Griffith College

EFFECTS OF GMP TRENDS ON THE PHARMACEUTICAL INDUSTRY IN NIGERIA

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DECLARATION

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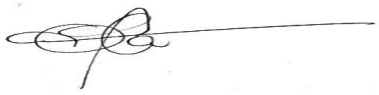

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ABSTRACT

The pharmaceutical industry is important to the economies of the world and for the preservation and promotion of the health of the human society. It is the industry that narrows the gap existing between health-span (disease-free lifetime) and lifespan, so that human beings can live longer and better lives. Therefore, good manufacturing practices are regulations/rules put in place to guide the conduct and operations of pharmaceutical firms to safeguard public health and safety from counterfeit, contaminated or falsified medications. There are trends that have emerged within the GMP space in the pharmaceutical industry which is what this research study has tried to investigate within the pharmaceutical industry in Nigeria. The gaps that exist in the subject area after literature search informed the objectives of the study which seeks to examine the perceptions of professionals regarding GMP trends in the pharmaceutical industry in Nigeria; evaluate the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria; find out the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria; and examine the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria. To execute the study, exploratory design using qualitative research method in which five (5) participants were selected through the convenience sampling technique was deployed. Semi-structured interviews were initiated through Google Meet to collect qualitative data from the interviewees. Gioia qualitative data analysis technique was employed to analyse the collected qualitative data. The study reveals that (i) based on professionals' perceptions, GMP trends in the pharmaceutical industry in Nigeria are characterised by trust, safety and quality; (ii) technology in the implementation of GMP trends in the pharmaceutical industry affects the entire product life cycle of pharmaceutical products; (iii) quality assurance as part of GMP trends in the pharmaceutical industry in Nigeria improves public health; and lastly (iv) new drug safety issues as part of GMP trends influence continuous drug products' monitoring for public safety. Findings show that GMP trends in the pharmaceutical industry have improved the industry but there is still room for growth and further development if the industry is to rival its counterparts in the rest the developed world especially in the area of greater technology adoption and tightening of the regulatory framework guiding the industry. The contribution of the current study will benefit academic researchers, regulators, pharmaceutical products' manufacturers, consumers and government.

Keywords: Good manufacturing practice, GMP trends, pharmaceutical industry, quality assurance, technology, new drug safety issues, Nigeria.

CHAPTER ONE

INTRODUCTION AND OBJECTIVES

1.1 Introduction

In theory and practice, it has been established in literature that the pharmaceutical industry is important to the economies of the world and for the preservation and promotion of the health of the human society, whether it is in the United Kingdom (Enterprise Ireland, 2020), the United States (Bunn, 2019), India (Kapoor, Vyas and Dadarwal, 2018), Russia (Mingazov, Tufetulov and Khadiullina, 2019), Australia (Steele, Ali, Levitskiy and Subramanian, 2020), Vietnam (Angelino, Khanh, Ha, and Pham, 2017), or Africa and Nigeria (Ogada, et al., 2020). The industry also makes essential medications that are efficacious, safe, pure and of quality accessible to people (Obuaku-Igwe, 2015; Ogaji, Alawode and Iranloye, 2014). According to Steele et al. (2020), industrial nations understand the importance of the pharmaceutical industry which explains why they synchronise their health and industrial interests. Steele et al. (2020) further argue that this has been proved to be true in the case of many countries particularly Australia where their health systems are combined with technological advances to bring about quality goods and services which enable economic development. Thus, whether locally or globally, the pharmaceutical industry significantly contributes to the development of the healthcare sector, technology and the economy (Agoulnik, 2018).

The global pharmaceutical industry was valued at $1.12 trillion market capitalisation in 2018 and has been predicted to attain $1.77 trillion by 2025 at a compound annual growth rate (CAGR) of 6.74% (Brand Essence Research, 2020). Mingazov et al. (2019) further hold the view in their study of the Russian economy that the pharmaceutical industry has a significant role it plays in shaping the pace and direction of innovation development which helps drug manufacturers to stay competitive in the global pharmaceutics market. However, these cited authors and many others in the pharmaceutical literature have also written in favour of good manufacturing practices (GMP) as important standardisation processes which can help guarantee a quality drug

manufacturing system in order to achieve the production and supply of quality drugs and realise universal health coverage for the citizens of the world (Ekeigwe, 2019).

Simply put, good manufacturing practice(s) (GMP) are rules and processes laid down for medicine manufacturers to follow and pattern their operations and systems after in order to produce products of high quality that are safe for human consumption and effective in the treatment of diseases (CPhI Insights, 2020; Pieroni and Pimentel, 2020; Steele et al., 2020). GMP standards or rules are set as guidance documents from regulatory authorities or passed as law by the various legislatures to ensure that manufacturers of pharmaceuticals are well regulated enough to play by the rules of honesty, product quality, human value and not just profit, and generally by standardised manufacturing operations (Sanjeevaiah and Munaga, 2017). GMP in the pharmaceutical industry refers to the system which ensures that products are being produced and controlled, thus maintaining quality standards. The purpose of designing the GMP is to minimise the risks that are a part of any production in the pharmaceutical industry which cannot be discarded through the testing of the final product (WHO, 2019). GMP is a standard that, in order to reduce the contamination of the product, takes protective measures for the external and internal conditions related to the organisation. Multiple steps, such as, raw materials, product development, production, storage, packaging, distribution, need the application of GMP in order to ensure that quality standards are being followed.

Furthermore, GMP applies to the entire life cycle stages of pharmaceuticals or medicines from the point of manufacture of medicinal products, technology transfer, commercial manufacturing, all the way to product discontinuation, thus strengthening the nexus that binds the development of medicines and manufacturing activities (Pharmaceutical Inspection Convention, 2018). Through the effective implementation of GMPs, advances in bio-engineering, new genetic and digital technologies have converged symbiotically to create new medical or medicine solutions that have narrowed the gap existing between health-span (disease-free lifetime) and lifespan, so that human beings can now live longer and better lives (Agoulnik, 2018). It is paramount that players in the pharmaceutical industry meet the GMP rules or regulations because most regulators base manufacturers' ability and commitment to meeting these rules as the prerequisite for awarding licenses to them to operate their pharmaceutical businesses, produce certain medicines and to escape regulatory sanctions some of whose penalties can cost an erring pharmaceutical

company up to $500 million in penalties and fines, remediation costs, lost sales and impact on corporate reputation (GTBank, 2018; Pieroni and Pimentel, 2020). Hence, compliance with the GMP is expected of medicine manufacturers to promote quality-assured and safe medicine for the public (Steele, et al., 2020) and to enjoy uninterrupted operations in their country of choice (Vugigi, 2017). However, there are emerging trends which are redefining how good manufacturing practices are being implemented. In a bid to understand these trends and how their effect on the pharmaceutical industry in Nigeria is the purpose of this research.

1.2 Problem Statement

There are numerous GMP trends that have emerged which are changing the face of the pharmaceutical industry globally. The emergence of these trends has been seen as an attempt to further strengthen GMP processes and the regulatory space as they impact the pharmaceutical industry. For example, Agoulnik (2018) and Marangon (2020) cite the rise of technologies such as Blockchain to improve drug traceability, and artificial intelligence to improve drug safety and help in the monitoring of adverse reactions from manufactured medicines. They also point out the role that monitoring technologies such as mHealth, wearables, and others can play in enhancing compliance with GMP rules. They particularly affirm that 3-D printing and Internet of Things (IoTs) can change the whole manufacturing process of medicines while gene editing (CRISPR-CAS9) and molecular engineering (CAR-T) can transform the traditional drug discovery and development pattern. Another study by Enterprise Ireland (2020) identifies the technology trend as it impacts on GMP rules vis-à-vis the pharmaceutical industry. It mentions that one of the ways technology can serve GMP regulations is through data security (Tauqeer, Myhr and Gopinathan, 2019). Another trend is drug safety which is one challenge that many pharmaceutical companies face (Abdellah, et al., 2016; Kim, et al., 2019). To pre-empt this issue becomes important for the survival and sustainability of pharmaceutical firms who may be forced to pay fines and penalties and suffer outright suspension of their operations if the new medicines they release causes serious hurts or leads to fatality for consumers. Another important GMP trend is quality assurance. This has to do with both the people working within the pharmaceutical industry as well as the products they are producing. Since poor quality pharmaceutics can cause pain to

consumers and lead to their deaths, quality assurance is needed all through the various phases of the medicine manufacturing process just as the professionals handling the manufacturing processes are expected to show knowledge, understanding of the basic requirements of the GMP rules and have the requisite skills needed for the job (European Medicines Agency, 2015; Giralt, et al., 2020; Marangon, 2020). These are the issues that will be examined in the current research study in the pharmaceutical industry in Nigeria.

1.3 Research Aim and Objectives

The general aim of this research is to investigate the effects of GMP trends on the pharmaceutical industry in Nigeria. The specific objectives to achieving the overall aim of the research are as follows:

i. To examine the perceptions of professionals regarding GMP trends in the pharmaceutical industry in Nigeria.
ii. To evaluate the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria.
iii. To find out the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria.
iv. To examine the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria.

1.3 Research Questions

The questions this research will be answering are as follows:

1. What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria?
2. What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria?
3. What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria?
4. What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria?

1.5 Significance of the Study

This study has academic as well as practical significance. As the global population grows, the need to develop quality, safe and efficacious pharmaceuticals to take care of the citizens of the world is heightened. Through this study, it is expected that the literature on GMP trends as they affect the pharmaceutical industry will be enhanced particularly that more information about the pharmaceutical industry in Africa's largest economy can be revealed. Also, since this study is going to be adopting qualitative research method and instrumentation, findings typically may not be generalisable but they will be useful for future research which may test the propositions found in the study using quantitative research method and instrumentation. In addition, interested researchers in this type of study may replicate the same in another emerging economy to compare results or findings.

Practically, this study will be useful to pharmaceutical companies themselves, particularly those ones operating in Nigeria and in other emerging economies. The need to understand the GMP trends that are impacting the pharmaceutical ecosystem and deploying some of the technologies and tools to improve their production processes will be a win-win for them, their local economies and the final consumers. Furthermore, this study will assist regulators to also find out what role they can play in motivating pharmaceutical companies to improve their manufacturing practices using the latest technologies that are available in the industry. This motivation can come by way of incentivisation, tax rebate, tax holidays and other perks which could lower the cost of integrating these modern tools and technologies in their manufacturing of drugs. A well-developed pharmaceutical industry is a good omen for any economy and society, hence the need for government, policymakers and regulators to get involved in ensuring that manufacturers of medicines in their local industry are not left behind in the current pharmatech advancements taking place all over the world.

This research could also inspire a new generation of investors and operators to emerge in the pharmaceutical industry in Nigeria and Africa with the sole purpose of reengineering the manufacturing process to catch up with global best practices. As the

country with the leading pharmaceutical industry in the West African sub-region, Nigerian pharmaceutical companies will benefit from this research. And by using the knowledge and ideas gained, these companies could bring a lot more transformation to the business of pharmaceutics manufacturing with numerous benefits that they and the society would gain from doing so.

1.7 Structure of Study

This study is structured in five chapters as follows:

Chapter One is the introduction and objectives section of the dissertation. It establishes the research gap which informed this study, identifies the gaps in literature which led to the formation of the aim and objectives of the study. It also lists the research questions and significance of the study.

Chapter Two discusses the relevant previous literature on the subject of inquiry. This will be done in this study using secondary data materials such as textbooks, peer-reviewed academic journals, global and national white papers and publications and unpublished materials such as dissertations and theses.

Chapter Three identifies the research methodology adopted for the study showing the logical processes followed for data collection and analysis.

Chapter Four presents the results and findings drawn from the collected and analysed primary data. It is these findings that are further discussed in the final and successive chapter.

Chapter Five concludes the research study. It provides a summary and discussions of the findings. It identifies the limitations of the study, its future research potential and also highlights the theoretical and practical implications of findings made.

CHAPTER TWO

2.1 Introduction

The literature review is a very important aspect of any academic research work. It is that section that refers to the previous related literature on the subject under study. It examines the keywords that make up the working title of the dissertation, adopts a theory or model that is used to analyse the research and appraises empirical findings of previous studies as they relate to the current research. It is the gaps in literature that formed part of the problem that this dissertation is put together to solve. Examining the previous literature and their findings as they relate to this research is also important because then, as this research progresses, it becomes easier to compare findings in the current research with those in the previous studies. This approach helps in comparing and contrasting these findings which can be useful for future research and for expanding or extending literature on the subject.

Applying this understanding to the current inquiry, the main keywords of this research are GMP, GMP trends and the pharmaceutical industry. In order to further situate this section and scope, the discussion on GMP trends and their impact on the pharmaceutical industry will be situated within Nigeria. In carrying out this review of literature, recent published and unpublished works of researchers, relevant institutions and practitioners will be appraised in order to avoid using dated information. All in all, the section will be executed in line with the research objectives guiding the entire process. For example, few selected studies below highlight their connection to the objectives of this study and why they were selected for review in this chapter.

S/N	The Current Study's Objectives	Few Selected Related Previous Study	Focus/Objectives of the Previous Studies
1	To examine the perceptions of professionals regarding GMP trends in the pharmaceutical industry in Nigeria.	Signore and Terry, 2005 Mingazov et al. (2019) Kim et al. (2019)	Good design practices as GMP trend Digital applications in the pharmaceutical industry as GMP trends Drug safety as a GMP tremd
2	To evaluate the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria.	Shaik et al. (2019) NASEM (2021)	Internet of Things, telecare technology, electronic medical record and digital documentation identified as influencing GMP in the pharmaceutical industry

			The role of innovative technologies as they influence GMP implementation in the pharmaceutical industry
3	To find out the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria.	Anyakora et al. (2017) Assche et al. (2018)	Quality assurance identified as trend used by pharmaceutical companies to meet WHO-GMP certification. Quality assurance studied as a predictor of GMP compliance in global pharmaceutical industries.
4	To examine the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria.	Fukuyama and Ono (2017) Guth et al. (2019)	New drug safety issues as an important subject in GMP implementation in Japan. Study on new drug safety as a way to secure proof of safety and clinical proof of efficacy for human consumption.

2.2 Good Manufacturing Practice (GMP)

The pharmaceutical industry is considered very critically strategic to the health of human beings and animals, and therefore has continued to experience stringent regulations as society evolved and there is advancement in technological innovations (Ciello, 2005). When regulators realised that quality was determined during the manufacturing process and not by the subsequent quality control measures put in place, the concept of good manufacturing practice was established (Bunn, 2019). Historically, good manufacturing practice (GMP) became the gold standard for the production of pharmaceutics from the 1960s following the Contergan (or Thalidomide) Scandal in Germany in which infants suffered birth defects and even deaths because their mothers, while pregnant, had taken the sleeping aid (Niggeman, 2019). Introduced in 1956 as Thalidomide under the trade name Contergan, the medication or sedative was meant to help those having trouble with sleep, anxiety, morning sickness or tension (Vargesson, 2015). But by the time the drug was banned in the 1960s, it had caused birth deformity and deaths to an estimated number of 20,000 victims worldwide (Zimmer, 2010). Another incident that jingled the warning bells on the need for stricter GMP at that period was the infection of millions of people with the SV40 simian virus after they had been immunised against polio with contaminated oral vaccines (Niggeman, 2019). While these incidents left ugly scars behind in the number of deaths and deformities they caused to their victims and the taint they brought to the healthcare system, they were a wake-up call to the nations of the world to take all facets/elements of GMP seriously in order to avert a repeat of such avoidable health disasters.

The World Health Organisation drafted its first text on GMP in 1967 and it was reproduced in 1971 after some revisions in the second edition of The International Pharmacopoeia (WHO, 2011). Subsequent revisions have brought in concepts of validation and product quality review under the discussion on quality assurance (WHO, 2011). Generally, WHO GMP states that only licenced manufacturers with a manufacturing authorisation should be involved in the production and business of licenced pharmaceutical products. WHO defines GMP as that part of quality assurance which makes sure that pharmaceutical products are consistently manufactured and controlled to achieve quality standards suitable for their intended use and as required or mandated by a regulator or body responsible for marketing authorisation (WHO, 2019). Haleem et al. (2005) argues that GMP rules cover the entire lifecycle of a drug or medication whether it is manufacturing, processing, packing, or holding of the pharmaceutical product to guarantee the public of the purity, quality and safety expected of the product.

Good manufacturing practice or current good manufacturing practice as it is referred to in the United States (they mean the same) simply provides a set of rules for manufacturers of medicines to follow in order to make sure such products are effective, of good quality and are safe for their intended users' ingestion (human beings or animals) (FDA, 2021). Compliance to the requirements of the GMP of a jurisdiction guarantees that manufacturers of medicinal products can be allowed by the regulators to keep producing and selling them in that market (FDA, 2021).

The South African Health products Regulatory Agency (SAHPRA) (2019) defines GMP as those procedures and principles that when complied with guarantee that pharmaceutics and related substances are safe, efficacious and of high quality.

While the definition of cGMP by the Food and Drug Administration of the United States, WHO and SAHPRA explain what the cGMP is as it refers to pharmaceutical products, the definition by Dalto (2015) embraces a wider understanding of the concept to include not only pharmaceutical products, but also beverages, foods and medical devices. In other words, any organisation involved in the manufacturing of products that relate to medical devices, pharmaceuticals, dietary supplements, food and beverages, is expected to abide

by the rules provided by the WHO and the regulator in its country of production or marketing or both.

GMP applies to the entire life cycle of a medicinal product, medical device or dietary supplement from the point of manufacture, technology transfer through to product discontinuation (Pharmaceutical Inspection Convention, 2018). That is to say that GMP promotes the need for drug manufacturers to ensure quality at every point in the medicine's life, from production, packaging, storage, transportation/logistics, to handling, dispensation and ingestion (Niggeman, 2019). Effective implementation of GMP contributes to better and more positive public health outcomes while its absence or weakness can create a barrier for quality healthcare for the world's people (Steele, et al. 2020).

However, as Ghanem (2019) noted, GMP is the minimum standard that pharmaceutical companies are expected to observe while producing medications for public consumption because in several countries, the requirements may vary depending on the regulator in question, the development of their regulatory competence and capabilities and the industry in question (Dalto, 2020). However, while there have been lists of 10 GMP rules including those that prescribed longer requirements (Kumar, et al., 2019), basic GMP requirements that manufacturers of pharmaceutics especially should be guided by which meets WHO's and other regulators' requirements have been suggested by Dalto (2020). According to him, manufacturers of medicine products should:

- maintain a hygienic and clean manufacturing area,
- control environmental conditions to avoid cross-contamination
- clearly define and control manufacturing/production processes
- validate important processes to guarantee compliance and consistency and evaluate changes that may happen to the production process
- properly document/record that product quality (e.g. for a drug) was achieved as expected
- using clear and simple-to-understand language
- properly train staff especially operators at the manufacturing facility to carry out instructions

- document deviations from quality expectations or product defects and investigate such
- maintain the manufacturing and distribution records of a manufactured batch to allow for traceability and full history
- store such records in a logical way for easy access
- utilise distribution methods that reduce/eliminate risks to product quality
- create a recall system to retrieve batches from supply or consumers when necessary
- investigate product complaints, quality defects and taking the appropriate measures when such happens

Source: Dalto (2020)

2.2.1 Good Manufacturing Practice (GMP) Trends in the Pharmaceutical Industry

As alluded to earlier, as society evolved and technological innovations emerged and made available, these have continued to be used to enhance the implementation of GMP processes by drug manufacturers (KPMG International, 2017; Taylor, et al. 2017). Therefore, GMP trends here suggest the movements, direction and tendencies which have continued to influence the implementation of GMP processes across the world. Some of these will be identified and briefly explained.

A trend which improves drug quality and helps to deliver better, faster and more valued medicine products to the market is Good Design Practices (GDPs) because GDPs are important references for planning and executing capital and business-aligned projects which perform and conform to the requirements of regulatory bodies (Signore and Terry, 2005).

Sanjeevaiah and Munaga (2017) identify annual product quality review as one of the trends shaping GMP implementation in the pharmaceutical industry. They described Annual Product Quality Review (APQR) as an evaluation executed in line with cGMP procedures given by different regulatory authorities. According to the authors, APQR is an annual review which helps to improve the quality standard of each medicinal product, verify that the production process is consistent and assess the suitability of its current

specifications in order to change product specifications or their manufacturing or control processes.

According to Mingazov et al. (2017), digitalisation is a GMP trend that increases interaction between manufacturers of medications and the end-users. More importantly, it helps the manufacturer to fulfil its GMP role by immediately finding out from the end-users/customers if any negative reactions exist after the drug ingestion. This helps the manufacturer to know what appropriate steps to initiate.

Also, literature has an abundant mention of the role of technological innovations as part of the GMP trends in the contemporary pharmaceutical industry. For instance, blockchain has been found useful for drug traceability; artificial intelligence has been found helpful in advancing the GMP goals because it connects manufacturers to customers which helps the former to know in time the effect of drug use on them and if any adverse reaction is present; artificial intelligence also provides a real-time monitoring of adverse reactions, increases the manufacturer-user engagement connection and supports a growing trend which has been called precision or personalised medicine (Agoulnik, 2018: Pieroni and Pimentel, 2020). Machine learning technologies, Internet of Things (IoT), mobile technology, cloud technology and personalised medicine are also technology tools which are used to support GMP compliance by pharmaceutical firms (Brand Essence Research, 2020).

New drug safety issues have become an important GMP trend which is why manufacturers of pharmaceutics now conduct premarket evaluations, post-market re-evaluations and report adverse drug reactions for immediate action (Kim et al. 2019). This saves pharmaceutical companies from the hefty fines that follow lack of monitoring which might result in the death of consumers.

Another trend is data integrity which refers to the degree that the data collected by a pharmaceutics manufacturer about a drug product is accurate, complete and consistent. To avoid regulatory sanctions with the accompanying heavy and detrimental fines and costs, drug manufacturers have been committing resources to improving their data

integrity; this helps them enjoy sustainable advantage and progress in a stiffly competitive industry (LCS, 2020).

Quality assurance is another trend in the pharmaceutical industry which has been helpful as a GMP mechanism. Although quality assurance is visible in the pharmaceutical value chain, it helps in the implementation of GMP processes and assists with the improvement and accuracy of data integrity (Bunn, 2019; SAHPRA, 2019; WHO, 2019; Marangon, 2020). It also helps pharmaceutical firms to avoid risks such as cross-contamination and mix-ups (e.g. false labelling) (Pezzola and Sweet, 2016). Other GMP trends are continuous manufacturing, collection of GMP inspection deficiency data, quality by design (QbD), smarter production environments, manufacturing execution systems (MES), and digital documentation (MHRA, 2016; Derico, 2017; Nasr, et al. 2017; Hussain, 2020; Jensen, 2020).

For the current research, the GMP trends that will be examined are quality assurance, new drug safety issues and technology.

2.3 The Global Pharmaceutical Industry and Regulations/Regulators

The pharmaceutical industry consists of organisations subjected to stiff regulations over the development and distribution of their pharmaceutical products (Jagun, 2018). Because their products affect the well-being and lives of people, pharmaceuticals are heavily regulated for the safety, efficacy, quality and purity (Who, 2011, 2019). The industry is made up of organisations involved in research, development, manufacturing, distribution and marketing of pharmaceuticals (Jagun, 2018). All over the world, the pharmaceutical industry plays an important role as a significant part of the healthcare system (Olaitan and Muhammad, 2018; Mingazov, et al. 2019; Orukotan and Oloninefa, 2019). Health and industrial interests are synchronised in industrialised nations as clearly shown in the UK, Germany, France, the United States, Australia, Japan and China where the interaction between the health systems and technological development in those societies generates economic development in the form of goods and services (Steele et al. 2020). As Agoulnik (2018) observed, advances in pharmatech, bio-engineering, digital and new genetic technologies have created medical solutions that have improved

the health-span (disease-free lifetime) and lifespan of people, making it possible for human beings to live better and longer lives.

In the UK, the pharmaceutical industry is a major centre for drug manufacturing and is also critical to the domestic economy (Enterprise Ireland, 2020). With 610 pharmaceutical enterprises as at 2018, the industry provides employment for 63,000 people and generates £21 billion as market value which has been forecasted to reach £25 billion in 2023. GlaxoSmithKline (GSK) and Astra Zeneca, two of the world's 15 leading pharmaceutical firms, have their headquarters in the UK (Enterprise Ireland, 2020). The United States, on the other hand, owns the biggest pharmaceutical market in the world which accounts for about 49% of global pharmaceutical sales and trailed by Europe (21.5%) (Enterprise Ireland, 2020). The global pharmaceutical sales were valued at $1.12 trillion in 2018 and have been predicted to increase to $1.77 trillion by 2025 (Brand Essence Research, 2020). China, Brazil, and India possess strong and growing pharmaceutical industries which some of the growing pharmaceutical markets in Asia, South America and Africa such as Nigeria, Egypt, Ethiopia and Kenya depend on for the importation of their Active Pharmaceutical Ingredients (APIs) as raw materials for their local pharmaceuticals production (Tiwari and Patel, 2020; Wah, et al. 2020).

The industrialised nations and emerging economies all have very developed and active regulatory authorities which ensure that the pharmaceutical companies in their countries adhere to the requirements of GMP as a basis for their operations. While the regulatory bodies vary from one country to another, a summary of selected regulatory institutions that monitor and implement the execution of GMP processes and procedures by drug companies in their countries has been listed in Table 2.1.

Table 2.1 Regulatory Institutions that Implement and Monitor GMPs in Selected Countries of the World

Organisation	Full Name of the Regulators	**Acronym**
Australia	Therapeutic Goods Administration	TGA
Canada	Health Canada - Regulatory Operations and Regions Branch (*Sante Canada - Direction générale des opérations réglementaires et des régions*)	RORB
Chinese Taipei	Taiwan Food and Drug Administration	TFDA

Denmark	Danish Medicines Agency	DKMA
France	Agence nationale de sécurité du médicament et des produits de santé (*French National Agency for Medicines and Health Products Safety)*	ANSM
	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (*French Agency for Food, Environmental & Occupational Health Safety*)	ANSES
Germany	Bundesministerium fur Gesundheit (*Federal Ministry of Health*)	BMG
	Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (*Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices*)	ZLG
Hong Kong SAR	Pharmacy and Poisons Board of Hong Kong	PPBHK
Indonesia	National Agency for Drug and Food Control	NADFC
Ireland	Health Products Regulatory Authority	HPRA
Israel	Institute for the Standardization and Control of Pharmaceuticals	ISCP
Italy	Agenzia Italiana del Farmaco	AIFA
Japan	Ministry of Health, Labour and Welfare	MHLW
	Pharmaceuticals and Medical Devices Agency	PMDA
	Japanese Prefectures	
Malaysia	National Pharmaceutical Regulatory Agency	NPRA
Mexico	Federal Commission for the Protection Against Sanitary Risks (*Comision Federal para la Proteccion contra Riesgos Sanitarios*)	COFEPRIS
Netherlands	Inspectie Gezondheidszorg en Jeugd (*Health and Youth Care Inspectorate*)	IGJ
Singapore	Health Sciences Authority	HSA
South Africa	Medicines Control Council/South African Health Products Regulatory Authority	MCC/SAHPRA
Spain	Agencia Española de Medicamentos y Productos Sanitarios (*Spanish Agency for Medicines and Medical Devices*)	AEMPS
Sweden	Medical Products Agency	MPA
Switzerland	Swiss Agency for Therapeutic Products	Swissmedic
Thailand	Food and Drug Administration	Thai FDA
United Kingdom	Medicines and Healthcare Products Regulatory Agency	MHRA
	Veterinary Medicines Directorate	VMD
United States of America	United States Food and Drug Administration	US FDA
WHO PQ	World Health Organisation Prequalification	WHO PQ

Source: SAHPRA (2019)

It should be highlighted that most of the regulations and pieces of legislation that guide the pharmaceutical industries of many countries in the world are inspired by the WHO GMP, the US Food and Drug Administration (FDA), the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) (Salvador, 2017; Shilesh and Senthilkumar, 2019).

2.3 The Pharmaceutical Industry and the Regulatory Environment in Nigeria

Nigeria has the largest domestic market in Africa and this size plays out in the pharmaceutical sector where the local demand for essential drugs is also huge (Jagun, 2018). The impact of the pharmaceutical industry on the Nigerian society, in terms of its contribution to the manufacturing of essential drugs, has been acknowledged in literature (Ikon and Chika, 2017; Jagun, 2018; Olaitan and Muhammad, 2018; Fatokun, 2020; High Commission of India, 2020; Tiwari and Patel, 2020). Through the industry, Nigeria has had access to pure, safe, efficacious and quality essential medicines. As at 2009, the market for pharmaceuticals in Nigeria was estimated by the Pharmaceutical Manufacturing Group of the Manufacturers Association of Nigeria (PMG-MAN) to be in the region of USD $2.0 billion annually and split into the following product sections (High Commission of India, 2020):

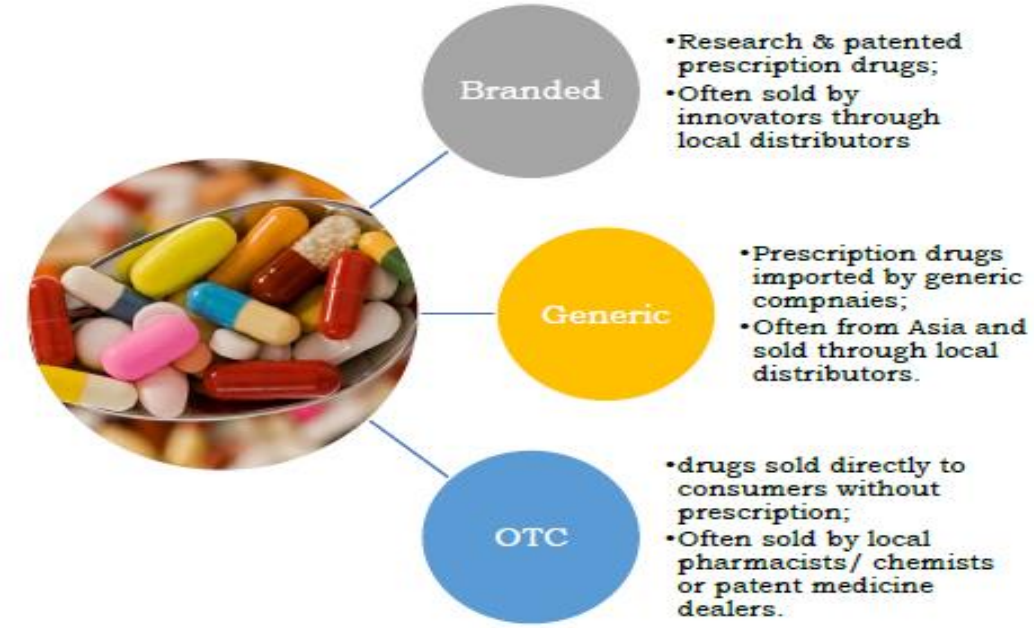
Table 2.2 Market value of the Pharmaceutical Market in Nigeria

Description	Value
Over The Counter (OTC) pharmaceuticals	US$900 million
Prescription ethical pharmaceuticals	US$500 million
Related healthcare and lifestyle products	US$500 million
Biological products (including vaccines, insulin, interferon, etc.)	US$100 million

Source: High Commission of India (2020)

The value of the pharmaceutical market in Nigeria has been projected to increase to USD $4 billion by 2026 while general consumption level is to hit $94 billion at the same period (Holt, Millroy and Mmopi, 2017). The pharmaceutical industry in Nigeria is divided into the following classifications as demonstrated in Figure 1:

Figure 1: Classification of the Nigerian Pharmaceutical Industry



Source: High Commission of India (2020)

The PMG-MAN states that there are more than 130 companies in the pharmaceutical sector in Nigeria but less than 10 are quoted on the Nigerian Stock Exchange (High Commission of India, 2020). In spite of the presence of domestic drug companies in Nigeria, the country of more than 200 million people still relies on over 70% of imported medical devices, pharmaceutical drugs and equipment to satisfy local demand since local production can only meet 25% of its local pharmaceutics need (High Commission of India, 2020).

Because of the disease pattern in Nigeria, Over The Counter (OTC) medicines (e.g. antimalarials, multivitamins and analgesics) constitute the largest share of the drug demand including other common therapeutics such as anti-TB, anti-diarrhoeal and antimicrobial medicines, artemisinin combination therapy (ACT) and Antiretroviral (ARV) drugs (High Commission of India, 2020).

The pharmaceutical sector in Nigeria has created more than 500,000 jobs in the country in the manufacturing category aside thousands of jobs that also exist in the research division (Fatokun, 2020). Although the pharmaceutical market in Nigeria depends on India and China mainly for most of its active pharmaceutical ingredients (APIs) for its

local production, the country is a force to reckon with in the Economic Community of West African States (ECOWAS) sub-region because it supplies 60% of the medication needs of that market (High Commission of India, 2020). As at 2018, nine pharmaceutical companies in Nigeria had a strong showing in the ECOWAS market with various products been shipped to the different countries in the sub-region; these companies are PZ Cussons Plc, Neimeth International Pharmaceuticals, Mopson Pharmaceutical Industries Ltd, May & Baker Nigeria Plc, GlaxoSmithKline Nigeria, Fidson Healthcare Plc, Evans Medical Plc, Emzor Pharmaceutical Industries Ltd, and Drug field Pharmaceuticals Ltd (Obukohwo et al. 2018). In addition, four indigenous pharmaceutical companies are WHO-GMP compliant, namely, Swiss Pharma Nigeria Limited, Chi Pharmaceuticals Limited, May & Baker Nigerian Limited and Evans Medical Limited (Vugigi, 2017). Data from the Pharmacists Council of Nigeria (PCN) show that the industry has over 292 importers of pharmaceutics, 130 registered drug manufacturers, 724 drug distributors, 1,534 retail pharmacies, and a total of 9,034 private and 14,607 public healthcare facilities (High Commission of India, 2020).

Local manufacturers in the industry employ mainly Nigerians at both technical and management levels while expatriates are contracted from time to time to train local staff in certain specialised areas (High Commission of India, 2020). Domestic demand for some categories of pharmaceuticals is met by Nigerian manufacturers in areas such as analgesic/antipyretic, antiretroviral, antimalarial, anticough, antibacterial, vitamins, antacids, haematinics, and others; and these could come in the forms of liquid preparations, ointments, capsules, tablets, creams, lotions, and ophthalmic preparations, all of which are essential drugs (Vugigi, 2017; Fatokun, 2020). The market share for the various classes of medicines domestically manufactured in Nigeria have been captured in Table 2.3.

Table 2.3 Market Share of Classes of Medicines in the Domestic Market in Nigeria

Name	**Market Share**
Others	3%
Anti TB medicines	4%
Cough and cold preparations	5%
External/ Topical preparations	5%
Antiretroviral medicines	6%
Antihypertensives	8%
Antimalarial Medicines	14%

Antibiotics + Antibacterials	15%
Multivitamins + Haematinics	15%
Analgesics/Antirheumatic/ Antipyretics	25%
Total	**100%**

Source: High Commission of India (2020)

The regulatory environment in the pharmaceutical sector in Nigeria is very active. These institutions have been arranged in Table 2.4 as follows:

Table 2.4 Regulatory Institutions in the Pharmaceutical Sector in Nigeria

Regulatory Agency/ Body	**Mandate**
Corporate Affairs Commission (CAC)	• Company registration
Federal Ministry of Commerce	• Registers brand name and approves trademark
Federal Ministry of Health	• Regulates the health industry generally
Medical and Dental Council of Nigeria	• Regulates medical and dentistry practice, and alternative/traditional medicine practice.
National Agency for Food and Drug Administration and Control (NAFDAC)	• Evaluates and registers pharmaceutical products • Conducts risk analysis of registered products and post-market surveillance • Controls import and export of pharmaceutical products • Regulates product promotion and public education
National Health Insurance Scheme (NHIS)	• Registers and regulates Health Maintenance Organisations (HMOs)
National Office for Technology Acquisition and Protection (NOTAP)	• Regulates technology acquisition and protection, including Intellectual Property Rights (IPR) patents, benefit sharing and other issues.
Nigerian Export Promotion Council (NEPC)	• Regulates export of pharmaceutical products
Standards Organisation of Organisation	• Works with the other regulators such as NAFDAC and NEPC to standardise the quality of products for the domestic and export markets
Pharmacists' Council of Nigeria (PCN)	• Registers and inspects pharmaceutical retail, wholesale and manufacturing premises • Registers pharmacists • Regulates practice of pharmacy • Inspects pharmaceutical manufacturing premises

Sources: Compiled by High Commission of India (2020) and modified by Researcher

In Nigeria, the pharmaceutical industry is being regulated by two institutions operating with permission under the Federal Ministry of Health, and they are: the Pharmacists'

Council of Nigeria (PCN) and the National Agency for Food and Drug Administration and Control (NAFDAC). The remit of their regulations has been indicated in Table 2.4.

Other stakeholders as identified by NAFDAC include:

- Pharmaceutical Manufacturers Group of Manufactures Association of Nigeria (PMG-MAN)
- Patent and Proprietary Medicine Dealers Association (PPMDA)
- Nigerian Association Of Lady Pharmacists (NALP)
- Nigerian Association Of Hospital Pharmacists (NAHP)
- National Institute for Pharmaceutical Research and Development (NIPRD)
- National Drug Law Enforcement Agency (NDLEA)
- Consumer Protection Council of Nigeria (CPC)
- Consumer Association of Nigeria
- Association of Food, Beverage and Tobacco Employees of Nigeria (AFBTE)
- The West African Pharmaceutical Manufacturers Association (WAPMA)
- Pharmaceutical Society of Nigeria (PSN)
- Association of Community Pharmacists of Nigeria (ACPN)

Source: NAFDAC (2020)

2.4 The Meta-Regulation Model

In employing a theory for this study, there are several theories to choose from such as systems theory, the institutional theory, the agency theory, the stakeholder theory, public interest theory and private interest theory, among others. All these theories are suitable when studying regulations and compliance to regulations by corporate institutions. However, the meta-regulation model refined by Grabosky (2017) seems most suitable for this study because rather than take a unilateral position like the institutional, stewardship, public interest and private interest theories which considers regulation or compliance to it as some form of uni-level approach, it offers a polycentric regulatory regime in which state and non-state actors jointly play a role in ensuring that effective regulation of corporate behaviour is assured. Michael Reagan and many others have been credited for their past works on meta-regulation which treated the subject as oversight

or regulations performed by government or its agencies, or as Bronwen Morgan's regulatory performance embedded within government policymaking (Braithwaite, 2017; Grabosky, 2017). Nevertheless, Braithwaite has suggested the need for enforced self-regulation by government agencies if they are to be effective in the discharge of their regulatory functions (Braithwaite, 2017). However, Grabosky's (2017) meta-regulation is a fusion of a regulatory space that includes both government agencies, private and public interest groups and self-regulation by the regulators. By working together, these groups can enhance the quality of regulation, keep corporate institutions on their toes, compel them to comply with regulatory or legislative demands, enforce punishment against erring corporate citizens and self-regulate their regulation processes for continuous improvement. This theory applies very much to this study as explained in the succeeding paragraph.

The reason for this polycentric nature of regulation is that government has been found to have suffered lapses in the regulatory space in the past leading to untoward consequences for society in many industries. Several public health disasters that took place in Nigeria, owing to poor regulation of pharmaceutical products, one of which led to an estimated 12,300 deaths of Nigerians and a loss of 892 million USD in annual costs, compel the use of this theory (Beargie, et al. 2019). Therefore, when regulators such as NAFDAC include public interest groups and private sector members, these groups can fill in the vacuum when government is unable or fails to respond to regulatory issues in a timely fashion. The weakness of this argument may be that without political or legislative power which the non-state actors do not have, their oversight functions may be deemed unconstitutional and they may be overreaching themselves. But the regulatory environment in Nigeria, which has both state, private and public interest groups working together, has helped to improve the regulatory outcomes in the pharmaceutical industry in Nigeria. The Nigerian government can do more by giving the non-state actors the opportunity to bring their expertise and skills into areas where the government's regulatory institution may be lacking knowledge or depth of understanding (e.g. technological innovations and production processes to enhance GMP implementation in the pharmaceutical industry). This cooperation can enhance the regulatory function of state regulators and at the same time foster the development of the industry concerned, in this case the pharmaceutical industry in Nigeria.

2.5 Empirical Review

This sub-section examines the objectives of the study from an empirical viewpoint by analysing previous related research investigations.

2.5.1 GMP trends in the pharmaceutical Industry

As alluded to earlier, there are many GMP trends in the modern pharmaceutical industry which are in place to improve drug companies' compliance to GMP processes and other state-sponsored or legislated regulations in place. Good Designs Practices (GDPs) have been seen as a trend which most pharmaceutical companies in the developed and developing countries have embraced to improve their compliance to GMP rules (Signore and Terry, 2005). Another trend is annual product quality review (APQR) which functions as a form of guidance for the effective regulation of the Indian pharmaceutical industry, and thus helps Indian pharmaceutical firms to improve on their compliance to GMP rules. Mingazov et al. (2019) have also mentioned the role of digitalisation of the pharmaceutical sector in Russia as having a revolutionary impact on the ability of pharmaceutical firms in the country to comply with GMP rules and other regulations.

Technology innovations such as blockchain, artificial intelligence, machine learning technologies mobile technology, cloud technology and Internet of Things have been found useful in different areas when it comes to GMP compliance by pharmaceutical companies in different parts of the developed world and emerging economies (Deloitte Centre for Health Solutions, 2018; Dumpala and Patil, 2020; Muritala and Adewole, 2019; Pieroni and Pimentel, 2020).

In their study of issues and future trends impacting drug safety in South Korea, Kim et al. (2019) identified new drug safety issues as an important GMP trend which now forces pharmaceutical manufacturers to carry out a series of coordinated premarket and postmarket evaluations and immediately report adverse drug reactions for fast action.

Data Integrity (LCS, 2020), quality assurance (Bunn, 2019; SAHPRA, 2019; WHO, 2019; Marangon, 2020), collection of GMP inspection deficiency data, Quality by Design (QbD),

continuous manufacturing, quality by design (QbD), smarter production environments, and digital documentation are other GMP trends in the pharmaceutical industry in use globally (MHRA, 2016; Derico, 2017; Nasr, et al. 2017; Hussain, 2020; Jensen, 2020).

None of these studies examined the availability of GMP trends in Nigeria which is the reason for this study.

2.5.2 Technological Innovations as Trends in the GMP implementation in the pharmaceutical Industry

Empirically, most of the studies in literature on technology innovations as GMP trends in the pharmaceutical industry dwelt on a review or analysis of technology transfer in the pharmaceutical industry without identifying the specific technologies that impacted the industry nor the GMP process. These studies are Mohite and Sangle (2017), Dumpala and Patil (2020) and Shalini et al. (2020). The only studies that empirically identified the role played by specific technologies in the pharmaceutical industries in general and specifically enhanced GMP compliance were research investigations by Shaikh et al. (2019) and NASEM (2021). Using quantitative survey research method and a structured questionnaire, Shaik et al. (2019) studied the role of technology innovations in the pharmaceutical industry in India. They found that new technologies such as Internet of Things, telecare technology, electronic medical record or digital documentation, barcode medicine identification, electronic prescription and others were in use in many parts of India and that these technologies helped to mechanise GMP compliance, and ultimately improved the quality, safety and efficacy of manufactured drugs and their monitoring in the country. NASEM (2021) is a multi-institutional study involving public and private institutions in the United States in which the role of new technologies and their impact on the pharmaceutical industry and GMP regulation was examined. Findings of the study show that while innovative technologies had advanced and continue to advance pharmaceutical manufacturing in the United States, much remains to be seen in the ability of these new technologies to aid flexible and agile pharmaceutical industry that would continue to manufacture high-quality and safe drugs for Americans without continuous and sustained regulatory oversight. These studies and others like them did not focus on

the African or Nigerian pharmaceutical sector, which is a gap this study will be addressing.

2.5.3 Quality assurance as a GMP trend in the pharmaceutical industry

Anyakora et al. (2017) in their study on cost benefit of investment on quality in pharmaceutical manufacturing with focus on WHO GMP pre- and post-certification of a Nigerian pharmaceutical manufacturer found that quality assurance was instrumental in the benefits enjoyed by Chi Pharmaceuticals Limited, one of the WHO-GMP compliant pharmaceutical operators in Nigeria. The study emphasised the need to improve on the facilities and the technical capacity by pharmaceutical firms in Nigeria and Africa in order to improve the quality assurance benchmarks needed to secure WHO-GMP pre-qualification. While the study focused on Nigeria and quality assurance as a GMP trend, the research did not address other GMP trends, which is a gap the current inquiry will be filling.

In their research investigation that delved into pharmaceutical quality assurance of local private distributors covering 13 low-income and middle-income countries, Assche et al. (2018) revealed that there is no harmonisation of regulatory systems in spite of the rapid globalisation impacting pharmaceutical production and distribution. In other words, the study found that the issue of quality assurance as a GMP trend was taking seriously by some of the countries that were part of the study while other countries did not really pay attention to the issue of quality assurance in their pharmaceutical industrial production and distribution. Only seven out of the 60 pharmaceutical enterprises that were investigated showed full compliance with GMP regulations while the rest displayed from non-compliance, low compliance to very low compliance. This means that the quality, purity, safety and efficacy of the drugs produced and distributed would be compromised. This study also focused on quality assurance alone as a GMP trend, leaving a gap for technology and new drug safety issues which will be investigated by the current research.

2.5.4 New drug safety issues as GMP trend in the Pharmaceutical industry

The report of primary research by the Center for Drug Evaluation and Research of the Food and Drug Administration of the United States shows how important new drug safety issues have been to the regulatory institution citing different engagements of technology,

technical competence and putting in place several regulatory structures to make sure drug safety was a standard in the United States' pharmaceutical sector (CDER, 2016). The report mentions the consistent efforts made by the FDA to modernise and strengthen its drug safety programmes and initiatives in the country in order to avert any public health threat which may arise as a result of an unanticipated drug safety problem. The report highlights the success recorded by the FDA owing to multidisciplinary partnerships and collaborations the FDA engaged including the adoption of technology platforms which helped to support its new drug reviews, and supported its surveillance and drug quality oversight functions.

In their research on the analysis of safety-related regulatory actions for new drugs in Japan by nature of identified risks, Fukuyama and Ono (2017) investigated 338 new molecular entities (NMEs) which were approved in Japan between the periods of 2004 and 2014. The results of the study showed that global GMP standards should be employed more seriously when conducting new drug safety analyses in order to optimise the advantage provided by the pharmacovigilance also established by many highly rated regulators such as the FDA and the EMA. They suggested that rather than expedite action for the release of new drugs in order to match the timing of the release of similar drugs in the EU and US, caution needs to be exercised to full run clinical tests based and adopt all GMP guidelines to ensure that such new drugs are found to be safe for public consumption.

The research by Guth et al. (2019) is an overview of safety pharmacology and toxicology in South Africa and is drawn from the Drug Safety Africa Meeting in Potchefstroom, held in South Africa. The study affirms that new drugs are becoming available to solve many life-threatening diseases affecting human beings but that the hallmark of any new drug should be the proof of its safety and clinical proof of its efficacy. The research infers the need for investment to be made in the area of new drug safety testing and analysis as a culture in Africa for the benefit of the people in dire need of therapeutic healing for the diseases afflicting citizens of the continent.

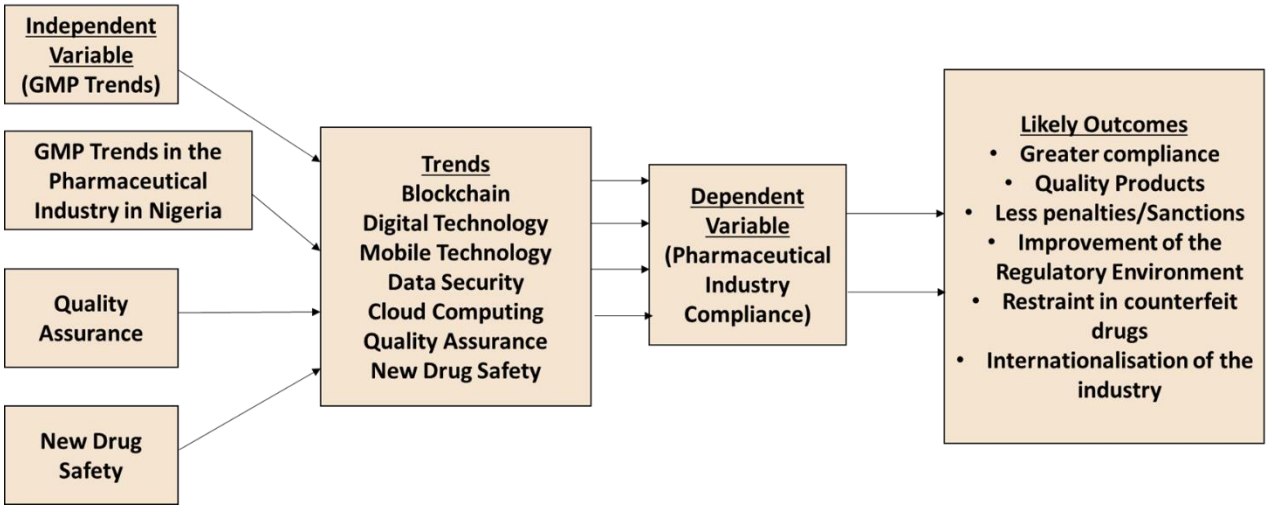
While all these studies agree on new drug safety issues as GMP trends in the pharmaceutical industry and the need to conduct tests on new drugs following GMP

guidelines, none of the studies was focused on Nigeria. In addition, they only addressed one of the GMP trends, new drug safety issues, leaving the other trends which this study will investigate.

2.6 Conceptual Framework

The conceptual framework below captures the research method and strategy for the current study in Figure 2, which is the conceptual framework:

Figure 2: Conceptual Framework



Source: Researcher (2021)

Figure 2 above is the conceptual framework of the present study which has the research intent to examine the effects of GMP trends on the pharmaceutical industry in Nigeria. The independent variable is GMP trends and the latent constructs of the predictor variable are GMP trends in the pharmaceutical industry in Nigeria, quality assurance and new drug safety issues. These constructs make up the trends that influence the compliance of the pharmaceutical industry to GMP rules. When effective, that is, when these trends such as use of technology, quality assurance and new drug safety issues enhance the compliance levels of the pharmaceutical industry to GMP regulations, the likely outcomes would be greater compliance, quality and safe products for human consumption, less penalties and sanctions for the pharmaceutical companies themselves, improvement of the regulatory environment, restraint in counterfeit drugs and the internationalisation of the industry.

2.7 Summary of the Literature Review

This review of literature has shown that there are numerous GMP trends that are redefining the manufacture and marketing of drugs by pharmaceutical companies all over the world. While the regulations may differ from country to country, there is a consensus that GMP rules are basic requirements which are expected of pharmaceutical manufacturers in any country to adhere to. Failure to adhere to these procedures can lead to fines and other costs which may disrupt the operations of the businesses concerned. Identifying the gaps that prompted this study, most of the reviewed previous studies that investigated GMP trends focused on Asia and America and a few on Nigeria, which makes this study imperative to examine the impact of GMP trends on the pharmaceutical industry in Nigeria. However, to make the work more robust, the research would also be investigating the impact of technological innovations, quality assurance and new drug safety issues as GMP trends on the pharmaceutical industry in Nigeria. Findings from the primary qualitative data to be collected regarding these gaps will be discussed later in this dissertation.

CHAPTER THREE

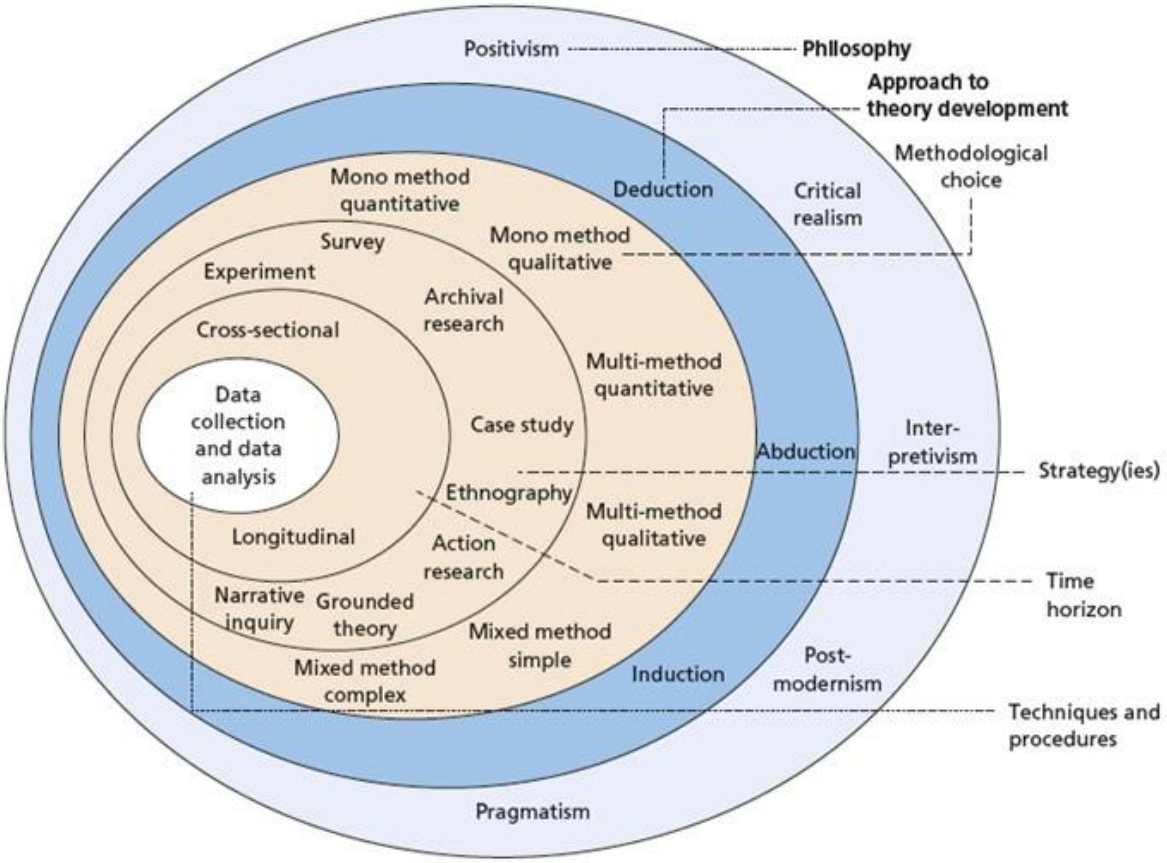
METHODOLOGY

3.1 Introduction

The research philosophy for this study is social constructivism, the research design is the descriptive design and the research method is qualitative method. The reason for the choice of the research philosophy, research design and method for this study will be explained shortly in the successive sections.

The methodology chapter is further guided by the research onion developed by Saunders, Lewis, Thornhill and Bristow (2016) as shown in Figure 3.1 below:

Figure 3 The Research Onion



Source: Saunders et al. (2016)

3.2 Research Philosophy

Social constructivism as a research philosophy is most suited to the present study because the researcher intends to collect data from interviewees who have useful experiences about GMP trends in the pharmaceutical industry in Nigeria. The interviewees by privilege of their training and work experiences understand what these trends are and will share their experiences of how these trends are applied to enhance GMP implementation in the pharmaceutical industry in Nigeria. Another reason for the adoption of this approach is the proposition in constructionism that truth, reality and knowledge is relative based on the perception of the knower (Adom et al. 2016; Saunders, et al. 2016; Okesina, 2020). Thus by engaging participants, the opinions and responses they share will help to generate important themes for analysis which can further the researcher's understanding regarding the subject matter. The researcher will commit to listening to the views/perceptions of interviewees and give interpretation to their shared experiences in this study.

3.3 Research Approach

The three main approaches in theory development are induction, deduction and abduction (Saunders, et al. 2019). The approach that aligns with the research philosophy of this study, i.e. social constructivism, is the inductive research approach. This is because constructivist research enables the researcher to understand a social event or phenomenon from the point of view of those who are participating in the research investigation (Okesina, 2020). This is why constructivist researchers begin with research participants in any inquiry and try as much as possible to understand the world or reality surrounding them from their interpretations which they convey through words (Okesina, 2020). Through dialogue or social interaction, the participants convey their interpretations of the research object to the researcher. The researcher then constructs or derives meanings from the subject of research interest through his/her own experience and that of the participants. This sometimes might involve the researcher getting involved in the activities carried out by participants to experience the true situation of things (Adom, et al. 2016). This approach encourages differences of opinions based on the differing perceptions of the research participants in combination with the experiences of the researcher. Thus, the inductive approach through constructionism

believes that all knowledge is dependent on the knowers' perceptions or interpretation and that research outcomes are made possible by the examining the contributions of those involved directly (Okesina, 2020). The elegance of induction, according to Saunders et al. (2016), is that it promotes alternative explanations of reality rather than the rigid methodology of cause-effect found in deductive research. This is why the inductive approach is concerned with the context or environment in which events happen, and chooses a small sample of people from the same context to collect their opinions regarding the research object being examined by the researcher (Žukauskas, et al. 2018; Okesina, 2020). As Saunders et al. (2016) noted, researchers who embrace this approach or tradition tend to work with qualitative method, instrumentation, data and data analysis in order to establish the different opinions of research participants regarding the phenomenon of research interest.

Social constructivism as mentioned before is usually associated with inductive research and inductive research is affiliated with qualitative method because the latter also depends on the views or perspectives of participants to understand the phenomenon under study and to develop subjective meanings concerning it (Kaushik and Walsh, 2019). This process is shaped from individual perceptions to broader or general patterns which lead to general understanding (Kaushik and Walsh, 2019).

While the qualitative method is not necessarily defined by the presence of independent and dependent variables and randomisation, which are known with quantitative studies, qualitative research studies are expected to be addressing research problems which can lead to theory building or knowledge discovery by understanding the pattern that leads to it (Okesina, 2020). Thus convenience or purposive sampling techniques or other non-probability sampling techniques are engaged for this kind of research in order for the researcher to be able to select participants whose quality responses because of their knowledge of the subject would lead to better research or robust outcomes (Okesina, 2020). This is why qualitative research uses unstructured procedures or processes and instruments to collect data such as in-depth unstructured interviews or semi-structured interviews and employs non-randomisation techniques in its sampling process (Makombe, 2017). Qualitative research methods can also be used to confirm the validity

of existing theory or knowledge as it is done in deductive research through quantitative methods (Makombe, 2017).

3.4 Research Design

Research design focuses on the blueprint of the research. It reveals the way the researcher will be going about the research and will be addressing the research problem and answering the research questions (Okesina, 2020). This blueprint, consequently, points to the research purpose, research strategy, data collection and analysis techniques, time horizon for the implementation of the research, ethical issues, research constraints and justification for the decisions reached regarding choices made (Saunders, et al. 2019; Okesina, 2020). Therefore, the research design reveals the conceptual structure which consists of the decisions made with regard to the strategies adopted for collecting, analysing and interpreting data (Makombe, 2017). The research design for this study, therefore, is exploratory in nature. The choice of this design is to help the research gain some/more insights into GMP trends which has been scarcely studied and to understand how the trends impact on the pharmaceutical industry in Nigeria. That is the main reason for choosing exploratory research design because it provides the opportunity to better understand a research problem or subject that has been sparsely studied prior to the research (Okesina, 2020).

3.4.1 Sampling and Selection of Participants

According to Wang and Gao (2020), there is purposefulness in qualitative research because it permits the careful or meticulous selection of participants who the researcher thinks are knowledgeable about the subject matter because of certain qualifications they possess (their age, experience, education, exposure, position at work in the society and other variables) which means that their views and perspectives will be valuable and could help to foster robust research outcomes. Although, the sampling process in qualitative research design has been accused of being nonprobabilistic and having capability of being biased, the compensation in the use of the method is the expectedly rich and informed data that the researcher collects from the participants (Wang and Gao, 2020). Consequently, the current research will be adopting semi-structured interviews and respondents will be selected based on convenience sampling because of the ease in

accessing them, their willingness to participate in the research, and the expected quality responses that will come from them by virtue of their knowledge, experience and exposure in the pharmaceutical industry in Nigeria. Five participants who are industry experts in the fields of quality assurance, pharmacology and drug production have been selected for the semi-structured interviews. They work with some of the leading pharmaceutical companies in Nigeria who also have presence in West Africa and have global affiliate connections. The choice of five participants for the interview has been confirmed as being adequate as saturation sets in between the 6th and 12th interview session (Guest, Bunce and Johnson, 2006). Participants were also to be professionals in any of these fields (pharmacy, quality assurance, quality control and production). This is because these professionals are likely to be aware of GMP trends as they affect or influence the pharmaceutical industry. Their profiles are as follows:

Table 3.4.1 Sociodemographic Information of Interviewees

Information	PGMP1	PGMP2	PGMP3	PGMP4	PGMP5
Gender	Female	Male	Male	Female	Male
Age	Late 40's	52	47	30's	40
Education	Master's Degree	Degree Holder	Degree Holder	Master's Degree	Master's Degree
Occupation	Pharmacist	Production (Chemical Engineering and Food Technology)	Pharmacist	Quality Assurance	Quality Assurance
Position	Senior Pharmacist	Production Manager	Manager	Quality Assurance Nutraceutical/ Pharma	Quality Assurance Chemist
Experience	15 years	25 years	20 years	10 years	15 years
Nationality	Nigerian	Nigerian	Nigerian	Nigerian	Nigerian

Source: Researcher (2021)

3.4.2 Semi-Structured Interview

The study has adopted semi-structured interview because of its advantages and usefulness, some of which are its flexibility in opening up discussions between the interviewer and participants; and its engaging nature which means that participants will be free to express themselves in a no-holds-barred way (Creswell and Poth, 2018). This method also helps in producing interesting responses which illuminate the reasons

behind the “what” or explain “why” certain positions or events or happenings are the way they are. An interview guide has been produced to focus and guide the discussions which are geared towards answering and addressing the research questions of the present study.

3.4.3 Transcription of the Semi-Structured Interviews

The semi-structured interviews were held online via Google Meet or Zoom platform depending on the preference of the participants. The researchers have all indicated their interest in having this interview through either of these channels because of the ease and wide popularity of the video platforms. The researcher would prefer Google Meet because it can record video easily without any cap on the timing. This is unlike Zoom which caps video recordings to 40 minutes for the free version and no cap on videos for the paid version. However, the researcher is open to any of the two online meeting platforms as long as it suits the respective participant better. During the interviews, jottings will be done to capture the views of the respondents while the videos of the interviews will be recorded for easy replay and transcription. A notebook was used to jot down important points made by the participants during the interviews. Using both the recorded video files and notebook jottings, the researcher will be able to effectively transcribe participants’ responses which will then be used for the data analysis.

3.5 Gioia Method for Data Analysis

There are actually five approaches in the conduct of qualitative data analysis, according to Salamzadeh (2020). These five qualitative data analysis approaches are the Anthropological approach, Gioia approach, Long Data Excerpts approach, Temporal Phases approach and Vignettes approach. However, of these five approaches, the Gioia approach has proved to offer more research rigour to the analysis of qualitative data in a very analytical, methodical and systematic way similar or akin to quantitative data analysis (Wang and Gao, 2020).

3.5.1 The Gioia Approach

The Gioia approach is a popular qualitative data analysis method which is used in qualitative research (Salamzadeh, 2020). It consists of three phases, namely, first-order code phase, second-order code phase and third-order code phase. In the first-order code phase, all the responses from the participants are collated and arranged in a first column. Thereafter, these participants' responses are categorised into similar themes in another column for easy analysis. In the third-order code phase, there is a deliberate narrowing of the second-order codes into single ideas or concepts which represent the codes. This entire process produces what is called the code map, which looks like a quantitative analysis or arrangement of themes into codes representing the mean ideas of participants based on their responses. It is this code map that would be discussed in the successive chapter.

3.5.2 Memo Writing

According to Wang and Gao (2020), at this stage, the researcher is involved in the transformation of data into theory. This stage consists of the analysis, classification and coding of data whose interpretation is later discussed extensively to tease out patterns, their meanings and impact on the research inquiry. At this stage, also, it must be mentioned that codes might be rewritten in order to conform to the responses given by participants. Furthermore, memo writing involves the interpretation or explanation and analysis which take place between the already generated codes, and the second-order and third-order code categories which represent the dominant themes, concepts and ideas generated in and through the data analysis.

3.6 Ethical Considerations

The reliability of the research instrument was confirmed by the supervisor of this study by ensuring that the research instrument was adequate to address the research objectives of this study. Before participants were engaged for the semi-structured interview, their informed consent was given voluntarily and the research purpose was explained to them, including their role which was limited to the information they would be supplying as responses to the questions contained in the interview guide. Participants

were also told that at any point in the interview, they were free to discontinue with the question-and-answer session at no negative consequence to their person. They were also assured that if they felt uncomfortable with any of the questions asked, they could decide to ignore it. They were promised that the information they would be providing as responses would only be used for the purposes of this research and that any information they give to the researcher would be treated anonymously.

CHAPTER FOUR

RESULTS

4.1 Introduction

This chapter presents the interview results on the effects of GMP trends on the pharmaceutical industry in Nigeria. Interviewee participants shared their informed perspectives and knowledge regarding GMP trends in the pharmaceutical industry in the country. Participants were asked questions that were derived from the research questions proposed for this study which are: (i) what perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria? (ii) what is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria? (iii) what is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria? (iv) what are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria?

This chapter begins with the analysis of the sociodemographic information of the interviewees. However, in analysing their sociodemographic information, participants' identities will be shielded in line with the research ethics guiding this study. In effect, instead of mentioning their names, participants will be given identifiers such as: Participant_GMP1 or PGMP1 (for participant 1), Participant_GMP2 or PGMP2 (for participant 2), Participant_GMP3 or PGMP3 (for participant 3), Participant_GMP4 or PGMP4 (for participant 4), and Participant_GMP5 or PGMP5 (for participant 5). The analysis of participants' responses regarding the sociodemographic information and to the research questions will follow. Gioia method of qualitative data analysis will be employed in the analysis of the data or interviewees' responses to the research questions.

4.2 Coding of Interview Participants' Identities

Table 4.2.1 Coding of Interview Participants

Participant ID#	Participant's Designation	Interview Status
1	Participant_GMP1 or PGMP1	Completed
2	Participant_GMP2 or PGMP2	Completed

3	Participant_GMP3 or PGMP3	Completed
4	Participant_GMP4 or PGMP4	Completed
5	Participant_GMP5 or PGMP5	Completed

Source: Researcher (2021)

From Table 4.2.1 reveals that five participants took part in the semi-structured interviews put in place for the current research which they also completed. They are given the above identifiers to anonymise their identities and responses to questions posed to them.

4.3 Analysis of Participants' Responses

The responses of participants in the interview have been organised in Table 4.3.1 below for better clarity.

Table 4.3.1 Participants' Responses to the Interview Questions

Participant ID#	RESEARCH QUESTIONS AND OBJECTIVES	Responses
PGMP1	RESEARCH QUESTION 1 What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 1 To examine the perceptions of professionals regarding GMP trends in the pharmaceutical industry in Nigeria.	• Certified modern drug manufacturing plants, quality control and assurance measures, employment of professionals and technology are GMP trends which help avoid health disasters and keep consumers safe. • Pharmaceutical products are traced today through batching or through a track and trace system implemented in the supply chain. • Documentation is another very important aspect of GMP trends and several pharmaceutical companies in the country that I know have digitalised the process of documenting their manufacturing processes.
PGMP1	RESEARCH QUESTION 2 What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 2 To evaluate the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria.	• We are making progress as a country in terms of the adoption of modern GMP trends by our pharmaceutical companies. • WHO and NAFDAC GMP certification manufacturing plants. • Use of technology in making, supplying and tracking drugs. • Manufacturing plants have secured ISO certifications (e.g. ISO certification 9001:2015) and many others. • Technology is key in sourcing active pharmaceutical ingredients, manufacturing, supplying and tracing pharmaceutical products. • Technology is useful in assembling raw materials, initiating the manufacturing of the product, packaging of products, distribution and monitoring.
PGMP1	RESEARCH QUESTION 3 What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 3	• Quality assurance gives confidence to regulators and consumers alike that the manufacturer is guided by quality considerations all through the product life cycle. • Quality assurance is a never ending process; attends to problem identified, and tests products all through the stages.

	To find out the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria.	
PGMP1	RESEARCH QUESTION 4 What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 4 To examine the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria.	• New drug safety issues include clinical trials and elaborate processes put in place to safeguard consumers when ingesting new drugs. • New drug issues promote quality and safety of drugs. • New drug safety issues involve the continuous testing of new drugs process through digitalisation, innovations, testing, improved production processes, distribution and traceability.
PGMP2	RESEARCH QUESTION 1 What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 1 To examine the perceptions of professionals regarding GMP trends in the pharmaceutical industry in Nigeria.	• Nigerian pharmaceutical manufacturers are staying abreast of the modern trends in GMP by working hard to qualify for WHO and NAFDAC GMP certifications and in line with global best practices which require ethical practices and documentation in the entire pharmaceutical value chain. • Nigeria is making progress in terms of the adoption of modern GMP trends by pharmaceutical companies in the country. • Pharmaceutical manufacturing firms in Nigeria are following global best practices.
PGMP2	RESEARCH QUESTION 2 What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 2 To evaluate the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria.	• Technology is helpful in having the right facilities and equipment for manufacturing, documentation of work processes, quality control, and elimination of product contamination. • Technology helps us in the documentation of manufacturing processes, and storage of information in the cloud as backup (SaaS). • Social media apps to monitor effects of pharmaceutical products on consumers and to receive feedback from consumers. • Considering blockchain in the area of record keeping. • Barcode medicine identification used for tracking. • Batching of products used for tracking and tracing.
PGMP2	RESEARCH QUESTION 3 What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 3 To find out the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria.	• Quality assurance helps during the research, and development of drugs for trials before manufacturing and sales. • Without quality assurance, pharmaceutical products can constitute a threat to public health.
PGMP2	RESEARCH QUESTION 4 What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 4 To examine the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria.	• Drug safety involves continuous monitoring of drug effect and reactions on users for their safety and continuous drug use.

PGMP 3	RESEARCH QUESTION 1 What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 1 To examine the perceptions of professionals regarding GMP trends in the pharmaceutical industry in Nigeria.	• GMP ensures that pharmaceutical manufacturing companies consistently manufacture and distribute products of high quality, safe and efficacious for patients. • In many advanced societies of the world, GMP rules are just the baseline as many global manufacturing firms have installed or established stricter GMP measures in order to improve their product quality and avoid product outcomes that can be injurious to public health and safety. • Modern trends in GMP implementation are driven by innovations happening in the society involving new processes, tools and technologies applied to pharmaceutical operations. • NAFDAC's traceability of genuine drugs through Mobile Authentication Service (MAS). • Digital documentation for ease in drug traceability. • Batching and distribution like barcoding to aid traceability and easy tracking. • 10 manufacturers in Nigeria already secured WHO-GMP certification aside NAFDAC GMP certifications which pharmaceutical manufacturing firms already have. • Regulatory environment is alive to its responsibilities thereby discouraging sharp practices from drug manufacturers and distributors.
PGMP 3	RESEARCH QUESTION 2 What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 2 To evaluate the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria.	• Technology is helping the industry. • Digital documentation. • Digital storage. • Digital processing. • Digital retrieval. • Logistics technology now used in drug traceability.
PGMP 3	RESEARCH QUESTION 3 What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 3 To find out the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria.	• Quality assurance guarantees the maintenance of quality all through the life cycle of a drug product.
PGMP 3	RESEARCH QUESTION 4 What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 4 To examine the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria.	• New drugs are subjected to the best practices of GMP rules which are designed to last the entire life cycle of a drug product (that is, from research to development to manufacturing, distribution and product discontinuation). • They guarantee the safety and health of consumers and to save the business from fines and penalties that may result from any form of negligence.
PGMP4	RESEARCH QUESTION 1 What perceptions do professionals have of GMP trends in the	• GMPs are those rules or procedures that manufacturers of medicines and other healthcare products are expected to keep so that their products can be of high quality and safe for human ingestion.

	pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 1 To examine the perceptions of professionals regarding GMP trends in the pharmaceutical industry in Nigeria.	• Trends include securing manufacturing GMP certifications from NAFDAC the regulator and the Pharmacists Council of Nigeria (PCN); ISO certifications (ISO 9001:2015; ISO 14001:2015) for Quality Management System (QMS) and Environment Management System (EMS) from the Standard Organisation of Nigeria (SON). • GMP certifications • Documentation and storage of manufactured drug information • Quality assurance through quality audits and checks. • Domestic pharmaceutical companies now have either WHO GMP certifications or NAFDAC GMP certifications or both. • Upgrade of manufacturing plants. • Hiring qualified personnel. • Training and retraining of staff in GMP global best practices.
PGMP4	RESEARCH QUESTION 2 What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 2 To evaluate the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria.	• Technology is helpful. • Digital documentation. • Digital retrieval of digital files. • Automation of processes through software applications. • Smart sensors in meeting drug compliance through testing and distribution.
PGMP4	RESEARCH QUESTION 3 What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 3 To find out the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria.	• Quality assurance is a very important part of GMP trends in the modern pharmaceutical industry. • Quality assurance promotes drug stability, the quality and safety of drugs at every phase in the life cycle of a pharmaceutical product.
PGMP4	RESEARCH QUESTION 4 What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 4 To examine the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria.	• New drug safety issues are lengthy processes involving clinical trials and repeat trials conducted to ascertain the safety, purity and quality of a drug product before mass production. • New drug safety measures engage GMP processes in all their phases to guarantee drug stability, quality and safety for human consumption.
PGMP5	RESEARCH QUESTION 1 What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 1 To examine the perceptions of professionals regarding GMP trends in the pharmaceutical industry in Nigeria.	• GMPs are the minimum standards that pharmaceutical companies are expected to keep in their manufacturing of medicines for public consumption (production to storage, distribution and monitoring of products). • Modern trends in the pharmaceutical industry include: ✓ Acquisition of GMP-compliant certifications from the regulators. ✓ Use of technology and qualified human resources. ✓ Nigeria is making progress in the pharmaceutical industry.

		✓ Nigerian manufacturers have secured WHO-GMP certifications. ✓ Digitalisation for documentation, audit and information sharing. ✓ Modernisation of operations.
PGMP 5	RESEARCH QUESTION 2 What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 2 To evaluate the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria.	• Technology is helpful. • Good design practices for the construction of modern manufacturing plants. • Annual product quality reviews. • Technology-aided interaction between manufacturers of drugs and end users. • Technology-aided drug testing procedures and packaging of final products for traceability.
PGMP 5	RESEARCH QUESTION 3 What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 3 To find out the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria.	• Control the laboratory environment (e.g. right materials for drug production, monitor/inspect/propose measures that improve final drug product. • Technology tools to record information about lab equipment and their scheduled calibrations, maintenance and documentation, ensure quality assurance and control measures are observed when we receive raw materials, assess and test quality of raw materials, and ensure that the quality of the final product meets with industry or regulatory standards. • Digital documentation, storage and retrieval of information. • GMP compliance not complete without effective quality assurance because it guarantees that the prescribed drug produces the desired effect when ingested by patients. • Quality assurance processes are engaged from the gathering of raw materials, to product development, manufacturing and distribution.
PGMP 5	RESEARCH QUESTION 4 What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria? RESEARCH OBJECTIVE 4 To examine the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria.	• New drug safety issues go hand in hand with GMP processes and are subject to GMP rules and procedures. • New drug safety issues require clinical testing and observation and are sustained throughout the life cycle of a medicine.

Source: Researcher (2021)

4.4 First-Order Codes Generated from Participants' Responses

From the participants' responses, first-order codes will be generated for this research investigation. The first-order of codes is the summarised responses of interviewees to the questions they were asked.

Table 4.4.1 First-Order Codes Generated from Participants' Responses

Research Questions	First-Order Codes
What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria?	1. GMP rules compel pharmaceutical manufacturing companies in Nigeria to consistently manufacture, store, distribute and monitor products to ensure safety and efficacy for patients through monitoring. 2. Nigeria is following global best practices in terms of the adoption of modern GMP trends by pharmaceutical companies in the country. 3. Modern trends in GMP implementation in pharmaceutical operations are driven by innovations happening in the society involving new processes, tools and technologies. 4. Domestic pharmaceutical companies now have either WHO GMP certifications or NAFDAC GMP certifications or both. 5. NAFDAC's traceability of drugs through Mobile Authentication Service (MAS). 6. Digital documentation for ease in drug traceability. 7. Batching and distribution like barcoding to aid traceability and easy tracking. 8. Trends include securing manufacturing GMP certifications from NAFDAC the regulator and the Pharmacists Council of Nigeria (PCN); ISO certifications (ISO 9001:2015; ISO 14001:2015) for Quality Management System (QMS) and Environment Management System (EMS) from the Standard Organisation of Nigeria (SON). 9. Digital storage of manufactured drug information, audit and information sharing. 10. Quality assurance through quality audits and checks. 11. Upgrade of manufacturing plants. 12. Hiring qualified personnel, training and retraining of staff in GMP global best practices. 13. Use of technology and modernisation of operations.
What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria?	1. Technology is helping the pharmaceutical industry. 2. Use of technology in assembling raw materials, manufacturing, packaging, supplying, tracing, tracking or monitoring pharmaceutical products. 3. Technology is helpful in drug testing procedures, quality control, and elimination of product contamination. 4. Social media apps to monitor the effects of pharmaceutical products on consumers and to help pharmaceutical makers receive feedback. 5. Blockchain in the area of record keeping. 6. Barcode medicine identification used for tracking. 7. Batching of products used for tracking and tracing. 8. Digital documentation of work processes, storage in the cloud (SaaS), processing and retrieval of digital files. 9. Logistics technology now used in drug traceability. 10. Automation of processes through software applications. 11. Smart sensors in meeting drug compliance through testing and distribution. 12. Good design practices for the construction of modern manufacturing plants. 13. Annual product quality reviews through technology.
What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria?	1. Quality assurance gives confidence to regulators and consumers alike that the manufacturer is guided by quality considerations all through the product life cycle. 2. Quality assurance is a never-ending process; attends to problem identified, and tests products all through the stages (pre- and post-market trials). 3. Without quality assurance, pharmaceutical products can constitute a threat to public health.

	4. Quality assurance promotes drug stability, the quality and safety of drugs at every phase in the life cycle of a pharmaceutical product. 5. Quality assurance assists in the control of the laboratory environment (e.g. right materials for drug production, monitor/inspect/propose measures that improve final drug product).
What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria?	1. New drugs are subjected to the best practices of GMP rules which are designed to last the entire life cycle of a drug product (research to development to manufacturing, distribution and product discontinuation). 2. New drug safety issues include clinical trials and elaborate processes which guarantee drug stability, safety, purity, and quality for human consumption. 3. New drug safety issues include the continuous testing of new drugs through digital innovations, improved production processes and distribution and traceability. 4. Drug safety involves continuous monitoring of drug effect and reactions on users for their safety and continuous drug use. 5. New drug safety issues save pharmaceutical manufacturers from fines and penalties that may result from any form of negligence.

Source: Researcher (2021)

Having generated the first-order codes from participants' responses, to create the second-order codes, dominant themes in the first-order codes will be isolated and distilled further (Gioia, et al. 2013). Third-order codes are a further distillation of the second-order codes.

4.5 Second-Order Codes

The second column of Table 4.4.1 depicts the second-order codes based on the distillation of the first-order codes. The second order of codes consist of common themes that resonate with the first-order codes consisting of interviewees' responses.

Table 4.5.1 Second-Order Codes Based on the Distillation of First-Order Codes

Research Questions	Second-Order Codes
What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria?	1. Trust 2. Safety 3. Quality
What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria?	1. Pre-Market Trials 2. Manufacturing 3. Distribution 4. Post-Market Trials (Monitoring)
What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria?	1. Regulatory and consumer confidence 2. Public Health
What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria?	1. Continuous Monitoring 2. Public Safety

Source: Researcher (2021)

4.6 Third-Order Codes

The third-order of codes is a further narrowing of the themes into single ideas or concepts. The third-order codes were selected from the second-order codes and indicated in the second column:

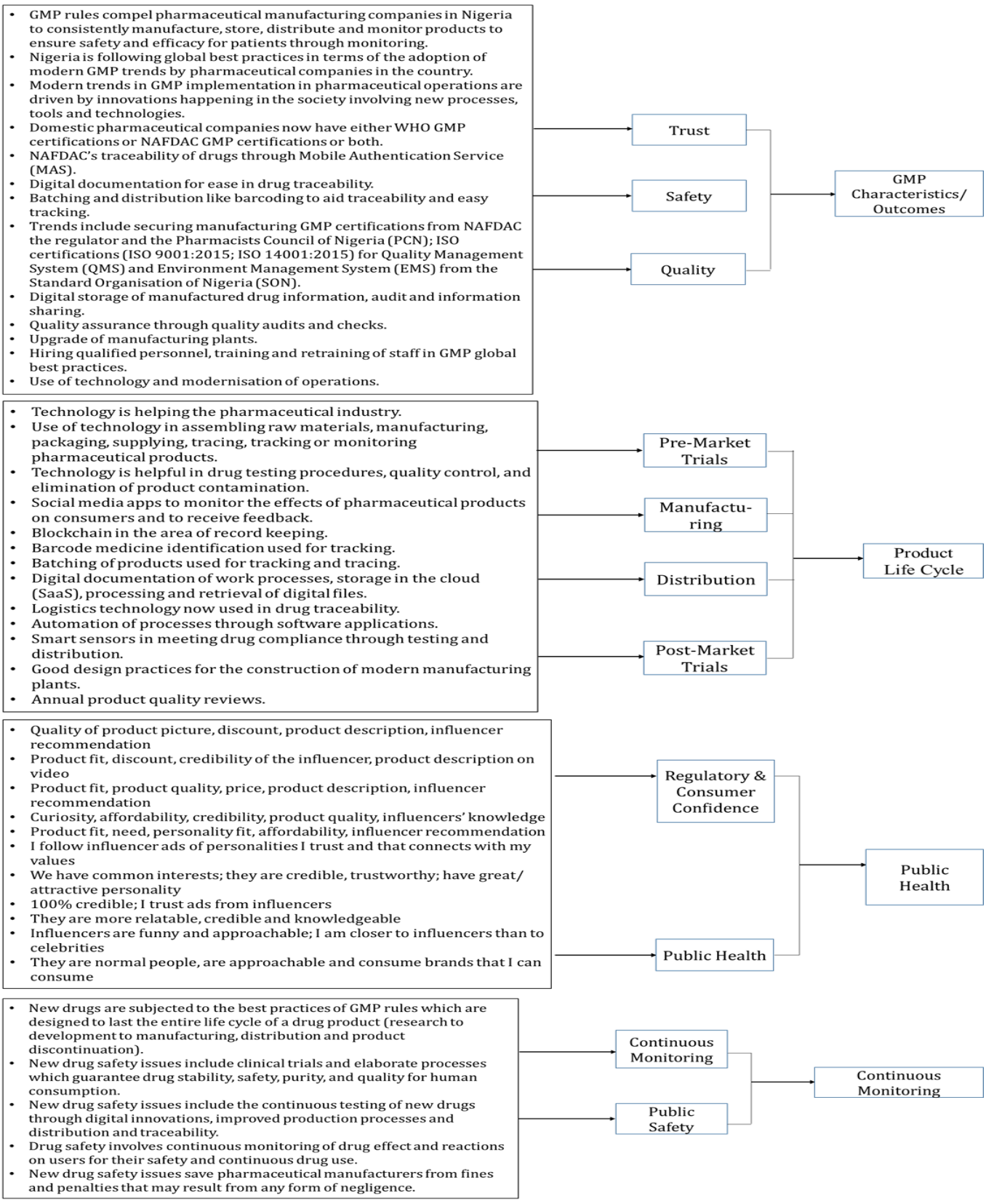
4.6.1 Third-Order Codes Based on the Distillation of Second-Order Codes

Research Questions	Third-Order Codes
What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria?	GMP Characteristics
What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria?	Product Life Cycle
What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria?	Public Health
What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria?	Continuous Monitoring

Source: Researcher (2021)

4.7 Results

Figure 4 Using Gioia Method to Create Coding Map of Summary of Results



Source: Researcher (2021)

4.8 Interpretation of Results

Based on the research questions of the current study, four coding phases were created. Therefore, this section is the interpretation of the summary of participants' responses relying on the four coding phases. In the next and final chapter, findings will be assessed against the positions in the previous literature on the effects of GMP trends on the pharmaceutical industry in Nigeria.

4.8.1 Interpretation of the Coding Outcomes for Research Question One

Research Question 1: What perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria? Regarding this question, participants' responses generated three codes under GMP Characteristics/Outcomes. These are: Trust, Safety and Quality.

4.8.1.1 Trust

A summary of participants' responses shows that they perceived one of the outcomes or goals or characteristics of GMP is to instil trust in the drug making, distribution and monitoring processes such that regulators would be sure that pharmaceutical manufacturers are doing the right thing and consumers would also have the confidence to ingest drugs made without any fear of being harmed doing so. This shows that professionals perceived that GMP trends prevent us from, according to PGMP1, "*…health disasters and keeps all of us safe when consuming medicines.*" The response of PGMP3 further confirms what professionals in the industry think of GMP trends: "*People feel aches, pains, discomforts when they go about their daily activities and sometimes accidents happen. These don't have to be automobile accidents but could be domestic accidents while gardening, you slip and fall, and injure yourself. Drugs are needed most times to help people cure the pains and aches they feel and to even get the needed cure. But in producing these drugs, care is taken to ensure that the goal of the manufacturing process is achieved. That goal is ensuring that the drugs are found to be effective and safe. That means that ingesting the drugs does not complicate the health problem but rather alleviates the condition. This is why good manufacturing practices are put in place for medicine manufacturers as a way*

to ensure that they consistently manufacture and/or distribute products that are of high quality and that are effective for patients' use and safe for human consumption."

4.8.1.2 Safety

The participants also highlighted the goal, outcome or characteristic of GMP trends as being the need to achieve safety always with the final medicine product in the hands of consumers. Interviewees reckoned that failure to achieve safety could lead to health disasters which could claim the lives of innocent consumers. This was affirmed by PGMP4, "*So it is better to honour the rules and this is important because human lives are involved. Any negligence that results into a contaminated pharmaceutical product or one whose clinical trial outcomes were falsified can lead to untold public health disaster. This is why it is good for the manufacturer and the society that only pharmaceutical companies that keep to GMP guidelines are the ones involved in the production and distribution of pharmaceutical products in any society.*" PGMP2 adds that: "*Drug safety is the concern of all stakeholders in the pharmaceutical industry right from the regulators to the manufacturers to the consumers and other important stakeholders. That is why the whole gamut of GMP processes whether documentation, validation, written procedures, use of the right and safe equipment and facilities is aligned with the best GMP procedures to ensure that before a new drug is launched, at least it has proven its effectiveness, purity and safety for human consumption."*

4.8.1.3 Quality

Participants also viewed GMP trends as providing the guarantee that only quality products would be manufactured, distributed and sold by medicine makers always without any compromise. This is why like all the trends (technology, quality assurance and new drug safety issues), the entire life cycle of a pharmaceutical product is taken into consideration. PGMP5 states that the goal of GMP trends is to "*…ensure that the quality of the final product meets with industry or regulatory standards".* Still on quality, PGMP1 makes a pertinent comment that appears quite informative and illuminating. She says, "Do you know that clinical trials are still ongoing for a popular analgesic like aspirin? So …the GMP process ensures that quality and safety are maintained throughout the entire life cycle of a product".

From the summary of participants' responses, it is obvious that their perceptions of GMP trends are that they help to promote trust in the society regarding the use of pharmaceutical products for human consumption and that safety and quality are the other characteristics or outcomes of GMP processes and trends.

4.8.2 Interpretation of the Coding Outcomes for Research Question Two

Research Question 2: What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria?

Participants' responses to the second research question generated the following four codes: pre-market trials, manufacturing, distribution and post-market trials. These four codes point to product life cycle, the third-order code derived from that analysis.

4.8.2.1 Pre-Market Trials

The participants emphasised the opinion that the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria is throughout the life cycle of the drug product starting from pre-market trials. Speaking about the pharmaceutical industry in Nigeria and the use of technology in the drug product life cycle, this is what PGMP1 has to say, "*There is nothing we can do today without technology. As an industry, we rely on technology throughout the product value chain.*" This implies that the pharmaceutical industry uses technology at the pre-market stages of a product. PGMP2 adds that: "*Technology is helping the implementation of the GMP in the pharmaceutical industry a great deal. Technology is helping in the area of having the right facilities and equipment for manufacturing. It is also helping in the area of documentation of work processes for compliance and tracking. Even in the area of written procedures, quality control, avoidance of contamination and in many areas, technology has been found useful*." The points that PGMP2 identified are important pre-market environment enabled by technology before pharmaceutical products are made.

4.8.2.2 Manufacturing

Participants also believed that technology is supportive of pharmaceutical products manufacturing. PGMP1 says that technology has been useful to the industry during, *"… sourcing of Active Pharmaceutical Ingredients for manufacturing, engaging in the manufacturing of products or even supplying and tracing products. Technology is key and Nigeria may not be at the level of the advanced countries but we are pushing the edges of the envelope in Africa in terms of technology adoption in the industry*." PGMP2 also says that "*Technology is helping in the area of having the right facilities and equipment for manufacturing.*"

4.8.2.3 Distribution

Technology was perceived by participants to be of great benefit in the distribution of pharmaceutical products. For example, PGMP3 says "*Then technology is helping the storage of documentation for manufacturing processes of drugs including modern logistical processes like batching and distribution like barcoding to aid traceability and easy tracking. A lot still needs to be done, I know, but Nigerian manufacturers are making the necessary efforts to embrace current technologies to improve their GMP processes."*

Speaking about sensors, which are used in the pharmaceutical industry, PGMP4 states that "*The sensors help in quality testing and distribution of drugs which enables distributors to restock in a timely manner and also helps our tracking of product.*"

4.8.2.4 Post-Market Trials

Another important use of technology in the product life cycle is at the stage of post-market trials. Pharmaceutical companies in Nigeria rely on technology tools to continue to monitor their products in distribution. PGMP2 has this to say, "*… we have developed our own social media applications to monitor the effect of our products on consumers and to continue to communicate with our distributors all over Nigeria to harvest feedback from them and their own customers. This helps to make sure we know how our products are performing. Then, as a company we are looking into the long-term benefits of blockchain because of its value in record keeping. All these are measures we are taking aside what is now normal in the industry such as barcode medicine identification which is used for*

tracking, batching of products which is also used for tracking and tracing and some technology tools I am not permitted to mention here."

From the above, it is apparent that pharmaceutical companies in Nigeria employ technology aids to conduct their pre-market, manufacturing, distribution and post-market activities regarding their manufactured drug products.

4.8.3 Interpretation of the Coding Outcomes for Research Question Three

Research Question 3: What is the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria? In discussing the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria, two codes emerged from the patterns of responses made by participants: regulatory and consumer confidence and public health.

4.8.3.1 Regulatory and consumer confidence

Regarding the impact of quality assurance as a GMP trend in the pharmaceutical industry, many of the participants agreed that quality assurance was an important process put in place to guarantee regulatory and consumer confidence in the industry and the products it makes. PGMP1 summarises this position: "*Quality assurance is very essential as part of the GMP process. It is what gives confidence to regulators and consumers alike that the pharmaceutical products manufacturer will live up to the expected obligations that all quality requirements will be followed. Quality assurance promotes the principles of fit for purpose and right the first time. It starts with the quality management of raw materials, the assembling process, quality production management involving products and components, actual production and inspection. Without quality assurance, immediate identification of problems that may impair patient safety or care will not be possible*."

4.8.3.2 Public Health

Participants also believe that quality assurance helps to foster public health. PGMP2 puts it this way, "*In fact, without quality assurance, pharmaceutical products can constitute a threat to public health. This is why Quality Assurance departments are committed to the*

effectiveness and safety of the pharmaceutical products their companies manufacture." This position was also shared by PGMP2 who asserts that without quality assurance throughout the life cycle of a drug product, "*Any negligence that results into a contaminated pharmaceutical product or one whose clinical trial outcomes were falsified can lead to untold public health disaster*."

Thus, participants showed by their responses that quality assurance was essential to guarantee regulatory and consumer confidence and public health.

4.8.4 Interpretation of the Coding Outcomes for Research Question Four

Research Question 4: What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria?

Two codes were generated from participants' responses on this question. The codes are: continuous monitoring and public safety and they both point to the third-order code, which is continuous monitoring.

4.8.4.1 Continuous Monitoring

Participants' responses reveal that interviewees believe that new drug safety issues require continuous monitoring throughout the life cycle of a medicine product. PGMP5 puts it this way, "*New drug safety issues are new trends that go hand in hand with GMP processes and are subject to GMP rules and procedures. For example, before new drugs secure approvals, they go through a long process of clinical testing and observation. At the point of mass production, GMP requirements are activated to ensure that the entire process of the new drug manufacturing follows best practices that will eliminate contamination, mistakes/errors and poor documentation. This continues even after the new drug is released into the market for human or veterinary consumption.*"

4.8.4.2 Public Safety

The summary of participants'' responses show that interviewees see new drug safety measures as a positive attempt to guarantee public safety throughout the life cycle of a

manufactured pharmaceutical product. PGMP1's explanation is befitting here: "*When drugs are being tested, they involve a small number of patients. But after the necessary approvals are received these drugs are mass produced for human consumption on a larger scale. But then regulators and the manufacturers will not go to sleep but will maintain vigilance by monitoring the reactions of the drug and if there are adverse effects that could endanger patients or users. If it is found that the drug safety ratio is high, continuous tests and trials will continue to ensure that the consumption of the drugs is safe for patients. Do you know that clinical trials are still ongoing for a popular analgesic like aspirin? So new drug safety issues align with the GMP process that ensures that quality and safety are maintained throughout the entire life cycle of a product*."

There will be a discussion of these results and findings in the next and final chapter.

CHAPTER FIVE

DISCUSSION AND CONCLUSION

5.1 Introduction

This research study explores the effects of GMP trends on the pharmaceutical industry in Nigeria using the social constructionist or constructivist research strategy and the Gioia qualitative data analysis for the coding, categorisation, analysis and interpretation of qualitative data which were collected during the semi-structured interview. This final chapter discusses the findings and results generated from the semi-structured interviews and gives a befitting conclusion to the study. In executing this final chapter, the summary of the results or findings will be done, while the findings and results made will be discussed in the light of evidence in previous literature. Afterwards, the contributions and weaknesses of this investigation will be identified before also mentioning the limitations of the study, its future research potential, the theoretical and practical implications of the findings and the conclusion.

5.2 Summary of Findings

Five interviewees were selected for the semi-structured interview based on convenience sampling. They were three males and two females. They had been accosted with the proposition to grant the researcher the interview through a field research assistant, and they obliged. They completed the initial consent forms before the interview sessions kicked off through Google Meet after a few weeks after. They fully cooperated with the interviewer/researcher during the interview process, and shared their professional knowledge and understanding regarding the questions posed to them.

Participants were college educated with three of them having a master's degree relevant to the pharmaceutical industry. The youngest of them was in her thirties while the oldest of them was 52. They are all Nigerians and while some of them had been educated abroad, they returned to Nigeria to contribute to the development of the pharmaceutical industry. Two of the interviewees work as Quality Assurance chemist (PGMP4) and Quality

Assurance manager (PGMP5) respectively. PGMP1 and PGMP3 are pharmacists while PGMP2 has a background in chemical engineering and food technology. The five interviewees occupied supervisory and managerial positions in their individual pharmaceutical firms.

The four phases of coding that were executed during the data analysis generated four propositions/themes based on the study's four research questions. These four propositions can be stated as conclusions for this study:

Conclusion 1: Based on professionals' perceptions, GMP trends in the pharmaceutical industry in Nigeria are characterised by trust, safety and quality.

Conclusion 2: Technology in the implementation of GMP trends in the pharmaceutical industry affects the entire product life cycle of pharmaceutical products.

Conclusion 3: Quality assurance as part of GMP trends in the pharmaceutical industry in Nigeria improves public health.

Conclusion 4: New drug safety issues as part of GMP trends influence continuous drug products' monitoring for public safety.

5.3 Discussion of Findings or Results Based on Extant Literature

In discussing the results, this will be done by comparing them with results or findings in previous studies.

5.3.1 Based on professionals' perceptions, GMP trends in the pharmaceutical industry in Nigeria are characterised by trust, safety and quality

The first result in the current research is that professionals in the pharmaceutical industry view GMP trends positively as they relate to the industry. Specifically, they believe in GMP trends because of the characteristics of trust, safety and quality they have which improve the drug making process(es) and guarantee the safety of healthcare product consumers.

In their cross-sectional survey study of 544 Malaysians regarding the challenges facing the Malaysian pharmaceutical sector in the areas of quality and affordability of national medications, Abdellah, et al. (2016) find that most Malaysian participants expressed confidence or trust in their national medications and do not bother for their safety while taking them. Part of the study was to also examine the manufacturing processes of the pharmaceutical companies in Malaysia which is related to GMP or best manufacturing practices. In a qualitative study carried out in Pakistan by Tauqeer, et al. (2019), they concluded that enforcement of GMP trends in pharmaceutical manufacturing ensured that patients receive effective and safe drugs and also builds confidence in the patients and public. With regard to safety, Ubajaka et al. (2016) in their qualitative study of factors associated with drug counterfeit in Nigeria from a twelve-year review, identified the role of NAFDAC in the introduction of GMP rules and GMP certification for pharmaceutical manufacturers in Nigeria to ensure safety in their drug production processes. In another qualitative study by Ekeigwe (2019) on the subject of drug manufacturing and access to medicines in West Africa with focus on challenges and remediation, Ekeigwe concludes the study by advocating for the need for all stakeholders, both local and international partners, to continue to push for best practices in drug making so as to guarantee the safety of everyone. Pertaining to quality, Sanjeevaiah and Munaga (2017) believe that that the whole essence of regulation is to guarantee that every drug product being manufactured or in circulation meets the expected regulatory quality standards which the GMP rules are about. In his book on good manufacturing practices for pharmaceuticals, Bunn (2019) recognises the place of strength, purity and quality in drug production as part of GMP regulations. Bunn (2019) pointed to the role of the FDA in the United States and how it ensures that manufacturers of pharmaceutical in the United States adhere to high manufacturing standards which enable each product they have on their stable to meet the strength, purity and quality standards required by the regulator.

From these previous studies, it is apparent that there is evidence in literature supporting the view that GMP rules or regulatory requirements insist on pharmaceutical manufacturers working hard to achieve trust, safety and quality with their products. This position confirms the first conclusion made by this study.

5.3.2 Technology in the implementation of GMP trends in the pharmaceutical industry affects the entire product life cycle of pharmaceutical products

Another finding made in this study affirms that technology in the implementation of GMP trends in the pharmaceutical industry affects the entire drug product life cycle (that is, pre-market trials, manufacturing, distribution and post-market trials or monitoring). In their study on the future of pharmaceutical manufacturing sciences, Rantanen and Khinast (2015) identify the role of technology in each phase of a medication's life cycle which improves the quality risk management. Sarkar and Kaur (2016) in their investigation of the Indian pharmaceutical industry with attention to its challenges and prospects also recognise the role that technology plays in the pre-marketing phase of medication production authorisations which is a prelude to the effective local production of pharmaceuticals. This view is also shared by the African Union when it established its African Medicines Agency and highlighted the role technology was going to play in the different facets of the medications' life cycles in Africa. Similarly, Ekeigwe (2019) emphasises the role of technology pharmacovigilance in Africa citing that through technology post-marketing surveillance would be better enhanced and sustained effectively. NAFDAC (2020) adds that when regulatory institutions utilise technology in the pharmaceutical industry in West Africa, it would improve their quality control and inspection tasks, modernise their data collection and processing capability, and harmonise regulatory initiatives while manufacturers of drugs would also benefit maximally in effectively producing quality drugs and monitoring the distribution of the drugs for public safety. Furthermore, Shaikh et al. (2019) and NASEM (2021) have all confirmed the important role technology tools such as Internet of Things, telecare technology, electronic medical record or digital documentation, barcode medicine identification, electronic prescription and others play in all the phases of the medication life cycle. Consequently, there is evidence in literature that supports the second conclusion which states that technology in the implementation of GMP trends on the pharmaceutical industry affects the entire product life cycle of pharmaceutical products.

5.3.3 Quality assurance as part of GMP trends in the pharmaceutical industry in Nigeria improves public health

The third conclusion made in this research study is that quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria improves public health. Rantanen and Khinast (2015) have emphasised the place of quality assurance in the future of pharmaceutical manufacturing as an important procedure that guarantees real-time quality assurance and process control which is the hallmark of modern process engineering. Angelino, Khanh, Ha and Pham (2017) reveal in their research on the Vietnamese pharmaceutical industry that in order to properly regulate the industry and enhance its development trajectory, thus making it competitive, the Vietnamese government formulated policies that included quality assurance for the better positioning and development of the industry. The importance of quality assurance in the drug production process has also been confirmed as a critical part of GMP compliance which ensures improvement in the quality management system for pharmaceutical firms (Pharmaceutical Inspection Convention, 2018). According to Bunn (2019), quality assurance guarantees increased public confidence in the pharmaceutical industry and in the products being made and distributed from that industry. Adoption of quality assurance in the pharmaceutical industry helps manufacturers to improve product quality outcomes, ensures that patient and public safety regarding the consumption of their medication products is guaranteed and saves them from quality assurance-related penalties, data integrity challenges and other unethical practices in which pharmaceutical companies could incur punitive fines, lost sales, remediation costs and reputation loss (Marangon, 2020). This is why, according to Marangon (2020), leading pharmaceutical companies spare no resources at acquiring latest technological tools and processes that could improve their quality assurance management in their drug production.

Thus, substantial evidence exists in literature confirming the third conclusion that quality assurance as part of GMP trends in the pharmaceutical industry in Nigeria improves public health.

5.3.4 New drug safety issues as part of GMP trends influence continuous drug products' monitoring for public safety

Lastly, the fourth conclusion by this research inquiry asserts that new drug safety issues as part of GMP trends influence continuous drug products' monitoring for public safety.

A report by the FDA's Center for Drug Evaluation and Research in the United States supports the view that drug safety issues are critical to the various standardisation processes put in place to ensure that public health threat arising from any poor handling of drug products in each of their phases that make up their life cycle is averted (CDER, 2016). This view was also sustained by Fukuyama and Ono (2017) who surveyed 338 new molecular entities (NMEs) in Japan on the safety-related regulatory actions for new drugs in the country and recommended that global GMP standards should be employed more effectively when conducting new drug safety analyses in order to optimise the advantage provided by the pharmacovigilance also established by many highly rated regulators such as the FDA and the EMA. Furthermore, Guth et al. (2019) are of the opinion that to enhance new drug safety issues regulators, governments and other stakeholders need to invest more new drug safety testing and analysis as a culture in Africa to achieve patient and public safety and health. Bunn (2019) also contends that to make pharmaceutical products safe for human and animal consumption, there is need to ensure continuous testing and monitoring of the whole drug manufacturing processes and life cycle. Kim, et al. (2019) also conclude in their study of issues and future trends impacting drug safety in South Korea that certain issues surrounding new drug safety, efficacy and purity need to be monitored to ensure that drugs promote patient and public safety. Like the FDA and EMA, NAFDAC (2020) believes that continuous drug monitoring should form part of the requirements for new drug safety issues in Nigeria. Thus, there is ample evidence in literature which underscores the need for continuous monitoring of new drug safety processes as a way of guaranteeing patient and public safety and health.

5.4 Contributions and Weaknesses of this Research

The current research study makes the following contributions to the literature on GMP and GMP trends in the pharmaceutical industry in Nigeria.

First, it confirms the position in literature that GMP and the trends of that process are perceived as promoting trust, safety and quality in the pharmaceutical industry in Nigeria. This is very important. This is because without this kind of perception that GMP processes when complied with can help to foster safety, trust and quality in the pharmaceutical industry in Nigeria, it might be difficult for manufacturers of

pharmaceutical to want to comply. Rather, unethical practices in the production, distribution and monitoring of medications might continue unabated.

Second, the current study also confirms the position that technology in the implementation of GMP trends in the pharmaceutical industry affects the entire product life cycle of pharmaceutical products. This is another very important contribution to the literature on GMP. By this finding, it means that focus should be placed on the continuous engagement of modern technology tools which can assist to improve the tasks involved in effective and safe production, distribution and monitoring of pharmaceutics all through the life cycle of such products.

Third, this research study also expands knowledge regarding the proposition that quality assurance as part of GMP trends in the pharmaceutical industry in Nigeria improves public health. By this contribution, it shows that quality assurance management in the pharmaceutical industry is critical for the management of quality and ultimately contributes to patient and public safety and health.

Fourth and the last contribution this study makes is that new drug safety issues are to be hinged on continuous monitoring and guided by public health concerns in order to produce drugs that continue to serve the therapeutic needs of the public. This contribution also enhances literature on the subject of drug safety issues by reinforcing the need for monitoring and public safety to avert public health risks.

Like most qualitative studies, one weakness the present investigation may have is the absence of quantitative data which through statistical measures and analysis might produce more robust outcomes. The size of participants which is suitable for qualitative research design will not be appropriate for quantitative research and this may constitute a serious drawback to findings made in this study. However, this research provides an explorative contribution that can be leveraged on by future researchers to conduct quantitative research investigations.

5.5 Limitations and Further Research

The small size of sample data which is a characteristic of qualitative research design may be considered a limitation of this research. In the same vein, the absence of quantitative data to complement the qualitative data collected for analysis may be considered as another limitation. However, the findings made by this study provide immense future research potential for researchers that might want to further empirically test the conclusions arrived at in this study. Other researchers might want to replicate this study in another study setting and pharmaceutical jurisdiction in other parts of the world to compare results vis-à-vis evidence in literature. Whether future researchers interested in this study employ qualitative, quantitative or mixed-methods research methodologies to further investigate findings made in this study, it is expected that improved research outcomes may be attained for the good of academic research, practical industry application and for society's well-being.

5.6 Research Implications and Applications

Academic researchers should continue to study ways and means by which good manufacturing practices will be entrenched in the pharmaceutical industry in Nigeria and all over the world because of the importance of the industry to the health and quality of life of citizens. Academic researchers should continue to examine innovative ways to improve technology, quality assurance and new drug safety regulatory applications to support GMP implementation in the pharmaceutical industry in Nigeria.

Since, GMP rules or regulations have been shown to inspire trust, safety and quality in the regulators as well as in the consumers, NAFDAC as the regulator should continue to demand and require pharmaceutical manufacturers in the country to uphold the highest ethical practices and standards that can sustain the industry, make it relevant to public health, and ensure that its products continue to contribute positively to consumers' well-being. Also, issues bordering on quality assurance, use of technology in the implementation of GMP rules and regulations and new drug safety issues which require continuous monitoring or quality and safety surveillance should continue to engage the attention of the regulators and other stakeholders. The regulators should also continue

to mete out stiff penalties and fines to defaulters among the manufacturers of medications in Nigeria who would prefer to profit from the misery and even deaths of consumers by running operations that are unethical and that might lead to public health disaster

Manufacturers themselves need to also embrace the tenets of GMP as it relates to the requirements that guide their drug manufacturing processes. By investing in technology tools, and quality assurance and new drug safety processes, pharmaceutical manufacturers will continue to remain relevant while promoting patient and public health and safety. While such investments might be staggering at the beginning, they will eventually pay off for compliant manufacturers when consumers will become loyal customers and increase demand for their drug products and healthcare services.

Government should continue to work with the regulatory agencies to hold pharmaceutical manufacturers accountable for their actions with regard to the timely and effective implementation of GMP standards in Nigeria. Government and the regulators should insist that any corporate body interested in drug manufacturing and distribution in any part of the value chain should comply with the expected regulatory demands. Those who break the law among the manufacturers should be punished according to law and compromised or compromising agents of regulators should also not be allowed an additional day on the job when they are discovered. Public health should continue to form the healthcare agenda of the Nigerian government compelling it to make more investments, provide incentives for investors in the pharmaceutical industry and offer support to manufacturers that have shown good behavior to inspire others to follow suit.

5.7 Conclusion

This research inquiry has examined the effects of GMP trends on the pharmaceutical industry in Nigeria. The Gioia qualitative data coding process was used for the data analysis. The research questions which the study attempted to answer are: (i) what perceptions do professionals have of GMP trends in the pharmaceutical industry in Nigeria? (ii) What is the impact of technology in the implementation of GMP on the pharmaceutical industry in Nigeria? (iii) What is the impact of quality assurance as part

of GMP trends on the pharmaceutical industry in Nigeria? (iv) What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria? To assist its qualitative data collection process, five professionals working for leading companies in the pharmaceutical industry in Nigeria were contacted. Their consent was given and thereafter, they participated in the semi-structured interviews which were organised via Google Meet. The research made four conclusions for the study. (i) Based on professionals' perceptions, GMP trends in the pharmaceutical industry in Nigeria are characterised by trust, safety and quality. (ii) Technology in the implementation of GMP trends on the pharmaceutical industry affects the entire product life cycle of pharmaceutical products. (iii) Quality assurance as part of GMP trends in the pharmaceutical industry in Nigeria improves public health. (iv) New drug safety issues as part of GMP trends influence continuous drug products' monitoring for public safety. The study makes important contributions to literature in the area of GMP and the trends that help its implementation in the pharmaceutical industry in Nigeria. Findings show that GMP trends in the pharmaceutical industry have improved the industry but there is still room for growth and further development if the industry is to rival its counterparts in the rest of the developed world especially in the area of greater technology adoption and tightening of the regulatory framework guiding the industry. Future research can further explore findings or results arrived at in this study by either deploying a mixed-methods research in order to overcome the disadvantages that qualitative research method might face or by studying the same subject matter in a different study setting. On the whole, academic researchers, regulators, pharmaceutical products' manufacturers, consumers and government will find this study helpful regarding the promotion of public health and safety in the pharmaceutical industry in Nigeria.

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APPENDICES

Ethics Declaration Form

PROJECT TITLE: EFFECTS OF GMP TRENDS ON THE PHARMACEUTICAL INDUSTRY IN NIGERIA
RESEARCHERS NAME: OLANREWAJU OLALEKAN ONAFUWA
PROGRAMME OF STUDY: PHARMACEUTICAL BUSINESS AND TECHNOLOGY
SUPERVISOR'S NAME: KATHY CLARKE

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

DECLARATION: The information in application form is accurate to the best of my knowledge. I undertake to abide by the ethical principles outlined by Innopharma/ Griffith Colleges ethics policy in my research project. I confirm that I have completed a full ethics assessment for my research project as per the college guidelines.

I confirm that the research contained within my research project proposal does not require Ethical review and/or subsequent approval by the GEC/Innopharma Ethics Committee.

STUDENT SIGNATUR 

DATE:23/03/2021

SUPERVISOR SIGNATURE: 

DATE: 25/03/2021

SECTION 1: ETHICS APPLICATION DETAILS

1.1 PROJECT TITLE I: EFFECTS OF GMP TRENDS ON THE PHARMACEUTICAL INDUSTRY IN NIGERIA

1.2 RESEARCHERS NAME: OLANREWAJU OLALEKAN ONAFUWA

1.3 PROGRAMME OF STUDY: PHARMACEUTICAL BUSINESS AND TECHNOLOGY

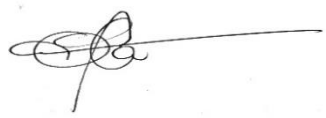
1.4 SUPERVISOR'S NAME: KATHY CLARKE

NOTE: Supervisors are responsible for ensuring that students fill in this form correctly and that all ethical areas have been considered.

1.5 DECLARATION: The information in this application form is accurate to the best of my knowledge. I undertake to abide by the ethical principles outlined by the Innopharma and Griffith College ethics policy. If this proposal is approved Griffith College Ethics Committee, I undertake to comply with any conditions required by the Committee. I confirm that this application is complete with all required documentation and signatures and that these are attached as appendices in an accompanied electronic document.

Yes **No**

STUDENT SIGNATURE:



DATE: 23/03/2021

SUPERVISOR SIGNATURE:

DATE: 29/03/2021

SECTION 2: DESCRIPTION OF RESEARCH STUDY

2.1 Purpose of research (300 words maximum) – *use literature review findings to guide you here*:

This research aims to investigate the effects of GMP trends on the pharmaceutical industry in Nigeria. The importance of the pharmaceutical industry to the health of the human society and the functioning of the economy has been established in literature (Bunn, 2019; Enterprise Ireland, 2020; Steele, Ali, Levitskiy and Subramanian, 2020). Because of the sensitivity of the industry, established national and international regulators expect pharmaceutical firms to abide by laid-down good manufacturing practices (GMPs) in all their operations in order to achieve/sustain the production of only quality medications, and safeguard the health of consumers, among others. GMPs are simply rules and processes laid down for medicine manufacturers to follow and pattern their operations and systems after in order to produce products of high quality that are safe for human consumption and effective in the treatment of diseases (CPhI Insights, 2020; Pieroni and Pimentel, 2020; Steele et al., 2020). GMP also applies to the entire life cycle stages of pharmaceuticals or medicines from the point of manufacture of medicinal products, technology transfer, commercial manufacturing, all the way to product discontinuation, thus strengthening the nexus that binds the development of medicines and manufacturing activities (Pharmaceutical Inspection Convention, 2018). However, there are trends which have been spotted in the regulation space which are designed to further strengthen the GMP processes as they impact the pharmaceutical industry. Some of these are technological innovations such as blockchain which improves drug traceability, and artificial intelligence which improves drug safety and helps in the monitoring of adverse reactions from manufactured medicines. These trends and others are changing the regulation and raising the standards expected of pharmaceutical companies globally. This study aims to investigate the effects of these GMP trends on the pharmaceutical industry in Nigeria and to support the research objectives.

2.2 Research methodology: *Please detail what cohort you are looking at and how you will engage with your participants (focus groups/interviews/online surveys etc).* (300 words maximum)

The research methodology adopted for this inquiry is qualitative research method involving the interview method and data collection through telephone interview. To save time, access knowledgeable participants, and because of the present COVID-19 restrictions. The primary qualitative data will be useful for the collection of information regarding the current trend in GMP implementation by pharmaceutical companies from the perception of participants, examination of technology in the implementation of GMP trends in the pharmaceutical industry, and the impact that quality assurance and new drug safety issues have on the industry. The data analysis will assist in identifying common themes from the collected data which would be coded and later summarised for discussions. The primary data would be complemented by the secondary data to be drawn from

journal articles, technical reports, white papers, books and other industry materials. Participants will be selected purposively from leading pharmaceutical industry players in Nigeria. About nine of these pharmaceutical companies are quoted on the Nigerian stock exchange and have been adjudged to have modern operations and to be guided by WHOGMP (GTBank, 2018). Through purposive sampling, only knowledgeable participants from the rank of junior Pharmacist to higher ranks will be selected. Also production managers or quality assurance managers will also make up the number of participants which should not exceed 5 (one each from 5 organisations to be selected from the nine leading pharmaceutical firms in Nigeria). This is to ensure that only those knowledgeable about the subject matter and the issues of GMP would participate in the interview process. Because these participants work for leading pharmaceutical companies in Nigeria, the expectation is that they will bring their knowledge and experience to bear on the interview process, thus enriching the robust outcomes.

2.3 Proposed questions for questionnaires and/or interviews **must be included**. You may attach a separate document as part of your appendices file if necessary.

The Interview Guide to be developed will consist of the following questions:

1. Can you introduce yourself, your position, and industry work experience?
2. What do you understand GMP to be?
3. What is your perception regarding GMP practice in the pharmaceutical industry in Nigeria?
4. What do you think of the GMP trends in the pharmaceutical industry in Nigeria?
5. Do you think that technology innovations such as blockchain, artificial intelligence, Internet of Things (IoT), Big Data, and other digital solutions contribute positively to the implementation of GMP in the pharmaceutical industry in Nigeria?
6. If yes, how do they contribute to GMP implementation in your organisation?
7. What is your view on the impact of quality assurance as part of GMP trends on the pharmaceutical industry in Nigeria?
8. What are the effects of new drug safety issues as part of GMP trends on the pharmaceutical industry in Nigeria?

SECTION 3: ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential Yes

No

Research into politically and/or racially/ethnically and/or commercially sensitive areas Yes

No

Sensitive, personal, professional, or corporate issues Yes

No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants Yes

No

Research that may negatively affect the reputation of Griffith College/Innopharma Yes

No

Use of personal records without consent Yes

No

Use of company data without consent Yes **No**

The offer of any inducements to participate Yes **No**

Audio or visual recording without consent Yes **No**

Using a language other than English Yes **No**

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English Yes **No**

Does your research group include any of the following (see below) Yes **No**

(Adult participants; Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control/influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in medical facility; persons under the age of 18)

If you have answered NO to ALL questions, you do not need to complete Section 4. Please go to Section 5.

If you have answered YES to ANY question in SECTION 3, you must fill in SECTION 4.

SECTION 4: ETHICAL IMPLICATIONS

Only fill in this section if you answered YES to ANY of the questions in Section 3

4.1. If your ethics related to ***Subject Matter***, outline your action plan to deal with such sensitive issues.
4.2. If your ethics related to ***Research Procedures***, outline your action plan to deal with sensitive research procedures.
4.3. If your ethics related to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 5: PARTICIPANTS

5.1. Outline your participant profile and why you have chosen them for this study

Do not provide names except where it is deemed impossible to conceal identity.

The participant profile will consist of junior to senior pharmacists, production managers and quality assurance managers. This shows that participants should at least be middle managers or supervisors and should be aware of the GMP regulations guiding their pharmaceutics production. They should have industry experience of at least 5 years possibly at top management levels and should be willing to participate in the study of their own accord.

5.2 How do you plan to gain access to/contact/approach your participant(s).

There are two ways. I have a contact person in one of the leading pharmaceutical companies in Nigeria who heads his firm's Quality Assurance. Through him, I expect to meet other colleagues in the other leading pharmaceutical firms who also will be participating in the interview. Moreover, since this kind of study would be helpful to these organisations, I do not see any resistance from these targeted professionals. Meanwhile, the telephone interview would be held at such times that would be favourable to their schedules. The other way is to approach any five of the 9 leading pharmaceutical companies in Nigeria and request a telephone interview with their head of Pharmacy of Quality Assurance. The contact I have could still prove useful in this regard by linking me up with one of these professionals thereby helping me out my foot in the door. All these will be done via the telephone. After meeting the participant, I would also ask him or her for recommendation to their colleagues in the other firms and since it is an industry, they know themselves.

SECTION 6: INFORMATION, CONSENT AND CONFIDENTIALITY

6.1 **Information Letter for participants**

You must submit an information letter for participants with this application, as part of your appendices document. A sample letter can be downloaded from Moodle.

Please confirm below that your information letter covers:

Description of the research topic and method	**Yes** No
Details of what participation will involve	**Yes** No
Rights to anonymity	**Yes** No
Confidentiality	**Yes** No
Rights to withdraw from the research	**Yes** No
The contact details of the researcher and supervisor (if necessary)	**Yes** No

6.2 Consent form for participants

Informed consent is required for most research. For online surveys signed consent is not required since completing the survey implies consent of participants but it is best practice to have an electronic mail trail when applicable (SurveyMonkey/Typeform). In all other research a signed consent form is required.
A sample consent form can be downloaded from Moodle.

Please indicate below if your research requires a signed consent form by selecting the relevant option only:
Yes: my research requires signed consent and I have attached a completed consent form in the appendices of my application.

SECTION 7: STORAGE OF MATERIALS

7.1. How do you propose to store the information & for how long? How will you manage data protection issues?
Information will be recorded with the consent of the participant on the telephone and later transcribed. This transcribed information would be made available to the college in an electronic format as part of the thesis submission and will be held for 3 years.
Current guidelines state that research data be stored for 7 years and then destroyed. Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/).

*The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission. The rationale is to keep **data** indefinitely as **long** as it is still useful and there is an intention to use them further for **research so if this is not the case then this can be stipulated here in defence of a shorter retention period**.*

SECTION 8: DOCUMENT CHECKLIST

NOTE: Applicants must attach an electronic document to include all appendices.

Which documents are attached? Please tick N/A if not applicable:

8.1 Information letter for participant **Yes** N/A

8.2 Consent form for participant **Yes** N/A

8.3 Questions/survey for interviewees/focus groups etc *(i.e complete/close to complete)* **Yes**N/A

8.4 Other document(s) - please specify below:
