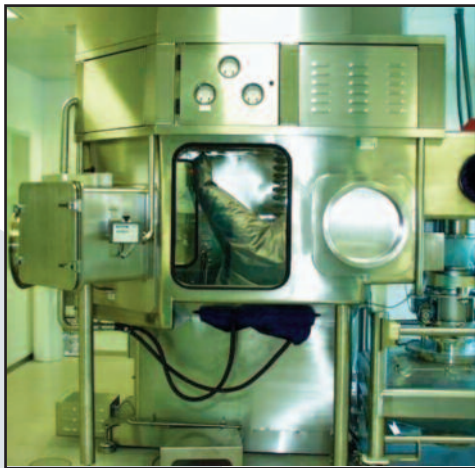
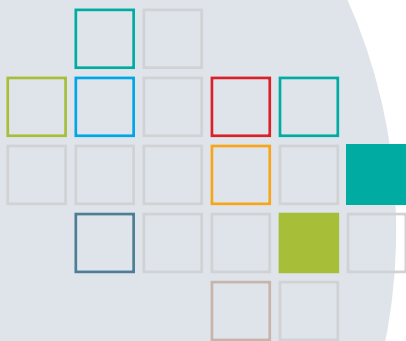


APV Conference "Highly Potent Drug Products in the Pharmaceutical Industry"



23 to 24 November 2015
Berlin, Germany

Course no. 6608



Pharmaceutical Manufacturing Quality Assurance

Summary and Objective

The conference provides not only a broad overview on all relevant aspects in the development, manufacturing and packaging of pharmaceutical products containing highly potent compounds for the different therapeutic areas and various dosage forms with different requirements, but also provides participants with access to all relevant resources and an understanding on the current status and future challenges in this area.

Besides the different topics presented by recognized experts in the area of high potent drug products, ranging from the design of facility concepts to development approaches to manufacturing concepts to regulatory aspects and to real live case studies from both "big pharma" corporates and contract manufacturing or research organizations, participants will gain a first hand experience on how these concepts are applied in the pharmaceutical environment and might be established in their own organizations.

Interactive discussions with the experts and other participants during scientific sessions, round table discussions, market place interaction and the final panel discussion will add further value.



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



Introduction and Importance of Highly Potent Drug Products

25% of all NCEs which are in R&D today are categorized as highly potent and when dealing with oncology even 60% of the candidates are HPAPI.

On the other hand especially these therapeutic fields, like oncology represent a high medical need and also generate substantial revenues, which accumulated to \$2.7 billion in 2012 already. These sales are however expected to increase further at a five-year cumulated growth rate of 11.6%, reaching \$7.05 billion by 2022 .

Also, when looking into the area of contract manufacturing the importance of HPAPIs and highly potent drug products is obvious with revenues of \$3.25 billion in 2011 or 10.3% market share or 7.2% of the total pharmaceutical contract manufacturing market. But not only oncological products and cytotoxics but also a substantial number of compounds with common pharmacologic principles like hormones, cholesterol lowering statins, analgesics or antipsychotics and many biologics or conjugated biologics do have very low occupational exposure levels (OEL) and are considered differently within the cGMP guidance and the different health authorities.

Besides these compounds with low or very low OELs there are also compounds without any threshold level, like alkylating agents, highly sensitizing compounds or living organisms, requiring even more stringent measures than those other compounds.

While most health authorities had so far considered all highly potent compounds or at least specific therapeutic areas to require dedicated facilities, there has been neither a sound scientific rationale for the assignment to dedicated or shared facilities from a GMP perspective, nor are the occupational safety, health & environmental requirements harmonized on an international level.

Thus the lack of harmonization and country specific, different requirements generates additional challenges for the pharmaceutical industry having to deal with such compounds and drug products in a global environment.

And not only due to the increased amount of compounds considered as highly potent, or the increasing differentiation of drug products with highly potent compounds but otherwise completely different needs and challenges, (such as oral drug products on the one hand and drug product device combinations or biologics on the other hand,) but also due to the increased awareness of the public on the risks and threats of such compounds and an increased globalization of the pharmaceutical industry, is this topic really a hot topic requiring a thorough understanding and international harmonization throughout the different stakeholders.

Latest Changes in the Regulatory View on Manufacturing of Highly Potent Drugs

The new Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use into effect since March 2015 with revisions in the definition of when dedicated facilities are required for the manufacturing of drug products, basing the decision on a risk based, toxicological and scientifically driven evaluation of whether threshold levels exist and can reliably be met and verified by technological, operational and analytical procedures.

The new EMA/CHMP/ CVMP/ SWP/169430/2012 Guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities fol-

lows the same approach and defines how such risk based PDE values are derived and set from NOAEL values for the development and production of drug products.

However, while this will then be mandatory for all new products there are still many open questions as to this new guidance. How to deal and apply this to the legacy products and how to actually introduce this system into the routines of the pharmaceutical industry and local health authorities alike for Europe, when other markets like Brazil and Japan are still going to apply their own, different requirements?

APV's Competences for Differentiation of this Conference versus the many Workshops and Seminars dealing with High Potent and Containment Topics

While there are multiples seminars and workshops offered each year dealing either with engineering aspects of high potent manufacturing or OEL categorization and monitoring of potent compounds or specific solutions individual organization or companies offer, this conference combines all aspects of the development, manufacturing and testing of highly potent compounds in the innovator industry as well as by CMO organizations, with hardware requirements and solutions, as well as regulatory requirements and views on the safe handling and categorization of such products – and most importantly with real life experiences and challenges the industry is facing.

The organization committee for the conference combines the knowledge of experts dealing with the topic of highly potent drug products in their daily business on both sides of the industry and on a global basis.

As a "non profit" organization the APV combines in its focus groups the expertise and knowledge of representatives from industry, regulatory and academia throughout all areas of drug product development, manufacturing, testing and authorization.

- In this first ever conference on highly potent drug products experts in the field from the focus groups of solid dosage forms, pharmaceutical engineering, biopharmaceuticals and biologics, analytics and quality assurance forces providing their experience and competence into the selection of topics, speakers and moderators for the round table discussions, as well as being present throughout the conference.
- Besides plenary talks on the topics of GMP, safety, health & environment and containment solutions there will be dosage form specific sessions on solid dosage forms, liquids, biopharmaceutical, dealing with the specific requirements, challenges and perspectives of those different dosage forms and their therapeutic indication.
- The conference also combines the providers of hardware solutions for facilities and equipment with service providers and users of both in various sessions and an interactive market pace set up.
- New technologies and trends as employed in other fields and their specific suitability and benefits in the area of highly potent drug products are addressed on day 2.
- Roundtable discussions will focus on specific topics encountered in the area of highly potent drug products and discuss hot topics, often discussed quite controversially in a forum of experts from both sides.
- Roundtables and plenum discussions provide the participants with the opportunity to contribute and discuss their own questions and views on specific topics with the experts and speakers of the conference.



Organization committee

*Iris Ziegler, Director Development and Production
Corden Pharma Plankstadt, Germany*

*Karoline Bechthold Peters, Head Clinical Manufacturing,
Process Science & Business Excellence
F. Hoffmann-La Roche, Switzerland*

*Susanne Page, Group Head Formulation Research and
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

Monday, 23 November 2015, 9:30 - 19:30

Plenary session “Occupational safety for handling of highly potent drug products”

International corporate standards for highly potent products
*Andreas Flückiger, Chief Occupational Health Officer,
F. Hoffmann-La Roche, Switzerland*

Hazard, Risk and Control Management in Manufacturing Potent APIs and Drug Products: SafeBridge® Potent Compound Safety Certification Assessment and Criteria
Justin Mason-Home, Managing Director, SafeBridge Europe, UK

Parallel scientific sessions “Containment for highly potent drug products”

Containment solutions in the pharmaceutical industry
Chair: Iris Ziegler

- Contained facilities for the manufacturing of cytotoxics as liquids and solids – interfering challenges for containment and product quality?

Roberto Margarita, PhD, Director, Global Antibiotics & Oncology Platforms, CordenPharma International, Italy

- Advantages and disadvantages of current containment-versions/creative solutions for machine cleaning in compliance with operator protection
Markus Mezger, Containment Specialist, HARRO HÖFLIGER Verpackungsmaschinen GmbH, Germany

- Upgrading existing facilities from non potent to high potent – how can it be done?

TBD

Containment for highly potent biotechnological products and their devices
Chair: Karoline Bechthold-Peters

- Closed RABS versus Isolators – aspects to consider for a clinical facility

Karoline Bechtold-Peters

- Cleaning validation for high potent drugs and appropriate design to enable cleaning

TBD

- Containment gloves – suitable materials and testing for integrity

Andreas Fritze, Pharmaceutical Development Unit Parenteral & Topical Dosage Forms, Novartis Pharma Stein AG, Switzerland



Plenary session "The regulatory and GMP landscape for highly potent drugs"

Industry perspective on the implementation of the EMA Guideline on Shared facilities
Horst-Dieter Friedel, Head of External Affairs, Bayer Pharma AG

Shared versus dedicated facilities in the perspective of FDA, Anvisa, Japan, ROW
Gregory Gallegos, Senior Technical Program Director, F. Hoffmann-La Roche, Switzerland

Parallel roundtable discussions

Technical trials and manufacturing of clinical supplies for highly potent compounds at excipient suppliers and equipment manufacturers
Moderator and introductory talk:
Norbert Pöllinger, PhD, Glatt Binzen, Germany

Handling of highly potent compounds in the analytical lab - challenges and successful solutions
Moderator and introductory talk:
Andreas Flückiger, Chief Occupational Health Officer, F. Hoffmann-La Roche, Switzerland

Market place event "Technical solutions and service providers for high potent manufacturing"

Table top exhibition with introductory short lectures



Reception and networking dinner

Tuesday, 24 November 2015, 8:30 - 16:15

Parallel scientific sessions "Landscape of highly potent compounds in the pharmaceutical industry – real life learnings and experiences"

Highly potent compounds in the innovator and generic industry
Chairs: Susanne Page and Karoline Bechthold Peters

- Challenges connected with the conjugation of ADCs
Mark Wright, Site Lead, Piramal Healthcare, UK
- Dry granulation as process technology for high potent compounds – a case study
Albert Barta, PhD, Boehringer Ingelheim Pharma GmbH & Co. KG, Pharmaceutical Development, Germany
- Real life experience of running a contained production line in development
Ruth Leu Marseiler, PDU Oral Team Head Supply, Novartis, Switzerland

Highly potent compounds in contract drug product manufacturing
Chair: Iris Ziegler

- Technology transfer of low dose and high dose tablets into a contained plant - a case study on the challenges of potency and process capability
Iris Ziegler
- Hard Capsules for highly potent drug products, from darkness to light
Norbert Straub, Excella, Germany
- Early Stage Development Strategies for Handling of Potent Compounds in a Multi-client Environment
Richard Fazackerley, Technical Director, Aesica Pharmaceuticals Ltd, UK
- Challenges in the manufacturing of parenteral drug products with highly potent compounds
Franz Kainz, Director Project Business EMEA, Evonik Degussa International, Switzerland



Plenary talk **Inspectors view on essentials from revised or new EU-Guidelines related to cross-contamination in shared facilities**

Rainer Gnihl, Regierungspräsidium Bayern, Germany

Plenary talk **QbD and PAT - the uneasy siblings in highly potent drug development**

Gert Thurau, Vice Director, F. Hoffmann-La Roche, Switzerland

Parallel scientific sessions **"New technologies"**

Use and advantages of new technologies and continuous manufacturing in the highly potent environment
Chair: Iris Ziegler

- A new manufacturing approach for drug products with potential benefits for highly potent compounds - Incorporating active substances into polymeric nanofibers via electrospinning

Geert Verreck, Janssen Pharmaceuticals, Belgium

- Secondary Manufacturing in a Box – How continuous processing can facilitate containment for high-potent compounds

Hubertus Rehbaum, Bohle, Germany

- Ins and outs of 3D printed oral dosage forms and how they might reduce "headaches" when working with highly potent compounds

Steven Erpelinck, TNO, Netherlands

- Manufacturing Does Forms of Highly-Potent Compounds in a Shirt-Sleeve Environment - The Liquid-Dispensing Technology

Mark Wilson, Director, PTS, R&D, GlaxoSmithKline, UK

Disposable technologies for high potent manufacturing

Chair: Horst-Dieter Friedel

- Containment validation of a tableting line for high potent formulations employing disposable containment solutions

Kristof De Groote, Product Manager Single Pot Processing, GEA Pharma Systems, Collette™

- Validation of secondary and primary containment solutions employing disposable containment technology

Joachim Stoye, Head of Technology Management, Andock-systeme G. Untch GmbH, Germany

Parallel roundtable discussions

Outsourcing versus in house manufacturing of highly potent drug products

Moderator and introductory talk:

Karoline Bechthold Peters

Highly potent compounds in early development – specific challenges and differences to commercial scale manufacturing

Moderator and introductory talk:

Susanne Page

Podium discussion **"Changing regulatory environment – future trends"**

Moderators

Iris Ziegler and Karoline Bechtold-Peters

Programme is subject to change

Location

Leonardo Royal Hotel Berlin
Alexanderplatz
Otto-Braun-Strasse 90
10249 Berlin, Germany
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Fax: +49 30 755 810

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. 6608
from 23 Nov. 2015 09:30
to 24 Nov. 2015 16:15

Registration fee

APV member 1360 EUR
Non-member 1490 EUR
(free of VAT according to § 4,22 UStG)
Coffee breaks, luncheons, dinner and electronical proceedings included.

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.

Members of authorities pay half of the APV member's and non-member's registration fee respectively.

Hotel reservation

Leonardo Royal Hotel Berlin
Alexanderplatz
Otto-Braun-Strasse 90
10249 Berlin, Germany
Phone: +49 30 755 430 0
Fax: +49 30 755 810

Participants should make their own hotel reservation referring to the APV seminar.

Deadline for special conference rate: 25 October 2015.

Special rate:
Single room incl. breakfast buffet from 89 EUR per night.

Mainz, April 2015

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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