EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Standard operating procedure

| Title: Scientific and administrative support to working groups and working party under the Compliance and Inspection Sector responsibility | | |
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## 1. Purpose

To ensure effective support, planning and preparation of all groups and working party under the Compliance and Inspection sector responsibility, i.e. GCP Inspectors Working Group, PhV Inspectors Working Group, GMP/GDP Inspectors Working Group and Quality Working Party (QWP).

## 2. Scope

This SOP applies to the Compliance and Inspection sector.

## 3. Responsibilities

It is the responsibility of the Head of Sector or each Section Head and respective Scientific Administrator responsible for the Working Group/Working Party to ensure that this procedure is adhered to. The responsibility for the execution of a particular part of this procedure is identified in the right-hand column of section 9.

## 4. Changes since last revision

Update to reflect the new organisational names in the Agency and changes with the organisation of WGs/WP.

## 5. Documents needed for this SOP

N/A.

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# 6. Related documents

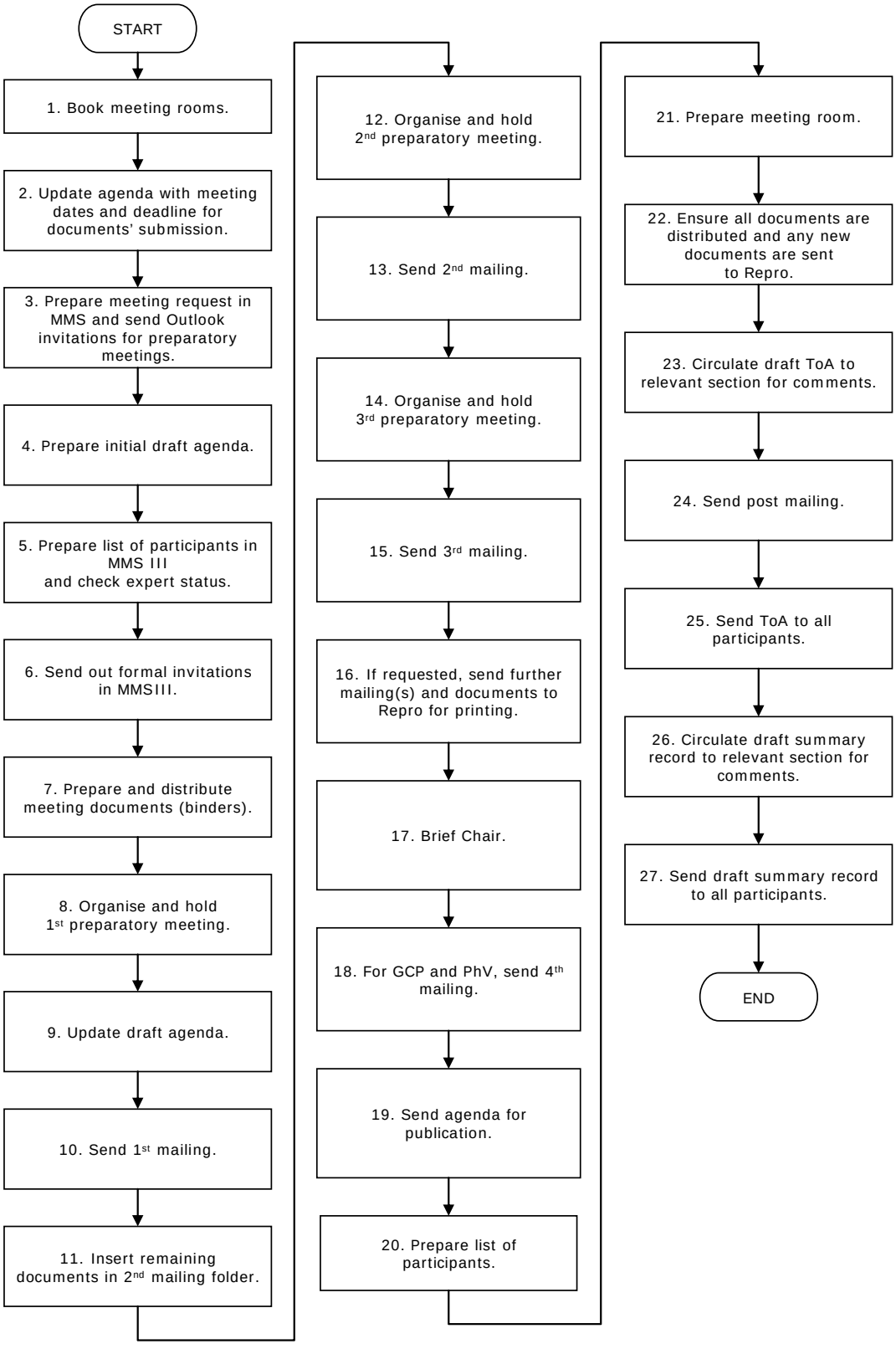
- SOP/EMEA/0040 Checking of Experts.
- MMS User Manual: Open MMS II and click on User Guide link.
- ECD (Eudra Common Directory) user guide.

# 7. Definitions

In this procedure the following abbreviations are used:

| | |
|---|---|
| AST | Assistant. |
| DREAM | Document Records and e-Archive Management. |
| Eudralink | Safe and secure method of sending confidential documents. |
| GCP | Good Clinical Practice. |
| GMP/GDP or GMDP | Good Manufacturing and Distribution Practice. |
| MCO | Meeting and Conference Organisation. |
| MMS | Meeting Management System. |
| PhV | Pharmacovigilance. |
| QWP | Quality Working Party. |
| SA | Scientific Administrator. |
| ToA | Table of Actions. |
| WG | Working group. |
| WP | Working party. |

# 8. Process map(s)/ flow chart(s)



# 9. Procedure

| Step | Action | Responsibility |
|---|---|---|
| 1 | Book meeting rooms 2 years in advance during the last quarter of every year.<br>Make sure the room bookings do not clash with Scientific Committees as well as national holidays in Member States. | AST |
| 2 | Include dates and deadline for meeting documents' submission on the last page of the next meeting agenda. | AST |
| 3 | By day -45, prepare **official meeting request in MMS** for official sign off and send **meeting requests for the preparatory meetings** using Microsoft Outlook. | AST |
| 4 | By day -40, prepare an **initial draft agenda** consulting the meeting chair and any EMA staff expected to contribute significantly to the meeting. | SA |
| 5 | By day -35, commence **preparation of list of participants** in MMS III and check expert status in the database according to SOP/EMEA/0040. | AST |
| 6 | By day -30, **send out formal invitations using MMS III (for GMP / GCP and PhV** together with draft agenda if ready). | AST |
| 7 | By day -24, **distribute binders with meeting documents to chairperson**, SA, and on request, other scientific sector staff involved in the meeting.<br>Keep binders up-to-date between now and date of meeting. | AST |
| 8 | By day -22, for **GMP**, **GCP and PhV**: organise and hold 1st preparatory meeting **with chairperson** and sector scientific staff as needed.<br>(The aim is to brief the chairperson and identify any new topics for the agenda). | SA |
| 9 | Update **draft agenda** to include documents and save in appropriate location in DREAM. | AST |
| 10 | By day -21, send **1st mailing** to all participants including updated agenda using MMS III. If there are confidential documents, send a separate 1st mailing to Observers. | AST |
| 11 | Insert remaining documents in **2nd mailing** folder in DREAM as they become ready. Changes to the agenda to be agreed by chairperson at this stage. | AST |
| 12 | By day -15, for **GMP, GCP and PhV**: organise and hold 2nd preparatory meeting **with chairperson** and sector scientific staff as needed.<br>(The aim is to brief the chairperson and identify any new topics for the agenda). | SA |
| 13 | By day -14, send **2nd mailing** to all participants including updated agenda using MMS III. If there are confidential documents, send a separate 2nd mailing to Observers. | AST |
| 14 | By day -8, for **GMP, GCP and PhV:** organise and hold **3rd preparatory meeting with chairperson** and sector scientific | SA |

| Step | Action | Responsibility |
|---|---|---|
| | staff as needed.<br>(The aim is to brief the chairperson and identify any new topics for the agenda). | |
| 15 | By day -6, send **3rd mailing** to all participants including updated agenda using MMS III. If there are confidential documents, send a separate 3rd mailing to Observers. | AST |
| 16 | After day-6, if requested by SA, send further mailing(s) and request **printing of documents** to Reprographics. Complete the self-explanatory form which can be found on the EMA internal website: Home > ISERV > Reprographics > Photocopying and send it to Reprographics.<br>See how many people have accepted to estimate the amount of copies to be done. | AST |
| 17 | By day -3, **final briefing of chairperson** if required. | SA |
| 18 | By day-2, **for GCP and PhV**: send **4th mailing** to all participants including updated agenda using MMS III. If there are confidential documents, send a separate 4th mailing to Observers. | |
| 19 | By day -2, **send agenda** to news.editors@ema.europa.eu. | AST |
| 20 | By day -1, prepare the list of participants using for template, the previous meeting's list of participants. | AST |
| 21 | By day -1, **prepare room for meeting.**<br>Collect any documents from Reprographics, prepare labels for the pigeon holes and insert the documents in the pigeon holes in numerical order. | AST |
| 22 | Ensure all documents are distributed, any new documents are copied by Reprographics (see step 16) and circulated in a timely manner (on the Photocopy request Form, mention Conference Services page number – 10 and whether the document is confidential so Conference Services pick up and distribute the document to the relevant people during the meeting) and that the computer and projector work properly at the start of the meeting. Give any other administrative support required during duration of the meeting. | AST |
| 23 | By day +3, **circulate draft ToA** for comments within the relevant section and other relevant EMA staff (deadline for comments: by day + 10). | SA |
| 24 | By day +7, send **post mailing**.<br>• **GMP and QWP** - Mail all documents circulated or updated during the meeting and the adopted summary record from the previous meeting to participants.<br>• **GCP and PhV** – send updated documents and non-electronically circulated documents together with the ToA.<br>If there are confidential documents, send a separate post mailing to Observers. | AST |
| 25 | By day + 11, send the ToA to all participants. | AST |
| 26 | By day +21, **circulate draft summary record for comments within the relevant section** and other relevant EMA staff | SA |

| Step | Action | Responsibility |
|---|---|---|
| | (deadline for comments: by day + 34). | |
| 27 | By day +1st mailing of the next meeting, send **draft summary record to participants.** | AST |

# 10. Records

All records generated after the relevant working groups and working party meetings are saved in DREAM under the following paths:

- For GMDP IWG: Cabinets/04. Inspections/4. GMP/GMP IWG/2. Meeting organisation/YYYY.
- For GCP IWG: Cabinets/04. Inspections/1. GCP/GCP IWG/2. Meeting organisation/YYYY.
- For PhV IWG: Cabinets/04. Inspections/2. PHV/PHV IWG/2. Meeting organisation/YYYY.
- For QWP: Cabinets/2b. Administration of Scientific meeting/WP and Drafting Groups/CxMP – QWP/2. Meeting organisation