ATMP activities at MEB (Netherlands)



ATMP stakeholder meetings (3/yr): Reviewers, Clinical Trial Regulators, Inspectorate, HTA, Ministry of Health, National Society of Pharmaceutical Industry, Academics, Academic hospital

Pipeline meetings: e.g. on Platforms

Advising in Academic Development Projects: e.g. DARE-NL (Collaborating Academic Hospitals)

QIG: EU catalyst for advanced manufacturing

Training, **quidance**

Assessment support

technology novelty

development throughout

tailored to

Support from

lifecycle





European medicines regulatory network

Rapporteurs and Assessment Teams Predictable reg framework Support EU innovation efforts

Support

International regulatory convergence

Quality Innovation Group 8 Core experts

QIG

(Chemical, Biological, ATMP & GMP)

+ ad hoc experts





Academic expertise

Research projects

Links







Point of entry to EMRN Informed open discussions



EU Innovation network, ITF, National IOs



QIG priority topics discussed at Listen & Learn Focus Groups 📀



EUROPEAN MEDICINES AGENCY

Decentralised manufacturing

Continuous manufacturing (Biologicals or End-to-End)

1st LLFG (13 March 2023)

Digitalisation and Automation of manufacturing and control

> What to document and How?

2nd LLFG (12 October 2023)

Actual examples, Tangible presentations

Lifecycle, PQS or dossier, level of detail

Close to Patient

POD, QP

Process models 3rd LLFG (4 June 2024)

Platform technologies 4th LLFG (Q4 2024) Personalised Medicines

Definition, End-to-End

Meeting reports incl. challenges, possible solut OIG will take to address the

Quality Innovation Group (QIG)

4th Listen and Learn Focus Group (LLFG) meeting report 19 - 20 November 2024

Guidance and product support



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

Scientific advices (n=6)

1:1

with

meetings

(n=17)

Developers

Support to

meetings (n=34)

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

OIG: 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
- AI in e.g. visual inspection
- Site visits (n=3)

Guidance

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

- Considerations on process models (2nd Draft in prep.)
- Reflections on DCM
- AI reflection paper contrib.
- 3-D Printing (draft)