Unlocking success in pharma: Turn the key for your own pharma excellence



Imagine simply turning a key to put your own factory of excellence into operation – a dream come true? A customer of Körber, an emerging pharma company from the US that is completely new to the market, decided on Körber's General Line Management Solution to complete their pharmaceutical site and install the equipment. With our extensive expertise in the pharmaceutical industry and the ability to provide everything in-house, we take the

burden off our clients' shoulders and support them on the way to their own factory of excellence.

In the dynamic pharmaceutical industry, companies constantly grapple with a range of challenges. Experience and resources are often limited, especially for companies that are newcomers to the pharmaceutical industry, let alone start-ups. These hurdles can hinder growth, operational efficiency and overall further increase complexity – as it did for one of our customers.

At a glance



Challenges

- Customer being a newcomer to the pharmaceutical industry
- Building a pharmaceutical site from scratch, including deployment of equipment & qualifying machines, is very time consuming and risky
- Search for a holistic solution & expertise in terms of pharma

-Ò- Solution

- Leveraging the General Line Management Solution by Körber
- Consulting experts from Körber acted as general line contractors & as the head of engineering for the
- Leading discussions on facilities, utilities & all equipment needed
- From facility design to successful implementation: Everything is project managed by Körber

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Customer benefits

- Customer received comprehensive guidance
 & expertise from our consulting experts
- · Peace of mind through holistic support
- · Risks are managed & mitigated
- Acting in the interest of the customer
 & supporting them in everything they require
- · Extensive knowledge of Körber machines
- Seamless interfaces within the K\u00f6rber Ecosystem
- Possibility of having it all provided in-house:
 Proximity between competencies within Körber



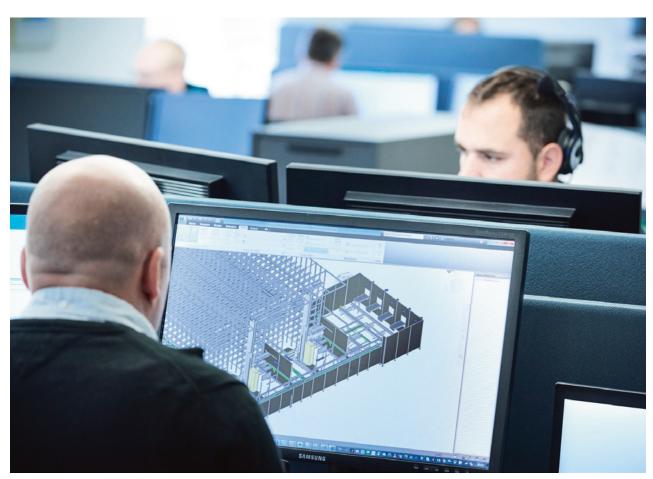
The challenge: Bridging the experience gap

Being completely new to the pharmaceutical industry, the emerging pharma company was at a loss as to building and qualifying a completely new packaging site. Because of lacking regulatory knowledge and best practices as well as inexperienced personnel in that specific area, they chose to contact the consulting experts of the Körber Business Area Pharma.

As part of our General Line Management Solution, our consultants went on to support our client on the way to their own packaging line. This included, as a first step, estimating all efforts and machinery required for it. They wished for a full validation package for their entire facility and regulatory oversight on all aspects of their business once operational. In order to precisely understand our customer's needs and develop the best possible roadmap, we met for a joint workshop and outlined the initial direction for the project at the location of the desired facility.

Since there was no facility in place yet, our consultants also helped with facility design and implementation. Thanks to our bright expertise and seamless interfaces within the Körber Ecosystem, we were able to customize a General Line Management Solution for the customer's needs. In general, we support clients in everything they require – such as providing solutions from Körber's Business Area Supply Chain and other Business Areas.

For this collaboration, next steps included assisting our client with their engineering needs and translating the facility design into architectural prints. One of our Körber consultants continuously acted as head of engineering, leading discussions on facilities, utilities, and all equipment needed for the new facility as well as assisting in their internal hiring and staffing process. Once again, thanks to the organizational proximity, our Körber consultants also concluded a flexible pay-per-use deal with the Körber packaging experts to accommodate the young company.



Körber specialist plans and adapts production line to meet client's unique requirements.



Our General Line Management Solution: Expertise meets execution

The aim of Körber's General Line Management Solution is to act as a general line contractor for our clients and to build production lines with different machines that match the needs of the product – getting the customer into production as soon as possible. The Körber consulting experts support with validating the production site under regulatory and internal requirements and procedures so that it is ready to be used.

The General Line Management Solution usually includes the following:

- · Specification of requirements
- · Communication between suppliers & customer
- Review & consolidation of provided specification & qualification documentations
- · Execution of all qualification activities including:
 - Commissioning: Factory Acceptance Test (FAT)
 & Site Acceptance Test (SAT)
 - Qualification: Installation/Operation Qualification (IOQ) & Performance Qualification (PQ)
- Integration into customer's digital landscape, including digitization consulting
- Engineering studies in preparation for additional products & qualification activities
- Adherence & support regarding all regulatory requirements related to the equipment

The exact scope of the General Line Management Solution by Körber can be adapted to your needs and expanded to, for example, include facility design, as was the case with this customer. Plus, while implementing the solution, we always keep an eye out for certain aspects like sustainability and keep processes as efficient and low waste as possible.

"Körber's General Line Management Solutions were invaluable to us. They equipped us with the understanding we needed to navigate the pharma industry successfully."

Feedback from customer

As part of a General Line Management Solution, Körber acts as a general line contractor, which is why, amongst other things, vendors are being managed to ensure smooth processes and a successful launch. Currently, the facility of our customer is being built and is now in its final stages of construction, getting ready for the deployment of equipment which is being commissioned and project managed to ensure a successful implementation.

"Our General Line
Management Solution is
designed to address the
unique challenges faced
by pharmaceutical
companies. We aim to
empower our clients with
the knowledge and skills
they need to thrive in the
pharma industry."

Tyler Foley, Senior Consultant, Körber Business Area Pharma



About Körber

We are Körber - an international technology group with more than 12,000 employees at over 100 locations worldwide and a common goal: We turn entrepreneurial thinking into customer success and shape technological change. In the Business Areas Digital, Pharma, Supply Chain, and Technologies, we offer products, solutions and services that inspire. We act fast to customer needs, we execute ideas seamlessly, and with our innovations we create added value for our customers. In doing so, we are increasingly building on ecosystems that solve the challenges of today and tomorrow. Körber AG is the holding company of the Körber Group.

Delivering the difference in pharma

At Business Area Pharma, we deliver the difference along the entire pharmaceutical value chain by offering a unique portfolio of integrated solutions. Based on in-depth 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.

Contact us today

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Delivering the difference in pharma

As your personal partner and pharma technology expert, we deliver industry-leading consultancy supporting you from requirement analysis to project implementation.

- · Access industry-leading experts that know pharma, biotech, and medical devices inside out
- · Design a solution specific to your business size and needs
- Connect to the future and benefit from our profound knowledge on upcoming trends in Pharma 4.0
- Unlock your business potential and receive support from over 2,500 pharma experts at 100 global locations

Industry sector
Pharma & Biotech
USA

