How to Improve Quality and Compliance with SAP?

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In This Session

You will gain insight into how quality management (QM) with SAP helps you to ensure product and process compliance with industry standards or legal requirements in the area of:

**Quality Planning**

- Closed-loop inspection planning using failure mode and effects analysis (FMEA) and control plan
- Get insights into new functions delivered with EHP 3 and 5 for SAP ERP

**Quality Assurance and Control**

- Regulatory compliance in quality operations (digital signature, change records)
- Get insights into new functions delivered with recent EHPs for SAP ERP

**Quality Improvement**

- Integrated problem management using quality notifications with SAP ERP
- Preview: SAP Quality Issue Management (new solution !)
Agenda

Introduction
Why quality and compliance are so important

Quality Planning
Tools for assuring closed loop inspection planning

Quality Assurance and Control
Digital signatures and change records

Quality Improvement
Various options to implement continuous improvements

Wrap Up
Summary
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Summary
Manufacturing Companies Feel the Impact
Pressure from many directions

- Material (Eco)Toxicity
- Product Environmental Footprint
- Superior Product Quality
- Material Recyclability

Manufacturing Companies

Legislation

Industry Regulations and Standards, e.g.
- REACH
- RoHS
- GxP
- ISO TS16949
- AS 9000
- (…)

Market Pressure
- Increasing competition from emerging markets
- Rising consumer expectations
- Cost pressure

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Quality Makes The Difference For Manufacturers To Satisfy Customer Needs

Global Networks Require Collaboration and Transparency

Higher product and process quality at lower costs
Built-in quality right from the beginning can save costs in the end

Ensuring product traceability and compliance
Comply with legal requirements and industry standards and ensure seamless traceability in case of issues

Differentiation by exceeding customer expectations
Quality is seen as competitive advantage to gain market shares
Quality Cycle

- Avoid defects right from the beginning
- Define, execute and monitor corrective and preventive actions
- Capture and monitor quality data; react on deviations and trends
What Will Be Highlighted In This Presentation

- **Quality Planning**
  - Failure Mode and Effects Analysis (FMEA) and Control Plan (EHP 3 + 5)
    -> *to comply with ISO TS 16949, QS9000, VDA,...*
  - EHS-QM interface for specifications (EHP 5)
    -> *to comply with ISO 9001,...*

- **Quality Assurance and Control**
  - Efficient quality operations in SAP ERP
    - Digital Signatures (EHP 3 + 6)
    - Enhanced change records (EHP 6)
    -> *to comply with GMP, FDA,...*

- **Continuous Improvement**
  - Enhancements for quality notifications in SAP ERP
    (EHP 5 + 6 and a new mobile application!)
    Preview: Quality Issue Management (new solution!)
    -> *to comply with ISO 9000, GMP,...*

VDA = German Automotive Association, GMP = Good Manufacturing Practices, FDA = Food and Drug Administration
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Closed-Loop Quality Management
Definition and Process

“Closed-loop inspection planning” is an integrated process which stretches across the entire life cycle of a product.

Typical process

Step 1a: FMEA and control plan
Using a cross-functional team of experts, create or update the FMEA to point out product and process characteristics with a high safety risk; copy these characteristics into a control plan, which gives an overview of all inspections for a final product, and from there maintain inspection plans and routings to start production.

Step 1b: From specifications in EHS to inspection planning in QM
As an alternative to step 1a, identify and maintain your critical quality characteristics in EHS specifications and create your inspection plans from there.

Step 2: Quality assurance & control
During production, implement control charts for statistical process control, which enables you to monitor your process and quality key figures.

Step 3: Exception management
Based on a reported problem (e.g., from a customer or from production), take immediate measures, trigger an investigation and check whether this defect needs to be added to the FMEA.
Closed-Loop Quality Management
The Step-by-Step Process

1a

FMEA (Product/Process)
Available with SAP ERP 6.0 EHP 3

Critical-to-Quality Characteristics

Control Plan
Available with SAP ERP 6.0 EHP 3

Inspection Plan
Available with SAP ERP 6.0 EHP 5

1b

Defects
Characteristics

Complaints (8D Process)

Quality Notification

Statistical Process Control

Zero-Defect Production

Defects
Characteristics

Available with SAP ERP 6.0 EHP 3

Defects
Characteristics

EHS Specification*

Available with SAP ERP 6.0 EHP 5

Defects
Characteristics

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Failure Mode and Effects Analysis (FMEA)

Typical Process

Risk analysis for distinct objects (material, operation) to identify possible defects of processes / products

**Typical Process Steps:**

1) Create FMEA for a distinct process or product.
2) Assign relevant objects.
3) Assign team and relevant documents.
4) Define structure: Product → Functions → Failures …
5) Classify the characteristics with a high safety risk.
6) Define preventive actions and detection actions.
7) Define and calculate risk priority numbers (RPN).
8) Form-based printout of the FMEA (VDA96* or QS9000)

* VDA = Verband der Automobilindustrie (German association of Automotive industry)
FMEA Cockpit (SAP ERP EHP 3)
Everything in one place…
Recent Enhancements for FMEA (SAP ERP EHP 5)

- **Interface** for data transfer (e.g. from legacy systems or other SAP objects such as Bill of Materials), see OSS Note 1329928

- **Integration with Quality Notifications** to transfer failures, causes, actions

- **Digital Signature** – individual and multilevel signature for FMEA header and Preventive and Detection Actions

- **Further Round-offs**
  - User Parameter for the FMEA type (e.g. product-FMEA, process-FMEA)
  - Flexible RPN definition
  - “Consistency Check” and “Check & Update Mechanism”
  - (…)
Control Plan
Typical Process

Plan and visualize all relevant inspections for the final product and all its components. Connect all information from the related objects.

Typical Process Steps:

1) Create a Control Plan (prototype, pre-launch, production)
2) Assign relevant objects
3) Assign team and relevant documents
4) Assign existing FMEAs
5) Retrieve existing quality notifications
6) Copy relevant characteristics from FMEA or other source
7) Transfer characteristics into routings and inspection plans
8) Form-based printout of the control plan (QS 9000)
Control Plan (SAP ERP EHP 3)
Structure

<table>
<thead>
<tr>
<th>Objects</th>
<th>Plant</th>
<th>Short text</th>
<th>Material</th>
<th>Created On</th>
<th>Change on</th>
<th>Valid On</th>
<th>Process Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN</td>
<td>1000</td>
<td>Driver Door</td>
<td>FMEA-0100</td>
<td>KNEIPF072 07.03.20</td>
<td></td>
<td></td>
<td>Goods Receipt</td>
</tr>
<tr>
<td>EN</td>
<td>1000</td>
<td>Window</td>
<td>FMEA-0010</td>
<td>KNEIPF072 07.03.20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EN</td>
<td>1000</td>
<td>Pane</td>
<td>FMEA-0001</td>
<td>KNEIPF072 07.03.20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1000</td>
<td>EN</td>
<td>GR Inspection plan: Window</td>
<td>FMEA-0001</td>
<td>KNEIPF072 07.03.20</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EN</td>
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<td>FMEA-0001</td>
<td>KNEIPF072 07.03.20</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Material (Pane)
- Process Type: Goods Receipt
- Q-Info Record
- Inspection Plan

Material (Guide bar)
- Process Type: Production
- FMEA
- Quality Notification internal
- Guide Bar

Driver Door
Window
Pane
Guide Bar
Cockpit for Inspection Plan Creation (SAP ERP EHP 5)
Integration of QM Inspection Plans with EHS Specifications

Further options due to the generic structure of the interface (BAdI concept)

- **EHS**
  - EHS / RM
  - Implemented with EhP 5

- **CAD**
  - CAD-drawing

- **TDT**
  - Technical Delivery Terms

- **Other**
  - Flat Files
  - External Specification Database

**CTQ (Critical to Quality) characteristic / Mapping-Table**

- **PULL-Mechanism**

**Create master inspection characteristics**
- Incomplete Copy Model
- Complete with QM relevant data & save master inspection characteristic

**Create Quality Inspection Plan**
- Choose EH&S specification and load characteristics
- Choose template of a Quality inspection plan or create a new one
- Assign master inspection characteristics and save

**Update Mechanism in case of changes of the source specification**

New transactions in SAP ERP
- QS21S
- QP21S
- QPCG
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Supporting Regulatory Compliance

**Digital Signature in QM**
- Sample Drawing
- Results Recording
- Usage Decision
- Change status of q-notifications and related tasks
- Change status of audits and related tasks
- Change status of FMEA and related tasks

**Electronic Batch Record**

**Audit Trail Functionality**

**Change Management**

**Batch Traceability**
Extended Digital Signature for Inspection Lots, Physical Samples and Quality Notifications (EHP 3 for SAP ERP)

**Business Goal**
Allow multiple signatures during results recording, sample drawing confirmation and quality notification processing and provide extended features through latest digital signature technology based on SAP NetWeaver.

**Solution**
- Activation of digital signatures via Customizing
- Ability to assign signature strategies to allow multi-level signatures during sample registration, results recording, and q-notification handling
- Multiple signature methods are possible (e.g. using external card readers)
- Printout of signature information and additional comments possible
- Digital Signature can be activated for status changes on notification header and for tasks
Enhancements of Digital Signature Functions (1)
New with EHP 6 for SAP ERP

Business and legal requirements (21 CFR Part 11)

For different steps within the signature process, you need to document through separate remarks, where or why the signature was provided.

For increased ease-of-use and process efficiency, you prepare standardized remarks (reasons) within Customizing.

You want to refer to context information in the remark text for increased transparency and traceability.

A complete traceability for changes in results recording is needed also when digital signature process is used.

Key Features

Define different remarks via Customizing for flexible assignment within the signature step.

Usage of different parameters as placeholders in the text to document business context, e.g. Inspection Lot, Operation number Physical-sample-drawing number, Current date/time (UTC)

All comments visible in signature log (DSAL) and enhanced change records for multi-signature steps
Enhancements of Digital Signature Functions (2)

How it looks like...

User assigns a remark containing contextual information

Default entry is proposed, but user can also select another remark text, related to the signature step
Extended Change Documents for Inspection Results
New with EHP 6 for SAP ERP

**Business Challenge**
Incomplete traceability of changes in recorded results, e.g. before inspection characteristic is closed.

**Solution Approach**
New function *"Immediate creation of change documents”*
To …
- Trace changes to inspection results at any time
- Independent of the status of the inspection characteristic, i.e. even before the characteristic is completed.
- For manual entering or results and imported from external sources via QM-IDI or BAPI.
- Activation via Customizing of “Settings at Plant Level”.

Notice: For lower Releases a solution is available for manually entered results via OSS note 581497.
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Continuous Improvement Cycle

- **Trigger**
  - Customer complaint
  - Complaint against vendor
  - Production failure
  - Internal problem
  - Audit finding

- **Structured analysis and investigation**
  - Find similar problems

- **Update of inspection plans or other documents,…**

- **Capture Problem**

- **Analyze Failure and Causes**

- **Find Solution & Define Actions**

- **Execute Actions: Improve & Control**

- **Look in various sources; define, distribute and monitor actions**
Example 1: Use Quality Notifications in SAP ERP
…to handle problems of all kinds

<table>
<thead>
<tr>
<th>Problem &amp; Complaint Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Workflow</td>
</tr>
<tr>
<td>■ Quality-related costs</td>
</tr>
<tr>
<td>■ Follow-up actions with standard examples</td>
</tr>
<tr>
<td>■ Solution Database</td>
</tr>
<tr>
<td>■ Web-based entry options</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corrective &amp; Preventive Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Status Management</td>
</tr>
<tr>
<td>■ Tracking and Monitoring</td>
</tr>
<tr>
<td>■ Use of Catalogs</td>
</tr>
</tbody>
</table>

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<tr>
<th>Quality Analytics</th>
</tr>
</thead>
<tbody>
<tr>
<td>■ QM Evaluation cockpit for Ad-hoc reporting</td>
</tr>
<tr>
<td>■ Predefined queries and key figures in SAP NetWeaver BI</td>
</tr>
<tr>
<td>■ Supplier evaluation</td>
</tr>
<tr>
<td>■ Full-text Search</td>
</tr>
</tbody>
</table>
Quality Notifications in SAP ERP
A Central Tool with Many Integration Touch Points

Evaluations
- Using the QM evaluation cockpit (EHP 3)

Integration into FMEA
- Defect evaluations (EHP 3)
- Transfer of defects into FMEA (EHP 5)

Functional Enhancements
- Full-text search (EHP 3)
- Digital signature (EHP 3)
- Multiple reference objects (EHP 4)
- Display of related quality notifications (EHP 5)
- Enhanced change of notification type (EHP 6)

Quality Collaboration
- 8D process (SAP Consulting solution)
- Exchange of quality issues between supplier or subcontractor and customer using SAP Supply Network Collaboration (EHP 5)

Create/Process on the Web or Mobile
- SAP portal role “Quality Inspector” (SAP ERP 6.0), with SAP Manufacturing Integration and Intelligence or using Web services
- Mobile application for iPhone

Exception Management in Production
- Create quality notifications from SAP Manufacturing Execution to trigger CAPA/8D process (ME 5.2, SP03)

Quality data on the shop floor
- Integration into shift notes and shift reports in PP (EHP 3 + EHP 5)

SOA
- Enterprise services (EHP 2 + EHP 5)
Extended Change of Notification Type (1)
New with EHP 6 for SAP ERP

**Business Challenge**
After creation of a q-notification, the user recognized that the notification type was not appropriate, as the actual case is requesting a different process and documentation.

**Solution: Change Q-Notification Types**
Within the QM transactions *Create Notification* (QM01) and *Change Notification* (QM02) the user can change the notification type.

**Prerequisites**
- User needs to have authorization to perform the change for the current notification type.
- The QM customizing settings define which combinations of q-notification types are allowed for an extended change.
- The notification does not yet have the status *Notification Completed*.
- The notification does not have the status *Defects Recording*.

**Important to know:**
- System does not assign a new notification number on change of the type.
- Changes are reflected in QMIS and “related notifications” function.
- You can tailor the change of notification type specifically for your enterprise via a given Business Add-In (BADI_IQS0_NOTIF_TYPE_CHANGE).
Extended Change of Notification Type (2)
How it looks like...
Mobile Application “SAP ERP Quality Issue”
…to Create Quality Notifications in SAP ERP

Key Characteristics

- Easy creation of quality issues with a mobile device anywhere within the company, directly upon detection of an issue
- Option to attach up to five pictures of the issue, which will be automatically uploaded to SAP ERP upon issue submission
- Option to track the status of issues created by the issue submitter

Key Benefits

- Employee efficiency and motivation – higher acceptance of process
- Submit issue directly upon detection of a defect
- Real-time data access and update status enable fast reaction and processing

Available for iPhone in the Apple App store

Demo Video available on YouTube!
Example 2: SAP Quality Issue Management (Preview)

Definition

What is “Quality Issue Management”? Management of all kinds of quality-related issues and activities triggered by any type of event, e.g. from complaints, product development, manufacturing, sales, or services, but also seen as engine for any other process that requires definition and management of issues and activities.

Why taking care of it?

- Compliance with Legal Regulations & Industry Standards
- Cost Reduction
- Competitive Advantage
- Customer Satisfaction
Modern and flexible approach for capturing and processing any kind of issue and its related activities, eg 8D, CAPA

- Allows easy tracking and analyzing issues and activities beyond applications and systems.
- Can integrate with processes in other applications by triggering issues in QIM or initiating follow-up actions in the related applications.
SAP QIM - Value Proposition

Flexible to adapt
Supports multiple use cases
Integration with SAP and non-SAP systems
Visibility of issues across systems
Easy to use
Cost reduction and enhanced compliance
Demo: SAP Quality Issue Management

Example:
Product complaint

Demo: Submit issue and trigger CAPA
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Key Points to Take Home

1. **End-to-end solution for quality management**
   Offers comprehensive functionality with low TCO

2. **Closed-loop inspection planning process**
   Supports compliance right from the start

3. **Transparent and redundant free quality data**
   Enforce traceability, visibility, and compliance

4. **Integrated tools to comply with regulatory requirements**
   Help to save cost and time

5. **New solution for SAP Quality Issue Management - Coming Soon**
   Provides a platform for global issue processing and monitoring across systems
Resources

- SAP Service Marketplace
  http://service.sap.com/qm
  (requires login credentials)

- SAP Manufacturing Homepage

- SAP Help Portal
  http://help.sap.com/ecc
Time for Questions!

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