

### Speakers



#### Dr Katja Aschermann Astator, Consultant Dr Katja Aschermann is an accom-

Dr Katja Aschermann is an accomplished leader in the biopharmaceutical industry with over 20 ye-

ars of experience in various senior positions. Her extensive experience spans from transforming academic spin-offs into GMP companies to submitting regulatory dossiers to the EMA. She is a member of the ECA ATMP-Interest Group Board and has participated in the development of the "National Strategy for Gene and Cell-Based Therapies". In November 2024 she started working as a freelance consultant.



Dr med Andreas Sputtek Medical Laboratory Bremen

Authorized Officer Andreas Sputtek held management positions in various medical laboratories and university hospitals, in particular at the University Medical Centre Hamburg-Eppendorf, where he was in charge of haematopoietic stem cell processing and quality control. In addition to his clinical work, he was involved in several scientific societies, including the Society for Cryobiology, of which he was President from 2006 to 2007. He was also a member of several editorial boards and organised scientific conferences in the field of cryobiology and transfusion medicine. Since 2017 he is Authorized Officer at Medical Laboratory Bremen.



#### Dr Enrico Ne Fujifilm Irvine Scientific Field Application Scientist Enrico is a Biomedical Sciences

Ph.D. and currently works as a Field Application Scientist at Fujifilm Irvine Scientific. He has experience in academic research, process development, and assay development in the biotech industry. In his role, he supports customers in their process development activities and collects feedback to drive new collaborations, applications, and product development initiatives.

# Freezing Cells From frozen to functionality

Live Online Training on Thursday, 15 May 2025, 13.00 h – 16.30 h (CEST)



# Highlights

- Fundamentals of Cryopreservation
- Alternatives to DMSO
- Performance of a Stability Study

# Programme

### Objectives

This course provides basic and advanced knowledge of cell cryopreservation, including the underlying biological and physical processes.

Participants will gain an overview of historical developments, current challenges and modern approaches to cell cryopreservation, particularly in the pharmaceutical environment. They will learn the correct freezing procedure and how to select an appropriate CPA for their cells.

# Background

Cryopreservation is a fundamental technology in transfusion medicine, cell and gene therapy, and pharmaceutical development, enabling the long-term storage and transport of viable blood cells, haematopoietic stem cells, and other cellular products.

The ability to preserve these cells while maintaining their functionality and therapeutic efficacy is essential for both clinical and commercial applications. However, cryopreservation is a complex process that requires an in-depth understanding of cellular responses to freezing, the selection of suitable cryoprotectants (CPAs), and the development of optimized freezing and thawing protocols.

This event will provide participants with the scientific, technical and regulatory knowledge necessary to navigate the challenges of cryopreservation and implement best practices in their respective fields.

### Target Audience

The event is aimed at professionals in the pharmaceutical industry, particularly development scientists and quality managers involved in the cryopreservation of cellular products. Specialists in cell and gene therapy, biotechnology, GMP production, as well as researchers in haematology and transfusion medicine will also benefit from the content.

### Programme

Some like it cold - How Blood Cells and peripheral Blood Stem Cells survive Freezing

- Historical review
- Basic processes involved in freezing cell suspensions
- Blood cells (red cells, platelets and leucocytes)
- Hematopoietic progenitor cells

#### Cryopreservation Medium for Cell and Gene Therapy: Excipient Quality, Properties, and Performance for scalable GMP Manufacturing

- Understand the regulatory landscape of cryopreservation in cell and gene therapy
- Review the pros and cons of different CPAs, and how the balance can change when scaling up
- Discover cryopreservation excipient solution options

### Stability Studies in the Context of Cryopreservation

- Introduction stability studies
- Freeze thaw stability study
- Long-term stability study
- Validation requirements



### Date of the Live Online Training

Thursday, 15 May 2025, 13.00 h – 16.30 h (CEST)

#### **Technical Requirements**

We use WebEx for our live online training courses and webinars. At https://www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

### Fees (per delegate, plus VAT)

ECA Members € 990 APIC Members € 1,040 Non-ECA Members € 1,090 EU GMP Inspectorates € 545 The fee is payable in advance after receipt of invoice.

#### Registration

Please register online at www.gmp-compliance.org under the number 22169.

#### Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

#### Conference language

The official conference language will be English.

#### Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

#### CONCEPT HEIDELBERG

P.O. Box 10 17 64 D-69007 Heidelberg Telefon +49(0) 62 21/84 44-0 Telefax 49(0) 62 21/84 44 34 E-Mail: info@concept-heidelberg.de www.concept-heidelberg.com

For questions regarding content please contact: Mr Clemens Mundo (Operations Director) at +49(0) 62 21/84 44 42, or at mundo@concept-heidelberg.de

For questions regarding organisation please contact: Ms Manuela Luckhaupt (Organisation Manager) at +49(0) 62 21/84 44 66 or at luckhaupt@concept-heidelberg.de