IDMP:Consolidated standards require comprehensive digitalization strategies

Regulation as an opportunity for digital transformation and process harmonization

Frankfurt, March 4, 2020 – The future is digital – this cross-sector process also includes the regulated processes of the pharmaceutical industry. In the future, a large number of structured data will have to be submitted to the authorities to enable cross-border identification of medicinal products (IDMP – Identification of Medicinal Products) on the European market. After years of preparation, the final implementation guideline has now been published (February 11, 2020, version 1) and increases pressure on the industry: "While a certain waiting period during the implementation was still in effect, the time runs from the publication of the implementation guideline version 2 (planned for autumn 2020) for ISO iteration 1. "The companies then have 24 months to implement a complex software and process project," says Karsten Krüger, Managing Partner of the pharmaceutical consultancy MAIN5. Companies then urgently need a viable solution for a regulatory information management system (RIMS) that manages drug data and facilitates harmonization. So far, even in pharmaceutical companies, various databases between the individual national and subsidiary companies have hardly been on a common standard.

Digitalization and big data

The move towards new systems makes sense in two respects. Harmonizing the data stocks and bringing them to a common standard helps companies to achieve leaner data and process structures. While the core idea behind the IDMP is in-depth knowledge of the medicinal products on the market with a special focus on their composition and their pharmacovigilance, a 360-degree view of the entire system and process landscape offers the potential for savings and more safety for patients and users. Medicines can be compared and active ingredients can be traced back to the manufacturer quickly. This can prevent harm to a patient in an emergency. “In the coming years, competition will be even tougher, and technologies such as artificial intelligence and big data will determine competitive advantages. Anyone now investing in a viable digitalization strategy is not only implementing current regulatory requirements, but also facilitating internal processes and improving the contribution margin,” says Karsten Krüger from MAIN5 about the upcoming changes.

Five ISO standards consolidated

For the implementation of the IDMP initiative, the EU is consolidating five ISO standards; a further worldwide expansion is conceivable. Pharmaceutical companies face the challenge of managing the growing number of structured data and using it profitably for the optimization of processes in the company. At the same time, processes for health insurance companies and – above all – patients also benefit. “With the IDMP, for the first time there is a comprehensive comparison of medications, dosages and active substances. This has savings potential for the cash system, and at the same time every patient receives more transparency than ever before,” says Karsten Krüger. Companies that invest in a comprehensive and sustainable structure will secure the greatest advantage.

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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