Quality Management in the Digital Age

An operational approach such as Pharma 4.0 that connects all resources via the Cloud can be a really good thing

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Rapid changes in molecular science have ushered in a new era of innovative biopharmaceuticals. The emergence of targeted therapies, the increased prevalence of large molecule medicines, and huge growth in the number of treatments for orphan diseases are just some of the factors that are having a significant impact on how medicines are created and manufactured on a large scale. Life sciences companies are replacing the one-drug-fits-all approach for average patient populations with more personalized therapies. In fact, 42 percent of drugs in the pipeline today are personalized medicine, according to a survey by the Tufts Center for the Study of Drug Development.[1]

These specialized drugs that give smaller patient groups the best therapies based on their genetic makeup and other predictive factors are replacing blockbuster mega-drugs designed to treat larger populations. For instance, the few drugs used to treat high cholesterol in the past have since splintered off into many targeted therapies based on the genetic variables of specific patient populations. This approach springs from discoveries in genomics − the structure, function and mapping of human genomes − and it's giving rise

not only to targeted therapies, but also to highly specialized diagnostic tools and personalized therapeutic drug monitoring.

A powerful example of personalized drug development in oncology is Zykadia, an inhibitor designed for patients with advanced non-small-cell lung cancer who have a specific gene mutation that causes tumors to become resistant to existing treatment. The drug, developed by Novartis, is targeted at very specific patient populations. The approval was lauded by the FDA, whose director of the Office of Hematology and Oncology Products noted, “today’s approval illustrates how a greater understanding of the underlying molecular pathways of disease can lead to the development of specific therapies aimed at these pathways.”[2]

VAST POTENTIAL FOR TARGETED DRUGS

Due to the enormous potential of these therapies, the White House has requested an initial budget of $215 million for its precision medicine initiative. President Obama believes “the possibilities are boundless” for specialized drugs and his administration aims to collect genetic data from one million Americans so scientists can develop therapies tailored to individual patients.[3]

In response to the shift to targeted drugs, many large life sciences companies have started to diversify their product portfolios to include these medicines. One powerful motivation for this change is financial returns from traditional drugs are shrinking in the face of increased competition from generics. Nearly 88 percent of prescriptions now filled as a generic in comparison with just 49 percent in 2000.[4]

While specialized therapies can produce better outcomes for patients, they also present manufacturing challenges. For example, targeted biologics are typically larger than small-molecule medicines and are often derived from living cells, resulting insignificant challenges to manufacturers. Personalized medicines are typically made in small batch sizes and have a wide variety of product variants. Small-batch production can be cumbersome because after every production run, equipment must be stopped, reconfigured, tested, and validated before the next batch can be produced. The downtime from such stoppages impacts efficiency and time-to-market. The FDA has tried to address batch-to-batch quality requirements for years and plans to provide incentives to companies that raise manufacturing quality. When it comes to regulating small batch sizes, documentation is especially critical because it helps capture a detailed picture of each step for staff and outsourced teams globally, and for inspectors.

CHANGE IS ESSENTIAL

Life sciences companies that don’t make changes to stay at the forefront of targeted medicines will struggle. A major part of those changes is revamping operations by implementing “Pharma 4.0,” a concept which has the potential to revolutionize operations from the inside out.

Pharma 4.0 is an operational approach that connects all resources − human, informational, and technological − in one virtual network. This connectivity extends from within the company to beyond its walls and combines diverse technologies such as cloud computing and big data analytics. Pharma 4.0 helps companies transition from robust but inflexible mass-production processes to more agile, highly automated methods that create tailored products quickly and cost-effectively.

In contrast to Pharma 4.0, many life sciences companies still store and disseminate manufacturing information on paper. This increases risk and slows down quality-control processes by limiting knowledge sharing and hindering collaboration among employees and partners alike. The latest cloud-based content management applications free managers to quickly route quality content and data throughout the entire company and vendor ecosystem using an efficient system for review and approval. Because all data are in cloud-connected systems staff have the visibility and access they need to monitor key performance indicators, guide the manufacturing process, and respond to incoming patient data that triggers the production of personally tailored medicines.

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