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Speakers

Dr Katja Aschermann
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Focus on Tissue: A Multidisciplinary Approach

Special handling and applications

Live Online Training on 19 September 2024

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 it intended for all person 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
Tetec AG
Vice President Quality

Over the last 20 years Katja Aschermann held various executive positions in the biological life science industry. During this time, she worked as Head of Quality Assurance, Head of Business Development, Director of Quality Control, Founder and Chief Operating Officer. Selected tasks of her professional career were transforming academical spin offs to GMP certified life science SMEs, merging of business units after acquisition and obtaining GMP manufacturing authorization for allogenic iPSC production in Germany.

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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Reservation Form (Please complete in full)

Focus on Tissue: A Multidisciplinary Approach
Live Online Training on 19 September 2024

Title, first name, surname

Department | Company

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

City | ZIP Code | Country

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E-Mail (Please fill in)

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Date of the Live Online Training
Thursday, 19 September 2024,
09.30 h – 15.30 h (CEST)

Technical Requirements
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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
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

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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