



Author: Ambar E. Rivera Miranda
 Advisor: Rafael A. Nieves Castro, PharmD.

Master in Manufacturing Engineering with Specialization in Automation

Abstract

Training compliance is a critical element of quality systems in regulated manufacturing. At the site studied, training status was monitored through manual extraction of LMS data and Excel-based tracking, resulting in limited visibility, delayed escalations, and administrative burden. Using the DMAIC methodology, the project team defined process gaps, quantified over 1,000 overdue trainings in 2024, and identified root causes through structured analysis. A Power BI dashboard was developed with LMS integration, providing real-time compliance visibility, automated pre-expiration alerts, and filtered access by job function. Post-implementation results included a 99.5% on-time completion rate, an 80–90% reduction in analyst workload, and strengthened audit preparedness. The system transitioned from reactive tracking to proactive compliance and is positioned as a scalable solution for broader quality system applications, including CAPAs and NCMRs.

Introduction

This project was initiated to address critical inefficiencies in the process that posed regulatory and operational risks. Compliance personnel manually extracted data from the Learning Management System (LMS) and maintained Excel-based trackers to monitor employee training status. This reactive, non-integrated approach lacked system-driven alerts, real-time data synchronization, and centralized visibility. The resulting delays in identifying overdue trainings led to escalations, deviation reports, and increased administrative workload. In the context of FDA 21 CFR Part 820 and ISO 13485 requirements for documented training and effectiveness verification, this project was launched to implement a data-driven, automated solution that would strengthen compliance infrastructure and enhance audit readiness.

Background

Maintaining accurate and timely training records is a regulatory expectation in medical device manufacturing, directly impacting audit readiness and product quality. Agencies such as the FDA (21 CFR Part 820) and ISO 13485:2016 require documented evidence of employee competence and ongoing training effectiveness. However, many manufacturing sites continue to depend on manual tracking systems, often based on Excel spreadsheets, which are vulnerable to human error, data gaps, and limited real-time visibility.

Recent literature highlights the limitations of such systems and supports the integration of Business Intelligence (BI) platforms to strengthen compliance infrastructures. Tools like Microsoft Power BI enable organizations to centralize training data, automate oversight, and enhance data accessibility. These platforms are consistent with ISO 9001:2015 principles, promoting continual improvement and operational transparency. By replacing manual compliance tracking with real-time dashboards, companies can reduce administrative burden and proactively address training gaps, aligning both with regulatory demands and modern quality system standards.

Problem

The training compliance process at the site lacked integration between the Learning Management System (LMS) and any form of automated monitoring or alerting mechanism. Compliance analysts manually exported data, calculated due dates, and maintained Excel-based trackers, introducing variability and risk into a process subject to FDA and ISO scrutiny. Overdue training instances routinely exceeded 1,000 cases in 2024, triggering formal deviations and requiring Product Impact Assessments.

The absence of real-time data access, proactive escalation triggers, and defined accountability pathways undermined both operational efficiency and audit readiness. A digital, role-based compliance infrastructure was required to enable timely intervention, data integrity, and sustainable control.

Methodology

This project applied the DMAIC methodology, a structured Six Sigma approach, to transition from manual compliance tracking to an automated, data-driven monitoring system.

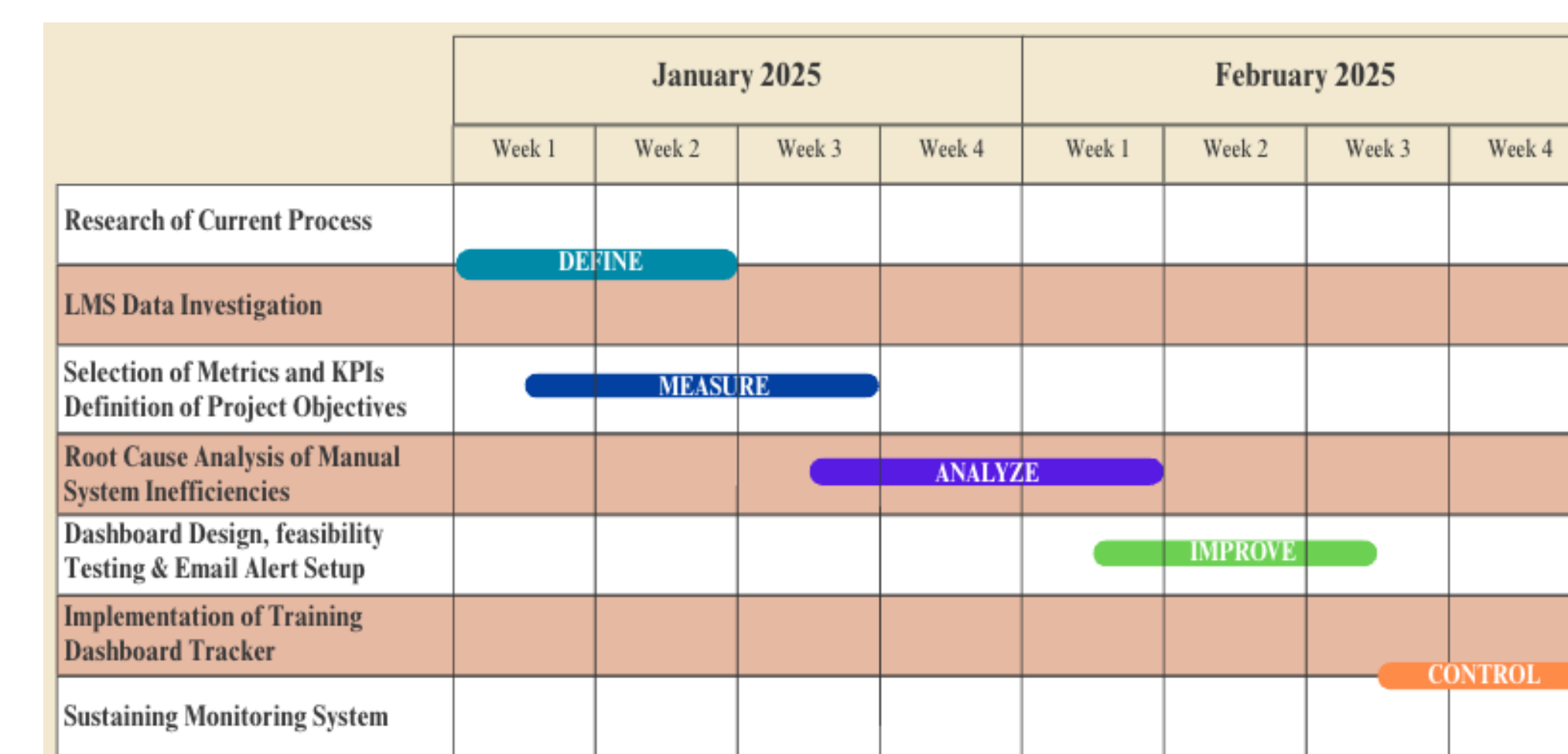


Figure 1: Project Timeline for Training Compliance Dashboard Project following DMAIC Methodology

Table 1: DMAIC Phase Summary

DMAIC Phase	Description
DEFINE	Define the training compliance tracking problem and project objectives.
MEASURE	Collect and measure data from the existing manual tracking system.
ANALYZE	Analyze the data to identify inefficiencies and root causes.
IMPROVE	Develop and implement the Power BI dashboard solution.
CONTROL	Establish controls to maintain and monitor training compliance improvements.

Results and Discussion

DEFINE PHASE

The Define phase established the project's scope based on clear operational gaps:

- No real-time visibility into training status
- Manual tracking using Excel
- Delayed identification of overdue trainings
- Heavy administrative workload on Compliance analysts
- These issues led to frequent escalations and a reactive compliance environment.

Project Goal: To develop an automated dashboard that could track training compliance in real-time and reduce overdue cases and manual burden.

MEASURE PHASE

Table 2: Training Compliance Summary – March to December 2024

Month	Overdue YTD	Completed On-time	Overdue (%)	Complete On-time (%)
Mar-24	130	13905	0.93%	99.1%
Apr-24	150	14122	1.05%	98.9%
May-24	265	18397	1.42%	98.6%
Jun-24	184	8291	2.17%	97.8%
Jul-24	159	10447	1.50%	98.5%
Aug-24	182	10589	1.69%	98.3%
Sep-24	138	13489	1.01%	99.0%
Oct-24	177	12248	1.42%	98.6%
Nov-24	157	14586	1.06%	98.9%
Dec-24	129	12421	1.03%	99.0%

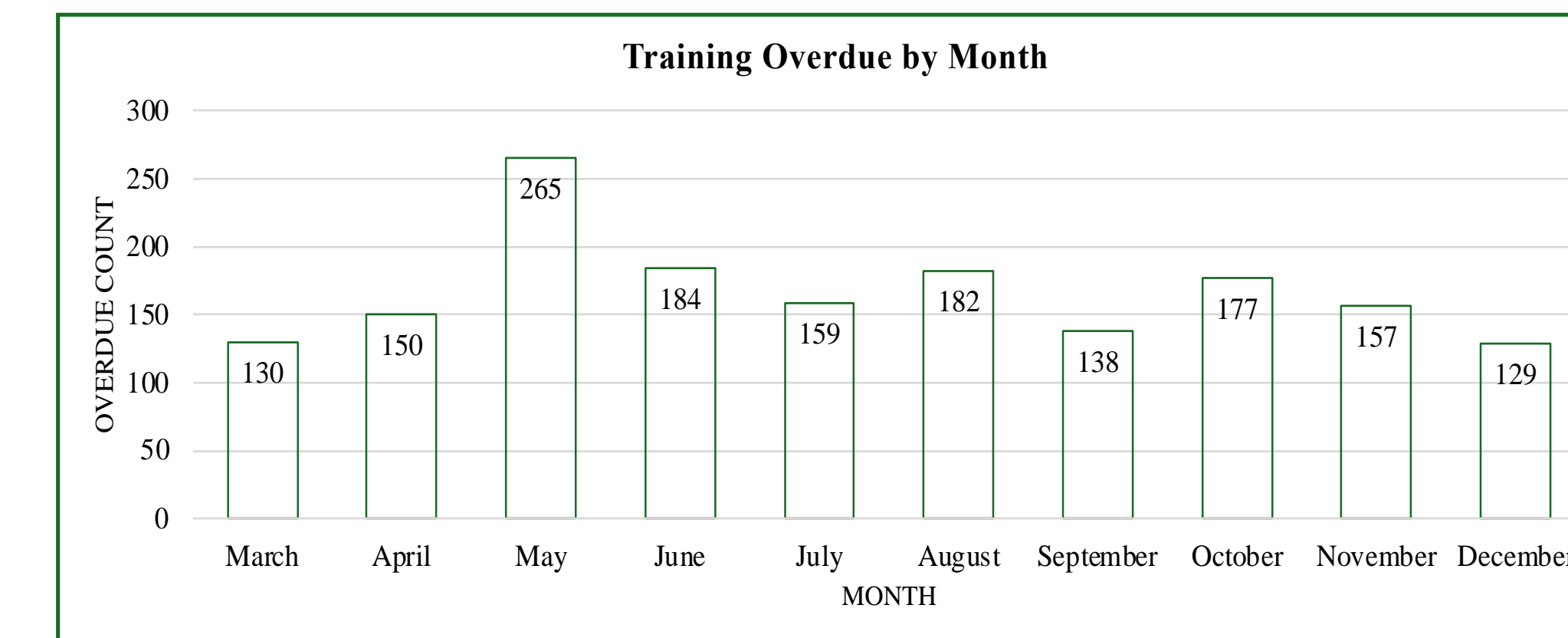


Figure 3: Training Overdue by Month – 2024

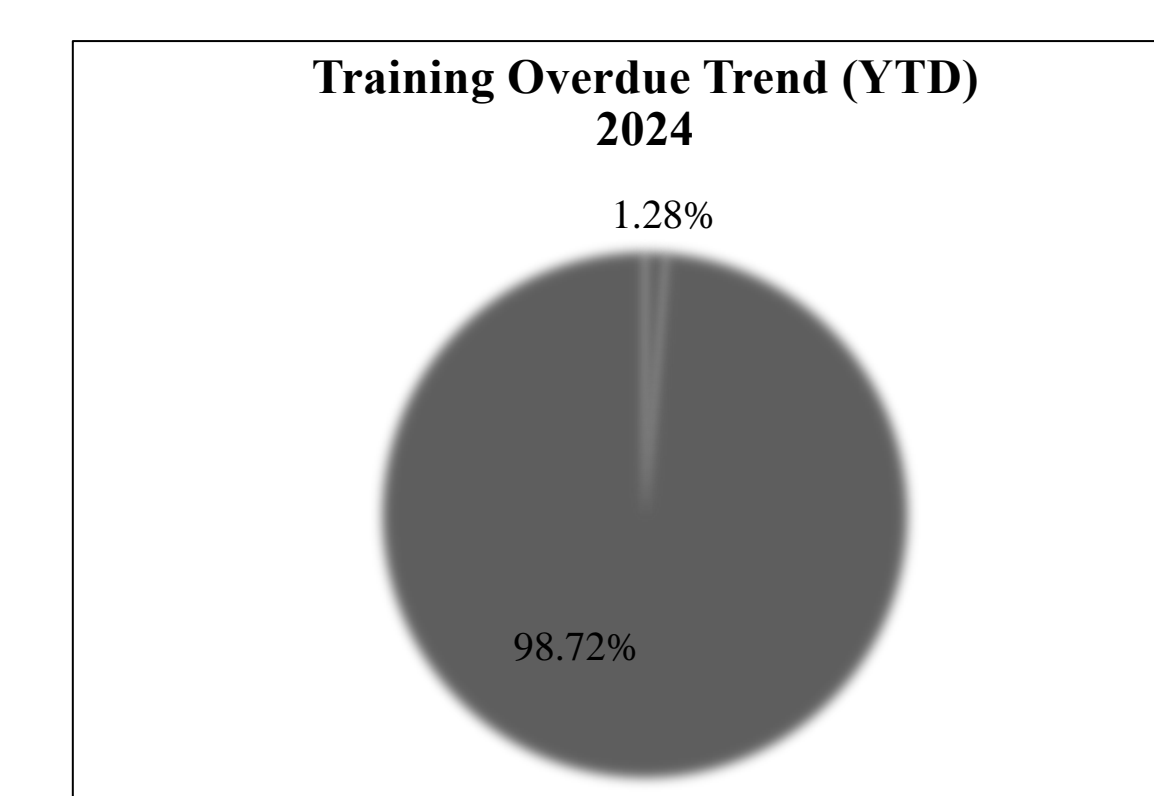


Figure 4: Training Overdue Trend (YTD) – 2024

ANALYZE PHASE

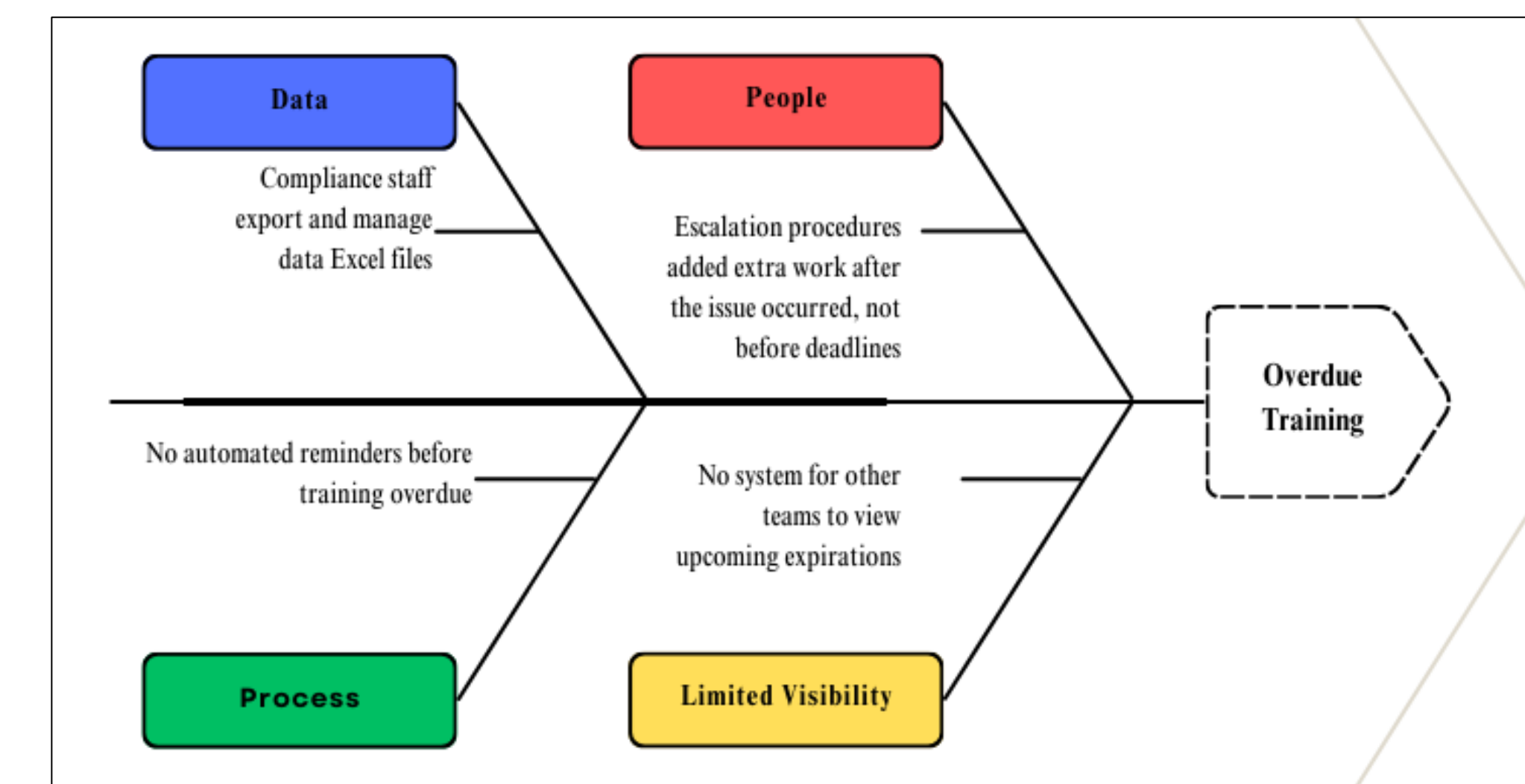


Figure 5: Root Cause Analysis - Training Compliance

IMPROVE PHASE



Figure 6: Training Compliance Dashboard Overview – Power BI Implementation (Displays real-time data by department, role, and training category)

Table 3: Training Compliance Metrics Post-Dashboard Implementation

Month	Overdue YTD	Completed On-time	Overdue (%)	Complete On-time (%)
Mar-25	56	9747	0.57%	99.4%
Apr-25	52	12354	0.42%	99.6%

CONTROL PHASE

Table 4: Control Plan for Training Compliance Dashboard.

Control Element	Monitoring Method	Responsible Party	Frequency
Data Refresh Accuracy	Confirm successful daily sync from LMS	Compliance Analyst/ Quality	Daily
Alert Functionality	Review Power Automate logs for delivery confirmation	Compliance / IT Support	Weekly
Manager Usage	Track informal feedback, resolve questions/issues	Compliance Team/ Quality	Monthly
Dashboard Performance	Validate filter functions, KPIs, and visual layouts	Power BI Developer (Quality Engineer)/Admin (Compliance team)	Quarterly

Conclusions

This project replaced a manual, spreadsheet-driven training compliance process with an automated Power BI dashboard integrated with the LMS. Using the DMAIC methodology, systemic gaps were identified and resolved through real-time metrics, automated alerts, and role-based visibility. The solution achieved a 99.5% on-time completion rate and reduced analyst workload by 80–90%. It improved audit preparedness and shifted the site's compliance approach from reactive to proactive—demonstrating how business intelligence tools can enhance regulatory performance and operational accountability in quality systems.

Future Work

- Extend the dashboard framework to monitor other quality systems such as CAPAs and NCMRs
- Incorporate feedback from end users to improve dashboard navigation and filter functionality

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