"Plug & Produce" in the Pharmaceutical Industry

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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
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.)
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
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- Outdated technology, obsolete asset inventory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
Goal “Plug & Produce”

Smart Factory – Plug & Produce
How to connect (new) equipment/machine/ sensors?
Smart Factory – Plug & Produce
Easy - Connect like a printer to a office network!

Standardization of equipment data models prerequisite for Plug and Produce!
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”
Basic Requirements “Generic Equipment Data Model”

- Machine Meta Data
- Batch Data
- Recipe Data
- Process Values (Data)
- Alarm Events
- Audit Trail Events
- Machine Logs
Standard OPC UA Data Structures
Proposal: OPC UA Information Model for Batch Control

• OPC UA
• ISA-88
• PackML
• OPC UA for Devices
• Proposal: ISA88UnitType
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.
ISA-88 – Batch Control Standard

- Process Model
- Physical Model
- State Model
- Recipe Management
- Production Information Management (=Batch Data)

- No OPC UA Companion Specification
PackML

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