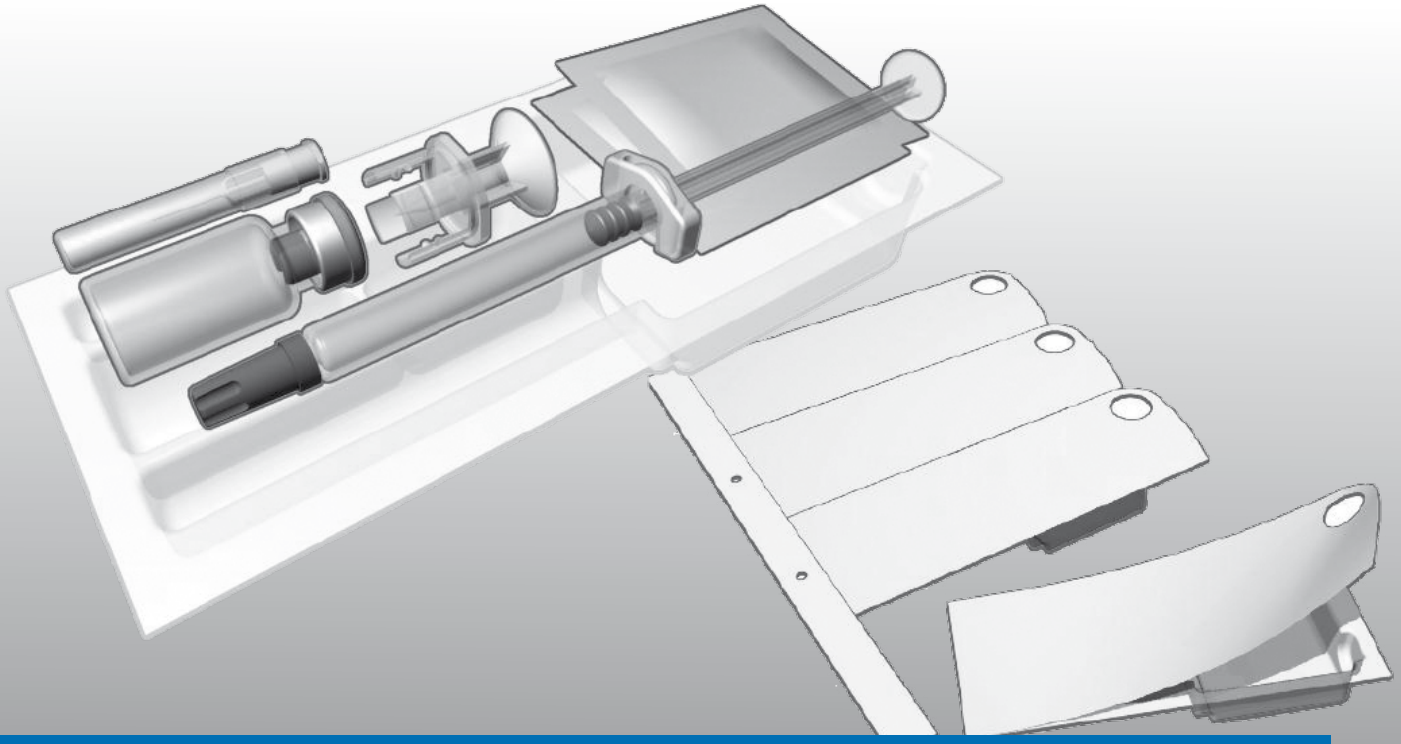

Image: Transcojet

Design Control for Drug – Device Combination Products

How to integrate Combination Product development activities within Pharma

2-3 June 2014, Berlin, Germany

SPEAKERS:

Mark A. Chipperfield
F. Hoffmann-La Roche Ltd., Switzerland

Dr Jochen Heinz
Transcoject, Germany

Nicole Melzer
Compliance Service Nord, Germany

Maja Rybka
Novartis Pharma, Switzerland

Lee Wood
F. Hoffmann-La Roche Ltd., Switzerland

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

ECA ACADEMY

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

2 – 3 June 2014, Berlin, Germany

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,
- the elements of the Design Control process,
- many of the relevant process interfaces (change management, vendor management, data handling),
- Risk Management as an important tool for device and combination product development, and
- how to test and document Design Verification and Design Validation.

Case Studies and Workshops 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. The existing 21CFR820 Quality Systems Requirements also define the Design Control development model.

In the EU, there is currently no equivalent term to "Combination Product", a product is either considered a Medical Device or a Medicinal Product. The bases for classification of a product are the Primary Mode of Action (PMOA) and the intended use. Regulation is based upon the Medical Device Directive or the Medicinal Product Directive.

As a consequence, drug manufacturers who extend their development and/or manufacturing operations into Medical Devices; or vice-versa; may not only need to follow traditional cGMP approaches, but may also have to fulfil additional requirements of Directives, ISO-Norms and the specific requirements of 21CFR820. They may have to develop or enhance their quality system to satisfy these additional requirements.

The Design Control process should follow the waterfall model as described in FDA's Design Control Guidance for Medical Device Manufacturers.
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.

It is the aim of this course to give an overview of the current requirements in Europe and in the US and to show how these requirements need to be translated in the development of drug – device combination products.

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.

Social Event

On 2 June 2014 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.

Programme

Regulatory Background

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

Maja Rybka

Device Development in large Pharma

- Integration of Medical Device development activities within large pharma
- Significant Challenges
- Experiences
- Recommendations to facilitate proficient Combination Product development

Mark A. Chipperfield

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

- Change Management
- Deviation Management
- Document Management

Maja Rybka

Risk Management

- Risk Management as a design-control element
- Regulatory background (Drugs, Medical Devices)
- Integration of Risk Management into Q-Systems
- Tools (FMEA, FTA, CED, HACCP)
- Documentation

Nicole Melzer

WORKSHOP I:
Usability Risk Management

- Introduction of regulatory requirements
- Methods and principles
- Practical application of Risk Management in small groups on prepared examples
- Discussion and refinement
- Concluding documentation

Moderator: Nicole Melzer

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-HE75

Lee Wood

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

- 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

Lee Wood

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

Speakers

Mark A. Chipperfield
F. Hoffmann-La Roche Ltd., Basel, Switzerland
Mark A. Chipperfield (M.Eng.) has spent the last 20 years working within large Pharma (GSK, sanofi-aventis, Novartis, Roche) in the field of drug delivery devices and special purpose packaging. 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. Outside of his day job, Mark is currently leading the PDA EU Interest Group for Combination Products.

Nicole Melzer
Compliance Service Nord, Germany
Nicole Melzer (Chemical Engineer) worked 12 years at GSK heading the Analytical Method Transfer Group and she was responsible for the Quality Assurance in the Analytical Laboratory. Subsequently Nicole Melzer joined Transcoject for 10 years. In the board of directors she was responsible for the Quality (Risk) Management and the Pharmaceutical Packaging (Pre-filled Syringes) and Aseptic Filling departments. Since 2013 Nicole Melzer is the managing director of Compliance Service Nord, a consulting service providing QM, QA and QC expertise for pharmaceutical and medical device industry.

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'.

Maja Rybka
Novartis Pharma AG, Basel, Switzerland
Maja Rybka was Project Manager for Medical Devices and Combination Products at Schering AG Berlin (1999 – 2007). After that she worked as Quality Systems Engineer responsible for quality- and regulatory compliance in the Device Development department at Novartis Pharma AG. Since 2010 she is Senior Quality Auditor for Medical Devices, Packaging and Drug Products. She is the author of the "Defect Evaluation List for Medical Needles" (Editio Cantor Publishing House).

Lee Wood
F. Hoffmann-La Roche Ltd., Basel, Switzerland,
Lee Wood leads the Human Factors Engineering group in Device Development at Roche Pharma applying HFE to development of medical devices and combination products. Prior to joining Roche Lee worked at Novartis Pharma (Principal Scientist/ HF Engineer) and Cambridge Consultants (Senior Product Designer). Lee is a Chartered Product Designer (MCSD) in the UK and a full member of the Human Factors and Ergonomics Society in the US. Lee also sits on the AAMI Human Factors Engineering committee.

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

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Design Control for Drug – Device Combination Products
2 – 3 June 2014, Berlin, Germany

☐ Mr. ☐ Ms.

Title, first name, surname

Company | Department

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

Street/P.O. Box

City | Zip Code | Country

Phone/Fax | E-Mail (please fill in)

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

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

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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)

Date

Monday, 2 June 2014, 09.00 – 18.00 h
(Registration and coffee 08.30 – 09.00 h)
Tuesday, 3 June 2014, 08.30 - 16.30 h

Venue

Steigenberger Hotel Am Kanzleramt
Ella Trebe Str. 5
10557 Berlin, Germany
Phone +49 (0)30 921 025 70
Fax +49 (0) 30 921 025 799

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
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 hotel. You will receive a room reservation form when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. 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

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