IGDRP Quality Working Group (WG)

13th May, 2015
EDQM
Strasbourg, FRANCE
The IGDRP

Working groups have been identified. These are:

• A Biowaivers working group (2013) - Bioequivalence Working Group (2016)
• WGs have mandates and workplan
The Quality WG - membership

• Agencia Nacional de Vigilancia Sanitaria (ANVISA)
• European Directorate for the Quality of Medicines and Healthcare (EDQM)
• European Union:
  – European Commission - DG SANTE (EC)
  – Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)
• Federal Commission for the Protection against Sanitary Risk (COFEPRIS)
• Health Canada
• Health Sciences Authority (HSA)
• Ministry of Food and Drug Safety (MFDS)
• Ministry of Health, Labour and Welfare (MHLW)
• Medicines Control Council (MCC)
• Swissmedic
• Taiwan Food and Drug Administration (TFDA)
• Therapeutic Goods Administration (TGA)
• World Health Organization (WHO)
Quality Working Group

Chair and co-chair – TGA and WHO, respectively

Objective: Establish a framework and mechanisms for information sharing and work sharing of Quality-related information. This is with a view to greater collaboration and potentially regulatory convergence in the assessment of ASMFs/DMFs and applications for generic drug products, taking into account established international initiatives and developments under progress.
Quality Working Group

A number of projects have been identified and started.

- Development of an ASMF/DMF lexicon of quality terms. Completed
- Agreement on the common ASMF/DMF information fields that should be recorded at the time of submission. Completed
- Agreement of a ASMF/DMF common quality assessment report template. Completed
- Consideration of the criteria for when a separate ASMF/DMF should be provided. e.g different polymorph, salt...
Quality Working Group

• Discussion and investigating the possibility of work/information sharing between IGDRP members regarding ASMF/DMFs.
  – Database
  – Secure IT platform

• Stakeholder engagement strategies
Quality Working Group

• Documents from the various projects undertaken by the WG are published on the IGDRP website.

• These are model documents and information. They are not mandatory for adoption by member organisations, but members are committed to their implementation when possible.
For further information

Contact

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The Therapeutic Goods Administration is currently serving as the secretariat until the end of 2016. For any enquiries, please use the form below.

Your name *

Your email address *

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