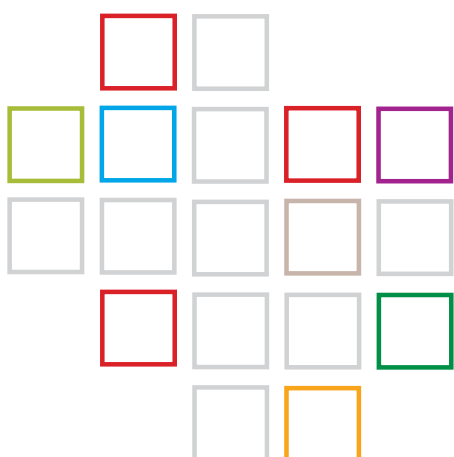


4th European Workshop on Protein Aggregation and Immunogenicity

DEADLINE
abstract submission
for a poster presentation
30 December 2018

28 to 29 January 2019
Salzburg, Austria

Course no. 6766



Biotechnology

Target group

The course is designed for all scientists involved in the development and manufacture of therapeutic proteins, working in Pharmaceutical and Biopharmaceutical Industry or at suppliers of analytical equipment or at service companies contributing, e.g. to analytical characterization of therapeutic protein drug products.



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



Goals of the seminar

Therapeutic protein candidates play an important role in the pipelines of pharmaceutical companies and the marketplace despite of specific analytical, formulation and safety challenges. This conference, held under the auspices of APV (www.apv-mainz.de), will focus on issues of protein aggregation and its impact on the immunogenicity of therapeutic proteins. Gathering opinion leaders from academia, industry and regulatory authorities, the conference will cover a broad range of topics from what causes aggregation of therapeutic proteins in formulation and processing, analytical methods of detecting aggregates, the utility of in vitro and animal models in assessing immunogenicity, to the clinical aspects of therapeutic protein immunogenicity. Options to control aggregates and particles in therapeutic protein formulation and processing will also be discussed from a hands-on experience. The seminar offers the opportunity to students to present their latest results in poster format, and the display of advanced analytical technology to suppliers in an industrial exhibition.

Organising committee

- Vasco Filipe, Sanofi (Chair)
- Karoline Bechtold-Peters, Novartis (Chair)
- John Carpenter, University of Colorado
- Wim Jiskoot, Leiden University
- Tarik Khan, Roche
- Hanns-Christian Mahler, Lonza
- Roman Mathaes, Lonza
- Tim Menzen, Coriolis Pharma
- Linda Narhi, Amgen

Abstract submission



Participants get the chance to submit abstracts for a poster presentation during the conference.

The abstract should be prepared using Microsoft Word as two A4 pages typed in Times New Roman, font size 12.

Please submit your abstracts by e-mail to Valentina Marinkova, marinkova@apv-mainz.de.
Deadline for abstract submission: **30 December 2018**.

Exhibition and sponsoring

For exhibition and sponsoring opportunities please get in touch with the APV headquarters, Valentina Marinkova, marinkova@apv-mainz.de.

Programme

Monday, 28 January 2019

10:00-18:00 h

Welcome address

Vasco Filipe, Sanofi, Paris, France
Karoline Bechtold-Peters, Novartis, Basel, Switzerland

Immunogenicity risk of biological medicinal products – A regulator’s view

Amy Rosenberg, FDA, United States

Session 1: Immunogenicity of therapeutic proteins

Overview about immunogenicity and state of the art assessments

Daniel Kramer, Sanofi, Frankfurt/Main, Germany

Clinical consequences of immunogenicity

Gertjan Wolbink, Sanquin, Amsterdam, Netherlands

T-cell assays confirm immunogenicity of tungsten-induced erythropoietin aggregates associated with pure red cell aplasia

Michael Kammüller, Novartis, Basel, Switzerland

Lab-on-chip immune organoids that recapitulate germinal centers

Ankur Singh – Cornell University, United States

Effect of aggregate size on monoclonal antibody immunogenicity in a mouse model

Wim Jiskoot, Leiden University/Coriolis, Netherlands

In silico prediction

Anne De Groot, EpiVax, Inc., USA

Update on the Cross-lab Study about Protein Aggregation and Biological Consequences

Tim Menzen, Coriolis, Martinsried, Germany

Discussion

Poster session and wine

Networking dinner

4th European Workshop on Protein Aggregation and Immunogenicity

Programme

Tuesday, 29 January 2019

08:30-16:30 h

Session 2: Protein aggregation and formulation

From Assays to Benefit/Risk Assessment: A European Assessors Perspective on Unwanted Immunogenicity of Biologicals

Guenter Waxenecker, AGES, Austria

A nanoparticle platform as highly controlled surface stress assay for antibody aggregation

Paolo Arosio, ETH Zurich, Zurich, Switzerland

Critical review of characterization methods for protein aggregates

Andrea Hawe, Coriolis, Martinsried, Germany

Effects of end-user handling on particle formation in therapeutic protein products

John F. Carpenter, University of Colorado, School of Pharmacy, Aurora, United States

Specification settings for protein aggregates - industrial perspective

Anja Matter, Lonza, Basel, Switzerland

Chemical degradation of Proteins

Christian Schöneich, Kansas University, USA

Protein-Device compatibility and integration

Ahmed Basheer, Lonza, Basel, Switzerland

Surfactants, Molecular Properties, Primary Packaging, and the Formation of Protein-Silicone Oil Particles

Tarik Khan, F. Hoffmann-La Roche Ltd., Basel, Switzerland

Biosimilars and protein aggregation

Andreas Seidl, Hexal, Oberhaching, Germany

Moderators of the workshop



Karoline Bechtold-Peters is pharmacist and holds a Doctor's degree from the University of Munich as well as a degree as "Fachapotheker" for Pharmaceutical Technology.

She began her industrial career in 1994 at Boehringer Ingelheim in Ingelheim developing solid dosage forms with the focus on powders for inhalation (e.g. Spiriva Inhalet). In 2000 she changed from the small molecule world to biopharmaceuticals building up Formulation Development at Boehringer Ingelheim's Biberach site. In 2003 Karoline took over the responsibility for global clinical supplies, aseptic process development and process transfer within Boehringer Ingelheim Biopharmaceuticals. Beginning of 2011, Karoline joined F. Hoffmann-La Roche AG in Basel, Switzerland, where she was appointed Head of Clinical Manufacturing, Process Science and Business Excellence. In September 2016 she moved finally to Novartis in Basel, Switzerland, as Senior Strategy & Technology Leader Pharmaceuticals, Global Drug Development / TRD (Biologics) and is part of the BioFuture team. Karoline is active in various associations (American Association of Pharmaceutical Scientists AAPS, Parenteral Drug Association PDA and International Association for Pharmaceutical Technology APV) and contributes frequently to conferences in the EU as well as in the US.



Vasco Filipe is a Biological Engineer and obtained a Ph.D. degree in Pharmaceutical Sciences from the Utrecht University (The Netherlands) in 2011.

His thesis focused on the physicochemical characteristics, stability in biological fluids and immunogenicity of monoclonal antibody aggregates. After a post-doc in 2012 on a similar topic, he then joined Adocia in 2013 (Lyon, France), where he worked as the Project Leader for monoclonal antibodies.

In 2015 he joined Sanofi in Paris (France), where he works as a Unit Head in the department of Pharmaceutical Development of Biologics.

Programme is subject to change

Location

Austria Trend Comfort
Hotel Salzburg West
Bundesstraße 4
5073 Salzburg-Wals
Austria
phone 0043 662 8581 0

Registration fee

Early bird until 25 November 2018
Industry 1390 EUR
Authority/University 695 EUR
Students* 150 EUR

(free of VAT according to § 4,22 UStG)

Rate from 26 November 2018
Industry 1490 EUR
Authority/University 745 EUR
Students* 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-Headquarters
Kurfürstenstraße 59
55118 Mainz/Germany
phone 0049 6131 97 69 0
fax 0049 6131 97 69 69
Eemail apv@apv-mainz.de
web www.apv-mainz.de

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

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

Hotel reservation

Austria Trend Comfort
Hotel Salzburg West
Bundesstraße 4
5073 Salzburg-Wals
Austria
phone 0043 662 8581 0
mail salzburg.west@austria-trend.at

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

Deadline for special conference
rate: 26 December 2018.

Special rate:
Single room incl. breakfast from
95,00 € per night.

Mainz, September 2018

Date

Course No. 6766
from 28 January 2019 10:00 h
to 29 January 2019 16:30 h

4th European Workshop on Protein Aggregation and Immunogenicity, 28 to 29 January 2019, Salzburg, Austria, Course no.: 6766

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

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