ISA 95 integration between SAP R/3 and Batch in pharmaceutical applications

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ABSTRACT

In this paper we will share past and present experiences using the ISA 95 integration model for business process transactions and data integration for Supply Chains. We will explore in particular an ERP and batch integration example from a functional, technical and evolutionary perspective focusing on regulated industries.

The ISA 95 Enterprise to Manufacturing integration model is used to structure the integration processes between business systems and the plant floor. Through the use of the ISA 95 “structures, a “common denominator” business model was established for integrating SAP’s R/3 PP-PI transactions and data structures with an ISA 88 batch automation data structure. The integration is transactional, bi-directional and addresses fault tolerance for long running, asynchronous transactions between SAP and the plant floor. In particular we will discuss on the challenges in integrating SAP PP-PI and a batch solution and how these challenges are addressed. We will share and compare our experiences in working with Microsoft .NET and IBM WebSphere products with these types of integration projects.

The setting for the applications presented will be the pharmaceutical and food and beverage industry. Specifically, our experiences in deploying a consistent security model, business processing, data transformation, master data and abnormal situation handling will be discussed.
Supply Chain perspective

In regulated industries, such as pharmaceuticals or food and beverage, the role of the supply chain is a key contributor to the bottom line profitability of an organization. Making sure the value chain is well integrated remains a prime focus for investment.

The following points cover five areas of manufacturing and distribution which companies will have to concentrate their efforts, if they are to create a supply chain that fulfills their future requirements:

- Supply Chain/Demand synchronization and strategic sourcing
- Scientific manufacturing
- New product and process development
- Restructuring and asset rationalization; and
- Techniques for extending reach to the customer.

The first objective is to increase productivity and maximize the efficiency of a company’s existing manufacturing facilities; the second, to ensure that its supply chain conforms to the EU and FDA’s new compliance agenda; and the third, to reorganize its plant(s), processes and people in readiness for the future (see figure 1).

Figure 1

Figure 1 describes the market pressures companies find themselves in: market changes, regulatory pressure, and fast product evolution. Factors that are available for companies to handle these pressures are:

- Portfolio. All companies have limited resources, so it is imperative to direct those resources – be they capital, plant, skills or management time – to the areas of the business that create most value.

Many pharmaceutical firms tend to look backwards, not forwards. They have supply chains that are engineered to manufacture traditional and well established products, rather than a much wider range of products, many of them biological rather than chemical in nature, that their business is
evolving towards. They will ultimately have to reorganize their manufacturing assets and, in doing so, take a zero-based view of the business, since a piecemeal or step-by-step approach to the restructuring of an organization and its assets is not effective.

- Evolving technology. Covering the entire spectrum, from automation systems to ERP systems, including the middle Collaborative Production Management (CPM) tier.
- Companies must learn how to make better use of their plant and people, and reduce their fixed costs. People, equipment, know-how, and intellectual property, must all be deployed in a more adaptive and flexible way. Three elements are essential here: a lean manufacturing culture; long-range modeling; and an integrated supply network. Some of these elements are hard to implement. For example lean manufacturing may be constrained by regulatory boundaries, but it is worth exploring to improve flexibility.

These factors will enable a company to restructure its assets, accelerate growth, and drive productivity and quality to a competitive bottom line.

**Role of ISA 95**

The above are general drivers for regulated companies to improve performance in a competitive market. These drivers have been mapped against the ISA-95 model as illustrated in table 1.

<table>
<thead>
<tr>
<th>Area of focus</th>
<th>Corresponding ISA 95 activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demand synchronization and strategic sourcing</td>
<td>Order Processing, Scheduling and Procurement</td>
</tr>
<tr>
<td>Restructuring and asset rationalization</td>
<td>Material and energy control, Procurement, Production Control, Maintenance management, Product Inventory control</td>
</tr>
<tr>
<td>Scientific manufacturing</td>
<td>Production Control</td>
</tr>
<tr>
<td>New product and process development</td>
<td>Process development relies in part on feedback from manufacturing, trying to improve it and adapt to change. R&amp;D for new products is not directly part of ISA 95, but the interaction between R&amp;D and Manufacturing is recognized and included.</td>
</tr>
<tr>
<td>Techniques for extending the reach to the customer</td>
<td>Marketing and sales, dynamic scheduling.</td>
</tr>
</tbody>
</table>

Table 1.

So far we have addressed the issues companies face, and how they can address them. We will focus on the Supply Chain as a major means of achieving the goal.

In the following we will provide specific examples, and the functional challenges that have been faced, and how they were solved.

**Typical case of a regulated manufacturer**

Figure 2 is a schematic representation of a typical production process.
The ERP level typically interacts with the plant in three areas: Material Handling, Production Planning and Production Response.

Material Handling makes sure that the right materials come to the floor at the right time in the right quantity. With a reference to the above, it is here that lean manufacturing could be explored. Discrete manufactures have been using the principles of lean manufacturing for a long time, yet in regulated business, these principles have seldom been implemented.

Production planning, which drives shorter time-horizon scheduling, is often well established. Typically the potential benefit of integration towards the operational side is under exploited.

Production Response ensures that data on production runs is collected from real-time operations, values are transferred up to the business system. Again, the level of integration is inadequate. A tighter integration would enable business systems to react to disturbances more quickly. An analogy would be the type of interaction that process control has evolved to, resulting in closed loop control.

Given these requirements, there are a number of challenges in implementing a process flow as described.

**Functional Challenges**

*Security.*

Any integrated system consists of multiple software packages. Typically these have their own security model, particularly when they are hosted on multiple platforms. In many current day scenarios, an operator may even have two screens, one for ERP information, the other for process or control information.

When programs call or pass information to other programs, the same security concerns apply. WebServices, the technique all major vendors are promoting, are an excellent example of a technology that requires the careful consideration of security issues on both the service provider and service consumers. Irrespective of the approach, a synchronized mechanism for managing inter-application security must exist.

*Business Process Synchronization.*

Business processes in most companies change constantly. Mergers and acquisitions, new products, new raw materials, new technologies, new regulations: all contribute to changes in business
processes. Companies that can quickly adapt their business processes will be able to turn change into a competitive advantage.

Through intra-company optimization, companies have engineered their business practices to enhance overall performance. By implementing internal system solutions such as ERPs and Supply Chain planning and execution systems, company management can make informed business decisions. Intra-company optimization extends real-time information throughout the organization, ensuring synergy among operations, finance, sales, purchasing and customer service.

Business process synchronization takes Supply Chain integration to the next level of efficiency, utilizing standardized information formats and communication points between organizations. Business process synchronization eliminates costs associated with inefficient movement of goods, redundant processes and excess inventory. It also promotes the collaboration of all supply chain partners - suppliers, manufacturers, distributors, wholesalers, third-party providers, transportation companies and retailers.

Data transformation

Today, most Supply Chain partners do not share business practice knowledge or content. Not only is the lack of standardized technology an impediment, the data itself can be an obstacle. When data is confidential, transmission requires a very secure data communications connection. If the data is volatile or a database is too large to transmit, continual, real-time access may not be feasible. Data mapping between systems must also be addressed. An excellent example is product codes, which are often different between ERP and manufacturing systems. Last but not least, data formats differ from system to system. A classic example is SAP’s date format, which is different from what most other programs use.

Master Data

All systems have their own data models and structures. The set of data that define the master data is likely to be needed in multiple systems. Each system has slightly different content or usage, entitling it to be the “master” of the data structure. The problem becomes more complex when changes are necessary to the master data. The change must be made in each system and must be synchronized with potential local changes. This opens up a potential for data inconsistency, errors, and bad quality.

Abnormal situation handling

Occasionally, things do not go according to plan. The way these abnormal situations are handled is critical to developing trust in an integrated system. If, for example, a fermentation vessel fails and goes out of production, the production orders currently scheduled for the vessel have to be re-scheduled. Business rules specify which customers may have to be notified if the delivery dates change.

It is our experience that the careful handling of “what-if’s” can be as complex as an entire “normal” situation project.

Solution

There is no magic bullet for implementing an integrated Supply Chain solution. Luckily the issue is well recognized and technology is quickly moving to help mitigate some of the issues. Later we will come to two platforms that help address this:: .NET from Microsoft and WebSphere from IBM.

In general we have used off-the-shelf products and avoided custom programming. The reasons are obvious: support, upgrading, and trained resources being the more obvious. The decisions have been driven by a few key requirements:

- Transactional integrity. A transaction is a coordinated series of modifications of data (such as stored in a database or a file system), guaranteed either to be successfully executed in the entirety, or not to be executed at all. To implement a transaction, a record is kept of the state of the data store before the transaction begins and, if one of the modifications fails, the
transaction returns failure and the initial state is restored (or “rolled back”). Transactions are used to maintain data integrity and consequently play an important role in business software programming.

- Persistence. Persisting data to a database in the context of the transaction is a key requirement.
- Business process enabled. Middleware has evolved from data handling to business process handling. The market is moving rapidly to provide solutions that allow more flexible business processing. Extending the use of the data rich middleware solutions towards flexible decision making is becoming a strong requirement.
- Business Intelligence and Business Analytics support.
- Personalized thin clients, visualizing the information in a distributed environment including PC’s, handhelds and mobile phones.
- Engineering tools. Each package involved may have its own engineering tools. The less tools, or the better they are integrated, the more effective the implementation and subsequent maintenance will be.

ISA 95 will play an increasingly important role in each solution. It is the “common denominator” data structure where the industry agrees upon, and where hopefully in the future more people will adhere to. Just as ISA 88 has done, to create a common vocabulary, ISA 95 makes the integration easier to implement by providing a common vocabulary and model.

Solution technologies

In our implementation work, we have focused on two main technology platforms: .NET and JAVA. Each has its own specifics and we will try to highlight a few of them we felt important.

.NET – Microsoft. This solution stack has been evolving over the past few years. Microsoft has gained a lot of momentum, and BizTalk Server 2004 is definitely aiming at the integration space in industrial settings.

We have focused on three areas: integration, analytics and collaboration. The technology stack deployed is described in figure 3.

![Diagram of Solution Technologies](image-url)

Fig. 3
Earlier we have listed requirements and we have mapped the features of the .NET platform to it.

<table>
<thead>
<tr>
<th>Functional requirement</th>
<th>.NET feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transactional integrity</td>
<td>BizTalk Server 2004 has an extensive model for state handling of transactions and handles roll-back situations.</td>
</tr>
<tr>
<td>Persistence</td>
<td>SQL Server is used to persist data while the combination of SQL Server and the tight integration with BizTalk makes sure that the context of data is stored correctly.</td>
</tr>
<tr>
<td>Business process enabled</td>
<td>Orchestrations are the concept used by BizTalk to implement, in a graphical form, the business logic. In addition, business rules can be used to make the implementation of decision logic more accessible to a business user.</td>
</tr>
<tr>
<td>Business Intelligence capable</td>
<td>SQL Server comes with an Analysis Server, used for business analytics.</td>
</tr>
<tr>
<td>Visualization – web enabled</td>
<td>Share Point Portal server is integrated well with BizTalk Server and the office suite products, making it the technology of choice for distributed visualization.</td>
</tr>
<tr>
<td>Engineering tools – integrated – easy to use</td>
<td>Visual Studio .NET – one integrated tool for all the applications.</td>
</tr>
</tbody>
</table>

A similar technology stack (fig. 4) and table is shown for IBM’s WebSphere solution:
Fig. 4

<table>
<thead>
<tr>
<th>Functional requirement</th>
<th>IBM WebSphere feature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transactional integrity</td>
<td>WebSphere ‘s J2EE Application Server and its implementation of JAVA beans has an extensive model for the state handling of transactions. Handling of rollback is typically left to the implementer.</td>
</tr>
<tr>
<td>Persistence</td>
<td>JAVA beans can be persisted in many databases (DB2, Oracle, SQL Server). This provides an open environment, capable of implementing complex persistence structures. The business transaction context relationship is harder to establish.</td>
</tr>
<tr>
<td>Business process enabled</td>
<td>WebSphere comes with industrial solutions in Supply Chain which can be used as a starting point and altered to match company specific requirements. Business process management (BPM) with IBM WebSphere MQ Workflow is another solution to automate business processes.</td>
</tr>
<tr>
<td>Business Intelligence capable</td>
<td>DB2 has OLAP functionality build in.</td>
</tr>
<tr>
<td>Visualization – web enabled</td>
<td>WebSphere portal delivers a single, point of personalized interaction with applications, content, processes, and people for a unified user experience.</td>
</tr>
</tbody>
</table>
Engineering tools – integrated – easy to use

WebSphere Studio Application Developer is a family of integrated development environments for Web, Java™, J2EE, Web Services, XML and data applications. It is a key element of the IBM Software Development Platform used to automate and integrate the software development process.

Resulting solution

Each of the above platforms enables a solution for integrating the Supply Chain. Some of the relevant results are listed below, focusing on work done linking SAP R/3 PP-PI to batch control.

Security. It is possible to implement a unified solution with each platform. Specifically, Microsoft’s Single-Sign-On utility provides an excellent environment where one security model can be used with multiple integrated applications (providing similar hardware and operating systems are used).

Transactional integrity. The PI-PCS interface has a strong transactional behavior built in. Downloaded information is only complete when an acknowledgement signal is obtained from the receiving system. Solutions such as BizTalk Server and WebSphere permit the processing of this transactional state cycle quite adequately.

Interoperability. In the R/3 environment, PP-PI’s PI-PCS interface is not available as a WebService. By deploying the techniques mentioned, we were able to expose the PI-PCS interface as WebService. BizTalk and WebSphere were able to interact with these WebServices successfully.

Data Mapping. The transformation of data structures is a particular concern, going from relational tables to hierarchical XML structures and back. Also the data semantics change. The solution obtained complied with both requirements.

Interoperability, comparison of .NET and WebSphere

Earlier in this document, both technology stacks were described: .NET and WebSphere. In the following section we will explore both platforms. A lot has been written about .NET and JAVA and a comparison often leads to very animated discussions. We have tried to speak from our experience in Supply Chain Integration.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>J2EE</th>
<th>.NET</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of use (development environment)</td>
<td>**</td>
<td>****</td>
<td>Visual Studio .NET is the single tool for the .NET platform. WebSphere Studio covers a lot of ground, but there are still other applications that require their own tool.</td>
</tr>
<tr>
<td>Scalability</td>
<td>***</td>
<td>**</td>
<td>Java code executes on mainframe computers. WebSphere Server can easily be distributed. BizTalk Server and SQL Server support scaling too, but IBM delivers successfully to small and large applications, and the evidence in scalability is still there.</td>
</tr>
</tbody>
</table>
Platform dependency | **** | * | Java is platform independent. .NET runs on the Microsoft platform only.
Performance | *** | *** | In our experience, both solutions provide adequate performance.
Speed of development – code generation | *** | ** | Both environments make use of Wizards to generate code. Wizards are excellent, but one wants control over their output. Java, more open, is more forgiving and lets the developer modify the generated code.
Open standards | **** | * | By definition, Java is an open standard.
One function, one software | * | **** | In the IBM portfolio, there are many different, sometimes overlapping solutions to the same problem. Microsoft’s solution portfolio is more streamlined. One solution for each challenge makes the choices easier, but also reduces the flexibility gained from a wider choice of solutions for the same problem.

**Conclusion**

Focus continues to be put on the Supply Chains and how they can generate value for companies. Success in integrating these Supply Chains within an organization or across multiple organizations can be an important means of achieving the goal of growth and success.

ISA 95’s integration concept fits nicely with the vision of integrated Supply Chains by addressing the major issue of Business to Manufacturing information exchange. A cross industry adoption of the standard will further accelerate the success of integration efforts.

Challenges such as security, transactional integrity, persistence have been addressed in multiple competing platforms: Microsoft’s .NET and the IBM WebSphere product family being the dominant players. Both solutions have advantages and shortcomings, but their inter-operability is largely enhanced by the use of WebServices, enabling the best of both worlds for the end-user.

Supply Chain integration will always be a challenging endeavor. Accepting the challenge is the starting point on road to success.