

Unique approach leads to unique advantages: Customer goes into production four weeks earlier thanks to pharmaceutical consulting by Körber



Having new machines qualified with ease and going into production on time – a dream come true? A Körber customer, one of the top global pharma companies, was not only able to go into production on time, but even four weeks earlier than planned – with the help of our Körber consulting experts and the Agile Machine Qualification approach. This speaks for itself: Our customer even wants to remain anonymous because they see our services as such a big advantage over the direct competition.

In the pharmaceutical industry, acquiring new machines for several different sites involves huge investments. The aim: To go into production as soon as possible so the investment amortizes quickly. However, if the qualification of the machines is not successful for various reasons, companies lose valuable time and money and the return on investment quickly falls short of expectations.

This happened to one of our customers, a top global player in parenteral production. As their product requires one hundred percent visual pharmaceutical inspection, they purchased automated visual inspection (AVI) machines by Körber for several production sites. Unfortunately, machine qualification turned out to be very time consuming because there were not enough resources on the customers' team. They went on to look for a solution that expedites time-to-market while reducing risk – and here is where Körber stepped in.

In accordance with the Körber Ecosystem, it only made sense for the customer to turn to Körber again, as we are the leading global expert in pharmaceutical technologies and provide extensive consulting know-how when it comes to machine qualification. Due to the proximity, synergies between our competencies could be leveraged, which enabled us to work even more time-efficiently. This resulted in an even faster time-to-market than we already achieve through our consulting experts and unique approach. This aspect has been such a great advantage for our customer that they want to remain anonymous and keep this head start for themselves.



At a glance

Challenges	Solution	Customer benefits
<ul style="list-style-type: none"> • Purchase of several AVI machines by Körber for different sites • Machine qualification is very time-consuming and pending due to lack of resources • Search for a solution that accelerates time-to-market while reducing risk 	<ul style="list-style-type: none"> • Cooperation with the consulting experts from Körber, who know the Körber inspection machines best thanks to our ecosystem • Performance of a risk assessment and implementation of the single-test approach, which prevents redundant testing and increases efficiency 	<ul style="list-style-type: none"> • Ready to start production four weeks earlier than expected • Agile Machine Qualification finalized with ease and success using unique Körber approach • Acted on behalf of the customer when communicating with the supplier • Risks are managed and mitigated • No redundant testing through single-test approach • Extensive knowledge of Körber machines due to the Körber Ecosystem • Proximity between competencies within Körber

Agile Machine Qualification at its best

Additionally, a clear asset for them was the Agile Machine Qualification approach the project team used, which is unique on the market. It is based on a single-test approach following the ASTM E2500 model as seen in figure 1 and a risk assessment. Usually, every part of a machine is tested to be completely sure everything runs as it's supposed to. But – it takes a lot

of time and effort. The single-test approach, however, avoids verifying an attribute redundantly several times through various stages of the testing timeline which makes testing more efficient. By using Good Engineering Practices guided by a risk-based process, test redundancies can be minimized, and the process is streamlined.



Figure 1: ASTM E2500 Model



Our customer had a specific timeframe in which the entire Machine Qualification needed to be completed. So, we took on the challenge and supported them in achieving their overall objective of efficiently bringing their product to the market within this established timeframe, which unfortunately had not worked out in a previous attempt by the customer. In a first step, we assessed the risk of the most critical parts of the machines and then only tested the necessary parts to avoid any redundancies from the FAT (factory acceptance test) in the SAT (site acceptance test).

To prove the added value and success of the single-test approach, we used the customers' test cases during the internal system tests of the supplier to address any issues. After all, the customer should be able to carry over the documented test results from the supplier's site, verifying any given machine function. The Körber project team had to be very flexible, applying critical thinking to ensure that no errors occurred and that steps did not need to be re-executed.

We made sure that our customer had no re-execution of testings due to errors which would have caused delays. We managed and mitigated all risks for a smooth execution from start to end.

This case proves that our services not only make the process faster but also more efficient. Our customer was extremely happy with the results and so convinced by the Körber approach that they immediately wanted to make use of our agile approach at other sites as well and stay anonymous in this case study at all costs to keep this enormous competitive advantage for themselves.

„Our customer – a top global player in pharma – recognizes our consulting expertise as a game-changing advantage over the direct competition. That's why they want to stay anonymous at all costs. We delivered exceptional results by bringing them into production four weeks ahead of schedule. This achievement is a testament to our commitment to excellence and unparalleled industry knowledge.“

Dr. Sukhada Chaturvedi,
International Account Manager
Körber Business Area Pharma

Feedback from Customer

This new testing and qualification model, developed in collaboration with Körber, can be used for future inspection lines and become a new standard and common approach. [...] This major milestone is a great achievement and would not have been possible so quickly without the dedication and passionate commitment of the Körber team.

Stay ahead with Körber

Ultimately, we were able to finalize the machine qualification not only on time, but four weeks earlier than expected. This was a huge win for our customer. With our lean and agile single-test approach for Machine Qualification as well as years of experience and direct access to the supplier being Körber, our consultants acted on behalf of the customer and managed all qualification activities. We took on this long and difficult task for them, sped up the process immensely, and took the pain out of it for them.



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 the 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.

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

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