ECA Academy
Your GMP/GDP Information Source

In cooperation with ISPE
ISPE Germany | Austria | Switzerland Affiliate

Speakers


Silke Büchl
Praevena


Dr Andreas Flückiger
Formerly
F. Hoffmann La-Roche


Oliver Gottlieb
NNE


Dr Martin Schöler
Fette Compacting


Dr Patrick Sproll
Lonza

NEWS

Stay informed with the GMP Newsletters from ECA

The ECA offers various free of charge GMP newsletters for which you can subscribe to according to your needs.

To subscribe, simply scan the QR code on the right or visit www.gmp-compliance.org/gmp-newsletter

Current Developments in Containment

The new SMEPAC Guideline

Live Online Training on 26 June 2025

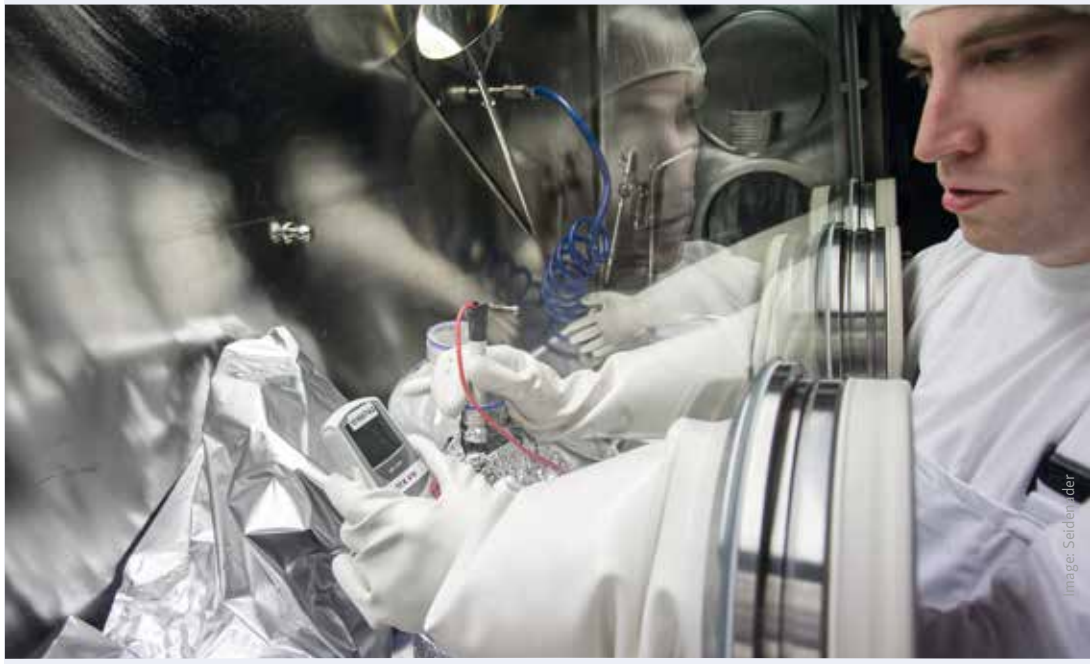
Image: Seidenader

Highlights

- Occupational health and GMP aspects
- How much containment is necessary
- Presentation of the new ISPE SMEPAC Guideline
- Containment Measurements in Practice
- Comparability of Measurements
- Handling Limit Values

Objective

The primary focus of this conference is the newly updated ISPE SMEPAC Guideline and its impact on modern containment strategies. By examining real-world measurement techniques, hazard assessments, and compliance best practices, participants will learn how to implement and validate robust containment measurements under the latest requirements, ensuring safety for workers as well as patients by reducing the risk of cross contamination.

Background

In our highly regulated environment GMP sets the baseline for safe and consistent production. Containment strategies bridge the gap between operational efficiency and regulatory compliance. By minimizing the risk of cross-contamination and exposure, effective containment systems not only safeguard product quality but also protect employees from potent or hazardous substances.

Recent developments underline the growing importance of containment. The new ISPE SMEPAC (Standardized Methodology for the Evaluation of Pharma Airborne Particle Emissions from Containment Systems) Guideline represents a significant milestone, offering a unified approach to assess and validate containment performance. This guideline provides clear methodologies for measuring airborne particulate concentrations, thus helping manufacturers align their processes with stringent safety and quality requirements. As advanced therapies continue to emerge – often involving highly potent active pharmaceutical ingredients (HPAPIs) – the need for robust containment systems becomes all the more critical.

This conference will delve into the multifaceted aspects of containment, focusing on how to effectively integrate GMP principles with cutting-edge technological solutions. Industry experts will share best practices for designing, implementing, and maintaining containment measures that meet current regulatory standards.

Target Audience

This conference targets professionals from production, engineering, quality and occupational health, as well as suppliers of containment solution, dealing with the tightness of containment systems.

Moderator

Martin Schöler

Programme

Introduction to Containment

- Occupational health and GMP aspects
- Containment systems
- Primary and secondary containment
- How much containment?
- Assessing the hazard (potency & toxicity)
- OEBs and OELs as determinants for containment

Presentation of the new SMEPAC Guideline

- The new guide
- Why was there a need for a new version?
- Who participated in it?
- What has changed?

Carrying out SMEPAC Measurements

- Monitoring concepts
- Roles and responsibilities
- Monitoring strategy (air, surface, direct reading, sampling heads)
- Do's and don'ts for SMEPAC monitoring
- Results as an example
- Statistical evaluation if not discussed otherwise

Comparability of Measurements

- The project dilemma: where are we now with expectations on containment performance and the reality of „measurement after delivery"?
- What does the new SMEPAC guideline say on comparability of measurements?
- Avoid misunderstanding: drug load vs. „total dust"
- Which factors are influencing a containment measurement?
- Case study: comparison of measurement results for the same equipment in different environments

Handling Limit Values in Practice

- SMEPAC vs occupational exposure measurements
- Monitoring occupational exposure for new containment systems
- Handling of occupational exposure measurement results

The new SMEPAC Guide

Previously titled ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment, this third edition has been renamed Standardized Methodology for the Evaluation of Pharma Airborne Particle Emissions from Containment Systems. It provides standardized methods for evaluating containment performance by sampling and analysing airborne and surface deposits of surrogate materials under defined test conditions, reflecting well-established industry and occupational hygiene practices.
This updated edition includes guidance on complex equipment and continuous manufacturing processes, expanded surrogate selection, and revised test protocols. It incorporates experiences from numerous containment assessments and serves as a worldwide resource for both equipment suppliers and end users. The SMEPAC Guide is available at www.ispe.org.

Speakers

Silke Büchl
Praevena

Silke Büchl is an IOHA-certified occupational hygienist with more than 20 years of experience in the field of occupational hygiene. She is the owner of Praevena AG, a service provider in the field of occupational hygiene. Praevena carries out occupational hygiene measurements and SMEPAC Measurements and supports in all matters relating to occupational hygiene.
After completing her Master's degree at the ETH Zurich/University of Lausanne in 2003, she worked as an occupational hygienist in various local and global positions at Novartis. In 2014 she moved to the service sector at Praevena AG.

Dr Andreas Flückiger
Formerly F. Hoffmann La-Roche

An occupational physician by training, Andreas Flückiger was the head of the occupational health services of the Roche Group for 32 years. Now retired from this position, he continues to be active as a consultant in occupational and GMP toxicology as well as process containment in the pharmaceutical industry. He is still engaged in various international organisations such as the International Association for Occupational and Environmental Health in the Chemical Industry (Medichem), the Society of Toxicology (SOT), ACGIH, and in working groups of the ISPE and ASTM.

Oliver Gottlieb
NNE

Oliver Gottlieb is a Process & Chemical Engineer and works for NNE as a Senior Specialist/SME in the process department for Drug Substance. He has more than 20 years of experience in the Pharmaceutical Industry with focus on containment and chemical API production. He is co-author of ISPE's SMEPAC Guide and Containment Manual.

Dr Martin Schöler
Fette Compacting

Martin Schöler is the Vice President Technology at Fette Compacting. He is an expert in containment technologies and has significantly contributed to the development of Fette Compacting`s Containment Guard method. Martin Schöler currently leads the Containment Working Group of ISPE D/A/CH and is one of the co-authors of the new ISPE SMEPAC Good Practice Guide.

Dr Patrick Sproll
Lonza

Patrick Sproll has been working as an Occupational Hygienist at Lonza Visp, Switzerland for the past four years. He is significantly involved in the occupational exposure monitoring program at Lonza Visp and other Swiss Lonza sites. He is a member of the steering committee COP Containment ISPE Affiliate DACH and actively participates in a network of Occupational Hygienists, Physicians and Toxicologists, who form a working group of the Basel Chemical Industry (BCI).

Your Benefits

Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „...All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the Live Online Training in detail and with which you document your training.

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Live Online Training: Current Developments in Containment
26 June 2025

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation.
Terms of payment: Payable without deductions within 10 days after receipt of invoice.

Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date Live Online Training
Thursday, 26 June 2025, 10.00 to approx. 16.50h
All times mentioned are CEST.

Technical Requirements
We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. Webex is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)
ECA Members € 990
APIC Members € 1.090
Non-ECA Members € 1.190
EU GMP Inspectorates € 595
The fee is payable in advance after receipt of invoice.

Registration
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22337. To avoid incorrect information, please give us the exact address and full name of the participant.

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Organisation and Contact
ECA has entrusted Concept Heidelberg with the organisation of this event.

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Robert Eicher (Operations Director) at
+49(0)62 21/84 44 12 or per e-mail at
eicher@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Manuela Luckhaupt (Organisation Manager) at
+49(0)62 21/84 44 66 or at
luckhaupt@concept-heidelberg.de.