Case Study: Automating Complaint Handling Process in a Medical Device Regulated Industry

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Abstract: This case study studies automating a manual complaint handling process in a medical device regulated industry. The project/study resulted in vast performance gains in productivity and regulatory compliance.

Keywords: Complaint Handling, Post-Market Surveillance, Medical Device, MDR

The project had following improvements;

- **77.9%** headcount reduction
- **96%** reduced processing time
- **3538%** productivity increase
- **92%** decrease in out-of-compliance incidents
- Independent audit findings eliminated

1 Introduction

The *Medical Device* industry is heavily regulated by various regulatory bodies around the globe, and with FDA 21 CFR Part 820 (United States), MDD/MDR, and ISO 13485 (Europe) as the major guiding regulations. The complaint handling requirements often result in resource intensive activities.

This case study focuses in developing and implementing a vastly automated complaint handling process and study its impact on resources and regulatory compliance.

2 Study Resources

Following resources was available for this case study;

2.1 Team Composition

- 20 people involved in total
- 12 people engaged full time
- 5 Complaint Handling Specialists,5 Engineers, 2 Customer Service Specialists

2.2 Audits of the systems

- 7 regulatory audits from 2017 to 2019
- 10 professional auditors
- 3 independent auditing organizations
- Audited to compliance with FDA CFR 21 Part 820, ISO 13485:2016, MDSAP (MDD/MDR)

2.3 Material

- Full access to an SAP production environment
- Laptops with MS Excel with VBA scripting
- Read/write to an internal production network

3 The Manual System

3.1 The Challenge

Initial review of the manual process revealed a highly repetitive and manual workflow with variables exposing the users to >10,000 possible outcomes for each complaint, consuming resources, causing delays and quality deficiencies (regulatory out-of-compliance).

3.2 Audit Result of the manual process

The system initially failed several independent audits year 2016 and 2017, which probed for an internal audit which revealed ~ 80% of the complaint reports containing some kind of out-of-compliance content, while also consuming over 18 hours / day to create. Only 10% were made within the regulatory required time limits, resulting in only 2% reports actually closed out accordingly to all the regulatory requirements.

4 New System Approach

4.1 Requirements

Based on the result from the manual process review, it was determined to standardize the workflow, eliminate waste, automate, and minimize variations.

4.2 Workflow

The new system was created as an MS Excel application with VBA programing since this allowed for a rapid development approach (rapid iterations/agile approach).

For each complaint, the new system performed hundreds of checks and matches with several decision matrices. The automation could automatically determine, write, and finalize reports from its own eligibility review. If user input was required, the automation would guide the user through the steps, and support the finalization of the report, all which the user could at any point change to his/her own discretion.

5 Deployment of The New System

5.1 Initial System Simulation

Before deployment of the initial system (known from hereon as ieration 1), a simulation with the users demonstrated a fully achieved regulatory compliance for March of 2017, with the simulated deployment on 17th March;

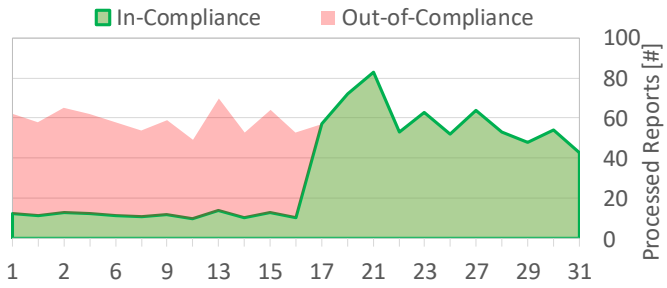
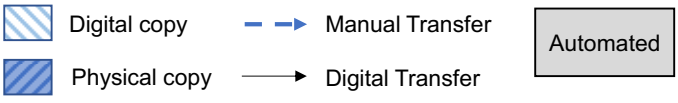


Figure 1. Simulation of the new system

Iteration 1 contained the application *Report Creator Frontend*, which also lowered the time consumption for report writing with 98.93%! However, the inefficiency of the reviewing process restricted the entire complaint handling process to only a total of ~20% gain in compliant productivity.

Legends;



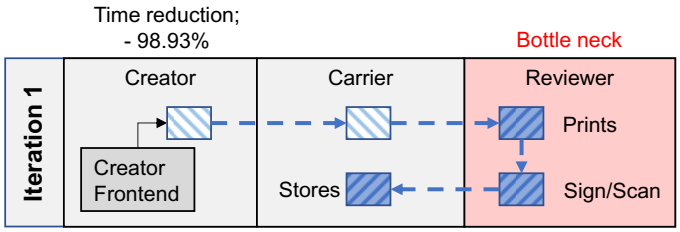


Figure 2. First iteration of the system

The second iteration (iteration 2) with deployment of the *Report Reviewer Frontend* lowered the reviewing time consumption with 71.74%, and thus the entire process achieved a total time reduction of 96.24% with the second iteration!

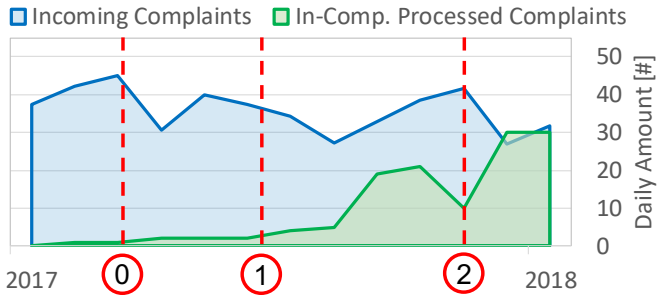


Figure 3. Iteration deployments and processing performance

However, the manual organization between creators, carriers and reviewers, resulted in only ~50% of in-compliance productivity due to losing material and issues organizing inter-dependent workflow. The carrier was therefore identified as the next bottle neck;

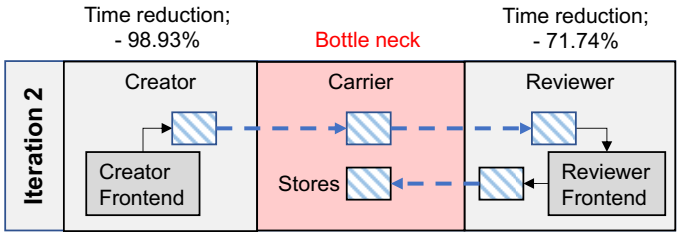


Figure 4. Second iteration of the system

The third iteration introduced a server-side repository, the Central Network Repository, in Q4 2017, and finally resolved the remaining issue.

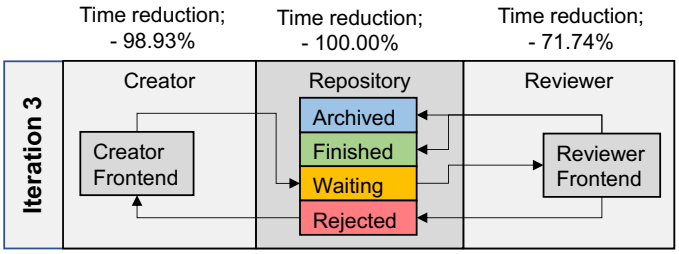


Figure 5. Final iteration of the system

The team with the third iteration of the new system achieved 100% in-compliance productivity with a total of 96.24% time reduction.

6 Final System Description

6.1 Completed Reports (PDF and CSV)

The automation creates a PDF (the Complaint Report) and a corresponding CSV file when completing a report. The CSV file contains the attributes used to create the complaint report and is used to create statistics and/or guide the automation when navigating the corporate ERP System (SAP) for long term storage.

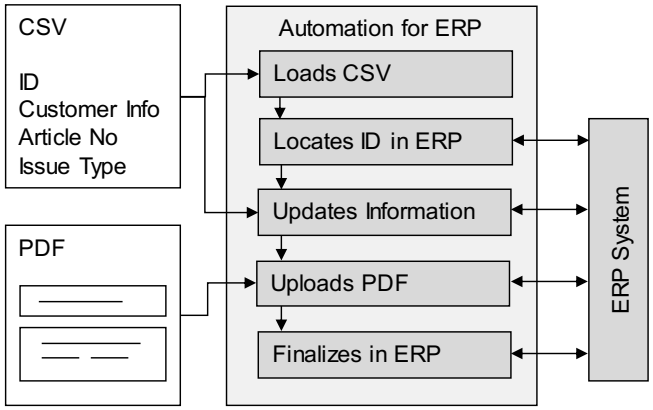
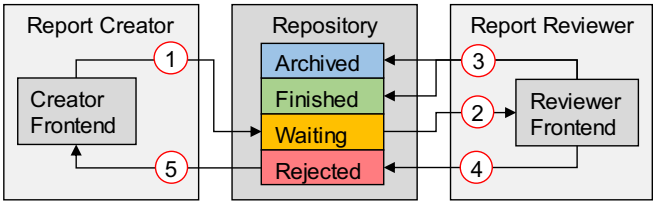


Figure 6. System output and relation with ERP (SAP)

The CSV file is also beneficial for mass-reporting to regulatory bodies, such as FDA who accepts either CSV or PDF files as complaint reports.

6.2 Applications and Central Repository

The system contains two frontends, one for the *Complaint Report Creator* and one for the *Complaint Report Reviewer*. Both applications managed the data through a central network repository (a production server).

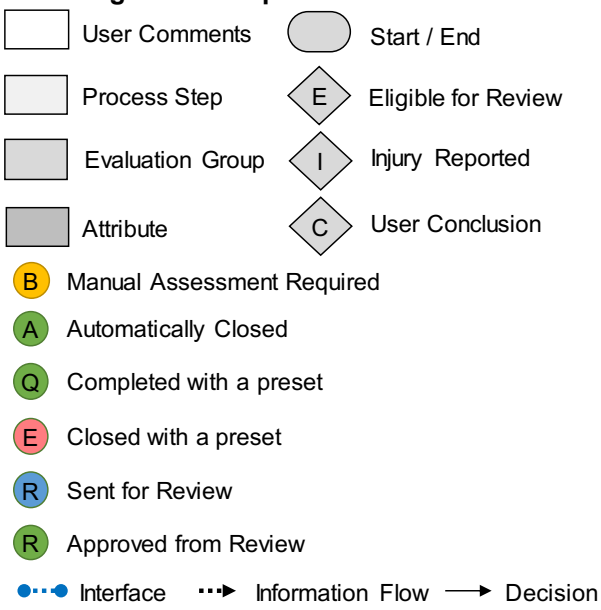


1. Sends report for Review
2. Loads report for Review
3. Approves report; Completed report sent to Finished, original review file to Archived
4. Rejects report
5. Loads rejected report for updates

Figure 7. The two frontends and central repository connection

This approach turned out highly efficient to develop and eliminated all user errors when organizing the workflow.

6.3 Legend Descriptions



6.4 The Report Creator - Eligibility Review

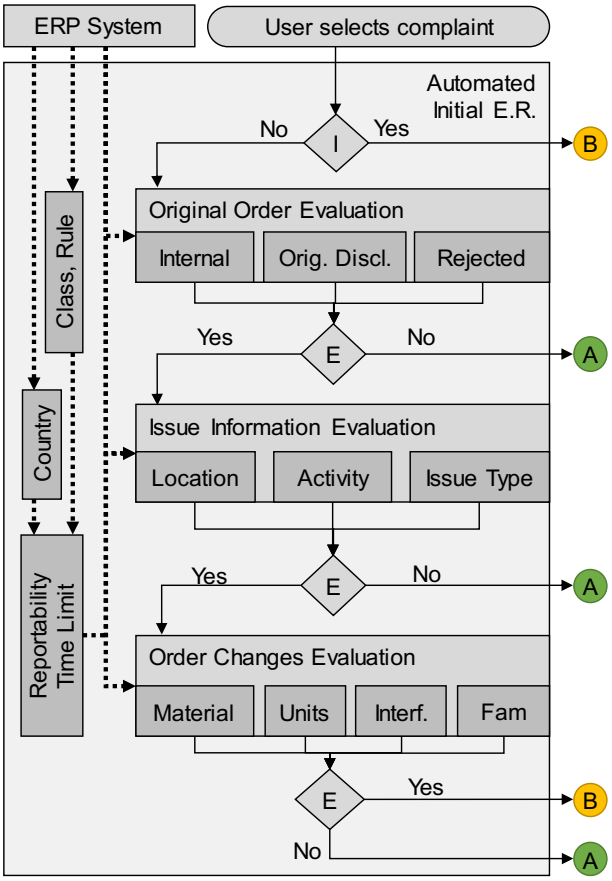


Figure 8. Automated eligibility review with the creator

The user selects a complaint to process, and the automation will first perform an *eligibility review* which is a series of automated preliminary investigations with data imported from the ERP (SAP), to determine if it can immediately, automatically close-out a complaint or if it needs further input/review from a user.

6.5 Eligible for further review

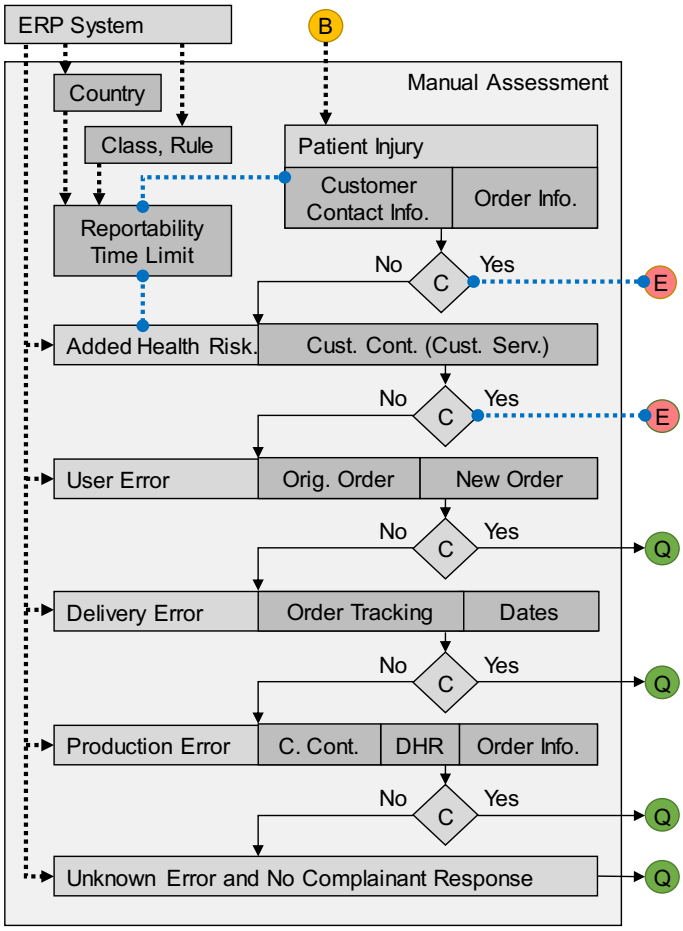


Figure 9. Manual assessment with the creator

If the user is required to provide input, the automation guides the user by providing necessary information and has presets for the most common conditions. The automation determines reportability time limits on initial complaint information.

6.6 Serious Events

Serious incidents will prompt to user to the Escalation Process which typically involves the initiation of a PFA / HHE (Field Action/Health Hazard Evaluation). The information from the initial assessments with the PFA / HHE must be present in the Complaint Report before continuation, hence the interface connection;

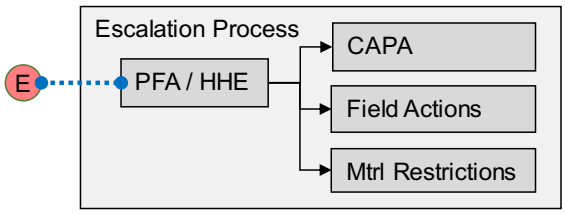


Figure 10. Relation with the Escalation Process

6.7 Final closure of the Complaint Report

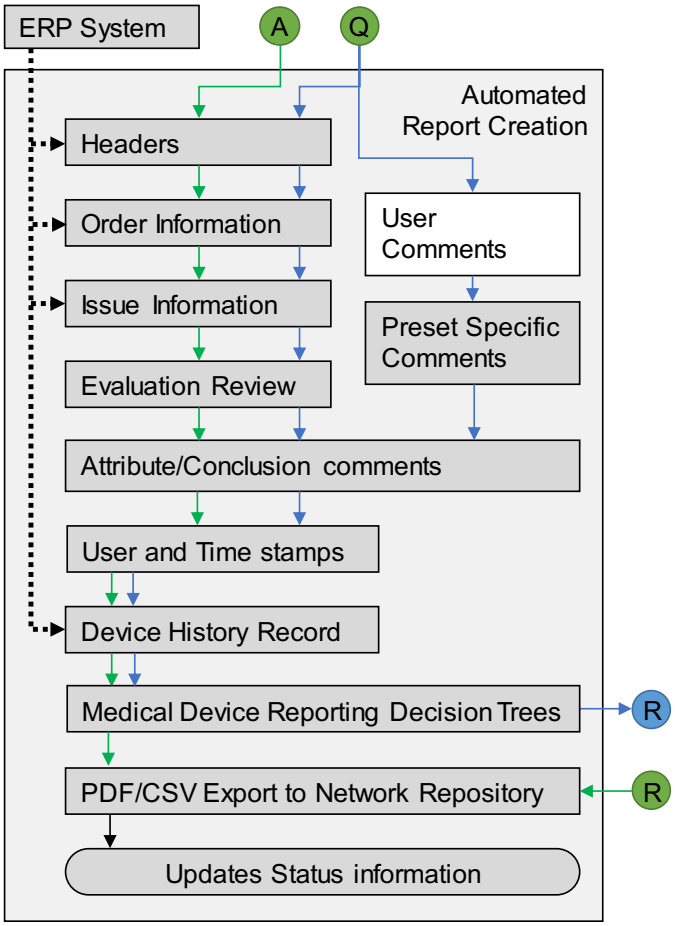


Figure 11. The automated report creation with the creator

The information from either user input or the initial automated eligibility review, enters the automated report creation. The only difference between automatically completed reports and manual ones, is the need of user input (manual statements), preset comments and a reviewer's decision.

6.8 Final Approver

The reviewer is informed by the automation if any serious event had occurred, how much time [days] is remaining before the decision must be made, and its unique ID.

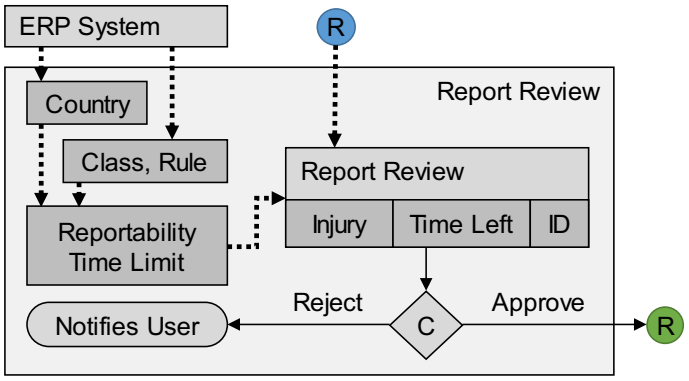


Figure 12. The reviewer and its relations

7 Final Result

7.1 Process History

The figures demonstrate the deployment of the iterations and visualization of sustained productivity;

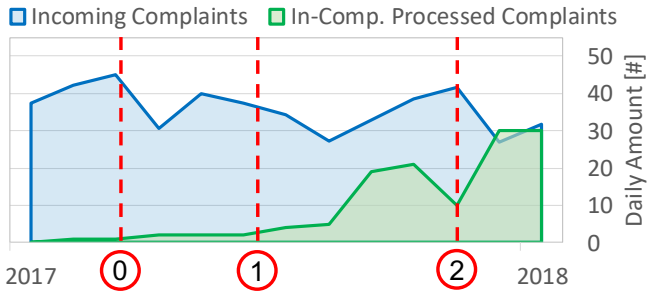


Figure 13. The deployment of the iterations

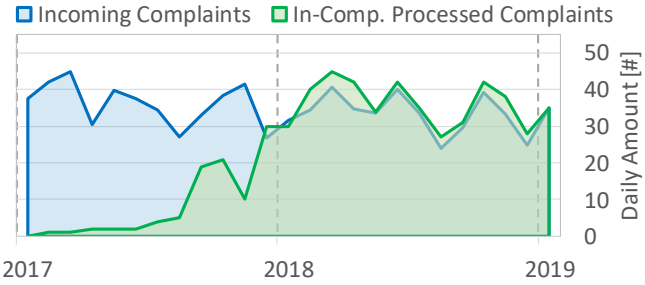


Figure 14. The continues process performance with the automation

7.2 Cost Savings

The new process resulted in significant increases in efficiency and effectiveness which enabled headcount reduction from initial 18 required employees to 4, while simultaneously outperforming the manual 2% compliance productivity compared to 100%;

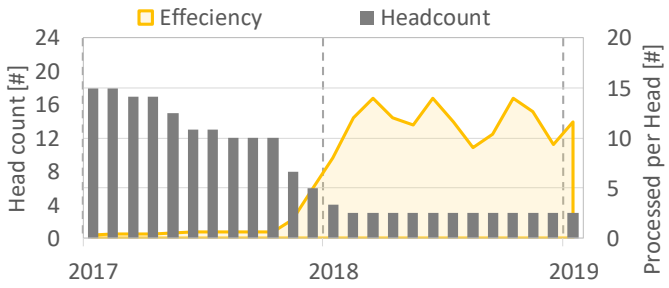


Figure 15. The required headcount amount and process efficiency

7.3 Audit Result of the New System

The new system was audited 2018 and 2019, managed by two independent external organizations and one independent internal. The system passed all the audits, without any observations while two audits concluded the new process being potentially "best-in-class".

8 Discussion

Complaints have a large commonality with each other, and the Medical Device Regulations are clear, which makes complaint handling a perfect subject for automations. The new system with its significant automations and guidance for the users resulted in;

1. 77.9% headcount reduction
2. 96% decreased processing time
3. 3538% increased productivity
4. 92% lowered out-of-compliance incidents per internal audits
5. Independent audit findings eliminated

With the gained resources from the significantly improved performance, it is possible to direct more resources to failure mode analysis to increase customer satisfaction and public safety.

Figure 16. Required headcount reduction

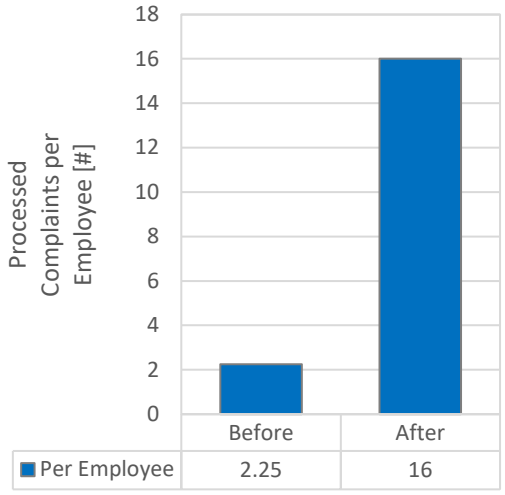


Figure 17. Productivity increase

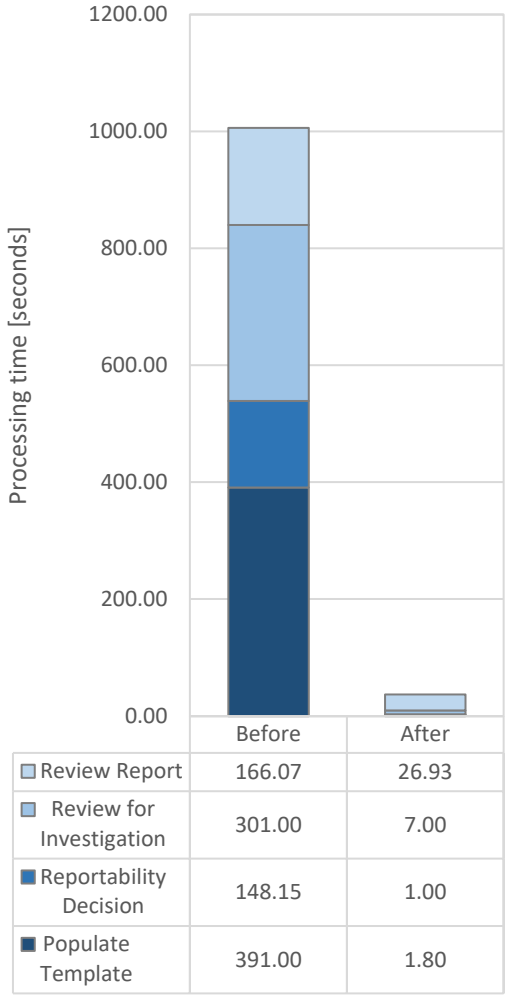


Figure 18. Processing time reduction per complaint report