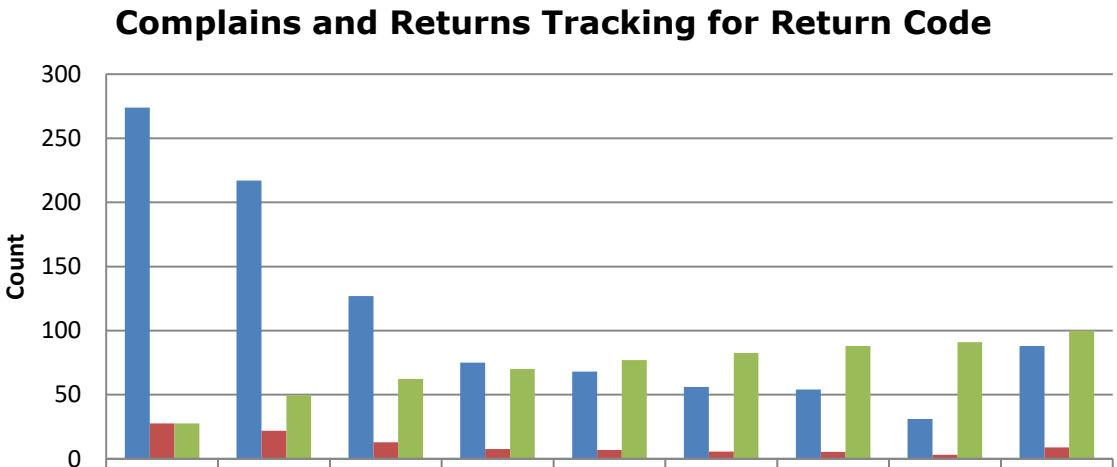
	Defective	Sale Error	Shop Error	Customer Error	Extra Product	Picked Wrong	Delivery Damage
count	274	217	127	75	68	56	54
percent	27.7	21.9	12.8	7.6	6.9	5.7	5.5
Cum %	27.7	49.6	62.4	70	76.9	82.5	88

Figure 5-Analysis for Product Type Using Returns Tracking

Customer returns are initiated by the sales representatives or project managers due to their direct relationship with the customers. However, one major obstacle was those customer complaints, or returns were not officially documented, and hence the reason for returns needed to be taken when the return was received back at the company's facility. Less number of employees in the customer service department was a reason as difficult to call the client and confirm the reason behind their return.

The study of details related to faulty products was carried out. There is inconsistent and incomplete information on returns found in some cases. However, most of the defectives

are found to be manufacturing-related vendor defects. Most frequent defectives are due to warping of the products, duplicate products in the market, Poor quality of raw material and lack of customer support, etc. GPC does not produce ingredients, so they buy it from different vendors. Similarly, wrongly written production tickets by sales representatives are also found to be a significant problem. It believed that purchasing errors and shop errors are mainly due to lack of training and poor attitude, which could be controlled immediately.

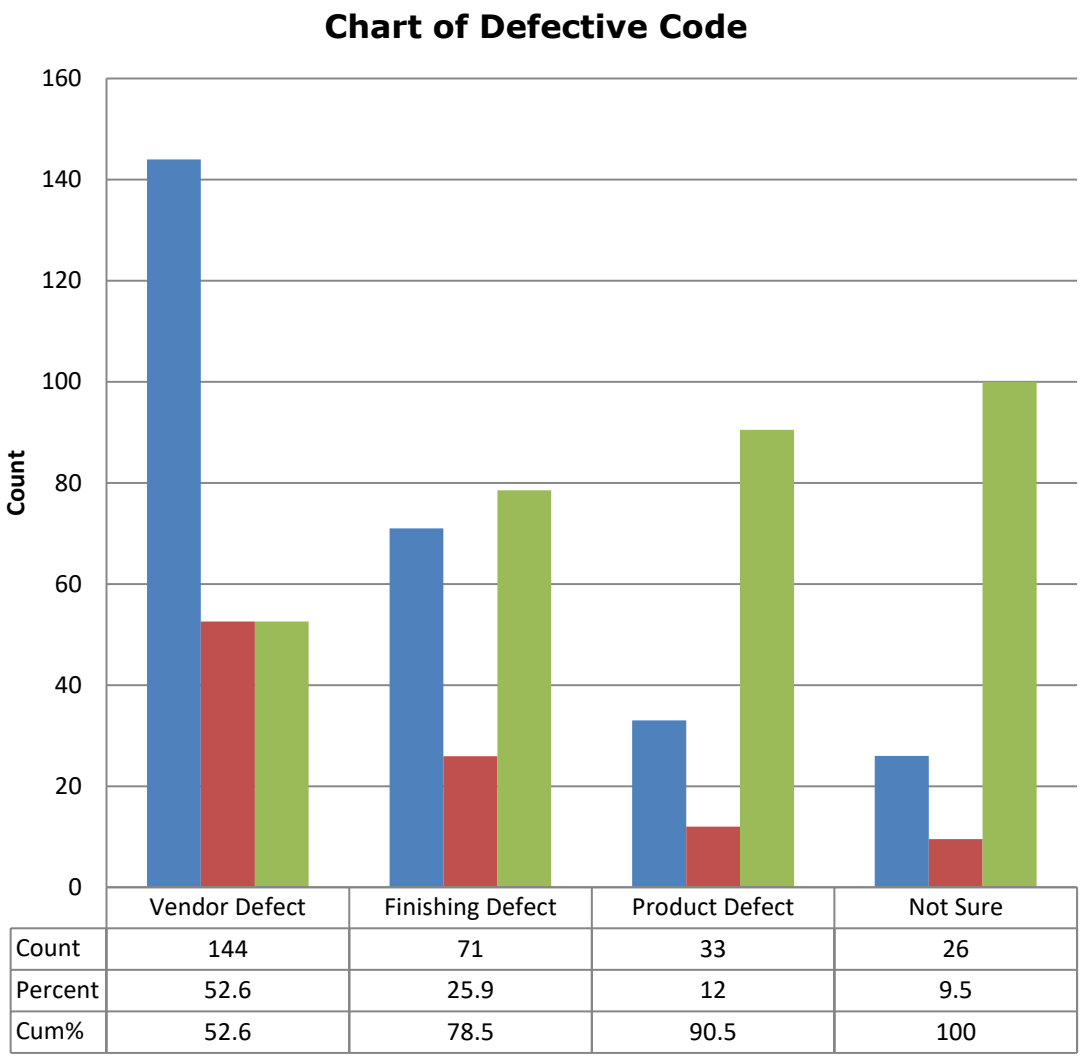


	Defective	Sale Error	Shop Error	Customer Error	Extra Product	Picked Wrong	Delivery Damage	Vendor Error	Others
Count	274	217	127	75	68	56	54	31	88
Percent	27.7	21.9	12.8	7.6	6.9	5.7	5.5	3.1	8.9
Cum %	27.7	49.6	62.4	70	76.9	82.5	88	91.1	100

Figure 6-Analysis for Return Codes Using Returns Tracking

Through this period, a short customer satisfaction survey was also conducted by the company. Some of the findings from the survey are discussed below.

1. Improvement of GPC delivery service as incomplete delivery orders is shipped.
2. Improve packaging to avoid delivery damages.
3. Delivery timing can be improved.
4. Products not machined to specifications. (Providing onsite service compensates machine errors).



	Vendor Defect	Finishing Defect	Product Defect	Not Sure
Count	144	71	33	26
Percent	52.6	25.9	12	9.5
Cum%	52.6	78.5	90.5	100

Figure 7-Analysis for Defective Codes Using Returns Tracking

4.4. Need for Quality Management at GPC

Analysis of the customer returns data showed that in most cases, returns are made due to operational error and manufacturing defects. If sales error, purchasing errors, and other errors can be controlled, the rate returns should be decreased. Hence, GPC needs an effective management system that will not only identify the root causes behind an increased number of customer returns but also control current processes and improve them to facilitate increased customer satisfaction. The company surprisingly lacks standardized documentation and monitoring activities required to identify, control, and correct problems before reaching the customer. However, there is a no quality-oriented culture in the company evident from the absence of any quality-related policy.

Info acquired through the returns tracking has helped GPC realized several quality-related problems within the organization. The inferior quality of raw material is one of the major reasons for product returns. Such manufacturing-related problems need to be recognized when the material is being received. Thus, the company needs a system that will organize its process, control its operations, document major findings, and facilitate evidence-based decision-making. The company needs appropriate documentation to enhance internal communication to avoid operational errors within the company. Similarly, GPC also requires an efficient training program to enhance quality understanding and increase proficiency levels on the assembly lines to ensure that manufacturing defects are detected and controlled. Top management of the company believes that the establishment of a QMS will enable the change in company culture and drive quality improvement within the company.

The major issue was many R&D and Engineering department members were focusing on re-investing project management and product development. In contrast, software development was utterly ignored in practices specifically in the planning and documentation principles related to these main R&D activities were outdated hardware and designer did not have any manual or training sessions for their work. They need more visibility and pre dilatability in the R&D procedures not to speak of uniformity. The production way for managing contract research and development activities, researchers, and project managers has to be prepared not only with more comprehensive guidelines but with more practical guidelines, document selections, and proper plan templates.

ISO 9001 considered being the perfect answer for all their demands, so following that, a recommendation for production and hardware and software quality manual was developed. Practices of hardware and software development like project manual that includes hardware/software instructions as well as design document skeleton and templates and a recommendation to R&D team was suggested to design software to enhance the visibility of software design it was suggested to implement ISO 9000-3 guidelines use as a framework for the software quality system because that gives a clear QMS and have been applied for the client.

4.5. Planning for Quality Management at GPC

This section discusses planning for quality system implementation was conducted at GPC. The earliest step in any Quality system implementation is an evaluation of the existing system with respect to the conditions of QMS.

1. It is essential to determine the gap between QMS requirements and organizations' current system to assess the exact needs of an organization. This also avoids duplicity and over the implementation of the QMS requirements and with over implementation program.
2. A gap analysis was used as the self-assessment tool to identify the genuine needs of the company. The gap analysis checklist was used to compare the requirements of QMS and current processes in the company.

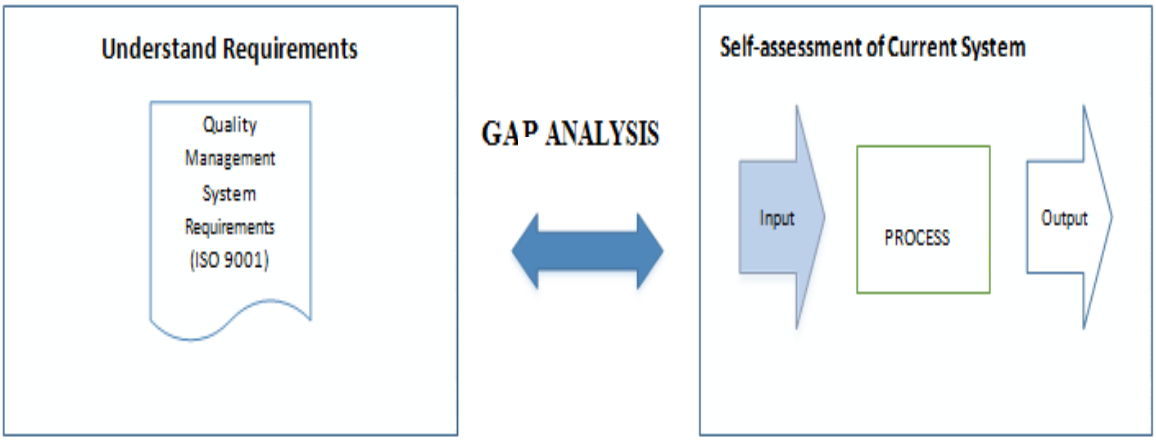


Figure 8-Gap Analysis with ISO 9001

The comprehensive gap analysis report is presented in table 3. The gap analysis findings are categorized as conforming, nonconforming, or opportunity for improvement. QMS requirements wholly formed at the company are called as conforming requirements. QMS requirements that are not yet being established within the company are named as nonconforming requirements. Similarly, partially set requirements that need further considerations to comply fully with QMS requirements are called as opportunities for improvement. Conforming elements are designated as Y (Yes); nonconforming elements are designated as N (No) and the chance of development as O.

From the above literature studies, it categorized the organizational barriers into 'barriers during QMS planning' and 'barriers during QMS implementation.' The gap analysis report and return tracking data were used together to develop a strategic implementation plan for QMS implementation at GPC. Based on the data acquired from the returns tracking and literature review findings, it found many significant gaps during the assessment of the current system at GPC. These conclusions also explained the lack of quality culture in the company. Gap analysis revealed GPC to have a no-quality system in its organization, lack of standardized processes, poor internal communication, and lack of documentation, etc.

The evaluation of the returns tracking data and gap analysis successfully identified the needs of the GPC. However, it was essential to get top management support and commitment to proceed with the implementation plan. The organization believed in QMS compliance. But it feared the change in the company's culture would be recognized by everyone. The company ran on a tight budget and could not guarantee the accessibility of resources that might be necessary. Thus, it was agreed to develop QMS and implement within small scopes that possessed higher risks of noncompliance.

4.6. QMS Development for GPC

In this section, it will be discussed about QMS development and implementation plan for GPC. QMS for GPC is developed around the actual needs of the company. These needs are determined by assessing the current quality system in the company using gap analysis and returns tracking data.

The study of returns tracking data collected at the company provided insight into current problems at the company and cause for customer dissatisfaction. Thus, QMS developed for GPC is intended to bridge the conclusions of the gap analysis. Having said that, the method adopted to design and develop QMS will overcome or mitigate the negative conclusions found in the literature. During this stage, it considered all the critical factors during phase First steps taken to overcome barriers are discussed below:

1. **Lack of leadership -** Operations manager, were given the responsibility of a Management Representative (MR), to be the central coordinator and leader to drive QMS. The development and implementation plans are communicated to the management through MR. Process owners are appointed as in charge of documentation related to their functions.
2. **Lack of understanding of QMS -** a QMS requirement is clarified in the gap analysis to make sure it is available to all the employees. Presentations are conducted to familiarize management with QMS and its needs.
3. **Employee resistance to change -** QMS documentation is approved by process performers before making them official.
4. **Absence of control over documentation -** It was essential to prevent waste in the form of excessive documents. Thus, QMS documentation was only developed for the requirements of the company.
5. **Failure to provide resources -** This hurdle was confronted by targeting QMS implementation only for a small scope that retained most risks. At the same, QMS

was incorporated within the current process with minimal change. There was a fear that documentation and transition might not be readily accepted by the employees despite seeing its benefits.

6. There were **no manuals and product plans** in the development labs and no required data maintenance and record.
7. **No work plan** for the Engineering department and engineering department is working on arbitrary calculations and working without any manual at the production area and without any safety precaution made.
8. **No QMS implemented** in the R&D department and QC lab plus no protocols for HPLC labs.

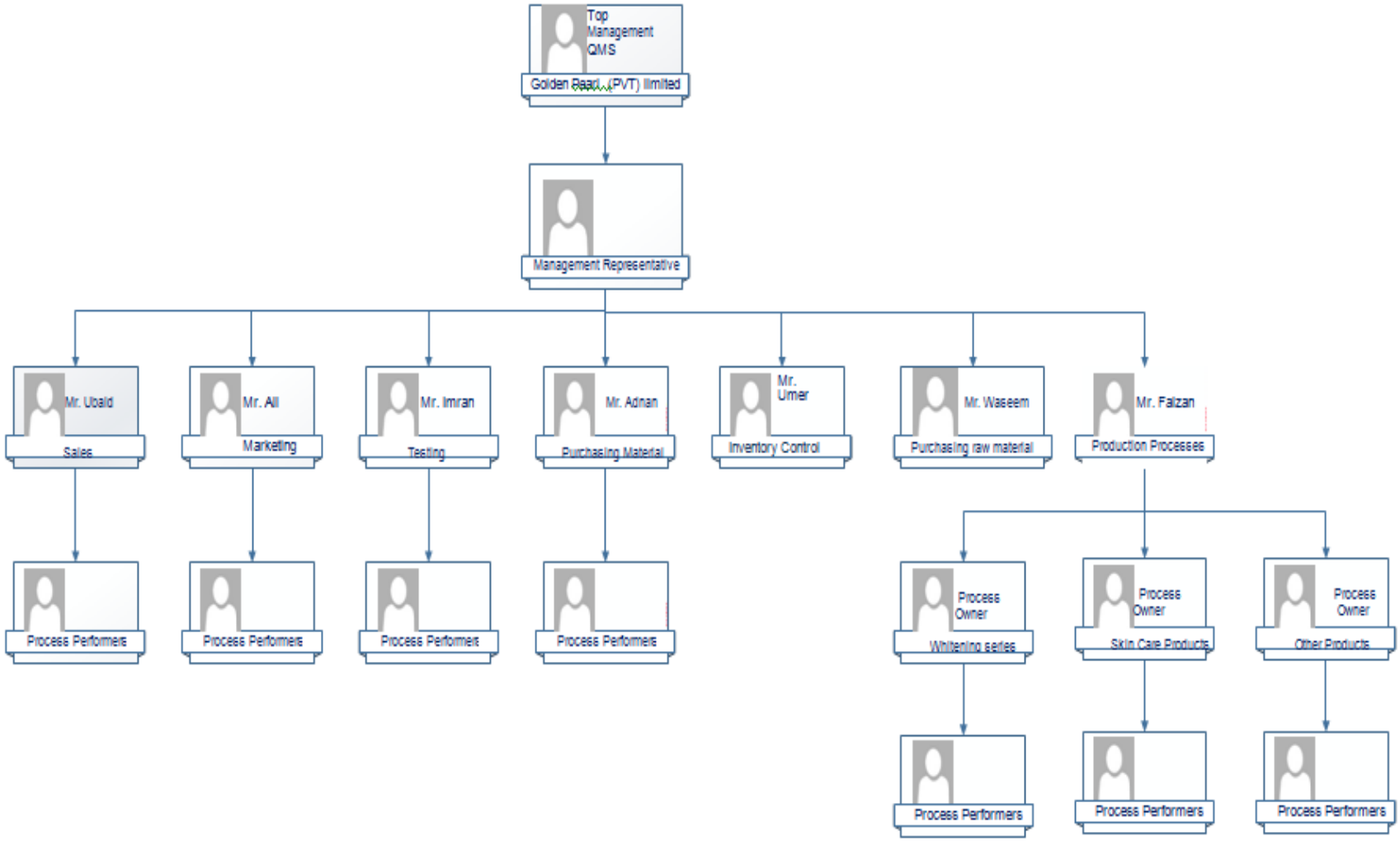


Figure 9-QMS Hierarchy Chart

Now, it discusses QMS for GPC in detail below. Phase 1 of QMS planning for GPC is explained from steps 1-3. Phase 2 QMS implementation is described from levels 4-7.

4.6.1. Step 1: Identification of real organizational needs

As per our recommended framework, the first stage was to determine the needs of GPC. Thus, it assessed the current quality system status of the company using the gap analysis tool and matched them using QMS requirements specified in ISO 9001 standards. The returns track also aided the required information to define the needs of the company. These requirements are written further down.

1. Documented procedures for standardized work
2. Measurement and monitoring of product realization processes to identify and control non-conforming products
3. Establishment of a data collection system to define process performance and facilitate significant-quality levels
4. Acceptance standards for each procedure
5. Receiving assessment plan for purchased products

Organizational processes known for the company are listed as follows:

1. Sales contract review process
2. Customer communication process
3. Purchasing process
4. Vendor evaluation process
5. Production control and product release process
6. Preventive Maintenance and calibrations
7. Packaging and delivery
8. Returns
9. Control of customer property
10. Monitoring, Measurement, and analysis

These processes are documented using process documented procedures, flow maps, records, as required. The interaction of these methods is documented using a 'process interaction matrix.'

4.6.2. Step 2: Develop QMS Infrastructure

QMS in any company cannot be successfully implemented without QMS infrastructure. It developed a QMS infrastructure based on five critical and mandatory QMS requirements. Failure to manage these requirements will ultimately lead to failure QMS. These are

1. Corrective and preventive actions
2. Management commitment
3. Internal audits
4. Control of documents and records
5. Control of nonconformance

It also believes that these are the most crucial requirements, and QMS cannot operate without these regardless of its scope. These processes are used to maintain and control the entire QMS system. QMS implementation at GPC was started by establishing a quality policy draft for the company. Thus, GPC created a quality policy draft for the company as described below: *"GPC is committed to beyond our customer's expectations through the quality of our services and products achieved by, continuous development in all areas, on time and accurate deliveries of our products, investment in our employee-owners and our structure and being accountable for our actions and results."*

Documents created for QMS infrastructure are,

1. Quality Manual
2. Quality Policy
3. Control of Documents and Records
4. Control of Nonconformance
5. Corrective and Preventive Actions
6. Management Review Meetings
7. Internal Quality Audits

It comprised of Quality policy and quality objectives created for QMS. It also contains the process connections and QMS hierarchy chart.

Control of Documents: This procedure illustrates the process of controlling documents and changes made to documents that are a part of the QMS at GPC. The requirements specified in this document are:

1. Approve documents for adequacy before issue,
2. Update and review as needed and re-approve documents,
3. Ensure that all the updates and the current revision status of documents are acknowledged,
4. Ensure that appropriate versions of applicable documents are available when needed
5. Ensure that documents remain legible and identifiable,

6. Ensure that documents of external origin, resolute by the organization to be essential for the planning and operations of the QMSs, are identified and their distribution controlled,
7. Avoid the unintended use of outdated documents, and to apply suitable identification to them if they are retained for any reason.

*A **Quality Record** related to the control of documents procedure is titled as 'master document index,' and its generic form is described in detail.*

Control of Records**:** This method specifies the controls needed for the storage, identification, retrieval, protection, disposition of record, and retention. Records are generated and analyzed to determine.

1. If the given procedure has attained its key accomplishment indicators within acceptable limits
2. If the given procedure is meeting its process criteria
3. If the given procedure has achieved its quality objective
4. If specific non-conformances or a nonconformance trend need corrective actions

*A **Quality Record** associated with this process is titled as 'master quality record index,' and its generic form is described.*

Control of Nonconformance: This process defines the requirements for identification, elimination, and disposition of non-conforming products. Products that do not conform to product demands are recognized and controlled to avoid their unintended use or delivery to the customer.

4.6.2.1. Internal Quality Audits Procedure: The objective of this process is to provide a planned and documented method for holding out internal quality audits to ensure that the QMS at GPC conforms to the obligations of the International Organization for Standardization 9001:2015. This procedure also provides provisions to verify whether the quality activities established at GPC comply with planned arrangements.

*There are four different **Quality Records** related with this procedure, and their generic versions are*

1. *Internal Quality Audit Schedule*
2. *Internal Quality Audit Report*
3. *Internal Quality Audit Feedback*

The additional document is developed for this procedure, which is titled 'Internal Auditors Manual.' The target of this manual is to give detailed information to the internal auditors of the company for creating and taking out internal audits for quality.

Corrective and Preventive Action (CAPA) Procedure: This process is used to establish and outline the process for documenting, analyzing, initiating, and fulfilling corrective and preventive actions.

1. *There are two **Quality Records** related to this procedure, and they are titled as 'corrective and preventive action' form and 'verification of the effectiveness of CAPA' form.*

		Type of Processes	Quality System Processes								Organizational Processes													
		Process No.	1	2	3	4	5	6			7	8	9	10	11	12	13	14	15	16				
Type of Processes	Process No.	Interaction of QMS and Organizational Processess.	Control of Documents		Control of Records		Internal Quality Audits		Control of Non-conformance		Corrective and Preventive Action		Management Review Meetings		Customer Communication (Requirements)		Sales Contract Review		Purchasing		Vendor Performance Evaluation		Receiving W1		Production Control and Product Release		Preventive Maintenance and Calibration		Packaging and Delivery		Returns		Control of Customer Property		Monitoring, Measurement and Analysis	
Quality System Processes	1	Control of Documents	■	■	>		>	<	>		>	<	>	<	>		>		>		>		>		>		>		>		>		>		>	<
	2	Control of Records			■	■	>	<	>	<	>	<	>	<	<		>		>		>		>		>		>		>		>		>		>	<
	3	Internal Quality Audits					■	■		<	>	<	>	<		<		<		<		<		<		<		<		<		<		<	>	<
	4	Control of Non-conformance							■	■	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<
	5	Corrective Action and Preventive Action									■	■	>	<		<		<		<		<		<		<		<		<		<		<	>	<
	6	Management Review Meetings											■	■	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<	>	<
Organizational Processes	7	Customer Communication (Requirements)													■	■	>	<	>	<		<		<		<						<		<	>	<
	8	Sales Contract Review															■	■	>	<		<				<						<		<	>	<
	9	Purchasing Process																	■	■	>	<	>	<		<						<		<	>	<
	10	Vendor Performance Evaluation																			■	■	>	<	>	<						<		<	>	<
	11	Receiving W1																					■	■	>	<				<		<		<	>	<
	12	Production Control and Product Release																							■	■	>	<	>	<		<		<	>	<
	13	Preventive Maintenance and Calibration																									■	■				<		<	>	<
	14	Packaging and Delivery																											■	■		<		<	>	<
	15	Returns																													■	■	>		>	<
	16	Control of Customer Property																															■	■	>	<
	17	Monitoring, Measurement and Analysis																																	■	■

	Process C		Process D	
Process A	>		>	
Process B			<	
Process C			>	<

Process Interaction Matrix.

Process 'A' provides i/p to Process 'C' and Process 'D'.
Process 'D' provides i/p to Process 'B' OR Process 'B' receives i/p from Process 'D'.
Process 'C ' may provides i/p to Process 'D'.
Process 'D' may provides i/p to Process 'C' OR Process 'C' may receive i/p from Process 'D'.

Figure 10-Identification and Interaction of processes

4.6.2.3. Management Review Meetings:

This method defines the process and methods for conducting Management Review Meetings, at planned intervals, of the QMS implemented at GPC to make sure its continued appropriateness, effectiveness, and adequacy.

*A **Quality Record** related to this procedure is titled a 'management review meeting' form report.*

4.6.3. Step 3: Develop QMS for Critically Dynamic Process

Aim of this step was to establish the most important process or functional area within the company that has the most adverse influence on GPC's capacity to provide quality products and services to the clients, due to high risks of nonconformance coupled with it. This was decided using the gap analysis report and performing a risk assessment for each nonconformance identified in the gap analysis findings. Each nonconformance was carefully evaluated on potential impact and action priority required. Info from the consumer survey analysis report and return track were also considered while defining the potential impact of the recognized risk, i.e., gap finding. Following risk assessment options are used:

Potential Impact of Risk	**Action Priority for the Risk**
Minimal Impact	*No Action required*
Moderate Impact	*Low Priority*
High Impact	*Medium Priority*
Severe Impact	*High Priority*

Table 1-Risk Assessment Category

Based on the risk assessment performed, the purchasing department was found to be the most critical functional area. GPC does not have fixed criteria to select vendors while purchasing raw material. Likewise, the company does not have any vendor evaluation criteria in place.

The vendor is selected based on the low price and quality of the products supplied. However, the company does not have any system establish to verify the quality of the purchased products and then facilitate evidence-based decisions.

This is an essential step in the product awareness process of the organization, as raw material is precisely supplied to the production or stored as inventory without any examination activities. Therefore, there was a demand for monitoring activities to identify the defective products provided by vendors and abolish them before production processes. This is also crucial as the gap finding also revealed that the company lacks control over its production processes.

There are no criteria for verifying the output of the prior process before accepting the next process. Thus, nonconforming material, if any, is not unchecked through the production

process and delivered to the product without final inspection. This was one of the main reasons for the high rate of customer returns, as discussed in the prior section. So also, due to the lack of a data collection system, product quality cannot be measured at any level of the production process. Thus, the quality level of the product cannot be evaluated. Hence, quality objectives and KPIs are recognized for organizational operations. A screenshot of the risk assessment is described in the following table. The full report is attached in Appendix Table 3.

All the nonconformities linked with purchasing would have a severe risk of supplying quality products to the customers. Nonconformities classified for the purchasing department, and product realization processes are also evident from the return tracking data analysis that highlighted the maximum number of defects due to vendor problems. Processes related to purchasing are documented as follows:

4.6.3.1. Purchasing Process:

The aim of this procedure is to describe the requirements for the effective purchasing process for GPC. This procedure is applied to all the vendors unless an exemption is approved by the management representative or the operations manager. This procedure describes requirements for control & selection of vendors, purchasing process & purchasing information, and verification of the purchased product. The assessment of vendor performance is described in a separate procedure titled '*vendor performance evaluation procedure.'*

4.6.3.2. Vendor Performance Evaluation Procedure:

It describes the process for performance evaluation of the vendor and its qualification criteria for the approved vendor's list. All the vendors are also assessed using a '*vendor quality questionnaire*' that comprises questions required to be answered by the vendor regarding its devotion to quality. Shipments are examined using a *'receiving inspection plan.'*

Vendor Performance Log: Info from the receiving inspection sheet is reassigned to the vendor performance log to evaluate the Total Score Earned by the vendor that defines the assessment of vendors into the AVL. Based on the accomplishment, vendors are assigned one of these quality statuses: (A*) Approved, Preferred, (A) Approved, (N) Non-Approved, or (P) Provisional.

GPC Risk Assessment and Gap Analysis

Sr. No.	ISO 9001:2015 QMS Requirements Clause 7.4. Purchasing Process	Gap Finding	Risk Impact	Action Priority
1	GPC has established criteria to select and evaluate suppliers?	N	Severe	High Priority
2	GPC has established procedures to evaluate its suppliers/vendor's ability to supply products that meet GPC's requirements.	N	Severe	High Priority
3	GPC ensures that supplier/vendor evaluation records are kept and discussed.	N	Severe	High Priority
4	GPC also ensures that all purchased products meet specified purchase requirements?	N	Severe	High Priority
5	GPC ensures that purchasing requirements are adequately specified before discussing them with suppliers/vendors.	N	Severe	High Priority
6	GPC has established product verification or inspection methods to ensure that purchased products meet purchase requirements.	N	Severe	High Priority

Table 2- GPC Risk Assessment and Gap Analysis

4.6.3.3. Approved Vendors List (AVL):

AVL is the list of vendors that fulfill GPC's quality expectations and fit into vendor selection criteria. Vendor quality performance is frequently monitored by inspecting every shipment of raw materials received at GPC. Any non- conformances found are documented on the '*receiving inspection sheet*' and controlled using the nonconformance procedure.

4.6.3.4. Vendor Quality Manual:

Generally, the purchasing department was documented using two procedures titled as 'purchasing processes and 'vendor performance evaluation and qualities to AVL.' A vendor quality manual was formed and supplied to vendors as guidelines manual that specified the expectations of the company. Each vendor was also assessed using a vendor quality survey and assessment by the end of every month by inspecting data to update the ranking of vendors

in the AVL.

Following vendor selection criteria (VSC) was endorsed by the Purchasing Manager (PM) and Operations Manager (OM) established at GPC:

- On-time Delivery: Shipment is received on the estimated time of arrivals (ETA) as listed on the purchase order.
- Quantity Accuracy: Quantity received vs. Quantity ordered.
- Quality of shipment (Product & Packaging Quality): Quality levels are acceptable or not for the condition of strapped, pallets, wrapped, and sturdy packaging (secure packaging).

It used the Likert scale as a reference to quantitively evaluates the vendor's quality performance. Vendor selection criteria were used key performance indicators. The vendor's performance will be determined using the Total score earned. Based on the Likert Scale, VSC will be given the following rankings during receiving inspection.

- Rating Of 1 = 0% – 39% (Not acceptable)
- Rating Of 2 = 40% – 59% (Requires Further Evaluation)
- Rating Of 3 = 60%-79% (Normal)
- Rating Of 4 = 80% – 89% (Satisfactory with Some Problems)
- Rating Of 5 = 90% - 100% (Appropriate Without Any Problems)

Total scores for VCS will be evaluated using weight factors. Amongst the VSC, the quality was the most important focus area, and hence it was assigned more points than other areas. Hence, it decided that the quality of shipment will be assigned total points of 40. Similarly, Quantity accuracy and on-time delivery are assigned 30 points each so that the total potential count a vendor would get for each shipment will be equivalent to 100. It used the rating from 1-5 with a total of 20 points each for easier calculations. It used the highest rating (5) to find out the total weight factor of each focus area (i.e., VSC). Hence the total weight factors for each measure are determined as follows.

- weight factor (Quantity Precision): Importance / Highest Rating = 30/5 = 6
- weight factor (On-time supply): Importance / Highest Rating = 30/5 = 6
- weight factor (Quality of Consignment): Importance / Highest Rating = 40/5 = 8

Cited weight factors will be used to find total scores for each vendor selection standards, as shown in figure 8. Based on the vendor performance evaluations, it categorized vendors as 'Approved, Preferred,' 'Approved,' 'Non-Approved,' and 'Provisional' Vendors. Vendors are identified as 'Approved, preferred 'vendors if they have continually delivered products in a way that meets and exceeds all of GPC's VSC. One of the following circumstances must be true

Vendor Evaluation Through Receiving Inspection

Key Performance Indicator *Vendor Selection Criteria*	**Performance Rating (PR)**	**KPI Weight Factor (WF)**	**Score Earned (%) (PR × WF)**
Quality of Shipment		**8**	
Quantity Accuracy		**6**	
On-time Delivery		**6**	
Total Score Earned			

Performance Rating:
1 = Unacceptable shipment
2 = Needs further analysis
3 = Average
4 = Acceptable with some problems
5 = Acceptable without problems

Figure 11-Vendor Evaluation Criteria

4.6.4. Step 4: Implement and Maintain QMS

This section will present the implementation part of the QMS. Due to the constraints in time, the QMS implementation was not entirely implemented in this company. The implementation plan adopted is discussed here. Prior to initiating the actual application of the documented process, all the documentation was approved by the management, process performers, the management representative, and the purchasing manager. The aim was to create significant-quality objectives. So, SMART (specific, measurable, achievable, realistic, and Timely) quality objectives are set for the purchasing department. These are zero purchasing errors and 90% acceptance of the incoming shipment.

4.6.5. Step 5 & 6: Expand QMS for additional Organizational process

As the implementation was not completely implemented, QMS expansion to other processes cannot be debated. However, an expansion plan is considered in this section to facilitate the development and eventual implementation of QMS throughout GPC. After the successful implementation of the QMS in the purchasing department, GPC should expand the scope to the most crucial procedure currently within the organization. To this stage, step 3 must be repeated by using gap analysis and risk assessment. Object Lesson learned during the prior stages must be utilized to effectively expand the scope to improve implementation measures for the QMS expansion. The figure below shows the complete interaction of all QMS processes, considering the full extent of the implementation of QMS at GPC.

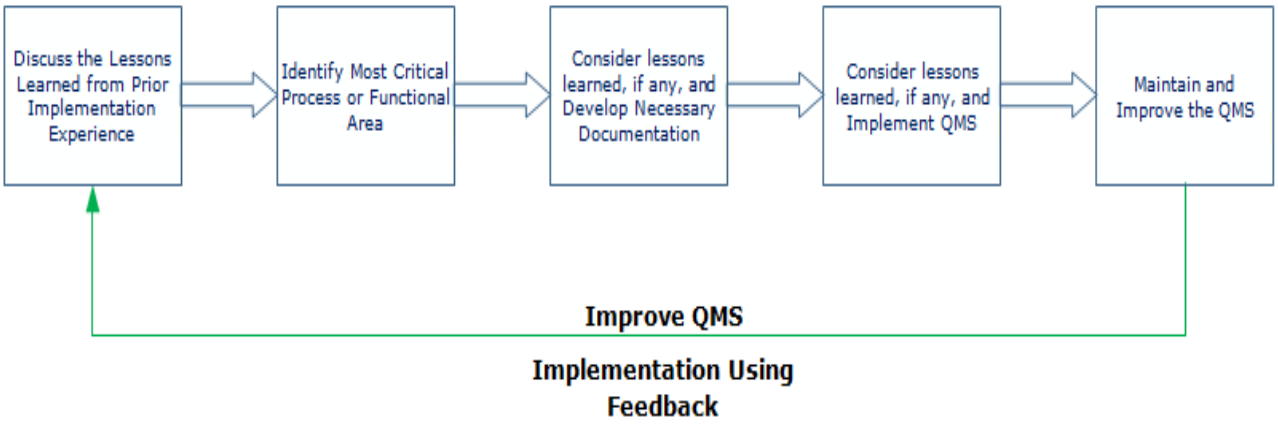


Figure 12- QMS Expansion Plan

4.6.6. Step 7: Maintain and Improve QMS implementation

To ensure that GPC reaps maximum internal benefits, it is essential to ensure that the QMS is maintained to drive continuous improvement. GPC must react to the lessons learned during the QMS implementation phase for prior scopes and use it as feedback and valuable information to improve the implementation methods during the expansion of the QMS scope. The purchasing manager must ensure that the performance of the purchasing process shall be tracked every month, and AVL is revised without failure to select vendors based on evidence data. The operations manager must ensure that the Control of non-conformance procedures and Corrective and preventive action procedure is always followed within the company. Internal audits are conducted using an internal audit schedule.

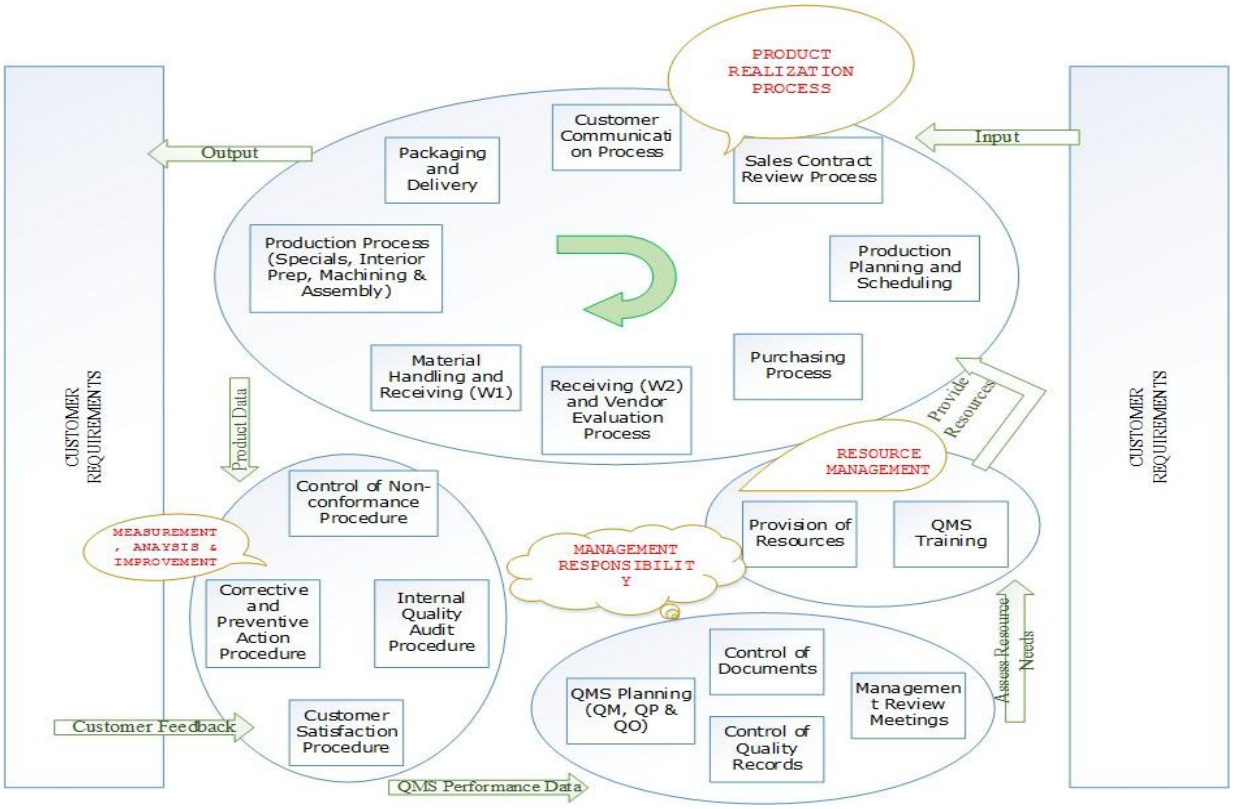


Figure 13-Process Interaction and Process-based Approach to QMS

CHAPTER 5

Conclusion and Future Limitation

5.1. CONCLUSION

The study proposed a quality management system implementation framework for Golden Pearl Cosmetics that wants to transfer from a no-quality system to an ISO 9001 QMS environment. The framework was built on assessing the needs of the GPC and integrating QMS with operational processes. This framework is explicitly applicable to the cosmetics industry that wants to achieve continuous improvement using QMS. The research planned a do-it-yourself approach that will significantly reduce costs linked with outside experts and consultants. Nevertheless, this framework is applicable only if an organization wants to adopt an incremental approach to continuous improvement. One major limitation is the long time that will be required to develop and implement QMS on smaller scopes and eventually to expand to organizational needs. It was also the first case study conducted for Golden Pearl Cosmetics for the engineering and R&D department. Thus, it also signifies the applicability of QMS in the Cosmetics industry.

Based on a detailed literature study, it was concluded that very few studies had been conducted related to QMS implementation and development for Cosmetics companies in Pakistan. It investigated several conceptual frameworks and compared them based on their applicability and impacts on organizational performance. It was found that many of these theoretical frameworks are too complicated and hence, does not have any implementation studies based on them. These outlines were classified based on impacts, i.e., adverse effect, QMS outputs, and QMS assets. Failed attempts and ineffectual implementation of QMS had negative effects on organizational performance. QMS assets are obtained with some degree of effective QMS implementation. Likewise, a successfully implemented QMS will deliver QMS outputs. The case study offered a cost-effective quality management model that can be adopted by any organization. This study will be useful for quality engineers, quality managers, quality consultants, and other quality practitioners looking to develop and implement QMS.

This research study found the validation of the proposed model challenging but successful. This case study revealed several issues for a cosmetics manufacturing company. A company without any quality system shortages in the data collection system required to facilitate evidence-based decision-making. This was found faithful at GPC as decisions were taken based on experiences rather than facts. QMS designed for the purchasing department focalized selection of vendors based on vendor assessments. A shortage of expertise to initiate quality

practices was another reason for GPC to not have any quality systems. This was especially true for GPC that run on a tight budget and lacked resources. Due to the absence of a documented quality system, the quality of processes and products could not be measured at GPC. The needs were recognized only when the rate of customer complaints went beyond the acceptable limits. Without QMS in place, there was a lack of control over organizational processes, lack of standardized procedures, lack of measurable performance indicators, correction system, and lack of problem detection.

Despite recognizing the need for QMS, there were many difficulties faced. All the processes in the company needed to be identified, verified, and properly documented. Due to a lack of time commitment to the project, top management of the company was not able to officially establish the quality policy. Due to a shortage of financial resources, the company was not able to hire an inspector necessary to perform an inspection of receiving shipments from the vendors. Hence, the duties were divided between employees, and therefore implementation processes were slower than expected. The operations manager of the company was appointed as the management representative to continuously monitor and facilitate QMS implementation throughout GPC. A hierarchy chart was developed to select QMS process owners and process performers. Notable benefits were achieved by GPC from this program. GPC obtained several QMS assets in the form date collection system that facilitates control, detection, and alteration of Nonconformance's, standardized operational processes with control of actions, evidence-based decision making using documented procedures, improved quality perception, and initiation of quality-oriented culture. These assets will provide GPC with improved operational performances, reduction of costs due to control of vendor problems and customer returns, and enhanced productivity using acceptance criteria, inspection checkpoints, and work instructions to perform the same work, the same way, and every time.

Based on the benefits achieved by GPC, our proposed framework was successfully validated with the help of this case study implementation. Our risk assessment on the gap analysis checklist can be used by any organization to identify critically essential processes and real organizational needs. Thus, it was recommended to use the proposed framework for future QMS implementation initiatives in any organization irrespective of its size and nature. This study provided generic versions of QMS documentation that can be used by quality practitioners seeking quality improvements in their organizations.

5.2. Limitation and Future Research

Despite their contributions, some limitations can be observed in this systematic review. Among them, it can be highlighted the lack of articles written in a language different than English,

which can be approached in future studies. It is also suggested more in-depth research about the influence of operational and market performances on economic-financial performance, a relation that was not analyzed in this article.

Future studies may also examine the validation of performance measures and the identification of explanatory variables for cause and effect relationships, such as situational contingencies and organizational culture, which may influence the relations between QMS and performance. It may also be investigated whether cross-sectional or longitudinal studies lead to different results on the impact of QMS on performance.

Implementation of forms and

Implementation of QMS for the R&D and engineering department is still awaited in GPC. Because of the limited time frame, they have hired a classified team for the development and improvement and expected to be covered in future work as now they are keen on their production line after management improvements.

Finally, it should be highlighted that the results of this systematic literature review are limited to the considered search terms. In this sense, the decision to apply the terms 'ISO 9001' and 'performance' for search studies on QMS, process management, and organizational performance in the selected databases may have left out some relevant articles on the subject. For this reason, it is suggested that search terms be expanded in future reviews.

Summary

A detailed framework is vital to facilitate quality system implementation. This study offers a cost-effective do-it-yourself approach to quality management. It proposes a quality system implementation framework for a cosmetic industry to enable its transition from a no-quality system to an ISO 9001:2015 quality management system. The proposed framework is verified using a case study of Golden Pearl Cosmetics (PVT) Ltd Company. The conclusions reveal several setbacks experienced during quality system implementation and suggest means to overcome them using a planned seven-step framework. This study also recommends an effective maintenance tool to facilitate continuous improvement in organizations with applying a quality management system. The study findings will be useful for quality managers, practitioners, engineers, R&D teams, and consultants in cosmetics companies and reveal several advantages that can be achieved by using the intended framework in any organization irrespective of its nature and size.

Kokkuvõte

Kvaliteedisüsteemi rakendamise hõlbustamiseks on oluline üksikasjalik raamistik. Käesolev uuring pakub kulutõhusat tee-ise lähenemist kvaliteedijuhtimisele. Selles pakutakse välja kosmeetikatööstusele kvaliteedisüsteemi rakendusraamistik, mis võimaldaks üleminekut mitte-kvaliteedisüsteemilt ISO 9001:2015 põhisele kvaliteedijuhtimissüsteemile. Kavandatud raamistik kontrollitakse, kasutades ettevõtte Golden Pearl Cosmetics (PVT) Ltd juhtumianalüüsi. Tulemused näitavad mitmeid kvaliteedisüsteemi rakendamise ajal kogetud tagasilööke ja nende ületamiseks pakutakse seitsmesammuline raamistik. Uuring soovitab ka tõhusat hooldusvahendit hõlbustamaks organisatsioonide pidevat parendamist pärast kvaliteedijuhtimissüsteemi juurutamist. Uuringutulemused on kasulikud kvaliteediala praktikutele, juhtidele, inseneridele, teadus- ja arendustegevuse meeskondadele ning kosmeetikaettevõtete konsultantidele, samuti avatakse mitmed võimalikud eelised, mida võib saavutada pakutud raamistiku rakendamisel ükskõik millises organisatsioonis, olenemata selle suurusest ja valdkonnast.

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Appendix

Table 3: Gap Analysis and Risk Assessment Report

(ISO 9001:2015 requirements were specified and explained below for this case study implementation.)

Table 3-Gap Analysis and Risk Assessment Report

Sr. No.	Quality Management Requirement - ISO 9001: 2015	Gap Finding / Risk (Y, N, O)	Potential Risk Impact	Action Priority
1	**Clause 4.1. General Requirements** GPC Industries has recognized all the organizational processes and resources required to carry out its executive activities, measure performance, and understand its suite of products and make improvements.	O	High	Medium Priority
2	GPC has formed criteria, methods, and specific KPIs to ensure that each process is effective.	O	High	Medium Priority
3	Interaction of organizational procedures and their control has been documented.	O	High	Medium Priority
4	GPC processes have the appropriate level of resources needed.	O	High	High Priority
5	GPC provides an appropriate level of information and instructions required for effective operations and monitoring.	O	High	High Priority
6	GPC processes are controlled, monitored, measure, and analyzed to verify process performance.	N	High	High Priority
7	**Clause 4.2. Documentation Requirements** GPC has a list of documentation currently in use.	N	Moderate	Medium Priority

8	GPC has developed and established 'Quality Policy' (QP)	N	High	High Priority
9	GPC has identified and established the required documentation and records.	N	Severe	High Priority
10	All the documents established at GPC accurately reflect 'what you do?' and 'how you do it?'.	N	Severe	High Priority
11	GPC has established the interaction and hierarchy of its QMS documentation.	N	High	Medium Priority
12	GPC has developed and distributed a 'Quality Manual' for its QMS.	N	High	Medium Priority
13	Quality Manual established at GPC accurately defines the scope (boundary) of its QMS.	N	High	Medium Priority
14	Quality Manual justifies all exclusions.	N	High	Medium Priority
15	All GPC procedures are well documented and/or referenced in its QualityManual.	N	High	Medium Priority
16	Quality Manual describes process interactions.	N	High	Medium Priority
17	Documents are approved before their distribution or reviewed and- approved whenever they are updated or revised.	N	High	High Priority
18	External documents used for GPC activities are also identified and managed and controlled.	O	Moderate	Medium Priority
19	Control of documents at GPC ensures the latest versions are used, and obsolete documents are prevented from any misuse and accidental use.	N	High	High Priority
20	GPC records are identifiable, legible, and retrievable.	O	Moderate	Medium

				Priority
21	GPC records can be used as evidence and prove that the requirements have been met.	N	High	High Priority
22	**Clause 5.1. Management Responsibility.** The top management of GPC completely supports the implementation and development of its QMS.	O	High	High Priority
23	Top management endorses the implementation and development of Quality Policy and Quality Objectives (QO).	Y	-	-
24	Management has communicated within GPC and believes in the importance of meeting statutory and regulatory requirements, customer requirements, and other QMS requirements.	Y	-	-
25	GPC's top management strongly supports the efforts to improve the effectiveness of its QMS continually.	O	High	High Priority
26	GPC's top management strongly supports the continual improvement of its processes by conducting a sufficient number of management review meetings to evaluate the performance of its QMS.	O	High	High Priority
27	**Clause 5.2. Customer Focus** GPC has identified its stakeholders and customers.	Y	-	-
28	GPC periodically reviews its customer requirements and satisfaction levels to enhance customer satisfaction.	O	Moderate	Medium Priority
29	GPC periodically conducts customer satisfaction surveys to ensure that customer requirement are met.	Y	-	-
22	**Clause 5.1. Management Responsibility.** The top management of GPC completely supports the implementation and development of its QMS.	O	High	High Priority
23	Top management supports the implementation of Quality Policy and	Y	-	-

	Quality Objectives (QO).			
24	Management has communicated within GPC and believes in the importance of meeting statutory and regulatory requirements, customer requirements, and other QMS requirements.	Y	-	-
25	GPC's top management strongly supports the efforts to improve the effectiveness of its QMS continually.	O	High	High Priority
26	GPC's top management strongly supports the continual improvement of its processes by conducting a sufficient number of management review meetings to evaluate the performance of its QMS.	O	High	High Priority
27	**Clause 5.2. Customer Focus** GPC has identified its stakeholders and customers.	Y	-	-
28	GPC periodically reviews its customer requirements and satisfaction levels to enhance customer satisfaction.	O	Moderate	Medium Priority
29	GPC periodically conducts customer satisfaction surveys to ensure that customer requirement are met.	Y	-	-
30	**Clause 5.3. Quality Policy** The quality policy is fit for its purpose and well communicated, discussed, and understood throughout GPC.	N	High	High Priority
31	The quality policy is reviewed periodically for its suitability?	N	High	High Priority
32	GPC's quality policy makes a pledge to continually improve the efficiency of the QMS by meeting its QO?	N	High	High Priority
33	**Clause 5.4. Planning** Top management, employees, managers, and supervisors support the establishment of Quality Objectives.	Y	-	-
34	GPC has established Quality objectives that are 'SMART,' i.e., specific,	N	High	High Priority

	measurable, achievable/attainable, realistic/relevant, and timely.			
35	Quality objectives are practical and support quality policy and other performance measures.	N	High	High Priority
36	GPC has planned for the ongoing maintenance and continual improvement of its QMS.	N	High	High Priority
37	GPC ensures to protect the integrity of your QMS whenever systemic changes are being planned and implemented.	N	High	High Priority
38	**Clause 5.5. Responsibility, Authority, and Communication.** GPC has defined, established, and conveyed responsibilities and authorities related to its QMS.	O	Moderate	Medium Priority
39	Top management, managers, engineers, and supervisors ensure that communication processes are established and routinely occur within GPC.	O	Moderate	High Priority
40	Top management ensures that the efficiency and performance of its QMS are conveyed and discussed throughout the organization.	N	High	Medium Priority
41	**Clause 5.6. Management Review** QMS is evaluated at planned intervals for its suitability, adequacy, and effectiveness.	N	High	High Priority
42	Top management, managers, and supervisors evaluate prospects for improvement regularly.	O	Moderate	Medium Priority
43	Top managers keep a record of management assessments.	N	High	High Priority
44	GPC examines and discusses previous management reviews and results in internal audits.	N	High	High Priority
45	GPC examines and analyzes the status and effectiveness of preventive & corrective actions and opportunities for improvement.	N	High	High Priority
	GPC examines and discusses feedback from customers, product			

46	conformity data, process performance data, and status of previous actions related to constant progress.	O	High	High Priority
47	Top management makes decisions and actions to enhance the suitability efficiency of its QMS.	N	High	High Priority
48	Top management takes decisions and actions to improve product and process performance to enhance its capability to meet client requirements.	O	Moderate	Medium Priority
49	Top management takes decisions and actions to change its objectives, quality policy, and performance metrics, when appropriate.	N	High	High Priority
50	Top management generates decisions and actions to discuss resource needs.	O	Moderate	Medium Priority
51	GPC has identified the resources needed to implement, maintain, and improve its QMS.	O	Moderate	Medium Priority
52	GPC has identified the resources needed to ensure the customer's needs are being met and to help enhance customer satisfaction.	O	High	High Priority
53	**Clause 6.2. Human Resources.** GPC has clearly identified the qualifications, skills, knowledge, and experience required by all the employees.	Y	-	-
54	GPC ensures that all employees have the appropriate qualifications, skills, knowledge, and experience, as required.	Y	-	-
55	GPC has recognized the competency requirements of personnel within its QMS who perform work that could immediately or indirectly affect its ability to meet product requirements.	Y	-	-
56	At GPC, training is provided, and other suitable steps are taken to meet its competency requirements.	Y	-	-
57	GPC ensures that all employees are aware of how their activities can affect GPC's ability to meet up product requirements and how	O	Moderate	Medium

	important their efforts are.			Priority
58	GPC evaluates the effectiveness of its training and awareness activities.	N	High	High Priority
59	GPC maintains suitable records of competency, education, training, experience, and skills of its employees.	O	Moderate	Medium Priority
60	GPC has identified the infrastructure needed to ensure that product requirements are met?	Y	-	-
61	GPC ensures that appropriate support, communication, and information is provided, as required, to ensure product requirements are successfully met.	O	Moderate	Medium Priority
62	GPC also ensures that the work environment is properly managed and maintained.	Y	-	-
63	**Clause 7.1. Product Realization.** GPC has identified processes for effective planning and control of its production processes required to realize its products.	O	Moderate	Medium Priority
64	GPC has identified processes to establish objectives and KPI's for its product realization processes.	N	High	High Priority
65	GPC has identified the necessary acceptance criteria, documents, and records required to carry out product realization processes effectively.	N	Severe	High Priority
66	GPC has also identified the monitoring, measurement, and verification methods required to control product quality throughout its product realization process.	N	Severe	High Priority
67	**Clause 7.2. Customer-related Processes** GPC has procedures in place to identify customer’s stated and unstated requirements like product specifications, delivery requirements, packaging requirements, etc.	Y	-	-

68	GPC has procedures in place to identify any statutory and regulatory requirements related to its customer's stated and unstated needs.	Y	-	-
69	GPC has processes in place to make sure that all the customer requirements are measured and assessed before commitments are made, and products are supplied.	O	High	High Priority
70	GPC ensures that any differences in initial quotations and original customer orders are resolved before starting its product realization processes.	Y	-	-
71	GPC has established documents and records to reflect changes in customer's product requirements?	O	Minimal	Medium Priority
72	GPC has procedures in place to ensure that all the customer requirements are considered with internal customers to provide GPC's capability to fulfill customer requirements before making any commitments.	O	High	High Priority
73	GPC ensures that any changes in customer orders are well communicated to relevant employees and functional areas.	O	Moderate	Medium priority
74	GPC has also established a process to handle customer inquiries, feedback, and complaints.	N	High	High Priority
75	GPC ensures that procedures are established to control how product information, contracts, and amendments to agreements are provided to its customers.	Y	-	-
76	**Clause 7.4. Purchasing Process.** GPC has established criteria to select and evaluate suppliers?	N	Severe	High Priority
77	GPC has established procedures to evaluate its suppliers/vendor's ability to supply products that meet GPC's requirements.	N	Severe	High Priority
78	GPC ensures that supplier/vendor evaluation records are kept and discussed.	N	Severe	High Priority

79	GPC also ensures that all purchased products meet specified purchase requirements?	N	Severe	High Priority
80	GPC ensures that purchasing requirements are adequately specified before discussing them with suppliers/vendors.	N	Severe	High Priority
81	GPC has established product verification or inspection methods to ensure that purchased products meet purchase requirements.	N	Severe	High Priority
82	**Clause 7.5 Production and Service Provision** Production at GPC is carried out under controlled conditions.	N	Severe	High Priority
83	GPC has established a plan for how production and service delivery will be monitored.	O	High	High Priority
84	GPC has planned how operational procedures will be used to monitor production and service delivery.	O	High	High Priority
85	GPC has planned how measurements are used to monitor production and service delivery.	N	Severe	High Priority
86	GPC has a procedure in place to monitor production after post-delivery activities.	N	High	High Priority
87	GPC has established criteria to help verify production processes.	N	Severe	High Priority
88	GPC has documented procedures to verify the performance of production	N	Severe	High Priority
89	GPC verifies its production and service provision processes whenever process outputs cannot be measured, monitored, or checked until after the product is in use or the service has been delivered.	N	High	High Priority
90	GPC has established procedures to identify and preserve the unique identity of its products throughout the product realization process.	O	Moderate	Medium Priority
91	GPC maintains records of the identity of products whenever traceability	O	Moderate	Low

	is required.			Priority
92	GPC maintains the monitoring and measurement status of your products throughout the product realization process?	N	Severe	High Priority
93	GPC has established procedures to identify property supplied to it by its customers.	O	Moderate	Medium Priority
94	GPC has established procedures to verify property supplied by customers.	O	Moderate	Medium Priority
95	GPC has established procedures to ensure customer property is protected from any damage.	O	Moderate	Medium Priority
96	GPC uses suitable detection methods to preserve raw materials, products, and other elements during internal handling and delivery to the planned destination within its organization.	Y	-	-
97	GPC ensures to preserve its products and components during delivery through adequate packaging.	Y	-	-
98	**Clause 8.1. Measurement, Analysis, and Improvement.** GPC has identified and implemented the measurement and monitoring, and analytical processes required to be able to validate conformity to QMS requirements and make improvements.	N	Severe	High Priority
99	GPC has identified & implemented monitoring & measurement processes required to be able to improve the effectiveness of its QMS continually.	N	Severe	High Priority
100	GPC has identified & implemented, where necessary, statistical measurement methods required to show that products meet requirements.	N	Severe	High Priority
101	GPC has identified and implemented necessary analytical processes to ensure that QMS requirements are being met and continually	N	Severe	High Priority

	improved.			
102	GPC has established monitoring processes to improve the effectiveness of its QMS continually.	N	Severe	High Priority
103	**Clause 8.2. Monitoring and Measurement** GPC has established and implemented methods used to monitor and measure customer satisfaction (perception).	O	Moderate	High Priority
104	GPC uses customer satisfaction levels as a measure of its performance.	-	-	-
105	GPC methods are capable of monitoring and measuring if its QMS can meet customer requirements or not.	N	Severe	High Priority
106	GPC has procedures in place to ensure that customer satisfaction information obtained is used as feedback to its QMS.	N	Severe	High Priority
107	**Clause 8.2.2. Internal Audit** GPC has established and implemented an internal audit procedure.	N	Severe	High Priority
108	GPC has documented its internal audit procedure.	N	Severe	High Priority
109	GPC has established procedures that define internal audits, its scope, and how it should be performed.	N	Severe	High Priority
110	GPC ensures that previous internal audits findings are also considered.	N	Severe	High Priority
111	GPC has defined the scope of internal audits.	N	Severe	High Priority
112	Audits are performed by independent personnel, and records are maintained.	N	Severe	High Priority
113	GPC ensures that educative action requests are commenced when nonconformities are found during audits.	N	Severe	High Priority
114	Process holders ensure that root causes of nonconformities are identified, and corrective actions are implemented effectively without delay.	N	Severe	High Priority

115	Process holders ensure that corrective actions are monitored and followed to verify its effectiveness.	N	Severe	High Priority
116	Process owners ensure that the results of verification activities are communicated to the top management.	N	Severe	High Priority
117	**Clause 8.2.3., 8.2.4. Monitoring & Measurement of Process & Product** GPC has established monitoring and measurement activities to ensure that its QMS is successfully achieving planned results.	N	High	High Priority
118	GPC has implemented procedures in place to ensure that corrective actions are requests and implemented when nonconformities are identified.	N	High	High Priority
119	GPC has implemented monitoring methods to verify that product characteristics have been met.	N	High	High Priority
120	Production documents of monitoring activities prove that acceptance criteria are met.	N	High	High Priority
121	GPC ensures that it performs monitoring & measuring activities before products are released to be delivered to its customers.	N	Severe	High Priority
122	**Clause 8.3. Control of Nonconforming Product** GPC has implemented a documented procedure for the identification an control of nonconforming products.	O	High	High Priority
123	The nonconforming procedure defines how to prevent unintended delivery or the use of non-conforming products.	N	Severe	High Priority
124	The nonconforming process also describes a plan on how to address the impacts and effects that result from the supply or use of nonconforming products.	N	Severe	High Priority
125	GPC has defined and allocated responsibilities related to nonconforming products.	O	High	High Priority

126	Does the nonconforming procedure also describe how nonconforming product records will be managed and maintained?	N	Severe	High Priority
127	The procedure implemented also describes nonconforming product correction and re-verification methods.	N	Severe	High Priority
128	GPC ensures that detected nonconformities are eliminated, records a maintained, and corrective actions are implemented to tack nonconforming products.	N	Severe	High Priority
129	**Clause 8.4. Analysis of Data** GPC ensures that relevant data is collected regularly and analyzed to ensure the suitability and adequacy of its QMS.	N	High	High Priority
130	Information and data related to customer processes are analyzed and communicated with the top management.	N	High	High Priority
131	**Clause 8.5. Improvement** GPC top management ensures that it works towards continually improving the overall effectiveness of its QMS.	N	High	High Priority
132	GPC uses methods like data analysis and objectives to make quality improvements?	N	High	High Priority
133	GPC performs internal audits to make improvements?	N	High	High Priority
134	GPC conducts management reviews to make quality improvements?	N	High	High Priority
135	GPC initiates and implements corrective actions to make quality improvements?	N	High	High Priority
136	GPC initiates and implements preventive actions to make quality improvements?	N	High	High Priority