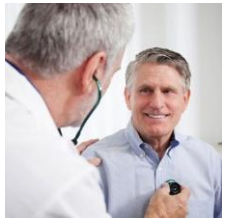
European Federation of Pharmaceutical Industries and Associations

Welcome & Introduction to the EFPIA Manufacturing and Quality Expert Group (MQEG) - Biomanufacturing Satellite Session

Markus Goese, F. Hoffmann-La Roche Ltd, on behalf of EFPIA MQEG Biomanufacturing team






CASSS CMC Strategy Forum EU

Basel – Oct. 20, 2025

Welcome to BASEL!

Source: https://www.basel.com/de/sehenswuerdigkeiten

Presentation Outline

1. Welcome & some facts about EFPIA

2. Highlights of the EFPIA MQEG Biomanufacturing team's work 2025 & outlook

3. Agenda of this year's MQEG Biomanufacturing Satellite Session at CASSS

About EFPIA

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the biopharmaceutical industry operating in Europe.

Through its direct membership of **36 national associations**, **40 leading pharmaceutical companies**, and a growing number of **small and medium-sized enterprises** (SMEs), EFPIA's mission is to create a collaborative environment that enables our members to innovate, discover, develop and deliver new therapies and vaccines for people across Europe, as well as contribute to the European economy.

More information is available on EFPIA website.

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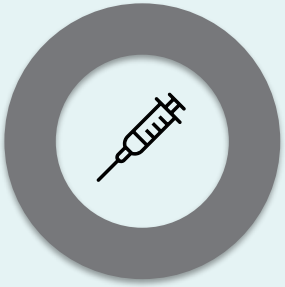
About EFPIA

60
staff members

40
member companies

36
member associations

41
partners in research



16
Vaccines Europe
An industry for healthy lives
members

13
SMEs

About EFPIA

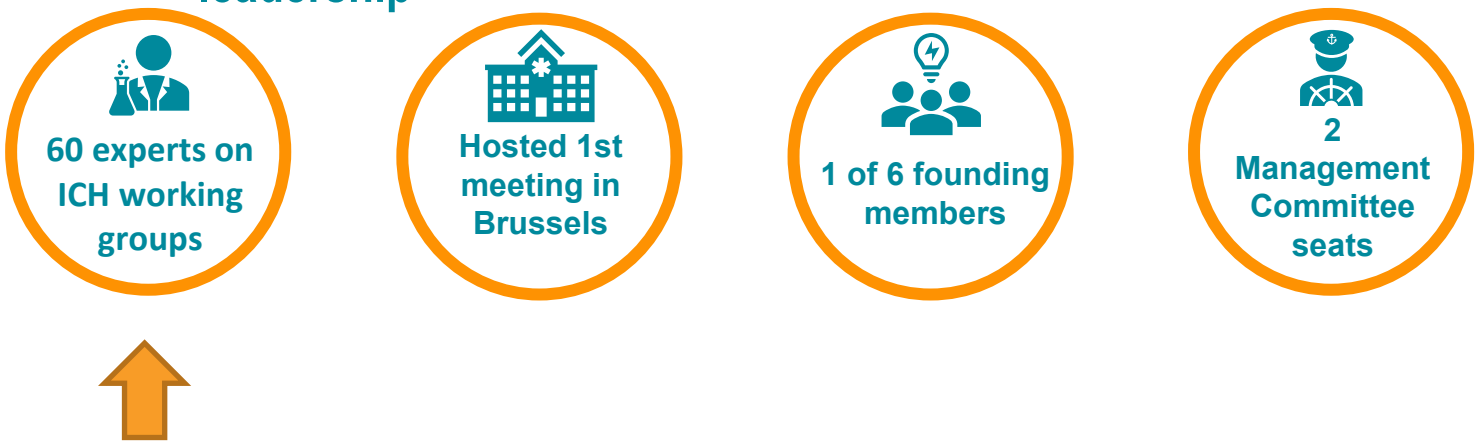
EFPIA's vision is for a healthier future for Europe. A future based on prevention, innovation, access to new treatments and better outcomes for patients

Repositioning industry as a partner in healthcare

#WeWontRest

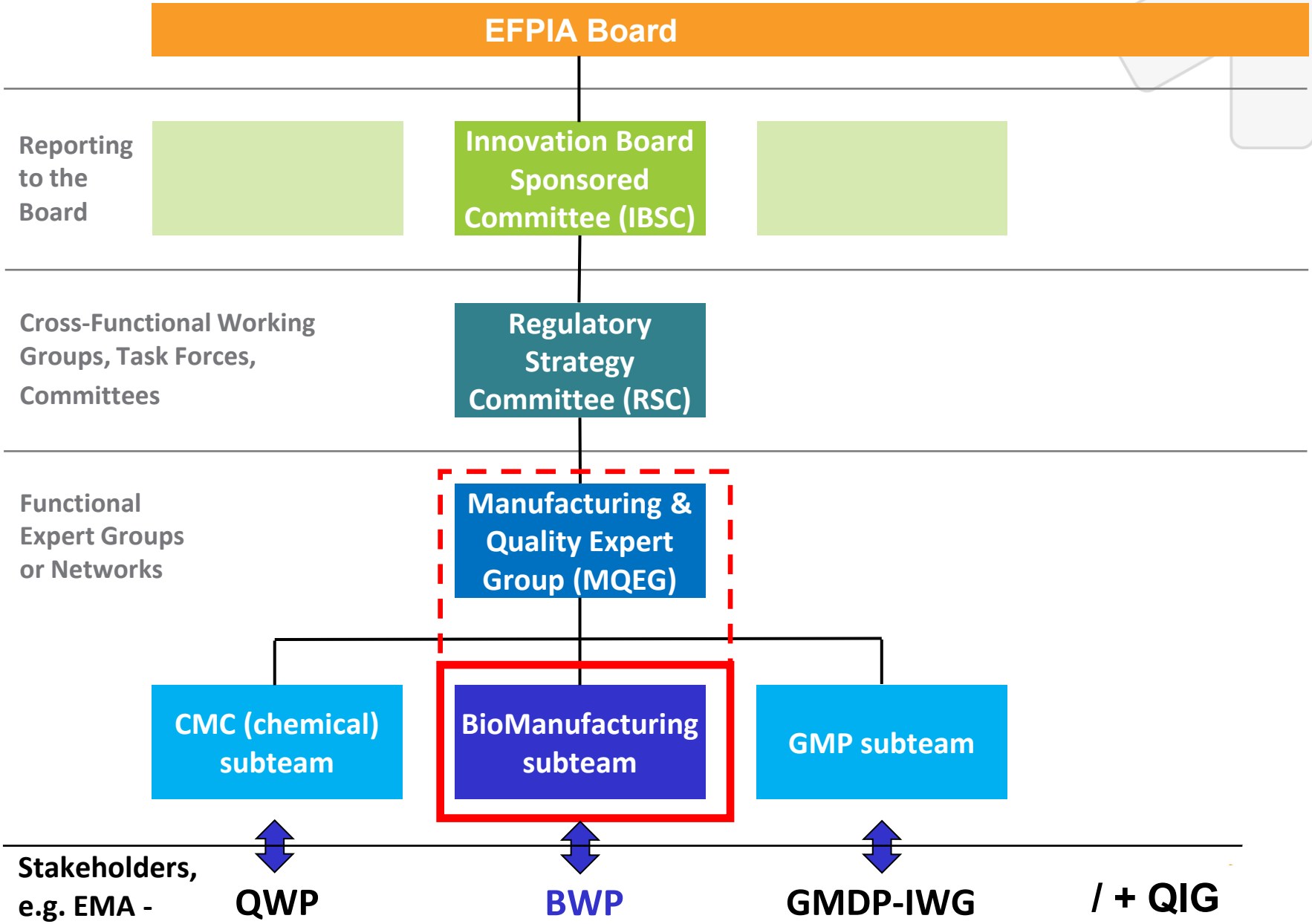
EFPIA - integral to ICH success

efpia leadership



EFPIA MQEG and its subteams support all nominated EFPIA experts in all active ICH Q & M (where relevant) working & discussion groups

Simplified EFPIA Governance & MQEG group



Recap: Example for EFPIA Input into EU Pharma Leg. revision

Further expand the Masterfile concept to fully enable manufacturing innovation – now in the EU Council discussion, see update later

- EFPIA/ VE / CEPI position paper "**Expanding Master Files for human medicinal products in the EU/EEA**" describing the status quo and necessary enhancements to the Masterfile system in the EU proofed to be very helpful in our advocacy work, eg. with the EU parliament on the new concept of **platform technology masterfiles**.

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CEPI

Vaccines Europe An industry for healthy lives

Expanding Master Files for human medicinal products in the EU/EEA

Executive Summary

Sponsors for Marketing Authorisation Applications of biological medicinal products (e.g. recombinant proteins, advanced therapy medicinal products, vaccines) frequently rely on collaboration with third party manufacturers to source components required to produce new, innovative medicines. These materials often have intellectual property held by the third-party suppliers, however, the current European regulatory framework has little capacity to protect proprietary confidential information between collaborating parties for biologicals, whereas small, synthetic molecule products have tools such as Active Substance Master Files with 'open' and 'closed' parts to protect IP. Other Master File tools currently exist in the EU, for vaccines with the Vaccine Antigen Master File (VAMF), the recent veterinary vaccine Platform Technology Master File (vPTMF), and for plasma-derived products with the Plasma Master File (PMF).

EFPIA Position: A further expansion of the master file concept to include platform technology master files would enable a world-leading regulatory framework for new pharmaceutical manufacturing technologies in Europe.

EMA-BWP IP Meeting Oct 8, 2025 - Final agenda extract

EFPIA MQEG Biomanufacturing subteam contributions

Agenda – BWP Interested Parties Meeting

8 October 2025 (14:00 – 17:30)

Description
Assessing Facility Functional Equivalency: 'Facility Fit' and Impact Risk for Differences Across Multiple Manufacturing Sites • Presentation from EFPIA/Vaccines Europe • Discussion
Enabling Global Implementation of Changes to Pyrogenicity and Endotoxin Testing • Presentation from EFPIA/Vaccines Europe • Discussion
Reconsidering sub-visible particle (SVP) limits for drug products in siliconized containers • Presentation from EFPIA/Vaccines Europe • Discussion
ADCs and AxCs - follow-up with the BWP on recent EFPIA member survey on Antibody Conjugates • Presentation from EFPIA/Vaccines Europe • Discussion
EFPIA Green Deal Cumulative Impact assessment: Introduction to key points of relevance for BWP • Presentation from EFPIA/Vaccines Europe • Discussion

See updates later

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Vaccines Europe
An industry for healthy lives

HOT TOPIC: Green Deal/ Sustainability:

EFPIA Cumulative Impact assessment

A thematic analysis of the cumulative impacts of the recent legislative changes (driven by the Green Deal)

EFPIA and its members recognise the urgent need to address climate change given the profound impact on both human health and nature and are committed to taking decisive actions to reduce environmental impacts across the value chain and contribute to building resilient and sustainable health system.

EU Legislative Landscape

The EU is undergoing substantial legislative change driven by the Green Deal, whilst also prioritising competitiveness as part of the EU Strategic Agenda 2024-2029.

Legislation Intent

Many of the new/proposed legislations are targeted at chemicals, food or the environment, but will also impact medicines, with some updated legislations bringing medicinal products into scope for the first time.

Cumulative Impacts

The cumulative impacts of these legislative changes will be felt by patients, healthcare systems and the pharmaceutical industry. Potential impacts include those to patients' access to medicines, and to the EU's innovation and its competitiveness as a global pharmaceutical development and manufacturing hub.

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New Position Paper (in preparation): Science and Risk-based Approaches for the Classification of Post-approval Changes for ATMPs in the EU

Recent Revisions of EU Variations Guideline

- Simplified some aspects and improved lifecycle management
- Further simplification for ATMPs could foster innovation, continuous improvement, and increase patient access.

Future Revision Possibilities

- Key opportunity to further adapt legislation for the lifecycle of ATMPs, e.g., integration of ICH Q12 concepts for post-approval changes.
- Promote international alignment of regulatory requirements consistent with ongoing EMA efforts to foster global convergence, harmonisation, and Reliance.
- Opportunity to enhance EU competitiveness with other regulatory regimes.

EFPIA Position Paper: Science and Risk-Based Approaches

- Highlights a framework that could support innovation for advanced therapies through use of ICH Q12 tools.
- Case studies illustrate how ICH Q12 tools and scientific and risk-based approaches can simplify post-approval regulatory submissions.

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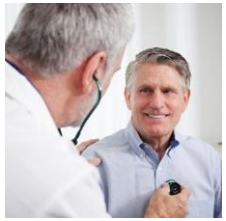
EFPIA Biomanufacturing Satellite Session at CASSS European Strategy Forum 2025

Karoline Bechtold-Peters (Novartis), Stuart Finnie (Gilead), and Helen Newton (MSD)






Agenda – EFPIA Satellite Session 2025 (1/2)

08:30-09:50 The Ballroom Level B2

EFPIA Biomanufacturing Group Satellite Session I: Working Subteams and Concept Paper Updates

Karoline Bechtold-Peters, Stu Finnie, Helen Newton
Presentation type: IP - In Person

The EFPIA Biomanufacturing Working Group is a cross-company industry team working to aid the development of biological products for patients. Through areas of special interests, the group supports and develops cutting edge science and technology strategies. In the first half of the session, the working group will showcase some of the current concept papers under development.

The second session will focus on Unlocking the Potential of Multispecific Antibodies: Design, Development, and Future Opportunities.

Session Speakers:

Welcome and Introduction to the EFPIA Biomanufacturing Working Group Satellite Session
Markus Goese, *F. Hoffmann-La Roche Ltd*

Antibody Drug Conjugates
Karoline Bechtold-Peters, *Novartis Pharma AG*

Prior and Platform Knowledge Use (Specifically Through a PTMF) in EU/EEA
Mihai Bilanin, *GlaxoSmithKline*

Polysorbates
Cyrille C. Chéry, *UCB Pharma SA*

Sister Sites Concept
Andrew Lennard, *Amgen Limited (UK)*

Subcutaneous Biologics
Karoline Bechtold-Peters, *Novartis Pharma AG*

09:50-10:20 The Ballroom Foyer Level B2

Networking Break

Presentation type: IP - In Person

Agenda – EFPIA Satellite Session 2025 (2/2)

10:20-12:25 The Ballroom Level B2

EFPIA Satellite Biomanufacturing Group Satellite Session II: Unlocking the Potential of Multispecific Antibodies: Design, Development, and Future Opportunities

Karoline Bechtold-Peters, Stu Finnie, Helen Newton
Presentation type: IP - In Person

Multispecific antibodies represent a transformative advancement over traditional monospecific formats, offering enhanced specificity, efficacy, and reduced drug resistance. These attributes translate into significant clinical benefits, particularly in the treatment of complex diseases.

These sophisticated molecules present unique challenges for CMC, such as managing product- and process-related impurities, quality control and analytical methods, and formulation strategies. This session explores the diverse design architectures of multispecifics—including case studies—and the engineering strategies behind them.

Session Speakers:

Challenges of Multispecific Antibodies From the Reviewers Perspective
Steffen Gross, *Paul-Ehrlich-Institut*

MAIT Engagers: Safer T-Cell Engagers With a Large Therapeutic Window for the Treatment of Cancer
Simon Plyte and Pierre-Emmanuel Gerard, *Biomunex Pharmaceuticals*

Design and CMC Considerations for Oligo-Functionalized Antibodies: The Case of Brainshuttle™-ASO Conjugates
Felix Schumacher, *F. Hoffmann-La Roche Ltd.*

Fab Arm Exchange Technologies and Considerations for mAbs
Christian Ostermeier, *Novartis Pharma AG*

Additional Panelists:

Marie Valentin, *WHO – World Health Organization*

12:25-13:30 Topaz 1 Level 2

Networking Lunch

Presentation type: IP - In Person

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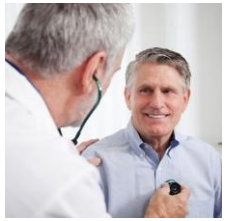
Thank you & Enjoy the session!



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