

INTERNATIONAL EXPERIENCE IN QUALITY MANAGEMENT IN THE PHARMACEUTICAL INDUSTRY: OPPORTUNITIES FOR ADAPTATION BY UKRAINIAN ENTERPRISES

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INTRODUCTION

The pharmaceutical industry is one of the most socially significant and highly regulated sectors of the economy, where quality management is directly connected with patient safety, therapeutic effectiveness, public health protection and trust in healthcare systems. Unlike many other industries, pharmaceutical production cannot rely only on final product testing, since any deviation in raw materials, manufacturing processes, storage conditions, documentation or distribution may create serious risks for patients and for the reputation of the enterprise. Therefore, quality in the pharmaceutical industry must be formed systematically at all stages of the product life cycle – from research and development to production, quality control, distribution, pharmacovigilance and post-marketing monitoring.

International experience shows that effective quality management in the pharmaceutical sector is based on the integration of regulatory requirements, managerial responsibility, risk-based approaches, process standardization, personnel competence and continuous improvement. Good Manufacturing Practice, the Pharmaceutical Quality System, Quality Risk Management, Total Quality Management, Kaizen principles and modern digital tools have become essential components of quality assurance in leading pharmaceutical markets. These approaches allow enterprises not only to comply with regulatory standards, but also to increase operational efficiency, reduce production risks, strengthen quality culture and ensure sustainable competitiveness in both domestic and international markets.

For Ukrainian pharmaceutical enterprises, the study and adaptation of international quality management practices is particularly important in the context of European integration, harmonization with EU regulatory requirements, increasing competition and the need to expand export opportunities. The pharmaceutical sector of Ukraine has significant potential for development;

however, its further growth requires systematic modernization of quality management systems, improvement of production processes, development of personnel competencies and implementation of internationally recognized standards. In this regard, foreign experience should not be mechanically copied, but critically analyzed and adapted to national regulatory, economic, technological and organizational conditions.

The adaptation of international quality management practices can become an important strategic tool for strengthening the competitiveness of Ukrainian pharmaceutical enterprises. It creates opportunities for improving compliance with international standards, increasing the reliability of production processes, enhancing the effectiveness of internal audits, developing a risk-oriented quality culture and supporting sustainable development of the pharmaceutical industry. Thus, the analysis of international experience in quality management is essential for identifying practical directions of modernization and for forming a conceptual basis for the further integration of Ukrainian pharmaceutical enterprises into the global pharmaceutical market.

1. Conceptual Foundations of Quality Management in the Pharmaceutical Industry

Quality management in the pharmaceutical industry should be considered not merely as a technical function of product inspection, but as an integrated managerial system aimed at ensuring the safety, efficacy, stability, reproducibility and regulatory compliance of pharmaceutical products throughout their entire life cycle. In pharmaceutical production, quality cannot be “added” to the final product at the stage of laboratory control; it must be designed, ensured, monitored and continuously improved at every stage – from pharmaceutical development, procurement of raw materials and manufacturing to storage, distribution, pharmacovigilance and post-marketing quality monitoring. This understanding corresponds to the logic of the GxP system, which covers good laboratory, clinical, manufacturing, pharmacy, distribution and storage practices and reflects the life-cycle nature of pharmaceutical quality management¹.

The conceptual basis of pharmaceutical quality management is formed by the interaction of several interrelated approaches: Good Manufacturing Practice (GMP), the Pharmaceutical Quality System (PQS), Quality Risk Management (QRM), Total Quality Management (TQM), Kaizen philosophy, process-based management, documentation discipline, personnel involvement and continuous improvement. The article by V. V. Liashenko-Shcherbakova, which forms

¹ Liashenko-Shcherbakova V. V. Analysis of the Application of Foreign Quality Management Experience in Pharmaceutical Enterprises of Ukraine. *Odeskyi Medychnyi Zhurnal*, 2024. 5(190), 95–101. DOI: 10.32782/2226-2008-2024-5-16.

the methodological basis for this subsection, emphasizes that international experience – particularly the practices of the USA, the European Union and Japan – demonstrates the decisive role of GMP, EMA guidelines, Kaizen and TQM in improving the quality, competitiveness and export potential of pharmaceutical enterprises².

A central element of quality management in the pharmaceutical industry is GMP. According to the World Health Organization, GMP defines quality measures for production and quality control and requires that production and testing processes be clearly defined, validated, reviewed and documented; it also requires suitable personnel, premises and materials for the production of pharmaceuticals and biological products, including vaccines³. In practical terms, GMP establishes requirements for the cleanliness and sterility of production areas, qualification of equipment, validation of processes, documentation of operations, control of raw materials, laboratory testing, deviation management, corrective and preventive actions, internal audits and personnel training. Thus, GMP provides the regulatory and operational foundation for ensuring that each batch of medicinal products meets predetermined quality standards.

However, contemporary pharmaceutical quality management goes beyond compliance with GMP as a minimum regulatory requirement. The modern concept of a Pharmaceutical Quality System, reflected in ICH Q10, interprets quality management as a comprehensive model that covers development and manufacture of pharmaceutical substances and drug products throughout the product life cycle⁴. In this sense, PQS integrates quality planning, process performance monitoring, product quality review, change management, knowledge management and continual improvement. The key managerial implication is that pharmaceutical enterprises must move from a reactive model of quality control to a proactive model of quality assurance and quality improvement, in which potential risks are identified before they affect the patient or the market.

Quality Risk Management is another conceptual pillar of pharmaceutical quality management. ICH Q9 describes quality risk management as a systematic approach that can be applied to pharmaceutical development, manufacturing, distribution, inspection and regulatory review processes⁵. From a managerial perspective, QRM allows pharmaceutical enterprises to prioritize risks according

² Liashenko-Shcherbakova V. V. Analysis of the Application of Foreign Quality Management Experience in Pharmaceutical Enterprises of Ukraine. *Odeskyi Medychnyi Zhurnal*, 2024. 5(190), 95–101. DOI: 10.32782/2226-2008-2024-5-16.

³ World Health Organization. Good Manufacturing Practice (GMP) Standards.

⁴ European Medicines Agency. ICH Q10 Pharmaceutical Quality System: Scientific Guideline.

⁵ European Medicines Agency. ICH Q9 Quality Risk Management: Scientific Guideline.

to their probability, severity and detectability, and to allocate resources to those processes that have the greatest potential impact on product quality and patient safety. In practice, this means using tools such as Failure Mode and Effects Analysis, risk ranking, root-cause analysis, hazard analysis, deviation trending and CAPA systems. The implementation of QRM is especially important for Ukrainian pharmaceutical enterprises seeking closer integration with EU regulatory expectations, because risk-based thinking has become a core element of European GMP and EMA quality guidance^{6, 7}.

The European model of pharmaceutical quality management is characterized by a harmonized regulatory framework, strong documentation requirements, responsibility of the manufacturer and contractors, integration of QRM, and increasing attention to environmental and occupational safety dimensions. The European Commission's EudraLex Volume 4 contains EU guidelines for Good Manufacturing Practice for medicinal products, while EMA quality guidelines support applicants in preparing marketing authorization applications and interpreting requirements for quality, safety and efficacy^{8, 9}. This model is important for Ukrainian pharmaceutical enterprises because EU market access requires not only formal compliance with GMP, but also a mature quality culture, reliable documentation, validated processes, supplier qualification, pharmacovigilance mechanisms and continuous readiness for inspection.

The Japanese approach, as analyzed in the article, highlights the role of Kaizen and Total Quality Management. Kaizen is based on the philosophy of continuous incremental improvement, employee involvement and systematic elimination of waste in production and management processes. TQM, in turn, views quality as the responsibility of the whole organization rather than a separate quality control department¹⁰. In pharmaceutical enterprises, these approaches are particularly valuable because they help build a stable quality culture, reduce process variability, strengthen internal communication, improve workplace discipline and create mechanisms through which employees contribute to quality improvement. Unlike narrow inspection-based control, TQM and Kaizen transform quality into an organizational value and a daily managerial practice.

⁶ European Medicines Agency. ICH Q9 Quality Risk Management: Scientific Guideline.

⁷ European Commission. EudraLex. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products.

⁸ European Commission. EudraLex. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products.

⁹ European Medicines Agency. Quality Guidelines.

¹⁰ Liashenko-Shcherbakova V. V. Analysis of the Application of Foreign Quality Management Experience in Pharmaceutical Enterprises of Ukraine. *Odeskyi Medychnyi Zhurnal*, 2024. 5(190), 95–101. DOI: 10.32782/2226-2008-2024-5-16.

The conceptual foundations of quality management in the pharmaceutical industry may therefore be summarized through several key principles. First, quality must be patient-oriented: the ultimate purpose of pharmaceutical quality is the protection of the patient through safe, effective and stable medicines. Second, quality must be process-based: every stage of development, production, storage and distribution should be described, standardized, validated and monitored. Third, quality must be risk-based: managerial decisions should be grounded in systematic assessment of potential risks to product quality and patient safety. Fourth, quality must be evidence-based: documentation, laboratory data, monitoring results, deviations, complaints and audit findings must become the basis for managerial decisions. Fifth, quality must be continuous: the system should not only maintain compliance but also stimulate improvement, modernization and learning. These principles are consistent with international quality management logic, including ISO quality management principles, which emphasize customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision-making and relationship management¹¹.

For Ukrainian pharmaceutical enterprises, the adaptation of international quality management experience should not be reduced to mechanical copying of foreign practices. The implementation of international standards requires modernization of production facilities, personnel training, improvement of internal procedures and adaptation to national regulatory and economic conditions. Therefore, the conceptual model of quality management for Ukrainian pharmaceutical enterprises should combine regulatory harmonization with strategic management. It should include GMP compliance, QRM implementation, digitalization of quality documentation, internal and external audits, personnel competence development, supplier quality management, environmental responsibility and continuous improvement culture.

A strategically important aspect is the integration of digital tools into quality management systems. Automated information systems, electronic documentation, digital batch records, monitoring sensors, data analytics and traceability tools strengthen the ability of pharmaceutical enterprises to detect deviations, prevent quality failures and ensure transparency of processes. In this context, digitalization should not be perceived only as an IT modernization issue; it is a managerial instrument for strengthening quality assurance, regulatory readiness and operational resilience. This direction is especially relevant for enterprises operating in highly regulated international markets, where data integrity, traceability and reliable evidence of compliance are essential.

¹¹ International Organization for Standardization. Quality Management Principles.

Thus, quality management in the pharmaceutical industry is a multidimensional managerial concept that combines regulatory compliance, technological control, risk management, organizational culture and strategic development. Its effectiveness depends not only on the existence of formal procedures, but also on leadership commitment, personnel competence, process discipline, documentation reliability, openness to audits and readiness for continuous improvement. The international experience of the USA, the EU and Japan demonstrate that the most sustainable pharmaceutical quality systems are those that integrate GMP requirements with QRM, TQM, Kaizen and life-cycle management. For Ukrainian pharmaceutical enterprises, such integration creates the basis for improving product quality, strengthening competitiveness, expanding export potential and increasing trust in national pharmaceutical production ^{12, 13, 14}.

2. International Regulatory Framework for Pharmaceutical Quality Assurance

The international regulatory framework for pharmaceutical quality assurance is based on the principle that the quality, safety and efficacy of medicinal products must be ensured through scientifically grounded, risk-oriented and continuously controlled systems. In modern pharmaceutical regulation, quality assurance is not interpreted as a separate laboratory or inspection function, but as a system of interrelated regulatory, technological and managerial requirements that cover pharmaceutical development, manufacturing, control, storage, distribution and post-marketing monitoring. This approach is reflected in the harmonized standards of the International Council for Harmonisation, the World Health Organization, the European Union and the U.S. Food and Drug Administration.

A key role in this framework belongs to Good Manufacturing Practice. GMP establishes mandatory requirements for premises, equipment, personnel, documentation, production operations, quality control, validation, deviation management, complaint handling and corrective and preventive actions. Its main purpose is to reduce risks that cannot be fully eliminated by final product testing, including contamination, cross-contamination, mix-ups,

¹² Liashenko-Shcherbakova V. V. Analysis of the Application of Foreign Quality Management Experience in Pharmaceutical Enterprises of Ukraine. *Odeskyi Medychnyi Zhurnal*, 2024. 5(190), 95–101. DOI: 10.32782/2226-2008-2024-5-16.

¹³ European Medicines Agency. ICH Q10 Pharmaceutical Quality System: Scientific Guideline.

¹⁴ European Commission. EudraLex. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products.

process variability and documentation errors^{15, 16}. The WHO GMP framework is especially important for countries seeking to strengthen national regulatory systems and improve access to international pharmaceutical markets, as it is used as a basis for inspection of manufacturing facilities and for confirming GMP status within international pharmaceutical trade¹⁷. In the European Union, GMP requirements are consolidated in EudraLex Volume 4, which provides the official EU guidelines for Good Manufacturing Practice for medicinal products¹⁸.

The ICH quality guidelines have significantly changed the philosophy of pharmaceutical quality assurance by shifting the focus from retrospective control to prospective product and process understanding. ICH Q8(R2) introduces the concept of pharmaceutical development as a scientific process aimed at designing a quality product and a manufacturing process capable of consistently delivering the intended product performance. This guideline creates the methodological basis for Quality by Design, according to which product quality should be built into the product and process from the development stage rather than tested only at the final stage. In practical terms, ICH Q8 encourages the definition of the Quality Target Product Profile, identification of Critical Quality Attributes, understanding of Critical Process Parameters, establishment of design space and development of a control strategy¹⁹.

ICH Q9(R1) complements this approach by introducing Quality Risk Management as a systematic process for the assessment, control, communication and review of risks to pharmaceutical quality²⁰. Its importance lies in the fact that pharmaceutical enterprises operate in conditions where not all risks have the same impact on product quality and patient safety. Therefore, managerial decisions should be based on the level of risk, scientific knowledge and process understanding. ICH Q9(R1) also emphasizes the need to reduce subjectivity in risk assessment and to ensure that the level of formality in risk management corresponds to the complexity and importance of the issue being addressed.

¹⁵ World Health Organization. WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles. WHO Technical Report Series No. 986, Annex 2, 2014.

¹⁶ European Commission. EudraLex. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products.

¹⁷ World Health Organization. WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles. WHO Technical Report Series No. 986, Annex 2, 2014.

¹⁸ European Commission. EudraLex – Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products.

¹⁹ Yu L. X., Amidon G., Khan M. A., Hoag S. W., Polli J., Raju G. K., & Woodcock J. Understanding Pharmaceutical Quality by Design. *AAPS Journal*, 2014, 16, 771–783.

²⁰ International Council for Harmonisation. ICH Q9(R1): Quality Risk Management. ICH Harmonised Guideline, 2022.

For pharmaceutical enterprises, this means that risk-based thinking should be integrated into deviation investigation, validation, supplier qualification, change control, audit planning and CAPA systems.

ICH Q10 develops these principles into a comprehensive model of the Pharmaceutical Quality System. The guideline applies to pharmaceutical drug substances and drug products, including biotechnology and biological products, throughout the product life cycle²¹. Its conceptual value lies in linking pharmaceutical development, technology transfer, commercial manufacturing and product discontinuation within a single quality system. ICH Q10 identifies management responsibility, process performance and product quality monitoring, corrective and preventive action, change management and management review as essential components of an effective Pharmaceutical Quality System. Therefore, ICH Q10 transforms quality assurance into a strategic management function that requires leadership commitment, organizational learning and continuous improvement.

The U.S. FDA Quality Systems Approach to Pharmaceutical CGMP Regulations is another influential regulatory model. It explains how modern quality systems and risk management approaches can be used to meet current good manufacturing practice requirements under U.S. regulation²². The FDA approach is important because it interprets CGMP not as a static set of technical rules, but as a flexible quality system based on management responsibility, resources, manufacturing operations, evaluation activities and continuous improvement. This model strengthens the role of senior management in quality assurance and underlines the need for an organizational environment in which quality decisions are supported by data, scientific evidence and systematic review.

The EU GMP Guidelines, presented in EudraLex Volume 4, are particularly relevant for Ukrainian pharmaceutical enterprises because of Ukraine's strategic orientation toward regulatory approximation with the European Union. EU GMP places strong emphasis on the Pharmaceutical Quality System, personnel competence, documentation reliability, outsourced activities, production and quality control operations, qualification and validation, and self-inspection²³. The EU model also gives special attention to the responsibilities of the Qualified Person, batch certification, supplier qualification and regulatory

²¹ International Council for Harmonisation. ICH Q10: Pharmaceutical Quality System. ICH Harmonised Guideline, 2008.

²² U.S. Food and Drug Administration. Guidance for Industry: Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations. FDA, 2006.

²³ European Commission. EudraLex. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products.

traceability. For Ukrainian enterprises, adaptation to EU GMP requires not only technical modernization of production facilities, but also improvement of internal governance, documentation culture, data integrity, audit readiness and risk-based decision-making.

WHO GMP performs a complementary function in the global regulatory architecture. While EU and FDA requirements are often associated with highly developed regulatory markets, WHO GMP provides a globally recognized basis for strengthening manufacturing quality, especially in countries with developing or transitional regulatory systems. WHO GMP is used as a standard for assessing manufacturing authorization applications, inspecting facilities and training inspectors, production personnel, quality control specialists and quality assurance staff²⁴. For Ukrainian pharmaceutical enterprises, WHO GMP can serve as a practical reference point for harmonizing national practices with international expectations and for preparing enterprises for more complex EU or FDA regulatory requirements.

Taken together, GMP, ICH Q8, ICH Q9, ICH Q10, FDA quality systems guidance, EU GMP and WHO GMP form a coherent international framework for pharmaceutical quality assurance. Their common logic is based on several principles: scientific justification of product and process design; prevention of quality defects rather than reliance on final inspection; systematic risk management; process validation and continuous monitoring; reliable documentation and data integrity; management responsibility; and continuous improvement. These principles are mutually reinforcing: ICH Q8 provides the scientific basis for product and process understanding; ICH Q9 provides the methodology for risk-based decision-making; ICH Q10 integrates these elements into a life-cycle Pharmaceutical Quality System; GMP establishes operational and regulatory discipline; and FDA, EU and WHO approaches provide institutional models for implementation.

For Ukrainian pharmaceutical enterprises, the adaptation of this international framework should be understood as a gradual institutional and managerial transformation. First, enterprises need to assess the maturity of their existing quality systems in relation to EU GMP, WHO GMP and ICH expectations. Second, they should strengthen Quality by Design practices in pharmaceutical development, especially for new products and technology transfer. Third, Quality Risk Management should be embedded into everyday managerial processes rather than used only formally during inspections. Fourth, Pharmaceutical Quality Systems should be supported by digital documentation,

²⁴ World Health Organization. WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles. WHO Technical Report Series No. 986, Annex 2, 2014.

deviation trending, change control, management review and CAPA effectiveness assessment. Finally, personnel training should focus not only on regulatory compliance, but also on quality culture, risk awareness, data integrity and process ownership.

Thus, the international regulatory framework for pharmaceutical quality assurance provides Ukrainian pharmaceutical enterprises with a structured pathway for modernization. Its adaptation creates opportunities to improve compliance with international standards, increase reliability of production processes, reduce regulatory risks, strengthen export potential and enhance trust in Ukrainian pharmaceutical products. However, successful adaptation requires a systemic approach: regulatory requirements must be translated into managerial routines, technological practices, personnel competencies and a sustainable quality culture.

3. Foreign Models and Practices of Pharmaceutical Quality Management

Foreign models of pharmaceutical quality management demonstrate that modern quality assurance is increasingly based not only on regulatory compliance, but also on the maturity of internal management systems, evidence-based decision-making, digital traceability, preventive risk control and continuous improvement. The experience of the European Union, the United States, Japan and international inspection networks shows that pharmaceutical quality is achieved through the integration of a Pharmaceutical Quality System, validation, quality risk management, audit mechanisms, product quality review, CAPA systems, supplier oversight and strong quality culture. In this context, quality management becomes a strategic function of the pharmaceutical enterprise, directly connected with patient safety, market access, regulatory trust and sustainable competitiveness.

The European model of pharmaceutical quality management is one of the most structured and institutionally developed. It is based on EU GMP requirements, consolidated in EudraLex Volume 4, which covers basic requirements for medicinal products, active substances, documentation, production, quality control, outsourced activities, complaints, recalls, self-inspection and qualification/validation²⁵. The EU approach is characterized by the strong role of the Pharmaceutical Quality System, the responsibility of senior management, the Qualified Person, product quality review and regular self-inspection. In EU GMP logic, quality management, GMP and quality risk

²⁵ European Commission. EudraLex. Volume 4: EU Guidelines for Good Manufacturing Practice for Medicinal Products.

management are interrelated concepts, while the Pharmaceutical Quality System must be fully documented, adequately resourced and continuously monitored²⁶. This model is important for Ukrainian pharmaceutical enterprises because it demonstrates that compliance with EU expectations requires not only modern equipment, but also a mature management architecture: clear distribution of responsibilities, controlled documentation, validated processes, periodic quality reviews and evidence of continuous improvement.

A specific feature of the European approach is the combination of product quality assurance with supply-chain security. The EU Falsified Medicines framework introduced obligatory safety features on the outer packaging of medicines, including a unique identifier and an anti-tampering device, as well as strengthened record-keeping requirements for wholesale distributors²⁷. For pharmaceutical enterprises, this means that quality management extends beyond the production site and includes serialization, verification, distribution control and protection against falsified medicines. The European model therefore treats traceability as part of patient safety and regulatory reliability, not only as a logistics function. For Ukrainian enterprises, adaptation of this practice would require investment in serialization systems, master data accuracy, digital verification procedures, cooperation with distributors and integration of quality assurance with supply-chain management.

The United States model is distinguished by a systems-based interpretation of current Good Manufacturing Practice. The FDA Quality Systems Approach to Pharmaceutical CGMP Regulations explains how modern quality systems and risk management can be used to meet CGMP requirements under 21 CFR parts 210 and 211²⁸. This approach is less focused on formal procedural compliance alone and more oriented toward the effectiveness of the quality system as a managerial mechanism. The FDA model emphasizes management responsibility, resources, manufacturing operations, evaluation activities, corrective and preventive actions, and continuous improvement. In practical terms, this means that pharmaceutical enterprises are expected to demonstrate not only that procedures exist, but also that they work, are reviewed, generate reliable data and lead to preventive managerial decisions.

An important practical component of the U.S. model is the lifecycle approach to process validation. FDA guidance defines process validation as a scientifically grounded activity that covers the entire manufacturing process

²⁶ European Commission. EU GMP Guide, Chapter 1: Pharmaceutical Quality System.

²⁷ European Commission. Falsified Medicines.

²⁸ U.S. Food and Drug Administration. Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations.

lifecycle and aligns validation with pharmaceutical development, quality risk management and the Pharmaceutical Quality System²⁹. This approach differs from the traditional understanding of validation as a one-time confirmation exercise. Instead, it includes process design, process qualification and continued process verification. For enterprises, this creates a practical requirement to monitor process variability during routine production, analyse deviations, identify trends, and maintain the process in a state of control. For Ukrainian pharmaceutical manufacturers, this practice is especially relevant for technology transfer, scale-up, modernization of production lines and preparation for inspections by highly regulated markets.

The U.S. model also gives particular attention to pharmaceutical supply-chain traceability. The Drug Supply Chain Security Act outlines the creation of an interoperable electronic system to identify and trace certain prescription drugs at the package level as they move through the supply chain. This system is aimed at preventing harmful or illegitimate products from entering the U.S. supply chain, detecting them if they appear and enabling rapid response. In comparison with the European model, which emphasizes verification and decommissioning of safety features at the dispensing stage, the U.S. approach places strong emphasis on interoperable electronic exchange of product tracing information among supply-chain participants. For Ukrainian pharmaceutical enterprises, the practical lesson is that export-oriented quality management should include not only GMP compliance, but also digital product identification, secure data exchange and rapid recall capability.

The Japanese model combines strict GMP discipline with a strong culture of operational improvement. Japan's GMP system is based on the Ministerial Ordinance on Standards for Manufacturing Control and Quality Control for Drugs and Quasi-drugs and is harmonized with ICH quality guidelines³⁰. A distinctive feature of the Japanese approach is the clear separation and interaction of manufacturing control and quality control as two mutually reinforcing pillars. The Japanese system emphasizes written procedures, manufacturing and testing records, scientific verification of methods, prevention of human error, contamination control and quality degradation prevention. This model is closely connected with broader Japanese management traditions, including Kaizen, standardization, employee involvement and incremental improvement. Therefore, pharmaceutical quality in Japan is not limited to inspection readiness; it is embedded in everyday production discipline and organizational behaviour.

²⁹ U.S. Food and Drug Administration. Process Validation: General Principles and Practices.

³⁰ Ministry of Health, Labour and Welfare of Japan. GMP System of Japan.

Japan's PMDA inspection system also demonstrates the importance of regulatory oversight for both domestic and foreign manufacturers. PMDA explains that GMP compliance inspection of foreign manufacturers assesses whether manufacturing control and quality control methods at relevant manufacturing sites comply with Japanese GMP, and that GMP compliance is a requirement for marketing approval in Japan³¹. This is especially important for enterprises that intend to enter foreign markets, because the quality system must be demonstrable not only in internal documents, but also during external regulatory assessment. The Japanese experience shows that quality assurance depends on the consistency between written procedures, production practice, testing records, deviation handling, validation evidence and management responsibility.

International inspection cooperation provides another important model for pharmaceutical quality management. The Pharmaceutical Inspection Co-operation Scheme, through its PIC/S GMP Guide, promotes harmonization of GMP inspection standards and quality expectations. PIC/S emphasizes that a Pharmaceutical Quality System must incorporate GMP and quality risk management, be documented, adequately resourced and regularly assessed through management review, self-inspection and quality audit³². The PIC/S model is particularly valuable because it supports convergence of inspection practices across countries. For Ukrainian pharmaceutical enterprises, alignment with PIC/S logic would strengthen inspection readiness, facilitate cooperation with foreign regulators and improve trust among international partners.

Corrective and Preventive Action systems are a common practical mechanism across EU, U.S., Japanese and PIC/S approaches. CAPA links deviation investigation, root-cause analysis, risk assessment and preventive management decisions. Modern pharmaceutical quality systems increasingly treat CAPA not as a formal response to nonconformities, but as a key instrument of organizational learning. Recent research emphasizes that CAPA contributes to pharmaceutical product quality by detecting, addressing and preventing quality failures in a structured way³³. In practice, effective CAPA requires clear classification of deviations, scientifically justified root-cause analysis, risk-based prioritization, implementation deadlines, verification of effectiveness and management review. For Ukrainian enterprises, the development of CAPA

³¹ Pharmaceuticals and Medical Devices Agency. GMP Compliance Inspection concerning Drugs and Quasi-drugs of Foreign Manufacturers.

³² Pharmaceutical Inspection Co-operation Scheme. PIC/S Guide to Good Manufacturing Practice for Medicinal Products, PE 009-17.

³³ Arunagiri T., et al. Enhancing Pharmaceutical Product Quality With a Corrective and Preventive Action System. 2024.

maturity can become one of the most practical steps toward stronger quality culture and reduced inspection risk.

Foreign practices also show that audit and self-inspection are not merely control procedures, but instruments for continual improvement. PIC/S GMP requirements emphasize self-inspection and quality audit as mechanisms for regularly appraising the effectiveness and applicability of the Pharmaceutical Quality System [9]. In mature pharmaceutical systems, audits are used not only to detect non-compliance, but also to identify weak signals, systemic risks, training needs, documentation gaps and opportunities for process improvement. A modern audit function should therefore be independent, risk-based, evidence-oriented and linked with CAPA, change control and management review.

A growing trend in foreign pharmaceutical quality management is the transition from document-heavy compliance to knowledge-based and data-driven quality systems. Studies of ICH Q10 implementation indicate that the guideline was introduced to address the gap between traditional GMP and broader pharmaceutical manufacturing quality systems³⁴. This means that leading enterprises increasingly use process data, statistical analysis, product quality reviews, digital batch records, deviation trending and quality metrics to support managerial decisions. In parallel, Quality by Design strengthens the role of scientific understanding in pharmaceutical development and manufacturing by connecting product attributes, process parameters, risk assessment and control strategy³⁵. For Ukrainian pharmaceutical enterprises, this trend creates a clear modernization direction: quality systems should become more analytical, digital and preventive.

The adaptation of foreign models by Ukrainian pharmaceutical enterprises should be selective and strategic. The EU model is most relevant for regulatory harmonization, Qualified Person responsibilities, documentation, validation, self-inspection and product quality review. The U.S. model is valuable for lifecycle process validation, quality metrics, risk-based inspection readiness and electronic traceability. The Japanese model offers practical lessons in standardization, operational discipline, employee involvement and continuous incremental improvement. PIC/S provides an international framework for inspection convergence and quality system maturity. Together, these models show that successful adaptation requires not mechanical copying of foreign standards, but the development of an integrated national and enterprise-level quality management model.

³⁴ VanDuyse S. A., et al. ICH Q10 Pharmaceutical Quality System Guidance: Understanding Its Impact on Pharmaceutical Quality. 2021.

³⁵ Yu L. X., et al. Understanding Pharmaceutical Quality by Design. AAPS Journal, 2014.

For Ukrainian pharmaceutical enterprises, priority areas of adaptation should include: implementation of a mature Pharmaceutical Quality System; strengthening of risk-based validation and continued process verification; development of serialization and traceability systems; digitalization of quality documentation; improvement of supplier qualification and outsourced activity control; introduction of systematic internal audits; enhancement of CAPA effectiveness; and formation of a quality culture based on leadership, personnel competence and continuous improvement. Such adaptation can improve compliance with international requirements, reduce quality risks, increase export readiness and strengthen confidence in Ukrainian pharmaceutical products in global markets.

Below is a comparative table of the foreign models and practices of pharmaceutical quality management is presented.

The most relevant elements for adaptation in Ukraine are: development of a mature Pharmaceutical Quality System, implementation of risk-based validation, strengthening of CAPA effectiveness, creation of digital traceability systems, improvement of supplier qualification, regular internal audits, transition to data-driven quality management, and formation of a sustainable quality culture. These areas are especially important for enterprises seeking EU market access, international partnerships, export expansion and stronger regulatory credibility.

A practical adaptation strategy should combine the EU model as the main regulatory orientation, the FDA model as a benchmark for lifecycle validation and quality metrics, the Japanese model as a source of operational discipline and continuous improvement, and the PIC/S/WHO approaches as instruments for inspection harmonization and gradual quality system maturity.

Table 1
Comparative Analysis of Foreign Models of Pharmaceutical Quality Management and Practical Adaptation for Ukrainian Enterprises

Foreign model / practice	Key quality management focus	Practical instruments used in the model	Best practical aspects for implementation in Ukrainian pharmaceutical enterprises	Expected managerial effect
European Union model: EU GMP and Pharmaceutical Quality System	Systemic integration of GMP, Pharmaceutical Quality System, Quality Risk Management, documentation, personnel responsibility, production control and self-inspection. EU GMP is structured in EudraLex Volume 4, including chapters on Pharmaceutical Quality System, personnel, premises and equipment, documentation, production and quality control.	Pharmaceutical Quality System; Product Quality Review; Qualified Person responsibility; validation and qualification; deviation management; documentation control; internal audits; outsourced activity control.	Ukrainian enterprises should prioritize harmonization with EU GMP requirements, especially in documentation discipline, validation, quality risk management, self-inspection, supplier qualification and management review. Particular attention should be paid to the development of a real, functioning Pharmaceutical Quality System rather than formal compliance procedures.	Strengthening of EU market readiness, higher inspection preparedness, improved regulatory trust and better integration into European pharmaceutical supply chains.
EU traceability and anti-falsification model	Protection of the legal supply chain from falsified medicines through product identification, verification and anti-tampering mechanisms. The EU Falsified Medicines framework requires safety features, including a unique identifier and anti-tampering device on medicine packaging.	Serialization; unique product identifiers; anti-tampering devices; verification of medicines; distributor record-keeping; recall traceability.	Ukrainian enterprises should gradually introduce serialization and digital verification tools, improve master data management and integrate quality assurance with logistics and distribution control. This is especially important for export-oriented manufacturers.	Better protection against falsified medicines, improved product traceability, faster recall procedures and stronger patient safety assurance.

Continuation of table 1

Foreign model / practice	Key quality management focus	Practical instruments used in the model	Best practical aspects for implementation in Ukrainian pharmaceutical enterprises	Expected managerial effect
United States model: FDA Quality Systems Approach to CGMP	Integration of modern quality systems and risk management into current Good Manufacturing Practice. FDA guidance describes a comprehensive quality systems model consistent with CGMP requirements for human and veterinary drugs, including biological products.	Management responsibility; quality planning; resource management; manufacturing operations control; evaluation activities; CAPA; quality metrics; continuous improvement.	Ukrainian enterprises should strengthen the role of senior management in quality assurance, introduce measurable quality indicators, use risk-based decision-making and evaluate the effectiveness of CAPA systems. Quality should be treated as a strategic management responsibility, not only as a technical department function.	Higher management accountability, stronger preventive control, better decision-making based on quality data and reduced recurrence of deviations.
United States model: lifecycle process validation	Validation is interpreted as a lifecycle activity, not as a one-time confirmation. FDA process validation guidance emphasizes that process validation continues throughout the product life cycle and should be supported by continual improvement mechanisms.	Process design; process qualification; continued process verification; process monitoring; deviation trending; statistical process control; validation master plan.	Ukrainian manufacturers should move from episodic validation to lifecycle validation, especially during technology transfer, scale-up, modernization of equipment and production of high-risk products. Continued process verification should be integrated into routine quality monitoring.	More stable manufacturing processes, lower variability, better evidence of control and stronger readiness for international inspections.
United States model: Drug Supply Chain Security Act	Electronic traceability of prescription medicines through the pharmaceutical supply chain. The DSCSA outlines an interoperable electronic system to identify and trace certain prescription drugs.	Electronic product tracing; package-level identification; data exchange between supply-chain participants; verification of trading partners; rapid investigation of illegitimate products.	Ukrainian enterprises should develop digital traceability infrastructure and prepare for interoperable data exchange with distributors, wholesalers and international partners. This requires cooperation between quality assurance, IT, logistics and regulatory affairs departments.	Improved supply-chain transparency, faster detection of suspicious products, stronger export potential and better recall management.

Continuation of table 1

Foreign model / practice	Key quality management focus	Practical instruments used in the model	Best practical aspects for implementation in Ukrainian pharmaceutical enterprises	Expected managerial effect
Japanese model: GMP discipline and operational standardization	Strong emphasis on manufacturing control, quality control, prevention of human error and compliance of manufacturing sites with Japanese GMP. PMDA conducts on-site and document-based inspections to assess whether manufacturing and quality controls comply with standards.	Strict written procedures; manufacturing and testing records; prevention of contamination and mix-ups; employee discipline; standard operating procedures; inspection readiness.	Ukrainian enterprises can adapt the Japanese focus on workplace discipline, standardization, personnel responsibility and prevention of human error. This is particularly relevant for sterile production, high-risk products and complex manufacturing processes.	Fewer operational deviations, stronger production discipline, better documentation reliability and improved consistency of product quality.
Japanese Kaizen-oriented quality culture	Continuous incremental improvement, employee involvement and daily operational problem-solving. Although Kaizen is not a regulatory requirement itself, it complements GMP by strengthening quality culture and process discipline.	Small-step improvements; staff participation; visual management; standardization; root-cause discussion; regular improvement meetings; prevention of repeated errors.	Ukrainian enterprises should introduce practical Kaizen tools at production-site level: short quality meetings, employee suggestions, visual deviation boards, 5S elements, standardization of workplace practices and team-based problem solving.	Formation of a living quality culture, greater employee involvement, faster identification of weak points and sustainable continuous improvement.

End of table 1

Foreign model / practice	Key quality management focus	Practical instruments used in the model	Best practical aspects for implementation in Ukrainian pharmaceutical enterprises	Expected managerial effect
PIC/S model: international inspection harmonization	Harmonization of GMP inspection standards and convergence of regulatory expectations. The PIC/S GMP Guide PE 009-17 provides internationally used GMP principles, including Pharmaceutical Quality System and quality risk management expectations.	Harmonized GMP inspections; self-inspection; quality audit; risk-based assessment; inspector training logic; alignment of national GMP practices with international expectations.	Ukrainian enterprises should use PIC/S principles as a benchmark for inspection readiness, internal audit design, quality system maturity assessment and preparation for cooperation with foreign regulators.	Improved international credibility, better audit preparedness, reduced regulatory uncertainty and stronger alignment with global GMP expectations.
WHO GMP model: global baseline for quality assurance	Establishment of internationally recognized basic GMP principles for pharmaceutical products, especially important for strengthening regulatory systems and ensuring access to quality medicines.	GMP standards; regulatory inspection principles; quality assurance of production and control; training of personnel and inspectors; support for national regulatory capacity.	Ukrainian enterprises can use WHO GMP as a practical baseline for companies that are still developing quality system maturity or preparing for more demanding EU/FDA-level requirements.	Gradual modernization of quality systems, improved national regulatory consistency and better preparation for international certification.
Data-driven quality management model	Transition from document-based compliance to knowledge-based and data-driven decision-making. This approach is reflected in modern FDA, EU and ICH-oriented quality systems, where quality metrics, deviation trends, process data and product quality reviews support managerial decisions.	Digital batch records; electronic documentation; quality metrics; deviation trend analysis; CAPA effectiveness checks; process monitoring; management review dashboards.	Ukrainian enterprises should invest in digital quality management systems, electronic document control, deviation databases, CAPA tracking and management dashboards. Digitalization should be implemented not as a separate IT project, but as part of quality governance.	Faster managerial response, better data integrity, reduced documentation errors, stronger evidence base for audits and more transparent quality control.

4. Challenges of Adapting International Quality Management Practices to Ukrainian Pharmaceutical Enterprises

The adaptation of international quality management practices to Ukrainian pharmaceutical enterprises is a strategically important but complex process. It requires not only formal harmonization with international standards, but also deep institutional, technological, organizational and cultural transformation. The most relevant elements for adaptation include the development of a mature Pharmaceutical Quality System, implementation of risk-based validation, strengthening of CAPA effectiveness, creation of digital traceability systems, improvement of supplier qualification, regular internal audits, transition to data-driven quality management and formation of a sustainable quality culture. These areas are especially important for enterprises seeking EU market access, international partnerships, export expansion and stronger regulatory credibility.

Ukraine is already moving toward regulatory convergence with the European Union. In 2026, official EU-integration communication emphasized that Ukraine is actively implementing regulatory standards harmonized with EU requirements, including GMP, while the principal tasks remain full alignment of the regulatory framework with EU requirements and transition to a modern system of state control. The same source also notes that European requirements such as GMP compliance and 2D coding should be considered investments in manufacturing development rather than only regulatory burdens. However, the practical implementation of these standards at enterprise level remains uneven, because companies differ significantly in financial capacity, technological readiness, quality system maturity, personnel competencies and export orientation.

One of the first challenges is institutional and regulatory transition. International quality management systems are effective only when enterprises operate within a predictable, transparent and professionally strong regulatory environment. Ukraine is working to establish a modern regulatory authority that will operate under rules harmonized with EU and global safety and quality standards. The reform concept emphasizes professional independence, transparency, innovation, electronic registers, eCTD, 2D coding, process automation and cooperation with EMA, WHO, FDA and other international institutions³⁶. For pharmaceutical enterprises, this creates both opportunities and uncertainty. On the one hand, a stronger regulator can improve international trust in Ukrainian medicines. On the other hand, the transition period may require companies to adapt

³⁶ Борщ В. І. Оцінювання потенціалу інноваційного розвитку фармацевтичного підприємства: виклики та сучасні підходи. *Вчені записки ТНУ імені В. І. Вернадського. Серія : Публічне управління та адміністрування*. 2024. DOI: <https://doi.org/10.32782/TNU-2663-6468/2024.6/25>.

quickly to new procedures, digital submission formats, inspection expectations, pharmacovigilance requirements and documentation standards.

The second challenge is the maturity of the Pharmaceutical Quality System. International models, especially EU GMP and ICH Q10 logic, require that quality assurance should be integrated into the entire management system of the enterprise. In the EU, GMP is defined as the minimum standard that manufacturers must meet in production processes, and any manufacturer of medicines intended for the EU market must comply with EU GMP regardless of geographical location. For Ukrainian enterprises, the problem is not only whether individual procedures exist, but whether they function as a coherent quality system. A mature Pharmaceutical Quality System requires management review, process monitoring, deviation trend analysis, CAPA effectiveness checks, change control, supplier qualification, product quality review and continuous improvement. Enterprises that treat GMP primarily as a set of documents prepared for inspection may face difficulties in demonstrating real system effectiveness to EU or other international regulators.

The third challenge concerns risk-based validation and lifecycle process control. The FDA process validation model is based on three stages: process design, process qualification and continued process verification, with the third stage requiring ongoing assurance during routine production that the process remains in a state of control. This approach is more demanding than traditional episodic validation because it requires continuous collection and analysis of process data, statistical understanding of variability, evaluation of critical parameters and regular reassessment of process performance. For Ukrainian enterprises, this may require investment in analytical capacity, data systems, validation specialists, quality engineers and production personnel training. The challenge is especially significant for enterprises modernizing production lines, introducing new technologies, performing technology transfer or preparing products for export to highly regulated markets.

The fourth challenge is the effectiveness of CAPA systems. Corrective and Preventive Action is one of the central mechanisms through which pharmaceutical enterprises demonstrate that they can identify, investigate and prevent the recurrence of quality problems. In mature international systems, CAPA is linked to deviation investigation, complaints, audit findings, out-of-specification results, supplier issues, change control and management review. However, in practice, CAPA often becomes formal when root-cause analysis is superficial, corrective actions are limited to retraining personnel, deadlines are not controlled, and effectiveness checks are not evidence-based. For Ukrainian enterprises, strengthening CAPA requires a transition from “closing deviations” to organizational learning. This means that each significant deviation should

generate knowledge about process weaknesses, human factors, documentation gaps, equipment limitations or supplier risks.

The fifth challenge is digital traceability and data integrity. Modern pharmaceutical quality management increasingly depends on reliable data: electronic batch records, laboratory information management systems, deviation databases, supplier databases, serialization systems, electronic document management and audit trails. The European and Ukrainian regulatory agenda also increasingly emphasizes 2D coding and digital tools. For Ukrainian enterprises, digitalization can improve transparency and inspection readiness, but it also creates new requirements for cybersecurity, validation of computerized systems, personnel training, data governance and integration between production, quality control, quality assurance, logistics and regulatory affairs. The risk is that digital tools may be introduced as isolated IT solutions rather than as part of a coherent quality management architecture.

The sixth challenge is supplier qualification and supply-chain resilience. Pharmaceutical quality depends not only on internal production processes, but also on the quality and reliability of active pharmaceutical ingredients, excipients, packaging materials, contract laboratories, logistics providers and distributors. In the context of war, disrupted logistics, energy risks and market uncertainty, supplier qualification becomes especially important. The OECD Economic Survey of Ukraine 2025 notes that the full-scale invasion has created an exceptionally uncertain outlook, while labour shortages and attacks on energy supply, logistics and businesses are slowing economic activity and increasing inflationary pressure. For pharmaceutical enterprises, this means that quality management must be integrated with resilience management: alternative suppliers, risk-based supplier audits, strategic stock planning, cold-chain reliability, emergency logistics and continuity plans should become part of the quality strategy.

The seventh challenge is audit readiness and inspection culture. International regulators increasingly expect enterprises to demonstrate not only compliance at a single point in time, but permanent readiness for inspection. EMA coordinates and harmonizes GMP activities at EU level, and EU competent authorities use risk-based approaches for routine inspections. In Ukraine, the State Service of Ukraine on Medicines and Drugs Control reported significant work in GMP certification in 2025, including processing applications, issuing conclusions and certificates, and conducting inspections, including for manufacturers located in frontline territories. This demonstrates that inspection capacity is functioning under difficult conditions, but enterprises still need to strengthen internal audit systems. Internal audits should not be limited to checklist verification; they should evaluate system effectiveness, recurring deviations, data integrity,

personnel competence, supplier risks and readiness for foreign regulatory inspections.

The eighth challenge is the transition to data-driven quality management. International practice increasingly moves from document-based compliance to quality decisions based on data. FDA quality systems guidance is intended to help manufacturers implement modern quality systems and risk management approaches consistent with CGMP requirements. For Ukrainian enterprises, the transition to data-driven quality management requires the development of quality metrics, dashboards, deviation trend analysis, CAPA performance indicators, product quality review analytics and management review based on evidence. The main barrier is not only technological, but also managerial: enterprises must develop the habit of using quality data for strategic decisions rather than only for regulatory reporting.

The ninth challenge is human capital and professional competencies. A mature quality system cannot function without qualified personnel who understand GMP, validation, QRM, CAPA, data integrity, documentation, audit logic and continuous improvement. In many enterprises, quality assurance departments are overloaded with documentation tasks, while production personnel may perceive quality requirements as external control rather than as part of daily professional responsibility. Adaptation of EU, FDA and Japanese approaches requires new roles and competencies: validation engineers, quality risk managers, data integrity specialists, internal auditors, supplier quality managers and digital quality system administrators. Therefore, personnel development should become a central component of adaptation, not an auxiliary activity.

The tenth challenge is financial and technological investment. Implementation of international quality practices requires resources: modernization of premises and equipment, validation activities, environmental monitoring systems, laboratory capacity, digital platforms, serialization, personnel training, external audits and consulting support. For small and medium-sized pharmaceutical enterprises, these investments may be difficult, especially under wartime economic constraints. However, postponing modernization may limit access to EU markets, international tenders, contract manufacturing opportunities and strategic partnerships. Therefore, investment in quality should be viewed as a long-term competitiveness factor rather than as a short-term compliance cost.

The eleventh challenge is the formation of a sustainable quality culture. The Japanese model demonstrates the importance of discipline, standardization, personnel involvement and continuous incremental improvement. For Ukrainian enterprises, the adoption of Kaizen-like practices, 5S elements, visual management, quality circles, short daily quality meetings and employee suggestion systems may help transform quality from a formal regulatory

requirement into a shared organizational value. However, this requires leadership commitment. Without visible support from top management, quality culture remains declarative. A sustainable quality culture emerges when employees at all levels understand that deviations should not be hidden, problems should be analysed systematically, and improvement should be part of daily work.

The twelfth challenge is international recognition and trust. Formal implementation of GMP is necessary but not always sufficient for full integration into international pharmaceutical markets. Mutual recognition, participation in international supply chains and access to EU or other regulated markets depend on the credibility of both national regulatory institutions and enterprise-level quality systems. The WHO Global Benchmarking Tool evaluates national regulatory systems and helps identify strengths, gaps, institutional development priorities and maturity levels. This is relevant for Ukraine because the international credibility of pharmaceutical products depends not only on individual manufacturers, but also on the maturity and reliability of the national regulatory system.

A practical adaptation strategy for Ukrainian pharmaceutical enterprises should therefore combine several international models. The EU model should serve as the main regulatory orientation because of Ukraine's European integration path and the need to align with EU GMP, GDP, serialization and inspection expectations. The FDA model should be used as a benchmark for lifecycle validation, quality metrics, management responsibility and data-driven decision-making. The Japanese model should be applied as a source of operational discipline, standardization, personnel involvement and continuous improvement. PIC/S and WHO approaches should support inspection harmonization, regulatory benchmarking and gradual improvement of system maturity.

The adaptation process should be implemented step by step. At the first stage, enterprises should conduct a gap analysis of their current quality systems against EU GMP, ICH Q8–Q10, FDA lifecycle validation principles and WHO/PIC/S expectations. At the second stage, they should prioritize high-risk areas: validation, CAPA, data integrity, supplier qualification, sterile production, outsourced activities and traceability. At the third stage, they should introduce digital tools for document control, deviation management, CAPA tracking, product quality review and management dashboards. At the fourth stage, enterprises should strengthen internal audit systems and link audit findings with risk management and management review. At the fifth stage, they should develop quality culture through leadership involvement, personnel training, communication, employee participation and continuous improvement practices.

Thus, the adaptation of international quality management practices to Ukrainian pharmaceutical enterprises is not a purely technical process. It is

a strategic transformation that combines regulatory harmonization, institutional trust, technological modernization, managerial maturity, personnel development and cultural change. The greatest challenge is to move from formal compliance to an integrated, preventive and evidence-based quality management model. If implemented systematically, this transformation can strengthen the competitiveness of Ukrainian pharmaceutical enterprises, improve export readiness, support EU market integration and increase trust in Ukrainian medicines at both national and international levels.

CONCLUSIONS

The analysis of foreign models and practices of pharmaceutical quality management demonstrates that the most successful regulatory systems are based on an integrated approach to quality assurance. The experience of the European Union, the United States, Japan, PIC/S and WHO confirms that pharmaceutical quality cannot be ensured only through final product control or formal compliance with regulatory requirements. It requires a mature Pharmaceutical Quality System, risk-based thinking, validated and continuously monitored processes, effective CAPA mechanisms, digital traceability, reliable supplier management, regular internal audits, data-driven decision-making and a strong organizational quality culture.

For Ukrainian pharmaceutical enterprises, the adaptation of these international practices should be understood as a strategic process of modernization rather than a purely technical or documentary task. The key objective is to move from fragmented compliance with individual requirements to a systemic model in which quality becomes an integral part of enterprise governance, production management, risk management, personnel development and market strategy. This is especially important in the context of European integration, export expansion, participation in international supply chains and the need to strengthen trust in Ukrainian pharmaceutical products.

Some practical recommendations, formulated on the basis of the conducted analysis, are as follows:

1. *To use the EU model as the main regulatory benchmark.* Ukrainian enterprises should gradually align their quality systems with EU GMP requirements, with particular attention to documentation control, validation, qualification, self-inspection, Product Quality Review, Qualified Person responsibilities, outsourced activity control and supplier qualification. This approach is the most relevant for enterprises seeking access to the EU market or cooperation with European partners.

2. *To strengthen the Pharmaceutical Quality System as a real managerial system.* A mature PQS should not be limited to a set of standard operating

procedures prepared for inspections. It should include regular management review, quality objectives, quality metrics, risk assessment, change control, deviation analysis, CAPA effectiveness evaluation, personnel training and continuous improvement. Senior management must be directly involved in quality governance and should treat quality as a strategic priority rather than a narrow technical function.

3. *To introduce risk-based validation and lifecycle process control.* Ukrainian pharmaceutical enterprises should move from episodic validation to a lifecycle model that includes process design, process qualification and continued process verification. This is particularly important for new products, technology transfer, equipment modernization, sterile manufacturing and production processes with high variability. Risk-based validation allows enterprises to focus resources on critical parameters and processes that have the greatest impact on patient safety and product quality.

4. *To improve the effectiveness of CAPA systems.* Corrective and Preventive Actions should become an instrument of organizational learning, not only a formal response to deviations. Each significant deviation, complaint, audit finding or out-of-specification result should be analysed through root-cause analysis, risk assessment, corrective action, preventive action and effectiveness verification. Enterprises should avoid superficial CAPA practices, especially those limited only to personnel retraining without deeper investigation of process, documentation, equipment or supplier-related causes.

5. *To develop digital traceability systems.* Ukrainian pharmaceutical enterprises should gradually implement serialization, electronic documentation, digital batch records, deviation databases, CAPA tracking systems, supplier databases and audit trails. Digital tools should support data integrity, transparency of operations, faster recall procedures and better inspection readiness. However, digitalization should not be implemented as an isolated IT project; it must be integrated into the overall quality management architecture.

6. *To strengthen supplier qualification and supply-chain quality management.* Pharmaceutical quality depends not only on internal production processes, but also on active pharmaceutical ingredients, excipients, packaging materials, logistics providers, contract laboratories and distributors. Ukrainian enterprises should introduce risk-based supplier evaluation, periodic supplier audits, quality agreements, alternative supplier strategies and continuous monitoring of supplier performance. In wartime and post-war conditions, supplier qualification should also be connected with resilience planning and continuity of supply.

7. *To transform internal audits into a tool for continuous improvement.* Internal audits should not be conducted only to formally meet regulatory

requirements. They should evaluate the real effectiveness of the Pharmaceutical Quality System, identify systemic weaknesses, assess recurring deviations, check data integrity, review personnel competence and generate practical improvement actions. Audit findings should be directly linked with CAPA, change control, management review and strategic quality planning.

8. *To adopt data-driven quality management.* Ukrainian enterprises should develop quality metrics and analytical dashboards that allow managers to monitor deviation trends, CAPA completion and effectiveness, process stability, complaint dynamics, supplier performance, validation status and audit results. Data should be used not only for reporting, but also for managerial decision-making. This will help enterprises shift from reactive problem-solving to preventive quality management.

9. *To adapt Japanese practices of operational discipline and continuous improvement.* Elements such as Kaizen, 5S, visual management, employee suggestions, short quality meetings and workplace standardization can be highly useful for Ukrainian pharmaceutical enterprises. These practices do not require only large financial investments; they require leadership, consistency, personnel involvement and daily attention to process discipline. Their implementation can help reduce human errors, improve workplace organization and strengthen quality culture.

10. *To invest in personnel competence.* Quality management systems are effective only when employees understand their role in ensuring product quality and patient safety. Ukrainian enterprises should provide regular training in GMP, GDP, QRM, validation, CAPA, data integrity, documentation, internal audit, supplier qualification and digital quality tools. Training should be practical, case-based and linked with real production and quality problems.

11. *To use PIC/S and WHO approaches as instruments for gradual quality system maturity.* These frameworks may serve as practical benchmarks for inspection readiness, regulatory convergence and institutional development. They are especially useful for enterprises that are gradually moving from national compliance to international market access.

Thus, the adaptation of international quality management practices to the Ukrainian pharmaceutical system requires a balanced and realistic strategy. The EU model should define the main regulatory direction; the FDA model should support lifecycle validation, quality metrics and data-driven management; the Japanese model should strengthen operational discipline and continuous improvement; and PIC/S and WHO approaches should support inspection harmonization and gradual maturity of the quality system.

The practical implementation of these best practices should be phased, risk-based and strategically coordinated. At the first stage, enterprises should

conduct a comprehensive gap analysis of their current quality systems. At the second stage, they should prioritize the most critical areas: validation, CAPA, supplier qualification, documentation control, internal audits and data integrity. At the third stage, they should implement digital tools and quality metrics. At the fourth stage, they should strengthen personnel competencies and quality culture. At the final stage, they should integrate continuous improvement into the daily management of pharmaceutical production.

In conclusion, international quality management practices offer Ukrainian pharmaceutical enterprises not only regulatory guidance, but also a practical pathway for increasing competitiveness, resilience and international credibility. Their successful adaptation can support the modernization of the Ukrainian pharmaceutical industry, improve access to global markets, enhance patient safety and strengthen confidence in Ukrainian medicines. The main condition for success is the transition from formal compliance to an integrated, preventive, evidence-based and continuously improving quality management system.

SUMMARY

The chapter examines international experience in pharmaceutical quality management and identifies opportunities for its practical adaptation by Ukrainian pharmaceutical enterprises. The analysis demonstrates that modern pharmaceutical quality assurance is based on an integrated system that combines regulatory compliance, scientific justification, risk-based decision-making, process validation, digital traceability, supplier control, internal audit and continuous improvement.

The international regulatory framework is formed by GMP, ICH Q8, ICH Q9, ICH Q10, EU GMP Guidelines, WHO GMP and the FDA Quality Systems Approach. These standards and guidelines emphasize that quality should be built into pharmaceutical products and manufacturing processes from the earliest stages of development and maintained throughout the entire product life cycle. Particular importance is given to Quality by Design, Quality Risk Management, the Pharmaceutical Quality System, lifecycle validation and data-driven monitoring of process performance.

The experience of the European Union, the United States, Japan, PIC/S and WHO shows that effective pharmaceutical quality management requires more than formal compliance with regulatory requirements. The EU model is especially relevant for Ukraine because it provides the main direction for regulatory harmonization, GMP compliance, documentation discipline, Product Quality Review, Qualified Person responsibility and supply-chain traceability. The U.S. model is valuable as a benchmark for lifecycle process validation, quality metrics, management responsibility and electronic traceability. The

Japanese model offers practical lessons in operational discipline, standardization, employee involvement and continuous improvement. PIC/S and WHO approaches support inspection harmonization, regulatory maturity and gradual strengthening of quality systems.

The chapter also highlights the main challenges of adapting international quality management practices to Ukrainian pharmaceutical enterprises. These include uneven maturity of Pharmaceutical Quality Systems, limited experience with risk-based validation, insufficient CAPA effectiveness, the need for digital traceability and data integrity, supplier qualification problems, wartime supply-chain risks, financial constraints, personnel competency gaps and the need to develop a sustainable quality culture. These challenges show that adaptation requires not only technical modernization, but also managerial, organizational and cultural transformation.

On the basis of the conducted analysis, the key practical recommendations include the gradual development of a mature Pharmaceutical Quality System, implementation of risk-based validation and lifecycle process control, strengthening of CAPA systems, introduction of digital traceability mechanisms, improvement of supplier qualification, regular conduct of internal audits, transition to data-driven quality management and formation of a quality culture based on leadership, personnel competence and continuous improvement.

Thus, the adaptation of international quality management practices can become a strategic pathway for the modernization of the Ukrainian pharmaceutical industry. It can improve regulatory compliance, increase export readiness, reduce quality risks, strengthen international credibility and support the integration of Ukrainian pharmaceutical enterprises into European and global pharmaceutical markets. The most effective adaptation strategy should combine the EU model as the main regulatory orientation, the FDA model as a benchmark for lifecycle validation and quality metrics, the Japanese model as a source of operational discipline and continuous improvement, and PIC/S and WHO approaches as instruments for inspection harmonization and gradual quality system maturity.

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