Integration with R/3 Quality Management and LIMS

Between the production plant and the laboratory analyzing production data, information on quality and analysis values need to be exchanged. This is carried out via the link of PP-PI to the R/3 Quality Management System, with or without a linking to external LIMS (laboratory information management systems).

The functionality of the R/3 Quality Management system comprises the maintenance of master data (integrated in production planning) as well as the control of inspection processing. The product quality can be pre-planned and monitored throughout all steps involved, from product development to preliminary planning, up to the production process itself. The R/3 QM system was developed according to ISO 9000.
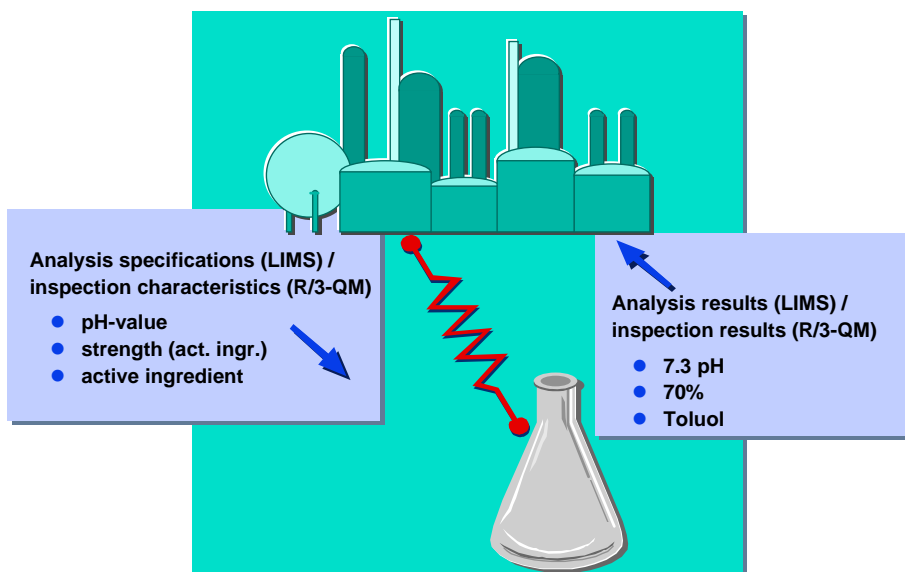

Fig. 9-1: Integration with LIMS or R/3 Quality Management

There is a basic difference between analyses accompanying the process (in-process control or inspection) and analyses which follow after the process has been carried out (post-process control/inspection).

❑ In the case of **in-process control,** process events are recorded directly during the production process, either by a process control system or a plant operator. This then determines the further processing in this production run.

❑   In the case of **post-process control,** inspection results are recorded after the production run and then passed on to the lab in order to make a decision on the further usage of a batch. This inspection can be carried out manually at the screen (manual entry of an inspection lot) or via a laboratory information system (LIMS) carrying out automatic inspection lot creation.

The results of both methods are then written to the batch record.

In-Process Control/ Inspection   At present, there is a distinct trend towards the linking of process-related analytical data and the process control functions generating them. This in-process control function integrates the equipment used for analysis, such as gas or liquid chromatography equipment, within the process control technology. In this way, account is taken of the fact that measured values from a process, such as the current pH value of a substance, are also relevant for the evaluation of the product quality, as well as for the continuation of the process. For PP-PI, the in-process control functions involve a transfer of inspection or test specifications to the process control module as part of the control recipe.

In many cases, the quality inspection of products as well as the in-process inspection is carried out in a production laboratory. The data exchange between production plant and quality control (lab) is carried out via the functions of *process management* (inspection results recording).

When a process order is released for production, an inspection lot for the lab can be generated from the process order. This inspection lot contains the analysis specifications, but you can also enter quality data directly in the control recipe and then transfer it to the inspection lot.

Fig. 9-2: Entry of inspection results data in QM

Furthermore, you can enter a manual inspection results request, in which a line operator is requested to enter inspection results for an operation when maintaining the PI sheet.

The capacity of a laboratory can be included in process planning. If the lab is contained as a resource in the recipe, the period in which it is used can also be scheduled. This is an important aspect to be considered if production takes place around the clock, but the lab is only available for a certain amount of hours during the day.

Planning of Laboratory Capacities

In order to link laboratory information systems with the automatic creation of inspection lots, as well as to enter inspection results manually, there is an interface between the PI sheet and the R/3 QM inspection results recording function.

Post-process Control Inspection

You can get further information on this interface in the manual *QM Inspection Data Interface (QM-IDI).*
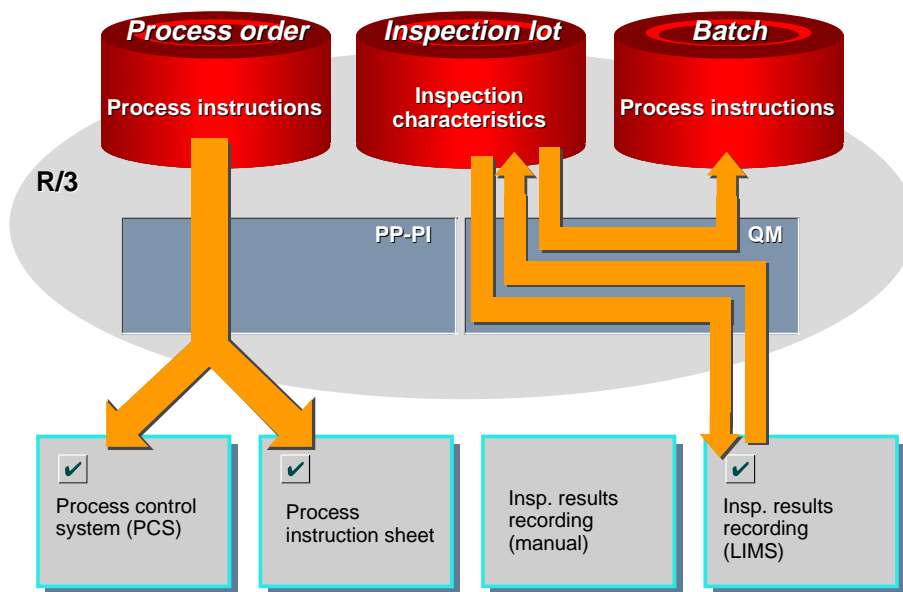

Fig. 9-3: Post-process inspection with entry of external inspection results

In order to inspect batches individually, they must first be uniquely identifiable. The materials management module MM can manage stock of a material in the form of individual batches. Here the attributes (classified characteristics) of a batch are specified using the R/3 classification system and the material allocated to a batch class. The batches of the material are distinguished according to characteristics defined for a batch class. Every batch is unique, since it has individually defined characteristics and values assigned to it.

Inspecting Batches

Using the MM batch management functionality, you can store and maintain enterprise-wide information on batches.

Generation of Inspection Lots

In the QM system, inspection lots carry out different functions, from their generation up to their archiving. When they are generated, inspection lots document an inspection request, meaning that the production situation requires an inspection to be carried out.

The inspection results entered during the inspection run are stored under the inspection lot number in the data base. The access to the individual inspection results is always carried out via the inspection lot. It is possible to allocate several partial lots to an inspection lot.

The total quantity of a process order can be split up into partial lots, if partial quantities with different characteristics exist. A partial lot is used to identify a certain production quantity during the production run. This quantity goes through several operations/phases. For each operation or phase, you can check different inspection characteristics and allocate the results to the partial lot.

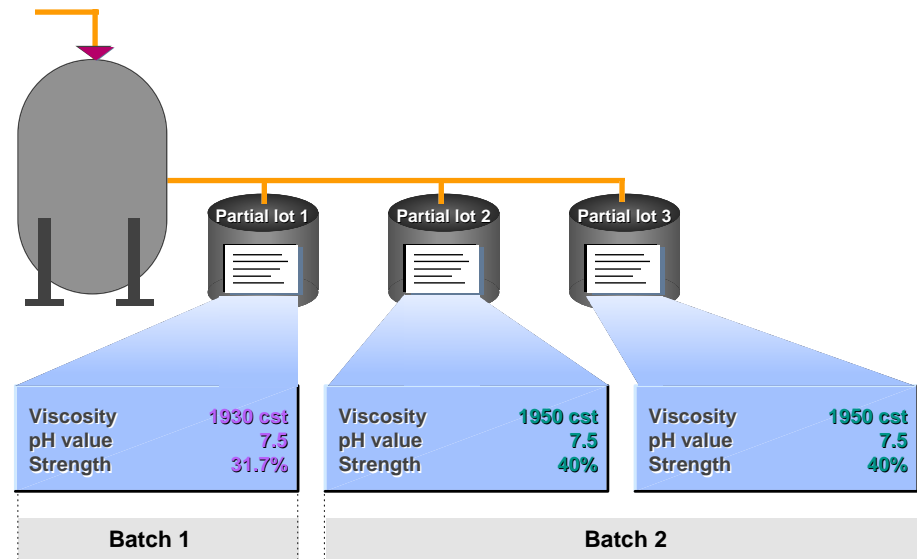The following figure illustrates the above:

Partial lot 1	Partial lot 2	Partial lot 3
Viscosity 1930 cst	Viscosity 1950 cst	Viscosity 1950 cst
pH value 7.5	pH value 7.5	pH value 7.5
Strength 31.7%	Strength 40%	Strength 40%
Batch 1	Batch 2	

Fig. 9-4: Generation of partial lots and allocation to batches

Allocation of Batches

If a finished product is managed by batches, it is possible to allocate the partial lots to individual batches after the process order has been carried out. The inspection characteristics are transferred to the classified data of the corresponding batch, and partial lots with the same or similar inspection results can be combined in one batch (see Fig. 9-4).

You can get further information on R/3 Quality Management in the Functions in Detail Brochure *Quality Management.*

Production and inspection operations are integrated within R/3 QM. Time or quantity-related inspection procedures enable you to monitor the quality of your processes on a continuous basis, as well as making it possible to define partial lots and batch information.

What links exist to check the quality of products from the PP-PI module?

❑   You can link external LIMS systems to PP-PI
❑   PP-PI is completely integrated in the inspection processing functionality of the R/3 Quality Management System.

What are the advantages provided by the integration of the QM system in the R/3 System?

The integrated system supports the elements of quality management according to ISO 9000. It links the functions of quality management with all enterprise-wide processes and thus enables these functions to be carried out during the entire life cycle of a product.