Biologics Quality Control Automation Ecosystems

David Wolton

Chair - Laboratory Automation Plug and Play interest group

Importance of Robot compatible equipment and consumables

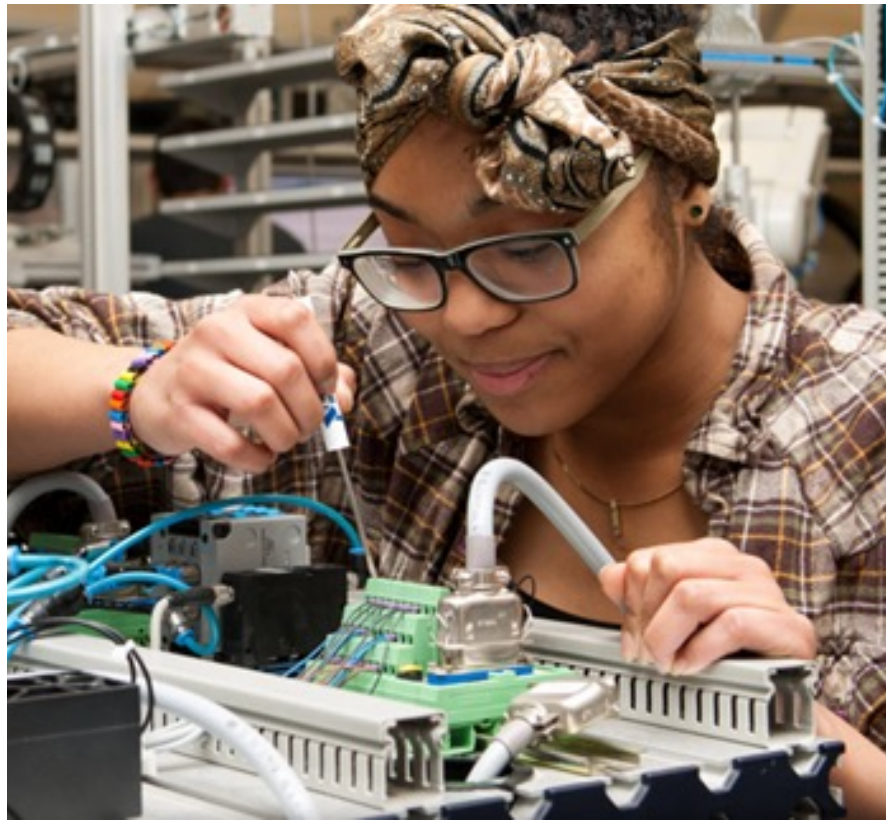
Robot Friendly

- Focus needs to be given to the design of robot compatible equipment and consumables.

"It is frustrating when you see we are going from no standards and everyone doing their own thing, to not the one standard, but a number of standards and confusion and that is unfortunate." Patrick Courtney

Cryovials & rack

Importance of the right skills in the Analytical Development Department.



- Roles and responsibilities need to change in the Pharma industry

"From a QC perspective, automated ecosystems do need to be delivered by those developing the assays"
Jim Brooks

Importance of automated storage systems for the ROI of Mobile robots

Automated storage

- This avoids robots waiting for humans, or humans waiting for robots

The shift from `*Integration companies*` to companies that `*sell products*`.

- Waters is selling the AA+ in significant quantities, what have they done right?
  - *Arm plus Integration, 150-200K (custom)*
  - *AA+, 40-70K (product)*
  - *'Turtle' mobile robot, 40-100K (product)*
  - *Mobile manipulator, 120-300K (custom)*

Pippetting Robot

What is a Quality Control automation Ecosystem?

PharmNXT

Sample transfer and sample reception are being targeted.

PharmNXT

24/7 assays are possible.

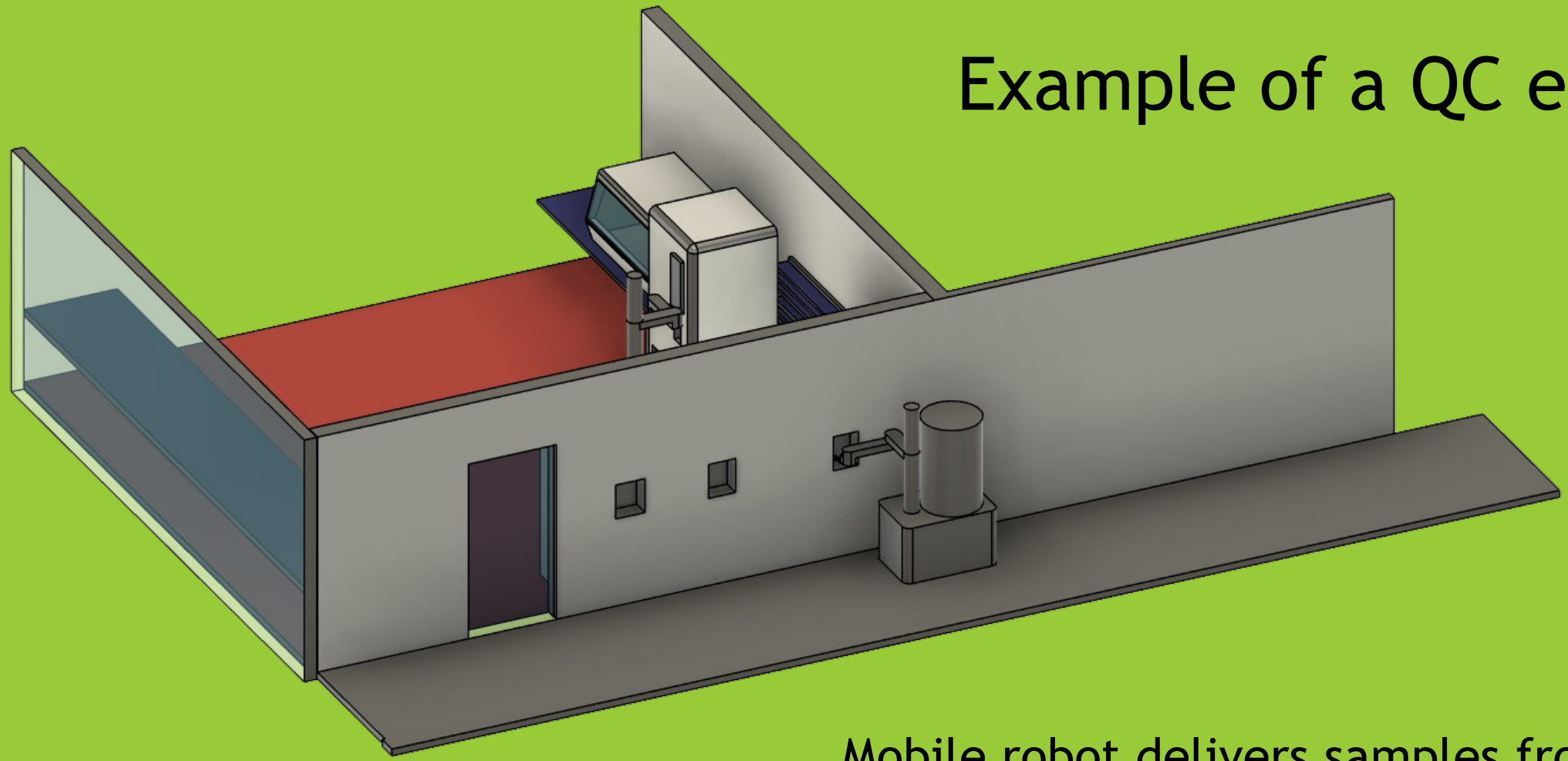
PharmNXT

60K

Cost effective plug and play robotics becoming available.

“What we need is integration across a standard framework, you know, work towards an environment where there is interoperability between components” Jim Brooks

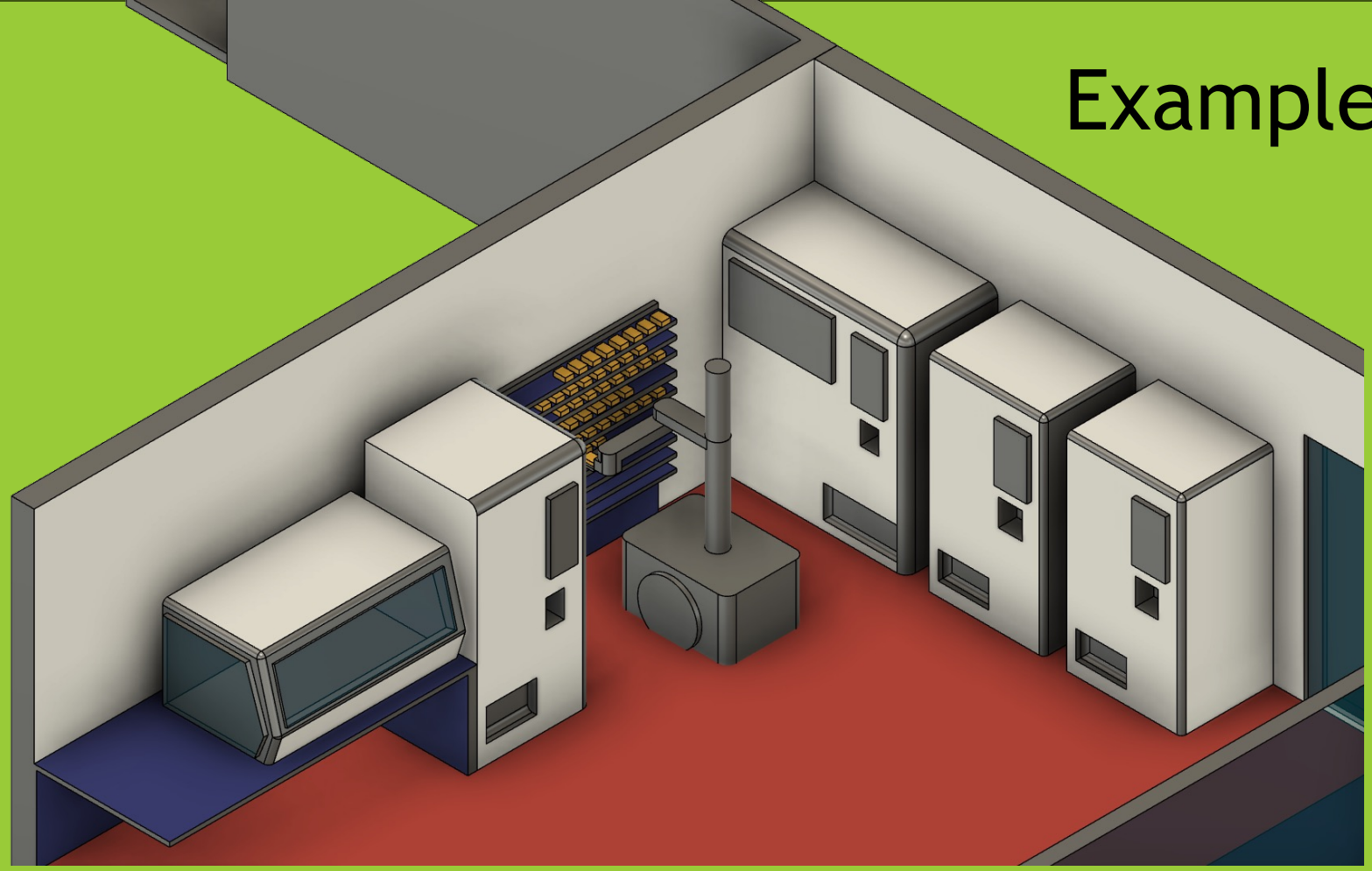
Example of a QC ecosystem



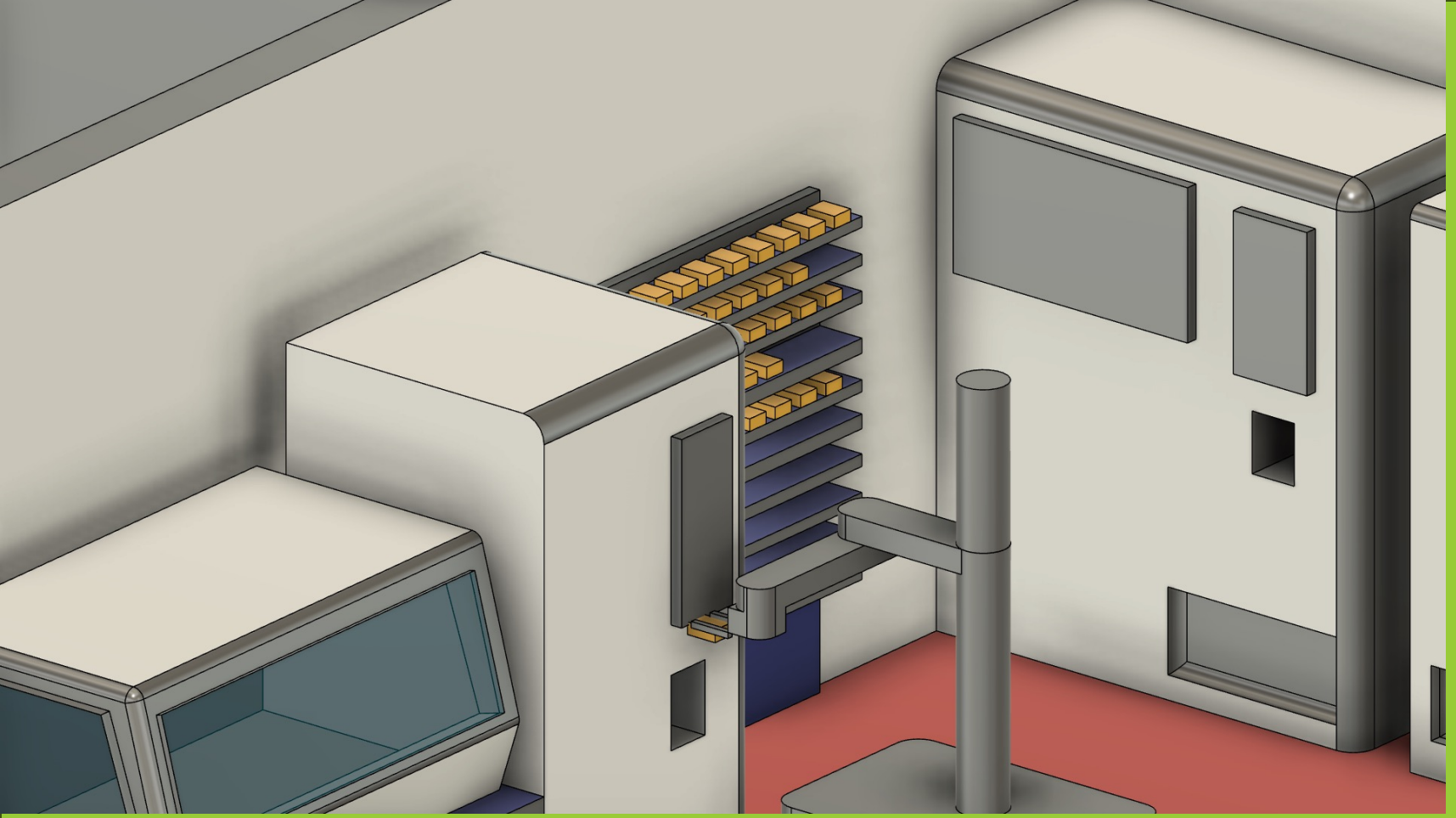
Mobile robot delivers samples from the production area to the QC lab through a hatch in the wall, directly to the automated storage.

“We need more (mature) conversations between the technology providers and the end users regarding specific use cases. .” Patrick Courtney

Example of a QC ecosystem



The mobile robot inside the lab can transport the consumables, reagents and samples around the lab.



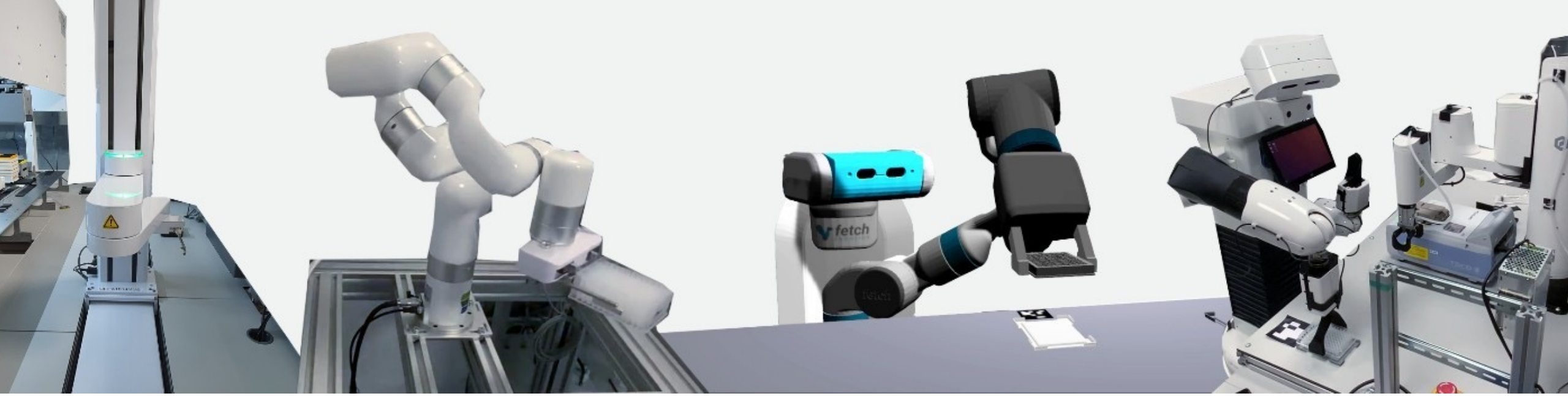
Example of a QC ecosystem

The mobile robot loads the reagents, consumables and samples into the integrated analytical device.

*"Where you see progress is where people are taking on **extra responsibility** outside their roles to embrace innovation.*
To move the industry forward as a whole there needs to be the right resources within those departments" Jim Brooks

How can Biopharma leaders help accelerate development of QC automation ecosystems?

- Roles
  - Head of automation covering both Research and Development e.g. Head of Analytical Development automation role
  - Skilled Mechatronics engineers and automation experts in Analytical Development and Research labs.
- Collaborations
  - Bring together equipment vendors, integrators and end users to standardize interfaces between robots/devices and equipment.
  - Bring together suppliers of consumables to standardise robot friendly containers.
  - Get Standards organisations and industry organisations on board for globally harmonised solutions.
- Development
  - We need the ability to develop equipment with the suppliers that will easily integrate into the ecosystems.



The Laboratory Automation Plug & Play (LAPP) Initiative

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Biologics Operations Consultant

Numeriq

SiLA Rapid Integration

ÓBUDAI EGYETEM
ÓBUDA UNIVERSITY

Future Labs Live, Basel, 27.JUN.2024

Motivation

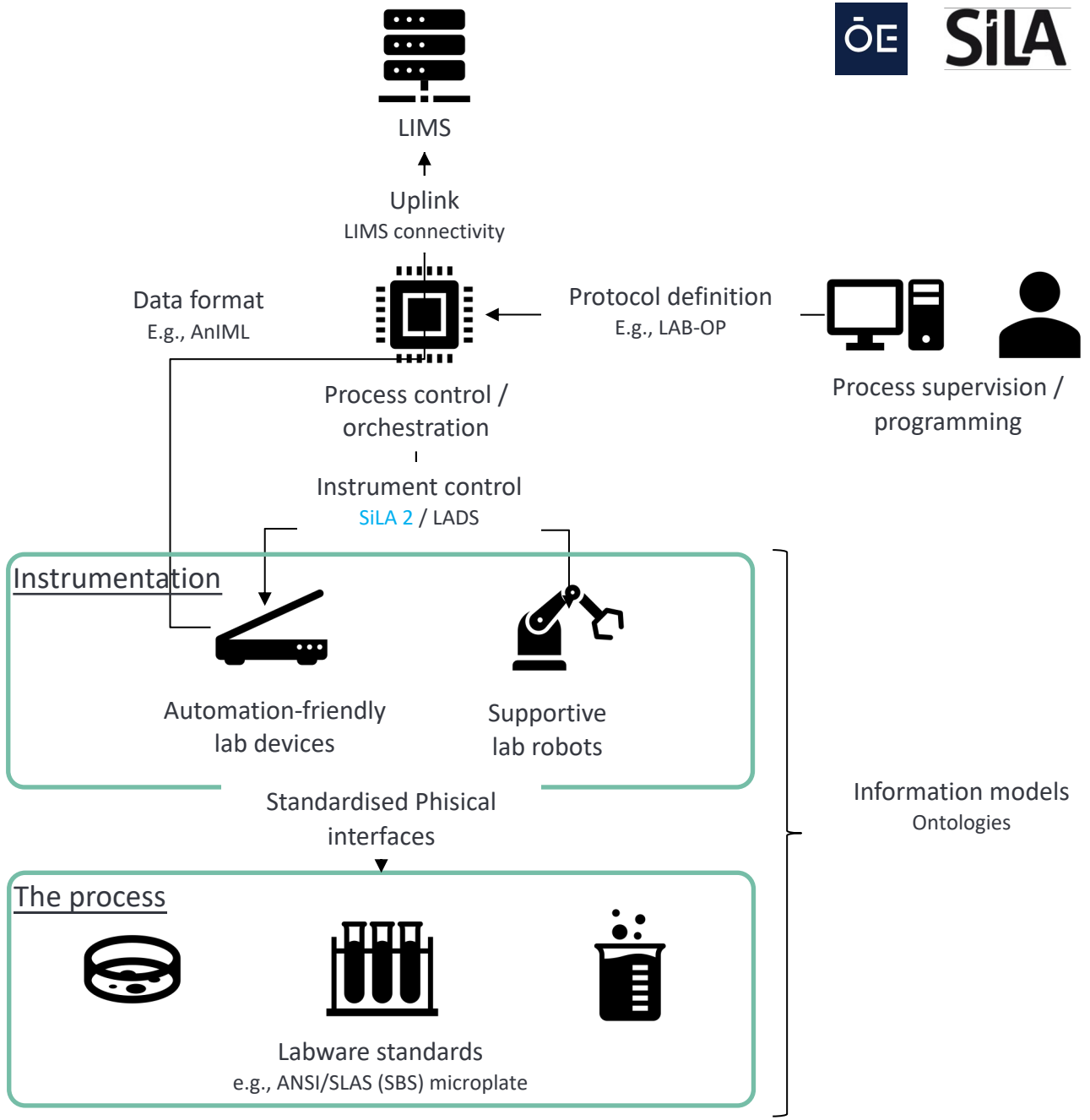
Motivation

Problem statement

- Lab automation systems are becoming increasingly **complex**
- The present-day landscape in terms of system architecture and interoperability is **heterogeneous**
- This poses a **barrier** for implementing **integrated systems**

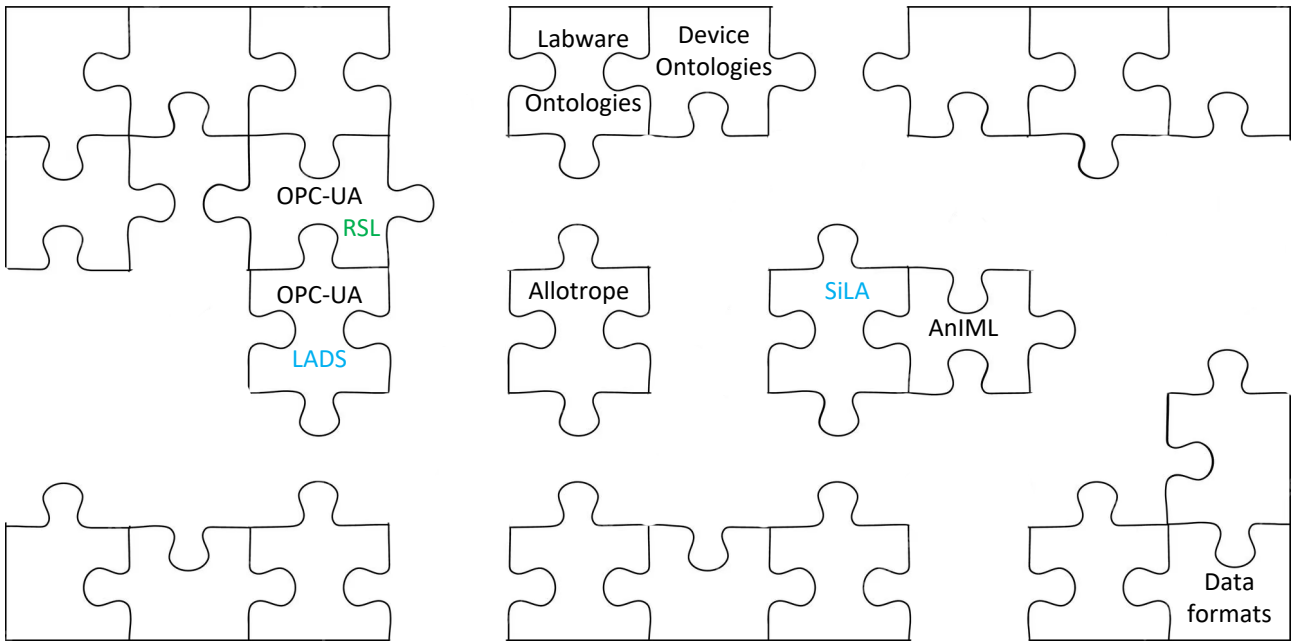
Vision

- Create a holistic and agnostic reference architecture model for the whole vertical of lab automation systems
- Outline the canonical layers and components in the integrated system
- Standardize the communication between the components
- Create semantic descriptions of capabilities on different granularity levels
- Bind it with a workflow representation framework that enables scalability and transferability between labs
- Create ontologies to represent information in a suitable fashion for advanced control on all levels

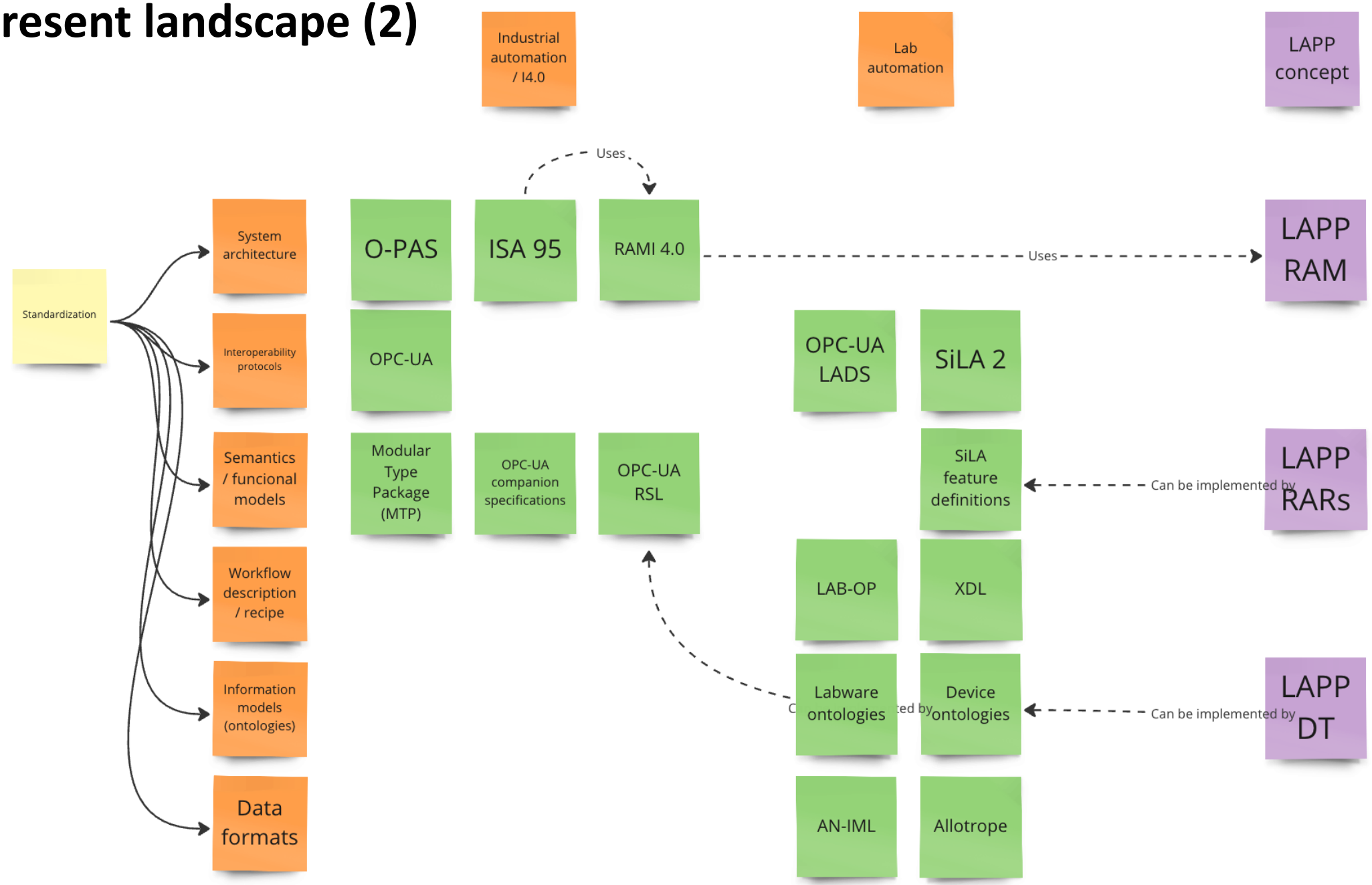


Present landscape (1)

- Building blocks for different aspects of the standardized architecture are alredy being worked on
- Partly overlapping/compeding endeavors



Present landscape (2)



The LAPP framework

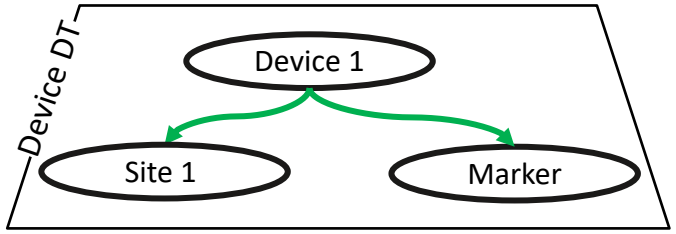
Layers and elements of the control architecture

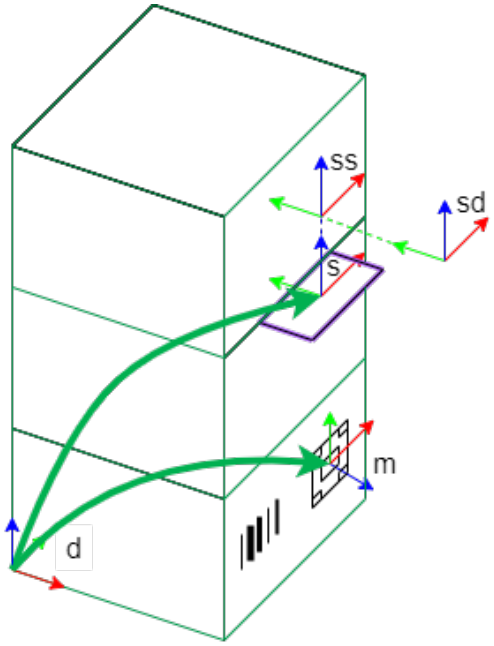
Level nr	Level name	Layers of the control architecture
7	Service	**Lab management** Laboratory Information Management System (LIMS), Electronic Lab Notebook (ELN)
6	Procedure (Experiment / assay)	**Automation scheduler** Laboratory Execution System (LES)
5	Task	**Device-level control** Dedicated PC
4	Subtask	
3	Motion sequence	
2	Motion primitive	**Embedded controller** Microcontroller or Programmable Logic Controller (PLC)
1	Actuator primitive	

Digital twin framework for manipulator robots

Device ontologies

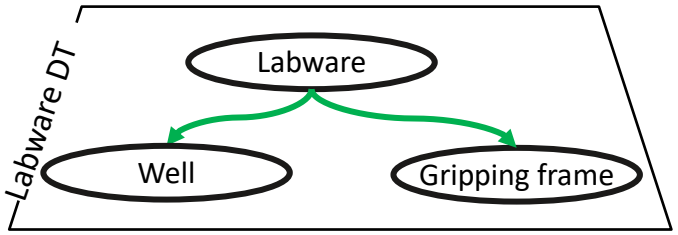
- Implementation of the LAPP Digital Twin (DT)
- Site and marker positions

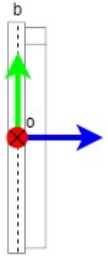


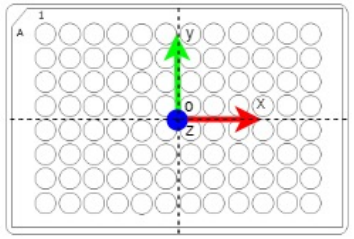


Labware ontologies

- Dimensions and gripping properties
- Well positions and properties
- Material properties

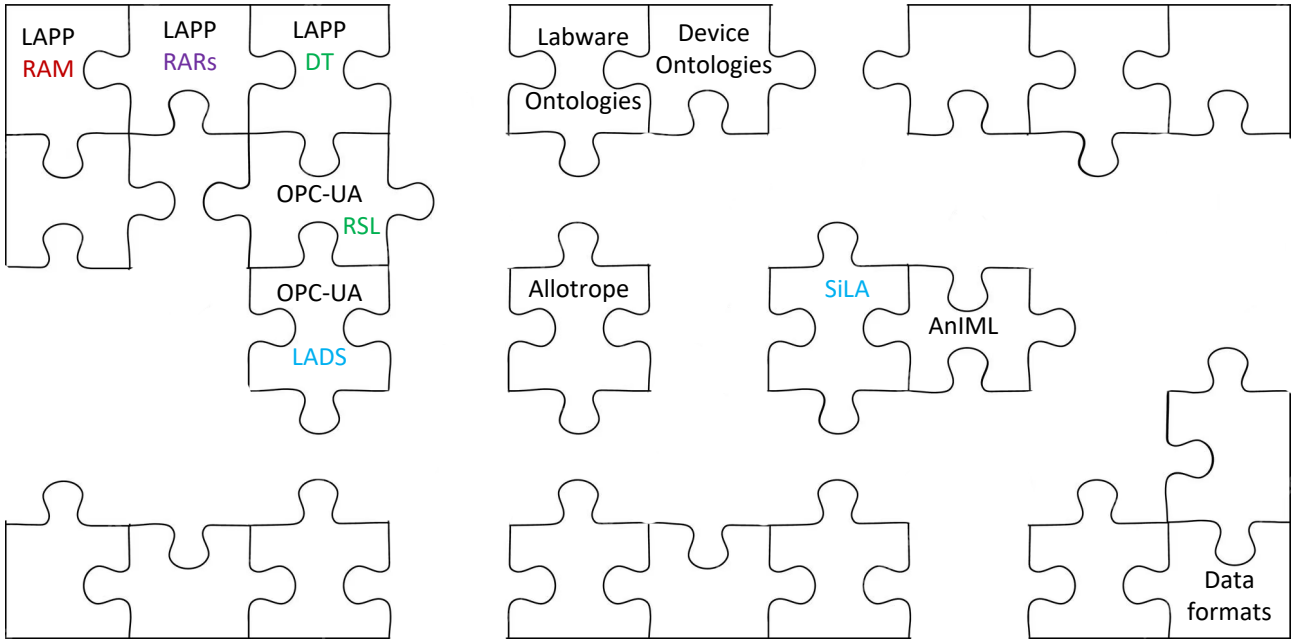






Mission

- Start from bottom-up **and** from top-down in parallel
- Create a high-level abstract and conceptual blueprint/guide document for lab integration
- Work on the building blocks, such as interoperability protocols and their domain-specific semantic descriptions (e.g., supportive robotics)
- Build the edge of the puzzle and in parallel islands around characteristic features



Roadmap

- Socialize and get feedback at conferences
  - Future Labs Live, Basel – 26-27.JUN.2024 (Ádám & Dave)
  - Future Labs Live, Philadelphia – 30-31.OCT.2024 (Eugene)
  - ISPE Pharma 4.0 - 10 - 11 Dec – Rome, Italy and Virtual
- Stakeholder management
- Series of Interviews
  - Bioprocess Online
- Whitepaper / guide document
  - Overview on present landscape around lab automation standardization
  - Identifying the gaps and missing interfaces
  - Proposing an over-arching high-level conceptual framework, based on RAMI 4.0 and the LAPP concept
- Shared User Requirement Specification to enforce adaptation by solution providers
  - Requiring the use of open, documented standards (e.g., SiLA or LADS)
- Support technical initiatives
- Facilitate a progressive implementation/roll-out lifecycle
  - Reference implementations (hackathons)
  - PoC projects (universities & research institutes)
  - Pilot projects (solution providers and users)

Who is involved?

Name	Company	Title	Role in initiative
David Wolton	Numeriq	Biologics Operations Consultant	Lead Steering Committee Subject Matter Expert (SME)
Eugene Tung	Merck	Executive Director of Manufacturing IT	SME, Presenter
Kurt In Albon	Lonza	Global Head of Digital Architecture Quality (DAQ)	SME
Miguel Alvarino Gil	Lonza	Quality Innovation Manager	SME
Christian Stirnimann	Roche	pRED Lab Automation Partner	SME
Tom Kissling	Roche	pRED Lab Automation Partner	SME
Ian Harley	Alexion (AZ)	Senior Manager IT Quality	SME
Sara Cesar	Novartis	Global QC and AS&T Head and Quality Lab Services Head	SME
Ádám Wolf	Takeda	Pharm Sci Robotics Program Lead	Lead Manuscript Subgroup SME, Presenter

Public LAPP project website

https://wlfdm.github.io/LAPP/