

# General Regulatory Update

**Catherine Neary**

**GMP Operations Manager**

---

**QP Forum – 12 May 2026**

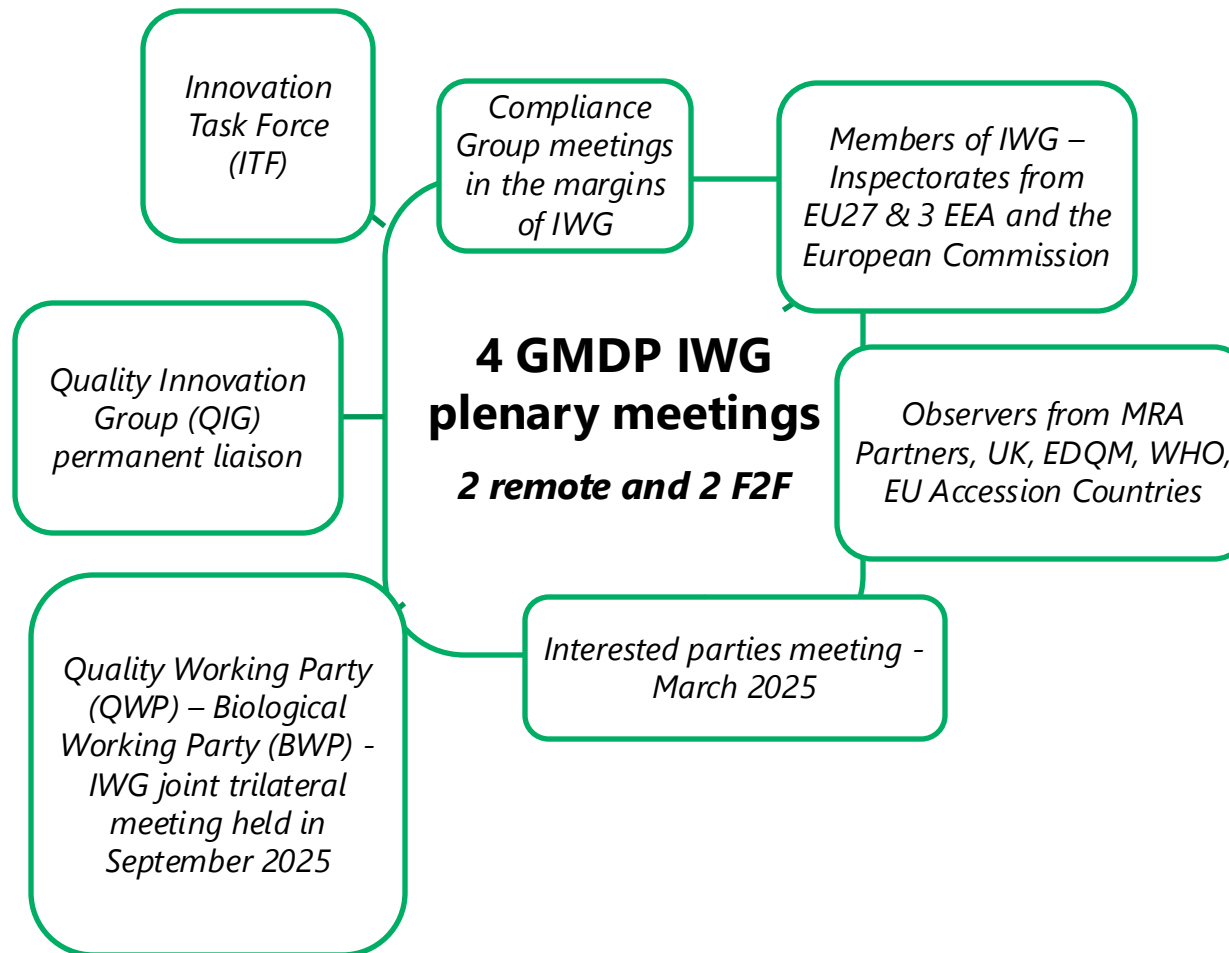


## General Regulatory Update

- ❖ GMDP IWG
- ❖ EU-US MRA
- ❖ GMP Guidance
- ❖ Veterinary Implementing Regulations
- ❖ Revision of Pharma Legislation concerning Human Medicines
- ❖ Compilation of Union Procedures on inspections and exchange of information (CoUP)
- ❖ Revision of Part IV Guidelines on GMP specific to ATMPs
- ❖ Revision to Chapter 1 of EU GMP Guide to reflect changes introduced in ICH Q9(R1) on Quality Risk Management (Kevin O'Donnell)



## GMDP IWG Meetings in 2025





## EU-US MRA

➤ **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 2 authorities currently pending
- The current list of recognised authorities for the veterinary scope is published by the European Commission
- Batch testing waiver will apply ONLY when all 27 MSs have been recognised by FDA for veterinary medicines inspections

➤ **Consideration of inclusion of vaccines and plasma derived products (PDP)**

Work on-going

➤ **Voluntary Reliance on FDA’s inspections conducted in third countries** - implemented as of 01 October 2025



# GMP Guidance

## Chapter 1

Draft guideline published on 03 September 2025 & consultation concluded on 03 December 2025

## Chapter 4 & Annex 11

Draft guidelines published on 10 July 2025 & consultation concluded on 07 October 2025

## Annex 3

Concept paper developed and adopted by GMDP IWG in November 2025

## Annex 4 & Annex 5

Updates paused during 2025 pending publication of Implementing Acts on GMP for veterinary medicines and veterinary active substances

## Annex 6

Concept paper developed and adopted by the GMDP IWG in November 2025

## Annex 14

Drafting group formed to begin work on preparing a concept paper

## Annex 15

Concept paper developed and adopted by GMDP IWG in November 2025

## Annex 19

Final guideline adopted by GMDP IWG in June 2025



# GMP Guidance

## Annex 22

In the context of revision to Annex 11, GMDP IWG agreed to create a separate Annex on Artificial Intelligence.

Draft guideline published on 10 July 2025 & consultation concluded on 07 October 2025.

## Guideline on GMP for ATMPs (Part IV)

Concept paper published on 08 May 2025 & consultation concluded on 08 July 2025

## Good Distribution Practice

Working group continued to meet in 2025 to work on topics identified in work programme

## Q&As

- Q&As on auditing for API manufacturers and the QP Declaration, revised in April 2025
- Update to Q&As on Annex 8: Sampling of starting and packaging materials: Glycerol and other excipients at high-risk of DEG/EG contamination, revised in January 2025
- Q&A on “certification” by a Qualified Person (QP), published in December 2025



# GMP Guidance

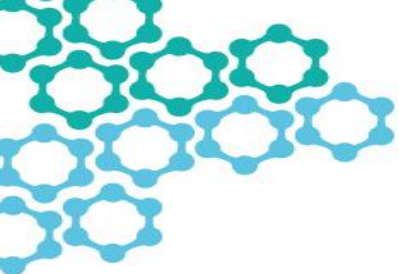
## Q&As

**Work is continuing on the following supplementary guidance:**

- Q&A on Decentralised Manufacturing
- Q&A on 3D Printing
- Q&A on Chapter 5

The GMDP IWG endorsed the **Guideline on Good Agricultural and Collection Practice Guideline (GACP) for starting materials of herbal origin** developed by the HMPC

The GMDP IWG endorsed **Q&A's on skip testing** developed by the Quality Working Party



## Veterinary Implementing Regulations

Volume 4 of "The rules governing medicinal products in the European Union" contains guidance for the interpretation of the principles and guidelines of good manufacturing practices for medicinal products for human and veterinary use laid down in Commission Directives 91/356/EEC, as amended by Directive 2003/94/EC, and 91/412/EEC respectively.

**Until 15 July 2026** the guidelines on **Good Manufacturing Practice of Volume 4** apply to **both human and veterinary** medicinal products.

**From 16 July 2026 onwards:**

❖ **Commission Implementing Regulation (EU) 2025/2091 of 17 October 2025 laying down good manufacturing practice for veterinary medicinal products in accordance with Regulation (EU) 2019/6 of the European Parliament and of the Council**

&

❖ **Commission Implementing Regulation (EU) 2025/2154 of 17 October 2025 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 apply for veterinary medicinal products**

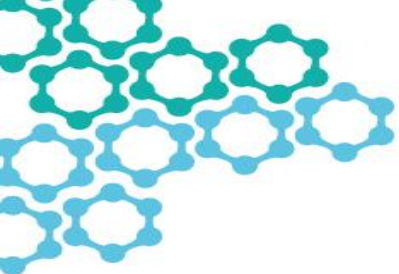


## Veterinary Implementing Regulations

- Despite having different legal bases, the **GMP requirements for veterinary medicinal products and their active substances will remain aligned with those for medicinal products for human use and their active substances.**
- 'Tables of correspondence' (ToC) provide an overview of the relations between the two Commission Implementing Regulations and GMP guidelines applicable to medicinal products for human and veterinary use, until 15/07/2026

[https://health.ec.europa.eu/document/download/c44db4fb-5706-4807-a038-672bb74f3478\\_en?filename=mp\\_gmp\\_vetmedproducts\\_correspondence\\_en.pdf](https://health.ec.europa.eu/document/download/c44db4fb-5706-4807-a038-672bb74f3478_en?filename=mp_gmp_vetmedproducts_correspondence_en.pdf)

[https://health.ec.europa.eu/document/download/2b77b613-456b-43e7-a63c-123720cf75a5\\_en?filename=mp\\_gmp\\_active-substances\\_vetmedproducts\\_correspondence\\_en.pdf](https://health.ec.europa.eu/document/download/2b77b613-456b-43e7-a63c-123720cf75a5_en?filename=mp_gmp_active-substances_vetmedproducts_correspondence_en.pdf)

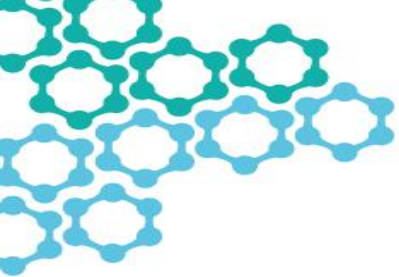


## Revision of Pharma Legislation concerning Human Medicines

- ❑ **New Directive** - (Directive 2001/83/EC to be repealed)
- ❑ **New Regulation** – (Regulation No 726/2004 to be repealed)

### Timelines

- ❑ December 2025: Political agreement on new pharmaceutical legislation
- ❑ 2026: Adopted acts of the new pharmaceutical legislation enter into force
- ❑ 2026-2028: Transition phase
  - EU Member States update their national laws to reflect the new rules
  - European Commission adopts implementing and delegated acts to help implement the new rules
  - EMA and national competent authorities develop implementation guidance and adapt their procedures and IT systems
- ❑ 2028 - New pharmaceutical legislation becomes applicable



## Compilation of Union Procedures on inspections and exchange of information (CoUP)

**August 2024 - CoUP was restructured** from one document into separate documents for every procedure/template

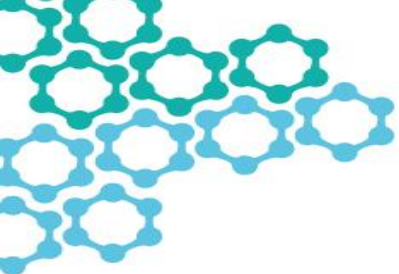
### 2025/2026 updates:

- **Management and classification of reports of suspected quality defects in medicinal products and risk based decision-making** (*adoption 20 April 2026; entry into force May 2026*)

*(Reason for revision: Addition of timelines for the different type of quality defects and some changes in relation to the revision of ICH Q9(R1). Appendix 1 of the Rapid Alert procedure has been added to this procedure)*

- **Co-ordinating GMP inspections for centrally authorised products** (*adoption May 2023; entry into force 01 January 2025*)

*(Reason for revision: Modifications were introduced as a result of the entry into application of the financial Regulation (EU) 2024/568 and associated working arrangements on fees and charges payable to the European Medicines Agency applicable from 1 January 2025)*



## Revision of Part IV Guidelines on GMP specific to ATMPs

- Concept Paper published on 08 May 2025
- Consultation concluded on 08 July 2025
- Proposed date for release of draft guideline – September 2026
- Deadline for stakeholders comments - December 2026
- Adoption in GMDP IWG - March 2027

Focus on alignment with revised Annex 1 while maintaining flexible approach for the production of ATMPs

- 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