EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Quality Innovation Group – An Overview

8th Industry Stakeholder Platform Meeting

Presented by Veronika Jekerle and Rob Bream 27th June 2022

An agency of the European Union

Overview of Presentation

EUROPEAN MEDICINES AGENCY

- Overview of Quality Innovation Group (QIG)
  - Vision
  - Timelines
- Summary of survey output
- Conclusions and questions for industry

The Vision

EUROPEAN MEDICINES AGENCY

EMRN

Predictable reg framework
Incentivise EU innovation

Training, guidance

Support

International regulatory convergence

FDA · pmda · ICH · PIC/S · ICMRA · IPRP International Pharmaceutical Regulators Programme

QIG

Core + ad hoc experts
Translate innovation into patient benefits

Assessment support

Quality domain:
BWP/QWP/IWG
liaison

Academic expertise
Research projects

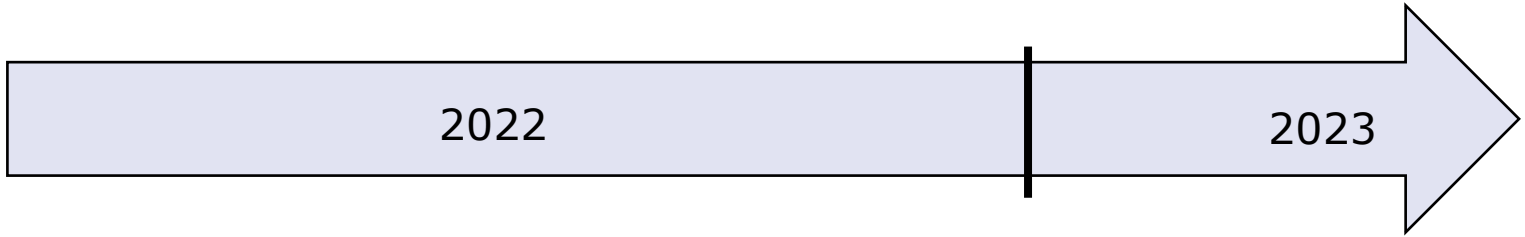
Support from development throughout lifecycle

Point of entry to EMRN
Informed open discussions

Links

EU Innovation network, ITF, National IOs

Timelines



Members

Candidate nominations + elections

operation

Topics

intelligence gathering (ITFs, survey, IP platforms etc.)

workplan

Industry

Listen and learn (IP/individual interactions)

product interactions

Academia

structured engagement with academia

Feedback from stakeholder survey – 37 inputs (34 H + 3 V)

Survey ran from December 2021 – February 11th 2022. For each topic, respondents were asked:

- What will be implemented in coming years?
- What are the perceived barriers in current legislation/guidance?
- What needs to change in legislation/guidance?

1. Manufacturing technology
2. Analytical technology
3. Control strategy approaches
4. Drug delivery systems
5. Devices and/or digital solutions
6. Materials
7. Facility designs or design concepts
8. Any other CMC developments

Type of organisation

	Answers	Ratio
Industry	25	67.57 %
Academia	3	8.11 %
Learned Society	6	16.22 %
CRO	1	2.7 %
Regulatory Agency	3	8.11 %

Overview of Survey Responses

Significant overlap across topics – answers are grouped accordingly:

1. Manufacturing technology + facility design
2. Analytical technology + control strategies
3. Drug delivery systems, materials and devices
4. Other CMC developments
5. Summary of barriers and legislative changes

Manufacturing Technology + Facility Design:

EUROPEAN MEDICINES AGENCY

- Continuous manufacturing (API, FP, chem and Bio) including e.g. microfluidics
- Pharma 4.0 – digitalisation, automation, robotics, AI
- Decentralised manufacturing, modular equipment including scale out, autonomous portable facilities, bedside manufacture (e.g. ATMPs and gene editing)
- 3D printing/additive manufacturing
- Cell processing technology (e.g. automated cell culture, high density cell banks, cell free transcription)
- mRNA platform technology (automated and chemically manufactured)
- Sterile filling technology (e.g. micro-filling) and requirements for sterile grade areas
- Flexible facility layouts with physical/spatial separation of operations and/or closed manufacturing systems, single use manufacturing equipment

Analytical Technology + Control Strategies:

- PAT, i.e. in-line/at-line/on-line analysis sensors, NIRS and RAMAN for RTRT and process control (including feedback loops)
- Data (*in silico*) modelling, statistics and digitalisation (predictive)
- Rapid biological methods (e.g. qPCR, solid phase cytometry)
- Novel biological methods (e.g. NGS, flow cytometry, conformational analysis/tomography, cell binding potency assays
- Multi-attribute methods
- Sterility methods
- Structural analysis methodology (size, conformation, macromolecule analytes)

Drug Delivery Systems, Devices, Digitalisation, Materials

- Wearable devices with sensors (e.g. for dosing, monitoring, efficacy)
- Patient compliance monitoring technology (wearable sensors, packaging/container closure, digitalised with e.g. cloud/AI link)
- Excipients including nanomaterials (inorganic, polymeric including peptides, lipids)
- Diagnostic devices
- Biomaterials including implants/inhaled (e.g. with surface modification, coated or bioconjugated)
- ATMP delivery systems/devices
- Micro-projection arrays (devices, vectors)
- Sensors for other purposes (anti-counterfeiting, stability and storage condition monitoring)
- Digitalisation and modelling (e.g. automation of process/method optimisation)

Other CMC Developments:

EUROPEAN MEDICINES AGENCY

- Digitalisation of dossiers + inspections
- Electronic PI
- Novel packaging formats and materials
- Stability modelling
- *In silico* prediction of properties (e.g. impurities, PK/PD)
- Sustainability (green chemistry, biocatalysis, replacement of animal methods, efficiency of equipment use)

General points made several times

- Pursue global harmonisation on standards, guidance via ICH, PIC/S etc.
- Create a point of contact and framework for interaction on novel manufacturing technologies

Perceived Barriers and Legislative Changes

EUROPEAN MEDICINES AGENCY

A high level overview of perceived barriers and proposed changes

- Provision of guidance on technologies which are not yet implemented in any products
- Change of legislation seen as too restrictive (e.g. alternative processes for biologics)
- Updates to guidance seen as out of date (EU and ICH level)
- Implementation of in draft and adopted ICH guidance not yet implemented in EU (e.g. Q12, Q13, Q14)

Conclusions and Follow up Questions

For the most part, answers reconfirm the analysis for the RSS 2025 – a bit more granularity in some places and some additional topics.

- Some of the points raised are not for QIG to address
- Scientific focus on innovative technology

Question for industry attendees:

- Does the survey summary reflect industry priorities?
- Considering previous interactions between industry/working parties
  - What worked well?
  - Additional relevant contact points from industry?

Any questions?

Further information

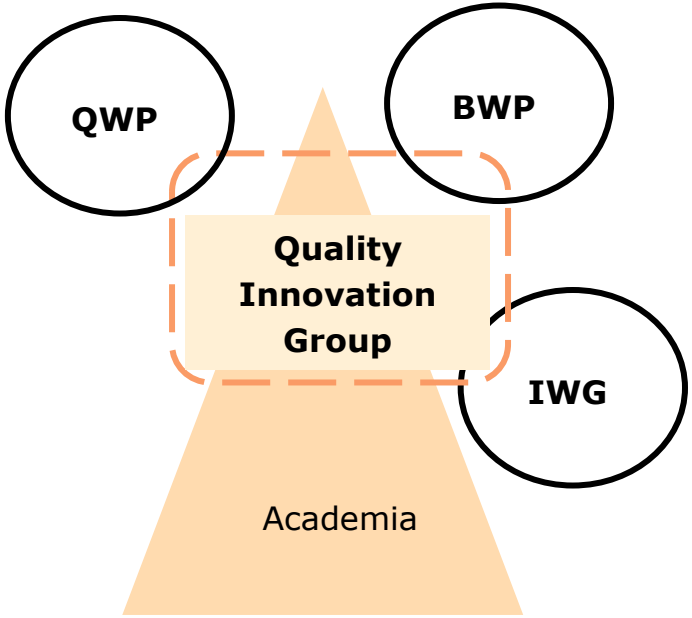
Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Telephone +31 (0)88 781 6000
Send us a question Go to www.ema.europa.eu/contact

Follow us on **@EMA_News**

Quality Innovation Group - Intent

EUROPEAN MEDICINES AGENCY

➢ Delivery of strategic network priority – Innovation



Highlighted coming technologies (RSS 2025)

- Novel manufacturing technologies (e.g. end to end continuous, CM for biologicals, 3D printing)
- Pharma 4.0: automation, artificial intelligence, big data approaches, data analytics & digital transformation in factories
- Decentralised manufacturing
- Novel delivery systems e.g. nano drug delivery systems
- Digital devices
- Genome editing (*in vivo*)