

ansm

Agence nationale de sécurité du médicament
et des produits de santé

The Quality Innovation Group

– Goals and operation



Surveiller les produits de santé
Traiter les situations à risque élevé
Contrôler les produits de santé
Inspecter
Lutter contre les pénuries des médicaments
Organiser le contrôle qualité des DM et des DMDIV
Instruire les demandes des usagers

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Contents

- Pharmaceutical Strategy for Europe and innovative trends
- Role of the Quality Innovation group (QIG)
- Priority topics for 2023
- What can stakeholders expect?

Pharmaceutical Strategy for Europe

'...aims at creating a future proof regulatory framework and at supporting industry in promoting research and technologies that actually reach **patients** in order to fulfil their **therapeutic needs** while addressing market failures'



The screenshot shows the European Commission website interface. At the top left is the European Commission logo. To its right is a language selector set to 'English' with a flag icon. Below the logo is a breadcrumb trail: 'Home > Live, work, travel in the EU > Public Health > Medicinal products >'. The main heading is 'Medicinal products'. Below this is a sub-menu with 'All topics' and 'Medicinal products'. The main content area is titled 'A pharmaceutical strategy for Europe'. Below the title is a short paragraph: 'Adopted on 25 November 2020, the Pharmaceutical Strategy for Europe (reader-friendly version) aims at creating a future proof regulatory framework and at supporting industry in promoting research and technologies that actually reach patients in order to fulfil their therapeutic needs while addressing market failures. It will also take into account the weaknesses exposed by the coronavirus pandemic and take appropriate actions to strengthen the system.'

https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en#next-steps

- ❖ Access (affordability & unmet medical need)
- ❖ Competitiveness, innovation, sustainability
- ❖ Crisis preparedness & response
- ❖ EU voice

Focussing Regulatory Science on support to innovation



https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/ema-regulatory-science-2025-strategic-reflection_en.pdf

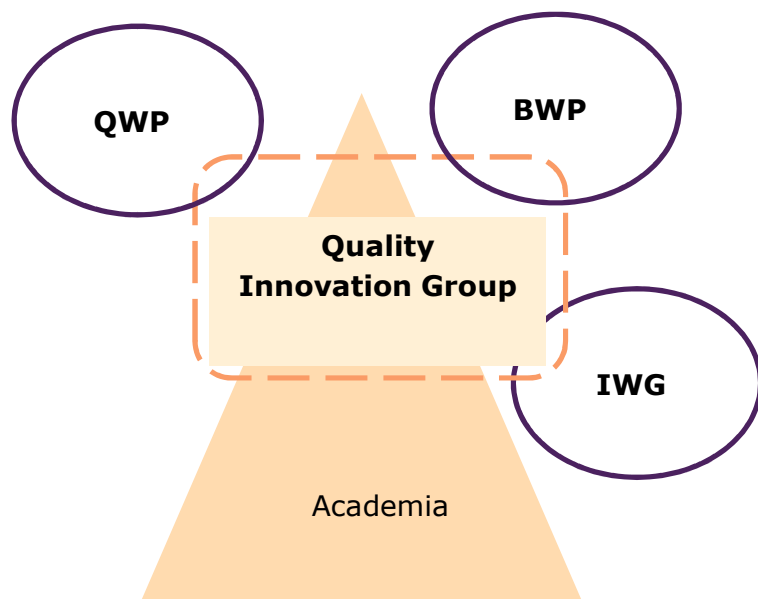
- ◆ **Goal 1: Catalyzing the integration of science and technology in medicines' development**
 - Facilitate the implementation of novel manufacturing technologies
 - Support translation of ATMPs into patient treatments
 - Develop understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals
- ◆ **Goal 5: Enabling and leveraging research and innovation in regulatory science**



Innovation Trends (2025 – 2030)

- Gene therapy and genome editing (i.e. *in vivo* gene editing)
- Microbiome products
- Digital health
- Vaccines using novel technologies (mRNA vaccines, viral vectors, nano-delivery systems)
- Nanomaterials/ innovate materials for targeted/ modified release formulations
- Novel manufacturing approaches (i.e. small portable manufacturing sites, decentralised manufacturing (e.g. cell processing ATMPs), 3D printing, end-to end CM)
- Automation, artificial intelligence/ big data approaches ('Pharma 4.0')
- Individualised therapies (i.e. platform approaches (e.g. oligonucleotides, genome editing, gene therapy) for rare & ultrarare diseases (1-100 patients))

Delivery of strategic network priority on Innovation – QIG



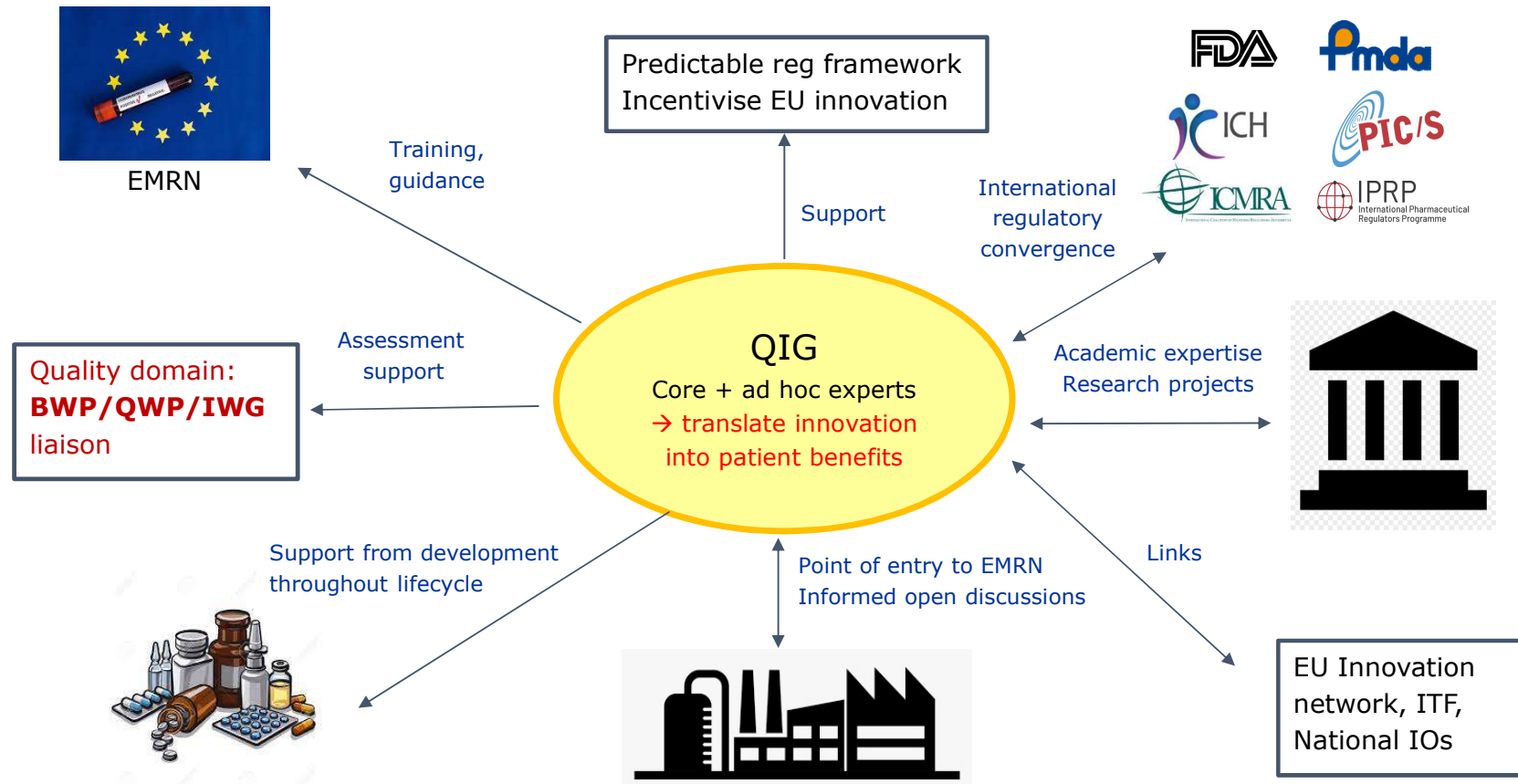
- Multidisciplinary expertise (assessment/inspection)
- Close link to working parties
- Academic expertise

Technology/innovation focused
→ Guidance (scientific & regulatory)

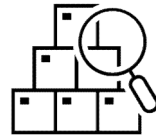
Product-specific support pathways

Harmonisation, training and knowledge building

QIG - the Vision



Priority topics - 2023



Decentralized manufacturing

- Advent of new therapeutic approaches which may need a “decentralised” manufacture (local to the patient)
- Supply facilitation

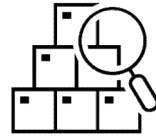
Continuous manufacturing

- Enhance process and product understanding
- Reduce production times
- Accommodate supply needs to demand

Digitalization

- Processes optimisation/ modernisation
- Accelerate development of new therapies for patients
- Shift away from production using fixed process parameters by using a system of real-time monitoring, simulation and self-control

Priority topics - 2023



- **Continuous manufacturing**

Focus: integrated DS/DP CM (end-to-end), BIO CM, performance-based control strategies

- **Decentralized manufacturing**

Focus: QP release, oversight, eligibility, GMP aspects, comparability

- **Automation/ Digitalization**

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

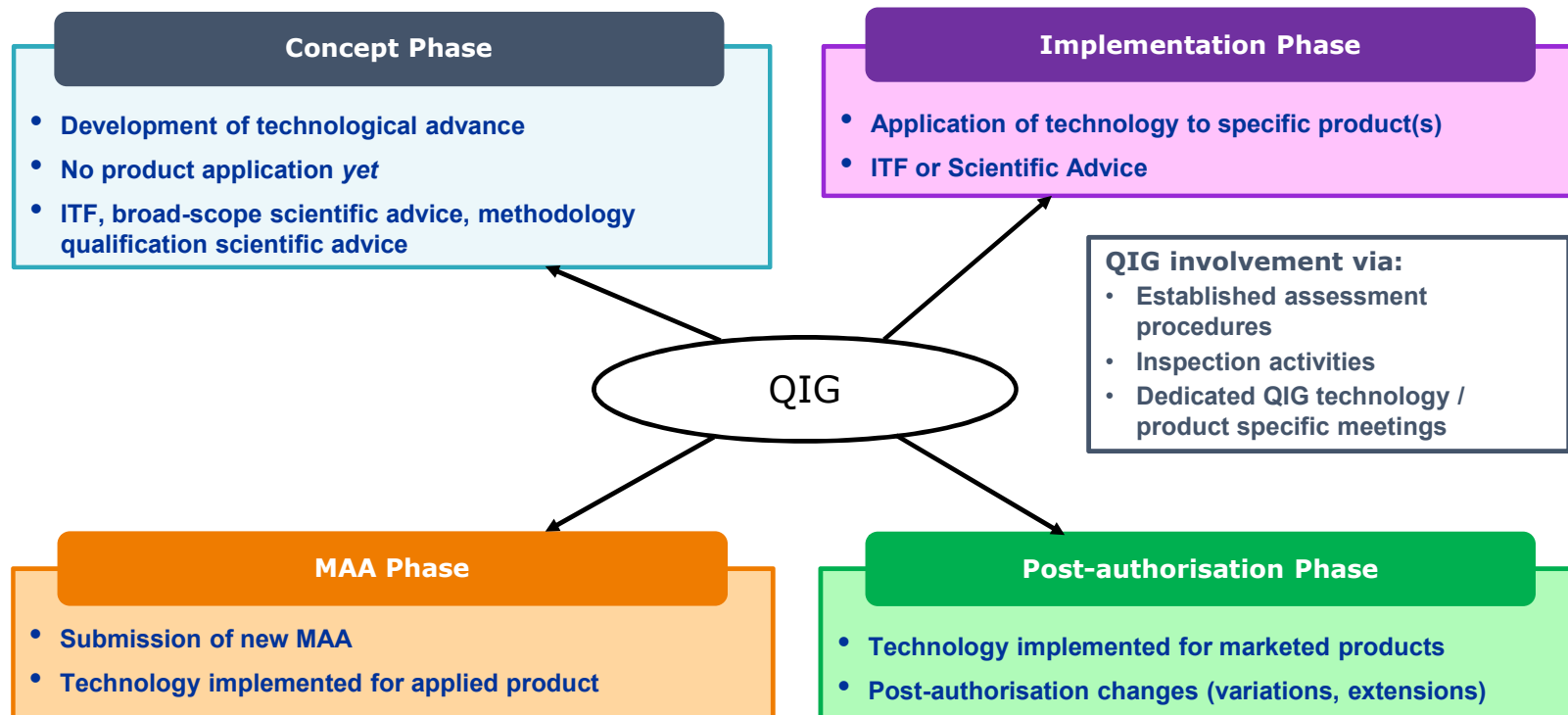
**1st Listen & Learn
Focus Group
LLFG March 2023**

What can Stakeholders expect



- Engagement through stakeholder organisations/IP platform (e.g. LLFG)
- 1-1 engagement with QIG on eligible product developments
- Coherence/ continuity in advice given for the implementation of the technology throughout product development, evaluation and lifecycle
- Knowledge gathering that feeds into topic-specific advice and guidance

QIG Input During Lifecycle – Possible Entry Points

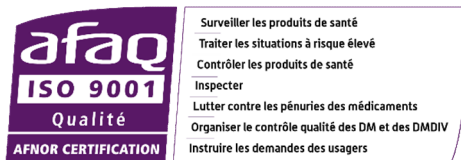


Any questions?

Further information

[Quality Innovation Group | European Medicines Agency \(europa.eu\)](https://www.ema.europa.eu/quality-innovation)

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