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# «СОЦІАЛЬНА ФАРМАЦІЯ: СТАН, ПРОБЛЕМИ ТА ПЕРСПЕКТИВИ»

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# ANALYSIS OF APPROACHES TO QUALITY MANAGEMENT IN LEADING PHARMACEUTICAL COMPANIES

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Modern approaches to quality management in leading pharmaceutical companies are analyzed. Key aspects of the implementation of international standards, the concept of quality management, digital technologies and statistical control methods are identified. The role of automation, risk management and staff training in improving the quality management system is investigated. Recommendations are offered for optimizing control processes and improving the efficiency of production processes in the pharmaceutical industry.

***Keywords:*** quality management, pharmaceutical industry, pharmaceutical companies, international standards, digital technologies.

**Introduction.** A quality management system (QMS) is a fundamental component of the effective functioning of any enterprise, particularly in the pharmaceutical sector, where it directly impacts public health and safety. Beyond meeting contemporary market demands, rising competition, and adherence to global benchmarks is a pivotal objective for pharmaceutical firms.

Pharmaceutical companies possess considerable potential for refining manufacturing workflows and bolstering its competitive standing in both local and international markets.

The pharmaceutical sector is among the most strictly regulated industries, as its products have a direct impact on the efficacy and safety of patient treatments. Amid ongoing globalization and continuous regulatory updates, businesses must adjust their quality management frameworks to emerging challenges, including digital transformation, process automation, enhanced internal oversight, and risk mitigation.

The companies are committed to maintaining superior product quality, aligning with international regulations, and fulfilling growing consumer demands [1].

The necessity of QMS enhancement is further reinforced by the need to minimize manufacturing expenses, improve resource utilization, and streamline supply chain operations. The adoption of cutting-edge quality management strategies not only helps reduce expenditures but also guarantees consistent product excellence, which is crucial for the pharmaceutical industry [2].

The significance of this topic is also linked to the increasing influence of digital technologies in quality management procedures. Implementing advanced tools such as data management systems, analytical platforms, and automated monitoring modules unlocks new possibilities for supervising, analyzing, and optimizing production processes.

**Purpose** is to analyze approaches to quality management in leading pharmaceutical companies.

**Methods and materials.** Content analysis, system analysis were used in the work.

**Research results.** Quality management is one of the most important components of the success of the pharmaceutical industry, as it directly affects the safety, efficacy and compliance of products with international standards. Leading pharmaceutical manufacturers use different approaches to quality management, focusing on the highest standards and innovative practices that ensure the safety and efficacy of medicines [3].

Table 1.1 presents an analysis of quality management aspects in leading foreign pharmaceutical companies.

A key component of quality management for leading pharmaceutical companies is strict adherence to GMP standards, which regulate all aspects of pharmaceutical production. These standards cover requirements for production facilities, equipment, manufacturing processes, quality control, storage conditions, and transportation. All stages of production must be documented and controlled to avoid deviations from established standards. The implementation of GMP guarantees consistent product quality and minimizes risks associated with the safety and efficacy of medicines.

*Table 1.1*

**Analysis of quality management aspects in leading foreign pharmaceutical companies**

| Company | Key approaches to quality management | Tools and methods | Features |
|---|---|---|---|
| Pfizer | Systematic approach to risk management, patient focus, data-driven decision-making | ISO 9001, Six Sigma, Lean, risk analysis | Global production and supply network, wide product range |
| Novartis | Strategic quality planning, innovation, cooperation with regulatory authorities | Balanced Scorecard, Six Sigma, Lean, artificial intelligence technologies | Focus on biotechnology, personalized medicine |
| Roche | Focus on scientific research, high ethical standards, partnership with patients | ISO 9001, Good Clinical Practice (GCP), Good Manufacturing Practice (GMP) | Leader in oncology, diagnostics |
| Sanofi | Systematic approach to quality management, focus on patient safety, sustainable development | ISO 9001, Six Sigma, Lean, environmental standards | Wide range of products, global presence |

Many leading pharmaceutical companies integrate their quality management systems with international standards such as ISO 9001 (General Requirements for Quality Management Systems) and ISO 13485 (Quality Management Systems for Medical Devices). These standards allow pharmaceutical companies to create a holistic quality control system that extends not only to drug production but also to all other processes, from development to sales.

Leading companies are actively implementing the concept of total quality management (TQM), which involves integrating quality management at all levels of the organization, from management to production workers. This approach includes not only quality control processes, but also aims to continuously improve productivity, reduce costs and increase customer satisfaction. Thanks to TQM, pharmaceutical

manufacturers focus on preventing errors, rather than correcting them, which contributes to improving product quality.

To ensure consistent quality at all stages of production, pharmaceutical companies actively use statistical methods such as control charts, variance analysis, and design of experiments. This allows not only to monitor production processes in real time, but also to predict possible errors at the development stage and make decisions to improve production conditions.

Leading pharmaceutical companies are actively using modern technologies to automate quality control processes. This includes the introduction of automated product monitoring and testing systems, the use of modern data analysis tools, and the application of real-time monitoring technologies for production processes. Digitalization allows for the reduction of human errors, acceleration of verification processes, and more accurate tracking of results.

An important aspect of quality management is training and development of personnel. Leading companies invest significant resources in the development of their employees, conducting regular training, seminars and certifications to maintain high quality standards. This allows companies to ensure that all employees understand the importance of quality control and are prepared to apply best practices in their work processes.

Thus, the approaches to quality management of leading pharmaceutical companies include the integration of international standards, continuous process improvement, the use of the latest technologies and systems, and a focus on the professional development of employees. All these approaches ensure high product quality, which is important for the pharmaceutical industry, where the safety and effectiveness of drugs are in the first place.

**Conclusions.** Quality management is a crucial factor in ensuring the safety, efficacy, and compliance of pharmaceutical products with international standards. Leading pharmaceutical companies adopt comprehensive approaches that integrate strict adherence to Good Manufacturing Practice (GMP), international quality

management standards (ISO 9001, ISO 13485), and advanced technologies to enhance efficiency and minimize risks.

A key trend in modern pharmaceutical quality management is the adoption of Total Quality Management (TQM), which emphasizes continuous improvement, proactive error prevention, and a company-wide commitment to quality. The use of statistical process control, risk management methodologies, and automation technologies further enhances consistency in production and reduces human errors.

Furthermore, digital transformation plays an increasing role in quality assurance, enabling real-time monitoring, predictive analytics, and data-driven decision-making. Companies also prioritize employee training and development, ensuring that personnel at all levels understand and implement best practices in quality management.

Ultimately, the integration of international standards, innovative technologies, and continuous process improvement strategies allows pharmaceutical companies to maintain high-quality products, meet regulatory requirements, and enhance their competitive position in both local and global markets. These approaches are essential for addressing emerging challenges in the industry while safeguarding patient health and safety.

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Проаналізовано сучасні підходи до управління якістю у провідних фармацевтичних компаніях. Визначено ключові аспекти впровадження міжнародних стандартів, концепції управління якістю, цифрових технологій та методів статистичного контролю. Досліджено роль автоматизації, ризик-менеджменту та підвищення кваліфікації персоналу у вдосконаленні системи управління якістю. Запропоновано рекомендації щодо оптимізації процесів контролю та покращення ефективності виробничих процесів у фармацевтичній галузі.

***Ключові слова:*** управління якістю, фармацевтична промисловість, фармацевтичні компанії, міжнародні стандарти, цифрові технології.