

## Pharma and laboratory solutions



All solutions enable the standardization of statistical data analysis and evaluation as well as the automatic generation of reports in the form of tables and / or graphics and thus contribute to process optimization.

Our applications include the trend towards product stability, monitoring of the production environment, process validation and ongoing review, regular product reviews, solution profiling, and assessment and validation of uncertainties of analytical methods.

In the area of production, we offer Statistical Process Control (SPC) and Overall Equipment Effectiveness Monitoring (OEE), Measurement System Analysis (MSA) and Preventive Maintenance (PM) support.

### Product Quality Review Module

The module provides data analysis during regular product inspection / monitoring.

### Process Validation Module

An automated, comprehensive data analysis solution during process validation is provided by this module.

### Environment Monitoring Module

A data analysis solution for monitoring and trend analysis of high quality equipment, devices, facilities and personnel is provided with this module.

### Dissolution Profile Comparison Module

Assessment of similarity between test and reference product dissolution profiles as recommended by the EMA and FDA is possible with this solution.

### Proficiency Testing Module

Evaluations of laboratory services and results comparisons of laboratories are optimally visualized with this module.

### Measurement Uncertainty Module

Estimation of measurement uncertainties, as recommended by GUM, can be presented with this module.

### Analytical Method Validation Module

It implements a comprehensive data analysis solution for the validation of analytical methods recommended by EMA, FDA and PN-ISO 5725.

### Product Stability Monitoring Module

Evaluations for product stability data as recommended by ICH Q1E are provided with this module.