13 January 2017
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Work plan for the GMP/GDP Inspectors Working Group for 2017

Chairperson: David Cockburn

Adopted: December 2016

1. Meetings scheduled for 2017

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

- 14 - 16 February 2017
- 30 May - 1 June 2017
- 25 - 27 September 2017
- 5 - 7 December 2017

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

A joint meeting with Quality Working Party (QWP) will take place during the September 2017 meeting (27 September).

A meeting with the group's Interested Parties is planned to coincide with the December 2017 meeting (6 December).

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

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2. Guidelines

2.1. New EU Guidelines

Action: Lead

GMP Guide: Annex 21 (Importation of medicinal products)

Target date	Q2 2017
Comments	To provide the European Commission with a draft text for public consultation.

GMP and Marketing Authorisation Holders

Target date	Q3 2017
Comments	To develop a Reflection Paper on the relationship between GMP Compliance and the responsibilities and activities of Marketing Authorisation Holders and Manufacturing Authorisation Holders.

Action: Specialised input

Development of GMP guidelines for advanced therapy medicinal products

Leading group	European Commission
Target date	Under responsibility of the European Commission
Comments	To continue to work with the European Commission and the Committee for Advanced Therapies (CAT) by providing expert input.

Development of the detailed Commission guidelines on GMP for investigational medicinal products for human use

Leading group	European Commission
Target date	Under responsibility of the European Commission
Comments	To continue to work with the European Commission by providing expert input.

2.2. EU Guidelines under revision

Action: Lead

GMP Guide: Introductions

Target date	Q4 2017
Comments	To provide the European Commission with a draft text in view of recent changes to the overall structure of EU GMP guidance, including IMPs, ATMPs and active substances.

GMP Guide: Chapter 1 (Pharmaceutical Quality System)

Target date	Q2 2017
Comments	To further explore whether it is possible to proceed with a proposal to amend the chapter in order to capture relevant principles aimed at reducing shortages caused by quality/manufacturing problems, taking account of the industry inter-association shortages taskforce guidelines.

GMP Guide: Chapter 4 (Documentation)

Target date	Q1 2017
Comments	To consider whether amendments are required in order to assure data integrity in the context of GMP. This would be in parallel with similar consideration of Annex 11 (Computerised Systems). To work with GCP IWG, GLP IWG and PhV IWG on this topic.

GMP Guide: Annex 1 (Manufacture of Sterile Medicinal Products)

Target date	Q2 2017
Comments	To provide the European Commission with a draft text for public consultation. To review public comments on Q&As dealing with the production of Water for Injections by Reverse Osmosis and control of biofilms and decide on appropriate way forward.

GMP Guide: Annex 11 (Computerised Systems)

Target date	Q1 2017
Comments	To consider whether amendments are required in order to assure data integrity in the context of GMP. This would be in parallel with similar consideration of Chapter 4 (Documentation). To work with GCP IWG, GLP IWG and PhV IWG on this topic.

GMP Guide: Annex 17 (Parametric Release)

Target date	Q2 2017
Comments	To provide the European Commission with a finalised text.

2.3. ICH Guidelines

ICH Q12 (Lifecycle Management)

Target date	Step 2a planned in June 2017
Comments	Step 1 initiated in September 2014 To support the EU members of the Expert Working Group (EWG) in developing the guideline with particular emphasis on GMP inspection and Pharmaceutical Quality System aspects.

3. Medicinal Products-specific activities

3.1. Pre-Authorisation activities

- Contribution to scientific advice procedures as required.

3.2. Evaluation and supervision activities

- Contribution to marketing authorisation procedures as required;
- Agreement on EMA's annual re-inspection programme;
- Development of procedures and co-ordination of inspections relating to centrally authorised products and plasma master files;
- The Agency will continue to make 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;
- Consideration is needed on the impact of initiatives designed to lead to earlier access to medicines on GMP inspections.

4. Input in European activities

4.1. Training for the network and knowledge building

- Organise training on EU inspection system for new inspectors. Dates and modality (virtual or face-to-face) to be confirmed;
- Organise specific virtual trainings:
  - Water for injections;
  - Market surveillance & Sampling and testing.

  Dates to be defined.
- Incorporation of national virtual trainings (in national languages) on the EU Network Training Centre platform;
- Develop a plan in order to deliver training in response to the "Multiannual work programme to 2020".

4.2. Other input in European activities

The group will undertake any other relevant work referred to it by the European Commission, Heads of Medicines Agencies or the scientific committees of the European Medicines Agency. This will include contributing as needed in the EU regulatory network's response to crises resulting from serious quality/manufacturing problems and/or GMP non-compliance.

Joint Audit Programme

- To ensure auditor resource contribution to the audit programme;
- 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 2017 is carried out and to report to the Heads of Medicines Agencies on the 2016 programme;
- To implement risk-based audit procedures;
- To monitor the results of audits and follow up as necessary;
- To develop a formal process for the follow-up of significant issues raised in the programme.

Compilation of Union Procedures on Inspections and Exchange of Information

- To develop harmonised approaches to compliance management;
- To finalise the procedure for dealing with serious GDP (Good Distribution Practice) non-compliance;
- To update the Manufacturing Authorisation and GMP certificate interpretation documents (i.e. "Special Requirements" menu) as part of the implementation of the revised GMP guidance on shared manufacturing facilities;
- To revise the procedures for handling Quality Defects and Rapid Alerts;
- To harmonise practices in relation to GMP certificates and non-compliance statements;

- To continue to identify GMP and GDP inspection related topics for development as Union procedures.

EudraGMDP database

- To continue to oversee the EudraGMDP database;
- To support the integration of the database with the Agency's Master Data Management project;
- To promote further use of the planning module as a tool for international collaboration.

Collaboration with European Commission

- EU enlargement: to develop contacts and collaboration 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 Clinical Trials Regulation (Regulation (EU) No 536/2014) on GMP inspection and related activities and agree on practical implementation steps;
  - Development of new legislation for veterinary medicinal products.
- 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.

Other EU collaborations

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:

- Joint CHMP/CVMP Quality Working Party;
- EU Process Analytical Technology team;
- Biologics Working Party;
- Safety Working Party;
- Heads of Medicines Agencies' Working Group of Enforcement Officers.

5. Input in International activities (beyond 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;
- continuing to leverage audits of the equivalence of GMP inspectorates conducted by international partners.

Heparin

To develop and implement an appropriate supervision plan for the heparin supply chain in consultation with international partners.

Mutual Recognition Agreements

To promote alignment of 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.

- **Canada**

  Once ratified, to move the Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada on the Mutual Recognition of the Compliance and Enforcement Programme regarding GMP for pharmaceutical products into operation.

- **Japan**

  To continue to work towards extension of the operational scope of the MRA.

- **Switzerland**

  To continue to maintain the functioning of the MRA and to work with the European Commission should changes to the agreement be considered.

- **Australia**

  To continue to maintain the functioning of the MRA;

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

- **New Zealand**

  To continue to maintain the functioning of the MRA.

- **Israel**

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

- **United States of America**

  To work on successful implementation of the EU-US MRA.

Other collaborations

- **India and China**

  Supporting collaborative initiatives with Indian and Chinese regulators (e.g. capacity building and training on EU GMP standards).

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

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

6. Contribution to dialogue and engagement with stakeholders and external parties

6.1. Workshops

Explore the possibility of organising together with SWP and vSWP a workshop for manufacturers, inspectors and toxicologists on the implementation of the updated shared facilities guidance.

6.2. Other activities with stakeholders and external parties

Improve collaboration with Industry associations and relevant professional associations (Interested Parties).

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

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2009/10/WC500004873.pdf