Biopharma Stability & Cold Stability for Biologics/Therapeutic Proteins including novel formats, Vaccines, Cell Therapies and mRNAs



14 - 15 May 2024 Lisbon, Portugal Course no. 6981



Biotechnology

Target group

Scientists and professionals involved in the research, development and manufacture of biologics including novel formats, vaccines, cell and gene therapies and mRNAs which are temperature sensitive and need cool storage or even frozen state. Drug Substance, Formulation and Analytical Experts, R&D managers, project/programme managers, academic researchers, engineers, cell & gene therapy experts, experts for simulation & modelling.





This seminar is organised by the focus group Biotechnology

Objectives

Topics covered:

- Mechanistic insights into freeze and cold storage preservation
- Controlling freezing & thawing
- Downscale models
- Simulation & Modelling
- Equipment and equipment engineering for freezing & thawing & cold storage
- Stabilization by excipients
- R&D strategies
- Alternative methods

Programme committee

- Karoline Bechtold-Peters, Novartis
- Jean-Rene Authelin, Sanofi
- John Carpenter, CUANSCHUTZ
- Tarik Khan, F. Hoffmann-La Roche
- Miguel Rodrigues, Smartfreez
- Michael Wiggenhorn, Coriolis Pharma
- Hans-Georg Eckert, Valicare
- Vasco Filipe, Sanofi
- Rui Estrela, Smartfreez

Course leader



Karoline Bechtold-Peters Novartis, Basel, Switzerland

Dr. Karoline Bechtold-Peters is pharmacist and received her doctorate from the Ludwigs-Maximilians-University of Munich in Pharmaceutical Technology in 1994 for

a thesis in the field of enteric-coated pancreatin pellets. In 1994, Karoline started at Boehringer Ingelheim in Ingelheim as Head of Laboratory in Solid Dosage Forms, focusing on powder inhalation therapeutics. In this context, Karoline was instrumental in the development of the blockbuster Spiriva. In 2000, she moved to the Business Unit Biopharmaceuticals of Boehringer Ingelheim and thus to Biberach to build-up Formulation Development of Therapeutic Proteins. In 2003 she was appointed 2003 Head of Global Clinical Supplies, Aseptic Process Development and Process Transfer. After several years in this position, Karoline moved to Basel, Switzerland, in 2011, to join Hoffmann La-Roche and was assigned Head of Drug Product Clinical Supply Center Basel within Global Biologics Europe and was responsible for the production of biopharmaceutical clinical supplies both for Roche and Genentech. It became her core task to ramp up the brand new clinical lines for sterile vials and syringes covering initial inspections and initial batch production from 2011 to 2013. The expansion of the production to Antibody-Drug-Conjugates followed. In 2016, Karoline joined Novartis Pharma AG in Basel to focus on more strategic and future-looking issues of Biopharmaceuticals as Senior Strategy and Technology Leader Pharmaceutics within Biologics Technical Development & Manufacturing (BTDM) and the team "BioFuture". Since the reorganization of the Biologics business, Karoline has been part of the Scientific Offices Drug Product Development within Global Biologics & Cell and Gene Therapy as Director Science & Technology, representing the focus on Innovation and External Engagement.

Programme

Tuesday, 14 May 2024

08:30 - 19:00 h

Welcome and introduction Karoline Bechtold-Peters

Setting the stage - stresses involved and consequences when freezing and thawing biologics Tarik Khan, Roche, Switzerland

General stability considerations for Biologics Modalities Vasco Filipe, Sanofi, France

Controlled Freezing&Thawing systems Reinhard Tober, Novartis, Switzerland

Coffee Break

Container options for frozen storage & related transportation issues Karoline Bechtold-Peters, Novartis, Switzerland

Validation of Freeze-Thaw processes Sarah Otte, Roche, Switzerland

F/T Downscale models and their performance Miguel Rodrigues, SmartFreez/University of Lisbon, Portugal

Lunch Break

Simulation capabilities and predictive tools for freezing & thawing Vitor Geraldes, University of Lisbon, Portugal

5°C cold storage: Use of multi-temperature-based stability prediction models for various CQAs Christopher Lentes, Roche, Switzerland

Effects of macromolecular crowding on protein stability Gary Pielak, University of North Carolina at Chapel Hill, USA

Discussion

Visit to Sintra

Visit to Aralab and SmartFreez capabilities

Dinner in the area of Sintra

Register until 16 February 2024 as we have only limited places for the visit to Aralab and SmartFreez

Wednesday, 15 May 2024

08:30 - 16:00 h

Ice-structure investigations using CT methods / novel methods e.g. to determine pH in the frozen state Astrid Hauptmann, Novartis, Switzerland

Effective preservation of human pluripotent stem cell-derived cardiomyocytes compatible with global distribution of cells for clinical applications Margarida Serra, IBET, Portugal

Case Studies from the field of

- Native and Non-Native aggregation pathways of antibodies anticipated by cold-accelerated studies Jean-Rene Authelin, Sanofi, France
- Solving the deep frozen challenge a case study for VSV-GP
- Thomas Kriehuber, Boehringer Ingelheim, GermanyStability of spray freeze dried particles with a
- comparative analysis to spray drying Susana Farinha, Hovione, Portugal
- Freezing-induced aggregation of a trimeric fusion protein with low conformational stability - a case study on how to mitigate the risk during late stage Thijs Cui, J&J, Denmark
- Discussion

Lunch break

Poster Session & Rapid Poster Talks Upon submission

Frozen liquid versus Lyo versus liquid - Phase I strategies Hanns-Christian Mahler, ten23, Switzerland

Sustainability - at which temperature do we store frozen DS? Wolfgang Friess, University of Munich, Germany

How to differentiate between F/T and other damage by image analysis Ted Randolph, University of Colorado, USA

GMP-ready continuous and controlled freeze-drying Thomas De Beer, Ghent University, Belgium

Final discussion and course closing

Programme subject to changes.

Our service for you



We provide transfers from the Acores Lisboa Hotel to the Aralab and social event location and after the social event transfers back to the hotel.

Registration by email apv@apv-mainz.de



Location			Registration fee		Registration	Hotelreservation
Hotel Açores Lisboa Avenida Columbano Bordalo Pinheiro, 3 1070-060 Lisboa Portugal phone 00351 217 222 920 mail hal@bhc.pt website www.bensaudehotels.com/ hotelacoreslisboa/		Until 16 February 2024 Industry Authority/University Students* From 17 February 2024 Industry	1590 EUR 795 EUR 250 EUR	APV-Geschäftsstelle Kurfürstenstraße 59 55118 Mainz/Germany Phone: 0049 6131 97 69 0 E-mail: apv@apv-mainz.de Web: www.apv-mainz.de	Hotel Açores Lisboa Avenida Columbano Bordalo Pinheiro, 3 1070-060 Lisboa Portugal phone 00351 217 222 920 mail hal@bhc.pt website www.bensaudehotels.com/ hotelacoreslisboa/	
			Authority/University Students*	845 EUR 290 EUR	You will receive a confirmation of your registration with the invoice.	Single room from 159 \in /night incl. breakfast. Participants should make their own hotel reservation* on the
Date		(free of VAT according to § 4,22 UStG) Coffee breaks, luncheon, dinner and			hotels website using the "promotional code": COLD-STABILITY2024 .	
Course no from 14 N	o.: 6981 Nav 2024	08:30 h 16:15 h	electronic proceedings included. * Limited places for full time students			Room rates valid until 20 March 2024.
to 15 Ma	y 2024		available; written evidenc submitted.	e must be		*Free cancellation until 01 April 2024.

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Registration As soon as you have found a seminar of your interest, it is very easy to register for it by e-mail or online. We will process your registration promptly and certainly are available for any questions that may arise.	Title, first name, last name *				
Registration confirmation After your registration was successfully processed, you will receive a confirmation	Company name *				
Before the event	Street/no. or P.O. box *				
important information about the seminar, such as time, date, addresses etc.	Location				
After the event You will receive a certificate confirming your participation Furthermore we would like to ask you	Zip-code and city *				
to fill-in our evaluation sheet to make sure we get better every time.	Phone				
Follow-up After the event, we are open to receive any suggestions and criticity that might arise during the seminar and	E-mail-address participant *				
will certainly help you with further questions you may have.	Order no. and/or invoicing address				
Declaration of consent in respect of data protec- tion					
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