THE DRIVE FOR GROWTH AND COMPLIANCE IN LIFE SCIENCES

DATA DRIVES EFFICIENT MANUFACTURING

Pharmaceutical manufacturers are facing more pressure than ever before, on cost reduction, compliance and tackling counterfeit products. As a leading provider of enterprise software to the industry, SAP has seen these pressures grow and has developed an end-to-end solution that greatly eases the burden.

The pharmaceutical sector faces pressure on many fronts, as an already highly regulated industry demands compliance, and increasingly competitive markets fuel a need for cost efficiency. Trimming costs from the manufacturing process is a key goal for major companies in the sector, and finding a technology partner that can provide a comprehensive IT solution, as opposed to stand-alone point solutions, is vital for maintaining a profitable business.

Through its 33 years of partnership with the life sciences industry, SAP has become the principal provider of enterprise systems to major pharmaceutical companies. With over 2500 installations of mySAP ERP among manufacturers of pharmaceuticals, biotechnology, medical devices and diagnostics, it has gained a keen insight into the needs of firms in these sectors, and has witnessed the growing cost pressure, complexity and compliance requirements its customers face.

Most major pharmaceutical companies rely on an SAP enterprise backbone. The firm recognizes a responsibility to help its customers meet the demands of a competitive, highly regulated marketplace and has developed an end-to-end suite of solutions specifically targeting the needs of the industry by extracting maximum value from its customers' data along the entire value chain, from R&D to sales and distribution.

> SAP's solutions provide a seamless path through the complex manufacturing process

By leveraging the central repository of data provided by its enterprise architecture, SAP is helping manufacturers move away from disconnected point solutions towards an integrated, industry-specific infrastructure that improves efficiency, ensures regulatory compliance and reduces total cost of ownership. 'We provide the platform for data infrastructure and the reuse of data in different departments, so that when a firm gets the go-ahead from the R&D department it can quickly and easily ramp up through the manufacturing process,' says Jim Sabogal, vice president of SAP's life sciences industry business unit.

With a global solution for all elements in the manufacturing process, pharmaceutical companies can guarantee high levels of safety and high-quality products, manufactured in compliance with the processes laid down by regulators such as the FDA.

Together, SAP's solutions, including clinical trials supply management, compliant manufacturing, SAP xMII integration and RFID automation, provide a seamless path through the complex manufacturing process. These component systems derive the maximum value from a company's data to deliver a flexible, scalable, compliant and competitive systems environment.

CTSM SETS THE STAGE

The stage at which good manufacturing processes start lies between R&D and full commercial production. Delivering samples for human trials is a crucial yet sometimes neglected phase of manufacturing. SAP has built on its recognized strengths in supply-chain management and logistics to address this disconnect.

There is often a wide gap in supply times for clinical samples. 'We enable companies to predict the demand for clinical supplies, better manage real-time data, reduce cycle times and plan the use of their resources,' says SAP solution manager Mandar Paralkar.

In order to improve time-to-value, pharmaceutical companies must achieve effective collaboration between research teams, manufacturing processes, contract organisations, regulators and clinical sites. In doing so, planning, production, inventory management and quality control are all issues that must be addressed. It is precisely these challenges that SAP's clinical trial supply management (CTSM) solution tackles. 'Average companies have disparate systems and, therefore, cycle times are

high,' adds Paralkar. 'We help companies move towards a proactive, integrated and collaborative model to help them manage their supply chain performance.'

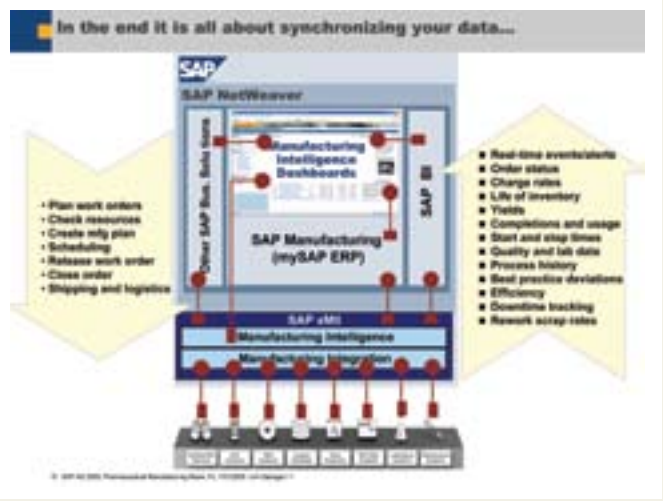
Typically, inefficiencies in clinical trials derive from long cycle times, delays in the delivery of therapeutics and excess drug inventory. As a result, clinical trials are a major contributor to drug development costs, given that they constitute a highly dynamic stage of the process.

Best-in-class companies, however, take a coordinated approach to the production and supply of clinical samples, thanks to having a consolidated view of logistical and manufacturing data. Such companies deliver materials to clinical trial sites 60 per cent faster than average firms.[1] 'Our aim is to make any company perform like the best in class,' says Paralkar.

This is achieved by using the SAP NetWeaver platform to connect databases such as laboratory information management systems (LIMS) with analytics for consolidated reporting. Sap NetWeaver is SAP's comprehensive integration and application platform that integrates with an existing IT infrastructure to facilitate reorganization of systems architecture and implement industry-specific business processes.

Using CTSM to manage the clinical trials process effectively provides a single source of data around which companies can maintain a complete track record of all clinical samples from production to reconciliation, allowing them to rationalize inventory and reduce costs. 'The Sap NetWeaver platform can be integrated into third party or legacy systems, with mySAP ERP managing the solutions,' notes Paralkar.

This architecture integrates data from the clinical research, clinical manufacturing functions and investigators at clinics and hospitals that interact with patients. From here, firms can extend their planning horizon from weeks to as far ahead as two to five years, while remaining responsive to change. They can also reduce order-to-delivery times, greatly improve on-time delivery, closely monitor outsourced manufacturing, and simplify the labelling, barcoding and tracking of samples throughout the supply chain.



SAP's NetWeaver integration and application platform

Real-time visibility throughout the life cycle of clinical samples promotes regulatory compliance, reduced inventory costs and immediate analysis of quality control testing. Typically, an integrated IT system can help to significantly reduce clinical trial supply cycle time.

Note

1 PRTM Comparative Benchmark Survey on Clinical Supply Management 2002

THE KEY TO COST-EFFECTIVE COMPLIANCE

Whether production is for clinical trials or commercial delivery, regulatory compliance is a crucial consideration. In a market with shrinking margins and growing competition from generic products, the industry is focused on improving efficiency in the supply chain and production processes. Managing compliance within this cost-conscious environment is a complex issue.

In recent years, the number of drug recalls instigated by the FDA suggests that compliance is proving to be a greater burden. The fact that in 2002 the FDA counted 354 prescription-drug recalls, up from 248 in 2001 and 176 in 1998, suggests that problems surrounding quality are growing.

Non-compliance can bring disastrous financial consequences, while systems and processes that ensure compliance seem to necessitate considerable investment. Either way, pharmaceutical companies appear to be facing a growing cost burden with regard to compliance and are hungry for a solution that can help them meet regulatory requirements in an efficient manner.

Recognizing this need has been the driver of SAP's compliant manufacturing solution for the pharmaceutical industry. 'Compliance is very important,' says SAP's Christoph Roller. 'Companies go out of business if they don't remain

compliant. However, to keep a system validated requires a big effort and a lot of resources. Pharmaceutical companies want to optimize their resources, but they hesitate to change them because they must be validated. So, there is a need to improve planning and resource optimization processes and adapt to new technology.'

> SAP provides the process tools for validation throughout the entire life cycle of the equipment

Compliant manufacturing relies on the integration of compliance processes, operations and quality management within the manufacturing chain. Using SAP for manufacturing processes allows visibility of data from the planning department to the shop floor, with a consolidated database that enables companies to make faster and more reliable decisions, while proven functionalities make GxP regulation compliance, data capture and reporting easier and more efficient. SAP leverages the use of a single set of data through planning, forecasting and production.

The mySAP Business Suite of products generates planning orders, which are converted into process orders that initiate production using data maintained in the company's central mySAP ERP system. mySAP Supply Chain Management (mySAP SCM) addresses planning issues at strategic, tactical and operational levels by helping companies anticipate market behavior and coordinate with supply network partners. Companies often duplicate sets of data when transferring them to the manufacturing execution systems (MESs), which may require numerous interfaces and a disparate array of local systems with asynchronous connection to the ERP system. In such an architecture there is less visibility of the manufacturing process, and a greatly increased amount of data to manage.

With the SAP architecture, planning and execution are driven from a single data set within mySAP ERP, improving visibility and aiding compliance. Furthermore, SAP's tools meet FDA requirements in terms of e-signatures and e-records. All signatures executed within mySAP ERP use cryptographic encryption techniques, so ensuring their integrity and preventing unauthorized access. The result is a toolset that provides a full audit trail and restricts changes in GxP critical areas. 'Using electronic digital signatures for critical GMP areas like quality management, you can increase ROI and decrease total cost of ownership [TCO],' notes Jürgen Thölke.

Connecting data capture, documentation and review is vital to ensuring compliant, efficient manufacturing, and this is what SAP's infrastructure delivers. 'As a software provider, we can deliver technology compliance and we can validate processes too, ' says Roller. 'With SAP, a customer has the ability to adapt to new processes or to new technology. We can offer a company the balance between the rigid need to comply and the flexibility to adapt to financial pressures or market events. SAP provides the process tools for validation throughout the entire life cycle of the equipment, thereby reducing the TCO, and accelerating the implementation and validation processes.'

BRIDGING THE GAP

To manage production in a compliant and efficient manner, yet maintain flexibility in response to market conditions, manufacturers must manage their businesses in real-time. For SAP, achieving this level of control means bringing the value of data in a company's ERP system all the way to the shop floor. This is the goal of the SAP xApps Manufacturing Integration and Intelligence (SAP xMII) composite application.

The SAP xMII application stems from SAP's recent acquisition of Lighthammer Software Development, which had established a market-leading position for enterprise manufacturing intelligence software. SAP xMII bridges the gap between individual items of production equipment and a firm's wider business strategy. It provides a real-time conduit for data regarding orders, materials, equipment status, costs and product quality to flow between ERP systems and the production line. Furthermore, it facilitates processes such as preventative maintenance, quality management and work centre analytics.

'SAP xMII solves a problem that no other enterprise company was looking at; the grey area between the enterprise level and the machine layer, where engineers deploy technology to improve processes,' says SAP's director of manufacturing applications Stephen Cloughley. 'With the investments companies have made over the last two decades in systems on the shop floor, there is often no real-time link to enterprise software. SAP xMII bridges that gap.'

By drawing on the central repository of data in the ERP system, SAP xMII ensures that at every level there is

but a single truth that defines the entire manufacturing process. The application's real-time analytics engine aggregates and delivers this unified vision of events, along with alerts, KPIs and decision support tools, to production personnel through role-based dashboards. Each person involved in the process, therefore, sees a relevant expression of the data.

Manufacturing integration is achieved by a single ISA-95 compliant layer, which enables mySAP ERP connectivity into real-time plant-floor applications to drive plant-to-enterprise business process interoperability. The result is an adaptive manufacturing process that delivers compliance, efficiency and real-time responsiveness. 'It enables customers to connect in real-time to shop floor systems such as LIMS from the ERP system,' notes Cloughley. 'Then there is an intelligence element that provides decision support based on aggregated data and analytics. SAP xMII makes data available so that it can be used to improve processes. Linking the system to the factory floor gives users better value for their SAP investment.'

In doing so, SAP helps to lower the TCO of the technology infrastructure. Such cost advantages are supplemented by improvements in the management of production line equipment that lower the amount of downtime by allowing line managers to plan outages more effectively. SAP xMII, therefore, plays a crucial role in improving efficiency, ensuring faster customer response times and driving productivity gains, especially when integrated with the other solutions in

THE RFID IMPERATIVE

Growing interest in radio frequency identification (RFID) technology has been noticeable in the pharmaceutical market, which is keen to adopt it in order to combat the circulation of counterfeit drugs.

RFID provides each bottle or package of drugs with a unique EPC

Though it has diverse uses, anti-counterfeiting is perceived as among the most valuable applications of RFID. 'In some industries, such as mass retail, there are a few business cases for RFID, mainly around supply chain efficiency,' says Krish Mantripragada, SAP's director of solution strategy for RFID. 'But in the pharmaceutical industry there are many strong business cases around key requirements such as patient safety, product integrity, anti-counterfeiting measures and the tracking of chargebacks and rebates. Each of these is significant enough to motivate the industry to pursue RFID.'

> RFID can help stem illegal product flow from one channel to another, which couldn't be tracked before

Growing regulatory pressure to find a technology for mass serialisation to enable item-level identification and product tracking is a key driver of RFID in the pharmaceutical industry. 'RFID is the most appropriate, low-cost technology to achieve this,' he adds. 'Previously, only batch or lot level identification has been possible, but this has limitations for certification, authenticity and the ability to track the source of a drug, where it has been and who has handled it.'

RFID gives each bottle or package of drugs a unique electronic product code (EPC). These codes can be read at a distance, out of line of sight as well as simultaneously, which benefits logistics process, product tracking and authentication. Counterfeit products can be more easily identified and eliminated from the supply chain, as they would have a duplicate EPC or would lack one entirely.

Further advantages are improved expiration management, the validation of recalled products and

enhanced monitoring of small samples for clinical trials. Pharmaceutical companies can also improve the monitoring or rebates and chargebacks for drugs sold through different channels. 'There is a huge difference in the price of a product depending on the channel through which it is sold,' says Mantripragada. 'RFID can help stem illegal product flow from one channel to another, which could not be tracked before. Item-level visibility also clarifies manufacturers' applications for chargebacks.'

The challenge for the industry is to integrate RFID tagging into the manufacturing process efficiently and effectively. SAP is keen to help its customers address this challenge. Manufacturers already using SAP systems for lot manufacturing and lot management can manage all individual EPCs for RFID tags through the SAP data repository, which acts as the system of record for all codes. As tags are produced on the packaging line, the SAP system automatically generates unique EPCs.

'Having the same repository for all of this information aids in processes such as recalls as well as in manufacturing and distribution,' notes Mantripragada. 'For each product the manufacturer is tapping into the same EPC database. There is no need to duplicate data in different locations. Through one system you can manage the life cycle of each serial number and every process will benefit from the visibility of this data.'

Any query on a questionable product can be quickly addressed by viewing the data repository, validating the serial number and the product attributes. 'Each vial, package or bottle has its own EPC,' he adds. 'This creates masses of data. Furthermore, for legal purposes, firms must manage their product data for five or perhaps seven years to remain compliant. If you want to authenticate a specific bottle and unequivocally state that it is yours, you need all the data in a central repository.'

Streamlining the amount of data and efficiently managing its availability is, therefore, vital. SAP's scalable solution, successfully piloted for two years, allows seamless access to EPC and product data stored in multiple locations. Beyond that, a central solution can connect all of these locations and make every item of RFID data visible within the company and to the extended supply chain from one location. The result is a system that can be quickly implemented in one manufacturing facility and easily rolled out to other locations, without compromising the efficient management of data.

A COMPREHENSIVE SOLUTION

The combination of SAP's solutions for pharmaceutical manufacturing relies on a number of key products and solutions, including NetWeaver and the mySAP Business Suite. It is the result of a concentrated effort to focus the power of such tools on the specific needs of the pharmaceutical industry.

At the heart of SAP's offering in the life sciences field is mySAP ERP, which acts as the single source of data driving the diverse elements of a company's business.

'For all the processes we outlined, SAP as a platform eliminates the need to move data between systems,' says Jim Sabogal, vice president of SAP's life sciences industry business unit. 'SAP provides a set of applications that allow the use of data from a single repository travelling back and forth between different departments and processes, from research and manufacturing to RFID tagging and distribution. We are an application solution provider with enterprise services included, unlike other middleware companies. We want to integrate the different data islands within a company. We can also bring in data from other providers, so even if a company has a majority of non-SAP systems its data can be brought into our enterprise services architecture.'

> SAP as a platform eliminates the need to move data between systems

With SAP already the key enabler of enterprise data functions in the sector, the set of solutions developed for the pharmaceutical industry are relatively easy to implement, either as separate elements rolled out steadily across facilities or as a large-scale reworking of the IT infrastructure. Together, they offer a set of integration and intelligence tools leveraging the SAP NetWeaver platform that provide cost efficiencies, extended supply chain visibility and performance improvements that no company in the pharmaceutical manufacturing sector can afford to ignore.