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Lab Instrument Integration Architecture: SiLA 2, Allotrope

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Published by IntuitionLabs · 2026-10-18 · lab instrument integration · lab instrument integration architecture · sila 2 · allotrope data format · allotrope simple model · lims instrument integration · opc ua lads · eln instrument data pipeline · laboratory data integration

Original article: <https://intuitionlabs.ai/articles/lab-instrument-integration-sila-2-allotrope-lims>



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Executive Summary

Lab instrument integration is two architecture problems that are often bought as one: controlling instruments (commands, status, error recovery) and making analytical data portable (formats, metadata, vocabularies). This report treats them separately. **SiLA 2** (Standardization in Laboratory Automation) addresses the first problem: it runs over HTTP/2 and serializes payloads with Protocol Buffers (silastandard.com). The **Allotrope Framework** addresses the second: its data format is a family of specifications for the acquisition, exchange, storage and access of analytical data (docs.allotrope.org). Neither replaces LIMS (laboratory information management system), ELN (electronic lab notebook), scheduler or vendor-driver roles.

As of October 2026, the public SiLA 2 documents are still Part A and Part B v1.1, dated 19 March 2022 (silastandard.com), while the `silabase` repository carries a newer tag titled "Official Release 1.2" (gitlab.com). The headline v1.1 change is a server-initiated connection method that lets instruments dial out to cloud or data-center applications (silastandard.com). On the data side, Allotrope's ADF content is licensed exclusively to Foundation members (allotropefoundation.org), whereas the JSON-based Allotrope Simple Model (ASM) is offered under three licenses (allotropefoundation.org).

Evidence on adoption is qualitative and vendor-specific. A peer-reviewed integration study noted that almost no off-the-shelf devices offered SiLA 2 servers at the time of writing (pmc.ncbi.nlm.nih.gov), and a 2026 commentary from ISPE describes the standards ecosystem as growing but fragmented (ispe.org). In a Deloitte survey of 103 biopharma executives, 45% named poor integration between lab systems and instruments as a top obstacle (www.deloitte.com). No public benchmark gives integration hours per instrument, so this report offers a reader-input burden model instead of invented labor figures.

The practical conclusion for brownfield estates is coexistence. Four patterns are compared: file drop with a parser to ASM, vendor SDK adapters behind a gateway, SiLA 2 for control with vendor files for data, and bidirectional SiLA 2 or OPC UA LADS control with standardized data. SiLA 2 and OPC UA LADS are

positioned as complementary in a July 2026 industry letter of intent ([sila-standard.com](https://www.sila-standard.com)). The draft revised EU GMP Annex 11 expects critical data transfers to rely on validated interfaces rather than manual transcription (health.ec.europa.eu), which argues for piloting one interface class at a time. No architecture in this report is "GxP compliant" by itself; compliance depends on how a regulated user validates and operates a specific deployment.

Introduction and Background

A pharma or biotech laboratory rarely has one instrument vendor. A typical estate mixes chromatography data systems (CDS), plate readers, liquid handlers, balances, mass spectrometers, robotic arms and schedulers, bought over fifteen years and connected through serial cables, shared folders, vendor toolkits and, increasingly, web APIs. Architects must decide whether to standardize that estate on a single protocol, put an integration gateway in front of it, rely on vendor APIs and files, and where a data standard such as Allotrope belongs. This report is written for lab-informatics architects, lab-automation leads, R&D platform owners and computer system validation (CSV) and quality assurance (QA) teams who face that decision.

The distinctive framing is the separation of the **control plane** (what tells an instrument to do something and reports what it is doing) from the **data plane** (how results and their context are represented, stored and exchanged). A communication protocol and a data model solve different problems, and a program that buys one may still lack the other.

SiLA itself makes the distinction when it compares itself with ASTM's AnIML (Analytical Information Markup Language): AnIML is a data standard, while SiLA 2 is a communication standard ([sila-standard.com](https://www.sila-standard.com)). The OPC Foundation draws the same line in its release on a joint demonstration with Allotrope: communication standards capture live data generated during experiments and result creation, while data standards document results with their context (opcfoundation.org).

IntuitionLabs is a life-sciences and AI consultancy. It is an adjacent advisor, not a vendor of SiLA 2 servers, gateways, LIMS, ELN or data-format software, and it is not one of the options compared here. Its perspective, offered in prose only, is that integration programs go better when the control question and the data question are scoped, funded and validated separately. Agent-to-device abstraction layers, such as Anthropic's Model Hardware Standard, target devices with programmable interfaces; agent-to-device integration is outside this report's scope ([Anthropic](https://www.anthropic.com)).

Vendor statements are labeled as vendor claims. Facts were checked against pages fetched on 18 October 2026. Support for specific instruments is firmware- and version-specific, so Table 2 is date-stamped and should be revalidated before any purchasing or validation decision.

Control Plane Versus Data Plane: Inventory and Responsibility Map

The first step in a brownfield program is an **instrument-by-interface inventory**, not a protocol choice. For each instrument, record the vendor control interface (SDK, REST API, serial, OPC UA, SiLA 2 server, none), the data export (native binary, vendor database, CSV, XML, ASM or ADF), the host operating system, the

software owner, and the validation status. The current EU GMP Annex 11 expects system descriptions that capture data flows and interfaces to other systems (health.ec.europa.eu), so the inventory doubles as a validation input.

Table 1 below maps each layer of a typical stack to what it controls, what data it carries, and where security and audit responsibilities sit. It is an analytical synthesis of the cited sources, not a vendor-neutral certification.

Layer / interface	Instrument control	Analytical data and metadata	Security and audit	Who owns it
SiLA 2 server on or beside an instrument	Commands (observable or unobservable) and Properties grouped in Features; clients call servers (silastandard.com)	Typed command responses; AnIML can be embedded to carry method and result data (silastandard.com)	Part A requires client-server communication to be secured by encryption (silastandard.com); authentication travels as metadata	Instrument vendor or integrator wrapper
OPC UA LADS server	Hardware View and Functional View with state machines (reference.opcfoundation.org)	A Program Manager organizes templates, runs and result data (reference.opcfoundation.org)	OPC UA security model (outside the quoted pages)	Instrument vendor, IT/OT team
Vendor SDK or API (for example CDS toolkits)	A CDS SDK can start, monitor and manage sequences and run queues (assets.thermofisher.com)	Raw data access, including audit trails (assets.thermofisher.com)	Extensions built by partners or customers are owned by those parties (assets.thermofisher.com)	Instrument software vendor plus extension author
File drop and parser	None (post hoc)	Text or Excel output converted to ASM JSON; proprietary binary formats are not converted by one open-source parser (github.com)	Folder permissions and checksum discipline are local responsibilities	Lab IT or integration team
Allotrope ADF / ASM / AFO	None; a data-format and vocabulary scope	ADF stores graph data structured by the ADM and classified by the AFO (docs.allotrope.org)	An ADF file includes checksums and an audit trail component (docs.allotrope.org)	Data platform owner
LIMS / ELN	Orchestrates work by sample, run or worklist	Record of results in context of samples and experiments	Application roles and audit trails; for example OData access that honors roles and limits visible fields (astrixinc.com)	Business and QA owners

The table shows that no single row covers every column. SiLA 2 and LADS are strong on commands and weak on being the system of record. Allotrope is strong on data semantics and silent on commands. LIMS and ELN hold business context but typically depend on one of the other rows to reach the instrument. The interpretive consequence is that "standardize on X" is only a meaningful sentence once the plane is named.

Key Changes in the Standards Landscape

SiLA 2 Version 1.1: Server-Initiated Connections

The most architecturally significant change in the published specification is the v1.1 addition of a Server-Initiated Connection Method (silastandard.com). In the original model, a SiLA client opens a connection to a server. In v1.1 an instrument can instead connect outward to a client, which Part A says allows applications to be placed in the cloud or in the corporate data center (silastandard.com), with encryption and authentication so that instruments can be firewalled (silastandard.com). Not every implementation has it: the Python reference repository's README states that only client-initiated connections are supported (gitlab.com), and the README points users to a more actively maintained Python implementation (gitlab.com).

Specification Status: v1.1 Documents and a 1.2 Tag

The SiLA standards page still offers its "latest release" download for Parts A and B, both dated 19 March 2022 (silastandard.com). Part C, the Standard Features Index, is release v1.0 dated 30 September 2019 (silastandard.com) and describes itself as an index linking to specific Feature specifications. The machine-readable base repository, `sila_base`, contains the Feature definitions of the standardization group (gitlab.com) and carries a tag titled "Official Release 1.2" from early 2026 (gitlab.com). This research found no corresponding v1.2 PDF of Parts A to C and no release notes explaining the scope of that tag, so readers should confirm the controlling version with the SiLA consortium before writing it into a URS (user requirement specification).

Allotrope: ASM, Quarterly Releases and Certification

Allotrope has shifted emphasis from the HDF5-based ADF toward the text-based ASM. The Foundation describes ASM as a standardized text-based representation of laboratory data that is both human and machine readable (allotropefoundation.org), bidirectionally compatible with Allotrope Data Models (allotropefoundation.org). The public ADF overview page lists ADF v1.5.3 RF (docs.allotrope.org), while the Foundation's September 2026 quarterly update reports new and updated ASM releases, a change in the Merged Ontology Suite (allotropefoundation.org), and an ASM Certification Program announced in April (allotropefoundation.org).

OPC UA LADS and the Complementary-Standards Position

OPC UA LADS (Laboratory and Analytical Device Standard, OPC 30500) is a manufacturer-independent, open standard for analytical and laboratory equipment (reference.opcfoundation.org), developed jointly by the OPC Foundation, SPECTARIS and VDMA (reference.opcfoundation.org). The OPC Foundation's document listing records v1.0.1, dated 18 January 2024, as an editorial update adding the LADS Owners page with no changes to the technical content (opcfoundation.org). The reference site's v1.0.0 listing, dated 30 November 2023 (reference.opcfoundation.org), therefore does not by itself indicate technical specification drift. Allotrope and the LADS group demonstrated mapping Allotrope ontology terms into OPC UA nodesets in a 2025 hackathon (opcfoundation.org).

In July 2026 SiLA published a Letter of Intent on Open Standards for Life Sciences, with a signature round for providers ready to commit to the direction (sila-standard.com). It sets a 2027 target for initial availability of compliant systems (sila-standard.com), asks for support directly on device firmware or embedded controllers, and states that recurring fees are not an option, only a one-time enablement fee (sila-standard.com). It is an advocacy document by interested parties rather than a standards-body harmonization, and it does not itself prove that any given device ships a server.

SiLA 2 Architecture: Clients, Servers, Features and Network Boundaries

Roles. SiLA 2 uses a client/server model that SiLA compares to a web server offering resources to a web browser. The roles are not tied to device types: a LIMS gateway, a scheduler or an orchestration app is typically a client, and an instrument or its wrapper is typically a server.

Transport. The specification runs over HTTP/2 with Protocol Buffers. HTTP/2 is a connection-oriented application-layer protocol (www.rfc-editor.org), Protocol Buffers is a language-neutral, platform-neutral mechanism for serializing structured data (protobuf.dev), and gRPC promotes the use of SSL/TLS (www.grpc.io) with optional certificates for mutual authentication (www.grpc.io). The SiLA mapping part (Part B) requires TLS encryption and the mDNS and DNS-SD discovery mechanisms (sila-standard.com).

Features, Commands and Properties. A Feature is the unit of capability. Part C describes standard Features such as a simulation mode and a controller that can pause, resume or stop a running observable command (sila-standard.com). Part A recommends that servers authenticate clients and lists locking, authorization and optional audit-trail Features. Feature authors can also define named execution errors so that clients can react to a known cause with known recovery steps. This error model is the hook for retry and idempotency tests in the pilot.

Discovery and network boundaries. Part A describes server discovery as intended to enable small, ad-hoc automation setups in labs. DNS-based service discovery adds no new DNS message structure or record types (www.rfc-editor.org), and multicast DNS names ending in .local are link-local (www.rfc-editor.org), which in practice confines discovery to one network segment. Part B notes that wide-area discovery needs a centralized repository (sila-standard.com). Discovery and connectivity are separate: a client can connect to a configured hostname or IP address and port when routing and firewall rules permit access and TLS trust is configured. A centralized registry or DNS service can help locate remote servers; the server-initiated method is useful when the instrument must initiate the connection outward ([SiLA Part B](#), [EOS manual connection](#)). NIST's zero trust model, which moves defenses away from static, network-based perimeters toward users, assets and resources (csrc.nist.gov), and NIST's operational technology security guide (csrc.nist.gov) are sensible reference frames for zoning instrument networks.

Metadata limits. Client metadata, the mechanism that carries items such as lock identifiers and access tokens, is meant for small pieces of data, and transmission might fail for values larger than 1 KB. Large identity assertions should therefore be exchanged for short tokens before calling instruments.

Reference implementations. SiLA's Java reference implementation warns that it might not comply with the latest version of the standard (gitlab.com), and Part A indicates that only the base repository, not the language repositories, forms part of the official standard, so reference code does not carry the standard's status.

Allotrope ADF, ADM and AFO, and What They Do Not Control

The Allotrope Framework has three core components: the Allotrope Data Format (ADF), the Allotrope Data Models (ADM) and the Allotrope Foundation Ontologies (AFO) (docs.allotrope.org). The Foundation's technology page adds ASM as a fourth content family (allotropefoundation.org).

ADF explained. The ADF is described as a family of specifications designed to standardize the acquisition, exchange, storage and access of analytical data (docs.allotrope.org). An ADF file has six components where all data is stored (docs.allotrope.org): data description in RDF (Resource Description Framework), named graphs, a data cube, a data package, checksums and an audit trail. Its quadruple-store API provides a persistence layer for the RDF data model based on HDF5 (docs.allotrope.org), and the packaging purpose is consistency and integrity of data files and metadata (docs.allotrope.org).

ADM and AFO: taxonomies and ontologies. The ADM constrains how ontologies are used by means of the Shapes Constraint Language (SHACL) (docs.allotrope.org). The AFO provides the vocabulary; its core modeled domains are Equipment, Material, Process and Results. For an architect, the AFO is where terms such as "retention time" or "plate reader" get stable identifiers, which is what lets a data platform compare results across vendors.

Access terms. As of October 2026, the Foundation's content page states that ADF content is licensed exclusively to members (allotropefoundation.org). ASM content has three licenses depending on intended usage and membership (allotropefoundation.org); the license for public commercial use permits commercial use but restricts modifications (allotropefoundation.org). AFO content is provided under a Creative Commons Attribution license. Membership has three levels based on organization size and type (allotropefoundation.org). The Full level applies at average annual revenue of \$7.5M USD or more, with a new-member fee of \$20,000 USD and a continuing fee of \$35,000 USD per year; the Associate level is for organizations below \$7.5M, at \$2,000 and \$3,500 respectively (allotropefoundation.org). Membership is open to hardware and software vendors and consulting firms as well as users (allotropefoundation.org). A 2024 review reports the Foundation was reworking its business model to lower the entry barrier for smaller companies (pubmed.ncbi.nlm.nih.gov).

What Allotrope does not control. No Allotrope page fetched for this report states in so many words that the framework excludes instrument control, so the following is an inference from scope statements. ADF is defined around data acquisition, exchange, storage and access, and ASM is defined as a representation of laboratory data. Neither defines commands, method execution or device discovery. In practice, tooling shows the same boundary: an open-source converter targets ASM output (github.com). Before claiming conformity to a published ASM release, verify the selected parser and bundled schema against that release, review the corresponding CHANGE_NOTES.md for documented deviations, and validate the output. Separately, a documented Chromeleon connector sends sequence data from the ELN to the CDS console through a separate integration from ASM output (help.benchling.com). The same connector page documents a scope limit: it can extract only data collected with the UV/VIS detector (help.benchling.com), a reminder that converter coverage must be checked per detector and technique.

Where Allotrope meets control standards. Allotrope's Fall 2025 workshop summary describes a dual-layer architecture in which OPC UA and ASM together bridge lab and manufacturing environments (allotropefoundation.org), and the quarterly update lists a showcase of LADS-compliant OPC UA servers (allotropefoundation.org).

Roles of LIMS, ELN, Schedulers, Gateways and Vendor Drivers

LIMS and ELN. These systems own sample, test and experiment context. They connect to instruments through whichever interface the vendor documents. LabWare, for example, states that its integration platform supports direct, file-based and API-driven integrations using standards such as REST/JSON, MQTT, XML, ASTM and HL7 (www.labware.com). Thermo Fisher's Chromeleon brochure lists SiLA 2 and AnIML bidirectional integration for one third-party LIMS (assets.thermofisher.com), so SiLA 2 LIMS integration exists today in at least one documented CDS-to-LIMS path (a vendor claim as of the 2022 brochure).

Schedulers and orchestrators. Scheduling software coordinates instruments on a deck or line. Biosero says its scheduler integrates with lab software through a RESTful API and database hooks (biosero.com) and offers an extension that records timestamped records of user and system activity for 21 CFR Part 11 contexts (biosero.com). HighRes Biosolutions says its Cellario OS connects with 500+ lab instruments and exposes flexible APIs (highresbio.com), positioning it as middleware for instruments that integrate via files, databases or APIs (highresbio.com). These are vendor claims.

Gateways and wrappers. A gateway translates between a consumer's preferred interface and an instrument's actual one. UniteLabs documents that when an instrument vendor ships a SiLA 2 server it can be discovered and used directly through its platform (docs.unitelabs.io), and lists connectors for liquid handlers from Hamilton, Agilent and Tecan (docs.unitelabs.io). The peer-reviewed study by Porr and colleagues describes the same idea: a central lab server channels all device communication and keeps a database record (pmc.ncbi.nlm.nih.gov).

Vendor drivers and APIs. Waters states that third-party vendors use the Empower Toolkit to create their applications and interfaces (support.waters.com), and Thermo Fisher states that drivers built with its Driver Development Kit are certified by Thermo Fisher (assets.thermofisher.com).

Table 2 below is a date-stamped support matrix of documented interfaces, as of 18 October 2026. Every row is a vendor statement on a vendor page; none was independently tested.

Vendor or product	Documented interface (vendor claim)	Basis and caveat
Tecan FluentControl 3.4	A "SiLA2 Driver 2.0" appears in the software compatibility list (www.tecan.com)	Compatibility list entry only; scope of Features not described on the page
Hamilton LabElite ID Reader	States it has SiLA compliant drivers for LIMS integration (hamiltoncompany.com)	Sample-management accessory; no first-party SiLA statement for liquid handlers was found
UniteLabs connectors	Connectors exposing instruments as SiLA 2 servers, including several liquid handlers (docs.unitelabs.io)	Third-party wrapper, not native firmware

Vendor or product	Documented interface (vendor claim)	Basis and caveat
VACUUBRAND LADS pumps	Says systems that support OPC UA can integrate its products with LADS interface (www.vacuubrand.com)	Blog post, undated; shown at analytica 2026
Thermo Chromeleon CDS	SDK for LIMS, ELN and automation connections (assets.thermofisher.com); third-party applications can use it to trigger sequences (assets.thermofisher.com)	Spec sheet dated 2023, brochure 2022
Waters Empower CDS	Toolkit used by third parties for applications and interfaces (support.waters.com)	Knowledge-base article; Waters' primary Toolkit pages were not retrievable
Agilent OpenLab CDS	ASM export of archived data presented at Allotrope Spring 2026 Connect, with batch conversion of historical datasets (allotropefoundation.org)	Allotrope's summary of a vendor talk; Agilent pages were not retrievable

Table 2 shows the pattern that dominates the evidence: native SiLA 2 servers exist, wrappers fill many gaps, and control-system vendors lean on SDKs and toolkits. The absence of a row for a given vendor means this research did not find a retrievable first-party statement, not that the vendor lacks support. Several vendor pages were blocked or silent, so a buyer must request a written, versioned interface statement per instrument model and firmware.

Four Coexistence Patterns, From File Drop to Bidirectional Control

The patterns below form a progression, but they are not stages every site must complete. Most large estates will run several at once.

- **Pattern 1, file drop with parser to standardized data.** Instruments write exports to a watched folder; a converter produces ASM or a vendor-neutral format; the LIMS or ELN ingests it. This changes nothing about control. It fits closed instruments with no usable API and archives that need harmonizing. An example in the Allotrope Spring 2026 summary is Agilent's export of archived OpenLab data to ASM with delivery to customer-defined destinations (allotropefoundation.org).
- **Pattern 2, vendor SDK adapters behind an integration gateway.** A gateway wraps each vendor API (CDS SDK, REST, OData) and exposes one interface to LIMS, ELN and scheduler. Ownership of the adapters is the key risk, because partner-built extensions are supported by their authors (assets.thermofisher.com).
- **Pattern 3, SiLA 2 for control, vendor files for data.** Orchestration software drives instruments through SiLA 2 Features while result files continue through Pattern 1. This is attractive for liquid handlers and automation cells where command-level control is the pain and the results are already well served by vendor software.
- **Pattern 4, standardized control and standardized data.** Instruments expose SiLA 2 or LADS servers and publish results as ASM, ADF or AnIML. The Letter of Intent proposes hybrid devices that offer a SiLA server for R&D users and an OPC UA server for IT/OT users, and positions LADS as the choice for high-reliability, continuously running automated lines (sila-standard.com). A framework paper (available as an arXiv preprint) makes a similar split, suggesting production-near environments such as QC suit LADS better than SiLA, which is aimed more at R&D (arxiv.org).

Table 3 below is a decision aid. It is an analytical judgment, not a measured comparison.

Pattern	Control path	Data path	Best fit	Main watch-outs
1. File drop and parser	None	Vendor export, converter, ASM or CSV	Closed or legacy instruments; archive harmonization	Binary formats and uncovered techniques are not converted by some open parsers (github.com); file-timing and partial-write handling
2. SDK adapters behind a gateway	Vendor SDK or API	Vendor database or export through the adapter	Mixed CDS estates with active vendor toolkits	Adapter ownership and re-certification at vendor upgrades
3. SiLA 2 control with vendor files	SiLA 2 client to server	Pattern 1	Automation cells, liquid handlers, new purchases	Servers may be wrappers rather than native; version drift between Feature definitions
4. Standardized control and data	SiLA 2 or LADS	ASM, ADF, AnIML	Greenfield suites; sites with leverage over vendors	Vendor availability; the 2027 target in the Letter of Intent is a target, not a guarantee

Table 3 argues for sequencing by risk and leverage: Pattern 1 is reversible and cheap to try, Pattern 2 is the realistic brownfield workhorse, and Patterns 3 and 4 are best applied where purchasing leverage exists. An estate does not need to pick one pattern for all instruments, and mixing patterns across a gateway layer is normal.

Implementation Considerations and Process Changes

Security, Identity and Network Design

Treat each instrument network as an operational technology zone. NIST's guide to operational technology security is the reference for zoning (csrc.nist.gov), and the draft revised Annex 11 (a consultation text, not an adopted one) calls for segmentation and firewalls (health.ec.europa.eu). Decide early whether clients reach instruments (inbound rules) or instruments dial out (server-initiated SiLA 2), and issue certificates accordingly. Plan certificate lifecycle and the mapping from enterprise identity to the short tokens SiLA metadata can carry.

Audit Trails and Records

FDA's data integrity guidance describes ALCOA attributes for records: attributable, legible, contemporaneously recorded, original or a true copy, and accurate (www.fda.gov). It defines an audit trail as a secure, computer-generated, time-stamped record (www.fda.gov) and metadata as the contextual information required to understand data (www.fda.gov). Part 11 requires that record changes not obscure previously recorded information (www.ecfr.gov). The guidance also distinguishes dynamic records, where the format allows interaction such as reprocessing chromatographic data (www.fda.gov), which matters for data-plane design: a converted file is a copy, so the architecture must say which artifact is the record and how the original and its audit trail are retained. PIC/S PI 041-1 states that interfaces between computerised systems present a risk, which supports qualifying each interface (picscheme.org).

Validation and Change Control

Part 11 requires validation of systems to ensure accuracy, reliability and consistent intended performance (www.ecfr.gov). FDA's data integrity guidance says the extent of validation studies should be commensurate with risk (www.fda.gov), consistent with ICH Q9(R1), which says rigor and formality of quality risk management should reflect available knowledge (database.ich.org). Consult your quality unit and regulatory counsel for the applicable obligations; this report does not label any architecture compliant.

Practical change-control rules: version-pin Feature definitions and ASM schemas in the configuration baseline; treat a gateway adapter update as a change to a validated interface; and keep a rollback path for converter versions, since the Allotrope ontology suite itself changes between quarterly releases (allotropefoundation.org).

Offline Recovery and Failure Handling

SiLA 2's observable commands exist for work whose results must not be lost if the connection drops, per Part A's design guidance. The gateway should persist command identifiers and reconcile after reconnect rather than resubmit blindly. For file-based paths, require atomic writes (write to a temporary name, then rename) and checksum comparison.

Pilot Sequence and Acceptance Tests

1. **Inventory and classify.** Complete the instrument-by-interface inventory and tag each instrument with pattern 1 to 4.
2. **Pick one control class and one data format.** For example, start-run and status for one liquid handler, and chromatography results to ASM for one CDS.
3. **Build the lineage diagram** as a text diagram in the validation package: instrument, driver or server, gateway, converter, data platform, LIMS or ELN, archive, with the record-of-truth marked at each hop.
4. **Run the acceptance tests below** in a non-production environment, then repeat in the qualified environment.
5. **Gate on exit criteria** agreed with QA before adding the next class.

The failure and retry tests should include:

- **Duplicate submission.** Send the same start command twice after a simulated timeout; expected result is one run, not two.
- **Mid-run disconnect.** Drop the connection during an observable command; expected result is that the client resumes tracking by identifier and the audit trail shows one continuous run.
- **Partial file.** Truncate an export during write; expected result is rejection and alert, not ingestion.
- **Clock skew.** Offset client and server clocks; expected result is audit-trail entries that remain attributable and orderable.
- **Schema or Feature version drift.** Upgrade the server's Feature version; expected result is a controlled failure or a documented compatibility pass.
- **Credential expiry.** Expire a token mid-sequence; expected result is a safe stop with a defined recovery path.

Data Analysis and Evidence

Quantitative evidence for this topic is thin, and several widely quoted numbers have no public originator. The evidence below is organized by what it can and cannot support.

Survey evidence. The Pistoia Alliance's 2025 Lab of the Future survey drew more than 200 experts in pharma, biotech, software, services, academia and non-profits (pistoiaalliance.org). In it, 80% reported using cloud data platforms in the lab, up from 70% in 2023 (pistoiaalliance.org), ELN adoption rose to 81% from 66% in 2024 (pistoiaalliance.org), data silos remained the top challenge at 57% but had fallen 9% since 2023 (pistoiaalliance.org), and managing data standards and ontologies was the area where help was most needed to make data FAIR (49%) (pistoiaalliance.org). Respondents are self-selected, so figures indicate direction, not prevalence.

Deloitte's 2025 survey of 103 biopharma executives, run by its own Center for Health Solutions with no external sponsor shown on the page, reported that 45% identified poor integration between lab systems and instruments as a top obstacle (www.deloitte.com) and 40% described their labs as digitally siloed (www.deloitte.com). A sample of 103 is small, and the survey is a single consultancy's research.

Ecosystem size. SiLA's FAQ says the organization counts over 1700 members (sila-standard.com), but the page is undated and membership includes a free personal tier, so it is not a count of deployed devices.

Version and date summary.

- **SiLA 2 Parts A and B:** v1.1, 19 March 2022; Part C index v1.0, 30 September 2019.
- **sila_base repository:** tag "Official Release 1.2", early 2026; no matching PDF found.
- **OPC UA LADS (OPC 30500-1):** 1.0.0 dated 30 November 2023 on the OPC reference site; a 1.0.1 patch release on the OPC document page.
- **Allotrope ADF public overview:** v1.5.3 RF; ASM and AFO released quarterly (September 2026 update).
- **Draft revised EU GMP Annex 11:** consultation draft; adopted text not located.

Reader-input integration burden model. Public sources provide no hours-per-instrument benchmarks, so the following model asks the reader to supply inputs and produces counts of things to build, validate and maintain, not labor estimates.

- Let **N** be the number of instruments, **K** the average number of command classes per instrument (for example start, abort, status, load method, retrieve result), **D** the average number of distinct output formats per instrument, **E** the number of environments (development, validation, production, per site), and **C** the number of consuming systems (LIMS, ELN, scheduler, data platform, archive).
- Point-to-point interfaces: roughly $N \times C$ connections, each carrying K command classes and D formats.
- Shared-layer interfaces: N adapters (one per instrument) plus C consumer connections, so $N + C$.
- Items to validate: multiply the chosen count by E, then by K for control and D for data.

(Hypothetical Example) With $N = 40$ instruments, $C = 4$ consumers, $K = 5$, $D = 2$ and $E = 3$: point-to-point implies 160 connections, against 44 for a shared layer; multiplying by E gives 480 versus 132 qualified connections. The example is arithmetic on invented inputs, not a forecast. The model's value is to show where

standardization removes multiplication (consumers) and where it does not (the N adapters still exist, and wrappers still count).

RFP Questions and Lock-In Risk

Put these questions in every instrument or software RFP and require written, versioned answers:

- **Control interface.** Does the instrument ship a native SiLA 2 or OPC UA LADS server, or a wrapper? Which specification version and which Features? Is the server-initiated connection method supported?
- **Data interface.** Which output formats are available, and is ASM, ADF or AnIML export supported for which techniques and detectors?
- **Licensing and fees.** Are interface or enablement fees one-time or recurring? The Letter of Intent proposes one-time enablement fees only, but that is a position of signatories, not a market norm.
- **Change control.** How are interface changes announced, and what regression evidence does the vendor provide?
- **Audit trail.** Which events at the interface are recorded, where, and can they be exported?
- **Exit.** Can all data be exported in a documented, non-proprietary format?

Lock-in appears in three places: proprietary toolkits whose extensions require vendor certification, gateway platforms whose adapters are not portable, and standardized data that sits behind member-only licenses. Mitigations are architectural: keep adapters thin and documented, store original files alongside converted data, and prefer public licensing paths (such as ASM's public options) when portability matters. Standards reduce, but do not eliminate, switching costs.

Implications and Future Directions

Two trends are visible in the 2025 and 2026 sources. First, control and data standards are converging at the interface: the OPC Foundation reports AFO terms mapped into OPC UA nodesets (opcfoundation.org), and Allotrope describes an OPC UA plus ASM architecture. Second, large pharma sponsors are pressing vendors directly, as the Letter of Intent shows, and ISPE's LAPP (Laboratory Automation Plug and Play) series says the framework builds on existing standards such as SiLA and OPC UA (ispe.org).

For brownfield estates, the implication is to invest in the seams: gateways with documented adapters, converters with version control, and a lineage model that marks the record of truth at each hop. A peer-reviewed 2022 study notes that a lack of interface standardization among hardware vendors leads to inflexible device setups and customized, expensive software solutions (portal.fis.tum.de); the open question for 2027 is whether native on-device servers become common enough to shrink the wrapper layer. Open items to monitor are the scope of the SiLA 1.2 tag, the adoption of the revised Annex 11, and ASM certification outcomes. For LADS, the official specification takes precedence over the online reference if they differ ([OPC Foundation](https://opcfoundation.org)). Readers should plan for revalidation as these change.

Frequently Asked Questions (FAQs)

What is the SiLA 2 standard for lab automation? It is a communication standard for lab devices and software, built on HTTP/2 and Protocol Buffers, in which servers expose Features containing Commands and Properties to clients.

How does SiLA 2 LIMS integration work? A LIMS or an orchestration layer acts as a client calling instrument servers, or sits behind a gateway that does. A CDS vendor brochure lists SiLA 2 and AnIML bidirectional integration for one third-party LIMS, as a vendor claim (assets.thermofisher.com). Many LIMS vendors document REST, file or ASTM/HL7 paths instead (see above).

Allotrope Data Format explained: is it just a file format? Partly. ADF is an HDF5-based container with RDF description, a data cube, a data package, checksums and an audit trail, used together with the ADM and AFO. ASM is the text-based JSON alternative.

What are the Allotrope Foundation taxonomies and ontologies? The AFO is the vocabulary suite, covering Equipment, Material, Process and Results. AFO content is available under a Creative Commons Attribution license.

SiLA 2 vs OPC UA for lab devices: which should we choose? The standards body positions them as complementary, and a framework paper suggests LADS suits production-near environments such as QC while SiLA suits R&D. A pragmatic answer is to require whichever a vendor supports natively, and to put a gateway in front of both.

What does a LIMS ELN instrument data pipeline look like? Instrument to driver or server, to gateway or file landing zone, to converter, to data platform and archive, with the LIMS or ELN receiving results and issuing worklists. The lineage diagram in the pilot sequence should show the record of truth at each hop.

How should teams approach lab instrument vendor API integration? Inventory interfaces, prefer documented and supported toolkits, assign adapter ownership, and test failure handling. Vendor statements that extensions are owned by their authors make this an explicit governance decision.

What is a sound laboratory data integration architecture? One that separates control from data, keeps original records, versions every schema and adapter, and documents interfaces for validation.

Conclusion

Lab instrument integration architecture is best approached as two decisions. For the control plane, SiLA 2 and OPC UA LADS are open, complementary options whose native availability in instruments is still uneven, which is why wrappers and gateways remain common. For the data plane, the Allotrope Framework provides data formats, models and ontologies, with ASM lowering the entry barrier, but its access terms differ by component and it does not command instruments.

Brownfield estates should inventory interfaces, choose patterns by instrument, and pilot one control class and one data format at a time against explicit failure tests. Regulatory texts such as Part 11, Annex 11 (current and draft) and PIC/S guidance point to validated interfaces, retained records and risk-based assurance, but none of them certifies an architecture; each deployment must be validated by its operator with its quality unit.

Source links

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