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IMPACT OF ENABLERS AND BARRIERS FOR COMPLIANCE WITH INTERNATIONALLY ACCEPTED QUALITY STANDARDS IN THE PHARMACEUTICAL INDUSTRY OF PAKISTAN

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Abstract

Introduction: *Drug safety, product reliability, and international market access rely on compliance with internationally accepted pharmaceutical standards of quality. In the case of developing nations like Pakistan, the pharmaceutical companies tend to have issues with adoption of superior regulatory frameworks as a result of financial, technological and institutional limitations. It is hence important to come up with an understanding of what affects compliance in order to enhance quality assurance practice in the pharmaceutical industry.*

Purpose: *The purpose of the study was to investigate the enablers and limitations influencing the adherence to internationally recognized quality standards in pharmaceutical industries in Karachi, Pakistan.*

Methodology: *A qualitative research design was followed through replica study. The interviews showed that 20 professionals working in the quality assurance, production management, regulatory affairs, and quality control departments in pharmaceutical companies were interviewed semi-structurally and using interviews. Thematic analysis was adopted to analyse the obtained data, to reveal major patterns associated with the regulatory awareness, organisational practices, barriers, as well as enabling factors contributing to compliance.*

Findings: *The findings revealed that the biggest barriers to compliance were financial constraints, lack of skilled labor force, technological constraints and regulatory delays. Meanwhile, organisational facilitators like employee education, executive buy-in, internal quality inspection and technology improvements were also significant towards the compliance with global standards. The familiarity with WHO GMP was rather high and the familiarity with more stringent international standards of GMP like EU GMP and US FDA standards was relatively low.*

Conclusion: *The paper concludes that to enhance pharmaceutical quality compliance in Pakistan, it is important to enhance workforce training, as well as organisational quality management systems, and regulatory transparency and institutional support.*

INTRODUCTION

The pharmaceutical industry is also essential in the provision of safe, effective, and high-quality medicines to populations across the globe. Pharmaceutical products and distribution are regulated by quality standards that are internationally accepted, such as Good Manufacturing practices (GMP) which are guidelines that are used to ensure that medicines are uniformly manufactured and regulated as per the quality requirements that suit its purpose (World Health Organization, 2014). Adherence to these standards is critical in safeguarding the health of the people, preventing the sale or manufacture of low quality or counterfeit medicines, and providing the drug manufacturing firms access to global markets. However, in most developing countries, pharmaceutical makers are faced with serious institutional, economic as well as regulatory issues that are barriers to effective implementation of these standards.

The quality assurance of pharmaceuticals has been a crucial issue all over the world as regulating bodies are fighting in the bid to stop the distribution of low quality and false drugs. Poor quality pharmaceuticals are very dangerous as they put the patient at risk, lead to antimicrobial resistance, and destroy confidence in the health care systems (Caudron et al., 2008). One of the main goals of pharmaceutical regulation is, therefore, to ensure that quality standards accepted on the international level have been met. Any quality management system in a pharmaceutical manufacturing facility has to use the appropriate documentation, validation operations, competent staff, and constant check-ups to keep the quality of any product and to be in a quality regulatory position (Chejor, 2024). These necessities complicate and demand a lot of resources to implement the international quality standards especially in the low-income and middle-income countries.

Pakistan is a major point of production of pharmaceutical products in South Asia and the spheres of pharmaceutical production in the country are growing fast and make most of the pharmaceutical demands in the country. The pharmaceutical industry is hundreds of pharmaceutical companies dealing with the production of thousands of pharmaceutical preparations to be consumed locally and exported (Rasheed et al., 2019). In the last twenty years, there has been a significant growth in the number of pharmaceutical manufacturing companies located in Pakistan, which indicates the development of increased demand for the services and medications in the healthcare sector. Although this growth took place, there has been a prevailing problem with many manufacturers facing a constant assurance of the international quality standards (Tauqeer et al., 2019). These challenges are available due to the action of a number of structural and institutional conditions, which consist of deficient technological infrastructure, constraints of regulatory capacity, and financial constraints.

Pakistan has experienced a major reform in the last few years regarding the regulatory environment surrounding production of pharmaceuticals. The setting up of the Drug Regulatory Authority of Pakistan, (DRAP) under the DRAP Act of 2012 was one of the most significant ones. DRAP was also established in order to centralize the regulatory control and enhance the quality assurance system of pharmaceuticals, medical equipment, and therapeutic products in the country (Rasheed, 2015). The authority has the responsibility of enforcing the established safety, quality, and efficacy standards to the pharmaceutical products made, imported, or distributed in Pakistan (Drug Regulatory Authority of Pakistan, 2023). Despite the fact that the establishment of DRAP shows significant progress in terms of enhanced regulatory control, research says that the authority itself continues to experience operational and institutional issues that influence whether it can establish compliance when it comes to the prominent effect of the enforcement (Mehmood, 2022).

The adherence to the Good Manufacturing Practices (GMP) should be discussed as the fundamental pillar of the pharmaceutical quality assurance. According to GMP guidelines, the emphasis is made on such factors as quality

management systems, process validation, quality control tests, and correctly trained personage to make sure that medicines are always produced as per specifications (World Health Organization, 2014). Nevertheless, the application of GMO standards may necessitate the large sum in order to invest in the contemporary manufacturing plants, new equipment and personnel training plans. In emerging markets like Pakistan, drug companies might not have the resources to invest in them because of the level of financial constraints and competition (Tauqeer et al., 2019). Such financial restraints may circumscribe the capacity of businesses to modernize their production and keep abreast with the global regulatory standards.

Another important determinant that affects the quality compliance of pharmaceuticals is the human resource capacity. The maintenance of effective quality management systems in pharmaceutical production units requires the presence of qualified pharmacists, quality assurance experts, and regulatory experts. Nevertheless, this issue concerns many developing countries that do not have a sufficient amount of skilled pharmaceutical specialists who are knowledgeable about regulatory issues and quality control (Roth et al., 2018). This lack may hamper the adoption of sophisticated quality management systems and the efficiency of regulation supervisory tools. It has been raised in the Pakistani setting by both pharmaceutical industries and government officials that there is a shortage of technical facilities and qualified staff who are capable of facilitating advanced quality assurance procedures (Tauqeer et al., 2019).

Weak regulatory enforcing mechanisms also constitute another significant hurdle to the ability of pharmaceutical quality compliance even in the developing countries. Developed pharmaceutical regulation assumes the presence of trained inspectors, laboratory testing, and open monitoring that is able to detect the non-compliance and provide the corrective measures. Nevertheless, the financial and institutional capacities of regulatory authorities in several low- and middle-income countries are limited, and it limits their capabilities of acting in line with quality standards (Roth et al., 2018). In Pakistan, the regulations reform has enhanced the control over pharmaceutical manufacturing operations, but there are loopholes in the implementation of quality levels and overseeing pharmaceutical supply chains (Rasheed et al., 2019).

In the pharmaceutical companies, organizational culture is also a key determinant of adhering to the quality standards. Quality culture should also be well-established and highly effective, which means the involvement of senior management in quality assurance and corporate culture of emphasis on patient safety and adherence to regulatory standards. Nevertheless, studies indicate that quality compliance can be viewed as a supplementary expenditure instead of an indispensable element of sustainable business activities in certain pharmaceutical companies that work in the developing markets (Tauqeer et al., 2019). The illusion may lessen the interest that companies have to invest in quality assurance facilities, and this may lead to more production of low quality medicines in the market.

Irrespective of these issues, there are a number of enabling factors that may foster the adherence to international pharmaceutical quality standards. The quality assurance system in pharmaceutical manufacturing organizations can be greatly enhanced with the help of regulatory changes, international cooperation, workforce education, and modern technology implementation (Mubarak et al., 2024). Other international organizations like the World Health Organization have also come up with the programs meant to enhance regulatory capacity and assist pharmaceutical manufacturers in realizing the GMP compliance. These programs underscore the need to have concerted actions between governments, regulatory bodies, and pharmaceutical firms in enhancing the quality of medicines and patient safety.

Karachi is commonly known as the pharmaceutical production hub in Pakistan, and is home to a large concentration of both local and international pharmaceutical firms. Pharmaceutical production, distribution and exporting in the country of origin significantly depends on the city. An inquiry into the

impediments and facilitators related to adherence to international quality standards in the Karachi-based pharmaceutical industry can inform further regarding more generalized structural problems with the pharmaceutical industry in the country. It is especially relevant that policymakers and regulatory agencies need to comprehend these factors to enforce better and more effective pharmaceutical control and enhance quality production of medicine.

Thus, this paper tends to investigate the enablers and barriers that play important roles in the compliance with internationally accepted quality standards in pharmaceutical manufacturing firms in Karachi Pakistan. The proposed study aims at giving a better insight into the institutional, organizational, and economic variables that influence pharmaceutical quality compliance in Pakistan by taking the insights of the past qualitative studies and integrating the feedback of industry experts, regulatory authorities, and academic experts.

2. Literature Review

2.1 Theoretical Framework

Theoretical basis underpinning the study of adherence to international pharmaceutical quality standards may be approached using a variety of organizational and institutional theories that explain reaction of firms on regulatory demands and quality management frameworks. Institutional Theory is one of the most popular views that are utilized to conduct research on regulatory compliance. According to this theory, organizations are guided by the external regulatory forces, professionalism, and their place in the society to conform and be legitimized to preserve their status in a particular institutional setup (Scott, 2014). The pharmaceutical industry has stringent conditions placed on it by the regulatory bodies regarding manufacturing processes, documentations and quality assurance measures. To stay in the regulatory favor and confidence of the people, pharmaceutical firms should hence adopt institutional practices that could be consistent with these requirements.

Institutional theory gives an explanation on the role of coercive, normative and mimetic pressures on organizational behavior. Telentoscopic forces are regulatory bodies that coerce compliance to the laws and standards. Normative pressures come in through professional associations and industry norms that influence practices in the companies. Mimetic powers take place when companies emulate the operations of business that are performing well in the same business environment (DiMaggio and Powell, 1983). These pressures in the pharmaceutical sector all pressurise the companies to embrace internationally accepted systems of quality management like GMP and ISO based systems.

The other theoretical perspective that is pertinent is the Resource-Based View (RBV) of the firm and this focuses on the importance of organizational resources and capabilities in attaining competitive advantage. This theory holds that companies that have valuable, rare and well developed internal resources are better positioned to undertake complex systems of operations such as having advanced quality management practices (Barney, 1991). In pharmaceutical production, these resources can be highly qualified staff, well-equipped laboratories, the latest technology in production as well as a good quality control system. Firms that do not have these resources might have a problem in meeting the International quality standards.

The Quality Management Theory is yet another key scheme to the interpretation of pharmaceutical compliance in quality. This theory emphasizes on the role of continuous improvement, customer focus, and systematic control of the process as a means of the high degree of product quality. The Total Quality Management (TQM) concept focuses on application of quality at every organizational level, which include the top management and the staffing members in operations (Oakland, 2014). Application of the TQM principles in the pharmaceutical setting can enhance quality assurance systems, consistency in manufacturing and decrease the chances of non-compliance of regulations.

Additionally, Compliance Theory explains the reaction of organizations in relation to practice of regulatory requirements depending on the

perceived benefits, costs, and enforcement systems. Whenever the perceived benefits of compliance by firms exceed the perceived cost, firms are more likely to comply (Ayres and Braithwaite, 1992). The advantages of compliance in the pharmaceutical industry are the opportunity to enter foreign markets, a better image of the brand, and a decreased chance of fines. Yet, minimal compliance strategies are the ways in which companies can strive to invest in quality systems when the cost of compliance is perceived to be high.

The combination of these theoretical points of view offers a clear and detailed framework of the analysis of the enablers and barriers that influence the quality compliance of pharmaceuticals. Institutional pressures lead to the firms adopting regulation standards, organizational resources determine their ability to adopt quality systems, and compliance motivations affect their decision to invest in regulation compliance.

2.2 Empirical Studies

A wealth of empirical literature on the difficulties of applying the pharmaceutical quality standards in the developing countries has been explored. These works demonstrate that there are various structural, institutional and organizational processes that affect adherence to international regulatory frameworks.

Studies carried out in various countries which are low or middle income have established that the regulatory capacity is important in pharmaceutical quality compliance. Poor regulatory mechanisms usually do not have the technical capacity to perform inspections, assess the manufacturing processes and trace pharmaceutical supply chains. Wirtz et al. (2017) discovered that creation of trained inspectors and laboratories are deficient in several regulatory agencies in developing countries, and this restricts their capacity to implement the quality of pharmaceuticals.

Another big obstacle to adherence to pharmaceutical quality standards is financial constraints. The infrastructure involved in executing GMP-conformable infrastructure will be very costly in terms of facility planning and equipment validation, environmental monitoring, and personnel training. According to Kaplan and Laing (2013), several pharmaceutical firms in the developing economies fail to provide the necessary financial resources to undertake them, especially where the firm is operating on a highly competitive market with minimal profit margins.

The technological disadvantages have also been cited as a serious challenge to pharmaceutical quality compliance. The current pharmaceutical production processes need a complex system of production devices, computerized monitoring and automatic control of quality. Firms under the assumption of outdated manufacturing technologies can struggle to fulfill the stringent demands of the documents and compliance with the regulations imposed by international bodies (Pisani et al., 2018).

Another important factor that determines effectiveness of pharmaceutical quality management systems is the human resource capacity. A number of studies have highlighted that pharmaceutical firms need highly trained professionals who would have a knowledge in quality assurance, regulatory matters and pharmaceutical engineering. Nonetheless, the problem with most developing countries is the lack of skilled pharmaceutical specialists who could guide complex quality systems (Al-Khalidi et al., 2020). This scarcity may severely upset the introduction of sophisticated quality management principles in the pharmaceutical manufacturing plant.

Organizational culture is also found to be a significant predictor of the compliance of pharmaceutical quality. Organizations with a more favorable culture emphasizing quality management will tend to invest in integrated enterprises of continuous improvement and one adhering strictly to regulatory matters. On the contrary, companies that focus on short-term monetary benefits rather than quality improvement in the long term might fail to pay important attention to certain quality assurance activities (Garcia et al., 2020).

Along with these challenges, some of the studies have also given enabling factors which facilitate compliance with quality of pharmaceuticals. Regulatory reform to enhance pharmaceutical governance is one of the most important enablers.

It is observed that fraudulent countries that have implemented modern regulations and open inspection systems have improved the quality of pharmaceutical manufacturing (Ndomondo-Sigonda et al., 2017).

Programs on international collaboration have also led to enhanced pharmaceutical regulatory systems. Technical assistance, training programs, and regulatory capacity-building initiatives that assist pharmaceutical manufacturers to embrace international quality standards are regularly implemented as programs with the support of global health organizations (Kohler & Dimancesco, 2020). These programs are especially relevant in the developing nations because regulatory bodies may not be adequately equipped technically to carry out sophisticated pharmaceutical quality systems.

Digitization of pharmaceutical production is another significant facilitating force. Accuracy and efficiency of the pharmaceutical production processes may be enhanced by many automated quality control mechanisms, electronic documentation platforms, and real-time monitoring technologies (Shah et al., 2016). These technologies minimize the possibility of human fallacy and increase the possibilities of companies to stay in compliance with the regulating requirements.

All in all, there is empirical evidence that compliance in pharmaceutical quality is affected by a complex of regulatory, financial, technological, and organizational factors. To solve these factors, effective cooperation of regulatory bodies, pharmaceutical companies, and international organizations are needed to enhance pharmaceutical systems of governance and quality assurance practice.

2.3 Research Gap

Although there is an increasing literature on the subject of quality compliance of pharmaceuticals in developing nations, there are still some critical gaps in research. To start with, most of the existing research concentrates more on the subject of regulatory issues on the national level without delving into the opinions of industry workers who present the actual situation in pharmaceutical production processes. It is necessary to understand the pharmaceutical managers, quality assurance specialists, and regulatory affairs professionals in order to identify feasible barriers and enablers that have influence on achieving international quality standard compliance.

Second, a significant part of the available literature is focused on quantitative research or policy studies, which offer very little regarding the organizational forces that affect the behavior of compliance in pharmaceutical firms. The qualitative research method would provide a more in-depth understanding of the institutional and cultural issues, which influence the decisions on compliance in the pharmaceutical organizations. These methods are especially applicable when studying problematic issues that cut across the board like organizational culture, managerial attitudes toward quality assurance, and institutional pressures about regulatory compliance.

Third, little research work has been conducted on the pharmaceutical manufacturing sector in Karachi which is the largest pharmaceutical manufacturing industry in Pakistan. Since the pharmaceutical companies are mostly found in this region, an analysis of the compliance problems in the pharmaceutical industry of Karachi can also be valuable information when it comes to systemic-wide concerns that are related to the pharmaceutical industry in the country in general.

Lastly, although some barriers to pharmaceutical compliance with quality have been revealed in past research, there is a gap that needs the replication research to verify and generalize previous findings in various organizational and regulatory settings. Replication studies will play critical roles in enhancing reliability of research results and enhance the external generalizability of the research conclusion to other pharmaceutical industry and regulatory conditions.

It is important to address such research gaps to formulate evidence-based measures that would help to enhance the pharmaceutical quality compliance in Pakistan. Through a qualitative replica study, which will target pharmaceutical manufacturers in Karachi, the study will aim at

providing a contribution to the current literature by offering an insight into the institutional, organizational and operational factors affecting the adherence to internationally accepted quality standards.

3. Methodology

3.1 Research Design

In this study, qualitative research design is taken to examine the enablers and barriers that influence compliance with internationally accepted quality standards in the pharmaceutical industry of Pakistan. A qualitative study is most suitable in exploring such complex institutional, organizational and behavioral variables affecting regulatory compliance. Compared to quantitative methods in which numerical variables play a key role, qualitative study has the capability to pursue intensive theme exploration, experiences, as well as contextual realities of stakeholders in the pharmaceutical production and regulatory systems.

The paper will be modeled as a simulated qualitative study of the Karachi -based pharmaceutical industries in Pakistan. A replication approach is useful in a research since it would enable the researcher to verify and build on the results of past studies as he investigates the phenomenon in a slightly different setting or using a different sample. Using the same qualitative research strategies employed in previous studies that investigated pharmaceutical quality compliance, this study is expected to validate the prior determined variables and also reveal new situational aspects that can affect the compliance in the pharmaceutical market of Karachi.

Qualitative research designs are important especially when regulatory compliance behaviors are to be understood in organisations since they are usually guided by managerial attitudes, institutional pressures, organisational culture, and regulatory environments. This study aims to offer the detailed information of the way in which pharmaceutical companies perceive international quality standards and how the organizational and institutional conditions have an effect on the way in which they comply using the qualitative inquiry.

3.2 Research Setting

The study was done in the pharmaceutical manufacturing industry in Karachi, Pakistan. Karachi is also known to be the biggest industrial and business city of the nation and a large manufacturing center of pharmaceuticals. The city has a large proportion of local and multinational pharmaceutical firms that manufacture various types of pharmaceutical products that are used domestically and in the export markets.

Karachi is a suitable place to conduct the analysis of adherence to the international quality standards as the pharmaceutical manufacturing facilities are concentrated in the city. The pharmaceutical companies in this region are susceptible to regulatory control in the nations but at the same time are trying to comply with international regulatory measures in exporting medicines. Such an environment offers a topical area of study concerning institutional, operationally, and regulatory variables that govern the quality compliance with pharmaceuticals.

Also, regulatory offices, pharmaceutical distribution networks, institutions of higher education, and research have been established in Karachi, which has led to a complex pharmaceutical ecosystem that influences the practices of quality management. A study of compliance issues in this context enables scholars to emerge with insights on how various stakeholders communicate in the healthcare pharmaceutical regulatory context.

3.3 Study Population

The research population was composed of the individuals employed in the pharmaceutical industry and associated regulation spheres. The selection of the participants was done on a basis of direct experience in the pharmaceutical manufacturing, quality assurance, regulatory affairs, or pharmaceutical policy formulation. Such people also have the experience and practical skills connected with the pharmaceutical quality management systems and the compliance requirements.

The sample participants were pharmaceutical manufacturing managers, quality assurance professionals, regulatory affairs specialists,

pharmacists operating in production facilities and the professionals engaged in pharmaceutical regulatory regulation. These persons were taken to be the correct individuals since their career demands them to have direct interactivity with the quality checks process, regulatory records, and compliance systems in the pharmaceutical manufacturing operational contexts.

The participants who belonged to various professional positions made the study include various perspectives to the issues of pharmaceutical quality compliance. The research was to be formed by means of including opinions of both regulatory experts and industry practitioners in order to create the all-inclusive perceptions regarding the contributing factors to the adherence to international quality standards.

3.4 Sampling Strategy

The participants to be used in the study were sampled using a purposive sampling technique. Purposive sampling is widely applied in qualitative studies when the respondents are sampled on the basis of their knowledge, experience and the suitability to the topic under study. This method enables the researchers to get data delivered by people that have special knowledge concerning the phenomenon being studied.

The sample was determined by certain inclusion criteria which were some level of professional experience in pharmaceutical manufacturing, quality assurance, regulatory affairs or pharmaceutical policy. People who had been serving in the pharmaceutical sector for at least a few years were given first preference since they could give a more insightful account on the regulatory compliance issues and practices inside the organization.

Theme saturation prevailed until the sampling process was completed. Thematic saturation takes place when further interviews are not able to produce new information or knowledge on research questions. Saturation will make sure that the data acquired is deep and wide in perspectives to aid quality qualitative analysis.

3.5 Data Collection Method

The data that is to be used in this study was collected through semi-structured interviews. The semi-structured interviews also enable the researcher to cover certain research areas and on the other hand give flexibility to the interviewees with which they might discuss issues that they consider as significant or of interest. This method helps the researcher to have rich and detailed information regarding the experiences and perceptions of the participants.

The interview guide was designed to support the process of data collection. Questions posed in the guide were open-ended questions that constituted the knowledge of the participants about the international pharmaceutical quality standards, organizational processes that sustain compliance, institutional issues that impact the regulatory compliance, and issues that facilitate the facilitation of quality management systems. These questions prompted the participants to elaborate about their experiences and observations.

The interviews were held in a professional and confidential manner in order to make the participants feel at ease when giving their views. The interviews ranged over a period of thirty to sixty minutes, depending on the availability of the participant and the degree of his/her engagement. The interviews involved participants expounding their answers and giving examples based on their work experiences.

All interviews were recorded by taking notes and recording when the participants allowed the exchange to be recorded. The fact that interviews were recorded meant that they could be transcribed properly and the data that could not be lost due to the process of collecting data.

3.6 Data Analysis

The thematic analysis was used to analyze the obtained data as it is a well-known qualitative method of data analysis that is aimed at identifying patterns and themes in the textual data. The thematic analysis enables the study to present qualitative data in a structured and organized manner and to create repetitive themes apparent in the responses of the respondents.

The processing of the analyzing statements started with the transcription of the recordings of the interviews to have written material of the data obtained. The transcriptions were also thoroughly examined in order to be accurate and comprehensive. When the research was first transcripted, the researcher made a preliminary reading of the information to get an idea of the content and highlight the preliminary patterns.

The second step was to encode the information by giving labels in the form of descriptive words to passages of texts which contained definite concepts or ideas. These codes were then categorized into wider categories depicting general themes about what pertains to the quality compliance in pharmaceuticals. Themes identified in the process were a reflection of the most important enablers and barriers in the compliance with international quality standards.

Lastly, the topics were evaluated and measured according to the research purposes and theoretical context. The step entailed the analysis of the interactions between institutional, organizational, and regulatory forces and their implications to compliance behavior in the pharmaceutical manufacturing context.

3.7 Ethical Considerations

Ethics were given due consideration during the implementation of the research process so that all participants and the study would be preserved. All interviewees participated in the study at their own will and prior to the research, they were briefed on the reason behind the study. They also made the participants aware of the fact that they could at any point in time opt out of the study to suffer no adverse effects.

The issue of confidentiality was upheld by citing the absence of revealing the identity and organizational membership of the participants in the study results. Interactive Transcripts Transcripts across the interviews were depersonalized to maintain anonymity of the participants. The data shown by respondents was utilized exclusively in academic research.

Also, the researcher made sure that all the data obtained were stored properly and could be accessed exclusively to conduct research. The observance of confidentiality and ethical transparency was deemed important to facilitate the honesty of the research respondents and make the research findings credible.

3.8 Trustworthiness of the Study

A number of strategies were used to improve the credibility of the research to ascertain the trustworthiness of the qualitative findings. The fact that the participants were chosen with the help of the relevant professional experience and data gathered with the assistance of various stakeholders in the pharmaceutical industry helped to enhance credibility. By doing this, the researcher was able to compare the various points of view and come up with common trends among responses.

The systematic recording of the research process, such as interview procedures, coding approaches and data analysis procedures were used to ensure its dependability. It is also important to keep good records so that the other researchers will be able to know how the study was done and assess the accuracy of the research.

The transferability has been supported by giving a descriptive account of the study environment, the nature of the participants and data collection methods. Such descriptions allow the reader to determine how the findings can be generalized to other pharmaceutical industries that are under the same regulatory settings.

4. Results

4.1 Participant and Organizational Profile

The sample size of the study was 20 participants who were selected based on major functional areas of the pharmaceutical industry in Karachi. Table 1 gives a summary of the demographic and professional characteristics; the distribution was equal between early-career and senior professionals and those who had experience of between 5 to 20 years. The profile has revealed that there were no limits to the hierarchical level of experience disclosed, which reinforced the credibility of reports regarding compliance practices, operational constraint, and engagement with regulatory purposes. The representatives used to be in the positions that are the focus of quality

compliance such as quality assurance, production, regulatory affairs, quality control and technical consultancy.

Table 1 Demographic Profile of Study Participants (n = 20)

Participant ID	Gender	Age Group	Education Level	Professional Role	Years of Experience
P1	Male	30–35	PharmD	QA Manager	8
P2	Male	36–40	MSc Pharmacy	Production Manager	12
P3	Female	28–32	PharmD	Regulatory Affairs Officer	6
P4	Male	41–45	PhD Pharmaceutics	Quality Director	15
P5	Female	30–34	MPhil Pharmacy	QA Officer	7
P6	Male	35–39	PharmD	Production Supervisor	10
P7	Male	29–33	MSc Pharmacy	Validation Engineer	6
P8	Female	38–42	PharmD	Regulatory Specialist	11
P9	Male	45–50	PhD Pharmacy	Technical Director	20
P10	Male	31–35	PharmD	QA Manager	9
P11	Female	27–30	PharmD	QC Analyst	5
P12	Male	40–44	MSc Pharmacy	Plant Manager	14
P13	Male	36–40	PharmD	Production Manager	12
P14	Female	33–37	MSc Pharmacy	Regulatory Affairs Officer	8
P15	Male	42–46	PharmD	QA Director	16

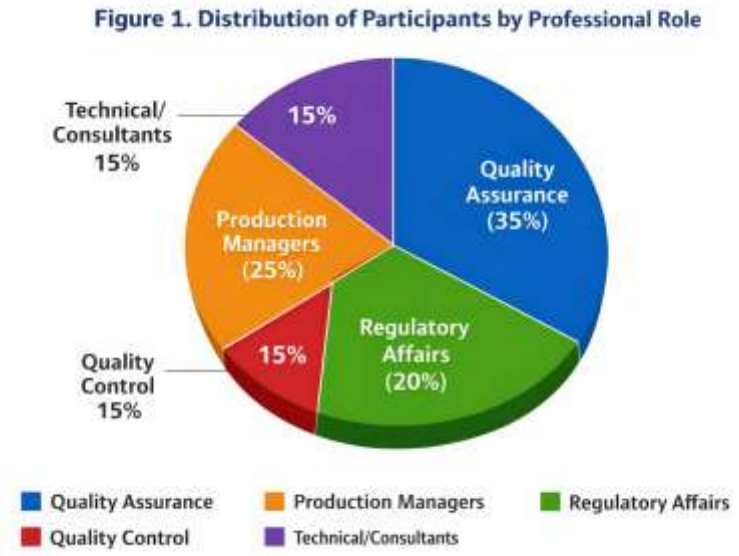
P16	Female	29–33	PharmD	QA Officer	6
P17	Male	37–41	MSc Pharmacy	Validation Specialist	11
P18	Male	34–38	PharmD	Production Supervisor	9
P19	Female	31–35	PharmD	QC Manager	8
P20	Male	44–48	PhD Pharmacy	Technical Consultant	18

Table 2 describes an organisational context that was studied in 10 pharmaceutical organisations. The sample also comprised local and multinational manufacturers and with different workforce size and capacity of manufacturing. The organisational diffusion is that the results represent a heterogeneous operating reality of firms specialising in either domestic generic producing firms, to export oriented firms producing injectables, vaccines and specialized therapeutic segments. This organisational heterogeneity is significant in understanding barriers and enablers since the expectations of compliance and access to resources are usually more high in the operations that are export related. Figure 1 shows the breakdown of the participants based on professional role and that the quality assurance and production-related roles constituted the greatest portion of the sample. This spread justifies the soundness of the findings since such functions have a direct role in day to day implementation of GMP and internal quality systems.

Table 2 Organizational Characteristics of Participating Pharmaceutical Companies (n = 10)

Company ID	Company Type	Number of Employees	Manufacturing Units	Primary Products	Export Activity
C1	Local	450	2	Tablets & Capsules	Limited
C2	Multinational	900	3	Injectables	High
C3	Local	320	1	Syrups & Suspensions	None
C4	Local	520	2	Antibiotics	Moderate
C5	Multinational	1100	3	Vaccines	High

C6	Local	270	1	Generics	Limited
C7	Local	390	2	Cardiovascular drugs	Moderate
C8	Multinational	950	3	Oncology drugs	High
C9	Local	310	1	Pain management drugs	None
C10	Local	480	2	Dermatology products	Limited

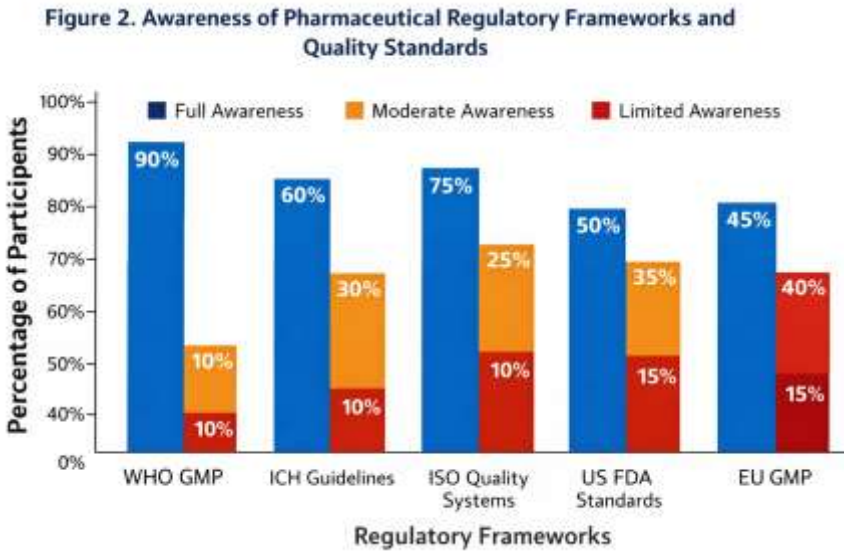


4.2 Awareness of International Quality Standards and Regulatory Frameworks

The respondents were found to have quite good knowledge of fundamental international quality standards, especially WHO GMP, indicating its central position in national and export compliance anticipations. According to Table 3, WHO GMP had the highest average response pattern of the fully aware group, which is to make the majority of respondents identify GMP as the standard model of understanding inspections, documentation practice, and facility requirements. Conversely, awareness of EU GMP and US FDA standards was relatively low with bigger proportions indicating moderate or limited awareness. This trend indicates the depth of knowledge level is also consistent with the probability of direct exposure implying that players in companies that are not as active in exporting might not necessarily have a regular interaction with harsher or highly specialised regulation models.

Table 3 Awareness of International Pharmaceutical Quality Standards (n = 20)

Standard	Fully Aware	Moderately Aware	Limited Awareness
WHO GMP	18	2	0
ICH Guidelines	12	6	2
ISO Quality Systems	15	4	1
US FDA Standards	10	7	3
EU GMP	9	8	3



The same pattern is represented in Figure 2 that illustrates the level of awareness with various frameworks. Figure 2 yields an interpretation which suggests that the perceived standards that are considered locally applied or frequently used in audits are more comprehensively recognized with those standards linked to increased costs of compliance having less even distribution in awareness. This also has effects on compliance capability in the sense that partial awareness usually translates into lopsided implementation particularly of constraints involving data integrity, depth of data validation, and rigor of change control. In general, it can be concluded that awareness exists but is not evenly distributed across standards, and this casts the idea that structured training should be delivered with an aim of meeting specific market needs.

4.3 Barriers to Compliance With International Quality Standards

The interviews revealed numerous interconnected barriers that influenced the outcome of compliance, the most rolled barrier was the resource constraints and the system constraints. The frequency of major categories of barriers in general is presented in Table 4 and depicts that the most frequent barriers were identified as a financial constraint. The conclusion of this finding is that compliance is generally viewed as resource consuming especially when companies strive to upgrade the facilities, enhance environmental monitoring or upgrade the quality

control labs. The second most commonly documented obstacle was the shortage of skilled workforce, as it continues to be a problem to recruit and retain qualified personnel skilled in the area of GMP documentation, validation, deviation management, and the creation of regulatory dossiers.

Table 4 Major Barriers to Compliance Identified During Interviews

Barrier Category	Number of Participants Mentioning	Percentage (%)
Financial Constraints	15	75
Limited Skilled Workforce	13	65
Regulatory Delays	12	60
Technological Limitations	11	55
Weak Quality Culture	9	45
Supply Chain Issues	8	40

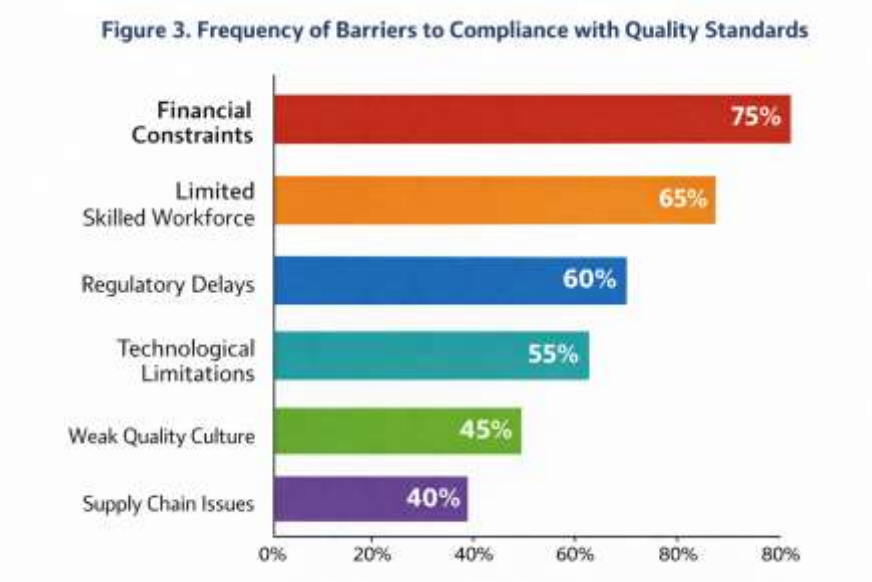


Figure 3 depicts the relative frequency of these barriers and visually enforces the superiority of financial constraints and workforce constraints. Consideration of Figure 3 indicates that in instances where there are clear regulatory expectations, the ability of firms to comply with them might be hindered as compliance is not a one-time program but a long-term program. Regulatory delays and technological constraints also surfaced, which means that the compliance is a venue of not only the inside ability, but also the outside world, such as the timeframe of approval and the availability of the contemporary production or quality control equipment.

Table 5 Barriers Reported by Professional Role

Barrier	QA Professionals	Production Managers	Regulatory Experts	Total Mentions
Financial Constraints	6	5	4	15
Skilled Workforce Shortage	5	4	4	13
Regulatory Delays	3	4	5	12
Technological Limitations	4	5	2	11
Weak Quality Culture	3	4	2	9

These findings are enhanced by differences within the professional roles. Table 5 indicates the manner in which the barriers were reported by regulatory experts, production managers, and quality assurance professionals. The regulatory experts placed stronger emphasis on regulatory delays, and this does not come as a surprise considering that they are directly involved in the submission of dossiers, the scheduled timing of conducting the inspection, and communication with the authorities. Technological constraints, which were more common, were pointed out by production managers as they indicated the ability of operations by the outdated equipment, limitations on maintenance and automation of the processes. A high income rate was reported by quality assurance professionals as far as there were reports of financial constraints and workforce shortages because of the obligation pertaining to the integrity of documents, compliance with training, and audit readiness. The merging of opinions on the functions indicates that the obstacles are not limited to a single operation and become systemic forces that impact the whole compliance ecosystem.

4.4 Enablers Supporting Compliance and Quality Improvement

In addition to barriers, the participants gave enabling conditions that serve in the support of long-lasting compliance and incremental maturity of high-quality systems. Table 6 presents the main enablers and shows that the most often mentioned was the staff training programs. This represents the common opinion that capability-building can at least partially balance the shortages of infrastructure and resources through better documentation practices, inspection preparedness and procedural discipline. The other high-frequency enabler is management commitment that supports the perspective where compliance with quality becomes better when the management considers quality as a strategic agenda as opposed to reactively prerequisite.

Table 6 Key Enablers Supporting Compliance with Quality Standards

Enabler	Frequency Mentioned	Percentage (%)
Staff Training Programs	16	80
Management Commitment	14	70
Regulatory Reforms	12	60
Technology Upgrades	11	55
International Collaboration	10	50
Quality Auditing Systems	9	45

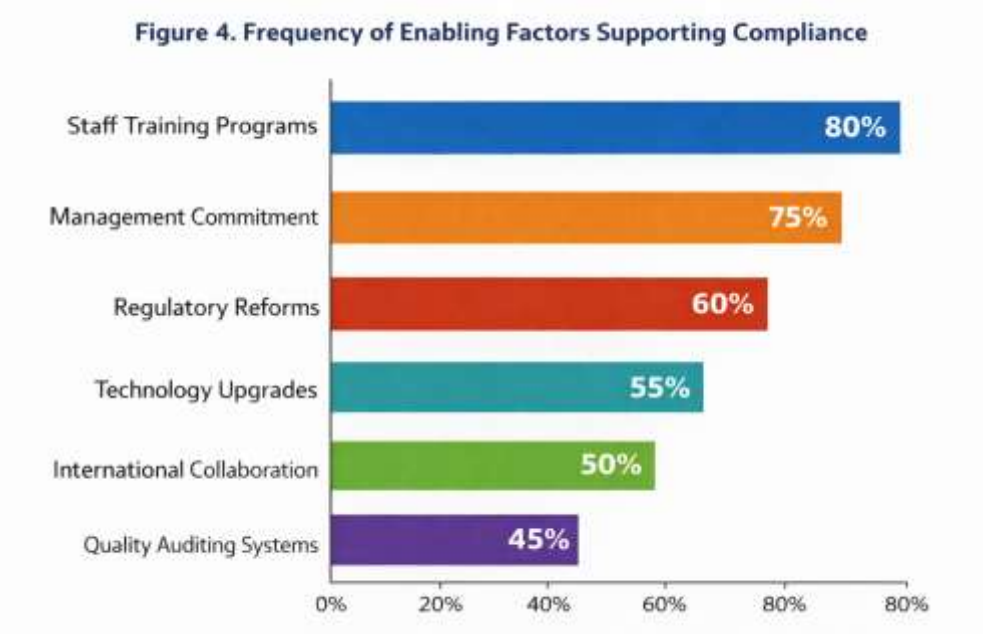


Figure 4 demonstrates the value of enabling factors according to participants and shows the perceived relevance of training and leadership support, then regulatory reforms, the upgrade of technologies, and international cooperation. Figure 4 can be interpreted to mean that enablers transpire in a variety of levels. Others are internal enablers, i.e. business leadership behaviour and the intensity of training whereas others ar e external e.g. regulatory reforms and the opportunities of collaboration. Systems of quality auditors have also been noted to be part of the enabling mechanisms which means that regular self-assessment and internal audits assist organisations in identifying gaps prior to the inspections.

Table 7 Comparison of Enablers Between Local and Multinational Companies

Enabler	Local Companies (n=7)	Multinational Companies (n=3)
Staff Training	5	3
Technology Investment	3	3
Quality Management Systems	4	3
Regulatory Collaboration	3	2
International Certification	2	3

The variations between enablers of local and multinational firms are another enlightenment. Table 7 is a comparative analysis of enabling factors by company types and reveals that multinationals indicated that they were stronger on technology investment and international certification activity. The staff training and internal quality management systems as a point of improvement more often were named by local companies, which indicated the possibility to rely on a gradual increase in capabilities instead of a massive change in the infrastructure. This trend suggests that compliance plans vary depending on organisational size with the multinationals employing global systems and capital facilities, whereas the local organisations focus on the interventions of scale that enhance preparedness with small budgetary allocations.

4.5 Organisational Practices Linked to Compliance Outcomes

The respondents narrated a series of organisational practices that act as practical means of conforming standards into day to day practices. Table 8 provides an overview of the quality management practices applied in companies and shows that internal quality audit and process validation are highly adopted, implying that the companies acknowledge them as being critical in GMP alignment. There was less adoption of the electronic documentation systems which were either cost restrained or remained a low level of digital transformation. It was found that there was moderate adoption of environmental monitoring and risk management systems which implied variability in the extent to which firms institutionalised proactive quality control in addition to baseline requirements.

Table 8 Organizational Quality Management Practices

Quality Practice	Companies Implementing	Percentage (%)
Internal Quality Audits	9	90
Process Validation	8	80
Electronic Documentation Systems	6	60
Environmental Monitoring	7	70
Risk Management Systems	5	50

Figure 5 gives a conceptual diagram between organisational practices and compliance outcomes. Figure 5 can be interpreted to show that one of the pathways through which practices of better quality management as embodied in internal audits, documentation and validation and risk management can lead to better results of compliance in terms of consistent product quality, risk of regulation and better market access. The figure assists in explaining why some practices were highlighted in the interviews. The compliance was usually framed by participants as the outcomes of normal systems working on a regular basis, as opposed to occasional inspection preparation actions.

4.6 Institutional and Regulatory Environment Shaping Compliance

The institutional environment was severally reported as a powerful contextual force that influenced organisational compliance decisions. The summary of regulatory and institutional factors as presented in table 9 indicates that the requirement to undergo inspection, the demand to obtain export certifications, documentation load, and product registration delays were the most frequently cited. These forces show that administrative processes as well as enforcement influence compliance. In cases where inspection criteria have been seen to be inconsistent with the way they are interpreted, or where they have no certain timelines, organisations might find it

challenging to plan upgrades, to schedule validations, or to plan production timelines to match the regulatory approvals.

Table 9 Institutional and Regulatory Influences on Compliance

Regulatory Factor	Participants Mentioning	Percentage (%)
DRAP Inspection Requirements	14	70
Export Certification Requirements	12	60
Regulatory Documentation Burden	11	55
Policy Uncertainty	8	40
Delays in Product Registration	10	50

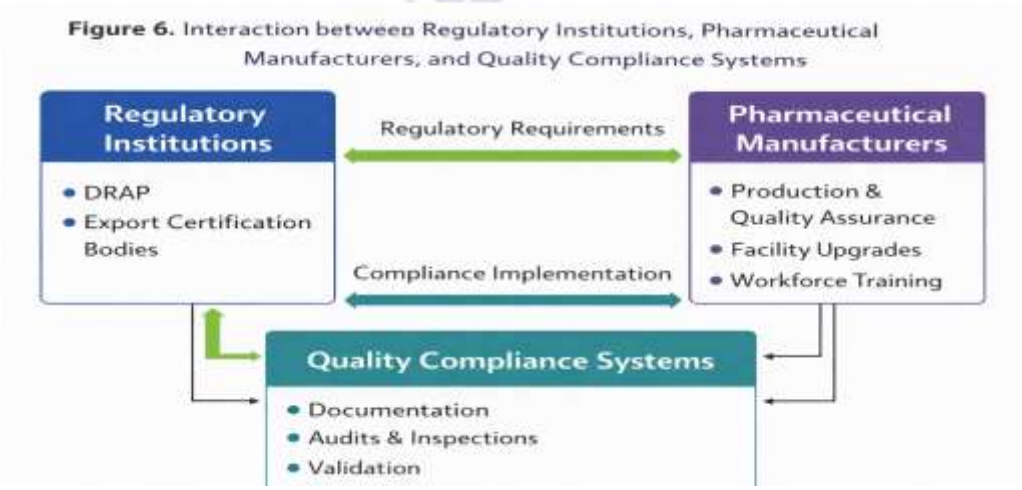


Figure 6. Interaction between Regulatory Institutions, Pharmaceutical Manufacturers, and Quality Compliance Systems

The relationship between quality compliance systems, pharmaceutical manufacturers and regulatory institutions is illustrated in figure 6. Being a one-directional process where the regulators set rules and the firms obey them is an interpretative idea that is supported by the interpretation of Figure 6. Rather, compliance is created through on-going interaction through requirements communication, implementation, audits, feedback and corrective measures. According to the accounts provided by participants, frictionality in compliance can be minimized through smoother interaction and better guidance, and delays and uncertainty can undermine motivation and slug implementation of improvement initiatives.

4.7 Consolidated Themes and Integrative Interpretation

The thematic framework employed unites all the major themes of the study into an overall summary as shown in Table 10, which summarises the themes as barriers, enablers, organisational practices, institutional factors, and industry dynamics. Information on Table 10 can be interpreted, on the one hand, to imply that the results of compliance should be viewed as the net influence of simultaneous pressures and supports. The rapidity and extent of compliance enhancement is inhibited by financial and manpower constraints and facilitated by training, management dedication and organized quality systems which in turn allow gradual advancements. Priorities are also determined by export opportunities and competition as companies that have future export plans are more motivated to attain greater expectations.

Table 10 Summary of Major Themes from Thematic Analysis

Theme Category	Subthemes Identified	Frequency
Barriers	Financial limitations, workforce shortage, regulatory delays	15
Enablers	Training programs, management commitment, technology adoption	14
Organizational Practices	Quality audits, validation procedures	11
Institutional Factors	Regulatory reforms, international standards pressure	10
Industry Dynamics	Competition and export opportunities	8

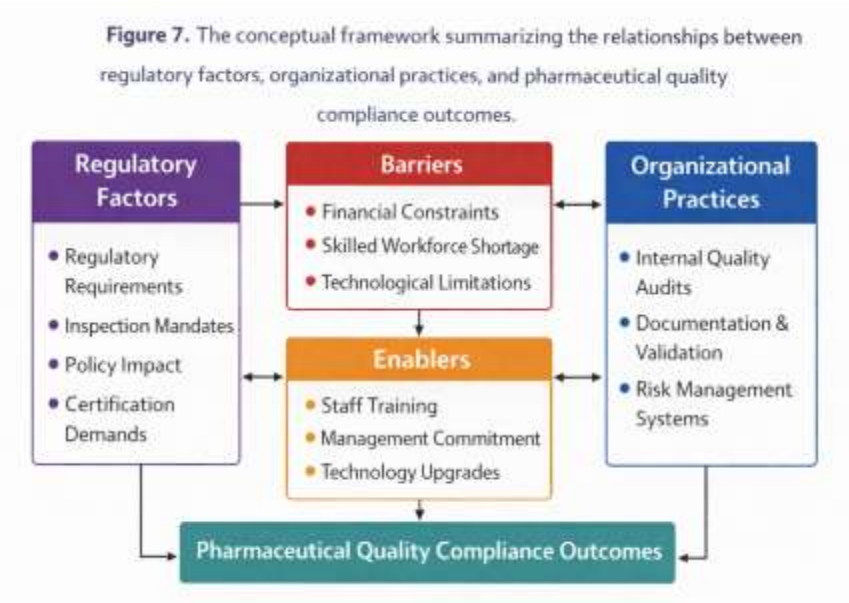


Figure 7. The conceptual framework summarizing the relationships between regulatory factors, organizational practices, and pharmaceutical quality compliance outcomes.

Figure 7 gives a conceptual framework of the relationship among regulatory factors, organisational practices and quality compliance outcomes. Based on the interpretation of Figure 7, the compliance outcomes might be considered as the downstream outcomes influenced by the signals of regulatory environment, internal organisational practices, and the facilitating investments, e.g. training and technology upgrades. The framework explains the interaction between regulatory needs and institutional demands and the internal systems to identify the processes of sustaining compliance, superficial commitment to compliance, and inconsistent compliance. Put collectively, the findings suggest that the current compliance issues in pharmaceutical companies in Karachi probably can be improved through the integrated use of both internal development of quality culture and abilities, not to mention the need to enhance the effectiveness of regulatory rules, technical support, and foreseeability of administrative procedures.

5. Discussion

The research results of the current study will be very insightful to understanding what factors contribute to compliance with internationally accepted pharmaceutical quality standards among pharmaceutical industries in Karachi, Pakistan. The findings point to the fact that adherence to international regulatory systems is influenced by internal organisational procedures and institutional regulatory factors as well as contextual limitations based on financial resources and labour capacity. Players of various positions have repeatedly stated that compliance of quality is not merely a technical imperative but an organisational process that is strategic and has to be continuously invested in training, infrastructure and regulatory conformity. The present findings can be linked to previous studies, which present the hypothesis that the quality system of pharmaceuticals is best when it is implemented into the organisational culture instead of the outside regulatory necessity (Sandle, 2016).

Among the greatest findings of the research is associated with the comparatively high awareness of the internationally recognised standards including WHO Good Manufacturing Practices (GMP). This is an indication that the regulatory environment in Pakistan has helped in enhancing awareness on the knowledge on the required level of pharmaceutical quality. Other past researches have also cited similar findings that the knowledge about GMP framework tends to rise when

national authorities coordinate their inspection procedures with international benchmarks and demand producers to make themselves evidently conforming to the inspection and tolerance when their establishments are assessed (Carleton & Barrows, 2017). But in the current study it was found that there was a relative sensitivity to more stringent structures like EU GMP as well as US FDA regulatory standards. This tendency goes in line with the results of Shah and Khan (2018), who note that the pharmaceutical companies, which focus on domestic markets, are more likely to focus on local regulatory needs, whereas the exposure to high specificity foreign regulatory mechanisms is not established unless the firms look at export opportunities.

The other important finding is connected with the financial constraints and workforce surpass as the major obstacles to compliance. Most of the respondents indicated that to establish high quality systems, substantial investments in infrastructure and technology as well as expertise in human capital are essential. The same was concluded by Ndomondo-Sigonda et al. (2017), who revealed that pharmaceutical companies in developing economies are frequently characterized by resource scarcity that does not support the adoption of high-quality regulatory standards. Such monetary constraints are of paramount relevance to those settings in which the pharmaceutical sector is subjected to pricing pressures as well as restricted access to financing technological supplies. Moreover, labor issues also proved to be an outstanding obstacle since compliance needs to be working with highly trained specialists who would be able to operate elaborate documentation frameworks, audit procedures, and regulatory filings. Research on the pharmaceutical manufacturing systems of emerging economies has also pinpointed the issue of insufficient experienced regulatory and quality personnel is a substantial limitation to attaining stable GMP standards (Newton, Bond, and Ashley, 2018).

Also found to have an impact on compliance outcomes were technological constraints and regulatory delays. The interviews implied that the presence of old manufacturing technologies and the scarcity of digital infrastructure may decrease the efficiency and pose high chances of having quality deviations. These results are consistent with the activity of Pisani, Foong, and Nair (2020), who revealed that the adoption of technology is the key to enhancing the reliability and quality assurance of pharmaceutical manufacturing. Delays in regulations, especially product registration and scheduling of inspection, were also seen as a hindrance that has the ability to derail operational planning and interest investments in compliance enhancement. This finding can be explained by the previous studies which regarded that administrative inefficiencies in the regulatory systems may indirectly influence the industry motivation to implement superior compliance practices (Kaplan and Laing, 2019).

Regardless of these obstacles, the research has found some enabling factors that facilitate the adherence to the international quality standards. The most commonly mentioned enablers were training programs and management commitment. This indicates that the issue of leadership in the organisation contributes significantly to the process of developing quality culture in the pharmaceutical organizations. Similar studies by Almuzaini, Choonara, and Sammons (2019) also revealed that the management commitment towards quality systems is highly effective in enhancing compliance with the regulatory requirement and promoting internal accountability means. Training programs are also important in enhancing the workforce, as well as the enhancement of procedural adherence. Constant professional development processes serve to prevent the situation when employees are not aware of the changing regulatory expectations, the changing documentation requirements, and the changing technological advances.

Internal quality audits, validation procedures, and risk systems seemed to have a strong relationship with better compliance results as well as organisational practices. Such practices constitute realistic processes by which the regulatory standards are converted into operational processes. Earlier studies have highlighted that institutionalisms of internal auditing and risk-based quality management mechanisms are

associated with increased sustainability of compliance by pharmaceutical organisations, but also lower the risks of product recalls or regulation sanctions (Sandle and Maddux, 2020). The current work validates the statement that these organisational practices are the main elements of a successful pharmaceutical quality management system.

The results also indicate the impact of the general regulatory and institutional setting. The respondents indicated that regulatory inspections, export certification conditions, and the policy frameworks have a great impact on compliance behaviour of organisations. The observation can be associated with the regulatory governance view, which states that the industry compliance is not only determined by the available internal capacity but also the clarity, consistency, and implementation of regulatory standards (Ragao Santosa, 2018). Pharmaceutical manufactures would be more attracted towards making long-run compliance measures when regulatory expectations are clear and foreseeable.

Implications of the Study

The results of this study also have a number of policy and practical implications on enhancing the compliance of pharmaceutical quality in Pakistan. To begin with, governmental bodies need to strengthen training and capacity building programs with the intent of improving expertise levels in the workforce with regards to the implementation of GMP and regulatory documentation. Cooperation of the regulators, universities and even industry associations would assist in overcoming the problem of lack of qualified specialists in pharmaceutical quality management. Secondly, the policy makers ought to take into account the mechanisms that would assist in technological modernisation in the pharmaceutical companies (especially those locally based companies, which might have no finances to upgrade their infrastructure). Third, better transparency of the regulations and fewer administrative delays might contribute to the industry confidence and more proactive compliance investments. These solutions might help to enhance the quality of domestic drugs and the competitiveness of the Pakistani pharmaceutical industry on the international level.

Limitations of the Study

Though the research is regarded as a valuable source of information about the issues in the compliance with the quality of pharmaceuticals, it is important to admit a number of limitations. One, the research was based on qualitative interviews with participants who were pharmaceutical companies in Karachi. Though this method was able to provide a prospective discourse into industry views, the results might not be the overall picture of other parts of the Pakistani country where regulatory and operational influences might vary. Second, the sample size is rather small, which is suitable to the qualitative research type, but makes the results inapplicable to the whole pharmaceutical industry. Third, the authors were not particularly interested in similar views of industry practitioners; they did not address interviewees of regulatory officials and policymakers, whose opinions could clarify more on the issue of the institutional barriers which influence compliance.

Conclusion

Finally, this paper has discussed the facilitators and obstacles affecting the capabilities of the Karachi, Pakistan, pharmaceutical company to work in accordance with the internationally recommended pharmaceutical quality standards. The results prove that compliance performance is conditioned by the complicated interaction of organisational activities, financial, and workforce limitations, and the regulatory framework. Although the level of awareness about international quality standards seems to be rather high among the representatives of the industry, the issues concerning the limitations of the resources used, the technological infrastructure, and the regulatory patterns make it difficult to comply with the higher levels of the regulatory requirements. Simultaneously, the facilitating conditions, including employee education, top management dedication, well-organized quality management infrastructure, etc., create avenues of

enhancing compliance performance. The increase in regulatory capability, the training of workforce, as well as technological innovation are all likely to be very important factors to enhance the pharmaceutical quality adherence to measures in Pakistan and the safety and reliability of the pharmaceutical products in the local and international markets.

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