Integration of Quality Management Systems

The Integration of Quality Management Systems ES bundle provides enterprise services for the exchange of inspection lot data, inspection results, and quality notification data between the Quality Management (QM) application in SAP ERP 6.0 and external quality management systems.

The SAP QM-ID interface provides the capability to exchange inspection lot data between SAP ERP QM and external QM systems. The Integration of Quality Management Systems ES bundle also aims to achieve data exchange between SAP ERP QM and external QM systems, and it adds the following benefits and advantages:

- New XML-based technology (web services)
- Higher flexibility (a subset of services can be deployed)
- Enhanced functionality (quality notifications and unplanned inspection points, for example)

Note: ES Bundle is not a successor of QM-ID interface. It is a new platform for the interfacing requirements.

This ES bundle bridges data from the quality planning level to the inspection of data level and right down to the instrument recording level. It can be used to exchange data between LIMS/CAQ systems and SAP ERP QM directly, with more flexibility than is provided by existing interfaces. IQMS can be used to integrate LIMS/CAQ systems via SAP xApps. The SAP xApp LIMS Connect (built by IBM) is based on SAP MII and connects different LIMS systems for data evaluation and statistical process control. Integration with the SAP ERP QM backend can be achieved by using the services provided in this bundle. SAP MII can consume the services to enable quality data entry and visualization without having external QM systems connected (SAP ERP QM can act as an enterprise LIMS with an SAP MII frontend).

This ES bundle does not supply or assume a dedicated user interface. It is intended as a way to integrate other applications that provide front-end functionality. A dedicated user interface template based on the supplied services could be created using SAP MII or using WebDynpro, Visual Composer, or Adobe technology, powered by SAP NetWeaver.

The enterprise services supplied by this ES bundle will be used by quality inspectors, operators, and lab technicians who are executing quality analyses and also entering inspection data manually or transferring data from electronic test devices. It is also applicable for production supervisors or quality managers who want to perform analysis of this data.

This ES bundle requires a company to use SAP ERP Quality Management. The services expose functionality of the SAP ERP QM business objects such as inspection lot, physical sample, and quality notification and can interoperate with an external QM solution.

**Audience**

Any industry that requires an integration of quality management systems with SAP ERP will derive value from implementing this ES bundle. Early beneficiaries include chemicals industry companies seeking a best practice solution as well as high-tech and automotive enterprises seeking to connect the shop floor with the top floor.

For details on Service Operations, Business Objects and Process Components, please check the ES Workplace.
How to Use This ES Bundle

Quality results recording and inspection management exist today in a heterogeneous landscape. A variety of different and often disconnected systems is distributed throughout the different business units in an enterprise. This has led to a complex infrastructure that can only be linked with the backend ERP system through custom-built connectors, if at all.

One side effect of this is redundant master and transactional data. A lab technician reads data from an electronic instrument but may be required to reenter that data manually into the backend system, a laborious and error-prone process. And this may need to take place several times during a single inspection process.

If there is a quality issue during an inspection, the data necessary to track down and understand this deviation may not be available to the technician at all.

The Integration of Quality Management Systems ES bundle, when used in conjunction with an existing quality management solution, ties together these disparate systems on a standard platform that exists across the enterprise and extends its functionality through enterprise services. These enterprise services provide the ability to:
- get work lists for material inspections
- record results
- record defects
- create unplanned samples
- create unplanned inspections
- modify data in material inspection samples
- make, update, and read usage decisions
- create, change, read, and find quality notifications

This section describes a series of use cases for the Integration of Quality Management Systems ES bundle. Each use case shows how different outcomes can be achieved by using the enterprise services in different combinations. While these examples illustrate a few ways that this ES bundle could be used, it is not limited to these examples. The intention is to show some of the flexibility and reusability of these business objects and enterprise services so that you will have a clearer understanding of how to best deploy them in your own environment.

Use Case 1: Basic Integration of Quality Management Systems

This example illustrates the most basic functions of quality management: getting work lists and recording results.

When an order of chemical compounds arrives from a vendor to a company, the warehouse clerk executes a stock posting in SAP ERP and the system automatically triggers the Material Inspection business object. This business object handles all of the enterprise services related to:
- detailing work lists
- performing inspection operations
- determining inspection characteristics for lots
- handling inspection results
- assigning attribute codes
- assigning defect codes
- creating inspection points
- finding inspection lot details
- creating physical samples with reference to an inspection lot
- recording defects
- making decisions about usage

The difference between the Material Inspection business object and the Material Inspection Sample business object has to do with subsets of inspection lots. Material Inspection is related to an inspection lot request that is sent to a plant to carry out a quality inspection for a specific quantity of material. Material Inspection Sample is related to a physical sample, or a subpopulation taken from a basic population to determine the quality of the basic population (the basic population can be an inspection lot).

The term physical sample typically describes formless subpopulations of bulk products or continuous products, which are taken from a basic population in a sample-drawing procedure. In SAP ERP QM, the physical sample is managed in the form of a data record, containing the following types of samples:
- Primary samples taken directly from the population
- Pooled samples created by pooling primary samples
- Reserve samples, primary samples that are reserved as specimen samples

In general, this means that a physical sample represents its own business object in SAP ERP which can be used as a subset of an inspection lot but can also exist independently. The examples in this bundle will deal primarily with Material Inspection.

When an inspection lot is created, a lab technician accesses it through a work list either in SAP ERP QM or in an external LIMS. The technician is now able to utilize data from several different enterprise services. One inspection lot may require several operations and could be assigned to different work centers to carry out each one. This process is defined by a
business architect who aids in the implementation of this solution.

The **Find Material Inspection Subset Operation by Elements** enterprise service pulls the specific operations to be carried out on the lot. Elements in this instance include different selection criteria, such as plant, date, material, batch number, inspection type, and inspection origin. The operation defines which lab carries out the task—the lot may undergo a microbiology test in one work center and then move to another work center for a chemical analysis and chromatography test. The term operation in this case can also be used to define different production line work centers, where machine 1 takes a sample and then machine 2 takes a different sample (the operation number and routing for this situation is predetermined in the process flow). The properties then detail what element of the lot is to be inspected: the pH value, the water content, the purity, and so forth. All of this type of data can be found with the **Read Subset Operation Inspection Activity** enterprise service.

Now the lab technician wants to display a list of inspection characteristics for one operation. The **Find Subset Operation Inspection Activity Basic Data by Elements** enterprise service finds the inspection characteristics for the lot and the **Read Subset Operation Inspection Activity** enterprise service provides details of the inspection characteristics.

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**Example of a user interface using SAP xMII that gets work list of material inspections using the following services:** Find Material Inspection Subset Operation by Elements, Find Subset Operation Inspection Activity Basic Data by Elements, and Read Subset Operation Inspection Activity (click to enlarge)

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At this point, the lab technician has all the relevant data tied to a lot that requires inspection and the operations to be carried out in order to properly inspect that lot. He now wants to measure and record the results. There are two types of results to record: those without inspection points and those with inspection points. The inspection point is a specific action that can be configured in SAP ERP QM. It offers the option of measuring one characteristic or taking multiple measurements during the course of a single inspection. The technician is tasked with measuring the temperature of a liquid, for example, that is being heated from 30 degrees to 60 degrees. He is instructed to take a temperature reading every 10 minutes, and as a result records results at 35, 45, and 50 degrees. In this case, the system would be configured to measure the characteristic temperature multiple times. Recording results inspection characteristics with or without multiple inspection points just one service: **Record Subset Operation Inspection Activity Result**. This service records data for all assigned inspection points and physical samples for one operation and updates them in the SAP ERP backend system.

Now that the data is available in the SAP ERP system, it can be used for analysis and planning. A production supervisor or quality manager might access this report, using the **Find Subset Operation Inspection Activity Basic Data by Elements** and **Read Subset Operation Inspection Activity** enterprise services, to decide whether or not the chemical compound meets all necessary requirements in order to be moved to the next step in the process chain.

Once the test results required for the inspection lot are captured, the quality manager can review them at will by invoking the **Read Material Inspection Subset Operation Activity Result and Finding** enterprise service operation. This service enables him to view all of the pertinent inspection characteristics in a single location, thus providing him with the transparency needed to make or update usage decisions via the **Create Material Inspection Decision** and **Update Material Inspection Decision** enterprise services. He reviews all the results and then selects a decision code using the **Find Quality Issue Category Catalogue by Quality Issue Notification Type** enterprise service to indicate whether the batch is accepted or rejected.

In some instances, the operator on the shop floor may be in a position to make a usage decision. A business architect could enable this functionality directly from a compatible LIMS system to utilize the **Create Material Inspection Decision** enterprise service. If an earlier decision needs to be amended or further explained, the operator could invoke the **Update Material Inspection Decision** enterprise service.

<table>
<thead>
<tr>
<th>Step</th>
<th>Enterprise Service Invoked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: To search for the specific that are carried out on the lot</td>
<td><strong>Find Material Inspection Subset Operation by Elements</strong></td>
</tr>
<tr>
<td>Step 2: To review the necessary information</td>
<td><strong>Read Subset Operation Inspection Activity</strong></td>
</tr>
</tbody>
</table>
Step 3: To find the inspection characteristics for the lot

| Find Subset Operation Inspection Activity Basic Data by Elements |

Step 4: To review the details of the inspection characteristics

| Read Subset Operation Inspection Activity |

Step 5: To record results of the inspection

| Record Subset Operation Inspection Activity Result |

Step 6: Other users can overview the inspection activities

| Find Subset Operation Inspection Activity Basic Data by Elements and Read Subset Operation Inspection Activity |

Step 7: To review the results of the inspection

| Read Material Inspection Subset Operation Activity Result and Finding |

Step 8: To make or update usage decisions

| Create Material Inspection Decision and Update Material Inspection Decision |

Step 9: To review all the results and to select a decision code

| Find Quality Issue Category Catalogue by Quality Issue Notification Type |

Step 10: If another user is in the position to make a usage decision, he or she can update the inspection lot with the usage decision

| Create Material Inspection Decision |

Step 11: To amend or further explain an earlier decision

| Update Material Inspection Decision |

Use Case 2: Recording Defects and Generating a Quality Issue Notification

The very reason for quality testing is to ferret out substandard results. This requires an operator or technician to notify the quality management system of deviations, even if they occur during the middle of an inspection. One valuable feature of the Integration of Quality Management Systems bundle is that a quality manager has the ability to learn about and act on such deviations even before a final inspection report is generated.

Example for possible user interface using SAP xMII: Results recording screen using the Record Subset Operation Inspection Activity Result enterprise service (click to enlarge)

To help illustrate this use case, let's imagine we are on the production line of a laptop manufacturing operation. An operator at the plant is charged with testing the motherboards on each laptop. He pulls up all the relevant data through the Material Inspection business object, as in use case 1, and begins recording results.

The first operation does not require inspection points; the operator simply determines whether the chipset is working. In some cases, the chip is not working properly and he records defects for inspection characteristics without inspection points using the Create Subset Operation Inspection Activity Finding enterprise service to specify a defect code. The operator can select from a list of possible defect codes through the Find Quality Issue Category Catalogue by Quality Issue Notification Type enterprise service.

Alternately, a LIMS system could be set up with a direct connection to the backend system. Instead of the lab technician manually entering the results, the lab information system on the shop floor would automatically flag defective readings and signal this to the backend system using the same set of enterprise services. This is the sort of flexibility that is only possible through enterprise SOA.
Once the backend system is updated with a defect record and a defect code, a corrective incident action process can be triggered via notifications or workflow. A request is automatically sent through the Quality Issue Notification business object, which uses enterprise services to dispatch the appropriate data to the production manager.

<table>
<thead>
<tr>
<th>Step</th>
<th>Enterprise Service Invoked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: The user notices a defect and wants to specify a defect code</td>
<td>Create Subset Operation Inspection Activity Finding</td>
</tr>
<tr>
<td>Step 2: The user can select from a list of possible defect codes</td>
<td>Find Quality Issue Category Catalogue by Quality Issue Notification Type</td>
</tr>
<tr>
<td>Step 3: When the system is updated with a defect record and a defect code, a request is automatically sent</td>
<td>Create Quality Issue Notification</td>
</tr>
</tbody>
</table>

**Use Case 3: Quality Issue Notification without Inspection Lot Defects**

Even when the delay has nothing to do with a defect, the Integration of Quality Management Systems ES bundle can also be used in simple communication between a factory floor and a manager using the Material Inspection business object. In this example, a Quality Issue Notification business object triggers the Create Quality Issue Notification enterprise service because of an accident on a factory floor that is temporary and fixable, even though for a short period quality is affected in the product.

A soda manufacturer bottles its high-end juice drinks in glass containers. A bottle accidentally breaks on the line at the point where the juice is being funnelled into the containers. Glass shards are all over the conveyer and may have gotten into the juice. An operator on the floor inputs a notice that activates the business object. A Quality Issue Notification enterprise service informs the manager that the line has to be cleaned up, and Find Quality Issue Category Catalogue by Quality Issue Notification Type helps the operator to properly code the report.

A quality manager receives the notification automatically and alerts both the quality supervisor and the production supervisor that a delay has occurred and that customers may need to be notified about possible delays in shipment.

Once the line has been cleaned and is cleared to resume manufacturing, the operator notifies the manager using the Change Quality Issue Notification enterprise service. The manager wants this update sent to the supervisor quickly and codes the report by running Find Quality Issue Category Catalogue by Quality Issue Notification Type enterprise service so that the supervisor can then make immediate decisions to adjust production, possibly speeding up the line to offset any delays so that customers receive their products on time.

This is just one of many ways that a Quality Issue Notification business object can be configured with different definitions to ultimately improve operations on the shop floor.

**Simple Sample App available**
If you are looking for best practices in consuming enterprise services from the Integration of Quality Management Systems ES bundle, please refer to Simple Samples for ES consumption to find ready-to-run examples, including testing data for immediate use. Please find the simple samples related to QM are listed under the topic “Quality Management”.

<table>
<thead>
<tr>
<th>Step</th>
<th>Enterprise Service Invoked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: An accident on a factory floor happened</td>
<td>Create Quality Issue Notification</td>
</tr>
<tr>
<td>Step 2: The user can properly code the report</td>
<td>Find Quality Issue Category Catalogue by Quality Issue Notification Type</td>
</tr>
<tr>
<td>Step 3: The user notifies the operator that the mess caused by the accident is cleaned</td>
<td>Change Quality Issue Notification</td>
</tr>
<tr>
<td>Step 4: To send the update to the supervisor quickly, the user searches for the right code from the catalogue needed for the usage decision</td>
<td>Find Quality Issue Category Catalogue by Quality Issue Notification Type</td>
</tr>
</tbody>
</table>

Use Case 4: Triggering Unplanned Inspections

Most of the time inspections work according to specifications. But there are always exceptions, and the planner or business architect cannot foresee every possibility. The Material Inspection Sample business object offers a way of building flexibility into the process so that a new inspection point or sample reading for an unplanned characteristic can be recorded.

An operator is taking pH values of a chemical, for example. The process operation says to take five samples. But the readout malfunctions, or the operator simply wasn't certain he got the right measurement. At this point, he would create a new inspection point using the Create Material Inspection Subset and Create Material Inspection Sample enterprise services to notify the backend system that a new inspection subset is being created and to record the results for that inspection sample.

<table>
<thead>
<tr>
<th>Step</th>
<th>Enterprise Service Invoked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: To create a new inspection point</td>
<td>Create Material Inspection Subset and Create Material Inspection Sample</td>
</tr>
</tbody>
</table>

Use Case 5: Creating Unplanned Inspection Samples and Inspection Lots

In the previous use case, the scope of a preexisting inspection lot whose inspection points were insufficient was extended by recording an additional inspection point that was not part of the original specifications.

In this use case, the operator has just been informed by his supervisor that yet another unplanned reserve sample must be created. However, in addition, this sample must be recorded as an inspection lot independent from that which the sample originally derives. The Integration of Quality Management Systems ES bundle provides enterprise services with which the operator can perform these tasks.

To create the new sample, the operator triggers the Create Material Inspection Sample service operation, logs the sample data, and saves it with a unique ID number. To create a new inspection lot that is stored in the SAP ERP QM backend with reference to the new sample's ID number, the operator invokes the Create Material Inspection with Reference to Material Inspection Sample service operation. It is at this point that he will also enter such data as the name of the plant in which the inspection is being conducted and the type of material being inspected. Should additional inspection lots be needed to record specific characteristics about this sample, they can be created at any time.

In the same process, it is also possible to use the Create Material Inspection Sample enterprise service, which will trigger an inspection using only the Material Inspection Sample business object.

After the material inspection or the material inspection sample has been created, someone else in the process might need to update these objects with additional data. Therefore, the Change Material Inspection and Change Material Inspection Sample service operations in the Integration of Quality Management Systems ES bundle provide inspection personnel with the flexibility needed to alter both the data and status of a given inspection or sample.
For example, the quality manager may wish to include a note that elaborates on data in a certain field, or she may want to further clarify existing text. On the other hand, it may be that the initiator of this sample request has not added all required data, so the status of the sample remains "Created." Later, after everything is prepared for the chemical analysis, the lab technician can change the sample’s status from "Created" to "Released" in order to enable results recording for this sample.

<table>
<thead>
<tr>
<th>Step</th>
<th>Enterprise Service Invoked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step 1: To create the new sample</td>
<td>Create Material Inspection Sample</td>
</tr>
<tr>
<td>Step 2: To create a new inspection lot with reference to the new sample’s ID number</td>
<td>Create Material Inspection with Reference to Material Inspection Sample</td>
</tr>
<tr>
<td>Step 3: To creates a new material inspection</td>
<td>Create Material Inspection Sample</td>
</tr>
<tr>
<td>Step 4: To update the material inspection or the material inspection sample with additional data</td>
<td>Change Material Inspection and Change Material Inspection Sample</td>
</tr>
</tbody>
</table>

**Certified Partner Applications implementing this ES Bundle**

**Certified Partner Applications for Integration of Quality Management Systems**

<table>
<thead>
<tr>
<th>Partner Company</th>
<th>Caliber Technologies Pvt Ltd</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and Version of the Certified Product</td>
<td>CaliberLIMS 3.0</td>
</tr>
<tr>
<td>Validity of the certification</td>
<td>October 15, 2011</td>
</tr>
<tr>
<td>Brief Description of the Certified Product</td>
<td>CaliberLIMS is a we technology based Laboratory Information Management System, that helps Pharma companies to enforce GLP and 21CFR part 11 standards and manage laboratory information to substantially reduce the risk of non compliance. Controlled sample management with audit trails and change management on all the functions ensure regulatory compliance requirement. CaliberLIMS addresses other day to day functional needs of a Laboratory like Chemicals Inventory Management with stock cards, Analyst competancy mapping and Management, Stability studies as per ICH guidelines, Instrument Calibration Management &amp; certification.</td>
</tr>
<tr>
<td>Implemented Use case(s)</td>
<td>Use Case 1: Basic Integration of Quality Management Systems</td>
</tr>
<tr>
<td>Partner Company</td>
<td>STARLIMS Corporation</td>
</tr>
<tr>
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</tr>
<tr>
<td>Name and Version of the Certified Product</td>
<td>STARLIMS v10 R2</td>
</tr>
<tr>
<td>Validity of the certification</td>
<td>November 10, 2011</td>
</tr>
<tr>
<td>Brief Description of the Certified Product</td>
<td>STARLIMS is a web-based off-the-shelf LIMS (Laboratory Information Management System) designed for a wide variety of laboratory environments operating in many scientific and industrial disciplines. STARLIMS consolidates disparate business processes into a single, compliant platform with comprehensive reporting, surveillance and networking capabilities. The result is vastly enhanced data management and sharing-within the laboratory and across the enterprise.</td>
</tr>
<tr>
<td>Implemented Use case(s)</td>
<td>Use Case 1: Basic Integration of Quality Management Systems</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Partner Company</th>
<th>LabWare, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and Version of the Certified Product</td>
<td>LabWare LIMS 6.0</td>
</tr>
<tr>
<td>Validity of the certification</td>
<td>December 15, 2011</td>
</tr>
<tr>
<td>Brief Description of the Certified Product</td>
<td>LabWare LIMS uses enterprise services to download Inspection Lots and post results and usage decisions back to SAP</td>
</tr>
<tr>
<td>Implemented Use case(s)</td>
<td>Use Case 1: Basic Integration of Quality Management Systems</td>
</tr>
</tbody>
</table>

Know - How Guide

Most of us find it difficult to realise the services from this bundle in a real time application. To ease this, our Solution Management team has developed a “Know-How Guide”. Please download from the below link, Read the article and download the guide.

http://www.sdn.sap.com/irj/scn/go/portal/prtroot/docs/library/uuid/306718f5-8922-2c10-89ae-8c2a6551f5e6

If any doubt, please contact Karthikeyan L - karthikeyan.l@sap.com

Future Directions

One possible future direction for the Integration of Quality Management Systems is extending this ES bundle to enable the flexible assignment of inspection characteristics or certificate creation. This ES bundle could also be complemented by another ES bundle dealing with QM inspection master data to extend to the actual quality planning stage, to help design the testing phases, and to organize and move the data through the process steps.

Connectivity
Integration of Quality Management Systems achieves connectivity between SAP ERP 6.0 and laboratory or in-process testing stations through SAP MII.

System Requirements

- SAP ERP 6.0
- SAP NetWeaver Process Integration (SAP NetWeaver PI, formerly known as SAP NetWeaver XI)
- SAP enhancement package 1 for SAP ERP 6.0
- SAP enhancement package 2 for SAP ERP 6.0
- SAP MII (optional)
- LIMS/CAQ system (optional)

Related ES Bundles

- Integration of Manufacturing Execution Systems
- Manufacturing Work Instructions
- Batch Traceability and Analytics

End-to-end Processes Where This ES Bundle Is Used

- Efficient Manufacturing Operations
- Embedded Product Compliance
- Integrated Product Development

Links

SDN and SAP Links

- SOA Homepage on SDN
- SAP Library information on Quality Management

Partner Links

- IDOS Software AG