

The Next *Big* Thing Better Business Processes

by Mike Jansen



Getting products to

market faster is an enormous pressure, even in companies years away from their first product approval.

Product lifecycle management can help reduce time to market by bringing together everything needed to track a product from conception to discontinuation.

An irony of biopharmaceutical companies is that although they live or die on scientific innovation, many cling to old business practices. Those traditional methods, although thoroughly proven, often lack the efficiency, strength, and robust crossplatform abilities needed to guide today's organizations through increasingly intricate cycles of researching, developing, and quickly and efficiently bringing new products to market.

Biopharmaceutical executives searching for more efficient ways to deal with the challenges of product development, regulatory compliance, best-practice management, and marketing might look to other industries for guidance. Such a search would bring them to an approach called product lifecycle management (PLM). But they don't necessarily have to look that far. PLM is already gaining interest and traction in the life sciences. In the coming quarters and years, the uptake of PLM in life sciences may well determine who wins and who loses. It is that important. This article explains what PLM is, how it can help a biopharmaceutical business, and what features to look for when selecting PLM software.

A WAY OF "LIFE"

Product lifecycle management is an approach to business management—a philosophy enabled by powerful IT tools—that addresses every aspect of product development and support.

PLM starts with product concepts and continues until products are discontinued. It is more than automation. Although automation can create more data, it does not provide the ability to handle and interpret that data. Thus mere automation does not translate into better decisions and shorter cycle times. PLM, on the other hand, when implemented well and embraced by an organization, creates a deep and far-reaching ability to manage and plan.

Companies in many industries—including aerospace and defense, automotive supply chain, consumer packaged goods, and electronics and industrial manufacturing—already rely on PLM. The approach is not experimental: In many industries, PLM has become a de facto standard for companies that want to increase their efficiency and profitability.

FREEDOM FROM BUREAUCRACY

A good PLM installation saves time and money and accelerates product development, which can affect revenues dramatically. PLM allows companies to bring products to market faster by eliminating internal friction points and paperwork. It helps with product launch planning, finds paths to higher product profitability, frees researchers to do their real jobs, and gives the business side current and accurate information on costs, projects, and progress. Those activities also produce improved quality and regulatory compliance and better-scaled production.

PLM can and should decrease inefficient divisions within organizations. Although biopharmaceutical companies have sometimes used information technology upgrades to improve the performance of individual departmental tasks, product development requires interdisciplinary cooperation that is hampered when organizations cling to isolated islands of technology. Companies that choose niche solutions addressing only one part of a drug's lifecycle may actually cause themselves more pain if competing software within the organization quickly creates corporate chaos.

Effectively implemented with the help of an experienced partner, PLM ends the traditional isolation of various product teams in the design, manufacturing, servicing, and quality assurance of product development, manufacturing, and support. Companies save time and money by avoiding the need for largely administrative product meetings. Paper-based change orders go away or are dramatically reduced. Time-saving web tools replace paper-based memos and minutes. And the assiduous requirements of regulatory documentation faced by the biopharmaceutical industry are more quickly met.

One of PLM's strengths is its ability to replace paper document archival and retrieval and runaround sign-off procedures with smooth, visible, secure digital records, permanently linked with the product in development, speeding the entire development process from target concept to launched drug product. That can have a huge effect for biopharmaceutical companies because their work is people intensive, which challenges productivity and efficiency. Doing things in parallel eliminates a lot of the cost and time involved in transferring information from one place to the next. One day faster to market is big. Reducing development cycle time by a month can be huge.

Getting Organized: The central organizing paradigm of PLM is the *product record*, which contains such essential product documentation as

master batch records, packaging component attributes, drawings and models, specifications, data sheets, revision histories, approved manufacturer lists, component pricing, product costing information, historical cost information, and product quality information. Ideally, the product record is configurable to allow different levels of access according to predetermined permissions. Thus change control board members no longer need to sit in endless, ineffective meetings or circle their buildings seeking signatures for change approvals. The result is that an effective PLM solution returns scientific and other valuable talent to constructive product development activities.

PLM BENEFITS

- Increased revenues
- Freedom from paperwork
- Faster time to market
- Improved compliance
- Streamlined product development and manufacturing
- Improved internal and external (supplier) collaboration
- Better, more organized historical data

Robust PLM tools simultaneously protect the integrity of the product record and instantly serve up formatted reports to authorized product team members, managers, and quality auditing organizations. Thus a complete and secure PLM solution provides comprehensive product overview and oversight, giving executives a wide-angle view of their organization's entire product portfolio and allowing informed comparisons and strategic assessments. It also provides an efficient mechanism for scheduling and controlling internal audits and managing organized responses to major postmarketing issues.

A customer might bring a quality issue to the surface. But other symptoms may have been upstream, perhaps from an outsourced manufacturer or packager. Problems

can be detected and corrected earlier in an environment where the external and internal constituents all have access to the information and communicate and collaborate easily.

FULL COMPLEMENT

The best-performing PLM software offers a single environment for managing program information centered on the product record. Program management information can include tasks, deliverables, issues, discussion threads, and product data. One benefit to a common environment is the ability to publish and implement procedures quickly, enabling swift enterprisewide adoption of best practices for product development and introduction.

The product record should also be a central organizing paradigm for secure, distributed access to critical product information. Individuals from purchasing, manufacturing, and supply organizations can participate in collaborative communications. Thus anyone with appropriate permissions, including suppliers, can initiate and immediately access changes in specifications or any other modifications.

The best PLM solutions offer an integrated, closed-loop capability for quickly identifying and correcting product quality problems. It should provide full visibility of product quality issues to individuals with appropriate permissions from marketing, sales, manufacturing, and the supply network, enabling product improvement collaboration among all affected parties. PLM can capture and track problems, simplify analysis, correlate issues to products, publish corrective and preventive actions for review and approval, and manage the ensuing change processes. The result is a cycle of product quality improvement that increases customer satisfaction, reduces compliance risk, and makes sales and marketing activities more efficient.

When choosing a system, look also for help with validation and regulation issues. Good PLM software accounts for the scrutiny and additional costs that regulated operations face. In fact, increasing regulatory requirements

make PLM software even more useful in biopharmaceuticals than in other, less regulated industries, leading to even greater returns on the original investment.

New product development often means using technologies owned by other corporations or institutions, and worthy PLM software should make that easier, too. Regardless of structure—patent in-licensing, crosslicensing agreements, coordinated development of marketable products, or other revenue sharing arrangements—a high degree of collaboration within and among organizations is required. PLM should enhance that collaboration.

Cost management tools
reduce costs throughout the product lifecycle by synchronizing manufacturing and sourcing teams with outsourced partners, leveraging combined sourcing strategies, and accelerating business processes to expedite cost decisions.

A strong product collaboration component also helps companies control costs by enabling the most complete possible communications around the product record. By making specification changes and other product information available in real time to everyone involved with a specific product (including supply chain partners around the world) best practices can be implemented rapidly. Lengthy paper-based procedures can be eliminated, saving valuable management and staff hours. Collaboration also saves valuable

resources by automating tasks such as producing and routing disposition orders arising from nonconforming materials discovered during incoming inspections.

Cost management tools also reduce costs throughout the product lifecycle by synchronizing manufacturing and sourcing teams with outsourced partners, leveraging combined sourcing strategies, and accelerating business processes to expedite cost decisions. These tools allow managers to anticipate where and when cost targets will be missed while there is still time for correction, and they automate repricing and negotiation.

HOLISTIC APPROACH

Because PLM product cost management also encompasses product labeling and shipping, it forms connections among vital, time-critical internal processes—from incoming inspection of materials, through manufacture, packaging, and shipping. That makes product data available wherever needed, enabling suppliers to accurately and rapidly manage supplier inputs throughout a product's lifecycle.

In a study of PLM's ability to help pharmaceutical companies with labeling, consultant David Williams of Calico Associates Limited found that it can


- Reduce time to market for approved drugs by 50%
- Reduce packaging errors for new product introductions to less than 10%
- Enable 5% lower material costs through reuse and compound standardization
- Lead to 20% lower scrap rates through consistency of product specification and an earlier view of product component changes
- Enable a 40% greater packaging change throughput with existing organizational resources
- Reduce errors in compliance regarding product information by up to 75%.

"The exact benefit for each company will be different," Williams wrote in the study. "Adoption of PLM solutions for packaging and printed packaging component management

could be expected to deliver seven-figure increases in profits with contributions from all elements."

THE CLOCK IS TICKING

Implementation of a major software package doesn't have to be a major ordeal. Experienced PLM vendors offer programs that can be installed in weeks, requiring few resources and no coding. As an example, one recent installation of PLM at a 3000-employee life sciences company active in some 70 countries took 14 weeks. The challenges of installation usually have less to do with technical issues and requirements and more to do with getting agreement on the set of business rules that the technology enables.

For many companies in the biopharma industry the clock is ticking. Management needs to be thinking about how to manage a product for profitability long before launch. PLM helps companies think strategically in that way. And compressing time to market is a tremendous boost to revenues. 

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