Documentation and Evaluation of Process Data

The logging and documentation of process data for recipes (planned values) and executed process orders (actual values) is becoming increasingly important for modern manufacturers.

- This data serves as proof of the correct execution of production runs and the compliance with legal requirements.
- It also serves as the basis for various evaluation purposes, in order to obtain reliable information on the utilization of resources, for example, or on obtained production yields. The evaluations can be used to detect and solve plant problems such as bottlenecks, malfunctions, environmental non-compliance, etc.

The following figure shows the data that can be maintained and displayed on various levels of an enterprise.

Fig. 11-1: Process data on different enterprise levels

Relevant Types of Queries

In order to obtain reliable key (performance) figures on production processes, managers may ask questions like:

- What critical processing stages affect quality and yield of products?
- Can we detect time or utilization-based trends?
- Can quality differences be attributed to, for example, raw material suppliers, operator group, manufacturing resources, time of day?

The R/3 System contains powerful graphic database manipulation and query tools enabling you to quickly and easily run evaluations such as the above, thus providing you with important key data on which to base further production decisions.

Process Data Documentation

Legal Requirements

Not only in the pharmaceutical industry do legal specifications increasingly require an individual logging of all steps involved in the production of a batch. All batch-specific data is collected in the batch record, which documents the entire process run. The FDA writes in its Good Manufacturing Practice that the following information must be documented:

- Process order number, batch number
- Charging and yield information
- Process instruction sheet
- Equipment / resources used
- Laboratory analysis values (quality data)
- Errors and malfunctions
- Location and ID of finished products
- Confirmation by line operator

Electronic Batch Record

The electronic batch record should contain all the above batch-related data. This data is partially taken from planned values from the master recipe, as well as from actual values from the process order. This record is user-defined, for example, according to the GMP guidelines.

When a process order is released for production, all the relevant data is written to the batch record. Up until the time the production run is finished, all the measured values and events that occurred are written to the batch record with a time stamp.

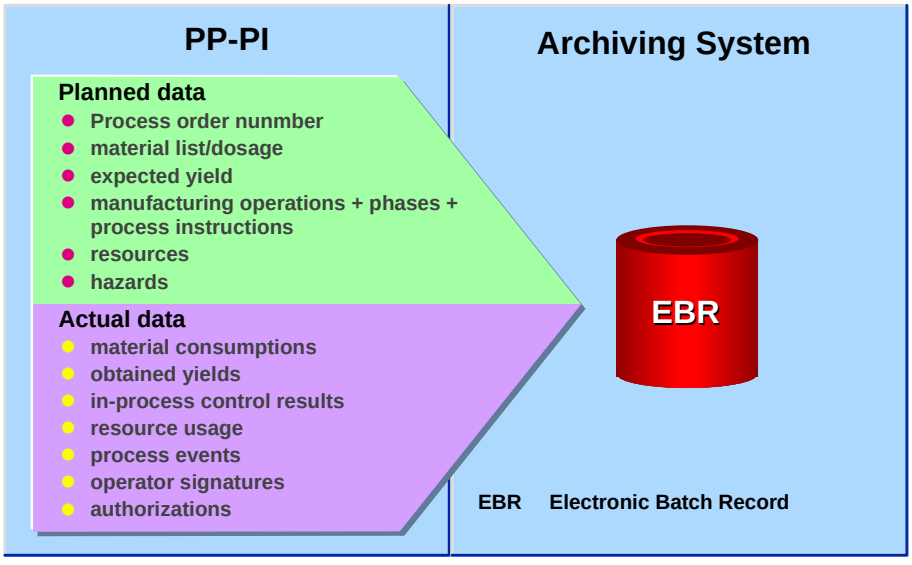

Fig. 11-2: Information included in the electronic batch record

Actual values are transmitted to PP-PI in the form of process messages coming from the process control system, from the line operator, or from the lab.

The data that the batch record is to contain can only be decided on from case to case, or from one process to another.

ArchiveLink Interface to Batch Record

Via the ArchiveLink Interface of the R/3 System, you can transfer planned and actual data for the generation of an electronic batch record to an optical archiving system.

The data to be transferred is made up of planned data from the process order as well as the actual data confirmed by process control in the form of process messages. These can be selected, sorted and stored in the database. Electronic batch record systems can make use of this pool of data for long-term archiving.

The same data source can also be used for emissions data or other documents requiring a log by law.

Possible List Types

The data to be archived is compiled in the form of print lists from the following objects:

- Process orders
- PI sheets, with comments and notes listed at the end
- Inspection lot data records
- Process messages from the process message log
- User-defined lists, provided that the user has generated and archived his own lists.

The process order is the main object used to generate lists.

Process Data Evaluation

Introduction

PP-PI provides or links into global evaluation possibilities enabling you to evaluate data on all levels of a firm:

- On the planning level (managers, MRP controllers) costing or performance data needs to be looked at, often in aggregated form. This could be yield data, data on resource output, etc.
- On the production level, typical evlautions are related to batches or their production runs, for example: how high was the actual yield of a certain product within a certain period?
- On the level of the process control system (line operator), for example, value ranges over a time scale are regarded, for example, temperature curves of a vessel during the course of a process order.

Evaluation/Analysis Tools

For the evaluation of process data and process events, PP-PI provides several tools to enable you to request, display and compare data at the time of production:

- The SAP Business Graphics
- The XXL Listviewer, with link to Microsoft-EXCEL
- The production information system, with link to SAP Business Graphics

On the following pages, the above tools for evaluating and displaying your process data are described.

LIS Production Information System

The production information system, which forms a part of the Logistics Information System, is a flexible tool to collect, aggregate and analyze data from process or shop floor control.

The goal of the production information system is to enable the user to define his views on information relevant to the application (for example, recipe data). The degree of information depth is user-defined.

After the list display of the data, you can have data on all list levels displayed in graphic form. You can obtain the following types of evaluations or analyses:

- Evaluations on resources, for example, planned and actual values
- Evaluations on materials used and their consumption - for example, what was consumed, comparison of planned / actual values, etc.
- Evaluations on product costs (overall costs, fixed costs, variable costs, planned costs)

The following graphic shows the planned and actual material consumption for selected process orders.

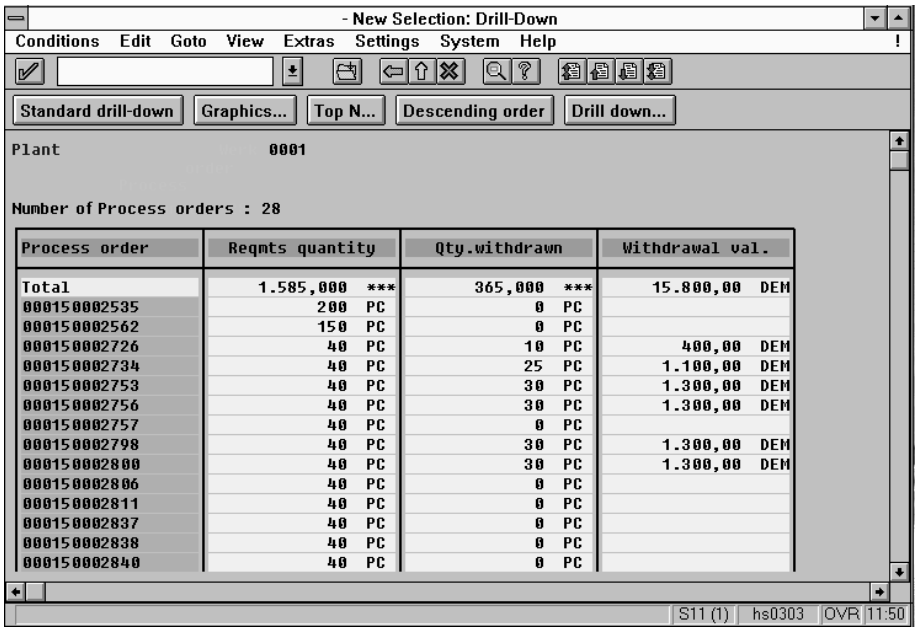

Fig. 11-3: Evaluation of material consumption (planned and actual values)

SAP Business Graphics

A clear graphic display of trends and material consumptions is available, among other things, using the SAP Business Graphics. In the following example, the obtained yields are displayed per process order, in list form as well as in graphic form.

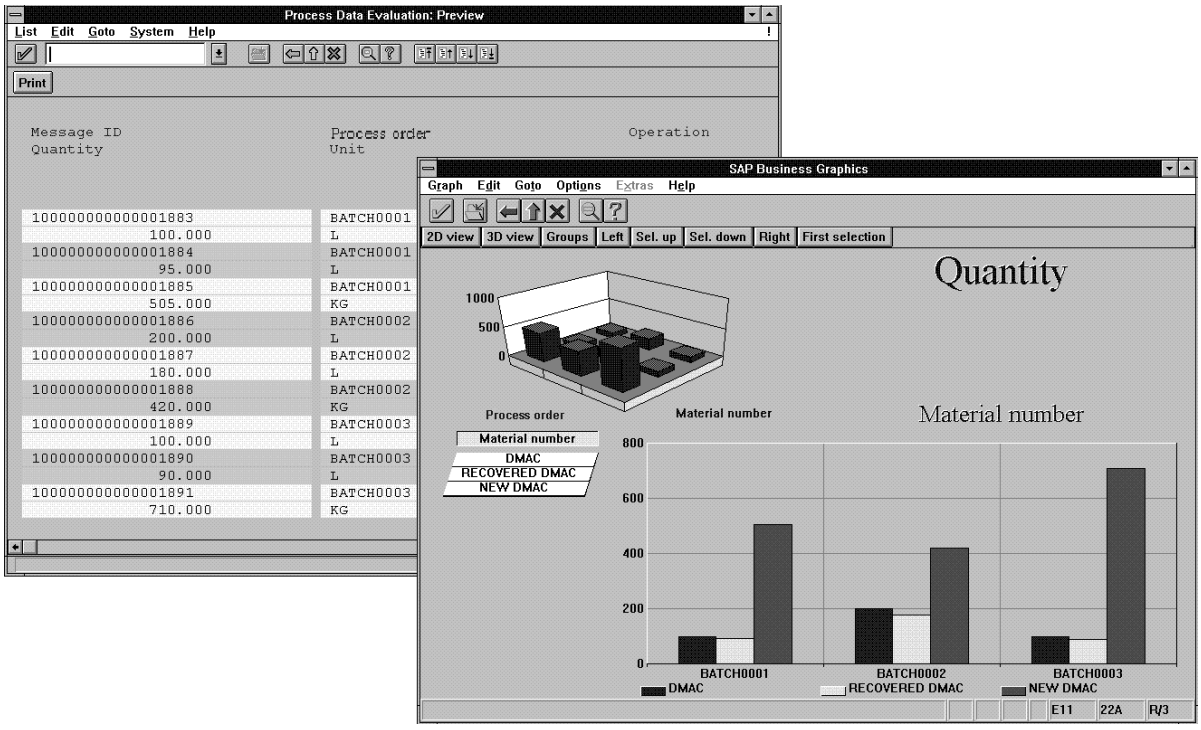

Fig. 11-4: Process data evaluation (material consumption), SAP Business Graphics

next chapter