Integrated Batch Solution for Pharmaceutical Rubber Production: The IPS Approach

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ABSTRACT

Talk integration to a vendor and a customer and you’re likely to get two very different points of view, despite the emergence of standards designed to reconcile these differences. By too carefully defining the limitations of software packages, we risk limiting the functionality of the very manufacturing operation we intended to improve. A responsive, integrated Batch Solution must be capable of positioning itself in the context of the Enterprise Production System, responsible not only for executing a planned sequence of operations, but also for the wider repercussions of its actions.

This paper describes the implementation of an Integrated Plant System (IPS) for a major multi-national pharmaceutical company.

Of particular interest from a Batch perspective, the asynchronous manual and automatic activities of over 100 recipes are tied to stock movements to ensure raw material is available at the right place and time. This illustrates the point that synchronization is integration, both at the Batch and Enterprise level. The production facility in Milan, Italy, was modeled using the IPS paradigm, and now coordinates all operational activities from equipment maintenance through inventory management to order scheduling and MRP.
1 OVERVIEW OF THE INDUSTRY TRENDS

The relationship between plant and enterprise has become critical in allowing companies to keep pace with the accelerating speed of business. Real time plant systems and information play a key role in enabling the supply chain to be responsive to the market.

To compete effectively, companies must be faster and more flexible in responding to customer demands. This is achieved by:

- **Reducing** the size of the task ahead by identifying solutions that are as focused and all encompassing as possible.
- **Reusing** whenever possible and protecting the investment made by encapsulating Legacy Systems
- **Choosing** a Component Based System that is the most flexible, fastest and easiest way to build up functionality, and the lowest cost architecture to own and maintain

As the expansion of e-business increases the pressure on manufacturers to better manage their Supply Chain, suppliers will try to find a way to accelerate the process of encapsulating existing systems, adding new functionality in the form of pre-configured components, and executing operational goals in the context of the Supply Chain.

**Success in the new e-business economy will depend on the synchronization and coordination of the plant as part of the Supply Chain.**

Batch production plants strongly reflect these evolving market trends. Being able to manage products of ever-smaller lots, reducing warehouse stock, checking quality on-line, respecting ever-closer delivery dates and, in general, adjusting production to the evolution of issues and ideas, is vital for the success of a company.

1.1 The IPS Approach

The Integrated Plant System (IPS) is the new and revolutionary concept for implementing ‘Whole Product’ industry-focused solutions that are dedicated to addressing the specific needs of niche markets. Focused on the MAKE process of the Supply Chain Operations Reference (SCOR) model and the synchronization and coordination of Plant and Supply Chain, an IPS uses a comprehensive set of products and services to provide maximum reusability, minimum integration work and lowest cost of ownership. Investment in IPS pays off in many ways:

Suppliers can:

- respond faster to the market with new and enhanced solutions through component re-use and standard implementations
- seamlessly integrate complementary products to achieve competitive advantage

End Users win by

- being able to choose smoothly integrated best of breed solutions to achieve competitive advantage at minimum cost.
- achieving the flexibility needed to accommodate the changing demands of the Supply Chain.

2 APPLICATION DEVELOPMENT METHODOLOGY
The supplier has adopted the proposed approach, which includes a framework engine able to smoothly encapsulate and synchronize the various production processes, while guaranteeing flexibility to the system.

The new module provides an object-oriented graphic environment, which guides users when carrying out projects via three different phases:

- **Analysis**: the production process’s modeling phase in which the following are defined: plant physical structure, flows of internal data and materials as well as the general rules governing them.

- **Development**: the phase in which standard library modules are added and/or legacy modules already present in the plant are encapsulated; or new software modules are created and are described by rules validated in the previous phase.

- **Administration**: the phase in which it is possible to monitor the execution of rules and quickly change the flow of either parameters (to keep the system up-to-date on changes in the plant or its products) or operating procedures.

### 2.1 Analysis Phase and Reference Model for Defining Data and Terminology: ISA S88

Although this phase often is not the most costly, nonetheless it has been shown that it is during this phase that decisions are taken which have the greatest bearing on the final cost of an entire automation project. Hence a tool, allowing for the proper management of this phase, is fundamentally important.

**Object-Oriented Analysis** (OOA) is a key to this step, since human beings automatically create a model of the reality surrounding them.

Operators and managers unconsciously fashion **objects**, such as the following:

- **Plant objects**: mixers, conveyor belts, weighing systems, etc.
- **Logical objects** (i.e. that which contain data): work orders, reports, quality certifications, etc.
- **Connections between objects**: flows of data and materials

All the above must be inserted into the MES system, which also serves establish a correct interpretation of the specifications and terminology employed in the application. In this phase the key factors in reducing time and costs are:

- The availability and involvement of key people within the customer’s organization
- Pre-structured libraries for creating models inside the IPS system.
- The system integrator’s Application Know-how of the sector

In this phase the plant model can be refined into successive steps, permitting area objects to ‘contain’ unit objects, which in turn ‘contain’ equipment objects, and so forth, in a process of validating and fine-tuning the model.

In the same way, the data model is represented by objects ‘pointing’ to various databases present in the plant: real-time, analysis, work order, Batch report databases, etc.
Thus, technology experts are able to navigate ‘deeply’ inside each of the model’s individual objects; managers will be able to arrive at the highest level of abstraction in order to have a vision of the overall functioning and exchanges of data occurring in the plant. When creating such models, ORSI has decided to employ the *de facto* standard in the Batch systems market – ISA S88. ORSI is, in addition, is monitoring the continuing growth of specific plants in addition to the standardization of ERP communication systems (which as of now are only available in draft documents regarding the new ISA S95 standard).

In a similar hierarchical manner, rules must be represented for managing the functioning. To store, structure and archive all production data is an important activity of any MES system; yet this is usually not enough. What ORSI has resolved to do is to help plant managers to **define rules** for managing such data to increase plant performance. The ability to make modifications and the simplicity in managing the software (via encapsulating the plant’s principal functions in graphical objects) permits users, among other activities, to export strategies implemented in diverse plants within the same company on different sites.

### 2.2 Development Phase

In the development phase, the key is **opening up communication outside** of the system being used. Quite often, the level of plant management is multi-form. This is also true, since many software packages or subsystems already come with a controller. The integration of the MES system with any existing DCS, PLC, single loop or any other intelligent management systems is, therefore, a basic requirement. Furthermore, it is necessary to be able to easily integrate business systems of a higher level (i.e. the management of warehouses, work orders, bills, etc.) as well as those pre-existing at the intermediate level (laboratory management, – LIMS, schedules, etc.). Complying with *de facto* standards (i.e. OPC, COM/DCOM, Java, etc.) facilitates this communication.

### 2.3 Administration

During the administration phase the key is **flexibility**. On-line changes to IPS logical rules for coordinating subsystems must be made by plant managers in a graphical as well as in a simple and fast manner. Indeed, it is important to point out that an MES system designed for Batch plants must be kept up-to-date in order to fulfill the basic demand: **providing a decision-making support tool**, by performing the appropriate data searches and presenting the appropriate information on the right PC of the right person at the right time (thereby, assessing the plant’s current state or that of the business in general).
3 OVERVIEW OF AUTOMATING BATCH SYSTEMS

In plant production management systems, the Batch module sector is one that is growing. The supplying of Batch management modules by producers of automation systems is subdivided into two major categories:

- Batch modules tied to traditional DCS systems
- Batch modules purely based on Software packages, which interact with every kind of PLC or DCS

**Batch modules inserted in DCS systems** generally have the following positive points:

- They are highly integrated with special management hardware;
- They can boast of having a widely installed base (even if often such references are relative to applications built with prior modules or via the *ad hoc* programming of the specific DCS).

However, they also present the following negative factors:

- Rigid or non-user-friendly programming environments: to make changes to recipes it is necessary for the DCS system programmer to intervene;
- No specific standard: typically each DCS has its own approach;
- Recipes are not easily exportable to a higher system and, in general, there are communication problems with management or ERP systems;
- Recipes are not portable from one plant to another if different control hardware is used.

**Batch modules purely based on Software packages** present diametrically opposite features; they are, in fact, relatively recent packages, yet have a great capacity to adapt to a ‘flexible’ production environment. Furthermore, they typically make explicit reference to the standard ISA S88 model, thereby rendering the terminology and structure of proposed solutions uniform. When compared to the small group of software modules currently on the market (all produced by medium-size companies in the United States),—the system used at Helvoet Pharma offers unique features such as:

- **rapid development** of new functionalities,
- genuine DNA **modular** architecture completely integrated with features of other classic suite modules. (*hot-backup redundancy*, when acquiring data from the field, is a particularly interesting feature for Batch plants);
- when configuring a single server – the capacity of restoring to the recipe’s most recent execution status in the event of a shutdown or power failure of the PC server, without therefore having to abort the batch;
- when using DCS controllers, it completes the **integration of procedure steps with programs** carried out in the controller;
- when using third party controllers, **stable links via direct and specific drivers** (and not by using old and unreliable DDE protocol or OPC, which is still slow) tested on hundreds of the HMI package applications (not only in the Batch environment);
• rapid connections with any **Relational Standard Database** via the Tracking module, which provides a large number of special drivers;
• integration of **error management** found in the recipe, via graphic flow-charts guiding the operator in the attempt to recover correctly any non-compliant batch;
• built in compliance with the **ISA S88, IEC 1131 standards** as well as with the coordination and synchronization of the plant as part of the Supply Chain.
The project for a new plant section at Helvoet Pharma started two years ago with the decision of investing over 10 Billions Dollars in new plants, equipment and modern systems to double the production of rubber caps for the pharmaceutical industry.

The mixer department, based on very modern procedures and equipped with advanced systems, is a 20-meter-high tower, which optimizes the space and allows a better material flow. From the automation standpoint, the process presents some really interesting features, e. g.:

- A section for the **manual weighing** of small components, done by specialized operators with the support of the tracking software directly connected to the weighing systems and to the bar codes on one side and to a centralized relational database (Oracle) on the other;
- A fully automatic **batch management** section for powder dosing, mixing and milling. This section is equipped with advanced automation systems connected over a fieldbus (Profibus) in redundant configuration.
- Each batch lasts just a few minutes. The manual weighing can be independent from the launch of batches in the automatic section. The system checks if all the recipe ingredients are available and **coordinates** the semi-automatic weighing of the polymer.
- It is necessary for an automated system to collect data and to allow quality reports and **Electronic Batch Reports** (EBR). The Batch system archives EBRs, containing the execution times of each single recipe phase, the most significant process variables for product quality (for example, the temperature in the mixer), possible alarms or non-compliancy.
- Last but not least, there’s a set of over 100 recipes to be managed and the need to easily and graphically change or add new products or product variations on the Batch Management System without having to code the controllers.

In this case, the system includes 2 controllers, with CPUs and redundant I/O bus, stations (for the Batch Management System, for the System and for the centralized database) and 13 client industrial cabinets provided joysticks and functional for easy use.

### 4.1 The Benefits

The new plant has seen the benefits:

- Reduction of Production Lead Time, with 70-75% average decrease in system deployment time and increase in manufacturing schedule adherence
- Improvement of Product Quality by increasing the production control by 80%, recouping material deficiencies and reducing the development time by 30-50%
- Increase of production throughput by 75% by being able to anticipate product demand, ensure product availability and provide capacity visibility to the Supply Chain
- Reduction of Cost of Ownership through a simple and graphic system management
- Significant reduction of inventory through coordinated plant operations (with the enterprise and the Supply Chain)
- Smooth encapsulation of Legacy System in the framework provided
- Significant increase of flexibility in responding to changing supplier and customers demands: orders may be modified during production
- Continuous improvement (starting small and growing on-line without reengineering.)

Fig. 9 The IPS Framework Concept