

IGDRP Quality Working Group (WG)

13th May, 2015

EDQM

Strasbourg, FRANCE

The IGDRP

Working groups have been identified. These are:

- An ASMF/DMF Working Group (2013) – Quality Working Group (2016)
- 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.

- A survey among member of their respective ASMF/DMF procedures.
The result of the survey was published in J. Pharm. Pharm. Sci., 19(2) 290-300, 2016.
<https://ejournals.library.ualberta.ca/index.php/JPPS/issue/view/1887>
- 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...

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- Discussion and investigating the possibility of work/information sharing between IGDRP members regarding ASMF/DMFs.
 - Database
 - Secure IT platform
- Stakeholder engagement strategies

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- 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

by IGDRP - 4 August 2015 - 9:28am

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