AGENDA

- Introduction (TaSiVa Film)

- Status Quo in the Industry

- Goal "Plug & Produce"

- OPC UA a real "Global Standard"

- Proposal: OPC UA for Batch Control

- Path forward

- Benefit

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Shaping the future together
"Introduction of a global patient centric approach"

1. **Address urgent and unmet needs**
   - Provide innovative medicine for patients worldwide

2. **Innovation, partnership**
   - Faster access for those who need our medicine

3. **"Safe drug delivery & fight against counter fight products"**
   - EU's February 2019 deadline for drug serialization, set by the EU's Falsified Medicines Directive (FMD)
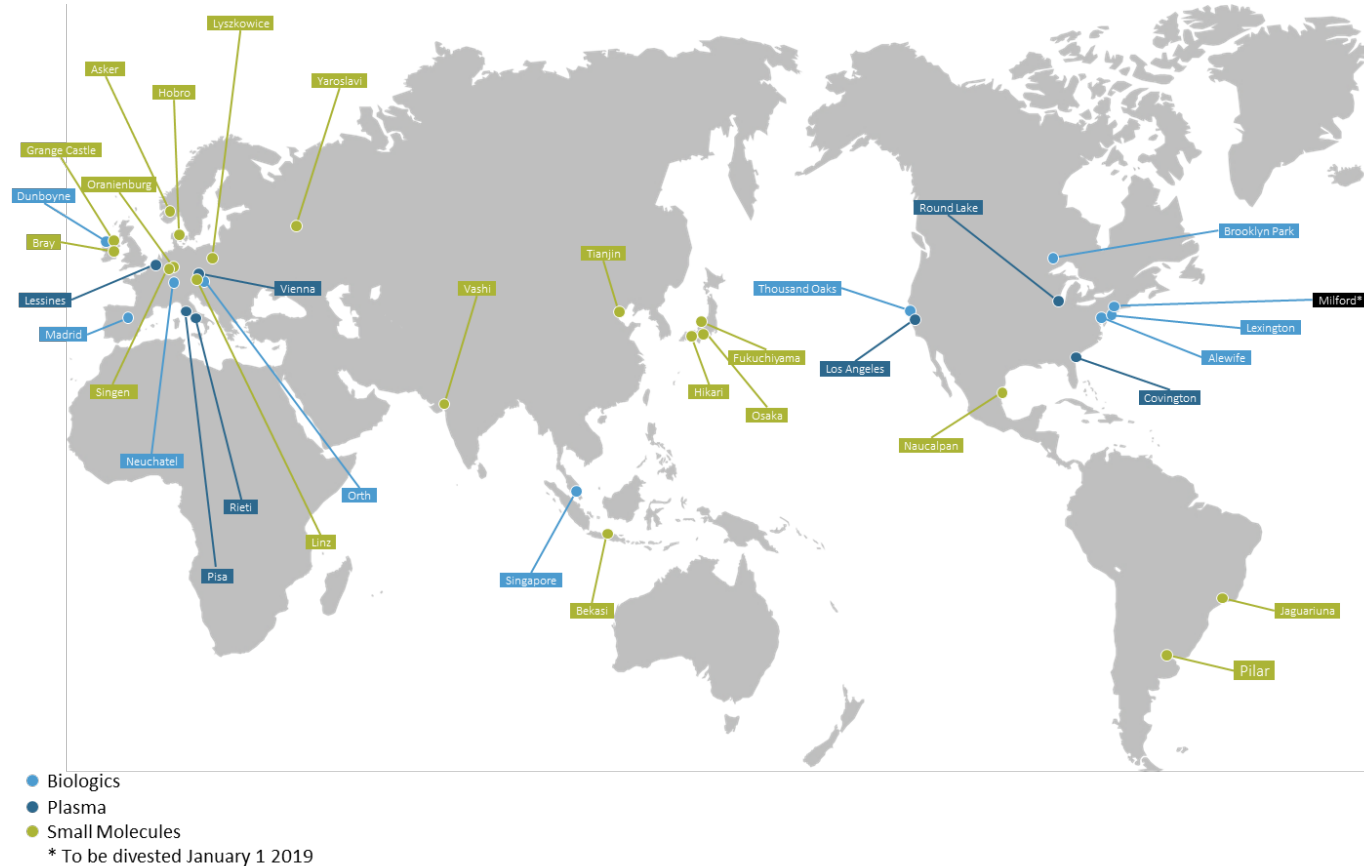
4. **"Digitalization" (Industry 4.0, IIoT)**
   - As enabler of "Plug & Produce" for new applications (E2E, Track & Trace etc.)

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Accelerating our Future – IoT – A data driven Organization
"Takeda´s Global Production Network "Plug & Produce"

- ● Biologics
- ● Plasma
- ● Small Molecules
- * To be divested January 1 2019

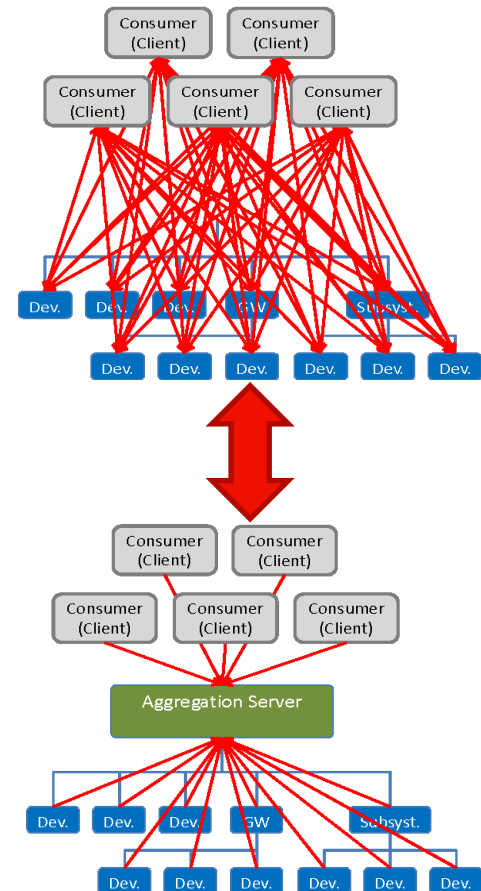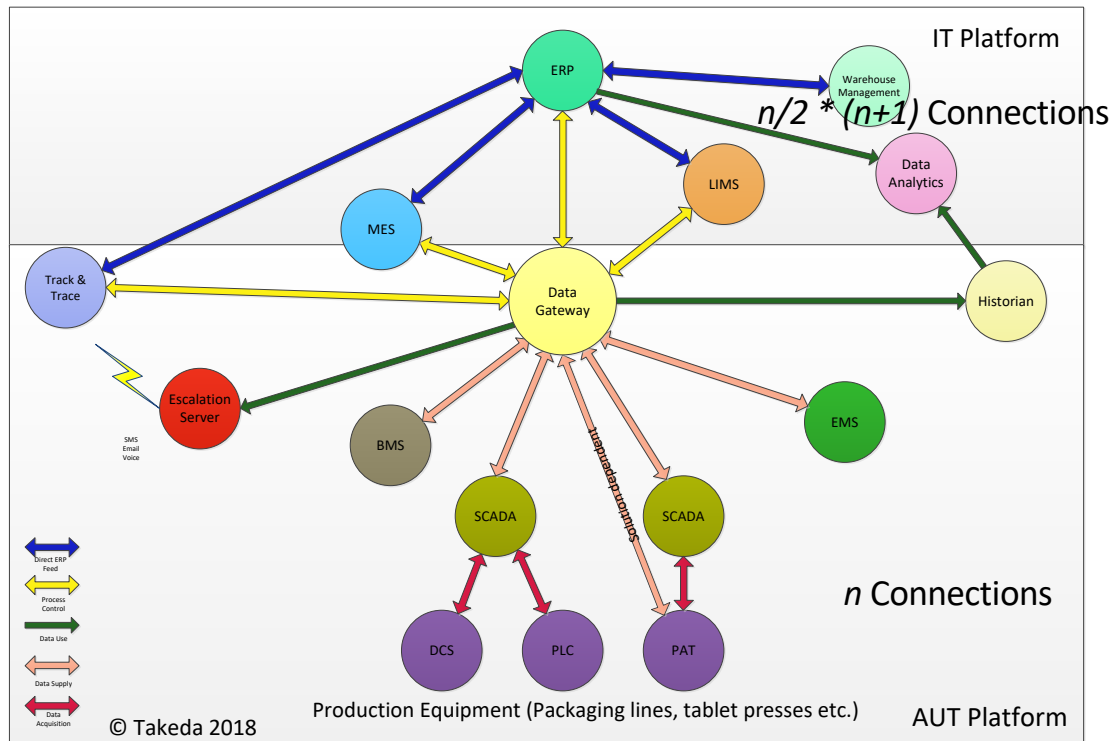Takeda Pharmaceutical Company Limited

Status Quo – Where we are in the Industry?

- "Weak, complex, aging" network infrastructure

- Many heterogenous island solutions

- Outdated technology, obsolete asset inventory

- Use of data is low, limited or inexistent

- GxP / Bio-Pharma requirements not considered

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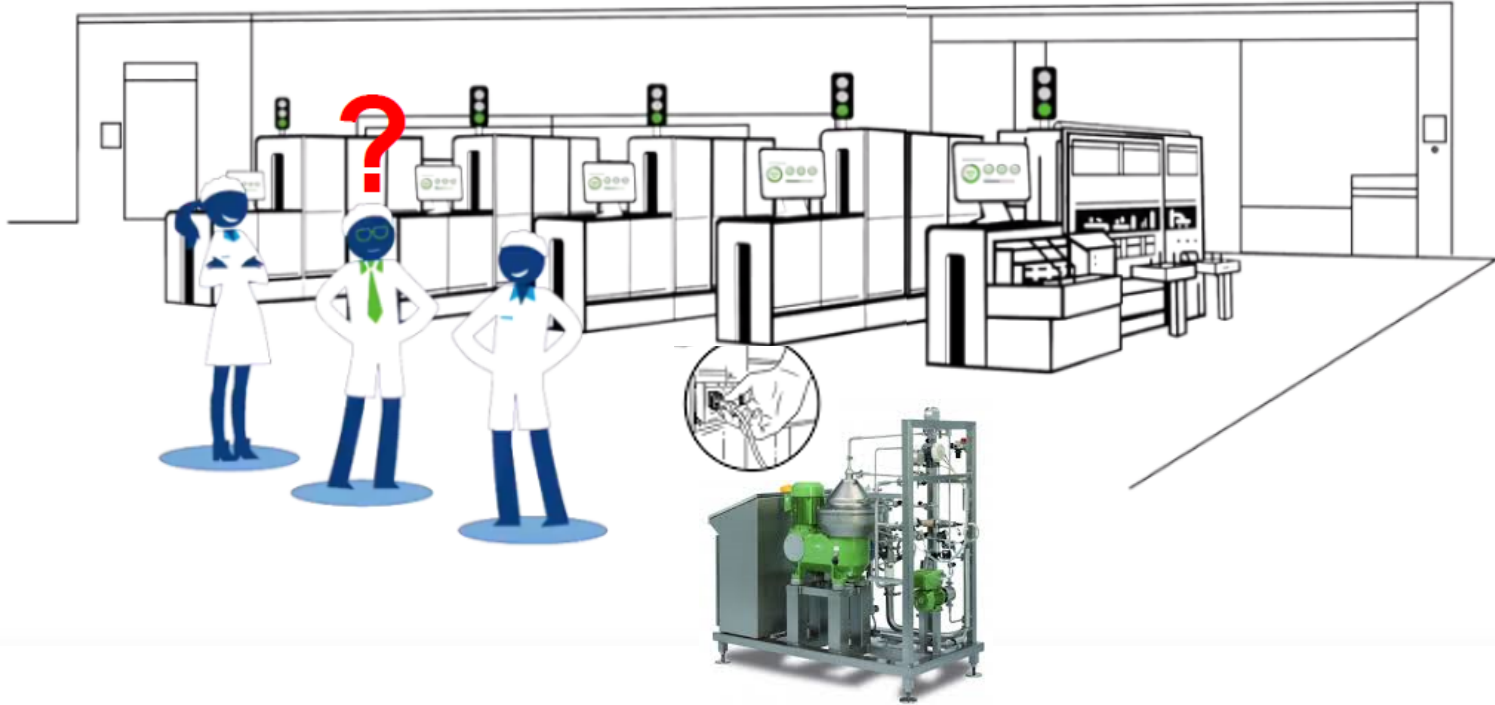# Goal "Plug & Produce"

$n/2 * (n+1)$ Connections

n Connections

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Source: OPC UA server aggregation - The foundation for an internet of portals, Daniel Grossmann et al, TH Ingolstadt, January 2015   https://www.researchgate.net/publication/283882805
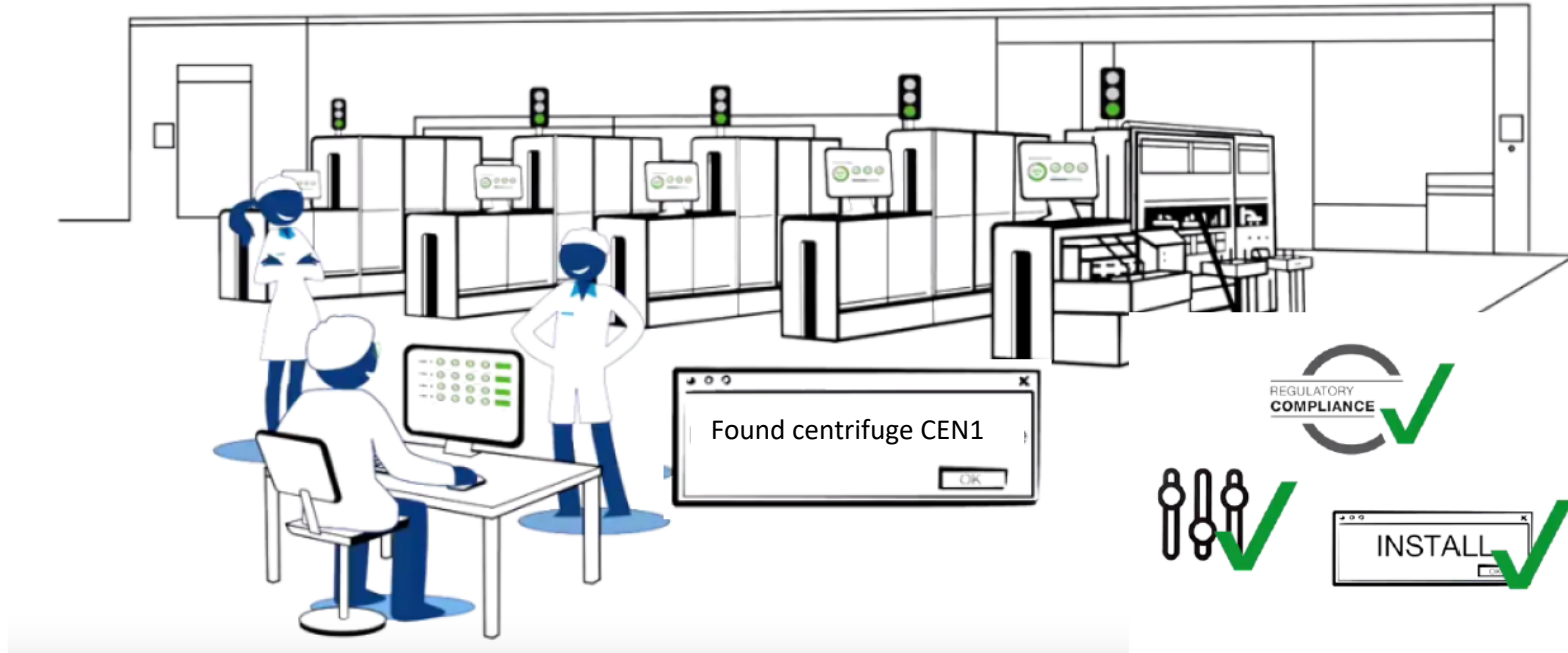
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Smart Factory – Plug & Produce
How to connect (new) equipment/machine/ sensors?

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Smart Factory – Plug & Produce

Easy - Connect like a printer to a office network!

Found centrifuge CEN1

OK

REGULATORY COMPLIANCE ✓

INSTALL ✓

Standardization of equipment data models prerequisite for Plug and Produce!

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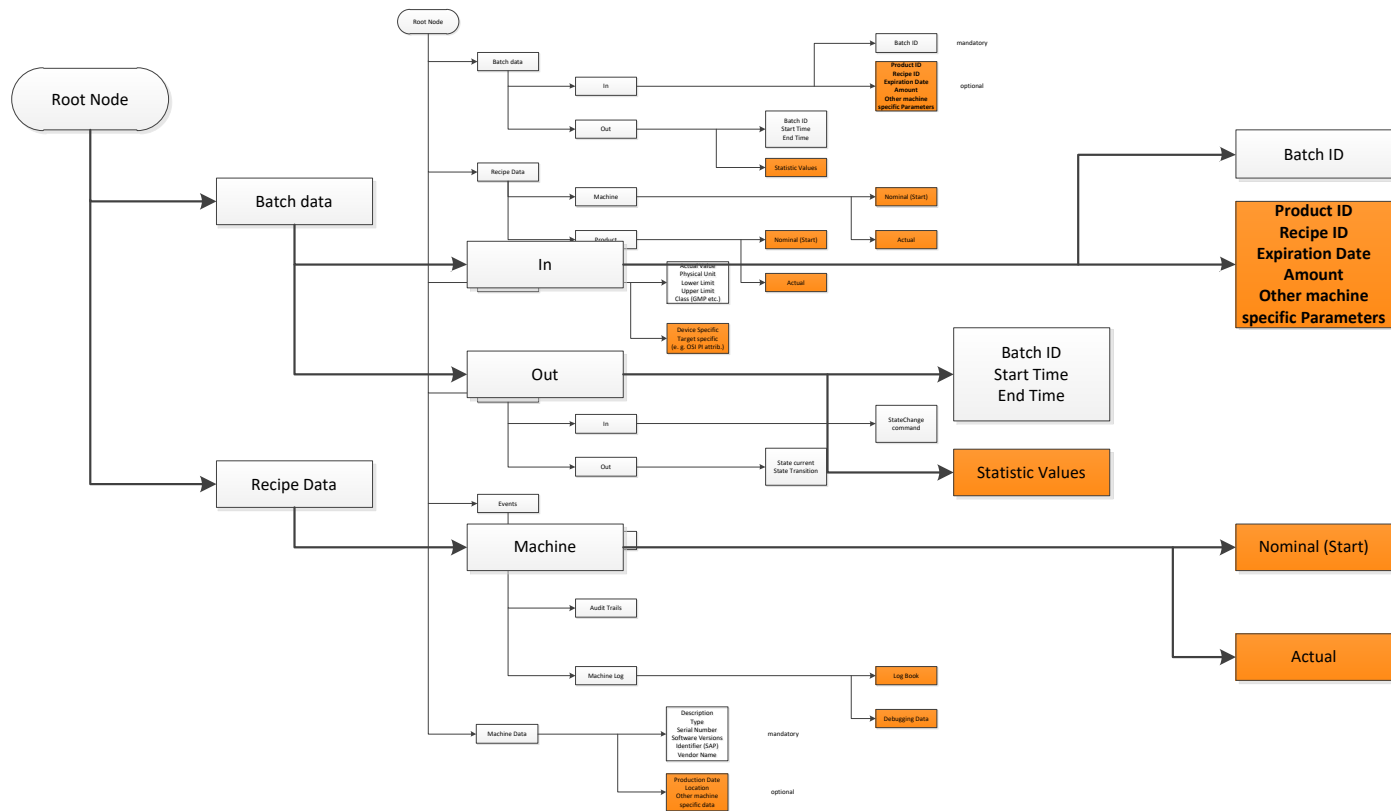
OPC UA a real "Global Standard"

- **First common digital Takeda OPC-UA work-shop in Oranienburg, Germany, in May 2019**

- **Learnings**
    - *"It´s not OPC UA Companion Spec. / PackML yes or no, it depends on which spec. parts are supported by your machine"*
    - *It is "Very important to see what other suppliers/partners are currently developing and where we can create synergies in working together across industries"*
    - *"We are not only manufacturers of machines or software developers, we are also dealing with big data which we want to use in real time to drive our business"*
    - *"We more often should take time and the opportunity to meet and work together with all partners to meet future needs"*
    - *"Our machines not only produce pharmaceuticals, they also produce data."*

- **Outcome**
    - *Draft "OPC UA Pharma Industry Information Model Specification"*

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Basic Requirements "Generic Equipment Data Model"

Machine Meta Data

Batch Data

Machine Logs

Recipe Data

Audit Trail Events

Process Values (Data)

Alarm Events

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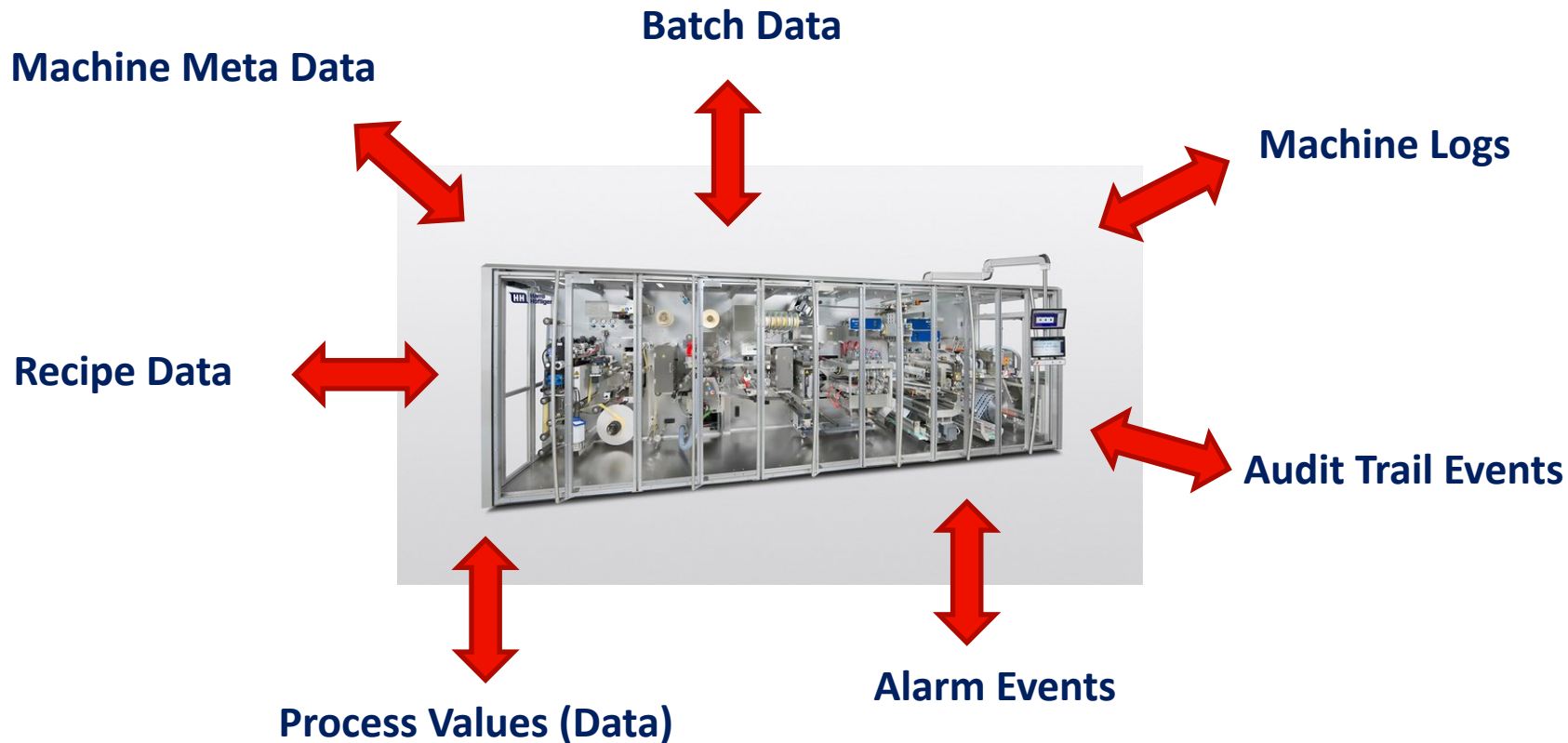
Standard OPC UA Data Structures

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Proposal: OPC UA Information Model for Batch Control

- OPC UA

- ISA-88

- PackML

- OPC UA for Devices

- Proposal: ISA88UnitType

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OPC UA (IEC 62541)

- **Common Modeling Language**
  - Objects & Variables
  - Meta data = Object Types & Variable Types
  - Methods
  - Data Types
  - Data Changes
  - Events

- **Base Information Model (OPC 10000-5)**
  - State Machines
  - Audit Trail Events

- **Alarms & Conditions (OPC 10000-9)**
  - Alarm Events
  - Active State
  - Acknowledge & Confirm
  - Alarm Limits
  - Etc.

- **Companion Specifications**
  - OPC UA for Devices (OPC 10000-100)
  - PackML (OPC 30050)
  - Weihenstephan (in preparation)
  - ISA-95 (OPC 10030)
  - Etc.

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ISA-88 – Batch Control Standard

- Process Model

- Physical Model

- State Model

- Recipe Management

- Production Information
  Management (=Batch Data)

- No OPC UA Companion
 Specification

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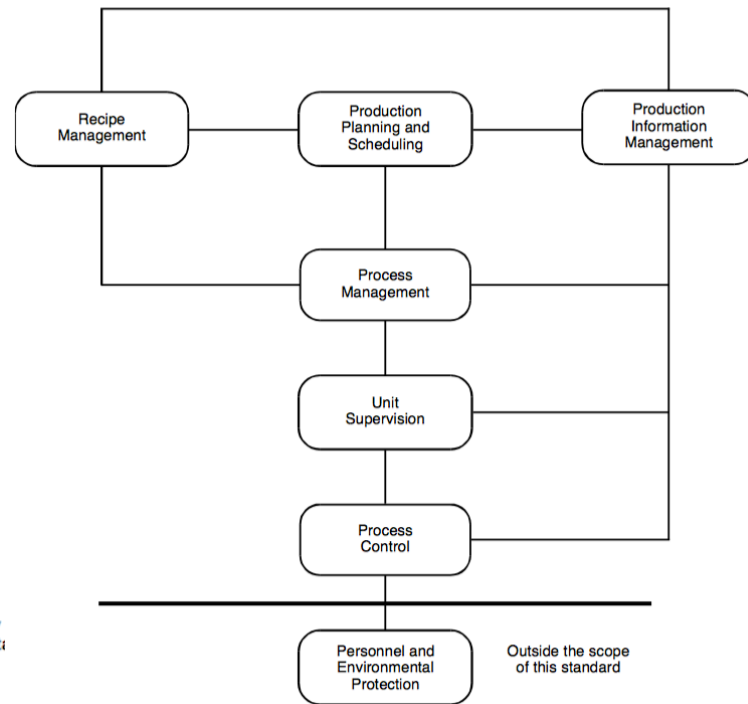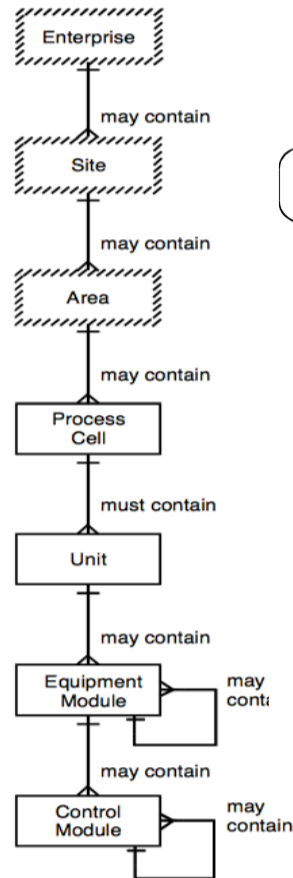
PackML

- Example implementation of ISA-88 for "Packaging Machines"
- Machine and Unit States
- PackTags
- OPC 30050 – OPC UA for PackML

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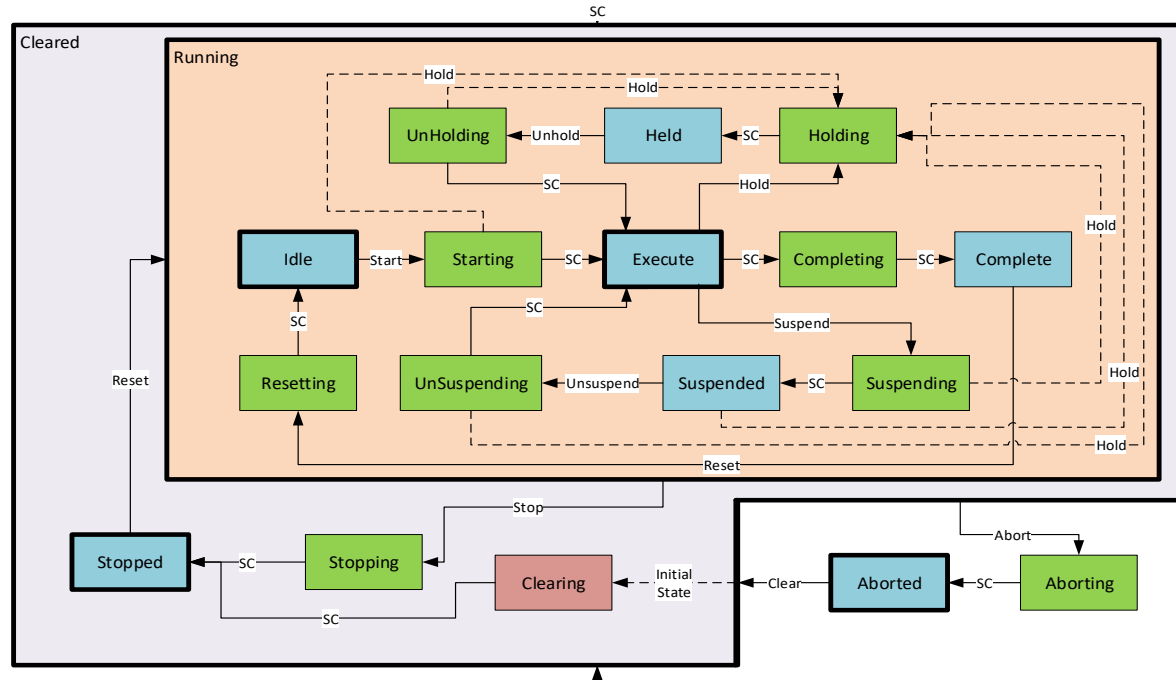
OPC UA for Devices

- **OPC 10000-100**
- **Base Model for Physical Devices**
- **Vendor Nameplate Interface**
  - Manufacturer information
  - SerialNumber
  - Etc.
- **Tag Nameplate Interface**
  - User point of view
  - AssetId (=Tag Name)
- **Device Health Interface**
  - NAMUR NE107 Status
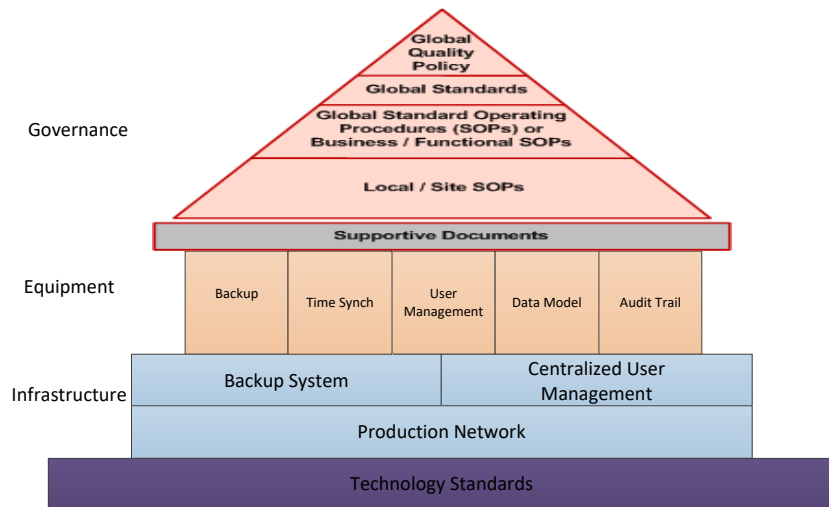- **Support Information**
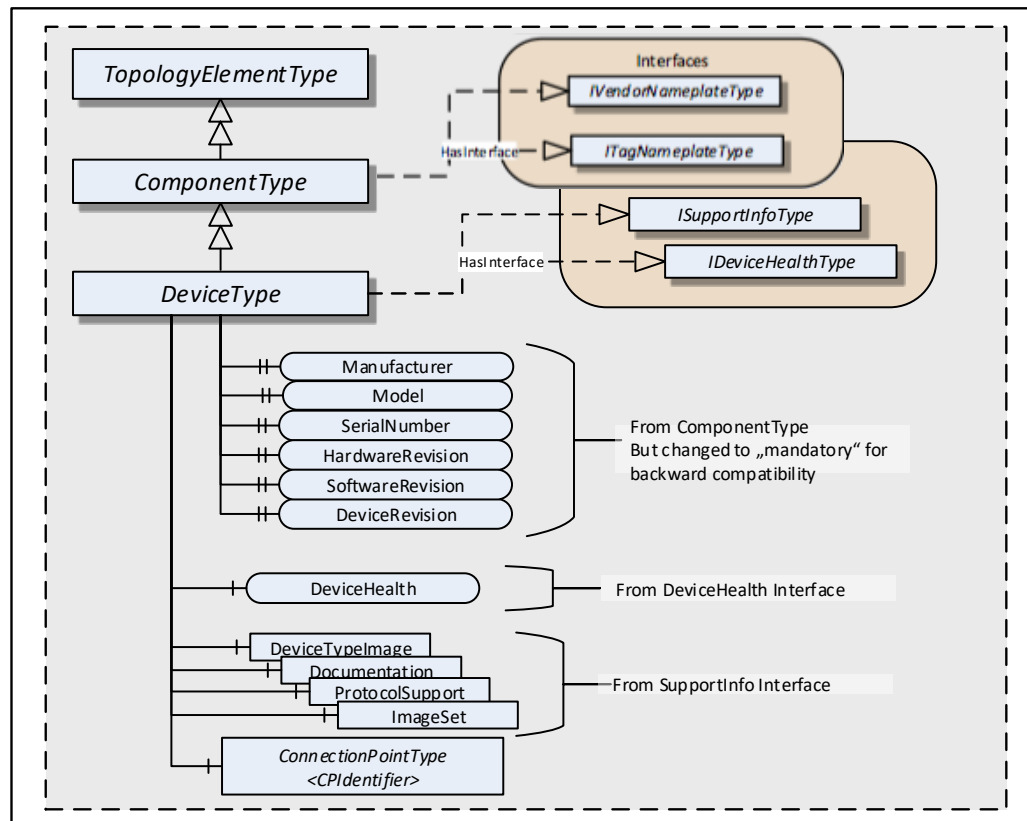
Proposal: ISA88UnitType

- **Unit Information**
  – Device "aspect"

- **Batch Information**

- **Recipe Information**

- **Physical Structure**
  – Equipment Modules
    - Control Modules
- **State**

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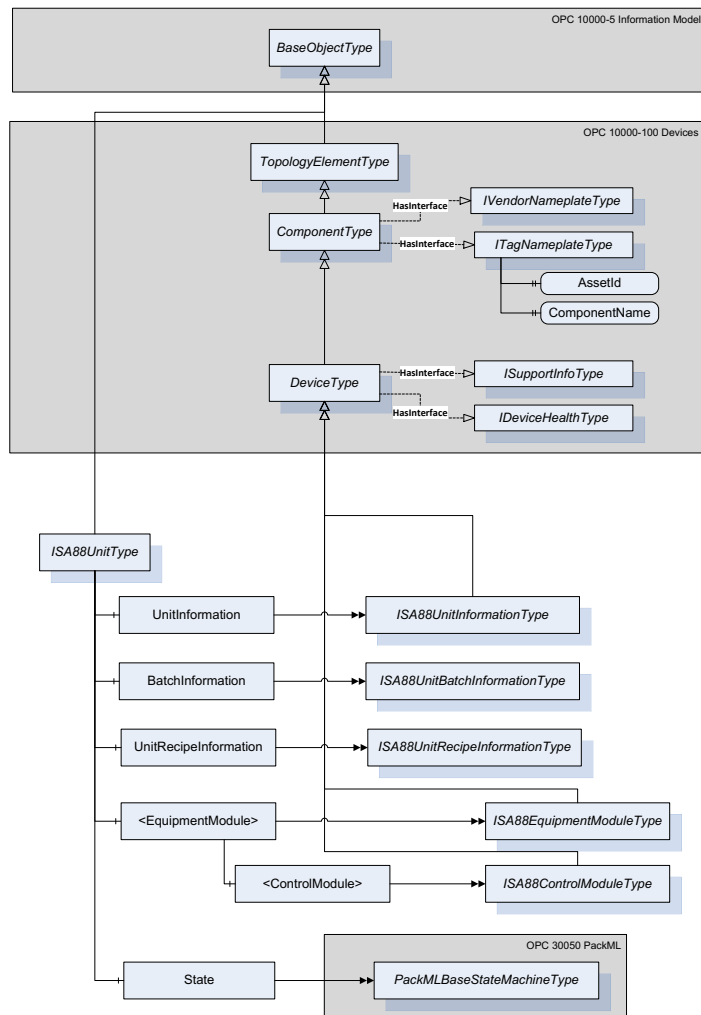
Path Forward

- **Harmonized / Open Infrastructure to plug in any equipment at any time**
  - Separation of office and production network including Cyber Security
  - Implementation of standard IT services analog to the Office world (SaaS)

- **Easy Design / Upgrade or replacement of equipment**

- **Centralized Message Gateway combined with Centralized Data Pool (Historian)**

- **Use & pilot new technologies /** concepts like OPC UA, PackML, MQTT and MTP

- **Be active in global communities for events** (like OPC UA Foundation) to drive standardization in the industry

Governance

- Global Quality Policy
- Global Standards
- Global Standard Operating Procedures (SOPs) or Business / Functional SOPs
- Local / Site SOPs
- Supportive Documents

Equipment

| Backup | Time Synch | User Management | Data Model | Audit Trail |

Infrastructure

Backup System	Centralized User Management
Production Network	
Technology Standards	

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Benefit – Real time Data

- Having the data real time available in any place – bidirectional exchange with established and qualified communication paths – no USB or other «ancient» methods

- Efficiency increase through consistent, automated processes

- Process optimization online/offline through full data analysis

- Predictive Maintenance through automated identification of failure patterns

- Data Integrity – Single source of truth

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Questions?

How do we look at the industry:
«Constantly value new and different innovations»
or
«Still have time to set the right standard for the organization driving transformation»?

Thanks a lot for your attention & stay smart!

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