Pharma 4.0 – time to rethink manufacturing and quality

The emergence of the Internet has fundamentally transformed many industries, however, it is only since the rise of the Industry 4.0 concept that the digital revolution has reached the core of industrial manufacturing. **Robert Gaertner,** Director of Strategy for Quality and Manufacturing, Veeva Systems, Europe considers its potential use within the pharmaceutical sector

The idea behind Industry 4.0 is to connect human resources, data, and physical machines in a cyber-physical network. Physical assets such as smart robots will adhere to common standards, enabling flexible pre-configuration on-the-fly and modular replacement of resources. A key component of the concept is the 'Internet of Things', which will establish intelligent machine-to-machine connectivity within and beyond company walls.

One of the key benefits of Industry 4.0 is that it best addresses the increasing need for individualised products, while dramatically improving productivity and lead times. On the other hand, large investments in the introduction of multiple new technologies will be required. For example, Cloud-based data management and advanced analytics are fundamental components, as full system integration will lead to enormous data volumes that need to be analysed and shared across the virtualised value chain.

Weighing costs and benefits, Industry 4.0 principles will initially be adopted by those industries that, based on market demands, have moved away from mass production and diversified to serve smaller segments with more tailored product offerings.

Looking at the current state of pharmaceutical manufacturing, it seems that a paradigm shift in technical operations would be a good pill to swallow. In the past decade, the environment for manufacturing and quality has become more challenging for various reasons.

First, there is the shift from the one-drug-fits-all approach towards individualised therapies. Without a doubt, personalised medicine with specialised drugs for smaller patient groups can significantly improve the effectiveness of treatments. Hence, this rising market demonstrates true innovation and is an opportunity for life science companies to secure their revenue streams by diversifying their portfolios. Manufacturing individualised drugs on a smaller scale is a challenge with several constraints when securing process robustness and proving stability on batch level.

Second, cost pressure and globalisation have led to increased outsourcing activities and, as a result, a highly complex supply chain. Although the cost of goods sold may be optimised, quality risks increase due to lack of global oversight and less control over end-to-end processes.

Last, but not least, counterfeiting is a serious problem. Initially a phenomenon in developing countries, free global trade has brought counterfeit drugs back to the originators' core markets. Stricter regulations have been introduced in different geographies without leading to common standards for track-and-trace solutions.

Quality and compliance

In a Pharma 4.0 world, there is no room for nostalgic paper filing, and a virtual value chain relies on seamless, real-time data exchange. Data integrity is high on the priority list of regulators and, considering the enormous amounts of data generated, this can only be secured by having one single source of truth.

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In contrast to the traditional paper-centric approaches, data management is not just about compliant record keeping. By leveraging Cloud-based data management and advanced analytics, key information can be generated going beyond compliance and supporting quality decisions and continuous improvement. Because all critical data resides in a GxP-regulated cloud, quality professionals will have the visibility and

access they need to monitor quality metrics, make fact-based quality decisions in a timely manner, supported by predictive analytics on quality parameters.

New ways of managing GxP-critical information is key, but this is only one example of technological developments that face quality and compliance professionals. To get ahead of these topics, decision-makers should acquire deep understanding of opportunities and risks associated with new concepts such as Industry 4.0 – not all aspects of it may be applicable to the highly regulated life sciences industry. In the future, quality should become a trusted advisor in terms of implementing new technological concepts in GxP-regulated areas, from a compliance perspective but also taking into consideration quality improvement opportunities and threads for all virtualised operations.

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Many life sciences companies have started to introduce some new technological capabilities in manufacturing, but without a more holistic strategy regarding GxP compliance, the value will not be fully unleashed. Industry 4.0 is a well-thought-out concept for modernising technical operations, and corporate quality can play a key role in leveraging it. Pharma 4.0 would not only lead to productivity gains and secure competitive advantage, but also significantly improve the robustness of product quality and the security of the supply chain to the patient.

In summary, pharmaceutical manufacturing and quality operations nowadays are suffering from the fact that they are obliged to serve a business model for which they were not originally designed. In addition, traditional interpretations of GxP compliance have cemented inflexible barriers and ways of working that slow down adoption of technological innovation.

It is the right time for the next industrial revolution and a radical revamping of technical operations from the inside out. Based on the common principles of Industry 4.0, a Pharma 4.0 initiative would not only fix agility and productivity issues, but also provide quality operations with better instruments to enforce product safety and supply chain security.

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