Task:
Potential Failure Mode & Effects Analysis (PFMEA) - Quality Risk Management

Overview:
This project focuses on identifying and analyzing potential failure modes within a process and evaluating their effects on product performance or system reliability. **PFMEA** is used as a preventive tool in **Quality Risk Management** to systematically assess risk, prioritize potential failures, and recommend actions to mitigate risks in product design or process development.

Key Components:

PFMEA Process:

- **Identification of Failure Modes:**
  Potential failure modes within a process or product are identified. Each failure mode represents ways in which a process can fail to meet customer or performance expectations.

- **Effects of Failure:**
  The potential effects of each failure are assessed to understand how it impacts system performance, product quality, or customer satisfaction. Critical failures that result in high risks or defects are highlighted.

- **Severity, Occurrence, and Detection:**

  - **Severity (S):** Measures the seriousness of the potential effect of failure.

  - **Occurrence (O):** Estimates the frequency with which the failure is likely to occur.

  - **Detection (D):** Gauges the likelihood that the failure will be detected before it reaches the customer.
    Each factor is scored, and these values are used to calculate the **Risk Priority Number (RPN)**.

- **Risk Priority Number (RPN):**
  The RPN is calculated as **RPN = S × O × D**, and it is used to prioritize which failure modes require the most attention. Higher RPNs indicate higher risks that must be addressed.

Key Findings:

- **High-Risk Failure Modes:**
  The analysis identified failure modes with the highest RPN scores. These failures are considered critical and require immediate corrective actions to mitigate the risk.

- **Common Causes of Failure:**
  Frequent causes of failure were linked to **process inefficiencies**, **human error**, or **design flaws**. These causes were prioritized for root-cause analysis and preventive actions.

- **Detection Challenges:**
  In some cases, the detection scores were high, meaning the failure was not easily identifiable before it impacted the customer. Improvement in detection methods, such as enhanced quality checks and automated monitoring systems, was recommended.

Recommendations for Risk Mitigation:

- **Process Redesign:**
  Redesigning certain aspects of the process to eliminate potential failure points and improve product reliability. This includes implementing new controls and standardizing work procedures to reduce human error.

- **Improved Detection Systems:**
  Investment in better detection technologies or quality control methods to catch failures early in the production process before they reach the customer.

- **Preventive Maintenance:**
  Scheduling regular maintenance and inspections to address equipment-related failures and ensure that machinery is functioning at optimal levels.

- **Employee Training Programs:**
  Enhancing training programs to improve worker competency in areas prone to human error, reducing the likelihood of mistakes during critical operations.

Skills Utilized:

- **Risk Management** (Failure Mode Identification, RPN Calculation)

- **Data Analysis** (Severity, Occurrence, Detection Analysis)

- **Quality Control** (Process Improvement, Risk Mitigation)

- **Root-Cause Analysis** (Identifying Common Causes of Failure)

- **Preventive Strategies** (Maintenance, Process Redesign)