



2023 Single-Use Pulse Webinar Series

ADVANCING FACILITY FLEXIBILITY THROUGH SINGLE-USE & AUTOMATION

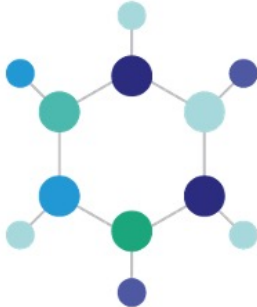
 Thursday, February 23, 2023

 10 – 11:00 AM EST

Presenter | Matt Kessler, MSD Switzerland

Moderator | Stuart Tindal, Sartorius

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Single-Use BioProcessing Automation Committee

Overview statement

Single-use bioprocessing automation is specific and increasingly more used, good practices and education should help to adopt single-use technologies more broadly and would provide insight where the industry should go (and avoid) related to this matter.

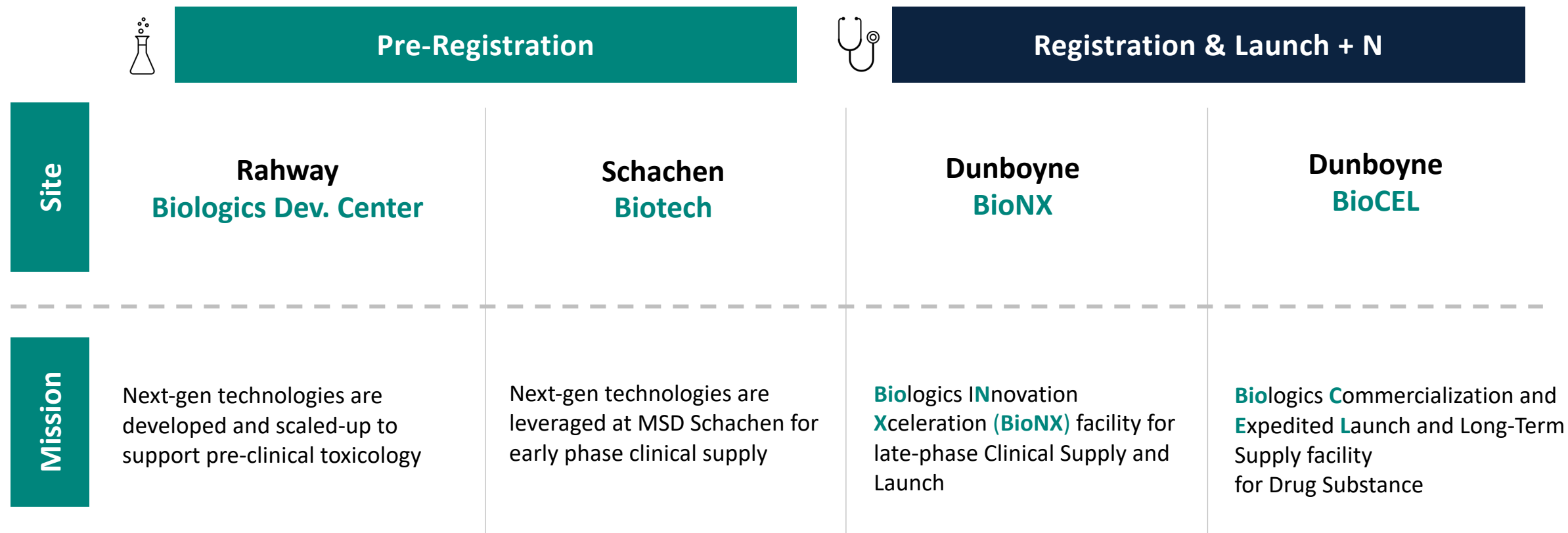
SU Automation Challenges

- 1. Communication protocols/ decentralized vs centralized control.**
 - Difficult to connect automation structures (no direct communication between systems), different integration/ interfaces scenarios and options for local to supervisory control.
- 2. Integration into quality records**
 - Integration of automation data into quality records. Regulatory compliance of automated systems.
- 3. Integrity, leak or Critical Quality Attribute testing single-use setup**
 - As single-use design complexity increases, also the integrity of these designs needs to be controlled/tested. Manual effort no automated solution.
- 4. Sensing performance & duration in single-use solutions**
 - Poor sensing and actuator performance for single-use offering, precision and accuracy is needed for long processes and control of these parameters.
- 5. Lack of automation in single-use process**
 - Only a limited amount of single-use process is automated, majority still requires manual intervention and no walk away processing.

Advancing Facility Flexibility through Single Use and Automation

Matt Kessler – Biologics Manufacturing Innovation, MSD
Switzerland

We are expanding our network capability in support of the Biologics pipeline

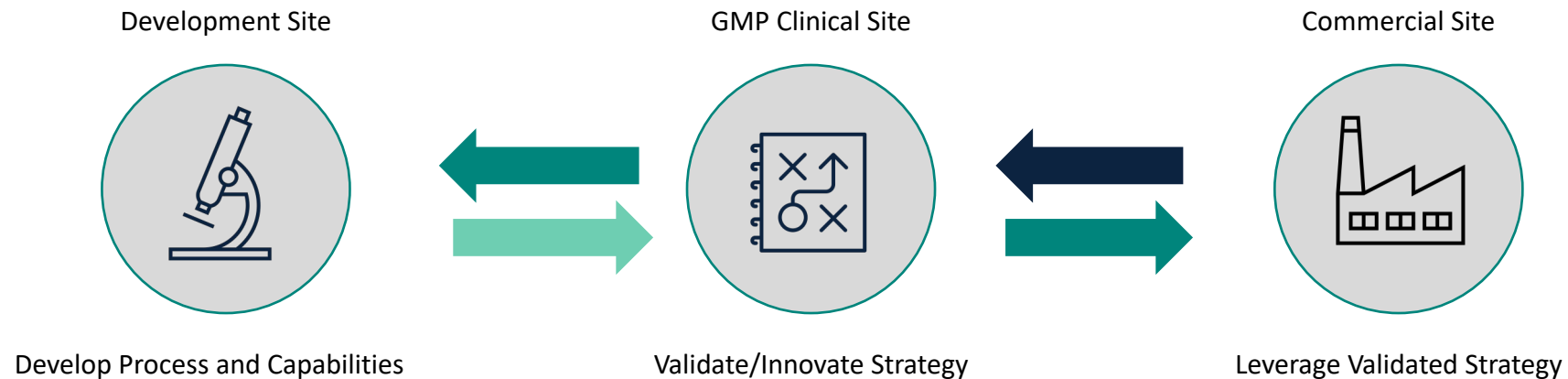


Age of disruption

Today's world of **un-met medical needs** and **challenges** means that we need to **approach differently**

Development and Transfer of Processes is extremely resource intensive:

- **Thousands of Man Hours** are needed to develop and transfer the process between nodes
- High **administrative burden** in modifying **qualified systems** and updating documentation



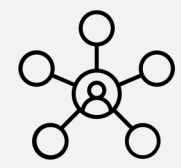
Automated Single Use Systems, with **Podular / Modular** facilities can help **alleviate that**.

Bringing order to chaos

Simplicity

Flexibility

Agility



Standardize



Parameterize



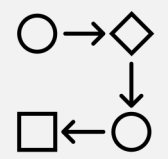
"Follow Me"



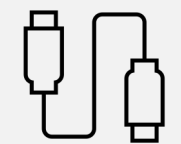
SU Components



PAT



**Digitize
with Intent**



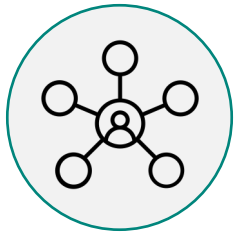
Plug-n-Play



Data Analysis

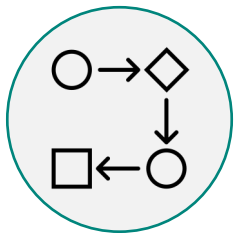
Simplicity

Simplicity



Standardize

After 3 times of doing the same thing-standardize formally



Digitize with Intent

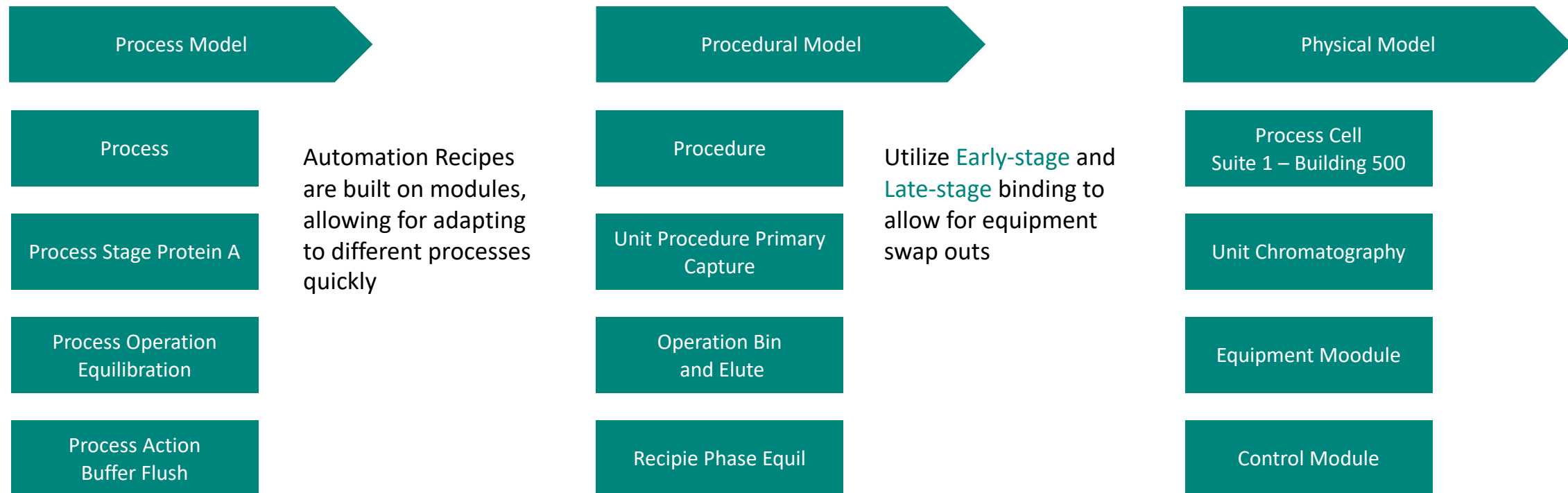
Remove interdependencies with digital business processes

The rapid pace of technology development allows us to constantly simplify in new ways. Imagine enabling new **capabilities** and **flexibility** like loading a **new App on your phone**

ISA-88 built for multi-product

Simplicity

The S-88 Model when implemented allows us to abstract the process from the automation and the equipment running on it.



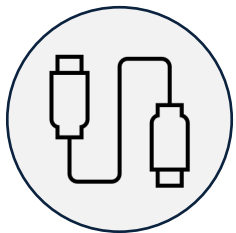
Flexibility builds on simplicity

Flexibility



Parameterize

Variables of process that can be in an automated recipe



Plug-n-Play

Seamless movement of equipment and devices

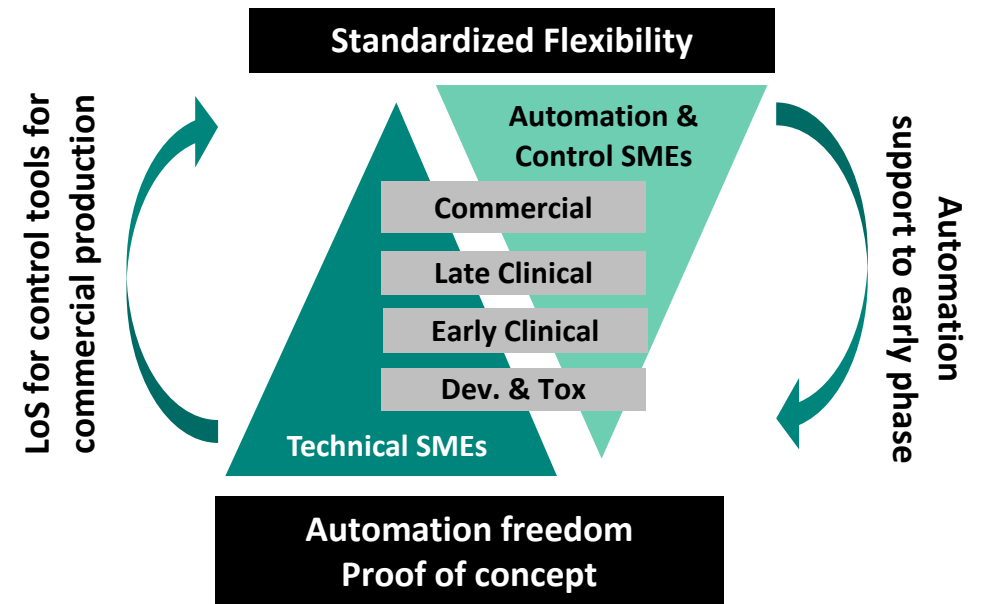
Flexibility is both a technology as well as a mentality. Understanding where flexibility is needed and where it is not helps ensure value to effort is sustainable.

Standardizing flexibility

Flexibility

Scale Out vs Scale Up while Standardizing Flexibility

- Allows agile **iterative improvements** over time, focusing on where flexibility is needed and isn't to maintain **sustainability**
- Utilizing S-88 Principles with **lack of Product-specific automation** enables **Program-to-Program reuse**
- Low customization, **minimal qualification efforts**, and standard structure **enables integration** with more systems **without complexity**
- Similarities in how we make a product, allows for **generic** master batch records and SOPS, creating consistent approach which **reduces operator errors** and **increases Right First Time**



Simplicity and flexibility enable agility

Agility



“Follow Me”

Right content, on right device at right time



Data Analysis

Aggregated data providing insights to trends

Virtualization and visualization of data enable teams to better collaborate, recognize shifts, and proactively move to minimize disruption.

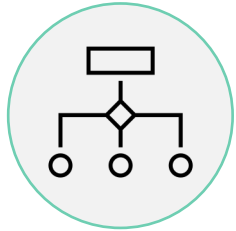
Agility from many aspects

Agility



Technology

Flexibility in Automation
Integration of PAT



Business processes

Alarm Rationalization
Flexibility on "who"



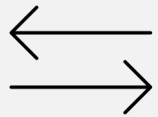
Behaviors

Process Understanding Risk
Based

To fully take advantage of the Single-use Automated System flexibility, we need to ensure that there is also agility in our Business Processes and Behaviors.

Where is the industry evolving

Module Type Package (MTP) is a modular framework that enables integration of systems and instruments quickly and easily.



Introduce **new devices** quickly **in hours** instead of weeks or months, with ability to change to **different devices** without **major changes**

- Services: heating, agitation, pH control
- Data: temperatures, pressures, flows
- Visualization: operator graphics
- Alarms
- Events/conditions
- OPC UA connectivity and tag information for obtaining the above items



Imagine instruments and systems that can **self-identify capabilities** updating graphics **automatically to reflect**

- Faster rearrangement of production equipment
- Almost zero automation engineering to copy a production line
- Reduction of qualification, validation, and documentation (approvals, etc.)

Summary

Single-use Production Equipment and Aligned Digital Automation Strategy can:

- Decrease tech transfer time between facilities with over 750 man-hours per product in comparison to stainless steel tech transfers
- Reduce supply chain risks, by having over 50% of the same components in use at other facilities
- 30-50% reduction of overall resources and administration needed

Acknowledgments

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MSD Ireland

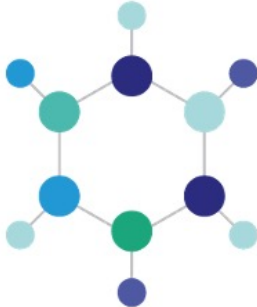
Tobias Zumbuhel

Questions?

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2023 Single-Use Pulse Webinar Series

IMPLEMENTATION OF X-RAY STERILIZATION OF SINGLE-USE SYSTEMS: WHAT TO EXPECT

 Thursday, March 9, 2023

 10 – 11:30 AM EST

Presenters

Samuel Dorey, Sartorius

James Hathcock, Pall Corporation