Honeywell

TION · GLOBAL EDITION · GLOBA

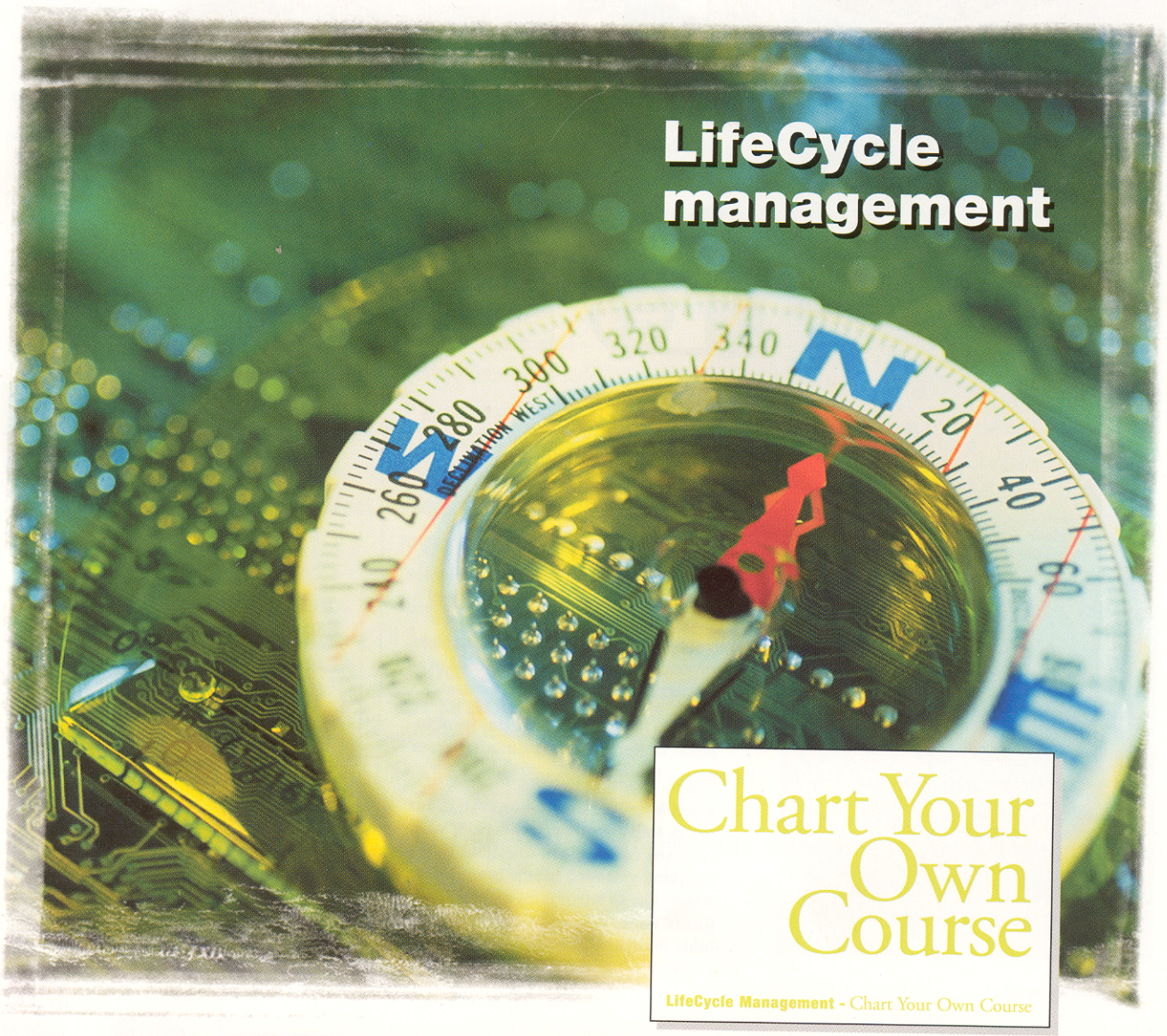
IAC JOURNAL

INDUSTRIAL AUTOMATION AND CONTROL

The UIS is your opportunity to make an impact

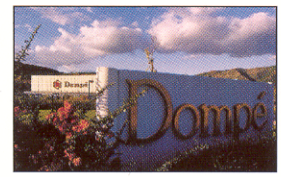
New Web Based Learning courses available

Dompé Pharmaceuticals retains POMS MES at plant in Italy



March 2001, Issue 4

Dompé Pharmaceuticals retains POMS MES at plant in Italy



Dompé Pharmaceuticals management recently made the decision to retain and upgrade their POMS® solution. This was due to their belief that the use of POMS solutions results in the consistent improvement of quality and a range of other benefits.

After establishing itself in the areas of respiratory and osteo-articular therapies, Dompé Pharmaceuticals moved into the biotechnological field with its innovative drugs and creative services. All research, development and production is carried out at the company's modern plant in L'Aquila, Italy, which was completed in 1993.

The L'Aquila production facility – constructed and operated in accordance with the highest international standards – has the capacity to produce tens of millions of units of high quality, low unit cost pharmaceutical products. These include liquid and solid formulations for oral administration, as well as ointments and creams for topical application.

Specific objectives

Dompé's association with the POMS suite of manufacturing solutions began with the need for an information tool able to work in a supervisory and managerial capacity during pharmaceutical manufacturing operations. Dompé's objective was to find a defined Operation Management system that could be implemented throughout the entire production area and which would:

- Keep data as close as possible to the generation point
- Avoid the manual handling of data
- Make input discriminations
- Record electronically each execution and interaction with the system (batch record).

Dompé's goal was achieved through the use of the POMS Manufacturing Execution System (POMS MES™) from Honeywell POMS, the global leader in the MES area.

Re-evaluation of decision

Recently, Dompé's management made the decision to retain and upgrade the POMS solution because of a firm belief that the use of POMS solutions results in the consistent improvement of quality. Furthermore, they realized that the newest generation of the POMS solution would significantly shorten the implementation and validation time of Dompé's offerings.

Exceptional and flexible functionality led Dompé to the upgraded POMS MES solution, which includes:

- The ability to define and manage product parameters external to the application
- The ability to communicate process parameters to POMS from Fix Dynamics and back, using OPC POMS Server
- Direct interface to scales
- Exceptions and deviations handling
- Software and recipe reusability
- Configurable system parameters
- Label printing
- Report printing
- Electronic signature compliance
- Automatic generation of Electronic Batch Records in PDF format.

Total production control

To ensure full control of all aspects of the production process, POMS MES was installed in all production areas: warehouse; dispensing; syrups bulk manufacturing; creams bulk manufacturing; granulates bulk manufacturing; syrups packaging; creams packaging; sachets packaging; and ampoules packaging.

Electronic Batch Records

At the end of a batch production at L'Aquila, the POMS MES system generates an Electronic Batch Record (EBR). At Dompé, an EBR is not considered complete until the following reports are generated and printed directly from the POMS MES system:

- Dispensing report
- Weight control report
- Manufacturing yield report
- Materials quantitative report
- Packaging yield report

The project was undertaken in accordance with the cGMP rules for the pharmaceutical and information technology arenas. The new system functionality, added by the developer to cover all the user requirements, was validated with the GAMP guidelines as a model.

With the project now complete, Dompé is able to deal with GMP compliance with the security and confidence that comes from utilizing the most current version of the industry-leading pharmaceutical operations tool, POMS MES. ■