Human Medicines Division

The 3-year work plan for the Inspectors Working Group

Name of Working Party:	**GMDP Inspectors Working Group**
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Work plan period: January 2026 – December 2028

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1. Introduction

This workplan sets out the routine activities of the GMDP IWG that contribute to the overall strategic objectives of the European Medicines Regulatory Network (EMRN). This GMDP IWG 3-year workplan is developed to complement the European Medicines Agencies Network Strategy (EMANS) 2028, "**Seizing Opportunities In A Changing Medicines Landscape**" strategic objectives and goals, which has a particular emphasis on supply chain integrity and resilience, product quality and the impact of new manufacturing technologies on the supply chain.

This workplan includes specific activities to achieve the overall strategic objective of Theme 5 to **"reinforce the oversight and protection of the supply chain and increase inspector capacity".**

In addition, the work of the GMDP IWG also may indirectly support the objectives of other thematic areas such as innovation and network capacity**.**

The work plan of the EMA Good Manufacturing and Distribution Practice Inspectors Working Group (GMDP IWG) is published for transparency and informational purposes. It reflects the planned activities and priority work items identified by the GMDP IWG at the time of publication.

The work plan shall be regularly reviewed and updated as necessary. Additional topics may be identified, and ongoing items may be adjusted, reprioritised, or expanded in response to regulatory developments, emerging public health needs, international collaboration activities or other considerations relevant to the mandate of the GMDP IWG.

Any new or revised work items will be reflected in this document or in the subsequent work plan. Such changes may be communicated through the appropriate EMA channels, where necessary.

2. Specific activities to deliver the strategic goals of EMANS 2028 Theme 5.

5.2.1 Ensure sufficient numbers of trained inspectors are continuously available to perform legal duties

- Develop and maintain the GMDP IWG training strategy, identifying priority areas for training and for collaboration with the MSs and international partners.
- Develop annual inspector training calendar according to IWG training strategy.

5.2.2 Use risk-based inspection planning, alternative inspection methodology and collaboration with international partners to better target oversight of the supply chain, including for key finished product and API manufacturers.

- Develop 3rd country inspection planning co-operation & co-ordination for all products (CAPs and NAPs).
- Update the CoUP to improve current risk-based approach to inspection planning.
- Promote use of reliance, hybrid inspection, distant Assessment for verification of GMP compliance

5.2.3 Strengthen monitoring and oversight of the supply chain to prevent entry of falsified human medicines in the supply chain.

- New guidance for wholesalers when performing risk assessment on the verification of authenticity of medicinal products at risk of falsifications.
- New/revised CoUP procedures on GDP aspects.

5.2.4 Keep good manufacturing practice (GMP) requirements updated in light of technological progress in manufacturing (e.g. with respect to digital, AI and other technological systems).

- Develop and publish updated guidance as needed, e.g Chapter 4, Annex 11 and Annex 22, maintenance and propose updates of IAs on GMP for veterinary medicines (from July 2026).
- Publish new Q&A's where needed, e.g., 3D printing.

5.2.5 Improve and inter-link information in current databases (e.g. EudraGMDP).

- Ensure all MS enter data in EudraGMDP (e.g. for human and veterinary products for GDP) as required by legislation.

3. GMP Requirements[1].

GMP Guide: Chapter 1 (Pharmaceutical Quality System)

Target date	Q4 2026
Comments	To provide the European Commission with a final text for the amended chapter in order to incorporate elements of ICH Q9(R1).

GMP Guide: Chapter 3 (Premises and Equipment)

Target date	Q4 2028
Comments	To provide the European Commission with a final text for the amended chapter following a review of the Chapter against current state of the art, and the revision will also take in consideration the impact on and potential need for a future update of the Veterinary GMP Implementing Acts. This review in parallel with the update of Chapter 5.

GMP Guide: Chapter 4 (Documentation)

Target date	Q4 2026
Comments	To provide the European Commission with a final text for the amended chapter in order to assure data integrity in the context of GMP. This would be in parallel with similar consideration of Annex 11 (Computerised Systems).

GMP Guide: Chapter 5 (Production)

Target date	Q4 2028
Comments	To provide the European Commission with a final text for the amended chapter following a review of the Chapter against current state of the art, and the revision will also take in consideration the impact on and potential need for a future update of the Veterinary GMP Implementing Acts. This review in parallel with the update of Chapter 3.

GMP Guide: Chapter 7 (Outsourced Activities)

Target date	Q4 2028
Comments	To provide the European Commission with a final text for the amended chapter following a review of the Chapter against current state of the art and to review and incorporate concepts found in already published guidance on outsourced activities.

[1] From 16/07/2026 onwards there will be separate implementing acts for GMP for veterinary medicines and therefore all updates indicated are for GMP for human medicines.

	The revision will also take in consideration the impact on and potential need for a future update of the Veterinary GMP Implementing Acts This review in parallel with the update of Chapter 9.

GMP Guide: Chapter 9 (Self-Inspection)

Target date	Q4 2028
Comments	To provide the European Commission with a final text for the amended chapter following a review of the Chapter against current state of the art and to review and incorporate concepts found in already published guidance on conducting audits. The revision will also take in consideration the impact on and potential need for a future update of the Veterinary GMP Implementing Acts. This review in parallel with the update of Chapter 7.

GMP Guide: Annex 3 Manufacture of Radiopharmaceuticals

Target date	Q4 2028
Comments	To provide the European Commission with a final text for an amended Annex 3 following a review and update of the Annex to reflect current state of the art.

GMP Guide: Annex 6 Manufacture of Medicinal Gases

Target date	Q4 2028
Comments	To provide the European Commission with a final text for an amended Annex 6 following a review and update of the Annex to reflect current state of the art.

GMP Guide: Annex 11 (Computerised Systems)

Target date	Q4 2026
Comments	To provide the European Commission with a final text for the amended annex in order to assure data integrity in the context of GMP. This would be in parallel with similar consideration of Chapter 4 (Documentation) and Annex 22.

GMP Guide: Annex 14 Manufacture of Medicinal Products Derived from Human Blood or Plasma

Target date	Q4 2028
Comments	To provide the European Commission with a final text for an amended Annex 14 following a review and update to take into account Regulation (EU) 2024/1938 of

	the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application.

GMP Guide: Annex 15 Qualification and Validation

Target date	Q4 2026
Comments	To provide the European Commission with a final text for an amended Annex 15 in the context of new technology in facilities, products and processes and following up on LLE recommendations, and extend the scope to APIs as well as to reflect changes from the revised ICH Q9 R1 on Quality Risk Management.

GMP Guide: Annex 22 Artificial Intelligence

Target date	Q4 2026
Comments	To provide the European Commission with a final text for the amended annex in order to assure use of artificial intelligence in the context of GMP. This would be in parallel with the update of Annex 11 and Chapter 4 (Documentation).

GMP Guide: Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products

Target date	Q4 2026
Comments	Review the Guidelines in collaboration with CAT and the European Commission following the publication of a new regulation on standards of quality and safety for substances of human origin intended for human application and need to update legal references and definitions. Review the Guidelines in light of the new Annex 1 Manufacture of Sterile Medicinal Products and consider whether any updates are necessary.

ICH Q12: Lifecycle management

Target date	Q4 2026
Comments	To agree an EU approach to documenting and communicating the effectiveness of a manufacturing site’s Pharmaceutical Quality System.

Good Distribution Practice Activities

Target date	Q4 2026

Comments	Develop a Q&A to provide guidance to WDA Holders on performing risk assessments on the verification of authenticity of medicinal products at risk of falsifications.

4. Communication and Stakeholder activities:

Input into International activities (beyond (V)ICH guidelines)

To continue to promote and strengthen international collaboration and convergence through the existing MRA platforms and other programmes (ICMRA – International Coalition of Medicines Regulatory Authorities, PIC/S, WHO) with a view to supporting capacity building.

Mutual Recognition Agreements

To support the European Commission in the equivalency assessment of the supervision of pharmaceutical manufacturers by third country authorities at their request for any new agreements or changes to existing agreements.

To support the European Commission in continuous assessment (audits) of the different MRA partners.

To promote / establish harmonised MRA maintenance programmes between the different MRA partners.

To continue progress towards the use of the EudraGMDP database by MRA partners to replace the paper exchange of GMP certificates.

- **Australia**

  To implement and maintain the functioning of the MRA;

  To support the European Commission in assessment efforts should APVMA request recognition as equivalent inspectorate.

- **Canada**

  To support the implementation and ongoing maintenance of the Comprehensive Economic and Trade Agreement (CETA) GMP Protocol.

- **Israel**

  To continue to maintain the functioning of the MRA (ACAA - Agreement on Conformity Assessment and Acceptance).

- **Japan**

  To continue to maintain the functioning of the MRA.

- **New Zealand**

  To continue to maintain the functioning of the MRA.

- **Switzerland**

  To continue to maintain the functioning of the MRA.

- **United States of America**

To continue to support the implementation of the EU-US MRA.

International Coalition of Medicines Regulatory Agencies (ICMRA).

Support the ICMRA goal of establishing a Pharmaceutical Quality Knowledge Management System (PQKMS) capability, including the Collaborative Hybrid Inspection Pilot.

Other collaborations

- **United Kingdom**

  To continue to support the functioning of the GMP aspects of the EU – UK Trade Co-operation Agreement.

- **EDQM (European Directorate for the Quality of Medicines and Healthcare)**

  To continue collaborative activities aimed at optimising the use of inspection and testing resources and capacity building.

- **India and China**

  To support collaborative initiatives of the EMA and MSs on inspections and India and China as well as with Indian and Chinese regulators (e.g. capacity building and training on EU GMP standards).

- **African Medicines Agency.**
- To support the establishment of the African Medicines Agency through training on relevant topics for GMP inspections.

Contribution to dialogue and engagement with stakeholders and external parties

Interested Parties

Improve collaboration with Industry associations and relevant professional associations (Interested Parties). Annual meeting with Industry Interested Parties from trade associations covering manufacture and distribution of human and veterinary medicines, as well as professional associations representing professionals working in the pharmaceutical industry on topics related to the IWG Workplan.

Workshops

Ad hoc workshops may be organised to support progress on topics identified in this work programme.

Other activities with stakeholders and external parties

In addition to the actions identified above, the working group can be involved in any other activities foreseen in its mandate:

Cross-domain activities:

To maintain dialogue and monitor developments in areas of common interest in order to communicate the work of the group and to assess the impact of other groups' activities on GMP and GDP guidance, Compilation of Union Procedures and other inspection related activities:

- CHMP/CVMP Quality Working Party, Biological Working Party. And Immunologicals Working Party
- Increase collaboration with Quality Working Party and Biological Working Party to support synergies between assessment and inspection activities supported by an annual joint meeting with BWP and QWP.
- Provide inspector input into the update of guidance related to the QP declaration and on co-processed excipients and is supported by annual joint meeting (also with BWP).
- Safety Working Party.
- Heads of Medicines Agencies' Working Group of Enforcement Officers and the Expert group on the delegated act on safety features for medicinal products for human use.
- Innovation Task Force (ITF).
- Quality Innovation Group (QIG).
  - In close collaboration with QIG, ensure learnings and knowledge gained from the QIG interaction on new manufacturing technologies and regulatory science developments is shared with GMDP IWG to equip EU GMP Inspectors with the skills required to assess these new technologies and ensure a harmonised approach.
- SPOC Working Party.
- Scientific Advice Working Party.
- Novel Therapy Working Party for veterinary medicines.

Collaboration with European Commission

- EU enlargement: to develop contacts, collaboration and tailored training/workshops in the field of GMP and GDP inspections with EU candidate and accession countries identified by the European Commission. These countries are invited to observe meetings of GMP/GDP IWG.
- Legislative developments: to monitor new legislation, to assess and advise on potential impact on GMP, GDP, inspections or inspection-related activities. Particular attention will be given to:
  - Assessment of the impact of the GMP Implementing Acts for veterinary medicines and active substances for veterinary medicines, on GMP inspection and related activities and agree on practical implementation steps;
  - Assessment of the impact of the regulation on veterinary medicinal products (regulation 2019/06/EC) on GMP inspection and related activities and agree on practical implementation steps;
  - Revision of the Pharmaceutical legislation for human medicines.
  - Revision of the legislation for Substances of Human Origin (SoHo).
- Article 111b(1) equivalency assessment: to support the European Commission in the equivalency assessment of the supervision of active substance manufacturers by third country authorities at their request.

Joint Audit Programme

- To contribute auditor resource to the audit programme (boosted by the EU4H JAP audit training work package).

- To collaborate with PIC/S (Pharmaceutical Inspection Convention/Co-operation Scheme) and MRA (Mutual Recognition Agreement) partners in joint audits.

Through the Compliance Group:

- To ensure that the agreed audit programme for the period covered by this workplan is carried out and to report to the Heads of Medicines Agencies on the audit programme;
- To implement risk-based audit procedures;
- To monitor the results of audits and follow up to maintain one harmonised EU GMDP inspectors network;
- To develop a formal process for the follow-up of significant issues raised in the Joint Audit Programme in close cooperation with the HMA and the EC.

Compilation of Union Procedures on Inspections and Exchange of Information

- To update the following procedures and consequently train inspectors as needed:
  - Guideline on training and qualifications of good manufacturing practice (GMP) inspectors.
  - Quality systems framework for Good Manufacturing Practice (GMP) inspectorates.
  - A model for risk-based planning for inspections of pharmaceutical manufacturers.
  - 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
  - To develop a new procedure on dealing with serious non-compliance with Good Distribution Practice.
  - To review the Good Distribution Practice inspection procedure to formalise the risk based approach used for GDP inspection planning.
- To gather during 2026-2028 GMP and GDP inspection related topics for development or revision of Union procedures, including necessary updates following the publication of implementing acts for GMP for veterinary medicines and GMP for active substances for veterinary medicines.
- To identify and implement (including training), as needed, updates following the publication of the PIC/s procedures for Inspection Reliance and Assessment of PQS (support for ICH Q12 implementation) and following the evaluation of the results of the Reliance Pilot conducted by IWG.

EudraGMDP database

- To continue to oversee the operation and maintenance of the EudraGMDP database and initiate the modernisation of the application to align with future regulatory and technological needs;
- To promote further use of the EudraGMDP as a tool for EU and international collaboration and reliance.

Training for the network and knowledge building

- To develop training for EU GMP inspectors in accordance with the GMDP IWG training strategy.

- To develop training for EU GMP inspectors, in collaboration with the European Commission, to support the implementation of the revised Chapter 4, Annex 11, Annex 22 during 2026 - 2028.
- To develop training for EU Inspectors on the implementing acts on GMP for Veterinary Medicinal Products, in particular training on GMP for Autogenous Vaccines and GMP for Novel Therapies.
- Development of a more detailed comparison between Veterinary and Human GMP that goes beyond the correlation tables agreed by the expert group and now published in Eudralex volume 4.

5. Operational goals: medicinal product-specific activities

Pre-Authorisation activities

- Contribution to Innovation Task Force discussions as required.
- Contribution to scientific advice procedures as required.
- Contribution to marketing authorisation procedures as required;
- GMP expertise and support to scientific aspects related to accelerated access schemes;

Evaluation and supervision activities

- Agreement on EMA's annual re-inspection programme. Develop a co-ordinated approach to third country inspections.
- Development of procedures and co-ordination of inspections relating to centrally authorised products and plasma master files for third-country blood establishments;
- Review of GMP provisions in the context of 'disruptive innovation' and propose revisions to GMP guidance interlinking with EMA Quality Innovation Group (QIG) and Innovation Task Force (ITF) and similar initiatives, as appropriate.
- Contribute to European Medicines Regulatory Network Strategy to 2028 as appropriate.
- Making best use of EU inspection resources by leveraging information from international regulatory authority partners wherever possible and implementing other risk-based approaches agreed in Union procedures. Consideration will also be given to leveraging knowledge gained from the equivalency assessments involved in the listing of third countries by virtue of Article 111b of Directive 2001/83/EC when planning inspections of active substance manufacturers;
- Contribute as needed to the European Medicines Regulatory Network, the MSSG and SPOC Working Party on dealing with shortages and availability, with a focus on issues concerning product quality and manufacturing.
- Development of procedures and guidance on Good Distribution Practice and GDP inspections in the EU/EEA".

6. Expertise required

The GMDP Inspectors Working group consists of senior GMP inspectors from all EEA human and veterinary inspectorates. It collaborates with GMP inspectors from international partner organisations (e.g., PIC/s) in the development of guidelines where appropriate and with other working parties where appropriate.

7. Meetings scheduled for 2026-2028

Face-to-face/virtual meetings are planned for the following dates:

2026	2027	2028 (To Be Confirmed)
10-12 March 2026. (remote)	9-11 March 2027	07-09 March 2028
9-11 June 2026 (F2F) IP Meeting	08-10 June 2027 (F2F) IP Meeting	06-08 June 2028 IP Meeting
22-24 Sept 2026. (remote)	21-23 Sept 2027	26-28 Sept 2028
(Joint BWP-QWP- IWG date TBC)	(Joint QWP/BWP- IWG date TBC)	(Joint QWP/BWP- IWG date TBC)
25-26 Nov 2026	23-25 Nov 2027	21-23 Nov 2028

The above mentioned dates may be modified as needed. Additional ad-hoc virtual meetings may be organised to progress guidelines, as required.

Four meetings of the Compliance Group will take place in the margins of the GMP/GDP IWG meetings.

Drafting group meetings will normally be held by teleconference but other virtual meeting technology may be used.