12 November 2024
EMA/188820/2024
Human Medicines Division

3-year work plan for the joint CHMP/CVMP Quality Working Party

Name of Working Party:	**Quality Working Party**
Chairperson:	Blanka Hirschlerová
Vice chair:	Nick Lee (H) and Marie-Helene Sabinotto (V)

Work plan period: 2025-2027

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of contents

1. Strategic goals

1.1. *Short-term strategic goals*

- Provide support to relevant Committees and Working Parties on all Quality matters pertaining to procedures for medicinal products containing chemical active substances or medical devices containing chemical active substances (i. e. ancillary substances)[1], with the aim to prepare QWP positions (peer reviewed/consensus driven positions) on quality aspects at key milestones of procedures for consideration into the benefit/risk discussion at CHMP.
- Continue to improve efficiency of internal interactions and QWP processes with a risk-based focus.
- Provide support to the EU Network on Quality matters related to decentralised/national procedures upon CMDh or CMDv requests. Support to the OMCL network, EDQM and other public health organisations in activities involving Quality matters of chemical medicinal products.
- Provide a forum for harmonisation of European approaches to Quality matters pertaining to the regulation of human and veterinary medicines containing chemical active substances and to ensure a common interpretation of EU guidelines related to Quality matters.
- Progress development of EU and international guidelines and identify/initiate new guidance topics as relevant. Consolidate learnings from new technologies (e.g., drug-device combinations) and provide support to training activities on implementation of priority guidelines.
- In collaboration with Quality Innovation Group (QIG) and other parties in the European Regulatory Network, advance international regulators and stakeholder interactions: academia, trade associations, interested parties, etc. Key areas for technical development / focus in collaboration with the QIG: PRIME early access and risk-based approaches, innovative materials and formulations, novel manufacturing approaches, new analytical technologies, digitalisation e. g., in manufacturing, and new concepts such as decentralized manufacturing, modelling, platform technologies and sustainable manufacturing.
- Provide oversight and leadership to Chemical Quality European Specialised Expert Community (ESEC).
- Support establishment of Operational Expert Groups (OEGs) to advise on events that directly impact the quality, safety and availability of medicines for patients (e.g., nitrosamines, titanium dioxide, COVID-19, medicines supply issues, etc.). Consolidate learnings from and support knowledge management in relation to such events.

1.2. *Long-term strategic goals*

The long-term strategic priorities for the QWP with reference to the European medicines agencies network strategy 2028 are as follows:

- Ensure the quality, in relation to the safety and efficacy, of marketed medicines.
- Reinforce scientific and regulatory capacity, resilience and capability of the network and improve the scientific quality of assessments.

[1] Chemical active substances refers to active substances obtained *via* chemical synthesis and to small molecules obtained by fermentation processes. The term chemical active substances is used throughout the document.

- Continue to streamline assessments by application of risk-proportionate approaches.
- Ensure dedicated collaboration with other Committees and Working Parties to advance regulatory science aspects of common interest, e.g., increasing overlap of synthetic processes / biology.
- In collaboration with QIG, facilitate the continued integration of science and technology in medicines development and ensure that the network has sufficient competencies to support innovation and associated technology platforms / regulatory science at various stages of medicines development. This includes support to digitalisation and personalised medicines.
- Increase collaboration with Good Manufacturing Practise (GMP)/Good Distribution Practice (GDP) Inspectors Working Group (GMDP IWG) to support synergies between assessment and inspection activities, consistent with simplification of dossiers and enabling risk ownership by Marketing Authorisation Holders.
- Advance collaboration with international partners to support harmonisation and encourage mutual reliance on assessments and inspections.
- Maintain appropriate regulatory science knowledge management as a resource to assist the network. In close collaboration with QIG, ESECs and other WPs of the Quality domain develop training related to new manufacturing technologies and regulatory science developments to equip EU assessors with the skills required to assess these new technologies.
- In collaboration with QIG, enhance collaboration with academic groups.
- Provide support to the European Commission on the development and implementation of new legislation, e.g., Pharma Strategy, Medical Devices, and the variations framework.
- Contribute to crisis and health threat responses and support network capability and agility as part of the response.

2. Tactical goals: activities/projects to deliver the strategic goals

2.1. *Guidance activities*

The below guideline activities reflect the strategic goals listed above, in particular to advance international harmonisation through support to (V)ICH guidelines, to support emerging technologies and to consolidate learnings/support knowledge management for strategic topic areas.

Guidance activities include review of existing QWP guidance and identification of published guidance that may benefit from revision.

Further guidance activities (new guidance/revisions) are expected in relation to the implementation of new/revised pharmaceutical legislation.

(A) Activities ongoing/to be finalised in 2025

EU Guidance documents, New, QWP lead:

- Questions and answers on comparison of quality attributes in support of therapeutical equivalence (H) – ongoing, publication of guidance in 2025

- Guideline on risk management requirements for elemental impurities in veterinary medicinal products (V) - publication of guideline in 2025
- Guideline on synthetic peptides (H/V) – publication of guideline in 2025
- Guideline on synthetic oligonucleotides (H/V) – publication of guideline in 2026
- Questions and answers on co-processed excipients (H/V) – publication of guidance in 2025

EU Guidance documents, New, QWP specialised input:

- QIG Preliminary Considerations on Pharmaceutical Process Models (H) – ongoing, led by QIG
- Guideline on requirements for clinical documentation for demonstration of therapeutic equivalence for nasal products (H) - ongoing, led by RIWP (Rheumatology and Immunology Working Party)
- Input into the generics drafting group (5-10 product specific guidelines are expected to be elaborated annually) (H)
- Guideline on the safety of nanoparticles – in the context of the establishment of maximum residue limits and veterinary marketing authorisations (V) – ongoing, led by NTWP (Novel Therapies and Technologies Working Party)

EU Guidance documents, Revision, QWP lead:

- Guideline on the Chemistry of Active Substances (H) – publication of revised guideline by Q4 2025
- Guideline on Radiopharmaceuticals (H) - ongoing, publication of revised guideline by Q4 2025
- Guideline on the pharmaceutical quality of inhalation and nasal medicinal products (H) – ongoing, publication of revised guideline in 2025
- In-use stability testing of veterinary medicinal products (excluding immunological veterinary medicinal products) (EMEA/CVMP/424/01 – FINAL) (V) – ongoing, finalisation by Q2 2025
- Maximum shelf-life for sterile medicinal products after first opening or following reconstitution (EMEA/CVMP/198/99 – FINAL) (V) – ongoing, finalisation by Q2 2025
- Guideline on Quality aspects of pharmaceutical veterinary medicines for administration via drinking water (EMEA/CVMP/540/03 Rev.1) (V) – ongoing, finalisation in 2026
- Revision of Annex I to Guideline for residual solvents (CPMP/ICH/283/95 / CVMP/VICH/502/99) (H/V) – publication of guidance in 2025

EU Guidance documents, Revision, QWP specialised input:

- Annex to the European Commission Guideline 'Excipients in the Label and Package leaflet for Medicinal Products for Human Use' (H) – ongoing, led by the NcWP
- Guideline on the requirements for clinical documentation for orally inhaled products (OIP) including the requirements for demonstration of therapeutic equivalence between two inhaled products for use in the treatment of Asthma and Chronic Obstructive Pulmonary Disease (COPD) in adults and for use in the treatment of asthma in children and adolescents, EMEA/CPMP/EWP/4151/00 Rev.1 (H) – publication of revised guideline, led by RIWP (Rheumatology and Immunology Working Party)
- Update of Question and Answers related to the QP declaration (H/V) - ongoing, led by GMDP-IWG

- Guideline on dossier requirements for anticancer medicinal products for dogs and cats (EMA/CVMP/28510/2008) – ongoing, led by EWP (V)
- Guideline on the conduct of bioequivalence studies for veterinary medicinal products (V) – ongoing, led by EWP (V)

(B) Activities to be started in 2025

EU Guidance documents, New/Revision, QWP lead/specialised input:

- Guidance supporting the implementation of the revised variation framework for human medicines (H or H/V)
- Update of existing question and answers to implement revisions required arising from changes arising from Regulation 2019/6 including those relating to the variations requirements and Annex II (V)

(C) Activities to be started in 2026-2027

QWP will consider the following:

- Guideline on medicinal gases: pharmaceutical documentation (including recommendation on non-clinical safety requirements for well-established medicinal gases) (H) – concept paper
- Revision of Guideline on excipients in the dossier for applications for marketing authorisation of a medicinal product (H)
- Revision of Guideline on ASMF procedure (H/V)
- Revision of Guideline on setting specifications for related impurities in antibiotics (H/V)
- Guideline on Use of near infrared spectroscopy (NIRS) by the pharmaceutical industry and the data requirements for new submissions and variations (H/V)
- The implications of any new legal frameworks and whether those are adequately covered by existing guidance documents.
- QWP guidance on drug-device combination products where an ancillary substance is incorporated into a device (e.g. drug-eluting stent). (H)
- To revise guidance related to investigational medicinal products in clinical trials. (H)

(D) Ongoing QWP support to (V)ICH guidelines (New/Revision/Training materials/Implementation)

- ICH Q1 Guidelines on Stability Testing and related ICH Q5C Guideline on Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products (revision)
- ICH Q2 Guideline on Analytical Validation (training and implementation)
- ICH Q3C Guideline for Residual Solvents (maintenance procedure)
- ICH Q3E Guideline on Extractables and Leachables (new)
- ICH Q6 Guideline on Specifications (revision)
- ICH Q12 Guideline on Lifecycle Management (implementation)

- ICH Q13 Guideline on Continuous Manufacturing of Drug Substances and Drug Products (training and implementation)
- ICH Q14 Guideline on Analytical Procedure Development (training and implementation)
- ICH M4Q(R2) Guideline on Common Technical Document for the registration of pharmaceuticals for human use – quality (revision)
- ICH M7 on Mutagenic Impurities (planned revision)
- VICH Guideline on between-strength biowaivers (new)
- VICH Guideline 60 on GMP for active substances for VMPs (new)
- VICH Guideline on stability of medicated premixes (revision)
- VICH Guideline 61 on pharmaceutical development (new)
- ICH Quality Discussion Group

Support as needed to (V)ICH discussions on topic selection/prioritisation, and future (V)ICH guideline activities.

2.2. *Training activities*

Continue training of quality assessors (human and veterinary, jointly, or separately) on a regular basis and building on the quality curriculum in the EU network training centre (EU-NTC) together with MWP, QIG, BWP and GMDP IWG as appropriate. This includes training and knowledge building on the implementation of (V)ICH guidelines, medicinal product/medical device combinations, modelling, and best practise for quality of decision making and reporting. Maintain awareness of issues arising from product-specific discussions, including training on QWP learnings as appropriate.

Training priorities for 2025:

- Training on quality and (bio)equivalence aspects of locally applied, locally acting cutaneous products and oral modified release products (together with MWP as appropriate) (H)
- Training on quality requirements for products intended for incorporation into animal feeding-stuffs (medicated premixes) (V)
- Variations with a particular focus on the recent revision (H)

Training under discussion for 2025-2027:

- Dissolution (for example, for new active substances used in medicinal products)
- ICH Q2/Q14
- ICH Q13

Further trainings may be added, as needed.

2.3. *Communication and Stakeholder activities*

2.3.1. European level

Continue to engage effectively with industry through Interested Party meeting platforms on a regular basis (i.e., yearly) to gain external perspective on regulatory science needs. Strategic direction is aligned with Agency priorities (work plan development). The Interested Parties' meeting can be

complemented by ad hoc meetings in smaller groups as needed, including jointly with other Working Parties.

In close collaboration with ESECs, contribute to horizon scanning with academic partners to determine future regulatory science needs.

To strengthen multistakeholder interactions on priority topics, QWP will continue to support workshops and continue to make the information available by broadcast / recording, and through meeting reports for public / stakeholder information.

Support priority initiatives on regulatory efficiency:

- the revision of the pharmaceutical legislation for human medicines, to provide for simplification, the streamlining of approval procedures and flexibility for the timely adaptation of technical requirements to scientific and technological developments.
- the revision of the variation framework for human medicines, through changes in legislation and guidelines, to make the lifecycle management of medicines more efficient and adapted to digitalisation.
- Continue to engage and provide expert support to other regulatory partners, such as Notified Bodies and the European Chemicals Agency (ECHA).

2.4. *International level*

Support harmonisation and encourage mutual reliance on assessments and inspections through collaboration with international regulatory authorities. Support discussions and initiatives of relevant international fora, including WHO, ICMRA. In particular, support to the collaborative ICMRA assessment pilots and support/training for the African Medicines Agency. Contribution on quality aspects to EMA-FDA collaboration on implementation of pre-approval GMP inspections in the context of the EU-US MRA, and dialogue on selected guidelines.

Continue to engage with Swissmedic (QWP observer).

QWP is also contributing in the International Pharmaceutical Regulators Programme (IPRP), and future collaboration with the American Society for Testing and Materials (ASTM) and the International Organization for Standardization (ISO) will be considered.

2.5. *Multidisciplinary collaboration*

Maintain, or strengthen as relevant, the ongoing collaboration with other working parties and groups, e.g., SAWP, QIG, GMDP-IWG, QRD as well as CMDh, BWP, MWP, NcWP, HMPC QDG, PDCO PF-OEG (for human medicinal products) and CMDv, SWP, EWP, IWP, NTWP (for veterinary medicinal products).

Collaboration with GMDP-IWG includes joint work in the area of Quality Defects and to update guidance related to the QP declaration and on co-processed excipients and is supported by annual joint QWP/BWP/GMDP-IWG plenary meetings.

Collaboration with MWP includes joint work in the area of bioequivalence and biowaivers requirements including the development of product-specific bioequivalence guidance and the use of Physiologically Based Biopharmaceutical Modelling (PBBM) in setting clinically relevant specifications, and in the area of comparing quality attributes.

Collaboration with NcWP includes joint work in the areas related to the safety evaluation of excipients, impurities including nitrosamines, extractables & leachables, and nanomaterials.

Continue to liaise and collaborate on quality-related matters with EDQM. Provide scientific input for the elaboration and revision of European Pharmacopoeia monographs, general chapters and notices, and scientific input and collaboration with EDQM including discussion at QWP on:

- EP terminology and standard terms
- scientific input on the project for impurities (review of qualification and limits of impurities of existing medicinal products authorised on the market in the EU/EEA with regards to new or revisions of specific monographs)
- prospective guidance, for example on the implementation of ICH guidelines e. g. ICH Q3D on elemental impurities)
- risk assessment and test recommendations for sampling and testing activities of decentralised products
- involvement in and contribution the EP certification scheme and to CEP procedures, - membership of CEP Steering Committee
- DCEP chemical TAB
- Involvement in and contribution to quality related seminars organised by EDQM
- Group 7/17/PAT expert group / HMA Post-Marketing Risk-Assessment Tool Working Group / Pharmacopoeial discussion group (PDG) contribution.

Continue collaboration with and provide QWP expert support to the OMCL network on the review of results from testing of centrally authorised products, on the risk assessment tool for products authorised via MRP/DCP and on surveillance studies.

Collaborate with the veterinary domain and the non-clinical domain for the review of product batch testing requirements with regards to the application of the 3Rs in batch release testing.

3. Operational goals: medicinal product-specific activities

3.1. *Pre-submission activities*

- Recommendations to CHMP and SAWP on applications for scientific advice and protocol assistance. This includes input related to nitrosamine impurities. For veterinary medicinal products these recommendations are to be provided upon CVMP's request only.
- Contribution to Innovation Task Force (ITF) and Quality Innovation Group (QIG).
- Contribution to scientific aspects in relation to procedures of PRIME designated product developments.
- Contribution to paediatric investigation plans (PIP) upon request of PDCO.

3.2. *Evaluation and supervision activities*

- Recommendation to CHMP on applications for marketing authorisations, line extensions, variations and referrals. For veterinary medicinal products these recommendations are to be provided upon CVMP's request only.
- Contribution to the assessment of New Active Substance claims.
- Assessment of the structural similarity of active substances to support the CHMP similarity assessment in the context of marketing authorisation applications and line extensions.

- Recommendation to CHMP on quality in relation to quality and safety aspects of ancillary substances in medical devices.
- Recommendation to CMDh/CMDv on requests, affecting scientific aspects in relation to nationally approved medicinal products.
- Recommendation to CHMP, as appropriate, on scientific opinion in cooperation with WHO for evaluation of medicinal products intended exclusively for markets outside the community.
- Support, as requested, to Inspections activities, quality defects, sampling and testing and liaison with OMCL network and EDQM on activities of mutual interest.
- Liaison with and specialised input to CHMP, CVMP, BWP, GMDP-IWG, QIG and other groups, working parties and committees, where required, on activities of mutual interest.
- Quality support to public health activities related to medicinal products containing chemical active substances.
- Support the ongoing work related to nitrosamines. This includes maintenance and updates to the published Q&A on root causes of formation, support for the development of new policies on nitrosamines as scientific understanding evolves, liaison with relevant stakeholders including international regulators (NITWG) and industry and provision of training for quality assessors.
- Support the ongoing work of the European Commission on replacement/removal of TiO_2 in medicinal products and engages with Interested Parties and industry stakeholders on this topic.

4. Abbreviations

List of Abbreviations	
BMWP	Biosimilar Medicinal Products Working Party
BWP	Biologics Working Party
CEP	Certificate of Suitability of the European Pharmacopoeia
CHMP	Committee for Medicinal Products for Human Use
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CMDv	Coordination Group for Mutual Recognition and Decentralised Procedures - Veterinary
CVMP	Committee for Medicinal Products for Veterinary Use
DCEP	Certification of Substances Department
DCP	Decentralised Procedure
ECHA	European Chemicals Agency
EDQM	European Directorate for the Quality of Medicines and HealthCare
EFSA	European Food Safety Authority
EMRN	European medicines regulatory network
EP	European Pharmacopoeia
ESEC	European Specialised Expert Community
EU/EEA	European Union / European Economic Area
EU-NTC	EU network training centre
EWP	Efficacy Working Party (EWP-V)
FDA	United States Food and Drug Administration
GDP	Good Distribution Practice
GMDP IWG	Good Manufacturing Practise/Good Distribution Practice Inspectors Working Group
GMP	Good Manufacturing Practise
H	Related to medicinal products for Human use
HAEMWP	Haematology Working Party
HMA	Heads of Medicines Agencies
HMPC QDG	Committee on Herbal Medicinal Products – Quality Drafting Group

List of Abbreviations	
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
IPRP	International Pharmaceutical Regulators Programme
IWP	Immunologicals Working Party
MRA	Mutual recognition agreement
MRP	Mutual Recognition Procedure
MWP	Methodology Working Party
NITWG	Nitrosamine International Technical Working Group
NTWP	Novel Therapies and Technologies Working Party
NAS	New Active Substance
NcWP	Non-clinical Working Party
OEG	Operational expert group
OMCL	Official medicines control laboratory
PBBM	Physiologically Based Biopharmaceutical Modelling
PDCO	Paediatric Committee
PF-OEG	Paediatric Formulation Operational Expert Group
PIP	Paediatric investigation plan
PRIME	Priority Medicines
QIG	Quality Innovation Group
QRD	Working Group on Quality Review of Documents
QWP	Quality Working Party
RIWP	Rheumatology and Immunology Working Party
RSS 2025	Regulatory Science Strategy 2025
SAWP	Scientific Advice Working Party
SWP	Safety Working Party (SWP-V)
TAB	Technical Advisory Boards
V	Related to medicinal products for Veterinary use
WHO	World Health Organization