Pharma Consulting

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Best practice

Digitizing pharmaceutical production with domain expertise

Pharmaceutical companies that want to modernize their production operations with a Manufacturing Execution System (MES) face a multitude of questions. The consulting experts from the Körber Business Area Pharma have the answers. They support companies on their entire journey, from the selection of the appropriate MES and its implementation, to its operation in everyday production. In doing so, these experts focus intently on establishing close partnerships and maintaining long-term customer relations.



When asked how he would describe his work in one sentence, Michael Völlinger replies, "I find the right Manufacturing Execution System for my customers in order to make their production operations even more efficient." Michael Völlinger is the Business Director Consulting at the Business Area Pharma of the international technology group Körber. He and his colleagues are well-versed in all the widely-used Manufacturing Execution Systems (MES) on the market. In addition, they are familiar with the specific processes and requirements of the pharmaceutical and biotechnology industry and contribute this valuable expertise to their projects. "We have more than 20 years of experience in this area, and we know that the integration of an MES is a challenging project for many companies. It's therefore very important that our customers can rest assured knowing they are working with the right project partner," says Völlinger. The implementation of an MES involves not only planning and technical aspects, but also "soft" factors.

Valid database instead of paper mess

Manufacturing Execution Systems (MES) have become almost indispensable for the pharmaceutical and biotechnology industry. Complex manufacturer standards and regulations concerning product quality and safety force companies to replace their conventional paper-based



"We have more than 20 years of experience with the common Manufacturing Execution Systems on the market."

Michael Völlinger Business Director Consulting at the Körber Business Area Pharma documentation and approval processes, which are prone to error. "An MES digitizes these processes so that they are easier to record and document in a legally-compliant manner," says Völlinger. Moreover, the MES serves as an overarching solution that controls, monitors, and synchronizes production in real time. "It enables companies to collect huge amounts of data from their production operations. This information can be used to analyze many processes and make them more efficient," says Völlinger. However, many different factors must be considered in the selection and integration of such a control system. For example, it must be determined which MES best fulfills the individual requirements, which system is future proof to the greatest extent, and how the associated change processes can be implemented so that all process areas are taken into account and all employees are involved. Moreover, the background of digitization raises additional questions, such as the use of cloud solutions, MES as a service (MES aaS), agile project development, and the validation of these approaches for Pharma 4.0. The consulting experts from the Körber Business Area Pharma also answer these complex questions for their customers.

Precise process analysis for tailored solutions

The MES specialists from Körber pursue a holistic approach in their projects. "Our work doesn't end with the selection of the right MES for the customer," says Völlinger. "We then help the customer to implement and calibrate it successfully and show them how to use it optimally in everyday production operations." Völlinger and his colleagues use a method known as Process Landscape[®], which was developed in-house, to create the right basis for this work as soon as a project is launched. This software is used to analyze and optimize the customer's production processes and to prepare them for the digitization. When selecting the right MES, the experts make sure that the control system fits with the customer's existing IT architecture, such as the Enterprise Resource Planning (ERP) system. This way, they ensure that the MES can be smoothly integrated into the production process.

Support in the change process

Besides the technical aspects, human factors also play a major role during the introduction of an MES. "Because such a control system changes the processes, the production employees should be involved in the project early on," says Völlinger. The specialists at Körber also address these issues by creating a change management office at the customer's facilities, for example. "This provides the customer with support during critical transfer processes, such as the transition from paper-based batch documentation to electronic batch recording," says Völlinger. The project plan follows a structured sequence: The planning phase is followed by the integration phase, which consists of function tests, training courses for the employees, and support for the launch of the modified processes. After the integration has been completed, teams of consultants from Körber remain on site to ensure the correct operation of the MES, guaranteeing smooth first-level and second-level support.

Sustained customer relations and many years of cooperation

The previous project partners include big international companies as well as small and mediumsize enterprises. "The MES specialists from Körber have successfully managed our project with their expertise and experience," says Christian Paunert, Head of CGS Management at Verla-Pharm, a market leader in the pharmaceutical magnesium sector. "We felt that we were in good hands at all times — including the support phase after the go-live." The project partners' level of satisfaction can also be expressed as a statistic: 97 percent of the new customers continue to work with Körber's MES specialists on a long-term basis. Many of these partnerships have now existed for ten or more years.

MES expertise and more

The core business of the consulting experts at the Körber Business Area Pharma is to provide advice about Manufacturing Execution Systems and their implementation and operation. Their solutions fulfill the typically complex requirements of the pharmaceutical industry such as the validation of IT systems (CSV), the complex requirements of serialization and Track & Trace, the collation of data based on Enterprise Manufacturing Intelligence, cGMP data integrity requirements, and warehouse management requirements. In addition, the experts supplement this with special services, including the implementation of Pharma 4.0 projects. An example of this is the use of the latest augmented reality technology to support line processes. "Our complementary services enable us to meet all of our customers' needs and supply everything from a single source," says Völlinger. As a result, pharmaceutical and biotech companies receive efficient and sustainable solutions that enable them to make reliable plans for many years to come.

Körber - delivering the difference in pharma

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If you want to learn more about Körber's consulting services for Manufacturing Execution Systems (MES), you can contact us at: <u>www.koerber-pharma.com/solutions/</u> <u>consulting</u>



of the customer relationships are long-term,

thanks to specialized expertise, reliable implementation, and customer-focused support.



Körber

We have you covered, always and everywhere

With local pharma experts around the world we support you wherever your business is located.



About Körber

We are Körber – an international technology group with about 10,000 employees, more than 100 locations worldwide and a common goal: We turn entrepreneurial thinking into customer success and shape technological change. In our five Business Areas Digital, Pharma, Supply Chain, Tissue and Tobacco, we offer products, solutions and services that inspire. We respond quickly to customer needs, we implement ideas seamlessly, and our innovations create added value for our customers. We are increasingly building on ecosystems that solve the challenges of today and tomorrow. Körber AG is the holding company of the <u>Körber Group</u>. We are the home for entrepreneurs – and turn entrepreneurial thinking into success for our customers.

Delivering the difference in pharma

At the Körber Business Area Pharma, we deliver the difference along the entire pharmaceutical value chain by offering a unique portfolio of integrated solutions. Based on indepth experience spanning consulting, inspection, transport systems, packaging machines and materials, track and trace and software, we understand the challenges in pharmaceutical processes and regulation that our customers face day to day, from the beginning to the end of their production. For them, we deliver the difference to unlock the potential of global pharmaceutical and biotech manufacturing.

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