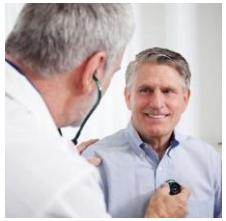
European Federation of Pharmaceutical Industries and Associations

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

Prague – June 23, 2026

Welcome to Prague

Source: Prague City Tourism (https://prague.eu/en/objevujte/)

Presentation Outline

1. Welcome & some facts about EFPIA

2. Highlights of the EFPIA MQEG Biomanufacturing team's work 2025/26 & outlook

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

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

40
partners in research

16
Vaccines Europe
An industry for healthy lives
members

13
SMEs

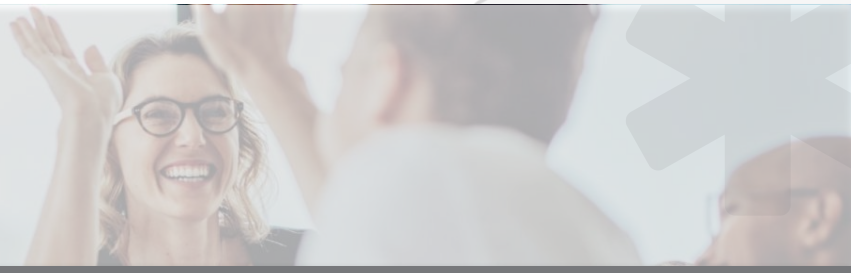
About EFPIA

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

50+
experts on working groups

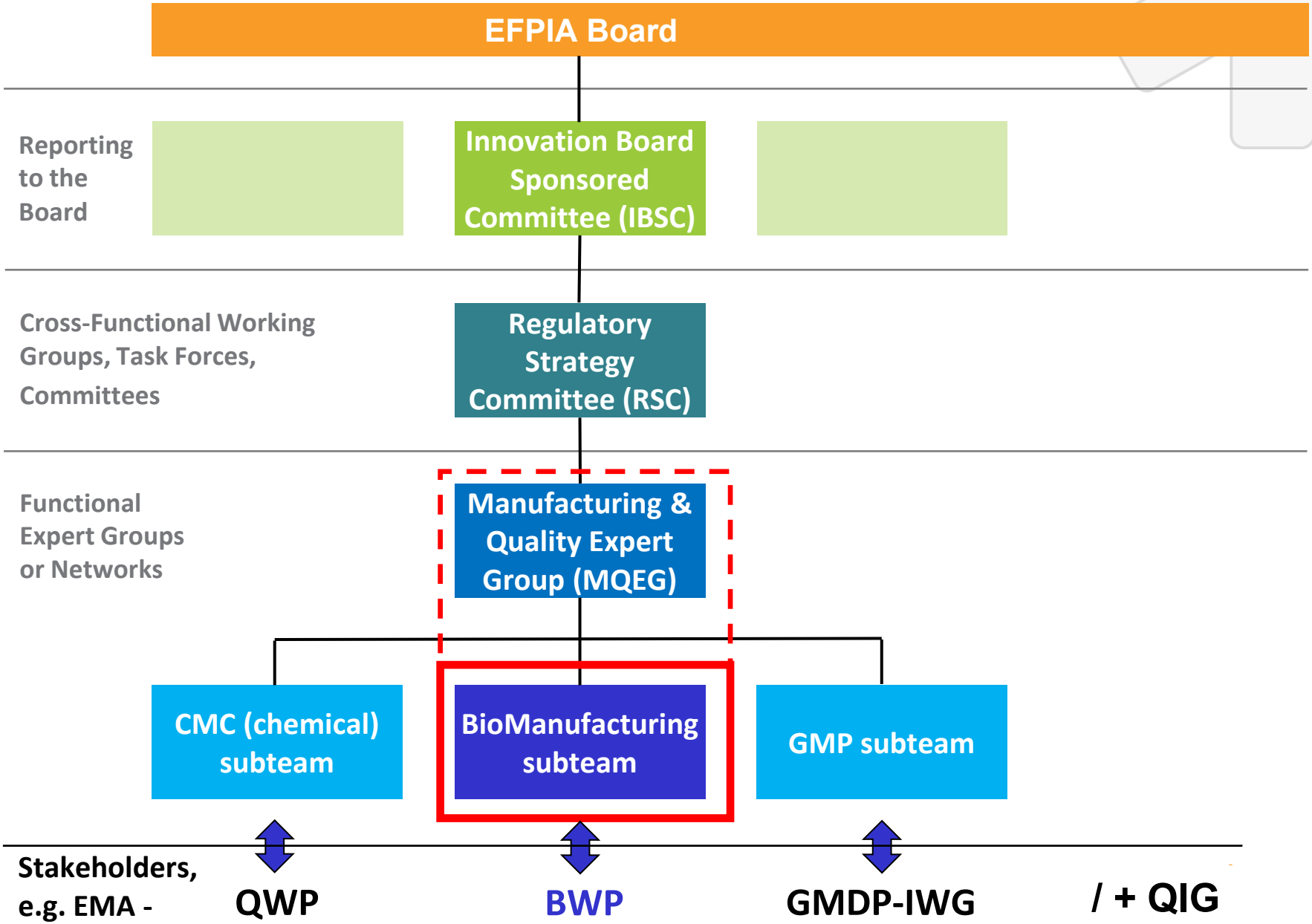
Hosted 1st
meeting in Brussels

1 of 6
founding members

2
Management Committee seats

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



Success example: EFPIA Input into EU Pharma Leg. revision

Further expand the Masterfile concept to fully enable manufacturing innovation -> The Platform Technology Master File (PTMF) made it into the final text of the new Directive (Article 26a)

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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 p
European regulatory framework ha
between collaborating parties for b
such as Active Substance Master Fil
tools currently exist in the EU, for v
veterinary vaccine Platform Techno
the Plasma Master File (PMF).

Article 26a

Platform technology master files

1. Marketing authorisation applicants may, instead of submitting the relevant data related to a platform technology, rely on a certified platform technology master file granted in accordance with paragraph 3. Marketing authorisation applicants shall describe the platform technology master file in accordance with the information referred to Annex II. The marketing authorisation applicants shall take into account the scientific guidelines published by the Agency in this regard.

Continuation of our publications on industry best practice strategy -

Example: Latest Publication from Polysorbate topic team

Journal of Pharmaceutical Sciences 115 (2026) 104169

Contents lists available at ScienceDirect

Journal of Pharmaceutical Sciences

journal homepage: www.jpharmsci.org

General Commentary

Do we worry too much about polysorbate degradation? An industry-wide perspective with real-life case studies☆

Check for updates

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Industry survey on polysorbate content decrease
Critical quality attributes
Polysorbate stability
Fatty acid particle formation
Toxicology and immunogenicity
Main degradation products

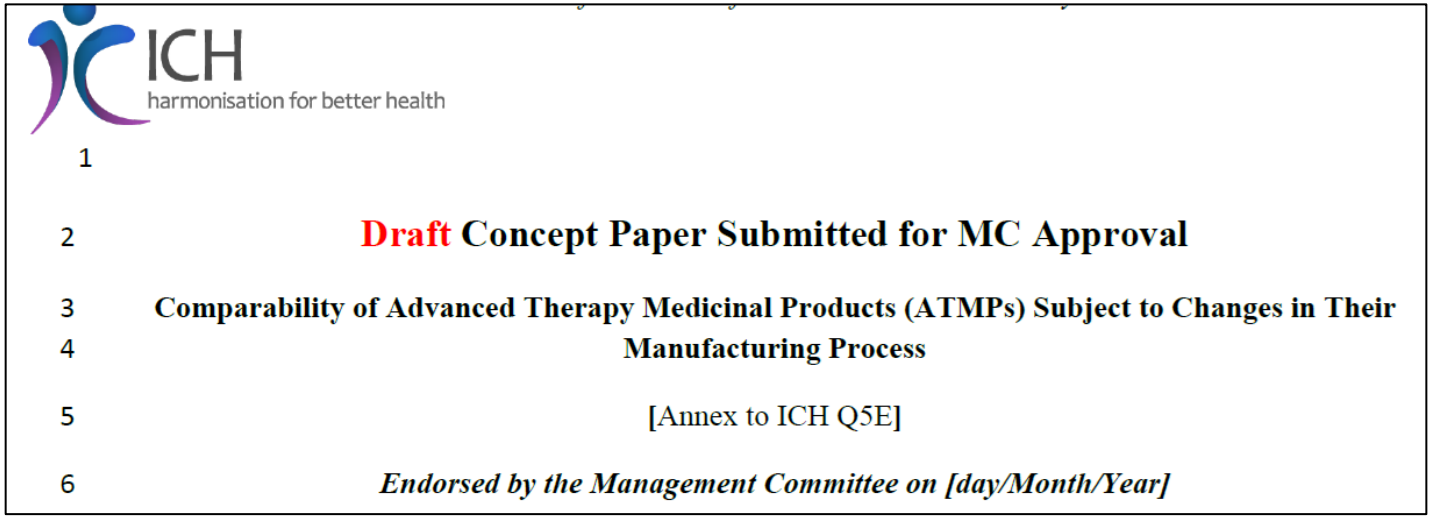
ABSTRACT

Polysorbates are commonly used in biotherapeutic drug formulations, but their stability over the course of the product's shelf life is a matter of concern. An industry-wide survey involving 15 biopharmaceutical companies found that 23 biotherapeutic drug products (DPs) in clinical development exhibited significant reductions in polysorbate (PS) content during long-term storage at 2–8 °C. In all cases, this decline did not impact critical quality attributes (CQAs), except for the formation of fatty acid (FA)-related sub-visible particles (SVP) in 7 DPs and FA-visible particles (VP) in 1 DP. Particle formation predominantly resulted from enzymatic or uncharacterized degradation mechanisms, not oxidative pathways. Corrective measures, such as optimization of downstream purification or reformulation, were undertaken only when SVP levels exceeded acceptable thresholds.

For PS20 and PS80, the levels of FAs generated were estimated and translated into predicted SVP levels based on theoretical assumptions. Additionally, the current understanding of PS degradation in biopharmaceuticals, based on the latest literature, is summarized, with consideration of safety and immunogenicity aspects related to the primary PS degradation products. Overall, PS degradation is considered manageable and not problematic under practical conditions. Enzymatic hydrolysis of PS is generally deemed acceptable, provided that all CQAs are maintained within specified limits. If FA-related particles are formed it is recommended that the PS degradation pathway is well characterized, and an appropriate control strategy be implemented.

>> more to come on polysorbate degradation in later part of this Satellite session

New Activity: Start EFPIA support of the ATMP Annex to ICH Q5E on Comparability



ICH
harmonisation for better health

1

2 **Draft Concept Paper Submitted for MC Approval**

3 **Comparability of Advanced Therapy Medicinal Products (ATMPs) Subject to Changes in Their**
4 **Manufacturing Process**

5 [Annex to ICH Q5E]

6 ***Endorsed by the Management Committee on [day/Month/Year]***

- **ICH Q5E Expert Working Group will meet in Rio de Janeiro in June with the following key deliverables:**
  - Consensus on Final Concept Paper
  - EWG Work Plan
  - Structure of Annex
- **Formation of EFPIA Q5E support team underway to provide further industry SME input "as needed" to the EFPIA ICH Q5E topic lead**
  - EFPIA Q5E topic lead has regular check-ins with MQEG Biomanufacturing Team as part of our "dedicated ICH support".

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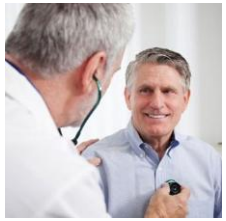
EFPIA Biomanufacturing Satellite Session at CASSS European Strategy Forum 2026

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






Agenda – EFPIA Satellite Session 2026

08:30 – 08:45	*Veronika Jekerle* *Sandra Auguste-Bowler* Opening of the CASSS EU CMC Strategy Forum
EFPIA Biomanufacturing Group Satellite Session Part I	
08:45 – 9:00	*Markus Goese* – Welcome to EFPIA session and updates on what is/was hot and what activities are ongoing
09:00 – 09:10	*Cyrille Chery* - How to implement polysorbate degradation control practically not daily life following our 3 publications
09:10 – 09:20	*Colin Cox* - Agile (Innovative) Manufacturing and decentralized/distributed manufacturing in latest regulatory environment including New EU Pharma Legislation
09:20 – 09:30	*Andrew Lennard* - perspectives on serving EFPIA for decades
EFPIA Biomanufacturing Group Satellite Session Part II: Comparability Assessment for Bioconjugates: Regulatory Expectations, Practical Experience, and Emerging Challenges Moderators: Helen Newton, Stuart Finnie, Karoline Bechtold-Peters	
09:30 – 09:50	Regulatory Perspectives on Comparability Evaluation of Antibody-Drug Conjugates (ADCs), *Pavel Šimek*, SÚKL
09:50 – 10:10	*Thomas Pohl* - Comparability strategies for Bioconjugates
10:10 – 10:40	Networking Break
10:40 – 11:00	*Katie Duncan* - Comparability case study from GSK
11:00 – 11:20	*Veronika Jekerle* - Platform approach (How platform concepts can be used (and where they break down) for conjugates
11:20 – 12:05	Panel Discussion – Q&A
12:05 – 12:10	Closing Remarks

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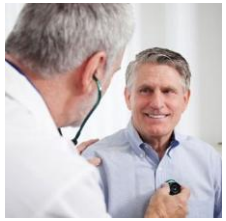
Thank you & Enjoy the session!



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