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Speakers

Dr Gerhard Bauer-Lewerenz
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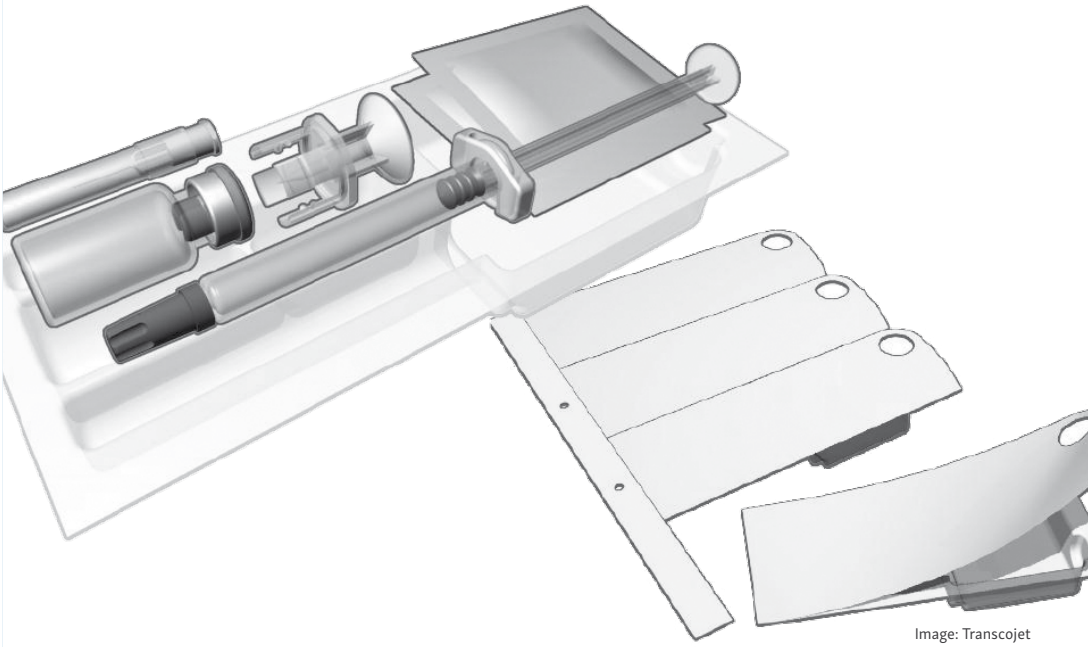
Design Controls for Drug – Device Combination Products

Live Online Training on 9/10 November 2021



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*How to ensure compliant Development and **Life-Cycle Management** for Drug-Device Combination Products*

Highlights

- Regulatory Requirements (USA/EU)
- Quality System requirements (USA/EU)
- Standards, process and guidance for:
  - Usability Engineering
  - Risk Management
  - Design Planning
  - Design Input / Output
  - Design Review
  - Design Verification / Validation
  - Design Transfer
  - Quality oversight
- Requirements for Single-Integral Products in EU
- External development, cross-party interfaces and integrating development
- Case Studies

Presentations and case studies will guide you step by step through the whole development process!

Objectives

This Live Online Training provides a comprehensive overview of the technical and regulatory requirements for the development and maintenance of drug-device combination products (with a focus on EU & US).

Participants will learn and understand

- the basics – distinctions between drugs, devices and 'combination products',
- the current applicable regulations, standards and guidelines related to the design and development of combination products and how to be compliant with those requirements
- the key elements of Design Controls, Risk Management and Usability Engineering.

Case Studies are an integral part of the course programme.

Background

More than half of the TOP20 drug products on the market include at least one device constituent part and are therefore considered Drug-device combination products. Drug-Device combination products are specifically regulated in the US. However, there is also an increasing oversight by regulatory authorities in the EU. Compliant development and life-cycle management are, therefore, essential for obtaining and maintain a marketing authorization for such products.

What is a Combination Product?
"Combination Product", as per 21 CFR Part 3.2(e), is a term defined by the FDA to cover products which consist of two or more components (i.e., drug, biologic, device) regulated under different regulations. The FDA differentiates between three basic types of combination products:

- **Single-entity** combination products,
- **Co-packaged** combination products,
- **Cross-labeled** combination products.

Beyond these basic types also combinations of those basic types are possible.

During the past years, FDA established regulations and guidances for Combination Products, which further clarify what Combination Products are and which rules apply to such combinations.

21 CFR Part 4, along with the final guidance "Current Good Manufacturing Practice (cGMP) Requirements for Combination Products", provides guidance on applicable quality requirements for combination products.

One essential requirement is to apply Design Controls as defined in 21 CFR Part 820.30 to the combination product as a whole. Design Controls are a set of quality practices and procedures to control the design process to assure that the combination product meets the user needs, intended uses and specified requirements. Design Controls support a systematic design and development process and ensure that the product fulfils those requirements which have been defined at the beginning of the project and that the final product fulfils the purpose. Design Controls are described in ISO 13485 (applicable for Medical Devices), in ISO 15378 (applicable to primary packaging materials) and even in the general standard for quality management system ISO 9001.

In the EU, so far, there has been no equivalent term to "Combination Product", a product is either considered a Medical Device or a Medicinal Product. Medical devices have to comply currently with the Medical Device Directive and shortly with the EU Medical Device Regulation (MDR). Even though the term Combination Product does not exist, also in EU, the Design Controls apply to the so-called single-integral products, which are similar to single-entity combination products as defined in the US.

Also shared in EU and US is the requirement to apply Risk Management to those products. The respective standard ISO 14971 has been revised in 2019. The course will consider the recent changes and provides guidance on how to apply Risk Management to drug-device combination products.

And lastly, also Usability Engineering, also known as Human Factors Engineering, needs to be considered in the Design and Development of combination products. The recent increase in attention to this topic has brought many manufacturers into difficulties as they aim to prove high levels of intuitive use, use safety and efficacy of the drug delivery system as a whole - for a Combination Product it is no longer just about the drug. Again, regulation, directives, guidance, standards and review expectations continue to evolve in this area.

This Live Online Training focuses on design controls as applicable to various combinations of drugs and biologics with devices. The course intends to set a solid basic understanding of the application on Design Controls as well as on the topics of Risk Management and Usability Engineering. Beyond the basic understanding, the course also aims to offer some practical experiences with the different elements to be considered.

Target Audience

This Live Online Training is designed for all scientists, engineers, managers and executives from Pharmaceutical and Biotech Development Units, including Device Development, Packaging Development, Quality Assurance, Regulatory Affairs, Marketing, and Project Management, who are involved in the development, industrialization and control of Drug-Device Combination Products.

This Live Online Training Course is recognized for the GMP/GDP Certification Scheme
Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. The Live Online Training is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

Programme Day 1

Provisional timetable, the actual schedule may vary depending on the situation

09.00 - 09.15 h Welcome and Introduction

09.15 - 09.45 h Regulatory Background

- Why do we need Design Controls for medical devices and combination products?
- Requirements in EU vs. US regarding the scope of Design Controls
- Requirements in EU for legal manufacturer vs. requirements in US for MAH
- Relevant standards in EU, US

09.45 - 10.30 h Design Controls – An Introduction

- Purpose of Design Controls / usability engineering / risk management
- Drug development vs. device development vs. combination product development
- Development vs. transfer vs. industrialization
- Processes required

10.30 - 10.45 h Break

10.45 - 11.15 h Design and Development Planning

- Definition of development scope
- Target product profile - How to determine the scope?
- Design reviews

11.15 - 12.00 h Introduction to Risk Management

- ISO 14971: Terms/definitions, process, relevance for design controls
- EU and US requirements
- Determine Known Use Problems

12.00 - 12.30 h Q&A Session 1

12.30 - 13.30 h Break

13.30 - 14.00 h Requirements for Single-Integral Products in EU

- How to demonstrate conformance with Annex I?
- Setup of technical documentation
- General safety & performance requirements

14.00 - 14.45 h Risk Management Part 2

- How to determine risk mitigations for design inputs
- Update of risk management during development
- Documentation of RM activities / RMF
- Preparation of post-market surveillance / PMS planning

14.45 - 15.00 h Break

15.00 - 15.45 h Case Study I: Pre-filled syringes

15.45 - 16.15 h Design Controls for Combination Products vs. Externally Developed Device Constituents

- How to link external development (of device constituent) with internal development of whole combination product
- Quality oversight approaches

16.15 - 16.45 h Design Controls and further Quality System Elements

- Procedures needed from Design Control perspective
- Other quality elements for combination products

16.45 - 17.15 h Q&A Session 2

Programme Day 2

08.30 - 09.30 h Design Input

- From user needs and other stakeholder needs to design input
- How to integrate results from UE, RM
- How to ensure „open-ended“ development
- Requirements for engineering techniques

09.30 - 10.30 h Design Output

- Development activities
- Definition of design outputs (Specifications)

10.30 - 10.45 h Coffee Break

10.45 - 11.45 h Design Verification

- Design verification activities
- How to consider verification during design input
- What to do if verification fails?

11.45 - 12.15 h Q&A Session 3

12.15 - 13.15 h Break

13.15 - 14.00 h Introduction to Usability Engineering

- IEC 62366-1
- How to determine user needs, user preference, use specification etc.

14.00 - 14.30 h Design Transfer

- Design Transfer - Why and how?
- DMR setup

14.30 - 14.45 h Break

14.45 - 15.45 h Design Validation / Usability Engineering Part 2

- Design validation approaches
- Planning, setup and conduct of summative studies
- Documentation of the UE activities
- UEF HF/UE Report as required by FDA

15.45 - 16.30 h Case Study II: Autoinjector Development (Some considerations when utilising syringes in auto-injectors)

16.30 - 17.00 h Q&A Session 4

Speakers

Dr Gerhard Bauer-Lewerenz,
Bauer-Lewenz Consulting, Germany

Dr Bauer-Lewerenz has more than 25 years of professional experience in the life science industry. He worked as Project Manager, Head of Controlling, Head of Procurement, external and internal consultant (GMP Compliance), and auditor of pharmaceutical, medical device, and API manufacturers in the EU, Asia, and the US. Since 2019 he has been working as a freelance consultant.

Ilanit Goldgraber,
West Pharma, Israel

Since 10 years Ilanit is RA Director at 'West Pharma. Services IL', a company which develops and manufactures devices for transfer, reconstitution and mixing of drugs. In her role she is responsible for managing all regulatory activities including regulatory strategy in product development, product submission and approval. She is actively involved in every stage of development of a new medical device and in the post-marketing activities with authorized medical device products.

Torsten Kneuss
Bayer AG, Berlin, Germany

Torsten Kneuss studied Business Administration and Engineering. Since 1999 he has been working with pharmaceutical packaging materials, medical devices and combination products, including several years within the field of quality control, development, operations, and pharmacovigilance. Since October 2020 he is, as a Quality Product Steward Medical Devices and Head of Project Office Medical Devices, responsible for devices and combination products within Bayer AG

Horst Koller
HK Packaging, Uznach, Switzerland

Prior to becoming a consultant, Horst Koller worked for Abbott Diagnostic and SCHOTT Pharmaceutical Packaging with a total of more than 20 years industry experience. His consulting company is focussing on Technical, Regulatory and QM Support around Primary and Secondary Packaging Systems including Medical Devices. He is an active member within the technical ISO Committees TC76 and TC84 as well as an active speaker on international conferences.

Lee Wood
medHF, Basel, Switzerland

Lee Wood is CEO and co-founder of medHF, a Medical Device and Combination Product Human Factors Engineering consultancy based in the Switzerland, UK and Austria. Prior to forming medHF, Lee was the Head of Human Factors Engineering at Roche Pharma and previously held Human Factors roles at Novartis Pharma and Cambridge Consultants.

Date of the Live Online Training

Tuesday, 9 November 2021, 9.00 to approx. 17.15 h CET
Wednesday, 10 November 2021, 8.30 to approx. 17.00 h CET

Technical Requirements

For our Live Online Trainings and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945
The conference 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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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.

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
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- Sterile Manufacturing
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- Medical Devices
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

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Reservation Form (Please complete in full)

Design Controls for Drug – Device Combination Products
Live Online Training on 9/10 November 2021

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 2 weeks prior to the conference 10 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation within 1 week prior to the conference 100 %.

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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 January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

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