



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CHMP/CVMP/QWP/780614/2011
Compliance and Inspection

Work Plan for the Joint CHMP/CVMP Quality Working Party 2012

Chairperson:

Jean-Louis Robert

Status

February 2012

The following work plan is a joint human and veterinary plan.

H - Indicates a Human only topic

V - Indicates a Veterinary only topic

H/V - Indicates a joint Human/Veterinary topic

1. Meetings scheduled for 2012

Plenary meetings (4/year):

- 31 January - 2 February 2012
- 2 – 4 May 2012 (including QWP/Interested Parties Meeting)
- 5-7 September 2012 (including Joint QWP/GMDP IWG Meeting)
- 20 - 22 November 2012

All QWP plenary meetings have participants with expertise in quality of human and veterinary medicinal products, observers from EDQM (European Directorate for Quality of Medicines and HealthCare), EU accession countries and occasionally from Regulatory Authorities outside the EU. Each meeting is scheduled to take 3 days involving about 60 members per meeting. Break Out Sessions on specific subjects, involving a subset of the participants are organised during the meetings.

- H/V Joint QWP/GMP Inspectors Meeting (1/year);
- H/V Interested Parties Meetings (1/year).



- Drafting/expert groups¹ involving, if appropriate, external experts and representatives of other working parties and/or inspectors:
 - H/V Joint QWP/BWP/GMDP IWG EMA Process Analytical Technology Team (4 x 1 day meetings);
 - Other drafting/expert groups, as deemed necessary.

2. Product related issues

- H/V Involvement in product dossiers;
- The following table provides the expected number of Quality Working Party contributions (number of involvements in dossier) in 2012 for scientific advice, protocol assistance, product assessment, and Post-Authorisation issues;

	Expected contributions in scientific advice and/or protocol assistance ²	Product assessment (pre- and post-authorisation issues)
Expected contribution	20	8

- H/V Review quality matters arising from assessment of applications and scientific advice/protocol assistance for the need to develop additional QWP Guidelines and/or Questions/Answers;
- H/V Provide advice on product related issues referred by the Committee on Herbal Medicinal Products (HMPC).

3. CHMP/CVMP Guidance documents

The QWP welcomes the contribution of interested parties to the consideration of additional topics for CXMP concept papers and guidelines. Contributions should preferably be made during the interested party meetings and in any case before the third quarter of a year to ensure consideration for the work plan of the following year.

New technologies and approaches to quality as described in ICH guidelines Q8 (Pharmaceutical Development), Q9 (Quality Risk Management), Q10 (Pharmaceutical Quality Systems) and Q11 (Development and Manufacture of Drug Substances):

- H/V Guideline on the Use of Near Infrared Spectroscopy (CPMP/QWP/3309/01 & EMEA/CVMP/961/01): Finalisation of revision;
- H Guideline on Parametric Release (CPMP/QWP/3015/99): Finalisation of revision;
- V Guideline on Parametric Release (EMEA/CVMP/QWP/339588/2005): consideration of and concept paper for the revision of;
- H/V Guideline on Process Validation (CHMP/QWP/848/96 & EMEA/CVMP/598/99): Finalisation of revision;

¹ If feasible and depending on its size and workload a drafting/expert meeting might be replaced by a virtual meeting

² This includes formal scientific advice procedures as well as other referrals

- V Guidance on genotoxic impurities in veterinary medicinal products: with SWP-V, consideration and contribution to a concept paper for the development of;
- H/V Work on the development of an EU harmonised approach to application of Quality Risk Management to the assessment of applications;
- H/V Discussion on the impact of new technologies and approaches as described in ICH guidelines Q8, Q9, Q10 and Q11 on other quality guidelines, e.g.:
 - Guidelines on Specifications (CPMP/ICH/367/96, 3AQ11a Volume IIIA & EMEA/CVMP/815/00);
 - Guidelines on Manufacture of the Finished Dosage Form (CPMP/QWP/848/96 & EMEA/CVMP/126/95);
 - Guidelines on the Chemistry of New Active Substances (CPMP/QWP/130/96-Rev1 & EMEA/CVMP/541/03).
- H Guideline on Pharmaceutical Development of Medicines for Paediatric Use: Finalisation;
- H/V Guideline on Setting Specifications for Related Impurities in Antibiotics: Finalisation;
- H Guideline on Radiopharmaceuticals Based on Monoclonal Antibodies (EudraLex 3AQ21A): Publication of the draft revised guideline for external consultation;
- H/V Guideline on Stability Testing for Applications for Variations to a Marketing Authorisation: Finalisation of revision;
- H Guideline on Modified Release Products: Finalisation;
- H/V Guidelines on Declaration of Storage Conditions (CPMP/QWP/609/96/Rev 2 & EMEA/CVMP/422/99/Rev.3): Start of revision in co-operation with the GMDP-IWG in order to address conditions during transportation;
- H Reflection Paper on Liposomal Products: Finalisation;
- H Reflection Paper on Injectable Micellar Systems: Finalisation;
- H/V Guideline on Active Substance Master File Procedure (refer to V.4 also): Finalisation; then update of any necessary associated guidelines, e.g., Guidelines on the Chemistry of New Active Substances (CPMP/QWP/130/96-Rev1 & EMEA/CVMP/541/03); Summary of requirements for active substances in the quality part of the dossier (EMEA/CVMP/1069/02 & EMEA/CVMP/1069/02);
- H/V QWP Questions/Answers document (EMA website): Update of the document after each QWP meeting;
- H/V Update, operation and maintenance of the QWP Quality Database, accessible to all quality assessors in the Member States, where harmonised decisions taken at QWP meetings are recorded;
- V Review of applicability and adaptation of CPMP/CHMP guidelines to veterinary medicinal products;
- H/V Review of validity of existing human and veterinary quality guidelines and other QWP guidance documents.

4. (V)ICH Guidelines and Activities

The Quality Working Party will contribute to development and implementation of applicable (V)ICH guidelines, in particular by contributing to the following activities:

H ICH:

- Finalisation of the ICH Q11 guideline on Development and Manufacture of Drug Substances after external consultation;
- Development of ICH M7 on Genotoxic Impurities;
- Development of ICH Q3D on Metal Impurities;
- Implementation in the EU of ICH Q8 (Pharmaceutical Development), Q9 (Quality Risk Management) and Q10 (Pharmaceutical Quality Systems);
- Discussion on Common technical document (ICH topic M4);
- Development, review and update of other ICH Quality Guidelines, as requested.

V VICH:

- Development of a VICH Guideline on the Evaluation of Stability Data;
- Development of a VICH Guideline on Bioequivalence;
- Development, review and update of other VICH quality guidelines, as requested;
- Other VICH quality developments, including application of ICH Q8, Q9, Q10 and Q11 to veterinary medicinal products.

5. EU Regulatory Activities

- H/V Provide advice/active participation for training of assessors;
- H/V Co-operation with EMA Committees;

In addition to the activities listed in sections 2 and 3:

- Provide recommendations to EMA committees (CHMP, CVMP, HMPC, COMP, PDCO and CAT), on matters relating directly or indirectly to the quality of medicinal products;
- On request from HMPC, update QWP guidelines or other guidance documents to take into account herbal medicinal products, also in relation to the legislative provisions for traditional herbal medicinal products.

H/V Co-operation with GMP/GDP inspectors working group:

- Facilitate the cooperation between quality assessors and GMP inspectors on general topics of mutual interest and in the assessment of applications;
- Facilitate the introduction of new approaches to manufacturing and control methodologies (e.g. PAT) through the EMA PAT Team: discussions on further development of the team and its mandate once sufficient experience is gained;
- Contribution to discussions on anti-falsification activities.

- H/V Contribute to the discussion at CMDh on improvement of the efficiencies of current practices related to the assessment of ASMFs. (Also applies to Veterinary.);
- H/V Co-operation with EMA Committees, and Working Parties and other groups operating in the field of quality (e.g., CAT, PDCO, BWP, IWP, GMDP IWG, CMDh, CMDv, JEG 3Rs).

6. Activities with external parties

H/V Collaboration with EDQM on:

- Project for impurities: review of qualification and limits of impurities of existing medicinal products authorised on the market in the EU/EEA, having regard to general chapters and monographs of the Ph.Eur. and Article 23 of Council Directive 2001/83/EC as amended and Article 27 of Directive 2001/82/EC as amended;
- Development and review of Pharmacopoeial monographs and general chapters and notices;
- Certification of Suitability Scheme policies and other related documents, including contribution to the setting up of a procedure to deal with withdrawals of Certificates of Suitability;
- Sampling and Testing of Centrally Authorised Products;
- Pharmacopoeial Discussion Group (PDG), through matters referred to the QWP by EDQM;
- Involvement in and contribution to quality related seminars organised by EDQM;

H/V Collaboration with Drug Regulatory Authorities outside the EU/EEA in addition to (V)ICH activities:

- Liaison with FDA (e.g. through the EMA PAT Team), Health Canada and Japanese Ministry of Health, Labour and Welfare, on matters of common interest.

H/V Collaboration with Interested Parties, including industry associations on:

- Consultation on QWP concept papers and guidelines;
- Continue dialogue on new technologies and approaches (e.g. through workshops with interested parties on topics of common interest, see also section 1).

H Support to joint project on evaluation of structural similarity with the University of Sheffield.

7. Organisational matters

Maintenance of adopted organisational documents:

- Mandate for Joint CHMP/CVMP Quality Working Party;
- Work plan;
- Quality database for assessors.