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Quality Management Principles in Drug Discovery R&D Projects

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Abstract

The study examines quality management principles relevant to modern drug discovery and development, with an emphasis on the economic and managerial consequences of inadequate quality in early-stage projects. The research novelty lies in the transfer of pharmaceutical quality system concepts, traditionally focused on manufacturing, into the upstream phases of target identification, hit and lead generation, and preclinical candidate selection. The article describes the main elements of pharmaceutical quality systems, including quality by design, quality risk management, and digital quality management platforms, and analyzes their applicability to discovery workflows. Particular attention is given to AI-enabled decision support, lifecycle-based risk management, and data-driven quality metrics. The objective of this work is to develop an integrated conceptual framework that links quality principles with portfolio decisions and early economic evaluation in drug discovery R&D. To achieve this objective, a narrative review, comparative analysis of regulatory guidance, and conceptual modeling methods are employed. The conclusion outlines managerial implications for pharmaceutical companies and research organizations. The article targets R&D managers, quality professionals, and project leaders working in pharmaceutical and early drug discovery settings.

Keywords: *Quality Management, Drug Discovery, Pharmaceutical R&D, Quality By Design, Quality Risk Management, ICH Q9, Pharmaceutical Quality System, Digital Quality Systems, Artificial Intelligence, R&D Portfolio Management.*

INTRODUCTION

Drug discovery R&D combines high scientific uncertainty with substantial sunk costs, long development cycles, and a pronounced probability of technical and regulatory failure. Early errors in target selection, assay design, compound profiling, or preclinical candidate characterization often result in late-stage attrition, costly rework, and suboptimal utilization of limited R&D budgets. At the same time, formal quality management in many organizations remains concentrated on development, scale-up, and commercial manufacturing, while early discovery processes rely on local practices, individual experience, and informal controls.

Pharmaceutical quality system concepts, based on international guidelines on pharmaceutical quality systems and quality risk management, describe a lifecycle-oriented model that integrates process understanding, risk-based controls, management responsibilities, continuous improvement, and knowledge management across development, manufacturing, and supply. Quality by design extends this model by embedding predefined target product profiles, critical quality attributes, and design spaces into development decisions. Digital quality platforms and AI-based analytics enhance the ability to collect, structure, and interpret large volumes of R&D data for proactive quality monitoring and early detection of failure modes.

For drug discovery organizations, the systematic adoption of such principles influences not only technical outcomes but also project economics. Better early decision quality lowers late-stage failure rates, improves the probability of technical success, and reduces unproductive expenditure on weak candidates. Quality management in discovery R&D, therefore, needs to be considered not as a regulatory necessity postponed until the clinical or manufacturing phases, but as an R&D management instrument that shapes portfolio value, resource utilization, and long-term competitiveness.

The objective of the article is to develop a structured view of quality management principles applicable to drug discovery R&D and to formulate a framework that links these principles with project governance, digital infrastructures, and the economic evaluation of early-stage projects.

The first research task is to systematize quality management principles relevant to the discovery stages, utilizing recent literature on pharmaceutical quality systems, quality risk management, quality by design, and digital quality platforms. The second task is to map these principles onto the main stages of the discovery pipeline and the interfaces with development and supply chains, identifying practical mechanisms and tools suitable for implementation in R&D projects. The third task is to propose a conceptual model for integrating risk-based and data-driven quality management

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with early portfolio and economic decisions in the drug discovery process.

The novelty of the study lies in the explicit transfer of modern pharmaceutical quality, risk, and digital management concepts, which are predominantly described for manufacturing environments, into upstream discovery workflows, with an emphasis on managerial and economic consequences for R&D portfolios rather than compliance alone.

MATERIALS AND METHODS

The analysis is based on recent regulatory documents and peer-reviewed publications that cover pharmaceutical quality systems, quality risk management, quality by design, digital quality infrastructures, and AI in drug discovery.

S.G. Bhandwalkar and co-authors [1] present a comprehensive review of pharmaceutical quality management systems, discussing total quality management, ICH Q10 implementation, CFR 21 Part 11 requirements, WHO-GMP expectations, and Six Sigma approaches within a unified framework. P. Dandekar and colleagues [2] examine the evolution of pharmaceutical quality control and assurance in the twenty-first century, stressing lifecycle thinking, risk-based validation, advanced analytics, and the impact of globalized supply chains. B. Elmadhoun et al. [3] analyse quality risk management in the final operational stages of sterile pharmaceutical manufacturing, demonstrating structured risk identification, evaluation, and control for sterilization, inspection, labeling, packaging, and storage processes with strong sustainability constraints.

The ICH guideline Q9 (R1) on Quality Risk Management [4] provides a formal definition of quality risk management processes, tools, and degrees of formality. It illustrates the integration of risk-based decision-making into development, manufacturing, and supply chain activities. S. Kant and co-authors [5] review the deployment of artificial intelligence across the drug discovery and development pipeline, highlighting implications for cost, timelines and probability of success, and discussing challenges related to data quality, interpretability and regulation. A. Khan and colleagues [6] describe quality by design as a newer technique for pharmaceutical product development, summarizing the use of target product profiles, critical quality attributes, design of experiments and process analytical technology for robust product and process design.

G. Kushwah et al. [7] review quality risk management as a contemporary international practice in the pharmaceutical industry, detailing the use of a broad set of risk tools and emphasizing the need for structured, lifecycle-wide risk communication and review. S. Prajwala and co-authors [8] focus on the implementation of the QbD paradigm and specific quality risk management tools for resolving formulation challenges in transdermal systems, illustrating how science- and risk-based approaches guide formulation decisions. P. Ullagaddi and colleagues [9] investigate digital transformation in the pharmaceutical industry, including electronic quality management systems, real-time dashboards, and data integrity controls, and describe their influence on compliance, efficiency, and decision support. S.A. VanDuyse et al. [10] quantify the impact of ICH Q10 pharmaceutical quality system guidance on manufacturers' quality systems using benchmarking data, showing the relationship between quality enablers and performance outcomes.

These materials collectively provide conceptual models, regulatory expectations, methodological tools, and empirical examples that can be extrapolated from manufacturing and late development to discovery R&D environments.

The study's methodological toolkit combines several analytical approaches. A targeted narrative review synthesizes recent guidance and scientific literature on pharmaceutical quality systems, risk management, quality by design, digital quality infrastructures, and AI in drug discovery. Comparative analysis is applied to align manufacturing-oriented guidance with the specific characteristics of discovery R&D, including high epistemic uncertainty, iterative experimentation, and exploratory project portfolios. A structured content analysis of the selected publications identifies recurring principles, enablers, and barriers. On this basis, conceptual modeling is employed to construct an integrated framework that links quality management principles with the stages of the discovery pipeline, digital architectures, and economic evaluation of R&D projects.

RESULTS

The synthesis of recent literature and regulatory guidance reveals a coherent set of quality management principles relevant for drug discovery R&D. Across pharmaceutical quality management system reviews and ICH Q10-related analyses, a lifecycle-oriented view of quality emerges, in which product realization, state of control, and continuous improvement are treated as interconnected objectives spanning development, manufacturing, and post-approval stages [1, 10]. When transferred to discovery R&D, this view implies that early scientific work should be organized so that later manufacturability, regulatory expectations, and supply reliability are considered from the outset, rather than being retrofitted at the development handoff.

Quality by design-focused publications emphasise systematic translation of patient and clinical needs into target product profiles and critical quality attributes, followed by structured exploration of design spaces through experimental design and process analytical technology [2, 6, 8]. For discovery, the same logic can be applied to define early "quality targets" for molecular entities and biological hypotheses: target validation strength, acceptable off-target risk, key properties of chemical series, translatability of preclinical models, and manufacturability constraints. The reviewed QbD literature indicates that an explicit definition of such targets, coupled with designed experimentation, reduces variability, exposes interactions between factors, and supports robust decision-making on candidate progression [2, 6, 8].

Risk-based decision making occupies a central position in both the revised ICH Q9 guideline and recent QRM reviews [3, 4, 7]. The guideline describes a structured sequence of risk assessment, control, communication, and review, supported by tools such as FMEA, HACCP, fault-tree analysis, and risk ranking [4]. Empirical studies of QRM adoption in sterile manufacturing have shown that the systematic use of such tools in late operational stages leads to more apparent prioritization of critical process parameters and better alignment between risk controls, sustainability constraints, and resource allocation [3]. General reviews of QRM practice emphasize the importance of cross-functional teams, transparent documentation, and continuous risk review, integrating new information from deviations, complaints, and process performance [7]. Transposed into discovery R&D, these concepts suggest that risk management should not be limited to safety and compliance risks but instead expanded to encompass scientific, technical, regulatory, and economic uncertainties surrounding targets, assays, models, and candidate profiles.

Digitalisation and data integrity constitute another recurrent theme. Analyses of twenty-first-century pharmaceutical QA/QC and digital transformation underscore that modern analytical methods, electronic quality management systems, and real-time dashboards expand the ability to monitor processes, trend performance data, manage changes, and conduct investigations [2, 9]. Electronic QMS implementations are associated with improved documentation control, faster deviation and CAPA processing, and greater transparency across sites [2]. Digital transformation work highlights the integration of manufacturing execution systems, laboratory information systems, and analytics platforms into a more connected quality information architecture [9].

AI-focused literature extends these developments by showing that machine learning and deep learning methods already influence multiple stages of the discovery and development pipeline, from target identification and virtual screening to predictive toxicology and clinical trial design [5]. AI applications described in recent reviews reduce screening volumes, prioritise compounds, predict pharmacokinetic liabilities, and identify complex patterns in multi-omics data, leading to faster and more informed decision-making. When viewed from a quality management perspective, AI systems become additional quality enablers: they provide predictive insights that can inform risk assessments, support the early definition of critical attributes, and optimize decision criteria for the progression or termination of discovery projects.

Figure 1 reflects these findings by consolidating an integrated quality management framework for drug discovery R&D. Along the horizontal axis, the figure distinguishes four primary discovery stages: target identification and validation, hit and lead generation, lead optimisation, and preclinical candidate selection. The vertical dimension outlines key quality principles derived from pharmaceutical quality systems, including QbD and QRM: lifecycle orientation, science- and risk-based decision-making, robust process and experiment design, knowledge and data management, management oversight, and continuous improvement [1–4, 6–8, 10]. Within each cell at the intersection of a stage and a principle, the framework locates representative practices: for example, risk-based target selection criteria and evidence thresholds in the first stage; design-of-experiments-driven SAR optimisation and pre-defined "kill" criteria in lead optimisation; or formal QRM exercises on developability, scale-up feasibility and supply chain vulnerabilities during candidate selection, supported by digital quality tools and AI analytics [3–6, 9].

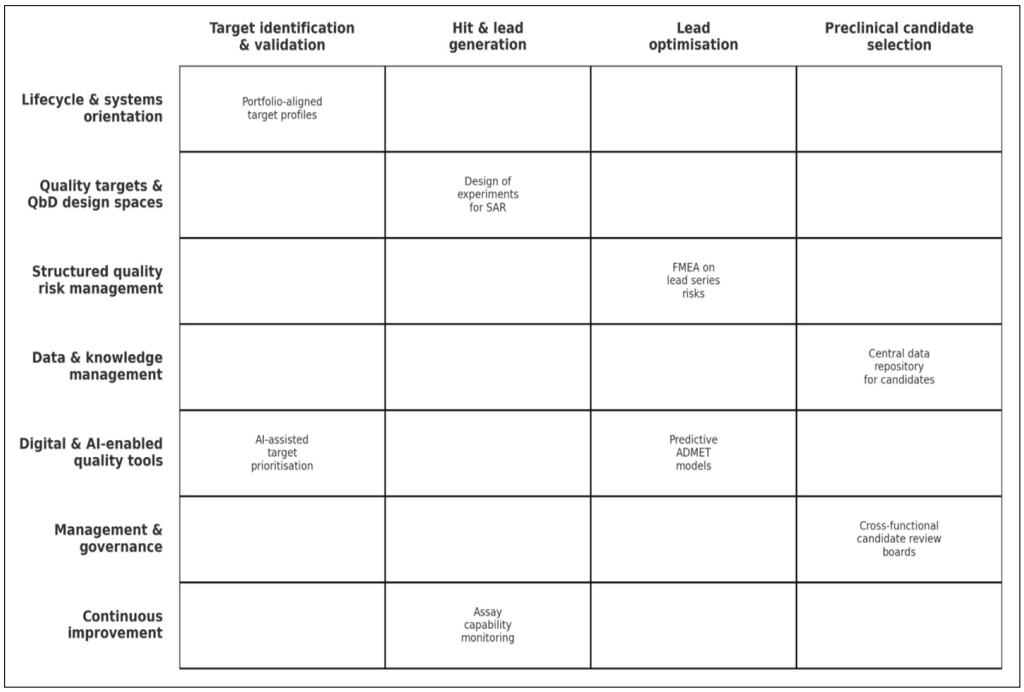

Figure 1. Integrated quality management framework for drug discovery R&D, linking discovery stages with lifecycle, risk-based, and digital quality principles (adapted from ICH Q9 (R1) and VanDuyse et al. [4, 10])

From an economic perspective, the reviewed AI and quality management literature indicates that early adoption of risk-based and data-driven practices has a significant impact on cost, time, and the probability of success. AI-enabled workflows reduce the need for extensive physical screening and identify promising targets and chemotypes earlier, which, when combined with QbD-type design thinking, narrows the set of candidates proceeding to expensive in vivo and preclinical development [5, 6, 8]. QRM applications in operational environments demonstrate that structured risk evaluations enable resources to be redirected towards high-risk, high-impact areas and that risk tools enhance the traceability of decisions [3, 7]. Within discovery, similar mechanisms apply when risk tools are used to prioritize project portfolios, allocate experimental budgets, and determine whether to evaluate hypotheses in parallel or sequentially.

The benchmarking work on ICH Q10 implementation indicates that a higher maturity of quality enablers, such as process performance monitoring, management review, CAPA management, and knowledge management, correlates with better quality outcomes and operational performance [10]. When mapped onto discovery R&D, this suggests that systematic monitoring of experimental processes (for example, assay robustness metrics or hit confirmation reproducibility), structured project review, and disciplined handling of deviations and lessons learned will have both quality and productivity effects. Reviews of total quality management and Six Sigma in the pharmaceutical industry reinforce that continuous improvement programs and statistical thinking reduce variability, improve process capability, and foster a culture of data-driven decision-making [1, 2].

Collectively, the results indicate that quality management principles relevant for drug discovery R&D can be grouped into six mutually reinforcing domains: lifecycle and systems orientation; explicit definition of quality targets and design spaces; structured risk management; digital and AI-enabled data and knowledge management; management responsibility and governance; and continuous improvement of both scientific and support processes. These domains can be directly linked to concrete practices and tools at each discovery stage, enabling a transition from informal, researcher-centred quality to organisational, system-based quality management in early R&D.

DISCUSSION

Interpretation of the results in light of recent literature reveals that mainstream pharmaceutical quality frameworks already incorporate elements suitable for discovery and R&D, yet their adoption upstream remains partial and fragmented. Total quality management and PQS reviews argue for organisation-wide involvement in quality, customer (patient) focus, process orientation, and continuous improvement [1, 2]. When these ideas are reframed for discovery, the "customer" extends to downstream development, manufacturing, and supply functions, which depend on the robustness, reproducibility, and manufacturability of candidates delivered by discovery teams.

A first group of implications relates to translating high-level principles into concrete operational practices in discovery projects. Table 1 summarises how core quality management principles identified in the literature correspond to typical practices along the discovery pipeline and shows representative sources. The synthesis suggests that lifecycle orientation in discovery necessitates an explicit connection between early hypotheses and downstream manufacturability and supply constraints, drawing on ICH Q10 interpretations of lifecycle quality [1, 10]. QbD-based literature suggests that quality targets should be defined not only for finished products but also for early molecular entities and experimental systems. For example, this involves specifying desired ranges of potency, selectivity, solubility, metabolic stability, and formulation feasibility, and exploring these design spaces through structured experimentation [2, 6, 8].

Table 1. Quality management principles and operationalisation in drug discovery R&D, with representative sources

Quality management principle	Operationalisation in drug discovery R&D	Representative sources
Lifecycle-based pharmaceutical quality system	Alignment of discovery targets and candidate profiles with downstream manufacturability, control strategy, and supply constraints; inclusion of development and supply functions in early governance forums	PQMS review [1]; QA/QC evolution [2]; Q10 impact analysis [10]
Quality by design and predefined quality targets	Definition of discovery-specific quality target profiles for molecular entities and preclinical candidates; use of the design of experiments to characterise SAR and developability windows	QbD reviews and case studies [2, 6, 8]
Structured quality risk management	Application of FMEA, HACCP, risk ranking, and fault-tree analysis to assess scientific, technical, and economic risks of targets, assays, and preclinical models; iterative review as evidence accrues	ICH Q9 (R1) [4]; QRM case study [3]; QRM review [7]
Data and knowledge management	Use of electronic lab notebooks, central data repositories, and metadata standards to preserve discovery knowledge and support reuse across projects	PQMS and QA/QC analyses [1, 2]; digital QMS literature [9]

Digital quality systems and analytics	Implementation of electronic QMS, dashboards for deviation/CAPA trends, process performance, and key discovery quality indicators; integration with LIMS and ELN systems	QA/QC in the twenty-first century [2]; digital transformation review [9]
AI-enabled decision support	Use of machine learning for target prioritisation, virtual screening, ADMET prediction, and anomaly detection in experimental data, embedded into risk assessments and project reviews	AI in drug discovery review [5]
Management responsibility and governance	Establishment of cross-functional quality and portfolio committees for discovery, periodic management reviews of discovery metrics, and risks	PQMS, Q10, and TQM analyses [1, 10]
Continuous improvement and statistical thinking	Routine use of trend analysis, capability indices, and structured lessons-learned for assays, models, and workflows; Six Sigma-style projects to reduce variability	TQM/Six Sigma review [1, 2]; QRM tools discussion [7]

The table highlights that the adoption of quality management in discovery R&D does not require entirely new principles; instead, it demands a deliberate extension and adaptation of existing frameworks to the characteristics of exploratory science, where knowledge is incomplete, hypotheses evolve rapidly, and failure is endemic. This adaptation must take into account the high degree of epistemic uncertainty emphasised in the revised ICH Q9 guideline, which recommends adjusting the formality of risk management to the level of uncertainty, importance, and complexity [4]. Discovery environments, characterized by high uncertainty and significant economic consequences of target or candidate failure, necessitate more formal risk management practices than those typically applied in academic-style research settings.

Quality risk management reviews emphasize that the practical application of FMEA, HACCP, and related tools helps to surface hidden process vulnerabilities, clarify assumptions, and structure decision-making [3, 4, 7]. In discovery R&D, this translates into formal risk workshops on target validity, the translational value of models, assay robustness, and off-target or toxicity risks, conducted with cross-functional teams that include discovery, DMPK, toxicology, formulation, and supply chain representatives. Recording these assessments in a QMS environment and reviewing them as evidence accumulates aligns with the iterative risk review loop described in ICH Q9 (R1) [4].

Digitalisation and AI have a dual influence. Digital QMS and analytics platforms, described in QA/QC and digital transformation publications, provide the backbone for documentation control, deviation, and CAPA management, electronic lab notebooks, and data lakes [2, 9]. AI-based tools leverage these data assets for predictive analytics, anomaly detection, and decision support across target selection, virtual screening, and route design [5]. Table 2 provides an overview of digital and AI-enabled tools that can support quality management in discovery R&D, drawing on reviewed AI and digital transformation literature.

Table 2. Digital and AI-enabled quality tools relevant for discovery R&D and expected impact

Tool category	**Typical use in discovery R&D quality management**	**Anticipated impact on quality, cost, and time**	**Representative sources**
Electronic quality management system (eQMS)	Management of SOPs, changes, deviations, CAPA, and training records for discovery units; integration with development and manufacturing QMS	Higher traceability, faster deviation closure, better alignment of discovery practices with corporate standards, and reduced compliance risk at hand-off	QA/QC evolution [2]; PQMS review [1]; digital transformation [9]
Electronic lab notebooks and LIMS	Standardised recording of experiments, assays, sample tracking, and metadata across discovery sites	Improved reproducibility and auditability of experiments; easier aggregation of data for risk assessments and design of experiments	QA/QC and digitalisation literature [2, 9]
Analytics dashboards and KPI platforms	Monitoring of hit confirmation rates, assay robustness indices, project milestone adherence, deviation rates, and CAPA effectiveness in discovery	Earlier detection of systematic issues, better resource allocation, and more informed management reviews	PQMS and digital transformation sources [1, 9]
AI-assisted target identification and validation	Prioritisation of targets based on multi-omics data, literature mining and network analysis; quantification of confidence in target–disease relationships	Reduced probability of pursuing weak or non-causal targets; higher expected success rate of downstream programmes	AI in drug discovery review [5]

AI-enabled virtual screening and de-novo design	In silico screening of large libraries, generative modelling of candidate structures, and prediction of on/off-target profiles	Lower screening costs, accelerated hit identification, and better initial quality of chemical series	AI literature [5]
Predictive ADMET and toxicity models	Early assessment of pharmacokinetic and safety liabilities using machine learning models	Earlier elimination of compounds with a high probability of failure improved the efficiency of in vivo studies	AI review and referenced ADMET studies [5]
AI-augmented QRM tools	Integration of predictive models into risk matrices and FMEA scoring, automated detection of emerging risks from data streams	More objective risk scoring, continuous updating of risk profiles, and improved prioritisation of mitigation actions	AI and QRM sources [4, 5, 7]

These tools collectively suggest a future state in which discovery R&D operates inside an integrated digital quality environment, where data from experiments, quality events, and project governance flow into a common analytical layer. In such a setting, the economic evaluation of discovery projects can incorporate not only classical financial parameters but also quality indicators, such as risk profiles, process capabilities, knowledge maturity, and data integrity metrics.

Digital and AI-enabled tools shift the feasible frontier of such formal practices. Electronic QMS and integrated analytics platforms reduce the administrative burden of documentation and facilitate real-time visibility of deviations, trends, and performance indicators, as indicated by QA/QC and digital transformation studies [2, 9]. AI-driven applications in target identification, virtual screening, and predictive safety, as described in recent reviews [5], can be integrated into QbD and QRM processes, allowing AI outputs to inform risk matrices, influence experiment design, and establish go/no-go criteria.

The discussion of QRM practices and revised ICH Q9 guidance underscores the importance of managing subjectivity, bias, and variability in risk assessments [4, 7]. For discovery portfolios, this implies that qualitative judgments on the scientific promise or "novelty" of targets should be grounded in structured evidence reviews, explicit assumptions, and transparent documentation. Cross-functional participation in risk assessments, combined with AI-supported evidence summaries, reduces individual bias and aligns risk perceptions across functions [4, 5, 7].

Finally, the benchmarking evidence on ICH Q10 implementation suggests that quality enablers, such as management review, CAPA effectiveness, and knowledge management, show a measurable association with quality outcomes [10]. Adoption of similar enablers in discovery R&D—regular management reviews of discovery quality metrics, structured root-cause analysis of failed programmes, systematic capture of lessons learned, and reuse of knowledge—links quality management directly with portfolio value and long-term learning.

CONCLUSION

The application of modern pharmaceutical quality management principles to drug discovery and R&D requires the reinterpretation of lifecycle-based pharmaceutical quality systems, quality by design, and quality risk management in an environment dominated by scientific uncertainty and exploratory experimentation. The analysis demonstrates that these principles can be translated into discovery-specific practices that influence target selection, assay and model design, lead optimisation and candidate selection, with direct impact on the economic performance of R&D portfolios.

Systematisation of recent literature and regulatory guidance leads to the identification of six main domains of quality management relevant for discovery: lifecycle and systems orientation, explicit quality targets and design spaces, structured risk management, digital and AI-enabled data and knowledge management, management responsibility and governance, and continuous improvement. Mapping these domains onto the discovery pipeline shows how each stage can incorporate concrete quality practices, from risk-based target and series prioritisation to formal QRM exercises at candidate selection.

The proposed integrated framework, reflected in the conceptual figure, links discovery stages with quality principles and operational tools, including digital QMS, analytics dashboards, and AI applications. This framework provides R&D managers with a structured basis for designing governance, metrics, and digital infrastructures that embed quality into daily discovery operations rather than treating it as a downstream compliance requirement.

The article can be used by pharmaceutical and biotech organisations, CROs, and academic drug discovery centres when designing or upgrading discovery quality systems, particularly where objectives include improved portfolio productivity, reduction of late-stage attrition, and more rigorous early economic evaluation of new drug discovery projects.

REFERENCES

1. Bhandwalkar, S. G., Bhopate, M. S., Khopade, S. S., & Kunjir, V. V. (2024). A review: Pharmaceutical quality management systems (TQM, CFR 21 Part 11, ICH Q10, WHO-GMP requirements, Six Sigma). International Journal of Pharmaceutical Research and Applications, 9(2), 102–122. DOI: 10.35629/7781-0902102122

2. Dandekar, P., Dandekar, M. R., & Putane, P. (2024). Pharmaceutical quality control and assurance in the 21st century. Asian Journal of Pharmaceutics, 18(3), 723–726. https://doi.org/10.22377/ajp.v18i3.5623

3. Elmadhoun, B., Jalali, A. H., Pahlevan, A., & Al-Fadhli, S. (2025). Quality risk management in the final operational stage of sterile pharmaceutical manufacturing: A case study highlighting the management of sustainable-related risks in product sterilization, inspection, labeling, packaging, and storage processes. Sustainability, 17(4), 1670. https://doi.org/10.3390/su17041670

4. International Council for Harmonisation. (2023). ICH guideline Q9 (R1) on quality risk management (Step 5, revision 2). European Medicines Agency. URL: https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human-use-ich-guideline-q9-r1-quality-risk-management-step-5-revision-2_en.pdf

5. Kant, S., Deepika, & Roy, S. (2025). Artificial intelligence in drug discovery and development: Transforming challenges into opportunities. Discover Pharmaceutical Sciences, 1, 7. https://doi.org/10.1007/s44395-025-00007-3

6. Khan, A., Naquvi, K. J., Haider, M. F., & Khan, M. A. (2024). Quality by design – newer technique for pharmaceutical product development. Intelligent Pharmacy, 2(1), 122–129. https://doi.org/10.1016/j.ipha.2023.10.004

7. Kushwah, G., Chhabra, G., Manocha, N., & Sarsodia, G. (2025). Quality risk management: A current international pharmaceutical industry practice to optimize the product quality. International Journal of Pharmaceutical Sciences, 3(7), 96–106. https://doi.org/10.5281/zenodo.15782537

8. Prajwala, S., Rali, S., & Kiran, I. (2024). Implementation of quality by design (QbD) paradigm and quality risk management tools for addressing formulation challenges for transdermal patch: A review. J Rep Pharm Sci, 2024, 12(1), 1-16. https://doi.org/10.5812/jrps.146211.

9. Ullagaddi, P. B., Sindhe, S. L., & co-authors. (2024). Digital transformation in the pharmaceutical industry. International Journal of Health Sciences, 8(3), 253–262. DOI:10.5539/ijbm.v19n5p16

10. VanDuyse, S. A., Fulford, M. J., & Bartlett, M. G. (2021). ICH Q10 pharmaceutical quality system guidance: Understanding its impact on pharmaceutical quality. The AAPS Journal, 23(6), 117. https://doi.org/10.1208/s12248-021-00657-y