SAP Quality Management: Overview and Plant Floor Integration Using SAP xMII

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Overview on SAP Quality Management

Plant Floor Integration: xMII and SAP QM

Customer Success Stories

Outlook
mySAP ERP Quality Management: What It Is

Quality Management
Staying Ahead of the Competition with Quality

Audit Management
- Assessments
- Supplier, Product, Process, System and Environmental Audits

Quality Engineering
- Specifications and Sampling Plans
- Document Management
- Stability Studies/Shelf Life Studies
- Advanced Product Quality Planning

Quality Control and Assurance
- Sample and Batch Management
- Quality Inspections
- Statistical Process Control (SPC)
- Integrated Problem Management
- Certificate of Analyses (CoA)
- Gauge Calibration and Control

Quality Improvement
- Corrective and Preventive Action (CAPA)
- Customer Complaint Management
- Quality Analytics
- Quality Manual
Key Functionality

- Audit planning (different audit types)
- Business partner management
- Audit scheduling and execution
- Audit valuation
- Corrective and Preventive Actions (CAPA) tracking
- Documentation of audit results
- Graphical evaluation of audit data
- Offline audit result capturing

Key Benefits

- Standard compliance QS 9000; ISO 9000; ISO 19011; ISO14000,…
- Consistent and transparent data – company-wide; easy communication of quality information across company boundaries
- Easy appraisal of quality performance through detailed documentation and flexible reporting
- Benchmarking quality performance
Key Functionality

- Inspection Planning / Specifications / Advanced Product Quality Planning
- Sampling Procedures (ISO 2859, ISO 3951)
- Recipe and Trial Management
- Stability/Shelf Life Study
- Integrated Document Management
- Master Data and Change Management
- Supplier Management

Key Benefits

- Consistent master data (free of redundancies: High product quality and compliance with standards
- Inspection planning integrated with purchasing and production
- Provides end users with direct access to relevant quality documentation
- Supports product development process
Key Functionality

- Quality Inspections
  - Goods receipt inspection
  - In/post-process control
  - Inspections at goods issue
  - Recurring inspections
- Test equipment Interfacing
- Usage Decision/Release
- Certificate of Analysis
- Statistical Process Control
- Problem Management
- Test Equipment Calibration
- Quality Information System

Key Benefits

- Supports automatic or manual triggered inspections
- Integrated tightly with supply chain and beyond (e.g. inventory)
- Enables monitoring of critical product and process characteristics and allows instantaneous intervention
- Documents product quality to achieve regulatory compliance
mySAP ERP QM: Quality Improvement

Key Functionality

- Problem/Complaint Management
  - Workflow
  - Quality-related cost
  - Follow-up functions
- Corrective And Preventive Actions (CAPA)
- Quality Analytics
  - Predefined queries
  - Early warning system
  - Control charts
  - Supplier evaluation
  - Results history

Key Benefits

- Comprehensive problem handling for all types of complaints within mySAP ERP
- Efficient processing of quality issues using workflows
- Higher quality performance, while lowering cost-of-quality delivery
- Documentation and audit trails enable rapid root-cause analysis to minimize cost of compliance and recalls
GMP/GLP Compliance Support

Digital Signature in QM
- Sample drawing
- Results recording
- Usage decision (release)

Electronic Batch Record (EBR)

Deviation Analysis

Audit Trail

Change Management

Batch Traceability
- Tight integration between QM and batch classification
- Batch where-used-list
- Batch Information Cockpit
Integrated Enterprise Quality Management

- **Human resources**: Workflow, authorization concept, QM manual
- **Logistics**: Inventory management, batch management, change handling, CAPA, data warehouse, document management
- **Finance and controlling**: Quality-related costs, revenues
- **Enterprise asset management**: Test equipment management, calibration planning and execution

Enterprise Quality Management within mySAP ERP

- **Research and development**: Stability studies, flexible specifications, recipe management, APQP
- **Procurement**: Inspection planning, supplier release and COA, goods receipt inspection, sample management, audit management
- **Production**: In-/post-process control, test equipment interfacing, deviation management, shop floor integration with xMII
- **Sales**: COA, quality data exchange, billing of analysis

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Manufacturing Quality Metrics Are Most Important

Q: How important are each of the following categories of metrics in measuring performance of your manufacturing operations? (1—not very important / 5—extremely important)

- Manufacturing quality: 94%
- Manufacturing costs: 87%
- Supplier quality: 87%
- Manufacturing responsiveness: 84%
- Schedule adherence: 81%
- Manufacturing flexibility: 76%
- Measuring demand/demand visibility: 73%

Source: AMR Research, 08/2006
SAP Quality Management enables Shop Floor Managers and Operators to manage and assure product quality, monitor and improve quality standards and document quality compliance, for subsequent audit.

**Key Benefits:**
- Higher product quality and customer satisfaction
- Superior, cost-effective quality compliance
- Exception based quality management
- Continuous quality improvement
**Quality Control in Manufacturing – Business Problem**

**Business problem**
Manufacturing and quality management systems are often separated. Triggering preventive actions through statistical process control and trend analysis as well as tracking of material defects is difficult.
SAP offers a powerful quality management solution as integral part of mySAP ERP, however, the user interface to record in-process quality data is not suitable for operators or quality inspectors in the shop floor.

**Solution: Use SAP xMII to combine Manufacturing and Quality Management Processes!**

**Value to Customer**
- Comprehensive view on quality and production data in SAP xMII
- Easy user interface to access SAP QM results recording
- Pre-built mySAP ERP integration
- Process optimization in the laboratory and production area
- Improved compliance through enhanced data visibility
- Easier to connect electronic test devices
What is the SAP xApp Manuf. Integration and Intelligence (xMII)?

The SAP xApp Manufacturing Integration and Intelligence (xMII) is a packaged composite application that delivers:

Manufacturing Intelligence: Real-time analytics engine that aggregates and delivers unified visualization of events, alerts, KPIs and decision support to production personnel thru role-based dashboards.

Manufacturing Integration: A single ISA-95 compliant layer enabling SAP ERP connectivity into real-time plant floor apps. (MES, SFA, LIMS,..) to drive plant-to-enterprise business process interoperability.

MES – Manufacturing Execution Systems, EMI – Enterprise Manufacturing Intelligence, BW – Business Warehouse (from SAP) SFAC – Shop Floor Automation & Control, LIMS = Laboratory Information Management Systems
SAP QM Productivity Pack for SAP xMII – Use Cases

**Content**
SAP will deliver **generic templates for quality data entry and visualization** that enable a state-of-the-art user interface for the operator who is responsible for in-process quality checks. A **seamless integration** between SAP xMII and the mySAP ERP QM backend will be provided.

**Use Cases for the Operator/Quality Inspector**
- Retrieve a work list of QM inspection lot operations for his work center in SAP xMII
- Record inspection results online (synchronized with mySAP ERP QM)
- Display inspection results
- Generate graphics for critical inspection characteristics (run chart, control chart, results history) to perform trend analysis
- Transfer results from electronic test devices
- Trigger quality notifications in mySAP ERP QM
mySAP ERP QM can be operated as a full-blown LIM-system
SAP xMII can integrate data from mySAP ERP QM (Rel. 4.6C and higher) and from 3rd party LIM-systems to improve productivity on the shop floor
Planned Availability for SAP xMII 11.5: Q4 2006

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Quality Control in Manufacturing: Process

Roles
- Quality Manager
- Operator
- Quality Inspector
- Plant Manager

- Quality Planning
- Released Production Order
- Record Quality Data (Results/Defects/IPC)
- Create inspection Lot (Automatically)
- Monitor Quality Data (SPC / SQC)
- Approve Batch / Orders
- Control Produced Batch / Orders
- Audit, on Demand and Review Results

Measure and improve KPIs

SAP xMII
Step 1: Quality Planning in mySAP ERP

- QM master data maintenance (characteristics, methods, ...)

- Central inspection planning and distribution via ALE possible

- Engineering Workbench (EWB) for mass maintenance of task lists

- Inspection operations integrated in routings/master recipes or as separate inspection plans

- Release production order to trigger in-process inspection

Demo Part 1

Role: Quality Planner
Step 2: Record Quality Data on Plant Floor Using SAP xMII

- Work lists with inspection lot operations (per work center)
- Display list of inspection points
- Select inspection characteristics (from QM inspection lot)
- Record results for characteristic
- Display run chart/control chart
- Exception management
- Automatic update of QM inspection lot in mySAP ERP

Roles: Quality Inspector or Operator

Demo Part 2

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Step 3: Quality Data Analysis - Options

Quality reporting in mySAP ERP:
- Inspection Work lists and reports
- Result histories and control charts
- Supplier evaluation
- QM Info System

Analytics based on mySAP BI:
- Predefined queries with aggregated data from q-notifications and inspection lots
- SAP Analytics Business Packages using mySAP BI content or ERP reports

Quality Analytics with SAP xMII

Roles: Production Supervisor, Plant Manager or Quality Manager
Tata Consulting Services (TCS) is providing additional examples for dashboards and composite applications based on SAP xMII, e.g. „Rapid Sigma“.
Partner xApps based on SAP xMII to Drive QM Integration (2)

Partner xApp from IBM: SAP xLC (LIMS Connect)
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Plant Floor Integration: xMII and SAP QM

Customer Success Stories

Outlook
Customer Success Story

Pratt and Whitney Canada

Driving Quality Improvement thru Higher Visibility and Responsiveness with SAP xMII
Results entry updates QM inspection lot
Value from the SAP xMII Solution:

Savings from Quality Cost Avoidance will be realized in six major areas:

- internal scrap rework & repair
- lower supplier scrap resulting in lower material prices
- reduction in QN (quality notification) items
- reduction in warranty expense caused by manufacturing escapes
- improvement in engine retest ratio, and

SAP’s xMII is a tool that will enable us to achieve roughly a $14 million saving per year in quality cost avoidance. In addition, we will avoid costly engine escapes at the end – each of which could potentially cost us half a million dollars. How many are we going to avoid, we cannot know. Statistically speaking, if we avoid one, it would pay for the system by itself.

Claude Poliquin, Business Development Manager- Quality
Presentation at the SAP xMII User Group Conference, Philadelphia, October 2005

* Customer escape is a defective aircraft engine or component delivered to the customer
SAP® for Pharmaceuticals: SAP QM Used as LIMS

ROCHE DIAGNOSTICS

Roche Diagnostics – based in Basel, Switzerland, and one of two divisions of the 100-year-old healthcare company F. Hoffmann-La Roche Ltd. – invents and manufactures reagents for medical diagnostics. Roche chose the quality management capabilities of mySAP™ Product Lifecycle Management (mySAP PLM) to improve and automate lab and production processes.

Key Challenges
- Manual, time-consuming, error-prone processes/redundant data
- Mounting regulatory pressures
- Difficulty in managing growing product lines

Implementation Highlight
Implemented solution as part of company-wide SAP® R/2® to SAP R/3® migration

Key Benefits
- Transparent laboratory processes/accurate documentation to ensure compliance with regulatory requirements
- Automated, streamlined processes – from laboratory to production
- Reduced IT complexity
- Increased quality of data in highly integrated system landscape

“We now know we can rely on our QM data and its documentation. This means our customers and our employees are assured of continuing, top-level product quality.”

Kai Rothermel, Information Manager SAP QM, Roche Diagnostics
Using SAP QM as Integrated Enterprise LIMS

The Solution
- LIMS is not a separate product but based on SAP Quality Management Application integrated in mySAP ERP
- Main focus is on In-Process and Quality Assurance & Control labs

Selected Reference Customers:
- BASF, Germany
- Roche Diagnostics, Germany
- Clariant, Switzerland
- DSM Fine Chemicals, Austria
- Olin Corporation, USA
- Dow Corning, USA
More Than 4000 Customers Use SAP QM Today!

“mySAP PLM QM accelerates the inspection processes up to 50%. Automation, both within mySAP PLM QM and selected bolt-ons (LIMS and Auto Data Collection), reduces our inspection costs by approximately $750,000 (USD) annually in our global labs, and assists in ISO, GMP, and legal compliance efforts.” (Source: Dow Corning, Midland, Michigan, U.S.A.)

“mySAP PLM offers a flexible and open solution for our quality management. We are using quality notifications to improve our company-specific development processes. The associated workflow functions enable us to efficiently solve problems that arise in the development phase.” (Source: Porsche AG, Germany)

“Our efforts are focused on our customers and their demands for high quality. The quality of purchased parts plays a decisive role. Thanks to the transparency of data in mySAP PLM Quality Management our optimization process is supported and we are in a position to improve our quality and thereby lower costs.” (Source: ZF Passau GmbH (Automotive Supplier), Germany)

“Using Quality Management with mySAP PLM as our Enterprise Laboratory Information Management System (LIMS), we were able to accelerate our inspection processes, reduce costs and fulfill legal requirements.” (Source: B.Braun Melsungen AG (Life Sciences), Germany)
New in Quality Management with mySAP ERP 2005

- **Multiple Specifications**
  - Plan, test, and classify batches according to different characteristics

- **“Operation Completion” Function**
  - Indicate when inspections are complete in one work center/laboratory and trigger follow-up actions

- **Flexible Reporting Capabilities**
  - Create analytical online reports on quality data combined with graphical representation

- **Enhancements to “Audit Management” Function**
  - Link corrective actions to ERP QM notifications and evaluate audit data with mySAP BI

- **Quality Inspection Engine (QIE)**
  - QIE is delivered with mySAP SCM 5.0/SAP NetWeaver 2004s to support service-based quality inspections in a heterogeneous system landscape
### Key Objectives for Quality Management with SAP

#### Strategic Themes
- Leverage SAP xMII for QM
- Adopt Enterprise SOA for QM scenarios
- Support improvement processes and compliance

#### Key Headlines
- Deliver QM content for SAP xMII
- Enable test equipments/interface box connectivity using SAP xMII
- Provide dashboard for Six Sigma Project Lead and Quality Inspector
- Provide Failure Mode and Effect Analysis (FMEA) tool to enable Design for Six Sigma and support NPDI process
- Enhance product compliance
- Continuous improvements for QM as LIMS/CAQ
- Develop enterprise services to enable new QM scenarios

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7 Key Points to Take Home

Quality Management from SAP ...

- Offers a solution seamlessly integrated with the supply chain with various control options at every stage
- Supports Good Manufacturing Practices (GMP) and other legal requirements
- Offers an end-to-end solution for QM and lowers Total Cost of Ownership (TCO)
- Provides consolidated and predefined quality key figures — they can be analyzed and drilled down to any detail
- Enables proactive tracking of Corrective And Preventive Actions (CAPA)
- Drives decision-making to the shop floor through integration with SAP xMII
- Is a flexible and scalable solution built on latest SAP NetWeaver technology
Thank you for your attention

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