Pharma Consulting

IQ/OQ execution

Have your machines qualified more efficiently and start production sooner than ever!

Why do you need IQ/OQ and PQ?

Legal requirements ensure that pharmaceutical manufacturers are obliged to qualify their process equipment. In this context, an IQ (Installation qualification), OQ (Operation qualification), and a PQ (Performance Qualification) are required. For this purpose, the IQ checks whether the installation has been carried out correctly, i.e. documentation of the machine is written. An OQ then checks the functionality of the machine in the next step and a PQ examines if the machine is fit for its intended purpose. The steps can be combined for simpler machines, while for more complex machines it may be necessary to separate them.

What is delivered within the project?

Based on existing standard documents, we can include special requirements and thus create the final qualification documents. Based on these, the created tests are then performed (option: creation of qualification documents if needed). The qualification documents are checked for correctness and machine functionality before the FAT as part of in-house testing.

What steps does such a project involve?

The scope of such a project depends on the customer's URS and the complexity of the machines. Based on existing standard documents, we can include special requirements and thus create the final qualification documents if needed. On the basis of these, the created tests are then carried out. At the same time it is also possible to to book a FAT/SAT support package or a URS directly. The more steps the consultant is involved in, the more efficiently he can act and accelerate your market entry considerably.

Project components

- Creation and design of test protocols if needed
- Implementation of Installation Qualification (IQ)
- Documentation IQ
- Checking the correctness of the IQ
- Execution of Operation Qualification (OQ)
- Documentation OQ
- Checking the correctness of the OQ
- Risk assessment

Deliverable: one (1) approved IQ/OQ documentation (based on standard documents) including test protocols and test reportings with results

Your benefits

Expertise

You can rely on our team of experienced pharma technology experts! Thanks to years of expertise, we know exactly how to execute IQ/OQ and PQ in the best possible way.

GMP compliance

Our experts know the pharmaceutical regulations inside out and ensure that their qualifications keep you GMP compliant at all times!

Time-to-market

We know our machines best. Thanks to our unique Körber Ecosystem synergies, we optimize the process and get you into production faster.

Peace of mind

Sit back and relax while we complete your projects for you successfully. Benefit from the highest quality without having to worry.

Availability

Our expertise is available to you anytime, anywhere. If needed, we can supply you with an entire team at locations worldwide to qualify your machines.

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