EffiChem

Confidence in Quality

# About Us

EffiChem is a leader in producing effective and efficient laboratory quality solutions. We've been providing our customers with easy-to-use, highly configurable method validation and laboratory information and quality management software for more than 15 years.

## Over 15 Years of Quality

**1994** **Concept**

The need for an effective way to manage laboratory quality during PhD studies spawns the EffiChem concept.

**1999** **Start**

EffiValidation 1.0 is developed and released. The first purchase orders are received.

**2004** **Growth**

Customers adopt EffiChem in the wider European market.

**2012** **New Features**

Improved design features greater product functionality.

**2015** **Version 4.0**

EffiChem 4.0 gives more flexibility and support for multiple languages.

**2016** **The World**

EffiChem customer base expands worldwide.

# EffiChem Products

## Confidence in Quality

EffiChem is the only Laboratory Information and Quality Management Software integrating Method Validation and Part 11 record keeping for ISO 17025-accredited and GMP compliant labs.

## We Offer 3 Ways to Achieve Quality

### Effi**Validation**

Method Validation

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.

### Effi**QS**

LIMS/QMS

Effectively manage all quality-related laboratory information. Document procedures, equipment, personnel, samples, and results for full transparency, so focusing on quality becomes second nature and maintaining ISO 17025 accreditation and GMP compliance is easy.

### Effi**Individual**

Configuration for Growth

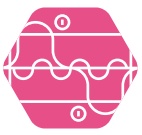
The power of EffiValidation, the control of EffiQS, plus the ability to create endless module configurations to meet the individual needs of your lab. Make sure your data is where you want it, when you want it, how you want it. It's the only quality solution you'll ever need.

## Key Benefits

**60% less data evaluation time**

**Eliminate errors**

**Reporting is simple but powerful**



**See results with one click**

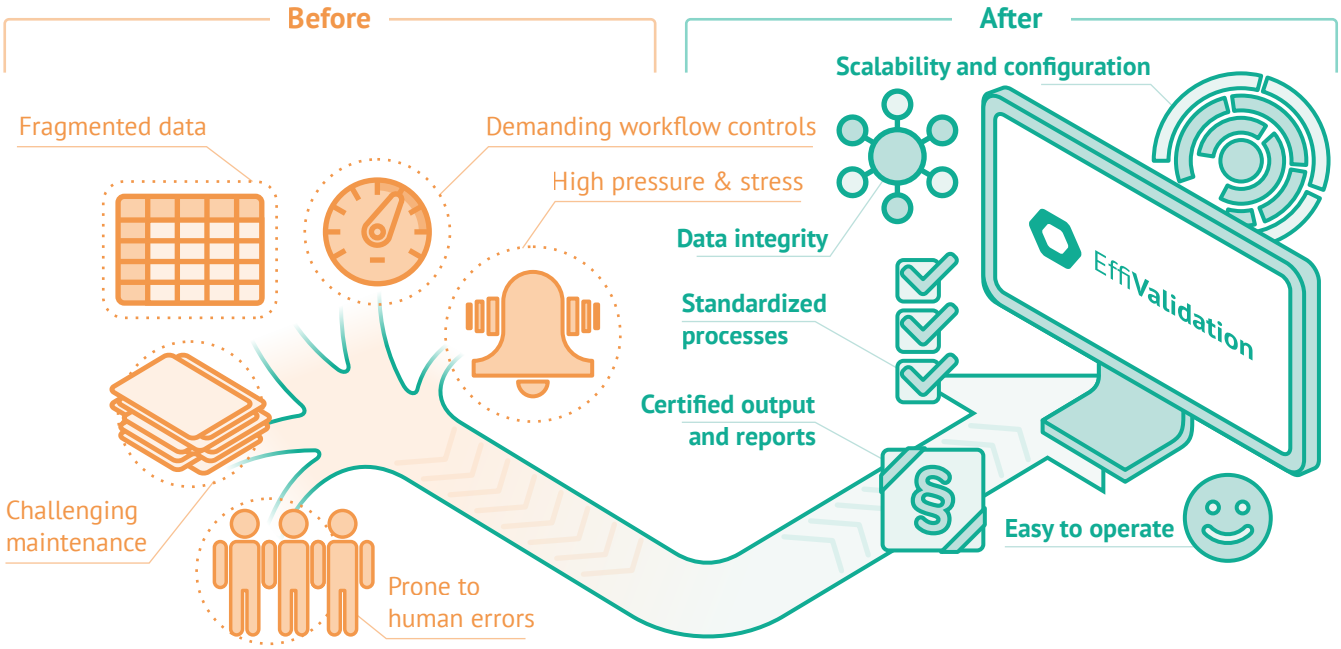
**Single data storage with 100% data integrity and traceability**

**Be ready for inspection at any moment**

# Switch to EffiChem

EffiChem gives you confidence, not only in quality laboratory results and products, but in data provided to auditors, accreditation, and inspectors.

## Complicated Processes Become Simple




### GAMP Compliance

EffiChem software is designed and developed in accordance with GAMP 5 guidance. EffiChem ensures the proper documentation and execution of all validation activities, specifically the Specifications and Testing components of GAMP 5 so that your lab's computer systems create as little risk as possible.

### 21 CFR Part 11 Compliance

EffiChem software is a closed system, with all 21 CFR Part 11 requirements accounted for, including limited system access, electronic audit trail, accurate copies, and accurate retrieval. You stay compliant with all current industry demands focused on data integrity and traceability.

### ISO 17025 Technical Requirements

EffiValidation was designed to not only reduce time, but improve quality and efficiency by taking the ambiguity out of method validation, while ensuring that data integrity is protected, and results are available at the click of a mouse. This means that you can save up to 60% more time when using EffiValidation.

### ISO 17025 Management Requirements

EffiQS covers the whole laboratory process, enabling you to manage every relevant aspect of your quality process from one place, and keep authenticated records that help you maintain ISO 17025 accreditation, GMP standards, and 21 CFR Part 11 compliant records.

# EffiChem Helps the World Meet its Quality Goals

**450** Institutions

**1080** Users

**30+** Countries

Coca-Cola

Nestlé

Unilever

Micron

CEZ GROUP

sabic

VEOLIA WATER

ArcelorMittal

USS

EASTMAN

Slovnaft

Ministry of Finance of The Czech Republic

ORLEN

# EffiValidation

## The Validation Suite

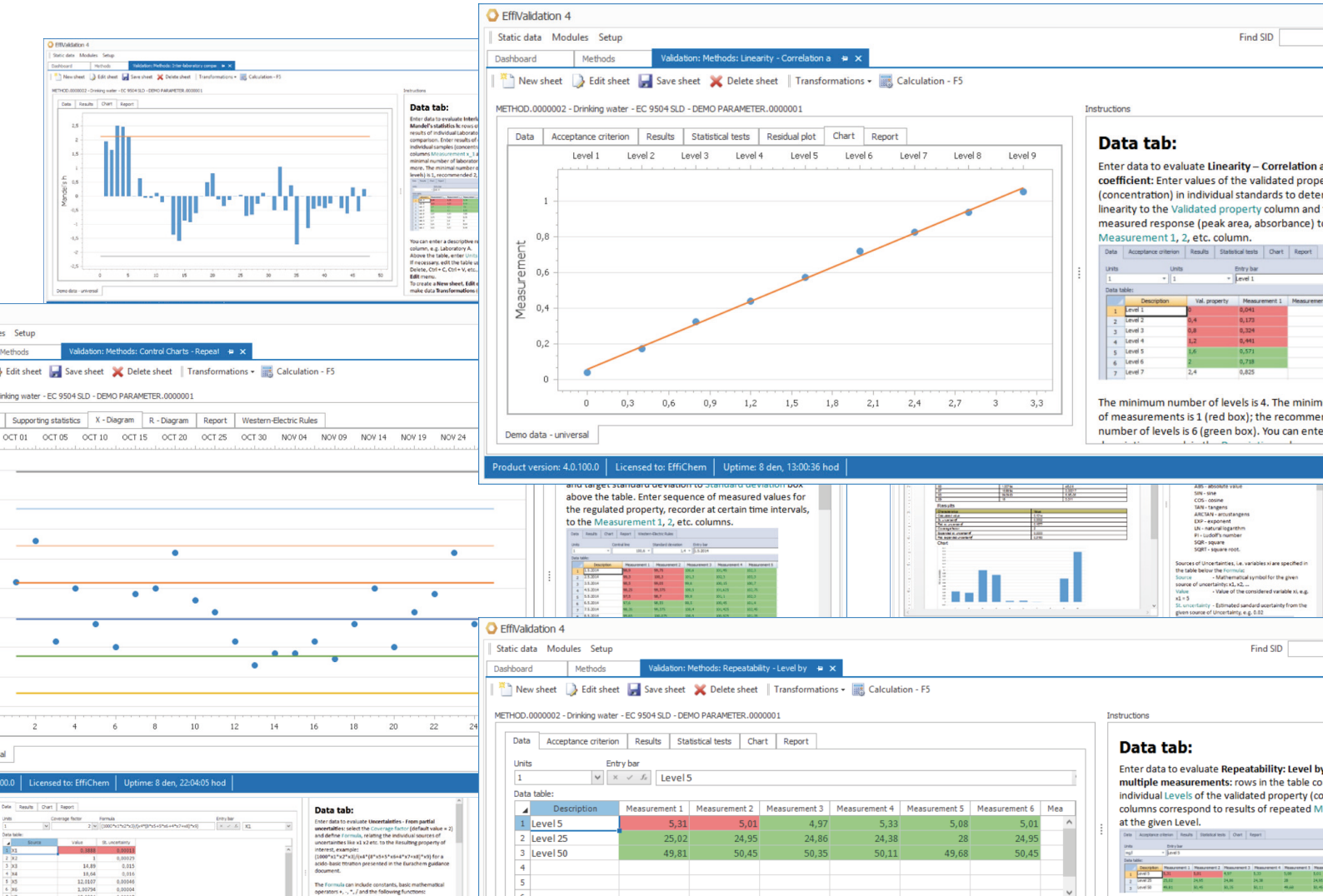

Easily meet the technical requirements of ISO 17025 and the requirements of ICH Q2 for the pharmaceutical industry. Powerful, easy-to-use features and one-click reporting minimize calculation errors and save time, so you can have confidence in quality.

## Key Features and Modules

- Method Validation
- Uncertainties
- Control Charts
- Calibration
- Inter-laboratory Comparison
- User-defined acceptance criteria
- Custom-configurable Method Validation Module
- No “Delete” function
- Six different language versions
- Additional method validation examples are available.

## Benefits

- Intuitive and easy to use in any lab
- Up to 60% time savings
- Minimize the risk of calculation errors
- One-click reporting
- Credibility for 21 CFR Part 11 is established
- Data integrity and traceability are hardwired
- Extensive documentation and training videos allow you to focus on results, not the software
- The confidence to pass regulatory inspections, lab accreditations, and customer audits with ease



# EffiQS

## Quality Management Simplified

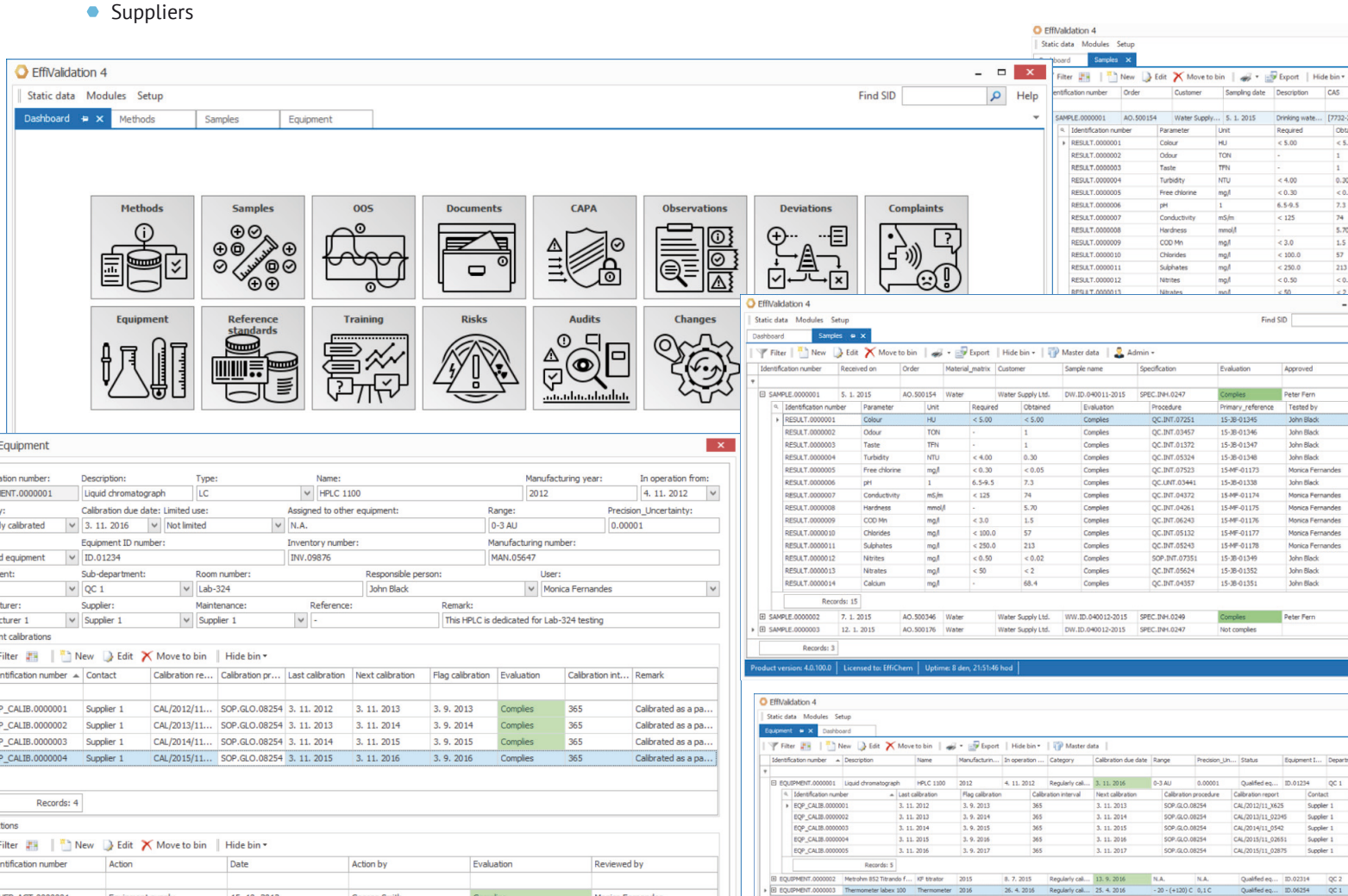

Effectively manage all quality-related laboratory information. EffiQS helps you document all relevant details for full transparency, so focusing on quality becomes second nature and maintaining ISO 17025 accreditation and GMP compliance is easy.

## Key Features and Modules

- Samples and Specifications
- Equipment
- Documents
- Deviations
- Contacts
- Reference Standards
- Chemicals
- OOS
- Controlled Documents
- Risks (register)
- Manufacturers
- Suppliers
- CAPA Management
- Audits & Observations
- Change Controls
- Complaints
- Methods
- Units
- Norms
- Personnel
- Departments
- Rooms
- Customers

## Benefits

- Simple, intuitive navigation for easy use
- All-in-one functionality saves headaches
- Minimizes the risk of recordkeeping or other human errors to avoid costly CAPA actions, downtime, and recalls
- One-click reporting for low-stress accreditation and audit response
- Data integrity and traceability are hardwired so you can give answers with confidence
- Extensive documentation and training materials allow you to focus on results, not the software
- The confidence to pass regulatory inspections, lab accreditations, and customer audits with ease



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