Plug & Play - auf dem Weg zum Industrie Standard

Status quo - PharmaForum 2021

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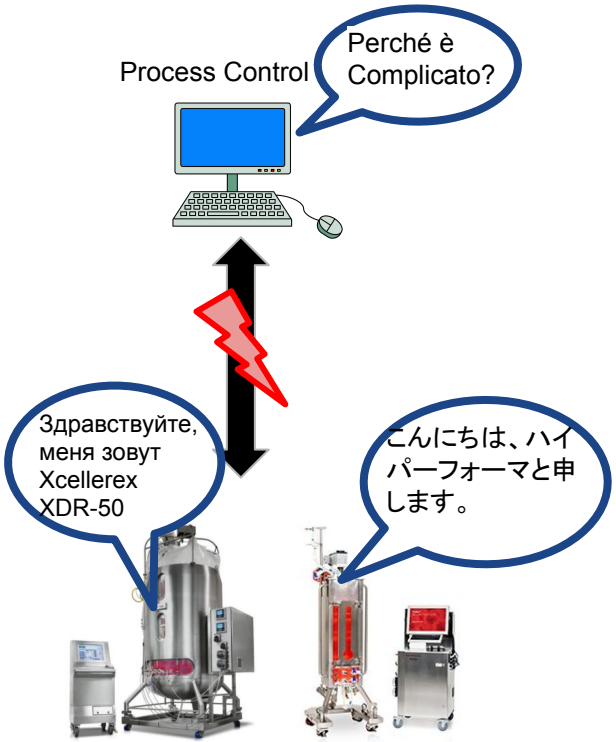
Challenges Process Equipment Integration as it is today

Proprietary Interface and Functions leads to….

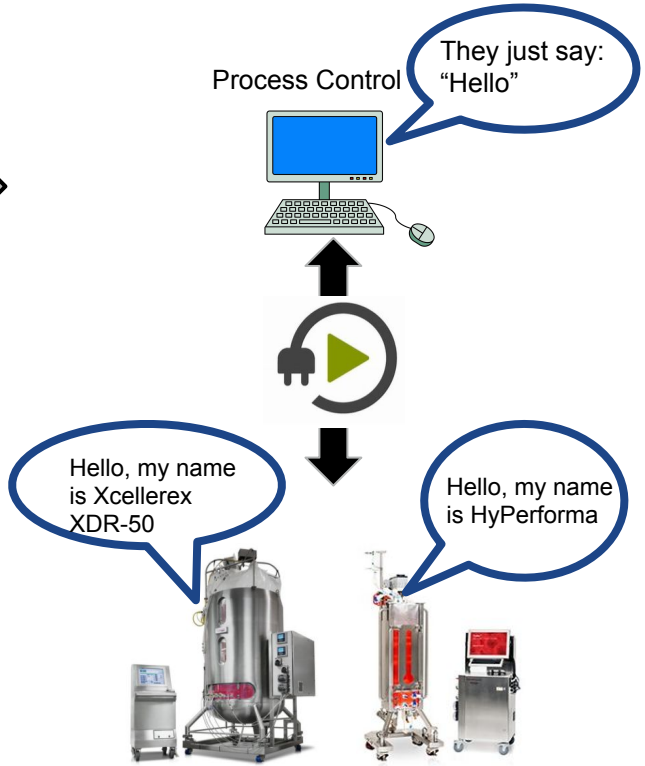
- No accepted industry standard to connect equipment to overarching systems exists today. This is leading to proprietary one off interfaces which each supplier.
- High Life-Cycle Costs through complexity in engineering, technical implementation and change management processes on customer and vendor side
- Longer project lead-time and effort (Engineering and Qualification) for integration and qualification as well life cycle
- Higher Risk on Data Integrity (DI) through different vendor standards and their maturity of DI compliance
- Vendor Dependencies - big hurdle for alternative sourcing
- Vendor resources availability

Solution - Standardization of Interfaces and Service Oriented Technology



As-Is situation

- Communication between process control level and process equipment
- Process Equipment functions as services
  - HMI
  - Standard process equipment phases as service to recipe management for process control
  - Alarms and Warnings
- Qualification and Validation



Target State

Establishment of Industry Standards

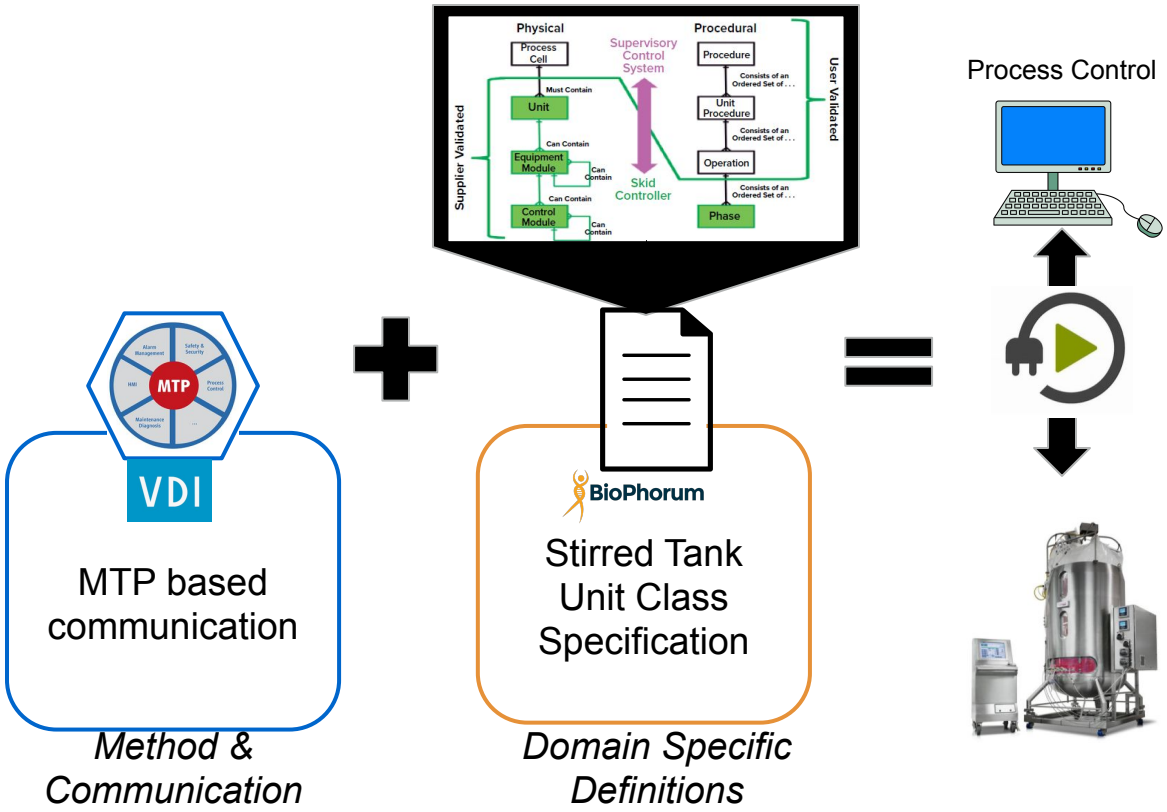
Non-Proprietary Interfaces generate benefits through Plug & Play

- Faster change over process
- Flexibility for Multi-purpose plants
- Data Integrity through standardization and pre-qualified functions and interfaces
- Vendor independency with regards to scope of automation

VDI-2658 Module Type Package & BioPhorums Specification

A standardized non-proprietary description of modules as enabler for orchestration based plug-and-produce strategies

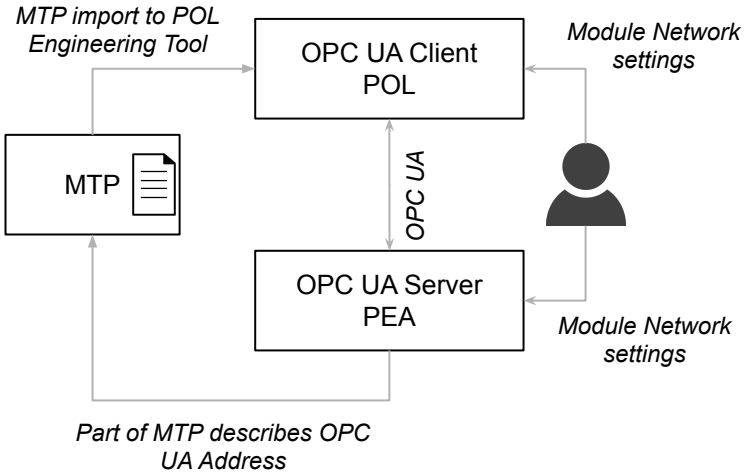
- Scope of VDI 2658 (MTP)
  as basis for modular automation
- International Standardization Process has started with IEC
- First Pilot projects initiated



MTP = Module Type Package

Aspects of Communication

Plug & Play



- OPC UA as runtime interface
- Following classical point-to-point in MTP V1.0
- Standard integration process

MTP = Module Type Package

PEA - Process Equipment Assembly
POL - Process Orchestration Layer

NAMUR Working Group Organizational Structure

Major part of VDI 2658 will be available within 2021

Standardization VDI/VDE/NAMUR 2658 (GMA 5.16) Status

WG: working group, CP: concept paper, CD: committee draft, PD: Public draft, IR: internal release, PR: public release)

2658-X	Title	WG	CP	CD	PD	IR	PR	Comment
1	Basic Concept				✓		✓	Released 10-2019
2	HMI Concept				✓		✓	Released 11-2019
3	HMI Interfaces				✓		✓	Released 09-2020
4	Process Control				✓			PD released 08-2020, *Objections Meeting 2021-03-12*
5	Runtime Concept							Makarov: CP WIP in TF, *PD release 06-2021*
5.1	Runtime OPC UA							Makarov: CD submitted, *PD release 07-2021*
6	Alarm Mgmt Concept				✓			PD released 01-2021, Objections until 31.3
7	Alarm Mgmt Modelle							Hoernicke/Stieler: in print, *PD release 02-2021*
7.1	Alarm Mgmt OPC UA							Braun: CD submitted, *PD rel. 08-2021*
8	Safety Concept							Horch/Knab: CP WIP in AK 4.5.1, *CD release 06-21*
9	Safety Interfaces							Horch/Knab: Follow up to 8 in TF GMA/VDI/NAMUR
10	Diag & Maint – PEA							Birkenkamp: CP WIP in AK 4.1.1, *CD release 04-21*
11	Diag & Maint – Plant							Birkenkamp: CP WIP in AK 4.1.1
12	PEA Qualification							*Henter: NAMUR/ZVEI AK 2.4.1*
14	Cross Communications							

- Part 6 and 7 released in DRAFT Status
- Update of Part 4 in development
  - 164 Review comments on DRAFT version
  - Bigger change is ongoing for release

BioPhorum - Stirred Tank Unit (STU)

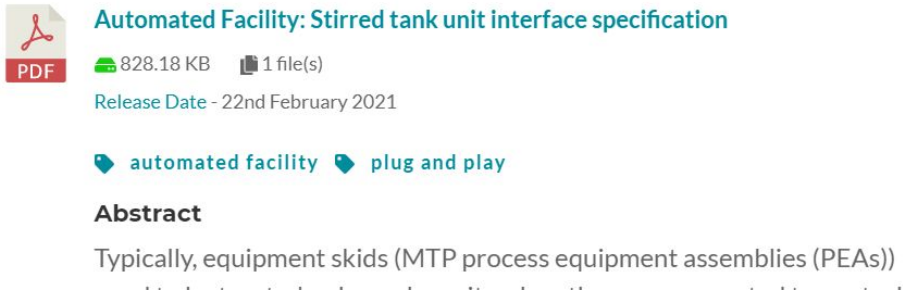
Equipment model - beyond protocol

BioPhorum published February 2021 the STU specification as 1st example of a data definition for the equipment class of stirred tanks. This is master class for others: rockers, media tanks, etc.

BioPhorum's data model is based on MTP.

Working group to define common data Model is consisting out of

- Pharmaceutical Manufacturers
- Equipment Suppliers
- Automation Vendors



https://www.biophorum.com/phorum/technology-roadmapping/downloads/

Status BioPhorum

Plug & Play - working papers

	Lead writer and Editor	Additional writers	Stage 1 - 6	Notes	Targeted publication date
Stirred Tank Unit	Rex and Steve	Kelsey, Bob, Mark, Pietro, Christoph, Chun, Gene, Jean-Luc, Rene, Chad, Keith, Uwe, Bruce, Derrick, Burkhard, Michel, and Stefan	5 / 6	Published LinkedIn post HERE	Published February 2021
Validation Strategy	Keith	Bob, Pietro, Jean-Luc, Tim, and Urs	2-3	Prioritised, due to send latest version for copy editing	April 2021
Audit Trail	Derrick	Gene, Rene, Jean-Luc, and Urs	3	Copy edit version #1 back for review	May 2021
Alarms and Events	Urs	Derrick, Rene, Jean-Luc, and Cormac	3	Document sent for final copy / design edit.	June 2021
Filtration	Pietro	Urs, Chad, Kelsey, Nik, Rex, Andy, and Chun	2	Will publish in second phase	TBD
Chromatography	Chun	Bruce, Andy	2	Will publish in second phase	TBD
Header Document	Greg	Michel, Bruce, and Jean-Luc	2	Content from STU IS used in first draft; authors to be assigned sections	TBD

Stage	Description
1	Initiation
2	Writing & editing
3	Copy edit, design and approval
4	Submitting to a journal
5	Publication in a journal
6	Ongoing communication

Feasibility Project

Integration of MTP in existing Distributed Control System (DCS)

BioPhorum
STU
Specification

BioPhorum
FSF PP01/2
F2F PP03 (2019)
F2F PP04 (10/20)
F2F PP05 (04/21)

PEA
Vendor

Import

Plant
Engineering
Environment

Generate

Runtime

POL (DCS)

- User Management
- Time Synchronisation
- Network Infrastructure

SU
Bioreactor
sartorius stedim biotech

SU
Bioreactor
MERCK

SU
Bioreactor
PALL
Pall Corporation

SU
Bioreactor
cytiva

Doing now what patients need next