20 November 2025
Inspections Office

Guidance for Rapporteurs and members of drafting groups of documents developed by the GMP/GDP Inspectors Working Group

1 Introduction

According to the mandate of the GMP/GDP Inspectors Working Group, among its tasks is the development and agreement, by consensus, of GMP/GDP related guidelines and high-level procedures on GMP and GDP inspection related activities. Normally, the lead for the development of any document is undertaken by a rapporteur appointed from within the members of the GMDP IWG.

The Agency recognises and appreciates that National Competent Authorities are making a significant commitment in terms of resources when undertaking the role of members of drafting groups, and especially the role of rapporteur. All Member States are therefore encouraged to share resources by contributing to this work, which is done for the benefit of the Community as a whole.

Inspectors from GMDP IWG members that participate in the development of the above documents are "European Experts"[1] and they are nominated by the national competent authorities of the Member States of the European Economic Area (EU Member States plus Iceland, Liechtenstein and Norway), as part of the European medicines regulatory network. The involvement of inspectors in GMDP IWG drafting groups will be in accordance with EMA Policy 0044 on the handling of competing interests of scientific committees' members and experts[2].

It is expected that the rapporteur and members of the drafting group may record their activities and their time participating in this work as part of ongoing Continuous Training. These records may be evaluated as part of the ongoing continuous training of inspectors and be counted within the overall 10 day per year training requirement for inspectors up to a maximum of 5 days.

[1] European experts | European Medicines Agency (EMA) (europa.eu)

[2] Handling competing interests | European Medicines Agency (EMA) (europa.eu)

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

2 Scope

The purpose of this document is to provide guidance on the responsibilities of rapporteurs and the members of the drafting group, as well as the EMA and EC. This guidance applies to GMDP IWG drafting groups for the development of the following type of documents.:

- Concept Papers
- New or amended text for the EU GMP or GDP Guide
- New or amended documents forming the Compilation of Community Procedures
- Reflection Papers
- Questions and Answers

This is list is not exhaustive, and these principles can apply to other types of documents or output that the GMDP IWG is requested to provide.

3 Appointment of Rapporteurs and members

Once the GMDP IWG has agreed to form a drafting group the rapporteur and members of the drafting group should be nominated. All members of the Inspectors Working Group are actively encouraged to accept rapporteurships or participate as a drafting group member in order to share the Group's workload in a fair way and to promote the active engagement of all National Competent Authorities in the Group's activities.

Acceptance of a rapporteurship is on a voluntary basis and is normally agreed during plenary meetings of the GMDP IWG. The rapporteur is normally a member of the GMDP IWG although he/she may choose to delegate the detailed tasks to a suitable expert within his own National Competent Authority. A member of the GMDP IWG's secretariat at the European Medicines Agency may act as a rapporteur where this is considered appropriate and agreed by the GMDP IWG.

All members of the GMDP IWG are actively encouraged to nominate inspectors to participate in drafting groups in order to share the IWG's workload in a fair way and to promote the active engagement of all National Competent Authorities in the IWG's activities.

4 Description of Documents

4.1 Concept Papers.

An **EMA concept paper** is a document developed by the GMDP IWG to outline the rationale and scope for a new or revised guideline and is used to gather feedback from stakeholders.

A concept paper is issued for each revision of GMP or GDP Guidelines published by the European Commission.

Depending on the extent of the revision, it can be decided that the concept paper, once endorsed by the IWG and agreed by the Commission, will be submitted for stakeholder consultation by EMA.

The decision to launch a stakeholder consultation should take into account the extent of the revision, innovative character and potential implications for stakeholders (eg resources/costs).

For consistency, unless justified, the corresponding revised draft guideline should be submitted to stakeholder consultation in the next step.

The concept paper should include at least the following elements: problem definition/trigger for the revision, objectives, impact assessment, timetable of the revision.

4.2 Draft Guidelines.

A GMP guideline published by the European Commission is an official document that provides principles, procedures, or best practices to support the implementation of EU GMP legislation.

The decision to launch a stakeholder consultation on a draft guideline should take into account the extent of the revision, innovative character and potential implications for stakeholders (eg resources/costs).

4.3 Reflection Papers.

A reflection paper is a document outlining the view of the European Medicines Agency (EMA) or one of its committees, working parties, or expert groups on a particular scientific, regulatory, or methodological issue. A reflection paper may be necessary to stimulate discussion and gather feedback from stakeholders or to clarify regulatory expectations in areas where formal guidance may not yet exist or to explore emerging topics.

Depending on the purpose of the reflection paper it may be released for stakeholder consultation to gather stakeholder input.

4.4 Questions and Answers (Q&A)

A Q &A is supplementary resource developed by the GMDP IWG to provide clarifications, harmonized interpretations, and regulatory assistance on topics that are often subject to different interpretations or require further explanation.

Depending on the purpose of the Q &A, a draft may be released for stakeholder consultation to gather stakeholder input.

4.5 Documents for the Compilation of Community Procedures.

Procedures or templates intended for the Compilation of Community Procedures are intended to support the work of the Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) inspectorates across the EU and EEA. Normally these updates to not require a stakeholder consultation but it may be useful for the IWG to consider in certain circumstances.

5 Responsibilities

5.1 Rapporteur

Upon appointment the rapporteur should follow this guidance.
The rapporteur should work with secretariat to co-ordinate the work of the drafting group.

The rapporteur may be required to allocate work within the group, and should strive to ensure fair distribution of the tasks and monitor work progress according to the work plan.
In cases where there is to be an amendment to a chapter or Annex of the EU GMP Guide the rapporteur should ensure the review of the entire chapter or Annex and seek input from the GMDP IWG on other changes that might be necessary to maintain the currency of the guidance.

In the case of amendments to, or new texts for inclusion in, the EU GMP Guide a Concept Paper is necessary. Upon appointment of the rapporteur the European Medicines Agency will provide the rapporteur with the appropriate guidance for drafting a Guideline and related documents. The rapporteur should also identify whether input from other stakeholders on the concept paper will be necessary.

In the case of an external consultation, the rapporteur should take account of comments received on the Concept Paper when drafting the relevant guidance and provide an explanation to the Group if any such comment is to be disregarded and the Group should agree to this.

The rapporteur may ask the Agency to set up a face-to-face meeting of the drafting group if required. Normally this should be restricted to a kick-off meeting but additional meetings may be agreed where justified and depending on availability of funds. The majority of drafting group interactions is expected to take place through the exchange of Emails, teleconferences or the use of web conferencing tools. To promote and facilitate a more even distribution of work between Member States and to minimise travelling the rapporteur, in agreement with the drafting group, may choose to organise a meeting outside of the offices of the European Medicines Agency in Amsterdam and may request the Agency to reimburse travel and accommodation expenses. In such cases a written request for authorisation must be forwarded well in advance of the proposed meeting to ADM-GMDP@ema.europa.eu with supporting evidence that the costs will be no more than those that would be incurred by having the meeting in Amsterdam.

The rapporteur will draft documents taking into account comments expressed by the drafting group, comments expressed during plenary meetings of the GMP/GDP IWG, unless it is already clear that the Group does not support the comment in question, and any written comments received. He should treat all comments in a balanced way and avoid bias towards his personal views or those expressed by his own National Competent Authority.

The rapporteur will provide drafts to the European Medicines Agency sufficiently in advance of plenary meetings of the Group in order that they can be distributed to the Group in time to allow for consultation within each National Competent Authority prior to the meeting. The deadlines provided on agenda and summary records of the Group's meetings should therefore be respected.

The rapporteur should report on progress at each plenary meeting of the Group, either verbally or in writing as necessary. This report should include an overview of any significant comments received since the last meeting and the outcome of the consideration of those comments. The report should also indicate any areas of difficulty, any specific requests for feedback from the Group and should in particular highlight cases where the timelines expressed in Concept Papers or published Work Plans, as relevant, cannot be met.

The rapporteur may ask the GMDP IWG for advice in case of divergent opinions within the drafting group on specific areas/topics.

When participating in international or other fora not specifically on behalf of the GMDP IWG, the rapporteur shall make clear that the views expressed are their own views and not those of the drafting group or GMDP IWG.

Draft documents tabled at plenary meetings of the Group should include the letterhead of the European Medicines Agency and be marked as confidential.

Regarding the revision of GMP guidelines, the drafting group, under the responsibility of its Rapporteur, should ensure that:

- the revision is focused and limited to essential elements for inclusion in the guidelines, and consistent with the concept paper for the revision;
- the number of requirements, the level of detail, and the degree of prescriptiveness is commensurate with the objectives of the guideline;
- there are no redundancies/overlap and inconsistencies in the revised guideline as regards to other chapters/annexes. These consistency and redundancy checks can be supported by IT tools;
- cross-references between chapters/annexes remain consistent within the guideline;
- new terms used are defined when needed and the impact of the revision on the GMP glossary should be assessed;
- in the case of a general revision of a GMP guideline, a correspondence table between the previous version and the new version may be used to check that any deletion of a requirement is intended.

The Rapporteur of the drafting group, in collaboration with the secretariat, is responsible for ensuring that the version submitted for endorsement by the IWG is a clean version, that the plan/presentation is consistent with the template and that the points listed above are met.

Templates will be provided by EMA secretariat for documents.

The rapporteur should take account of comments received from any stakeholder consultation and provide a tabulated summary of the major comments together with the outcome following consideration of each comment, and this should be tabled at a plenary meeting of GMP/GDP IWG before final agreement of the text. The European Medicines Agency will provide the rapporteur with the template document for this purpose.

5.2 EU GMDP Inspectors, inspectors from IWG Observer Authorities and PIC/s GMDP Inspectors participating as members of Drafting Groups.

The Agency recognises and appreciates that GMDP guidelines are international in nature and welcomes collaboration and participation of inspectors from IWG Observer authorities and PIC/s GMP inspectors as members of drafting groups.

The secretariat will communicate with PIC/s to arrange for PIC/s GMP inspectors to participate in GMP guideline development.

Inspectors normally agree to join a drafting group on a voluntary basis and their participation is normally agreed by GMDP IWG during plenary meetings of the IWG.

Volunteering inspectors should ensure that prior to volunteering that they have secured the necessary national authority support for their participation in the drafting group.

Drafting group members shall actively co-operate with the rapporteur to ensure that they are available to participate in drafting group meetings, undertake work allocated by the Rapporteur and provide constructive input to the work of the drafting group respecting the deadlines set out by the rapporteur.

A drafting group member may lead or be part of subgroups for the drafting of specific paragraph of the guideline if requested by the Rapporteur.

IWG Observer authorities and PIC/s GMP inspectors should identify to the rapporteur and the secretariat any conflict of interest prior to their involvement in drafting group activities.

When participating in international or other fora not specifically on behalf of the GMDP IWG, members shall make clear that the views expressed are their own views and not those of the drafting group or the GMDP IWG.

5.3 Observers to drafting groups.

Observers to the work of a drafting group may be permitted subject to the agreement of the rapporteur and IWG. Observers shall not make contributions to the work of the drafting group.

Motivated requests to participate as observer should be made to the EMA secretariat in time for agreement at the next GMDP IWG.

Observer places in drafting groups will be limited to ensure the functioning of the drafting group.

5.4 Secretariat (European Medicines Agency) for GMP/GDP IWG

The secretariat will ensure that the drafting group will operate in accordance with EMA policies and procedures regarding meetings, and development of guidelines.

The secretariat will check the status of experts involved in drafting groups and request relevant documentation from experts as needed.

The secretariat will provide the rapporteur with the appropriate guidance and formats as relevant to the documents in question.

The secretariat will give proper consideration to all requests from rapporteurs for face-to-face meetings of drafting groups in Amsterdam and where appropriate will send invitations, provide a meeting room in Amsterdam and any further support as agreed. When requested in writing the secretariat will seek Agency authorisation for reimbursement of travel and accommodation expenses for drafting group meetings outside of its Amsterdam offices and will inform the rapporteur of the outcome.

The secretariat will, upon request, set up teleconference calls for drafting groups using its own teleconferencing facilities or set up web conferences, and arrange for the supply of relevant software and training when needed.

The secretariat will review final drafts for consistency with other relevant guidelines, and in particular in the case of an amendment to the GMP or GDP Guide, consistency within the Guide itself, and where

necessary will suggest amendments to the text to the rapporteur. Where possible it may also suggest linguistic corrections where the rapporteur is not a native English speaker

The secretariat will also review final drafts for consistency with EMA and EUMRN goals and objectives.

The secretariat will also ensure that draft documents to be adopted by IWG have undergone a regulatory and legal review with relevant EMA departments or offices.

The secretariat will provide advice on other Groups or Working Parties that should be consulted prior to the finalisation of drafts. The secretariat will if necessary convert final drafts into the correct format for publication or transmission to the European Commission and will publish or transmit final documents to the European Commission as appropriate. The European Medicines Agency publishes Concept Papers, Reflection Papers, Questions & Answers and the Compilation of Community Procedures on Inspections and Exchange of Information. The European Commission publishes draft GMP and GDP guidance for public consultation, adopted amendments and additions to the GMP or Guide and the summary of public comments.

5.5 GMP/GDP IWG

The IWG will provide all necessary scientific support to the rapporteur.

Each member of the IWG will ensure that all relevant experts within his own National Competent Authority are consulted on each draft tabled at meetings and provide the resulting feedback to the rapporteur at the plenary meetings or in writing.

The IWG will ensure that comments received during external consultations have been satisfactorily addressed by the rapporteur.

The GMDP IWG endorses guidelines prior to their adoption and publication by the Commission on the EudraLex volume 4 website.

5.6 European Commission

The European Commission performs a legal review of documents for the GMP Guide or Compilation of Community procedures before these are adopted.

6 Continuous Professional Development.

Participation in guideline development at EU or international level as a rapporteur, or as a member or observer should be recorded as part of continuous training as described in the Compilation of Union Procedures. Such records may be evaluated by their authority as part of the ongoing continuous training of inspectors and be counted within the overall 10 day per year training requirement for inspectors up to a maximum of 5 days.

7 Further Information

Documents produced in accordance with this guidance are subject to the Procedure for European Union Guidelines and Related Documents within the Pharmaceutical Legislative Framework:

https://docs.eudra.org/webtop/drl/objectId/090142b281b4c4f7