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Pharmaceutical Quality and Inspection Offices
Human Medicines Division

3-year rolling work plan for the Quality Innovation Group (QIG)

Name of Operational Expert Group	**Quality Innovation Group**
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Work plan period: 2025-2027

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1. Strategic goals

1.1. Short-term strategic goals

- QIG priority areas:

  Main focus will be to continue the work on process models and platform technologies started in 2024, and continuous manufacturing (CM) (particularly end-to-end CM and CM for biologicals), decentralized manufacturing (DM) and digitalization started in 2023 to ensure the EU regulatory network is prepared to regulate those. Other innovative topics such as 3-D (bio)printing, individualised therapies, analytical innovations and novel automated and/or other advanced manufacturing technologies will be embraced as experience evolves.

- Strengthen the EU regulatory network
  - Serve as a forum to support the development, implementation, risk-based quality assessment and GMP inspection of advanced manufacturing technologies.
  - Provide support to relevant Committees and Working Parties on all Quality and GMP aspects pertaining to procedures embracing advanced manufacturing technologies.
  - Support scientific and regulatory capacity and capability of the network and improving the scientific quality of evaluations on matters pertaining to innovation in pharmaceutical manufacturing in close collaboration with the BWP, QWP and GDMP-IWG.
  - Upon request by the Quality Domain Governance, provide recommendations on matters relating directly or indirectly to the quality and GMP requirements of advanced manufacturing technologies.
  - Consolidate learnings and in collaboration with BWP, QWP and/or GDMP-IWG and other experts from the EU regulatory network, develop EU and international guidance documents (e.g. Q&As, position statements) on process models, DM, etc as needed.
  - Develop or contribute to training for EU quality assessors and/or GMP inspectors related to advanced manufacturing technologies with the aim of strengthening the assessment and inspection expertise and capabilities.
  - Ensure dedicated collaboration with other Committees, Working Parties or groups, including EMA offices (e.g., ITF/Innovation Office) and the cross-functional AI Coordination Group, to advance regulatory science aspects of common interest.
- Stakeholder support
  - Provide a point of entry for developers, including academics, to discuss innovative approaches to be used in development, manufacturing and/or control of medicines; ensuring continuity from early discussions into actual medicinal product evaluation.
- International collaboration
  - Build and maintain collaborative relationships with international regulators (e.g. FDA, Swissmedic, PDMA) to jointly support international harmonization on identified topics of common interest (e.g., CM, process models, DM, AI), using existing mechanisms (e.g., parallel/consultative advice, ICMRA, etc.), to promote the adoption of advanced manufacturing technologies.

- Pursue collaboration between the European regulatory network, academia, trade associations and industry interested parties as a way to increase the effectiveness, awareness and reputation of the EU as a centre for innovation.
- Voice the EU's position in international fora such as ICH, PICs and promote cross-regional convergence in close collaboration with international partners to address the global approach to development and implementation of advanced manufacturing technologies.
- Enhance knowledge on specific topics by consulting additional (ad hoc) experts from the EU regulatory network, external experts from academia and/or from the pharmaceutical industry or other sectors, as needed.

1.2. Long-term strategic goals

The long-term strategic priorities for the QIG with reference to the European medicines regulatory network (EMRN) and EMA Regulatory Science Strategy (RSS) to 2025 are as follows:

- Enable and leverage research and quality innovation in regulatory science.
- Facilitate the translation of innovative approaches into medicinal products manufacture and/or facilities by using proactive identification of new technologies expected to impact regulatory decision making and provide adequate regulatory responses. Future priority topics will be identified based on the development and maturity of other innovative manufacturing technologies in the next years.
- In collaboration with BWP, QWP and/or GDMP-IWG, provide support to the European Commission on the development and implementation of new legislation.
- In collaboration with BWP, QWP, GDMP-IWG and MWP, catalyse the integration of science and technology in the quality and GMP-related aspects of medicines development and ensure the network has appropriate competences to support innovation and associated technology platforms / regulatory science at various stages of medicines development. This includes support to e.g. digitalisation, personalised medicines and use of advanced manufacturing technologies to support sustainability.
- In collaboration with GMDP-IWG, consider and assess the GMP implications of new and innovative control and manufacturing technologies/approaches, and evaluate the needed regulatory activities, e.g. future guidance documents, to foster innovation and accelerate the adoption in the manufacture and control of medicines.
- In collaboration with QWP, BWP and NcWP contribute to the development, understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals.
- Seek further collaboration with international regulators (in addition to FDA) on priority topics, to achieve alignment in a global regulatory environment and facilitate the implementation of innovative approaches worldwide.
- Identify topics for collaboration between the European regulatory network and academia in the area of pharmaceutical innovation and manufacturing. For this purpose, the QIG will work with academics and/or other national or international regulators, with the aim of publishing papers, and strengthening the EU's position as a centre for innovation.

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

2.1. Guidance activities

This section reflects the strategic goals listed above, in particular to support the implementation of advanced manufacturing technologies, advance international harmonisation through support to relevant ICH guidelines, and to consolidate learnings/support knowledge management for strategic topic areas.

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 2025/2026

EU Guidance documents, New, QIG lead:

- QIG Preliminary Considerations on Pharmaceutical Process Models

EU Guidance documents, New, QIG specialised input

- Questions and Answers on *3D printing*
- Questions and Answers on *Decentralised Manufacturing*
- *GMP Annex 11 on Computerised Systems*

(B) Activities to be started in 2025

- Upon maturity of a topic, including agreed outcomes from Listen and Learn Focus Group (LLFG) meetings with stakeholders, develop additional guidance documents in consultation with relevant working parties/working groups and committees (e.g. platform technologies).
- Support EU delegations in the development and implementation of relevant ICH guidelines within QIG's scope, including update to EU/EMA guidelines related to the implementation of ICH guidelines.

(C) Activities to be started in 2026-2027

QIG will identify future guidance needs based on the development and maturity of other innovative manufacturing technologies and relevant discussions with stakeholders.

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

- ICH Guideline Q13 on Continuous manufacturing of Drug Substances and Drug Products
- Support as needed to ICH discussions on topic selection/prioritisation, and future ICH guideline activities

2.2. Training and workshop activities

Support training of quality assessors and GMP inspectors on topics within the remit of the QIG and building on the quality/GMP curriculum in the EU network training centre (EU-NTC), together with BWP, QWP, GMDP IWG and/or CAT, as appropriate, to build up expertise and capabilities, and support harmonisation on assessments and inspections. This includes training and knowledge building on process modelling, the implementation of ICH guidelines, best practise for quality of decision making and reporting, and innovative CMC technologies. Maintain awareness of issues arising from QIG discussions, including training on QIG learnings as appropriate.

Training priorities for 2025:

QIG will also regularly share information with BWP, QWP and GDMP-IWG as appropriate. Based on the progression of the topics, and if the regular updates to BWP, QWP, GMDP IWG are not sufficient, the QIG will consider developing dedicated training sessions on relevant topics (e.g. process models, DM).

Training under discussion for 2025-2027:

- ICH Q13 training
- Process models

Further trainings may be added, as needed.

2.3. Communication and Stakeholder activities

2.3.1. European level

Continue to engage effectively with industry and academia through Listen and Learn Focus Group (LLFG) meetings on a regular basis (i.e., yearly), and/or ad hoc 1:1 meetings with stakeholders to gain external perspective on regulatory science needs. Strategic direction is aligned with Agency priorities.

Strengthening links to academia working through the Quality domain is considered essential to determine future regulatory science needs.

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

On request, provide support to the revision of the pharma legislation for relevant topics (e.g. platform technologies, decentralised manufacturing).

2.3.2. International level

- Collaborate with FDA on identified areas of common interest; share learnings and gained knowledge to support the development and implementation of advanced manufacturing technologies (see 1.1).
- Continue to engage with Swiss Medic (QIG observer).
- Maintain dialogue with other international regulators on identified areas of common interest; identify further aeras of common interest; share learnings and gained knowledge to mature discussions on advanced technologies.

- 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 ICH, ICMRA, PICs. In particular, support to the outcome from the collaborative ICMRA assessment pilots.

2.4. Multidisciplinary collaboration

- Maintain, or strengthen as relevant, the ongoing collaboration with other working parties and groups, for example on guidance, e.g., BWP, QWP, GMDP IWG, SAWP, MWP, EMA regulatory affairs, ITF, the cross-functional AI Coordination Group, Novel Therapies and Technologies Working Party (NTWP) (for veterinary medicinal products) and the EU and national innovation offices.
- Strengthening the links with academia, research institutions, learned societies and Industry interested parties in priority topics and identifying and involving of ad-hoc experts as required.

3. Operational goals: medicinal product-specific activities

3.1. Pre-submission activities

- Support BWP, QWP, CxMP, CAT and SAWP on applications for scientific advice and protocol assistance pertaining to advanced manufacturing technologies and facility designs under QIG oversight.
- Hold 1:1 QIG meetings with applicants
- Contribution to Innovation Task Force on products/technologies under QIG remit.

3.2. Evaluation and supervision activities

- Support assessment of applications employing innovative manufacturing technologies and facility design approaches as delegated by CxMP, CAT, and/or QWP/BWP/GDMP-IWG.
- Liaison with and specialised input to CxMP, CAT, BWP, QWP, and GMDP-IWG, and other groups, working parties and committees, where required, on activities of mutual interest.

4. Abbreviations

List of Abbreviations	
BWP	Biologics Working Party
CHMP	Committee for Medicinal Products for Human Use
CVMP	Committee for Medicinal Products for Veterinary Use
DCP	Decentralised Procedure
EMRN	European medicines regulatory network

List of Abbreviations	
ESEC	European Specialised Expert Community
EU/EEA	European Union / European Economic Area
EU-NTC	EU network training centre
FDA	United States Food and Drug Administration
GMDP IWG	Good Manufacturing Practise/Good Distribution Practice Inspectors Working Group
GMP	Good Manufacturing Practise
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
MWP	Methodology Working Party
NTWP	Novel Therapies and Technologies Working Party
OEG	Operational expert group
QIG	Quality Innovation Group
QWP	Quality Working Party
RSS 2025	Regulatory Science Strategy 2025
SAWP	Scientific Advice Working Party