Design Control for Drug – Device Combination Products

How to integrate Combination Product development activities within Pharma

18 - 19 May 2017, Hamburg, Germany

LEARNING OBJECTIVES:

- Regulatory Requirements
  - USA, EU
- Device Development in large Pharma
- Design Control Process
- Interfaces: Change Management, Vendor Management, and Data Handling
- Risk Management as a Design Control Element
- Design Verification
  - Verification Levels, Test Methods
- Regulations, Standards and Guidance in Human Factors Validation
- External Development:
  - Vendor Qualification, Audits, Quality Agreements
- Case Studies: Pre-Filled Syringes / 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
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 definition of a Combination Product,
- current status of guidelines and standards,
- the elements of the Design Control process,
- many of the relevant process interfaces (change management, vendor management, data handling),
- Risk Management and Human Factors Engineering as important processes in device and combination product development, and
- how to test and document Design Verification and 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 Medical Device Directive or the Medicinal Product Directive - however there are some recent and ongoing initiatives for change; the Medical Device Regulation, ISO 13485:2016, ISO14971, IEC 62366, ISO 9001, PS 9000 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.

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

Maja Rybka

Device Development - Challenges and Considerations
- Integration of Medical Device development activities within Pharma
- Significant Challenges & Experiences
- Combination product stability & shelf-life
- Control Strategy
- Product Remediation
- Recommendations to facilitate proficient Combination Product development

Mark A. Chipperfield

Further Quality System Elements for Medical Device Development and Design Control Interfaces
- Document Management
- Change Management
- Deviation Management

Maja Rybka

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**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)

*Mark A. Chipperfield*

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

*Dr Jochen Heinz*

**Case Study I: Pre-Filled Syringes**

*Dr Jochen Heinz*

**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-HF75

*Lee Wood*

**Case Study II: Human Factors Validation**

*Lee Wood*

**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

*Maja Rybka*

**Case Study III: Inhaler Development**

*Mark A. Chipperfield*

**Case Study IV: Autoinjector Development**

*Mark A. Chipperfield*

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

*Mark A. Chipperfield*

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**Speakers**

**Mark A. Chipperfield (M.Eng), Principal Consultant, Corvus Device Limited, 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 in several forms: solution/suspension inhalers, multi-dose disposable and reusable dry powder inhalers, convenience kits, pen injectors, auto-injectors, dispensers and special purpose applicators. Since 2015, he has been an independent Consultant supporting Pharma companies, Suppliers and device innovators across the globe; to develop, launch and maintain their products. He has co-authored a study case chapter within the PDA publication ‘Combination Products: Implementation of cGMP requirements.’

**Dr Jochen Heinz, Transcoject GmbH & Co. KG, Neumünster, Germany**

Jochen Heinz has a Master of Engineering in Material-Science and Technology. Since 2001 he is 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 is founder and CEO of PTM Consulting which supports Life Science companies providing solutions for Project Portfolio Management development, industrialization and product/process optimization. He has long time experience in Risk Management projects applied across the entire product lifecycle. Before that he worked for GSK where he was in charge of the development and industrialization of sterile and not-sterile delivery systems and packaging technologies and as consultant for Flextronics, focusing on risk management processes and quality systems for medical design and manufacturing centers.

**Maja Rybka, Quality Consultant, Witten, Germany**

Maja Rybka is Biomedical Engineer by training and after two years in biomaterial research at the university in Rostock she worked for 8 years as Project Manager for Medical Devices and Combination Products at Schering AG Berlin. From 2007 to 2010 she worked as Quality Systems Engineer responsible for quality- and regulatory compliance in the Device Development department at Novartis Pharma AG Basel. Since 2010 she was Senior Quality Auditor for Medical Devices, Packaging and Drug Products. Today she works part-time as Quality Consultant and she studies dental medicine at the University Witten/Herdecke. She is the author of the “Defect Evaluation List for Medical Needles” (Editio Cantor Publishing House).

**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. Lee holds a Master’s degree with distinction in Healthcare Human Factors from University of Derby, UK and a Bachelor’s degree with first class honor’s in Product Design from University of Wales, UK. Lee is also a Chartered Product Designer (MCSD).
**Reservation Form (Please complete in full)**

**Design Control for Drug-Device Combination Products**

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**Dates**

- **Thursday, 18 May 2017**, 09.00 – 18.00 h (Registration and coffee 08.30 – 09.00 h)
- **Friday, 19 May 2017**, 08.30 – 16.30 h

**Venue**

Barceló Hotel Hamburg
Ferdinandstrasse 15
20095 Hamburg, Germany

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**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 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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**For questions regarding reservation, hotel, organisation etc.:**

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