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SCIENCE MEDICINES HEALTH

EMA Quality Innovation Group (QIG):

Two years experience in regulatory support of Innovation in pharmaceutical manufacturing

ISG, 30.06.2025

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QIG: EU catalyst for advanced manufacturing

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EMRN

European medicines regulatory network

Predictable reg framework
Support EU innovation efforts

Training, guidance

Support

International regulatory convergence

Assessment support tailored to technology novelty

Rapporteurs and Assessment Teams

QIG

Quality Innovation Group

8 Core experts

(Chemical, Biological, ATMP & GMP)

+ ad hoc experts

Academic expertise
Research projects

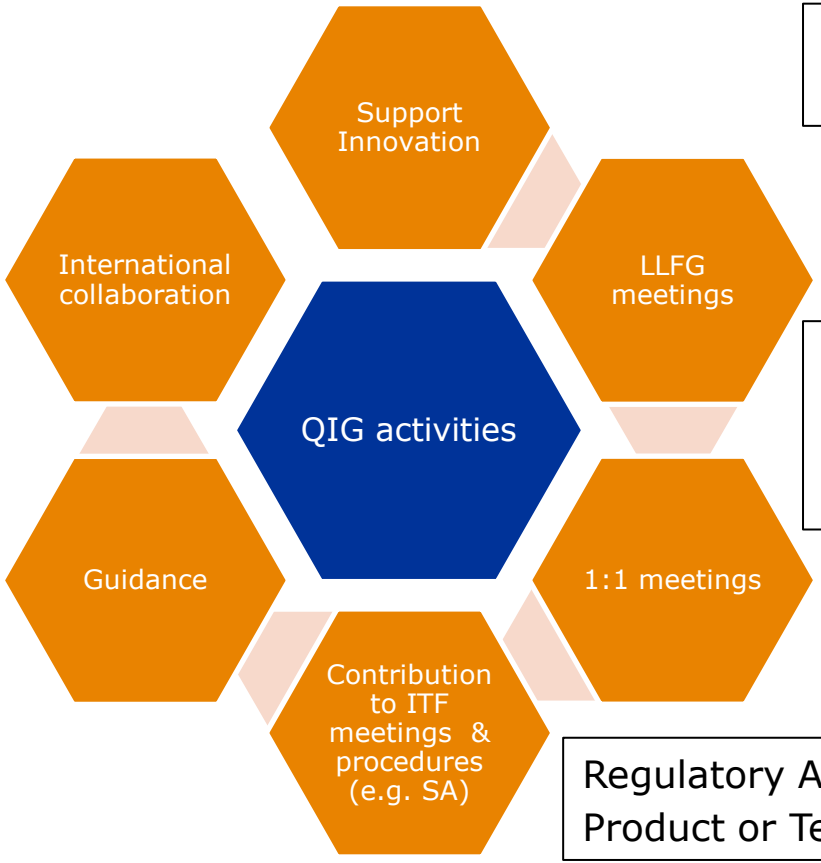
Support from development throughout lifecycle

Point of entry to EMRN
Informed open discussions

Links

EU Innovation network, ITF, National IOs

Quality Innovation Group -Activities



Entry point for interaction with EU regulators on Advanced Manufacturing

LLFG: Listen & Learn Focus Groups

Stakeholders with expertise/experience, Academics, Learned societies

Upon invitation, after expressing interest

Regulatory Advice on Novel Product or Technology

QIG priority topics discussed at Listen & Learn Focus Groups

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Close to Patient
POD, QP

Decentralised manufacturing

Continuous manufacturing (Biologicals or End-to-End)

1st LLFG (13 March 2023)

Digitalisation and Automation of manufacturing and control

2nd LLFG (12 October 2023)

What to document and How?

Actual examples, Tangible presentations

Lifecycle, PQS or dossier, level of detail

Process models

3rd LLFG (4 June 2024)

Platform technologies

4th LLFG (Q4 2024)

Personalised Medicines

5th LLFG (Q2 2025)

Definition, End-to-End

Meeting reports incl. **challenges, possible solutions and concrete actions** that QIG will take to address the challenges

Guidance and product support

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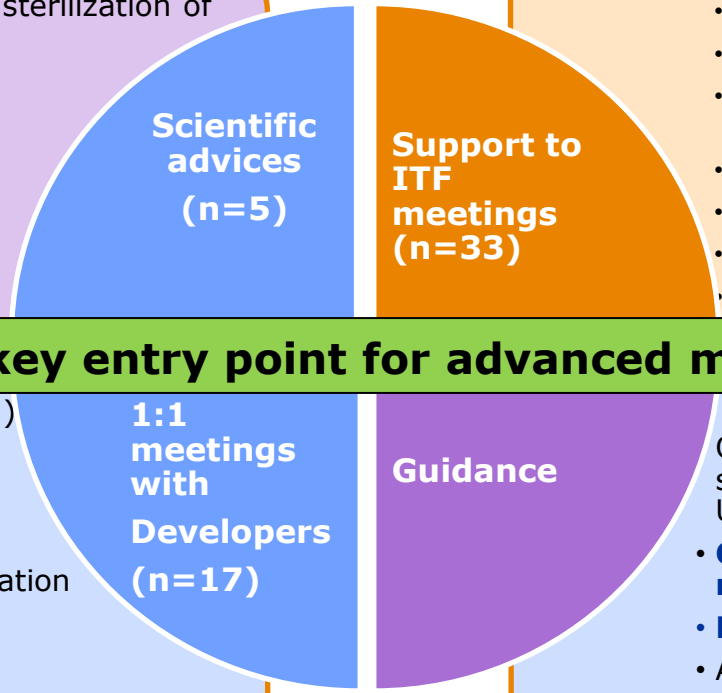
- **Helping avoid shortages**: X-ray sterilization of single use systems
- **Reduce cost**: Robotic aseptic
- **Improve supply capacity**: DCM
- Bioinformatics: NGS, Neoantigens
- Bacteriophages

- Process automation
- CM for biologics
- Decentralised Manufacturing
- Artificial Intelligence (diverse applications)
- RNA writing technology
- 3D bioprinting
- iPSCs
- Drug device



QIG: key entry point for advanced manufacturing

- Decentralised manufacturing (DCM)
- Automated cell manufacturing
- Digital twins
- Modelling DSP Control strategy
- Continuous Manufacturing: Formulation
- High Tech Facility
- 3-D printing
- Novel technology for virus detection
- **Site visits (n=3)**

Q&A on use of X-ray sterilisation processes for Single Use Systems- **published**

- **Considerations on process models (Draft)**
- **Reflections on DCM**
- AI reflection paper contrib.
- 3-D Printing (draft)

Product support by QIG

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Direct Contact
- Technology or product focused
- QIG expert assigned

Scientific Advice
- QIG expert primary assessor
- technology or product focused
- QIG Input into inspection

Initial MA application
- QIG expert input as part of assessment team
- QIG Input into inspection

Variation/line extensions
QIG expert input into review & inspection

Product and Technology support across lifecycle

Entry point to QIG
Expert advice (CMC/Inspection)
No formal assessment

Assessment activities
assigned QIG expert for primary assessment / peer review

Listen-learn Focus group meetings

Challenges & solutions gaps

+

1 – to - 1 Meetings (QIG + Applicant/Sponsor)

Support to specific Product/technology assessment

Knowledge Assessment outcomes

Guidance International convergence Training

International collaboration: FDA, Swiss Medic, PMDA & ICMRA

Knowledge sharing

- Bi-monthly meetings
- Attend & Share learnings from workshops, company meetings
- Staff/ expert exchanges

Product specific advices / assessments

- Consultative / parallel scientific advices /collaborative assessments leading to harmonised outcomes (where possible)
- Joint (hybrid) site visits / inspections

Guidance development

- Exchanging priorities, topics of common interest
- Aligned or joined guidance/Q&As, joint ICH proposals

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QIG members

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EMA Team

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