

## **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:-*

# Second International Conference On Harmonisation Orlando 1993

**KJ Lindholm-Leary**



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