

13th SBS International Research Conference - SBS-IRC25
24.10.2025, Zurich, Switzerland
DOI: <http://doi.org/10.70301/CONF.SBS-JABR.2025.1/1.5>

5. Development of Process-Oriented Quality Management Systems for Pharmaceutical Enterprises

Zhanel Baizhumanova¹, Nabira Zharkinbayeva¹

¹SBS Swiss Business School, Zurich, Switzerland

Corresponding Author: Nabira Zharkinbayeva

Article Information

- **Date of Receiving:** 21.09.2025
- **Date of Acceptance:** 22.10.2025.
- **JEL Classification Codes:** L65, M11, O32

Abstract

This study presents a bibliometric analysis of scientific publications on process-oriented quality management systems in the pharmaceutical industry. The aim of the study is to identify key trends, popular topics and gaps in the existing literature. The data were collected from the Web of Science Core Collection, which includes 2147 English-language articles published between 2020 and 2025. The content analysis undertaken in the methodological part allowed to identify the most cited articles related to Pharma 4.0, digital technologies and artificial intelligence-based quality systems. The analysis of the obtained data shows that this research area is still evolving, although it covers a wide range of topics in the pharmaceutical industry. The findings indicated common studies in the areas of productivity, innovation, business process management and quality by design, digital transformation, while in the pharmaceutical sector the focus was often on systematic reviews of drug safety and regulatory practices. The results of this study allowed to define a conceptual framework, content and direction that could become the foundation for future quantitative and qualitative research, highlighting existing gaps and problems in the subject area.

Keywords: *Process-oriented quality management, pharmaceutical management, pharmaceutical quality system management, bibliometric analysis, Pharma 4.0*

5.1 Introduction

5.1.1 Background of the Research

Quality management systems (QMS) are essential in the pharmaceutical industry. They assist companies in complying with strict regulations and ensure medicines are safe, effective and of high quality (World Health Organization, 2021). A strong QMS is necessary at every stage, from manufacturing to distribution, helps organizations improve their processes and meet the expectations of governments and health organizations (Asif et al., 2013). In recent years, the pharmaceutical industry has experienced significant changes. New technologies, innovative treatments and increased global collaboration have emerged (Baimbetova, 2025). Because of this, traditional quality control methods are no longer sufficient. Nowadays, experts and companies are placing greater emphasis on process-oriented quality management systems. This approach means that quality should not only be verified at the end but also integrated into the entire process from the start. There are new concepts like Quality by Design (QbD) and digital tools, known as “Pharma 4.0,” which help make medical systems more modern, innovative and practical (Chang & Lin, 2019; Zhang, 2021; Khoklov & Pyatigorskaya, 2025).

This study analyzes the literature on process-oriented quality management systems in the pharmaceutical industry using advanced technological tools. The results of such research are expected to help the researcher understand how research in this area has evolved and where the gaps exist. The purpose of this article is to provide a clear overview of the published literature on process-oriented quality management systems in the pharmaceutical sector. The research aims to identify patterns, key themes and areas requiring further study.

5.1.2 Problem Statement and Research Inquiry

Although many researchers write about Quality Management Systems, the information is often scattered. Some articles focus on risk management, others on technology or production issues, but they mostly fail to connect these topics. This makes it difficult to see the whole picture. There is no clear summary of all the work done in the quality management system within pharmaceutical area and it is not clear which topics are most studied or which need more attention. According to literature one of solution is to use bibliometric analysis statistics (Van Eck & Waltman, 2010). This method helps examine many research articles at once using. It can design which topics are popular, who the leading researchers are, which countries or universities publish the most and how ideas are connected (Sartal et al., 2020; Patel & Desai, 2022).

5.1.3 Research Questions

To study the research problems indicated above this research aim to find answers to the following research questions:

Which topics would have the greatest impact on quality management systems in the pharmaceutical industry that have not been sufficiently researched?

What conceptual model reveal the existing gaps in the QMS within the pharmaceutical industry?

How collaborative research practices and co-authorship methods produce the best research results?

By answering these questions, the study aims to contribute to the theoretical understanding of the existing areas requiring research attention, as well as to contribute to the missing knowledge for practical application of existing advanced technologies by providing a clear overview of the published works on process-oriented quality management systems in the pharmaceutical sector.

5.1.4 Significance and Justification of the Research

The paper provides content analysis of the theoretical and methodological aspects of the formation of process-oriented quality management systems in the pharmaceutical industry. Particularly, the research used bibliometric analysis to examine scientific publications on QMS in the pharmaceutical area. Bibliometric methods help analyze a large number of articles through statistical tools and visual maps (Kamble et al., 2020). This enables the researcher to identify key trends, topics and relationships between authors or institutions.

The dataset was extracted from the Web of Science Core Collection, one of the leading databases for peer-reviewed scientific literature. Analyzed obtained data insights to expand the scope of research in future studies using quantitative methods and a case study qualitative approach.

5.2 Literature Review

5.2.1 Trends in the global pharmaceutical market

As scientific innovation advances, the pharmaceutical industry faces challenges in supply chain sustainability, trade restrictions and more. As geopolitical tensions impact API sourcing strategies and governments tighten environmental regulations, pharmaceutical company leaders are forced to seek new solutions in supply, pricing and manufacturing (Marante, 2025).

Meanwhile, the pharmaceutical industry is undergoing a digital transformation, with AI, machine learning and predictive analytics playing an increasingly important role in R&D, clinical trials and market intelligence. Data digitalization is transforming every sector, including the pharmaceutical industry as a key beneficiary (Marante, 2025).

In global practice, the document that defines the requirements for the production and quality control of medicines is the “Rules for the production of medicines” - “Good Manufacturing Practice for Medicinal Products (GMP)” (World Health Organization Guidelines, 2025). This GMP rule establishes requirements for quality control, personnel, premises and equipment, documentation, product manufacturing and analysis, complaints and product recall procedures. According to GMP requirements, the facility must have the required number and qualifications of personnel. The job responsibilities of each employee must be documented and understood by each employee. All employees must also be familiar with the requirements of this standard that apply to their area of work.

However, for such a set of elements to be perceived as a system, well-established relationships and connections between individual elements are necessary, forming a unified whole. These building blocks, which form a unified supply chain of automated systems, have been developed specifically for the pharmaceutical industry and reflect the entire business process chain, enabling control of the quality management system.

A quality management system guides and manages a pharmaceutical company with regard to quality. Specifically, the Good Manufacturing Practices (GMP) rule lists individual elements that must be included in a pharmaceutical quality system and is identified as: “Organization of Production and Quality Control of Medicines,” “Quality Control,” “Product Quality Review,” and “Quality Risk Management” (Osmolovskaya, 2015).

It should be noted that the top management of a pharmaceutical organization bears primary responsibility for the existence of an effective pharmaceutical quality system, for the availability of the necessary resources, for the fact that duties, responsibilities and authorities are defined, communicated, implemented and carried out in all divisions of the enterprise (Osmolovskaya, 2015).

With the advent of new technologies, recent years have seen an increase in the number of changes being made to regulatory documents in the field of quality management. While previously, even a minor clarification planned for inclusion in an existing standard could be discussed for years, now the pace of innovation is simply meteoric (Marante, 2025). This also applies to the documents of the international standards organization “Good Manufacturing Practice for Medicinal Products” (World Health Organization Guidelines, 2025).

Thus, to meet such challenges process-oriented quality management systems, the introduction of digital systems becomes relevant. Particularly, the three major forces shaping the future of pharma: from the growth of therapeutic areas to AI-driven transformation and the evolution of supply chains provide insight into how companies can remain competitive (Marante, 2025). Data digitalization is transforming every sector, including the pharmaceutical industry (Marante, 2025), becoming one of the priority solutions, where process-oriented quality management systems are becoming one of the leading solutions of business processes in such industries.

5.2.2 Pharmaceutical industry Kazakhstan: current trends and future developments

Citizen health has always been a key factor in the well-being of any society. In Kazakhstan, with the constant expansion of production and environmental degradation, the problem of disease evolution and their effective treatment is becoming increasingly pressing (Smagulova, 2025). Therefore, the dynamic development of the pharmaceutical market is a vital priority, as humanity requires a constant supply of medications.

The country’s pharmaceutical industry development strategy sets ambitious goals, including breakthrough scientific, technological and socially oriented development of the pharmaceutical industry, the creation of a highly productive export-oriented sector and, consequently, an increase in pharmaceutical exports (SK-Pharmacia, 2022; Pharmnewsz, 2024). Strategic objectives include establishing and maintaining close ties between science, education and existing pharmaceutical production, which will stimulate the development of fundamental science and strengthen Kazakhstan’s scientific heritage (SK-Pharmacia, 2022).

The country’s developed pharmaceutical industry is considered an indicator of the country’s highly innovative economy. With the arrival of foreign partners, production sites certified to international GMP standards have begun to emerge in Kazakhstan. Leading domestic pharmaceutical companies have now started receiving GMP certificates (SK-Pharmacia, 2022). It should be noted that most of these companies are enterprises with foreign participation. GMP certificates for certain production facilities should help increase production volumes and facilitate the freer promotion of domestic drugs on foreign markets.

In May 2025, as part of the Kazakhstan International Exhibition “Equipment, Raw Materials and Technologies for the Pharmaceutical Industry” via PharmaTech Kazakhstan, a conference on current issues in the pharmaceutical industry’s development was held with the support of the Association for the Support and Development of Pharmaceutical Activities of the Republic of Kazakhstan. Representatives of government agencies, industry associations, businesses and international companies participated in the event (Baimbetova, 2025). According to Smagulova (2025) the chief expert of the Department for the Development of the Pharmaceutical and Medical Industry of the Ministry of Health of the Republic of Kazakhstan, Kazakhstan has made significant progress in developing local pharmaceutical production over the past few decades. The expert also noted that in 2024, the pharmaceutical market was worth \$2.5 billion, of which 13.1% was accounted for by domestic producers.

Overall, the Kazakhstani pharmaceutical market is relatively young; however, over the years, significant progress has been made to develop the domestic pharmaceutical industry (Kazakhstan Pharmaceutical, 2025). However, Kazakhstan is one of the fastest-growing manufacturing industries, boasting leading indicators both in the Central Asian region and within the Eurasian Economic Union (EAEU) single market (SK-Pharmacia, 2022). Thus, manufacturing production growth in 2024 amounted to 106.9%. The industrial production index for basic pharmaceuticals and pharmaceutical products was 114.1% (Stat.gov.kz, 2025).

Also, Sultanov (2025), President of the Association of Manufacturers of Pharmaceutical and Medical Products “PharmMedIndustry of Kazakhstan,” noted that Kazakhstan’s pharmaceutical industry has currently achieved significant achievements following the introduction of support measures for domestic production and SK-Pharmacia LLC, which enabled the conclusion of long-term contracts. For example, in 2009, production volume was only 14.9 billion Kazakh tenge. Today, this figure has grown to 171 billion tenge - more than 12 times claim him. Sultanov (2025) emphasized this is the result of systematic efforts by the government, investors and the manufacturers themselves in innovation practice.

Nevertheless, the shortage of medicines and medical supplies, the degree of product range expansion and service quality remain important research issues today. Literature notes that the main global trends in the development of Kazakhstan’s pharmaceutical market include consolidation and the growth of vertically integrated companies. Specifically, according to a quantitative study by Vostok-Capital (2024), the key challenges facing the pharmaceutical industry in Kazakhstan include (Kazakhstan Pharmaceutical, 2025):

- a shortage of medicines, dressings, equipment and medical instruments;
- low wages for healthcare workers, preventing the attraction and retention of highly qualified personnel.
- the need to modernize and adapt the pharmaceutical industry to modern market conditions, and others.

A Vostok-Capital study published in the Kazakhstan Pharmaceutical (2025) also notes the need for stronger government regulation and guaranteed financial support for the successful modernization and adaptation of the pharmaceutical industry, aimed at eliminating its intellectual, technological, and infrastructural gaps. They also note the need for reorganization of the pharmaceutical industry, which will require streamlining the registration, certification and quality control processes for medicines and medical equipment, highlighting the importance of developing process-oriented Quality Management Systems in the country.

Furthermore, a study by Vostok-Capital (2024) identified several innovative solutions and services in the pharmaceutical industry to address the identified challenges. Specifically, the researchers noted that services using artificial intelligence and digital technologies could significantly improve the efficiency of translating, processing and storing medical data. This approach will enable the use of electronic prescriptions, electronic medical records and telemedicine. Furthermore, the researchers note that digitalization of processes will help reduce bureaucracy, improve information accuracy, and ensure more productive collaboration between doctors, patients, and pharmacists (Kazakhstan Pharmaceutical, 2025).

Thus, a process-oriented QMS, as one of the innovative solutions and services, is expected to contribute to the development of the pharmaceutical industry in Kazakhstan, improve the quality and accessibility of medical care and ensure more efficient use of resources and processes in the organization and production.

5.2.3 *Quality management systems*

5.2.3.1 *Quality management systems in the enterprises*

In the context of the emergence and development of the digital economy, the widespread implementation of a modern quality management system and international standards in priority industries and sectors of the economy is a key task (Averin, 2023). A quality management system ensures the competitiveness of national products and increasing their export potential is directly related to ensuring the quality and safety of products, both in the domestic and foreign markets and plays a crucial role in economic development (Movahedi et al., 2013; Averin, 2023).

A quality management system is a set of processes, policies and procedures that an organization establishes to ensure the consistent quality of its products or services and enhance customer satisfaction (ISO, 2015). The primary goal of a quality management system is the continuous improvement of business processes, the reduction of errors and the standardization of activities to meet customer requirements and international standards (Movahedi et al., 2013).

However, alongside the benefits of implementing a quality management system, it's important to note the key challenges associated with its operation. Particular attention is paid to the stages of implementing a quality management system and the challenges an organization may face at each stage (Grebennikova, 2009; Averin, 2023).

The organization of a QMS involves the creation of the following documentation structure (Howard, 2001; ISO, 2015):

- Quality manual.
- Quality policy and objectives.
- Documented procedures.
- Process and procedure regulations, work instructions.
- Quality records, etc.

Difficulties in business processes may arise from the moment a quality management system is implemented notes Grebennikova (2009). According to practical evidence implementing an innovation may entail restructuring several organizational processes. Issues may arise due to staff

being unprepared to work under the new conditions. Such problems are avoided or mitigated when implementation is accompanied by a staff training program (Grebennikova, 2009).

However, modern technologies can significantly accelerate and simplify the process of developing and updating a QMS. Indeed, methods for constructing one can vary significantly. For example, most organizations choose the simplest and most common method - developing QMS regulatory documents manually, without the use of automation tools (Grebennikova, 2009). To achieve this, a bureau or an entire department is created that focuses on keeping these documents up-to-date. There are several reasons for this: ignorance of the existence of information systems that automate the documentation process; a lack of understanding of the scope of QMS documentation and the work required to keep it up-to-date; and a focus on obtaining certification rather than building an effective management system (Grebennikova, 2009; Averin, 2023).

This indicates that a quality management system is a technological system of internal corporate management aimed at achieving specific quality criteria for manufactured products, operational processes and the entire range of enterprise activities. Implementing a QMS IT product at an enterprise allows for the creation of an internal corporate system in which each enterprise process is distributed and documented in a unified system for recording the movement of goods and services. Quality management through such process tracking systems allows for the application of requirements not directly to the quality of pharmaceutical products, but rather to the management system, which in turn is designed to ensure a predictable and stable level of product quality, the production process and the organization's overall operations.

Thus, despite all the challenges and complexities, QMS implementation is expected to benefit the overall economy, improve enterprise competitiveness, optimize business processes, increase resource efficiency and reduce production costs by reducing defects. This business process optimization helps attract investment in any industry as well.

5.2.3.2 Quality management systems in the pharmaceutical industry

Several commonly used quality management systems in the pharmaceutical industry include Good Pharmacy Practice, the process-based approach, ICH Q10 and other ISO standards (ISO 9000-2015, 2025).

Quality management in the pharmaceutical industry can be achieved using a process-based approach through the implementation of GMP. Tsivov & Orlov (2018) believe that consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coordinated system. However, when choosing an approach, a pharmaceutical company should focus on four elements according to Tsivov & Orlov (2018):

- senior management review,
- process and product quality monitoring system,
- change management system,
- corrective and preventive action system.

On the other hand, Mukhanova & Makhatova (2014) report that pharmaceutical companies worldwide, in order to comply with legal and market requirements, are forced to simultaneously

implement multiple management systems, several of which were mentioned above. The difficulty of finding partners drives this decision and also increases the opportunity to participate in tenders or government procurement.

Bragin & Korolkov (2006) propose creating integrated management systems based on a process approach to ensure enterprise stability and viability. They believe that combining multiple systems will ensure flawless measurement of process effectiveness and efficiency and their improvement. For more effective overall management, integrated organizational management also includes subsystems - second-level systems - such as a quality management system, social and environmental management, risk management, knowledge management and others. This approach is particularly suitable for improving quality management in organizations with various organizational structures, including multi-level ones (Bragin & Korolkov, 2006).

However, Aleksandrov et al. (2007) proposed a list of quality management parameters for a pharmaceutical enterprise, which can already be considered as an integrated system that achieves high product quality, process quality and structural quality. These are:

- product development in compliance with all requirements and standards (ISO);
- preparation of clear documentation for all production and control operations in accordance with the standard;
- clear definition of responsibilities and authorities;
- implementation of measures for the production, supply and use of appropriate raw materials and packaging materials;
- implementation of intermediate product, process control and validation;
- control and inspection of finished products in strict compliance with standard and legal requirements;
- systematic implementation of self-inspection procedures (internal quality self-audit), which enables regular assessment of the effectiveness and efficiency of the quality assurance system.

Aleksandrov et al. (2007) claim that various components of an organization's management system can be integrated into a single management system if the above-mentioned pharmaceutical product quality management parameters are maintained. Such integration, according to experts, facilitates planning, resource allocation, the definition of additional goals and the evaluation of the organization's overall performance.

5.2.4 Conclusion of the Literature Review

According to the reviewed materials, data digitalization in pharmaceutical organizations is a priority, with process-oriented quality management systems becoming a better automated solution (Marante, 2025) than manual accounting methods using simple computing tools that have no connection with databases (Grebennikova, 2009; Averin, 2023).

This review demonstrates that QMS issues in the pharmaceutical industry remain relevant and, moreover, that old problems have not yet been resolved. Many pharmaceutical organizations use manual record-keeping, which is incapable of ensuring quality management.

To advance QMS, the key forces shaping the future of the pharmaceutical industry were

examined: from the growth of therapeutic areas to artificial intelligence-based transformation and the evolution of supply chains, which provide insight into how companies can remain competitive (Marante, 2025). Integrated approaches to solving the management system problem by combining multiple systems have also been described (Bragin & Korolkov, 2006; Aleksandrov et al., 2007). This solution clearly remains relevant and can improve the quality of process performance and efficiency measurement and improvement.

The literature reviewed was found to be widely dispersed across the study periods. To determine the conceptual robustness of the problem under study, the study then attempts to conduct a content analysis to establish strong conceptual links related to process-oriented quality management systems in the pharmaceutical industry. The goal is to identify and understand key trends, themes and gaps in this field through a review of publications, keywords and references to further construct a conceptual foundation.

5.3 Methodology

5.3.1 Research Design

The research paradigm of this study was built on interpretivist's approach. The qualitative method was aimed to become a preliminary step of collecting of research building information to construct conceptual foundation and develop hypothesis statement for the wider next coming dissertation research purpose to survey and case study research.

In this study, bibliometric content analysis was used to examine scientific publications on process-oriented quality management systems in the pharmaceutical industry. Bibliometric methods help analyze many articles through statistical tools and visual maps (Kamble et al., 2020).

Content analysis was performed using VOSviewer software to process, to analyze and visualize the data on:

- Bibliometric Analysis of Keywords: Process-Oriented Quality Management
- Bibliometric Analysis of Keywords: Process-Oriented Quality Management and Pharmaceutical Enterprises
- Bibliometric Analysis of the Citations and Publications

5.3.2 Data collection and sources

The dataset comprised around 2,147 articles published between 2020 and 2025 on process-oriented QMS in the pharmaceutical industry, published over the last 5 years. These publications were selected from the Web of Science Core Collection one of the leading databases for peer-reviewed scientific literature - English-language articles and represent the most relevant research in the searching field.

5.3.3 Design of the research instrument

VOSviewer is a free software tool developed at Leiden University primarily for the creation

and visualization of bibliometric networks (VOSviewer, 2023). The software VOSviewer enables the creation of visual maps that display relationships between elements such as keywords, authors and institutions. It, also, allows analysing: co-authorship analysis to identify collaboration networks between researchers and countries; keyword co-occurrence analysis to discover common research topics and their connections; citation analysis to highlight the most frequently cited publications and authors; and institution and country analysis to show which organizations and regions contribute most to this field. The software groups items into clusters, helping the researcher understand the main themes and directions in the searching area.

VOSviewer allows to create visualizations based on data from bibliographic databases primarily in English papers: Web of Science, Scopus, PubMed, Dimensions or reference manager files: RIS, Bibtex, EndNote. As a result, some relevant articles published in other databases or languages may not be represented in the analysis.

5.4 Data Analysis

The VOSviewer enables the definition of three key features: keyword co-occurrence, which identifies topics that appear together; co-authorship, which reveals how researchers collaborate; and citation patterns, which determine the most influential papers. The results indicate and give understanding how research in this area has evolved and where gaps exist. Since this paper aims to provide a clear overview of what has been published about process-oriented QMS in the pharmaceutical sector it gives information to identify patterns, key topics and areas requiring further research.

The bibliometric analysis made able to identify key trends, topics and relationships between authors or institutions. The most interesting big areas fall into:

- process-oriented quality management;
- pharmaceutical enterprises.

During the analysis of obtained data reviews, book chapters, and non-research materials were excluded. All selected records were stored in a format suitable for bibliometric analysis, including information such as title, author names, keywords, publication year, institution and number of citations.

From extracted pull of data, it was found that most of the examined articles appeared in journals related to quality management, pharmaceutical sciences, innovation and industrial engineering. The most frequent journals included Cogent Business & Management, Chemometrics and Intelligent Laboratory Systems and Journal of Business Research. The analysis also showed that many articles were written by authors from multiple countries, which reflects international collaboration. The most active countries were Pakistan, Brazil, Spain and Morocco. These countries contributed several influential papers, especially on topics such as digital transformation, knowledge sharing and Pharma 4.0.

Overall, the results show that interest in process-oriented quality management in pharma is growing. However, the number of publications is still limited compared to other well-established research areas. This means that the topic is still emerging and has potential for further research.

5.5 Findings of the Research

5.5.1 Bibliometric Analysis of Keywords: Process-Oriented Quality Management

Keyword analysis of the selected 2,147 articles published between 2020 and 2025 displays a keyword co-occurrence map, indicating the frequency of co-occurrence of specific terms and identifying which topics are closely related.

Figure 1 demonstrates represent keywords; size indicates frequency; colors show clusters; lines represent co-occurrence links. In the case of “process-oriented quality management”, the visualization shows a strong network of connected terms. The most central and frequent keywords are “quality”, “management”, “impact” and “performance”. These terms appear in large font and bright colors, which means they are essential in this field.

The keyword “process-oriented quality management” is linked closely with terms like “business process management”, “implementation”, “innovation”, “strategy” and “framework”. This suggests that researchers often focus on how to plan, manage and improve processes in quality systems.

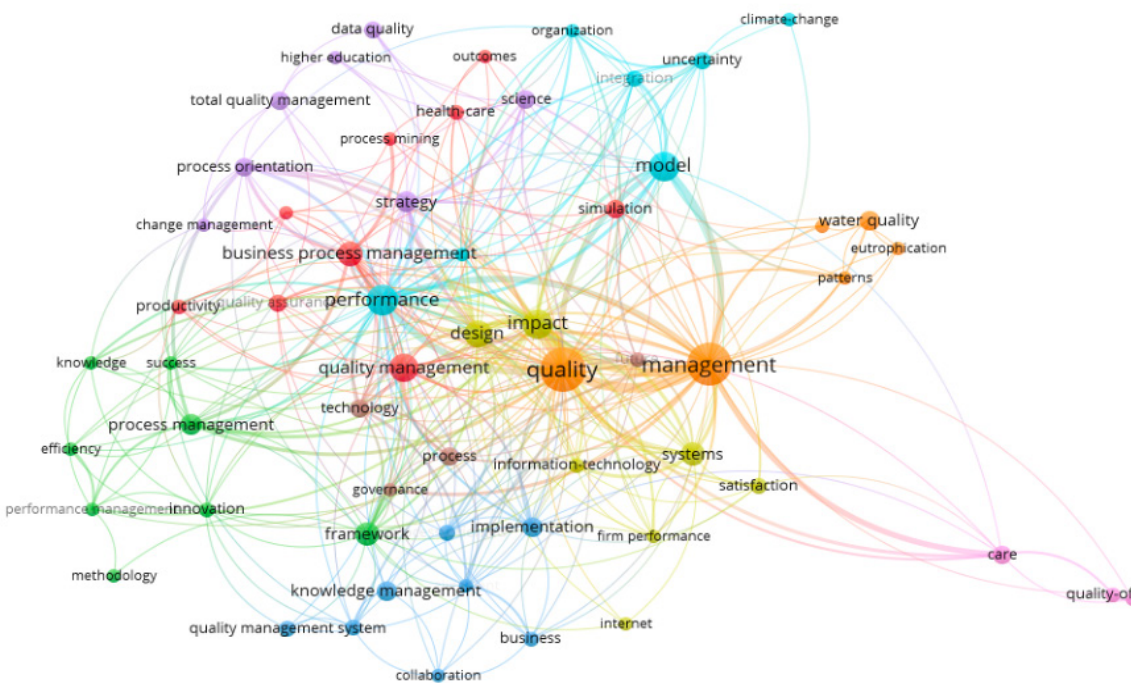


Figure 1. Bibliometric analysis of Process-Oriented Quality Management Concept extracted via VOSviewer based on co-occurrence analysis of keywords from the Web of Science Core Collection selected publications between 2020–2025

Other related topics in Figure 1 include “process mining”, “governance”, “knowledge management” and “technology.” These words show that many articles also explore digital tools, data analysis and knowledge sharing as part of improving quality systems.

The map also shows several clusters (groups of keywords) with different colors. Each cluster represents a sub-topic in the research field. For example:

- The red cluster focuses on business processes, performance and strategy.
- The blue cluster includes implementation, information systems and firm performance.
- The green cluster is related to innovation, methodology and process management.

This keyword analysis shows that research in this area covers both technical and organizational aspects. It combines topics from management science, information systems and industrial engineering. The wide variety of linked terms also suggests that the field is interdisciplinary and continues to grow.

In summary, the keyword “process-oriented quality management” is part of a broad and active research area. The analysis shows strong connections with themes like digitalization, innovation, performance and knowledge systems (see Figure 2), defining related concepts.

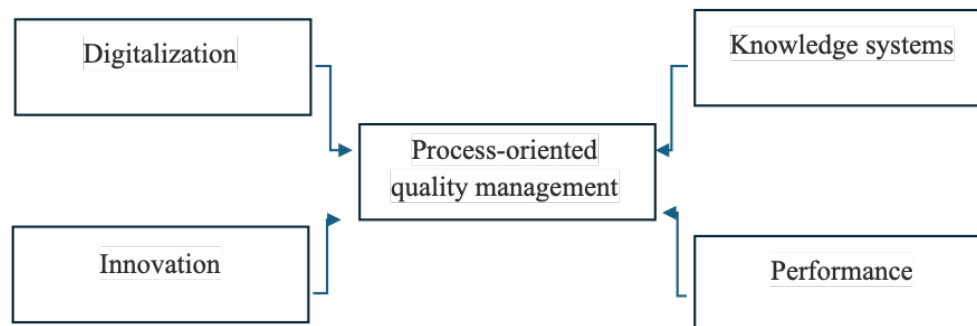


Figure 2. Conceptual Model-1

5.5.2 Bibliometric Analysis of Keywords: Process-Oriented Quality Management and Pharmaceutical Enterprises

To explore how process-oriented quality management is studied within the pharmaceutical sector, it was performed a second keyword analysis using VOSviewer. This time the map was focused on publications that include both process-oriented quality management and pharmaceutical enterprises.

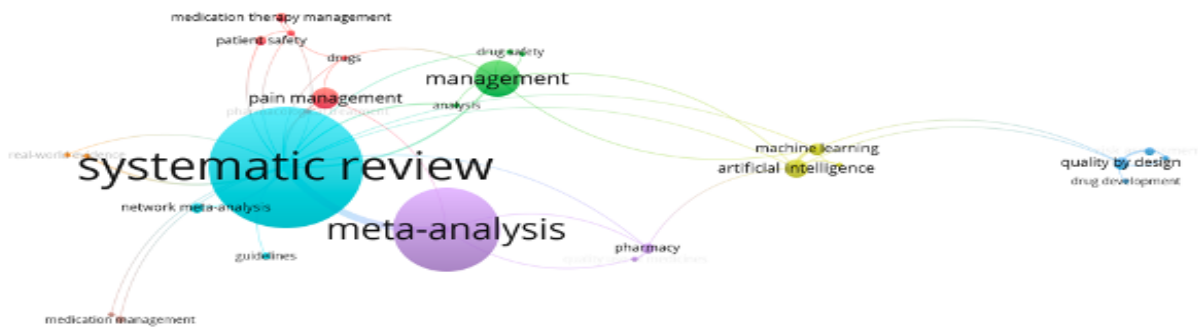


Figure 3. Bibliometric Analysis of Process-Oriented Quality Management and Pharmaceutical Enterprises Concepts extracted via VOSviewer software on co-occurrence patterns of keywords from the Web of Science Core Collection selected publications between 2020-2025

According to the obtained data in Figure 3, the most frequent and central keywords are: “systematic review”, “meta-analysis”, “management”, and “pain management”. The large size of the terms “systematic review” and “meta-analysis” suggests that many publications in this area are based on reviewing and summarizing previous studies, rather than presenting new experiments or case studies.

Several keywords, such as “patient safety”, “medication therapy management”, “drug safety” and “guidelines” show that much of the research is connected to clinical and pharmaceutical care, especially around the safe use of medications.

Emerging terms like “machine learning” and “artificial intelligence” also appear, indicating a growing interest in digital tools for improving quality and decision-making in pharmaceutical environments. However, their position on the edge of the network and smaller size suggest that these topics are still developing within this field.

Other notable keywords include “quality by design” and “drug development,” which are part of regulatory and manufacturing frameworks in the pharmaceutical industry. These terms are linked to modern approaches that support process control and product quality throughout the drug lifecycle.

It is necessary to mention that the map shows fewer keywords and smaller clusters than in the general process-oriented quality management map. This suggests that the pharmaceutical-focused literature is narrower and more concentrated, often centered around review-based research and healthcare applications rather than broad operational strategies. The related to the research finding concepts from bibliometric analysis of process-oriented quality management and pharmaceutical enterprises demonstrated in Figure 4.

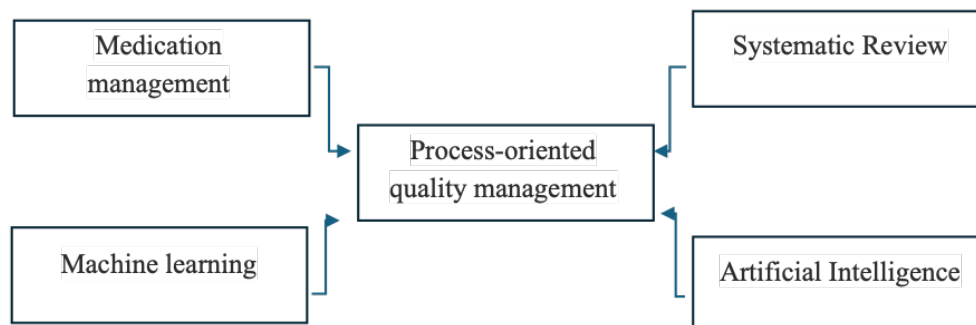


Figure 4. Conceptual Model-2

In summary, the combination of keywords shows that the field is still growing and that many studies focus on evidence-based evaluations, safety and digital tools. There is still space for more original research on how process-oriented quality management can be applied in pharmaceutical production and industry settings.

5.5.3 Bibliometric Analysis of the Citations and Publications

In the third step it was analyzed the number of publications and their citations to understand which articles and authors are the most influential in the field of process-oriented quality management in the pharmaceutical industry.

From the dataset, several publications received a high number of citations, showing that they had a substantial impact on later research. The most cited article in the collection is “Pharma 4.0: Transforming pharmaceutical manufacturing through innovation”, which received 64 citations. This shows that digital transformation and innovation are central themes in the current discussion on quality management.

Other highly cited papers include:

- “Quality by design (QbD) approach: regulatory need” – 44 citations
- “Artificial intelligence in pharmaceutical quality systems” – 36 citations
- “Implementation of total quality management in healthcare” – 31 citations
- “Knowledge management for pharmaceutical enterprises” – 29 citations

These articles focus on essential topics such as regulatory strategies, technology use and organizational frameworks, which are key to improving quality systems in pharma (see Figure 5). In terms of publication volume, most articles were written on topics such as quality performance, digital systems and business process improvement. The citation analysis also showed that collaboration between authors and institutions plays an important role. Articles with multiple authors from different countries were often more cited, which suggests that international cooperation increases research visibility and impact.

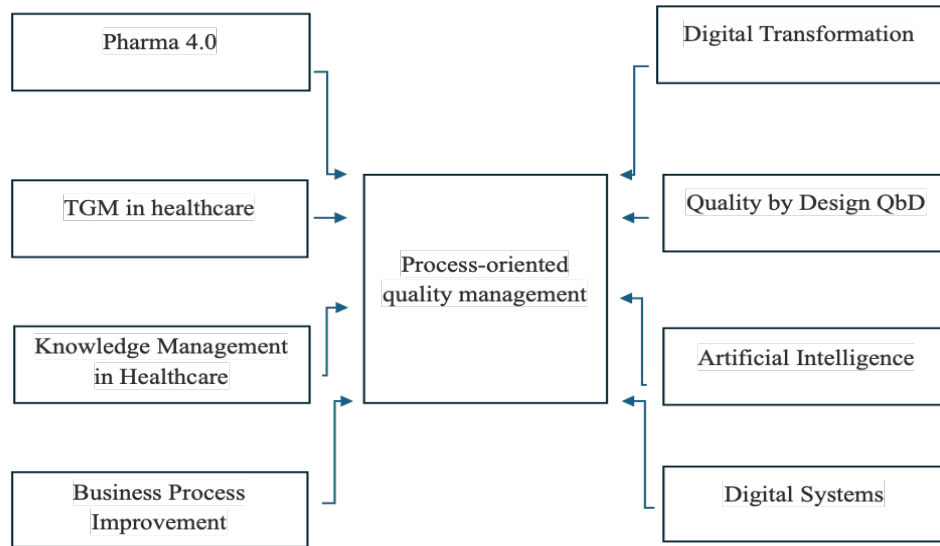


Figure 5. Conceptual Model-3

In summary, the citation and publication analysis shows that while the total number of studies is still limited, several key papers have shaped the direction of the field. The most cited works highlight the importance of technology, regulation and innovation in process-oriented quality management for pharmaceutical enterprises.

5.5.4 Initial Conclusion

Analyzed data indicate that the literature is still fragmented and there is not enough integration between theory and practice. Different research groups often work alone and there are few shared models or methods. This shows that more collaboration and real-world case studies are needed.

The study helps to understand how this field is developing and where the main gaps are. It can support researchers, professionals and decision-makers who want to improve quality systems in the pharmaceutical industry. In the future, it is essential to connect process management, technology and regulatory goals to build more effective and process-driven quality systems.

5.6 Conclusion

5.6.1 Conclusion and Recommendations

The results of this study show that research on process-oriented quality management systems in the pharmaceutical industry is growing but still developing. The bibliometric analysis made gave the idea of main trends, topics and gaps in the searching field by examining publications, keywords and citations.

First, the number of publications has increased in recent years. This suggests that more researchers are now interested in improving quality systems using a process-focused approach. However, the total number of articles is still small compared to other topics in pharmaceutical science or quality management. This shows that the topic is essential but still underexplored and more research is needed.

Second, the keyword analysis revealed that process-oriented QMS is often studied together with business process management, performance, innovation and strategy. In the pharmaceutical sector, the focus is more on systematic reviews, drug safety and patient care. This means that different areas of research approach the topic from various perspectives. While management researchers look at process design and effectiveness, pharmaceutical researchers are more concerned with regulations and clinical outcomes. This separation shows a gap between technical process development and practical application in real pharmaceutical environments.

Third, the citation analysis showed that the most cited articles are related to Pharma 4.0, Quality by Design (QbD) and digital tools like artificial intelligence. This means that technology and innovation are becoming more critical in the design of quality systems. The most influential authors and articles are often from countries that invest in pharmaceutical research and digital transformation. International cooperation also plays a significant role in the visibility and success of research in this area.

However, the study also found that many articles are not well-connected. Different authors and institutions work separately and there are few common research frameworks. This suggests a lack of integration and a need for more shared models, definitions and best practices in the field. Also, most of the work is focused on theory or review and there are fewer case studies or examples of real applications in industry.

In general, the findings show that process-oriented QMS in the pharmaceutical industry is an emerging topic that combines ideas from management, engineering and health care sciences. There is a need to bring these areas together to develop for more practical and effective quality systems that meet both business goals and patient needs in the medical aspects.

5.6.2 Gaps and Further Research Recommendations

The analysis found that most research focuses on topics such as performance improvement, digital transformation, innovation and regulatory systems. In the pharmaceutical sector, the most common themes are related to drug safety, quality by design and systematic reviews. The most cited articles are those that discuss modern tools and technologies like artificial intelligence and Pharma 4.0. For example, for Kazakhstan “Pharma 4.0” approaches totally new in the medicine and pharmaceutical field. But this digital transformation implementation tools or processes are not designed or studied much in the pharmaceutical industry, and it can serve as prospects for further research.

Also, since it was found that process-oriented QMS in the pharmaceutical industry publications are of a great interest in medical sciences then the found and designed conceptual models in this research can be used as a platform of a further research conceptual foundation constructing for the wider study or in the dissertation research through both quantitative and qualitative research design.

5.7 References

- Aleksandrov, A.V., Lyulina, N.V. & Barabanova, V.D. (2007). Construction of integrated management systems for a pharmaceutical enterprise (Part I). *Remedium Bulletin*. No. 12. P. 58-60.
- Asif, M., Awan, M., Khan, M., & Ahmad, N. (2013). A model for total quality management implementation and its impact on organizational performance. *Total Quality Management & Business Excellence*. 24(5-6).
- Averin A.Yu., (2023). The essence of the quality management system at industrial enterprises and the stages of their development. *Economy and Society Bulletin*. No. 11(113)-1 www.iupr.ru
- Baimbetova, O. (2025). Development of the pharmaceutical industry in Kazakhstan: prospects, investments and regulation. *Pharmaceutical review of Kazakhstan*. <https://pharmreviews.kz/stati/sobytiya/razvitie-farmatsevticheskoy-otrasli-v-kazakhstane-perspektivy-investitsii-i-regulirovanie>
- Bragin, V.V. & Korolkov, V.F. (2006). *Organization Management. Business Development Strategy*. P. 480. ISBN 5-98906-001-7
- Chang, H., & Lin, M. (2019). Applying artificial intelligence to pharmaceutical quality management systems. *Expert Systems with Applications*. 131.
- Grebennikova, K.K. (2009) Quality Management System: Advantages of implementation and challenges of functioning. *Bulletin of Economy and management in the 21st century: development trends. Economics and Quality Management Section*. Vladivostok State University of Economics. <https://cyberleninka.ru/article/n/sistema-menedzhmenta-kachestva-preimuschestva-vnedreniya-i-problemy-funktsionirovaniya-1/viewer>
- Howard S. Gitlow, (2001). *Quality Management Systems. A Practical Guide*. St. Luis Press. ISBN 1-574-44261-9
- ISO 9000-2015. (2025). *Quality Management Systems. Fundamentals and Vocabulary*. <https://www.iso.org/ru/quality-management>
- ISO (2025). *Quality Management Systems Standards*. <https://www.iso.org/ru/quality-management/what-is-qms>
- Kamble, S., Gunasekaran, A., & Sharma, R. (2020). Computers in Industry. Analysis of the driving forces of Industry 4.0 in manufacturing. *A global study*, 120.
- Kazakhstan Pharmaceutical. (2025). Vostok-Capital 2024 report on the pharmaceutical industry of the Republic of Kazakhstan. *Kazakhstan Pharmaceutical Bulletin*.
- Khoklov, A.L. & Pyatigorskaya, N.V. (2025). *Pharmaceutical industry 4.0. Digital transformation*. Moscow: OKI Publishing House, 312 p. ISSN 0235-2990. <https://izdat-ok.ru/farmaceuticheskaya-otrasl-4-0-cifrovaya-transformaciya>
- Marante, T. (2025) Therapeutic Areas, AI and Supply Chains. *The Future of Pharmaceuticals in 2030*. <https://pharmaoffer.com>
- Movahedi, M. Movahedi, M. & Teimourpour, N. (2013). A study on effect of performing quality management system on organizational productivity. *Management Science Letters*. No. 3(4):1063-1072. DOI: 10.5267/j.msl.2013.03.022
- Mukhanova, G. & Makhatova, A. (2014). Integrated quality management system: current issues of adaptation and implementation in the pharmaceutical industry of Kazakhstan. *KazNU Bulletin. Eco-*

- nomics series*. No. 2 (102). ISSN 1563-0358.
- Osmolovskaya, I.A. (2015). A look at the pharmaceutical quality system from the point of view of management systems. *Lexpharma Electronic Journal*. <https://lexpharma.org/qms-documents-development/vzglyad-na-farmatsevticheskuyu-sistemu-kachestva-s-tochki-zreniya-sistem-upravleniya/>
- Patel, N., & Desai, M. (2022). Quality by Design (QbD) approach: A regulatory need. *Regulatory Affairs Journal*. 14 (2).
- Pharmnews.kz. (2024). Pharmaceutical industry of Kazakhstan – current trends and future development. *Pharmnews.kz*. https://pharmnews.kz/ru/article/farmaceuticheskaya-industriya-kazahstana--tekuschie-tendencii-i-budushee-razvitiye_24066
- Sartal, A., Bellas, R., & Mejías, A. (2020). Process-oriented quality management systems in Industry 4.0 environments. *A case from the pharmaceutical sector*. 117.
- Smagulova, F. (2025). Report at the conference of the Kazakhstan International Exhibition “Equipment, Raw Materials and Technologies for the Pharmaceutical Industry”. *PharmaTech Kazakhstan*. <https://pharmreviews.kz>
- Stat.gov.kz. (2025). *Industrial production statistics*. Key performance indicators of the industry of the Republic of Kazakhstan 2024. https://stat.gov.kz/ru/industries/business-statistics/stat-industrial-production/publications/347187/?sphrase_id=920830
- Sultanov, R. (2025). Report of Association of Manufacturers of Pharmaceutical and Medical Products. *PharmMedIndustry of Kazakhstan*. <https://pharmreviews.kz>
- Tsivov, A. V. & Orlov, V. Yu. (2018). *Pharmaceutical Quality System and Good Manufacturing Practices*. Text Book. Moscow: P. G. Demidov Yaroslavl State University. Yaroslavl: Yaroslavl State University, 11 p.
- Van Eck, N. J., & Waltman, L. (2010). Software Survey: VOSviewer, a Computer Program for Bibliometric Mapping. *Scientometrics*. 84, 523-538. <https://doi.org/10.1007/s11192-009-0146-3>
- VOSviewer. (2023). *VOSviewer version 1.6.20*. <https://www.vosviewer.com/getting-started>
- World Health Organization. (2021). *World Health Organization*. Implementing quality management systems in national regulatory authorities: examples and practices. ISBN 978-92-4-003414-3; ISBN 978-92-4-003413-6. <http://www.wipo.int/amc/en/mediation/rules/>.
- World Health Organization. (2025). *WHO Good Manufacturing Practices Guidelines*. <https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/guidelines/production>
- Zhang, J. (2021). Role of machine learning in modern pharmaceutical quality systems. *Journal of Internet Technology*. 135.