ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Katja Aschermann
Astator

Dr Verena Plattner
Austrian Agency for Health and Food Safety (AGES)

Dr Pia Strasser
Austrian Agency for Health and Food Safety (AGES)

Tissue – QC, Inspections and other Challenges

Special handling and applications

Live Online Training on 26 February 2026

Highlights

- Donor Eligibility
- How to handle Process Changes
- Regulatory Requirements for Transportation and Storage
- QC of Raw Materials

Objectives

In this live online training you will be familiarized with the current regulatory requirements for Tissue Engineered Medical Products (TEMPs) and experts from authorities and industry will give you an insight into important topics related to TEMPs such as the management of process changes, donor eligibility, transport and storage as well as biovigilance.

Background

Tissue engineering and the development of Tissue Engineered Medical Products (TEMPs) represent an innovative and rapidly evolving field that merges the principles of engineering and biological sciences. The primary aim is to develop biological substitutes that can repair, replace, maintain or enhance tissue function. These innovative therapy methods open up new possibilities in biological reconstruction. Cartilage, bone and skin defects can be treated with autologous tissue replacement. However, the path from conceptualization to clinical application of TEMPs is fraught with unique challenges and stringent regulatory requirements.

One of the most significant challenges in the field of tissue engineering is related to the use of allogeneic donors - donations from individuals genetically different within the same species - for the creation of TEMPs. The field must navigate the complexities of process changes in the manufacturing of TEMPs, which can significantly impact the product's characteristics. Such changes require rigorous validation to ensure they meet the stringent standards set by regulatory bodies and are safe for patient use.

The transportation and storage of cells and tissues for medical applications are governed by comprehensive regulatory requirements designed to preserve their viability and functionality. Authorities like the FDA and EMA have established guidelines to minimize risks associated with contamination, degradation, and other factors that could compromise the therapeutic value of these products. Despite these regulations, the sector faces challenges in consistently meeting these standards, leading to deficiencies that can affect patient safety and treatment outcomes.

Quality control (QC) is another cornerstone in the production of TEMPs, ensuring that these products meet predefined quality criteria and are safe for clinical use. This involves evaluating Critical Quality Attributes (CQA), key product characteristics that must be measured, and conducting rigorous testing of raw materials. The complexity of TEMPs and their components poses significant challenges in QC, requiring sophisticated analytical methods and strategies to assess and ensure their quality throughout the manufacturing process.

Overall, it can be assumed that the development of new TEMPs will continue to progress rapidly over the next few years. However, realizing these potentials requires overcoming specific challenges, including ensuring donor eligibility, managing process changes, adhering to stringent regulatory requirements for transportation and storage, implementing quality control measures, and enhancing biovigilance. By addressing these challenges, the field can continue to advance and provide significant benefits to patients worldwide.

Target Audience

This course is intended for all persons from

- design and development of TEMPs
- manufacturing and process development
- regulatory authorities
- research institutions
- quality assurance and quality control

who have daily contact with TEMPs.

Programme

TEMPs and their Specific Challenges
Dr Katja Aschermann

- Specific challenges of TEMPs
- US donor eligibility for allogeneic donors
- Process changes

Cell and Tissue Inspections: Regulatory Requirements for Transportation and Storage
Dr Verena Plattner

- Authorities' perspective
- Regulatory requirements for transportation and storage
- Current deficiencies

Quality Control for TEMPs
Dr Katja Aschermann

- From CQA to quality control strategy
- Challenges
- QC of raw materials

Adverse Reactions and Events
Dr Pia Strasser

- Introduction and definition in biovigilance
- Correct implementation of reporting
- Examples from daily business

Speakers

Dr Katja Aschermann
Astator
Consultant

Dr Katja Aschermann is an accomplished leader in the biopharmaceutical industry with over 20 years 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 Verena Plattner
Austrian Agency for Health and Food Safety (AGES)
Head of Department Blood, Tissue & Vigilance

Dr Verena Plattner holds a doctorate in pharmacy from the University of Vienna. She has been a GDP/GMP inspector at AGES since June 2009, later becoming deputy head of the inspections department and heading the blood, tissue and vigilance department since December 2013. She is also a representative in international regulatory affairs and represents Austria in various NCA meetings of the European Commission related to blood, blood components, cells and tissues as well as in the Inspector's Expert Subgroup and in the EDQM, CD-P-TO. Dr Plattner is also a valued member of the Austrian Commission for Blood.

Dr Pia Strasser
Austrian Agency for Health and Food Safety (AGES)
Assessor for Haemovigilance, Tissue and Cells Vigilance

Dr Pia Strasser completed her medical studies at the Medical University of Vienna and has extensive expertise in the field of haemovigilance and vigilance for tissues and cells, a role she has held at AGES since September 2011. Based on her experience, she represented Austria in the European Commission's Vigilance Expert Sub-group in 2013, 2015 and 2016. Since summer 2024, she has been a member in the Vigilance Expert Sub-group again.

Moderator

Clemens Mundo, Concept Heidelberg

You cannot attend the Live Online Event?

We also offer many of the training courses and conferences mentioned in this brochure as recordings.
This means that you can watch the videos of the event „on demand" - whenever it suits your time - on our web server. Quite uncomplicated without software - simply in the browser.

Interested? You can find all recorded events at
www.gmp-compliance.org/recordings.

Stay informed with the GMP Newsletters from ECA

The ECA offers various free of charge GMP newsletters for which you can subscribe to according to your needs.

To subscribe, simply scan the QR code or visit www.gmp-compliance.org/gmp-newsletter

If the bill-to-address deviates from the specifications on the right, please fill out here:

_____

_____

_____

_____

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

Tissue – QC, Inspections and other Challenges
Live Online Training on 26 February 2026

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, or speakers without notice or to cancel an event.
If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. **Terms of payment**: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Thursday, 26 February 2026,
09.30 h – 15.30 h (CET)

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 € 1,090
APIC Members € 1,190
Non-ECA Members € 1,290
EU GMP Inspectorates € 645
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22161.

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.

Your Benefit: Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training...." This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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
Phone: +49(0) 62 21/84 44-0
Fax: +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:
Mr Ronny Strohwald (Organisation Manager) at
+49(0)62 21/84 44 51 or at
strohwald@concept-heidelberg.de.