

ICMRA-industry virtual workshop: Strengthening regulatory convergence and reliance through Pharmaceutical Quality Knowledge Management

Friday, September 19, 2025

7:00 – 9:00 ET | 13:00 – 15:00 CET

AGENDA

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|-------------|---|
| 7:00 – 7:05 | ICMRA welcoming remarks
<i>Lorraine Nolan, Chief Executive, HPRA</i> |
| 7:05 – 7:10 | Industry welcoming remarks
<i>Ginny Beakes-Read,</i>
<i>Head, Global Regulatory Policy Group,</i>
<i>Johnson & Johnson representing IFPMA</i> |
| 7:10 – 7:20 | ICMRA presentation
<i>"ICMRA PQKM pilots: Experience to date and looking to the future"</i>
<i>Sean Barry, Senior Pharmaceutical Assessor (Biologicals), HPRA</i> |
| 7:20 – 7:30 | Industry presentation
<i>"ICMRA PQKMS Pilots – industry perspective"</i>
<i>Markus Goese, Head EU CMC Regulatory Policy, F. Hoffmann-La Roche Ltd</i> |
| 7:30 – 8:10 | Panel 1 - Experience and engagement on the Collaborative Assessment of Post-Approval Change Management Protocols Pilot
<i>Co-moderated by</i>
<i>Janis Bernat, Director, Scientific & Regulatory Affairs, IFPMA</i>
<i>William Lewallen, International Program Analyst, CDER, FDA</i> |

Panellists: Regulators

Larry Lee,
Deputy Director of Operations,
Office of Pharmaceutical Quality, FDA

Yasuhiro Kishioka,
PhD, Review Director,
Office of Cellular and Tissue-
based Products, PMDA

Evdokia Korakianiti,
Head of Quality and Safety,
Human Medicines Div, EMA

Sean Barry,
Senior Pharmaceutical Assessor (Biologicals),
HPRA

Panellists: Industry

Mark Pellett,
Executive Director and Section Head, CMC
Regulatory Affairs, AstraZeneca

Wan-Li LIAO,
GRA CMC Regulatory Intelligence Associate
Director, Merck KGaA

Sarah Miksinski,
Executive Director, CMC Regulatory Affairs,
Gilead Sciences Inc.

Lisa Little-Tranter,
Senior Director, CMC Biologics Global,
Merck/MSD

Evangelos Bakopanos,
Manager, Biotherapeutics Quality Division 2
BRDD, CORR, Health Canada

Markus Goese,
Head EU CMC Regulatory Policy,
F. Hoffmann-La Roche Ltd

Ramesh Potla,
Senior Technical Regulatory Advisor – Biologics
Global Regulatory Affairs CMC at Takeda

Nick Cappuccino
Chair, IGBA Science Committee

8:10 – 8:50 **Panel 2: Experience and Engagement on the Collaborative Hybrid Inspection Pilot (CHIP) Pilot**

Co-moderated by

Sérgio Cavaleiro Filho, Manager, Regulatory Affairs, IFPMA

Michael McDonald, Executive Assistant to the Chief Executive, HPRA

Panellists: Regulators

Brendan Cuddy,
Scientific Senior Specialist, Quality and Safety of
Medicines Department (H-QS), EMA

Magda Joseph,
Regional Manager of GMP Inspections, Regulatory
Operations and Enforcement Branch, Health Canada

Christian Schaerer,
Head of Inspectorate,
Swissmedic

Lane Christensen,
Branch Chief - Chemistry, Manufacturing & Controls,
OPQ/CDER, FDA

Roberto Conocchia,
GMP Technical Lead, EMA

Panellists: Industry

Stephen Mahoney,
Executive Director,
Head of Quality Policy & Advocacy, Gilead

Andrea Kurz,
Lead External Advocacy Europe,
Quality Policy & Advocacy,
F. Hoffmann-La Roche Ltd

8:50 – 8:55 **Industry concluding remarks and key takeaways**

Ginny Beakes-Read,
Head, Global Regulatory Policy Group,
Johnson & Johnson representing IFPMA

8:55 – 9:00 **ICMRA concluding remarks and key takeaways**

Theresa Mullin,
Associate Director for Strategic Initiatives,
CDER, FDA