



# 2023 Single-Use Pulse Webinar Series

## **AUTOMATION CHALLENGES IN THE DESIGN & EXECUTION OF A SINGLE-USE FACILITY**

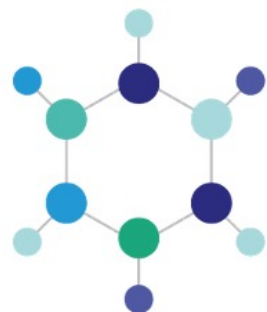
 Thursday, February 16, 2023

 10 – 11:00 AM EST

**Presenter** | Jeffrey Leverton, Wood PLC

**Moderator** | Stuart Tindal, Sartorius

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# BPSA Single-Use Pulse Series Brought to You By

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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.

Use-Cases and Solutions regarding automation challenges experienced during the design & execution of a single-use facility.

Jeff Leverton  
Wood

# Agenda & Objective

- Challenges to anticipate during equipment selection and how to overcome them;
- Data integrity, compliant ways to collect data from OEM Vendor equipment and the pitfalls;
- Examples of automation challenges in single-use plant design and solutions;
- How the design of equipment communication can impact your change management strategy;
- How upfront equipment specifications can avoid future issues even for “off-the-shelf equipment;” and
- When to:
  - Remove a vendors control system
  - Integrate it into the process control system
  - Not fix something that is not broken.

Note: This presentation will only address concerns from an automation perspective.

# Questions to ask

## Questions to ask yourself as you select equipment:

- 1) Does your company have automation standards/equipment specifications that you need to follow?
- 2) Do you have data integrity requirements you need to meet and a DI plan?
- 3) Will this equipment make GMP product?
- 4) What is your automation strategy? End to end automation or islands of automation?
- 5) Will you be using an MES and/or electronic batch records?
- 6) Is this equipment going into an existing facility or a new facility?
- 7) Will this equipment be dedicated to one location?
- 8) What is your redundancy philosophy?



# Typical Procurement Process

## Typical equipment procurement process:

- One of 3 things occur –
  - 1) you have a piece of equipment in you small scale/development area, so you purchase the same manufacturer for your commercial facility
  - 2) You have a vendor you have used before or heard of and decide to use it
  - 3) You go out for 3 bids and decide commercially/technically on a piece of equipment
- Automation is usually brought in after the potential vendors are selected or the vendor has been awarded to review the submittal. At this point it is luck if the vendor's platform match's the one selected for the plant.
- The team reviews the equipment submittal against dozens of specifications that your consultant sent the vendor.
- At this point, the DI requirements are usually not defined so you cannot use these as selection criteria for equipment.
- If you do not have specifications submitted to the vendor as part of the bid or the right specifications, then any changes to the system will be change orders.

# Single Use Typical to Single Use Plants

- Complication!
- Tubing everywhere!
- Challenges which are not automation issues in the typical sense of the word but can provide unique challenges that can be attributed to automation.
  - 1) Tubing stretches which impacts characteristics is it automation, maintenance or operator issue?
  - 2) Pump pushes the fluid the wrong way automation? Operator?
  - 3) Lends to individual control systems because of unique equipment.

# Data Integrity Challenges

- A lot of the equipment vendors out there do not fully understand 21 CFR Part 11 or Data Integrity Requirements and it is almost a guarantee they will not understand or meet each companies' interpretation of these requirements.
- As you place the order for the piece of equipment do you know how long you need to store the data?
- The data storage on each piece of equipment comes in different flavors if you are using the control system provided the vendor.
- Do you have a plan for addressing the offline data in the event it is needed for an investigation or audit request? Will you restore it to your production machine and overwrite the current data? Do you have a spare system? Have you created an offline tool for retrieval?
- Does your equipment support unique individual user access?

# Data Integrity Challenges

- How will you meet your Data Integrity testing requirements are you leveraging vendor testing? If so, will you have the right infrastructure in place during vendor testing to test the system as you will operate it in production?
- Will you have your Validation Master Plan, Automation Validation Plan and Data Integrity Plan in Place prior to testing?

# Control System Challenges

- Equipment can be supplied with flavors of control systems do you have automation engineers that know each of these systems?
- Are you relying on vendor support? How will they support?
- Some vendors require you to take training to get full access to their software and this can cost \$30,000 not including travel are you budgeting for this or are you making other plans?
- Will you collect data from the equipment?
- On the equipment are you using vendor supplied batch reports?
- Do you require remote notifications, or do you have other plans?
- Are you using portable equipment?
- Do you need to be able to swap out equipment in you production lines on the event of failure?

# Communication

- Have a design in mind how you want to handle change management/configuration management.
- Do you need instruments to communicate to other locations besides the control system?
- How will you handle instrument and VFD configuration?
- Will you use shared drives or software?

# Using your own Control System

There may be times to use your own control system but, in my opinion, these are few and far between and need to be well thought out. Some of the reasons are below:

- You need the equipment to be part of your part control system because of your Batch or Continuous process strategy.
- Maybe closing DI gaps at the extreme
- Maybe for training reasons at the extreme

There can be consequences of making this change:

- The vendor may not support the equipment after this change
- The warranty will be voided
- The cost will be greater because the discount if any from removing the control system will not offset the development costs
- This will impact schedule unless there is float because you will have to reverse engineer how the equipment will work, and you will need experts on the equipment

# Jeff's Best Practices

- 1) Have your own automation and equipment specifications before you start the project.
- 2) Have your Data Integrity requirements defined before you start purchasing equipment.
- 3) Have your validation plans and data integrity plans written
- 4) Review your potential equipment selections against your specifications and data integrity requirements.
- 5) Once selection is made get a jump on closing specification and requirement gaps
- 6) Work with vendor to meet critical requirements and specifications
- 7) Leverage vendor testing and have your infrastructure in place so that you do not have to repeat any testing
- 8) Select an automation partner that has experience integrating vendor equipment into other systems. Most can handle single systems less have experience or are good at this type of integration.
- 9) Plan for how you will handle support. If you plan on using remote support, use solutions that can limit your cyber security and regulatory risk.
- 10) Design the systems with data integrity and cyber security in mind.
- 11) Define your master data what will you use in investigations and audits



# Future Potentials

- OPA Open Process Automation Forum
- Companies providing prebuilt, pre-configured, and qualified plants.

# Questions?

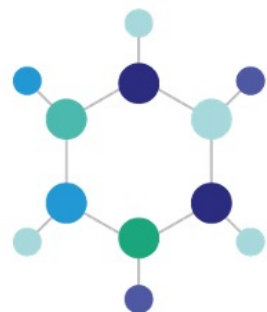


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# 2023 Single-Use Pulse Webinar Series

## 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