



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 November 2017
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Inspections, Human Medicines Pharmacovigilance & Committees Division

Work plan for the GMP/GDP Inspectors Working Group for 2018

Chairperson: Brendan Cuddy

Adopted: December 2017

The activities outlined in the work plan for 2018 have been agreed in view of preparation for the Agency's relocation as a result of the UK's exit from the EU and its impact on the Agency's business continuity, and may be subject to further review and reprioritisation in accordance with the business continuity plan of the Agency.

1. Meetings scheduled for 2018

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

- 27 February – 1 March 2018
- 4 – 6 June 2018
- 4 – 6 December 2018

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

A meeting with the group's Interested Parties is planned to coincide with the December 2018 meeting (5 December).

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



2. Guidelines

2.1. New EU Guidelines

Action: Lead

GMP Guide: Annex 21 (Importation of medicinal products)

Target date	Q4 2018
Comments	To provide the European Commission with a final text for publication.

GMP and Marketing Authorisation Holders

Target date	Q4 2018
Comments	To finalise 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

Guideline on the sterilisation of the medicinal product, active substance, excipient and primary container, EMA/CHMP/CVMP/QWP/BWP/850374/2015 (H/V)

Leading group	Quality Working Party (QWP)
Target date	Final guideline to be published Q2 2018
Comments	Public consultation of the draft guideline ended 13 October 2016.

2.2. EU Guidelines under revision

Action: Lead

GMP Guide: Introductions

Target date	Q4 2018
Comments	To provide the European Commission with a final text in view of recent changes to the legal basis for GMP affecting the overall structure of EU GMP guidance, including authorised products, IMPs, ATMPs and active substances.

GMP Guide: Chapter 1 (Pharmaceutical Quality System)

Target date	Q4 2018
Comments	To draft a proposal to amend the chapter in order to encourage industry adoption of risk-based approaches to prevention of shortages, taking account initiatives such as HMA-EMA Taskforce and the industry inter-association guidelines.

GMP Guide: Chapter 4 (Documentation)

Target date	Q4 2018
Comments	To draft a proposal to amend the chapter 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	Q4 2018
Comments	To incorporate guidance included in Q&As dealing with the production of Water for Injections by Reverse Osmosis and control of biofilms. To provide the European Commission with a final text for publication.

GMP Guide: Annex 11 (Computerised Systems)

Target date	Q4 2018
Comments	To draft a proposal to amend the chapter 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.

Action: Specialised input

Guideline on the manufacture of the finished dosage form (V)

Leading group	Quality Working Party (QWP)
Target date	Draft guideline to be released for 6 month public consultation Q1 2018
Comments	Public consultation of the concept paper ended 17 October 2015.

Guideline on quality of water for pharmaceutical use (H+V)

Leading group	Quality Working Party (QWP)
Target date	Draft guideline to be released for 6 month public consultation Q3 2018
Comments	Public consultation of the concept paper ended 6 June 2017.

2.3. ICH Guidelines

ICH Q12 (Lifecycle Management)

Target date	Ongoing
Comments	Step 2b initiated in November 2017 Step 2a initiated in June 2017 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.

2.4. Other guidance

Action: Lead

Q&As on the implementation of the updated shared facilities guidance

Target date	Q2 2018
Comments	To publish Q&As.

3. Medicinal Product-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 for third-country blood establishments;
- Making 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;

- GMP expertise and support to scientific aspects related to accelerated access schemes;
- Review of GMP provisions in the context of 'disruptive innovation' and propose revisions to GMP guidance interlinking with EMA Innovation Task Force and similar initiatives, as appropriate.

4. Input into European activities

4.1. 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.

4.2. 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 2018 is carried out and to report to the Heads of Medicines Agencies on the 2017 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.

4.3. Compilation of Union Procedures on Inspections and Exchange of Information

- To finalise the update of the procedure for dealing with serious GMP non-compliance;

- To finalise the procedure for dealing with serious GDP 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;
- To identify and implement, as needed, editorial updates following the entry into force of the new delegated regulation for GMP, the Clinical Trial Regulation and GMP for IMP;
- To identify and implement, as needed, updates following the publication of the GMP guideline for ATMPs.

4.4. 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 EU and international collaboration;
- To identify and implement, as needed, editorial updates following the entry into force of the new delegated regulation for GMP, the Clinical Trial Regulation and GMP for IMP.

4.5. Training for the network and knowledge management

- Support one annual inspector training event during 2018.
- Develop a plan in order to deliver training in response to the “Multiannual work programme to 2020”.

4.6. 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.

4.7. Other input into 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.

5. Input into 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.

5.1. Mutual Recognition Agreements

To support the European Commission in the equivalency assessment of the supervision of finished product manufacturers by third country authorities at their request for any new agreements or changes to existing 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.

- **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.

- **Canada**

To support the implementation and ongoing maintenance of the Comprehensive Economic and Trade Agreement (CETA).

- **Israel**

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

- **Japan**

To continue to maintain the functioning of the MRA.

- **New Zealand**

To continue to maintain the functioning of the MRA.

- **Switzerland**

To continue to maintain the functioning of the MRA.

- **United States of America**

To continue to support the implementation of the EU-US MRA.

5.2. Other collaborations

- **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.

- **India and China**

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

- **International collaboration on supervision of Heparin supply chain**

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

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

6.1. Workshops

To support training for inspectors 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