ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Packaging Manager

Speakers

Steve Augustyn
Cambridge Design Partnership, UK

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Design Controls for Drug-Device Combination Products

Live Online Training on 15/16 October 2024

How to ensure GMP 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
- Case Studies

Presentations and Case Studies will guide you step by step through the whole development process!

Objectives

This Live Online Course 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. GMP 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 are in different extent 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 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 current standard 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 course 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 Course 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.

Programme Day 1

Design Controls – An Introduction

- What are Design Controls?
- Purpose of Design Controls / Usability Engineering / Risk Management
- Drug Development vs. Device Development vs. Combination Product Development
- Terminology (e.g. DHF)

Design Planning and Design Review

- Definition of development scope / scope of Design Control
- Other planning activities
- Design Review Requirements

FDA Regulatory Expectations on Drug-Device Combinations

- Types of Combination Products and impact on GMP Requirements
- Which Medical Device Quality Systems are required and at which facilities are they required to be implemented?
- Expectations for Clinical Phases and for Submissions
- Post Marketing expectations

EU Requirements for Drug-Device Combinations

- Applicable EU regulations and guidances for Drug-Device Combinations
- Requirements for Single-Integral Products
- Setup of technical documentation
- Notified Body Opinion process

Q&A Session 1

Introduction to Risk Management

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

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

Case Study I: Risk Management (Example)

- Documentation of Risk Management activities / Risk Management File
- Update of risk management during development
- Preparation of post-market surveillance (PMS) / PMS planning

Q&A Session 2

Programme Day 2

Design Output

- Development activities
- Definition of Design Outputs (Specifications)
- Quality Control Strategy

Introduction to Usability Engineering

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

Design Verification

- Design verification activities
- How to consider verification during design input
- What to do if verification fails?
- Requirements for test methods and for use of statistical techniques

Design Transfer

- Design Transfer – Why and how?
- Device Master Record setup

Q&A Session 3

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

Design Changes

- Design Change Control
- How to implement Design Change Control in Pharma

Case Study II: Development of an Auto-Injector

- Design Control, Risk Management and Usability Engineering aspects
- Setup of a technical documentation for Notified Body opinion

Q&A Session 4

Speakers

Steve Augustyn
Cambridge Design Partnership, UK

Steve is a British Standards Institution (BSI) recognised expert on injection devices and has been a member of the ISO TC-84 committee (Devices for administration of medicinal products and catheters) for over ten years.

Dr Gerhard Bauer-Lewerenz
Bauer-Lewerenz Consulting,Germany

Dr Bauer has more than 25 years of professional experience in the Life Science Industry. He has experience as project manager, Head of Controlling, Head of Procurement, external and internal consulting (GMP Compliance), Audits of pharmaceuticals, medical devices, and API manufacturers in the EU, Asia, and the US. Since After 12 years with the Fresenius Group he served as consultant and manager with the Chemgineering Group since 2004 and works as freelance consultant since 2019

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.

Dr Daneil Meier
Confinis AG, Switzerland

Daniel Meier is currently senior consultant for RA, QA and QM services for clients including, product registrations in US and EU, remediation of technical documentation according MDR, implementation of (electronic) QMS and development project support of medical devices and combination products. He has more than 35 years experience with Medical Devices and Medicinal Products.

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.

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Reservation Form (Please complete in full)

Design Controls for Drug – Device Combination Products
Live Online Training on 15/16 October 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

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 %.

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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 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

Tuesday, 15 October 2024, 9.00 to approx. 17.15 h CEST
Wednesday, 16 October 2024, 9.00 to approx. 17.30 h CEST

Technical Requirements

We use Webex for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our events 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 € 1,690
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 – or search and register directly at www.gmp-compliance.org under the number 20635. To avoid incorrect information, please give us the exact address and full name of the participant.

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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand" – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at www.gmp-compliance.org/recordings.

Organisation and Contact

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

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Your Benefits

Internationally Acknowledged Certificate from ECA Academy


CERTIFICATE

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 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. This training course 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.

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
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- 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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WH/24072024