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Design Control for Drug – Device Combination Products

How to integrate Combination Product development activities within Pharma

SPEAKERS:

Mark A. Chipperfield
Corvus Device Limited, UK

Dr Jochen Heinz
Transcoject, Germany

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Lee Wood
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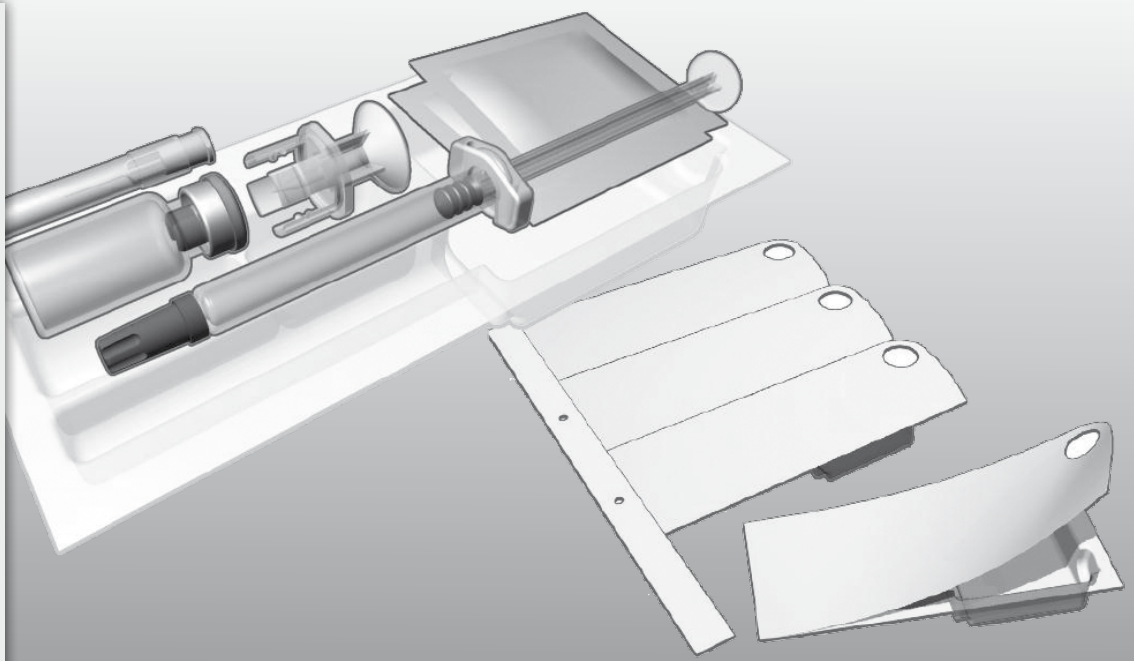

Image: Transcojet

16 - 17 May 2019, Copenhagen, Denmark

LEARNING OBJECTIVES:

- Regulatory Requirements (USA/EU)
- Quality System requirements (USA/EU)
- Standards, process and guidance in the following:
  - Management Responsibility
  - Design Control
  - Risk Management
  - Human Factors Engineering
  - Purchasing Control
  - CAPA
- External development, cross-party interfaces and integrating development
- Development Case Studies:
  - Pre-Filled Syringe (PFS)
  - (PFS-based) Autoinjector
  - Inhaler

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“.
Please find details at www.gmp-certification.eu

Design Control for Drug – Device Combination Products

16 - 17 May 2019, Copenhagen, Denmark

Learning Objectives

This Education Course provides a comprehensive overview of the regulatory requirements for the combination of medical devices with drug products (EU & US). Participants will learn and understand

- the basics – distinctions between drugs, devices and 'combination products',
- the current applicable regulations, standards and guidelines
- the key elements of the Design Control, Risk Management and Human Factors Engineering processes,
- many of the relevant process interfaces (change management, vendor management, data handling),
- specific presentations in quality systems, vendor management, design verification and human factors design validation.

Case Studies are an integral part of the course programme.

Background

"Combination Product" is a term defined by the FDA to cover various combinations of drugs, biologics and medical devices. Since 2002, there has been an Office of Combination Products (OCP) at the FDA. Alongside several historical guidances and regulations, the FDA has issued the 21 CFR Part 4 regulation on the current Good Manufacturing Practice (cGMP) requirements applicable to Combination Products, effective on July 22, 2013. In January 2015 FDA published the draft-guidance "Current Good Manufacturing Practice Requirements for Combination Products" which also brings more clarification to this topic.

In the EU, there is currently no equivalent term to "Combination Product", a product is either considered a Medical Device or a Medicinal Product. Classification of the product is based upon the Primary Mode of Action (PMOA) and the intended use. Regulation is based upon the Medicinal Product Directive and Medical Device Directive (transitioning to the Medical Device Regulation in May 2020). There are some recent and ongoing initiatives for change; the Medical Device Regulation, ISO 13485:2016, ISO14971 update in preparation, IEC 62366, ISO 9001, PS 9000, etc which impact the development activities within the pharmaceutical industry in future.

As a consequence, drug manufacturers who extend their development and/or manufacturing operations into delivery (Medical) devices; or vice-versa; may not only need to follow traditional cGMP approaches, but may also have to fulfil additional requirements of Regulation, Directives, Normative Standards and guidances. They will likely have to develop or enhance their quality system to satisfy these additional requirements.

The existing 21CFR820 Quality Systems Requirements (1996) defines several requirements including the Design Control development model which needs to be applied both pre- and post-production to the device constituent part of the Drug-Device Combination Products. ISO 13485:2016 also brings specific Quality System requirements.

Additionally, the recent increase in attention to Human Factors Engineering; or Usability Engineering; has led 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.

For the established pharmaceutical industry it can be a challenge to adopt new vocabulary and approaches (e.g. Design Control, Design Input, Design Output, Design Verification, Design Review, Design Validation, Design Transfer, etc.) into their existing and traditional development processes.

Target Group

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, industrialisation and control of drug-device combination products.

Programme

Regulatory Background

- Requirements for Medical Devices and Drug Delivery Products (Single Integral Product, EU)
- Requirements for Drug – Device Combination Products, USA
- Design control requirements

Device Development - Challenges and Considerations

- Design Control
- Significant Challenges & Experiences
- Combination product considerations, e.g. stability & shelf-life, control strategy, etc
- Product Remediation
- Recommendations to facilitate proficient Combination Product development

Further Quality System Elements for Medical Device Development and Design Control Interfaces

- Document Management
- Change Management
- Deviation Management

Risk Management

- What is a "Risk"
- Regulatory background (Drugs, Medical Devices)
- Risk Management as a design control element
- Integration of Risk Management into the company
- Tools (FMEA, FTA, HACCP)

Design Verification

- Design verification as a design control element
- Regulatory background
- PRS and URS
- Verification levels
- Test methods
- Protocols, reports and documentation

Case Study I: Pre-Filled Syringes

Introduction to Human Factors Engineering

- Introduction to discipline of Human Factors Engineering
- The current state of the regulatory environment
- The requirements of Human Factors Engineering as an activity under design controls, IEC62366 and ANSI-HE75

Case Study II: Human Factors Validation
Introduction and example of Human Factors Validation

- Pre-requisites as part of design controls
  - Planning, Health Authority Submission, Ethics Approval
  - Key considerations for study design
  - GMP Quality considerations
  - Key trends in regulatory feedback

External Development

- Vendor qualification and audits
- Quality Agreements

Case Study III: Inhaler Development

- Some considerations when developing inhalation combination products

Case Study IV: Autoinjector Development

- Some considerations when utilising syringes in autoinjector combination products

Case Study V: Integrating Design Controls, Risk Management and Human Factors

- Ensuring integrated key concepts during development and post-market activities

Speakers

Mark A .Chipperfield (M.Eng)
Principal Consultant, Corvus Device Ltd, UK
Mark A. Chipperfield spent 20 years working within large Pharma (GSK, sanofi-aventis, Novartis, Roche). Through his career to date he has been heavily involved in development of combination products Since 2015, he has been an independent Consultant.

Dr Jochen Heinz
Transcoject GmbH & Co. KG, Neumünster, Germany
Since 2001, Jochen Heinz has been working for Transcoject, a manufacturer of medical products. In the board of directors he is in charge for 'New Products'. Prior to that he was responsible at Schott Glas for the product development of the business unit 'Pharmaceutical Packaging'.

Paolo Mazzoni
PTM Consulting, Italy
Paolo Mazzoni worked for GSK and Flextronics in the past. Today he 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.

Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

Reservation Form (Please complete in full)

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Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | Purchase Order No, if applicable

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

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Date

Thursday, 16 May 2019, 09.00 – 18.30 h
(Registration and coffee 08.30 – 09.00 h)
Friday, 17 May 2019 , 08.30 - 16.30 h

Venue

Radisson Blu Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
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Scandinavia.meetings.events@radissonblu.com

Fees (per delegate plus VAT)

ECA Members € 1,490
APIC Members € 1,590
Non-ECA Members € 1,690
EU GMP Inspectorates € 845
The course fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

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

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.

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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