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An Overview of Emerging Trends in Pharmaceutical Quality Assurance

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ABSTRACT :

Quality by Design (QbD) was originally created in the wide field of quality management, but it has recently been refined and formalized in terms that will support pharmaceutical firms in achieving excellence in operations and marketing. Despite a few notable success stories, the pharmaceutical sector has not yet fully embraced QbD, particularly in typical commercial manufacturing. The aim of this review is to investigate the existing application of QbD methodology and tools in the pharmaceutical business, with a focus on identifying potential possibilities and gaps that may be addressed to enhance the uptake of QbD. Globalisation of the pharmaceutical industry has increased the demand for more effective surveillance systems to ensure the quality of the final product. Moreover, tighter regulation and quicker approval processes encourage even greater efficiency with scarce regulatory resources. The objective of this review is to examine how QbD methodologies and tools are currently being used in the pharmaceutical industry, looking for patterns and trends as well as opportunities and gaps that could be taken into consideration to increase QbD adoption. Risk-based quality assessment of new pharmaceuticals, generic pharmaceuticals, over-the-counter pharmaceuticals, and biotechnology products, including biosimilars, is based on science and research.

Keywords: Quality By Design, Globalisation, Pharmaceutical Robots, Biotechnology Products, Pharmaceutical Industry.

Introduction :

Through modernization efforts, the U.S. Food and Drug Administration's Centre for Drug Evaluation and Research (CDER) has been working for more than 10 years to raise the Caliber of pharmaceutical development and manufacture [1]. But during this time, issues including drug shortages and recalls linked to inadequate pharmaceutical production methods have increased. Quality errors, especially those pertaining to facility improvements and product manufacturing, are thought to be the cause of almost two thirds of all medication shortages [2].

It is becoming more difficult to keep an eye on the quality of products because the pharmaceutical sector is growing globally at a rate that has never been witnessed before. Furthermore, pressure exists to implement new regulatory obligations—like accelerated approval processes—with limited financial resources. With the intention of bolstering pharmaceutical quality in the face of present and upcoming challenges, the FDA founded the Office of Pharmaceutical Quality (OPQ) inside CDER on January 11, 2015 [3]. Supporting the FDA's pharmaceutical quality objectives and priorities is the aim of OPQ's scientific and research program [4].

Quality planning, which is where QbD got its start, is one of the three quality pillars Joseph M. Juran created and named the Juran's Trilogy. The other two are quality control and improvement. The overarching idea is that capital allocation and manufacturing should happen once quality has been established. In actuality, this implies that businesses should begin by defining their quality objectives, creating features for their goods that help them achieve these objectives, creating processes that allow them to be delivered, and setting up controls that allow for consistent operation. As a result, QbD is concentrated on effectively and consistently meeting customer requirements [5,6].

More specifically, QbD suggests that quality be embedded in the process and product during development, going beyond the traditional Quality by Testing (QbT) approach, which mainly examines the quality of the final product. Quality-based development, or QbD, is a systematic approach to product development that begins with predefined objectives and places emphasis on process control and product and process understanding. It is based on sound research and excellent risk control [7]. Although this strategy is not new, the pharmaceutical industry has only recently started to adopt it, in contrast to other firms. Particularly for recently released pharmaceutical medications that are still in the development stage, this method is currently gaining ground quickly [8].

Benefits of QbD [9,10] :

Enhance product quality

Quality-by-design (QBD) ensures items are made well, not just checked before they get shipped out. It makes sure smoother output with less variation present by looking for and removing potential sources of variation during production. This approach made it possible to enhance the pharmaceutical products' general quality and quantity of defects at the same time.

regulatory compliance

The approach is embraced by two regulatory ageist organizations, namely, FDA and EMA, because it matches their focus on risk management and scientific knowledge. QbD may lower the possibility of non-compliance and make the approval process run more smoothly. P.S. The text you have provided contains HTML tags. It is important to retain them where it is necessary as failure to do so may result in failure of system execution.

Marlet Competitiveness

Companies using QbD stand out in the market by making higher quality, more reliable, and more efficient goods. Therefore, this can lead to greater customer satisfaction and an increase in market size.

flexibility and adaptability

QbD offers the possibility of making continuous improvements in processes and adaptability in the face of changes in raw materials, equipment, among other things. To maintain the quality of the product, it's necessary that this adaptability be present in a constantly changing industrial setting.

The structed approach

QbD encourage deep understating off process and product characteristic, this foster innovation by allowing companies to explore new formulation process and technology with a clear understating of their impact on product quality.

Improve patient safety

The reason that patient safety is enhanced and efficacy of therapy is maximized through QbD is because it assures an unchanging level of quality expected from drugs. Expected benefits to patients are enhanced health from treatment and increased trust by patients in drug developers as they use a product they can rely on.

Current utilization of qbd methodology and tools [11,12]

risk assesement

The use of failure mode and effect analysis (FMEA), Hazars analysis and critical control point (HACCP), and Rosk matrices in the true sense, among others, have made risk assessment a critical aspect of QBD. Such methodologies also serve as the means through which MSD priority risk is pinpointed so that both risk character and rank can be properly dealt with.

process analytical technology

Many people use the PAT for overseeing and managing the production progression immediately. Just like chromatography, Raman and near-infrared (NIR) spectsroscopy are some of the main techniques that the PAT system primarily uses and which are suitable for continuous assessment of data to ensure that the production remains constant in quality as well as the best quality.

Design of experiment

A crucial one for understanding the relationship between product variables and quality is the design of experiments (DoE), often using techniques such as factorial design, response surface technique, and mixture design in order to optimise manufacturing processes.

Multivariable data analysis

MDVA is used to analyze complex datasets from experiments conducted at PAT and DoE. Clustering, regression analysis, and principal component analysis (PCA) are common methods that people use to explore variability as well as the behaviour of processes.

Pattern and trends in QbD Adoption [13]

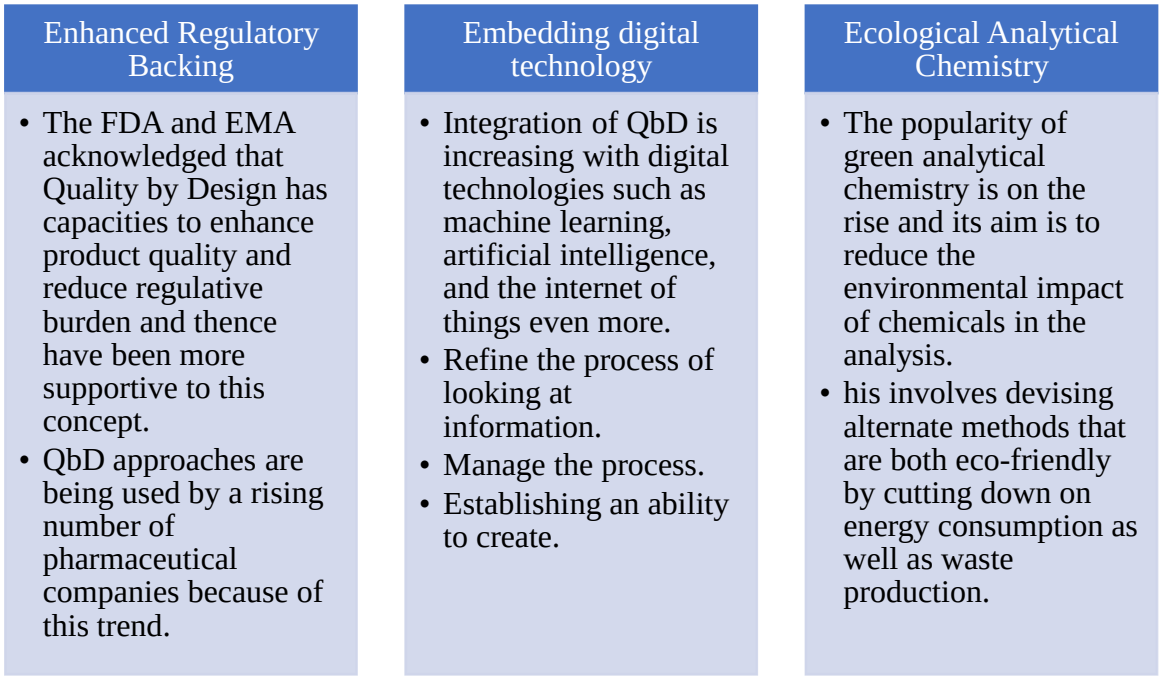


Figure 1. Pattern and trends in QbD Adoption

Quality by Design in analytical method validation [14,15,16]

Review of the Quality by Design (Qbd) model

The concept of Quality by design focuses primarily on estimating and dealing with the potential issues as early as possible. It involves identifying critical control method parameters (CCMP), determining the method ruggedness through risk-based approach tools and setting analytical target profile (ATPs). The systematic optimization of often involves the application of experimental techniques.

The implementation in pharmaceutical industry

Pharmaceutical companies are now using quality by design (QbD) for method validation in order to increase the robustness and dependability of research and development methods. This will result in consistent, dependable, and well-understood analytical methods with the incorporation of essential QbD components.

Advantages That a Qbd Approach Has in Method Validation.

Several advantages of Qbd methodology include enhanced regulatory compliance, decreased variability and improved method resilience which fosters innovation and ongoing development in analytical techniques.

Insurance Policy for QbD by Pharmacopeia [17,18,19]

Unites Stated Pharmacopeia

The USP has including QbD concepts into its method validation chapter. For instance, <1225> specifies the roles of QbD in method validation.

European Pharmacopoeia

European Pharmacopoeia: They have also adopted the principle of Qbd in their guidelines for the development and validation of analytical methods. These guidelines provide a comprehensive understanding of the analytic operation and it is important parameters.

Global Symposium on Harmonization

ICH guidelines say use Qbd for pharmaceutical development and manufacturing, including analytical methodologies. Q8 pharmaceutical development, Q9 quality risk management, and Q10 pharmaceutical quality system specifically.

Trends in the pharmaceutical industry :

7.1 National and International: -

The pharmaceutical sector has experienced a true globalization in recent years, encompassing all phases of the drug development process. Eighty percent of active pharmaceutical components and more than forty percent of completed pharmaceuticals are made outside of the United States [20]. Today's producers of medicines have a worldwide perspective while developing and producing their products, concentrating on streamlining production across several locations in nations with widely disparate technological and regulatory capacities. Pharmaceutical companies will only be looking to a worldwide market in the future, driven by growth in "premiering" nations (such as China, Brazil, Russia, India, and South Korea) [21] and aging demographic trends in wealthy nations [22].

The COVID-19 pandemic has recently brought to light a number of weaknesses and difficulties brought forth by the pharmaceutical industry's globalization. The COVID-19 pandemic has brought to light the vital issue of supply chain security and robustness, which has been an increasing worry for the previous two decades. It is imperative that this issue be addressed swiftly.
Globalization has resulted in the following: [23,24]

- There is a need for more harmonization when it comes to quality standards and regulations. This will prevent manufacturers from having to deal with contradictory, redundant requirements across national borders that add to costs without adding value.
- The intricacy of the pharmaceutical supply chain has escalated due to many factors such as regional sourcing, global integration, catering to diverse client demands, adapting to technological advancements, and business amalgamations.
- In particular, supply chain vulnerabilities have increased due to globalization, which has prompted stakeholders to look at other track and trace (T&T) solutions, such blockchain, to strengthen security and transparency.
- Preserving the uniformity and calibre of medications while lowering the obstacles to their accessibility is a major concern in a worldwide marketplace.
- Quality expectations must be controlled to ensure that patients and providers worldwide have access to high-quality medications while also facilitating effective drug discovery, production, and distribution on a global scale.

New therapies and modalities :

The emergence of progressively intricate and advanced therapies and treatment modalities has been a significant trend in the pharmaceutical business.

- Roughly 74% of clinical-phase initiatives in a 2017 review study on the drug development pipeline had the potential to be first-in-class [25].
- Combination goods, such as drug-device and diagnostic-drug solutions that improve the targeting and delivery of medications, are becoming more and more prevalent.
- Digital drugs are emerging as a competitive threat to traditional pharmaceuticals. Technology is used in digital treatment to track, treat, and prevent illness.
- In the fascinating and quickly developing field of cell and gene therapies, personalized or precision medicine tailor's goods to specific patients based on their genetic makeup and expected outcomes.
- The drug development process has changed as a result of advances in software and engineering technologies, moving from analytical tools like data modelling and analytics to gene sequencing and process engineering. Close coordination with business, regulators, and other stakeholders will be necessary to ensure quality standards in this fast-paced world of rapidly advancing technology.

The way that quality can be assessed and determined needs to change in light of these new, cutting-edge therapies and modalities. In order to provide consistent and reasonable standards for these items and assist assure their quality, new modalities may need to redefine the traditional quality requirements of identification, strength, quality, and purity [26].

Innovative manufacturing methods :

New and alternative technology and manufacturing processes are beginning to be adopted by the pharmaceutical sector. This change is being fuelled by objectives including higher output, less of an impact on the environment, less likelihood of drug product quality issues, and quicker time to market.

- Pharmaceutical production is moving away from the conventional "batch" method, which produces final goods through sporadic steps, and toward more effective methods and control strategies (such as continuous manufacturing, "on-demand" manufacturing, and automation) for producing drug substances and drug products [27].
- A greater number of components and intermediates can be measured with a growing level of accuracy thanks to improved data and analytical technology.
- Utilizing electronic data collecting, processing, and monitoring devices is a common practice in in silico modelling approaches like digital twins.
- The emergence of novel trends in manufacturing, such 3D printing and disposable/single-use equipment, enables modularized manufacturing to increase capacity without requiring modifications to facilities or machinery [28].

These creative manufacturing strategies will keep gaining favor in the sector as long as technology keeps developing. To ensure that new technologies are introduced and supported in a way that allows for timely implementation, regulatory channels that set clear expectations are required.

Application of automation and robotics in laboratory :

Automation is a common application of robotics in the pharmaceutical industry for various manufacturing processes, drug screening, and research. The majority of analytical instruments are mechanised, which makes the tedious analytical procedures easier. Increased productivity results in a significant reduction in the workload for the QC department. If the analytical section does not receive its results on time, the automated systems can help. The incorporation of robotics and automated systems enables quick sampling and testing of all the quantities. There would be very little danger of losing any batches due to the continuous testing. All test findings are guaranteed to be handled or saved correctly thanks to these analytic instruments' design. The majority of systems follow the FDA's guidelines for maintaining data security because they never alter the data. A QC their involvement is superfluous in situations such as an automated HPLC system, in which samples are collected, examined, and the results are transmitted straight to a central computer. Automation and automated system can therefore be very beneficial to the laboratory system used in the pharmaceutical industry [29].

10.1 Automated Management

Numerous integrated sensors are available to identify the elements at every step of the process, ensuring error-free operation and system control. The computerised systems are so sophisticated that if a group is found to be non-compliant, it may be further programmed to start or stop recording. The detectors, which are positioned throughout automated systems, enable ongoing observation of the process variables. Conversely, the computer receives this data, processes it, and makes critical decisions such as rejecting groups or shutting down the system. In such cases, human intervention will be limited because the many systems involved only need to operate as intended. If the workforce understood the automated procedures well, they would be better able to adapt to automation [30].

Some sectors include the production systems, air handling units, WFI systems, and pure steam systems as critical systems. One advantage of this is that it gives control over all quality-related factors. If there is an issue of any kind with any of the tools, the staff is notified. Such combination systems are essential in the manufacturing of parenteral, etc., where extreme caution is required because even a slight deviation from the required conditions affects the product's quality [31].

10.2 Employing the bots [32]

Robotic process automation (RPA) and robotic cognitive automation (RCA), as well as their validation, offer life sciences organisations a wide range of opportunities within Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), and Good Laboratory Practices (GLP). Among these applications are:

- Simplifying the laborious manufacturing process of product labelling
- facilitating the development of pharmacovigilance by offering the resources and ability to handle large amounts of data on the distribution and quality of products
- preserving official records, such as study procedures for new drug applications, that are mandated by precedent rules and subject to FDA inspection
- Improving the efficacy of training and learning management systems (LMS) through the automation of training assignments, identification of gaps, and correspondence with impacted individuals
- identifying high-risk abnormalities in images by processing and interpreting clinical trial data on a broad scale, including radiology reports.

Additionally, regulators are expressing more interest in the application of R&CA in validation procedures. Authorities require businesses to address the hazards connected with new technologies while still promoting innovation.

10.3 Considerations for an RPA approach [33]:

The implementation of RPA follows the tried-and-true process for validating computer systems: define the limits and functionality of the system, build controls around it, confirm that the controls perform as expected, and then make the system available for usage.

The adoption of RPA may span several systems, which may increase the need for change control. It is crucial to comprehend the larger environment in which RPA technologies are being developed and incorporated into existing systems, even when employing tried-and-true techniques and tactics.

Following the development and deployment of the bots in accordance with standard operating procedures, the company needs to commit to an internal or vendor-led maintenance strategy.

Other things to think about when using RPA are:

1. Early implementation of a controls framework to set the bar for quality for deployment across the entire organisation and direct actions during the RPA life cycle
2. integrating RPA into the organization's broader change management plan to prevent unforeseen consequences from changes
3. a framework for controls that emphasises the balancing act between high-risk automated operations and human involvement
4. Due to increased processing speed, there is a greater emphasis on testing and validation to ensure they can execute operations within boundary constraints and issue alarms if they can't.
5. security-based measures to guarantee that only users with permission—including authorised bots—are able to access particular areas of the system
6. Validation of periodic maintenance, carried out more frequently in the early stages of development, to ensure that modifications to upstream systems haven't impacted bot functionality.

Pat (process analytical technology) and automation :

To monitor critical quality attributes, a PAT system must assess product quality in real-time without triggering reorganisation. When spectrum instruments such as UV-Vis, Raman, NIR, etc. are used, they need to be calibrated. Then, one or more multivariate prediction models are used to translate the spectrum responses into quality ratings. These models analyse the data and provide real-time predictions about the qualitative characteristics of a product, making it possible to create control programmers that guarantee the creation of trustworthy, high-quality goods. This robotic and automated approach is very apart from traditional process management. When "Quality by Testing" is put into practice, the process is complete. Conventional process control relies on assumed raw material characteristics and control equations that are established through experimentation. PAT-based control systems use real-time quality indicators that account for differences in materials and methods to guarantee quality at the end of the process. [34].

11.1 Automation and Digitization of Quality Assurance and Control Systems

Quality management is essential to both quality assurance and quality control. Market research and experimental data demonstrate the procedure's efficacy, and pharmaceutical companies endorse it. Pharmaceutical quality control is often associated with the International Conference on Harmonisation (ICH) Q10 model, which is based on the International Organisation for Standardisation (ISO) Quality standards, including Good Manufacturing Practices (GMP). The International Conference on Consensus (ICH) "Q8 Drug Development" and the International Conference on Harmonisation (ICH) "Q9 Quality Risk Management"[35]

The International Conference on Harmonisation (ICH) Q10 has three main objectives.

- Completing goods orders.
- Provide a controlled environment and keep it that way;
- Encourage more development [36].

11.2 Continuous Manufacturing Automation

Up until a technological malfunction, manufacturing robots are capable of operating continuously for extended periods of time. All it needs is a regular source of electricity and maintenance. Consequently, these continuing processes can benefit industries monetarily. When it comes to forcing people to work longer hours, there are some restrictions, such as the state of their physical and mental health. This does not apply to machines, so there is no problem. With proper maintenance, all of the equipment will run smoothly and without any hiccups for an extended period of time. This could be the first thing to blame for the unemployment rate. The government and manufacturers should look into this as the working society would not want this to happen. This could have an effect on the industry [37].

11.3 Example of an industry:

11.3.1.1PAT provides on-site analysis within a unified continuous manufacturing setup.

The pharmaceutical industry frequently uses batch-wise production, but this method is not without its difficulties. Issues with supply chains, quality control, and technology can all pose obstacles. connected continuous manufacturing, or ICM, has garnered more attention lately. ICM uses several connected unit processes to maximise output. ICM systems make use of model-based management systems that have some features from Process Analytical Technology (PAT). The prototype plant's effective manufacturing of API and tablets in accordance with specifications shows how real-time PAT combined with integrated system management may increase output, lower energy usage, shorten lead times and inventory levels, and need less capital [38].

6.3.2 Packaging that Doesn't Clearly Show Tampering: The Foil Inspection Method Using Deep Learning and Machine Vision:

Using deep learning and analytical machine vision, this application demonstrates how to develop and implement a hybrid surveillance system in the field. High detection accuracy for defect characteristics whether or not they are expressed explicitly is achieved by skilfully integrating the system's capabilities. Many places had successfully adopted one such strategy for a variety of items. The system maintained a low false failure rate while accurately identifying serious seal flaws. [39]. The automations using artificial intelligence and robotics in pharmaceutical industry is depicted in the figure 1. Automations utilising AI and Robotics in Pharmaceutical industry.

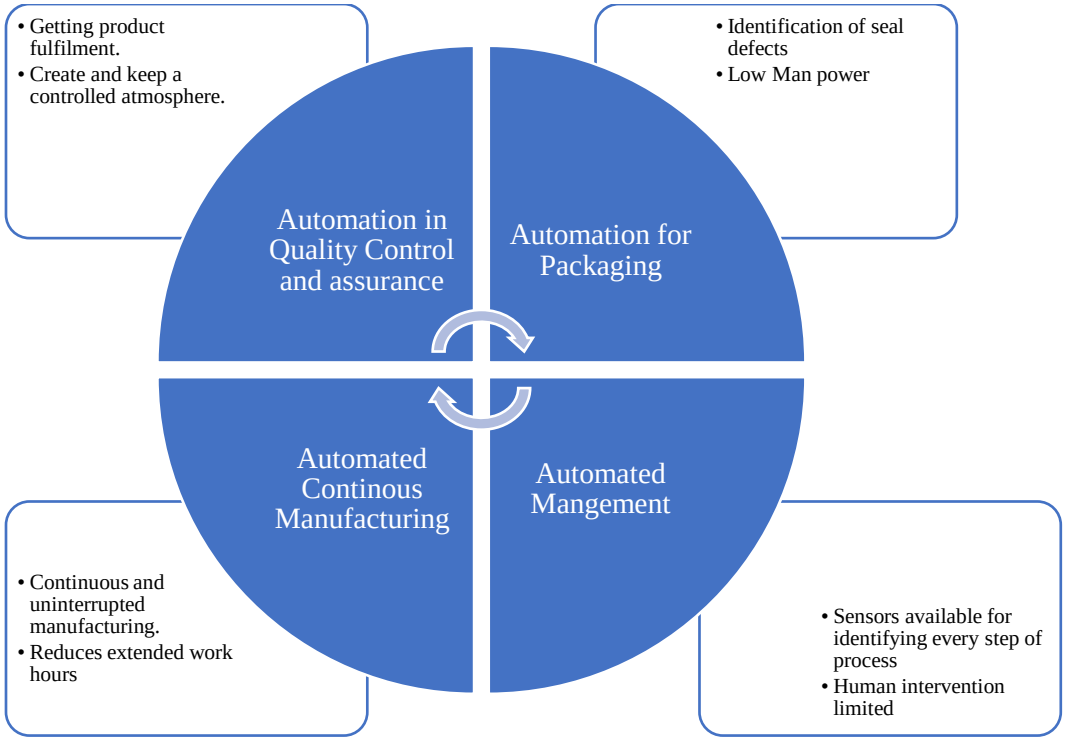


Figure 2. Automations utilising AI and Robotics in Pharmaceutical industry

Shifts in quality paradigm :

significant industrial trends are often linked to, and the outcome of, fundamental and interconnected changes in the way business, government agencies, and standards setting organizations view and evaluate quality.

12.1 Paradigm Shift 1: Integrated risk-based approaches replace compliance-centric ones

Meeting regulatory requirements, such as current good manufacturing practices (CGMP) [40,41], which include federal regulations on testing and distribution permission, was previously a top priority when making decisions about products [42]. This concentration frequently resulted in an end-product testing focus that produced a pass/fail outcome [43]. But rather than just complying, it's now understood that the ultimate objective is to guarantee quality throughout the entire process of developing and manufacturing a product, using sophisticated quality systems and metrics. Pass/fail assessments are more effective when there is a deeper comprehension and knowledge of the product.

Therefore:

Pathways for recognizing and reducing risks throughout the lifecycle of medication are being investigation by the pharmaceutical industry and regulation [44].

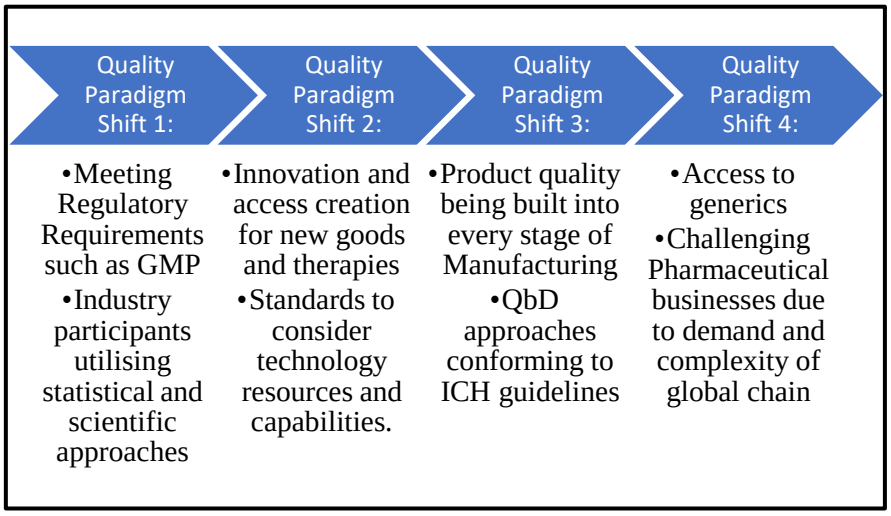
- Industry participants are using scientific and statistical approaches more often to evaluate and manage risks in a proactive manner, trying to avoid failures instead of just responding to them after the fact.
- Predictive analytics is being utilized to enhance comprehension and predict areas of vulnerability and danger.
- The pharmaceutical industry is adopting risk-based and scientific methodologies to create patient-centred control plans.
- This updated version preserves the original text while enhancing readability and clarity.

12.2 Paradigm Shift 2: Transitioning from Outcome-Based and Flexible Performance Approaches to Prescriptive Approaches

- •Standards should reduce barriers to innovation and access and allow for the creation of new goods and therapies.
- Standards must take into consideration the vast differences in technology resources and capabilities between industries and governments around the world.
- Performance and outcome-based standards should be the main emphasis of standard design in order to provide stakeholders with options to produce goods of the same or higher quality.

12.3 Paradigm Shift 3: Product Quality Instead of Testing Products

Figure 3. Addressing Quality Shift Paradigms



- The idea that quality should be included into products at every stage of manufacturing instead of depending only on testing the final product is starting to catch on [45].
- Quality by Design (QbD) approaches are being used by the pharmaceutical sector and authorities at increasing rate. In QbD, process control and product quality parameters are defined by an organized method that conforms to the principles provided in ICH guidelines Q8–11[46].
- Adjustments can be made in real-time within predetermined quality ranges for a variety of goods and production facilities using QbD and process analytical technology (PAT). These in-process control methods provide improved quality assurance and enable real-time release testing of pharmaceutical goods in contrast to conventional end-product testing [47].

12.4 Paradigm Shift #4: A Quality Environment Is Needed to Guarantee Supply Chain Resilience

Pharmaceuticals, especially cheaply cost generics, are now more easily accessible to patients both domestically and internationally thanks to the pharmaceutical industry and the globalization of the supply chain. Regrettably, this change creates a worldwide supply chain with several weak points and elevated threats to pharmaceutical quality. More specifically, the increased likelihood of pharmaceutical shortages for numerous essential medications is one of the primary concerns arising from the global supply chain. Pharmaceutical businesses may find it challenging to quickly increase production in response to increases in demand because of the logistical and regulatory problems posed by the complexity of the global supply chain [48]. Shifts in Quality Paradigm have been depicted in figure 3.

The global scope of the sector has resulted in the likelihood of data fraud, a potential shortage of medicines, and the risk of contaminated raw materials and finished products reaching the market [49]. The COVID-19 pandemic recently exposed these flaws, leading to suggestions to improve the variety and redundancy of the supply chain and to restart producing native products [50].
One possible way to create a framework that adequately addresses the challenges posed by the new global supply chain and encourages quality and supply chain robustness is to:

- Develop standards that help ensure data integrity and lay the groundwork for efficient remote audits and inspections.
- The creation of best practices and standards to help with supplier qualification and enhanced raw material evaluation.
- Employing best practices and guidelines that compel manufacturers to conduct risk assessments in order to identify possible weak points in their supply chain such as using "just-in-time" manufacturing or relying on a single source for intermediates and raw materials and to develop suitable countermeasures to reduce these risks (51).

Attempts to address paradigm shifts :

Several organizations, such as the Product Quality Research Institute (PQRI), the American Association of Pharmaceutical Scientists (AAPS), and the National Institute for Pharmaceutical Technology and Education (NIPTE), are deeply engaged in collaborative endeavours to delve into and propel forward regulatory science areas concerning the effectiveness and quality of pharmaceutical research and development as well as manufacturing. Various stakeholders, including authorities, industry players, academics, and pharmacopoeias, acknowledge the importance of transitioning towards new guidelines and standards. They are collaborating to enhance both the quality and accessibility of medicines, with recent efforts exemplified by the signing of a Memorandum of Understanding (MOU) between the US Food and Drug Administration (FDA) and the National Institute of Standards and Technology (NIST). As part of the Pharmaceutical Quality for the Twenty-First Century initiative, the FDA has introduced a Quality Maturity Model (QMM) to support this endeavour [52].

Conclusion :

It is evident that the QbD paradigm, which stresses a comprehensive understanding of the product and process, is expected to guide modern drug product development. Nevertheless, based on the findings of this analysis, the pharmaceutical industry has not yet fully adopted and utilized the QbD strategy. Traditional quality paradigms are undergoing substantial adjustments as a result of changes in the pharmaceutical sector. It will take creative and novel thinking to successfully navigate through these changes, as well as more cooperation across more diversified and global group of stakeholders.

List of abbreviation

1. QbD: - Quality by Design
2. CDER: - Centre for Drug Evaluation and Research
3. OPQ: - Office of Pharmaceutical Quality
4. FDA: - Food and Drug Administration
5. QbT: - Quality by Testing
6. QbD: - Quality-based development
7. T&T :- track and trace
8. HPLC: - High Performance liquid chromatography
9. QC: - Quality control
10. WFI: - Water for Injection
11. GLP: - Good Laboratory Practices
12. LMS: - learning management systems
13. R&CA: - Robotics and cognitive abbrivation
14. RPA: - Robotics and Proccess automation
15. PAT- process analytical technology
16. GMP: - Good Manufacturing Practices
17. ICH: - International Conference on Harmonisation
18. ISO: - International Organisation for Standardisation
19. ICM: - Integrated Continuous Manufacturing Systems
20. MOU: - Memorandum of Understanding
21. NIST: - National Institute of Standards and Technology
22. QMM: - Quality Maturity Model
23. NIPTE: - National Institute for Pharmaceutical Technology and Education
24. AAPS: - American Association of Pharmaceutical Scientists
25. PQRI :- Product Quality Research Institute

Data Availability statement

Data would be made available on reasonable request.

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Conflict of Interest

The authors declare that they do not have any conflicts of interest to disclose.

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