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Modern Strategies for Managing Deviations and Corrective and Preventive Actions in the Pharmaceutical Quality System

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Abstract

The article examines the transformation of deviation management and corrective and preventive actions (CAPA) in the pharmaceutical quality system as a key decision-making mechanism. The relevance of the work is determined by a shift in regulatory and manufacturing focus from the formal closure of records to demonstrable reductions in patient risk, strengthened data integrity, and enhanced quality maturity in the context of increasingly complex technologies and supply chains. The aim of the study is to analytically synthesize the latest empirical and methodological sources to construct a risk-based, data-driven model for managing deviations and CAPAs. The novelty of the approach lies in integrating metrics of quality system performance, the structure of inspectional non-conformities by criticality, and data integrity strategies into a single conceptual framework that interprets deviations as controllable signals rather than administrative exceptions. Based on narrative evidence synthesis, a model of the deviation and CAPA life cycle is proposed, in which the contours of immediate risk containment, evidence-based investigation grounded in testable hypotheses, and systematically designed corrective and preventive actions, with subsequent evaluation of their effectiveness against predefined metrics, are clearly differentiated. It is demonstrated that the transition from a reactive logic to a predictive one relies on cross-functional interaction, discipline in primary actions, the embedding of changes into change control, qualification, and validation procedures, as well as on digital connectivity of records in electronic quality systems, which enables trending of weak signals and prevention of regulatorily significant non-conformities. The article will be of interest to quality assurance professionals, managers of pharmaceutical manufacturing sites, validation experts, and developers of electronic quality management systems.

Keywords: *Pharmaceutical Quality System, Deviations, Corrective and Preventive Actions, CAPA.*

INTRODUCTION

The pharmaceutical quality system provides a unified framework within which deviations and corrective and preventive actions function as a kind of nervous system: they register failures, assess their significance for the patient, and transform local observations into managerial decisions that affect product release, process reproducibility, and the demonstrability of compliance with good practice requirements. In the context of continuous professional development, this is particularly important, because competence is measured not by knowledge of formal definitions, but by the ability to rapidly and soundly relate an individual event to a quality risk, delineate the boundaries of potential impact, and select the depth of investigation in such a way as to avoid losing either critical signals or resources on secondary issues. This framing is consistent with the contemporary understanding of quality system maturity as the capability to reproducibly deliver outcomes in the face of variability in input factors and inevitable noise disturbances (Fellows et al., 2022).

The classical approach often manifests as a reactive logic: the event is treated as an exception that needs to be closed, rather than as data for refining control; the investigation is reduced to a search for a culprit, and the actions are limited to additional training and rewriting of procedures without assessing systemic barriers and without demonstrating effectiveness. In practice, this generates two typical distortions: first, accumulation of formally closed records with persistence of recurring causes; second, a gap between documentation and real process management, where the quality of evidence (including data integrity) becomes a weak link rather than a pillar for decision-making. Contemporary reviews of data integrity indicate that violations in this domain frequently appear as paper deviations but in essence

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reflect defects in the management of the recording system, access control, and traceability, that is, they have a systemic nature and cannot be eliminated by administrative measures alone (Charoo et al., 2023).

Modern strategy for managing deviations and corrective and preventive actions is generally understood as a risk-based, data-driven model in which the key task becomes the speed and quality of decision-making while preserving evidentiary robustness: rapid containment and impact assessment are complemented by an investigation constructed around testable hypotheses, and the actions themselves are designed as system-level changes (control strategy, technical barriers, digital traceability) rather than as a list of formal assignments. Empirical studies that use indicators of quality system performance demonstrate statistically significant associations between characteristics of deviations, the effectiveness of corrective and preventive actions, and operational outcomes (for example, right first time, complaints, inspection results), thereby reinforcing the thesis that analytical thinking and work with metrics are necessary elements in the training of professionals (Wang et al., 2021).

MATERIALS AND METHODS

The material for the study consisted of a deliberately limited corpus of six key publications representing different axes of the modern pharmaceutical quality system: an empirical–methodological view of quality practice maturity and supply chain resilience (Fellows et al., 2022); a quantitative operationalization of QMS functioning and the links between deviation/CAPA characteristics and manufacturing outcomes (Wang et al., 2021); the issue of data integrity as a systemic source of deviations and regulatory observations (Charoo et al., 2023); applied strategies for ensuring data integrity at the level of practices and control measures (Gokulakrishnan & Venkataraman, 2024); a review of the distribution of non-compliances by criticality based on GMP inspections from 2013–2022 as an external marker of regulatory attention and risk (Lebanova et al., 2024); and a process-oriented description of early actions and information gathering in deviation investigations as the foundation of evidential robustness (Pazhayattil & Sharma, 2025). This configuration enabled maintaining a balance between the conceptual level (quality system maturity, metrics, risk orientation) and the applied level (discipline in primary actions, investigation, data integration, and control barriers) without expanding the subject beyond CAPA and deviation management.

The research methodology is an analytical synthesis (narrative evidence synthesis) with elements of comparative and content analysis: the propositions of the sources were decomposed into operational units (signal/deviation - risk containment - fact collection and preservation of evidence - causal structure - CAPA design as a systemic change - effectiveness verification), followed by a comparison of how different authors anchor these units to patient risk, data evidentiality, and process controllability (Pazhayattil & Sharma, 2025; Charoo et al., 2023; Gokulakrishnan & Venkataraman, 2024). Additionally, a two-level mapping was applied: the level of quality practice maturity and sustainable reproducibility of outcomes under inevitable variability (Fellows et al., 2022) and the level of measurability and feedback through QMS metrics (Wang et al., 2021), with calibration of priorities via the structure of inspectional non-compliances by criticality as an indicator of where regulatory risk materializes most frequently (Lebanova et al., 2024). The result was a conceptual model of modern strategies for managing deviations and CAPA, in which the emphasis is placed not on formal closure of records, but on reproducible decision logic, testable investigation hypotheses, and demonstrable effectiveness of interventions, including components of data integrity and systemic barriers (Charoo et al., 2023; Gokulakrishnan & Venkataraman, 2024).

RESULTS AND DISCUSSION

Once deviations and corrective and preventive actions are established as mechanisms for managerial decisions in the pharmaceutical quality system, the next critical step is to define, in a uniform manner, what constitutes a deviation and how it should be read in the process context. In practice, it is advisable to treat deviations as recorded discrepancies between the expected state of control and the actual course of operations, and to group the sources of such discrepancies according to the environment in which they arise: manufacturing (process parameters, environmental conditions, execution errors), quality control laboratory (anomalies in testing, methodological non-conformities), data (incompleteness, lack of traceability, violations of recording and verification requirements), equipment and infrastructure (failures, incorrect configuration, qualification status) (Gokulakrishnan & Venkataraman, 2024). Within this approach, it is essential that the event is captured not for the sake of a ticket, but for the sake of subsequent decision-making: first, notification, collection of primary facts, and preservation of evidence are ensured, and then classification and selection of the investigation trajectory are performed, with the speed of primary actions considered an element of the quality of the system itself.

Risk-based classification of deviations is typically implemented as a three-level gradation by severity of consequences: critical, major, and minor. Its value lies not in the terminology as such, but in the fact that the level of risk determines the depth of investigation, the set of approvals, and the requirements for the evidential robustness of conclusions. If the potential risk to the patient and quality is high (for example, sterility, dosage, cross-contamination, or data integrity is affected), any cost savings in the investigation becomes a latent system debt, which is repaid through recurrence and inspection outcomes. It is telling that, in an analysis of non-compliances identified during

good manufacturing practice inspections in Europe from 2013–2022, 1458 recorded non-compliances, 9% were classified as critical and 37% as major; that is, nearly every second observation fell into areas of heightened regulatory attention. This structure underscores the need for strict, reproducible logic in prioritization and in selecting the depth of investigation (Lebanova et al., 2024).

Primary triage of a deviation should lead to immediate containment measures that separate risk management from root cause identification: the potential impact on the product, batch, and associated batches is assessed first, followed by isolation of the affected materials and results (quarantine, physical segregation, status blocking), implementation of temporary controls (enhanced monitoring, additional checks, temporary restriction of operations), and, in parallel, assurance of data preservation so that the subsequent investigation is grounded in observations rather than reconstructed from memory (Gokulakrishnan & Venkataraman, 2024). Contemporary logic is deliberately pragmatic here: containment must be sufficiently stringent to halt the spread of risk, and sufficiently precise to avoid paralyzing the system; hence the emphasis on rapid actions, immediate information capture, and discipline in handling data as evidence.

Role allocation in deviation management should be organized not according to administrative hierarchy, but according to evidentiary and control functions: manufacturing is responsible for operational description of facts and implementation of containment; quality control for correctness of test data and assessment of applicability of results; engineering for technical diagnostics and equipment condition; and quality assurance for independent risk assessment, selection of investigation depth, and endorsement of decisions regarding product status. When interaction is structured as a short cross-functional cycle within the first 24–48 hours, the likelihood of a tunnel explanation decreases and the likelihood of identifying the systemic mechanism increases; for a system of continuous education, this provides a practical framework: the professional learns not only to record an event but also to translate it into a sequence of actions in which each role adds verifiable knowledge rather than opinions (Pazhayattil & Sharma, 2025). The Pharmaceutical Quality System Deviation Management Timeline is shown in Figure 1.

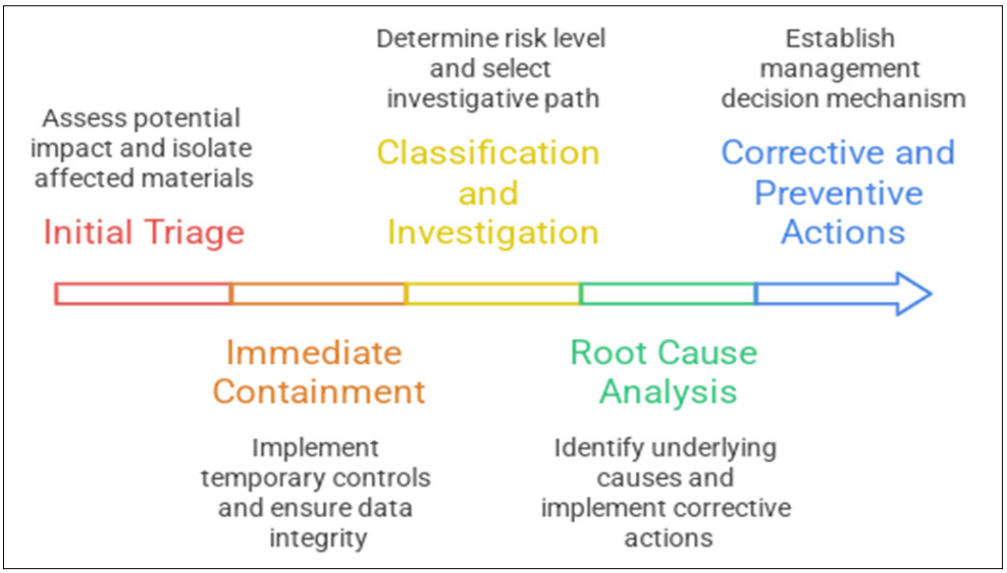

Fig. 1. Pharmaceutical Quality System Deviation Management Timeline

After primary triage of the deviation and risk containment, the key task becomes investigation, which must not substitute for quality management's search for a convenient explanation, but rather reconstruct the causal structure of the event. Another aspect of a well-designed problem statement is that the difference should be stated as a verifiable fact, regardless of premises, judgments, or post hoc conclusions. As a consequence, the context, or the so-called zone of applicability, and the order of events contributing to the emergence of the difference should be described in detail, as context is usually the source of the fact that the difference is not reducible to a single cause but rather a chain of causes. It is important to gather facts in a way that the facts and evidence that emerge are not shaped by the process. Otherwise, the investigation is nothing more than a reconstruction of who is the loudest and most persuasive.

Evidence-based explanation is hypothesis-driven: An explanation is a hypothesis, i.e., a guess about the causes, that is supported or disproven by observations, texts, measurements, or reproducible experiments to an acceptable risk. The intellectual key is differentiation: the hypothesis is not an explanation until it specifies clearly what features are present if it is true and absent if it is false. This way of thinking seeks to discourage a single root-cause narrative and instead promotes the idea that the cause lies at the intersection of conditions rather than at a single point, so that the investigation's story becomes a test of causal links and every assertion is based on data.

The choice of root cause analysis tools depends on complexity and the degree of uncertainty. For simple, local situations, stepwise formulation of clarifying questions is useful, progressively unpacking the causal chain down to a controllable factor. When several competing factors are presumed, a cause-and-effect diagram is appropriate, allowing the structuring of alternatives by categories and making gaps in evidence visible. For complex failures, where combinations of events are possible, it is more appropriate to decompose the undesirable outcome into combinations of conditions and failures, and to perform barrier analysis, which considers which measures should have prevented the event, why they did not act, and at which point the system permitted risk to pass through. These approaches are not mutually exclusive: in a mature investigation, they are combined to achieve both clarity and verifiability of conclusions. The Root Cause Analysis Process is shown in Figure 2.

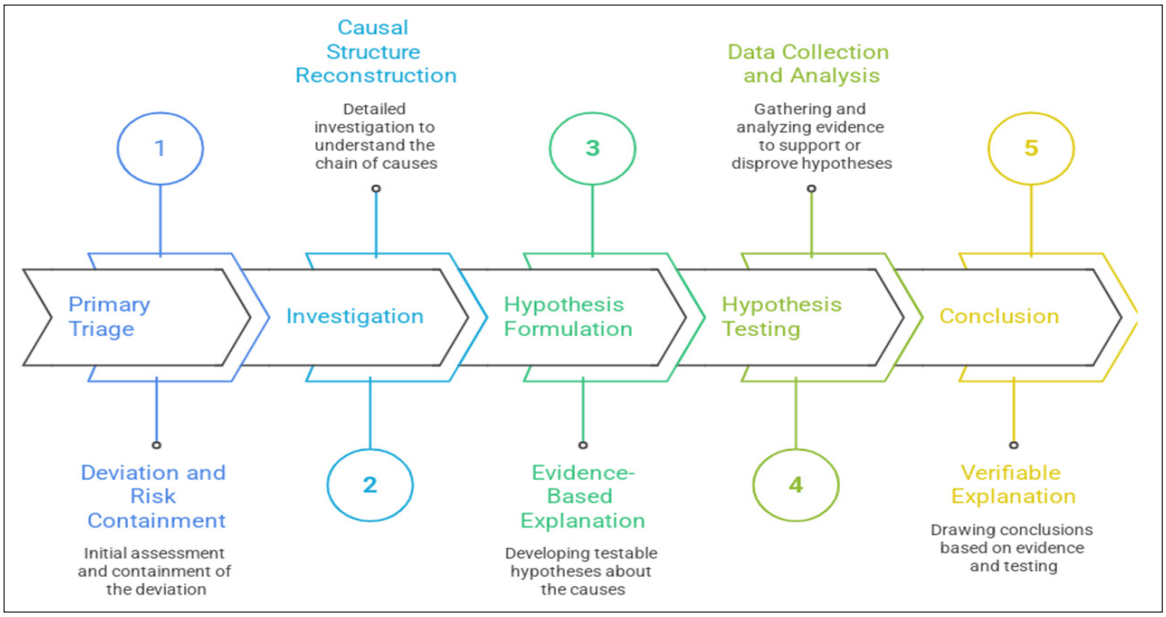

Fig. 2. Root Cause Analysis Process

The most frequent errors are premature termination of causal inquiry and the substitution of systemic analysis with personal attribution. Explanations through human error often capture only the last visible point in the chain and ignore the conditions that made the error likely or unnoticeable. Similarly, turning corrective and preventive actions into additional training without modifying processes and control measures creates an illusion of intervention but does not reduce the likelihood of recurrence, because it does not eliminate the mechanism that caused the deviation. Particularly hazardous is the absence of barrier analysis: when it is not assessed which control measures were in place, how they were intended to function, and why they failed, the system loses its ability to learn from events and begins to reproduce them in new forms.

Once verifiable causal links have been established in the investigation, corrective and preventive actions move from the realm of explanations into the realm of controllable changes. They need to be regarded as a life cycle rather than as a checklist of tasks: first, the intervention concept is formulated; then it is implemented through controlled procedures; and only thereafter is its effectiveness confirmed in the real process. This sequence protects the quality system from self-deception, whereby an event is closed in documentation but continues to recur in manufacturing or the laboratory in a modified form.

Corrective actions are appropriate when the cause has already materialized, and there is a need to eliminate the mechanism that led to the deviation, as well as to restore control, including confidence in data and product status. Preventive actions are justified when the analysis indicates that conditions exist under which a similar mechanism may be realized, even if the current batch is not affected or the impact has not been demonstrated; this is particularly characteristic of trends, weak signals, and recurrent minor non-conformities. In practice, both varieties are often intertwined: the corrective component removes the specific failure, and the preventive one extends the protection boundaries to prevent the migration of risk to adjacent processes, shifts, products, or sites.

The quality of the intervention concept is determined by how systemic the chosen solution is. Preference should be given to measures that change the process design and make the error highly unlikely or immediately detectable, rather than measures that shift responsibility onto operator attentiveness. These may include design constraints, interlocks, guiding elements, automatic checks, and refinement of the control strategy, when parameters, control frequency, and decision criteria reflect the actual process variability. Administrative measures, including revisions to procedures and training, remain important but serve primarily as support for

systemic changes rather than as their substitute; otherwise, the system begins to accumulate paper-based protection that cannot withstand the pressure of time, shift patterns, and production load.

Implementing actions must be embedded in the quality system's controlled loops; otherwise, they will not be sustainable. Any change affecting the process, equipment, computerized systems, or test methods must pass through the change control procedure with assessment of risks, dependencies, and impact on regulatory commitments. Revision of procedures must be accompanied by verification of their applicability in real conditions and by training to confirm that the new rules are genuinely reproducible and understood. If the actions require testing, reconfiguration, or the extension of process boundaries, validation and qualification activities are necessary to demonstrate that the intervention has not created a new risk and has not degraded the process's ability to consistently assure quality.

Effectiveness verification completes the life cycle and distinguishes controlled improvement from formal closure. It is insufficient merely to assert non-recurrence; the required indicators, their direction of change, and the observation period must be defined in advance, taking into account batch frequency and natural variability. In some cases, process and control signal indicators are more critical. For others, data quality, equipment stability, or reduced recurrence of a specific mechanism are decisive. Independent verification by the quality assurance unit or another function that did not participate in action design reduces the risk of bias and helps reveal blind spots when the intervention has been implemented correctly but has not affected the true mechanism, or has improved a local area at the cost of deterioration of an adjacent one. The Corrective and Preventive Action Lifecycle is shown in Figure 3.

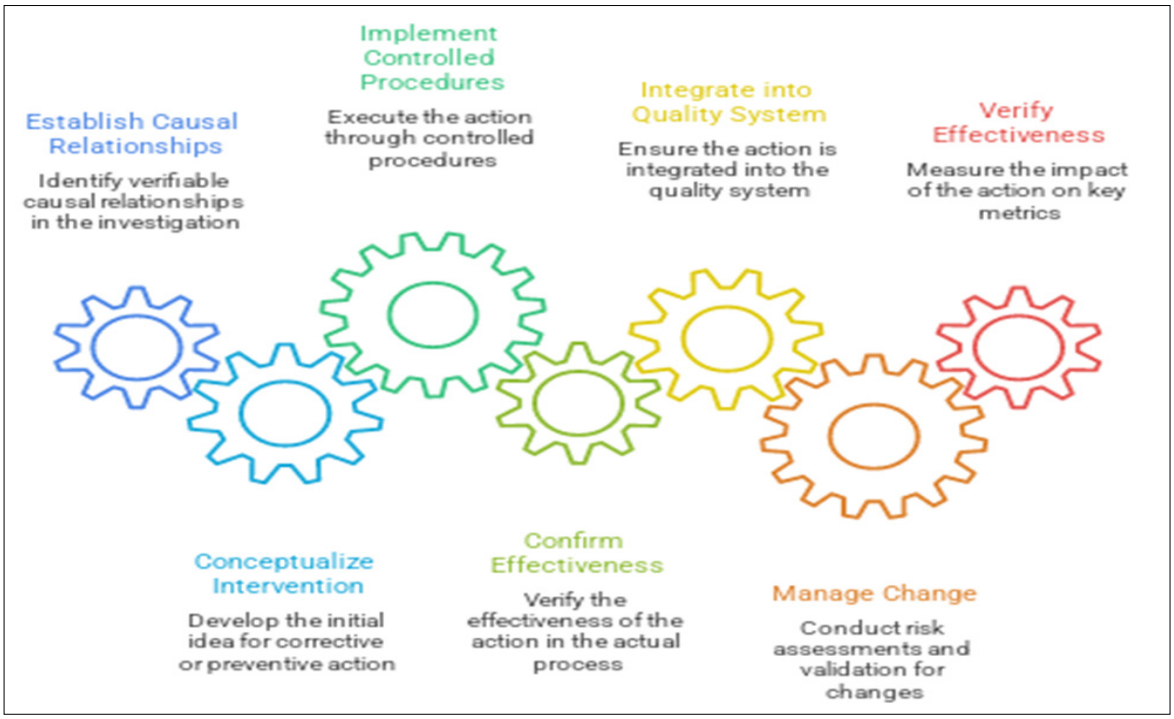

Fig. 3. Corrective and Preventive Action Lifecycle

When corrective and preventive actions are structured as a life cycle, the quality system gains the ability to move from reaction to anticipation, and at this point trending and digital connectivity of data become decisive: recurrence of minor non-conformities, shifts in parameter distributions, anomalies in laboratory results, or equipment instability should be regarded as weak signals for which escalation criteria and triggers for preventive actions are predefined in order to prevent transformation of a trend into an event with product impact. An electronic quality management system reinforces this approach by linking records of deviations, investigations, changes, training, and equipment status into a single causal network, automatically routing decisions based on risk level and making patterns visible through analytical dashboards, where data are transformed into a manageable picture rather than an archive. However, digitalization does not function without a quality culture and consideration of the human factor: deviation reports must be perceived as a contribution to resilience, and processes and procedures must be designed to reduce the probability of error and increase its detectability at the moment of occurrence rather than post factum. Within this logic, key performance indicators are required not for reporting, but for feedback: the recurrence of mechanisms, speed of containment, effectiveness of actions, and accumulation of outstanding commitments are assessed with due regard for risk, so that management is directed toward reducing uncertainty and strengthening control rather than cosmetically improving record closure times.

CONCLUSION

In its contemporary interpretation, the pharmaceutical quality system is manifested not through the mere existence of formal procedures, but through the ability to convert deviations and CAPA into a controlled flow of evidence and decisions: the event is captured as a discrepancy between the expected state of control and the actual course of operations, risk management is then promptly separated from root cause analysis, through containment, assessment of potential impact on the product, and preservation of data as evidence, and only thereafter is the investigation initiated, the scale of which is determined by risk-based classification. It is precisely at this juncture that classical reactivity, inclined to close records instead of refining control, becomes a source of systemic debt: it generates recurrence of causes, paper deviations, and vulnerability of data integrity, whereas a mature model requires a cross-functional cycle within the first 24–48 hours and a disciplined way of thinking in which the problem is formulated as a testable fact and the causal structure is reconstructed through hypotheses subject to confirmation or refutation by observations, documents, and technical measurements.

The transition from explanations to changes is achieved when CAPA are understood as a life cycle rather than as a list of assignments: corrective actions restore control and eliminate the mechanism of an already realized deviation, while preventive actions expand protection boundaries, drawing on trends and weak signals, with priority given to systemic barriers and control strategy rather than to administrative substitutes in the form of training alone and rewriting of procedures. Embedding actions into the circuits of change control, qualification, and validation protects against the emergence of new risk, and effectiveness verification requires predefined metrics and an observation period, since mere absence of recurrence is not, in itself, proof of success. Against this background, trending and digital connectivity of data, particularly in electronic quality management systems that link deviations, investigations, changes, training, and equipment status into a single causal network, become not an embellishment but a prerequisite for moving from reaction to anticipation: metrics serve as feedback, the quality culture sustains the motivation to report deviations, and the system as a whole strengthens control by reducing uncertainty rather than cosmetically improving record closure timelines.

REFERENCES

1. Charoo, N. A., Khan, M. A., & Rahman, Z. (2023). Data integrity issues in the pharmaceutical industry: Common observations, challenges, and mitigation strategies. *International Journal of Pharmaceutics*, *631*, 122503. https://doi.org/10.1016/j.ijpharm.2022.122503
2. Fellows, M., Friedli, T., Li, Y., Maguire, J., Rakala, N., Ritz, M., Bernasconi, M., Seiss, M., Stiber, N., Swatek, M., & Viehmann, A. (2022). Benchmarking the Quality Practices of Global Pharmaceutical Manufacturing to Advance Supply Chain Resilience. *The AAPS Journal*, *24*, 111. https://doi.org/10.1208/s12248-022-00761-7
3. Gokulakrishnan, D., & Venkataraman, S. (2024). Ensuring Data Integrity: Best Practices and Strategies In the Pharmaceutical Industry. *Intelligent Pharmacy*, *3*(4), 296–303. https://doi.org/10.1016/j.ipha.2024.09.010
4. Lebanova, H., Stoev, S., & Petrova, G. (2024). Analysis of non-compliances identified in GMP inspections between 2013 and 2022. *Pharmacia*, *71*, 1–6. https://doi.org/10.3897/pharmacia.71.e120053
5. Pazhayattil, A. B., & Sharma, S. (2025). Initial Actions and Information Gathering. In: Pharmaceutical Manufacturing Deviation and Failure Investigations. *AAPS Introductions in the Pharmaceutical Sciences*, *3*. https://doi.org/10.1007/978-3-031-86504-6_1
6. Wang, G., Wang, W., & Zheng, Q. (2021). Quantitative Analysis of the QMS for Pharmaceutical Manufacturing. *Journal of Pharmaceutical Innovation*, *17*(4), 1091–1108. https://doi.org/10.1007/s12247-021-09579-w