



Speakers



Dr Katja Aschermann
Astator



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



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Focus on Tissue: A Multidisciplinary Approach

Special handling and applications



Live Online Training on 30 January 2025



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

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- 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

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

Quality Control for TEMPs

Dr Katja Aschermann

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

Adverse Reactions and Events

Dr Pia Strasser

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- 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 Nov 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. She then handed over this direct representation to a colleague and has since acted as her deputy.

Moderator

Clemens Mundo, Concept Heidelberg

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Focus on Tissue: A Multidisciplinary Approach Live Online Training on 30 January 2025

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Company

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Date of the Live Online Training

Thursday, 30 January 2025,
09.30 h – 15.30 h (CET)

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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 21300.**

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.

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