

NEW

TTC TECHNOLOGY TRAINING CENTER

Workshop 238

COMPETENT CONTAINMENT

27 February – 01 March 2018



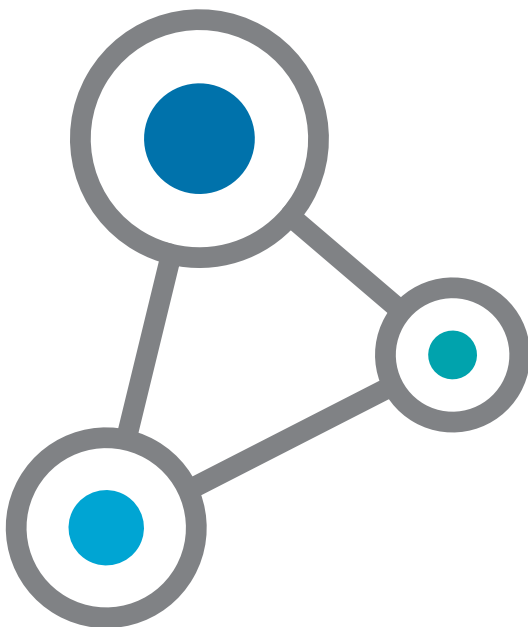
WHY TO ATTEND

More and more of the new OSD drugs comprise of highly active components, where just milligrams of API are required for one daily medical dose. Thus, the pharmaceutical industry is facing increasing demand from regulatory authorities to achieve lower limits with regards to cross contamination. On the other side, rising HSE requirements come up, in order to avoid negative health effects to the personnel producing those medicines. PDE, OEL, or OEB are the major key words related to that topic.

How much containment is actually required? How do I work with products with an OEL less than $1 \mu\text{g}/\text{m}^3$? How clean is clean? How do I achieve the required cleanliness of my equipment? What is the regulatory authorities view on containment and highly active API? Questions which will be discussed and answered in our seminar.

WHO SHOULD ATTEND

If you are working with highly active pharmaceutical products for OSD, or your company intends to work with them, you will take great advantage in participating in this seminar. Practical examples and demonstrations will illustrate appropriate solutions to engineers, pharmacists, and operators working in or for the pharmaceutical industries.



PROGRAM

TUESDAY, 27 FEBRUARY 2018

12:00 Transfer from hotel to TTC

12:15 **Snack in buffet, reception and registration**

12:50 Introduction. **Andreas Gottschalk**

13:00 **Containment in OSD Production.** Conceptual Requirements and Components for production with Highly Active Pharmaceutical Ingredients. There is no question, that containment is required, when highly active products are processed for OSD. The question is where and how much containment is required. **Michael Maintok**

13:45 **ISPE Containment Manual.** After its release in German and since 2017 in English language the ISPE Containment Manual developed to a Standard for Questions on Containment. **Richard Denk**

14:30 **Coffee break**

15:00 **Tablet Compression with Highly Active API.** Strategies and Solutions in Tablet Compression Machines. **Joerg Gierds**

15:45 **Semi- and fully automatic cleaning of fluidized bed installations applying WIP and CIP.** Exploring how to best use cleaning systems in the latest pharmaceutical processes - illustrated on fluidized bed systems. **Axel Schiffmann**

16:30 **Split butterfly valve systems and contained handling.** Especially the interfaces to the production area must be considered, when high containment qualities are required. Split butterfly valves are the standard device for charging and discharging procedures. **Erich Nussbaumer**

17:15 **Transfer to hotel**

19:30 **Workshop dinner**

WEDNESDAY, 28 FEBRUARY 2018

08:40 Transfer from hotel to TTC

09:00 **Containment in Lab Equipment OSD.** Small batches with highly active ingredients. Is there „just“ the isolator, to manage the required containment level? Containment for batch sizes from grams to kilograms for an OEL level below 1 µg/m³
Michael Maintok

09:45 **Washing Systems.** Cleaning and washing are key procedures in high containment applications. Manual cleaning is more and more replaced by validatable, automatic cleaning systems also for IBC containers. **Erich Nussbaumer**

10:30 **Coffee break**

10:45	Transfer to Innovation Center
11:00	From lab to production scale - a look at equipment for the real world. Discovering the full range of state-of-the-art fluidized beds units from grams to tons. Team Innovation Center
12:00	Lunch
13:00	Facility Design for highly active products. Containment considerations and challenges in planning facilities for highly active products in the Pharmaceutical Industry. Hubert Rassi
13:45	Isolators designed for occupational safety and GMP requirements. The OEL for operator protection as well as cleaning and cross contamination requirements needs additional features to cover both. Richard Denk
14:30	Coffee break
15:00	Challenges during performing APCPPE – former SMEPAC. Insights into performing exposure measurements at a tableting machine or a fluidized bed dryer (FBD) according to the APCPPE protocol. Silke Büchel , Ramona Labatzke
15:45	Filling high potent formulations into hard capsules: Flexible solutions for R&D and production. Filling technology / scale-up / 100% in-line mass verification inside containment. Karlheinz Seyfang
16:30	Containment Production. Production of highly active pharmaceuticals at a CMO's facility. Iris Ziegler
17:15	Transfer to hotel
18:45	Transfer to Workshop dinner

THURSDAY, 01 MARCH 2018

08:40 Check-out from hotel and transfer to TTC

09:00 **Containment aspects in GMP and SHE.** General aspects and the related chapter in the ISPE Containment handbook.
Andreas Flückiger

09:45 **Barrier Systems.** Solutions for highly active products.
Rainer Hundeiker

10:30 **Coffee break**

11:00 **Potent drugs in solid dosage form development.** A balanced approach of containment and protective means to guarantee staff and environmental safety. **Norbert Pöllinger**

11:45 **Flexible containment systems.** Single use systems - limits, pro's and con's. **Viktor Schnyder**

12:30 **Summary and snack buffet**

13:00 Transfer to Basel, German Railway Station (Badischer Bahnhof), Swiss Railway Station (SBB) and EuroAirport



SPEAKERS

Silke Büchel	Praevena AG, Switzerland
Richard Denk	Skan AG, Switzerland
Dr. Andreas Flückiger	F. Hoffmann-La Roche AG, Switzerland
Joerg Gierds	Fette Compacting, Germany
Bastian Heinecke	Glatt Systemtechnik GmbH, Germany
Rainer Hundeiker	Weiss Technik GmbH, Germany
Ramona Labatzke	Praevena AG, Switzerland
Michael Maintok	Glatt GmbH, Germany
Erich Nussbaumer	Glatt GmbH, Germany
Dr. Norbert Pöllinger	Glatt GmbH, Germany
Hubert Rassi	Glatt Ingenieurtechnik GmbH, Germany
Dr. Axel Schiffmann	F. Hoffmann-La Roche AG, Switzerland
Viktor Schnyder	Lugaia AG, Switzerland
Dr. Karl-Heinz Seyfang	Harro Höfliger GmbH, Germany
Dr. Iris Ziegler	Corden Pharma GmbH, Germany

MODERATION

Andreas Gottschalk, Technology Training Center, Germany

DETAILS

- >> The participation fee is € 1490,- (exclusive of VAT).
- >> This fee includes participation, accompanying course notes, daytime catering and dinner. Any other expenses are to be borne by the attendee.
- >> Free attendance granted to a limited number of students.
- >> Participation is limited. Registrations will be confirmed on a first come first serve basis.
- >> Courses taking place in Germany are subject to Value Added Tax (VAT).
- >> Each participant will receive a certificate of attendance at the end of the course.

ORGANIZATON AND LOCATION

TTC - Technology Training Center

Regina Bernstein / Andreas Gottschalk / Bianca Nowak

Werner-Glatt-Straße 1, 79589 Binzen, Germany

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For further information or online registration please visit us on

www.ttc-binzen.de

REGISTRATION

Workshop:

COMPETENT CONTAINMENT

27 FEBRUARY – 01 MARCH 2017

Name

Company

Dept.

Function

Address

Phone

Fax

E-mail

Yes, I want to receive information about future TTC workshops.

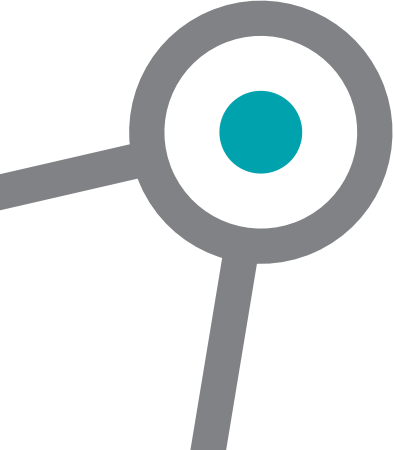
Signature

Accomodation required from

Check-in day:

Check-out day: _____ = _____ nights

(Approx. 79,00 €/night incl. breakfast)



Technology Training Center

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Germany

