IBM Life Sciences
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Achieving business integration across the pharmaceutical value chain

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Introduction

The pharmaceutical industry is undergoing unprecedented change – most of it undesired – as it struggles to meet high expectations of investors in an increasingly demanding regulatory environment.

The process of successfully launching a new drug involves many scientific and medical professionals – distributed inside and outside companies – with the total cost of each successful product estimated at $800 million. Historically, the drug discovery, development and launch processes have been managed within functions that operate in narrow silos. These disparate processes result in costly inefficiencies and hinder cross-departmental communication and dialogue. Additionally, the majority of working procedures are paper-based – leading to inaccuracies, long feedback loops and delays.

Unless pharmaceutical companies change historic working practices, they will find it increasingly difficult to fuel the double-digit earning growth that has become expected of the industry.

Troubles down the pipeline

Communication and integration challenges extend beyond research and development (R&D). For example, a key decision point in having regulatory agencies accept and approve a new drug application (NDA) is the readiness and robustness of the proposed manufacturing process and equipment. Unfortunately, the pharmaceutical industry has had a poor history of involving manufacturing early on and during R&D phases. Initial interest would ensure that operational factors are considered with plenty of time to fine tune if necessary.

The pharmaceutical industry has had a poor history of involving manufacturing early on and during R&D phases. Initial interest, by way of PLM, would ensure that operational factors are considered with plenty of time to make alterations if necessary.

Currently, a number of leading companies are addressing this weakness. Yet, they tend to do so on a project-by-project basis and without a standardized and institutionalized approach supported by appropriate information technology (IT) solutions.

A thorny path forward

After product launch, the key challenge is to drive product revenue up to peak sales as quickly as possible – especially before other innovating companies bring out similar competing drugs. Later on, the most critical challenge is in the lead-up to patent expiry – usually around 10 years after launch – when the product often faces vigorous competition from so-called "generic" copies.

Recent history shows that in such cases revenue falls by about 80 percent within days of patent expiration. The implication for ethical pharmaceutical companies is to recognize that at some point after launch the product goes into a mature phase, where high volume, low-cost production becomes critical in maximizing the economic return of the product. During the mature phase, rigorous control of product portfolio management is essential. Typically, the 80/20 rule, which applies in most business scenarios, is even more accentuated in pharmaceuticals. Rather than 80 percent of revenue, or profit, coming from only 20 percent of products, often the relationship is more like 80/5. The inference is that for a typical pharma company, with 10,000 final product presentations, 9,500 of these are only bringing in 20 percent of the revenue and are often being sold at very low profit margins or, in some cases, at a loss. As portfolio complexity increases, this issue will become even more critical.

Product portfolio complexity is becoming increasingly intensified as key customers demand tailored packaging of medicines – leading to active ingredients, formulations and delivery mechanisms more conducive to the demands of patient genotyping, life quality and cost.

A number of factors will drive portfolio complexity. Increasingly, large buying groups will demand tailored packaging and labeling. This is without considering the future demands of tailored medicines defined by genomic profiling where the "one size fits all" blockbuster model must give way to active ingredients, formulations and delivery mechanisms more conducive to the demands of patient genotyping, life quality and cost.

Planning ahead

In order to maximize competitiveness, pharmaceutical companies will need to conduct ongoing analysis of their product portfolio in a way that allows clear categorization of products across key criteria, including strategic importance, contribution to revenue, share of profit, ease of supply, and so on. This will allow management to develop sourcing policies such as "make versus buy," or even to employ sell strategies that migrate products to other manufacturing or marketing organizations. Additionally, manufacturing and supply chain strategies will have an important role in portfolio management by differentiating and distinguishing optimal sources of supply, innovation and core technological expertise.

PLM: Breeding collaboration, innovation and domination

As a concept, product lifecycle management (PLM), has existed for many years – originating in the electronics and automotive sectors. The PLM approach integrates, in a process-oriented way, cross-functional product management processes across extended supply chains…from a supplier's supplier to a customer's customer. It allows a company to actively manage the way in which a product is being sourced, manufactured and planned throughout its lifecycle – from early development, through scale-up and launch to maturity and decline phases.

PLM: Enabling e-business across industry and lines of business

PLM focus varies from industry to industry and is quite different within process manufacturing operations as compared to discrete production. The latter features a strong emphasis on discrete product data management (PDM) and on design for manufacture, which is product data orientated.

PLM builds off the PDM foundation yet adds collaborative customer and supplier processes. In pharmaceuticals, the key driver will be to enable rapid global product launches within facilities containing robust and compliant – from a regulatory standpoint – manufacturing operations. A further top requirement in pharmaceuticals is an effective structure for the management of globally harmonized product master data and specifications.

Technical operations will help to resolve and plan for the answers to many questions, including: Can the process be repeated consistently? Is it robust? What about issues of operator safety? Are there potentially harmful by-products requiring investments to ensure operator protection? Can the product be launched at an acceptable level of cost of goods sold?

As the need for truly integrated manufacturing and supply chain systems materializes, standardization in data definitions and product-numbering policies will be essential. This push to integration will be propelled by the critical need of pharmaceutical companies to easily transfer products throughout the product lifecycle – from launch sites to low-cost manufacturing during the mature phases. It will also be driven by companies demanding that enterprise resource planning (ERP) systems come closer to "single instance" while at the same time needing to interface ERP with other systems, including advanced planning and scheduling (APS), manufacturing execution systems (MES), and content or document management systems (C/DMS).

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PLM: Preparing the pharmaceutical industry for the future…today

In the years to come, the most important driver of growth within the pharmaceutical industry will be effective new product introduction (NPI). The word "effectiveness," in the case of new medicines, can tend to be subjective. Often, it depends on who is asking the question – regulatory agencies, the patient, the doctor or even health insurance companies. Typically, among these audiences, the bottom line is an acceptable trade-off between medical effectiveness (efficacy), cost, convenience and quality of life.

Another important constituency, often overlooked in the past, is technical operations, which is largely responsible for manufacturing and managing the product supply chain. The criteria in this instance will include questions about manufacturability. Can the process be repeated consistently? Is it robust? What about issues of operator safety? Are there potentially harmful by-products or intermediates, which might require significant investments to ensure operator protection? Can the product be launched at an acceptable level of COGS (cost of goods sold)? The answers to these technical questions are best addressed early in the product development phases. This requires an effective knowledge management approach and the integration of diverse teams of development scientists, manufacturing process engineers and supply chain experts.

Today, scientific functions responsible for development activities are in fragmented, functional silos with little horizontal integration between them. With PLM, however, integration will occur – eliminating cost- and time-draining inefficiencies. For example, as external suppliers of materials and technologies become increasingly critical, these key functions would be incorporated into

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streamlined enterprise processes. This will require an interactive and dynamic multi-way flow of learning, knowledge and experience, ensuring that technical issues are kept off the critical path to launch and that products require minimal post-launch improvements. PLM offers the approach and methodologies necessary for bringing these disparate functions together – using tools and language easily shared and understood across the enterprise and entire value chain.

Ultimately, and perhaps most importantly, PLM can allow companies to establish an integrated framework for top-down regulatory compliance, strategic sourcing, predictable and traceable quality, product data and specification management, manufacturing execution and corrective actions, and product safety. In other words, PLM provides an ideal approach to coordinate strategic IT and business initiatives.

Racing to get up to speed

The pharmaceutical industry has gone through waves of consolidation in the past 10 years, which are set to continue as companies seek to secure access to key products and markets. For manufacturing operations, the immediate priorities following a merger are often to rationalize excess capacity and to integrate enterprise systems. Consequently, most companies are still in the process of implementing or aligning ERP and mission-critical systems.

In order to remain competitive, it is time for companies to move onto the next logical phase of systems integration – including implementing shop-floor batch recording and execution systems (MES), strategic supply chain solutions (APS), and process-oriented approaches required for enabling PLM – while at the same time becoming a strategic weapon in maximizing product economic value from launch to phase-out. For the first time in the history of the industry, technical operations will have the opportunity to play a key role in achieving strategic corporate goals.

Winning the race

In the past three or so decades it has become increasingly apparent that technology offers powerful solutions for achieving improved productivity, knowledge-sharing and efficiency. With PLM, this will be the case, especially as commercially available systems fulfill the demanding requirements of the regulated pharma industry.

For all the advantages that technology can bring, process and people, together with an organization's culture, are the most important considerations in implementing new solutions. Naturally, change will need to be proactively managed throughout PLM implementation, particularly since PLM links discovery, development, launch, technical operations, sales and marketing, and finance. Given the integration of disparate functions, methodologies and knowledge capital across the value chain, it is no surprise that human tendencies will play a pivotal role in the overall success of PLM.

Notwithstanding, the return on investment is clear: PLM affords the pharmaceutical industry the opportunity to fully harness existing knowledge and power, and promises to fill many of the information and efficiency gaps existing in enterprises today.

Sustaining victory

The roadmap to success will not be difficult to chart, as it includes many elements we are familiar with from previous technology implementations. The keys to success will lie more in process harmonization and integration, as well as obligatory change management approaches. Following this sequence, the implementation of technological tools are essential to driving performance and realizing complex business objectives.

Adopting PLM and partnering with leading technology experts remains at the heart of success and achieving a competitive advantage as the pharmaceutical industry continues to endure rigorous innovation and mounting market demands.

IBM and Life Sciences

As proven leaders in PLM, IBM is best positioned to address the unique needs of the pharmaceutical industry. In fact, IBM has 150,000 service professionals in 150 countries, including more than 1,300 experts dedicated to PLM. Furthermore, IBM offers the hardware, services and middleware necessary to fuel PLM: the power of product innovation and increased speed to market.

The IBM commitment to the life sciences industry is defined by the establishment of the specialized IBM Life Sciences Solutions business unit, which is dedicated to bringing leading-edge technology out of the laboratory and into the marketplace for customers and IBM Business Partners in the fields of pharmaceutical research, biotechnology, genomics, proteomics, health care and other life sciences. Long-term projects at the IBM Computational Biology Center and the IBM Deep Computing Institute foster IBM collaboration with life sciences companies to bring scientific needs and expertise directly into the development of life sciences infrastructure solutions.

For more information

To learn more about IBM Life Sciences Solutions and IBM Life Science Business Partners, visit the IBM Web site at:

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Jim's early career was spent in process development and manufacturing plant installation. He followed this with a three-year stint in production managment before moving into the project management of manufacturing systems. This experience gave him a good understanding of both sides of the R&D and manufacturing divide, and what is needed to ensure effective integration. In his consulting career, over the past 15 years, he has worked with most of the major pharmaceutical and biotech companies to address supply chain and manufacturing issues. A major focus of his work in the past 10 years has been the integration of R&D and technical operations. Jim leads IBM's consulting practice for Pharmaceutical Supply Chain and Operations in EMEA.

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