The Quality Documentation of Biological IMPs

How to write the Quality Part of an IMPD

Requirements on chemical and pharmaceutical quality documentation for an IMP dossier

17 – 18 November 2015, Berlin, Germany

SPEAKERS:

Dr Wolfram Eisenreich
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Horn Pharmaceutical Consulting, Germany

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PROGRAMME:

- Drug substance and drug product quality data – what has to be considered
- Substantial amendments and notification obligations
- Stability Considerations
- Quality information of comparator products and placebos
- IMPD for biotech products
- Manufacture of clinical trial formulations
- Planning of an IMPD
- Quality information required for global clinical trials

ECA ACADEMY

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

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Objectives

This education course highlights the **key principles of the Quality Part of an IMPD** for Investigational Medicinal Products both of chemical and biotechnological origin. You will get to know the essential aspects relevant for compiling the IMPD Quality Part and you will learn

- How to prepare and process the quality related information for drug substance and drug product
- How to manage and document changes concerning quality data
- How to consider quality parameters of drug substance and drug product with potential clinical relevance
- How to describe the manufacturing process development for a biotech IMP
- How to process and document stability data for an IMPD of a biotech product

Background

An IMPD is required for every Investigational Medicinal Product (IMP) to be used in a clinical study, regardless of whether it is the test product itself, a reference product already authorised or a placebo. The IMPD includes summaries of information related to the quality, manufacture and control of the IMP as well as data from non-clinical and clinical studies. Furthermore it contains an overall risk-benefit assessment and critical analyses of the non-clinical and clinical data related to the potential risks and benefits of the proposed study.

In March 2006 the CHMP "Guideline on the Requirements to the Chemical and Pharmaceutical Quality Documentation concerning Investigational Medicinal Products in Clinical Trials" was published in Chapter III of Volume 10 of EudraLex.

Another CHMP Guidance for Biologicals entitled "Guideline on the Requirements for Quality Documentation concerning Biological Investigational Medicinal Products in Clinical Trials" was adopted in March 2012 and became effective in April 2012.

Target Group

This education course is designed for all persons involved in the compilation of IMPDs who want to become familiar with the requirements for the quality documentation of investigational medicinal products. The course will be of interest in particular for personnel from Regulatory Affairs as well as for personnel from Quality Assurance, Quality Control and Production.

Programme

Why do we need an IMPD? - Legal Framework and Regulatory Requirements

- Regulatory Requirements
- Challenges
- Practical Hints
- Sources of Information

General Requirements to an IMPD

- Structure and Content
- Planning
- Preparation
- Submission

Quality Documentation for a Biotech IMPD – Manufacturing Process and Analytical Characterisation

- Description of the manufacturing process, control of critical steps
- Manufacturing process development
- Characterisation and control of the active substance

Quality Documentation for a Biotech IMPD – Product Control and Stability Studies

- Control of excipients
- Specifications, batch analysis
- Stability data
- Substantial amendments

Drug Substance – Description of the Manufacturing Process

- Control of critical steps and intermediates
- Control of Impurities
- Analytical Procedures and validation requirements
- Justification of specifications and stability data

Writing of the Drug Product Section of an IMPD

- Key aspects
- Practical examples

Quality Information of Authorised Modified and non-modified Comparator Products

- Description and Composition
- Summary of Product Characteristics (SmPC)
- Additional information for Phase II and Phase III clinical trials
- Quality information on existing active substances in bio-equivalence studies
- Quality information on placebo products

Case Study: Planning of an IMPD

This workshop will focus on the essentials of clinical trials. The participants will get practical advice on how to successfully plan and prepare IMPDs.

How to Manage and Document Changes to IMP Quality Data – Substantial Amendments

- Changes that need to be notified
- Amendments that are to be regarded as "substantial"
- When have changes to be notified?
- Some examples

Quality information required for global clinical trials

- Role of Investigators Brochure
- IMPD vs IND?
- Other countries e.g. Canada, Japan, China etc. – one dossier for all?

Social Event

On 17 November 2015, 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.

Speakers

Dr Wolfram Eisenreich

Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Dr Eisenreich is a pharmacist by training and received his PhD at the Ludwig-Maximilians-University Munich in 2002. In 2003 he joined Boehringer Ingelheim and headed formulation development groups in Biberach, Germany and Ridgefield, USA. Since 2010 he is heading the Central Clinical Trial Bulk Manufacture Solids group at Boehringer Ingelheim. Amongst other things he is now responsible for blinding of comparator products, development of matching placebo products and authoring of the respective IMP documents.

Dr Siegfried Giess

Paul Ehrlich Institute, Germany

In his present position, Dr Giess works at the Paul-Ehrlich-Institut, the Federal Institute for Vaccines and Biomedicines in Germany. He is deputy head of the Department of Immunology and head of the Immunochemistry-Section. He is engaged in testing activities of the OMCL network and involved in the quality assessment of immunoglobulins, immunsera and monoclonal antibodies. Dr Giess is nominated expert of the CHMP at the European Medicines Agency (EMA). He is member of the Working Party Monoclonal Antibodies of the EP Commission and belongs to the USP Monoclonal Antibodies Expert Panel. He is member of the Heads of Medicines Agencies Working Group on Product Testing and member of the BWP Drafting Group for the "Guideline on the Requirements for Quality Documentation concerning Biological Investigational Medicinal Products in Clinical trials".

Dr Hiltrud Horn

Horn Pharmaceutical Consulting, Germany

Dr Hiltrud Horn is managing director of HORN PHARMACEUTICAL CONSULTING. From 1990 to 1997, she was employed by Hoffmann-La Roche in Quality Control/Quality Assurance. From 1997 to 1999, she dealt with medical writing in the 'International Drug Regulatory Affairs and Project Management' department of the same company. In 1999, she joined Knoll AG as head of the departments 'Regulatory Compliance and CMC Documentation' and 'Dossier Production and Compliance' for international drug registration. In 2002, she started at Cap Gemini Ernst & Young, where she was the responsible consultant for questions concerning biotechnology and life sciences.

Dr Claus-Dieter Schiller

F. Hoffmann-La Roche AG, Switzerland

Since 1995, Dr Schiller is working in Global Technical Registration of F. Hoffmann-La Roche. Dr Schiller has held different positions within Technical Registration dealing with different aspects of filings of synthetic products ranging from clinical trials, NDAs to post-approval changes. In his present position he is group manager of Documentation & Training. Dr Schiller has been a member of the former Quality adhoc Group of EFPIA.

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:

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Date

Tuesday, 17 November 2015, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 18 November 2015, 8.30 – 16.00 h

Venue

Steigenberger Hotel Berlin
Los-Angeles-Platz 1
10789 Berlin, Germany
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Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference 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 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. 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

ECA has entrusted Concept Heidelberg with the organisation of this event.

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