

11 September 2024

Quality Innovation Group (QIG) Listen and Learn Focus Group (LLFG) meeting on Platforms Technologies Agenda

19th - 20th November 2024

Virtual meeting

Chair: Marcel Hoefnagel

Day 1

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Timing		Contributors:
09:30 – 09:45	Opening of the LLFG Welcome to participants. Introduction to QIG, meeting scope and objectives of the 4 th QIG LLFG.	Marcel Hoefnagel (QIG Chair, MEB)
09:45 – 10:15	1: Use of Prior Knowledge and Platform Approaches: an EU Regulatory Perspective	René Thürmer (QIG Member, BfArM)
Session 1		
10:15 – 10:25	2. Platforms technologies are critical to accelerating vaccine development	Cathy Hoath - CEPI
10:25 – 10:55	3: mRNA-LNP platform technology to support specification setting and determination of product shelf life	Brian Doyle - Moderna
10:55 – 11:10	Q&A	

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11:10 - 11:25

Coffee break

11:25 – 11:55	4: Platforms for medicinal products manufactured using prior knowledge, IMPs considerations	Francesco Cicirello - ISPE (BioNTech)
11:55 – 12:10	Q&A	
12:10 – 12:40	5: MAPS technology, a cutting-edge platform manufacturing	Mónica Perea-Vélez, Christophe Verriest, Roland Mainil, Xavier Otte – PDA (GSK)
12:40 – 12:55	Q&A	

12:55 – 13:55

Lunch

13:55 – 14:25	6: Viralgen - Platform strategy	César Trigueros, María Orío Silvia Gómez (Viralgen)
14:25 – 14:40	Q&A	
14:40 – 15:10	7: Optimising development of gene therapies for rare genetic diseases	Sean Russell - Fondazione Telethon ETS
15:10 – 15:25	Q&A	

15:25 - 15:40

Coffee break

15:40 – 16:10	8: Prime editing platform technologies	Barrett Nehilla - Prime Medicine
16:10 – 16:25	Q&A	
16:25 – 17:25	Panel Discussion	Presenters + Marcos Timón (QIG Member, AEMPS) + Silke Schüle (QIG Member, PEI)
17:25 – 17:30	Closure of day	<i>QIG Chair</i>

Day 2

Timing		Contributors:
Session 2		
09:00 – 09:10	Opening of the second day Introduction to day 2 meeting scope	Marcel Hoefnagel - QIG Chair (MEB)
09:10 – 09:40	1: Platforms – an EFPIA/VE perspective (Continuous Direct Compression (CDC) platform focus)	Matt Popkin – EFPIA (GSK), Andrea Ruggiero – EFPIA (Merck), Meike Vanhooren – EFPIA (Pfizer), Mihai Bilanin– EFPIA (GSK)
09:40 – 09:55	Q&A	
09:55 – 10:25	2: Application of a platform approach to oligonucleotide drug substance development	Jenny Franklin - EPOC (Ionis), Dominik Altevogt - EPOC (Novartis)
10:25 – 10:40	Q&A	
10:40 – 11:10	3: Strategy for implementation of a platform approach for synthetic oligonucleotides	Roger Stadler - BioSpring
11:10 – 11:25	Q&A	
11:25 – 11:40	Coffee Break	
11:40 – 12:10	4: Statistical approaches to develop data-driven prior knowledge into a platform.	Beate Presser – CMC Statistical Network Europe (Boehringer-Ingelheim), Kevin Lief – CMC Statistical Network Europe (GSK)
12:10 – 12:25	Q&A	
12:25 – 13:25	Lunch Break	
13:25 – 14:25	Panel Discussion	Presenters + René Thürmer (QIG Member, BfArM) + Ciara Turley (QIG Member, HPRA)
14:25 – 14:45	Coffee break-survey	
14:45 – 15:30	Sum up, next steps and closure of meeting	<i>QIG chair and members</i>

QIG LLFG Organising Committee Members

EU

Marcel Hoefnagel, MEB, The Netherlands, QIG Chair.

Leticia Martinez Peyrat, ANSM, France, QIG Member.

Barbara Stubbe, FAGG, Belgium, QIG Member.

Christina Meissner, AGES, Austria, QIG Member.

Silke Schüle, PEI, Germany, QIG Member.

Marcos Timón, AEMPS, Spain, QIG Member.

René Thürmer, BfArM, Germany, QIG Member.

Ciara Turley, HPRA, Ireland, QIG Member.

Sean Barry, HPRA, Ireland.

Tone Agasoster, NOMA, Norway.

Greger Abrahamsen, NOMA, Norway.

EMA

Ragini Shivji, Quality Office, European Medicines Agency

Dolores Hernan, Quality Office, European Medicines Agency

Evdokia Korakianiti, Quality and Safety Department, European Medicines Agency

Veronika Jekerle, Quality Office, European Medicines Agency

Peter Twomey, Inspections Office, European Medicines Agency

Giampiero Lorenti, Inspections Office, European Medicines Agency

Miguel Rodriguez, Inspections Office, European Medicines Agency