The Future with Product Intelligence

Descriptive
What happened?

Diagnostic
Why did it happen?

Predictive
What happens next and when?

Prescriptive
When this happens, take these steps.

Reveals Insight at the Intersections of Data
Product Lifecycle Management

Pre-Production

- Design Controls
  - Requirements Management
  - Risk Management
  - Test Management

- Collaborative Design Tools
  - CAD
  - ECAD
  - PDM

- Integrated Product Simulation
  - Acoustics
  - Electrical
  - Structural
  - Chemistry
  - Fluids
  - Thermal
  - Durability
  - E-Mag
  - Vibration
  - Dynamics
  - Motion
  - Design Exploration
  - Systems / Controls (HIL, MIL, SIL)

- Manufacturing Simulation
  - Factory Layout
  - Robotics
  - Ergonomics
  - Process Modeling

- Digital Part Manufacturing
  - CAM
  - CMM / Variation
  - Work Instructions

Production

- Manufacturing Execution
  - Dispatch
  - Operator MGMT
  - SPC
  - E-Sig
  - Labeling
  - Process Performance Intelligence

- Human Resource Management

- Clinical Trial Management

- Application Lifecycle Management

- Supply Chain Management

- Customer Relationship Management

- Learning Management System

Post-Production

- Enterprise Resource Planning

- Product Performance Intelligence

- QMS System
  - CAPA
  - Complaints
  - MDR, FAR
  - LIMS
  - Adverse Event Reporting

- Human Resource Management
  - Social Media, News, Weather,

- Clinical Trial Management

- Application Lifecycle Management

- Supply Chain Management

- Customer Relationship Management

- Learning Management System

- Enterprise Resource Planning

- Product Performance Intelligence

- QMS System
  - CAPA
  - Complaints
  - MDR, FAR
  - LIMS
  - Adverse Event Reporting
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
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.
Field Complaint – Root Cause Identification using Analysis Tools and AI for Prediction of Future Issues

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.


- PLM
- MES
- QMS
- ERP
- SCM
- CRM

Manufacturing Issues Identified for Specific Location

High Risk for Product failure with specific configuration manufactured at specific site

Design Issues Identified for Specific Product Configuration
Predictive Output #1 – Expect problems with this manufacturing process due to past experience

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

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