

## **ICH**

The term ICH is international conference harmonisation of technical requirements for registration of pharmaceuticals for human use.

The name of ICH has now become more associated with the process of harmonisation, than the actual conferences. The ICH project is unique and since 1991 it has brought together by Drug Regulatory Authorities and experts from the pharmaceutical industry in USA, European union and Japan to develop agreement on core documentation, technical requirements and dossier for registration of new drugs.

The vast majority of new drugs and medicines are developed in Western Europe, Japan and USA and therefore when ICH was established, it was agreed that its scope would be confined to registration in these three regions.

The ICH was born in 1990 .The first ICH was held from 5-7 November 1991 at Brussels.

### **MEMBERS OF ICH:**

1) ICH is a joint initiative involving both regulations and industry as equal partners. There are six parties directly involved representing the regulation bodies and the research based industry associations in each region. The parties involved from the European Union, Japan and USA are:

- i) European Commission
- ii) European Federation of Pharmaceutical Industries Associations.
- iii) Ministry of Health and Welfare
- iv) Japan Pharmaceutical Manufacturers Association
- v) US Food and Drug Administration
- vi) Pharmaceutical Research and Manufacturers of America

Each of the six co-sponsors has two seats on the ICH steering committee which oversees the harmonization activities.

2) There are three observers:

- i) World Health Organization
- ii) European Free Trade Area (EFTA) represented at ICH by Switzerland and Canada.
- iii) EFTA represented at ICH by the drugs Directorate Health Canada.

Each of the observer parties has a seat on the ICH steering committee.

3)The International Federation of Pharmaceutical Manufacturers Association(IFPMA) which is a federation of member associations representing the research based pharmaceutical industry and other manufacturers of prescription medicines in 56 countries has been closely associated IFPMA has two seats on the ICH steering committee as non-voting members.

4) For smooth running of ICH, each of six co-sponsors designate an ICH coordinator to act as the main contact point with the ICH secretariat and ensure that ICH documents are distributed to the appropriate persons within the area of their responsibilities.

5)Each party has also established a contact network of experts with in their own organization (or region) in order to ensure that they reflect the views and policies of the co sponsor they represent the way in which this network operates differs according to administrative structure of the party concerned.

### **SCHEDULE OF MEETINGS:**

ICH meeting have been held every alternate year .These have takenplace in 1991,1993,1995,1997 and the last one was held in November 2000 at San Diego in USA.

### **ACTIVITIES OF ICH:**

*The first phase of ICH (1991-1997):-*

The fourth international conference on Harmonisation, Brussels, 16-18 July 1997, marked the completion of first phase of activities.

*The development of Guidelines:-*

# Proceedings Of The Fifth International Conference On Harmonisation San Diego 2000 Ich 5

**John P. Griffin, John Posner, Geoffrey R.  
Barker**



## **Proceedings Of The Fifth International Conference On Harmonisation San Diego 2000 Ich 5:**

**The Textbook of Pharmaceutical Medicine** John P. Griffin, John Posner, Geoffrey R. Barker, 2013-03-29 The Textbook of Pharmaceutical Medicine is the standard reference for everyone working and learning in pharmaceutical medicine It is a comprehensive resource covering the processes and practices by which medicines are developed tested and approved and the recognised text for the Diploma in Pharmaceutical Medicine from the Faculty of Pharmaceutical Medicine This fully revised Seventh Edition which includes two new Editors encompasses current developments within pharmaceutical medicine with new chapters on biological therapeutics pharmacovigilance vaccines drugs for cancer drug development in paediatrics and neonatology the clinical trials directive life cycle management of medicines counterfeit medicines and medical marketing Also included for easy reference and referred to throughout the text are the Declaration of Helsinki Guidelines and Documentation for Implementation of Clinical Trials relevant European Directives and the Syllabus for Pharmaceutical Medicine Written by an international team of leading academics medical directors and lawyers The Textbook of Pharmaceutical Medicine Seventh Edition meets the needs of both those working in pharmaceutical medicine and preparing for the Diploma in Pharmaceutical Medicine The text breaks down into three core sections Part I Research and Development Part II Regulation Part III Healthcare marketplace View Table of Contents in detail **International Cooperation, Convergence and Harmonization of Pharmaceutical Regulations** Pierre-Louis Lezot, 2013-12-05 International Cooperation Convergence and Harmonization of Pharmaceutical Regulations A Global Perspective provides the current status of the complex and broad phenomenon of cooperation convergence and harmonization in the pharmaceutical sector Part I thoroughly evaluates its added value and its critical parameters and influencing factors Part II in order to recommend actions and measures to support the next steps for cooperation convergence and harmonization Part III All of these recommendations in the book support the establishment of a better coordinated global pharmaceutical system which represents the best realistic alternative to fulfill the objective to establish a global coalition of regulators and to respond to an increased demand to further cooperation in the pharmaceutical sector This proposed framework which leverages all of the ongoing positive cooperation initiatives and uses as foundations all of the numerous harmonization projects developed over the years presents advantages for all stakeholders and would definitively have significant added value to the promotion and protection of global public health The status of all major worldwide harmonization and cooperation initiatives at bilateral regional and global levels The value of cooperation in the pharmaceutical sector and the driving factors behind harmonization The proposition of a structure for the global pharmaceutical system and timely recommendations for enhancing international cooperation as well as further discussion and policy changes in this area **Anaesthesia, Pain, Intensive Care and Emergency Medicine — A.P.I.C.E.** A. Gullo, 2012-12-06 Basic research progress in technology and informatics and the success of clinical pharmacology are the fundamental bases of this interesting field of medicine

Nowadays critical care medicine is no longer for experts only but it is a field in which researchers and clinicians nurses and technical staff work in an interdisciplinary way each offering their own skills The volume is divided in six sections devoted to critical care key issues to lung diseases to trauma to acid base equilibrium to perioperative medicine and to obstetrics

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