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Failure Mode and Effects Analysis of High-Performance Liquid Chromatography Systems: A Systemic Reliability and Risk Mitigation Approach

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ABSTRACT

High-Performance Liquid Chromatography (HPLC) is one of the most widely used analytical techniques in pharmaceutical, biomedical, environmental, and chemical laboratories due to its high precision, sensitivity, and reproducibility. Despite its widespread application, the increasing complexity of modern HPLC systems introduces numerous systemic vulnerabilities that can adversely affect analytical performance, operational reliability, and regulatory compliance. This study presents a comprehensive Failure Mode and Effects Analysis (FMEA) of HPLC systems, focusing on non-operator-induced failures associated with mechanical, fluidic, electronic, and digital subsystems. A hybrid qualitative-quantitative framework based on ISO 31010 risk assessment principles was employed to identify potential failure modes and evaluate their associated risks using Severity (S), Occurrence (O), and Detection (D) indices. Risk Priority Numbers (RPNs) were subsequently calculated to prioritize critical system vulnerabilities. The analysis revealed that column clogging, pump seal degradation, and check-valve malfunction constitute the most significant risks affecting HPLC performance. Column clogging recorded the highest RPN value (240), indicating a substantial threat to system reliability and analytical accuracy. The study further demonstrates how predictive maintenance strategies, reliability engineering principles, and Internet of Things (IoT)-enabled monitoring systems can enhance early fault detection and support proactive maintenance planning. The proposed hybrid reliability framework provides a practical approach for improving equipment availability, reducing downtime, and strengthening quality assurance in both advanced and resource-constrained laboratory environments. The findings highlight the importance of integrating risk assessment, predictive diagnostics, and digital monitoring technologies to ensure sustainable HPLC system performance and regulatory compliance.

1. INTRODUCTION

High-Performance Liquid Chromatography (HPLC) remains one of the most important analytical techniques employed in modern scientific laboratories for the separation, identification, and quantification of chemical compounds [1]. Its applications extend across pharmaceutical manufacturing, clinical diagnostics, forensic investigations, environmental monitoring, and biochemical research [2].

The reliability of HPLC systems is critical because analytical decisions often depend on the accuracy and precision of generated results. Modern HPLC systems consist of interconnected mechanical, fluidic, electronic, and software-based subsystems including pumps, injectors, columns, detectors, and data acquisition units [3]. Failure of any of these components can compromise analytical quality, increase operational costs, and result in regulatory non-compliance.

Traditional maintenance approaches in many laboratories rely on corrective actions after equipment failure has occurred. However, increasing demands for quality assurance and laboratory accreditation require more proactive approaches to equipment management [4]. Reliability engineering tools such as Failure Mode and Effects Analysis (FMEA) provide a structured methodology for identifying potential failure modes, assessing associated risks, and implementing preventive actions before critical failures occur [5].

FMEA has been widely applied in manufacturing, aerospace, healthcare, and industrial process systems to improve operational reliability and reduce risk [6]. However, limited studies have focused on its application to analytical laboratory instrumentation, particularly HPLC systems. Consequently, this study aims to apply FMEA principles to evaluate systemic failure modes in HPLC systems and propose risk mitigation strategies that can improve equipment reliability and laboratory productivity.

2. MATERIALS AND METHOD

2.1. Analytical Framework

This study employed a qualitative-quantitative Failure Mode and Effects Analysis (FMEA) framework based on ISO 31010:2019 risk assessment guidelines and ISO/IEC 17025:2017 laboratory quality requirements [7,8].

2.2. Identification of Failure Modes

Potential failure modes were identified through:

- Review of peer-reviewed scientific literature.
- Evaluation of manufacturer maintenance manuals.
- Assessment of laboratory troubleshooting records.
- Analysis of regulatory and quality assurance guidelines.

The identified failure modes were categorized into mechanical, fluidic, electronic, software, and environmental failures.

2.3. Risk Assessment Procedure

Each identified failure mode was evaluated using the standard FMEA parameters of Severity (S), Occurrence (O), and Detection (D). Scores ranging from 1 to 10 were assigned according to established FMEA guidelines. These scores were subsequently used to calculate the Risk Priority Number (RPN) for each failure mode.

2.4. Risk Priority Number

The scoring of Severity (S), Occurrence (O), and Detection (D) indices were performed based on published FMEA guidelines and expert judgment derived from laboratory maintenance experience and literature reports. The Risk Priority Number (RPN) is computed as:

$$\text{RPN} = \text{S} \times \text{O} \times \text{D} \quad (1)$$

where:

S= Severity of failure (impact on system performance)
O= Occurrence probability (likelihood of failure)
D= Detection capability (likelihood of early detection)

Each parameter is rated on a scale of 1 to 10 based on standardized FMEA scoring criteria. The resulting RPN values range from 1 to 1000, with higher values indicating greater system risk.

2.5 Reliability Engineering Model

To further quantify system reliability, the failure rate $\lambda$of HPLC components can be expressed as:

$$\lambda = \frac{N_f}{T} \quad (2)$$

where:

- λ= Failure rate
- N_f= Number of observed failures
- T= Total operational time

This equation enables estimation of how frequently systemic failures occur in subsystems such as pumps, detectors, and autosamplers.

The reliability of an HPLC subsystem over time can be modeled using the exponential reliability function:

$$R(t) = e^{-\lambda t} \quad (3)$$

where:

- $R(t)$= Probability that the system operates without failure up to time t
- λ= Failure rate
- t= Time

This model is particularly applicable to components experiencing random failure behavior, such as electronic sensors and detector systems.

System availability, which reflects the proportion of time the HPLC system remains operational, is defined as:

$$A = \frac{MTBF}{MTBF+MTTR} \quad (4)$$

where:

- A= Availability
- $MTBF$= Mean Time Between Failures
- $MTTR$= Mean Time To Repair

High availability is critical in regulated laboratory environments to ensure consistent analytical throughput and compliance.

Given the high-pressure operation of HPLC systems, fluid dynamics can be approximated using:

$$\Delta P = \frac{F \cdot \eta \cdot L}{r^4} \quad (5)$$

where:

- ΔP= Pressure drops across the column
- F= Flow rate
- η= Viscosity of the mobile phase
- L= Column length
- r= Column radius

This relationship explains how column clogging or viscosity changes contribute to overpressure events—one of the highest-risk failure modes identified in this study.

These equations collectively support a quantitative understanding of system reliability and failure behavior in HPLC instrumentation. While RPN provides a prioritized ranking of failure modes, reliability and availability models enable predictive maintenance planning.

The integration of these mathematical tools into the FMEA framework enhances the transition from qualitative risk assessment to a more robust, data-driven reliability engineering approach. The overall reliability engineering framework adopted in this study is illustrated in Figure 1, showing the integration of FMEA, risk prioritization, predictive maintenance, and IoT-enabled monitoring for enhanced HPLC system reliability.

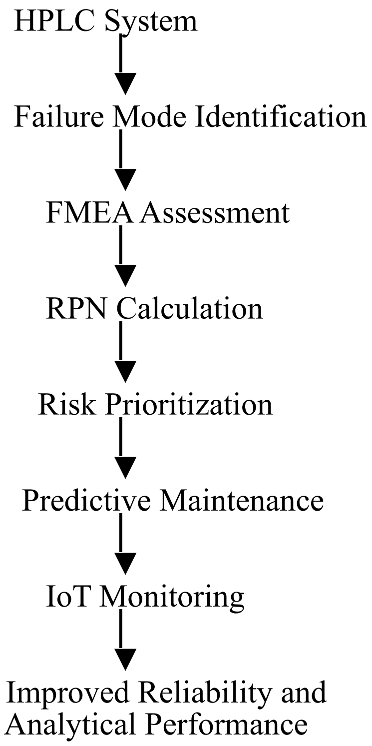

Figure 1. *Proposed Reliability Engineering Framework for HPLC System*

3. RESULTS AND DISCUSSION

3.1. Identified Failure Modes

The FMEA identified key systemic failure modes affecting HPLC systems, including pump seal degradation, column frit clogging, check valve malfunction, detector lamp drift, and autosampler wear.

Table 1. *FMEA Risk Assessment of HPLC System Failures*

Failure Mode	Severity(S)	Occurrence (O)	Detection(D)	RPN	Risk Category
Column clogging	8	6	5	240	Very High
Pump seal degradation	7	6	5	210	High
Check-valve failure	6	6	5	180	Moderate-High
Detector drift	7	4	6	168	Moderate
Autosampler wear	5	5	6	150	Moderate

The comparative distribution of Risk Priority Numbers (RPNs) among the identified failure modes is presented in Figure 2. Column clogging and pump seal degradation exhibited the highest RPN values, indicating that fluidic subsystem failures represent the most significant threats to HPLC system reliability

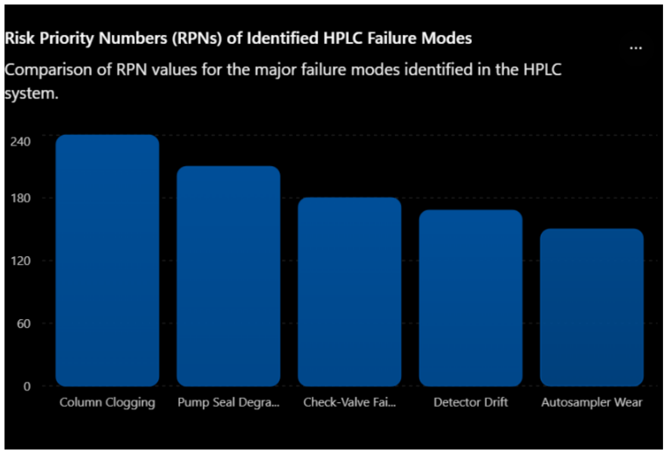

Figure 2. *Risk Priority Numbers (RPNs) of identified HPLC failure Modes*

Figure 2. Comparative distribution of Risk Priority Numbers (RPNs) for identified HPLC failure modes. Column clogging and pump seal degradation exhibited the highest risk levels.

Column frit clogging (240) and pump seal degradation (210) exhibited the highest Risk Priority Numbers (RPNs), reflecting their potential to significantly disrupt system performance and analytical reliability [9].

Check-valve malfunction was associated with flow irregularities resulting from contamination and particulate accumulation. Similar observations have been reported in previous studies on HPLC troubleshooting and reliability assessment [10].

Detector lamp drift, associated with aging components, reduces sensitivity and affects quantification accuracy, particularly in trace analysis [11]. Detector drift and autosampler wear demonstrated moderate risk levels. However, prolonged operation without preventive maintenance may increase their impact on analytical accuracy and instrument performance.

Column clogging (RPN = 240) and pump degradation (RPN = 210) were identified as the most critical risks as shown in Table 1 above.

3.2. Reliability Engineering Perspective

The findings indicate that fluidic subsystem failures constitute the most significant reliability threat in HPLC systems. These failures often develop gradually and may remain undetected until analytical performance deteriorates significantly.

The findings also reveal that the most critical failures in HPLC systems are predominantly systemic rather than operator-induced. Design limitations, material degradation, and inadequate maintenance frameworks were identified as primary contributors to system instability. Additionally, the increasing integration of digital systems has introduced new vulnerabilities, particularly in the form of sensor drift and software-related failures. This study significantly extends the traditional application of Failure Mode and Effects Analysis (FMEA) by integrating advanced reliability engineering concepts tailored to modern laboratory environments. First, the incorporation of predictive maintenance models transforms FMEA from a static risk assessment tool into a dynamic, data-driven framework. Predictive maintenance leverages historical performance data, statistical modeling, and machine learning techniques to anticipate potential failures before they occur. This approach reduces unplanned downtime, enhances equipment lifespan, and optimizes maintenance scheduling [10,12]. Second, the study proposes the integration of Internet of Things (IoT)-enabled diagnostic systems within HPLC instrumentation. By embedding sensors capable of real-time monitoring of pressure, temperature, flow rate, and system integrity, laboratories can achieve continuous system surveillance. These IoT frameworks enable remote diagnostics, automated alerts, and rapid fault localization, thereby significantly improving operational efficiency and reliability [8]. Third, this work introduces a hybrid reliability model that combines traditional FMEA with digital monitoring technologies. In this model, FMEA serves as the foundational risk identification tool, while real-time data analytics continuously update risk parameters such as occurrence and detection indices. This creates an adaptive risk management system capable of responding to evolving operational conditions [13]. The integration of these elements represents a paradigm shift from conventional reactive maintenance approaches toward a proactive, intelligent reliability management system. This contribution is particularly relevant for both advanced laboratories and resource-constrained settings, where optimizing equipment performance and minimizing operational costs are critical.

4. CONCLUSION

This study applied Failure Mode and Effects Analysis (FMEA) to identify and prioritize systemic failure modes in High-Performance Liquid Chromatography systems. Column clogging, pump seal degradation, and check-valve malfunction were identified as the most critical failure modes affecting system reliability and analytical performance. These findings are consistent with previous studies on HPLC reliability and failure analysis [9,11]. The findings demonstrate that proactive maintenance approaches supported by reliability engineering principles can significantly improve equipment availability and reduce laboratory downtime. Integration of predictive maintenance, digital diagnostics, and IoT-based monitoring technologies offers a practical framework for enhancing HPLC reliability in both advanced and resource-constrained laboratory settings [12]. To enhance HPLC system reliability, a multifaceted approach is recommended. Future research should focus on validating the proposed reliability framework using real-world operational data and machine-learning-based predictive maintenance models. Maintenance practices should transition toward predictive strategies supported by Computerized Maintenance Management System (CMMS) platforms, ensuring timely calibration and servicing. Quality assurance measures must emphasize supplier certification and material compatibility testing to prevent contamination-related failures. Furthermore, digital integration through validated software systems and automated fault detection algorithms is essential for modern laboratory operations. Environmental control, including temperature and humidity regulation, alongside stable power supply systems, is also critical for sustaining optimal instrument performance.

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Conflict of Interest Declaration

The authors declare that there is no conflict of interest regarding the publication of this work.

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