30 June 2022
EMA/619783/2022
European Medicines Agency

Provisional mandate, objectives and rules of procedure for the Quality Innovation Group (QIG)

These mandate, objectives and rules of procedures will be incorporated in and adapted as required to the general rules of procedures governing all Working Parties, Operational Expert Groups and Drafting Groups.

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

1. General considerations

The Quality Innovation Group (QIG) is being established by the European Medicines Agency (EMA) with the aim to support the translation of innovative approaches to the design, manufacture and quality control of medicines for the benefit of patients. These include, but are not limited to, innovative technologies, novel materials, novel devices and digitalization, henceforth referred to as innovative innovative pharmaceutical manufacturing approaches.

The role of the QIG is to ensure that the EU regulatory network keeps pace with innovation, identifies and addresses gaps to ensure that the EU regulatory framework is reliable and predictable for developers of innovative technologies and fosters innovation in EU. The QIG will further support the progress of these technologies into actual medicinal product regulatory submissions, such as scientific advice, marketing authorisation applications, related post-authorisation lifecycle changes and routine manufacturing and control operations.

The QIG will perform horizon scanning in order to identify forthcoming innovative pharmaceutical manufacturing approaches and proactively formulate appropriate regulatory responses to these technologies as they mature (e.g. developing position papers, Q&A documents, etc.).

The QIG will contribute to a harmonised EU approach for the quality assessment of regulatory submissions and GMP inspections of manufacturers of medicinal products/systems/facilities that use and/or reference innovative pharmaceutical manufacturing approaches.

The QIG will establish a research agenda proposing topics for regulatory science research collaboration between the European regulatory network and academia in order to increase the visibility and reputation of the EU as a centre for innovation.

The QIG will provide a forum for exchange and interaction within the EU regulatory network, as well as between EU regulators and external stakeholders (e.g. industry, academia).

In addition, taking into account the global approach to development and manufacture of medicines, the QIG will establish close collaborations with international partners to facilitate regulatory convergence.

2. Mandate and objectives

Mandate

The QIG is mandated by EMA and its scientific committees to facilitate the implementation of innovative pharmaceutical manufacturing approaches that relate to the design, manufacture and quality control of medicinal products containing chemical, biological and/or biotechnologically derived substances and Advanced Therapy Medicinal Products (ATMPs) in the EU. This is to be achieved by:

1. Identifying innovative pharmaceutical manufacturing approaches and addressing the regulatory challenges associated with them;
2. Facilitating their translation into medicinal products or manufacturing and control facilities;
3. Ensuring a harmonised EU approach for the quality assessment of regulatory submissions and GMP inspections of medicinal products/systems/facilities that use and/or reference innovative technologies falling with their scope;
4. Pursuing a research driven agenda based on collaboration between the European regulatory network and academia in order to increase the effectiveness and awareness of the EU as a centre for innovation.

The QIG will strengthen knowledge on specific topics through consultation with additional (ad-hoc) experts from the EU regulatory network, external experts drawn from academia and/or pharma or other industries as needed.

The QIG will inform the EU position at international fora e.g. ICH, ICMRA, PICs, IPRP and facilitate cross regional convergence in close collaboration with international partners to take into account the global approach to development and manufacture of medicines.

In addition, product-specific or technology specific discussions with international partners may be initiated, when warranted, through existing channels (e.g. EMA-FDA parallel scientific advice) and confidentiality agreements.

The QIG will report to the Quality Domain Governance and inform the EMA Committees and Working Parties as needed.

For the performance of its duties, QIG will liaise with the Biologics Working Party (BWP), the Quality Working Party (QWP) and the GDMP Inspectors Working Group (IWG), as appropriate, and will share the knowledge as it evolves, with the aim to increase the assessment and inspection capacity of the EU Regulatory Network in dealing with innovative technologies.

Objectives:

The main tasks of the QIG comprise:

1. Provide a point of entry for developers to discuss new approaches to be used in development, manufacturing and/or control of medicines from conception (to product development and throughout the product lifecycle aiming to understand challenges and facilitate their uptake). The scope includes applications focussed on technology only. To ensure continuity from early discussions into actual medicinal product evaluation, it is envisaged a QIG member will conduct the primary assessment as part of the (Co)-Rapporteur team or alternatively, act as CHMP peer reviewer.
2. Proactive identification of new technologies expected to impact regulatory decision making in the medium to long term. Targeted engagement with ad hoc experts and academia in pharmaceutical sciences and other related disciplines/industries to increase awareness and develop regulatory policies.
3. Upon request by the Quality Domain Governance, provide recommendations on matters relating directly or indirectly to the quality and GMP requirements of medicinal products including, but not limited to the following:
    - Data requirements and regulatory impact arising from the implementation of innovative quality and manufacturing technologies, e.g.:
        - analytical technologies;
        - control strategy approaches;
        - devices;
        - drug delivery systems;
        - materials;
        - manufacturing technologies and novel facility designs for active substances and finished products, including continuous manufacturing and decentralised manufacturing;
        - digitalisation.

- Implications for the regulatory and supervisory system arising from the implementation of innovative quality and manufacturing technologies.

4. Timely preparation, review and/or update of quality position papers and contribute to the preparation of guidance documents pertaining to innovative quality and manufacturing technologies in order to support the EU network and stakeholders in implementing new technologies in collaboration with BWP, QWP and/or GMDP IWG, as required.
5. Contribution to quality-related workshops / training for EU quality assessors and GMP inspectors to strengthen the assessment and inspection capability of the network.
6. Engagement with relevant groups, including EMA offices (e.g. ITF/Innovation Office/SME Office) and the HMA Innovation Office in order to ensure harmonization across the EU and to optimize resources.
7. Set up of communication platforms with industry, academia and regulators, specifically:
   - International regulators active in this area (e.g. ICMRA, FDA (ETT), PDMA (ETG)) with regular meetings and exchange of information.
   - Academia, such that QIG acts a hub for information flow from key European academic stakeholders into those areas falling under the remit of the QIG.
   - Industry interested parties (pharma- and non-pharma companies, pharmaceutical industry associations, learned societies, public health-care professional organisations), as identified by the QIG.
8. Identification of topics for regulatory research collaboration between the European regulatory network and academia. In this regard, the QIG will collaborate with academia, and/or with other NCAs or international regulators, with the goal of publishing papers to further establish the EU as a centre for innovation and make it a predictable place for developers to invest in innovative approaches.

3. Composition and rules of participation

Core membership:

The QIG is composed of experts selected from the European experts database according to their specific expertise.

A chairperson is elected to manage the work of the group. The appointed chair will become a member of the Domain Governance.

A maximum of 8 reimbursed core QIG members will be appointed as per the general rules applicable to expert groups. The group may be enlarged at a later stage if required depending on workload considerations. A review of the composition will take place after the first year of operation. Membership will be reviewed on a regular basis, based on activity level and evolving needs. The chair shall be appointed for a 3-year term, renewable once.

Membership should comprise two members representing each of the following areas:

- quality assessment for chemical medicinal products;
- quality assessment for biological medicinal products and ATMPs;
- GMDP inspections.

Membership will be reviewed depending on future workload and topics on a 3-year basis.

Members are expected to support the activities which are described in the QIG work plan.

Membership of a working group implies a commitment to participate actively in the work of the group, regularly attend the entire meeting of the working group and take part in correspondence between meetings.

QIG members are expected to provide scientific leadership across the EU Network on relevant topics including training.

Criteria to be considered for QIG Core membership:

- Proven experience of assessing the quality of biological and/or chemical active substances and medicinal products or conducting GMP inspections;
- Demonstrated and documented experience in developing appropriate regulatory approaches for innovative technologies (e.g. relevant publications, participation in drafting or expert groups, participation at conferences)
- Experience in developing and/or implementing novel technologies in academic and/or industrial settings
- Solution-oriented and self-motivated with interest in innovation.
- A confirmation letter from the expert confirming his/her availability to participate to commit approximately 20% of his/her time to the work of the QIG as well as to take rapporteurship/s for tasks relevant to his/her expertise, as applicable. The time commitment will be reviewed after 1 year.
- Experience in working in multi-disciplinary environments focussed on delivering quality outputs in a timely and decisive manner.

A balanced composition across disciplines based on the above criteria is desired.

Ad hoc experts:

Given the broad scope of the QIG, in order to ensure the best available expertise on a particular technology/topic is part of its discussions, additional experts from the EU regulatory network may be invited to participate in the activities of the QIG on an *ad hoc* basis. EMA conflict of interest policy is applicable to these *ad hoc* experts.

External experts:

External experts from academia, technology developers, or medicinal product developers may be invited to provide documentation and participate in specific discussions to further understanding and knowledge. External experts will be understood to have a conflict of interest and will not participate in any deliberative discussions or decisions made by the QIG.

4. Meeting frequency

Plenary meetings at EMA, Amsterdam

- Plenary meetings are not expected to exceed six per year, organised (where possible) congruent to QWP, BWP and/or GMDP IWG meetings. Stakeholder interactions should be accommodated as needed. Topics / frequency for "Listen and Learn" platforms are to be part of the work plan. Nonetheless, *ad hoc* meetings will be organized if required.

- Meeting duration will be determined based on the topics in the agenda.
- One face-to-face meeting per year is foreseen.

Meetings with international regulators

- Where appropriate, it is aimed to have meetings with key regulators from other regions (US and Japan, etc.) to try to achieve cross regional convergence.

Reimbursement:

- QIG core members are to be reimbursed in accordance with EMA reimbursement rules.

5. Rules of procedure

5.1. Responsibilities of chairperson

The chairperson is responsible for the efficient conduct of the business of the QIG and shall in particular:

- Plan the work of the QIG together with the EMA Secretariat
- Monitor, together with the EMA Secretariat, that the rules of procedure are respected
- Ensure that, at the beginning of each meeting, any potential conflict of interest is declared regarding any particular item to be discussed by the QIG
- Aim to achieve consensus on issues discussed by the QIG
- Decide in exceptional cases when a vote is necessary
- Ensure, together with the QIG and the EMA Secretariat, the regulatory and scientific consistency of the QIG's recommendations
- Co-ordinate together with the EMA Secretariat the work of the QIG with that of other relevant working parties (i.e. BWP, QWP and IWG) of the Agency
- Report on the activities of the QIG to the CHMP, CVMP, CAT or other working party as appropriate

5.2. Election/nomination of chairperson

The chairperson shall be elected as per the general rules applicable to expert groups for a term of three years, which may be renewed once.

Nominations should be submitted in writing to the EMA Secretariat before the defined deadline.

Candidates shall submit a brief résumé in support of their candidature at the time of the nomination.

The election of the chairperson shall follow the same procedure as that for the election of the chairperson of the CHMP as stated in Article 3, paragraphs 1 to 6, of the Rules of Procedure of the CHMP.

5.3. Organisation of meetings and reporting arrangements

- The dates of meetings are decided on an annual basis in consultation with the QIG. The QIG may organize ad-hoc meetings if required.

- The draft agenda for every meeting shall be circulated, together with the related documents, by the EMA Secretariat, in consultation with the chairperson.
- When a member of the QIG is unable to participate in a meeting, part of meeting, or discussion topic due to a conflict of interest, he/she must inform the Secretariat in advance in writing.
- The QIG may identify and propose topics for consideration. A proposal for a guidance document shall be transmitted to the Quality Domain governance accompanied by a justification (i.e. problem statement and proposed solutions) for endorsement.
- A guideline or policy recommendation from the QIG shall be transmitted to the relevant working parties or working group and Committee(s) for adoption, as agreed with the chair.
- Industry and academia will be invited to give oral presentations during QIG meetings on matters directly related to the activities of the QIG, as appropriate.
- The QIG shall prepare an annual work plan for adoption by the Quality Domain governance. The work plan shall be regularly reviewed and updated as necessary with the agreement of the Quality Domain governance. The adopted annual work plan shall be circulated to the BWP, QWP and GMDP IWG for information.
- Agenda and minutes of the meetings of the QIG shall be circulated to the Quality Domain governance, BWP, QWP and GMDP IWG and an update provided at their plenaries.
- A report shall be prepared on an annual basis summarising the work of the QIG versus the work plan.

5.4. Guarantees of independence

The members of the QIG and experts from the EU regulatory network referred to above shall not have any direct interests in the pharmaceutical industry, which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner and shall make an annual declaration of interests. The Declarations of Interests of the QIG members shall be made available on the Agency's website.

Members of the QIG and experts from the EU regulatory network attending these meetings shall declare at the beginning of each meeting any specific interests, which could be considered to be prejudicial to their independence with respect to the points of the agenda. These declarations shall be made available to the public.

The specific provisions for handling Declarations of Interests and confidentiality undertakings as defined in the European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts (EMA/MB/89351/2020) are applicable to members of the QIG and ad-hoc experts participating in QIG activities.

5.5. Code of conduct

Members of the QIG and experts participating in the EMA's activities shall abide by the principles set out in the European Medicines Agency Code of Conduct (EMA/385894/2012).

6. Agency secretariat

Under the authority of the Executive Director, the EMA Secretariat shall provide technical, scientific and administrative support to the QIG. This includes the following:

- Provide technical and scientific support to rapporteurs and other members of the QIG;
- Provide legal, regulatory and scientific support to the QIG;
- Prepare and co-ordinate the work of the QIG in consultation with the chairperson(s);
- Ensure, if appropriate, that the timelines laid down by EU legislation for the adoption of the opinions are complied with;
- Organise meetings of the QIG ensuring, together with the respective rapporteurs, the timely availability of meeting documents;
- Facilitate the necessary contacts between the QIG, relevant working parties/IWG and Committees and other EU and non EU groups;
- Ensure adequate co-ordination of the work carried out within the QIG, the EMA scientific committees and other concerned working parties and/or groups;
- Contribute to the overall quality assurance and assurance of scientific and regulatory consistency of the documents/recommendations of the QIG in cooperation with the chairperson, as appropriate;
- Support the preparation of relevant meeting records where needed (e.g. agendas, minutes);
- Contribute to the identification of experts

7. Coordination group and consistency group

Not applicable.

8. Relationship with other WPs, committees and groups

As indicated above, in order to ensure harmonization across EU and to optimize resources, the QIG will develop formal links to relevant scientific committees, working parties and expert groups, as well as the HMA Innovation Office.

In addition, it is foreseen that the QIG develops and implements an agile and proactive communication pathway between industry, academia and regulators, establishing formal links with:

- International regulators active in this area (e.g. ICMRA, FDA (ETT), PDMA (ETG)) with regular meetings and exchange of information.
- Academia, such that it acts a hub for information flow from key European academic stakeholders into EMA working parties, in those areas falling under the remit of the QIG.
- Industry interested parties (covering pharma- and non-pharma companies, pharmaceutical industry associations learned societies, public health-care professional organisations), as identified by the QIG

9. General provisions

The Members of the QIG shall be bound, even after the cessation of their duties, not to disclose any information, which, by its nature, must be covered by individual professional secrecy. When participating in international or other fora on behalf of the EMA/CXMP, members shall ensure that the views expressed are those of the EMA/CXMP.

When participating in international or other fora not specifically on behalf of the EMA/CXMP, members shall make clear that the views expressed are their own views and not those of the EMA/CXMP.