



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 October 2023

Quality Innovation Group (QIG)
Listen and Learn Focus Group
Digital Novel Technologies
Agenda

12th - 13th October 2023

Day 1-Room 2B

Chair: Marcel Hoefnagel

Timing		Contributors:
09:00 – 09:15	Welcome to participants. Introduction to QIG, meeting scope and objectives of the LLFG.	<i>Chair</i>
09:15 – 09:45	Presentation 1: Enabling Techs in regulated Pharma: 35 Case Studies.	<i>Teresa Minero (ISPE)</i>
Session 1: Process models, digital twins		
09:45 – 10:15	Presentation 2: Advanced digital control concepts for continuous manufacturing processes.	<i>Selma Celikovic (RCPE)</i>
10:15 – 10:25	Q&A	
10:25 – 10:45	Coffee break	

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10:45 – 11:15	Presentation 3: End-to-End Digital Twins for Process Control.	<i>Thomas Zahel (Körber Pharma)</i>
11:15 – 11:25	Q&A	
11:25 – 11:55	Presentation 4: System Modeling Applications for Pharmaceutical Process Development.	<i>Ben Stevens, Neil Hodnett Gabriele Bano (GSK)</i>
11:55 – 12:05	Q&A	
12:05 – 13:00	Lunch	
13:00 – 13:30	Presentation 5: Combination of computational fluid dynamics (CFD) derived compartment models (CMs) with biological kinetic models as an improved hybrid tool to enable fast development, scale up and control of vaccines manufacture.	<i>Krist V. Gernaey, Monica Perea Velez (Inno4vac)</i>
13:30 – 13:40	Q&A	
13:40 – 14:10	Presentation 6: Model-based process development and operation.	<i>Dr. Moritz von Stosch (DataHow)</i>
14:10 – 15:00	Short 5 min intro: AI and digitalization technologies applied to ATMP manufacturing Panel discussion	<i>Dr Stephen Goldrick (AIDPATH)</i> <i>QIG members + speakers</i> <i>Sharmista Chatterjee (FDA)</i> <i>Tom O'Connor (FDA)</i> <i>Gert Thureau (Roche)</i> <i>Ben Stevens (GSK)</i> <i>Akansha Tyagi (PWC)</i> <i>Andrew Lennard (Amgen)</i> <i>Stephen Goldrick (University of London)</i>

		<i>Thomas de Beer and Alexander De Man (Ghent University)</i>
15:00 – 15:30	Coffee break-survey	
15:30 – 16:00	Sum up, next steps and closure of day	<i>QIG</i>

Day 2-Room 2A

Timing		Contributors:
Session 2: AI, ML for GMP applications		
09:00 – 09:10	Introduction to meeting Day 2 scope	<i>Chair</i>
09:10 – 09:40	Presentation 1: Frame-by-Frame Risk Profiling Technology (& VR)	<i>Zoe Ann Lentz (Moderna)</i>
09:40 – 09:50	Q&A	
09:50 – 10:20	Presentation 2: Automated Reading of Agar Plates using AI	<i>Karen Capper (Astra Zeneca)</i>
10:20 – 10:30	Q&A	
10:30 – 11:00	Presentation 3: Artificial Intelligence for Chromatographic Peak Integration.	<i>Andrea Ruggiero, Abhijeet Satwekar (Merck)</i>
11:00 – 11:10	Q&A	
11:10 – 11:25	Break	
11:25 – 11:55	Presentation 4: Visual Inspection Robot with Machine Learning Algorithms.	<i>Dominic Baca, Dottie Wacker - White, Gert Thureau (Roche)</i>
11:55 – 12:05	Q&A	
12:05 – 13:05 Lunch break		
13:05 – 14:30	Panel Discussion	<i>QIG members + speakers + Sharmista Chatterjee (FDA) Tom O'Connor (FDA) Dominic Baca (Roche)</i>

		<i>Gitte Windfeldt (Novo Nordisk)</i> <i>Kare Capper (Astra Zeneca)</i> <i>Abhijeet Satwekar and Andrea Ruggiero (Merck)</i> <i>Al Goodwin (Amgen)</i>
14:30 – 15:00	Coffee break-survey	
15:00 –15:30	Sum up of challenges, solutions and follow-ups and closure of meeting	<i>QIG</i>

QIG Members

Name and Surname	Agency (Member State)
Marcel Hoefnagel (Chair)	MEB (The Netherlands)
Giampiero Lorenti	AIFA (Italy)
Leticia Martinez Peyrat	ANSM (France)
Christina Meissner	AGES (Austria)
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