Purpose

The Regulators Forum was originally created as a safe harbor for discussion and promotion of harmonization among regulatory authorities and Regional Harmonization Initiatives (RHIs), hereafter referred to as "members". The Regulators Forum has evolved to the point of needing a more formal structure and the following Terms of Reference were created to provide for future activities.

The purpose of the International Pharmaceutical Regulators Forum (IPRF) is to create an environment for members to exchange of information on issues of mutual concern and regulatory cooperation. This dedicated venue will maximize potential efficiencies in addressing the increasingly complex global context of medicines regulation, will facilitate the implementation of ICH and other internationally harmonized technical guidelines for pharmaceuticals for human use and will contribute to the coordination of a range of international efforts related to regulation of medicinal products for human use.

Members

The following organisations are participating in the meetings and activities of the IPRF.

- Therapeutic Goods Administration, Australia
- Brazilian Health Surveillance Agency, Brazil
- Health Products and Food Branch, Health Canada, Canada
- China Food and Drug Administration, China
- European Medicines Agency and DG SANCO, EU
- Ministry of Health, Labour and Welfare and Pharmaceuticals and Medical Devices Agency, Japan
- Ministry of Food and Drug Safety, Republic of Korea
- Roszdravnadzor, Russia
- Health Sciences Authority, Singapore
- Swissmedic, Switzerland
- Food and Drug Administration, USA

Regional Harmonization Initiatives

- APEC (Asia-Pacific Economic Cooperation)
- ASEAN (The Association of Southeast Asian Nations)
- EAC (East African Community)
- GCC (Cooperation Council for the Arab States of the Gulf)
- PANDRH (Pan American Network for Drug Regulatory Harmonization)
- SADC (Southern African Development Community)

World Health Organization

- WHO

IPRF Working Groups

One of the objectives of the IPRF is to identify the need for harmonization or regulatory convergence, as well as for regulatory cooperation, including work-sharing, in specific areas. Several working groups are already in operation:

Biosimilars Working Group

Cell Therapy Working Group

Gene Therapy Working Group

ICH E6 (Good Clinical Practices) Working Group

Public information from the IPRF Working Groups

The Outcome of Discussions by International Regulatory Experts in the Discussion Group on ICH E6 guideline

Posted by admin on October 17, 2014

ICH E6 (GCP) Working Group
General Principles for the Education and Training of GCP Inspectors

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