Available online on 15 Jun, 2026 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University

Review Article Open Access

Application of Failure Modes and Effects Analysis (FMEA) for Conducting Multiple Risk Assessments in a New Pharmaceutical Facility

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Abstract

Global pharmaceutical compliance frameworks, WHO GMP, and ICH Q9 (R1) all require the application of Quality Risk Management (QRM). Infrastructure, clean utilities, sterilization systems, environmental controls, and process equipment are all intricately integrated in recently built pharmaceutical production plants, generating a number of possible sites of failure during commissioning. Therefore, to guarantee operational robustness and regulatory compliance, a proactive and organized risk assessment strategy is crucial.

For the risk-based commissioning of a new oral solid dosage production facility, this study suggests an integrated, multi-domain application of FMEA. A group of people from different departments worked together to use FMEA in five important areas: the steps for introducing new products, the equipment used for sterilizing, the system for making pure steam, the system for making purified water, and the design and layout of the facility. ICH Q9-aligned Severity, Occurrence, and Detection score was used to identify and rank the risks. The design concept for facility lifecycle management included structured mitigation techniques.

The suggested integrated FMEA model supports ongoing GMP adherence and improved quality assurance during pharmaceutical facility implementation by providing a scalable and regulatory-aligned method for early risk identification, cross-functional cooperation, and proactive compliance management.

Conclusion: This paper demonstrates that the combination of an inter-domain application of the FMEA provides a structured and efficient approach to risk identification and reduction during commissioning of pharmaceutical facilities. It ensures enhanced operational reliability, cross-functional teamwork and continuous compliance with GMPs, by complying with ICH Q9. Altogether, it can be concluded that the model offers a versatile model of the proactive quality risk management in modern pharmaceutical manufacturing.

Keywords: Quality Risk Management, FMEA, ICH Q9 (R1), GMP Compliance, Pharmaceutical Facility Design, Risk-Based Commissioning

Article Info: Received 16 Feb 2026; Review Completed 18 Apr 2026; Accepted 28 Apr 2026

Cite this article as:
Patel H, Movaliya V, Kanaki N, Zaveri M, Verma R, Patel Z. Application of Failure Modes and Effects Analysis (FMEA) for Conducting Multiple Risk Assessments in a New Pharmaceutical Facility. Int. J. Drug Reg. Affairs [Internet]. 2026 Jun 15 [cited 2026 Jun 15]; 14(2):1-3. Available from: http://ijdra.com/index.php/journal/article/view/868

DOI: https://doi.org/10.22270/ijdra.v14i2.868
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1. Introduction

Traditional quality control-driven approaches have given way to risk-based pharmaceutical quality systems that are regulated by globally harmonized standards in the pharmaceutical manufacturing environment. Q9 (R1) from ICH says that Quality Risk Management (QRM) is a planned method to find, lower, talk about, and judge risks to product quality at all stages of its life. Regulatory bodies all over the world expect risk-based decision-making to be used in the planning, building, testing, and ongoing operations of facilities. (1)

New pharmaceutical manufacturing facilities, especially those that make Oral Solid Dosage (OSD), have complicated, multi-layered systems that include planning for infrastructure, zoning for HVAC, clean utilities, sterilization systems, automated equipment, and environmental monitoring. Because these systems rely on each other, a failure in one subsystem could cause operations to stop, break the rules, or change the quality of the product. (2)

Most traditional risk management methods focused on looking into deviations after they happened or validating specific processes. But new rules mean that facility lifecycle management must now include proactive identification of possible failure modes in the early stages. Early detection and mitigation of design- and utility-related hazards significantly reduce downstream quality failures and compliance gaps. (3)

Analysis of Failure Modes and Effects (FMEA) is a structured, quantitative way to look at risk that is often used in drug research and production. FMEA lets you prioritize your mitigation efforts by systematically finding failure modes, figuring out what caused them and what they did, and giving them Severity, Occurrence, and Detection scores. Even though FMEA has been used a lot for certain manufacturing processes, not much research has been done on how it can be used together across clean utilities, sterilization systems, facility infrastructure, and product launch under one commissioning plan. (4)

This study proposes a systematic, multi-domain FMEA methodology employed for the commissioning of a new pharmaceutical production facility. The framework's support for risk-based decision-making across facility-level and process-level systems improves lifecycle quality management and regulatory preparation. This is in line with ICH Q9 principles. (1)

2. Study Design

2.1. Structure for Risk Governance and Study Design

For a new pharmaceutical manufacturing facility that will make solid dosage forms for oral use, a systematic, cross-functional risk assessment model was created. Study employed a prospective risk assessment methodology during facility commissioning. (5)

A group of professionals from different fields:

- QA department
- Engineering department
- Production department
- RA department
- Validation

2.2. The range of risk assessment

FMEA was put into action in a planned way in five important areas:

- Building and facility
- Purified water generating system
- Pure steam generating system
- Autoclave
- Introduction of product

Before the assessment, the system boundaries were clearly defined to avoid scope overlap.

2.3. Framework for the FMEA Methodology

The specified sequence was followed in the FMEA process:

- Defining the system or subsystem
- Identifying possible modes of failure
- Identifying the root causes; identifying possible impacts on quality, safety, or compliance
- Assigning severity, occurrence, and detection scores
- Prioritizing risks according to predetermined acceptance criteria
- Creating mitigation plans
- Post-mitigation evaluation

ICH Q9-aligned predetermined qualitative descriptors were used to develop risk score criteria. Internal quality risk acceptability standards were used to classify risk levels into Low, Medium, and High categories.] (6)

3. Study Outcomes

Using FMEA fully in five areas made it easier to find and rank risks in a systematic way when the facility was being built.

At the facility level, risks associated with ventilation, safety systems, zoning, the movement of people and materials, and layout design were identified and assessed. Before operations could begin, the evaluation made sure that all problems with the infrastructure were fixed.

We used clean utility systems to learn about potential operational risks, such as system integrity, pressure stability, and monitoring reliability. These systems make distilled steam and clean water. For the first time, the system's structured framework made it possible to use strategies for monitoring and preventive maintenance.

We looked at how sterilization systems and important tools could make things less safe, less reliable, and less effective. This helped us figure out which parts of validation were the most important.

They looked at the environmental monitoring and automation systems to make sure that the alarms were set up and watched in a way that followed GMP rules.

During the product launch, important steps like dispensing, mixing, granulation, compression, and coating were checked for possible risks of being unpredictable or getting mixed up with other products. You could plan for problems ahead of time with the integrated framework instead of just looking at the end result.

The multi-domain FMEA model made structured risk-based commissioning easier because it could be used in a lot of different fields, such as utilities, manufacturing, equipment, and infrastructure.

4. Discussion

The findings underscore the significance of employing Quality Risk Management in the initial construction of pharmaceutical facilities. FMEA is frequently applied to processes; however, if you want to fully understand how the whole system works, it is better to use it on utilities and building infrastructure.

The operation of a utility and the construction of a facility directly influence production quality. We can avert future quality issues by examining these systems comprehensively. This study utilized a cross-functional methodology to assess the viability of practical mitigation planning and fair risk identification.

The integrated framework facilitates long-term risk management by ensuring that systems, processes, or

equipment undergo regular assessments following updates. This is the content of ICH Q9 and ICH Q10.

Identifying risks in advance during commissioning facilitates inspections and demonstrates a commitment to quality from a compliance perspective. The proposed framework provides a valuable example of structured risk-based implementation applicable to other pharmaceutical companies.

5. Conclusion

Utilizing FMEA to construct a new pharmaceutical production facility is a strategic and methodical approach to address quality risks.

This approach facilitates the early identification and prioritization of potential failure modes by examining the risks associated with manufacturing, clean utilities, sterilization systems, environmental monitoring, and facility infrastructure. This enhances long-term quality assurance, operational reliability, and adherence to good manufacturing practices (GMP).

The proposed model facilitates risk management throughout the entire lifecycle of a building and a product. It adheres to the ICH Q9 (R1) guidelines for a widely applicable method.

Acknowledgments

We would like to express our sincere gratitude to the editorial team and reviewers of the International Journal of Drug Regulatory Affairs for their valuable feedback and support throughout the review and publication process. Their constructive comments have significantly enhanced the quality of the article.

Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

Financial Disclosure statement:

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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