



## Work instructions

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|---|---------------------|-----------------------------|
| Title: Announcement of Good Clinical Practice/Pharmacovigilance inspection to reporting inspectorate, applicant and 3 <sup>rd</sup> country inspectorate prepared by P-CI-CNC |                     |                             |
| Applies to: Clinical and Non-Clinical Compliance, Compliance and Inspection Sector  |                     |                             |
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### 1. Changes since last revision

New WIN.

### 2. Records

Declaration of Interest is available in Experts database electronically. Signed evaluation forms of inspectors with Risk 2 or more are filed in PDF in DREAM in 01.Evaluation of medicines/ in respective product folder/07.Inspection/GCP or PhV.

Copy of the inspection request and the inspections correspondence is filed in DREAM in 01.Evaluation of medicines/ in respective product folder/07.Inspection/GCP or PhV and hard copy in respective product binder located in P-CI-CNC section.

### 3. Instructions

The tasks in this WIN are performed by P-CI-CNC assistants.

#### ***Documents needed for this WIN***

- Template of Announcement letter of joint EMA-FDA GCP inspection to Applicant:  
*X:\Templates\Others\Compliance and Inspection\GCP\Inspection correspondence\Notification to the applicant.*



- Template of Follow up Letter on GCP Inspection to Applicant\_Joint EMA-FDA inspection:  
*X:\Templates\Others\Compliance and Inspection\GCP\Inspection correspondence\Notification to the applicant.*
- Template of list of contact persons for this inspection in *X:\Templates\Others\Compliance and Inspection\GCP\Inspection correspondence\Notification to the Reporting Inspectorate or*
- Template of list of contact persons for this inspection in *X:\Templates\Others\Compliance and Inspection\PhV\PhV Inspection correspondence.*

For inspections concerning veterinary medicines only:

- Guide to naming documents in DREAM/MMD, EMA/249194/2007-Rev.1
- Guidance document: CVMP agenda – Management of documents and agenda points, EMA/463490/2008-Rev.2

### ***Related documents***

- SOP/INSP/2020 Co-ordination of GCP inspections.
- SOP/INSP/2045 Co-ordination of Pharmacovigilance inspections.
- SOP/PDM/1004 Core master files of medicinal products for human and veterinary use following the centralised procedure.
- Core Master File – Compliance and Inspection. Doc. Ref.: EMA/641169/2010.

### ***Abbreviations***

- CHMP                      Committee for Medicinal Products for Human Use
- CVMP                      Committee for Medicinal Products for Veterinary Use
- CxMP                      Committee for Medicinal Products for Human/Veterinary Use
- GCP                        Good Clinical Practice
- IREQ                        Inspection request
- PhV                        Pharmacovigilance
- PTL                        Product Team Leader
- ECD                        Eudra Common Directory
- FDA                        US Food and Drug Administration

### ***3.1. Clarification of inspection***

- The starting point of this process is when the assistant receives by e-mail a link to the relevant product folder in DREAM where the IREQ is saved requesting tabling it for adoption at next CxMP meeting.
- Clarify with Scientific Administrator the type of inspection (routine, triggered, Joint EMA/FDA GCP inspection).

### **3.2. Inspection request (IREQ)**

- Once scientific administrator sends IREQ by email, check if the EMA reference number is stated. If it is not, enter it.
- Print the IREQ.
- Give the IREQ for signature to Head of Clinical and Non-Clinical Compliance Section.
- Create 6 subfolders in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV called: Notification to the applicant and Notification to the Reporting Inspectorate, Inspection Reports, Notification to 3rd country inspectorates (if applicable), Mails, Payments, Declaration of interest Evaluation.

For inspections concerning human medicines:

- Name the word version of IREQ: name of product/ Inspection request for GCP or PhV inspection. Table it via Meeting Management Documents to CHMP for adoption.
- Create PDF of the signed IREQ, file it in the product folder and file the original in hard copy in the product folder.
- When CHMP adopts the IREQ, add the signed PDF version to Core Master File in DREAM. If CHMP does not adopt the IREQ, the whole process of sending of correspondence referred to in this WIN ends.

For inspections concerning veterinary medicines (PhV only):

- Change name of IREQ document as outlined in guidance document: Guide to naming documents in DREAM/MMD, [EMA/249194/2007-Rev.1](#).
- Table IREQ via Meeting Management Documents to CVMP.
- Add and link tabled document to the CVMP agenda as described in the guidance document: CVMP agenda – Management of documents and agenda points, [EMA/463490/2008-Rev.2](#)
- When CVMP adopts IREQ, scan it to PDF, save in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/PhV and
- When CVMP adopts the IREQ, add the signed PDF version to Core Master File in DREAM. If CVMP does not adopt the IREQ, the whole process of sending of correspondence referred to in this WIN ends.

### **3.3. Creating inspection binders**

- Create a new hard copy product binder indicating name of the product, name of the Marketing Authorisation Holder and EMA inspection number. Insert in the binder 5 coloured paper separators and name them: IREQ, Correspondence, Contract and Payment, Inspection report, Follow-up.

### **3.4. Checking EMA Experts Database and the Declaration of Interest of the Expert**

- When the Scientific Administrator sends request to prepare the inspection announcement letters, check if the expert's name is in the EMA Experts Database and what risk level is he/she attributed.
- If the expert has risk 1, go to 3.5.

- If expert has risk level 2 or 3 print out form located in Excel/File new/Experts and CV of the relevant expert from Experts CV and give to scientific administrator for evaluation.
- Evaluation form including CV is scanned and saved in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV Declaration of interest Evaluation.
- If the expert is evaluated by scientific administrator and the expert can perform or be present at the inspection, go to 3.5.
- If the expert is evaluated by scientific administrator and the expert cannot perform or be present at the inspection, await further instructions from scientific administrator.

### **3.5. Announcement letters of GCP/PhV inspection**

#### **3.5.1. Announcement of GCP/PhV inspection to the applicant**

##### **3.5.1.1. Announcement of GCP/PhV inspection (other than Joint EMA/FDA GCP inspection) to the applicant**

- Draft a letter within 10 working days from adoption by CHMP/CVMP using BI Production GxP <http://bi.eudra.org>. Templates/choose relevant letter/Select Inspection Request number (for example GCP/2011/XXX)/Export/Open, when the letter is created, save it on L:drive as DOC (Word document) not as RTF (Rich Text Format), name it "Letter <dd/mm/yyyy> Announcement of <GCP or PhV> inspection to Applicant\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the applicant.
- Send the link of the letter by email to the scientific administrator for checking. When the letter is checked, print the letter and give it back to the scientific administrator for signature.
- When the letter is signed, scan the letter, name it: "Letter <dd/mm/yyyy> Announcement of <GCP or PhV> inspection to Applicant\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the applicant.
- Add the PDF of the letter to Core Master File in DREAM.
- Send the letter via Eudralink to the applicant and copy Rapporteur, Co-Rapporteur, Inspectors, relevant EMA PTL and EMA GCP functional inspection inbox ([gcp@ema.europa.eu](mailto:gcp@ema.europa.eu)).
- Save the Eudralink message in DREAM:
  - Open up Eudralink message;
  - File/Save as;
  - Save as "HTML only" on your desktop with name "Eudralink Letter <dd/mm/yyyy> Announcement of GCP inspection to Applicant\_<product name>";
  - Import it to DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the applicant.
- Make a copy of the letter and file it in hard copy product binder.
- Post the original of the letter to the applicant in hard copy.
- Forward the Eudralink message received by auto forward to inbox to *Outlook/Folder list/All Public Folders/Human products* to respective product folder.

Go to step 3.5.2

### **3.5.1.2. Announcement of Joint EMA/FDA GCP inspection to the applicant**

- Draft a letter within 10 working days from adoption by CHMP/CVMP using BI Production GxP <http://bi.eudra.org>. Templates/choose relevant letter/Select Inspection Request number (for example GCP/2011/XXX)/Export/Open, when the letter is created, save it on L:drive as DOC (Word document) not as RTF (Rich Text Format), name it "Letter <dd/mm/yyyy> Announcement of Joint EMA FDA GCP inspection to Applicant\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP/ Notification to the applicant.
- Add to the letter 3<sup>rd</sup> paragraph from the template of the Joint EMA/FDA inspection letter located in the X:\Templates\Others\Compliance and Inspection\GCP\Inspection correspondence\Notification to the applicant. Add in cc an email address of FDA functional inbox ([OC-OIP-Europe@fda.hhs.gov](mailto:OC-OIP-Europe@fda.hhs.gov)) and contact point for GCP Inspections in FDA (name to be confirmed with scientific administrator).
- Send the link of the letter by email to the scientific administrator for checking. When the letter is checked, print the letter and give it back to the scientific administrator for signature.
- When the letter is signed, scan the letter, name it: "Letter <dd/mm/yyyy> Announcement of *Joint EMA FDA GCP* inspection to Applicant\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP/ Notification to the applicant.
- Add the PDF of the letter to Core Master File in DREAM.
- Send the letter via Eudralink to the applicant and copy Rapporteur, Co-Rapporteur, Inspectors, relevant EMA PTL, EMA GCP functional inspection inbox ([gcp@ema.europa.eu](mailto:gcp@ema.europa.eu)), FDA Functional inbox ([OC-OIP-Europe@fda.hhs.gov](mailto:OC-OIP-Europe@fda.hhs.gov)) and FDA contact point for GCP Inspection. Save the Eudralink message in DREAM:
  - Open up Eudralink message;
  - File/Save as;
  - Save as "HTML only" on your desktop with name "Eudralink Letter <dd/mm/yyyy> Announcement of GCP Joint EMA FDA Joint inspection to Applicant\_<product name>";
  - Import it to DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the applicant.
- Make a copy of the letter and file it in hard copy product binder.
- Post the original of the letter to the applicant in hard copy.
- Forward the Eudralink message received by auto forward to inbox to *Outlook/Folder list/All Public Folders/Human products* to respective product folder.
- Go to step 3.5.3

### **3.5.1.3. Follow-up letter**

- This step is only applicable only in case there is a change in the inspection (address of the site, name of the inspector, study number, etc.) Assistant is informed by the scientific administrator.
- Draft a letter using as a template the initially sent Announcement of GCP/PhV inspection to the applicant or Announcement of Joint EMA/FDA GCP inspection to the applicant and name it "Follow up letter <dd/mm/yyyy> on <GCP PhV> inspection to Applicant\_<product name> or Follow up letter <dd/mm/yyyy> on Joint EMA FDA GCP inspection to Applicant\_<product name> and save it

in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the applicant.

- Send the link of the letter by email to the scientific administrator for checking. When the letter is checked, print the letter and give it back to the scientific administrator for signature.
- When the letter is signed, scan the letter, name it: "Follow up letter <dd/mm/yyyy> on <GCP PhV> inspection to Applicant\_<product name>" or Follow up letter <dd/mm/yyyy> on Joint EMA FDA GCP inspection to Applicant\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the applicant.
- Add the PDF of the letter to Core Master File in DREAM.
- Send the letter via Eudralink to the applicant and copy Rapporteur, Co-Rapporteur, Inspectors, relevant EMA PTL and EMA GCP functional inspection inbox (gcp@ema.europa.eu).
- Save the Eudralink message in DREAM:
  - Open up Eudralink message;
  - File/Save as;
  - Save as "HTML only" on your desktop with name "Eudralink Follow up letter <dd/mm/yyyy> on <GCP PhV> inspection to Applicant\_<product name>" or Follow up letter <dd/mm/yyyy> on Joint EMA FDA GCP inspection to Applicant\_<product name>"
  - Import it to DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the applicant.
- Make a copy of the letter and file it in hard copy product binder.
- Post the original of the letter to the applicant in hard copy.
- Forward the Eudralink message received by auto forward to inbox to *Outlook/Folder list/All Public Folders/Human products* to respective product folder.

### **3.5.2. Announcement of GCP/PhV inspection to the Reporting Inspectorate**

#### **3.5.2.1. Announcement of GCP/PhV inspection (other than Joint EMA/FDA GCP inspection) to the reporting inspectorate**

- Draft a letter within 10 working days from adoption by CHMP/CVMP using BI Production GxP <http://bi.eudra.org>. Templates/choose relevant letter/Select Inspection Request number (for example GCP/2011/XXX)/Export/Open, when the letter is created, save it on L:drive as DOC (Word document) not as RTF (Rich Text Format), name it "Letter <dd/mm/yyyy> Announcement of <GCP PhV> inspection to reporting inspectorate\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the Reporting Inspectorate.
- Send the link of the letter by email to the scientific administrator for checking. When the letter is checked, print the letter and give it back to the scientific administrator for signature.
- Create a list of contact persons using template called list\_Ct\_list of contact persons for this inspection located in X:\Templates\Others\Compliance and Inspection\GCP\Inspection correspondence\Notification to the Reporting Inspectorate. Names of contact persons are to be found in ECD.
- Create a correspondence package consisting of:

- Letter <dd/mm/yyyy> Announcement of <GCP or PhV> inspection to reporting inspectorate\_<product name>.
  - Attachment 1: Copy of the Inspection Request (original filed in hard copy product binder in P-CI-CNC section archive).
  - Attachment 2: list of contact persons for this inspection.
  - Attachment 3: Copy of the Letter <dd/mm/yyyy> Announcement of <GCP or PhV> inspection to Applicant\_<product name>.
- Give the correspondence package to the scientific administrator for final check.
  - When received from scientific administrator after checking, scan the correspondence package, name it: "Letter <dd/mm/yyyy> Announcement of <GCP PhV> inspection to reporting inspectorate\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the Reporting Inspectorate.
  - Add the PDF of the letter to Core Master File in DREAM.
  - Send the letter in PDF to the applicant with cc to Rapporteur, Co-Rapporteur, Inspectors, relevant EMA PTL and EMA GCP functional inspection inbox (gcp@ema.europa.eu) via Eudralink.
  - Save the Eudralink message in DREAM:
    - Open up Eudralink message;
    - File/Save as;
    - Save as "HTML only" on your desktop with name "Eudralink Letter <dd/mm/yyyy> Announcement of <GCP or PhV> inspection to reporting inspectorate\_<product name>" ;
    - Import it to DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the Reporting Inspectorate.
  - File the original of the letter including attachments number 2 in hard copy product binder.
  - Make one copy of the whole package of Letter <dd/mm/yyyy> Announcement of <GCP or PhV> inspection to reporting inspectorate\_<product name> and give it to the Sector's Initiating agent.
  - Forward the Eudralink message received by auto forward to inbox to Outlook/Folder list/All Public Folders/Human products to respective product folder.

In case one of the inspected sites is in third country, go to step 3.5.3. If not, your task of sending inspection correspondence is finished.

### **3.5.2.2. Announcement of Joint EMA/FDA GCP inspection to the reporting inspectorate**

Do this step only if the inspection is considered to be a joint EMA/FDA GCP inspection.

- Draft a letter within 10 working days from adoption by CHMP/CVMP using BI Production GxP <http://bi.eudra.org>. Templates/choose relevant letter/Select Inspection Request number (for example GCP/2011/XXX)/Export/Open, when the letter is created, save it on L:drive as DOC (Word document) not as RTF (Rich Text Format), name it "Letter <dd/mm/yyyy> Announcement of Joint EMA FDA GCP inspection to reporting inspectorate\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the Reporting Inspectorate.

- Add in cc an email address of FDA functional inbox ([OC-OIP-Europe@fda.hhs.gov](mailto:OC-OIP-Europe@fda.hhs.gov)) and contact point for GCP Inspections in FDA (name to be confirmed with scientific administrator).
- Create a list of contact persons using template called list`Ct`list of contact persons for this inspection located in X:\Templates\Others\Compliance and Inspection\GCP\Inspection correspondence\Notification to the Reporting Inspectorate. Names of contact persons are to be found in ECD.
- Create a correspondence package consisting of:
  - Letter <dd/mm/yyyy> Announcement of Joint EMA FDA GCP inspection to reporting inspectorate\_<product name>.
  - Attachment 1: Copy of the Inspection Request (original filed in hard copy product binder in P-CI-CNC section archive).
  - Attachment 2: list`Ct`list of contact persons for this inspection.
  - Attachment 3: Copy of the Letter <dd/mm/yyyy> Announcement of Joint EMA FDA GCP inspection to Applicant\_<product name>.
- Give the correspondence package to the scientific administrator for final check.
- Send the link of the letter by email to the scientific administrator for checking and to specify in the body of the letter that the inspection is a Joint EMA FDA GCP inspection. When the letter is checked, print the letter and give it back to the scientific administrator for signature.
- When received from scientific administrator scan the correspondence package, name it: "Letter <dd/mm/yyyy> Announcement of *Joint EMA FDA* GCP inspection to reporting inspectorate\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the Reporting Inspectorate.
- Add the PDF of the letter to Core Master File in DREAM.
- Send the letter via Eudralink to the applicant and copy Rapporteur, Co-Rapporteur, Inspectors, relevant EMA PTL, EMA GCP functional inspection inbox ([gcp@ema.europa.eu](mailto:gcp@ema.europa.eu)), FDA Functional inbox ([OC-OIP-Europe@fda.hhs.gov](mailto:OC-OIP-Europe@fda.hhs.gov)) and contact point for GCP Inspections in FDA.
- Save the Eudralink message in DREAM:
  - Open up Eudralink message;
  - File/Save as;
  - Save as "HTML only" on your desktop with name "Eudralink Letter <dd/mm/yyyy> Announcement of *Joint EMA FDA* GCP inspection to reporting inspectorate\_<product name>";
  - Import it to DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to the Reporting Inspectorate.
- File the original of the letter including attachments number 2 in hard copy product binder.
- Make one copy of the whole package of Letter <dd/mm/yyyy> Announcement of *Joint EMA FDA* GCP inspection to reporting inspectorate\_<product name> and give it to the Sector's Initiating agent.
- Forward the Eudralink message received by auto forward to inbox to Outlook/Folder list/All Public Folders/Human products to respective product folder.



In case one of the inspected sites is in third country other than USA, go to step 3.5.3. If not, your task of sending inspection correspondence is finished.

### **3.5.3. Announcement of GCP/PhV inspection to the third country inspectorate**

#### ***3.5.3.1. Announcement of GCP/PhV inspection to the third country inspectorate (other than Joint EMA/FDA GCP inspection)***

- Request a contact point of third country inspectorate for the inspection from scientific administrator.
- Enter the name, address, email address of contact point for the correspondence in third country inspectorate into the Corporate GxP.
- Draft a letter within 10 working days from adoption by CHMP/CVMP using BI Production GxP <http://bi.eudra.org>. Templates/choose relevant letter/Select Inspection Request number (for example GCP/2011/XXX)/Export/Open, when the letter is created, save it on L:drive as DOC (Word document) not as RTF (Rich Text Format), name it it "Letter <dd/mm/yyyy> Announcement of <GCP PhV> inspection to third country inspectorate\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to 3rd country inspectorates.
- Send the link of the letter by email to the scientific administrator for checking. When the letter is checked, print the letter and give it back to the scientific administrator for signature.
- Scan the letter, name it: "Letter <dd/mm/yyyy> Announcement of <GCP PhV> inspection to third country inspectorate\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to 3rd country inspectorates.
- Add the PDF of the letter to Core Master File in DREAM.
- Send the letter in PDF to the addressee with cc to Rapporteur, Co-Rapporteur, Inspectors, relevant EMA PTL, EMA GCP functional inspection inbox ([gcp@ema.europa.eu](mailto:gcp@ema.europa.eu)) and to the EMA International Liaison Officer via Eudralink.
- Save the Eudralink message in DREAM:
  - Open up Eudralink message;
  - File/Save as;
  - Save as "HTML only" on your desktop with name "Eudralink Letter <dd/mm/yyyy> Announcement of <GCP PhV> inspection to third country inspectorate\_<product name>";
  - Import it to DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to 3rd country inspectorates.
- File the original of the letter in hard copy product binder.
- Forward the Eudralink message received by auto forward to inbox to *Outlook/Folder list/All Public Folders/Human products* to respective product folder. Announcement of Joint EMA/FDA GCP inspection to the third country inspectorate

### 3.5.3.2. Announcement of Joint EMA/FDA GCP inspection to the third country inspectorate

Do this step only if the inspection is considered to be a joint EMA/FDA GCP inspection.

- Request a contact point of third country inspectorate for the inspection from scientific administrator.
- Enter the name, address, email address of contact point for the correspondence in third country inspectorate to the Corporate GxP.
- Draft a letter within 10 working days from adoption by CHMP/CVMP using BI Production GxP <http://bi.eudra.org>. Templates/choose relevant letter/Select Inspection Request number (for example GCP/2011/XXX)/Export/Open, when the letter is created, save it on L:drive as DOC (Word document) not as RTF (Rich Text Format), name it it "Letter <dd/mm/yyyy> Announcement of Joint EMA FDA GCP inspection to third country inspectorate\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to 3rd country inspectorates.
- Send the link of the letter by email to the scientific administrator for checking and to specify in the body of the letter that the inspection is a Joint EMA FDA GCP inspection. Add in cc an email address of FDA functional inbox ([OC-OIP-Europe@fda.hhs.gov](mailto:OC-OIP-Europe@fda.hhs.gov)) and contact point for GCP Inspections in FDA (name to be confirmed with scientific administrator). When the letter is checked, print the letter and give it back to the scientific administrator for signature.
- Scan the letter, name it: "Letter <dd/mm/yyyy> Announcement of Joint EMA FDA GCP inspection to third country inspectorate\_<product name>" and save it in DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to 3rd country inspectorates.
- Add the PDF of the letter to Core Master File in DREAM.
- Send the letter via Eudralink to the applicant and copy Rapporteur, Co-Rapporteur, Inspectors, relevant EMA PTL, EMA GCP functional inspection inbox ([gcp@ema.europa.eu](mailto:gcp@ema.europa.eu)), FDA Functional inbox ([OC-OIP-Europe@fda.hhs.gov](mailto:OC-OIP-Europe@fda.hhs.gov)), contact point for GCP Inspections in FDA and to the EMA International Liaison Officer via Eudralink.
- Save the Eudralink message in DREAM:
  - Open up Eudralink message;
  - File/Save as;
  - Save as "HTML only" on your desktop with name "Eudralink Letter <dd/mm/yyyy> Announcement of *Joint EMA FDA GCP* inspection to third country inspectorate\_<product name>";
  - Import it to DREAM under 01.Evaluation of medicines/relevant product folder/07.Inspection/GCP or PhV/ Notification to 3rd country inspectorates.
- File the original of the letter in hard copy product binder.
- Forward the Eudralink message received by auto forward to inbox to *Outlook/Folder list/All Public Folders/Human products* to respective product folder.

Your task on sending inspection correspondence is finished.