15 December 2023
EMA/477650/2023
Human Medicines Division

3-year work plan for the Quality Innovation Group

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Work plan period: January 2024 – December 2026

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1. Strategic goals

1.1. *Short-term strategic goals*

- Provide support to relevant Committees and Working Parties on all Quality and GMP aspects pertaining to procedures embracing advanced manufacturing technologies.
- Serve as a forum to support the development, implementation, risk-based quality assessment and GMP inspection of advanced manufacturing technologies. With regards to the QIG priority areas for 2024 main focus will be on the use of process models and platform technologies and continue the work on continuous manufacturing (CM) (particularly end-to-end CM and CM for biologicals), decentralized manufacturing 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 (bioinformatic tools), analytical innovations and novel automated sterile manufacturing and cleaning technologies will be embraced as experience evolves.
- Provide a point of entry for developers 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.
- 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, decentralized manufacturing (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.
- Build a collaborative relationship with international regulators (e.g. FDA) 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, 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.
- In collaboration with BWP, QWP and other parties in the European Regulatory Network, advance international regulators and stakeholder interactions: academia, trade associations, interested parties, etc.

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:

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 sufficient competences to support innovation and associated technology platforms / regulatory science at various stages of medicines development. This includes support to digitalisation and personalised medicines.
- In collaboration with GMDP-IWG, QIG will analyse the possible implications of new manufacturing technologies in order to regulate the new supply chains needed and will consider whether a GMP annex should be developed to address the adoption of new and innovative technologies in the manufacture of medicines.
- Ensure dedicated collaboration with other Committees, Working Parties or groups, including EMA offices (e.g., ITF/Innovation Office/AI Task Force) to advance regulatory science aspects of common interest.
- Enable and leverage research and Quality innovation in regulatory science.
- Seek further collaboration with international regulators (in addition to FDA) on priority topics, e.g., in the form of joint/parallel scientific advice, papers or Q&As, to achieve alignment in a global regulatory environment and facilitate the implementation of innovative approaches worldwide.
- Enhance collaboration with academic groups in the area of pharmaceutical innovation and manufacturing.
- Identify topics for collaboration between the European regulatory network and academia in the field of regulatory research. For this purpose, the QIG will work with academics and/or other national or international regulators, with the aim of publishing papers, furthermore, strengthening the EU's position as a centre for innovation.
- The QIG will provide input and support the GMDP IWG in the revision process of the GMP guideline on computerised systems (Annex 11), such as guidance on the use of artificial intelligence (AI) and machine learning (ML) models, as necessary.

2. Tactical goals: activities/projects to deliver 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 2024

EU guidance documents, New, QIG lead:

- Questions and Answers on Process Models

(B) Activities to be started in 2024

EU guidance, Revision, QIG lead:

- Upon maturity of a topic, including agreed outcomes from Listen and Learn Focus Group (LLFG) meetings with stakeholders, develop guidance documents in consultation with relevant working parties/working groups and committees.
- 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 2025-2026

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)

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

2.2. *Training activities*

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

Training planned for 2024:

- Based on the progression of the topics the QIG will consider training sessions on modelling and DM. QIG will also regularly share information with BWP, QWP and GDMP-IWG as appropriate.
- ICH Q13 training

Training under discussion for 2024-2026:

- Inspection related training for novel manufacturing technologies

2.3. *Communication and Stakeholder activities*

2.3.1. European level

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

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.

2.3.2. International level

- Maintain dialogue with 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.
- 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).
- 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, EMA AI Task Force 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-Authorisation 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.
- 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 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.

List of Abbreviations	
BWP	Biologics Working Party
CAT	Committee for Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
EU-NTC	EU network training centre
GMDP IWG	Good Manufacturing Practice/Good Distribution Practice Inspectors Working Group
GMP	Good Manufacturing Practice
ICH	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
ICMRA	International Coalition of Medicines Regulatory Authorities
MWP	Methodology Working Party
QIG	Quality Innovation Group
QWP	Quality Working Party
RSS 2025	Regulatory Science Strategy 2025
SAWP	Scientific Advice Working Party