
PDA
Parenteral Drug Association


BioPhorum

The Science, Implications and Implementation of PUPSIT (Pre-Use Post Sterilization Integrity Testing) – A 3 Part Webinar Series

Sept 1: The Role of PUPSIT in the Assurance of Sterilising Filtration

Sept 8: *Assessing the Risk of Filter Masking*

Sept 21: *Practical Implication and Decision Making of PUPSIT*

Sterile Filtration Quality Risk Management (SFQRM) Consortium

Companies have struggled with the implementation of the PUPSIT(Pre-Use Post Sterilizaiton Integrity Testing) requirement as EU and other regulatory authorities have increased their enforcement of its use for sterile products.

To address this issue PDA and BioPhorum formed the Sterile Filtration Quality Risk Management (SFQRM) consortium in 2017.

The consortium brought together a group of over 50 subject matter experts, over a 3-year period, and are now ready to share their groundbreaking results and insight.

Today's Moderator and Expert Q&A Panel

Moderator:

Hal Baseman	Chief Operating Officer at Valsource Inc.

Expert Q&A Panel:

Mandar Dixit	Principal Process Expert, Sartorius Stedim North America Inc
Steve Ensign	Senior Consultant Engineer, Eli Lilly
Maik Jornitz	President and CEO of G-CON Manufacturing Inc.
Brian Thome PhD.	Principal Engineer, Parenteral Manufacturing Sciences, Biogen
Carl Weitzmann PhD.	Associate Director, Process Technology Platform, Sanofi Pasteur

Today's Presenter

Maik W. Jornitz

President and CEO of G-CON Manufacturing Inc

Mr. Jornitz is a technical expert with over 30 years of experience in bioprocesses, especially sterilizing grade filtration and single-use technologies, including regulatory requirements, integrity testing, systems design, and optimization. Jornitz has published 11 books, 18 book chapters and over 100 scientific papers. He is the former Chair of the PDA Board of Directors and Science Advisory Board, and member of multiple PDA Task Forces. He is working member of Biophorum, ASTM, an advisory board member of the Biotechnology Industry Council, ICAV and multiple science journals. He recently has been recognized as one of the top ten global industry influencers. As a faculty member of various training activities, including PDA TRI, he trains members of the industry and regulatory authorities on a frequent basis. He received his M.Eng. in Bioengineering at the University of Applied Sciences in Hamburg, Germany and accomplished the PED program at IMD Business School in Lausanne, Switzerland

-Presentation by Maik Jornitz-

Q&A Session

-Panelist Bios-

Mandar Dixit

Principal Process Expert, Sartorius Stedim North America Inc.

Mr. Dixit has 15 years of experience in the BioProcessing industry with a special focus on filtration and purification technologies. He proactively collaborates with early and late-stage Process Development and MSAT leaders globally to overcome their challenges through testing appropriate high-performance solutions across the entire process chain. He is a member of PDA and ACS BioTechnology Division. Mr. Dixit has presented papers and posters at conferences & co-authored papers in trade journals on various topics related to Filtration and Downstream Processing. He received his Bachelor's Degree in Chemical Engineering from IIT-Bombay in India and his Master's Degree in Chemical Engineering from Louisiana State University in Baton Rouge, LA.

Hal Baseman

Chief Operating Officer at Valsource Inc

Mr. Baseman is the Chief Operating Officer at Valsource Inc. with over 40 years in pharmaceutical industry. He has held PDA positions as Board Chair, SAB Co-chair, Co-lead for Aseptic Processing Points to Consider, Process Validation IG, TR 22, 44, and 60, and is a long standing member of TRI faculty. Hal co-chairs the Annex 1 response team, Portfolio Steering Committee, and MSOP and is a member of the QRM for Aseptic Processing Standards task force and the PUPSIT consortium committee. Hal holds MBA from LaSalle University and B.S. Biology from Ursinus College.

Steve Ensign

Senior Consultant Engineer

Eli Lilly

Mr. Ensign has over 30 years of experience in the pharmaceutical industry and has had numerous assignments in engineering projects and process, TSMS, manufacturing, leadership and Six Sigma (Black Belt) in the parenteral operations area. Previous assignments have included new product development, scale-ups, building and starting up new facilities. His current position is working to increase pre-filled syringe capacity in the US and Europe for current and new products.. Mr. Ensign received a B.S. in Mechanical Engineering from the University of Illinois in 1988 and Six Sigma Black Belt certification in 2005.

Brian Thome PhD.

Principal Engineer, Parenteral Manufacturing Sciences, Biogen

Brian is a process engineer who has worked across the fill finish spectrum over his twelve year career in the biopharma industry including formulations, lyophilization, process development, analytics and technology transfer. The last ten years have been spent at Biogen where he has led tech parenteral drug product technology transfers to external manufacturing partners as part of the launch of three commercial products. He currently leads a team responsible for process validation and ongoing technical process ownership for Biogen's commercial parenteral products. Brian is from Seattle, Washington, USA and currently lives in Zürich, Switzerland. He received his doctorate in Chemical Engineering from Washington State University.

Carl Weitzmann PhD

Associate Director, Process Technology Platform

Sanofi Pasteur

Carl Weitzmann is Associate Director in the Process Technology platform at Sanofi Pasteur, located at the vaccines production site in Swiftwater Pennsylvania, with responsibility for filtration processes. He has held positions at Wyeth (Pearl River) and at Sanofi in R&D QA, R&D Process Development, and Manufacturing Technology, spanning development and technology transfer of multiple vaccine and biological products. He holds a Ph.D. in Biochemistry from the University of Pennsylvania, with a strong background in enzymology, protein chemistry, and molecular biology, 20 years' experience in the pharmaceutical industry dealing with process, aseptic process, cleaning, and filter validation, and 10 years' experience in filter manufacture and validation.