APV Hot Topic Conference

Biologicals, Medical Devices and Combination Products – challenges for packaging materials

– good practices and new trends

28 to 29 September 2017
Berlin, Germany

Course no. 6690

Hot Topics

APV
MAKING SCIENCE WORK

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

Hot Topics

A seminar organised by the APV focus group Packaging

Objectives

This conference provides up-to-date knowledge about packaging solutions for biologicals, medical devices and combination products.

- Which challenges do we have with filling of biologicals?
- Which parameters and special requirements for the materials are relevant?
- Which measuring procedures and methods for closure integrity do exist?
- Which materials are used?
- Do we have to consider different aspects in the development of packaging materials for biologicals?
- How are biologicals different in regards to leachable?
- What devices we need in future?

All the presentations in the conference will give some interesting answers.

Target audience

This conference addresses all who are entrusted with the development, processing, application, quality control and/or quality assurance of packaging materials for biologics, medical devices and combination products.

Find out more about best practices, current developments and new trends.

Take advantage of the opportunity for discussing with specialists and sharing experiences with colleagues.

Programme

Thursday, 28 September 2017 13:00-17:30 h

Welcome and introduction
Dr. Udo Janske
Merck

Requirements for Primary Packaging Materials in Fill & Finish of Biologicals
- Possible Impurities
- Detection of particles and defects
- What we like to have from our supplier of primary packaging material?

Dr. Udo Janske

Development of Packaging configurations for Biologics and Medical Devices

Case Study – part 1:
Development of Prefilled syringe to be used within an Autoinjector
- Selection of primary packaging components
- Protein stability aspects (Silicone oil, tungsten, shear stress etc.)
- Physical aspects (break-loose & glide forces, plunger position, transportation etc.)
- Design Control
- Implementation on commercial scale equipment

Dr. Verena Geidobler
Boehringer Ingelheim Pharma GmbH & Co. KG

Case Study – part 2:
Finish process incl. autoinjector assembly
- Device and secondary packaging components
- Preparation for Finish process
- Autoinjector assembly and packaging process
- Functional release tests

Alexander Bauer
Boehringer Ingelheim Pharma GmbH & Co. KG

Special Requirements on Glass
- Glass Quality
- Manufacture of Primary Packaging Material made of Tubular Glass
- Quality Assurance
- Possible Interactions (e.g. with silicon oil)
- Trends (e. g. PFS = Pre-Fillable Syringes)

Alfred Breunig
Nipro PharmaPackaging Germany GmbH

Q&A

Social event

All participants are cordially invited to meet for dinner and a guided Berlin city tour on the evening of the first conference day.

Friday, 29 September 2017 09:00-15:30 h

Special requirements for Elastomers and Polymer Container
- Overview of suitable container closure systems for parenteral injection devices
- Manufacturing processes
- Quality Assurance
- Compatibility with demanding drug compounds
- Performance and functional requirements
- Customer case study
- Outlook (higher viscosities, higher volumes, intradermal delivery, patch injector etc.)

Dr. Mike Schäfers
West Pharmaceutical Services Deutschland GmbH & Co. KG

Biologicals, Medical Devices and Combination Products – challenges for packaging materials

Extractable and Leachable Studies for Biologicals – Does the maximum daily administered dose approach apply to biologics?

- What do the available guidelines say about Extractables and Leachables?
- Guidelines: PQRI vs. ICH M7.
- How to implement the requirements of guidelines into the extraction study?
- How to evaluate the data from an extraction study and what implications are there for a leachable study?
- Concepts for a Leachable study: Targeted vs. non-targeted approach.
- How are Biologicals different in regards to leachable?
- Does the daily administered dose approach apply for Biologics?
- What can we learn from the Eprex case?
- Protein-reactive extractable and leachables and possible implications.
- A screening method for protein-reactive extractables.

Dr. Steven A. Watt
A&M STABTEST Labor für Analytik und Stabilitätsprüfung GmbH

Container Closure Integrity Testing for Drug Products

- Revision of USP <1207>
- Methods for CCIT: Probabelistic vs. deterministic methods
- pCCI, mCCI (including correlation studies and establishing acceptance criteria)
- Artificial leaks
- Practical advises for CCIT
- CCIT in the product life cycle
- Capping
- RSF testing
- Practical advises: Defining capping process parameters

Roman Mathäs
Lonza Drug Product Services

Challenge and Requirements of different Quality Systems – ISO 13485 vs. ISO 15378 (GMP)

- Guidelines, Norms and Applications
- Impact and targets from the different quality systems
- Monitoring and control from suppliers – whats important and what are the challange?
- Qualification and Validation were changed – from a static to a life cycle system

Wolfgang Hähnel
testo industrial services AG

Q&A

Programme is subject to change

Moderator an Speaker

Dr. Udo Janske started his professional carreer at Merck, Darmstadt, Germany in 1987. Currently he is Director for Sterile Production and Packaging of Liquids. Dr. Udo Janske is Pharmacist with special qualification in pharmaceutical technology. He has many experiences in making and packaging of solids and liquids. Since 1984 he is member of APV and active member of the special focus group packaging.

Speakers

Alexander Bauer studied Process Engineering with focus on Biotechnology at the University of applied Sciences in Nuremberg. In November 2002 he joined Boehringer Ingelheim as a Packaging Engineer for developing primary packaging configurations for Biologics. In 2005 he switched positions for developing packaging configurations and packaging processes for liquid and solid oral drug products (NCE) and for transferring those to international launch sites. At the beginning of 2012 Alexander Bauer returned to the BI Division Biopharmaceutics and since then he is heading a team which takes care of all packaging related topics within the Fill & Finish Department and supports other sites within the Boehringer Ingelheim organization.

Alfred Breunig is the Director Technical Customer Support & Regulatory Affairs at Nipro Pharma Packaging Germany GmbH (abbreviated: NPG). NPG (former "MGlas AG") is a manufacturer of primary packaging materials made of tubular glass for the pharmaceutical industry. After heading the chemical-physical and microbiological laboratories from 1982 to 1990, Alfred Breunig became the Quality Director. In 2004, he took over the newly created position of the Director Technical Customer Support & Regulatory Affairs. Alfred Breunig is Chairman of the Working Group "Quality Assurance for Primary Packaging Materials Made of Tubular Glass" in the BV Glas (association of the German glass industry). Furthermore, he is Chairman of the standardization committee NA 063-02-11 ("QM Systems for Primary Packaging Materials") at the German Institute for Standardization (DIN, Berlin) and member/expert of the standardization committees (DIN) NA 063-02-01 "Injection Systems", NA 063-02-03 "Infusion and Injection Containers Made of Tubular Glass" and NA 063-01-11 "Small Bore Connectors". In addition, Alfred Breunig is a member of APV and PDA, where he works in Task Forces addressing the quality assurance of primary packaging materials made of glass.

Biologicals, Medical Devices and Combination Products – challenges for packaging materials

Speakers

Wolfgang Hähnel is an over 20 years experienced GMP and QM-System Consultant, which worked in start of his career in the engineering department of the BASF AG in Ludwigshafen.
After these time, he worked by different service provider and collect many experience about all aspects of qualification, validation and GMP upgrade projects in the life science industry.
From 2003 to 2011, he worked for an High Level Consultancy Company in Germany and Switzerland and supported a lot of project as project leader and as an GMP Senior Consultant (sometimes as Qualified Person).
From 2012, Mr. Hähnel worked as Managing Director of testo industrial services AG, Switzerland and as a GMP Senior Consultant in different customer projects. Also he create and execute many trainings and seminars.

Roman Mathäs is a Senior Group Leader within the Lonza Drug Product Service organization. He is leading the Lonza particle lab and the container closure integrity testing. In this role, Roman is responsible for container closure integrity testing of vials and pre-filled syringes and process development of capping/crimping.
Prior to this assignment, Roman was working within Roche/Genentech network supporting process development of the commercial manufacturing vial capping process.
Roman is a pharmacist by training and conducted his studies at the University of Marburg and King's College London. He holds a PhD in pharmaceutical technology from the University of Munich for work on subvisible particle characterization.

Dr. Verena Geidobler studied Pharmaceutical Sciences (B.Sc. and M.Sc.) at the Ludwig-Maximilians-University in Munich. In 2011, she joined the group of Prof. Dr. Wolfgang Frieß at the LMU (Chair of Pharmaceutical Technology and Biopharmaceutics) as a PhD student working on the project "Interactions of formulation and disposables in biopharmaceutical drug product manufacturing". During her research, she focused on particle shedding from silicone tubing during peristaltic pumping, protein adsorption to single-use bags and preservative sorption in silicone tubing. In 2015, she joined Boehringer Ingelheim as a lab head for Primary Packaging Development. Together with her team she is responsible for the selection and implementation of primary packaging components as well as test methods and development studies that prove the suitability of the chosen packaging materials.

Dr. Mike Schaefers is Vice President Global Product Management & Marketing Operations at West Pharmaceutical Services.
He studied chemistry and business management and received his PhD from the Ruhr University in Bochum, Germany in 1996. After 4 years of business experience at the drug delivery company R. P. Scherer GmbH & Co. KG in Eberbach, Germany he joined West Pharmaceutical Services in 2000 where he headed the Scientific & Technical Customer Service Group for the European and Asian-Pacific market, before he became in 2005 responsible for Marketing and Technical Customer Service in Europe at West. In 2012 he assumed responsibility for West s global Marketing activities within the Pharmaceutical Packaging System division before he took over in 2016 the company wide responsibility for product and portfolio management as well as Marketing Operations at West.
He is member of the Parenteral Drug Association (PDA) and the Arbeitsgemeinschaft für pharmazeutische Verfahrenstechnik (APV) and a frequent speaker and organizer of conferences.

After studying biology at the Bielefeld University and graduating with a PhD in genetics and molecular biology in 2005, **Dr. Steven Watt** was granted a position as a postdoctoral candidate. There he was in charge of a mass spectrometry service unit, dealing with proteome and metabolome projects. In 2009 he joined Thermo Fisher Scientific as an instructor for scientific and pharmaceutical mass spectrometry applications. In his current position as a business development manager at A&M STABTEST he is involved in customer relations, marketing and the development of new analytical services in the field of pharmaceutical analysis.

Registration by fax +49 6131 9769-69

Location

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Anhalter Straße 8-9
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Telefax +49 30 26483 900
E-mail: Berlin@relexa-hotel.de

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. 6690
from 28 September 2017 13:00 h
to 29. September 2017 15:30 h

Registration fee

Industry (regular)	1390 EUR
Industry (early bird[1])	1290 EUR
Authorities (regular)	695 EUR
Authorities (early bird[1])	645 EUR

[1]early bird until 31. July 2017

Students[2] 178 EUR
(free of VAT according to § 4,22 UStG)
Coffee breaks, lunch, dinner and electronic proceedings included.

[2]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

relexa hotel Stuttgarter Hof
Anhalter Straße 8-9
10963 Berlin
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Telefon +49 30 26483 0
Telefax +49 30 26483 929
E-mail:
reservierung.berlin@relexa-hotel.de

Participants should make their own hotel reservation referring to the keyword "APV 28.09.17".
Deadline for special conference rate: 16. August 2017.

Special rate:
Single room incl. breakfast buffet from 109 EUR per night.

Biologicals, Medical Devices and Combination Products – challenges for packaging materials, Course No. 6690

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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