ISPE Connecting Pharmaceutical Knowledge

OPC DAY FINLAND 2021 VIRTUAL EVENT 16.11.2021

"ISPE Pharma 4.0"

Plug and Produce

Presented by

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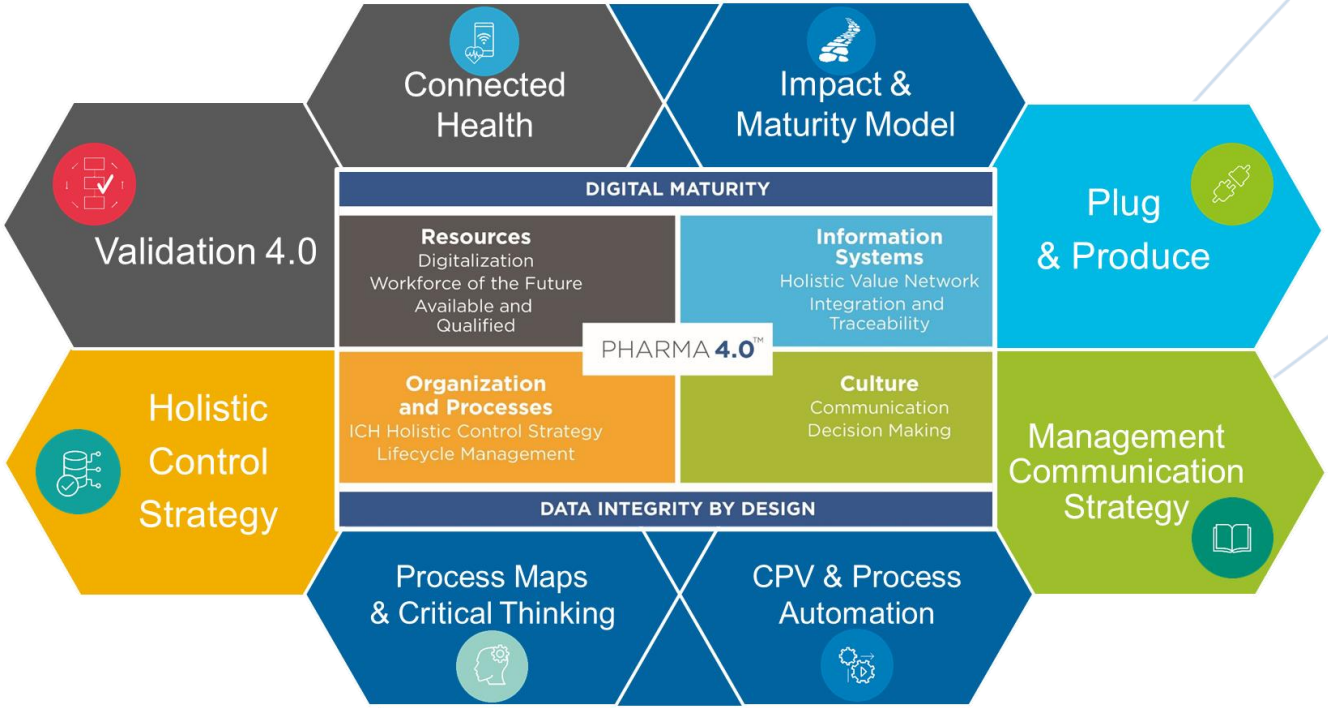
AGENDA

- Introduction Pharma 4.0 and “Plug & Produce”
- Three Big Questions?
- Vision Smart Factory – “Plug & Produce”
- Corner Stones
- ISPE Plug & Produce Workstream 1 “Connectivity”

Introduction Pharma 4.0 and “Plug & Produce”

ISPE’s Pharma 4.0 Special Interest Group (SIG)



ISPE Pharma 4.0 “Plug and Produce”
Three Big Questions

How do we translate the business needs into the digital reality of Pharma 4.0?

What is needed for the integration of OT and IT?

How to approach Pharma 4.0 “Plug and Produce” in practice?

OT = Operational Technology
IT = Information Technology

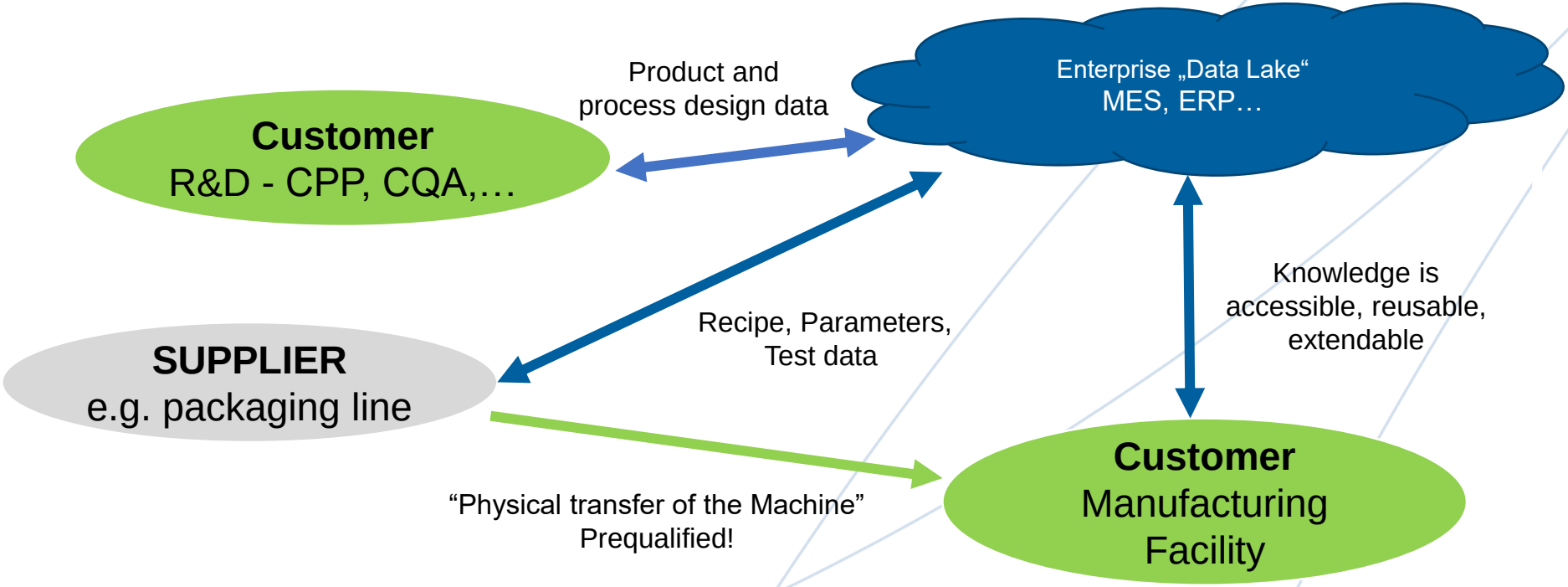
Vision Smart Factory – “Plug & Produce”

Easy - Connect like a printer to an office network!

Standardization of equipment data models pre-requisite for Plug and Produce!

“Plug-In” framework for “Pre-Qualified” Machines / Equipments

Reduce engineering, testing, validation…

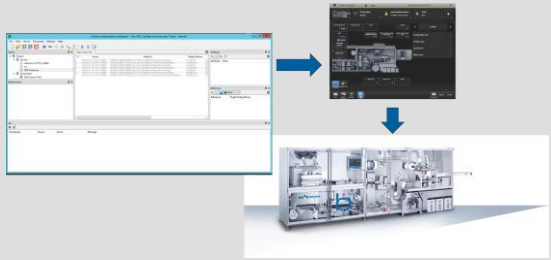


Pharma 4.0 – Plug & Produce Journey
ISPE Proof of Concept (PoCs) – Prototype – Pilots

Connectivity

Service and Transaction

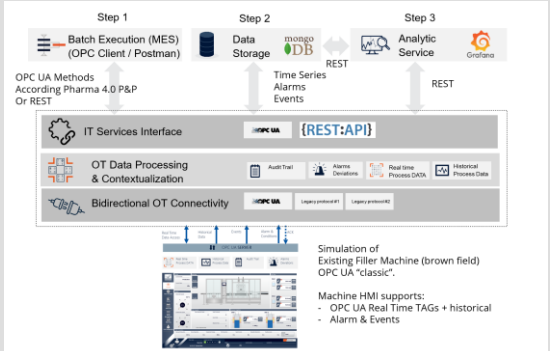
(WS1)



Micro – Service

based integration between machines and IT systems

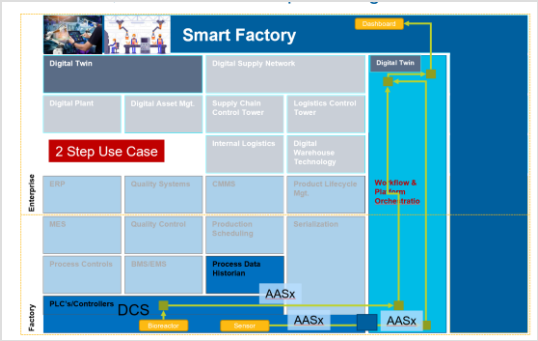
(WS 2)



Use Case Creation and new concept development

Admin Shell Concept and Digital Twin

(WS 3)

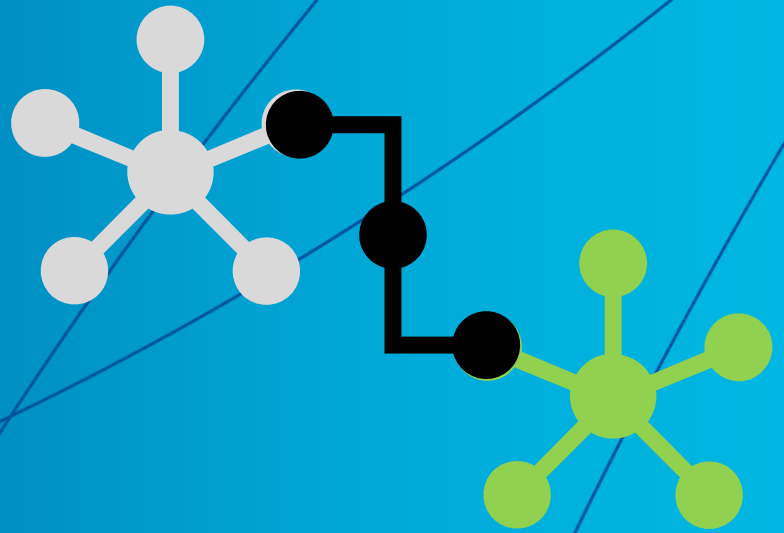


Corner stones Connectivity

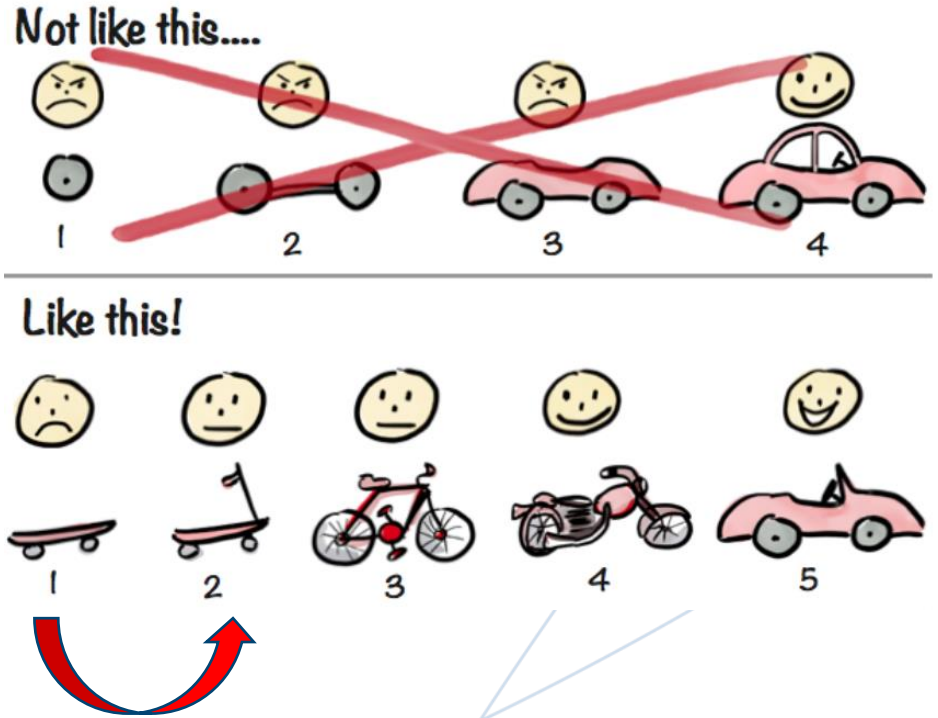
- **Ownership**
  - Each supplier will have to **design its equipment/system** in a way **that it can communicate bi-directional and provide scalable and interoperable digital functionalities.** **"This presume that vendors takes ownership of their interfaces and provide a best practice interface as a standard position in their offerings."**
- **Machine self-introduction**
  - **"This needs a machine-readable interface description provided by the machine and systems vendor." Plug and Produce** will become reality **through standardized configuration** and provides integration opportunities of discrete machines as well modular type plants incl. MTP.
- **"Shift left"**
  - **New communication standards** will simplify the data exchange between systems and to plug in equipment at any time. **“In WS 1 with the concept paper This Concept Paper proposes to ship the equipment’s interface data model in the standardized OPC Nodeset2 XML format to the customer prior to the systems meeting on-site.“**
- **"Start Easy"**
  - **“Acceptance before completeness”**. Key for **time to market of new pharmaceutical products** and **path for agile project delivery.**

ISPE Plug & Produce Workstream 1 – “Connectivity”

Henrik Stellmann, Körber (Werum)



Walk before you run



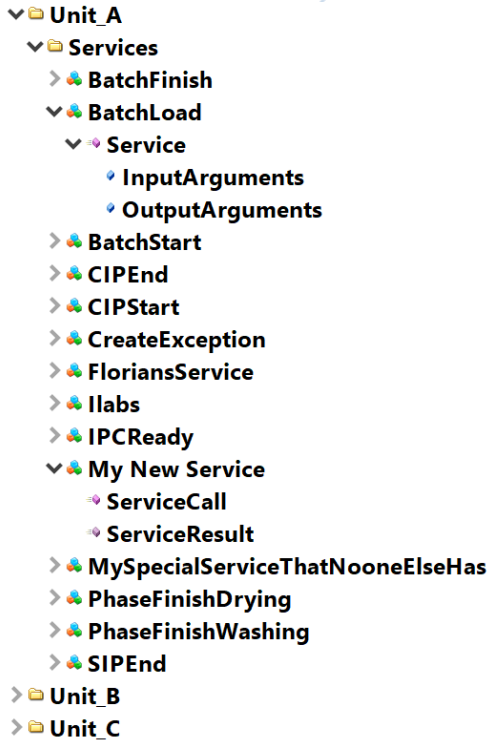
Concept Paper

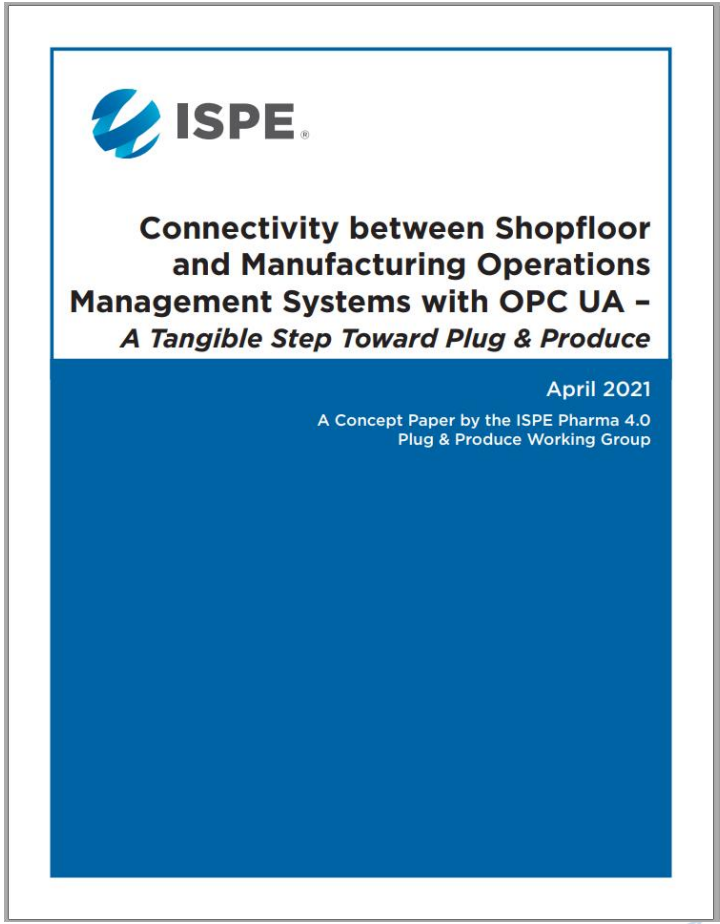
- **Improve one thing**
  - Scope Creep is your biggest enemy
- **Standard technology**
  - OPC UA
- **"Fail Fast"**
  - Prototype as you go

Use case independent?

- Pharma industry is horizontal to the machine type silos, see companion specs
- There is a quite literally an infinite number of use cases out there
- New use cases will come faster than we can standardize
- If we need flexibility anyways (because "we are special"), why not *start* with the extreme?

- More of a meta model ("rule-set“) than an actual text-book-data-model.
- Quite different approach than most (all?) other initiatives.





Acknowledgements

This Concept Paper represents the outcome of work done by the members of Workstream 1 – Connectivity – of the ISPE Pharma 4.0 "Plug and Produce" Workgroup as well as experiences and input from the individuals listed and does not reflect the views of any one individual or company.

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Challenges

Complexity & Availability

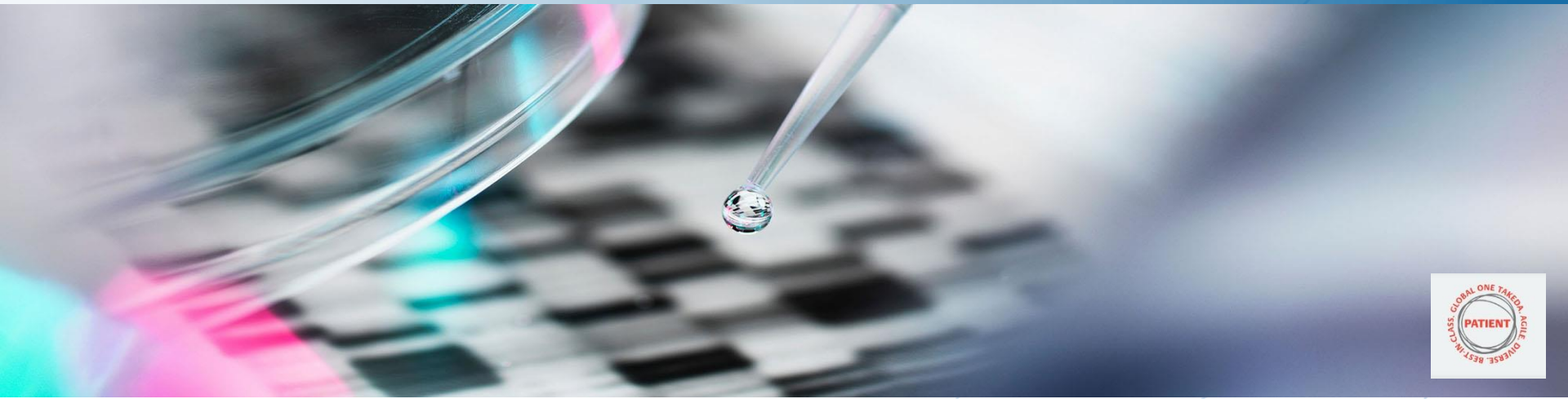
- *Inherent **complexity** - in September 2020, the specification consisted of 3151 pages in 15 documents*
- *[..] Due to this complexity, existing implementations are usually **incomplete**.*
- *[..] integrating various PLC technologies, each delivered with a **different and limited implementation** of the OPC UA protocol.*

- Wikipedia

Conclusion

- Obvious choice for many reasons
  - Big advantages
  - Well thought trough
  - Powerful toolbox
  - End user requested
- Achieved the goal
  - Found sustainable solutions
  - … as a team!
  - Will continue to built on OPC UA
- Actual implementations about to go life
  - Currently testing with multiple vendors and customers

Thanks a lot for your attention & stay connected!



ISPE PHARMA 4.0
"Plug & Produce" Working Group

https://ispe.org/initiatives/pharma-4.0

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Q & A –Discussion