Paving A Pathway To Pharma 4.0

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Pharmaceutical manufacturers find themselves at a critical juncture. In the past 30 years, pharma has seen some significant shifts. Consider the expanding range of drug therapies, once confined almost exclusively to small molecule drugs. Biologics now comprise a substantial share of the market, and novel treatments such as cell and gene therapies are rapidly gaining traction. Another major trend is the rise of outsourced manufacturing, primarily for small molecule drugs.

Despite these changes — and the concurrent digital revolution the world has experienced — pharma manufacturers have doggedly resisted technological innovation. Most drugs are still made in plants where manual tasks are prevalent and production records are paper-based, leaving the manufacturing process all too opaque. The complex regulatory environment is often cited as the main impediment to innovation, although that explanation is somewhat simplistic. Regardless of the reason, the time has come for the industry to embrace digital transformation, also known as Pharma 4.0. At this point in the digital age, it is simply not sustainable for pharma companies to have such limited visibility into how their products are made — especially in outsourced manufacturing scenarios.

To catch up to other industries, pharma must take the crucial first step of aggressively automating shop floors. In addition to bringing greater consistency and reliability to the manufacturing process, automation will provide the information foundation needed for digital transformation. Achieving Pharma 4.0 will also require companies to adopt emerging technologies that enable them to reimagine critical business processes which, like shop floors, are also dominated by laborious and error-prone document-centric approaches. In other words, pharma must extend its digital transformation to the complete manufacturing lifecycle.

Discrete manufacturers have taken that approach since the 1980s. In the discrete world, all phases of the product lifecycle revolve around digital tools such as computer-aided design and simulation — from initial concept through product design, scaleup and manufacturing. It is difficult to imagine using any discrete product today that was not designed digitally.

In much the same way, pharma manufacturers must embark on digital transformation by first digitizing the product and process definition — whether they are making small or large molecule drugs, or cell or gene therapies. Today’s document-based approach must be replaced by one driven by digital process design,

simulation and knowledge management. It must start with initial tech transfer from R&D and continue throughout the product lifecycle, with a digital thread connecting systems, steps and stakeholders as the process evolves and moves between sites, both internal and external.

This digital design-based approach will free up the resources and eliminate the errors associated with manual transcription processes. Scientists and engineers will be able to predict and correct problems through simulation before committing to production. The process design can automatically configure shop floor systems — eliminating a key barrier to automation, as developing and maintaining recipe-based control systems is currently time-consuming and prohibitive. (This is especially true for multi-product manufacturing plants, which are the norm in pharma.)

With digital design and simulation at the core of the IT architecture — and process automation, manufacturing execution and measurement technologies deployed on the shop floor — the pathway to Pharma 4.0 will be established. The industry will be poised to realize the promise of advanced analytics capabilities now becoming available with cloud-based technologies, the industrial internet of things, artificial intelligence and machine learning.

A digitally transformed pharma manufacturing supply chain will enable an information- and analytics-rich environment that improves manufacturing reliability, reduces costs and — most importantly — ensures patients receive the highest-quality products. Additionally, bringing pharma into the 21st century will help the industry continue to attract the most talented scientists and engineers.

Pharma must leave behind its change-averse mindset and join other industries in the aggressive pursuit of digital transformation. Embracing the promise of Pharma 4.0 will usher in a modern, fully transparent approach to drug manufacturing with myriad advantages. Pharma can certainly afford to make the investments necessary to regain the ground it has lost to other industries in terms of technological innovation. Arguably, it cannot afford not to.