

Case Study

Human Error Software Solution

For an Asia-based investigation management specialist for the pharmaceutical industry.

PROJECT OVERVIEW

The client helps organizations analyze, assess and determine the human committed errors with a robust and sustainable system with effective Corrective and Preventive Actions (CAPA). They were in pursuit of a technology partner to digitize the investigation management mechanism with a modern web interface.



Capability
Enterprise
Software



Industry
Healthcare



Country
India

KEY FEATURES

Rishabh enabled the client by developing Human Error Solution Software (HESS) to serve the highly-regulated pharma industry. It helps improve human reliability, product quality, achieve regulatory compliance, and reduce risk.

Problem & Investigation Management

View, list, search, approve, store, discard, and download the list of problems with multiple problem types that can be filtered by investigation ID, issue type, date, status & other relevant parameters.

Workflow & Task Management

Automate & streamline a proper workflow for corrective and preventive actions to close issues on time and ensure consistent quality and strict compliance at every step of the quality control process.

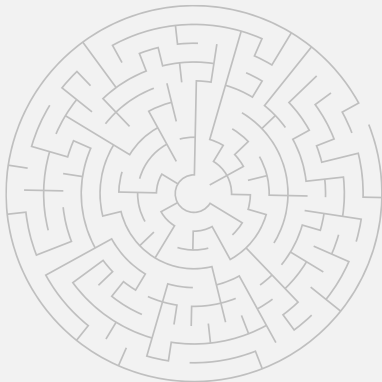
Dashboard & Reports

Drive a culture of continuous improvement by generating reports that help resolve quality issues, avoid recurrence, execute containment actions and validate the efficacy of root cause elimination.

Alerts & Notifications

Faster issue management & acceleration of CAPA cycle time by addressing quality issues quickly and efficiently. Offers real-time collaboration for investigations with an update on reviews, approvals, action plans and schedules.

CHALLENGES

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- Absence of dedicated technology-based Human Error (HE) detection and investigation platform
 - Addressing the wrong issues due to inadequate investigations
 - Insufficient root cause analysis
 - Ineffective Recommendations System
 - Productivity loss & customer dissatisfaction

SOLUTION

Team Rishabh helped automate the manual process for HE tracking with a dedicated system and beyond conventional QMS. The process focused on two essential aspects; 1) Mapping of Error Code on System 2) Creation of Operational Configuration management framework.

Defining Configuration Framework

Helped the client rectify and improve upon their product quality by configuring, implementing and integrating the following tools & adhering to compliances:

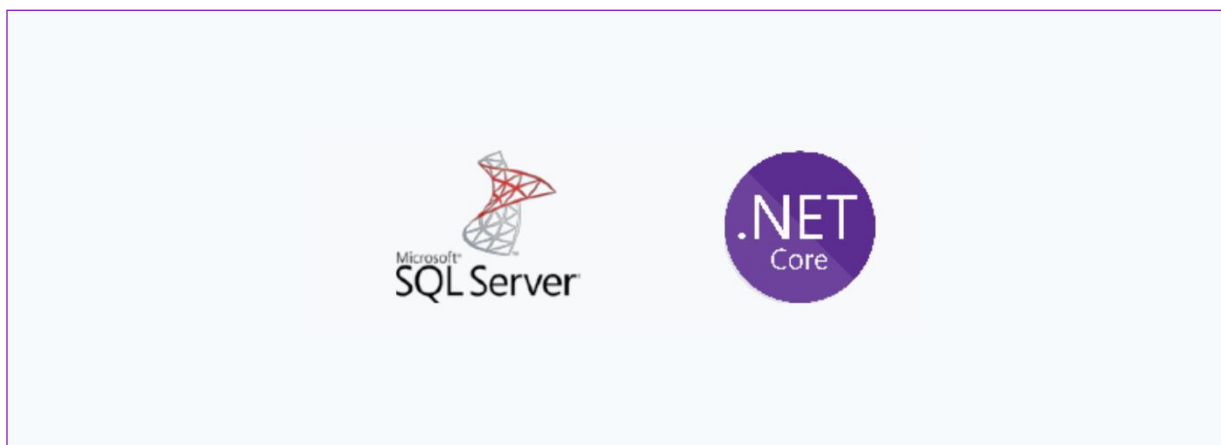
- Root Cause Determination Tool (RCDT)
- Cognitive Load Assessment Tool (CLAT)
- RCDT Corrective And Preventive Action (RCDT Recommendations)
- CLAT Corrective And Preventive Action (CLAT Recommendations)
- 21 CFR 11 compliance

Authorization & Role Permission Management

Provided architectural guidance and implemented best practices to help streamline and automate the flow of data between crucial operational management systems along with an identity management database for:

- Roles & User Management
- Site Management
- Department Management
- Permission Management

TECHNOLOGIES & TOOLS



Outcomes

53%

speedup of
action process

43%

increase
in
reliability

100%

accurate audit trail
for each process

ABOUT RISHABH SOFTWARE

As a Digital Engineering and Enterprise Transformation leader, we empower businesses to scale, innovate, and thrive in today's digital-first world through technology rooted in trust and transparency. We leverage emerging capabilities such as Cloud, Data Engineering & Analytics, AI, Automation and Application Engineering to drive digital transformation and unlock new opportunities. We have successfully served across 25+ countries, and we work towards customer delight as "WE CARE."

✉ sales@rishabhsoft.com

☎ +1-877-747-4224

