DocuWare | HEALTHCARE

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There are few fields where regulations are as stringent as in the pharmaceutical industry. For many years, cytostatic manufacturer Pharmigon has relied on DocuWare for ensuring the ultra-secure documentation and archiving of its production and patient data.

pharmigon
we care

Lejla Razic, Pharmacist and CEO, Pharmigon, Donauwörth,
meets all rigorous industry guidelines with DocuWare:

"In our organization, DocuWare is seamlessly integrated with our industry solution.

This has enabled us to meet the strict requirements of GMP-compliant production – efficiently and in a user-friendly manner."

Location:	Germany
Industry:	Healthcare
Deployment:	On-Premises
Department:	Production, Technical and Commercial Administration
Integration:	Pharmacy Management System / Sterile Management System

"Not only DocuWare's high level of functionality, but also its clear and intuitive user interface, ensures that users in our company quickly appreciated and accepted DocuWare."

Pharmigon manufactures patient-specific and highly specialized preparations on behalf of pharmacies, primarily for the targeted treatment of tumors. Production takes place in state-of-the-art clean room laboratories, which are equipped with precise computer-assisted monitoring in accordance with "Good Manufacturing Practice" (GMP). Document processing and archiving are two key elements for GMP-compliant quality management. Pharmigon has relied on digital document management for many years.

GMP-compliant production requires that all documentation – such as work instructions, forms and plans – are version-controlled and subject to a defined life cycle. In addition, it is necessary to create paper-based or electronic records in accordance with the principles of good documentation practice and data integrity, to archive them for a specified period of time, and protect them against tampering or manipulation.

In addition to the system's high level of functionality and intuitive use, the seamless integration into their existing pharmacy management system was a decisive factor in choosing DocuWare. This makes it possible to automatically transfer production documents, patient data or commercial records from the industry solution to the central document pool. Pharmigon employees also have three powerful document scanners at their disposal for digitizing paper documents. Indexing and filing are carried out via barcodes applied to each order.

Digital workflow guarantees maximum production reliability

Production protocols, which describe the manufacturing process in detail, are created in the Pharmacy Management System and contain relevant classification terms for each preparation, such as batch number, manufacturing date, active ingredients or processor. During archiving, DocuWare adopts these details as index terms and uses them as central parameters for the subsequent workflow to verify correct manufacturing. An initial check is performed by the production manager, a second by the quality control department. If the quality control department also confirms the correctness of the manufactured substance with an electronic stamp, a final release is made by a responsible employee. This guarantees the safety of the manufactured preparation. In this way, 50 protocols with several hundred pages are produced daily. There are also test results on the microbiological production conditions in the clean room. Commercial administrative documents from order processing or ordering and accounting are produced at the Berlin headquarters. For

"Without a document management system that is both highly functional and secure, we would not be able to meet the high demands for GMP-compliant production."

reasons of data protection, these documents are stored and processed in a separate archive and separate from the patient and product information of the Donauwörth production site.

Adding mobile workflows

Based on their positive experience, the company is continuously identifying new areas to use digital document management, for example in the area of "mobility". The aim is to define workflows to enable stamp-controlled approval processes to be carried out at any time and from any location via mobile devices. The time-critical delivery of preparations should thus be ensured. There is also potential for optimization in the area of production-accompanying documentation of clean room conditions, the so-called laboratory logbook. Many parameters are currently still recorded here on paper. The development of a digital form and its linkage with the production protocols is now on management's to-do list.

"The central document pool has already established itself in many corporate divisions. By the end of 2019, it already comprised more than 200,000."