

INNOVATION
WITHOUT LIMITATION

Quality Systems

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Agenda



- Quality Systems – Product Overview
- Demo
- Open Forum Discussion

Aras Quality Management System

- Quality Management System (QMS) is a new application comprising:
 - Quality Planning (QP) - QMS 11R1 (Released: Dec 2015)
 - Replaces previous Aras application
 - Quality Systems (QS) - QMS 11R2
 - Derived from existing Community offering
 - Expected availability: Q3 2016
- **Focus for today is Quality Systems(QMS 11R2)**

Quality Planning (Proactive)

- Design
 - FMEA
- Process
 - PFMEA
 - Flow Diagrams
 - Control Plan

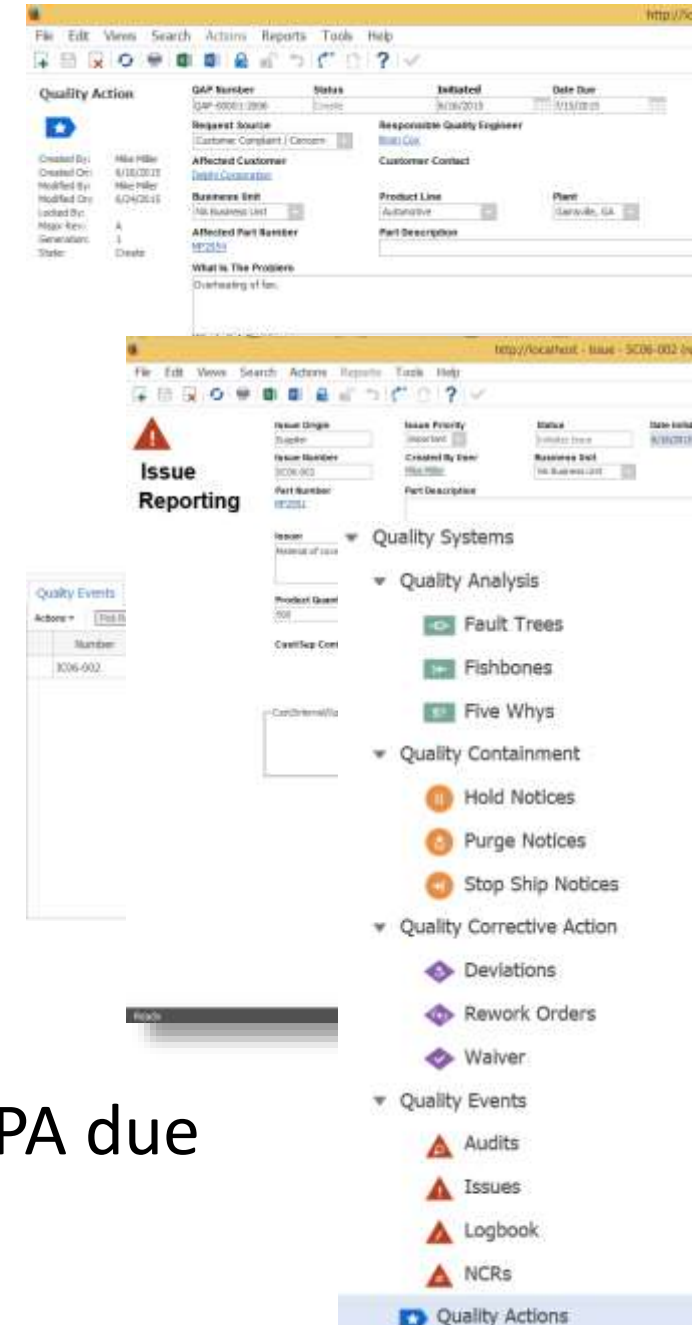
Quality Systems (Reactive)

- Quality Events
 - Issues, Audits, NCRs..
- Quality Containment
 - Hold Notice, Purge Notice..
- Quality Analysis
 - 5-Whys, FTA, Fishbone
- CAPA



Quality Systems – Key Use Cases

- Manage CAPA data and processes in PLM
 - Single source – Design, Manufacturing and Quality data
 - Leverage core PLM capabilities – Workflow, Document Management, Search, Change, Reporting
- Track CAPA and affected Items
- Manage CAPA audit trail for regulatory compliance
- Report/Dashboard
 - Ability to track key CAPA metrics - % CAPA closed, % CAPA due



Quality Systems – Key Items



QUALITY EVENT

- Audits
- Issues
- Logbook
- NCRs

QUALITY CONTAINMENT

- Hold Notices
- Purge Notices
- Stop Ship Notices

QUALITY ANALYSIS

- Fault Trees
- Fishbones
- Five Whys

QUALITY CORRECTIVE ACTION

- Deviations
- Rework Orders
- Waiver

QUALITY PREVENTIVE ACTION

- Documents
- ECRs
- Process Plans

Discussion Topics



- QS Community solution?
- Core elements of your Quality Systems?
- Your CAPA process?
- How do you decide which issue kicks off a CAPA?
- Internal and External players in your CAPA process?
- How do you decide if a CAPA is effective?