EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 November 2015
EMA/CHMP/CVMP/QWP/479335/2015
Compliance and Inspection

Work plan for the joint CHMP/CVMP Quality Working Party 2016

Adopted:

November 2015

Chairperson:

Jean-Louis Robert

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 2016

Plenary meetings (4/year):

- 1 – 3 March 2016;
- 31 May – 2 June 2016 (including QWP/Interested Parties meeting);
- 19 – 21 September 2016 (including joint QWP/GMDP IWG meeting); and
- 29 November – 1 December 2016.

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.

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2015. Reproduction is authorised provided the source is acknowledged.

- H/V joint QWP/GMP inspectors meeting (1/year);
- H/V interested parties meetings (1/year),
- Drafting/expert groups involving, if appropriate, external experts and representatives of other working parties and/or inspectors (virtual meetings - as deemed necessary);
- QWP core team (11 virtual meetings/year); and
- H/V joint QWP/BWP/GMDP IWG EMA Process Analytical Technology team (2 x 1 day meetings + 2 virtual meetings).

2. Product related issues

- H/V involvement in product dossiers.
- The following table provides the expected number of Quality Working Party contributions (including QWP Core Team contributions) in 2016 for scientific advice, protocol assistance, product assessment and post-authorisation issues.

	Expected contributions in scientific advice and/or protocol assistance [1]	Product assessment (pre- and post-authorisation issues)
Expected contribution (number of involvements in dossier)	80	50

- 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 provides 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 and V guidelines on the manufacture of the finished dosage form (CPMP/QWP/848/96 & EMEA/CVMP/126/95): revision;

[1] This includes formal scientific advice procedures as well as other referrals.

  - H and V guidelines on the chemistry of active substances (bridged revision of H/V guideline on the chemistry of active substances (3AQ5a/1987 & H&V guidelines on the chemistry of new active substances (CPMP/QWP/130/96-Rev1 & EMEA/CVMP/541/03); and
  - H/V Q/As documents on QbD pilot.
- V guidance on genotoxic impurities in veterinary medicinal products: (multidisciplinary topic led by SWP) contribution to the development;
- V guidance on (the conduct of efficacy studies for) intramammary products for use in cattle: (multidisciplinary topic led by EWP) revision; contribution to the development of an Annex on Biowaivers;
- V guidance on quality data requirements for veterinary medicinal products intended for use in minor uses or minor species: revision;
- V guidance on conduct of bioequivalence studies for veterinary medicinal products: (multidisciplinary topic led by EWP) contribution to the revision;
- H and V reflection papers on the chemical structure and properties criteria to be considered for the evaluation of new active substance (NAS) status of chemical substances;
- H/V reflection paper on the assessment of the quality of medicinal products containing existing/known active substances: revision;
- H reflection paper on quality aspects of medicines for older people;
- H guideline on quality and equivalence of topical products;
- H/V guideline on the selection of sterilisation processes for drug products, active substances and primary packaging;
- H/V reflection paper on dissolution specification for immediate release products;
- H/V guideline on regulatory acceptance of 3Rs (replacement, reduction, refinement) testing approaches: (multidisciplinary topic led by JEG 3Rs): contribution to;
- H guideline on the requirements to the chemical and pharmaceutical quality documentation concerning investigational medicinal products in clinical trials & new Clinical Trials Regulation (H): revision;
- H/V QWP questions/answers document (EMA website): maintenance;
- 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;
- H/V update, operation and maintenance of the QWP core team database, accessible to all quality assessors in the member states, where decisions taken at QWP core team virtual meetings are recorded; and
- 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 the development and implementation of applicable (V)ICH guidelines, in particular by contributing to the following activities:

ICH:

- ICH Q3D on metal impurities – EU assessment strategy;
- ICH Q11 – API Starting Materials Implementation Working Group;
- ICH Q12 – Lifecycle management;
- Discussion on common technical document (ICH topic M4); and
- Development, review and update of other ICH quality guidelines, as requested.

VICH:

- Contribute to the development of new guidance on the stability testing of new drug substances and products for climatic zones III and IV;
- Contribute to development of new guideline on fixed combinations (EWP-V lead); and
- Development, review and update of other VICH quality guidelines, as requested.

5. EU regulatory activities

- H/V provides 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, CAT and PRAC), on matters relating directly or indirectly to the quality of medicinal products; and
  - 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; and
  - H contribution to discussions on anti-falsification activities.

- H/V contributes to the discussion at CMDh and CMDv on the improvement of the efficiencies of current practices related to the assessment of ASMFs.
- 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, SAWP, 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 and article 27 of Directive 2001/82/EC;
- Development and review of pharmacopoeial monographs and general chapters and notices;
- Sampling and testing of centrally authorised products;
- Pharmacopoeial discussion group (PDG), through matters referred to the QWP by EDQM;
- Involvement in and contribution to CEP procedures; and
- 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; and
- Continue dialogue on new technologies and approaches (e.g. through workshops with interested parties on topics of common interest, see also section 1).

7. Organisational matters

Maintenance of adopted organisational documents:

- Mandate for joint CHMP/CVMP Quality Working Party;
- Work plan;
- Quality database for assessors; and
- QWP core team database.

Organisation of trainings for quality assessors.

EU joint regulators/ industry workshop ICH Q3D guideline.