ECA Academy
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GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Dr Wolfram Eisenreich
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How to Write the Quality Part of an IMPD

Live Online Training on 06/07 October 2021

Highlights

- 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
- Specific aspects for a paediatric Q-IMPD

Requirements to chemical and pharmaceutical quality documentation for an IMP dossier

Objectives

This Live Online Training 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 Audience

This Live Online Training 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 training 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 Case Study 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

How to Handle Paediatric Formulations

- What is a Paediatric Investigation Plan (PIP)? Legal framework and content of the quality part
- Specific aspects for the formulation development (taste, preservatives, etc.)
- Specific aspects for a paediatric Q-IMPD

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?

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. He worked for one year as a Postdoctoral Scientist at GlaxoSmithKline at three different departments and locations in the USA. 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 Jörg Engelbergs, Paul-Ehrlich-Institut (PEI), Germany Federal Agency for Vaccines and Biomedicines

Dr Engelbergs studied biology at the university of Düsseldorf and Duisburg-Essen. After his PhD he worked in different positions at the German Cancer Center before he joined the PEI in 2006 as Scientific-Regulatory Expert Biomedicines (Quality, Non-Clinic, Pers. Medicines - Biomarker/CDx).

Sonja Estermann, F. Hoffmann-La Roche Ltd, Switzerland

Ms Estermann has more than 20 years experience in regulatory, working since 2004 at F. Hoffmann-La Roche Ltd as Global Technical Regulatory Manager with expertise in paediatrics. Prior to Roche she worked in Regulatory Affairs at Pfizer Switzerland. She started her career as a community pharmacist and head of QC/FTL "Qualified Person" in the Pharmacy Hotz/Galepharm Switzerland. Ms Estermann holds an M.S. in Pharmacy from the University of Basel, Switzerland and a post diploma HF in Business Economics.

Dr Hiltrud Horn, Horn Pharmaceutical Consulting, Germany

Dr Horn is managing director of HORN PHARMACEUTICAL CONSULTING with focus on CMC, GMP and Regulatory Affairs. She started in pharma industry in 1990 and held several managerial positions within Hoffmann-La Roche in Basel and Knoll (Abbott) with global responsibility within QC / QA / Regulatory Affairs / Project Management / Medical Writing.

Dr Claus-Dieter Schiller, F. Hoffmann-La Roche AG, Switzerland

Dr Schiller has studied Chemistry at the University in Regensburg. He received his PhD at the Institute of Pharmaceutical Chemistry in Regensburg. Since 1995 he 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.

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Reservation Form (Please complete in full)

How to Write the Quality Part of an IMPD
Live Online Training on 06/07 October 2021

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Date of the Live Online Training
Wednesday, 06 October 2021, 09.00 – 17.30 h CEST
Thursday, 07 October 2021, 09.00 – 16.00 h CEST

Technical Requirements
For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

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.

Registration
Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate
The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Your Benefit
Internationally Acknowledged Certificate from ECA Academy
The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training.... “ This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

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