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Exploring the Implementation of An Integrated Management System (IMS) In A Pharmaceutical Manufacturing Company in Guyana.

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By

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**ABSTRACT**

**Purpose:** For businesses to grow, expand and, most importantly, sustain themselves in the future, it is essential to ensure that products and services produced by the organization are in line with stakeholders’ expectations. Globalization and foreign trade between Guyana and countries worldwide have increased drastically during the past few years. For businesses in Guyana to compete and gain market recognition, organizations must comply with regulations and laws set forth by local, regional and international trade parties. The study aims to guide the Management of the pharmaceutical firm in Guyana in implementing an Integrated Management System (IMS) within its operation to ensure the long-term sustainability of the business.

**Approach:** The study will be conducted in a pharmaceutical manufacturing facility in Guyana. Data retrieved from the literature will be used to design a framework for implementing the Integrated management system (IMS). The Plan-Do-Check-Act (PDCA) cycle will be used as a guideline in the implementation process. A study will adopt a qualitative approach to determine the barriers and benefits during implementation.

**Research Value:** The research will contribute to the existing literature by providing information on the compatibility of the Management Systems (MS) constituting an integration of GMP 21 CFR 111, HACCP, ISO 9001:2015, ISO 14001:2015 and ISO 45001:2018. The research findings will also provide new information to the pharmaceutical industry in Guyana regarding an implementation framework, identifying benefits and barriers to implementing and identifying the best strategy for the implementation process. Other industries, especially the food industry in Guyana, can also benefit from the findings in developing and implementing an IMS within their organization.

**Research limitation:** The research was found to be related to several limitations. Firstly, a generalized assumption of the findings will be difficult to obtain due to a qualitative methodology approach. The framework that will be developed will be specific to the operations at NEW GPC INC., a pharmaceutical firm. To verify whether the framework applies to other industries or organizations, researchers must determine if these companies have different requirements. Secondly, the research findings will be limited to the context of Guyana. The research should be compared to those conducted in regions such as other South American countries and Caribbean countries to validate the findings.

**Keywords:** Pharmaceutical industry, Integrated Management System (IMS), International Organization for Standardization (ISO), Management Systems (MS), ISO 9001:2015, ISO 14001:2015, ISO 45001:2018, Good Manufacturing Practices (GMP), Hazard Analysis Critical Control Point (HACCP), Plan-Do-Check-Act (PDCA) Cycle.

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**List of Abbreviations**

|  |  |
| --- | --- |
| IMS | Integrated Management System |
| MS | Management System |
| GMP | Good Manufacturing Practices |
| GHP | Good Hygienic Practices |
| GDP | Good distribution practices |
| HACCP | Hazard Analysis Critical Control Point |
| ISO | International Organization for Standardization |
| PDCA | Plan-Do-Check-Act |
| TA | Thematic Analysis |

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**CHAPTER 1:**

**INTRODUCTION**

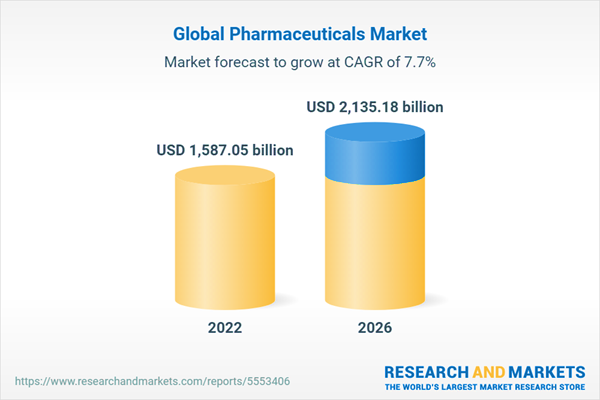
**1.1. Background**

**International Pharmaceutical Manufacturing**

The health and well-being of society depend on the pharmaceutical manufacturing industry (Joshi and Upadhyay 2020). Especially during the COVID-19 pandemic and with over 420 emergency disease outbreaks worldwide over the past two years, the most recent being recorded on 24 February 2023 | MERS-CoV outbreak in Saudi Arabia (WHO 2023).

The global pharmaceutical market is primarily responsible for the “research, development, production and distribution of pharmaceuticals” (Mikulic 2023). The pharmaceutical industry has been recorded as one of the fastest-growing industries (Joshi and Upadhyay 2020). By the end of 2021, the pharmaceutical sector was valued at over $1.4 trillion due to the COVID-19 pandemic. According to Figure 1.1, The global pharmaceuticals market is expected to grow from $1587.05 billion in 2022 to $2135.18 billion in 2026 at a compound annual growth rate (CAGR) of 7.7% (ReportLinker 2022).

*Figure 1.1: Global Pharmaceutical Market estimated growth.*

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(ReportLinker 2022)

**Globalization and International Trade in Guyana**

Guyana, a developing country, is located in South America and houses a population of approximately 800,000. This country was known as one of the poorest countries in the world. However, the oil discovery in 2015 has led to significant changes in the country's growth and development. Despite the outbreak of covid-19 pandemic in 2019, Guyana was one of the few countries whose economy kept growing throughout the pandemic (Irwin-Hunt 2023).

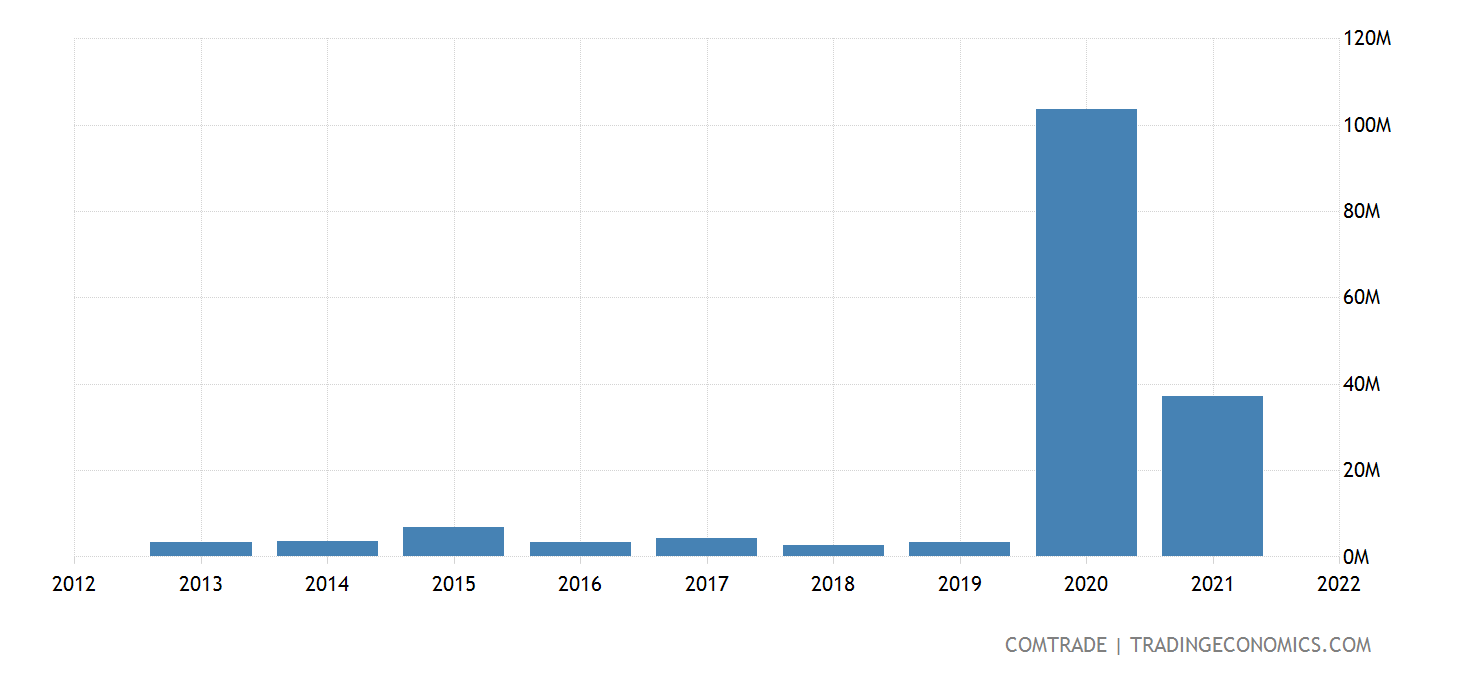
For decades, Guyana has been famishing for foreign investments. Today, according to the Foreign Direct Investment (FDI) Report 2021, it holds the title of the leadership of FDI in the Caribbean, surpassing the multi-year leader, the Dominican Republic. The report indicates that Guyana has pulled approximately 50% of the total FDI attracted in the Caribbean (OILNOW 2022). According to the World Bank, Guyana's GDP has increased more than four times its value, from 3.22% in 2015 to 14.44% in 2021 (Macrotrends LLC 2023).

Attractiveness to foreign investors and trade derives from the country's oil boom, which has increased globalization to unimaginable in this small South American country (Guyana Times 2022).

**Pharmaceutical Manufacturing in Guyana**

In 2021, Guyana's pharmaceutical product exports were US$37.2 Million, according to the United Nations Comtrade database on international trade, Figure 1.2. (Trading Economic 2023).

*Figure 1.2: Export of pharmaceutical product from Guyana.*



*(Trading Economic 2023)*

Pharmaceutical products manufactured in Guyana are exported mainly to the United Kingdom (UK), the United States of America (USA), Canada and the Caribbean. Due to increasing globalization, Guyana’s export of pharmaceuticals is expected to grow tremendously in the near future.

Some of the most famous pharmaceutical products exported from Guyana include Nutrophos, Ferrol and Limocol (Figure 1.3). Many worldwide have used these products for decades. Some world brands, such as Limocol, are manufactured and produced solely by New Guyana Pharmaceutical Cooperation (NEW GPC INC.).

Figure 1.3: Pharmaceutical Products exported from New GPC Inc



. (New GPC Inc. 2023)

**The Future of Pharmaceutical Manufacturing in Guyana**

According to reports made in 2022, pharmaceutical manufacturing in Guyana is on the verge of a new era. Guyana has joined a new initiative to increase the pharmaceutical manufacturing capacity worldwide by having better access when needed in one's own country. This initiative was formed through the South-South Cooperation between the Caribbean, Latin America and Africa (News Room 2022).

The Covid-19 pandemic was evidence that a more resilient and efficient system of making pharmaceuticals available to every country without disruptions is needed. The initiative aims to focus more on locally producing medications, vaccines and health technology, hence increasing the health sector resilience and the country's economy. However, it was clear that the initiative will remain in line with complying with all necessary regulations, such as the COP21 Paris Agreement (News Room 2022).

In upholding its commitment to developing the country’s health care system, the Government of Guyana will soon establish a local pharmaceutical vaccination plant (News Room 2023).

**Development of the Pharmaceutical industry**

The nature of the pharmaceutical industry is ever-changing to become much more diverse and accessible (Joshi and Upadhyay 2020). Many of the exported pharmaceuticals are produced to maintain old traditions and practices. However, this poses a challenge as its production process must comply with international standards for the exported products (Vladimirovna 2015).

The pharmaceutical industry, produced mainly for local consumption, faces significant challenges as these products are to be compared with domestic or imported equivalence. To ensure its sustainable development in the future, the organization must equip itself with the knowledge of current trends driving the growth of the global pharmaceutical industry and prepare itself to meet the demands as they seek to have its products become leaders in the worldwide marketplace.

More than producing quality products alone is required in the current era of business. Safety is essential to human resources development, health, and well-being. Consumers and stakeholders are also moving towards caring for the environment we live and operate in (Ikrama, Sroufeb and Zhanga 2020). As such, the regulatory requirement for business worldwide has become more demanding. Research has proven that implementing an IMS can make a business more sustainable in the future (Pop, Dracea, and Vlădulescu 2018; Ispas and Mironeasa 2022; Nunhes, Barnardo and Oliveira 2019).

Especially for a time like this in Guyana, where globalization is booming and international trade has increased. According to the International Trade Administration (2023), Guyana is emerging as an attractive potential trade and investment market due to oil discovery (International Trade Administration 2023).

**1.2. Research Purpose**

**1.2.1. Aim**

To implement an Integrated Management System (IMS): HACCP, GMP 21 CFR 111, ISO 9001:2015, ISO 14001:2018, and ISO 45001:2018 at NEW GPC INC., Guyana.

**1.2.2 Objectives**

1. To develop a framework for implementing an IMS at NEW GPC INC.
2. To examine the factors affecting the implementation process of an IMS.
3. To define the benefits of implementing an IMS at NEW GPC INC.

**1.3. Rational**

Regarding the certification rate in countries worldwide, Guyana, a developing country, falls into the category of countries practicing the minimum requirement in quality and safety and have the least internationally certified companies (ISO 2023). According to the 2021 ISO on Management System certification survey, twenty-two (22) organizations are ISO 9001:2015 approved, two (2) are ISO 14001:2015 certified, and three (3) are ISO 45001.

Companies around the country are looking to use the opportunity of the oil sector for growth and, as such, are seeking to be internationally certified. Oil production has attracted numerous international companies in Guyana that are already ISO certified in many areas. For businesses in Guyana to sustain themselves and have an opportunity to compete with internationally certified companies, they must achieve international certification.

New GPC INC. is one of the two pharmaceutical manufacturing companies in Guyana and the largest pharmaceutical manufacturing company in the Caribbean that is currently GMP 21 CFR certified by the US FDA. The firm seeks international certification covering quality, product safety, environmental sustainability and workers' health and safety to ensure a sustainable future.

Because there is currently no research on implementing an IMS in Guyana, the study aims to assist the organization in developing a framework for implementing an IMS. It will also help identify critical factors affecting the implementation process and define the benefits gained through the implementation process.

**CHAPTER 2:**

**LITERATURE REVIEW**

**2.1. Safety and Quality in the Pharmaceutical Industry**

Pharmaceutical manufacturers have a great responsibility to ensure that the products produced for distribution comply with at least the basic manufacturing requirements, such as Good Manufacturing Practices (GMP), Good Hygienic Practices (GHP), and Good Distribution Practices (GDP) (Joshi and Upadhyay 2020; Jannah et al. 2020). By adhering to these requirements, manufacturers are confident that their products are up to standards and can be considered safe for consumption. Product safety is the standard expectation of all consumers. As such, it is the responsibility of the producers to ensure that customers' expectations are met or even exceeded (Sulaiman et al. 2021).

The primary purpose of the Pharmaceuticals industry is to produce products that will help treat and cure diseases, help to build the body's immune system and overall, help maintain good health. With that being said, all pharmaceutical products being produced for sale should be safe and should not, at any cost, make the customer's health degrade (Haleem et al. 2015).

Despite following the basic requirements for safety and quality, contaminated pharmaceutical products remain a significant challenge the industry continues to face (Vijayakumar, Al‐Aboody and Sandle 2016; Neupane et al. 2022). According to Jimenez (2019), there has been a considerable increase in microbial contamination of sterile and non-sterile pharmaceuticals produced in the United States based on research from a survey done during the period from 2012 to 2019. US FDA has also recalled ten products for 2023 that were deemed unsafe for public consumption (US FDA 2023). Most recently, as of October 2022, 70 children in West Africa died from consuming a cough syrup contaminated with "unacceptable amounts of diethylene glycol and ethylene glycol," a chemical mainly for industrial use (Thiagarajan 2022).

The production of contaminated pharmaceutical products can lead to significant consequences, from compromising the safety of patients to risking business sustainability. As such, to prevent the contamination of products, it is integral that all stages, from procurement through processing, storage and delivery in the manufacturing process, follow stringent product safety and quality rules and regulations (Jimenez 2019).

Despite quality and safety apprehended as different characteristics of pharmaceutical products, managing these characteristics are interconnected (Liu, Pu and Sun 2017). However, it is essential to distinguish between both due to the risk that it may lead to illness or even death. Safety is absolute and unforgiving. Food is either safe or unsafe; there is no in-between. The safety aspect of a pharmaceutical product is usually primary before the product can enter the respective territory market (Gordon 2017).

Alternatively, quality is produced based on satisfying the customer's need, assuming the product is already considered safe for consumption. Product quality is also defined by meeting specific quality criteria set by stakeholders. Quality, from the eyes of the manufacturer, will be related to producing a product consistent with set requirements (MacCormick and Sanders 2022). The need for quality and safety is derived from areas such as customer feedback, the development of new technology, and current market trends (Neupane et al. 2022; MacCormick and Sanders 2022). While the specification for safety is minimal and cannot be negotiated with due to its associated health risks, quality is derived from all other aspects of the product, including security. Quality is regulated by many factors on noncompliance, whether legal, regulatory, consumer expectations, certification, etc. (Gordon 2017).

**2.2. Local and International Certification**

Aside from satisfying the basic safety and quality requirements of products needed to fulfil market requirements, consumer demand is ever-changing (Gordon 2017). These changes are a result of globalization. As the world develops, there is an increase in movement between cultures and traditions. In addition to globalization, the invention of new technology also plays a vital role in the changing demand of customers (Pop, Dracea and Vladulescu 2018; Mazeika, Pilena, and Dalbergo 2022).

As the world evolves, businesses are forced to look beyond the immediate process of producing products or services. For example, stakeholders demand that manufacturers and producers take social responsivity for managing and protecting the environment in which they operate. In addition to the growing concern for the environment, a similar level of respect is focused on the health and safety of the employees (Basaran 2018).

The manufacturing system is built based on private and public regulations that are deemed mandatory. Government officials of the local authority play an essential role in ensuring that manufacturing organizations follow the minimum requirement of quality and safety during operations to protect consumers from harmful products. In addition to the public sector regulations, there has been an increase in laws within the private sector due to consumers’ demands. As such, keeping up with the rules and regulations governing the pharmaceutical manufacturing sector is becoming more complex and demanding (Maccormick and Sanders 2022).

Due to globalization with a higher interconnecting between markets, the quality and safety requirement of products extends beyond that of the local jurisdiction, and to compete with the international market and increase market shares, manufacturing sectors need to in cooperate these standards within their operations (Pop, Dracea and Vladulescu 2018; Mazeika, Pilena and Dalbergo 2022). Hence private standards, such as International Organization for Standardization (ISO), exist to help bridge the gap and develop firms to comply with international regulations (Gordon 2017).

**2.3. Management Systems**

Within the line of management systems that governs the manufacturing industry, there are categorized into different levels. Starting with the essential safety system such as GMP, GHP, and GDP; advanced safety systems such as HACCP, followed by the basic quality systems ISO 9001:2015, and then an equivalent MS or a higher level, such as an IMS (Lokunarangodage, Wickramasinghe and Ranaweera 2015).

Figure 2.1: Components of a Quality Management System.

*(**Lokunarangodage, Wickramasinghe, and Ranaweera 2015)*

**2.3.1. Good manufacturing practice (GMP)**

GMP certification is considered a compulsory prerequisite program for any manufacturing facility, and it lays the foundation for producing quality and safe products (Kamble, Gunasekaran and Dhone 2020). GMP Regulations are the basis for which manufacturing facilities should comply, a requirement implemented by local and regional authorities (Gouveia et al. 2015; Roien et al. 2022). These practices are mandatory in producing medical devices, food, medications, food processors, etc. and guarantee that the products made by these organizations can be considered safe and effective (Gouveia et al. 2015). The approach adopted by GMP integrates quality and safety in every step of the manufacturing process and eliminates the risk of contamination, mix-ups, and errors. Following the basic requirements during manufacturing protects the buyer from harm (Hole, Hole and McFalone-Shaw 2021). Quality approaches specified by GMP systems include but are not limited to quality objectives, standard operating procedures (SOPs), product and process validation, testing of raw materials and finished products, investigation of nonconformities, record control, training and competency assessment of staff, and equipment verification ([Sarvari et al. 2020](https://www.sciencedirect.com/science/article/pii/S2590156721000244" \l "bb0645)).

Around the world, routine GMP inspections are carried out by various regulatory bodies, such as US FDA, European Medicines Agency (EMA), and Medicines and Healthcare Products Regulatory Agency (MHRA), to ensure pharmaceutical products' safe and quality manufacturing (Abdellah et al. 2016).

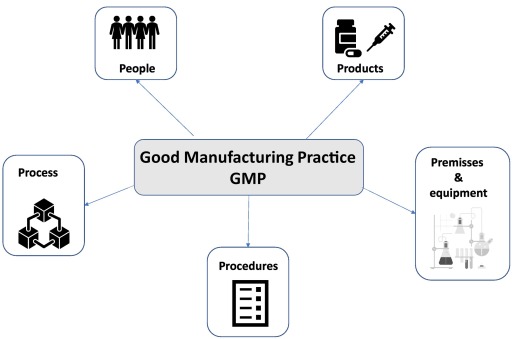
According to Haleem et al. (2015), GMP focuses on reducing or preventing the introduction of hazards associated with the finished pharmaceutical product. The related risks extend to identifying errors in the labelling process. As a result, the patient may receive the wrong medication, contamination of the product that can lead to serious health issues or even death and finally, incorrect quality of ingredients being added to the product that may result in adverse health effects or poor treatment (Nayak et al. 2019).

GMP guidelines cover production, storage, dispensing, raw materials, facilities, equipment, training, and employee hygiene within pharmaceutical manufacturing (Abou-El-Enein et al. 2013). In addition, each process or testing must be guided by clearly defined instructions that are documented, reviewed and approved by the Quality Assurance department. The GMP guidelines facilitate quality integration in every manufacturing process step as it cannot be added to the finished product (Nally 2016; Jain and Jain 2017).

Furthermore, GMP certification is used by many companies worldwide to expand their potential to export pharmaceutical products (Jerez 2020).

GMP focuses on five (5) main manufacturing parameters: People, Processes, Procedures, Premises Equipment and Products. These areas represent the most controlled areas during the manufacturing process. By applying GMP in these areas, organizations can guarantee product safety and quality (Hole, Hole and McFalone-Shaw 2021).

Figure 2.2: Principles of GMP.



*(Hole, Hole and McFalone-Shaw 2021)*

**2.3.2. Hazard Analysis Critical Control Point (HACCP)**

Product safety is the number one priority in the pharmaceutical manufacturing industry, as the products will directly impact the health of its users. HACCP is an advanced safety management system used in the food and Pharmaceutical Industries for years (Kharub, Limon and Sharma 2018). This system primarily focuses on identifying, evaluating and preventing or reducing identified risks relating to the product's manufacturing process (Haleem et al. 2015). This system adopts a systematic approach to ensure the finished product is safe for consumption (Orlenko and Yakovenko 2020).

Before adopting this system in the manufacturing process, it is critical first to implement the basic prerequisite program such as GMP. GMP sets the foundation for successfully applying the HACCP structure within the operations (Pop, Dracea and Vlădulescu 2018). HACCP was initiated in the 1960s by collaborating with NASA and the US Army to ensure that the food sent to space is safe for astronaut consumption (Priya and Chaudhary 2021). Identifying and controlling risk is essential to the pharmaceutical industry and every other sector. As a result, HACCP principles are adopted by many different industries, such as chemical manufacturing, automobile and aviation (Kharub, Limon and Sharma 2018).

In addition to protecting the product's safety, some studies have shown that HACCP protects the employee's health and well-being (Jain 2014). Other research has shown a limitation to the HACCP system regarding ensuring safety from an unknown risk (Jawed et al. 2020). Another limitation of this system was its association with financial loss if not implemented properly (O'Neill, Sohal and Teng 2016).

The HACCP system reduces biological, chemical or physical hazards while manufacturing pharmaceutical products. Combined with other quality systems such as GMP, it has been proven to reduce the risk associated with the manufacturing process to a high degree (Orlenko and Yakovenko 2020; Kharub, Limon and Sharma 2018; Priya and Chaudhary 2021).

The success of the HACCP system lies in seven main principles. These include: Conducting a hazard analysis; Determining the critical control points (CCPs); Establishing target levels and critical limit(s); Establishing a system to monitor the CCPs; Establishing the corrective action to be taken when monitoring indicates that a particular CCP is not under control; Establish procedures to verify that the HACCP system is working effectively, and finally, Establish documentation concerning all policies and keep records appropriate to these principles and their application (Priya and Chaudhary 2021). HACCP principles aim to manufacture safe products. In addition, it also reduces the dependency on endpoint testing to ensure product acceptance, which can be laborious and time-consuming. In terms of risks, it examines each manufacturing process step to reduce, eliminate and control any identified hazard (Shelar 2020).

**2.3.3. International Organization for Standardization (ISO)**

"ISO is an independent, non-governmental international organization with a membership of 167 national standards bodies." (ISO 2023). Experts come together to share their knowledge and develop guidelines to help organizations throughout the world to provide services and product that satisfies the ever-changing demand of society, ensure continuous improvement, along with management commitment, innovation and build the firm's capacity and competency in competing with both local and international market (Gordon 2017). The organization continues to push to collaborate with other recognized institutes to continue improving the performance of businesses worldwide, for example, joining the fight against global warming (Navarro et al. 2018).

**2.3.3.1. ISO 9001:2015 - Quality Standards**

In 1987, the ISO 9000 family came into exitance, the standard for Quality Management systems. This standard focuses on producing quality products and services within the organization (ISO 2023). Today it is the most popular and widely used standard in the world, used by many organizations in every field of work (Bravi and Murmura 2022). Through the years, several amendments were made to the ISO 9000 standard. Still, in 2015, significant changes occurred in the standard's structure and content, resulting in the ISO 9001:2015 Quality Management system (Bravi, Murmura and Santos 2019). The ISO 9001:2015 standard is more flexible and simpler to implement; it requires more commitment from top management, there is a greater focus on customer satisfaction, risk management and communication, less documentation is needed and finally, a higher level structure that will allow the easy integration of other management standards, such as ISO 14001 and ISO 45000 (Rebelo, Santos and Silva 2017; Fonseca and Dominguez 2018).

The application of the ISO 9001:2015 principles is universal and can be applied to any organization. According to research, by implementing ISO 9001:2015, companies have gained significant benefits such as increased customer satisfaction, improved product quality, increased market shares, and reduced cost (Siltori 2020; Chairani 2016). By producing the best quality products, the business will attract loyal customers. ISO 9001:2015 certification helped organizations to reduce production costs and rejection rates (Khan et al. 2021).

However, many studies have criticized the ISO 9001:2015 standard as they claim the implantation process is related to a high cost and changing workplace culture can be very challenging (Kakouris and Sfakianaki 2018; Kafetzopoulos, Psomas and Gotzamani 2015). Successful implementation lies in achieving management commitment, training and a commitment to Continous improvement (Bravi and Murmura 2022; Purwanto et al. 2020).

**2.3.3.2. ISO 14001:2015 - Environmental Standard**

ISO 14001:2015 guides organizations in developing an Environmental Management System. The purpose of this standard lies in enabling organizations to manage and sustain the environment in which it operates and to reduce any significant impact they may have on the ecosystem (Khattak and Ilyas 2018). Studies have shown that by implementing the ISO 14001:2015 standard, the organization can improve its financial and economic performance (Iatridis and Kesidou 2018; Souza and Alves 2018) as it reduces operation cost, reduce waste and improve process efficiency (Vijayvargy, Thakkar and Agarwal 2017; Camilleri 2019a, 2020), helps to promote a culture of continuous improvement (Camilleri 2019b; Santos et al. 2016; Vijayvargy, Thakkar and Agarwal 2017) through training and development of human resources (Camilleri 2021a). Due to the effect and amendments of environmental regulations worldwide, firms should adopt the ISO 14001 certification to gain a competitive market advantage (Ikram et al. 2019; Hojnik, Ruzzier and Manolova 2018). Despite its many benefits, ISO 14001 requires a significant amount of investment in time and money (Camilleri 2022), and its successful implementation is highly dependent on management and the employee's commitment (Zorpas 2020; Riaz and Saeed 2020). In addition, researchers indicate a need for more consensus to show the actual effectiveness of ISO 14001 (Boiral et al. 2018; Carmilleri 2022).

**2.3.3.3. ISO 45001:2018 - Occupational Health and Safety Standard**

A firm's human resources are its most valuable asset (Swepston 2018). It was recorded that over 7600 people die every day due to work-related accidents or occupational diseases (Jannah et al. 2020). This means the loss of human resources from the nation's economy and reduced income and social protection for employees and their families. As such, there is a need for immediate action toward properly managing workplace health and safety (Solc et al. 2022). The development of safety management began in the 1900s with the focus being on accident prevention, followed by pre-accident prevention, system approach (BS 8800/OHSAS 18000), and finally, in 2018, the introduction of the world's first international standard, ISO 45001:2018 (Solc et al. 2022).

In 2018, ISO developed an international management system that focuses on ensuring the health and well-being of employees. It was designed from the British Standard BS OHSAS 18001, a well-known practice by many European organizations. Due to the inefficiency of the OHSAS 18001, ISO was developed to be more proactive, and it applies to any organization (Nagyova et al. 2018; Lee et al. 2020). In addition to taking on a more proactive approach, its structure was designed to be integrated easily with other popular ISO standards (Morgado, Silva and Fonseca 2019; Karanikas et al. 2022).

According to a survey carried out by the ISO to track the certification level of the various management systems around the world, ISO 45001:2018 has seen a drastic increase in certification by 393% in the years 2019 and 2020 when compared to the most popular ISO standards, ISO 9001 increase by 4% and ISO 14001 increased by 11.5% (Solc et al. 2022).

Despite ISO 45001:2018 main focus on safeguarding the health and well-being of the employees, it also benefits the work environment and economic benefits and reduces the number of work-related accidents and incidents (Solc et al. 2022). According to Malinda and Soediantono (2022), by implementing ISO 45001:2018 Management system, firms can benefit directly by increasing their capacity to comply with regulatory demands, reducing workplace incidents and accidents, reducing insurance costs, reducing employee absenteeism and turnover rate, and minimizing downtime in operation. However, despite its advantages, its implementation may be challenging based on available resources, management commitment, cultural maturity, and skilled and knowledgeable qualified personnel (Karanikas et al. 2021).

**2.4. Integrated Management System (IMS)**

As globalization and international trading increase worldwide, operations in the manufacturer’s setting become more complex as companies must comply with the law and regulations set forth by local and international legislation. Firms must adopt multiple management systems (Nunhes, Motta, and de Oliveira 2016; Nunhes and Oliveira 2020; Ispas and Mironeasa 2022).

An IMS binds all the common elements in each system into one system (Olaru et al. 2014). Most updated or current ISO standards have been designed to allow their integration into other ISO standards (Muzaimi, Chew and Hamid 2017; Talapatra, Uddin and Rahman 2018). However, integration can also be accomplished with means other than ISO (Vladimirovna 2015). Organizations worldwide are looking to implement an IMS due to the many benefits it can provide to the firm, for example, ensuring the firm’s commitment to continuous improvement, keeping up with the ever-changing demand of the population, increasing market shares by increasing compliance with the various market regulations, gaining competitive market advantage and most importantly securing a future for the organization (Muzaimi, Chew and Hamid 2017; Ikram, Sroufe and Zhang 2020).

By integrating the desired MS standards, the organization can achieve its objectives, such as ensuring product quality, safety, environmental sustainability and occupational health and safety. An IMS allows the firm to reach international and local market legal requirements, automatically increasing the firm’s chance of participating in international tendering (Vladimirovna 2015). IMS is designed to integrate its processes, resources, and documents (Ikram, Sroufe and Zhang 2020) into one system. According to the literature, IMS is done mainly on three primary standards of quality, environment and occupational health and safety (Samy, Samy, and Ammasaiappan 2015; Magd and Karyamsetty 2020; Abad, Dalmau and Vilajosana 2014; Olaru et al. 2014). However, other ISO standards are also becoming more popular in the context of IMS, for example, ISO 9001/ISO 14001/ISO 45001/ISO 27001 (Hannigan et al. 2019). In addition, ISO standards are also being integrated with other international standards such as GMP and HACCP (Vladimirovna 2015).

With the ISO standards, there are eight common principle areas of integration in the IMS, which are as follows: “customer focus and satisfaction, leadership commitment, employee participation, training and development, facts-based decision making, continuous improvement, employee health and safety and realization of social responsibility, and sustainable development” (Magd and Karyamsetty 2020). Successful integration of management systems relies on systems planning, application, continuous revision and improvement to ensure the integrated system complies with all regulations set by the individual MSSs (Rebelo et al. 2016).

Based on the organization’s objective, the integration of MS can be achieved on a partial basis or a complete basis. Under partial integration, selected elements are integrated at a middle management level, and as such, integration is achieved below 100%. On the other hand, full integration entails combining all the elements of each MS to make a single MS, assuming integration is achieved 100% at the executive and corporate management level (Talapatra, Uddin and Rahman 2018).

**2.5. IMS approached**

Even though there is no standard published or no single validated strategy used in the integration process, many organizations, as well as researchers, have developed several techniques that can be used in achieving an IMS. However, the purpose of each approach remains the same. They all seek continuous improvement, creating a system compliant with laws and regulations in different territories and, most importantly, ensuring the firm's sustainable future (Ispas and Mironeasa 2022). IMS strategies were designed based on the organization's or researcher's needs and interests (Basaran 2018; Chountalas and Tepaskoualos 2019). After deciding on the level of integration needed, a strategy is developed or adopted based on existing literature. The most common approaches identified in the literature include Integration based on a system approach (Chountalas and Tepaskoualos 2019), *IMS matrix* (Basaran 2018), *ISO Guide 72* (Ispas and Mironeasa 2022), *ISO 9001-based integration model* (Barnado et al. 2012), *ISO 14001-based integration model* (Basaran 2018), *Co-establishment of ISO 9001 and ISO 14001, followed by the integration of others* (Domingues et al. 2016) and Integration based on integrated procedures or integrated processes (Talapatra, Uddin and Rahman 2018).

**2.6. Benefits of IMS**

IMS is becoming more and more popular in business around the world due to the many benefits it offers to the organization. Some of the benefits include reducing the number of documentation and redundancy within the system (Basaran 2018), improving operation efficiency (Zeng, Tam and Khoa 2015), reducing the complexity and tension when managing numerous MS (Ispas and Mironeasa 2022), reduce the time needed to conduct audits (Muzaimi, Chew & Hamid 2017), reduce overall operational cost (Samy, Samy, and Ammasaiappan 2015), increases employee satisfaction ((Zeng, Tam and Khoa 2015), more efficient and effective use of resources, Improves organizational growth and development (Muzaimi, Chew and Hamid 2017), improves communication, encourage teamwork, builds a culture of continuous improvement and development (Samy, Samy, and Ammasaiappan 2015), improving product quality, environmental sustainability and workplace health and safety (Basaran 2018). Other benefits include increased customer satisfaction (Abad, Dalmau and Vilajosana 2014), enhanced company reputation (Basaran 2018), increased organization competitive advantage (Barnardo, Farrero and Casadesus 2016) and increased compliance with local, regional and international legislation (Ispas and Mironeasa 2022).

**2.7. Barriers to implementing IMS**

Implementing an IMS has always been a challenging task for any organization. The implementation process can be affected by several factors. Researchers have categorized barriers to IMS into two main categories, internal and external. The internal barriers are related to factors such as the organizational structure, culture, resources, level of knowledge and competency. External factors relate to the company’s customers, stakeholders, certifying bodies, laws and regulations, and the environment (Ispas and Mironeasa 2022).

The successful implementation depends on several factors, such as the availability of resources (Bernardo, Castán and Casadesús 2016; Rebelo et al. 2016), organizational culture (Muzaimi, Chew and Hamid 2017), management commitment (Rebelo et al. 2016), nature and complexity of the operations (Magd and Karyamsetty 2020; Samy, Samy, and Ammasaiappan 2015), knowledge and competency of the human resources, and the type and number of management systems to be integrated (Samy, Samy, and Ammasaiappan 2015; Basaran 2018).

For these barriers to be overcome, it is essential that they are identified at an early stage and dealt with most effectively. If not, this may prolong the integration process and increase difficulty throughout the implementation process (Muzaimi, Chew and Hamid 2017).

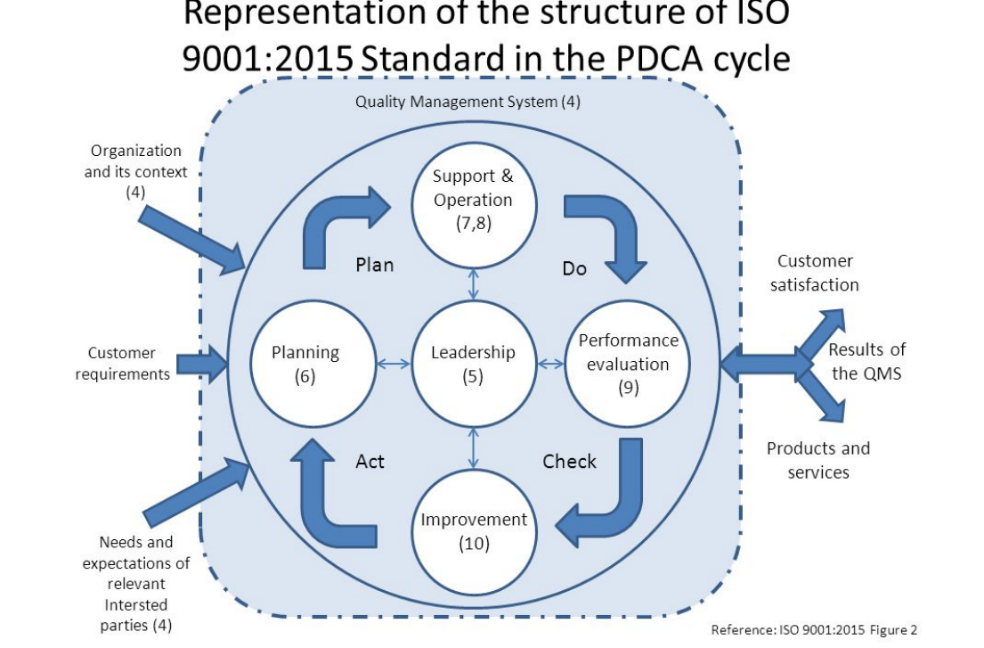
According to Ispas and Mironeasa (2022), the most common factors considered crucial for successfully implementing an IMS are leadership or top management’s commitment, adequate resource availability, effective communication, stakeholder focus, education and training, systems and processes and continuous improvement through performance measurement.

However, Barnardo et al. (2018) indicated that a significant factor in determining the level and success of successful implementation could be the level at which a county is considered a low-certified country. MS Integration has a higher success rate in high-certifying countries, such as the UK (Barnardo et al. 2018), mainly due to the availability of specialized and experienced human resources in the MS integration.

**2.8. PDCA Cycle in the Implementation of IMS**

The Plan–Do–Check–Act (PDCA) cycle, also known as the Deming cycle, was developed in the 1950s by W. Edwards Deming in Japan. The foundation of this cycle is based on the principle of continuous (Kania and Spilka 2016). During the past decade, the ISO started developing its international management system standards according to a unified structure, making it easy for organizations to integrate their MSS into a single system.

The ISO MS was built on the foundation of the PDCA structure (Majerník et al. 2017). According to Samani et al. (2019), the similarities between the PDCA cycle and MS requirements can facilitate the development of an effective and efficient IMS structure.



*Figure 2.3: Structure of PDCA Cycle in the ISO MS (ISO 2023)*

Based on the requirement of the ISO MS, several common elements were identified: “organizational context, leadership, planning, support, operations, performance appraisal, and improvements” (Samani et al. 2019). Each part has been designed to fit the structure of the PDCA cycle. The high level of similarities in the system and requirements of the standards can easily facilitate easy integration (Ispas and Mironeasa 2022). Many researchers have supported using the PDCA cycle in implementing an IMS (Rebelo, Santos and Silva 2016; Samani et al. 2019; Heleta, Grubor and Veljkovic 2013; Nunhes, Barbosa and de Oliveira 2017; Domingues, Sampaio and Arezes 2016; Chountalas and Tepaskoualos 2019).

The supporters of the PDCA cycle in implementing IMS continue to increase worldwide. Researchers have indicated that the PDCA implementation framework results in a low cost of implementation (Ispas and Mironeasa 2022).

**2.9. Research Gap**

The current study identifies two main gaps in the literature. The first relates to implementing an IMS constituting the five (5) selected MS: GMP 21 CFR 111, HACCP, ISO 9001:2015, ISO 14001:2018, and ISO 45001:2018. Although several pieces of literature have been identified that explore the implementation of an IMS, the MS within the integration consists mainly of ISO MS standards: ISO 9001, ISO 14001 and ISO 45001 (Basaran 2018). As such, more literature is needed to explore the integration of ISO MS alongside other MS, such as GMP and HACCP. The study aims to build the existing literature on integrating a unique MS system. It was stated in the current literature that all MS can be combined using the guidelines of the PDCA cycle (Ispas and Mironeasa 2022). The researcher will develop and integrate a framework for New GPC Inc. IMS using the PDCA cycle as a guide.

The second gap identified in the literature is related to implementing an IMS in Guyana's business environment. As mentioned previously, Guyana is a low-certifying country, which can be a factor in determining the successful implementation of an IMS. This research aims to develop the existing literature on the performance of IMS in Guyana's pharmaceutical industry, especially examining the factors that may affect its implementation and determining how the country's unique culture and diversity may affect its successful performance.

**CHAPTER 3:**

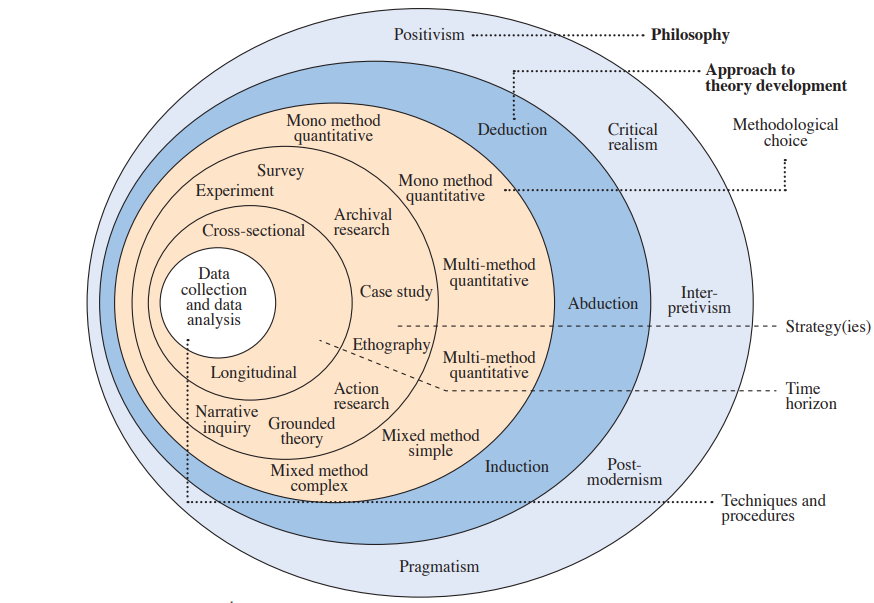
**METHODOLOGY AND PLAN FOR INVESTIGATION**

**3.1. Research Process**

Embarking on the journey of a new research area or exploring and expanding existing ones is essential as it brings further information to the world. However, determining the methodology or strategy used to collect and analyze the research data is necessary (Melnikovas 2018). Within the field of social sciences, the “Research Onion” proposed by Saunders, Lewis and Thornhill (2019) can be used as a guide for business studies. Several studies have supported the concept of the research onion, as it was proven to be a framework that can be used to carry out research in a coherent, set-by-step process (Muranganwa 2016; Raithatha 2017). Even though it was developed as a research framework in the field of social sciences, its success in other areas of study, such as computer sciences (Muranganwa 2016) and Information technology (Lloyd 2012), was also noted.

A research plan is essential to define how we carry out the research, but explaining why the said plan of the investigation was chosen is also crucial as it will add more value to the study (Melnikovas 2018).

The research onion consists of several layers, and each layer should be considered to produce an effective methodology (Raithatha 2017).



*Figure 3.1: The Research Onion (Saunders, Lewis and Thornhill (2019).*

**3.2 Research Philosophy**

The research philosophy can be described as the beliefs or assumptions that guide the research design and the execution of the research study (Saunders, Lewis and Thornhill 2019). It is also the process through which knowledge is developed by studying the nature of that knowledge, determining how it came into existence and how it can be transferred through language and time (Hürlimann 2019).

Some main concepts defining philosophy include *Ontology, epistemology*and*axiology*.

*Ontological* studies are based on the reality of nature (Saunders, Lewis and Thornhill 2019). The researcher's point of view is influenced by existing knowledge (Hürlimann 2019). *Epistemology* examines the researcher's standpoint on accepting existing knowledge (Clark and Winegard 2020). The study will test the accuracy and reliability of the knowledge and explore how it can be transferred accurately. On the other hand, *Axiological* assumptions are influenced mainly by one's values and ethics (Saunders, Lewis and Thornhill 2019).

In the field of research, these assumptions are further distinguished as being *objective* or *subjective*. The concept of objectivism is based on the belief that social reality is independent of social actors. Within this concept, social science is seen similarly to natural sciences. As it is perceived as such, irrespective of how social actors think or act, social entities continue to exist without any influence from social actors (Saunders, Lewis and Thornhill 2019). Hence, Ontology embraces realism. Objective epistemology tests hypothesis, make observation and test measurable facts to understand the actual truth about the social world. Axiological objectivist seeks to pursue a value-free research approach (Hürlimann 2019).

Subjectivist assumptions claim social reality depends on social actors (Saunders, Lewis and Thornhill 2019). Oncological subjectivist claims that there is no single reality and that fact can be multiple based on the perspective of different social actors. If social existence depends on social actors like ourselves, everyone will have different experiences and, as such, have a different opinion about social reality (Saunders, Lewis and Thornhill 2019).

Finally, philosophies can be further categorized in business and management as *positivism, critical realism, interpretivism, postmodernism*and*pragmatic approach.*

Positivism is the backbone philosophical view of natural sciences, where facts are obtained directly from real-time experiments and rejects theoretical assumptions—derived from quantitative data. Hypotheses are tested against facts and used as scientific evidence to develop universal laws of nature (Alharahsheh and Pius 2020; Saunders, Lewis and Thornhill 2019).

In Critical realism, one cannot depend entirely on experience and senses to understand the truth about an event, but knowing the background structure of reality is essential to shape the observable fact. Reality is external and independent, and to understand the truth, we need to understand the underlying social structure of the occurring phenomenon (Hürlimann 2019).

Interpretivism is based on social and natural phenomena that are entirely different and cannot be treated alike. As such, social sciences research should adopt a different methodological approach than natural sciences (Alharahsheh and Pius 2020). This philosophy does not believe humans should be defined by universal law as people originate from different backgrounds, such as language, culture and ethnicity, and will have varying experiences when faced with other circumstances (Hürlimann 2019). Interpretative philosophy aims to create new and richer meaning to understanding the social world around us. In addition, the researcher's values and beliefs play an essential role in the research process (Saunders, Lewis and Thornhill 2019).

Within the postmodernism approach, the researcher seeks to challenge the known truth or knowledge and give voice to alternate views deemed insignificant to a defined understanding. It is the opposite of the positivist approach. This approach believes that it is a language that structures the social world. Language can be biased and incomplete, especially when put forth by a particular group at a specific time. Alternatives exist related to every general knowledge, and instead of blocking out these alternatives, we can create a richer culture by exploring each choice (Saunders, Lewis and Thornhill 2019; Hürlimann 2019).

The pragmatic approach pays little attention to theoretical concepts and more to what is practically possible (Kaushik and Walsh 2019). It can adopt the multiple-method approach and considers facts, figures, knowledge, experiences and values. This approach can also be subjective or objective. The endpoint is finding a practical solution to the problem. Pragmatism believes there is no single method, point of view or reality to an entity but multiple. However, the chosen method must produce accurate and reliable results (Saunders, Lewis and Thornhill 2019).

*The chosen research philosophy:****Interpretivist Approach – Subjective Epistemology***

Based on the research's aim and objectives and the nature of the study, the researcher will adopt an interpretive research approach based on subjective epistemology.

Epistemology is the path to discovering knowledge. Most importantly, this approach is based on the researcher's ability to uncover the inside of reality. In the social sciences field, many researchers engage in epistemological studies because it helps to discover the truth about reality (Saunders, Lewis and Thornhill 2019). However, it was critiqued in several ways. Information can be biased and influenced by external factors such as tribalism. However, this limitation lies in the researcher's ability to discover the absolute truth and perceive the world through their eyes (Clark and Winegard 2020).

The researcher strongly supports the belief that social sciences are separate from natural sciences and that reality varies for each individual based on many factors, such as cultural background, lifestyle and experience. However, even though this research approach adds a richer and deeper meaning to the social context of the research, it's highly subjected to bias because the result may be influenced by the researcher's own beliefs and culture. The results also make it difficult to broadly view a larger population or social context (Hammersley 2013).

The current study seeks to understand the science of human interaction with the implemented MS. Researchers claim that the success of IMS implementation will depend on several factors, such as the organization itself, its human resources, size and organizational culture. The present study will be conducted in Guyana, a multicultural, multiethnic country unique to the rest of the world. The researcher aims to identify, through its objectives, what are the factors affecting the successful implementation of the IMS and the benefits it will offer specific to the target pharmaceutical company in Guyana. Through a subjective approach, the researcher will identify how social actors may affect the implementation process.

In addition to an interpretive approach, the researcher will adopt the pragmatic approach to develop an IMS framework for the pharmaceutical firm. Pragmatic research is considered neither interpretivism nor positivism. It accounts for research that may apply a single or multi approaches to achieving the researcher's goals and objectives. It takes on more of a practical approach and gives the researcher the freedom to utilize whatever method is needed to find a realistic solution to the research problem (Kaushik and Walsh 2019). However, Clarke and Visser (2018) indicated that undertaking this type of methodology might be challenging for a novice researcher since it requires the researcher to have a broad range of knowledge and experience in research methodology. Novice researchers may become frustrated and be flooded with the anxiety of the methodological hazards that lie ahead in the swamp (Finlay 2002).

The researcher will utilize both methods to achieve the research objectives. Developing and implementing a unique framework is more achievable through a practical approach (Saunders, Lewis and Thornhill 2019); hence a pragmatic approach is another potential approach that the researcher can use. The remaining objectives will be achieved through an interpretive approach, where the researcher will be engaged with the participants in one-to-one discussions to get a deeper understanding of the factors affecting the implementation process and the organization's benefits. In addition to interacting with the participants, the researcher's personal experience and observation will contribute to the research findings.

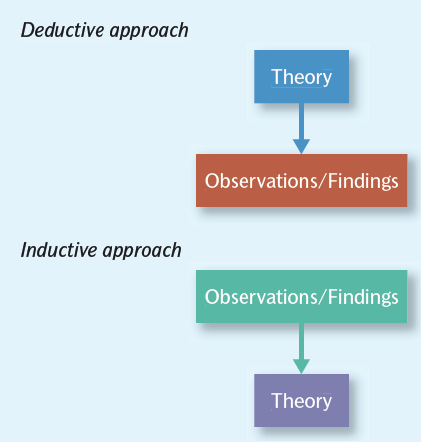
* 1. **Approaches to theory development**

The second layer of the research onion represents the three main approaches to theory development: *deduction, induction* and *abduction.*

A deductive approach begins with a theory that is scrutinized through rigorous testing. A hypothesis is developed based on the general idea to verify whether the view is accurate. This type of approach is the backbone of natural sciences research. It usually encompasses a highly structured methodology (Bryman 2012). It should also be operationalized, meaning it should have a way to measure the facts, usually quantitatively, and most of the findings are generalized. According to Saunders, Lewis and Thornhill (2019), the positivist research philosophy mainly supports the deductive approach.

The inductive approach works the opposite way. This approach works by making observations and findings that lead to a potential theory (Bryman 2012). This type of research is mainly adopted by social sciences research and is primarily qualitative. The study is predominantly subjective and will likely adopt the interpretivism philosophy (Saunders, Lewis and Thornhill 2019).

On the other hand, the Abduction approach is neither deductive nor inductive but rather a combination of both. Upon discovering a surprising fact, a theory is developed and tested (Saunders, Lewis and Thornhill 2019). No research is entirely deductive or inductive (Awuzie and McDermott 2017). Abduction is commonly adopted by pragmatism, postmodernism, and critical realism (Gómez and Mouselli 2018).



*Figure 3.2: Difference between deductive and inductive approach (Bryman 2012).*

*The Chosen Research Approach****: Inductive Approach***

According to Bryman (2012), the inductive reasoning approach uses the observed data to formulate a possible theory of the studied phenomenon. Unlike the deductive method, it allows a flexible methodological approach and provides an in-depth understanding of the findings. However, the research findings can be highly biased due to their subjective nature. The time needed to obtain data can be long, and more than a large amount of empirical data will be required to formulate a hypothesis (Saunders, Lewis and Thornhill 2019).

The researcher will be utilizing primary data collected from the interviews and through observation to explore the implementation of an IMS. The research will adopt an inductive approach. The data will generate themes and identify patterns that will be used to get a deeper understanding of the factors affecting the implementation process and to identify ways in which the organization benefitted through the process. Research data will also be used to develop an IMS framework most suited to improve efficiency within the firm’s operation.

**3.4. Research Methodology**

Within the structure of the research onion, there are three methodology approaches researchers can familiarize themselves with when carrying out research in the social science field, *quantitative, qualitative* and *mix-method*. However, the choice of method depends on the research problem, the researcher's interest, the reporting audience and whether numerical or textual data collection will be required (Bryman 2012).

The quantitative method approach is made through experiments, and data are collected and reported mainly in a statistical or numerical format. In this type of research, the researcher is not part of the experiment and close-end questions are used primarily. This type of research focuses on how a particular variable affects another, irrespective of the effects of other existing variables surrounding the experiment. The methodology is adopted mainly in the positivist approach (Hürlimann 2019).

On the other hand, qualitative methodology utilizes data that are not numerical, such as text, pictures, documents and photos, and is focused on understanding the complexity of human interaction (Sarwano 2022). In this research method, the researcher forms part of the research instruments, and open-ended questions are used rather than closed-ended questions in the quantitative approach. It results mainly in inductive data to get a deeper and more holistic understanding of the studied entity (Robson and McCartan 2016).

Thirdly, the Mix-method approach adopts both a qualitative and quantitative methodology. According to Creswell (2013), the mixed method approach combines textual and numerical data to better understand the object under study and is gaining rapid popularity in the social sciences field.

*The chosen Research Methodology:* ***Qualitative methodology***

The current research will adopt a qualitative methodology approach. Qualitative research methods are employed when the researcher wishes to gain a deeper understanding of the phenomenon through the experience of those who directly experienced it and apprehend their perspective and viewpoint of that phenomenon (Graebner, Martin and Roundy 2012). However, the findings are limited to having a generalized concept, a limited number of people are studied, and the research findings will be based on the perspective of the target population, hence being biased. In addition, analyzing the data can also be challenging as text are often more difficult to reduce and identify patterns than numbers as data (Creswell 2013).

Based on the objective of the current research, the chosen research methodology was best suited as it will be focused on obtaining data through the participant's feelings and thoughts as they interact with the implemented system. Mainly textual data will be collected through an in-depth semi-structured interview.

**3.5 Research Strategy**

The next step after determining the research methodology is identifying the best-suited research strategy. The strategy developed will define a path to answering the research question (Bryman 2012). The main research strategies include Experiment, Survey, Archival Research, Case Study, Ethnography, Action Research, Grounded Theory, and Narrative Inquiry (Saunders, Lewis and Thornhill 2019).

The chosen Research Strategy: **Action Research/**Archival Research/Narrative Inquiry

The research strategy the researcher will adopt will be governed mainly by Action Research. However, the researcher will adopt archival and narrative inquiry strategies within the action research to fully achieve the study's aims and objectives.

Action Research is a developing strategy that is growing in social science (Coghlan et al. 2018). A higher success is achieved when there is a participative collaboration between the researcher and the organization. It seeks to find real solutions to real problems under which the organization operates and its implications going beyond the actual research (Saunders, Lewis and Thornhill 2019). Action research is when a researcher becomes intimate with the research environment. Opponents believe that action research is limited to the environment in which the research project occurred and will be difficult to generalize or repeat (Coghlan et al. 2018).

The current study will be governed to a large extent by an action research strategy, as the action research is best suited for a student undertaking research in their organization. In the current study, the researcher is an employee of the organization under investigation and will play an active role in implementing the IMS. As an employee, the researcher seeks to solve an actual problem in the organization through full participation and collaboration with the employer. For developing a potential IMS framework for NEW GPC INC., the researcher and the quality assurance department employees will review the literature and related standards to identify any possible framework that can be used fully or partially in the research project. After developing a potential framework, participation and collaboration between the researcher and participants will continue throughout the implementation process.

Within the action research strategy, archival research will also be conducted. The term 'archival' is associated with historical data, meaning recent or historical and includes data acquired from existing records and documents (Saunders, Lewis and Thornhill 2019). Data derived from these types of records are usually secondary, meaning the data was not initially intended for the specific research process but for some other. The archival research strategy allows the researcher to study societal change (Gollnhofer et al. 2021). This strategy also helps the researcher saves time and money. However, this strategy is related to several limitations. The researcher may need help finding the correct information; information may need to be updated, found to be biased and even written in a language that may be difficult for the researcher to understand (Saunders, Lewis and Thornhill 2019).

For the current research, secondary information collected will be of high quality, standards and validity as the researcher will analyze data from peer-reviewed articles, books and international guidelines (ISO). The researcher will use archival research to obtain secondary data that can be used to develop a potential framework for IMS at NEW GPC INC. The data will be used to identify similar elements within the MS, act as a guide in integrating the MS, and identify possible strategies used in the integration process, such as using the PDCA cycle.

The researcher will also adopt the strategy of narrative inquiry. Narrative inquiry is more than storytelling but a method of investigation that uses storytelling to uncover lost meaning and details in one's personal experience (Wang and Geale 2015). Through storytelling, the participant (narrator) will interpret the events, and the researcher will have to analyze the data to understand the situation better. Sample sizes are usually small using in-depth narrative interviews. The participants are selectively appointed (Saunders, Lewis and Thornhill 2019).

Narrative inquiry is used to acquire varying realities of the situation and a deeper understanding based on different participants' experiences and options. Through this strategy, marginalized individuals' voices will be heard, and information on unrecorded past data can be obtained (Saunders, Lewis and Thornhill 2019). Yet, there are limitations related to this type of strategy. The Hawthorne effect is usually seen in social experiments where the human subjects under study might portray a different behaviour from what is expected (Wang and Geale 2015). The researcher should understand the subject well enough to represent their experience or opinions accurately. Data retrieved through a narrative inquiry can be a lot and will require much time to decode and analyze (Lindsay and Schwind 2016)

As mentioned, the researcher will utilize in-depth interviews to understand the employees' knowledge and thoughts on IMS. Through the interview process, the researcher will also be able to identify the barriers and benefits of the implementation process. This will provide primary data used mainly for this current researcher and only relevant to the specific pharmaceutical manufacturing company under study, NEW GPC INC.

**3.6 Time Horizon**

Data may be collected in a specific set time or over some time. This decision will depend entirely on the researcher's interest, aims, objectives, and type of research. According to the research Onion, there are two primary time horizons in which analysis is carried out: cross-sectional and longitudinal (Saunders, Lewis and Thornhill 2019).

Cross-sectional studies are conducted in a specific period. Data is collected from a large group of people in the same period. While, In Longitudinal studies, data is collected over a predefined period from a consistent group of people.

The Chosen Time Horizon: **Longitudinal Study**

The researcher chooses to conduct the research over some time, a Longitudinal study. When studying organizational change and development, the longitudinal study is the most appropriate method (Saunders, Lewis and Thornhill 2019). It also allows for more robust assertions regarding the correlation between two or more variables, as trends can be observed with the studied population over a more extended period. However, the drawbacks of utilizing this time horizon are related to high cost and time consumption. A weakened assertion may also affect some studies due to participants' withdrawal (Caruana et al. 2015).

The current research may take an average period of 2 to 2 ½ years, depending on the complexity of integrating the MS and the level of cooperation given by the staff at NEW GPC INC. During the first six months of the commencement of the research, the development of the NEW GPC INC. IMS Framework will be completed. The implementation process will occur in the following 12 to 18 months. Finally, after a successful implementation, an in-depth semi-structured interview will be conducted to identify the barriers and benefits of the IMS implementation.

**3.7. Sampling and Data Collection**

**3.7.1. Selected Organization**

The research will be conducted at one of the Caribbean’s oldest and largest pharmaceutical manufacturing companies in Guyana, NEW GPC INC. The company’s roots date back to the 1920s, and it is the sole manufactures of some of the world’s well-known dietary supplements, such as Ferrol and Nutrophos. TEW GPC INC. manufactures approximately two hundred generic and over-the-counter products. The company’s product line also extends to cosmetics and detergents. The organization employs over 200 employees (NEW GPC INC. 2023).

In keeping up with its mission and vision of being the market leader in providing the highest quality pharmaceutical products locally and regionally, the company seeks to improve its overall operation to ensure a sustainable future by implementing an IMS in quality, health and environmental sustainability.

**3. 7. 2. Participants**

The study aims to conduct In-depth semi-structured interviews will staff from each department and every organizational level. The departments include Quality Assurance, Quality Control, Production, Sanitation, Engineering, Human Resources, Wearhouse, Sales and Marketing, Trading, Finance and Procurement. From the potential group of participants, selected individuals will represent managers, supervisors, and floor operation staff, such as technicians, batch leaders, sanitation staff, and production line staff.

Implementing the IMS will affect operations in every department and every staff level within the organizational chain. The researcher believes that taking on the above approach will give her a more profound and greater understanding of the occurring phenomenon.

Even though Management staff will be planning and implementing this change in the MS, the floor staff will work intimately with the system. They will have varying experiences and thoughts on the implemented system.

The researcher aims to achieve a sample size of approximately 30 participants or above. A minimum sample size of 25 to 30 is required for semi-structured in-depth interviews. In addition, a sample size of at least 30 is necessary to carry out a meaningful analysis, according to Saunders, Lewis and Thornhill (2019).

**3.7.3 Sampling method: Heterogeneous Purposive Sampling**

Sampling is choosing the right participants to provide valid information to answer the researcher’s questions. In qualitative research, the selection is made intentionally and not randomly. Several sampling strategies are available and popular in qualitative research. These include “purposive sampling, criterion sampling, theoretical sampling, convenience sampling and snowball sampling” (Moser and Korstijens 2018).

The researcher chose to adopt a heterogeneous purposive sampling as it was identified as the best-suited sampling strategy for achieving the research’s aims and objectives.

Purposive sampling is also called judgement sampling, as the participants will be selected based on specific characteristics they possess (Farrugia 2019). The researcher knows what needs to be known and will seek to find people who can and is willing to provide the relevant information on the phenomenon under study based on their knowledge and personal experience (Etikan, Musa and Alkassim 2016).

In adopting the maximum variation sampling, the researcher aims to study the phenomenon from all angles, identifying as many themes as possible. This approach will assist the researcher in achieving a greater understanding of the phenomenon (Saunders, Lewis and Thornhill 2019). Despite its main advantage of generating rich data that may provide a broader understanding of the phenomenon and identify unique themes or patterns, this approach will give less in-depth knowledge than if the researcher were to utilize homogeneous purposive sampling (Saunders, Lewis and Thornhill 2019). The approach is also highly criticized for being associated with researchers’ bias due to its subjective nature (Sharma 2017).

Even though participants will be sharing the same experience of implementing an IMS, based on varying characteristics such as their educational level and background, placement at the organizational level, and specific job duties and responsibilities, these researcher aims to gather extensive information from these participants based on their personal experience and opinion.

Even though the sampling size for the selected approach requires a smaller sample size of 25 to 30, the sample size determined by the researcher will be guided on the extent to which the researcher considers the data acquired to reach a saturation point. Data saturation is a collection of adequate data to answer the research question, and additional data may be deemed redundant (Saunders, Lewis and Thornhill 2019). The researcher will decide when data saturation has been met based on whether sufficient information has been gathered and whether sampling should continue or stop.

**3.7. 4 Data collection**

Data collection will be done for both primary and secondary data. Primary data will be collected through participation and in-depth semi-structured interview. Secondary data will be collected using specific search engines via the internet.

**Primary Data**

Primary data is collected for the main purpose of the research. Its limitations lie mainly in its time consumption, but the data gathered is specifically for the research aims and objectives (Adams, Khan and Raeside 2014).

**Primary data collection method:**

1. Participation

Participation allows the researcher to collect first-hand data from the participants being studied. The researcher becomes directly involved with the participants to observe, feel and hear the experience of those under study (Saunders, Lewis and Thornhill 2019). It gives a deeper understanding of the phenomenon being studied. However, being intimately involved in the process can be time-consuming (Robson and McCartan 2016).

1. Semi-structured In-depth Interview

Interviews are conducted similarly to having a conversation with the participant under study. The discussion begins by presenting a general topic related to the research topic and, as the interview proceeds, shows more selected cases to gain data relevant to the study (Saunders, Lewis and Thornhill 2019). A primary advantage of the interview technique is having access to large amounts of data. However, the success of the interview technique depends on the researcher’s ability to interview to gain the accuracy and reliability of data. The researcher should build a good relationship with the participant to build confidence and trust. The researcher should also be patient and interact and collaborate well with the participant throughout the process (Kallio et al. 2016).

The semi-structured interview is the most straightforward and well-known qualitative data collection instrument. Its main advantage is imposing follow-up questions based on the participant’s response and allowing the participant to express their feelings freely (Galletta 2012). The extent of this user-friendly approach has been questioned due to its complexity and excessive data required (Kallio et al. 2016).

In developing an appropriate and practical IMS framework for NEW GPC INC., the researcher will be the leading participant acting as the team leader. In collaboration with the Quality Assurance team, she will collect and analyze peer-reviewed literature and Management standards to identify common MS elements and a possible IMS implementation strategy. The researcher will also participate in every step in the implementation process to assist and guide employees to operate in compliance with the IMS developed.

After the implementation of the MS, an in-depth semi-structured interview will be conducted with the selected employees, allowing for exploring their perspectives and experiences. A sample of the questions that will be used in the interview is provided in Appendix 1. The interviews will be conducted in a one-to-one session to reduce bias in data. The interview will also be undertaken as soon as possible to ensure better participant recall (Radvansky et al. 2022). This approach of interviews will be best suited to identify the barriers and benefits of IMS implantation from the different organizational levels, points of view, and experiences of each participant (Gómez and Mouselli 2018).

***Interview question designs***

The primary purpose of the interview is to get a deeper understanding of implementing an IMS at NEW GPC INC. The interview questions will seek to understand how certain factors or characteristics relating to the participant or surrounding environment may affect the implementation process.

The interview questions will be designed in three sections. The first section will ask generalized questions to help build trust and develop a feeling of security and comfort. This is done to build a comfortable environment for the interviewer and the interviewee.

The second set of questions will aim to better understand the participant’s background and experience. For instance, questions will be related to their years of working experience, specific job descriptions, educational background, or specialty area.

Finally, the remaining questions will be focused on extracting information from the employees on their experience working with the IMS. Specifically, what were some of the challenges in implementing the system, and can they identify any benefits from the implementation process?

**Secondary Data**

Secondary Data are data utilized in the research initially meant for a different purpose. The main advantage of using secondary data is reducing the time the researcher will spend retrieving data to be analyzed (Saunders, Lewis and Thornhill 2019). The limitations, however, are related to the quality, quantity and data associated with specific context to what is being studied in the current research (Gómez and Mouselli 2018).

Secondary data will be retrieved from academic peer-reviewed journals and international standards and guidelines. This data will be used to develop the IMS framework for NEW GPC INC.

**Secondary data collection method**

Information technology has made it simple and easy for researchers to search specific data and information via the Internet. With the invention of search tools, such as Google, and online storage data platforms, it’s easier for researchers to gain access to a large amount of data within a short period online (Sugiura, Wiles and Pope 2017).

The databases the researcher will use include Business Source Complete, Google Scholar, Emerald Insight, SAGE Discipline Hub: Business and Management, Science Direct, The Web of Science, Taylor and Francis and Scopus (Ispas and Mironeasa 2022).

**3.8 Qualitative Data Analysis**

Unlike quantitative data that can be analyzed using standard rules, qualitative data are more difficult to decode and analyze (Bryman 2012). Several techniques have been identified by many authors that are widely used to analyze qualitative data. These include narrative analysis, content analysis, Domain Analysis, Taxonomic Analysis, Componential Analysis, Themes analysis and Ground theory analysis (Lewandowski 2015).

Chosen data analysis technique: **Thematic Analysis (TA)**

Data analysis through thematic analysis involves “identifying, analyzing, and reporting patterns (themes) within data” (Castleberry and Nolen 2018). According to Yin (2016), qualitative data analysis can be achieved in five steps: “compiling, disassembling, reassembling, interpreting, and concluding.” Data (i.e., collected through interviews, focus groups, collated responses and other textual data) is analyzed in the first step. The data must be transcribed into a workable format. According to Sutton and August (2015), the researcher should do the transcription because the researcher must become intimately familiar with the data to get a deeper understanding (Castleberry and Nolen 2018). After organizing the data, the next step would be to dissect the information into different components. The data is separated into separate parts through the disassembling process. This is called data coding.

Auston and Sutton (2014) defined coding as “the process by which raw data are gradually converted into usable data through the identification of themes, concepts, or ideas that have some connection with each other.” It is also through this process that similarities and differences are identified in the data. In Thematic analysis, a code serves as an identifier to recover and sort comparable data across the dataset associated with the specific code (Castleberry and Nolen 2018). During the reassembling process, related codes are put together to form themes. These themes are seen as patterns within the data (Kiger and Varpio 2020). The theme developed should be closely linked to answering a research question/s. To show a clearer picture of the themes achieved from the data analysis, the researcher may utilize visual tools such as diagrams, flowcharts, thematic maps, matrices and hierarchies (Castleberry and Nolen 2018). Interpreting the data is the final and most crucial stage in thematic analysis. These interpretations or derived conclusions should in some way provide an answer to the research’s aims and objectives. Thematic maps developed during this stage will detail the identified themes and patterns among the codes (Castleberry and Nolen 2018).

According to the literature, TA is the most uncomplicated, enjoyable, and flexible qualitative data analysis method (Javadi and Zarea 2016). It is the first choice and most commonly used by the novel researcher (Castleberry and Nolen 2018). The results derived through TA are also simple to understand, even for the less educated population (Javadi and Zarea 2016). However, despite its advantages, it is highly criticized. Its result is associated with bias due to the nature in which the data is analyzed. The question arises, does the researcher tells the truth or the reality of the data? Hence, the value and validity of the findings derived through TA depend on the researcher’s ability to interpret and report the data without any influence from their presumptions (Saldana 2016).

The current research will use a Computer Assisted Qualitative Data Analysis (CAQDAS), NVivo, to analyze the data. The computer software programs are easy to use and allow for a more profound and complex qualitative data analysis (Castleberry and Nolen 2018).

**3.9. Validity, Reliability and Generalizability**

Because of its highly subjective nature in analyzing and reporting data, qualitative research was questioned about its quality and trustworthiness. It was considered a flawed research methodology (Coleman 2022). Similar to quantitative data, assessing the quality of qualitative research relies on three main principles, *validity, reliability* and *generalizability* (Nha 2021; Aguinis & Solarino 2019).

**3.9.1 Validity**

Mears (2017) states, “The validity of interview research is related to its appropriateness for studying what it claims to inform and its veracity in reporting.”

In qualitative data, validity can be defined as the appropriateness of the research design and data to be analyzed. Validity is confirmed once the research methodology, design, data collection, data sampling, data analysis and the data itself will produce results to accomplish the research’s aims and objectives (Nha 2021; Aguinis & Solarino 2019). According to Nha (2021), in a study, an instrument is valid if it measures what it was intended to measure.

Based on the nature and objectives of the research, the aim can only be achieved through a qualitative methodological approach. The researcher chooses to conduct a one and one semi-structured interview with the employees to obtain a more profound and greater understanding of the subject under study. Validity will be achieved as the research design and data acquired will be appropriate to produce the desired results.

**3.9.2. Reliability**

Reliability in qualitative research can be seen in its consistency (Nha 2021). Some variation in response may be accepted as it adds richness to the data collected. However, the data must fall within the category of answering the same research question (Leung 2015).

The study will achieve reliability by putting forth the same general question to all employees. To enhance reliability, the researcher will ensure adequate engagement with the participants to ensure no new insight into the study (Aguinis & Solarino 2019).

**3.9.3. Generalizability**

Achieving generalizability in qualitative research has been a significant challenge. These studies are usually based on a specific population, geographic location, ethnicity, specific organization, testing specific traits, etc. and reproducing the exact setting will take much work (Leung 2015). The term generalizability relates to the findings of the study having the potential to be adopted by a larger and more generalized population (Hays and McKibben 2021). The concept of generalizability in qualitative research was considered unnecessary or inappropriate by many authors (Carminati 2018; Smith 2018).

The research will not make claims of generalizability as it will target a specific organization with selected participants in a particular period.

**3.10. Ethics**

Research ethics refers to a set of values, standards of behaviour and institutional schemes that guide the research process from start to finish (Bryman 2012). Ethical issues in research are increasing rapidly, especially in social sciences, where a researcher would conduct research involving human subjects (Madhushani 2016). Before its approval, it should be compulsory that a research proposal be checked for ethical consent. Before the commencement of the research, it should be scanned to identify the potential risk of breaching any ethical protocol, guidelines, codes and principles. It should be noted that ethical issues may arise at any stage of the research project: data collection, data analysis and the reporting of data (Bryman 2012). According to Bos (2020), qualitative methodology is at a higher risk of ethical issues than quantitative methodology. In adhering to all moral principles, the researcher adds integrity to their work, shows respect to participants and other related subjects, it helps to avoid harm to the researcher and the topics under study, it builds a relationship of trust and security where participants will have the choice to decide on their own whether they wish to participate or not and will be assured of their input will be confidential to the highest level (Bos 2020). The researcher is responsible for ensuring compliance with all ethical standards, codes, and principles throughout the research process (Asiedu et al. 2021).

Before proceeding with the research proposal, the researcher will seek approval from Robert Gordon University’s ethical committee. In addition, the student will also adhere to the data management policy developed by the university to guide data collection, storage and management. In complying with the University’s Research Ethics policy, each student must fill out the Student Project Ethical Review (SPER) form (See attached, Appendix 2) to help promote good ethical conduct during research at the university.

Since the research will be done in one specific organization, a confidentiality agreement (See attached, Appendix 3) will be signed between the researcher and the organization. Approximately 30 employees will be the target participant population, and each participant will be given a detailed background of the research project. Participants will be informed that this is a voluntary act and will be free to leave at any stage during the research process. Each participant will also fill out a participant consent form (See attached, Appendix 4).

The student will gather, analyze and store data confidentially. Participants will be interviewed singly on a one-to-one basis to allow them to feel free and comfortable during the interview. The names of the participant will be anonymous, as participants will be identified by a code, starting with the upper case first letter of the various organizational level (Manager - M, Supervisors - S, Junior staff – J, etc.) followed by a number starting from number 1 and ending at whatever number the Manager level participants stops at, e.g. M1 – first manager participant. This also ensures that information is obtained confidentially. Information will be stored and analyzed on the researcher’s desktop, held in a highly secured area and require a unique password to operate that the researcher will only know. The student and no other individual will analyze and manage the primary data. After the analysis, data that will no longer be needed after the investigation will be deleted from the system, along with primary documents. However, for future reference, in aiming to conduct more advanced or in-depth research, the necessary documents will be stored in an archived password-protected folder on the desktop. Hard copies of primary data will be scanned and stored in the said folder.

**CHAPTER 4:**

**COHERENCE AND CONTRIBUTION**

The research aims to develop an appropriate IMS framework for a pharmaceutical manufacturing firm in Guyana and to identify related barriers and benefits of implementing the IMS.

The introduction chapter provided background information on the development of the pharmaceutical industry worldwide, specifically in Guyana. It also lays the foundation for why the manufacturing company under study will seek to implement an IMS.

After a thorough review of the literature, valid reasons were identified for the importance of manufacturing pharmaceutical products that must be safe and of quality before use by consumers. Due to globalization and international trade increases, companies need help in complying with local and international requirements. The requirements vary and are based on the exported territory, changes in regulations, laws and international standards. Implementing an IMS is linked with multiple benefits to help organizations comply with these requirements better.

In studying the literature, more research was needed on implementing an IMS in a pharmaceutical manufacturing company. IMS was mainly done in food manufacturing, where pharmaceutical manufacturing requirements are closely related. In addition, MS constituting an IMS is primarily associated with the ISO standards, the majority comprising ISO 9001:2015 and ISO 45001:2018. Another area that seeks more research is where the implementation process included other MS, such as GMP and HACCP, along with ISO standards in the IMS structure. As of present, there is yet to be a single validated approach to implementing an IMS. Different researchers developed different strategies based on several factors, such as the type and size of the industry, the cultural background of the organization and the researcher's aims and objectives. The benefits and barriers identified in the literature also vary based on the specific organization under study. A general and well know approach in the implementation process of Management Systems is the use of the PDCA cycle. Many studies have shown the success of implementing an IMS through this cycle.

Due to the nature of the research, the researcher will adopt a research philosophy of subjective epistemology under interpretivism. Under this philosophy, social actors' behaviour impacts the knowledge known to society. The theories developed will be based on an inductive approach, where data acquired will be used to generate possible views or findings. The research methodology will be qualitative, with data obtained mainly in textual format. In collecting the primary data, the research will conduct in-depth semi-structured interviews with potential participants. Thirty participants from different departments and different organizational levels will be interviewed. In analyzing the data and reporting the findings, the researcher will utilize thematic data analysis techniques using a software program, NVIVO. Thematic analysis entails how data are transcribed from their raw format into a more organized manner to identify codes and use them to identify themes within the data further. The data is then displayed in a visual format that helps the researcher and its reader easily interpret and understand the key findings of the research. Before the commencement of the study, the research will be screened to identify possible risks of breaching ethical protocols. The researcher is responsible for ensuring that the research is conducted ethically throughout the research process.

A literature review identified a few gaps which the researcher aims to acknowledge through the completion of the research project. The first gap concerns identifying an IMS framework consisting of the following MS: GMP, HACCP, ISO 9001:2015, ISO 14001:2018, and ISO 45001: 2018. Because more IMS implemented would usually constitute mainly MS under the ISO system, the current research will add value in developing a framework comprising the particular MS understudy.

Finally, IMS has never been studied in any industry in Guyana. This will be the first of its kind to add to the existing literature. This study will add new insight into the IMS implementation process within the pharmaceutical industry, specifically in pharmaceutical manufacturing in Guyana.

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**APPENDICES**

**Appendix 1 – Interview Questions**

1. How long have you been employed at NEW GPC INC?
2. What is your role in the organization?
3. Do you enjoy your work here?
4. What do you like about the company in terms of operation?
5. Are you aware of the current MS in operation?
6. What is your experience working with the system?
7. Was it challenging to adapt to? Details?
8. Do you find the current Management system beneficial in any way? To you personally? Professionally? The organization? The environment?

**Appendix 2 – SPER Form**

**Student Project Ethical Review (SPER) form**

**The aim of the University’s *Research Ethics Policy* is to establish and promote good ethical practice in the conduct of academic research. The questionnaire is intended to enable researchers to undertake an initial self-assessment of ethical issues in their research. Ethical conduct is not primarily a matter of following fixed rules; it depends on researchers developing a considered, flexible and thoughtful practice.**

**The questionnaire aims to engage researchers discursively with the ethical dimensions of their work and potential ethical issues, and the main focus of any subsequent review is not to ‘approve’ or ‘disapprove’ of a project but to make sure that this process has taken place.**

The *Research Ethics Policy* is available at [www.rgu.ac.uk/research-ethics-policy](http://www.rgu.ac.uk/research-ethics-policy)

|  |  |
| --- | --- |
| **Student Name** | Vidya Ram |
| **Supervisor** | Jonny Kennedy |
| **Project Title** | Exploring the implementation of an Integrated Management System (IMS) in a Pharmaceutical Manufacturing company in Guyana. |
| **Course of Study** | Msc Quality Management |
| **School/Department** | Aberdeen business school |

|  |  |  |  |
| --- | --- | --- | --- |
| **Part 1: Descriptive Questions** | | | |
| **1.** | Does the research involve, or does information in the research relate to:  [*[see Guidance Note 1]*](#GuidanceNote1) | **Yes** | **No** |
|  | (a) individual human subjects | √ |  |
|  | (b) groups (e.g. families, communities, crowds) |  | x |
|  | (c) organisations | √ |  |
|  | (d) animals? |  | x |
|  | (e) genetically-modified organisms [www.rgu.ac.uk/hr/healthsafety/page.cfm?pge=26027#122628](http://www4.rgu.ac.uk/hr/healthsafety/page.cfm?pge=26027#122628) |  | x |
|  | Please provide further details:  The research will be undertaken at a pharmaceutical manufacturing company in Guyana, NEW GPC INC. A total of 95 Employees will be selected from each department to participate in an in-depth semi-structured interview. | | |
|  |  | | |
| **2.** | Will the research deal with information which is private or confidential?  [*[see Guidance Note 2]*](#GuidanceNote2) | **Yes** | **No** |
| √ |  |
|  | Please provide further details:  Information retrieved during the interview may contain confidential information to the organization and participants. As such, all information collected will be kept safe and secure. | | |
|  | N/A | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Part 2: The Impact Of The Research** | | | |
| **3.** | In the process of doing the research, is there any potential for harm to be done to, or costs to be imposed on: [*[see Guidance Note 3(i)]*](#GuidanceNote3i) | **Yes** | **No** |
|  | (a) research participants? |  | X |
|  | (b) research subjects? [*[see Guidance Note 3(ii)]*](#GuidanceNote3ii) |  | X |
|  | (c) you, as the researcher? |  | X |
|  | (d) third parties? [*[see Guidance Note 3(iii)]*](#GuidanceNote3iii) |  | x |
|  | Please state what you believe are the implications of the research: | | |
|  | N/A | | |
| **4.** | When the research is complete, could negative consequences follow: | **Yes** | **No** |
|  | (a) for research subjects |  | X |
|  | (b) or elsewhere? [*[see Guidance Note 4]*](#GuidanceNote4) |  | x |
|  | Please state what you believe are the consequences of the research: | | |
|  | N/A | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Part 3: Ethical Procedures** | | | | |
| **5.** | Does the research require informed consent or approval from: [*[see Guidance Note 5(i)]*](#GuidanceNote5i) | | **Yes** | **No** |
|  | (a) research participants? | | √ |  |
|  | (b) research subjects? [*[see Guidance Note 5(ii)]*](#GuidanceNote5ii) | | √ |  |
|  | (c) external bodies? [*[see Guidance Note 5(iii)]*](#GuidanceNote5iii) | |  | x |
|  | If you answered yes to any of the above, please explain your answer: | | | |
|  | Before the project begins, written consent will be obtained from the organization and the selected participants. | | | |
| **6.** | Are there reasons why research subjects may need safeguards or protection? [*[see Guidance Note 6]*](#GuidanceNote6) | | **Yes** | **No** |
|  | x |
|  | If you answered yes to the above, please state the reasons and indicate the measures to be taken to address them: | | | |
|  | N/A | | | |
| **7.** | Does the research involve any “regulated work with children” and/or “regulated work with protected adults”, therefore requiring membership of the *Protecting Vulnerable Groups (PVG) Scheme*? [*[see Guidance Note 7]*](#GuidanceNote7) | | **Yes** | **No** |
|  | **x** |
|  | [Please note: if the research potentially involves “regulated work”, this MUST be raised with your HR Business Partner immediately. In this instance, the Human Resources Department will conduct a detailed assessment and confirm whether PVG Membership is required.] | | | |
|  | (a) PVG membership is not required. | | √ |  |
|  | (b) PVG membership may be required for working with children. | |  | x |
|  | (c) PVG membership may be required for working with protected adults. | |  | x |
|  | (d) PVG membership may be required for working with both children and protected adults. | |  | x |
|  | If you answered yes to (b), (c) or (d) above, please give further information about the work you will be required to undertake and the nature of the contact with these groups. Please provide as much detail as possible: | | | |
|  | **N/A** | | | |
|  | Are you already a PVG member? | | **Yes** | **No** |
|  | x |
|  | If yes, please provide your PVG Scheme number: | N/A | | |
| **8.** | Are specified procedures or safeguards required for recording, management, or storage of data? [*[see Guidance Note 8]*](#GuidanceNote8) | | **Yes** | **No** |
| √ |  |
|  | If you answered yes to any of the above, please give details: | | | |
|  | At NEW GPC INC., there is two Standard Operating Procedure (SOP) in place for the control of records (NGPC-G11) and the control of documents (NGPC-G10) that the researcher will use to store and protect confidential data relating to the research.  The researcher will also adhere to the standard protocols developed by the university in relation to the policy that governs Research Data Management. This policy will also cover areas in data security and confidentiality. | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Part 4: The Research Relationship** | | | | |
| **9.** | Does the research require you to give or make undertakings to research participants or subjects about the use of data? [*[see Guidance Note 9]*](#GuidanceNote9) | **Yes** | **No** | |
| √ |  | |
|  | If you answered yes to the above, please outline the likely undertakings: | | | |
|  | A confidentiality agreement will be made between the organization under study and the researcher to ensure that sensitive data acquired during the research remains confidential. | | | |
| **10.** | Is the research likely to be affected by the relationship with a sponsor, funder or employer? [*[see Guidance Note 10]*](#GuidanceNote10) | **Yes** | **No** | |
|  | x | |
|  | If you answered yes to the above, please identify how the research may be affected: | | |
|  |  | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Part 5: Other Issues** | | | | |
| **11.** | Are there any other ethical issues not covered by this form that you should raise? | **Yes** | **No** |
|  | x |
|  |  | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Statement by Student** | | | |
| **I believe that the information I have given in this form is correct, and that I have addressed the ethical issues as fully as possible at this stage.** | | | |
| **Signature:** | **V. Ram** | **Date:** | **12th April 2023** |

**If any ethical issues arise during the course of the research, students should complete a further Student Project Ethical Review (SPER) form.**

The *Research Ethics Policy* is available at [www.rgu.ac.uk/research-ethics-policy](http://www.rgu.ac.uk/research-ethics-policy)

**Appendix 3 – Confidentiality Agreement**

This Agreement is made and entered into by and between New GPC Inc. ("Company") and the undersigned Student at Robert Gordon University ("Student") to receive certain confidential information of the Company to enable the Student to undertake the Project described at the end of this Agreement ("Project").

Company and Student at this moment agree as follows:

1. "Confidential Information" means the proprietary and confidential information of the Company marked or identified as such, following Section 2 below.
2. To be treated as Confidential Information, any information provided by Company to Student in tangible form shall be marked "Proprietary and Confidential" or similar markings. Information disclosed orally must be identified as confidential at the time of disclosure and summarized in writing within 30 days of exposure.
3. No information will be Confidential Information that: (i) is already known to the Student, (ii) is or becomes publicly known through no wrongful act of the Student, or (iii) is received by the Student from a third party without similar restrictions and breach of this Agreement.
4. Except as provided herein, the Student will not disclose confidential information to anyone else. Students will not use personal information other than in connection with the Project.
5. The Student may disclose Confidential Information (i) in response to the lawful request or requirement of a governmental agency or by the requirement of law and (ii) to the faculty member supervising the Project, provided that the faculty member has signed a non-disclosure agreement with the Company.
6. The Company understands that to complete the course requirements in which they are enrolled, the Student must give a substantive presentation concerning the Project to an audience that will not have signed non-disclosure agreements and that such representation will include information about the Company. The Company will work with the Student to prevent including Confidential Information in the presentation and any written materials prepared by the Student.
7. All Confidential Information delivered by Company to Student will be and remain the property of the Company. All Confidential Information, and any copies thereof, will be promptly returned to the Company or destroyed by Student upon Company's request.
8. The Student's obligations under this Agreement shall terminate at the end of the completion of the Project.
9. This Agreement may not be modified except by a written instruction signed on behalf of each party. All notices, requests or consents in connection with this Agreement shall be given in writing and emailed.

Executed as of the date and year first above written:

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| --- | --- |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company:  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Student  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address |

Description of Project:

The project is based on exploring the implementation of an Integrated Management System (IMS) at NEW GPC INC. The integrated system will include a combination of Management Systems under quality, food safety, environmental sustainability and occupational health and safety. Within a collaborative approach, the student and the employer will work together to develop a suitable integration framework, implement the management system according to the developed framework and finally identify related barriers and benefits.

**Appendix 4 – Participant Consent Form**

**“Exploring the Implementation of An Integrated Management System (IMS) In A Pharmaceutical Manufacturing Company in Guyana.”**

1. I…………………………………………………. voluntarily agree to participate in this research study.
2. I understand that even if I agree to participate now, I can withdraw or refuse to answer any question without any consequences.
3. I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.
4. I have had the purpose and nature of the study explained to me during a presentation, and I have had the opportunity to ask questions about the study.
5. I understand that participation involves giving my input on implementing an Integrated Management System within the organization’s operation.
6. I understand that I will not benefit directly from participating in this research.
7. I agree to my interview being audio-recorded.
8. I understand that all information I provide for this study will be treated confidentially.
9. I understand that in any report on the results of this research, my identity will remain anonymous.
10. I understand that if I inform the researcher that I or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission.
11. I understand that signed consent forms and original audio recordings will be retained in the researcher’s laptop and password protected, which only the researcher can access. The information will be kept until the student completes her assessment.
12. I understand that under freedom of information legalization, I can access the information I have provided at any time while it is in storage as specified above.
13. I understand that I am free to contact any people involved in the research to seek further clarification and information.

*Signature of research participant*

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Signature of participant Date

*Signature of researcher*

The participant is giving informed consent to participate in this study.

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Signature of researcher Date