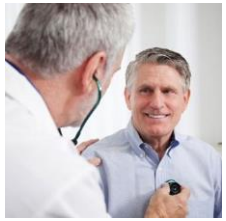
European Federation of Pharmaceutical Industries and Associations

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

Rotterdam – Oct. 21, 2024

Welcome to Rotterdam!

Source: https://www.netherlands-tourism.com/rotterdam

Presentation Outline

1. Welcome & some facts about EFPIA

2. Highlights of EFPIA MQEG Biomanufacturing team's achievements & outlook 2024-2025

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 **37 national associations**, **38 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

58
staff members

38
member companies

37
member associations

38
partners in research

14
Vaccines Europe
An industry for healthy lives
members

15
SMEs

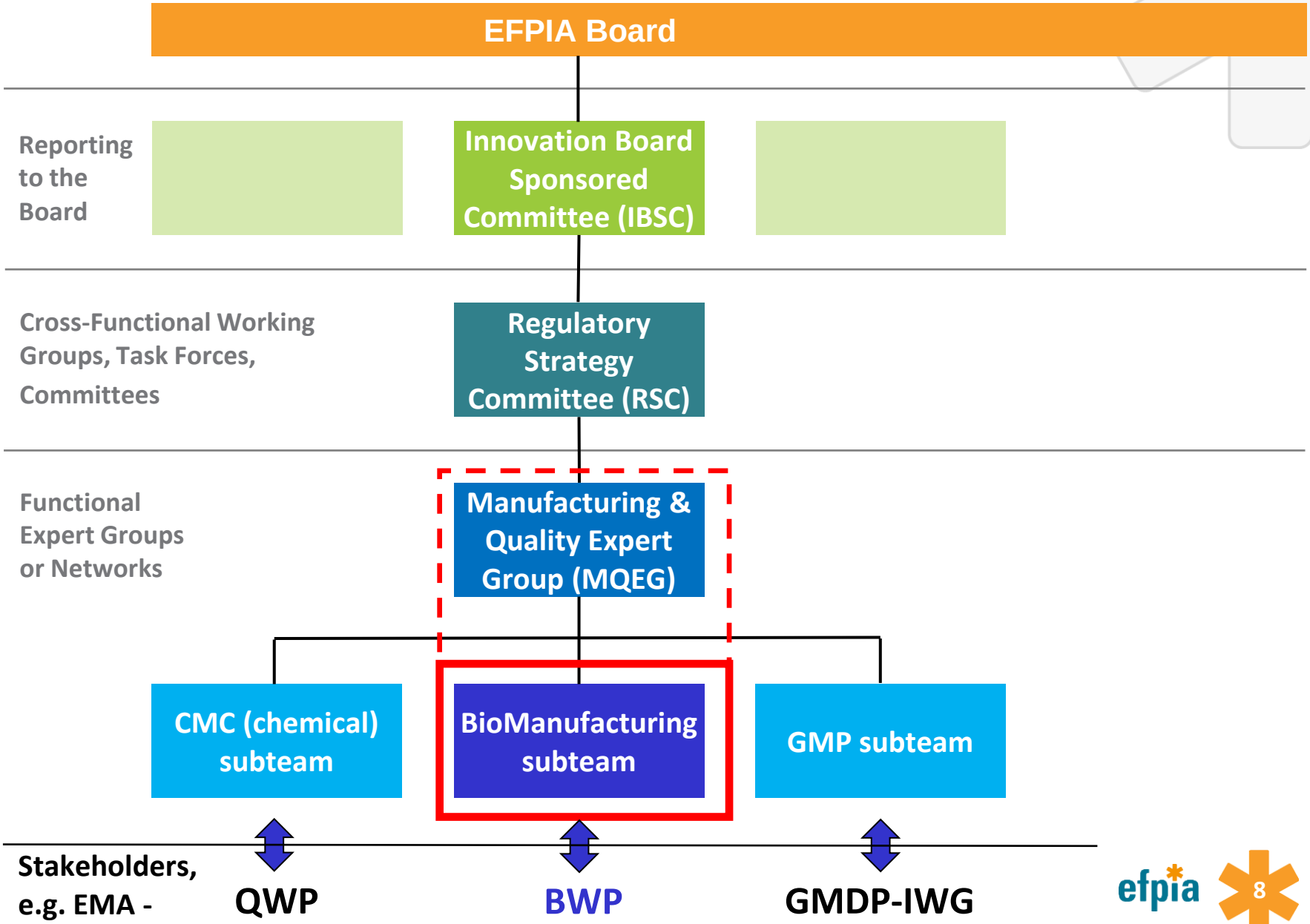
Our vision

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

Simplified EFPIA Governance & MQEG group



EFPIA MQEG BIOMANUFACTURING subteam

Some key activities 2024-2025

ICH support:

- ICH Q1/Q5C Stability revision
- ICH Q5A(R2) Viral safety – training material
- ICH Q6A/B Specifications revision
- ATMPs: ICH CGTDG

Interactions with EU regulators:

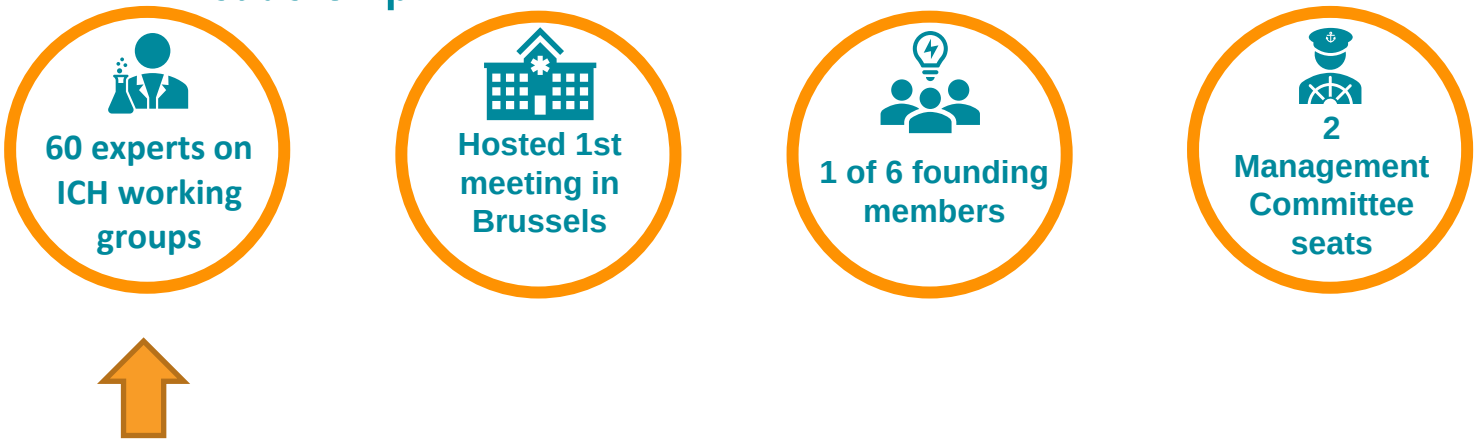
- BWP IP meeting, QIG Lessons Learned Focus Group (LLFG)

Work on industry position papers:

- Expansion of EU Masterfile Concept
- Antibody-drug conjugates (new team)
- Clonality, characterization & viral safety of cell lines (NGS & others)
- Multi-Attribute Method (MAM) by MS in QC
- Risk-based setting of sterile filtration bioburden limits
- Polysorbate

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

EMA-BWP IP Meeting Oct 9, 2024 - Final agenda extract

EFPIA MQEG Biomanufacturing subteam once more very active with significant contributions

Agenda – BWP Interested Parties Meeting

9 October 2024 (13:30 – 17:00)

Time	Description
13:50-14:15	**CMC Data Package for 'Sister' Bio-manufacturing Sites** • Presentation from EFPIA/Vaccines Europe • Discussion
14:15-14:40	**BWP Q&A - follow-up** **a) Method ID** **b) Low Endotoxin Recovery** • Presentation from EFPIA/Vaccines Europe • Discussion
14:40 - 15:05	**Use of Stable (non-clonal) Cell Line Pools for Biologics Drug Substance Manufacturing** • Presentation from EFPIA/Vaccines Europe • Discussion
15:20-15:45	**Sustainability** • Presentation from EFPIA/Vaccines Europe • Discussion

Example for EFPIA Input into EU Pharma Leg. revision

Further expand the Masterfile concept to fully enable manufacturing innovation – progress update

- 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.

Biomanufacturing/ NGS team published position paper on the EFPIA website

- *This article aims at **complementing the recent revision of ICH Q5A** by providing the position of the EFPIA Supportive Group "Clonality, Characterisation and Viral Safety of Cell Lines" on NGS implementation for adventitious virus detection. Envisaged as a **practical guide**, the paper addresses questions related to analytical method validation and corresponding pre-requisites originating from method development. **It discusses the benefits and limitations of analytical comparability studies between NGS and conventional virus detection assays .***

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Considerations for Validation and Implementation of Next Generation Sequencing for Adventitious Virus Detection for Biological Medicinal Products

Author: Group Clonality, Characterisation and Viral Safety of Cell Lines
Date: June 2024 **Version:** final

Position Paper

Executive Summary

Viral safety of biological medicinal products relies on extensive testing of the materials used in manufacturing, including cell banks of animal origin as a critical starting material. The ICH Q5A guideline, used worldwide as a reference for viral safety, has been recently revised to integrate the most up-to-date scientific knowledge and approaches developed over the last decades. Among them, Next Generation Sequencing (NGS) has emerged as a promising technology to detect a broad spectrum of viruses. Also known as high-throughput sequencing, NGS allows massive parallel generation of nucleic acid sequence data without prior sequence information, offering the potential to detect unknown or unexpected viruses.

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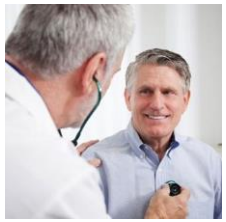
EFPIA Biomanufacturing Satellite Session at CASSS European Strategy Forum 2024

Fionnuala O'Driscoll (Eli Lilly), Karoline Bechtold-Peters (Novartis) and Helen Newton (MSD)






EFPIA Satellite Session 2024 - Scope

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 cover the topic of "Alternative Microbiological Methods".

Monitoring the microbial condition of the manufacturing environment during aseptic processes is key to ensuring the sterility of the product. This has been done for many decades by means of laid out settling plates, which are then incubated. However, as only a fraction of the germs are capable of culture, this technology will not provide a complete picture of the microbial quality of the environment. Alternative microbial methods that use the biofluorescence of microbes, for example, can measure microbes in the environment with high sensitivity and enable real-time monitoring. The qualification of the method as a sole environmental control requires a great deal of effort, as it is not described in pharmacopoeias. In our session, we will explain the basic principle of environmental monitoring using biofluorescence and provide case studies for implementation in aseptic production. Ways to make the method acceptable and the assessment of how and whether alternative microbial methods for environmental monitoring can increase aseptic safety will be examined from a regulatory perspective.

A Q&A and lively panel discussion is intended.

Agenda – EFPIA Satellite Session 2024 (1/2)

08:30-08:45 Mainport Ballroom

Welcome and Introduction to the EFPIA Biomanufacturing Group Satellite Session

Karoline Bechtold-Peters, Helen Newton, Fionnuala O'Driscoll

Session Chairs: Karoline Bechtold-Peters, *Novartis Pharma AG*, Helen Louise Newton, *Merck Sharp & Dohme U.K. Limited*, Fionnuala O'Driscoll, *Eli Lilly Kinsale Limited*

Introduced by: Markus Goese, *F. Hoffmann-La Roche Ltd.*

08:45-10:00 Mainport Ballroom

EFPIA Biomanufacturing Group Satellite Session I: Concept Paper Updates

Karoline Bechtold-Peters, Helen Newton, Fionnuala O'Driscoll

Session Chairs: Karoline Bechtold-Peters, *Novartis Pharma AG*, Helen Louise Newton, *Merck Sharp & Dohme U.K. Limited*, Fionnuala O'Driscoll, *Eli Lilly Kinsale Limited*

Session Speakers:

Use of Multi-Attribute-Method by Mass Spectrometry as a QC Release and Stability Tool for Biopharmaceuticals – the EFPIA Perspective
Annick Gervais, *UCB Pharma S.A.*

Navigating Challenges in Subcutaneous Biologics: Advancing High and Ultra-High Concentration Technologies with a Patient-Centric Approach
Karoline Bechtold-Peters, *Novartis Pharma AG*

Agile Manufacturing in Pharma: Harnessing Mobile/Modular Standardized Units for Decentralized Production, New Regulatory Concepts, and the Evolving Role of the Qualified Person Following the New EU Pharma Legislation
Andrea Kurz, *F. Hoffmann-La Roche Ltd.*

Additional Panelists:

Thomas Pohl, *Novartis Pharma AG*

Agenda – EFPIA Satellite Session 2024 (2/2)

10:00-10:30 Mainport Ballroom

Networking Break

10:30-12:30 Mainport Ballroom

EFPIA Biomanufacturing Group Satellite Session II: Alternative & Rapid Microbiological Methods

Karoline Bechtold-Peters, Helen Newton, Fionnuala O'Driscoll

Session Chairs: Karoline Bechtold-Peters, *Novartis Pharma AG*, Helen Louise Newton, *Merck Sharp & Dohme U.K. Limited*, Fionnuala O'Driscoll, *Eli Lilly Kinsale Limited*

Session Speakers:

EU GMPs Annex 1: 2022 - New Role of the Microbiologists on Aseptic Processes
Gilberto Dalmaso, *GDM Pharma Consulting (Virtual Presentation)*

Alternative Microbiological Methods Implementation Case Study – BFPC
Thais Vilgren, *Novo Nordisk A/S*

Accelerating Sterility Testing: A Case Study on Implementing the 7-day Celsis Method
Jonas van den Berg, *Roche Diagnostics GmbH*

12:30-12:35 Mainport Ballroom

EFPIA Closing Remarks

Karoline Bechtold-Peters, Helen Newton, Fionnuala O'Driscoll

Session Chairs: Karoline Bechtold-Peters, *Novartis Pharma AG*, Helen Louise Newton, *Merck Sharp & Dohme U.K. Limited*, Fionnuala O'Driscoll, *Eli Lilly Kinsale Limited*

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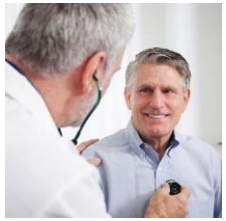
Thank you!



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