The Future with Product Intelligence





Reveals Insight at the Intersections of Data





Restricted

Field Complaint – Root Cause Identification using Analysis Tools and AI for Prediction of Future Issues

Scenario Description : A multi-use product has shown accelerated wear, leading to worn/broken parts which can cause patient harm. Product is expected to undergo extensive sterilization procedure between uses.

Enterprise Systems Involved

- QMS
 - Complaint Management
 - Adverse Event Reporting
 - CAPA
 - MDR / FAR
- MES (DHR)
- PLM (DHF, DMR)
 - CAx / PDM
 - Simulation Management
 - Req, Risk, Test Management
- ERP
- CRM
- SCM



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Traditional Process : Complaint logged which initiates activities running in series and parallel to determine root cause of problem. Companies will rely heavily on manual data analysis when working in each system; esp concerning when linkages are not available.

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UDI



Using AI Tools : Complaint logged which initiates Holistic Root Cause Analysis of Entire System (given the data is "good/clean"). Data is standardized and outliers are quickly identified, leading to cause of product failure.

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<u>Predictive Output #1 – Expect problems with this manufacturing process due to past experience</u>

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<u>Prediction Output #2 – This combination of parts has a history of failure; redesign should be</u> considered

<u>Prediction Output #3 – Caregiver misuse of product common enough that patient harm is high;</u> product labeling for use and human factors engineering steps need to be taken