infoteam software

WHITEPAPER

zenLAB® – Middleware framework for networked laboratories

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1 With zenLAB® for integrated software for equipment and laboratories

Laboratory 4.0 – this term now covers far more substance than just a few years ago. Thanks to new technological developments, particularly from the 'Industry 4.0' field (keywords 'Industrial Internet of Things' or IIoT), the comprehensive networking of devices, structured data collection, the linking and analysis of measurement and device data as well as integrated automation of work processes are within reach.

Laboratory managers now have the opportunity to harness previously untapped potential for synergies and capitalise more on existing resources. This would simultaneously increase efficiency and quality in the laboratory since automation can reduce manual processes, support employees in error-prone routine work and check results for plausibility, which ultimately frees up yet more time for higher-skilled work. Two conditions must be met for this: uniform device interfaces and integrated software solutions that interconnect people, devices, data, work processes and resources.

In terms of integrated software solutions, the zenLAB framework provides a ready-made software architecture and basic functionalities for developing laboratory-specific, networked middleware and manufacturer-specific connectivity solutions for laboratory equipment. It shortens the development time, allowing the time and technical freedom to focus on tailor-made solutions. Only then can perfect software applications emerge – applications that in times of stricter regulations, rising expenses and increased complexity, intuitively support laboratory staff and give them more time and freedom to concentrate on essential tasks in the laboratory.

2 Device manufacturers: Connectivity for devices with zenLAB®

With few exceptions, however, it is still true today: laboratory and medical devices operate independently; centrally-controlled automated processes are rare and experimental data must be manually entered into higher IT systems, e.g. laboratory information management systems (LIMS). Not only is this approach error-prone and inefficient but also means that a variety of optimisation options such as predictive maintenance is not even available.

Despite the wide variety of applications, software for operating and configuring devices almost always includes the same identical basic components. These include, for example, basic communication capabilities between devices and with other systems, user administration and an expandable service-oriented architecture. The development of connectivity solutions for devices is essentially always based on the same basic components and only later customised. It is precisely these basic components that the zenLAB framework provides for a wide variety of applications. This means that there is no need for them to be redeveloped every time and the focus is on customisation right from the start. This shortens the time to market, reduces risks and makes subsequent maintenance cheaper, saving money that can, for example, be directed to improved user experience. This especially applies to the development of software intended to be used later in the normatively regulated environment where even further reaching technical specifications and documentation requirements must be met for certification.[1]

The expansion of connectivity solutions for middleware, which as software supports entire product lines of manufacturers, is significantly simplified thanks to the high degree of flexibility and the plug-in approach of zenLAB (see Figure 4).

1 As an experienced software development partner and distributor, infoteam Software AG has had a certified quality management system in accordance with ISO 13485 for many years. It includes its own development process that meets all IEC 62304 requirements. It is designed for agile software development (e.g. Scrum) and includes risk management in accordance with ISO 14971, usability engineering in accordance with IEC 62366-1 as well as templates and processes for developing and marketing software as a class 1 to 3 medical device (or safety class A to C under IEC 62304). It also complies with Standard IEC 82304-1 in relation to standalone software.

3 Laboratory operator: customised middleware with zenLAB®

Today's higher standard software for laboratories (e.g. LIMS) is mostly designed as generic and therefore offers a wide range of functionalities for many different application options. However, most laboratories only use a fraction of the available features for their specific needs – the vast majority of the functions on offer remain unused and are therefore superfluous, detrimental even, in the case of a normatively regulated environment. At the same time, such standard software has hardly any options for adapting to laboratory-specific processes. Customisation is therefore only possible to a very limited extent or with major additional development expense.

This has given rise to the idea of scalable customised middleware, creating a tier between devices and LIMS (see Fig. 1). On the one hand, the middleware flexibly networks devices (ideally via standardised interfaces[2]) with each other, combines measurement and device data in a coherent and structured manner and, on the other hand, provides the relevant data to the LIMS. Among them and depending on requirements, it can, for example, coordinate, prioritise and perform trial orders centrally, analyse data, monitor processes or support electronic documentation. Thanks to integrated user management, multiple users can access middleware applications via different devices according to their user rights.

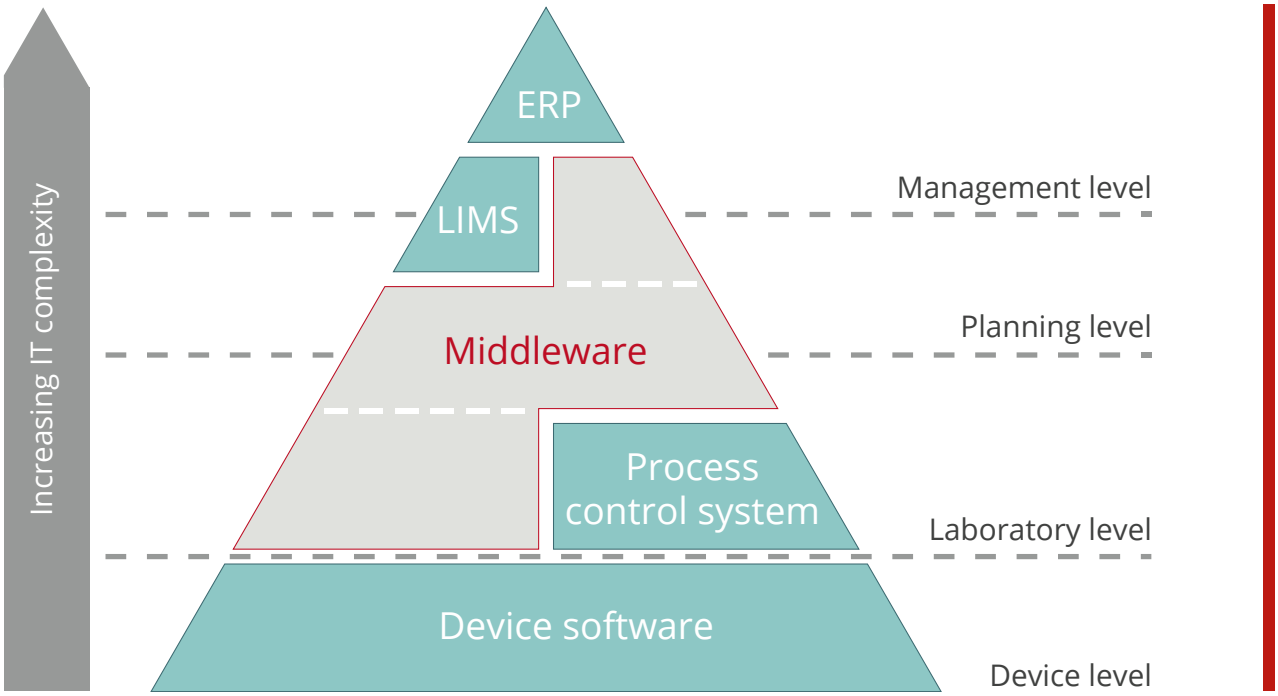

Fig. 1: Scalable customised middleware can be adapted to the particular conditions and requirements of each laboratory and flexibly expanded at any time. zenLAB supplies the necessary standard components.

2 infoteam Software AG has been committed to device and platform independent device standards in the laboratory environment for many years, for example as a member of the industry association, SPECTARIS, for an industry standard based on OPC UA.

Just like connectivity solutions, the development of laboratory-specific middleware solutions always fundamentally builds on the same basic components and only later undergoes customisation. Once more, the zenLAB framework provides exactly these basic components for various applications.

Unlike standard software that imposes a rigid structure on laboratories and users with its top-down approach, middleware solutions based on zenLAB deliberately take a bottom-up approach: The goal is a software solution that foregoes the surplus of unused functionalities and instead focuses on each individual laboratory's individual requirements.

4 The basis of zenLAB®

The fundamental idea of zenLAB is based on three central elements:

1. The ready-made zenLAB software architecture (see Fig. 2) enables devices, databases and higher IT systems such as LIMS to flexibly network (see Sections 4.1, 4.2 and 4.3).

2. The zenLAB database allows for the structured storage of data, whereby in many cases zenLAB supports the integration of preexisting databases (see Section 4.1).

3. The zenLAB plug-in approach ensures that functionalities can be added, expanded and used in zenLAB at any time. Several pre-developed plug-ins are also provided by zenLAB in the form of basic components. They are essential for most IT platforms in the laboratory, which is why new development would be an unnecessary expense (see Section 4.2). Individual and project-specific plug-ins, called modules, meet laboratory-specific requirements. Such modules can be used in the same way as the basic components (see Section 4.3).

The significant advantage of this structure is that zenLAB is highly flexible and can be adapted to almost any pre-existing infrastructure. These include, for example, laboratory equipment, medical devices, interfaces, databases, LIMS and processes. In addition, the framework is highly scalable: Only the plug-ins required become part of the software.

4.1 The software architecture | zenLAB® Essentials

zenLAB Essentials is the central core of zenLAB and includes, among other things, three libraries that are needed for all middleware solutions:

1. Data access layer: interface between zenLAB and the database[3]
2. Logging: logging of all technical processes
3. Localisation: language library for multilingual use

In addition, zenLAB Essentials includes a central host[4], which constitutes the communication interface to the basic components and specific modules. These modules can then also use all the data and functions that zenLAB Essentials, databases, basic components or connected devices and higher IT structures make available (e.g. LIMS).

4.2 The software architecture | zenLAB® basic components

zenLAB has five basic components that can be used flexibly according to existing individual requirements. Above all, in addition to simplified technical administration, this modularity enhances the scalability and flexibility of the framework for the specific application.

3 This is where all the data comes together. For example, in addition to work orders, test parameters and measured values, it also includes provisional results and findings calculated from measurement data or information about users and device configurations. Since zenLAB uses object-relational-mapping (ORM) technology, the user can access existing databases so that no new databases need to be constructed according to predefined structures. For this purpose, zenLAB natively supports popular databases such as Microsoft SQL Server, MySQL and Oracle.
The data model (the definition of how the data is stored in the database and processed) varies to some extent depending on the application. While basic components such as user management are generic, application-specific modules often require adjustments. The data model is therefore defined during the requirements phase in close collaboration with the customer.

4 Put simply, host services coordinate requests from external clients. The host forwards the request for processing and then returns the result back to the client.

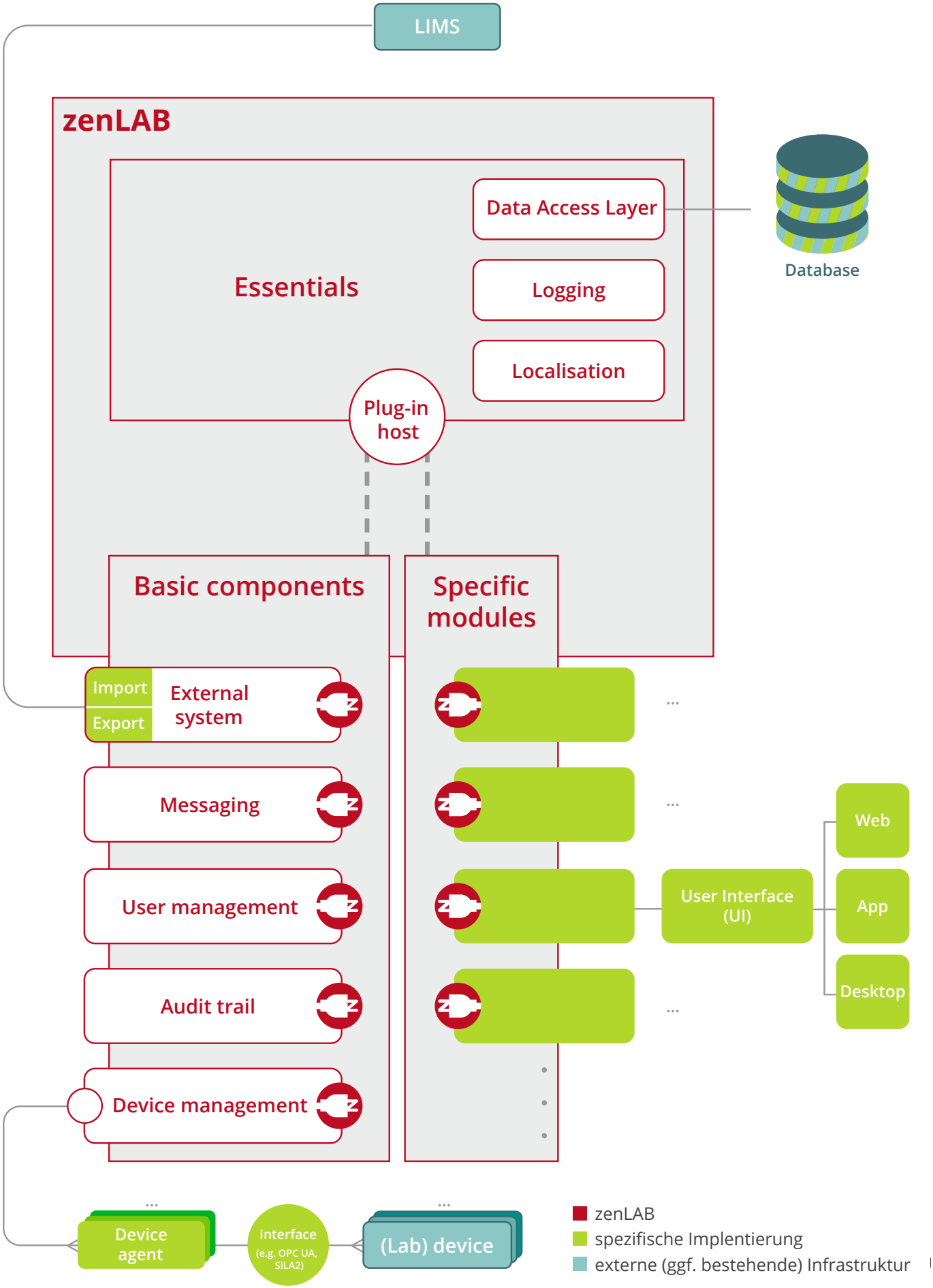

Fig. 2: The zenLAB architecture consists of zenLAB Essentials, the basic components as well as specific modules and, as a middleware and connectivity solution, enables continuous networking between the laboratory and management levels.

1. Messaging: the centralised management of messages via the generic messaging module. It provides a range of messages (for example, when a new reading from a laboratory instrument is available) that other plug-ins can use if required.

2. User management: The integrated user administration offers the option for users with different responsibilities and rights to work in parallel with the system. This is especially relevant if several specific modules are included for different user groups in zenLAB or when a plug-in provides functionalities for different user groups.

3. Device management: the device management module integrates devices into the overall system. For this purpose, it provides a host which can be accessed by specifically developed device agents with completely flexible device interfaces No complex adjustment to zenLAB (or even to an LIMS) is therefore needed for a new device to be integrated but only the creation of a new device agent with an appropriate interface. The same applies to changes to devices already integrated. In this case, adjusting the agent is sufficient.

4. Audit trail: In order to be able to provide evidence in audits that laboratory processes have been carried out according to specifications, the relevant processes must be documented. The digital documentation must ensure, among other things, that the data stored cannot be altered.

5. External system: The connection of existing higher IT systems (e.g. LIMS) for continuous communication from the device to management level is carried out via the external system module. It allows the implementation of common data protocols, such as HL7 for applications in healthcare or AnIML for applications in laboratory automation. For this, only the inputs and outputs of the module need to be adapted to the respective systems.

4.3 Software architecture | specific modules

zenLAB is designed in such a way that modules developed specifically for a device or laboratory can connect to the entire system at any time and, if necessary, can access the whole structure (similar to the basic components).

Such modules are small, independent programs, specially and custom designed for the requirements, processes and conditions of each laboratory, the functionality of which are virtually unlimited. Even open source software or software tools from other manufacturers can be integrated and used if needed. For example, specific modules can perform tasks such as device control, scheduling tests, usage management and LIMS functions.
Each specific module generally has a user interface, which is clearly defined and therefore self-contained. For example, a single module can provide the user with various interfaces (GUIs) based on different technologies and designed for different end devices (desktop GUI, web-based GUI, GUI for mobile devices). Project-specific developments can be based on existing implementations for user interfaces.
The zenLAB architecture makes it possible to run specific modules on different servers and to access the zenLAB plug-in host from there. This is particularly relevant for large and/or growing laboratories as several departments with their own specific zenLAB modules can still use the central zenLAB infrastructure

5 Four stages for Laboratory 4.0 – with zenLAB® as a foundation

Laboratories that today often still have processes that are only integrated and automated to a small extent can generally be expanded to become a continuously networked digital Laboratory 4.0 via four stages, which are usually built on one another. These steps reduce manual work and independently-operating automation processes by gradually networking the data sources available and automating laboratory-specific processes as much as possible.

5.1 Networking and control (*Control*$_1$)

By connecting different laboratory or medical devices to one network and integrating them into the overall system, users can control the devices centrally. At the same time, test and device data are available globally within the system in a uniform and structured way.

Depending on authorisation, users from the laboratory to management level as well as basic components and specific modules can use this data for further processing or documentation. To take the first step, zenLAB supports the:

- integration of devices via standardised or proprietary interfaces (e.g. SiLA, OPC UA.)
- control of different devices (and different manufacturers) across laboratories via central user interfaces
- consolidation and pre-processing of process, measurement and metadata, and the transfer of this data to higher-level IT systems

In addition, laboratory-specific modules are often used at this stage to plan processes.

5.2 Analysis and visualisation of data (*Analyse*$_2$)

The quick access to data as well as the evaluation, consolidation and compressing of data make it possible to create valid bases for decision-making. This is one of the most important requirements when introducing and using software platforms in the laboratory and forms the second stage on the path to Laboratory 4.0. This usually involves laboratory-specific requirements, represented by individually developed modules.
This means that digital, networked laboratory systems can consolidate and standardise available data for analysis processes (and beyond for optimisation processes – see Section 5.4). Various approaches are offered for this purpose depending on the requirements and objectives, ranging from simple statistical techniques to complex AI models. The field of data science and analytics covers the implementation of such methods.[5]

5 See the 'Data Science & Analytics' white paper, infoteam Software AG

With device integration (see *Control*$_1$), as well as the basic components and its architecture, zenLAB facilitates the development of appropriate modules. These include, for example, the:

- visualisation of experiment data
- evaluation of experiment data, including by integrating standard software (design of experiments, LabVIEW, etc.)
- evaluation of process data (e.g. operating data from devices or environmental characteristics)
- identification of hidden relationships as a basis for further optimisation (e.g. data mining)

5.3 Coordination and documentation (*Operate*$_3$)

The documentation of laboratory processes must increasingly meet the requirements of ISO 9001 as laboratory processes more frequently require the cooperation of people and devices. At the same time, data integrity (i.e. the quality and reliability of data) is becoming more relevant in the laboratory, which is why many laboratories are also accredited according to ISO 17025. This affects the digitisation of laboratories because the standards provide supporting evidence that data has been correctly, completely and unchangeably obtained and stored in the laboratory.
Many electronic lab notebooks (ELN) primarily consolidate human-collected data and data collected by devices. However, the generic software products used as ELN struggle to reproduce laboratory-specific functions anywhere near the extent required in Laboratory 4.0.
Building on *Control*$_1$ and *Analyse*$_2$, zenLAB serves as a basis for developing laboratory-specific modules for the documented performance of analyses and experiments. For example:

- digital documentation integrated into individual laboratory processes
- the management and retrieval of standard operating procedures (SOPs)

5.4 Efficiency and reliability (*Optimise*$_4$)

Laboratory managers are often faced with the challenge of achieving optimal efficiency in a laboratory with limited capacities and resources. Thanks to analyses modules (see Section 5.2), digital, networked laboratory systems are for the first time opening up the possibility of using available data for optimising processes all the way to decision automation.
Building on *Control*$_1$, *Analyse*$_2$ and *Operate*$_3$, zenLAB provides the basis for developing and integrating such specific modules. Potential applications are:

- usage optimisation of laboratory equipment and space both through recommendations for action and automated operations
- digital time management for laboratory personnel
- inventory, maintenance scheduling and fleet management of devices both through recommendations for action and automated operations

6 Compliance with standards and guidelines

In many cases, software solutions for laboratories, laboratory equipment or medical products must meet strict the requirements of applicable standards and guidelines. In particular, these include:

- IVDR: In Vitro Diagnostic Regulation (EU)
- MDR: Medical Device Regulation (EU) | medical device requirements, security, etc.
- ISO 13485: Quality management and product safety for medical device manufacturers (EU)
- IEC 62304: Medical device software – software life cycle processes (EU)
- ISO 14971: Risk management for medical devices (EU)
- IEC 62366-1: Usability for medical devices (EU)
- GMP: Good manufacturing practices (EU & USA)
- EU-GMP Guideline Annex 11
- GLP: Good laboratory practices (EU & USA)
- GAMP5: Good automated manufacturing practices (EU & US) | computer system validation
- FDA 21 CFR Part 11: Requirements for the immutability of data (USA)

- FDA 21 CFR Part 820: Quality management for medical device manufacturers → QSR documents (USA)

In many cases, zenLAB supports the development of standard-compliant software platforms and of standard-compliant plug-ins. The zenLAB architecture, basic components and their documentation are based on the leading standards. In addition, a large number of prepared templates for standard-compliant documentation of specific modules is available.

7 Conclusion

Digital, networked devices and laboratories enable an entirely new dimension of control, analysis, operation and optimisation. As a result and despite growing rules and regulations, they increase both the efficiency and the quality of laboratory work. Available resources can be used more efficiently and software solutions can intuitively support routine work. Laboratory workers therefore acquire new freedom to use their time and expertise productively.
Such digital, networked labs require standardised connectivity solutions for devices and customised software solutions for laboratories. Conventional standard software is not designed for such tasks: It comes with numerous functions that are rarely entirely necessary and often cannot be adapted to individual processes. However, the zenLAB® framework provides a ready-made infrastructure in order to develop individual, lean and thus easy-to-maintain middleware on the basis of the available basic components available. Existing laboratory processes are adapted via specially developed modules that can be integrated in zenLAB as plug-ins at any time and provided across laboratories with different user rights.

About infoteam Software Group

infoteam Software Group has been implementing unique software solutions for their customers in the industry, infrastructure, life science and public service markets for almost 40 years. Its core business comprises the partial and total development of control and embedded software, middleware and application software – agile, modern and in line with the latest security requirements. Special areas of expertise include normatively regulated software for use in medical and laboratory equipment (IVDR, MDR, FDA, ISO 13485, IEC 62304, etc.) as well as functionally safe software at the highest safety level (IEC 61508, EN 50128, etc.). The service portfolio is well rounded as a result of many years of experience in data analysis, AI and machine learning.

infoteam Software Group employs more than 300 people and has offices and subsidiaries in Germany, the Czech Republic, Switzerland and China. The parent company, infoteam Software AG, is headquartered in Bubenreuth near Erlangen, Germany.

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