

PHARMACEUTICAL COMPANY // DATA INTEGRITY PROJECT

OVERVIEW //

The customer

The customer is a leading company in Research and Development of innovative pharmaceuticals.

The business problem

Data Integrity is becoming an essential topic not only in the eyes of authorities such as the Food and Drug Administration (FDA) but also for the pharmaceutical companies themselves. To clarify the current fit of laboratory equipment with data integrity requirements on customer side, adesso conducted assessments for each equipment in scope.

Outcome and Value

Upon successful completion of the project, the client has now a clear view over each laboratory equipment and how it meets the data integrity standards. The identified gaps were classified and mitigation actions defined. Furthermore, a single point of truth with regards to equipment data was created.

Key deliverables

- > Creation of a central equipment data base
- > As-Is analysis with regards to data integrity requirements
- > FMEA analysis of identified data integrity gaps
- > Recommendation for mitigation actions

Project figures

Duration: 08/2019 – 01/2020
 Scope: 143 equipments assessed
 Service: Data Integrity consulting

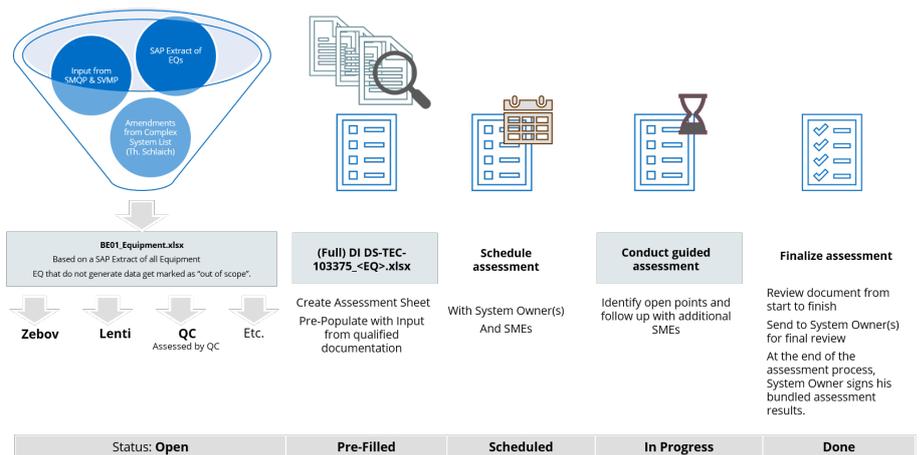


fig 1: Approach for Data Integrity Assessments

The solution

The information age and digitalization bring with it enormous amounts of data created and stored. Especially in the pharma sector, it is crucial to have correct data when executing controls and tracing customer requests and complaints to ensure a safe product. To clarify the current fit of laboratory equipment with data integrity requirements on customer side, adesso conducted assessments with the system owner and where required with further stakeholders (e.g. the CSV Lead). Each equipment was assessed in guided interview sessions and identified gaps built the input for the further FMEA analysis (Failure Mode and Effects Analysis). In the FMEA analysis risks were classified and mitigation actions and their responsibilities defined. Gaps can be easily identified, grouped and solutions can be developed. After closing the gaps, the customer is compliant with the authorities in the area of data integrity.

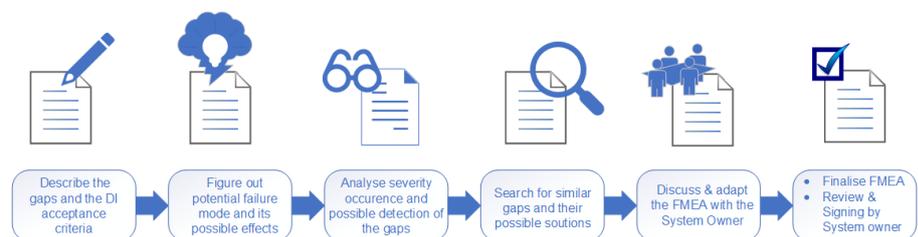


fig 2: Approach for performing FMEA (Failure mode and effects analysis)

adesso Schweiz AG

As an independent consulting and IT service provider, adesso provides consulting and software development services to ensure your projects are successful and your applications are future-proof. Our mission is to optimise core business processes through the targeted use of cutting-edge IT. In doing so, we focus on being close to our customers and adapting to their needs.

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