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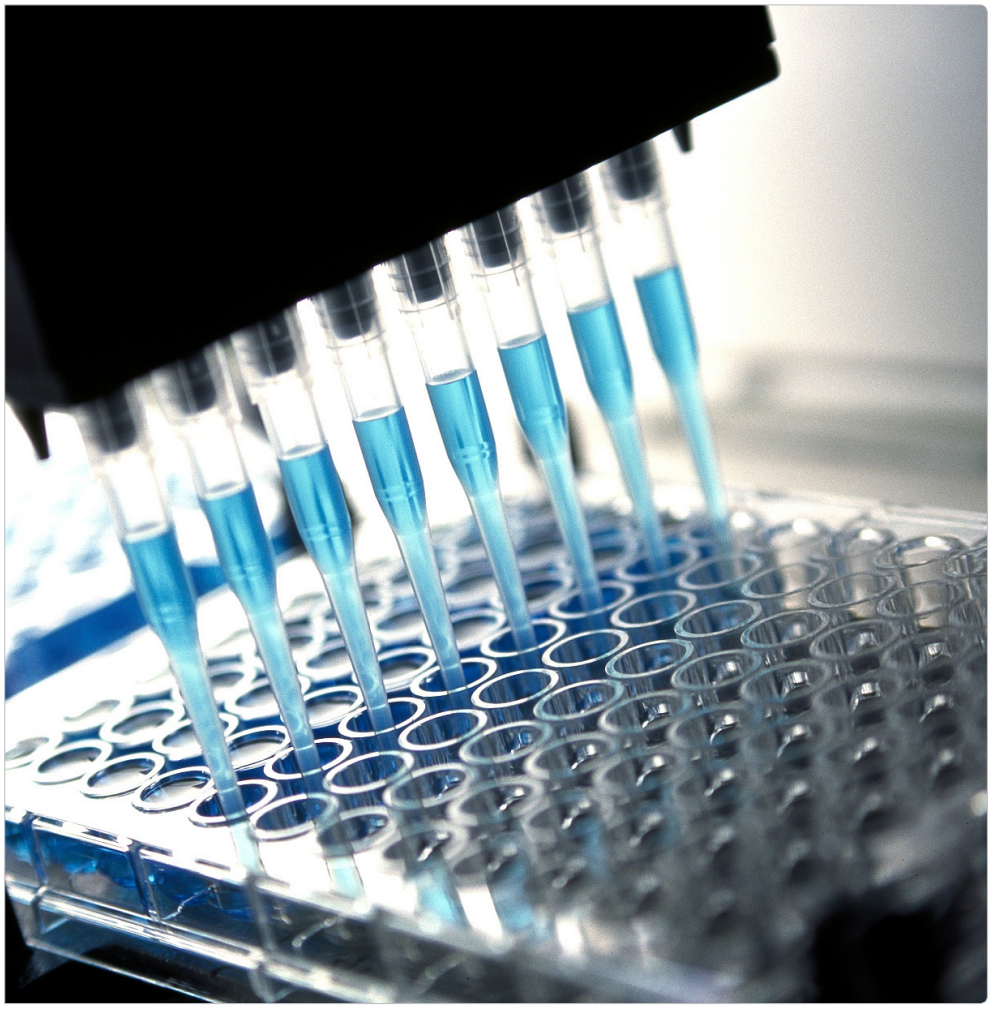
Whitepaper

iLAB software framework for intelligent laboratory automation



iLAB software framework for intelligent laboratory automation

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SUMMARY
- Basis for the development of individual software solutions for the laboratory automation
- Secure database access, logging, tracing, user management, error handling, GUI, mobile users

KEYWORDS
Laboratory automation, standardisation, SiLA, AnIML LIMS, database, DoE, PMS, IVDD, FDA, optimisation, analysis, operation, control, standard-compliant documentation

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1 Introduction and motivation

Laboratory automation – this term now denotes a lot more than it did just a few years ago. New technological developments enable extensive interconnectivity of devices, connection of information and automation of work processes. However, this advancement also increases the pressure on laboratory operators to make optimal use of existing resources. In accordance with the Industry 4.0 concept which is well established in the industrial world, the term Laboratory 4.0 was coined. In the Laboratory 4.0 concept of the future, synergies are used, errors avoided and efficiency increased through digitalisation and interconnectivity. Employees also stand to benefit, as they are no longer required to take care of error-prone routine work and can instead focus on tasks more appropriate to their level of qualification.

This interconnectivity can be achieved through integrated software solutions which connect devices, information, resources and workflows.

2 Customised middleware – tailored solution

The technical implementation of the desired digitalisation and interconnectivity in laboratories requires knowledge of common laboratory processes as well as intelligent concepts in software development. With its decades of experience in regulated environments, laboratory automation and industrial automation, infoteam Software AG was able to implement a concept of customised middleware. As middleware, the iLAB software framework connects laboratory devices with higher-level IT systems and already provides a variety of basic functionalities, such as secure data access and user management. Cost-intensive parallel development of recurring, frequently required functionality is thus avoided. In accordance with this basic structure, additional functionality is redeveloped for each customer and for the specific application.

For you, as a customer, this bottom-up approach means that the ready-made, lean software solution is precisely tailored to your needs in the laboratory and investments will be utilised precisely.

For a specific example and implementation of iLAB as customised middleware in relation to bioprocess development, see the publication “A scalable software framework for data integration in bioprocess development” (Aschoff, Schmid).

3 iLAB software framework – basis

The iLAB software framework addresses the key technical aspects and challenges involved in the implementation of an integrated IT platform for an automated laboratory. iLAB provides an infrastructure which is used for all modules and is based on established technology. This infrastructure contains components which can be used with virtually every IT platform, such as logging (recording of events or messages during operation) or localisation (adaptation into other languages). Furthermore, there are some laboratory-specific functions, such as a mechanism which ensures fail-safe, efficient recording of an audit trail. The iLAB infrastructure also provides a plug-in architecture which ensures that the framework can be scaled and configured to your requirements even after commissioning.

3.1 Architecture

At the heart of the iLAB reference architecture (fig. 1) is the iLAB service host, which combines a central database with business logic components. These components are designed in a modular style. For one, to simplify the technical administration, but in particular, to guarantee the scalability and increased flexibility of the entire framework for the relevant customer project. This modularity is achieved by implementing a plug-in concept. Plug-ins are complete software modules that add specific features to the framework. They are used both at the business logic level and at the user

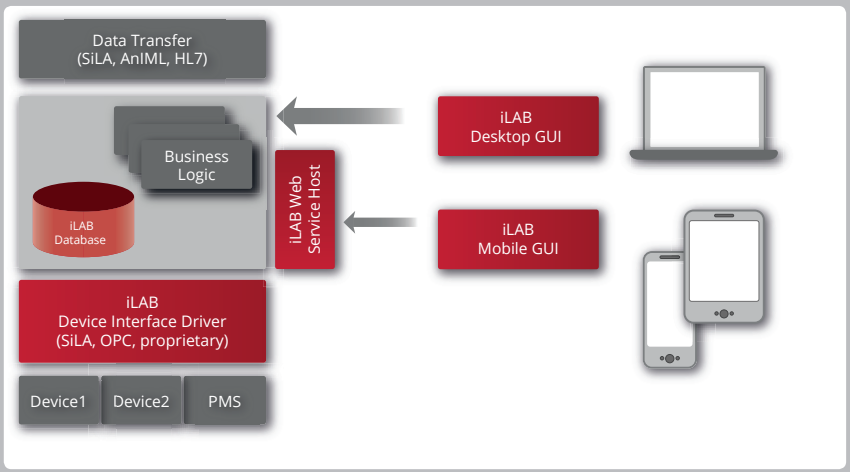

Figure 1:
iLAB reference architecture

interface level. However, the two levels are kept strictly apart. This enables different user interfaces (GUI) based on various different technologies (desktop GUI, web-based GUI, GUI for mobile devices) to be used for the same business logic components.

iLAB enables devices and data to be integrated from laboratory and device level through to higher-level software systems such as LIMS. Communication between iLAB and laboratory devices is carried out via a generic driver model (iLAB Device Interface Driver), where standardised interfaces (SiLA) and proprietary drivers can be integrated.

iLAB and higher-level IT systems are interconnected via a data interface which enables established data protocols to be implemented, such as HL7 for healthcare applications or AnIML for laboratory automation applications.

The underlying concept of the architecture enables iLAB business logic components to be hosted on multiple servers. Consequently, the system is easily scalable in case of rising demands in the laboratory, which require, for example, the integration of significantly more laboratory devices.

3.2 Plug-in concept

The iLAB plug-in concept is largely responsible for the scalability and flexibility of the framework. As the standard components of iLAB, such as user management, audit trail and error handling, were developed in the form of plug-ins, customers can select the specific standard components that they need for their individual solution. Therefore, unnecessary plug-ins are not included in the product, meaning that there is less validation work required. Additional plug-ins can be developed and added efficiently. The handling of multiple experiments as well as the level of detail of the experiments and the related workflows are adapted to the specific organisational structures in the respective laboratory.

Software components relating to user interaction are part of the UI of iLAB and are connected to the business logic in the iLAB server host. The two software parts can also run on different computers. Consequently, the iLAB Service Host may be installed on a central laboratory server, with the user interface on several distributed computers in the laboratory or in external offices. Due to the complete, strict encapsulation of the components, GUI functions or the layout can be adapted (e.g. according to the customer's CI) without any impact on the business logic.

The user interface (UI) components contain predefined interfaces for data visualisation and the configuration of protocols. In addition, there are functions for device control as well as interfaces for distributed control panels and mobile devices. The most important application for internal visualisation is a rapid summary of measurement values over a specific period of time, during processing or after a pass has completed. If functions beyond the scope of the internal display options are required for analysing data or drawing up reports, external software tools integrated via import/ export plug-ins can be used.

3.3 Database

All data is brought together in the iLAB database. In addition to test parameters and measurement values, this also includes values determined from measurement data or information about users or device configuration. As iLAB uses object-relational mapping(ORM) technology, the user is not bound to one stipulated database. In many cases, there already are databases available, so new databases do not need to be built. iLAB currently supports Microsoft SQL Server, MySQL and Oracle databases.

The data model, namely the definition of how the data is saved and processed in the database, may vary depending on the application. While components such as user management are generic, other application-specific components are adapted to the corresponding solution. The data model is defined in close coordination with the customer during the requirements phase.

4 iLAB software framework – modules

Across four modules, the iLAB software framework provides basic functions which are tailored to intelligent laboratory applications and which can be individually expanded (fig. 2).

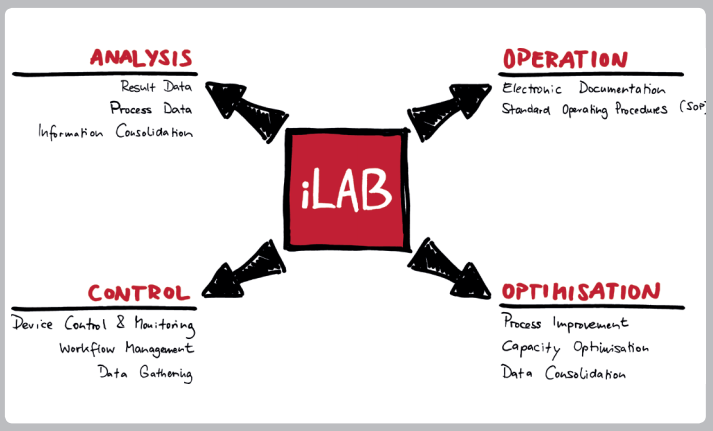

Figure 2:
iLAB modules

4.1 iLAB Control

A typical application for iLAB in laboratories is the integration of various laboratory devices into a network which is controlled centrally via a single user interface. To ensure flexibility in the selection of devices as well as rapid integration and simple replacement of devices in the case of new system configurations, iLAB uses a standardised, manufacturer-independent interface based on the SiLA standard.

iLAB Control helps you to optimise your laboratory applications by:

- Integrating devices via standardised or proprietary interfaces, such as SiLA
- Controlling devices via a standardised user interface
- Consolidation and sharing of process data, measurement data and meta-data with higher-level IT systems

4.2 iLAB Analysis

Rapid access to data as well as evaluation and compression of data in order to draw up bases for decision making are some of the key factors relating to the introduction and use of software systems and platforms in laboratories. iLAB offers various plug-ins for data analysis, including visualisation and monitoring of measurement values during processing, a search engine for comparing data from different tests and identification of trends and patterns in large measurement and process volumes.

Typical applications of iLAB Analysis include:

- Evaluation of experiment data by connecting specific software tools (design of experiments, LabVIEW, etc.)
- Evaluation of process data (e.g. operating data for devices or environmental figures)
- Data mining applications for knowledge discovery of previously unknown connections (e.g. predictive maintenance or meteorological influences on experiments)

4.3 iLAB Optimisation

Laboratory managers want to achieve optimum efficiency with existing, yet limited, laboratory capacity and resources. New approaches for intelligent laboratory management are therefore becoming more important. Modern laboratories increase efficiency through digitalisation and interconnectivity by developing synergies and opening up previously untapped potential.

Below are some of the tasks which the iLAB Optimisation module can handle:

- Analysis of utilisation data for laboratory devices and laboratories space
- Inventory of devices
- Digital time management for laboratory workspaces (reserving, coordinating, etc.)

4.4 iLAB Operation

Due to the growing importance of data integrity in laboratories, as reflected in changing priorities in the case of FDA audits, for example, research laboratories also increasingly need to fulfil the requirements of DIN EN ISO 9001. This influences the documentation of results and demonstration of correctness as well as data integrity.

The iLAB software framework can offer the following functions with the iLAB Operation module:

- Digital documentation (electronic lab notebook – ELN), integrated in the laboratory workflow in accordance with DIN EN ISO 9001
- Management and retrieval of digital operating procedures (SOP)
- Integration of digital time management via iLAB Optimisation
- Integration of laboratory devices via iLAB Control
- Evaluation of experiment data via iLAB Analysis

5 Compliance with guidelines and standards

infoteam Software AG has extensive expertise in laboratory automation and in the development of software for laboratory devices and in-vitro diagnostic (IVD) systems.

To be prepared for use in regulated environments, the iLAB software framework was developed so that all the information and documents required for approval are available in accordance with the following guidelines and documents.

- IEC 62366: Application of usability engineering to medical devices
- IEC 62304: Software life cycle process for medical device software
- IVDD: In vitro diagnostic medical devices directive 98/79/EC
- DIN EN ISO 13485: Quality management and product safety

The basic functions of the iLAB software framework were developed in accordance with the requirements of the following guidelines:

- FDA CFR 21 Part 11
- EU-GMP Guideline Annex 11

The above aspects significantly simplify and speed up the development and approval of systems based on iLAB for IVD and applications in GMP environments.

6 List of references

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7 Glossar

AnIML	Analytical Information Markup Language
CFR	Code of Federal Regulations
CI	Corporate Identity
ELN	Electronic Lab Notebook
FDA	Food and Drug Administration
GMP	Good Manufacturing Practice
GUI	Graphical User Interface
IVD	In-Vitro Diagnostics
LIMS	Laboratory Information Management-System
SiLA	Standardisation in Lab Automation
SQL	Structured Query Language
UI	User Interface

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