12. Official GAMP® 5 Conference: Data Integrity in the World of Pharma 4.0

Business processes between digital transformation and regulation

Frankfurt/Mannheim, December 5, 2019 – The pharmaceutical industry is in a state of tension: Business processes need to be digitized, but industry is subject to GxP regulations. These regulations are designed to ensure patient safety, product quality and data integrity. As a result, many industry trends, such as production and business processes, can only be implemented with additions or limitations.The pharmaceutical experts from MAIN5, a leading consulting company in the industry, also participated in the 12th GAMP® 5 conference in Mannheim. "With increasing pressure, the pharmaceutical industry faces great changes due to the ongoing digitalization and can only make economic gains by accepting these challenges actively. However, the regulated environment must always be considered, what influences the selection of products and suppliers as well as the legally compliant implementation of Pharma 4.0 projects," says Alexander Tryba, MAIN5 partner.

Data integrity in Big Data

A paradigm shift in the industry must also take place, as a study by MAIN5 revealed in the summer: according to "Pharma Insights 2019", 65 percent of pharmaceutical processes are focused only on the next audit. 70 percent of the surveyed industry experts also see the history as a source of process, but not modern and lean models. Another topic in Mannheim during the two conference days is the structured collection and legally compliant use of data and information – or "big data". 64 percent of those surveyed assume that no more than half of the data generated will be analyzed in order to optimize future processes. "When it comes to gathering information and analyzing data, as well as all digitized processes, there are three main pillars that must fit: product quality, patient safety, and data integrity," says pharmaceutical consultant Tryba.

Bridging the gap between compliance and quality

Overall, the value creation processes in the process industry offer enormous potential and can only benefit from general digitalization.Therefore, many old systems have to be replaced and new data models have to be created, the MAIN5 experts agree. Meanwhile, the replacement of paper processes and full integration into systems is a crucial component. "Useful information must be extracted from documents, and a harmonized and system-wide data model must be created for the companies. This means that specialist departments, quality management and IT work together on processes in the pharmaceutical companies. Likewise, a comprehensive safety management must be created. However, the pharmaceutical industry also has the opportunity, due to its many years of experience with regulations, to become one of the flagship international industries in terms of security and digitization," explains Alexander Tryba of MAIN5.

About MAIN5 (www.main5.de)
MAIN5 was established in 2013 as a Management Consulting firm and focuses on strategy, process and solution consulting with international life science companies in the regulated R&D and Regulatory Affairs and Quality Management sectors. The consultants at Main5 combine their methodical and systematic approach with years of experience in the industry. The holistic approach, which places the primary focus of the route to the digital future on people, is also used to implement complex ideas from leading industry customers.

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