2nd APV Conference on "Highly Potent Drug Products in the Pharmaceutical Industry"

19 to 20 March 2019
Wiesloch/Heidelberg, Germany

Course no. 6764

Pharmaceutical Manufacturing
Quality Assurance

incl. company site visit to Corden Pharma Plankstadt

APV
MAKING SCIENCE WORK

Arbeitsgemeinschaft für Pharmazeutische Verfahrenstechnik e.V.
Gemeinnütziger wissenschaftlicher Verein
International Association for Pharmaceutical Technology

Summary and objectives

After the huge success of the first APV conference on highly potent drug products in 2015, this year's second conference on highly potent drug products will again focus on the development and manufacturing of drug products in an highly potent environment rather than the generic challenges of highly potent drug substances as such, which are already covered widely in a range of other conferences.
In contrast to these the APV 2nd Conference on Highly Potent Drug Products in the Pharmaceutical Industry will provide participants with an inside view of the everyday challenges when having to develop, manufacture and test drug products with highly potent drug compounds. You will also have the opportunity to have discussions with the experts on practical hurdles faced when working with these compounds in a development or GMP environment and to solutions, which have proven to be working in a highly potent routine.

Besides an overview on innovation in the area and the regulatory status for handling such products, the conference will focus on these practical aspects different stakeholders are facing when handling highly potent drug products.
Furthermore the topics and discussions also highlight challenges for interfaces between the various parties involved in the manufacturing and administration of highly potent drug products.
Therefore, this interdisciplinary conference is going to address the topic of highly potent drug products in a holistic approach involving not only the chemists, formulation scientists, analytical experts, quality officers and safety officers in both the development and production environment, but also the dispensing pharmacists in the hospital or community pharmacy and the handling of such products at the patient level.
Both, the invited speakers and the organizers of the conference are experts in the area and willing to share their own experience in this field of growing interest but also still unmet challenges with the participants during this unique conference. And they will openly discuss different philosophies and approaches as applied by different companies.

In addition to plenary talks from the experts in the area and round table discussions participants will also have the opportunity to see the manufacturing of highly potent drug products in "real life" when they visit the Corden Pharma Plankstadt facilities in Plankstadt, a specialist provider for the development and manufacturing of highly potent solid dosage forms.

The conference includes a visit to the Corden site where participants will see both,
- the recently established, fully contained high potent development area for OEB 3 – OEB 5 compounds suitable for small scale feasibility trials at a batch size of 10 – 500 g in a non GMP environment and
- the latest addition to the company's highly potent manufacturing plants; the fully contained OEB 5 plant for commercial scale manufacturing at a scale of 100 – 500 kg

An table top exhibition with solution providers for the development and manufacturing of highly potent drug products will also provide the opportunity to directly discuss technical and set up solutions with the providers during the conference.

Organization committee

Iris Ziegler
Director Development and Production
Corden Pharma Plankstadt, Germany

Karoline Bechthold Peters
Senior Strategy & Technology Leader Pharmaceutics
Novartis, Switzerland

Susanne Page
Head of Formulation Research & Development
F. Hoffmann-La Roche, Switzerland

Horst-Dieter Friedel, Head of External Affairs
Bayer Pharma AG, Product Supply Pharma - Quality Assurance Pharma and API Berlin, Germany

Programme

Tuesday, 19 March 2019, 08:30 - 18:00 h

Roundtable Discussion with the Experts

Challenges when working with highly potent compounds and drug products – the human factor?
- Moderator: Christian Wilkens, Jopp & Wilkens Management Consulting Group, Germany
- Big Pharma's perspective from Dr. Susanne Page, Head of Formulation Research & Development, F. Hoffmann- La Roche, Switzerland
- CDMO's perspective from Dr. Christoph Rott, Formulation Lead, Corden Pharma Plankstadt, Germany

This round table discussion will address the human factor part of HPAPI and highly potent manufacturing, which is often ignored but actually very important. How can we best integrate the operators with their emotional aspects and apply true leadership by supervisors to ensure a safe working environment?
These and other questions will be discussed in a round table discussion with experts and participants in order to provide recommendations for implementation on the shop floor.

Session 1
Handling of Highly Potent Compounds

The Challange of handling high potent medication in the health care system
Prof. Dr. rer. nat. Irene Krämer, Director of hospital pharmacy, University Hospital, Johannes Gutenberg-University Mainz, Germany

Quantitative assessment of drug exposures and related health risks in nurses and pharmacists
Dr. Silke Weber, Roche

Which dosage form to select? The pros and cons of various dosage forms in an high potent environment
Dr. Iris Ziegler, Director Pharmaceutical Sciences & QbD, Corden Pharma International, Germany

Can we avoid handling drug substances as powders at all? Intelligent solutions reducing exposure
Tobias Struller, Manager Process Performance and Qualification, Manufacturing Department, Baxter Oncology GmbH, Germany

Session 2
- Safe Handling of Highly Potent Drug Products in the Pharmaceutical Industry

International corporate standards for highly potent products
Dr. Silke Weber, F. Hoffmann-La Roche, Switzerland

Criticality of Biological Drugs regarding PDE and OEL – the different corporate philosophies / Novartis View
Marc Abromovitz, Head Industrial Hygiene, Novartis, Switzerland

Panel Discussion: with all speakers of this session

Visits to Corden Pharma Plankstadt, a Specialist for Development and Production of Highly Potent Drug Products
Seeing a state of the art, highly potent working environment for early feasibility screening and full scale production in small groups and ability to discuss real life experiences: Visits to Corden Pharma Plankstadt, a high potent specialist offering contract development and contract manufacturing services for solid dosage forms with highly potent compounds

Networking dinner at 19:00 h

Wednesday, 20 March 2019, 08:00 - 16:00

Session 3
Risk Minimisation via Informed Decision

Making Intelligent drug substance - drug product interfaces to reduce the risks - strategies and possibilities within a company
Dr. Rainer Nicolai, F. Hoffmann-La Roche, Switzerland

Risk control strategy: Handling of HPAPIs in the laboratory environment and challenges of process transfer into fullcommercial scale
Alexandru Gheorghe, Group Leader Process Development, Health Care, Evonik Nutrition & Care

Session 4
Highly Potent Compounds in the Pharmaceutical Industry – Real Life Learnings and Experiences

SHE monitoring and simulation of exposure - how to do in real life?
Dr. Lars Restetzki, Business Process Manager, Commercial Production Rocephin, F. Hoffmann-La Roche, Switzerland

Cleaning as most critical step in high potent manufacturing - technical and practical solutions at a CDMO
Norbert Straub, Director Development & Transfer Pharma, Excella, Germany

Cleaning as most critical step in high potent manufacturing - intelligent technologies available from equipment manufacturers
Michael Maintok, Business Development Key Technologies, Glatt, Germany

Session 5
Regulatory and GMP Landscape for Highly Potent Drugs

Requirements for the PDE report – what is needed and how to write it?
Dr. Claudia Sehner, Principal Scientist, Nonclinical Drug Safety, Boehringer Ingelheim, Germany

An inspector's view: What is essential in shared facilities according to the revised or new EU-Guidelines with regard to cross-contamination?
Dr. Franz Schönfeld, Regierung von Oberfranken, Germany

Shared facilities for highly potent and cytotoxic drugs - Will ANIVSA follow the EMA's approach?
Andreas Flückiger, F. Hoffmann-La Roche, Switzerland

Final discussion and conclusions

Programme subjected to be changed.

Registration by fax +49 6131 9769-69

Location

Best Western Plus Palatin Kongresshotel
Ringstraße 17-19
69168 Wiesloch
Phone: +49 6222 582 010
Fax: +49 6222 582 555

I herewith repealable authorise APV to use my E-mail address to send me APV relevant material including current programme information. My acceptance can be cancelled at any time in writing

Date

Course no. 6764
from 19 March 2019 08:30
to 20 March 2019 16:00

Registration fee

Industry	1490 EUR
Acadmia/Authorities	745 EUR
Student*	178 EUR

(free of VAT according to § 4,22 UStG)
Coffee breaks, luncheons, dinner and electronic proceedings included.

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

Registration

APV-Geschäftsstelle
Kurfürstenstraße 59
55118 Mainz/Germany
Phone: +49 6131 9769-0
Fax: +49 6131 9769-69
e-mail: apv@apv-mainz.de

You will receive a confirmation of your registration with the invoice.

Hotel reservation

Best Western Plus Palatin Kongresshotel
Ringstraße 17-19
69168 Wiesloch
Phone: +49 6222 582 010
Fax: +49 6222 582 555
Participants should make their own hotel reservation referring to the "APV" seminar.
Special conference rate valid until 04 February 2019: Single room incl. breakfast buffet from 119 EUR per night.
Please use the following link for booking with the keyword "APV": https://goo.gl/u2nlrP (ignore the Login-ID and password, jsut insert the keyword/ Stichwort "APV")

Course no. 6764, 2nd APV Conference on "Highly Potent Drug Products in the Pharmaceutical Industry", 19 to 20 March 2019, Wiesloch, Germany

Registration
As soon as you have found a seminar of your interest, it is very easy to register for it via fax, e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.

Registration confirmation
After your registration was successfully processed, you will receive a confirmation.

Before the event
A few days before the event starts, you will receive important information about the seminar, such as time, date, addresses etc.

After the event
You will receive a certificate confirming your participation. Furthermore, we would like to ask you to fill-in our evaluation sheet to make sure we get better every time.

Follow-up
After the event, we are open to receive any suggestions and critique that might arise during the seminar and will certainly help you with further questions you may have.

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