Service Overview

N-Wissen provides a complete validation service for laboratory, industrial equipment and instrumentation according to the latest regulations of the USP, FDA, EP, etc. Our validation documents follow strictly the recommendation and instructions of the latest versions of the pharmacopeia. The customer will get detailed report about the procedure of the instrument qualification and the training certificate of the users in order to fully validate the qualification process.

IQ, OQ, PQ and PV documentations are available on request. Fully validated calibration tools are used for qualification procedures. Additionally, we provide maintenance contracts which are customized individually to the requirements of the customer.

Installation Qualification (IQ)	✓
Operational Qualification (OQ)	✓
Performance Qualifications (PQ)	✓
Performance Verification (PV)	✓
User Training (UT)	✓
Preventive Maintenance Contracts & Re-Qualification programs	✓

Installation Qualification (IQ)

- Delivery description: instrument, components, manufacture, model, serial number, software, etc
- Delivery condition: including inspection of instrument, software, manuals, accessories, etc
- Comparison of equipment, as received, with purchase order
- Unpacking the equipment and checking for any damage or missing
- Verifying environmental conditions
- Installing of equipment and power up
- Check completeness of documentation
- Installation Verification
- Network and Data Storage

Operational Qualification (OQ)

- Checking fixed parameters
- Data storage, Backup and Archiving (if applicable)
- Instrument Function Tests
- Perform initial calibration of equipment
- Document equipment settings
- Adjustment of the instrument will be performed in order to comply with manufacturers specifications (If applicable)

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Performance Qualifications (PQ)

- Define performance criteria and test procedures (SOP)
- Select critical parameters
- Define test intervals, e.g. daily, weekly
- Define corrective actions in case of non-conformance

Performance Verification (PV)

- Define re-qualification activities such as Preventative Maintenance, Calibration, etc.
- Define re-qualification frequency such as annually or semi-annually

User Training (UT)

The training materials will be offered by N-Wissen. After the training, the participants will receive their certificates. The topics of the training are:

- Short introduction about Theory and Applications
- Overview about Qualification Procedure (for the inspection and audit)
- Required maintenance by the user (daily, weekly, monthly, etc)
- Information management (if applicable)
- Pharmacopeia Regulations (if required)
- Possible configurations and other options

Preventive Maintenance Contracts (PMS)

N-Wissen offers effective preventive maintenance programs and re-qualification procedures which include the following advantages:

- Assure compliance and the continuity of validated equipment status
- Make the operation of equipment reliable
- Extend lifetime of instrument
- Detailed performance monitoring and reporting

The Service contract includes:

- Scheduled preventive maintenance (Each 6-Months or 12-Months option)
- Documenting the Status of the instrument (Status check up)
- Performance assurance tests
- On-Site maintenance
- Scheduled maintenance spare-parts
- Performance improvements recommendation
- On-going training of users
- Reduced prices of repairs, service and spare parts
- Fast reaction time (First reaction within 24 hours)
- Excellent Support and fast delivery of consumables and spare parts (available in stock)

Visit our Website for more information www.n-wissen.de

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