EUROPEAN MEDICINES AGENCY
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Concept Paper on the Revision of Chapter 6 of the EU GMP Guide Quality Control

Agreed by GMP/GDP Inspectors Working Group	September 2010
Deadline for comments	28 February 2011

Comments should be provided using this template. The completed comments form should be sent to ADM-GMDP@ema.europa.eu

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1. Introduction

Chapter 6 of the EU GMP guide provides general guidance on the Quality Control Department and Good Quality Control Laboratory Practice including specific aspects for documentation, sampling and testing. General aspects for premises and equipment, documentation and the use of contract laboratories are linked to Chapters 3, 4 and 7, respectively, of the EU GMP guide.

2. Problem Statement

During inspections, GMP inspectors have noted that the root causes for suspected out-of-specification (OOS) results are sometimes attributed to a lack of test method validation in the context of transfer of analytical methods. Such situations also occur frequently at contract Quality Control laboratories.

3. Discussion

In the context of globalisation of manufacturing activities and the development of new concepts like Quality by Design, where technology transfer is expected to happen worldwide both within and between companies, within the same country as well as between countries, the need for guidance for transfer of analytical methods has been identified.

The revision process for Chapter 6 will also assess the need to take into consideration:

- the current guidance in Annexes 16, 19 and 20,
- the ICH Q8, Q9, Q10 documents,
- the draft document ICH Q11,
- the ongoing revision of Chapters 4, 7 and Annex 11,
- the development of new technologies such as Near Infrared Spectroscopy (NIR) in the context of raw material identification and Process Analytical Technology (PAT).

The need to provide specific guidance for endotoxin and microbiological testing will also be considered.

4. Recommendation

It is therefore recommended that a specific section of Chapter 6 should be developed to provide guidance to industry and Inspectors for the transfer of analytical methods from one laboratory to another.

The content of Chapter 6 should also be reviewed to include guidance on technical transfer in conjunction with the new concepts and guidelines mentioned above.

5. Proposed Timetable

- Adoption of the Concept Paper by the GMP/GDP IWG at the September meeting in 2010.
- Preparation of a first draft by the drafting group by the September 2011 meeting of GMP/GDP IWG.
- Discussion on the draft at the September 2011 meeting during the joint meeting with the QWP. BWP will also be consulted for comments.

- Adoption of the final draft at the February 2012 meeting.
- It is anticipated that the start of consultation on a new guideline could be achieved after the February 2011 meeting.
- Public consultation for a minimum of three months (approximately June 2012).
- Adoption of the final document by GMP GDP IWG during the last meeting in 2012 for adoption and publication by the European Commission.

6. Resource Requirements for Preparation

A drafting group of Inspectors has already been identified with United Kingdom (H), Ireland, EDQM and France (H) as rapporteur. The drafting group will liaise and exchange experiences with OMCLs. The drafting group will meet via teleconference as well as at dedicated drafting group meetings of which three or four may be required.

7. Impact Assessment (Anticipated)

The clear requirements for transfer of analytical methods would be the main factor which would impact additional burden on companies because at the moment, some of them have not implemented such a process.

Others changes would include clarification of guidance but would not have resource implications. These changes would facilitate a harmonised regulatory policy.

The impact on Annex 8 will also be considered in the context of identification of raw materials.

8. Interested Parties

The drafting group will liaise and exchange experiences from PIC/S and MRA partners.

The draft guideline will be made publicly available to interested parties for a minimum 3 month consultation period before finalisation.

9. References to Literature, Guidelines etc.

1. Guideline of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Q2 (R1): Validation of Analytical procedures: Text and Methodology.
2. The European Pharmacopoeia.
3. Official Medicines Control Laboratories Network or the Council of Europe, Quality Assurance Documents: PA/PH/OMCL (05) 47 DEF – Validation of Analytical Procedures.
4. WHO guideline on Transfer of technology. Draft Document QAS/08.259 rev 1, September 2009.
5. WHO Good practices for pharmaceutical quality control laboratories. Draft Document QAS/09.296 May 2009.
6. The U.S. Pharmacopoeia., 31st edition. General chapters: < 1225> Validation of compendial procedures, 2009.

7. ICH Harmonized tripartite Guideline. Pharmaceutical development. Q8
8. ICH Harmonized tripartite Guideline. Quality Risk Management. Q9
9. ICH Harmonized tripartite Guideline. Pharmaceutical Quality System. Q10
10. ICH Harmonized tripartite drafted Guideline Development and Manufacture of Drugs Substances Q11,
11. EU GMP Guide, Annexes 8,16 and 19.
12. Draft or adopted version of chapter 4 and Annex 11.
13. Draft or adopted version of the Note for Guidance for Near Infrared Spectroscopy.