



## Wyeth Focuses on an Integrated View of Operations With SAP MII

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An efficient manufacturing response to downstream customer demand is a core capability of a demand-driven value network (DDVN). Effective execution in manufacturing requires an integrated view of operations and ancillary functions, such as warehousing, quality, and logistics. This integrated view would allow life sciences companies to aggregate, contextualize, and analyze operational data to efficiently orchestrate their product supply responses across an entire network.

However, in life sciences companies, an integrated view of manufacturing operations has been largely nonexistent, with the industry replete with supporting evidence of this claim. Consider the product supply cycle times measured in weeks, inventories measured in months, and stockouts reported on a daily basis as just a few examples.

### Enterprise with(out) an integrated view

One issue life sciences companies face is that every addition to the IT architecture requires validation, with most additions perceived as risky and expensive. Validation decisions often depend on the application and corporate regulatory officer's interpretation of Food and Drug Administration (FDA) regulations. Therefore, an analytical application, or one that presents actionable information, may or may not require validation. This uncertainty has historically been a stumbling block for companies wishing to adopt new technology or add additional decision support capabilities on top of existing applications.

As a consequence, life sciences companies tend to lag other industry segments in adoption of technology that could alleviate the visibility and integration conundrum. Without an integrated view of single plant operations, extending integration to a multisite network is ineffective, if not impossible.

### A Perfect Plant for life sciences

In late April 2008, **SAP** unveiled the Perfect Plant Center of Excellence for life sciences, representing the company's collective efforts with its partners **Tata Consultancy Services (TCS)** and MES provider **Werum** (see "SAP's Perfect Plant Predicated on Being Powered by Perfect Partners"). In this particular case, SAP worked with TCS and Werum to develop a scenario that integrates the flow of order and materials information from SAP to Werum's MES.

This workflow provides visibility into the results of the production execution process through finished goods testing and release. As demonstrated, it's largely an inside-the-four-walls view, typical of what is seen in many life sciences companies. However, it demonstrates the power of providing visibility into current production status as well as other performance metrics that are vital to continuous improvement. This scenario also hints at the power of giving supply network partners visibility into current operations.

SAP's Perfect Plant landscape is enabled by integrating applications at the enterprise level with operational systems, such as MES and laboratory information management systems (LIMS) using SAP MII. The application facilitates integration of data and workflows between SAP and non-SAP applications alike, precluding the need for lengthy and expensive custom integrations. Life sciences companies utilizing SAP for core financial or ERP functionality should use the application's capabilities to drive business process and IT integration efforts. **Wyeth Pharmaceuticals** implemented SAP MII in its manufacturing operations with exactly this goal in mind.

### Case study: SAP MII at Wyeth

At SAPHIRE 08, Wyeth Pharmaceuticals articulated its challenges with aggregating real-time data across its ERP, MES, LIMS, and quality management systems (QMS). Specifically, the company identified the delivery of actionable insights, contextualized to specific roles on the plant floor, as a key concern. To address them, Wyeth contracted TCS to deliver a performance management application called Data Analysis and Reporting Tool (DART).

The goals of DART were to enable real-time, role-based data retrieval, analysis, compliance, and visualization capabilities. It was also designed to support fact-based, good manufacturing practice (GMP) decisions in order to drive measurable process quality improvements. DART, as built by TCS on SAP MII, connected ERP, MES, LIMS, and document management in a suite of integrated standard systems for Wyeth.

At SAPHIRE, Wyeth reported an ROI in millions of dollars per plant from its DART initiative using SAP MII. DART and the suite of integrated standard systems delivered benefits in terms of real-time data retrieval, analysis and visualization, process improvements, and fact-based, GMP decision-making capabilities.

Wyeth attributed the ROI to the following:

- Labor reductions during annual report compilation activities
- Exception-based management of electronic batch records (EBR)
- Reduced cycle times

The company also realized decreased compliance exceptions and a 40% improvement in sales per employee.

### **Insight from a Wyeth leader**

To obtain direct user feedback, AMR Research recently reviewed Wyeth's MII experience with Greg Spotts, Director of Process Excellence, Wyeth Business Systems and Processes. Mr. Spotts' focus has been on partnering with manufacturing, quality, and supply chain to implement DART. He shared his experience using SAP MII to integrate MES, LIMS, and QMS with Wyeth's enterprise applications.

#### *The situation*

In scope for SAP MII implementation were 12 manufacturing locations worldwide. Wyeth has automated manufacturing execution, laboratory information, and key documentation management functionality at these sites. At the enterprise level, it utilizes SAP for its MRP, human resources, and core financial functionality.

The company employs a shared funding model between the plants and central IT departments to drive a sense of shared ownership in decision making and deployment that extends far beyond financing. Wyeth's IT architecture is designed to provide an appropriate degree of system and process autonomy at the site level to address unique IT requirements, while achieving integration at the enterprise level.

#### *The status and benefits*

So far, Wyeth has implemented version 11.5 of SAP MII at one-third of its manufacturing locations. It is currently working with TCS on developing templates and application functionality with SAP MII to achieve integration. During this period of initial implementation, the company is tracking progress of integration capabilities to ensure it captures the four intended benefits in business process and IT architecture design.

- **Process monitoring**—With integration, Wyeth has the ability to monitor production and adjust operating conditions to increase yield and decrease exceptions. This was the company's top priority, and it's realizing benefits even at this early phase of implementation.
- **Exception management**—Functionality developed using SAP MII is helping Wyeth to collapse the time required to identify, investigate, and respond to manufacturing and laboratory exceptions. These activities can be time and resource intensive, but it's clear the benefits realized make it worth it.
- **Batch disposition**—Since the initial implementation of SAP MII, Wyeth has made progress in streamlining and automating batch disposition reporting processes. Following full deployment, it expects to manage change control data, laboratory results, batch genealogy, and final batch release activities all in one set of integrated workflows.
- **Annual product reviews (APRs)**—Following full deployment, the company expects to consolidate all APR reporting into one set of integrated workflows and shift resources currently dedicated to reporting to more value-added analytical activities.

### **SAP MII: Limitations exists, but the ease of integration can't be beat**

That said, SAP MII is still first and foremost a toolkit (see "Ecosystem Partners Co-Innovate, xMII Takes the Pause That Refreshes"), and Wyeth has experienced firsthand some of its limitations.

For starters, SAP MII is essentially a development platform, and does not contain plug-and-play reporting and analytical applications. This was a challenge for the Wyeth team to overcome initially. In retrospect, it was not clearly understood in the evaluation and procurement process.

With those limitations in mind, when it comes to the ease with which clients can utilize SAP MII to create transaction-level integrations between third-party applications and SAP, the application can't be beat. The real issue, as Mr. Spotts discovered, is SAP MII's absence of a packaged approach to application lifecycle maintenance and management. For the time being, users looking to deploy SAP MII are best served by looking to partners like TCS and others to bring commercial product discipline to their deployments.

Is your company considering integration of site operations with your SAP enterprise-level applications? If so, we welcome the opportunity to discuss your initiatives—wmcdonnell@amrresearch.com, asmith@amrresearch.com, and hmooraj@amrresearch.com.