DIA/EFPIA Information Day on ICH

Event #14114
28 March 2014
Hotel NH Danube City, Vienna, Austria

Programme Committee

Sabine Luik
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Consultant, Switzerland

About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe. Through its direct membership of 33 national associations and 40 leading pharmaceutical companies, EFPIA is the voice on the EU scene of 1,900 companies committed to researching, developing and bringing to patients new medicines that will improve health and the quality of life around the world.

About DIA

DIA is a neutral, global, professional and member-driven association of nearly 18,000 professionals involved in the discovery, development and life cycle management of pharmaceuticals, biotechnology, medical devices and related health care products. Through our international educational offerings and myriad networking opportunities, DIA is an independent non-profit organisation who provides a global forum for knowledge exchange that fosters the innovation of products, technologies and services to improve health and well-being worldwide. Headquarters are in Horsham, PA, USA, with offices in Basel, Switzerland; Tokyo, Japan; Mumbai, India; Beijing, China; Washington, D.C.; and Latin America.

For more information, visit www.diahome.org or call DIA Europe +41 61 225 51 51.

Overview

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry of Europe, Japan and the US to discuss scientific and technical aspects of drug registration. Since its inception in 1990, ICH has gradually evolved to respond to the increasingly global face of drug development, so that the benefits of international harmonisation for better global health can be realised worldwide.
ICH's mission is to achieve greater harmonisation to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner.
During the Information Day, an update will be given both on status of active topics, new topics and ICH reforms regarding transparency, membership, governance and future funding.

Key Topics

- Recent developments within ICH, e.g. increased transparency, revised ICH Procedures and MedDRA governance and development
- Future of ICH, e.g. new topics, membership, governance and funding
- Update on active electronic and pharmacovigilance topics
- Update on evolving safety and quality topics

Objectives

At the conclusion of this Information Day, participants should be able to:
- Share knowledge about revised ICH Procedures and MedDRA development
- Understand the background for ICH reforms
- Discuss the status of active electronic and pharmacovigilance topics
- Discuss the status of evolving safety and quality topics

Who Will Attend

Professionals in regulatory affairs, regulatory submissions, pharmacovigilance, toxicology and quality assurance / quality control from industry and drug regulatory authorities, who want to be updated on the future of ICH and the status of active ICH topics.

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits and certificates are available.

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FRIDAY | 28 MARCH 2014

08:00 REGISTRATION

09:00 Session 1

RECENT DEVELOPMENTS OF ICH

Session Chairperson:
Sarah Adam, ICH Manager, ICH Secretariat, Switzerland

In 2012, building on 20 years of successful collaboration towards achieving greater international harmonisation for pharmaceutical products registration, the six official ICH parties have agreed on new principles of governance which better define the role of the regulator and industry parties within ICH, and also confirmed their commitment to strengthen ICH's global outreach.
In June 2013, these new principles were integrated into the ICH Procedures document and applied to the ICH harmonisation process. At the same time, the Steering Committee agreed measures aimed at further increased transparency such as the publication on the ICH public website of: the entire ICH Procedures document, the working plans for each ongoing technical topic and the decisions taken at the SC meetings.
This session aims to present the main changes in the revised ICH Procedures and also to provide you an overview of recent progress made towards ICH increased transparency. Information will also be given on recent development and governance of MedDRA.

Revised ICH Procedures to clarify Roles of Regulators / Industry
Sarah Adam, ICH Manager, ICH Secretariat, Switzerland

Increased Transparency of ICH Activities
Cornelia Meyer, ICH Coordinator, ICH Secretariat, Switzerland

MedDRA Governance and Development
Claudia Lehmann, Head Global Pharmacovigilance Operations, Boehringer Ingelheim Pharma, Germany

10:30 COFFEE BREAK

11:00 Session 2

FUTURE OF ICH

Session Chairperson:
Lenita Lindstroem-Gommers, EU Member ICH Steering Committee, Senior Policy Officer, European Commission / DG SANCO, EU

The session will give the background to initiatives from the EU to reform ICH and from EFPIA to develop new ICH topics. An update on what has been agreed so far and information on ongoing discussions on the future of ICH will be also given.

New ICH Topics
Paer Tellner, EFPIA, Belgium

ICH Reforms, Discussions regarding Membership and Governance
Lenita Lindstroem-Gommers, EU Member ICH Steering Committee, Senior Policy Officer, European Commission / DG SANCO, EU

Principles for Funding of ICH in the Future
Paer Tellner, EFPIA, Belgium

12:30 LUNCH

14:00 Session 3

ELECTRONIC AND PHARMACOVIGILANCE TOPICS

Session Chairperson:
Joerg Schnitzler, Head of Regulatory Affairs Operations, Boehringer Ingelheim, Germany

Growing needs for efficient handling of regulatory information require innovative electronic standards. Ten years after the successful introduction of eCTD v3.2.2 the M8 Expert Working Group (EWG) is currently working on the next major version of eCTD introducing v4.0 as a versatile exchange standard for electronic regulated product submissions. The M2 EWG provides in this context the framework for the development of new electronic ICH standards involving Standards Developing Organisations (SDOs). In parallel M2 currently evaluates, under its original mandate, future document standards for regulatory information addressing requirements for more structured information. Latest Pharmacovigilance activities include the preparation of a Q&A regarding the implementation and technical maintenance of the "Periodic Benefit / Risk Evaluation Report", which the E2C(R2) Implementation Working Group (IWG) worked on after successfully reaching Step 4 in May 2013.

M2 Electronic Standards for the Transfer of Regulatory Information
Stan van Belkum, Programme Manager, Medicines Evaluation Board, The Netherlands

M8 The Electronic Common Technical Document
Joerg Schnitzler, Head of Regulatory Affairs Operations, Boehringer Ingelheim, Germany

E2C (R2) Periodic Benefit / Risk Evaluation Report
Valerie Simmons, EU QPPV, Executive, Global Product Safety, Lilly, UK

15:30 COFFEE BREAK

16:00 Session 4

SAFETY AND QUALITY

Session Chairperson:
Steven Spanhaak, Director / Senior Scientific Advisor, Tox Path Management, Janssen, Belgium

This session aims to provide information regarding a number of (evolving) ICH Safety and Quality guidelines. The presented spectrum ranges from more specific Safety (ICH S10, photosafety) and Quality (ICH Q7, GMP) topics to a clear area of overlap between Safety and Quality: impurity management (ICH Q3D, elemental impurities and ICH M7, DNA reactive impurities).
Especially in the area of impurity management the last decade has provided a series of guidance documents to industry ranging from mutagenic impurities to metal catalysts. Although it is obvious that the common goal is to guarantee patient safety and quality of the products, the ever increasing challenge for industry and regulators is to strike a balance between perceived risks, (technical) capabilities and various guidelines.

S10 Photosafety Evaluation
Ulla Waendel Liminga, Scientific Director, Medical Products Agency, Sweden

M7 Assessment and Control of DNA Reactive Impurities in Pharmaceuticals
Steven Spanhaak, Director / Senior Scientific Advisor, Tox Path Management, Janssen, Belgium

Q3D Elemental Impurities
Mike James, GlaxoSmithKline, UK

Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients
Stephan Roenninger, Director External Affairs Europe, International Quality, Amgen (Europe) GmbH, Switzerland

17:30 END OF INFORMATION DAY

REGISTRATION FORM

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ID #14114

FEES

	Member	Non-Member
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Academia/Charitable/Government/Non-profit (Full-time)*	€ 375.00 ❑	€ 505.00 ❑
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TOTAL AMOUNT DUE: _____

*All fees will be subject to the Austrian VAT at 20%

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Payment is due 30 days after registration and must be paid in full by commencement of the event.

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Date	Signature

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- Industry (Member/Non-member) € 200.00
- Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

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The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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