



2023 Single-Use Pulse Webinar Series

From Theory to Practice: the Design, Control & Monitoring of Single-Use Systems (SUS) for Integrity Assurance

Tuesday, October 31 | 10 - 11:30am ET

Presenters

Patrick Evrard, Cytiva, BPSA Integrity Committee Chair

Monica Cardona, Millipore Sigma

Charlotte Masy, GSK

Nathalie Pathier, Sartorius

Scott Patterson, ILC Dover

Changhong Zhang, Sanofi



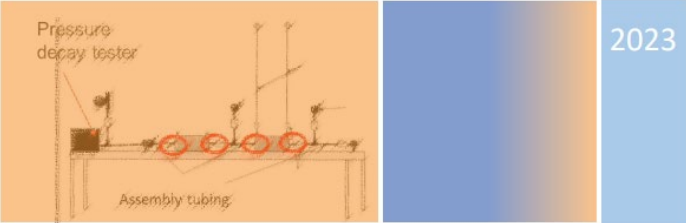
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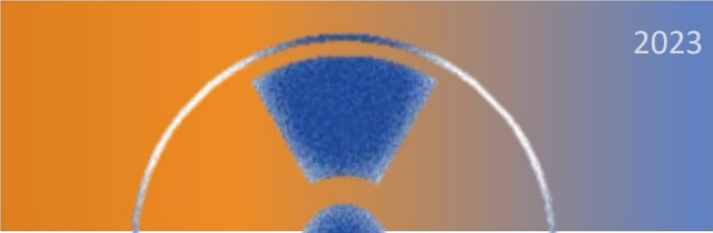


2023

DESIGN, CONTROL AND MONITORING OF SUS FOR INTEGRITY ASSURANCE VOLUME 2

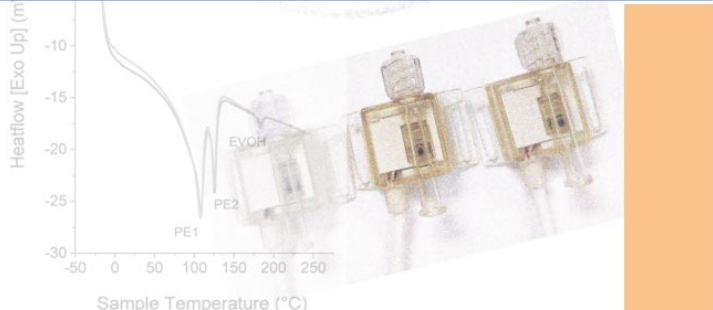


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X-RAY STERILIZATION OF SINGLE-USE BIOPROCESS EQUIPMENT PART II – REPRESENTATIVE QUALIFICATION DATA



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You will find a treasure trove of technical guides and recorded webinars on the BPSA website:

www.bpsalliance.org

Panel Experts



Patrick Evrard, Cytiva
BPSA Integrity Assurance
Committee Chair



Monica Cardona
Millipore Sigma



Charlotte Masy
GSK



Nathalie Pathier
Sartorius



Scott Patterson
ILC Dover



Changhong Zhang
Sanofi

Introduction: Technical Guide Overview



- 1 - Intent and Scope
- 2 - Introduction
- 3 - Case Study - Design, Qualification and Validation of a SUS for a Critical Application Using QbD Principles
- 4 - Case Studies - Integrity Issues with Various Components
- 5 - Integrity Testing Technologies - Updates
- 6 - Handling Practices and Training
- 7 - Industry Interest Group Initiatives and Regulatory Updates
- 8 - Specific Case Studies
- 9 - Conclusions

Panel Questions:

What are possible testing strategies and how to define a proper ICS (Integrity Control Strategy)?

Panel Questions:

The Technical Guide presents an approach of implementing highly sensitive test methods with different detection limits - for storage or for transfer applications. What led you to have this differentiated approach?

Panel Questions:

What is your return on experience after having implemented 100% integrity testing for the systems used in critical-to-integrity applications? Is it worth the journey? What are the benefits and eventually the drawbacks?

Panel Questions:

Over the last years, how have the standards and regulatory landscape on SUS integrity evolved?

Panel Questions:

Different testing technologies are described in the Technical Guide. Should all end-users select the most sensitive one?

Panel Questions:

Powder handling with SUS is not often covered in articles and literature. Is there a specific approach to follow when implementing SUS for powder handling?

Panel Questions:

What is the main difference between "solid handling" (powders) and classical liquid handling?"

Panel Questions:

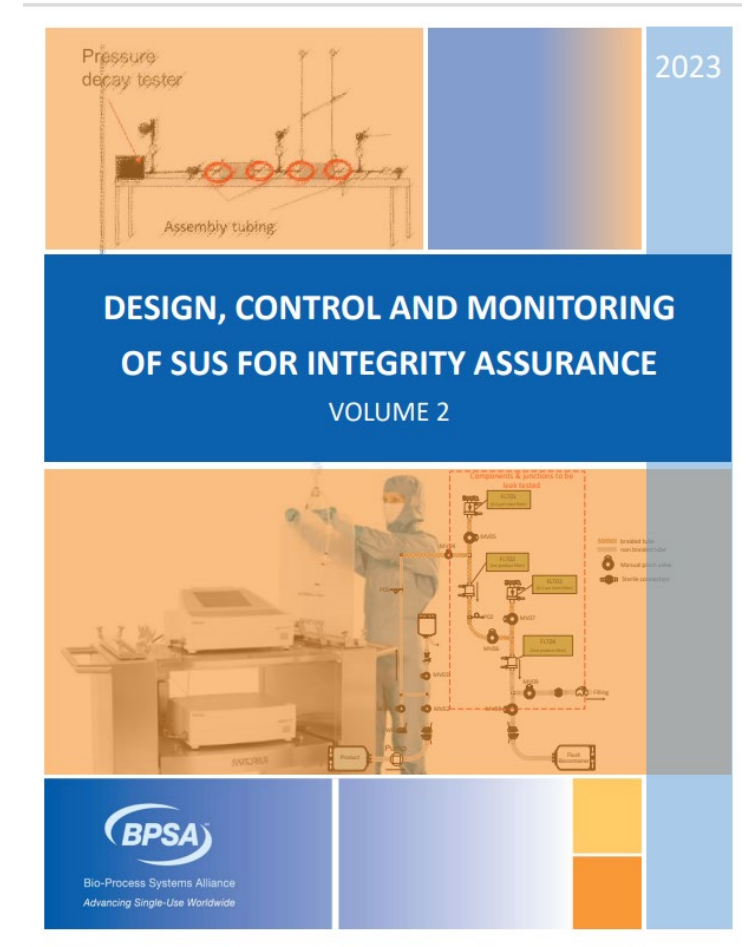
What are the main benefits of using a structured QbD approach to design, qualify and implement a SUS as described in one of the case studies?

Thank you!

Questions?

Thank you for your participation!

Visit [Technical Guides - Bio-Process Systems Alliance \(bpsalliance.org\)](https://www.bpsalliance.org) to download a copy of *BPSA's Technical Guide on Integrity Assurance, Volume 2*.



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Save the Date: 2024 BPSA Summit



**2024 BPSA International
Single-Use Summit**
July 22-24, 2024
Four Seasons | Washington, DC
www.bpsalliance.org

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