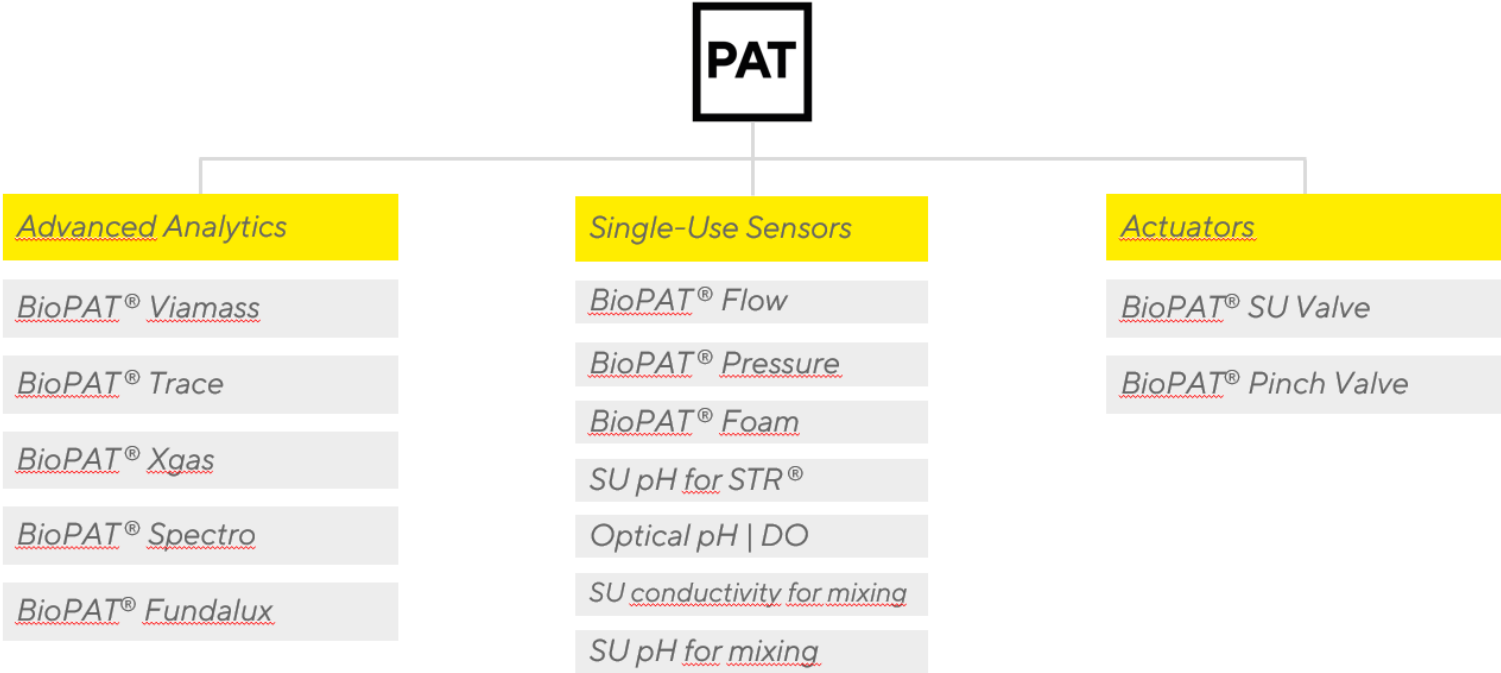


Sensors and Automation in Single- Use Systems

Sartorius, Göttingen, October, 2024

Sensors in Single-Use Applications

SU Component Portfolio



New developments



- BioPAT[®] Cond|pH
- BioPAT[®] Spectro UV
- BioPAT[®] Low Flow
- BioPAT[®] Foam for Biostat STR[®] Microbial

BioPAT[®] Cond|pH

Inline SU Inline SU Conductivity Sensor with optional SU pH sensor (dry- and wet-storable options)

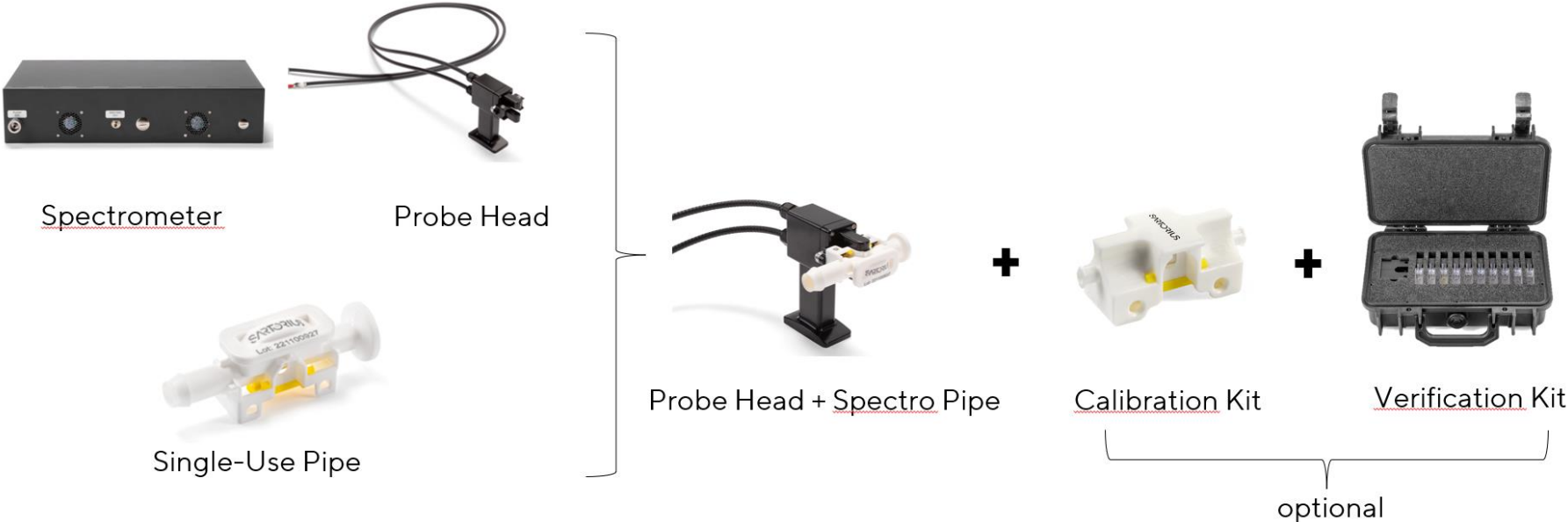
Features:

- State-of-the art sensor technology
- Standardized fluid connections
- Fully validated material selection
- Cost-efficient and small footprint
- 2 y Shelf-life after irradiation
- Optimized flow cell with regards to hold-up volume and reaction time
- Planned sizes: 1/8", 1/4", 3/8", 1/2"



BioPAT[®] Spectro UV

Scalable inline SU UV spectroscopy



BioPAT® Spectro UV

Scalable inline SU UV spectroscopy



Features:

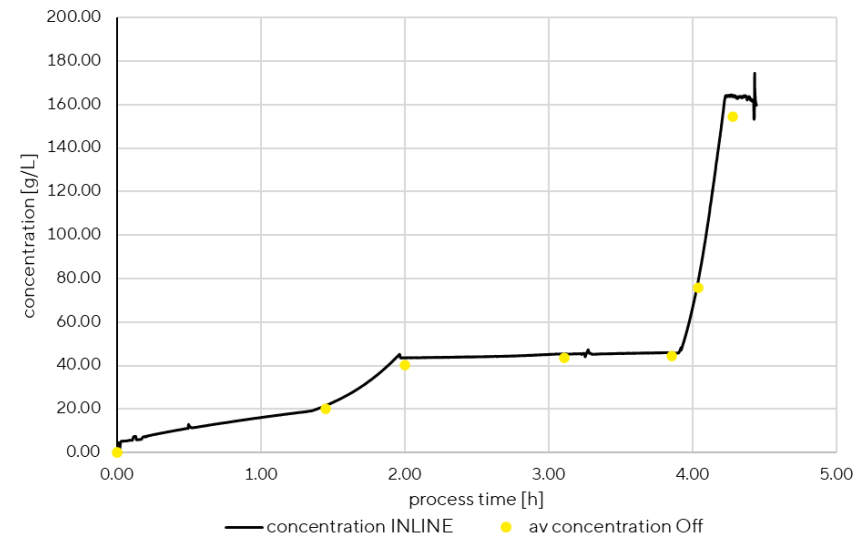
- 1 Channel | 2 Channel Systems
- Spectral Range 190-380 nm
- High measurement frequency up to 10 Hz
- Full spectra recording for use in MVDA
- Embedded SIMCA-QPe enables multivariate concentration prediction

Customer Use Case:

Overcoming Signal Saturation in UF|DF Processes by selecting the right wavelengths of the spectra

Two separate linear regression models applied at 298 and 304 nm

Inline values fit perfectly with offline analytic (SoloVPE)



BioPAT[®] Low Flow – Inline SU Ultrasonic Flow Sensor

Features:

- Ultrasonic time-transit sensor technology with multiple measurement paths
- High accuracy (1.5% c.V. + offset)
- Sizes: 1/8", 1/4" and 3/8"
- Flow range: 1 – 10 000 ml/min
- Air quantification feature



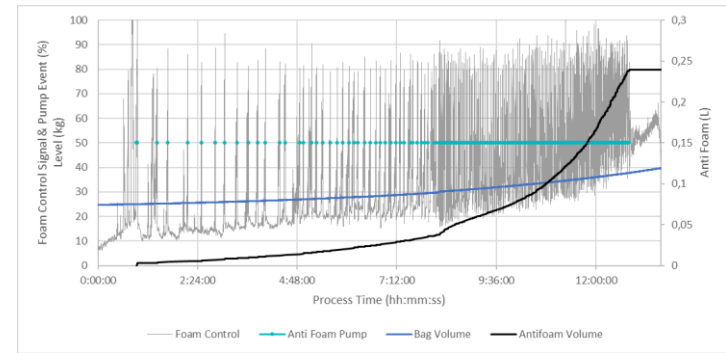
Automated Foam Control using BioPAT® Foam in Biostat STR® Microbial



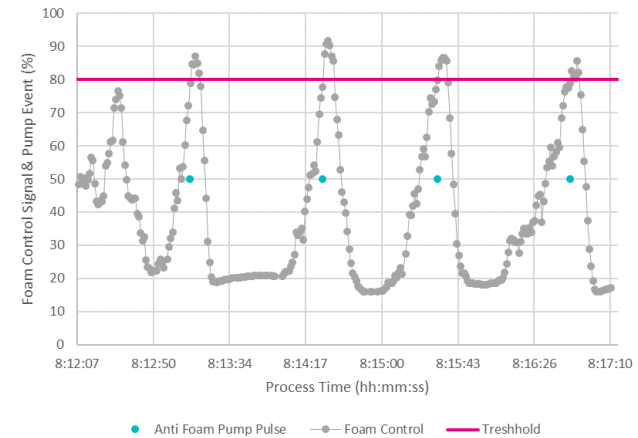
Schematic displaying Foam Control and High Foam patch positioning



Real life view on Foam Control patch positioning



Foam Control triggers with high frequency the addition of anti-foam agent in an *E. coli* fed-batch process.

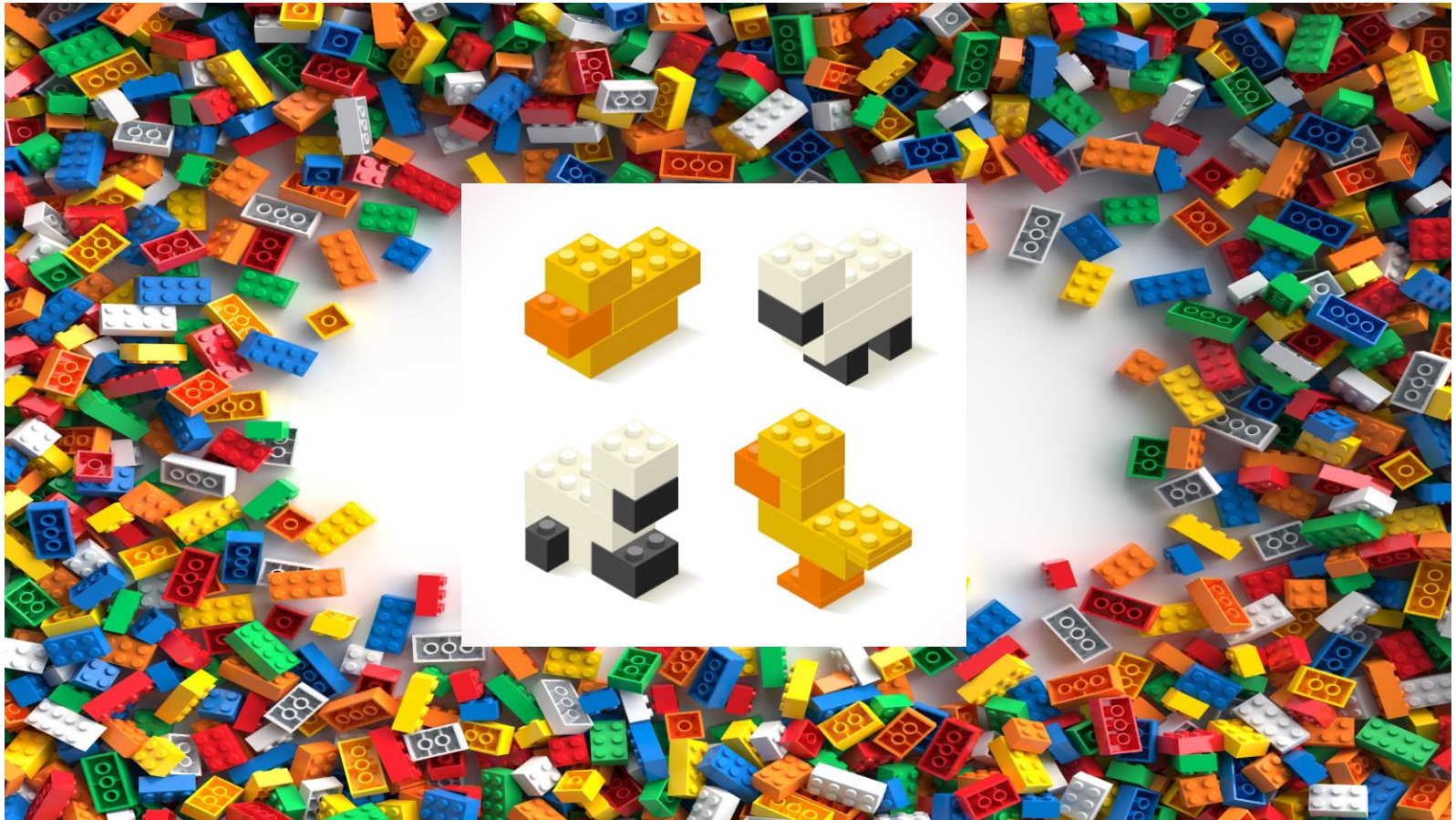


Zoom-in, displaying single foam events. Every time the sensor threshold of 80% is exceeded the pump triggers impulse (teal dot) to add anti-foam agent.

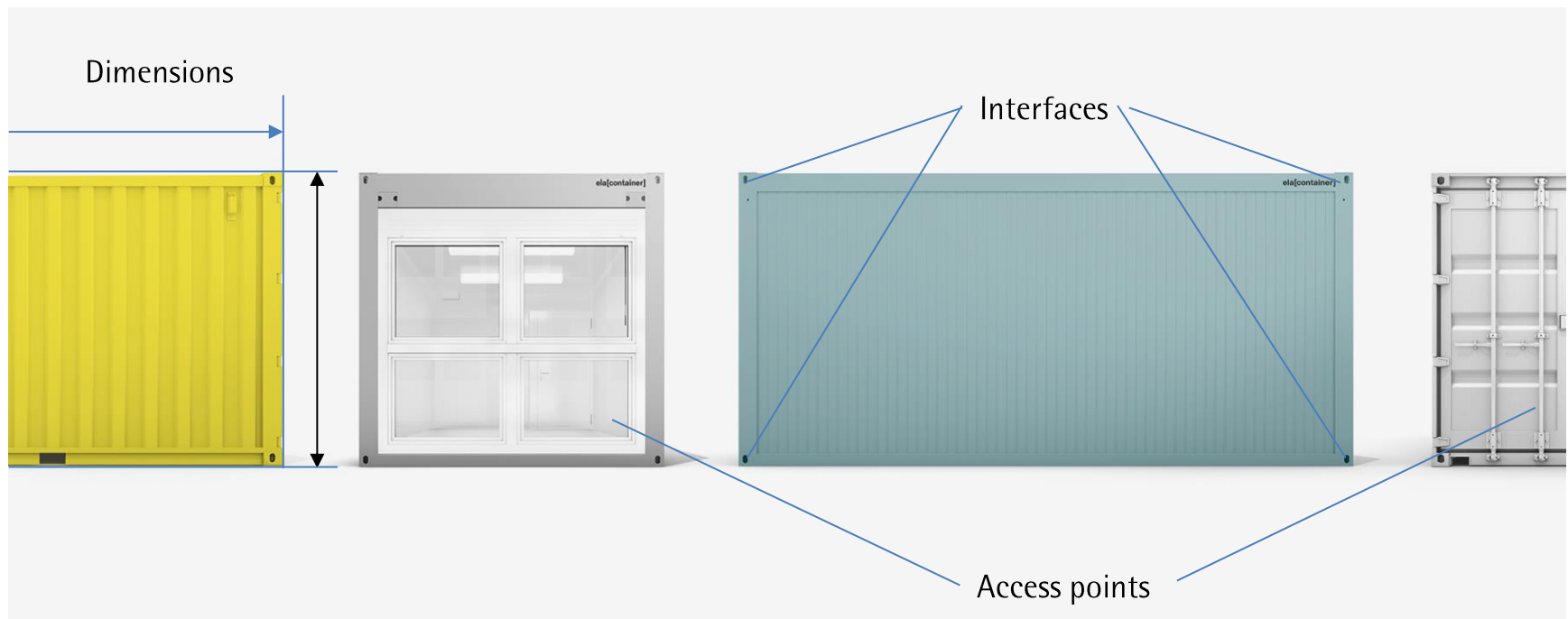
Automation for Single-Use Applications

How modularization can help future manufacturing concepts

Modularization needs Standardization



Example Container



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Benefits of Modularization

Increase in Efficiency

- container boosted worldwide logistic chains
- interoperability between:
ships, trucks, airplanes



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Benefits of Modularization (cont.)

Increase in Flexibility

- SmartHome modules
- fast and easy setup
- flexibility of networks (initial and in lifecycle)
- change functionality of module by parametrization
- easy integration of new appliances
- interoperability between vendors partly given



Bosch SmartHome program

Modularization in single-use technologies

Past



- High initial cost
- Considerable cleaning effort
- Risk of cross-contamination
- **Mostly dedicated plants with dedicated, 'monolithic' automation**

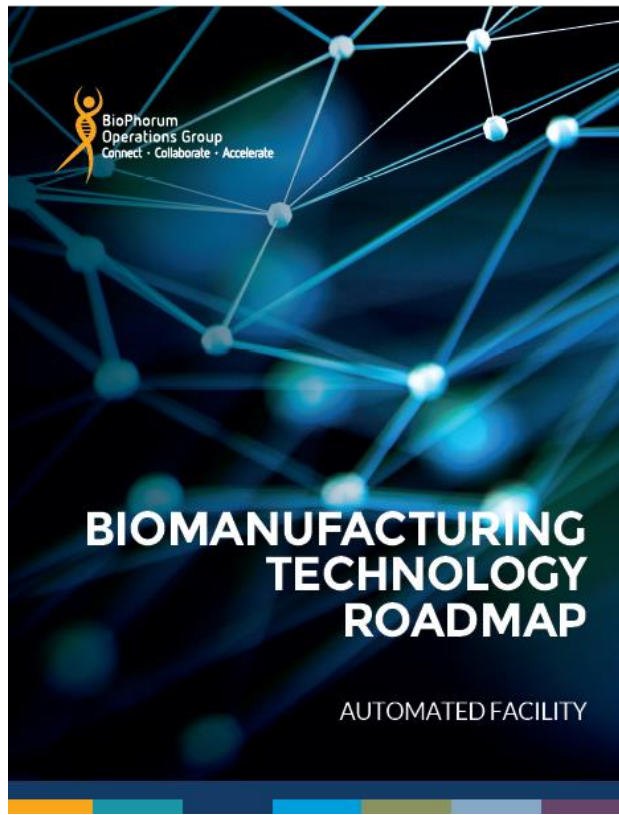
Present



- + CAPEX reduction over entire lifecycle
- + Lower water and energy consumption
- + **Higher flexibility**
- + **Base for flexible manufacturing (ballroom)**
- + **Modularization needed (Hardware & Automation)**

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Automated Facilities need standardized integration to reduce build times of facilities



“
...
full integration allows
quicker and cheaper build times ...”

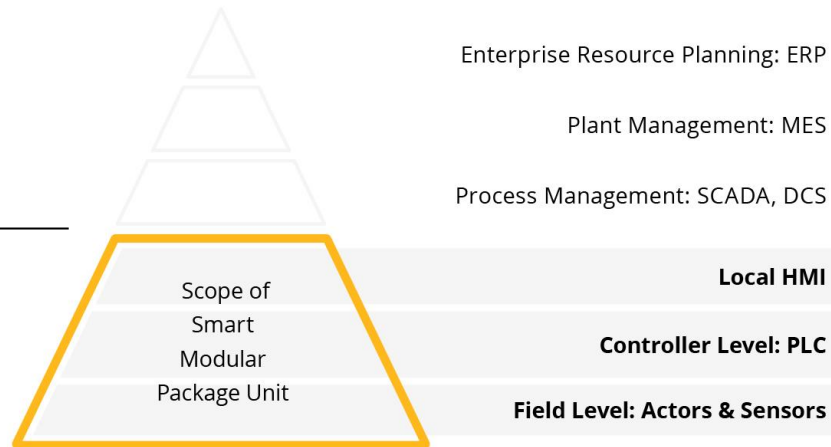
*BPOG Technology Roadmap
Automated Facility*

Smart Modular Package Units

- ... focus on local automation of a process step
- ... integrates well into upper SCADA or DCS world
- ... has a range of interfaces
- ... integrates sensors and actuators
- ... form basic controls
- ... offers executable sequences & recipes

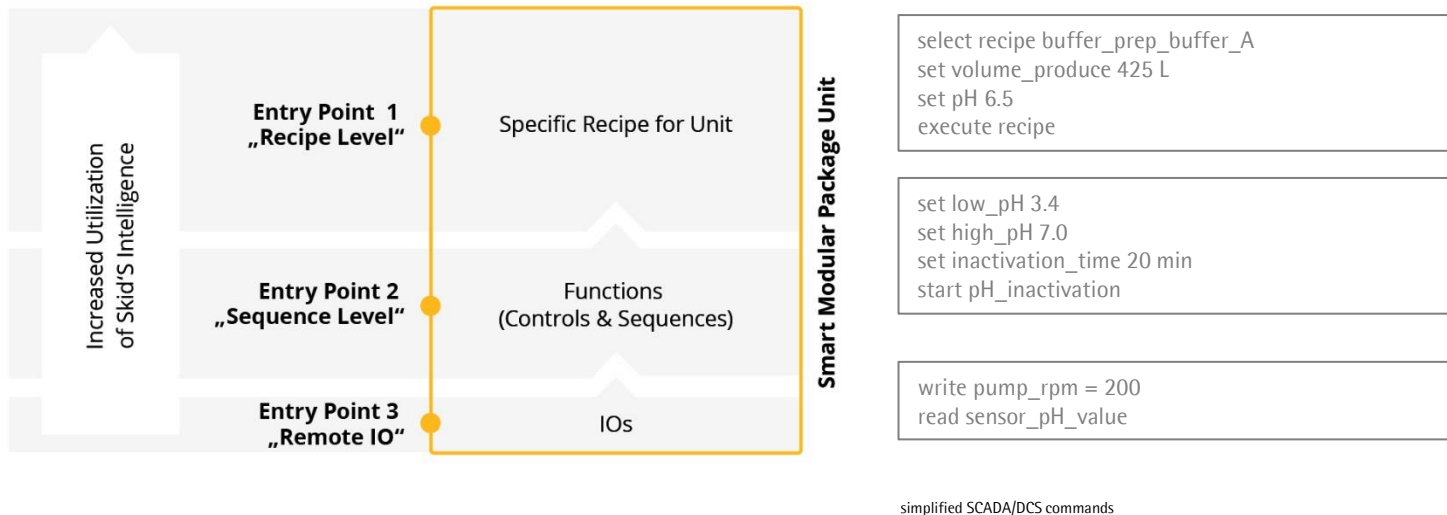


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Integration of package unit into SCADA / DCS - Options

Based on customer requirements different integration options can be used:



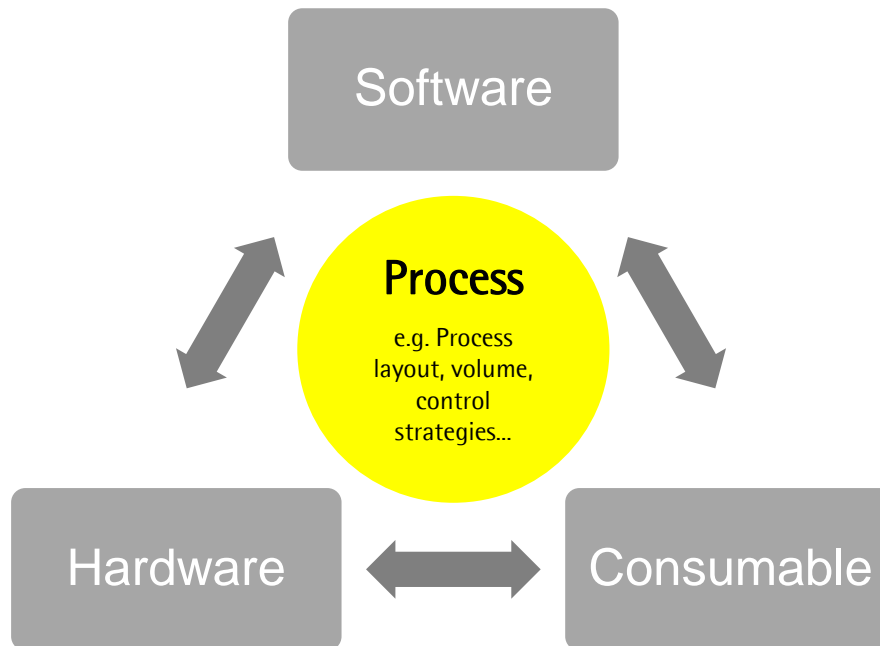
Modular Integration lead to 50-75% time reduction

Activity	Remote IO	Modular Integration
Functional Specification	●	●
Software Design Specification	●	○
Hardware Design Specification	●	○
Module Design and Configuration Specifications (CM/EM/EPH)	●	○
Construction, Coding and Configuration	●	●
Module Design and Configuration Testing (CM/EM/EPH)	●	○
Software Integration Testing	●	●
Hardware Acceptance Testing	●	●
Factory Acceptance Testing	●	●
Site Acceptance Testing	●	●

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based on entry level 2 – Sequence Level

Software, Hardware & Consumables have to follow process requirements



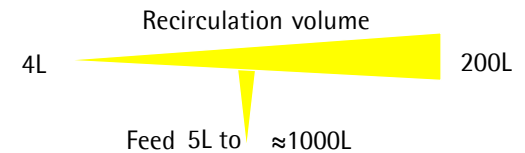
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Case FlexAct® | Crossflow filtration: example parametrization

Design space flexibility (over 30k variations)

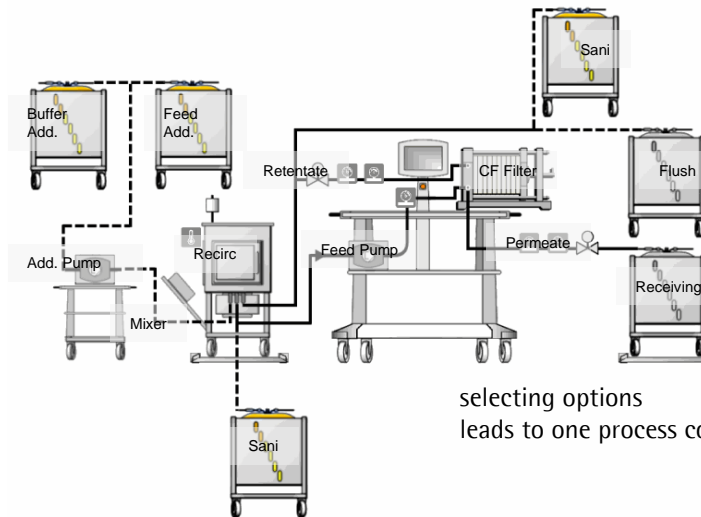


Example options:

Sartorius filter option:
Membrane material,
molecular weight cut off or
3rd party filters

Process control
Temperature control, pH
and conductivity
monitoring

Permeate tubing diameter
½", 3/8" and ¼"

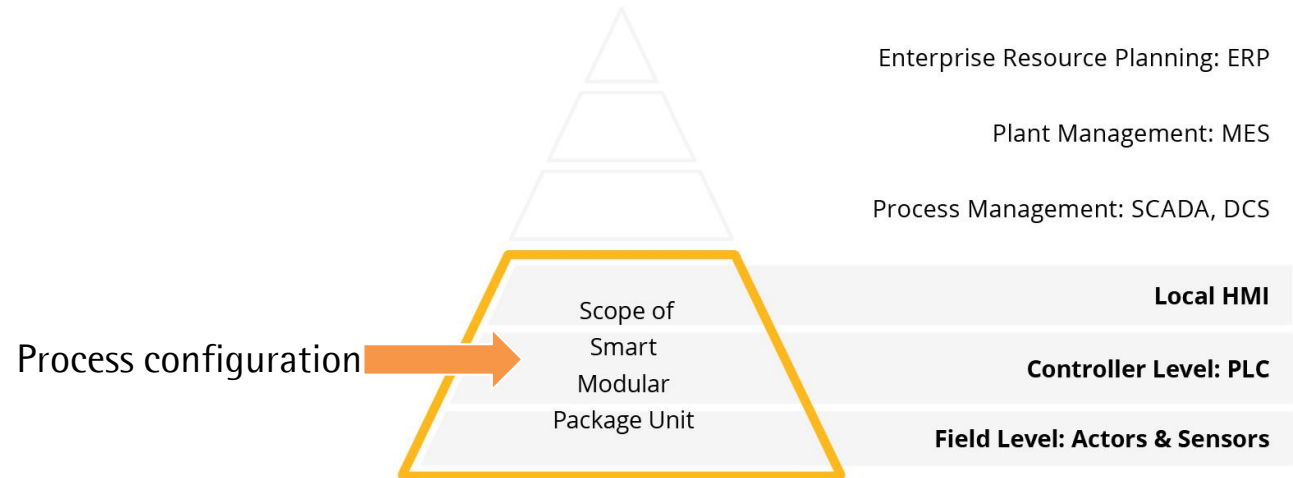


selecting options
leads to one process configuration

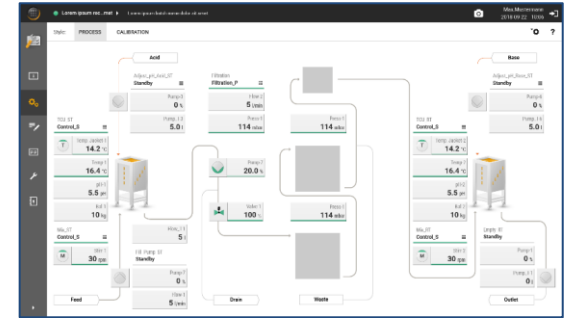
Automation flexibility

Based on the process configuration, the system will:

- ... change the unit operation e.g. buffer-preparation, crossflow filtration ...
- ... activate the right sensors & actuators including controls
- ... pre-parametrize sequences & recipes
- ... adapt the HMI



Automation and user interface follows selected hardware and consumables



Change your hardware and consumable set-up

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Seed train products: Biostat[®] RM and STR[®] powered by Biobrain[®]

- Today a closer look at local automation
- Biopharma customer requirements



Some definitions

- What's in ?

Embedded

Integral part of our bioprocess instrument

Enable

Functions needed for the instrument in USP, DSP & FMT

Local

Represent the local automation

- What's out ?

Not a focus on the whole production line

- Automation of a full production line
- Process Recipe & batch report
- Full process data historian



Produce as early as possible

"Time-to-facility is business critical for many commercial manufacturing scenarios"

- Produce early with GMP compliance and integrate later
 - Biobrain® GMP stand-alone capability
 - No initial integration
 - Generate batch record, stored and archived

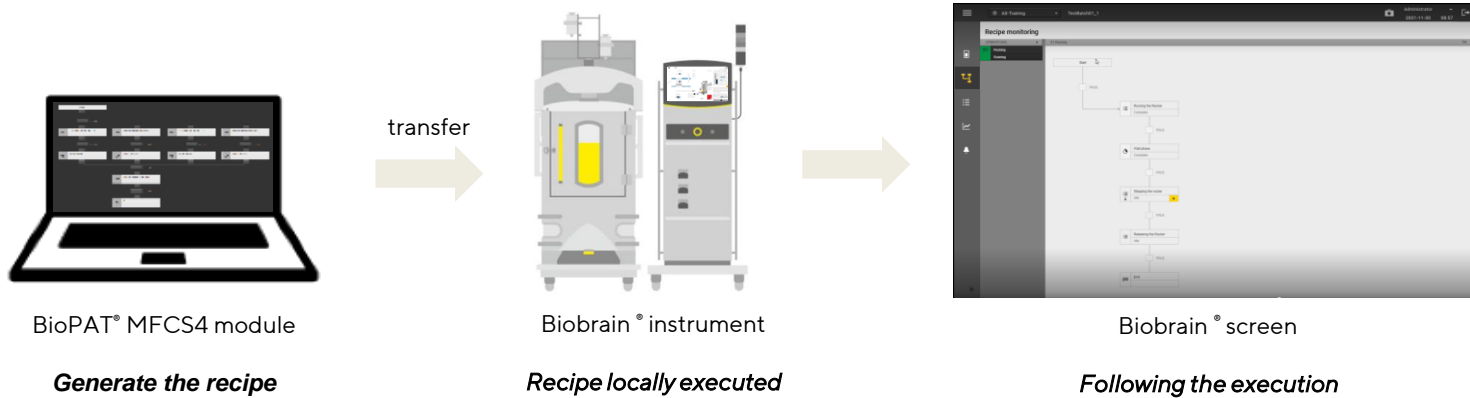
- Integrate faster with support
 - Up-to-date OPC UA interface standard in Biobrain®
 - Transfer all recorded process data, alarms & events and audit trails upwards
 - Execute ANSI-88 conform functions in Biobrain® by higher automation systems
 - Detailed documentations & interface consulting service are easing implementation



Advanced process control reduces risk of batch loss

“False operator actions are a major root cause for rejected batches”

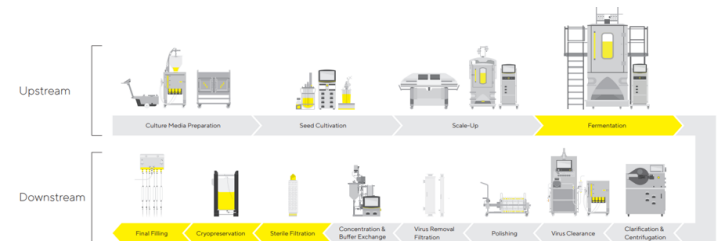
- Automate as much as possible to reduce operator interaction



- Customized recipe service available

Key for flexible, modular manufacturing concepts

- Modularity does not stop with hardware
- Hardware, Consumable and Software to follow process requirements
- Flexibility is important to adapt for process changes
- Different integration scenarios support:
 - Produce as early as possible
 - Speed up in integration
 - Reduce errors



Thank You !

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