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Quality and Safety of Medicines Department

Annual report of the Good Manufacturing and Distribution Practice Inspectors Working Group 2025

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

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Introduction

This document is the annual report of the GMP/GDP Inspectors Working Group (GMP/GDP IWG) for the year 2025. This group was established at EMA in 1996.

The GMP/GDP IWG provides input and recommendations on all matters relating directly or indirectly to Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).

The GMP/GDP IWG focuses on harmonisation and co-ordination of GMP and GDP related activities at EU level and maintains close co-operation with the European Commission and with international partner authorities. The group's role and activities are described in more detail in its mandate available here; Good Manufacturing Practice (GMP)/Distribution Practice (GDP) Inspectors Working Group | European Medicines Agency (EMA) (europa.eu) which was last revised in 2024.

This annual report is set out in line with the format and objectives of the 3-year work plan.

Meetings

The GMP/GDP IWG meetings took place on:

- 11 – 13 March 2025, combined with a Meeting with Interested Parties on 13 March (WebEx meeting);
- 3-5 June 2025 (In Person Meeting);
- 23 – 25 September 2025 (WebEx meeting);
- 25 – 27 November 2025 (In Person Meeting).

The Compliance Group, managing the Joint Audit Programme (JAP) on behalf of HMA, also met on four occasions in 2025 in the margins of the above-mentioned plenary meetings. The GMDP IWG met with the QWP and the BWP on 29th September 2025 for a joint trilateral meeting (WebEx meeting).

Drafting group meetings for ongoing topics were held by teleconference or through other virtual meeting technology.

GMP and GDP inspections in 2025

2025 marked the full return to normal operations for GMP and GDP inspections within the EEA and for third countries following the end of the Covid-19 public health emergency.

Mutual recognition agreements (MRAs) and other agreements on GMP

MRA General

MRA related work was maintained in 2025.

MRA with USA

Work continued on the inclusion of veterinary medicines in the operational scope of the EU – US Mutual Recognition Agreement. The current list of recognised authorities for the veterinary scope is published by the European Commission.

The GMP/GDP IWG continued to provide the forum to discuss and clarify the technical and practical aspects for the implementation and maintenance of the MRA. The projects concerned amongst other, work towards expansion of the MRA to vaccines and plasma derived products and reliance on FDA's inspections conducted in third countries. The latter provision of the MRA was implemented on 1 October 2025.

A representative from US FDA attended all GMDP IWG meetings throughout 2025.

MRA with Japan

There were no changes to the existing MRA with Japan throughout 2025.

A representative from PMDA attended March, June and November 2025 GMDP IWG meetings.

MRA with Canada (CETA)

No changes were made to the agreement with Canada during 2025.

A representative from Health Canada attended all GMDP IWG meetings in 2025.

MRA with Switzerland

No changes were made to the MRA with Switzerland during 2025.

A representative from Swissmedic attended all GMDP IWG meetings throughout 2025.

MRA with Australia

There were no changes made to the existing MRA with Australia throughout 2025.
Representatives from Australia attended all GMDP IWG meetings throughout 2025.

MRA with New Zealand

There were no changes to the existing MRA with New Zealand throughout 2025.

ACAA with Israel

There were no changes to the existing ACAA co-operation with Israel in 2025.

A representative from the Ministry of Health attended the March and June 2025 GMP/GDP IWG meetings.

Support for EU Accession Countries

Observers from Albania, Bosnia and Herzegovina, Georgia, Kosovo, Moldova, Montenegro, North Macedonia, Serbia, Turkiye and Ukraine attended GMDP IWG meetings throughout 2025 under a programme of support of EU candidate countries including through a new cycle of the Instrument for Pre-Accession Assistance.

Other international collaborations on GMP

EDQM attended all four GMP/GDP IWG meetings in 2025 as an observer and informed the GMDP IWG during the year on a number of topics of common interest including the progress of sampling and testing programmes, the proceedings of the annual OMCL meeting, the EDQM reinspection programme and the CEP Steering Committee.

WHO and PIC/S observers also attended the GMDP IWG meetings throughout 2025.

The United Kingdom attended all four GMP/GDP IWG meetings in 2025 as an observer.

Harmonisation topics

Joint Audit Programme (JAP)

During 2025 the Compliance Group (CG), a Sub-group of the GMDP IWG responsible for coordination of the JAP, met on five occasions. Throughout 2025 the Compliance Group monitored the implementation of open corrective and preventive actions (CAPAs), adopted final reports and closed some of the JAP audits.

The Compliance Group worked also closely with the EU4Health Joint Action 11 in the review of JAP procedures.
During 2025 9 JAP on-site audits were conducted.

Compilation of Union Procedures on Inspections and Exchange of Information

Work has continued throughout the year on revising the following Community procedures.

- Quality systems framework for Good Manufacturing Practice (GMP) inspectorates.
- Management and classification of reports of suspected quality defects in medicinal products and risk-based decision-making.
- Management of rapid alerts arising from quality defects risk assessment.
- Guideline on training and qualifications of good manufacturing practice (GMP) inspectors.
- A model for risk-based planning for inspections of pharmaceutical manufacturers.

Inspector Training

The following GMP Inspector training events were held in 2025 with support from EU4H.

Quality Risk Management training, 28-30 January 2025, EMA Amsterdam

How to inspect quality control laboratories, 3 June 2025, AGES Vienna

How to write inspection reports, 2-3 October 2025, AGES Vienna

Inspecting Data Integrity Training, 13-14 October 2025, EMA Amsterdam

ATMP for GMP inspectors' training course, 15-17 December 2025, FAMHP Brussels

Joint Inspector Training Visits in 2025.

The Joint Inspector Training Visits programme supported by the EU4H Joint Action has continued in 2025 with several observed inspections to support training and capacity development.

Expert Community

The GMDP IWG together with EMA established an expert community of GMP inspectors to facilitate interaction and exchange of information between inspectors across the EEA.

Good Manufacturing Practice (GMP) Guidelines

Chapter 1 of the Guidelines on Good Manufacturing Practice – Pharmaceutical Quality System

A draft Chapter 1 guideline was published by the European Commission for stakeholder consultation on 3rd September 2025 and the consultation concluded on 3rd December 2025. The GMDP IWG drafting continues to work on a final guideline taking into account the comments received from stakeholders.

Chapter 4 of the Guidelines on Good Manufacturing Practice – Documentation

A draft Chapter 4 guideline was published by the European Commission for stakeholder consultation on 10th July 2025 and the consultation concluded on 7th October 2025. The GMDP IWG drafting group continues to work on a final guideline taking into account the comments received from stakeholders.

Annex 3 – Manufacture of Radiopharmaceuticals

A drafting group has been formed to work on the update of Annex 3. A concept paper has been developed and adopted by the GMDP IWG in November 2025.

Annex 4 - Manufacture of Veterinary Medicinal Products other Than Immunological Veterinary Medicinal Products.

The GMDP IWG agreed to pause the drafting of an updated Annex 5 during 2025 pending publication of the Implementing Acts on GMP for veterinary medicines and veterinary active substances.

Annex 5 - Manufacture Of Immunological Veterinary Medicinal Products

The GMDPIWG agreed to pause the drafting of an updated Annex 5 during 2025 pending publication of the Implementing Acts on GMP for veterinary medicines and veterinary active substances.

Annex 6 – Manufacture of Medicinal Gases

A drafting group has been formed to work on the update of Annex 6. A concept paper has been developed and adopted by the GMDP IWG in November 2025.

Annex 11 – Validation of Computerised Systems

A draft Annex 11 guideline was published by the European Commission for stakeholder consultation on 10th July 2025 and the consultation concluded on 7th October 2025. The GMDP IWG drafting group continues to work on a final guideline taking into account the comments received from stakeholders.

Annex 14 – Manufacture of Plasma Derived Products

A drafting group has been formed to begin work on preparing a concept paper for the update of Annex 14.

Annex 15 – Qualification and Validation

A drafting group has been formed to work on the update of Annex 15. A concept paper has been developed and adopted by the GMDP IWG in November 2025.

Annex 19 – Reference and Retention Samples

A final guideline was adopted by the GMDP IWG in June 2025.

Annex 22 – Artificial Intelligence

During 2025, in the context of working on a revision to Annex 11, the GMDP IWG agreed to create a separate GMP Annex on Artificial Intelligence, referred to Annex 22.

The draft Annex 22 guideline was subsequently published by the European Commission for stakeholder consultation on 10th July 2025 and the consultation concluded on 7th October 2025. The GMDP IWG drafting continues to work on a final guideline taking into account the comments received from stakeholders.

GMP requirements for Advanced Therapy Medicinal Products (Part IV)

A concept paper was published by the European Medicines Agency for stakeholder consultation on 8th May 2025 and the consultation concluded on 8th July 2025. The drafting group is now working on a draft guideline taking into account the comments received from stakeholders.

Questions & Answers (Q&As)

Work was carried out on a number of Q&As, guidance documents and templates with a view to harmonising interpretation and expectations on various GMP topics. The following were published in 2025.

- Q&As on auditing for API manufacturers and the QP Declaration, revised in April 2025
- Updates to Q&A's 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

Work is continuing on the following supplementary guidance;

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

The GMDP IWG endorsed the Good Agricultural Practice Guideline developed by the HMPC.

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

Good Distribution Practice

The GDP working group continued to meet in 2025 to work on topics identified in their work programme. The group has also expanded to include further members and 1 observer. An in-person meeting was held on 20-21 March 2025 as a joint meeting with the EU4H11 subgroup working on harmonisation and implementation of JAP for GDP.

Inspections, Non-compliance, Quality Defects and Referrals

Nitrosamine contamination and Sartans Lessons Learnt

The IWG continued to be informed of the latest developments concerning nitrosamines as discussed by the Nitrosamines Implementation Oversight Group (NIOG).

1. EudraGMDP database

Several minor changes have been implemented in EudraGMDP modules in order to reflect network needs. The GMP/GDP IWG was consulted / informed on all proposed changes to the database and provided technical input and direction as needed, ensuring national systems were updated accordingly and that there was appropriate communication to stakeholders.

2. Collaboration with the European Commission

New legislative developments were monitored to assess and advise on the potential impact on GMP, GDP, inspections or inspection-related activities. In particular, attention was paid to developments related to the Revision of the Pharmaceutical Legislation for human and the Implementing Acts on GMP for veterinary medicinal products and active substances.

Liaison with other groups

The GMP/GDP IWG maintained dialogue and monitored developments involving external groups in areas of common interest. The aim was to communicate the work of the Group and to assess the impact of other groups' activities on GMP/GDP guidance, the Compilation of Union Procedures and other inspection-related activities.

Pharmaceutical Inspection Co-operation Scheme (PIC/s)

The GMP/GDP IWG continued the close collaboration with PIC/s on the harmonisation of guidance and procedures, training events and the (re) assessment of inspectorates as topics of strategic importance. The IWG and PIC/s liaisons have attended each other's meetings and working groups.

International Conference on Harmonisation for Registration Of Pharmaceuticals For Human Use (ICH)

The GMP/GDP IWG continued to be consulted on a number of topics in connection with the revisions and implementation of specific chapters and annexes and developing specific training material for ICH guidelines.

International Conference on Harmonisation for Registration of Veterinary Products (VICH)

The GMP/GDP IWG were consulted on the development of a GMP for veterinary active pharmaceutical ingredients.

Interested Parties

A Formal interested parties meeting was held in March 2025.

The following organisations participated in the meeting with Interested Parties in 2025: AESGP (Association of the European Self-Medication Industry), APIC (Active Pharmaceutical Ingredients Committee), EFPIA (European Federation of Pharmaceutical Industries and Associations), Medicines for Europe, EIPG (European Industrial Pharmacists Group), EQPA (European QP Association), Animal Health Europe (formerly IFAH-Europe), ISPE (International Society for Pharmaceutical Engineering), PDA (Parenteral Drug Association), GIRP (European Healthcare Distribution Association, EAEPC (European Association of Euro-Pharmaceutical Companies representing Europe's licensed parallel distribution industry),, *Vaccines Europe (VE), Plasma Protein Therapeutics Association (PPTA)*, *European Association for Logistics and Transportation in Healthcare (Ealth)*, *International Plasma and Fractionation Association (IPFA) (invited) and International Pharmaceutical Excipients Council – Europe (IPEC).*

Quality Working Party and Biologicals Working Party

There were regular exchanges on matters of joint interest with both groups during the year. In addition, the second annual joint trilateral meeting with IWG, BWP and QWP was held in September 2024.

Innovation Task Force (ITF)

The GMDP IWG agreed to take part in relevant ITF meetings in order to provide a platform for early interactions with companies in relation to new technologies and they reviewed a small number of case studies on innovative manufacturing technologies during 2025.

Quality Innovation Group

The GMDP IWG has been closely informed and consulted where necessary on the work of the Quality Innovation Group. The QIG representatives reported on the work of the group in 2025, including Listen and Learn Focus Group meeting on Personalised Medicines (8-9 April 2025), a breakout session to discuss a decision tree to guide pharmaceutical process models risk determination (18 November 2025) as well as the requests for scientific advice received from applicants as well as 1:1 meetings between the QIG and applicants. The IWG was also consulted by QIG in specific topics concerning inspections and GMP expectations.