Pharmaceutical Instrument Qualification

Anton Paar

Qualification Services

Accurate.
Traceable.
Compliant.

PHARMACEUTICAL AND BIOPHARMACEUTICAL MANUFACTURING IS TIGHTLY REGULATED TO ENSURE PRODUCT SAFETY. MANUFACTURERS SEEK TO OPERATE IN A FULLY QUALIFIED ENVIRONMENT WITH VALIDATED PROCESSES.

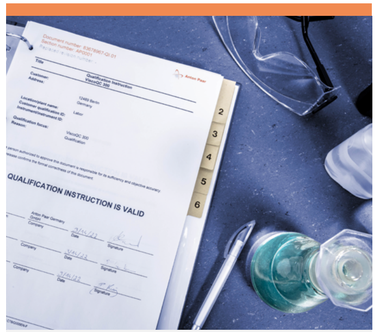
For business reasons, time- and cost-efficient qualification and validation protocols must be balanced against the comprehensive and, of course, fully traceable efforts involved. The current trend is to focus on single-test approaches, employing tests and evaluations that are as safe, effective, and efficient as possible.

To support your compliance and traceability needs, Anton Paar offers more than 80 instrument-specific qualification packages as well as qualified installation support. This qualification service reduces the work required by your in-house personnel to make your new instrument ready for routine operation by 60 % to 70 %.

The packages go significantly beyond simple installation: They're prepared individually for every system and include all required documents for complying with relevant regulations.

FIND OUT MORE

www.anton-paar.com/apb-pharmaqualification



QUALIFICATION DOCUMENTS

More than the sum of their pages, Anton Paar qualification documents are designed according to regulatory standards and help avoid non-compliance and other risks. Coupled with the in-depth knowledge and experience of our experts for your instrument, they're the basis for validated measurement protocols and processes.

Comprehensive chapters also cover electronic signatures and validation of key functions of system software. Seamlessly integrated in your own qualification process, you save valuable time and attain system productivity quicker.

Add in documents for regular service and maintenance activities, and you can be sure your instrument, measurements, and methods are always perfectly aligned with analytical purpose over the instruments' complete usage life-cycle.

HIGHLIGHTS

- Clear risk assessment and avoidance of non-compliance
- Crucial instrument and software qualification
- Expert know-how
- Instrument SOP
- Computer system validation (CSV)
- 21 CFR Part 11 compliance
- Regulatory guidelines: FDA 4Q model
- Productivity: GMP-compliant service activities

QUALIFICATION SERVICES AND PROCESSES

Our comprehensive packages combine industry-leading scope with specialist knowledge. They comprise user training, proof of performance to certified standards, and your very own sample. You'll have your Anton Paar instrument operating in no time – with a qualified system from beginning to end.

HIGHLIGHTS

- More than installation: a complete package
- User training included
- Instrument calibration and proof of specifications (with traceable standards)
- Sample feasibility check
- Qualified system across the instrument, results, data management, and review

AUDIT READINESS

Our proven solutions make sure you pass internal reviews and external regulatory audits.

All points and chapters are signed off via a six-eye principle, and the key facts are summed up at the front of the documentation. This allows you to easily provide information, minimize questions, diminish the effort required for proof, and focus on other topics related to the inspections.

HIGHLIGHTS

- Full step-by-step documentation
- System status at a glance

AP CONNECT PHARMA

Streamline your dataflow and satisfy all your data integrity requirements with AP Connect Pharma. Connect and collect, plug and play. All your lab data is stored in a single hub – just a click away. The lab execution software AP Connect Pharma connects your instruments, communicates measurement information and metadata, ensures compliance, and simplifies reporting.

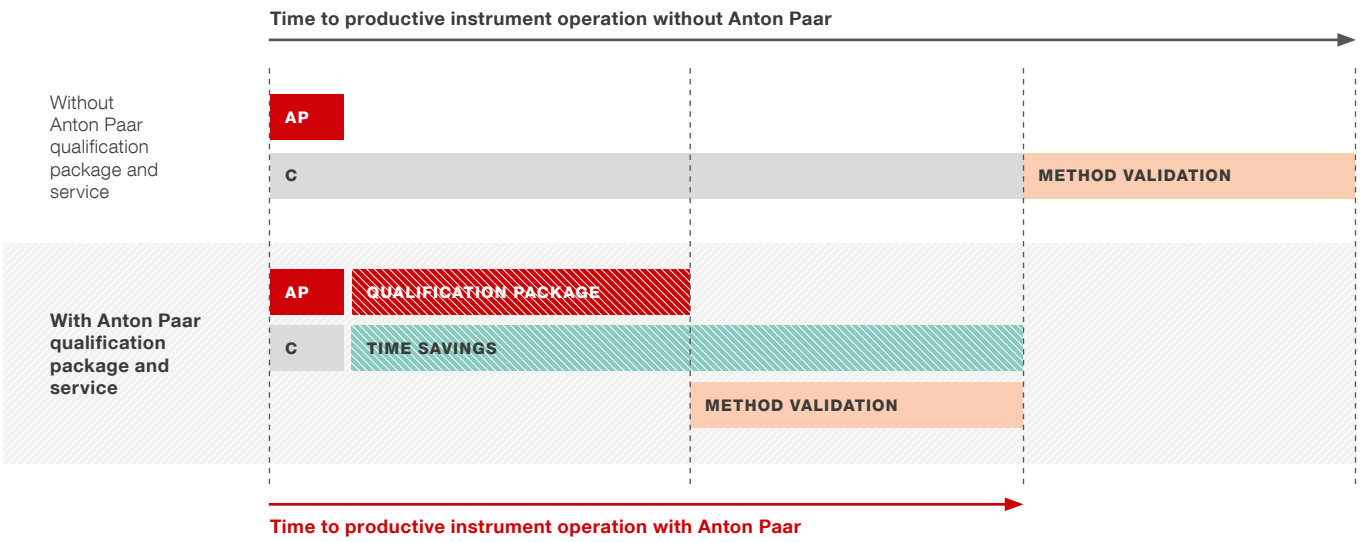
HIGHLIGHTS

- Data and metadata in one place
- Traceability of changes: simple deviation detection
- Customized remote review and approval
- Connectivity to other computer systems

Time Savings
by Anton Paar

	Steps to qualify your instrument	Steps included in Anton Paar Qualification Service
Requirement & Engineering		
URS - User Requirements Specification	✓	✓
Configuration Specification & Installation		✓
Risk Analysis	✓	✓
Instrument Qualification		
Configuration Testing (IQ)	✓	✓
Functional Testing (OQ)	✓	✓
21 CFR Part 11 Compliance Check	✓	✓
Requirements Testing (PQ)	✓	(✓)
Instrument SOP “How To”	✓	✓

(✓) Normally performed jointly with customer reference sample, can be performed without Anton Paar.
The marked section shows the scope supported by Anton Paar instrument qualification and tight supplier-customer collaboration. Anton Paar qualification documents for regulated industries follow the guidelines in <USP 1058>, <USP 1225>, EP Vol. 4 Annex 11 & 15, and PIC/S chapter 5 & 6. This is valid for initial qualification and individual requalification during regular maintenance and service activities.



Anton Paar pharmaceutical instrument qualification services save you time and effort, and seamlessly integrate into your own qualification and validation processes. This is valid for the initial instrument purchase as well as for recurring activities like instrument maintenance, **and keeps your instrument qualified and productive over its entire lifetime.**

AP: Anton Paar Standard Documentation
C: Customer

XPAIP204EN-A

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