

ValPro System Qualification Package

Tools for robust and expedient validation of your process analyzer

Today, your company must comply with extensive industry and government regulations. The Thermo Scientific ValPro™ system qualification package was developed specifically to help you with regulatory compliance. This package includes software, extensive documentation and a validation wheel with USP- or EP- recommended NIST and NPL traceable standards.*



Complete Regulatory Compliance

ValPro system qualification tools provide a complete package used to achieve instrument compliance with cGMP and FDA regulatory requirements. At the same time, it provides all the necessary components to comply with Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) testing. ValPro is the first qualification system to provide you with:

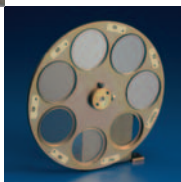
- A validation wheel with serialized and traceable NIST or NPL standards
- Complete instrument and software DQ documentation
- Tools to comply with 21 CFR Part 11
- Complete installation procedures, certification, testing routines and documentation for IQ
- Test methodologies from the European, United States, and Japanese pharmacopeial bodies
- Instrument tests for wavelength accuracy, spectrophotometric noise and photometric linearity
- Automated operation of all instrument tests
- Complete troubleshooting diagnostic information
- Templates and test limits for other NIST, NPL or user-defined testing standards
- Templates for recommended qualification standard operating procedures (SOPs)
- Historical validation reports with audit trails
- Example OQ and PQ procedures

Design Qualification

To comply with DQ, the ValPro documentation provides a detailed explanation of our analyzer hardware and software product development cycles. It also explains how we qualify suppliers, document projects, test products, archive test results and perform product testing.

In addition, ValPro includes detailed information for software DQ. This information explains how our software products comply with cGMPs, ISO 9000 protocols and the FDA's Code of Federal Regulation's for off-the-shelf software packages. ValPro works in conjunction with Thermo Scientific RESULT™ analyzer software. It includes the testing tools needed to prove that RESULT software provides reproducible and accurate outcomes to allow ongoing OQ testing of your analyzer. These tools, coupled with detailed documentation, allow RESULT to stand up to the most stringent regulatory agency audits. Software testing procedures are outlined for:

- Software coding
- Code archiving
- Off-site code storage
- Algorithm documentation and verification
- Software revision control
- Software issue tracking
- Documentation



Validation wheel with pharmacopeial recommended traceable standards



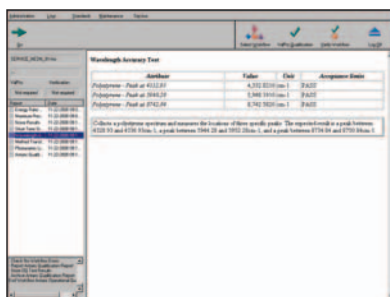
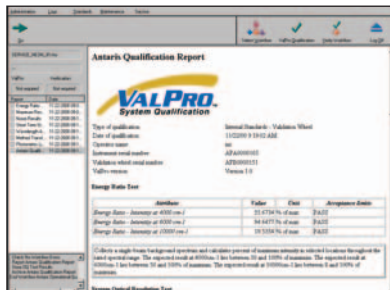
* USP recommended methodology for FT-NIR based systems, EP recommendations for FT-IR systems.

Installation Qualification

Certified support personnel install your system and ensure that it meets or exceeds manufacturing specifications. ValPro system qualification offers detailed installation procedures (SOP), reports and certification documentation so all systems are installed in accordance with IQ specifications. In addition, it provides a detailed explanation of the instrument tests used during the installation and qualification process. The IQ protocol includes United States Pharmacopeial (USP) recommended tests to verify instrument wavelength accuracy, precision and linearity. In addition, tests are performed to check instrument stability, performance and resolution.

Automated Operational Qualification

The product's automated approach allows you to perform instrument qualification tests (qualification SOP) at any time. It provides detailed qualification reports, qualification histories and complete troubleshooting information, with the option to perform OQ testing as frequently as your needs require. In addition, its open architecture provides many testing templates that can be easily modified to incorporate your own standards for OQ testing.



ValPro qualification reports

For third party verification, we offer bi-annual and annual re-qualification services for continuous compliance. Along with the automated system tests for source performance, resolution and short/long-term stability, the package also incorporates tests for:

- Wavelength accuracy
- Photometric linearity
- Spectrophotometric noise
- Stability

Performance Qualification

ValPro system qualification provides the tools to assist you with performance qualification. Its unmatched design provides the flexibility needed to accommodate any qualification requirement. Its unique approach allows independent qualification of the spectrometer, sampling technique and qualitative or quantitative methods. This, coupled with a large selection of customizable testing templates, allows any user-defined or industry-recommended qualification standards to be incorporated into the package. It is compatible with all qualification standards including:

- ASTM
- NIST
- NPL
- User-defined standards

Certified Qualification Experts

For complete regulatory compliance, support personnel are trained and certified to perform installation and qualification. These qualification experts stay proficient with annual re-certification training to ensure you have complete and consistent qualification support.

ValPro system qualification, in conjunction with our certified support personnel, guarantees that your instruments are installed and qualified properly – eliminating potential regulatory difficulties.

Software Requirements

- RESULT 1.0 or later version
- Windows NT®, 2000, or XP Professional

