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White Paper:

How Software Helps
Pharma/Biotech Maximize the
Value of External Resources

Perhaps more than any other industry, pharmaceutical and biotech companies rely on external resources—such as investors, strategic alliances, partnerships, licensing deals, and outside service providers—to finance products, expand geographically, lower costs, and, ultimately, increase revenues. This paper focuses on the specific ways in which software developed for the pharmaceutical/ biotech industry can help companies (a) secure the funding they may need to finance new products, (b) substantially lower costs through the effective management of strategic outsourcing, and (c) maximize the benefits of mergers and acquisitions.

Helping Small Pharma/Biotech Companies to Finance New Products

Raising Capital through Venture Funds or an IPO /FOPO

When raising capital through venture funds or an IPO/ FOPO (Follow-On Public Offering), pharma/biotech companies must make presentations that rely on all the information currently known about a product and its capabilities. The ability to readily access relevant documents to prepare strong presentations (which includes the ability to quickly answer questions) is critical.

Document control software developed for pharma/biotech is specifically designed to help organize the hundreds of thousands of documents that companies generate on chemical and biologic compounds. Many of these documents are the results of collaborative efforts and have the potential of one day leading to important medical breakthroughs. The ability of a system to accept documents from any source (including lab notebooks), and to organize and secure this information so that it can be quickly accessed by authorized users from any location, can make the difference between a company's ultimate success or failure. Having a secure, centralized database that can be accessed via the web from anywhere in the world is thus of vital importance, both with respect to sharing documents, and, as we shall see, with respect to managing the various phases of a product's lifecycle.

In addition to organizing documents, software for the pharma/biotech industry is designed to ensure that only the most current, up-to-date documents can be accessed. This is accomplished through automated approval routings and electronic signatures for signing off on product development documents and other important documents such as CAPA, SOP, and change control documents. Once a document is signed off on, any previous version is automatically placed into an archive, where it can be accessed by audit management software developed for regulated companies.

Flexible document organization capabilities, the ability to accommodate and manage multiple document types, ready access to the most current version of any document—plus security features that define access and user rights—provide a valuable source of secure product information and data. This not only increases the likelihood of important research breakthroughs, it enables scientists, marketing executives and senior management to develop strong product presentations. The ability “to chunk” pertinent information and datasets to be incorporated into presentations is also vitally important, as this helps non-scientists more readily understand the value of emerging products. In addition, the ability of the software to provide links from pre-developed outlines can be extremely helpful in guiding product presentations.

Related supporting resources include:

- Collaboration tools that allow team members to work together on product presentations (once the redlining process is complete, documents can be routed through an approval process to ensure that only approved documents are accessed for the presentations);
- Email reminders that keep the presentation development process moving forward and enable reviewers' questions to be answered immediately; and
- Overview reports, drawn from both external suppliers and internal interdisciplinary teams, that can be easily retrieved from anywhere in the world via web access.

Exploring Partnerships, Strategic Alliances and Licensing Deals

Typically, the search for partnerships, strategic alliances, and licensing deals is a collaborative effort that involves business development, marketing executives and patent attorneys. The likelihood of the success of this type of venture, and its associated value, depends to a large degree on the availability of developed documents that describe the viability, attributes and strengths of a product, as well as its rationale and ability to meet specific needs. A company's ability to access information on manufacturing batches, CAPAs, and related information is imperative.

Software processes that update a centralized database guarantee quick access to all of the most up-to-date data related to specific products. This enables companies to "walk" prospective partners through product data in a way that can make product presentations extremely impressive.

Web-based systems enable product and domain area experts to participate from remote locations, if necessary. With the enhanced security features currently available, each cross-functional team leader's signature can be attached to the relevant documents. This assures business development and senior management that the documents were reviewed by an expert prior to being shared with outside companies.

The above efforts benefit the most from product information that is staged to allow for interest at different levels: a cursory review in the beginning of the process that grows as potential licensees or prospective partners become more interested.

Another key benefit of the software is its ability to track and record the documents that are accessed. Knowing what documents potential partners or licensees spend their time on can vastly improve the process as a whole.

Lowering Costs through Strategic Outsourcing

Large companies, too, can benefit from the capabilities of software currently available for the pharma/biotech industry. Although not dependent on funding, most large companies are extremely interested in cost savings that can accrue from the ability to outsource to lower-cost regions of the world.

According to a recent PriceWaterhouseCoopers survey cited in *Pharmaceutical Technology Europe*, this is a trend that is expected to continue and expand. Not only in terms of the number of western companies seeking to outsource, but in terms of the outsourcing relationship. Thus far, for example, much of the focus has been on the outsourcing of drug manufacturing, with companies in Asia providing a supportive role to US and European companies. Increasingly, however, Asian companies are being viewed more as potential partners, with US and multinational companies (MNC) looking to outsource R&D and clinical trials as well. To quote PricewaterhouseCoopers:

A new business model of the MNC is to focus on sales and marketing, with other activities outsourced. Not surprisingly, as the industry moves to this future model, strategic partnerships or long-term partnerships are the preferred route, favored by 82% of the multinational pharmaceutical companies we surveyed who outsource. ¹

China and India lead the list of target countries for greater expansion, with Singapore and South Korea next in the sights of MNCs, another PricewaterhouseCoopers source told *Reuters*. ²

According to *Contract Pharma*, however, some pharma/biotech companies are wary of China and India, due to potential problems with intellectual property rights and patents. Despite these concerns, however, a group of thirty biomanufacturing directors interviewed by *Contract Pharma* all indicated that they would consider outsourcing to Asia under the right conditions. (The “right conditions” being: compliance with cGMP requirements as substantiated by an in-depth audit, experienced employees, and substantial discounts.) ³ This unanimous agreement by biomanufacturers is significant, given that the outsourcing of biopharmaceuticals has tended to lag behind that of chemical pharmaceuticals.

Obviously, companies seeking to outsource to remote regions of the world can benefit enormously from software processes developed for the pharma/biotech industry that are web-based and update a centralized database. Such systems ensure accountability and tracking, and are specifically designed to manage operations anywhere in the world. Equally important is the ability the software to meet Title 21 federal regulations, which establish current good laboratory and manufacturing practices, as well as regulations for clinical trials, institutional review boards, etc. ³

Examples of the pharma/biotech solutions currently available include:

- Audit management solutions
- Employee training and testing software
- Software for building the regulatory submission as the data from clinical trials come in
- CAPA software
- Deviation management software
- Complaint handling and tracking
- Out of Specification (OSS)
- Electronic Batch records (EBR)
- Change control software
- Document control software

In essence, with these and other centralized, web-based, integrated quality management solutions, it really makes no difference where the functionality associated with any given phase of a product's lifecycle happens to be located. Software implementation best practices, collaboration tools, and automated document routing and approval processes via electronic signatures ensure an optimally functioning system, regardless of whether a company's operations are concentrated at a single venue or circumnavigate the globe. Some software companies even offer multi-language capabilities, as well as processes for handling multiple time zones.

Due Diligence Considerations

In general, the term *due diligence* is used in the context of performing the investigations necessary, or securing the assurances warranted, to protect one's interests.

For pharmaceutical and biotech companies looking to outsource their manufacturing, R&D—or any other product phase—to lower-cost regions of the world, performing due diligence is of vital importance. As noted above, part of this entails making sure that companies “being outsourced to” are onboard with respect to quality management and federal compliance regulations. It is also important to ensure connectivity with the quality management system of the outsourcer. This can entail providing the necessary software and/or connectivity solutions (to be discussed further in the section on mergers and acquisitions).

For small pharma/biotech companies looking for funding or partnership deals, the situation is considerably different. In this case, it is *they* who are being investigated. Their ability to respond quickly and effectively to the due diligence inquiries of prospective investors or partners is essential to their success. This entails the ability to supply detailed information about a product, its capabilities, and its current market need. It also entails being able to convince potential investors or partners that their company has everything it could possibly need except for the funding to bring its project successfully to fruition in a time-efficient manner. This is where specialized, automated processes can help by ensuring the efficiency and control needed in the extremely complex business of bringing a new drug to market.

Trying to convince well-seasoned investors of the efficiency of your processes and their compliance to FDA standards—without having the quality software to prove it—can be an upstream battle, assuming anyone sticks around long enough to listen. On the other hand, being able to show that you have a strong, viable product, and that all your research, collaboration, and formulation documents—as well as your quality standards, in vivo studies, and preliminary ADME/Tox data—are well-organized and readily accessible, via software designed to meet FDA quality audit requirements, tells an entirely different story. It communicates to potential investors and partners not only that you're serious, but that you really know what you're doing and can deliver on the product as promised in a timely manner.

Maximizing the Value of Acquisitions and Mergers

In a paper titled, “Mergers and Acquisitions in the Pharmaceutical and Biotech Industries,” the National Bureau of Economic Research claims that mergers among large firms are frequently a response to excess capacity due to anticipated patent expirations and gaps in a company’s product pipeline.⁴ Another common reason for mergers (and acquisitions) is the desire to have a stronger presence in another geographical area. Whatever the reason, regulated companies with thousands of employees in sites scattered across the country or around the world face quality management challenges that are unique to their size and the complexity of their operations.

In terms of quality management, large-scale companies must manage enterprise-wide quality processes and at the same time control local processes in individual business entities. A pharmaceutical or biotech company that has made an acquisition—or two companies that have merged—frequently finds itself with two separate systems. Realistically, a pharmaceutical or biotech company with a different division for each product in development might have a wide range of compliance needs that are not fully met by most enterprise-wide systems.

In addition, large-scale companies typically have invested substantial amounts of money in electronic repositories that are good for storing SOPs and other documents necessary for compliance, but are incapable of controlling documents from other quality processes such as training and corrective action/preventive action (CAPA). Or, large-scale companies may rely on enterprise applications such as ERP, CRM, and MES that are not connected to a quality management system at all.

These types of situations require advanced connectivity solutions specifically designed for connecting different processes and data repositories to provide a holistic quality management system. This enables companies to integrate ERP, CRM, and other enterprise applications with CAPA, training, audit, change control, deviations, etc., and exchange files and data between these quality solutions and the enterprise applications.⁵

Summary

Specialized software developed for the pharma/biotech industry can be a boon for small to mid-sized pharmaceutical and biotechnology companies in need of funding to finance new products. It helps companies organize the hundreds to thousands of documents that they’ve accumulated on chemical and biologic compounds—including valuable collaboration documents scanned in from lab notes books. It also provides access to the most recent product development documents and datasets. This helps companies develop strong product presentations without having to cull through masses of documents to find the information they need.

For developed products, information on manufacturing batches, deviations, and CAPAs is imperative. Software that automates the production process and automatically generates these and other critical documents saves a tremendous amount of time and is impressive to potential investors.

For larger companies seeking to cut costs through outsourcing to companies in lower-cost regions of the world, specialized software for the pharma and biotech industry is critical. Such systems ensure accountability, tracking, and are specifically designed to manage operations anywhere in the world through their centralized, web-based infrastructure. Equally important is the ability of the software to help companies meet Title 21 federal regulations, which establish current good laboratory and manufacturing practices, as well as regulations for clinical trials, institutional review boards, etc.

Large-scale companies seeking to merge with or acquire another company typically have invested substantial amounts of money in electronic repositories that are good for storing SOPs and other documents necessary for compliance, but may be incapable of controlling documents from other critical quality processes such as training and corrective action/preventive action (CAPA). Or, large-scale companies may rely on enterprise applications such as ERP, CRM, and MES that are not connected to a quality management system. These types of situations require advanced connectivity solutions, specifically designed to connect different processes and data repositories to provide a holistic quality management system. This connectivity enables large companies to leverage their existing repositories by integrating them with other quality applications without expensive custom coding.

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About MasterControl

MasterControl Inc. is a global provider of GxP process and document management software solutions for life science companies. The MasterControl(tm) suite is easy to use, easy to deploy, easy to validate, and easy to maintain. It incorporates industry best practices for automating and connecting every stage of the product development cycle, while facilitating regulatory compliance. By combining an integrated platform with a continuum of risk-based software validation products and services, MasterControl drives down the total cost of ownership and enables customers to extend their investment across the enterprise. Hundreds of companies worldwide use MasterControl for easier compliance, faster validation, and better process management. For more information, visit www.mastercontrol.com, or call 800-825-9117.



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MasterControl Inc.

USA

6322 S. 3000 E. Suite 110
Salt Lake City, UT 84121

P. 800.825.9117

F. 801.942.7088

www.mastercontrol.com

UK

7200 The Quorum
Oxford Business Park North
Garsington Road
Oxford OX4 2JZ
United Kingdom

P. +44 (0) 1865 481481

F. +44 (0) 1865 481482

www.mastercontrolglobal.co.uk