Design Controls for Drug – Device Combination Products

21 – 23 October 2020 | Berlin, Germany

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
- Workshops and Case Studies

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

Speakers

Ilanit Goldgraber
West Pharma, Israel

Torsten Kneuss
Bayer, Germany

Horst Koller
HK Packaging, Switzerland

Paolo Mazzoni
PTM Consulting, Italy

Lee Wood
medHF, Switzerland

Presentations and workshops will guide you step by step through the whole development process!
**Objective**

This Education 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.

Workshops and 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 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 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

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

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

Design and Development Planning

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

Usability Engineering

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

Risk Management

- ISO 14971: Terms/definition, process
- Determine known use problems
- 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

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

Design Output

- Development activities
- Definition of design outputs ( Specifications )

Design Verification

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

Design Validation

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

Design Transfer

- Design Transfer - Why and how?
- DMR setup

Workshops & Case Studies will guide you step by step through the whole development process:

Workshops:

- Usability engineering (Setting up use specification, task analysis etc.)
- How to draft a risk analysis
- Design input (Setup user needs and design inputs)
- Design transfer (Determine elements required / to be transferred)
- General safety & performance requirements

Case Studies:

- Pre-Filled syringes
- Autoinjector development (Some considerations when utilising syringes in auto-injectors)

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

Design Controls and further Quality System Elements

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

Requirements for Single-Integral Products in EU

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

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 November 2017 he is, as a Quality Manager Combination Products, 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.

Paolo Mazzoni, PTM Consulting, Italy
Paolo Mazzoni is founder and CEO of PTM Consulting which supports Life Science companies providing solutions for Project Portfolio Management development, industrialization and product/process optimization.

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
Wednesday, 21 October 2020, 9.00 to approx. 17.30 h
(Registration and coffee from 8.30-9.00 h)
Thursday, 22 October 2020, 8.30 to approx. 17.30 h
Friday, 23 October 2020, 8.30 to approx. 16.00 h

Venue
Hyperion Hotel Berlin
Prager Straße 12
10779 Berlin, Germany
Phone +49(0)30/236250 0
Email Hyperion.berlin@h-hotels.com

Fees (per delegate, plus VAT)
ECA Members € 2,080
APIC Members € 2,180
Non-ECA Members € 2,280
EU GMP Inspectorates € 1,140

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on all days and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the course. Reservation should be made directly with the hotel. Early reservation is recommended.

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

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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For questions regarding reservation, hotel, organisation etc. please contact:
Mr Rouwen Schopka (Organisation Manager) at +49(0)62 21/84 44 13, or per e-mail at schopka@concept-heidelberg.de.

Social Event
In the evening of the first course day, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.

GMP/GDP Certification Scheme
Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. 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.
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 week prior to the conference: 50%.
   - Cancellation within 1 week 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.

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.

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

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Reservation Form (Please complete in full)

Design Controls for Drug – Device Combination Products, 21–23 October 2020, Berlin, Germany

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)