

AGILE PRODUCT LIFECYCLE MANAGEMENT FOR BIOTECH SOLUTIONS PROVIDERS

Serving an Industry in Crisis

Drug patent expirations, shorter periods of marketing exclusivity, price controls and competitive pressures have resulted in an acute need for new chemical entities (NCEs) in the pharmaceutical industry. Biotech Solutions providers have responded by industrializing the process of life science research, providing fast, automated systems such as high-throughput sequencing, SNP interrogation and compound screening systems that produce data more quickly and at lower cost than the benchtop processes they replace. To continue to profit from their role at the head of the drug discovery value chain, Biotech Solutions providers must step up development and delivery of new products that address the specialized needs of the pharmaceutical industry, such as:

- Instrumentation systems that exploit new technologies and materials, enabling miniaturization, automation, and parallel sample processing.
- Reagents and other consumables that meet the market's quality and reproducibility requirements, are available to ship in customized configurations on demand, and reach the customer's lab before they expire.
- Software that comes out on time with the required feature set, sophisticated data management and analysis capabilities, a competitive, easy-to-use interface, and multiple-architecture compatibility.
- Whole platforms that support pharmaceutical industry customers' needs to maintain an operational environment that complies with FDA regulations and those of other regulatory and quality certification organizations.

To address the opportunities and challenges of meeting these specialized needs profitably, Biotech Solutions providers have begun to adopt operational processes and technologies that enable them to speed product development, maintain profitable margins, and implement and verify manufacturing and product quality programs. Particular areas of concern typically include:

- Introducing new technology into product development quickly and economically
- Making accurate product portfolio and resource allocation decisions
- Reducing man-hours lost to document procedures and administrative detail
- Controlling and reducing direct materials costs and other COGS components
- Improving product quality
- Ensuring compliance with quality initiatives

Companies often invest in information technology upgrades that deliver on the vendor's promise to improve the speed and execution of certain departmental tasks. But product development is an inter-departmental exercise that does not benefit appreciably from

isolated upgrades to individual departmental functions. To achieve faster revenue growth, higher profitability, and economical conformance with increasing regulatory requirements, biotech solutions providers must now industrialize their own operations with enterprise business solutions for faster product development, better cost management, and effective quality program implementation.

Agile Product Lifecycle Management and the Agile Product Record

Agile Product Lifecycle Management (PLM) is an enterprise software solution that ends the traditional isolation between product teams involved in product design, engineering, manufacturing, service, and quality. Agile PLM lets companies discontinue product meetings, paper-based ECO and MCO procedures, time-consuming field service reports, and the memos and minutes companies traditionally produce and keep so that individuals in one work team can see what another work team is doing and synchronize their efforts at intervals.

The organizing paradigm of Agile PLM is the Agile Product Record, which maintains essential product documentation such as bills of material, component attributes, drawings and models, specifications, data sheets, revision histories, AMLs, parts pricing, product costing information, historical cost information, QA reports, and manufacturing and service procedures in a secure, organized, digital format. The Agile Product Record is continuously accessible to individuals in all product work teams according to configurable permissions. These individuals can interact with each other through the Agile Product Record to effect fast, digital product development processes such as paperless ECO or MCO sign-offs that take place without CCB meetings. Account-linked user access controls let strategic supply partners participate in product design through secure external networks. Field service personnel can participate in organized, effective CAPA systems by reporting product issues from the field and accessing field service protocols on-line.

Agile Product Lifecycle Management is a scalable enterprise solution consisting of five components: *Agile Program Execution*, *Agile Product Collaboration*, *Agile Product Cost Management*, and *Agile Product Service and Improvement*.

Agile Program Execution

Agile Program Execution is a unified environment for maintaining and serving program information such as tasks, issues, discussion threads, product data, progress on deliverables and availability of resources. Agile Program Execution also provides an efficient mechanism for scheduling and controlling internal audits and executing organized responses to post-marketing issues.

Agile Product Collaboration

Agile Product Collaboration enables authorized individuals from engineering, purchasing, manufacturing, supply organizations, technology partners, the customer base, and others to communicate with one another through documented interactions with the Agile Product Record. Agile Product collaboration eliminates paper and paper procedures and brings the capabilities of all available resources to bear on managed decision-making, enabling better outcomes and faster execution.

Agile Product Cost Management

Agile Product Cost Management analyzes and introduces supply cost information into the Agile Product Record. Design-phase collaborations with strategic suppliers, enabled through Agile Product Cost Management, build profit into each product from the beginning. Agile Product Cost Management analyzes cost and supply data on a continuous basis and identifies opportunities for cost reductions.

Agile Product Service and Improvement

Agile Product Service and Improvement analyzes the Agile Product Record to identify product quality problems before they become major issues. By enabling closed-loop CAPA procedures, Agile Product Service and Improvement helps bring product advancements to market faster and at lower price points, increasing both product quality and customer satisfaction.

Agile Validation Protocol Paks

Some Biotech Solutions providers must maintain product development environments that comply with certain rules and guidances of the US FDA and other regulatory bodies. Agile Product Collaboration can query the Agile Product Record to produce key documentation such as product change histories, design history files, SOPs, and effect analysis documentation on-demand for review by internal quality management or external certification organizations. Developed by a respected third-party validator, Validation Protocol Paks document the installation and performance of the Agile Product Lifecycle Management solution itself. Validation Protocol Paks are available for all of Agile's out-of-the-box software solutions, and contain:

- Master Validation Plan
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Traceability Matrix
- Final Validation Report

Product Lifecycle Management for Biotech Solutions Providers

To capture and maintain market leadership, Biotech Solutions providers need to accelerate product revenues, improve profit margins, and meet the industry's quality requirements for design, manufacturing, documentation and support. Agile Product Lifecycle Management helps introduce new technologies into rapid product development cycles by enabling organized communication between product development teams and technology partners, and by enabling executive management to make informed product portfolio and resource allocations decisions. Agile Product Lifecycle Management increases returns from product development programs by allowing Biotech Solutions providers to get their products to market sooner and by reducing manufacturing and materials costs.

By closing the loop between the customer's experience and product engineering, Agile Product Lifecycle Management initiates an upward spiral of continuous product improvement and customer satisfaction. The Agile Product Record at the center of Agile Product Lifecycle Management includes comprehensive quality documentation that can be queried to prepare formatted documents on demand for internal review or external audit. Validation Protocol Paks for each modular component of Agile's Product Lifecycle Management solution provides third-party validation of the proper installation, functioning and performance of the Agile Product Lifecycle Management software at a fraction of the cost usually associated with validating enterprise software solutions.

Agile Software has already helped more than 850 companies save billions of dollars. Join Biotech Solutions providers like Caliper Technologies Corp, Cepheid, Luminex Corporation, Symyx Technologies, Inc., Thermo LabSystems and Xenogen Corporation, who are already realizing the benefits of Agile Product Lifecycle Management solutions. To learn more, visit <http://www.agile.com/industry/biotechsolutions.asp>, or call (408) 975-3900.

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