Quality Innovation Group (QIG)

Listen and Learn Focus Group (LLFG) meeting on Process Models

Agenda

4th - 5th June 2024

Hybrid meeting

Day 1-Room 2B

Chair: Marcel Hoefnagel

Timing		Contributors:
09:00 – 09:15	**Opening of the LLFG** Welcome to participants. Introduction to QIG, meeting scope and objectives of the 3rd QIG LLFG.	Marcel Hoefnagel (QIG Chair – MEB)
09:15 – 09:45	Presentation 1: QIG Preliminary Considerations on process models. Overview of major comments received during the public consultation.	Leticia Martinez Peyrat (QIG Member - ANSM)
Session 1		
09:45 – 10:15	Presentation 2: Application of the EMA Preliminary Considerations to Real Process Model Examples – an EFPIA perspective	Matt Popkin, Gert Thurau (EFPIA)
10:15 – 10:25	Q&A	

10:25 – 10:45	**Coffee break**	
10:45 – 11:15	Presentation 3: Uncertainty Quantification of Process Models: Key to Risk-Informed Decision Making throughout the Product Life Cycle	Thomas Zahel (ISPE)
11:15 – 11:25	Q&A	
11:25 – 11:55	Presentation 4: Case Study on the Qualification of Mechanistic Downstream Process Models as Part of Regulatory Submissions	Till Briskot, Simon Kluters, Joey Studts (Boehringer Ingelheim)
11:55 – 12:05	Q&A	
12:05 – 13:00	**Lunch**	
13:00 – 13:30	Presentation 5: Sensor -fusion case-study	Nuno Matos, Pedro Valente (Hovione)
13:30 – 13:40	Q&A	
13:40 – 14:10	Presentation 6: Predictive Models for accelerated process design and development of high-quality medicines	Pankaj Doshi (Pfizer)
14:10 – 15:00	Panel discussion	QIG Members + Thomas O'Connor and Sharmista Chatterjee (US-FDA) + Academia + Presenters of the day
15:00 – 15:30	**Coffee break**	
15:30 – 16:00	Sum up, next steps and closure of day	*QIG*

Day 2-Room 1A

Timing		Contributors:
	Session 2	
09:00 – 09:10	**Introduction to meeting Day 2 scope**	*Chair*
09:10 – 09:40	Presentation 1: Silico Modeling	Pablo Rolandi, Fabrice Schlegel (Amgen)
09:40 – 09:50	Q&A	
09:50 – 10:20	Presentation 2: Lyophilization Modelling for Process Development and Control	Domenico Colucci, Bernadette Scutellá, Ben Stevens (GSK)
10:20 – 10:30	Q&A	
10:30 – 11:00	Presentation 3: Machine Learning Process Model for Prediction of Variant Attributes in a Monoclonal Antibody DS Process	Andreas Kleeb, Margaux Penwarden, Christina Heinlein (F. Hoffmann-La Roche)
11:00 – 11:10	Q&A	
11:10 – 11:25	**Break**	
11:25 – 11:55	Presentation 4: Cross-Program mRNA Process Models with Interpretable Machine Learning (ML)	Gang Wang (Moderna)
11:55 – 12:05	Q&A	
12:05 – 13:00	**Lunch Break**	
13:00 – 14:00	Panel Discussion	*QIG Members* + Thomas O'Connor and Sharmista Chatterjee (US-FDA) + *speakers of the day*
14:00 – 14:30	**Coffee break-survey**	
14:30 –15:30	Sum up of challenges, solutions and follow-ups and closure of meeting	*QIG*

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.

Nick Lee, HPRA, Ireland, QWP Member

Mats Welin, Läkemedelsverket, Sweden, BWP Member

EMA

Dolores Hernan, Quality Office, European Medicines Agency

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Veronika Jekerle, Quality Office, European Medicines Agency

Peter Twomey, Inspections Office, European Medicines Agency

Giampiero Lorenti, Inspections Office, European Medicines Agency

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Miguel Rodriguez, Inspections Office, European Medicines Agency