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Patient access through innovation

Quality Innovation Group - one year after launch

Industry Standing meeting, June 2023

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Overview

- EU vision on advanced manufacturing
- Quality Innovation group - Where we are
    - Product support
    - Gaining knowledge
    - International outreach
- What's next

EU vision for advanced manufacturing

EU, an attractive competitive environment to host sites using advanced manufacturing technologies for EU and global supply aiming to support availability of medicines for patients

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European Health Union: Commission proposes pharmaceuticals reform for more accessible, affordable and innovative medicines

Access	Availability	Affordability
Competitive regulatory framework	Compliance Environmental Sustainability	Compat AMR

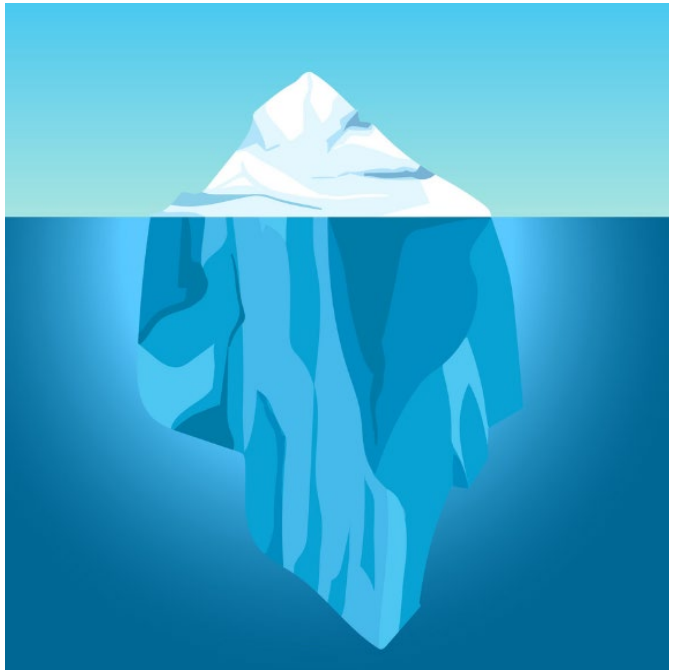
….an attractive and **innovation-friendly framework** for research, development, and production of medicines in Europe;

Enhance **availability;** and ensure medicines can always be supplied to patients, regardless of where they live in the EU ….

What we've seen and expect

We have some experience already

- Decentralised manufacturing proposal for ATMP manufacturing
- Pharma 4.0 facility for vaccine production
- Modular pharmaceutical micro factories for manufacture of DS & Bulk DP of an mRNA vaccine
- Continuous manufacturing for vaccine formulation and finish



More are to come with digitalisation,

- AI based models (Adaptive, self-learning models)
- Robotics
- .....

QIG- One year after launch- E. Korakianiti PhD- June 2023

Opportunity taken or missed?

Opportunity NOT to be missed

What do we need to make this happen?

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Predictable regulatory framework

Exchange of knowledge btw developers & regulators

Regional convergence

QIG role and interface

Predictable regulatory framework

EMRN

training

international convergence

EMA's Quality domain working parties: **BWP/QWP/IWG**

support

Quality Innovation Group

academic expertise research projects

across lifecycle

point of entry

links

EU Innovation network, ITF, National IOs

What can stakeholders expect from QIG

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Direct eligibility request
- Technology or product focussed
- 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 - – discussion on issues/risks and advice on how to address them.
If needed, advice on work packages to deliver ahead of follow-on procedures.

Assessment activities
assigned QIG expert for primary assessment / peer review

Meetings with stakeholders:

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

Status update - achievements

QIG established, monthly meetings

Workplan published

- Continuous and decentralised manufacturing
- Automaduct supporttion and digitalisation

Continuum support pathway developed

Contacts with key Int Partners initiated

- 1st Listen and Learn Platform on March 13th . Report published on 13th May
- Several follow-up 1-1 meetings with developers on specific cases (e.g digital twins, DCM, robotics)
- Follow up with PEI on DCM for mRNA vaccines
- Preparatory meetings with key industry experts, academics and EU network experts in preparation of LLFG on automation in Oct

Meetings with academics and vendors ongoing

FDA, PMDA part of the 1st LLFG meeting ; Common areas of interest identified

Discussions with US FDA (CBER, CDER, ORA). Aim:

- Exchange of info on products ; Develop common understanding and guidance ; Collaborative assessments

SAs ongoing with QIG involvement

Guidance development / update as a result of the LLFG e.g.

- process models; interim approach for DCM; GMP supervision of DCM sites; Revision NIR GL addendum; Potential revision of the Q&A on NORs/PARs/DSp

Next steps

1-1 meetings with developers ongoing

2nd Listen and Learn focus group on Pharma 4.0 in Q3/4 2023

Conclusions

Advanced Manufacturing can support medicines availability – key EU priority

Applications can be approved within the current framework despite the regulatory challenges. It is possible- QIG is in discussions with developers!

To allow for broader uptake we need a predictable adapted regulatory framework addressing advanced manufacturing specificities and alleviate the burden related to inspection requirements and lifecycle updates- key priority for EU

QIG is an enabler, to get a better understanding of the regulatory challenges developers face and guide towards solutions aligned where possible with key Int Partners. We are already delivering concrete outcomes!

Contact QIG , Participate @ the 2nd LLFG, we want to learn with you!

Opportunity taken

Let’s work together for better medicines for patients and strengthening their availability

QIG link

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

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Industry speakers at 1st LLFG meeting