enaio®

OPTIMAL SYSTEMS

Laboratory Content Management Software

An ECM-based modular software solution to organize and document lab workflows

optimal-systems.de

software for movers and shakers

3 Core modules of the Laboratory Content Center
4 Laboratory Content Center (enaio®)
7 Centralized sample management
8 enaio® labs – digital lab folder
10 enaio® lims
12 Biobanking/Big Data management
13 Quality Management Suite
14 Content Management
15 References

Core modules of the Laboratory Content Center (enaio®)

- **Mobile sample registration** – app to collect sample data on site
- **Centralized sample management** – wizard for all data collection points to classify and record sample information
- **enaio® labs** – module to process and document lab orders
- **enaio® lims** – addition to enaio® labs for lab workflow automation
- **Biobanking** – module for registration, management and analysis of large datasets
- **Quality Management Suite** – administration and control of procedural instructions, SOPs as well as deviation and change processes
- **Enterprise Content Management** – digital files for customers, suppliers, staff contracts and projects as well as mail and invoice receipt processing

Laboratory Content Center (enaio®)

The laboratory content solution is an electronic case processing software, that combines administration, documentation (enaio® labs), sample processing (enaio® lims), process analysis, quality management (Quality Management Suite) and content management in all kinds of laboratories. Based on an enterprise content management system (enaio®) the modular software allows the adaption of the system to specific customer requirements. All modules can be configured separately to suit the requirements of specific users, labs or departments. The general data management is performed within the Laboratory Content Center (enaio®) – the basic software module. By using enaio®, daily tasks will become more efficient, more effective and more transparent.

Document Management System (DMS): Due to the integrated DMS, all kinds of electronic files, such as office documents, pictures or emails, can be easily be managed and accessed. All documents belonging to a lab workflow are collected within a digital file. Additions to the file can be carried out by drag and drop or automated import actions. The software layout is based on recent versions of Microsoft Office and can adapted to user requirements.

Digital workflows: By using software guided lab workflows, all kinds of management and lab documentation processes can be simplified and accelerated. Processes like plausibility checks, workflow based checklists, multi-level approvals or QM-workflows can easily be standardized and displayed within the software. Automated deletion of data or documents (depending on statutory provisions) is another aspect, especially in the regulatory area. An immense benefit is the graphical workflow editor allowing the user to easily adapt workflows to the specific situation.

Lab Report: Processes of different departments can be linked and analyzed within individual reports. Due to the access to batch management, process management (enaio® labs), purchase and order handling, a useful overview about resources, budgets and internal processes can be provided. All data can then be analyzed statistically and displayed graphically.

Mobile client enaio®: mobile client allows a quick access to all data, business processes and projects from wherever you are. Lab orders, scientific results, user requests or incidents can easily be accessed or forwarded to a specific team member. Documents and data recorded externally can be shared ad hoc via a portal for efficient communication within the team and with external partners.

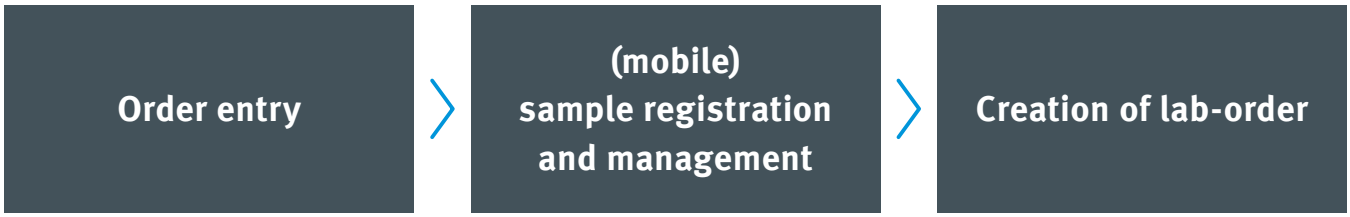
Advantages of the mobile client:

- On site sample registration including GPS/GIS integration
- Access to mobile file
- Safe transfer of orders or data to internal or external partners
- Network and partner management
- Mobile control and administration of lab processes

Advantages

- Extensive full text search functions, filters and configurable search parameters
- Business intelligence (ordering, forecasting, resource planning etc.)
- High access security due to differentiated user administration and rights management
- Efficient digital workflow management
- High degree of transparency due to consistent documentation of lab processes
- Possibility of a stepwise software launch (due to the system's modular structure)
- High safety level due to state-of-the-art encryption and electronic signatures
- High system stability due to load balancing and cluster capability
- Graphical editors for straightforward modification of workflows, reports and data forms etc.

Centralized Sample Management

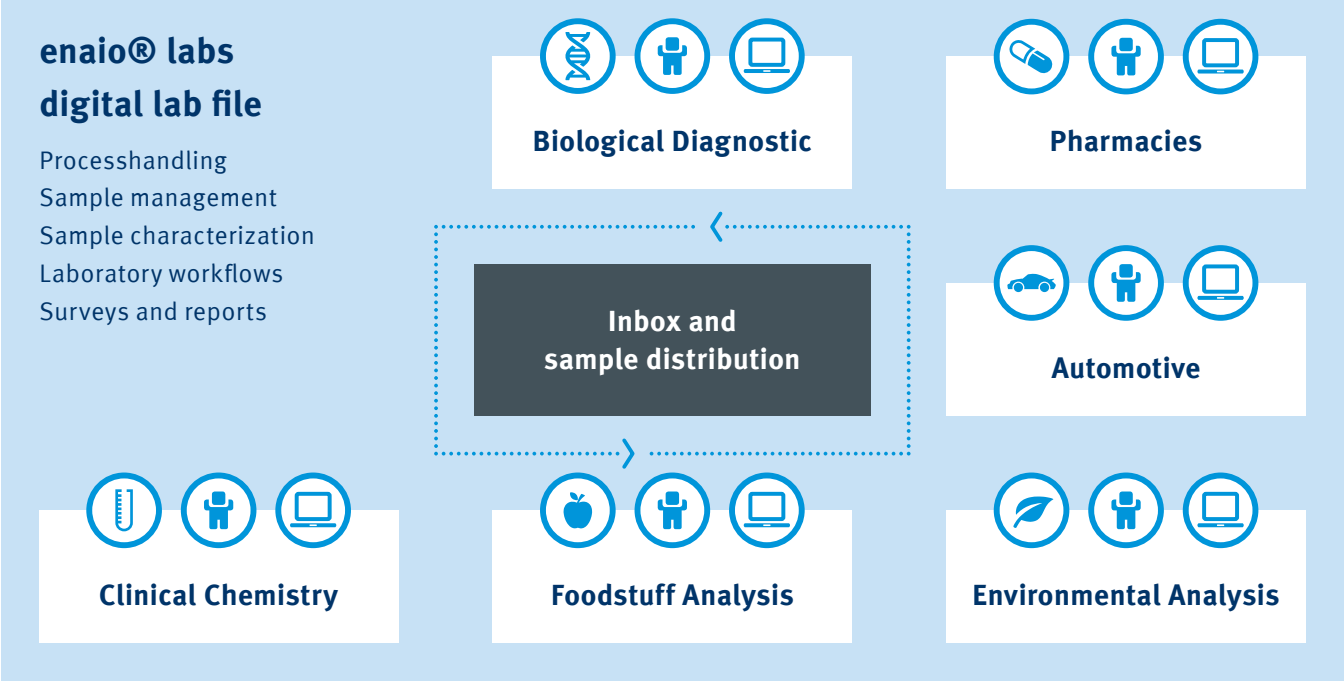


Via a registration wizard, samples and related data can easily be collected, classified and transferred to enaio® labs, independently from the location, the kind of sample and the collecting department. Additional data, such as GPS/GIS, can automatically be recorded. After the sample registration, the software offers the possibility to automatically integrate the samples into an electronic workflow and start an order for enaio® labs. In this regard the entire sample life cycle is logged and can be reviewed or backtraced at any time. Due to barcode or RFID guided sample identification system, the centralized sample management allows the localization of a sample within a process step, within user groups or within a storage freezer system.

The mobile sample registration provides the possibility to collect primary sample data (kind of sample, amount, origin etc.) as well as secondary data (GIS information, pictures, videos etc.) from smart phones, tablets or browsers and integrate them into the centralized sample management by secure data transfer. Thereby the samples are assigned to a specific customer or lab order. A barcode or RFID system ensures transparency and sample recognition.

- On site sample registration and GPS/GIS integration
- Integration of data loggers and online measurements
- Filing of pictures, videos and metadata
- Consistent capturing and documentation
- Secure storage, transfer and synchronization
- Available for iOS, Android and Windows

enaio® labs – the digital lab file



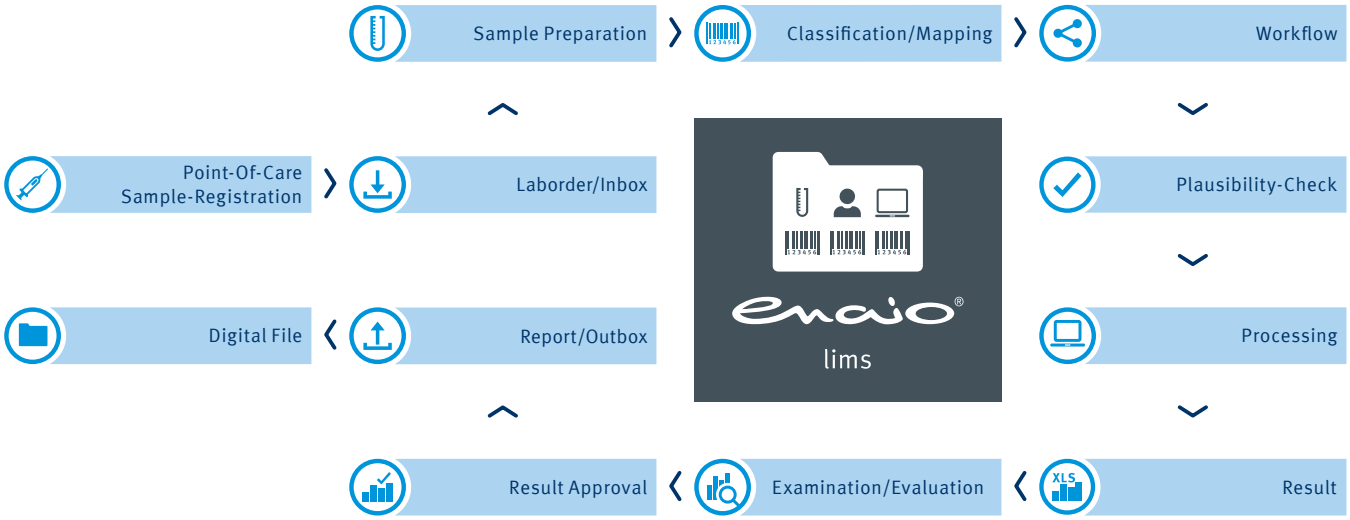
enaio® labs is the basic module to manage and log all lab processes. All kinds of investigational processes can be displayed as an interdisciplinary laboratory file – starting from basic research to FDA approved GMP-labs. enaio® labs can be adapted to user specific requirements.

Customer-specific deployments are already available for diagnostic labs, clinical chemistry, toxicology, food safety, environmental analytics, forensic science, and pharmacy and automotive. According to the specific strategy of your company, enaio® labs can be extended with the additional modules enaio® lims and Biobanking. enaio® labs supports all kinds of data formats, such as Microsoft Office documents, pictures, emails etc. Specific data forms can easily be configured for each data object and process. Any kind of metadata, (e.g. experimenter, address data, date, investigation method, equipment, batch number, text modules etc.) which are entered into these data forms, can, together with the measurement results, be transferred into a report automatically or by the push of a button. The software supports electronic signatures, long-term electronic archiving and secure data transfer. Intelligent full text search, search filters and configurable requests make for a quick availability of measurement data and documents. By means of flexible evaluation possibilities, you always stay on top of all processes.

enaio® labs key functions

- Digital laboratory file
- Modules available for any laboratory-related context
- Manual or automated data import
- Text recognition (OCR) and integration of paper documents
- Differentiated rights management system and user administration
- Extensive full-text search function, search filters and configurable search parameters
- Sample registration and barcode or RFID identification system
- Sample and batch management
- Resource planning and stockpiling
- Device and equipment management
- Laboratory workflow & process management
- Result management and mailing
- Generation of reports and protocols
- Statistical calculations

enaio® lims



enaio® lims includes the functions of enaio® labs, but more than that, it enables a consistent documentation and control of the sample processing and analysis. Through automation and standardization of workflows, the efficiency, safety and transparency of laboratory analysis increases. It enables the full integration of the entire laboratory, including the communication with peripheral software systems and all major types of analytical equipment – whether it is a pipetting robot, a capillary electrophoresis, a MALDI-TOF-MS, HPLC or PCR. By integration of peripheral software systems, sample, process and analysis data can be transferred and reviewed without any media dis-continuity. Tests on plausibility, contamination, min/max concentrations and thresholds can be executed and assist scientists in focussing on the relevant questions.

enaio® lims key functions

- Add-on to enaio® labs (digital laboratory file)
- Customer-specific deployments for Biological Diagnostics, Clinical Chemistry, Toxicology, Food Control Analysis, Environmental Analysis, Forensic Science, Pharmacy and Automotive
- Sample and batch management
- Device and instrument management
- Laboratory application management
- Sample registration and barcode or RFID identification system
- Configurable laboratory workflow and process management
- Plausibility check
- Automated sample processing
- Configurable contamination check
- Bi-directional interfaces to instruments and analysis software
- Result verification and clearance workflow
- Generation of protocols and reports
- Display and review of analysis data

Biobanking/Big Data

Based on a database and document management system, the Laboratory Content Center provides the possibility to collect big data sets from any place – whether it is from point of care diagnostics, data loggers, clinical studies, research cooperations, or the management of laboratory organism populations.

With the help of barcode or RFID identification systems, any investigated object can be clearly identified, assigned and processed. For a standardized collection of analysis data and classification with sample collection data (sample ID, meta-data, individual parameters, life circumstances, disease data, environmental data), data entry forms can be customized effortless via a graphical editor. The software supports any kind of data formats, e.g. pictures, videos, Microsoft Office documents or secondary data such as GPS/GIS information.

For a flexible evaluation of specific analysis data, any number of characterizing metadata and data objects can be linked to each other. These extensive linking possibilities enable the generation of population-based and investigation- or parameter-specific hit lists. By the means of filter and group functions, big data sets can be reduced according to specific criteria, to make significant comparisons within analyses data –whether it is, genetic material, course of a disease or phenotypic characteristics. Based on the hit list, statistical parameters can be calculated and displayed graphically (e.g. charts, linear regression, tables, box plots and other diagrams). For sensible data the software provides possibilities for encryption or the definition of user groups and clauses to allow a user-specific access to the database.

Advantages at a glance

- Location-independent consolidation and management of sample stocks
- Barcode and RFID systems for identification of samples and laboratory organisms
- Flexible linking of extensive sample collection and analysis data
- Possibilities for encryption and anonymization of sensitive data
- Bi-directional interfaces to pipette robots and lab systems for supply and storage of samples
- Deep integration in existing IT landscapes and secure interfaces to Clinical Information Systems
- Extensive search and evaluation functions
- Content Mining: Grading of hits according to rating and accentuation of search terms
- Full text search throughout all contents (documents and other data)
- Configurable hit lists with filter and group function
- High-performance import/export of analysis data
- Statistical calculation and visualization
- Connection to analysis software (e.g. RelVIS – relation visualization in big data-sets)
- Revision-safe long-term archiving

Quality Management Suite

The development of medical devices, methods and pharmaceuticals requires a large amount of know-how and a demonstrable commitment quality management. A mature QM system requires immense human and technical resources. The monitoring of deadlines and guidelines as well as the provision and distribution of documents are examples of processes that can be supported by software, especially when the amount of managed documents is growing rapidly. Such systems need to be highly specialized and integrated, in order to increase process efficiency.

Efficient Quality Management: With ECM-Software from OPTIMAL SYSTEMS your quality management can be organized considerably more efficiently. The workflow functionality offers the possibility to control strict process sequences, and to improve the monitoring of dates. Automatic escalation scenarios can be defined in case of upcoming deadlines.

OPTIMAL SYSTEMS offers tailor-made solutions for regulated industries such as GMP or manufacturing of medical devices. Validated and tested best practice solutions ensure a more efficient creation and administration of information and documents. Solutions are available for quality management, change control management, deviation management, audit management, document registration, contract management and equipment management.

Advantages at a glance

- Secure digital management of QM documents
- Complete digital display of the entire QM manual
- Secure workflows to supervise and control process sequences
- Exact date monitoring
- Secure application of electronic signatures
- Precise control and logging of CAPA-processes
- Facilitated timely recording of reclamations and secure workflow-controlled processing
- Clearly arranged processing, control and monitoring of Change Request processes
- Best practice solutions include the following guidelines:
  - GxP
  - DIN ISO 13485
  - CFR 21 Part 11 und Part 820
  - Audit-proof archiving
  - GDPdU

Enterprise Content Management

The Laboratory Content Center can modularly be extended by other professional solutions and transferred to other management sectors, business units and areas of activity. Due to the configurability of the underlying ECM-System, any kind of data and documents can be organized process specific in digital filing cabinets. Wherever there are files or documents to be managed, wherever data is generated and devices or software communicate with each other, wherever there is an exchange of data with customers – the Enterprise Content Management system can be adjusted to our customers' needs. Besides the availability of standard interfaces to common ERP and cashier systems, the software provides easy import and export possibilities to most and from established internal or external software systems and enables a deep integration in common IT landscapes.

Optional extensions:

- Digital supplier file
- Digital customer file
- Automated invoice receipt processing Applicant and HR management
- Contract management
- Project management
- Deep integration into common IT landscapes:
  - ERP systems (SAP, Microsoft Dynamics NAV, SAGE etc.)
  - Cashier systems
  - Specialized applications (e.g. public administration)
  - Microsoft SharePoint
  - Microsoft Office (Word, Excel, PPT, Visio etc.)

References

State Office of Criminal Investigations (Mecklenburg-Western Pomerania, Germany): ECM in Forensics – enaio® forensic lims

Software by OPTIMAL SYSTEMS is used in forensics in the field of DNA and textile analysis. As a centralized information management platform, it enables the digital processing of all crime scene traces and material samples in the laboratory.

All data and documents are structured by enaio® and stored in digital process files. With enaio® forensic-lims, an accredited and consistent verification management for forensic investigations can could be realized. Thanks to the electronic processing system and the digital management of trace data, working with forensic documents and processes on a daily basis becomes easier, more transparent and more efficient.

Solution

› enaio® forensic-lims

State Office of Criminal Investigations (Thuringia, Germany): Centralized trace registration, search and archival storage system – enaio® forensic labs

Software by OPTIMAL SYSTEMS is used for a state-wide centralized management of court exhibits and processing for all kinds of traces. enaio® forensic-labs enables a consistent verification management for all forensic traces, sub-traces and investigations, including the documentation of the complete forensic processing. After the trace investigation all results are documented and transferred into expert reports. The software sup-ports the accreditation of the associated laboratories according to DIN EN ISO/IEC 17025.

Solution

› enaio® forensic-labs

Let’s start your project!

Get in touch with our ECM software specialists. They would love to assist you, making your lab more efficient, your analyses safer and your staff happier. To arrange a live presentation in your company, just give us a call or send an email to jena@optimal-systems.de.

OPTIMAL SYSTEMS
Vertriebsgesellschaft mbH Jena

Ein Unternehmen der
OPTIMAL SYSTEMS Gruppe

Carl-Zeiss-Platz 1
07743 Jena

Tel. +49 3641 87410-00
Fax +49 3641 87410-11
jena@optimal-systems.de