EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quality Innovation Group

Status update and Listen-learn focus group meeting

Industry standing group meeting – 22 November 2022

Veronika Jekerle

The Vision

EMRN

Training, guidance

Predictable reg framework
Incentivise EU innovation

Support

International regulatory convergence

FDA · Pmda · ICH · PIC/S · ICMRA · IPRP International Pharmaceutical Regulators Programme

QIG

Core experts
+ ad hoc experts

Assessment support

Quality domain:
BWP/QWP/IWG
liaison

Academic expertise
Research projects

Support from development throughout lifecycle

Point of entry to EMRN
Informed open discussions

Links

EU Innovation network, ITF,

Quality Innovation Group

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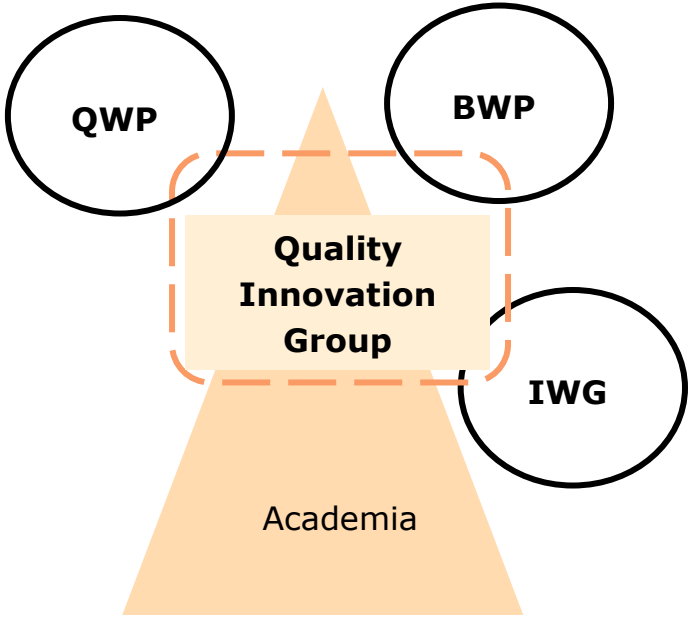
➢ Delivery of strategic network priority on Innovation



- Multidisciplinary expertise (assessment/inspection)
- Close link to working parties
- Academic expertise

Key objectives

Facilitate translation of innovation in manufacturing & pharmaceutical aspects

- Guidance (scientific & regulatory)
- Product-specific support pathways
- Training and knowledge building
- International convergence

Composition

Members	
Core Members:	**Marcel Hoefnagel - Chairperson** Barbara Stubbe Christina Meissner Giampiero Lorenti Leticia Martinez-Peyrat Marcos Timon Rene Thürmer Silke Schüle
Ad hoc experts (topic dependent):	Network experts Academic experts

Mandate

General consideration

Mandate and objectives

Composition and rules of participation

Meeting frequency

Rules of procedure

Agency secretariat

Relationship with other WPs, committees and groups

General provisions

https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/quality-innovation-group

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.

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.

Status update

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Constitution

Members
Mandate
Kick-off

Processes

Product support pathways
Alignment with ITF/EU-IN
Engagement strategy
International outreach (FDA/PMDA)

Topics

Intelligence
Priority topics
Workplan
Academic expertise

Engagement

External communication
EMA website
Stakeholder fora
List & Learn Focus Groups

2022

2023

Priority topics

Input:

- EMA Regulatory Science Strategy to 2025
- Stakeholders' responses to QIG survey
- Overview of ITF meetings (2019-2021)
- Scientific advices
- Information from NCAs
- FDA/PMDA information

Continuous manufacturing

Scope

- Bio/Biotechnology/end-to-end

Justification

- Perceived and existing regulatory/scientific barriers

Focus

- End-to-end approach, GMP requirements, performance-based control strategies, alternative processes

Decentralised manufacture

Scope

- Innovative approach, precision medicine, increased agility in manufacture

Justification

- Flexibility for new sites, GMP aspects, validation, comparability, control

Focus

- QP release, oversight, eligibility, GMP aspects, scientific data requirements

Digitalisation

Scope

- Automation and digitalization in pharmaceutical manufacturing

Justification

- Paradigm shift in manufacturing (real-time monitoring, simulation, self control, decision making) and additional skills

Focus

- Data requirements: validation evidence, self-learning modules, flexibility, GMP aspects, live decision making, QP release and inspection

Listen & Learn Focus Groups

What?

QIG interaction with external stakeholders to share knowledge and experience on innovative products/processes/control strategies/facilities and discuss challenges & possible solutions

Who?

Experts from academia, industry, regulatory network and QIG

When?

First L&L FG to be held virtually on *13th March 2023*

Themes

1. Continuous manufacturing (CM) of biological active substances and/or finished products

2. Decentralised manufacturing

Next steps

Call for abstracts on proposed topics/presentations by *20th January 2023*

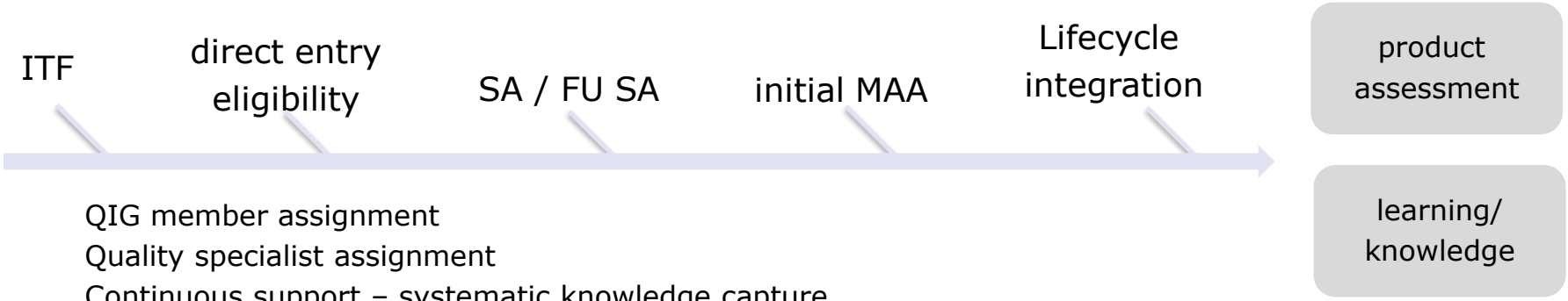
Interested companies/organisations encouraged to outline projects and work together on case studies where possible

Product support pathway

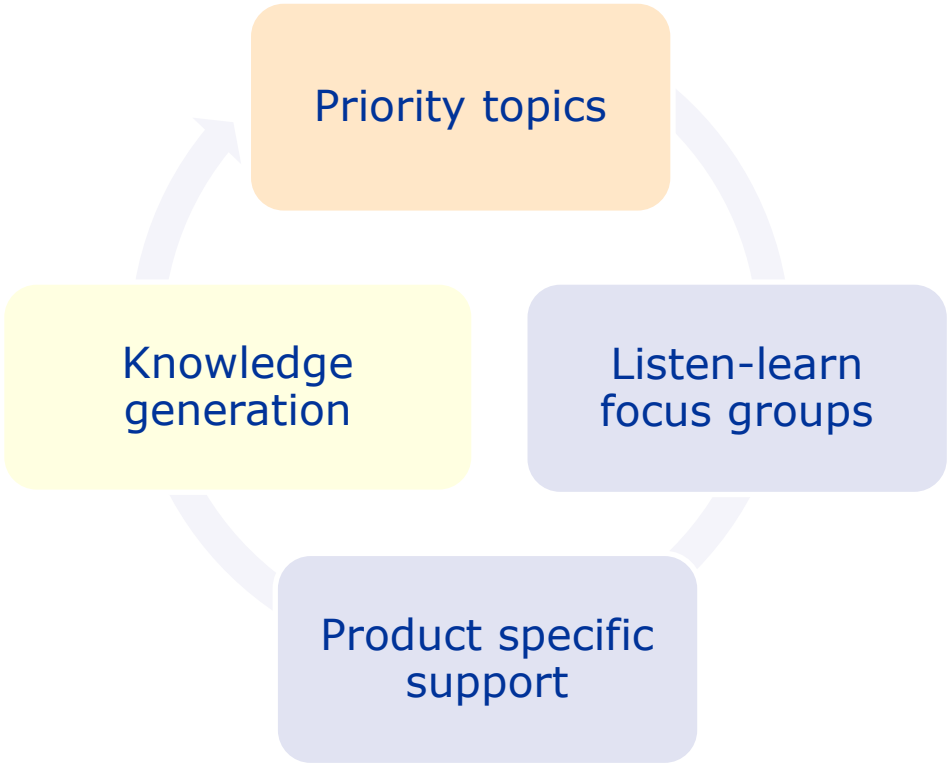
Mandate: (…) "to ensure continuity from early discussions into actual medicinal product evaluation, it is envisaged a QIG member will conduct the primary assessment as part of the (Co)-Rapporteur team or alternatively, act as CHMP peer reviewer."

→ mechanism to integrate QIG experts into assessment / inspection of a product in scope

- Eligibility criteria
- Knowledge sharing & capacity building



What can Industry expect:



Topics (1st priority)

Advanced manufacturing approaches

- Continuous Manufacturing for Biologicals
- Decentralised manufacture
- Digitalisation/automation
- Other (feedback from Industry)

Deliverable

- Challenges/solutions
- Case studies
- Guidance
- Training material
- Communication material

ITF and QIG

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Innovation Task Force (ITF)

Early informal meetings to support **innovative drug development**

- Early landing platform
- One off, follow-up usually not planned
- Multidisciplinary, scope goes beyond manufacturing/CMC
- Covers products/technologies with an innovative component
- Industry and Regulators (EMA/network)

Quality Innovation Group

Specific support on **key technology topics**

- Eligibility based on topic priorities & maturity of technology
- Scope on manufacturing/CMC and facility
- Ongoing product-specific interaction across lifecycle
- Industry with Regulators (EMA/network) & Academia
- International outreach
- Scientific guidance development

Next Steps

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Communication

- Press release on 21st November 2022 concerning QIG constitution
- Website (https://www.ema.europa.eu/en/committees/working-parties-other-groups/chmp/quality-innovation-group)

Industry Listen/Learn focus group

- Confirmed date: 13 March 2023
- Invitation to be sent out shortly
- Objective: learning from meeting to finetune QIG work programme and consider need for 1-to-1 follow up closed meetings on eligible topics

Preparation:

- call for abstracts on topics (i.e. continuous manufacturing for biologicals &r decentralised manufacturing) + prepare joint case studies reflecting challenges
- identify technical experts to participate

Meeting highlights & presentations will be published

Any questions?

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Send us a question Go to www.ema.europa.eu/contact

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