

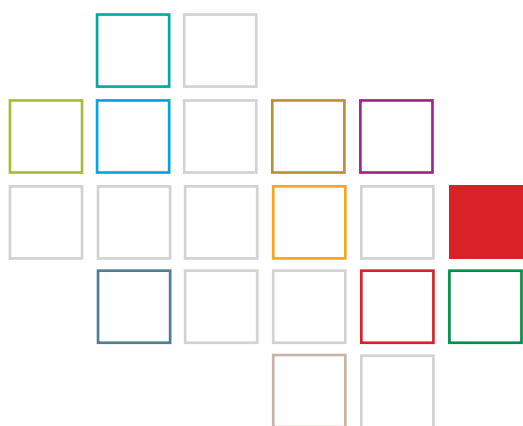
# APV Workshop on Protein Stability

**DEADLINE**  
abstract submission  
for a poster presentation  
30 December 2019



05 to 06 February 2020  
Munich, Germany

Course no. 6793



## 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.



### Goals of the seminar

Therapeutic protein candidates play an increasingly important role in the pipelines of pharmaceutical companies and the marketplace for the treatment of a wide range of diseases. This conference, held under the auspices of APV ([www.apv-mainz.de](http://www.apv-mainz.de)), will focus on protein stability challenges encountered during the development of these drugs. Gathering opinion leaders from academia, industry and regulatory authorities, the conference will cover a broad range of topics from what causes degradation of therapeutic proteins in formulation and processing, analytical methods of detecting aggregates and other degraded species and new approaches to stabilize and deliver protein drugs. Options to control aggregates and particles in therapeutic protein formulation and processing will also be discussed from a hands-on experience. The seminar will also offer the opportunity to students and researchers to present their latest results and to vendors to showcase their advancements e.g. in poster analytical technology in an industrial exhibition.

### Organising committee

- Vasco Filipe, Sanofi, France (Chair)
- Karoline Bechtold-Peters, Novartis, Switzerland (Chair)
- John Carpenter, University of Colorado, USA
- Wim Jiskoot, Leiden University, Netherlands
- Tarik Khan, Roche, Switzerland
- Michael Wiggenhorn, Coriolis Pharma, Germany

### 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 Heide Zwyer, [hz@apv-mainz.de](mailto:hz@apv-mainz.de).  
Deadline for abstract submission:  
30 December 2019.

### Exhibition and sponsoring

For exhibition and sponsoring opportunities please get in touch with Heide Zwyer, [hz@apv-mainz.de](mailto:hz@apv-mainz.de).

### Programme

Wednesday, 05 February 2020 9:00-20:00 h

#### Welcome address

Karoline Bechtold-Peters and Vasco Filipe

#### Session 1: Protein degradation and aggregation mechanisms

##### Protein stability and degradation in health and disease

Rasmus Hartmann-Petersen, The Linderstrøm-Lang Centre for Protein Science, Department of Biology, University Copenhagen, Denmark

##### Short-term assessment of non-native protein aggregation to predict formulations with higher physical stability

Hristo Svilenov, University Munich, Germany

##### Forced Degradation of Therapeutic Proteins

Vito Fódera, University Copenhagen, Denmark

##### Protein aggregation propensity assessment by CFD simulations

Miguel Rodrigues, University Lisbon, Portugal

##### Mechanisms for Protein Aggregation and Stabilization in Solution, at Interfaces and during Freezing and Drying

John Carpenter, University Colorado, USA

#### Session 2: Protein characterization and analytics

##### A multi-company assessment of submicron particle levels in biotechnology-derived protein products by NTA and RMM

Stanley Kwok, Seattle Genetics, USA

##### Use of Multiple Attribute Analysis by MS (MAM) for continuous cQA monitoring

Christoph Rösli, Novartis, Switzerland

##### Recent advances in submicron and micron particle analysis for biopharmaceuticals

Tim Menzen, Coriolis, Germany

##### HOS characterization of pharmaceutical proteins by 2D NMR methyl fingerprinting

Joan Malstrom, Novo Nordisk, Denmark

##### in-use stability of proteins in a hospital setting

Alain Astier, Hospital Mondor, France

##### ICH Q14 QbD in Analytics – Opportunities for Method Development and Life Cycle Management,

Christof Finkler, Roche, Switzerland is invited

#### Discussion

#### Poster session and wine

#### Networking dinner

# APV Workshop on Protein Stability

## Programme

Thursday, 06 February 2020

08:30-17:00 h

### Keynote

Regulatory talk on protein stability requirements and ongoing research

Ashwinkumar Bhirde, FDA, USA

### Session 3: Formulation and manufacturing

#### Polysorbate degradation

Klaus Wuchner, J&J, Switzerland and Wendelin Kranz, Coriolis, Germany

#### Challenges of Using Closed System Transfer Devices for Preparation of Biological Drug Products

Pierre Goldbach, Roche, Switzerland

#### Characterization of proteins in frozen state by microCT and freeze-thaw stabilization strategies

Jakob Bücheler, Novartis, Switzerland

#### Fill & Finish of highly concentrated mAb formulations, case studies

Marie Wacquet, Sanofi, France

#### Stability-relevant drug-device interactions

Oliver Germershaus, University of Applied Sciences North-West Switzerland, Muttenz, Switzerland

### Session 4: Novel approaches and technologies

#### Innovative formulation development approaches to achieve enhanced stability of biologics

Andreas Seidl, Leukocare, Germany

#### The use of excipients for in-vivo improvement and stabilization strategies for proteins

Emmanuel Dauty, Adocia, France

#### Stabilization of proteins by novel continuous lyophilization process

Thomas de Beer, University Ghent, Belgium

#### Long acting injectables of fragile molecules - opportunities from new delivery technologies for the delivery of T-cell engagers

Joël Richard, Medincell, France

#### Podium discussion

#### Wrap up

Karoline Bechtold-Peters and Vasco Filipe

#### Adjournment

## Moderators of the workshop

**Karoline Bechtold-Peters, Novartis, Basel**



**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 Pharmaceutics, 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, Sanofi, Paris**



**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 Section Head of Formulation and Process Development of Biologics.

Programme is subject to change

## Location

Maritim Hotel München  
Goethestraße 7  
80336 München  
Germany  
phone 0049 89 55235 0

## Registration fee

Industry 1390 EUR  
Authority/University 695 EUR  
Students\* 150 EUR  
(free of VAT according to § 4,22 UStG)

Rate from 01 December 2019  
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-Geschäftsstelle  
Kurfürstenstraße 59  
55118 Mainz/Germany  
Phone: 0049 6131 97 69 0  
Fax: 0049 6131 97 69 69  
E-mail: [apv@apv-mainz.de](mailto:apv@apv-mainz.de)  
Web: [www.apv-mainz.de](http://www.apv-mainz.de)

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

## Hotelreservation

Maritim Hotel München  
Goethestraße 7  
80336 München  
Germany  
phone 0049 89 55235 0  
mail [info.mun@maritim.de](mailto:info.mun@maritim.de)

Participants should make their own hotel reservation referring to the APV seminar. Deadline for special conference rate: 20 December 2019. Special rate: Single room incl. breakfast from 137,00 € per night.

## Date

Course no.: 6793  
from 05 February 2020 08:30 h  
to 06 February 2020 17:00 h

Mainz, March 2019

## APV Workshop on Protein Stability, 05 to 06 February, Munich, Germany, Course no.: 6793

### 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.

### Declaration of consent in respect of data protection

By registering for this seminar, I agree that the APV uses my data for the purpose of processing the order and provides me with all relevant information.

I also agree that APV may contact me for the purpose of exchanging similar information by email or post.

Your data will not be shared with third parties. You have a right of withdrawal at any time without giving reasons.

All other information can be found in our privacy policy ([www.apv-mainz.de/en/imprint/data-protection-statement/](http://www.apv-mainz.de/en/imprint/data-protection-statement/)).

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Company name \*

Street/no. or P.O. box \*

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Zip-code and city \*

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E-mail-address participant \*

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(You will receive further payment information with the invoice)

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Signature \*

\* Mandatory

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