FOR INTERNAL USE

EXTEND – Instrument Services

Installation and IQ | OQ
Lab Products & Services

- ✓ Optimal functioning
- ✓ Complete documentation
- ✓ Training
- ✓ GMP/GLP-compliant IQ | OQ

Our Service Promise

When our Service Team carries out installation and IQ | OQ device qualification, we ensure:

- that the devices will function correctly without problems. Service includes:
  - site analysis
  - professional installation of the device and accessories
  - all necessary calibration and test certificates
- that the customer will be able to use the devices immediately after the installation
- that the staff will receive training and will be instructed how to operate the equipment
- comprehensive and product specific documentation provided at the time of installation
- the necessary proof of suitability via comprehensive IQ|OQ documentation

FAQ

Q: What is a regulated environment?
A: The pharmaceuticals market is one of the most heavily regulated fields in the industry. Companies operating in this regulated market are required to comply with a large number of specifications and guidelines. The regulations are drawn up and put forward by national governments and international institutions, and by more local professional organizations and associations. Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) have significant roles to play here.

Q: What is a qualification (IQ | OQ)?
A: Qualification of devices and systems involves checking whether or not a device or system is suitable for the designated task. Qualification is usually divided into steps, namely Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). The aim of this process is to document proof of suitability.

Q: What is a calibration and what is an adjustment?
A.: By "calibration," we mean the identification and documentation of any deviation in the display on a measurement device from the correct value for the measurement parameter. If applicable, the measurement uncertainty of the measurement device is determined during calibration. The correction of this deviation in the measurement is what we call "adjustment."

Q: What is an accredited calibration?
A.: During an accredited calibration, the calibration procedure is inspected and approved by an independent body. Accredited calibration certificates instill a high level of confidence and are recognized as being proof of traceability.

▶ What You Need to Know When Selling Installation and IQ | OQ Packages

Installation and IQ|OQ packages are available for all lab instrument products

- In addition to the service itself, the packages also include transport costs and calibration | test certificates
- IQ | OQ packages always include installation by professionals

Each lab instrument product offer should include the appropriate installation or IQ | OQ package

- Ask the customer whether the device will be used in a regulated environment. If their answer is yes, offer them the IQ|OQ package; if no, then offer them the installation package.
- Generally speaking, discounts are not offered on service packages.

The corresponding data sheet should always be part of the quoted offer appendix

- Data sheets are available in the DDM

After the quoted offer is accepted

- Inform the relevant service organization, which will agree on a date | time for the installation and | or IQ | OQ with the customer
- The Service Department will need the following information:
  - Customer ref. number
  - Customer contact information (including telephone number and | or e-mail address)
  - Copy of the quoted offer
  - Device data