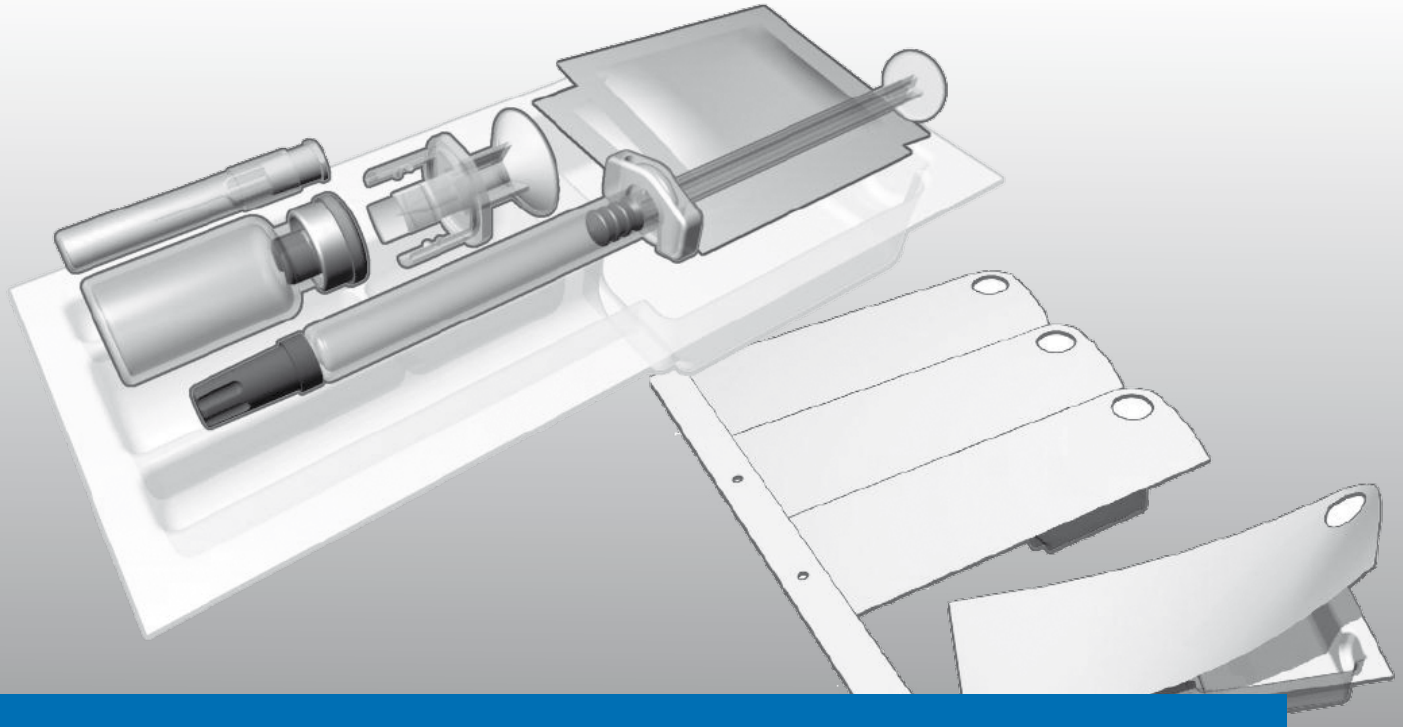

Image: Transcojet

Design Control for Drug – Device Combination Products

How to Integrate Combination Product Development Activities within Pharma

25 – 26 June 2012, Heidelberg, Germany

SPEAKERS:

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

Dr Jochen Heinz
Transcoject, 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
EUROPEAN COMPLIANCE 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

25 – 26 June 2012, Heidelberg, Germany

Learning Objectives

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

- the definition of a Combination Product,
- the elements of the Design Control Process,
- the interfaces (change management, vendor management, data handling),
- Risk Management as an important tool for Design Control, and
- how to test and document Design Verification and Design Validation.

Case Studies and Workshops are also an integral part of the course programme.

Background

"Design Control" was a term that was originally used only in the development and manufacture of medical devices. In the meantime "Design Control" became an important issue for the development of pharmaceutical drug products just as well (ICH Q8, Q9, and Q 10). There are more and more requirements and requests from the regulatory authorities relating to "Design Control" for Combination Products.

"Combination Product" is a US term and there is even an Office of Combination Products at the FDA since 2002. In contradiction to that the EU has no definition of a "Combination Product", it is either a Medical Device or a Medicinal Product. The decision how to classify a product depends on its Primary Mode of Action (PMOA) and the intended use.

As a consequence with regard to the existing Quality Systems, drug manufacturer may not only follow GMP but also have to fulfil new Medical Device Directive and ISO requirements for device manufacturers, or in the US a drug manufacturer regulated by 21 CFR Part 210/211 has to add specific requirements from 21 CFR 820 for device manufacturer. In Europe a drug manufacturer may also have to maintain two quality systems (EU GMP and ISO 13485 for device manufacturer) depending if an ISO certification is required.

One impact of these combined quality systems is the demand for a "Design Control" when developing a combination product. The implementation of a complete Design Control Process should follow the waterfall model as described in FDA's Design Control Guidance for Medical Device Manufacturer.
For people working in the pharmaceutical industry it is a challenge to transfer all these new terms (Design Process, Design Verification, Design Validation, Design Transfer, etc.) to their existing and traditional development processes.

It is the aim of this course to give an overview over the current requirements in Europe and in the US and to show how all these requirements need to be translated in the development of drug – device combination products like pre-filled syringes, etc.

Target Group

This Course is designed for all scientists, engineers and managers and executives from Pharmaceutical and Biotech Development Units, including Packaging Development, Quality Assurance, Regulatory Affairs, Marketing, and Project Management, who are involved in the development and control of drug-device combination products.

Social Event

On 25 June 2012 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)
- EU – ISO 13485
- USA: CFR 210 / 211 and QSR (CFR 820)

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 Chipperfield

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

- Change Management
- Deviation Management
- Data Handling

Maja Rybka

Risk Management
- Risk Management as a design-control element
- Regluatory background
- Medical devices and pharmaceutical containers
- FMEA
- Application examples
- Documentation

Dr Jochen Heinz

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: Dr Jochen Heinz

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

Human Factors Validation
- The emerging landscape of regulations, standards and guidance's in Human Factors Engineering
- The requirements of Human Factors Engineering as an activity taking place under GMP quality system regulation
- Considerations for effectively planning and conducting a HFE validation study, addressing topics such as:
  - Ensuring the study validates the URS
  - Types of assessment which can be made
  - Adequate sampling of end users

Lee Wood

WORKSHOP II: Design Validation
- Selecting inclusion and exclusion criteria
- Determining the sample
- Selecting study objectives and measurable variables
- Ensuring data integrity, etc.

Moderator: Lee Wood

External Development
- Vendor qualification and audits
- Quality Agreements

Maja Rybka

Case Studies:
- A: Pre-Filled Syringes (Dr. Jochen Heinz)
- B: Autoinjector Development (Mark Chipperfield)
- C: Inhaler Development (Mark Chipperfield)

Speakers

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

Mark A. Chipperfield (M. Eng) has spent the last 18 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 and special purpose applicators.

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 studied Biomedical Engineering and worked after her studies at the University Rostock in biomaterial research. From 1999 to 2007 she was Project Manager for Medical Devices and Combination Products at Schering AG Berlin. 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, Device Development

Lee Wood is a Human Factors Engineer currently working for Roche Pharma in Basel. Lee has 8 years of experience and has worked for both Novartis and Cambridge Consultants conducting Human Factors Engineering to the development of medical devices and combination products. At Novartis Lee led the implementation of the Human Factors strategy in device development and he has directed over 40 usability studies at various development stages ranging from front-end requirement definition to validation and addressing HF issues in registration. Lee is a full member of the US Human Factors and Ergonomics Society and is a Chartered Designer.

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:

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

Design Control for Drug – Device Combination Products
25 – 26 June 2012, Heidelberg, 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)

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 %.

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. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)!

Date

Monday, 25 June 2012, 09.00 – 17.30 h
(Registration and coffee 08.30 – 09.00 h)
Tuesday, 26 June 2012, 08.30 - 16.00 h

Venue

nh Hotel Heidelberg
Bergheimer Str. 91
69115 Heidelberg, Germany
Phone +49 (0) 6221 1327 0
Fax +49 (0) 6221 1327 100

Fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT (does not include ECA Membership).
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 or be sure to mention "ECA" to receive the specially negotiated rate (single room € 124,- per night incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 28 May 2012. 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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