

# Agile qualification, accelerated delivery: How Körber's pharma consultants enable a successful facility launch



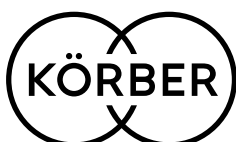
**In the past solving major medical problems used to be a question of “how”. For biotech companies that specialize in mRNA medicines and vaccines, it is now a question of “when”.**

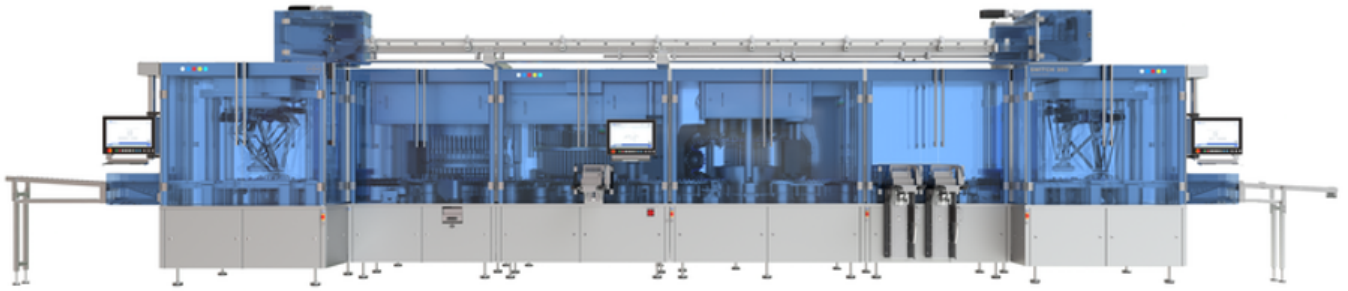
One essential step in speeding up development and implementation is rapid commissioning of new machines through effective qualification and validation processes – one of Körber's key capabilities

since you can rely on the close cooperation between inspection and consulting experts right from the start. A worldwide leading biotech company focusing on RNA therapeutics utilizes Körber's expertise for the qualification of the Körber Switch 350 inspection machine in two of their new facilities. Find out in this case study how the company overcomes challenges in their qualification project with the help of the custom-fit support of Körber's equipment and validation specialists in machine qualification.

## At a glance

Challenges	Solution	Benefits
<ul style="list-style-type: none"><li>• Processes not yet fully established in new facility</li><li>• Developing technical knowledge related to machine</li><li>• Gaining experience for qualification processes</li><li>• Critical timeline due to dependency on government funding</li><li>• Different time zones, work cultures and multiple stakeholders</li></ul>	<ul style="list-style-type: none"><li>• Körber's flexibility and expertise to tackle the challenges</li><li>• An extension of Körber's consulting scope to provide guidance in specifications, testing documents and protocols and SOP writing</li><li>• Körber's proven agile machine qualification based on a single-test approach and risk assessment</li></ul>	<ul style="list-style-type: none"><li>• Körber's support of project teams by acting as transversal resource, specializing in machine qualification and understanding machines as a whole</li><li>• Resonating machine expertise with customer</li><li>• Faster go-to-production by increasing efficiency and saving time</li></ul>





Switch 350: A flexible high-performance inspection machine for syringes and vials up to 350 containers/min with de- and renesters for vials and syringes alike. Benefit from a comprehensive solution for inspecting pharmaceutical containers, eliminating the need for multiple machines while ensuring high efficiency and quality.

### **Overcoming challenges: Agile machine qualification with Körber**

The biotech company has become well-known for specializing in mRNA medicines and vaccines since their development of a COVID-19 vaccine. As the world has recently experienced, speed in research, development and bringing medical treatments to market can be critical to saving billions of lives. During the qualification phase of the Körber Switch 350 inspection machine at their new site, they are facing several significant challenges: Since the site has just been set up, there is great potential to establish processes, expand knowledge of visual inspection, and gain valuable experience in implementing the new machine – with Körber as the perfect partner. The project also has to meet a strict timeline due to its dependence on government funding. Additionally, the coordination across three different time zones and work cultures, as well as with multiple stakeholders, poses further logistical challenges.

### **Meeting your needs with flexibility, expertise and innovation**

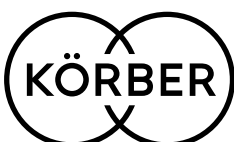
The worldwide leading biotech company for RNA therapeutics partners with Körber to leverage their deep expertise in agile machine qualification. The challenges are met with flexibility and innovative methods through the unique synergies of the Körber Ecosystem: The team provides deliverables like test strategies and guides and improves testing Standard Operating Procedures (SOPs).

That is not only accelerating their qualification process, but also improving the training of future employees to ensure every step in the process is well understood. Körber’s extensive knowledge and adaptability makes them the perfect partner.

### **Rapid commissioning by agile machine qualification**

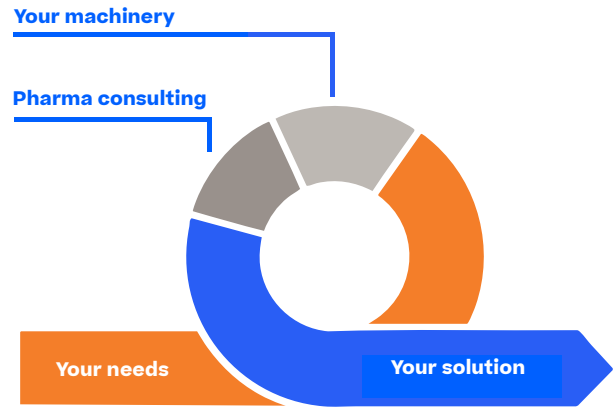
By employing the method of agile machine qualification, Körber’s consulting team uses a single-test approach and risk assessment of specific machine parts, testing only functionalities impacted by the system relocation to avoid redundancies. This method proves to be time-saving and efficient due to Körber’s familiarity with their own machines and their ecosystem synergies. The goal is the rapid commissioning of the Switch 350 being achieved through the preparation, strategy development and verification phases.

**“By utilizing Körber’s expertise and deep knowledge throughout the qualification process, we have the chance to shorten our time to production substantially.”**



## Single-test and risk assessment

- Foundation of single test approach in agile machine qualification
- Strictly limiting the amount of testing to what is critical and impacted by the relocation of the machine from the supplier to the customer site
- Iterative process throughout system lifecycle
- Ensuring patient safety, product quality, and data integrity while reducing effort



## Transversal resource: Supporting the teams

The collaboration brings several key benefits: Körber acts as a transversal resource, specializing in agile machine qualification and understanding the machine as a whole thus being able to actively support project teams on-site. Körber's deep knowledge of the machine resonates well with the company. Efficiency and time savings are being significantly increased, ensuring the Switch 350 in their new facility can go into production faster. This project is part of a broader initiative to establish manufacturing capabilities in the region that usually relies on imported goods, contributing to sustainability by reducing dependency on imports and therefore CO<sub>2</sub> emissions.

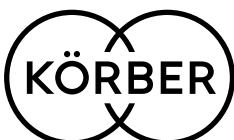
## Empowering with agility

Körber's agile machine qualification approach not only meets the company's needs in reducing their overall effort but also showcases Körber's ability to deliver efficient expert solutions under tight timelines and complex conditions, making them an ideal partner. Regularly trained experts specialized in Körber machines and Körber's unique ecosystem synergies significantly accelerate your time-to-market, bringing you to the top of global pharmaceutical and biotech manufacturing. Count on us – we act globally and locally to unleash the full potential of your business.



**“Körber knows their own machines well and gets it right the first time, which saves customers a lot of time.”**

**Walyd Khenoussi**  
CQV Consultant,  
Körber Business Area Pharma



## About Körber

We are Körber – an international technology group with more than 13,000 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

**Your expert team of Körber Pharma**

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- Unlock your business potential and receive support from over 2,500 pharma experts at 100 global locations

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