EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Preparation of the annual GMP re-inspection programme		
Applies to: P-CI-MQC Section		
Status: **PUBLIC**		Document no.: WIN/INSP/2046
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Signature: On file	Signature: On file	Supersedes: N/A
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1. Changes since last revision

New WIN.

2. Records

Electronic copies of the documents prepared are stored in DREAM under Cabinets/04. Inspections/4. GMP/Planning and reporting/GMP inspections coordination.

Emails circulated for the preparation and finalisation of the programme are copied in the GMPINS mailbox, which can be found in Outlook under Public Folders / All Public Folders / Compliance and Inspection / MQC / GMPINS.

Documents needed for this WIN

- Template 1: Informing MAH about probable inspection request, saved in the X drive under: X:\Templates\Others\Compliance and Inspection\GMP\Inspection Coordination.

Related documents

- Compilation of Community procedures on inspections and exchange of information: EMA Public website > Home > Regulatory > Human medicines/Veterinary medicines > Inspections > GMP/GDP compliance > Community procedures.
- SOP/EMA/0101 Conducting checks for conflicts of interest of Agency employees assigned duties relating to medicinal products for human or veterinary use.
- SOP/INSP/2048 Co-ordination of GMP/GDP inspections.

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- WIN/INSP/2047 Inspection of quality control facilities located in 3rd countries.

3. Instructions

Abbreviations

AS = Active Substance.

CAP = Centrally Authorised Product.

CxMP = Committee for Medicinal Product for Human/Veterinary use.

EEA = European Economic Area.

EU = European Union.

GDP = Good Distribution Practice.

GMP = Good Manufacturing Practice.

MA = Marketing Authorisation.

MAH = Marketing Authorisation Holder.

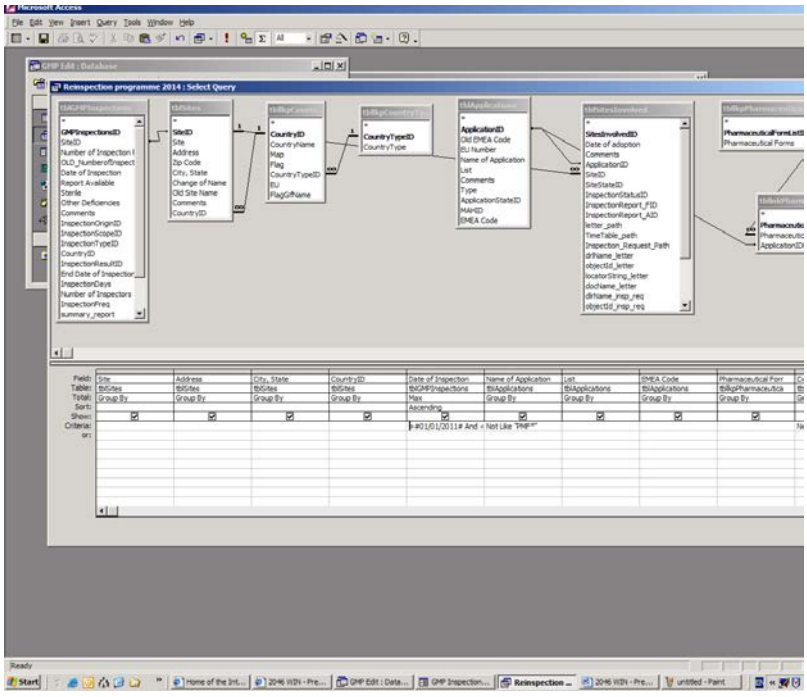
NCA = National Competent Authority.

P-CI-MQC = Manufacturing and Quality Compliance section, Compliance and Inspection sector, Patient Health Protection unit.

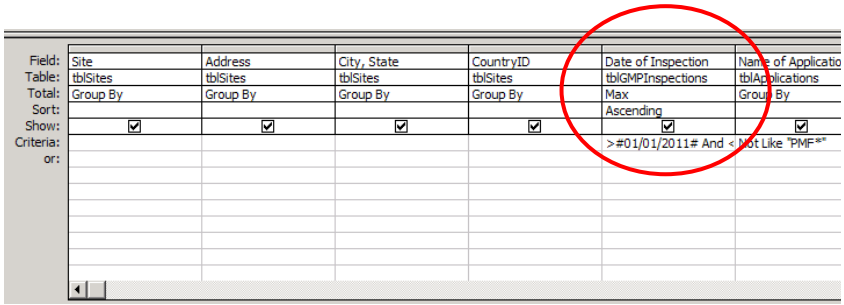
This WIN provides instructions for the preparation of the annual Good Manufacturing Practice (GMP) re-inspection programme for the year X. Such programme will include all the sites located in third countries (excluding those where a valid GMP agreement for the dosage form and/or the activity in question is in place) and for which a GMP inspection will be requested by the CxMP in the year X. Inspections requested in the year X are expected to be completed within 12 months from the month they were adopted unless otherwise justified. Because of the requirement set in the Compilation of Community Procedures, a site is usually re-inspected with a frequency which does not exceed three years unless otherwise justified[1]. This means that, in principle, sites where inspections are to be carried out in the year X+1, have been last inspected in the year X-2. In order to identify the manufacturing sites to be inspected, the P-CI-MQC section maintain an Access-based database (in this WIN called GMP database) in which these sites are recorded, together with the inspections dates.

[1] For inspections of quality control facilities located in 3rd countries, the interval between inspections should be no longer than 5 years (see WIN/INSP/2047).

Step	Action	Responsibility
1.	By October of year X-1, in order to comply with the requirements of the Compilation of Community Procedures on the re-inspections frequency and on request of the Administrator, prepare a query in the GMP database according to the following instructions: • Select `Objects-Queries' in the 'GMP Edit: Database' window; • Select, copy and paste one of the existing queries called `Re-inspection Programme YYYY'; • Rename new query with current year and double-click to open it; • Click on the first icon  on the toolbar to change to 'Design View' (see screenshot):	Assistant



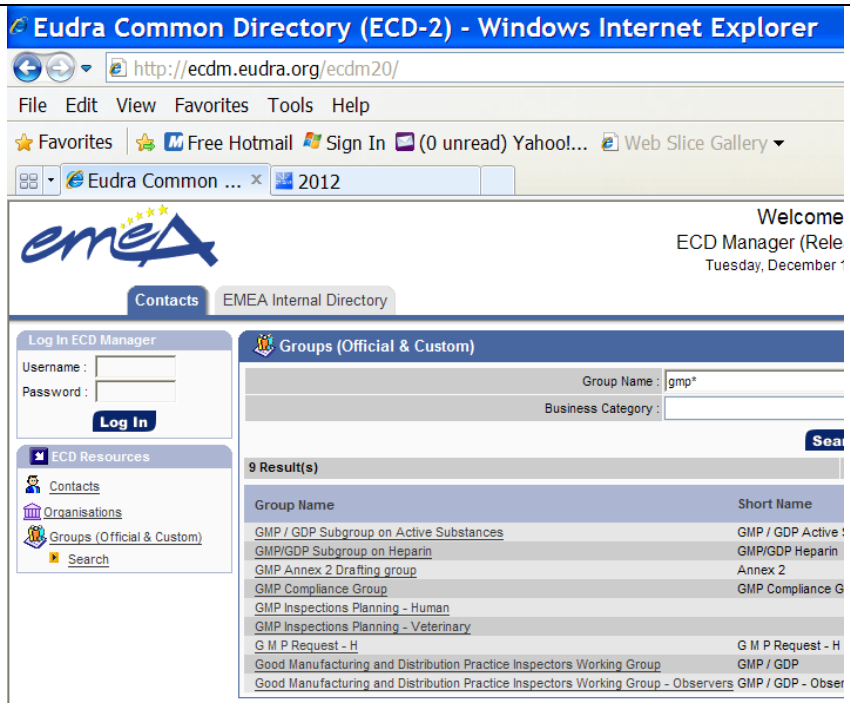
• Modify the query by changing the 'Criteria' in the 'Date of inspection' field, to include the dates of inspections carried out between 1 January and 31 December of the year X-2 (e.g. for the 2013 programme, >#01/01/2011# And <#31/12/2011#);



• In order to identify quality control facilities, run also a query for

Step	Action	Responsibility
	years X-3 and X-4, as this would allow to identify quality control sites that are re-inspected within the longest allowed interval of 5 years; • Click on the first icon  on the toolbar to change to 'Datasheet View'; • Click on 'Save' in order to export the query. These queries will allow to identify the sites inspected in the year X-2, X-3, or X-4.	
2.	The query will allow to obtain the following information for each site: • Full address; • Date of last inspection; • Name and pharmaceutical form(s) of each centrally authorised product (CAP) for which one or more manufacturing activities are carried out at the site; Export the result of the query into an Excel spreadsheet: • Click on `File'; • Select `Export'; • Choose location where the file will be saved (e.g. desktop); • Save as `Microsoft Excel 97-2000' format.	Assistant
3.	Add to the spreadsheet the following information for each site: • For each combination CAP/pharmaceutical form, the location of the batch release site; • For each CAP, whether it is a human/veterinary product; • For each combination CAP/pharmaceutical form, the list of activities carried out at the site; • Supervisory authority based on the country where the batch release site is located; • Proposed lead inspectorate chosen among the supervisory authorities; • Proposed supporting inspectorate chosen among the supervisory authorities; • Proposed reporting deadline (12 months from the month of adoption unless otherwise justified). If necessary, remove the following information from the spreadsheet:	Administrator

Step	Action	Responsibility
	• Sites located in third countries with a valid GMP agreement for the dosage form and/or the activity in question; • Sites where manufacture of non-sterile active substances for chemical products is carried out; • Sites where manufacture of AS intermediate for chemical products is carried out; • Sites where quality control for non-sterile active substances for chemical products is carried out. Keep in the list: • Sites which manufacture sterile active substances for chemical products; • Sites which manufacture active substances for biological products; • Sites where quality control of sterile active substances for chemical products is carried out. Their inspection will be subject to the instructions contained in WIN/INSP/2047.	
4.	By the end of November of year X-1 send the spreadsheet with the draft re-inspection programme to the GMP contact persons of the National Competent Authorities (NCAs) in the EU/EEA Member States, asking to provide feedback in relation to: • Inspection team; • Sites recently inspected as part of their national inspection programmes; • Plan to inspect the sites as part of their national inspection programmes. The list of contact persons can be found on the EMA intranet > Business applications > Eudra Common Directory > Contacts > Groups (Official and Custom). Type ‘gmp*’ in the field ‘Group Name’ and select GMP Inspections Planning – Human/Veterinary, as appropriate (see screenshot):	Administrator

Step	Action	Responsibility
		
5.	Collect feedback from NCAs and prepare table with final re-inspection programme, for circulation to the GMP contact persons identified in step 4 by the end of December of year X-1.	Administrator
6.	For each product included in the programme, write an email to the relevant Marketing Authorisation Holder (MAH) informing that the site where the product is manufactured/packaged/tested etc. is going to be inspected using template 1. The email is to be sent by the end of December of year X-1 for the inspections to be requested between January and June of year X; by the end of May of year X, for the inspections to be requested between July and December of year X. Ask to provide the following information: • Whether the site has had an inspection in the last two years; • Whether the site will be withdrawn from the marketing authorisation (MA) in the next six months.	Administrator
7.	Use the information collected in step 6 to finalise the spreadsheet by deleting sites or products which are not due to be inspected.	Administrator
8.	Assign an inspection co-ordinator to each site. This is done by checking in Siamed II who is the GMP inspection co-ordinator for most of the products related to the site. Appointment of the inspection co-ordinator is agreed with the Section Head who is responsible for the implementation of the SOP/EMA/0101.	Administrator
9.	On an on-going basis, add to the scope of a site's inspection, those products (either new or existing) for which a new application (or a line extension/variation) shows that the site will be included in the products' MAs.	Assistant

Step	Action	Responsibility
	Continue with step 4 of SOP/INSP/2048.	