

Standardization in Lab Automation

Flexible and rapid system integration through standards for communication and data handling.

www.sila-standard.org

Challenges in Lab Automation

Pharma companies and academic research institutions are under growing pressure to increase the return on their R&D investments. They require flexible automation systems that adapt easily to new applications. Users request to rapidly accommodate innovations provided by instrument suppliers on their systems, regardless of the vendor.

However, due to the lack of compatibility, automation users are restricted in choosing specific instruments. Adapting existing hardware and software to new workflows is difficult and time consuming. As a consequence, only few specialized labs are able to manage complex automation systems.

The SiLA Solution

Designing an integrated system necessarily means making choices. Steps have been taken to allow more modularity, i.e. devices can be swapped into and out of an integrated system with minimal disruption, however this is typically limited to one manufacturer. In order to achieve true "plug-and-play" automation, regardless of integrator, a set of industry wide standards should be adopted. The SiLA (Standards in Laboratory Automation) Consortium exists for this purpose.

A precedent for this is in the SBS (now SLAS) standard for microtiter plates which allowed researchers to choose which plates to use based on utility and price without concern that the plates would be compatible with their instrumentation. SiLA attempts to do the same for device and data interfaces, allowing the researcher to choose solutions based on the best functional fit, without concern as to whether they will work seamlessly in their system.

SiLA Consortium

The SiLA consortium for Standardization in Lab Automation develops and introduces a new interface and data management standard allowing rapid integration of lab automation systems. Leading system manufacturers, software suppliers, system integrators and Pharma/Biotech corporations have joined the SiLA consortium and contribute in different technical work groups with their highly skilled experts.

SiLA is a not-for-profit membership corporation with a global footprint and is open to institutions, corporations and individuals active in the life science lab automation industry. The SiLA consortium continuously extends the scope of its standardization activities and offers professional training, support and certification services to its members.

Since 2011 the SiLA consortium has a representation in the USA to enhance the possibilities of our American members Technical Workgroups (status January 2012)

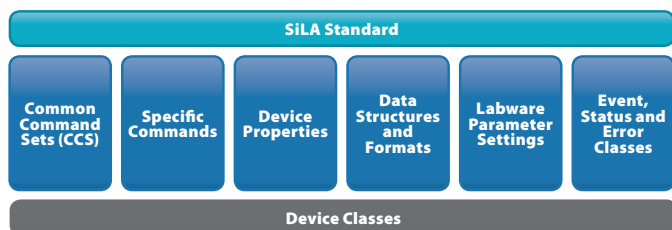
- ▶ General interface specification – maintenance
- ▶ Common command pool for multiple device classes – maintenance
- ▶ Data Capture – maintenance
- ▶ LIMS – planned
- ▶ Enterprise data management – planned
- ▶ Labware specification parameters – maintenance
- ▶ Imaging – planned
- ▶ Remote Service & Monitoring – planned
- ▶ PMS (Process Management System)/Backbone – planned
- ▶ Pipettor – active

Standardization Concept

The SiLA Interface Standard defines a set of generic Device Class Interfaces. These encompass any type of instrument that can be integrated into a larger system. Each Device Class comes with its specific Common Command Set. This is used to communicate with devices and to control them, regardless of their particular make and brand. SiLA also provides guidelines to implement supplier-specific

device commands and parameters, thus enabling unique instrument features.

Additional SiLA standards address labware parameters and result data formats. They facilitate the integration of upstream and downstream tasks into automated processes.



Device Classes

SiLA defines Device Classes encompassing most commonly used device types in the lab automation environment (such as pipettors, readers, centrifuges, cameras, etc.).

Common Command Sets (CCS)

For each Device Class, a common set of commands, as well as event, status, and error classes is defined. All major device functions are programmable through common commands.

Specific Commands

Functions exceeding the Common Command Set can be provided by the device supplier as Specific Commands. They have to comply with the SiLA command definition standard guidelines.

Device Properties

SiLA compliant devices are able to provide information about their device class, configuration, Common Command Set, and their Specific Commands, upon request.

Data Structures and Formats

Devices (e.g. plate readers, microscopes) provide data in standardized file formats and structure.

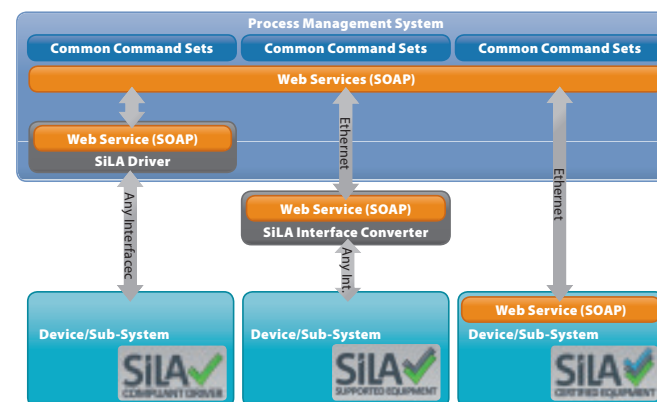
Labware Parameter Settings

Labware specific device setup is supported by standardized and machine readable labware specifications provided by labware manufacturers.

Interface Standard

The SiLA interface standard covers all ISO/OSI levels of the control interface from physical to application layer. By supporting three different integration levels, SiLA provides a unique, standardized interface between lab automation devices/

sub-systems and systems controls. SiLA compliance can be achieved by providing SiLA drivers, interface converters or native, directly embedded SiLA device interfaces.

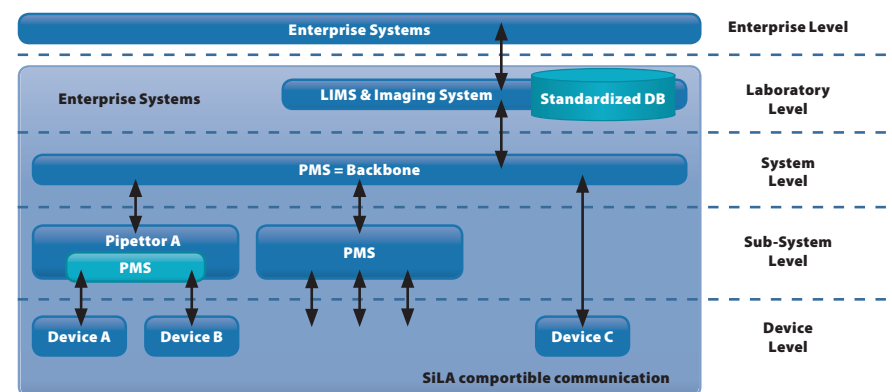


System Standard

SiLA is aiming to standardize data exchange and handling on various levels in the laboratory and from the laboratory towards the enterprise system. Please find in the following list the areas, where SiLA currently have standardization workgroups established:

- ▶ Device Control and Interface Standard: Standardizes Data formats and Telegrams to exchange data between process management systems and devices – maintenance
- ▶ Command Dictionary: Standardizes mandatory and optional command sets for each device class – maintenance
- ▶ Data Capture: Standardizes complex plate reader data types for data exchange – maintenance

- ▶ Labware Specification: Standardizes labware properties for liquid handling plates – maintenance
- ▶ Pipettor: Standardizes common pipettor functionality – active
- ▶ PMS (Process Management System)/Backbone: Standardizes modular function blocks to define higher level application process functionality – planned
- ▶ LIMS: Standardizes harmonized data storage – planned
- ▶ Imaging: Standardizes image data formats and image analysis functionality – planned
- ▶ Enterprise Data Exchange: Integration of Enterprise level system – planned



Data Capture Standard

The SiLA Data Capture Standard allows not only a harmonized data access to the devices but is the basis for further data mining and analysis functionality accessing a standardized database. The Data Capture Standard covers the following main features:

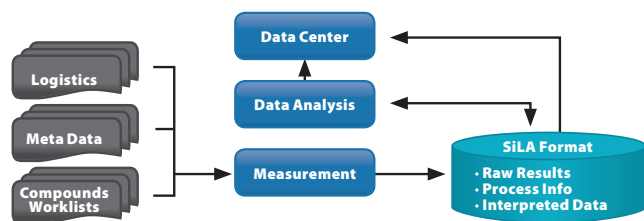
Glossary, Data Dictionary: Basis for standardized Data

Interfaces and Data Formats

Raw Results, Data Format: Base Format XML

Data Integration, Traceability: Definition of Meta Data, Raw Data, Interpreted Data, Logistics Data

Data Capture Workflow: Definition of Data Identification, Data Access, Data Processing, Storage/Archiving



Certification guarantees Compliance

The SiLA standards cover the specifications that make devices exchangeable. But what is a standard without a guarantee, that the product claiming to be compliant actually is? So SiLA is going this extra mile and not only proposes on how to achieve compatibility but also delivers rules and regulations to prove its claims. SiLA not only defines a standard but also delivers the infrastructure where suppliers will get support from an independent validation authority to prove its claims.

- ▶ Independence and impartiality of the test site
- ▶ Technical expertise and adequate space, equipment and test tools
- ▶ The accreditation is valid for three years.

Certification of products

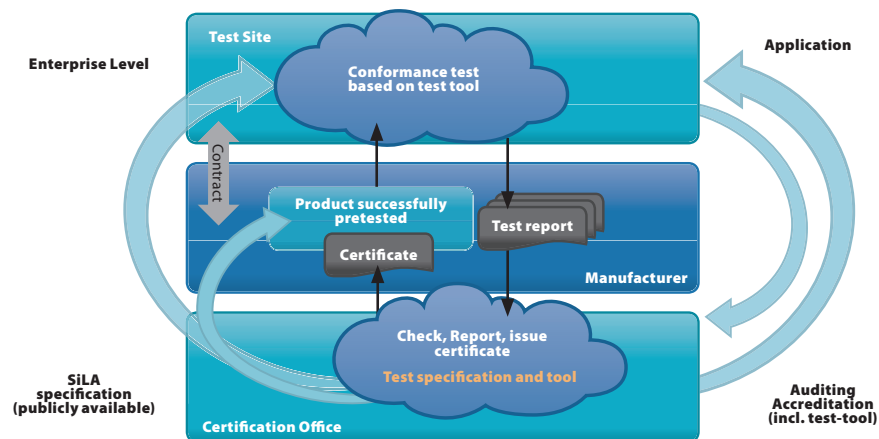
- ▶ SiLA conformance is tested based on test spec using a SiLA test tool.
- ▶ Test results have to be treated as strictly confidential.

Organization of SiLA Certification Office

- ▶ Accreditation of test sites
- ▶ Establishment of a quality management system and test procedures

Certification Costs

- ▶ Costs for test and certification services are determined by the test sites themselves, depending on the tests to be performed.



Benefits using SiLA Standards

Benefits for System Users

- ▶ Comparable data from different laboratories/processes
- ▶ Extended automation and application innovations through standardization
- ▶ Reduced process costs and improved performance
- ▶ Reduced service cost
- ▶ Improved business performance through overall process optimization
- ▶ User based solutions can be easily shared among the community without manufacturer-based restrictions.
- ▶ Integrated systems can be chosen based on functional fit rather than who has the driver you're interested in.
- ▶ New devices can be added to existing systems without the added expense of new driver development.
- ▶ Standardized data interfaces will allow easier implementation into existing LIMS.

Benefits for Integrators

- ▶ Reduced project risks
- ▶ Reduced integration, adaptation and servicing costs
- ▶ Wider choice of devices/sub-systems
- ▶ Fewer driver/device compatibility problems
- ▶ Focussing on innovation and not on redundant driver development

Benefits for Device Suppliers

- ▶ Single interface for multiple integrators
- ▶ Extended market reach through standardization
- ▶ Fast Time to market as system level is already supporting standard drivers
- ▶ Enabling lab automation enterprise network
- ▶ Updated device drivers will already be SiLA compatible and not require re-writing

Services for SiLA Members

Active members can contribute in the definition of the standard and have early access to the work results of all other SiLA workgroups. Therefore an early adoption of the standard in their products can be reached, which qualifies for participation in "Pilot Projects". Networking & Cooperation with other

SiLA Members or even a cooperation in research and proof of concept projects are other benefits a SiLA member can get. The SiLA Consortium offers without limitation the services listed below to its members:

- ▶ Development and Improvement of SiLA Standards
- ▶ Promotion of SiLA standards
- ▶ SiLA Partner Training & Certification
- ▶ Self Certification & Test Processing Tools
- ▶ Guidelines and Templates for SiLA Compliance Assessment
- ▶ Certification of standardized products
- ▶ Promotion of Standard products on the Web
- ▶ Organization of SiLA Conferences
- ▶ Joint SiLA-booth at other Conferences/Exhibitions
- ▶ SiLA Professional Services
- ▶ Technical Support & Consulting
- ▶ Implementation / Integration
- ▶ Validation

How to become a Member

SiLA operates as a not-for-profit-membership organization. SiLA offers different membership models suited to a wide spectrum of interests, needs and involvement possibilities. The SiLA Consortium is open to all integrators, device manufacturers, and Pharma and Biotech organizations. Corporations and organizations interested in signing up for membership are invited to contact us at:

SiLA Consortium
 Laubisrütistrasse 44
 8712 Stäfa
 T +41 44 927 15 15
 F +41 44 927 15 10
 Email: info@silastandard.org
 Web: www.silastandard.org