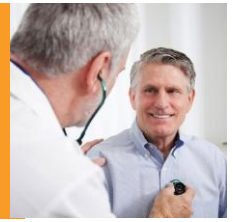
European Federation of Pharmaceutical Industries and Associations

Achieving Positive Change to the Global CMC Regulatory Environment

Andrew Lennard

Amgen Regulatory CMC: External Engagement & Advocacy






EFPIA Biomanufacturing Group Satellite Session Part I

23 June 2026

Before EFPIA

A career path from protein chemistry to CMC regulatory advocacy

Biochemist / Protein chemist
Histones, chromatin structure using chemical cross-linking

Industry Research leadership
Yamanouchi / Astellas
Built molecular biology capability; IL-1ra (*kineret*), developed cell-based high-throughput screens

Regulatory consultancy CMC
ERA Consulting (London)
EU regulatory landscape, analytical methods, characterisation & comparability (anti-TNFα) and biosimilars (*filgrastims, EPOs*)

01 02 03 04 career change 05 06

Molecular biologist
1. **LGME labs** (Strasbourg)
2. **ICRF labs** (London)

Molecular biology
Mammalian transcription factors, viral & eukaryotic promoters & gene structure

Biotech drug discovery
Lorantis
Start-up immunology.
Protein engineering
PCR cDNA; Notch pathway,
(*Imdelltra and AMG 430*)

Regulatory CMC
Amgen
- EU & RoW filings: clinical to MA to variations
- Move to 'External Engagement & Advocacy'

Moving from drug discovery to regulatory strategy and external advocacy

Working in EFPIA

From participation to influence: networks, regulatory access and outputs

Join EFPIA MQEG teams (from EBE)

Biomanufacturing & CMC teams:
Numerous opportunities for a multitude of topics

Attend meetings & contribute to teams, gain trust & respect

EFPIA topics & cross-industry publications

- visibleparticles,
- bioburden sample size,
- DDC control strategy, device platforms
- Nitrosamine risk to biologicals,
- Agile manufacture and the Sister Site concept

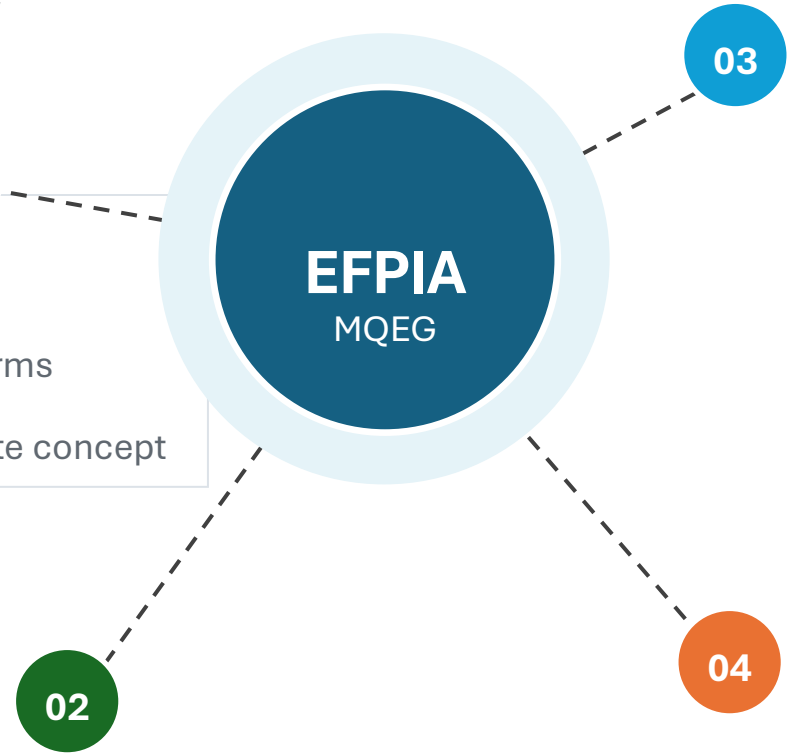
Gain credibility

Build the network

Attend and actively participate in CASSS-Europe + EFPIA satellite meetings

Meet industry colleagues, regulators & EDQM personnel

Be bold; say hello and get known



Lead

Take on team leadership roles

- **Stability**
- **Nitrosamines in biologicals**
- **Sister Sites concept**

Hands up and get in early

ICH opportunities

- **ICH Support teams**
  - Q13, M4Q, Q6

ICH Q1 Stability guideline revision

- **EFPIA Stability topic lead**

Opportunities to engage with EMA regulators

1. EMA workshops through EFPIA

- Prior Knowledge
- CMC acceleration tools

2. BWP Interested Parties

- EMA IMPD guideline
- Clinically relevant specifications
- Alternative PPQ strategies
- Low risk site transfers
- Replacing RPT and LAL-BET tests

3. EMA QIG meetings

- Continuous manufacture
- Process modelling
- Sustainability

EFPIA – European Federation of Pharmaceutical Industries Association
MQEG – Manufacturing & Quality Expert Group
EBE – European Biopharmaceutical Enterprises

How to Succeed(?) Through EFPIA

A Personal Reflection

Find the next impactful topic

- Use EFPIA to stay ahead of the game

Make advocacy work sustainable

- Work in EFPIA teams, find time and mold output beneficial to your business, keeping patients ‘in sight’.

Convert participation into outputs

- Cross-industry EFPIA papers and CASSS-EU presentations

Build recognition and access across the biopharma industry

- Lead teams, meet regulators and volunteer early

Use EFPIA as a route into ICH

- Spot out-of-date regulatory guidance or new areas lacking guidance
- Secure expert-group support
- Be a heard voice across your EFPIA industry colleagues
- Make an impactful difference to the regulatory landscape and to the patients that are in need of new or improved medicines

Thank You to the Following for Making All this Happen

Amgen Inc & Ltd

- RACMC – global, regional/local, site
- Reg Affairs – Therapeutic Areas
- Product Quality & Quality Compliance
- Process Development – DS & DP
- Analytical Sciences
- Supply Chain

EFPIA

- MQEG
- CMC team
- Biomanufacturing team

CASSS

- Staff
- WCBP Steering Committee
- CMC Strategy Fora Steering Committees