HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

General Regulatory Update

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QP Forum – May 13th 2025

Current Regulatory Topics (Interested Parties)

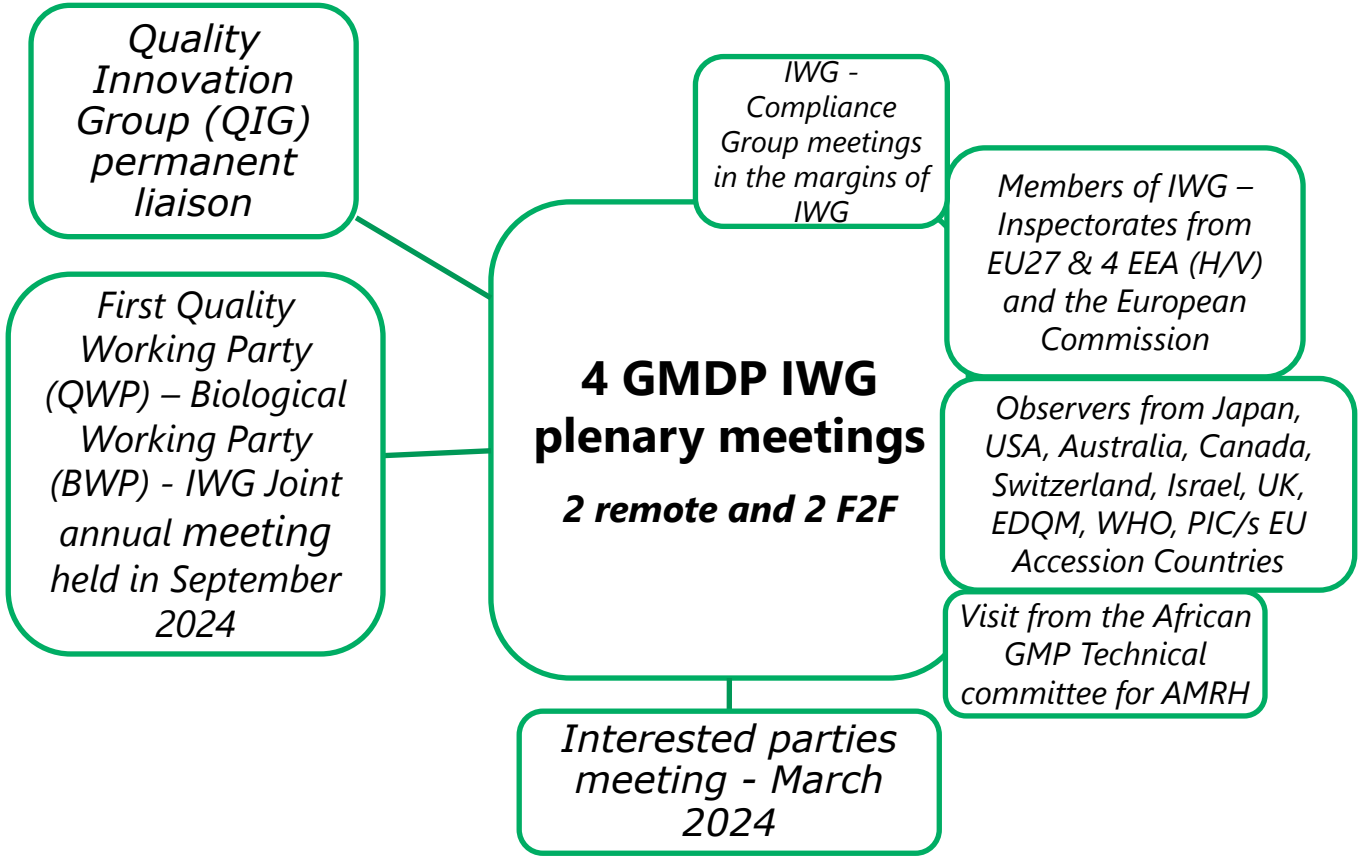
Annual Meeting of Inspectors Working Group with Interested Parties

Interested Parties include representative bodies for:

- Human medicines
- Veterinary medicines
- Qualified Persons

Meeting took place during March 2025

GMDP IWG Meetings in 2024



Courtesy of EMA

MRAs

- **Expansion of scope to include veterinary medicines in the operational scope of the EU – US Mutual Recognition Agreement**
  - Work continued on the inclusion of veterinary medicines in the operational scope with 3 authorities currently pending
  - The current list of recognised authorities for the veterinary scope is published by the European Commission
  - Batch testing waiving would only start to apply when all EU veterinary authorities have been recognised by the US
- **Consideration of inclusion of vaccines and plasma derived products (PDP)**
- Work on-going (EU inspectors observed 2 FDA PDP inspections in the EU in 2024)

Courtesy of EMA

GMP certificate

- **Automatic Extension**
  - Employed during Covid-19 pandemic
  - Back to normal scheduling and conduct of on-site inspections
  - Blanket approach no longer required
  - Automatic extension finished in December 2024
  - Case by case assessment when required for certain sites
  - On site inspection is the primary means of verification of compliance
  - Other tools : Distant assessments, Hybrid inspections, Reliance on other authorities

GMP Guidance

Annex 11 and **Chapter 4** drafting group in progress with expected guidelines to be published for consultation in 2025

Annexes 4 and **5** in progress

Annex 19

IWG adopted revision on reference and retention samples for Parallel Distribution/Importation, currently for publication

Revisions of **Annexes 3, 6, 15** new drafting groups started

Started a *targeted revision* on the **Guideline on GMP for ATMPs** (to align with Annex 1 revision)

Formed the IWG **Drafting Group on Good Distribution Practice**

Q&As & Guidance

- Q&A on Annex 1
- Q&A on Suspicious offers for Wholesalers and Brokers
- Q&A on Annex 14 concerning APIs derived from human plasma
- Q&A on Annex 16 concerning traceability of the supply chain for QP batch release.
- Distant Assessment Guidance

Courtesy of EMA

Veterinary Implementing Regulations

- **COMMISSION IMPLEMENTING REGULATION (EU) …/… of XXX laying down good manufacturing practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council**
- https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13994-Veterinary-medicines-rules-on-good-manufacturing-practices_en

- **COMMISSION IMPLEMENTING REGULATION (EU) …/… of XXX laying down good manufacturing practice for active substances used as starting materials in veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council**
- https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14388-Veterinary-medicines-rules-on-good-manufacturing-practices-for-active-substances-used-as-starting-materials_en

- Short public consultation 22nd January – 19th February 2025
- Text finalised and now awaiting translation / publication in the Official Journal

Veterinary Implementing Regulations

- Different structure to the current GMP Guide
- Reflect specific GMP requirements
- Legal text (uses **shall** instead of **should**)
- Largely aligned with GMP requirements for human medicines (except vet specific aspects)
- Implementing Regulations will be changed as needed

Revision of Pharma Legislation concerning Human Medicines

New Directive - (Directive 2001/83/EC to be repealed)

New Regulation – (Regulation No 726/2004 to be repealed)

Some topics

- Decentralised Manufacturing
- Aspects related to QP
- Financial importation
- Inspections – (proposal for EMA inspectorate)

Proposal for GMP / GDP requirements within Implementing Acts

Compilation of Union Procedures & EudraGMDP

Compilation of Union Procedures on Inspections and Exchange of Information (CoUP) restructured from one document into separate documents for every procedure/template

EudraGMDP database

Restructuring to facilitate access as well as review and revision of the individual documents

Several minor changes have been implemented in EudraGMDP modules

Courtesy of EMA

EudraGMDP – support to Industry Stakeholders

EMA communication channels

- **IT issues/technical questions** on **EudraGMDP** should be raised via ServiceNow, the new EMA Service Desk platform

- Issues related to the data in **OMS** should be raised via SPOR

- **Regulatory questions** via AskEMA

HPRA communication channels

- Queries relating to content of documents issued by the HPRA on EudraGMDP (e.g. MIAs, GMP Certs, ASR, WDA, GDP certs) should be addressed to compliance@hpra.ie

Interested Parties Topics

Revision of ICH Q9 (R1)

- Some consequential targeted revisions of text in GMP Guide

  Chapter 1 - Pharmaceutical Quality System

  Annex 15 - Qualification and Validation

Revision of Part IV GMP for ATMP

- Concept Paper published
- Consultation Period 8th May – 8th July 2025

- Focus on alignment with revised Annex 1 while maintaining flexible approach
  - Use of ICHQ9 & ICHQ10
  - Concept of Contamination Control Strategy
  - New technologies for manufacture of ATMPs (automation, single use systems, rapid micro)
  - Qualification and management of cleanrooms
  - Guidance on use of RABS & Isolators whilst still facilitating use of BSCs

International collaboration

Support for candidate countries for EU Accession

Support for the development of the African Medicines Agency

Close collaboration with PIC/s on guidelines and inspector training

Observers from Albania, Bosnia and Herzegovina, Georgia, Kosovo, Moldova, Montenegro, North Macedonia, Serbia, Turkiye and Ukraine attended GMDP IWG meetings throughout 2024

Support with GMP Training

Delegation of the African Medicines Regulatory Harmonisation Initiative GMP Technical Committee (AMRH GMP TC) observed part of the June 2024 plenary meeting

EMA Liaison to the AMRH GMP TC

Continued work under the established international collaboration schemes for API Inspection programme and the ICMRA Hybrid Inspection Pilot

Courtesy of EMA

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Thank You

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