



March 15, 2020

SPECTARIS e.V.
Werderscher Markt 15 | 10117 Berlin

White paper



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Machine integration following lab workflow: A new standard for the smart laboratory

Goal: Key competitive benefits

The efficient networking of machines, automated systems and processes is the key to securing advantages in an increasingly competitive laboratory market. This applies equally to the users of analytical and laboratory equipment as well as to manufacturers.

According to a study carried out by McKinsey¹, up to 50% of costs can be cut and up to 70% savings achieved in terms of delivery times through digitalisation and automation in quality laboratories. This puts real-time approvals for processes and products within your grasp. Alongside a considerable reduction in the effort needed for documentation and testing through the automatic capture of results, other factors also play a major role. The elimination of human errors, for instance, and reduced variance in test sequences leads not only to improvements in quality but also to greater forward visibility in terms of planning personnel resources, processes and material consumption. One basic prerequisite is the highest possible degree of connectivity across all equipment, automated systems and processes. All this is equally applicable to other industrial and research laboratories in the fields of analytics, biotech and process industries.

The interdisciplinary and cross-company SPECTARIS 'Networked Laboratory Equipment' working group has taken up the challenge of promoting the standardisation of interfaces in laboratories with a view to serving the interests of the industry. The objective of the working group is the creation of a cross-brand open standard which comprehensively takes on board the requirements of various branches, disciplines and business processes, and is sustainable and adaptable to future requirements in the field of digitalisation and automation. The name of the standard is LADS² – Laboratory Agnostic Device Standard.

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¹ McKinsey&Company: "Digitalization, automation, and online testing: The future of pharma quality control"

² LADS is a registered trademark



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Status quo

Current laboratory infrastructures comprise many highly specialised items of apparatus from a variety of manufacturers. Multiple interfaces and data formats aggravate the networking of pieces of equipment and their integration into existing IT infrastructures. This, though, is the most important prerequisite for consistent digitalisation and efficient automation. At the moment, what is lacking is a comprehensive, efficient and robust solution!

Notwithstanding that, partial successes have already been achieved. For example, Ethernet in combination with TCP/IP is increasingly establishing itself as the fundamental communication infrastructure. Standards for data formats such as JCAMP², AnIML and Allotrope are already well advanced. Standards, such as SiLA, specialising in controlling individual pieces of laboratory equipment and addressing less industrialised market sectors, are gradually gaining ground.

However, despite the achievements mentioned, requirements for a cross-brand, industrially viable, comprehensive and future-proof technology have not yet been sufficiently addressed. There is still a lot of catching up to do in order to take full account of today's demands and there is work to do in following up on emerging developments. It does not suffice, for example, to consider the automation of equipment, systems and processes in isolation. Data exchange with existing third-party systems, e.g. ERP, LIMS or control stations, has to be just as much part of the equation as compliance with the increasing number of regulatory stipulations imposed by state institutions. And the administration of sub-systems which increasingly have a reciprocal effect on each other should not be neglected.

This is precisely where the working group sets in. The standard under development is intended to go beyond the provision of a simple, robust and industrially viable protocol for controlling equipment. A holistic approach is adopted by integrating requirements relating to data exchange, by reflecting regulatory demands and by taking on board solutions to administrative issues.

² JCAMP (Joint Committee on Atomic and Molecular Physical Data): The JCAMP format is an international exchange format in the field of spectroscopy.



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Classification of SPECTARIS activities

Particularly in bulk industrial production and in the process industry, OPC UA has won through over recent years to become the worldwide standard. This is reflected in the fact that more than 750 reputable manufacturers subscribe to this standard as well as in the thousands of available OPC UA-enabled products across a broad selection of industries. As a result of its widespread use, OPC UA is well-defined, very highly adaptable, proven in practice and the focus of ongoing further development. This already comprehensively encompasses aspects such as cyber-security, which are only now entering the public consciousness. So the standard, based on the proven OPC-UA protocol suite with its validated built-in security (including end2end encryption), perfectly fulfills today's and tomorrow's cyber security requirements throughout the industry.

Parallel to this, there are also many new standards, many of them highly specialised, which cater with their own concepts to the needs of specific fields of application. SiLA, a standard from the world of lab automation, is just one example. The following figure illustrates the structure of existing OPC UA-based solutions compared with SiLA2 in the ISO-OSI layer model.

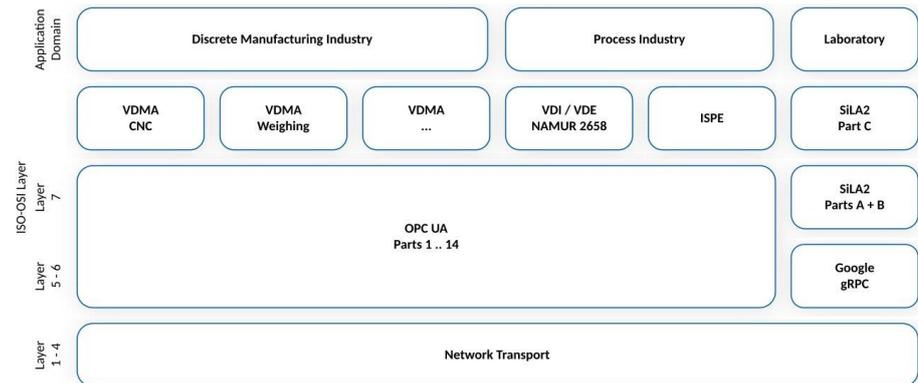


Figure 1: Assignment of existing standardisation environment into the ISO-OSI layer model

The laboratory market is increasingly aligning itself with industrial automation processes and the adopted approaches, thereby profiting from the many decades of experience already gathered in industrial settings. The associated benefits have been collated by the SPECTARIS 'Networked Laboratory Equipment' working group, resulting in the decision to adopt OPC UA as the standard technology for networking equipment, systems and processes in the laboratory. This not only facilitates connectivity in the laboratory but also enables integration with typical industrial infrastructure. This can ensure that future



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solutions integrate more simply and robustly in existing local infrastructure, without having to entertain compromises which might jeopardise automation opportunities.

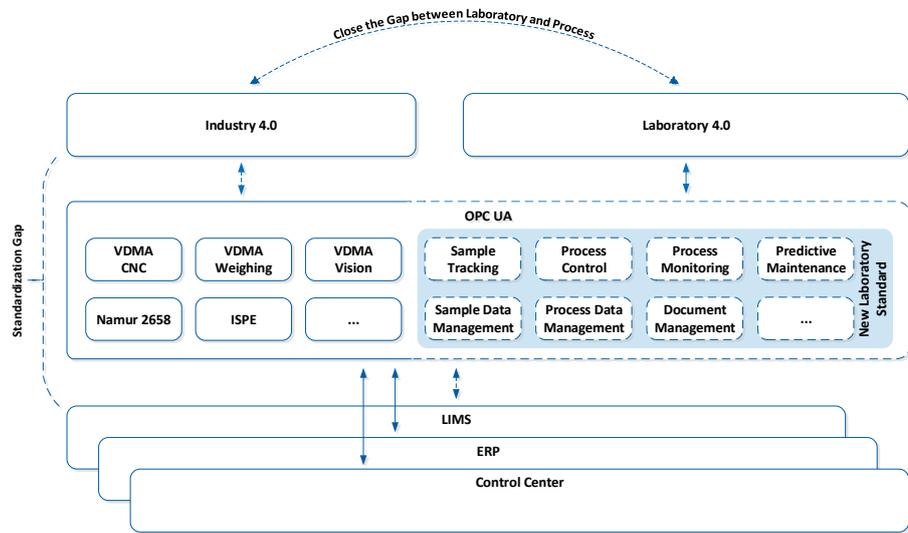


Figure 2: Integration of SPECTARIS activities in the OPC UA environment

OPC UA implementations have existed for many years in a broad range of software stacks from a variety of suppliers with different licence models. Solution to match virtually all requirements, from Open Source through to commercial implementations with appropriate support, are available. And today, there is already one or the other OPC UA specialist in every larger industrial company.

In the first instance, OPC UA only defines the service-oriented skeletal structure and the basic services necessary to run an OPC UA-based application, such as security management, session management or event management. Domain-specific extensions are defined via so-called Companion Specifications. In the initial stage, therefore, the activities of the working group will concentrate on drawing up a Companion Specification-compliant information model tailored to the needs of the laboratory environment. In a second and subsequent stage, this will be registered as an official OPC UA Companion Specification.



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Approach

Its specific properties must take a back seat on the level of machine, system and process automation. An automation concept differentiated according to equipment types (gnostic approach) in a laboratory context involving a large number of device types would invariably result in an unmanageable level of complexity. Innovation cycles, short in comparison to other branches, would demand the equally short-term development of associated standards. Consequently, the working group has opted for a more general (agnostic) attempt at a solution. Independent of the various device types, the same information model, tailored to the automation of laboratory equipment, is always used in all cases. This is illustrated by the following figure.

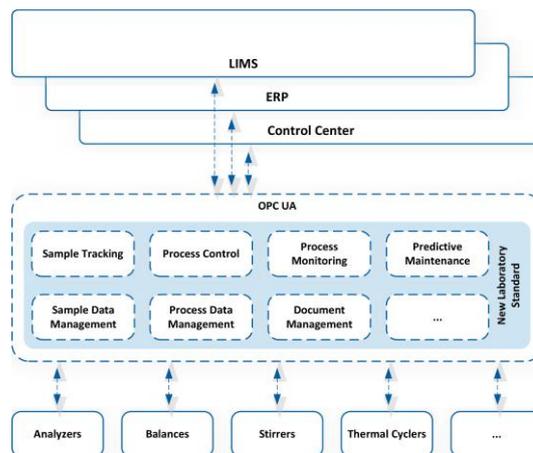


Figure 3: Approach to solving the problem of a standard, model-independent information model

Thanks to its open, flexible and modular structure, OPC UA does not present any limitations to the creation of an information model tailored to the needs of automation as a single OPC UA server is able to provide multiple OPC UA services. If access to product-specific properties is required, the device supplier can also offer further OPC UA services with optional access to these properties. Even in highly specialised applications, this guarantees that there are no restrictions whatsoever limiting access to specific device functions whilst at the same time ensuring that existing automation solutions can be fully exploited.

Our mission: High quality

One important aspect which is key to the successful long-term establishment and acceptance of any future standard is the high quality of the products which subscribe to



March 15, 2020

White paper

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this standard. As a result, the development of the standard will also include the provision of a reference implementation. Via this reference implementation, devices and software components can be certified according to the standard and assessed for conformity. Only the certification of all networked components is able to ensure that the requisite degree of interoperability can be achieved whilst at the same time reducing the effort involved.

Compatibility with other standards

As the various (specific) standards basically address the same or similar problems in integrating devices in the laboratory environment, close contact and a lively exchange of information with the relevant standardisation bodies is important to the working group in order to ensure long-term interoperability and, above all, the scalability of any solutions they arrive at.

Our activities

Completed activities

- Determination of technology and approach to modelling
- Definition of Code of Cooperation
- Onboarding of first users

Current activities

- Creation of a structure for exchanging information with users (User Review Committees)
- Development of taxonomy for branch of industry
- Development of an information model for the industry

Planned activities

- Development of reference implementation
- Establishment of a central test facility and a certification model
- Establishment of a platform for exchanging information with other standardisation bodies
- Publication of the standard and community building



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Schedule

Based on these requirements relating to a suitable standard, the working group compiled a roadmap to promote achieving their objectives. This includes planning for an OPC UA-compliant interface definition and the implementation of a reference. Publication as a registered OPC UA Companion Specification is intended in a subsequent stage but this aspect has not been included at this juncture due to legal framework conditions which still require clarification.

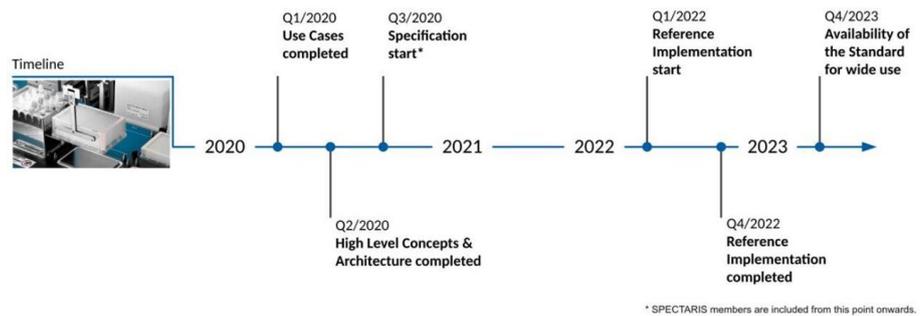


Fig. 4: Schedule for implementation of proposed standard

Administration & opportunities for involvement

The working group offers various forms of involvement and cooperation within the network. These are scalable to cater for the capacities and capabilities of participating companies and range from simply monitoring the activities of the group, to providing feedback through to active cooperation in shaping the standard.

Core Members

Core members represent the body with a focus on the long-term strategic establishment and further development of standards. This includes networking and collaboration with other initiatives as well as the development of reference implementations and the acquisition of new users.

Contributing Members

Contributing members assist with development work by offering their expertise and technical skills. In addition to this, they advise core members with respect to the requirements of their clients.



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Observing Members

Observing members monitor the development of standards and provide feedback on emerging trends in the various markets. They serve as creative minds and sparring partners, but without any obligations.

Review committees

Various review committees ensures a close exchange of views and information between the working group, equipment manufacturers and users. They ensure ongoing reconciliation between the development of standards and their use in practice.

Interested companies are invited to contact Birgit Ladwig. For further information: www.spectaris.de.

Members of the SPECTARIS 'Networked laboratory equipment' working group

SPECTARIS is the high-tech industry's German association and represents more than 400 businesses, mainly SMEs, in the fields of analysis, bio-engineering and laboratory technology, medical technology, consumer optics and photonics. The industry association 'Analysis, bio-engineering and lab technology' brings together around 90 manufacturers whose products are deployed in laboratories in food processing and quality control, environmental technology and material testing as well as in pharmaceutical, chemical and medical laboratories.