Aseptic Process Simulation (Media Fill)

22 May 2025
Online Seminar

Kurs-Nr. 7043

ONLINE SEMINAR

Pharmaceutical Manufacturing

Target group

This seminar is designed to equip participants with the necessary knowledge and skills to ensure compliance with regulatory requirements and optimize APS (Aseptic Process Simulation) activities in their organizations.

MAKING SCIENCE WORK

Objectives

The seminar aims to provide a comprehensive understanding of the regulatory requirements for aseptic process simulation (APS) across various dosage forms. Participants will gain insights into critical aspects of the process, including vacuum control, ventilation, process step durations, and best practices to optimize APS while avoiding common pitfalls.

A significant focus will be placed on quality and environmental protection measures, such as environmental monitoring during APS and recommendations for leak rate testing. Additionally, the seminar will cover essential topics on qualification and validation of rooms, systems, personnel, and processes, including RABS (Restricted Access Barrier Systems) and isolators, as well as airflow visualization and cleanroom class A qualification.

Participants will also learn about APS design and oversight, covering key factors like material formats, packaging materials, holding times, filling time, and bracketing considerations.

The target group includes pharmaceutical professionals directly involved in manufacturing or validation of aseptic processes, quality assurance specialists, regulatory affairs managers, process engineers and developers, as well as technical leaders responsible for implementing and overseeing APS standards.

Chairman and speaker

Christian Gavranovic
PPT Pharma Process Technology, Deutschland

Christian Gavranovic started his career as a process and project engineer at Boehringer Ingelheim in Ingelheim. He subsequently gained further experience as a quality assurance manager for aseptic filling and as an operations assistant in the area of final packaging. Since 2021, he has been working at PPT as the lead for the Quality and Compliance department, supporting his clients in meeting all regulatory requirements.

Luigi Scaffidi
Boehringer Ingelheim, Deutschland

Luigi Scaffidi began his career in 1986 at Boehringer Ingelheim in Ingelheim, with a training as a biology laboratory technician. Since then, he has worked in various fields, including research (e.g., cell culture, in vivo/in vitro metabolism) and development (e.g., device and packaging development for sterile and non-sterile dosage forms). In 2012, he transitioned to quality assurance (Aseptic Quality Assurance), focusing on aseptic processes, hygiene, qualification, and validation.

Alexandra Hertrampf
Merck Healthcare KGaA

Dr. Alexandra Hertrampf studied pharmacy at the University of Jena. She subsequently earned her doctorate in chemistry at the Technical University of Lisbon in collaboration with Merck KGaA. In 2015, She started as laboratory manager the role of laboratory manager for sterile biotechnological medicinal products at Merck KGaA. In 2018, she transitioned to the production of sterile medicinal products as associate director, where she was responsible for compliance and various manufacturing processes, including compounding, filling, visual inspection, and packaging. Since June 2022, Alexandra works as the plant manager for the manufacturing and packaging of sterile medicinal products.

Stefan Schneid
Bayer

Dr. Stefan Schneid is currently the Scientific Lead Parenterals in CMC Drug Product and Science Fellow at Bayer AG. He is responsible for scientific and strategic advancement of formulation and process development for novel biological entities, small molecules and new modalities. He is involved in parenteral development and marketed projects from the preclinical stage up to transfer to commercial production. Previously, Stefan worked as a Laboratory Head in Bayer's parenteral formulation development group. Prior to joining Bayer, he was a R&D manager at Syntacoll, where he was responsible for developing novel formulations for drug-containing biodegradable implants. Stefan spent one year as a visiting scientist in Prof. Michael Pikal's lab at the University of Connecticut. He holds a degree in pharmacy from the University of Munich and a Ph.D. in pharmaceutics from the University of Erlangen.

Programme

Thursday, 22 May 2025 09:00 - 13:15 h CET

Regulatory aspects and recommendations
- Regulatory Requirements and Recommendations for APS
- APS in various dosage forms
- Incubation of the units, Reconciliation
- Environmental monitoring during APS
- Personnel Qualification

Luigi Scaffidi, Boehringer Ingelheim

Requirements for the APS
- Qualification/validation of rooms, systems, personnel, and processes
- Qualification/validation of RABS/Isolator
- Interface to Airflow Visualization / Qualification of clean room class A

Christian Gavranovic, PPT Pharma Process Technology GmbH

Requirements for
- QA Oversight
- APS Design
  - Formats
  - Packaging materials
  - Holding times
  - Filling time
  - Bracketing

Alexandra Hertrampf, Merck Healthcare KGaA

Points to consider for APS of lyophilizers
- Critical Aspects of Process (Vacuum, Ventilation, Step Durations)
- Best Practices and Things to avoid
- Recommendations for Leak Rate Testing

Stefan Schneid, Bayer

Q+A – Session and Final discussion
Luigi Scaffidi, Stefan Schneid, Christian Gavranovic, and Alexandra Hertrampf

Programme is subject to change

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Registration

To register for the APV seminar, you can easily sign up online. Your registration will be processed promptly, and we are happy to assist you if you have any questions.

Once you successfully complete the online registration, you will receive a confirmation and an invoice via email.

Directly to the seminar/registration:

apv-mainz.de/en/events/seminars/details/seminar/7043

Registration fee

Industry	400,00 EUR
Authority/University	200,00 EUR
Students*	50,00 EUR

(free of VAT according to § 4,22 UStG) electronic proceedings included.

* Limited places for full time students available; written evidence must be submitted.

Live Online Seminar

Course no.: 7043

Date

22 May 2025 09:00 - 13:15 h

APV MAKING SCIENCE WORK

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Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

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