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THE LEGAL INCORPORATION OF WHO GOOD MANUFACTURING PRACTICES IN GCC PHARMACEUTICAL LEGISLATION: FROM SOFT LAW TO HARD LAW

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ABSTRACT

Pharmaceutical manufacturing has been extensively examined from technical and economic perspectives. Nevertheless, insufficient focus has been placed on its legal regulation, especially in the Gulf region. This study examines the legal incorporation of WHO Good Manufacturing Practices (GMP) into the Gulf Cooperation Council's (GCC) pharmaceutical legislation and the mechanisms that ensure pharmaceutical quality and integrity. The proliferation of substandard and counterfeit medical products endangers patients and undermines trust in national healthcare systems. The paper adopts an inductive and analytical doctrinal approach and examines relevant pharmaceutical legislation in the United Arab Emirates, the Kingdom of Saudi Arabia, and Qatar. It analyses statutory standards imposed on manufacturing practices, licensing requirements, marketing controls, and supervisory mechanisms. This study highlights the need to strengthen legal coordination and clarify compliance standards, thus ensuring the integrity of pharmaceutical manufacturing and effectively transforming WHO GMP from soft guidelines into binding legal obligations within the GCC legal framework.

KEYWORDS: Quality – Pharmaceutical Regulation – Manufacturing – Gulf Cooperation Council (GCC) – Health Law - Good Manufacturing Practice (GMP).

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1. INTRODUCTION

1.1. Theoretical Framework

Medicine is vital for human health and survival. Therefore, the pharmaceutical industry is just as important as the food industry. Medicine is a strategic commodity related to citizen safety and national security. The absence of quality medicine can result in the loss of productive members of society from work, while its availability can enable sick individuals to return to work, significantly impacting the development plans of the state

The pharmaceutical industry is characterised by significant risks. Unsafe production and distribution of drugs can have numerous adverse effects on human health, sometimes even resulting in patient death. Therefore, the pharmaceutical industry must be regulated by the state through specific registration and monitoring regulations, as well as compliance with Good Manufacturing Practices (GMP).[i]

The Gulf States have a duty to take the necessary legal measures to ensure their populations have access to essential medicines through all available means. An efficient and legally effective national health system is crucial to guaranteeing the availability of quality medicines, especially essential ones, in sufficient quantities always and in all public health facilities.

These countries exert strenuous efforts to protect the public from unsafe and substandard medicines, prevent the marketing and sale of counterfeit and adulterated drugs after registration, and impose deterrent penalties for such actions that affect public health. Ensuring the quality of medicines involves various legal considerations including the oversight of the pharmaceutical industry, conducting regular factory inspections to confirm compliance with health regulations, and the registration and marketing of only safe, high-quality products substantiated by clinical trials that comply with ethical and medical standards.

1.2. Research Problem

Even though the World Health Organization's (WHO) Good Manufacturing Practices (GMP) are non-legally binding technical guidelines, their actual application in the laws of the (GCC) countries raises an important legal question. To what extent have these technical standards become binding in the pharmaceutical industry? More specifically, is there still a gap between international standards for excellent pharmaceutical manufacturing and their application in each GCC country? This study examines whether the pharmaceutical laws of the GCC countries merely refer to WHO GMP as a standard of good practice, or whether they effectively transform it into a legal requirement that could lead to legal consequences for non-compliance.

1.3. Research Questions

This paper raises several questions about the adequacy of legal texts in some Gulf Cooperation Council (GCC) countries to ensure the production of safe and high-quality locally manufactured pharmaceutical products. Currently, several laws regulate drug manufacturing in the UAE, Saudi Arabia, and Qatar. However, this comparative analytical study attempts to clarify the theoretical legal framework and the practical application of the controls and standards that pharmaceutical manufacturers must adhere to during the manufacturing process in their pharmaceutical facilities in these countries.

1.4. Research Contribution

This paper provides an overview of the impact of legislation on the production of high-quality and safe pharmaceuticals, based on an analysis of legal texts and a review of relevant literature. It addresses the key challenges associated with implementing legal controls in pharmaceutical establishments and proposes potential recommendations for their successful application. Its primary contribution is to ensure the safe manufacturing of medicines in the GCC countries.

1.5. Research Objectives

This study aims to examine the fundamental legal principles governing the local manufacturing of pharmaceuticals in the UAE,[ii] Saudi Arabia,[iii] and Qatar,[iv] with a particular focus on the growing importance of these principles given the pharmaceutical industry's connection to public health on the one hand and its status as a growing investment sector in these countries on the other. The study seeks to illustrate that the pharmaceutical manufacturing process is not solely a matter of practical and technical aspects but that legal considerations constitute a crucial framework for ensuring the production of safe and highly effective pharmaceutical products.

Research Justification: The increasing economic value and vital importance of the pharmaceutical sector necessitate a review of existing legislative frameworks. This research aims to examine the legal aspects of addressing issues related to the complexities of pharmaceutical manufacturing processes, thereby contributing to the development

of effective regulatory responses.

1.6. Scope Of the Study

The scope of this study is limited to studying the legal system of the pharmaceutical industry in only three countries of the GCC: the United Arab Emirates, the Kingdom of Saudi Arabia and the State of Qatar.

1.7. Research Methodology

This study adopts a research methodology based on the comparative analysis of legislation related to the pharmaceutical industry in the GCC countries. The goal is to evaluate how well these rules help improve pharmaceutical manufacturing efficiency by comparing them and to provide a fact-based answer to the main research question.

1.8. Research Structure

The research begins with an introductory discussion on the importance of local pharmaceutical manufacturing in the GCC countries. The second section focuses on the conceptual framework of pharmaceutical products. The next section presents a comparative analysis of the legislation governing the complex processes of drug manufacturing in these countries. Following this, the fourth section conducts a comparative analysis of the legal controls governing the complex process of medicine manufacturing in these countries. The final section presents recommendations, with a particular emphasis on legal compliance with (GMP).

2. THE IMPORTANCE OF PHARMACEUTICAL MANUFACTURING IN THE GCC COUNTRIES

If the Gulf countries succeed in raising the pharmaceutical products produced by local pharmaceutical factories and companies to the level of high-quality pharmaceutical products capable of competing locally and globally, by imposing and implementing a sound system of health laws related to the pharmaceutical industry, they will reap numerous benefits from this, some of which relate to public health in the country, such as the existence of a national system for drug safety, and some of which relate to the economic aspect, such as lower medicine prices (Naohiko Wakutsu et al., 2023).

2.1. Establishing A National Drug Safety System

Enabling any country to exercise control over its pharmaceutical sector gives it the advantage of safeguarding its national pharmaceutical security. This ensures full independence in the supply and distribution of products from domestic pharmaceutical manufacturers (Essam A. Tawfik et al., 2022). As a result, the country can produce the medicines it needs in the event of any national public health crisis while also avoiding reliance on foreign suppliers, an inherently insecure position.

For example, the global supply of antiviral drugs may, in certain circumstances, prove insufficient to meet steadily increasing international demand—particularly in GCC countries during an outbreak. This was clearly demonstrated in the recent crisis concerning access by poorer nations to COVID-19 vaccines. Thus, if the GCC countries possessed adequate technological capacity and expertise in vaccine manufacturing, they would have been able to produce a domestic antiviral vaccine without relying on international pharmaceutical companies or appealing to the United Nations for equitable vaccine distribution, thereby ensuring that non-producing countries could secure the doses they required.

2.2. Reduction in the Price of Medicine

In countries that often lack innovative domestic pharmaceutical industries capable of influencing public health outcomes, the availability of medicines used to treat common diseases depends largely on what transnational pharmaceutical companies provide. These companies are typically in a monopolistic position with respect to such medicines and therefore set prices at their discretion, which are often extremely high—particularly for medicines protected by patents (Mousa, 2006; Bayoume, 2004; Abdou, M.M; Maryam Al Matrooshi, 2021).

As a notable example, the treatment of HIV, which is relatively widespread in poor African countries and some South American nations, requires a substantial financial cost. Many people in these countries cannot afford these medicines. This is especially challenging since people in these countries often rely on their personal financial means to purchase these medicines in the absence of comprehensive social insurance that would otherwise cover a significant portion of the cost (MFUKA, 2002). Therefore, one important solution is for these nations to gain control over the technical knowledge that enables them to produce low-cost local medicines (Abdou, 2016). This would create a form of competition with the pharmaceutical products offered by transnational companies, thereby leading to a reduction in their prices (Naohiko Wakutsu et al., 2023).

2.3. Supporting the Industrial Development Plan

Enabling the GCC countries to reach the stage of local pharmaceutical production will provide them with independent technological capabilities, helping these countries achieve industrial control over this vital sector. This means they would gain access to the core technologies underlying pharmaceutical industries and develop the technical expertise necessary to understand, manage and advance this pharmaceutical know-how (Remiche, 1983). In the same line of thought, through research and development activities, the country will be able to create new medicines or improve pharmaceutical manufacturing methods. Consequently, the domestic pharmaceutical market will improve and evolve, potentially providing an opportunity to enter the export market (Tissot Françoise et al., 1994).

Based on this, taking the necessary measures to gain control over the pharmaceutical manufacturing sector in the GCC countries is not only about advancing the pharmaceutical industry itself, it will also have a positive impact on the country's industrial development plans and policies (Tissot Françoise et al., 1994). Hence, gaining control over pharmaceutical industrial methods would lead to the establishment of an industrial zone supporting this sector, providing production equipment, and enhancing the industrial and research infrastructure related to it, which ultimately serves the country's overall development plan (Warren Kaplan & Richard Laing, 2005; Liping Fu et al., 2022; Imad Abu Reid et al., 2025).

3. THE CONCEPTUAL FRAMEWORK OF THE PHARMACEUTICAL PRODUCT

The pharmaceutical product is a fundamental part of the healthcare system, helps in the prevention, diagnosis, treatment, or mitigation of diseases. The conceptual framework aims to clarify the nature of the pharmaceutical product and identify its various types. This structure includes the legal definitions of the product, as well as its classification based on its composition and use, providing the foundation for understanding the laws and regulations governing pharmaceutical products in the GCC countries.

3.1. The Legal Concept of the Pharmaceutical Product

The UAE legislator defined the pharmaceutical product as "Any product that contains an active substance or group of active substances that achieves the intended purpose of use thereof in or on the human or animal body through a biological effect, and which is manufactured, sold, or offered for use in the following cases: 1. Diagnosis, treatment, cure, relief, or prevention of a disease. 2. Restoring, renewing, modifying, or correcting the physiological functions."[v] Meanwhile, the Saudi regulator defined a pharmaceutical preparation as "any product manufactured pharmaceutically that contains one or more substances used externally or internally for treating or preventing diseases in humans or animals."[vi] As for the Qatari legislator, no specific legal definition of the pharmaceutical product has been established; nevertheless, one can implicitly infer its concept as: "Any drug, medicinal plant, or pharmaceutical substance used externally, internally, or by injection for the purpose of preventing, treating, or diagnosing diseases in humans or animals."[vii]

The author argues that the UAE legislator's definition, despite its comprehensiveness and focus on biological effects and bodily functions, is complex, difficult to apply in practice, and may raise debates over whether certain products are intended to modify physiological functions. It also does not clarify the status of medicinal plants. In contrast, the Saudi regulator's definition, though simple and easy to implement, is very limited, focusing solely on treatment and prevention and excluding modern biological products, physiological function modifiers, or medicinal plants. As for Qatar, its definition is informal and flexible, creating legal uncertainty and remaining vague regarding biological effects or the scope of use, which may leave gaps for the exploitation of non-traditional products.

Thus, a comparative analysis reveals a difference in the legislative philosophy surrounding the concept of a pharmaceutical product within the legislation of the three GCC countries. The UAE legislator adopted a modern approach that incorporates biotechnological advancements in the pharmaceutical industry, as evidenced by its reliance on a functional definition of a pharmaceutical product based on its biological effects and its modification of physiological functions. In contrast, the Saudi regulator adopted a traditional approach that focuses on the purpose of the pharmaceutical product, whether for treatment or prevention. While the Qatari legislator adopted a flexible conceptual approach and avoided providing a precise definition of medicine, this approach nevertheless leaves room for interpretation regarding what constitutes a medicine and weakens the degree of legal certainty.

This difference in legislative philosophy among the three countries has practical implications for the application of GMPs issued by WHO. A precise definition of what constitutes a pharmaceutical product is essential for determining which products

are subject to these practices. Therefore, this difference can lead to a weak level of legislative harmonisation among the GCC countries and hinder the possibility of mutual recognition in the field of pharmaceutical regulation.

From this standpoint, and to address the weaknesses of the previous legislative definitions, the author proposes the following concept of a pharmaceutical product: "Any pharmaceutical product, medicinal plant, or active substance, manufactured or prepared scientifically and containing one or more substances, used internally, externally, or by injection for the prevention, treatment, diagnosis, or modification of physiological functions in humans or animals, provided that its use is supported by scientific evidence and subject to health regulation."

3.2. Types of Manufactured Pharmaceutical Products

Manufactured pharmaceutical products are a key component of the healthcare sector, contributing to the prevention, diagnosis, and effective treatment of diseases. Classifying these products according to their nature and origin is an essential step in understanding their legal and regulatory role in the market. This classification includes innovative medicines, generic medicines, herbal medicines and biological medicines facilitating the determination of registration requirements, quality control measures, and manufacturing and distribution standards. Studying these types provides a comprehensive view of the wide variety of manufactured pharmaceutical products and how laws in (GCC) countries address each type to ensure consumer safety and treatment effectiveness.

A) **Innovative Medicines:** From a legislative standpoint, this type of drug can be defined as:"A Pharmaceutical Product that is the first of its kind in its category, either because it contains new components or formulations that have not been used before to treat a specific condition or is used in new ways". [viii] Thus, an effective and safe treatment for a medical issue is characterised as an innovative treatment, which is defined by novel pharmaceuticals that provide significant health advantages to patients and receive regulatory approval. In scholarly literature, innovation in new medicines is generally linked to the degree of therapeutic benefit and novelty compared to existing therapeutic options (Naohiko Wakutsu et al., 2023).

B) **Generic Medicines:** The European Medicines Agency defined it as: "a medicine that is developed to be the same as a medicine that has already been authorised. Its authorisation is based on efficacy and safety data from studies on the authorised medicine. A company can only market a generic medicine once the 10-year exclusivity period for the original medicine has expired." (European Medicines Agency, 2026). To some degree, the Saudi Food and Drug Authority defined it as: "A product created to be equivalent to the innovative / brand name product in dosage form, strength, route of administration, quality, performance characteristics and therapeutic indication(s)" (Saudi Food and Drug Authority, 2026). Thus, the generic medicines are drugs intended to be interchangeable with the original brand of medicine, produced without authorisation from the original manufacturer and marketed following the expiration of patent or other exclusivity rights (Sneha Panigrahy & Sunetra Chaudhari, 2022).

C) **Herbal Medicine:** The Saudi Food and Drug Authority defined it as: "Any plant or herb that have medical claims and manufactured in a pharmaceutical form" (Saudi Food and Drug Authority, 2026). These medicinal products derived from herbal or natural sources, such as plant materials, extracts, or plant components, used for therapeutic purposes, prevention, or health support (Hassan Hussein Musa et al., 2022). Additionally, these products are widely recognised in scientific and regulatory contexts as distinct from purely synthetic pharmaceuticals due to their natural origin and complex chemical composition (Egyptian Drug Authority, 2020).

D) **Biological Medicines:** The Saudi Food and Drug Authority defined it as: "Biological products that are derived from biological sources or produced by using biotechnology methods such as vaccines, blood derivatives, recombinant proteins and gene/cell therapies." (Saudi Food and Drug Authority, 2026). Therefore, the biological medicines are derived or manufactured from a living biological system, and they include hormones (e.g. insulin), enzymes (to speed up chemical reactions), blood factors (to regulate clotting), antibodies (to support the immune system), vaccines and advanced therapies (such as cell, gene and tissue therapy products) (abpi, 2014).

4. LEGAL REGULATIONS FOR

PHARMACEUTICAL MANUFACTURING IN THE (GCC) COUNTRIES

The core problem addressed by this section lies in the lack of legal certainty regarding local drug manufacturing in the GCC countries. The legislation governing the complex and vital process of drug manufacturing, which is directly linked to human health, contains ambiguities that could lead to outcomes detrimental to the production of quality medicines. This highlights the need to clarify the legal controls required to achieve legal certainty concerning the pharmaceutical industry in these countries, in accordance with the most important World Health Organization's Good Manufacturing Practices (GMP) standards (World Health Organization, 2023).

4.1. Pharmaceutical Quality System

The manufacturer must assume responsibility for the quality of the pharmaceutical products to ensure that they are fit for their intended use, comply with the requirements of the marketing authorisation and do not place patients at risk due to inadequate safety, quality or efficacy. Achieving this quality objective is the responsibility of senior management and requires participation and commitment from staff across various departments and all levels within the company, as well as from the company's suppliers and distributors. To achieve this quality objective reliably there must be a comprehensively designed and correctly implemented pharmaceutical quality system (PQS) incorporating GMP and QRM (World Health Organization, 2023).

Through an analysis of the legal provisions of the (GCC) countries and a comparison among them, it can be concluded that this principle has been incorporated as a legally binding obligation, the breach of which gives rise to legal liability. In the Kingdom of Saudi Arabia, it is prohibited to manufacture or formulate a pharmaceutical product in violation of the registration requirements or any provision of the Law or its Implementing Regulations. [ix] These regulations require pharmaceutical factories to comply with all technical specifications set by the Saudi Food and Drug Authority (SFDA),[x] and obtain a (GMP) certificate,[xi] and maintain a scientific office primarily responsible for providing accurate pharmaceutical information about the manufactured products.[xii]

Similarly, under UAE law, no medical product intended for marketing within the country may be manufactured without obtaining marketing authorization from the relevant authority. The product must be manufactured in a factory licensed within the country, in accordance with the regulations and standards set forth by the law.[xiii] Additionally, pharmaceutical manufacturers are required to obtain a (GMP) certificate to ensure the quality, efficiency, and safety of the pharmaceutical facility from the UAE Medicines Authority.[xiv]

As for Qatari legislation, Article (2) of Law No. (1) of 1986 concerning the registration of pharmaceutical companies stipulates that no pharmaceutical company may carry out its activities or distribute any medicine within the country except after completing the registration procedures set forth in this law, its executive regulations and decisions, and fulfilling the requirements requested by the competent official authorities or prescribed by any other applicable laws.

Thus, despite the achievement of a degree of objective convergence in the regulatory goal of the drug control system in the three countries, the difference in the mechanisms of obligation and control may affect the level of procedural homogeneity between the systems, which may complicate efforts to coordinate or mutual recognition within the Gulf framework unless it is supported by unifying the standards of implementation and control.

4.2. Documentation and Traceability

This process ensures accurate record-keeping for each batch of product, documentation of deviations, and product traceability from raw materials to the final product. In Saudi Arabia, Article (15/1) prohibits the possession of products without source documents and quantity records, while Article (16) mandates reporting any violations. Implementing regulations specify recall and traceability mechanisms. In the UAE, laws require the implementation of a Master File system[xv] to maintain quality and traceability records, including risk-based monitoring, and ensure product and company registration before marketing. In Qatar, Law No. 1 of 1986 guarantees product registration, providing a clear database of product records and traceability. These principles reflect the Gulf Cooperation Council's consensus on the importance of accurate documentation as a tool for oversight and transparency.

Thus, documentation and traceability are a shared legal pillar between international standards and national legislation, enabling monitoring of every stage of production and investigation of violations. Regulatory requirements in Saudi Arabia, the UAE, and Qatar go beyond mere document retention; they mandate systematic and legally verifiable

documentation, reflecting a commitment to implementing international standards within the national legislative framework to enhance drug safety and quality.

Comparative analysis reveals differences in the mechanisms for implementing requirements among the three countries. Saudi regulations focus on document ownership and reporting violations. Emirati legislation relies on master files and risk monitoring. In contrast, Qatar provides a central database for product registration and tracking. Thus, despite similar regulatory objectives, the different mechanisms may affect procedural consistency across systems. This necessitates the harmonization of documentation and tracking standards to support coordination and mutual recognition within the GCC.

4.3. Process Control and Validation

This principle relates to process verification, inspection of raw materials and finished products, and contamination prevention to ensure continuous product quality. In Saudi Arabia, Article (17) prohibits the distribution of any product before registration, Article (28) prohibits commercial production before obtaining approvals, and Article (24) grants the authority to withdraw registration in cases of non-compliance, with implementing regulations specifying inspection and quality verification requirements. In the UAE, Article (126) prohibits the manufacture or marketing of any product without prior approval. In Qatar, Law No. 1 of 1986, along with specific ministerial decrees (such as Decree No. 12 of 1987 concerning technical inspection), stipulates that pharmaceutical products may not be marketed without prior approval, with ministerial decrees further reinforcing technical compliance.

Hence, the principle of process control and verification is one of the most fundamental technical principles of GMP, and it is reflected in national legislation as an explicit regulatory requirement for granting licenses and approvals. By requiring process definition, documentation, and verification of effectiveness, these technical requirements are transformed into clear legal obligations applicable to pharmaceutical manufacturing plants in Saudi Arabia, the UAE, and Qatar, thus providing a foundation for effective regulatory oversight and quality control.

From this perspective, it can be asserted that all three countries are dedicated to the concept of prohibiting manufacturing or selling without authorisation, thus indicating a level of regulatory convergence concerning the technical assurance of pharmaceutical products. Nonetheless, the methods for enacting this idea inside the legislation of the three countries differ. Saudi Arabia adopts a detailed, textual model with precise implementing regulations. The UAE adopts a general provision in its law. Qatar integrates the basic law with ministerial decrees to define the technical requirements. These differences in integration mechanisms may not affect the substantive adherence to GMP standards, but they could pose a challenge to regional harmonisation of inspection and control standards, as countries may require unified mechanisms for coordination and implementation to ensure a similar level of quality.

Table 1: Linking WHO GMP Principles to GCC Pharmaceutical Regulations

WHO GMP principle	Technical Meaning (GMP)	Saudi Arabia (Law/Regulation)	UAE (Law/Regulation)	Qatar (Law/Ministerial Decision)
Comprehensive Quality Management System	Establishment of a full quality system, written procedures, defined responsibilities, risk management, and periodic review.	- Article 30: Compliance with GMP guidelines. - Article 5: Technical director (licensed pharmacist). - Executive Regulation: Detailed quality system requirements.	- Article 27: Medical Product Manufacturing Conditions – quality requirements for manufacturing medical products (Federal Decree-Law No.□38/2024) - Article 28: Good Practice – explicit reference to "Good Practices"	- Law No. 1 of 1986: Requirement for drug companies to register their products prior to marketing.

Documentation and Traceability	Maintaining records, batch documentation, deviation reporting, and full traceability of the product	- Article 15/1: Prohibition of possession of products without source documents and quantity records. - Article 16: Obligation to report violations. - Executive Regulation: Recall and traceability mechanisms.	- Article 28: Good Practice (documentation & quality procedures) - Article 26: Accredited or Licensed Laboratory – laboratory and testing requirements (Requirement for a Master File system and record-keeping for quality and traceability, including risk-based monitoring).	- Law No. 1 of 1986: Registration of companies and products ensures record-keeping and traceability prior to marketing
Process Validation and Continuous Control	Equipment qualification, process validation, raw material and final product testing, contamination prevention	- Article 17: Prohibition of marketing any pharmaceutical before registration. - Article 28: Prohibition of commercial production before registration. - Article 24: Authority to revoke registration in case of non-compliance. - Executive Regulation: Detailed requirements for QC and validation.	- Article 27: Manufacturing Conditions (compliance with approved manufacturing conditions). - Article 28: Good Practice (includes tests and quality controls). (Prohibition of manufacturing or marketing any product without prior approval; includes inspection, recall, and inventory monitoring).	Law No. 1 of 1986: Prohibition of marketing any pharmaceutical product without prior legal approval; ministerial decisions supplement technical compliance.

The comparison between the most important guidelines for good manufacturing practices for medicines issued by the WHO and the medical legislations in the GCC countries showed a relative disparity between the three countries under comparison. The laws of the United Arab Emirates and Saudi Arabia were found to be the most modern and comprehensive, aligning with leading global GMP practices, particularly concerning quality management, documentation, verification of manufacturing processes, and the legal liability of pharmaceutical professionals. Hence, these national laws thus provide a practical regulatory framework that ensures legal compliance with international standards at all stages of drug manufacturing.

In contrast, Qatari law was less detailed than those of Saudi Arabia and the UAE concerning quality management system requirements, detailed batch documentation, and periodic inspections. There was a lack of clarity regarding quality control procedures or operational verification standards for each factory. Qatari law relied more heavily on the registration and pre-inspection phases, which may limit the effectiveness of ongoing monitoring.

5. CONCLUSION

This study finds that although the World Health Organization's Good Manufacturing Practices (GMP) are formally non-binding, they have gained binding legal effects within GCC pharmaceutical legislation through statutory incorporation and enforcement. A comparative analysis of the UAE, Saudi Arabia, and Qatar shows varying degrees of integration of GMP principles. The differences are most evident in pharmaceutical quality systems, documentation and traceability, and process validation.

5.1. Results

1- WHO GMP guidelines, although technically non-binding, have been transformed into legally enforceable obligations within GCC pharmaceutical legislation through licensing, inspection, and liability mechanisms.

2- There is noticeable fragmentation among GCC countries in the depth and clarity of GMP incorporation, particularly regarding ongoing monitoring and operational verification standards.

3- The regulatory frameworks in the UAE and Saudi Arabia demonstrate stronger alignment with international GMP standards through explicit quality management requirements, certification obligations, and supervisory authority.

4- Qatari legislation relies predominantly on pre-marketing registration and initial approval procedures, with comparatively less emphasis on continuous quality system verification.

5- Clear statutory articulation of quality control obligations enhances legal certainty, strengthens accountability, and improves the overall integrity of pharmaceutical manufacturing.

5.2. Recommendations

1- Establish a unified or model GMP-based legislative framework at the GCC level to

reduce regulatory fragmentation and ensure consistent quality assurance standards across member states.

2- Expand and clarify legal provisions concerning post-registration inspections, batch verification, and enforcement mechanisms to ensure sustained compliance rather than reliance on initial licensing controls.

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