ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Regulatory Affairs Manager

Speakers

Dr Wolfram Eisenreich
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

Dr Jörg Engelbergs
Paul- Ehrlich- Institut, Germany

Dr Hiltrud Horn
Horn Pharmaceutical Consulting, Germany

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

How to write the Quality Part of an IMPD

08/09 December 2020 | Prague, Czech Republic

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

Requirements to chemical and pharmaceutical quality documentation for an IMP dossier

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 Audience

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

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.

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).

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.

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)

How to write the Quality Part of an IMPD, 08/09 December 2020, Prague, Czech Republic

Title, first name, surname

Department Company

Important: Please indicate your company's VAT ID Number Purchase Order Number, if applicable

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 %,
- Cancellation until 1 weeks prior to the conference 50 %
- Cancellation 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 HEIDELBERGwill 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)! (As of January 2012).
German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at https://www.gmp-compliance.org/privacy-policy). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date
Tuesday, 08 December 2020, 9.00 – 17.30 h
(Registration and coffee 8.30 – 9.00 h)
Wednesday, 09 December 2020, 8.30 – 15.45 h

Venue
Corinthia Hotel Prague
Kongresova 1
14069 Prague 4, Czech Republic
Phone +420 (261) 191 111
Email prague@corinthia.com

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 HEIDELBERG 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. 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.

GMP/GDP Certification Scheme
Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance.

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64 | D-69007 Heidelberg
Telefon +49(0) 62 21/84 44-0 | Telefax +49(0) 62 21/84 44 34
E-Mail: info@concept-heidelberg.de
www.concept-heidelberg.com

For questions regarding content:
Ms Anne Günster (Operations Director) at
+49(0)62 21/84 44 50, or per e-mail at
guenster@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
+49(0)62 21/84 44 22, or per e-mail at
bach@concept-heidelberg.de.