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Development Of Analysis Methods Based On Scientific Approach And Risk-Based Approach In The Pharmaceutical Industry: Narrative Review

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Abstract
The development of analytical methods and quality systems in the pharmaceutical industry is now shifting from the conventional trial and error approach to a systematic, scientific, and risk-based approach to meet international regulatory demands. This article aims to examine the effectiveness of implementing the concepts of Analytical Quality by Design (AQbD), Quality by Design (QbD), and various risk management instruments in improving product quality and operational efficiency in the pharmaceutical industry. Methods: This study is the result of a literature review of 15 scientific journals discussing analytical method development, process validation, product stability, and operational risk management. The analysis shows that the application of AQbD and QbD through parameters such as Analytical Target Profile (ATP) and Design of Experiments (DoE) can increase the robustness of analytical methods and reduce the risk of failures such as Out of Specification (OOS). The use of risk management tools such as Failure Mode and Effect Analysis (FMEA) has proven effective in identifying cross-contamination risks and distribution process failures. The integration of scientific and risk-based approaches has a significant positive impact in ensuring quality consistency, accelerating time-to-market, and supporting compliance with ICH guidelines (Q8, Q9, Q10, Q14).

Keywords: ***Analytical Quality by Design (AQbD), Quality by Design (QbD), Risk-Based Approach, Pharmaceutical Industry, Quality Risk Management.***

INTRODUCTION

The development of the modern pharmaceutical industry demands a quality assurance system capable of ensuring consistent product safety, effectiveness, and stability throughout storage and use. Drug stability is a critical parameter because it directly relates to the quality and safety of pharmaceutical products. Furthermore, advances in modern formulation technology have made pharmaceutical products increasingly sensitive to environmental influences, necessitating standardized quality control in accordance with International Council for Harmonization (ICH) guidelines (Harahap et al., 2026).

The implementation of these quality guidelines is closely related to risk management in the pharmaceutical industry, which aims to identify and control potential deviations that could impact product quality. Various root cause analysis methods such as Fishbone Diagrams, 5 Whys, and Failure Mode and Effect Analysis (FMEA) are used to help determine the root cause of problems so that corrective and preventive actions can be implemented effectively (Susendi et al., 2021). A risk management approach is also applied to pharmaceutical education laboratories through an ISO 9001:2015-based quality management system to improve the effectiveness of laboratory management and the quality of educational services (Rusdiana & Fitra, 2023).

The pharmaceutical industry also faces various operational risks originating from production processes, people, and work systems. Therefore, the implementation of ISO 31000:2018-based risk management is necessary to maintain operational continuity and the quality of pharmaceutical products (Pharmacopia, 2024). One important risk in the production process is cross-contamination, which can impact product safety and quality. Therefore, the FMEA method is used to identify and evaluate potential risks so that control measures can be implemented optimally (Azzahra et al., 2024).

These quality improvement efforts have led to the development of the Quality by Design (QbD) approach in the development and validation of pharmaceutical production processes. This approach

emphasizes a scientific understanding of processes to produce products with consistent quality and reduce variability in the production process (Sinuraya, 2010). The QbD concept later evolved into Analytical Quality by Design (AQbD) in the field of pharmaceutical analysis, which aims to produce more robust, efficient, and risk-management-based analytical methods through the application of Design of Experiments (DoE) and ICH Q14 guidelines (Ambekar, 2025).

The application of AQbD has been proven to improve the quality, flexibility, and efficiency of pharmaceutical analytical methods while supporting the concept of green analytical chemistry by reducing the use of solvents and chemical waste (Das & Maity, 2017) (Thorat et al., 2026). Thus, the implementation of risk management, QbD, and AQbD is an important strategy in supporting the development of a pharmaceutical industry that is more effective, safe, and in accordance with modern regulations (Dewi et al., 2022).

RESEARCH METHODS

This research was conducted using a systematic literature review of various scientific literature related to the development of risk analysis and management methods in the pharmaceutical industry. Data collection was conducted through a search of scientific articles from digital databases, such as Google Scholar, focusing on publications published between 2017 and 2026. Fifteen relevant journals were selected as primary data sources, including industry case studies, experimental research, and narrative reviews on the application of Quality by Design (QbD) and Analytical Quality by Design (AQbD).

The analysis was conducted by reviewing various scientific instruments such as Design of Experiments (DoE), Central Composite Design (CCD), and Definitive Screening Design (DSD) in process optimization. Furthermore, risk evaluation was conducted by examining the application of quality risk management tools such as Failure Mode and Effect Analysis (FMEA), Fishbone Diagram, 5 Why Analysis, and Cause-Effect Matrix (CEM). All these studies are synthesized by referring to international regulatory standards, including the International Council for Harmonization (ICH) guidelines Q8, Q9, Q10, Q1A(R2), and Q14, as well as operational frameworks such as ISO 31000:2018 and GAMP 5 to draw comprehensive conclusions.

RESULTS AND DISCUSSION

No.	Journal	Author	Analytical/Scientific Methods	Risk Based Approach (RBA)	Main Results/Conclusions	Relevance to Method Development
1	Risk Assessment of the Storage and Distribution Process of Raw Materials in Pharmaceutical Industry Warehouses Using the Failure Mode and Effect Analysis Method Approach	(Musyaffa et al., 2024)	Using observational methods and systematic analysis with FMEA for identification, analysis, and evaluation of risks in the storage and distribution of raw materials.	Using severity, occurrence, and detection parameters to determine the risk level and priority of control actions.	FMEA is able to identify potential process failures and help determine preventive measures to maintain the quality of pharmaceutical products.	Demonstrates that the development of pharmaceutical work systems and methods must be carried out scientifically and risk-based to ensure product quality remains guaranteed.
2	Approach of Analytical Quality by Design and Regulatory Need	(Mahapatra, 2022)	Using the AQbD approach through ATP, CQA, MODR, and DoE to understand the variables that influence the performance of analytical methods.	Conduct risk identification using risk management tools according to ICH Q8, Q9, and Q10.	AQbD improves method robustness, reduces OOS, and increases the efficiency of analytical method validation.	It is highly relevant as it discusses the development of pharmaceutical analysis methods based on international scientific and regulatory approaches.
3	Quality by Design Approach for an Orally Disintegrating Tablet Analytical Method Validation	(Demirel et al., 2018)	Using AQbD in the development of NP-HPLC methods through ATP, DoE, CCD, CQA, and Ishikawa diagrams.	Using Fishbone diagram and FMEA to identify risk factors that affect HPLC method performance.	Produces a valid, robust, accurate, and precise NP-HPLC method for tadalafil impurity analysis.	Provides a real example of the development of AQbD-based HPLC analysis methods in the pharmaceutical industry.
4	An industrial case study: QbD to accelerate time-to-market of a	(Testas et al., 2021)	Using the Quality by Design (QbD) methodology which includes Design of	Conducting Criticality Assessment (CA) using Cause-Effect Matrix (CEM) and	The implementation of QbD successfully increases the understanding of products and processes	Demonstrates how statistical tools (DoE/DSD) can be used to optimize

	drug product		Experiments (DoE), Definitive Screening Design (DSD), and multivariate linear regression using JMP® and MATLAB software.	Failure Mode and Effect Analysis (FMEA) to identify critical quality attributes (CQAs) and critical process parameters (CPPs).	systematically, which in turn accelerates time-to-market and reduces the risk of product defects.	formulations and define a Design Space that provides regulatory flexibility.
5	Case Study Risk Based Approach for Life Cycle Computerized System in Pharmaceutical Industry	(Fitrio, 2019)	Using the framework Good Automated Manufacturing Practice (GAMP) 5 dari ISPE dan model validasi V (Validation V model framework)	Apply risk management throughout the system lifecycle (from planning to termination), including classifying systems based on their impact on patient safety, product quality, and data integrity.	A risk-based approach enables the pharmaceutical industry to meet cGMP standards more efficiently through measurable controls at every stage of the computerized system life cycle.	Emphasizes the importance of GMP data evaluation and software categorization (GAMP 5) in designing a validation strategy appropriate to the complexity of the system.
6.	Drug Stability in Pharmaceutical Product Development: A Review Based on International Council for Harmonisation (ICH) Guidelines	(Harahap et al., 2026)	Narrative literature review based on ICH Q1A(R2) guidelines	A risk-based approach to the quality, safety, effectiveness and shelf life of pharmaceutical products	Stability studies play a critical role in ensuring the quality and effectiveness of pharmaceutical products throughout their shelf life. ICH guidelines contribute to the global harmonization of pharmaceutical product quality.	Highly relevant in pharmaceutical formulation development and product stability validation.
7.	A Study of Root Cause Analysis Methods Used in Risk Managemen	(Susendi et al., 2021)	Literature review using Fishbone Diagram, Pareto Analysis, 5 Whys,	Implementation of Quality by Design (QbD) and quality risk management in the	Each root cause analysis method has advantages and disadvantages in identifying root causes and	Relevant in the development of quality management systems and risk control

	t in the Pharmaceutical Industry		Brainstorming, FMEA, and Six Sigma methods	pharmaceutical industry	controlling quality risks.	in the pharmaceutical industry.
8.	Pharmaceutical Laboratory Risk Management Analysis for ISO 9001:2015 Requirements Using the 5 Why Analysis Method	(Rusdiana & Fitra, 2023)	Field observations and interviews using the 5 Why Analysis method	ISO 9001:2015 based laboratory risk management	Priority risks were found in the form of difficulty finding equipment and a lack of practical materials due to a lack of laboratory administration procedures.	Relevant for the implementation of pharmaceutical laboratory quality management systems.
9.	Operational Risk Management at PT Kimia Farma Sungwun Pharmacopia	(Pharmacopia, 2024)	Qualitative descriptive method based on ISO 31000:2018	Implementation of operational risk management based on ISO 31000:2018	17 operational risks were found, ranging from low to extreme risks, and required risk mitigation strategies.	Relevant for operational risk management of the pharmaceutical raw materials industry.
10.	Risk Assessment using Failure Mode and Effects Analysis (FMEA) Method related to Cross-Contamination in Packaging Area in XYZ Pharmaceutical Industry	(Azzahra et al., 2024)	Direct observation and risk analysis using the FMEA method with RPN calculations	Quality risk assessment related to cross-contamination in pharmaceutical packaging areas	A low to very high risk of cross-contamination was found, requiring immediate control measures.	Highly relevant for quality control, cleaning process validation, and cross-contamination prevention.
11.	Quality by Design (QbD) Approach in Granulation Process Validation in Tablet Production	(Sinuraya, 2010)	Review of articles/literature studies using Google Scholar literature related to QbD, process validation,	Pendekatan QbD berbasis pengendalian mutu dan validasi proses granulasi tablet.	QbD approach based on quality control and validation of tablet granulation process.	Relevant in the validation of granulation processes and the development of the quality of pharmaceutic

			granulation, and tablets.			al tablet preparations.
12.	A Comprehensive Review of Analytical Quality by Design, ICH Q14, and Design of Experiments in Pharmaceutical Analysis	(Ambekar, 2025)	Review articles regarding AQbD, ICH Q14, and Design of Experiments (DoE) in pharmaceutical analysis.	Risk-based and design space approaches in the development of pharmaceutical analysis methods.	The integration of AQbD, ICH Q14, and DoE improves the robustness, efficiency, flexibility, and regulatory compliance of analytical methods.	Highly relevant for the development of modern risk-based pharmaceutical analysis methods.
13.	Analytical Quality by Design (AQbD): A New Horizon For Robust Analytics in Pharmaceutical Process and Automation	(Das & Maity, 2017)	Literature study related to AQbD, DoE, FDA, ICH, and MODR in pharmaceutical analysis methods.	The AQbD approach is based on risk management and quality control of analytical methods.	AQbD produces a method that is more robust, flexible, and reduces the risk of OOS and OOT compared to conventional methods.	Relevant for validation of analytical methods and optimization of pharmaceutical analytical processes.
14	Analytical Quality by Design (AQbD) Approach for the Simultaneous Quantification of FDC in a Cardiovascular Drug by RP-HPLC Method	(Thorat et al., 2026)	RP-HPLC method with AQbD and Central Composite Design (CCD) approaches.	AQbD and green chemistry approaches in RP-HPLC method validation.	The RP-HPLC method is well validated with linearity, precision, accuracy, and robustness that meet ICH guidelines and is more environmentally friendly.	Highly relevant for the development of RP-HPLC methods and continuous pharmaceutical analysis.
15.	Quality By Design: Approach to Analytical Method Validation	(Dewi et al., 2022)	Review articles on AQbD, ATP, CQA, DoE, MODR, and control strategy.	A risk-based approach to pharmaceutical analytical method validation.	AQbD improves method understanding, reduces method failures, and supports the development of efficient and robust methods.	Relevant in validation of analytical methods and development of pharmaceutical quality systems.

The development of analytical methods in the pharmaceutical industry plays a crucial role in ensuring the quality, safety, and effectiveness of pharmaceutical products. Analytical methods are used to ensure that raw materials, intermediates, and finished products meet established specifications,

ensuring consistent product quality. With technological advancements and increasing demands from international regulations, analytical method development is no longer based on conventional trial and error, but rather on a systematic, scientific, risk-based approach. This approach aims to improve understanding of analytical methods, ensuring high levels of accuracy, precision, sensitivity, specificity, and robustness. Furthermore, a scientific, risk-based approach supports the implementation of a pharmaceutical quality system in accordance with International Council for Harmonization (ICH) guidelines, such as ICH Q8, ICH Q9, ICH Q10, and ICH Q14, which emphasize the importance of scientific understanding and risk control throughout the pharmaceutical product lifecycle (Ambekar, 2025).

The scientific approach to analytical method development is generally implemented through the concepts of Analytical Quality by Design (AQbD) and Quality by Design (QbD). The AQbD concept emphasizes that method quality must be built from the beginning of development through an understanding of the relationship between method parameters and expected analytical results. The AQbD stages include establishing an Analytical Target Profile (ATP), identifying Critical Quality Attributes (CQAs), determining Critical Method Parameters (CMPs), and optimizing the method using Design of Experiments (DoE). This approach enables the pharmaceutical industry to understand the influence of method variables on analytical performance, thereby minimizing the risk of method failures such as Out of Specification (OOS) and Out of Trend (OOT). Furthermore, a risk-based approach is implemented through risk identification, evaluation, and control using various risk management tools such as Failure Mode and Effect Analysis (FMEA), Fishbone Diagram, Risk Priority Number (RPN), Cause Effect Matrix (CEM), and 5 Why Analysis (Mahapatra, 2022).

Based on a review of 15 journals, most studies indicate that a scientific and risk-based approach has a significant positive impact on the development of analytical methods and quality systems in the pharmaceutical industry. Research (Musyaffa et al., 2024) demonstrated that the FMEA method is effective in identifying risks in the storage and distribution of raw materials in pharmaceutical warehouses. Using severity, occurrence, and detection parameters, the industry can prioritize risks and systematically implement preventive measures to maintain raw material quality and prevent product damage during distribution. These research findings demonstrate that a risk-based approach is crucial for maintaining consistent pharmaceutical product quality.

The application of AQbD in analytical method development is also discussed in research (Mahapatra, 2022), which shows that the use of ATP, CQA, MODR, and DoE can improve the robustness of analytical methods and reduce the risk of method failure. The study also explains that the integration of ICH Q8, Q9, and Q10 guidelines can improve method validation efficiency and strengthen compliance with international regulations. Similar results were also described by (Dewi et al., 2022), who stated that the application of AQbD can improve understanding of analytical method performance through systematic control strategies, thereby making the developed method more efficient and suited to the needs of the modern pharmaceutical industry.

Research (Demirel et al., 2018) demonstrated that the application of AQbD to the NP-HPLC method for tadalafil impurity analysis produced a valid, accurate, precise, and robust method. This study used a Fishbone Diagram and FMEA to identify risk factors affecting HPLC method performance. The results showed that identifying risks early in method development significantly improved the quality of the analytical method. Furthermore, research (Das & Maity, 2017) explained that AQbD is a modern approach capable of producing more flexible and robust analytical methods than conventional methods because it uses a scientific and risk-based approach throughout all stages of method development.

The use of Design of Experiments (DoE) is also essential in analytical method development and pharmaceutical process optimization. Research (Testas et al., 2021) shows that the use of QbD, Definitive Screening Design (DSD), and multivariate regression approaches can accelerate the time-to-market of pharmaceutical products and reduce the risk of product defects by determining the optimal design space. These research results indicate that understanding the relationship between

process variables and product quality attributes can improve the efficiency of pharmaceutical product development. Similar results are also described by (Ambekar, 2025), who stated that the integration of AQbD, ICH Q14, and DoE can increase regulatory flexibility, method validation efficiency, and robustness of pharmaceutical analysis methods, thus making the developed methods more systematic and compliant with international regulations.

Research (Thorat et al., 2026) shows that the application of AQbD and Central Composite Design (CCD) to the RP-HPLC method produces an analytical method that meets ICH validation parameters such as linearity, precision, accuracy, and robustness. Furthermore, the study applied green chemistry concepts, making the developed method more environmentally friendly. This demonstrates that the development of modern analytical methods focuses not only on the quality of analytical results but also considers sustainability and environmental safety.

In addition to analytical method development, journal reviews also show that a risk-based approach is applied to various other aspects of the pharmaceutical industry, such as process validation, product stability, computerized systems, laboratories, and operational risk management. Research (Sinuraya, 2010) shows that the application of QbD to tablet granulation process validation can produce granules and tablets with more consistent quality and reduce variability in the production process. Research (Harahap et al., 2026) also shows that stability studies based on ICH Q1A(R2) guidelines are crucial in ensuring the quality, safety, effectiveness, and shelf life of pharmaceutical products during storage and distribution.

A risk-based approach to computerized pharmaceutical industry systems is discussed in research (Fitrio, 2019), which uses the GAMP 5 framework and the V validation model to maintain data integrity and improve system validation efficiency in accordance with cGMP principles. The research demonstrates that implementing risk management throughout the entire lifecycle of a computerized system can improve data security and pharmaceutical system effectiveness. Furthermore, research (Pharmacopia, 2024) demonstrates that implementing ISO 31000:2018-based operational risk management can identify various operational risks, from low to extreme, in the pharmaceutical raw materials industry, enabling more effective risk mitigation strategies.

Research related to root cause analysis and risk control has also shown significant results. (Susendi et al., 2021) explained that the Fishbone Diagram, Pareto Analysis, 5 Whys, Brainstorming, FMEA, and Six Sigma methods play a crucial role in identifying root causes and controlling quality risks in the pharmaceutical industry. This research demonstrates that a scientific approach to root cause analysis can help the pharmaceutical industry improve its quality management system more effectively. This is supported by research (Rusdiana & Fitra, 2023), which shows that the 5 Whys Analysis method can be used to identify the root causes of problems in pharmaceutical laboratories, such as difficulty finding equipment and shortages of laboratory materials due to weak laboratory administration systems.

Research (Azzahra et al., 2024) also demonstrated that the FMEA method is effective in assessing cross-contamination risks in pharmaceutical packaging areas. The results indicated low to very high risks, necessitating immediate control measures to prevent product quality degradation. This study confirms the importance of a risk-based approach in quality control and cross-contamination prevention in the pharmaceutical industry.

Overall, the review of 15 journals shows that the development of analytical methods based on scientific and risk-based approaches has a significant positive impact on the pharmaceutical industry. This approach has been proven to improve the robustness of analytical methods, reduce the risk of method and product failure, strengthen quality management systems, increase validation efficiency, accelerate product development, and support compliance with international regulations. The application of AQbD, QbD, FMEA, DoE, and various other risk management tools also helps the pharmaceutical industry improve product quality consistently and sustainably. Therefore, scientific and risk-based approaches are essential components in the development of modern pharmaceutical

analytical methods to ensure safe, effective, high-quality pharmaceutical products that comply with global regulatory standards.

CONCLUSIONS

Based on the results of the narrative review, it can be concluded that the development of analytical methods in the pharmaceutical industry currently uses a scientific approach and a risk-based approach (RBA) through the application of Quality by Design (QbD), Analytical Quality by Design (AQbD), Design of Experiments (DoE), and various risk management methods such as FMEA and 5 Why Analysis. This approach has been proven to improve the quality, robustness, accuracy, and efficiency of analytical methods and helps minimize the risk of failure of pharmaceutical methods and products. In addition, the application of a risk-based approach also supports process validation, quality control, product stability, and compliance with international regulations such as ICH Q8, Q9, Q10, and Q14. Overall, the scientific and risk-based approach has a positive impact on ensuring the quality, safety, effectiveness, and sustainability of pharmaceutical products, making it an important part of the development of the modern pharmaceutical industry.

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