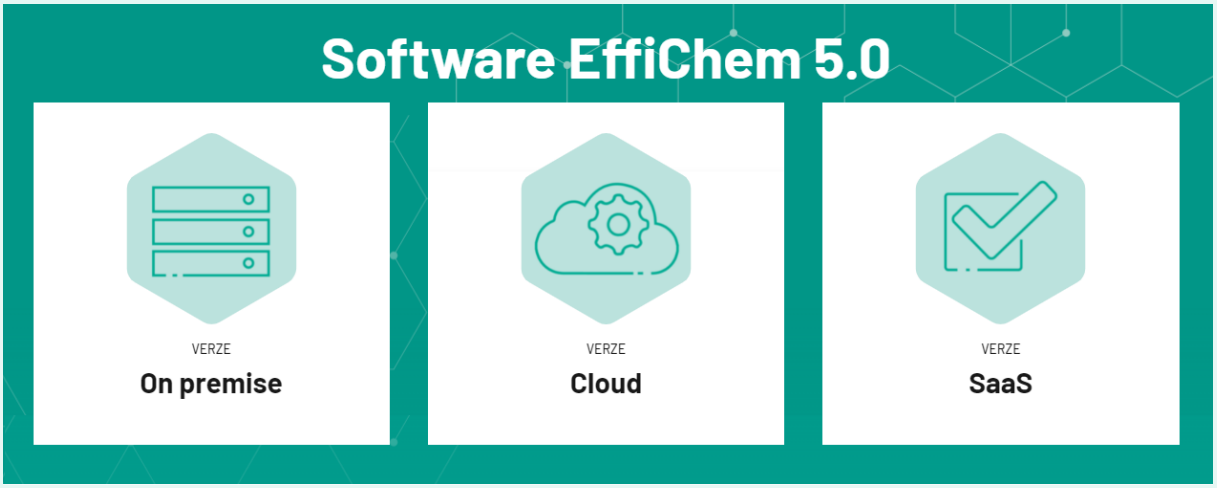
EffiChem 5.0 software for easier lab compliance and operation

Already 5th version of the EffiChem software helps pharmaceutical companies and ISO 17025 accredited laboratories.



Why EffiChem 5.0:

Data integrity In compliance with the current regulations and standards, according to authority requirements and customer expectations. Data security, integrity and 100% traceability guaranteed.	*Productive laboratory* Laboratory process automation by means of configurable workflows; from sample receipt to Certificate of Analysis or a Test Report, incl. email notifications and managerial reporting.
Paperless quality records Controlled documents and training, deviations, change controls, OOS investigations, complaints, audits, observations and CAPA management.	*Individual approach* Case-by-case implementations, matching the size, requirements and expectations of the individual customers. A long-term partnership. Simple for IT administrators.

Key References:

EffiChem software

EffiChem portfolio offers a number of options, meeting the user requirements from the individual customer perspective, according to the requested scope, modules and functionalities; fitting the technical requirements, cost expectations and operational, maintenance, support and IT administration requirements.

Characteristics and functions

A highly configurable, all-in-one LIMS, QMS, DMS, LMS and Statistical Data Evaluation solution.

Description

General

- MS SQL database
- Highly configurable modules, workflows, roles and user privileges
- Full-text search in (non-proprietary) documents and records
- Filtering
- Searching by means of SQL queries into database
- Message center, email notifications, task assignment, automatic reminders and task escalation if not complete
- Un-limited configurable print reports in multiple languages in parallel, e.g. local plus English

Security, data integrity and traceability

- In compliance with GAMP 5, 21 CFR Part 11 and Annex 11 EU GMP
- In compliance with ISO 17025, focus on art. 7.11
- Functionalities: Audit trail, History of records, Electronic records and Electronic signatures, incl. History sign off

LIMS: Laboratory Information and Management System

- Samples and results
- Specifications, incl. limits and other acceptance criteria
- Stability studies
- Environmental monitoring and utility monitoring
- Out of specification (OOS) and Out of trend (OOT) results
- Methods
- Equipment / Instrument calibration
- Equipment and ERP connection (under preparation)
- Reference standards/materials
- Columns
- Chemicals
- Material items
- Solutions

QMS: Quality Management System

- Deviations
- Change control
- Audits and audit observations
- CAPA management (corrective and preventive actions)
- Complaints
- Risk analysis and risk management
- Vendor qualification

DMS and LMS: Document Management System and Learning Management System

Controlled documents

- Documents
- Meta-data
- Multiple configurable workflows
- Version control (working, approved and released documents)
- Controlled printing

Training:

- Training tests
- Test questions
- Test score/overview per document, per user or per user-group
- Email notifications, Test reminders, Task assignment, Task/Reminder escalation over time and managerial layers

Training monitoring:

- Completed tests
- In-completed tests
- Test overview and reporting

Statistical Data Evaluation – Method validation, Uncertainties, Control charts, Calibrations, Inter-laboratory comparison

- Method validation
- Uncertainty estimation
- Control charts
- Calibration
- Inter-laboratory comparison

EffiChem solutions

Farmaceutical industry
ISO 17025 accredited laboratories
LIMS – Laboratory management
QMS – Quality management
DMS – Document management
Statistical Data Evaluation

Pharmaceutical industry

Quality Control GMP (Good manufacturing practice) and GLP (Good Laboratory Practice) laboratories, contract testing laboratories.

Characteristics and functions

The software was developed in compliance with the harmonized GMP requirements for US, EU, JP and the World, including the US FDA 21 CFR Part 210 and 211, Volume 4 EU GMP, Supplement 11 (Annex 11), 21 CFR Part 11 and in in line with GAMP 5 for validation of computerized systems.

LIMS modules and functions

The LIMS is used to manage the processes in the laboratory and keep the related quality records. The basic process is the testing of samples or batches, recording of results and comparing them with the specifications. This process consists of the sample receipt, testing and results entry, sample inspection, approval and reporting. This is preceded by the creation of specifications and the development and validation of test methods, which are also recorded, managed and evaluated through the LIMS. The same applies to equipment registration and calibration management, to reference materials certification and validity monitoring, and to the registration of chemicals, solutions, chromatographic columns and auxiliary materials.

The LIMS also enables effective planning, recording and evaluation of stability studies, recording of environmental monitoring data and data from supporting systems. It can work with barcodes and QR codes and supports managerial reporting.
We are currently developing the connection of LIMS with different types of equipment and ERP systems (under preparation).

QMS modules and functions

The QMS modules can be used for record keeping and quality management of the control laboratory or the entire pharmaceutical company. The scope includes the recording and evaluation of deviations, change management process, audits and observations, CAPA management (corrective and preventive actions, investigation of Out-of-Specification (OOS) and Out-of-trend (OOT) results, complaint handling and risk management.
Workflows are configured to match the customer requirements and processes, and can use email notifications, task assignments, escalation and other general functionalities, including managerial reporting.

DMS and LMS modules and functions

Document management and training is an integral part of the entire Quality Management System. It can include the complete process from the document creation, review, approval, to activation/release, periodic revisions, archiving or document cancellation.
The training management is linked to the documentation, starting with the creation of Tests, Test questions and the definition of the correct answers, enabling to record and evaluate the user answers, quantify the test score, initiate re-testing if not previously successful, monitor the training deadlines, document the complete and in-complete training and remind and escalate missing trainings.

For Document Management and Training, workflows can be configured according to customer requirements and the processes, and can use email notifications, task assignments, escalation and other general functionalities, including managerial reporting.

Statical Data Evaluation

Statistical Data Evaluation can be done either in the LIMS module Methods, Samples or configured individually. The assessment typically includes evaluation of the method validation data, estimation of uncertainties of test results, development and use of control charts, creation and use of calibration models and evaluation of inter-laboratory comparisons.
If there are multiple options for statistical evaluation, all options are included. E.g. for a correct evaluation of Accuracy, it offers a t-test and regression; for linearity, there is the correlation coefficient calculation, ANOVA or a Sign test. The output of the statistical data evaluation is a numerical result, a graph and an automatically generated report.

Customer support and services

Product selection (On premise, Cloud or SaaS) according to customer requirements.

Configuration of modules and functionalities according to user specification

Documentation, validation and service support by EffiChem.

Project management: from the project goals and scope to go live operation.

ISO17025 accredited laboratories

Solutions for ISO 17025 accredited laboratories – providing accreditation system and/or statistical data evaluation of method validation, uncertainties and control charts.

Characteristics and functions

The software was developed in compliance with the requirements of ISO 17025 incl. art. 7.11, harmonized GMP requirements incl.US FDA 21 CFR Part 210 and 211, Volume 4 EU GMP, Supplement 11 (Annex 11), 21 CFR Part 11 and in line with GAMP 5 for validation of computerized systems.

LIMS modules and functions

The LIMS is used to manage the processes in the laboratory and keep the related quality records. The basic process is the testing of samples or batches, recording of results and comparing them with the specifications. This process consists of the sample receipt, testing and results entry, sample inspection, approval and reporting. This is preceded by the creation of specifications and the development and validation of test methods, which are also recorded, managed and evaluated through the LIMS. The same applies to equipment registration and calibration management, to reference materials certification and validity monitoring, and to the registration of chemicals, solutions, chromatographic columns and auxiliary materials.

The LIMS also enables effective planning, recording and evaluation of stability studies, recording of environmental monitoring data and data from supporting systems. It can work with barcodes and QR codes and supports managerial reporting.
We are currently developing the connection of LIMS with different types of equipment and ERP systems (under preparation).

QMS modules and functions

The QMS modules can be used for record keeping and quality management of the control laboratory or the entire pharmaceutical company. The scope includes the recording and evaluation of deviations, change management process, audits and observations, CAPA management (corrective and preventive actions, investigation of Out-of-Specification (OOS) and Out-of-trend (OOT) results, complaint handling and risk management.
Workflows are configured to match the customer requirements and processes, and can use email notifications, task assignments, escalation and other general functionalities, including managerial reporting.

DMS and LMS modules and functions

Document management and training is an integral part of the entire Quality Management System. It can include the complete process from the document creation, review, approval, to activation/release, periodic revisions, archiving or document cancellation.
The training management is linked to the documentation, starting with the creation of Tests, Test questions and the definition of the correct answers, enabling to record and evaluate the user answers, quantify the test score, initiate re-testing if not previously successful, monitor the training deadlines, document the complete and in-complete training and remind and escalate missing trainings.

For Document Management and Training, workflows can be configured according to customer requirements and the processes, and can use email notifications, task assignments, escalation and other general functionalities, including managerial reporting.

Statical Data Evaluation

Statistical Data Evaluation can be done either in the LIMS module Methods, Samples or configured individually. The assessment typically includes evaluation of the method validation data, estimation of uncertainties of test results, development and use of control charts, creation and use of calibration models and evaluation of inter-laboratory comparisons.

If there are multiple options for statistical evaluation, all options are included. E.g. for a correct evaluation of Accuracy, it offers a t-test and regression; for linearity, there is the correlation coefficient calculation, ANOVA or a Sign test. The output of the statistical data evaluation is a numerical result, a graph and an automatically generated report.

ISO 17025 requirements covered by EffiChem 5.0:

ISO17025	Requirement	EffiChem software
6.4	Equipment	Equipment
6.4.13	Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, where applicable:	Equipment module
7.2	Selection and verification of methods	Methods module > Method validation
7.2.1.3	The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so.	Methods module > Method validation
7.2.1.5	The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required	Methods module > Method validation

ISO17025	Requirement	EffiChem software
	performance. Records of the verification shall be retained.	
7.2.2	Validation of methods	Methods module > Method validation
7.2.2.1	The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application. NOTE 2 The techniques used for method validation can be one of, or a combination of, the following: a) calibration or evaluation of bias and precision using reference standards or reference materials; b) systematic assessment of the factors influencing the result; c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed; d) comparison of results achieved with other validated methods; e) interlaboratory comparisons; f) evaluation of measurement uncertainty of the results based on an understanding of the theoretical principles of the method and practical experience of the performance of the sampling or test method.	Methods module > Method validation > Accuracy and Precision > Robustness > Inter-laboratory comparison > Uncertainties from Partial uncertainties or Uncertainties form Precision evaluation of from Control charts
7.2.2.2	When changes are made to a validated method, the influence of such changes shall be determined and where they are found to affect the original validation, a new method validation shall be performed.	Methods module > Method validation > revalidation after a change, with a full Audit trail and History
7.2.2.3	The performance characteristics of validated methods, as assessed for the intended use, shall	Methods module

ISO17025	Requirement	EffiChem software
	be relevant to the customers' needs and consistent with specified requirements. NOTE Performance characteristics can include, but are not limited to, measurement range, accuracy, measurement uncertainty of the results, limit of detection, limit of quantification, selectivity of the method, linearity, repeatability or reproducibility, robustness against external influences or cross-sensitivity against interference from the matrix of the sample or test object, and bias.	> Method validation > Range > Uncertainty > Precision > Limit of detection > Limit of Quantification > Selectivity > Linearity > Robustness > Accuracy (Bias)
7.2.2.4	The laboratory shall retain the following records of validation: a) the validation procedure used; b) specification of the requirements; c) determination of the performance characteristics of the method; d) results obtained; e) a statement on the validity of the method, detailing its fitness for the intended use.	Methods module > Method validation Validatiom procedure Acceptance criteria Algorithms and characteristics Results Statement of validity
7.5	Technical records	
7.5.1	The laboratory shall ensure that technical records for each laboratory activity contain the results, report and sufficient information to facilitate, if possible, identification of factors affecting the measurement result and its associated measurement uncertainty and enable the repetition of the laboratory activity under conditions as close as possible to the original. The technical records shall include the date and the identity of personnel responsible for each laboratory activity and for checking data and results. Original observations, data and calculations shall be recorded at the time they are made and shall be identifiable with the specific task.	Samples module > Results Primary records

ISO17025	Requirement	EffiChem software
7.5.2	The laboratory shall ensure that amendments to technical records can be tracked to previous versions or to original observations. Both the original and amended data and files shall be retained, including the date	Audit trail and History of records
7.6	Evaluation of measurement uncertainty	Methods module > Uncertainty estimation
7.6.1	Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.	Methods module > Uncertainty estimation > Partial uncertainties
7.6.2	A laboratory performing calibrations, including of its own equipment, shall evaluate the measurement uncertainty for all calibrations.	Methods module > Uncertainty estimation
7.6.3	A laboratory performing testing shall evaluate measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an estimation shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method. NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions. NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.	Methods module > Uncertainty estimation > Partial uncertainties or from > Precision data or from > Control charts
7.7	Ensuring the validity of results	Control charts
7.7.1	The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results.	Control charts

ISO17025	Requirement	EffiChem software
7.7.2	The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:	Module Methods > Inter-laboratory comparison
7.8	Reporting of results	Samples module
7.9	Complaints	Complaints module
7.10	Nonconforming work	Non-confirming work module or Out-of-Specification module
7.11	Control of data and information management	Software validation and data integrity
7.11.1	The laboratory shall have access to the data and information needed to perform laboratory activities.	Software security > Access control
7.11.2	The laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data shall be validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction. Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, they shall be authorized, documented and validated before implementation. NOTE 1 In this document “laboratory information management system(s)” includes the management of data and information contained in both computerized and non-computerized systems. Some of the requirements can be more applicable to computerized systems than to non-computerized systems. NOTE 2 Commercial off-the-shelf software in general use within its designed application range can be considered to be sufficiently validated.	Software validation and data integrity
7.11.3	The laboratory information management system(s) shall:	Software validation and security

ISO17025	Requirement	EffiChem software
	a) be protected from unauthorized access; b) be safeguarded against tampering and loss; c) be operated in an environment that complies with provider or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; d) be maintained in a manner that ensures the integrity of the data and information; e) include recording system failures and the appropriate immediate and corrective actions.	> Access control
7.11.4	When a laboratory information management system is managed and maintained off-site or through an external provider, the laboratory shall ensure that the provider or operator of the system complies with all applicable requirements of this document.	Software validation and vendor qualification
7.11.5	The laboratory shall ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel.	LIMS documentation
7.11.6	Calculations and data transfers shall be checked in an appropriate and systematic manner.	Audit rail and History of records
8	Management system requirements	Controlled documents
8.2	Management system documentation (Option A)	Controlled documents
8.3	Control of management system documents (Option A)	Controlled documents
8.4	Control of records (Option A)	Controlled documents and records
8.5	Actions to address risks and opportunities (Option A)	Risk analysis and Risk assessment
8.6	Improvement (Option A)	Improvement module
8.7	Corrective actions (Option A)	CAPA module
8.8	Internal audits (Option A)	Internal audits module
8.9	Management reviews (Option A)	LIMS reporting functionalities

LIMS – Laboratory Management

Laboratory Information and Management System, LIMS, enables to keep records and effectively manage processes in a laboratory.

Main LIMS functionalities and modules

- Sample/batch management and Results keeping, incl. Review and approval cycle and development of Certificates of Analysis or Test reports
- Management of Specifications and test Methods
- Management of Stability studies
- Equipment/instrument management and calibration
- Reference standards/materials management
- Environmental and utility monitoring
- Support bar and QR codes
- Managerial reporting and overviews
- Equipment and ERP systems connection (under development)

Samples and results management

The basic process in the laboratory is the management of Samples and Results. The process begins with the receipt of a sample into the laboratory, continues with its registration and assignment of test specifications, testing and recording of results, automatic evaluation of results against specifications, review and approval of results, approval of the sample, creation and printing of the Certificate of Analysis or Test Reports, and/or release of the corresponding batch for further use.

Other modules and functionalities

Methods, Equipment, Reference standards and other

Sample management can be linked to records of test methods, measuring equipment, reference standards, chemicals, chromatographic columns, solutions and auxiliary materials. The system offers additional functionalities such as sampling records, re-testing, sample-cloning, evaluation according to multiple customer specifications, and maintenance and evaluation of stability studies.

Workflows and Roles

Samples can be managed individually by a sample-type and processed according to a configurable workflow, e.g. QC workflow, ISO17025 workflow, R&D workflow, etc., using specific user Roles, privileges and the approval processes. The modules are to configurable as well, i.e. the fields/entries and the print reports in multiple languages.

Configuration and task and timelines monitoring

The same principles of configuration and workflow options apply to the recording and approval of stability studies, test methods, equipment and calibrations, reference standards, solutions, columns, chemicals and consumables. Automatic monitoring of tasks and timelines to ensure the validity of equipment calibrations, the validity of reference standards, solutions, etc., can be done either graphically – by using a traffic light system, or by means of email notifications, reminders and escalations.

Audit trail and History of records

An Audit trail and History are maintained for all required records. The Audit trail review is facilitated with filters, allowing to find the required information and sign off the history, it required. All operations and records are 100% traceable. Records cannot be deleted or falsified. They can only be moved into a trash in a controlled manner, and reviewed/restored if required.

General functionalities

In all LIMS modules, the users can use general functions such as filtering, full-text search, export and import, attachments (PDF, docx, xlsx, jpg, png, etc.), links to related records, and use managerial tools to generate reports or run SQL queries through the LIMS database.

LIMS and DMS/QMS connection

LIMS modules can be connected with the Documentation Management System - DMS (e.g. to connect Methods), Quality Management System - QMS (to connect Out-of-Specification results - OOS, deviations, change controls, CAPAs, complaints, etc.) and Statistical Data Evaluation (method validation, uncertainty estimation, control charts and calibration modules).

LIMS, DMS, QMS and SDE can be linked into a single validated environment without the need of interfaces to other systems. The connection and maintenance of all records and processes in one single system speeds up the laboratory operation and the approval processes, eliminates the need for user login to multiple applications and meets the data integrity requirements.

Currently, we develop the connection of LIMS to various laboratory equipment and ERP systems with the ability to extract, store and data-mine large volumes of primary data.

QMS – Quality Management

Quality Management System, QMS, is used to keep records and manage the quality processes in a control laboratory or the entire organization. An integral part of the QMS is the documentation management and training described under DMS and LMS.

Main QMS functionalities and modules

- Deviation management
- Change control management
- Audits and observations
- CAPA management
- Out-of-Specifications (OOS)
- Complaints
- Risk management

Deviation or non-conforming work management

Deviation management or non-conforming work module allows you to record a deviation from a procedure, method, process, specification, or other; and to evaluate and record whether it is significant or not. The system will help investigate and record the root cause of the deviation and ensure through corrective and preventive actions that the deviation does not recur. In addition to improving quality, this also has an impact on the cost. The greatest benefit of a successful deviation management is that the same deviations will not occur again and will not require resources to investigate and address the impact.

Other modules

Change control management

Change management is one of the basic requirements of a Quality Management System in the pharmaceutical industry. It enables to evaluate and record whether or not a proposed change has an impact on the marketing authorization of a medicinal product and to manage actions to ensure that the implementation of the change does not disrupt the terms of the marketing authorization. Change management includes changes in equipment, processes, materials, specifications, methods, documentation, computer systems, suppliers, labelling and packaging, EHS changes and validation changes.

CAPA management (Preventive and Corrective Actions)

CAPA management allows to address and respond to adverse events, complaints, audit observations and deviations. CAPA management ensures the process of implementing actions and monitors their effectiveness over time. The timely implementation and closure of CAPAs is typically monitored via company's key performance indicators (KPIs).

Out-of-Specification investigations (OOS)

OOS follows up on the management of Samples and Results, in case the test result reported by the first analyst is outside the limit prescribed by the specification. An investigation process is then initiated to determine if the root cause of the Out-of-Specification result is assignable (instrument error, analyst error, etc.) or non-assignable. Depending on this, the testing is either repeated by the first analyst, or a 2nd or 3rd analyst are involved, or the sample is re-sampled and a re-test plan is approved and implemented. All this can be recorded in the system and linked to the other related records (Samples, Deviations, CAPA, etc.).

Complaint management

Complaints handling is an element of the Quality System in both pharmaceutical industry and ISO 17025 accredited laboratories. The aim is to retain customers, comply with regulations and avoid potential disputes over product quality or service. The customer complaint management system enables to record, investigate and respond to complaints. In addition, it is also suitable to track trends in complaints, enabling the management reporting and follow-up on the implementation of the CAPA actions.

Audits and observations

Audits by government bodies, regulatory authorities, customers, or in-house, examine critical processes, identify gaps and help laboratories and companies to improve quality. The Audit management module enables efficient recording of audits, observations and the management and implementation of the appropriate corrective and preventive actions (CAPAs) to ensure proper resolution and communication of to remediation to the auditor.

Vendor qualification

The Vendor approval system was designed to ensure that suppliers of materials and services, selected by the company, are reliable and have adequate quality, and that they deliver on time and accurately according to the specifications and purchase orders. The Vendor qualification module allows to standardize the supplier approval process according to defined criteria, related to the type and criticality of the deliveries. The module offers effective reporting, based on the supplier group, type of

approval, etc. and enables to track the deviations in deliveries or the resolution of the CAPA actions. This extends the company's Quality System towards its supply chain partners.

Risk management

Risk management is a systematic approach to the analysis, evaluation, mitigation and re-evaluation of risks, particularly required in the pharmaceutical and medical device industry and ISO 17025 accredited laboratories. The risk management module enables the integration of risk management processes with other quality management processes - deviations, changes, complaints and audit observations – to facilitate the implementation and maintenance of a risk management program in accordance with ICH Q9 and ISO 14971.

Other functionalities

Configurable workflows and roles

Any workflow or a process usually starts with a registration of the event or a case, event description, review, approval, execution of the related CAPA actions, event closure and archiving. To strengthen and simplify the workflow management, graphical features can be used to monitor deadlines, e.g. the traffic light system, or email notifications and message centre, including automated reminders and escalation models.

Audit trail and History

The system maintains an Audit trail and History of records. It also supports audit trail review by means of filters and allows to sign off the record History. All records, workflow, workflow phase changes and user activities are 100% traceable and cannot be tampered with or deleted.
Undesired records can be moved into a bin, with a full history and rationale, from where they can be restored or their History can be viewed.

General functionalities

In all modules, the users can use general functions like filters, full-text search, exports and imports, attachments (PDF, docx, xlsx, jpg, png, etc.), links to related records and managerial reporting using configurable reports or MS SQL queries.

QMS and DMS/LIMS connection

The QMS modules can be linked to each other or to DMS and LIMS, all in one single validated environment. The connection and maintenance of all records from one single system speeds up the laboratory operation and the approval processes, eliminates the need for user login to multiple applications and meets the data integrity requirements.

DMS and LMS – Document Management and Training

The Document Management System and Trainig/Learning Management System, DMS and LMS, are used to manage the documentation and training of the control laboratory or the entire organization. The DMS and LMS is an integral part of the Quality Management System, which is described on the QMS page.

Scope and use

- Documentation management, including drafting, review, approval, release, periodic review, cancellation and archiving
- Training management, including tests, test questions, answers, evaluation and scoring of actual answers, re-testing, tracking and documentation of completed and in-uncompleted training, escalation of in-complete training

Controlled documentation

The documentation management process starts with the registration of the document in the system, continues with the creation of the draft, review, approval and release, based on which the document is activated and made available to other users. Once activated, the document can be used for training and actual work. The document can be further revised via period reviews, scheduled or unscheduled, or archived when not needed.

Other modules and functionalities

Training

The Training system is connected with the Documentation module. For every document/released version, a test can be created. The Test consists of Questions for which a set of correct and incorrect Answers is pre-defined, as well as the min percentage of correct Answers required. When a Test is assigned to a user (via Role, Group, or individually), the user is prompted for the Test. The user answers the Test questions, thus meeting or not meeting the % requirement. When the test is not successfully completed, it can be repeated and/or escalated to a supervisor.

Training evaluation and reporting

The system provides standardized reports on completed and the in-completed tests, either per individual user or by a user group/department. This simplifies the process of proving documented evidence that the employees are trained in accordance with their job description and requirements.

Configurable workflows

Document management and training management can be managed through a number of flexible workflows. Their structure is not limited or dependent on the type of document, the organization of the work teams, the approval panels, or the user Roles and approval permissions. This enables the standardization of the document approval process and training, in accordance with the expected company's quality policy. The automation of the processes enables deadlines to be monitored, human errors to be detected and reduced, and when training requirements are not met, this can be visualized and escalated to supervisors and a higher management.

Audit trail and History

An Audit trail and History is maintained for all Documents and Training records. Due to filters and search functions, it is easy to review Audit rail and sign off the History, if required. All records and worfklow changes are 100% traceable and cannot be falsified or deleted. Undesired records can only be moved to a bin with a rationale. From the bin, they can be recovered or the History reviewed.

DMS/LMS connection with QMS and LIMS

Documents and Training can be linked with other QMS and LIMS modules, resulting into one single environment, enabling the complete quality and laboratory management from one validated system that meets all security and data integrity requirements.

Statistical Data Evaluation

Statistical Data Evaluation models and functions are used to evaluate analytical method validations, estimate measurement uncertainties, maintain control charts and calibration models, and evaluate interlaboratory comparisons.

Scope and use

- Execution, assessment and reporting of method validation studies
- Estimation of uncertainties
- Development and use of control charts
- Development of use of calibration models
- Evaluation of inter-laboratory comparisons

Method validation

Repeatability

Repeatability is a measure of the method Precision obtained under the ideal measurement conditions (single instrument, single analyst, a short period of time) and can be evaluated in two ways in the EffiChem software:
- From multiple measurements on a level
- From parallel measurements

Intermediate precision

Intermediate precision is a Precision measure between Repeatability and Reproducibility. It can be evaluated From multiple measurements of Parallel measurements per level.

Reproducibility

Reproducibility is a Precision measure obtained under the worst measurement conditions (multiple instruments, multiple analysts, a long period of time) and can be evaluated From multiple measurements or From parallel measurements per level.

Accuracy

Method accuracy describes the degree of agreement of a measurement with a reference value/method. The accuracy can be evaluated in several ways, depending on the concentration range and the data availability:
- Limited concentration range - sample reconstitution possible
- Limited concentration range - reference material available
- Large concentration range - blank available: regression
- Large concentration range - blank not available: t-test
- Large concentration range - blank not available : regression
- Comparison of 2 methods/laboratories: t-test by levels
- Comparison of 2 methods/labs: t-test for difference in results

Linearity

Linearity describes the degree of linear dependence between the concentration and the measured signal. It is evaluated in different ways depending on the availability, type and design of the validation data:

- Correlation and QC coefficient
- ANOVA for Lack of fit
- Significance of the quadratic term
- Sign test

Limit of detection and Limit of quantification

The detection and quantification limits are concentration levels at which the signal can be distinguished from the noise or the concentration of the analyte being measured can be reliably quantified. The limits can be evaluated in several ways:
- 3s - IUPAC
- 3s - blank correction
- 3s - continuously measured blank
- From the calibration line

Robustness

Robustness is an ability of the method to cope with small changes in the method setup or in the adherence to the prescribed conditions, such as pH of the mobile phase in HPLC or detector temperature in GC, without having impact on result. Robustness can be evaluated in EffiChem software in two ways:
- Dong's algorithm
- AOAC with evaluation of

Selectivity

Selectivity is the ability of a method to selectively measure the concentration of the analyte of interest in the presence of potent interferents. Selectivity can be evaluated in several ways:
- By comparing calibration lines
- By comparing the results with a standard
- By comparing the results with measurements without interferents

Sensitivity

Sensitivity is the measure of change in the measurand (signal) per unit change in the concentration. It is calculated as the slope of the calibration line between the concentration and the measurand.

Blank

A blank experiment measures the magnitude of the measurand in a sample with zero concentration. It is the basis for calculating the Limit of detection and the Limit of quantification.

System Suitability Check

System suitability check is the confirmation that the system meets the prescribed parameters, namely PhEur requirements or USP/FDA requirements:
- Repeatability of injection according USP
- Capacity factor according to USP
- Resolution according to USP
- Tailing according USP
- Theoretical plate number according USP
- Theoretical plate number according PhEur
- Resolution according PhEur
- Symmetry factor according PhEur

Uncertainties, control charts and other

Control charts

Control charts are developed to monitor and evaluate the degree of variability in the Method or Results over time, to evaluate trends and to set warning and action limits. There are several types of control charts in the EffiChem software to select from, depending on data availability, design and range:

- Individual values – control characteristics determined
- Individual values - control characteristics not determined
- Repeated measurements - control characteristics determined
- Repeated measurements - control characteristics not determined
- Multivariate-variate control chart
- X-diagram (Control chart for Average)
- R-diagram (Control chart for Range)
- Western-Electric rules for evaluation of control charts

Uncertainty

Quantifying Uncertainty in analytical measurement is one of the key requirements of ISO17025. Several approaches or methods can be used for this purpose, depending on the situation and data availability:

- From Precision data - multiple measurements
- From Precision data - parallel measurements
- From Control charts - individual measurements
- From Control chart - multiple measurements
- From Partial uncertainties

Calibration

A linear or quadratic calibration model allows to estimate the concentration or the property of interest of the unknown sample from the value of the measurand. In addition, the calibration model is used for other purposes, e.g. to determine Linearity, Limit of detection. Limit of quantification and to determine the method Sensitivity.

Inter-laboratory comparison

Inter-laboratory comparisons is used to assess whether a laboratory participating in an interlaboratory comparison is reporting results that are significantly different from those of other laboratories, or not. Furthermore, the inter-laboratory comparison can be used to evaluate the method Repeatability and Reproducibility. The following algorithms are included in the EffiChem software:

- Mandel statistics H
- Mandel statistics K
- Collaborative studies

Audit trail and History

The Audit trail and History are kept for all Statistical Data Evaluations done. All records are 100% traceable and cannot be falsified or deleted. Undesired records can be moved to a bin with a rationale provided.

Connection with LIMS modules

The Statistical Data Evaluation can be either linked to the LIMS module Methods, or configured separately, within one single validated system, meeting the data integrity requirements defined.

EffiChem services

- **Project definition**
- **Project implementation**
- **Testing and validation**
- **Documentation**
- **Training and support**
- **Maintenance, support and further development**

Project definition

- Project goal
- Scope, modules and functionalities
- User requirements specification
- Risks assessment
- Validation master plan

Project implementation

- Build configuration
- Test and freeze configuration
- Introduce/import static and master data

Testing and validation

- FAT testing
- Installation qualification
- Operational qualification
- Performance qualification

Documentation

- Policies
- SOP development
- Work instructions

Training and support

- User training
- Administrator training
- QA training

Maintenance, support and enhancement

- Infrastructure readiness check
- Installation and support
- Backup and recovery
- Security
- Functional enhancement

EffiChem

Confidence in Quality

Purkyňova 649/127, Brno 612 00, Czech Republic

www.effichem.com

email: effichem@effichem.com