

# EffiValidation

Method Validation Tools Purpose-Built to be Fast, Accurate, and Compliant

Easily meet the technical requirements of ISO 17025 and requirements of ICH Q2. Powerful, easy-to-use features and one-click reporting minimize calculation errors, guarantee data integrity, establish credibility for 21 CFR Part 11, and save 60% more time, so you can achieve confidence in quality.

## General

- Database
- User-Defined Software Design
- System ID and Searching
- Print/Export

## Methods

- Method Validation
- Uncertainties
- Control Charts/Trending
- Calibration
- Inter-laboratory Comparison
- User-defined Acceptance Criteria

## Static Data

- Units
- Norms
- Personnel
- Departments
- Rooms
- Customers
- Manufacturers
- Suppliers

## Software Validation and Data Security

- User Privileges, Security Policy, Audit Trail
- Software Validation (IQ, OQ)
- 21 CFR Part 11 (e-Records and e-Signatures)

# EffiValidation

## All Method Validation Features\*

- Multi-Component Analysis
- HPLC System Suitability (FDA/PhEur)
- System Suitability
- Method Transfer
- Retrospective Validation
- Validation of main substance determination
- Validation of impurity determination
- Fully customizable interface
- Query capability
- Data import
- Internal data linking
- Data warehouse
- Dynamic workflows
- Global audit trail
- Audit trail by record
- Configurable roles/security and administrator management
- Version control
- Data backup and recovery
- Custom reporting
- Report printing
- Label support
- Barcode support
- Export reports to PDF
- Export to MS Word, XML, HTML
- Module-based
- Mobile device integration
- Alarms/alerts
- Multilingual

\*In addition to modules listed on reverse side.