EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4. Quality Innovation Group

2023 achievements and plans for 2024

Industry standing group meeting – 23 November 2024

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Overview

Innovation strategic priority for EU

Quality Innovation group (QIG)

2023 QIG activities

QIG and FDA collaboration

Patients in EU and globally expect that medicines are available and are of the best possible quality.

Innovation always a strategic priority for EU

EU strategies on Innovation

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*

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

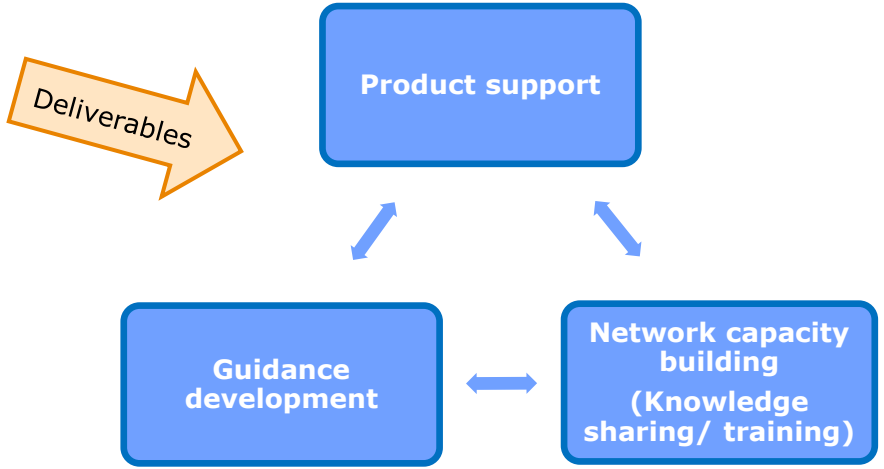
https://health.ec.europa.eu/medicinal-products/pharmaceutical-strategy-europe_en#next-steps

Digitalisation & innovation:

- ✓ **emerging new manufacturing methods**
- ✓ master files
- ✓ personalised medicines & platform approaches
- ✓ Variations & lifecycle management

EMRN priority areas in innovation

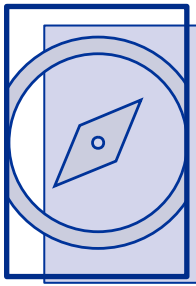
- ✓ Novel manufacturing including digitalisation in manufacturing
- ✓ Advanced therapies
- ✓ Novel materials (inc. nano)



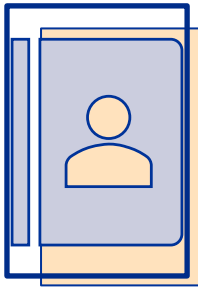
Benefits:

- Better understanding and control of manufacturing processes
- Faster scale-up/out
- ✓ Better quality medicines for patients
- ✓ More robust supply chains, strengthening medicines availability

The 3 pillars of a regulatory framework that supports innovation



Flexible framework adapted to current state of science



Predictability – clarity on regulatory expectations

Single contact that follows through product development, IMP, approval and major related lifecycle changes

Globally harmonisation

QIG :

EMRN

Predictable reg framework
Incentivise EU innovation

Training, guidance

Support

International regulatory convergence

QIG

Core (8) + ad hoc experts

→ translate innovation into patient benefits

Quality domain: **BWP/QWP/IWG** liaison

Assessment support

Academic expertise
Research projects

Support from development throughout lifecycle

Point of entry to EMRN
Informed open discussions

Links

EU Innovation network, ITF, National IOs

Status update – 2023 priorities & activities

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2023 priority topics

- Continuous Manufacturing for Biologicals, E2E
- Decentralised manufacture
- Digitalisation/automation
- Other (feedback from Industry)

[2023 work plan for the Quality Innovation Group (QIG) - Consolidated workplan (europa.eu)]

Lesson and learn focus group meetings- scope

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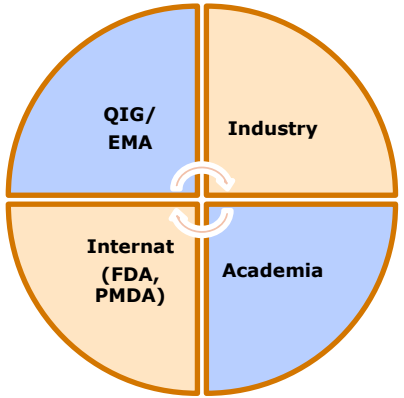
Gather information from stakeholders on the latest innovations in drug manufacturing & control and facilities design

Identify and discuss **challenges** and **proposed solutions**

Create a reliable and predictable pathway for developers of innovative technologies.

Support implementation of advanced manufacturing technologies



2023 – 1st LLFG meeting (13 March 2023)

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Topics

1. Continuous manufacturing

2. Decentralized manufacturing

Challenges

- Regulatory expectations for **process models** (dossier vs PQS, lifecycle)
- Comparability of products from different DM sites
- Control of variability of starting material (e.g. patient-derived starting material)?
- Registration and maintenance of DM sites in dossiers?
- Qualified Person oversight

Deliverables & Follow-up

Meeting report

Development of Q&A on process models (on-going)

Internal reflections on DM (on-going)

Follow-up 1:1 mtgs

2023 – 2nd LLFG meeting (12-13 October 2023)

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Topics

3. Digital novel technologies to manufacturing and QC testing

Challenges

- Lack of clear AI definition
- Uncertainty of regulatory acceptance of models
- Uncertainty on regulatory requirements for process models
- Expectations for AI/ML models

Deliverables & Follow-up

- Meeting report (in preparation)
- Development of Q&A on process models (on-going)
- Revision of EU GMP Annex 11 (AI/ML)
- Follow-up 1:1 mtgs

2023 – additional activities

- DM
- CAR-T cell automated manufacturing
- Digital twins
- CM for vaccine formulation
- Modelling

- Process automation
- E2E CM for biologics
- DM
- AI
- RNA writing technology

- SA on X-ray sterilization of single use systems
- SA on Robotic filling technology (GMP)
- SA on DM

- Q&A on use of X-ray sterilisation processes for Single Use Systems
- Q&A on process models (on-going)
- Internal reflections on DM (on-going)
- Contrib EMA RP on AI

2023 QIG activities –QIG/EMA F2F with FDA

To meet representatives from CDER and CBER to:

- ✓ **exchange experience and current thinking** on scientific and regulatory aspects of advanced manufacturing (AM) e.g. models, DM, AI;
- ✓ explore avenues for **closer collaboration** in this area and **support international harmonization**

Areas for collaboration in advanced manufacturing

Knowledge sharing

- Sharing learnings from workshops, company meetings
- Attending workshops and LLFGs
- Staff/ expert exchanges

Product specific advices / assessments

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

Guidance development

- Exchanging priorities, agreeing on topics of common interest
- Aligned or joined guidance and Q&As, joint proposals to ICH

Thinking globally… for advanced manufacturing

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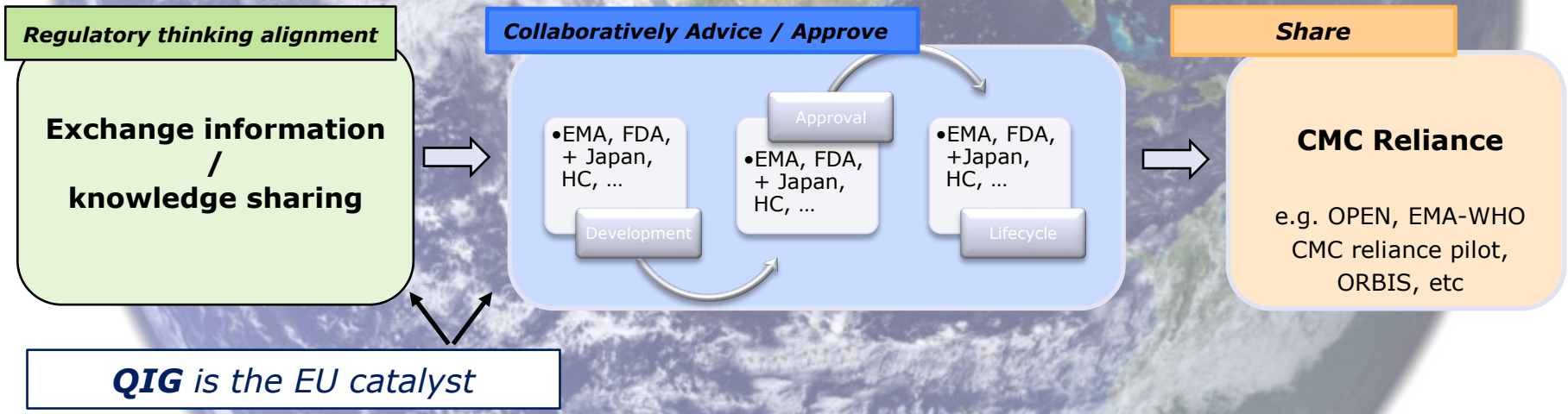
Align/ Advice / Approve collaboratively and share

- Exchange information; knowledge sharing; regulatory thinking alignment
- Use collaborative ICMRA pathways (incl Insp) for consultative advices and approval (either in the initial MAA or as a variation)
- Then Build on existing regional initiatives like ORBIS, OPEN, EMA-WHO CMC reliance pilot to allow other Regulators to onboard this journey and facilitate approvals in different regions so more patients can benefit



What's next?

- Continue stakeholder support on advanced manufacturing through existing channels e.g. SA (EU only or joint with FDA), QIG 1:1 or ITF meetings, LLFG meetings
- Continue work on 2023 priority topics and monitor progress in other areas
- Close collaboration with FDA on topics of mutual interest, considering joint SA, MAA reviews, guidance when relevant
- Continue collaboration with industry interested parties and academia

Let's continue the collaboration to foster (quality) innovation for patients' medicines access

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Quality Innovation Group | European Medicines Agency (europa.eu)

Acknowledgements

QIG members

See composition session of:

Quality Innovation Group | European Medicines Agency (europa.eu)

EMA

Inspection office

Pharmaceutical quality office

Any questions?

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