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

Friday, September 19, 2025

ICMRA

INTERNATIONAL COALITION OF MEDICINES REGULATORY AUTHORITIES

Meeting Welcome Announcement

Welcome to today's ICMRA-industry virtual workshop Development of a Pharmaceutical Quality Knowledge Management System.

Please note, as an attendee you will not be able to use your microphone to speak during the webinar.

The chat box will be used to share links and resources during the workshop.

When the time comes for attendee questions, please use the **Q&A function** to input any question you would like addressed by our panelists.

If you have any IT related questions, please send them to corey.farley@fda.hhs.gov.

Thank you for your time!

ICMRA Welcoming Remarks

Lorraine Nolan, Chief Executive, HPRA

Industry Welcoming Remarks

Ginny Beakes-Read, IFPMA

Background to the ICMRA PQKM project and progress to date

ICMRA-industry virtual workshop

19 Sept 2025

Seán Barry (HPRA) (on behalf of the ICMRA PQKM working group)

Collaborative assessment pilot cases

Application	Product	Indication	Proposed change	Lead Authority	Participating Authorities	Observer Authorities
Pilot Case 1	Monoclonal antibody	Follicular lymphoma	Additional active substance manufacturing site and additional QC testing site	EMA	FDA	PMDA
Pilot Case 2	Small molecule	Hyperkalaemia	Additional drug product manufacturing site	FDA	EMA	PMDA, Health Canada, HSA, ANVISA
Pilot Case 3	Small molecule	Non-small cell lung cancer	Additional active substance manufacturing site	PMDA	FDA, EMA, MHRA, Swissmedic	HSA, Health Canada, TGA
Pilot Case 4	Antibody drug conjugate	Metastatic triple-negative breast cancer	Additional active substance intermediate manufacturing site and additional QC testing site	FDA	EMA, MHRA, Swissmedic	Health Canada
Pilot Case 5	Monoclonal antibody	Multiple cancer indications	Improvements to the manufacturing process	EMA	FDA, PMDA, Health Canada	HSA, Swissmedic

Lead Authority

- Assess application
- Propose IRs
- Coordinate all activities
- Lead on project calls
- Consolidates IRs
- Applicants' main contact

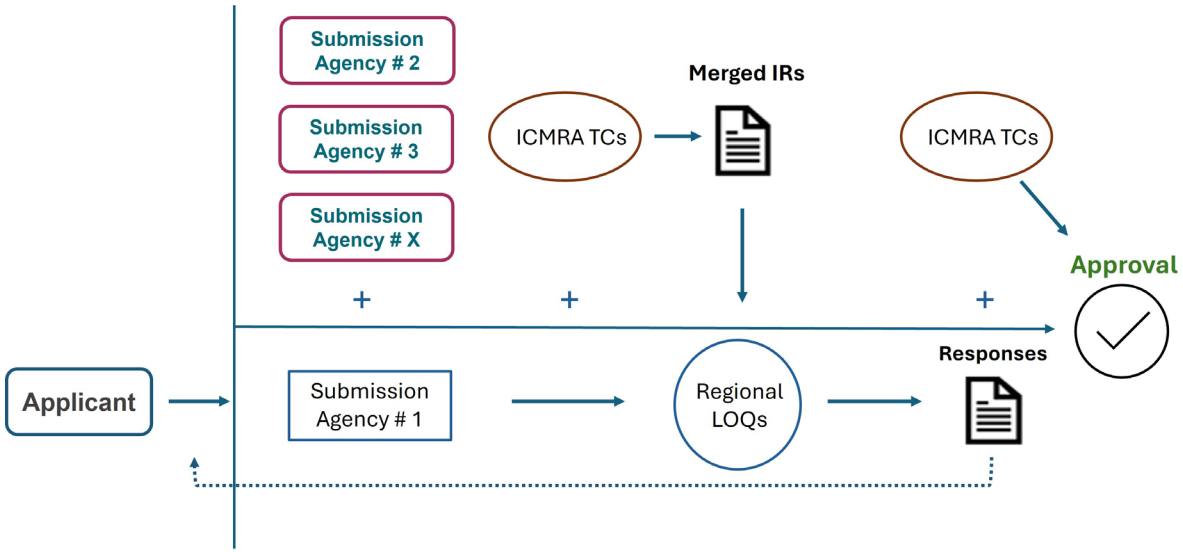
Participating Authorities

- Conduct independent assessment
- Participate in discussion meetings
- Propose IRs

Observer Authorities

- Participate in discussion meetings
- Cannot raise IRs

Regional Procedures & ICMRA Pilots: How They Work Together



- Once accepted into the ICMRA pilot, the procedure runs in parallel with standard regional procedures
- Applicants submit formal applications through the usual regional channels (for participating agencies only — not observers)
- Submissions are flagged for ICMRA pilot inclusion, alerting agency procedure managers to track them accordingly
- A harmonised set of LOQs/IRs is prepared and sent to applicants by the ICMRA lead
- In line with legal requirements, participating authorities may also send LOQs/IRs separately
- However, a single harmonised response document can be shared with all participating agencies to streamline communication

Key achievements

Streamlined Timelines

- Agreed a common **120 day assessment timetable**
- **Near-simultaneous approvals** — a global first!

Overall duration (days)	Max difference in approval dates between participating authorities
115	0
118	0
105	0
122	2
119	12

Efficiency & Harmonisation

- **88% of all assessment IRs** harmonized via intensive discussions
- Harmonisation achieved across all sections of Module 3
- **~25% reduction** in total IRs due to collaborative review meetings
- All 5 collaborative assessments completed successfully with **harmonised outcomes**
- No increase in standard expectations → the regulatory bar remained unchanged
- **Positive feedback** from industry and regulators (based on survey results)
- Increased resource requirements, especially for regulators

Regional Specificities

- Some region-specific IRs (e.g. method transfer data, validation report requirements)
- A few region-specific administrative questions (e.g. applicant forms, GMP documentation)

Key Benefits of Collaborative Assessment

Benefits for industry

- Harmonized 120 day approval timeline across multiple jurisdictions
- Alignment on CMC data requirements across regions
- Increased predictability
- Faster implementation of global manufacturing changes
- Agile response to market shifts and capacity demands
- Reduced risk of divergence in global dossiers

Benefits for regulators

- Enhanced knowledge sharing among global authorities
- Deeper insight into regulatory practices of other agencies
- Builds trust and confidence for future reliance and work-sharing
- Supports international harmonisation and convergence

Benefits for Patients

- Increased availability of critical medicines through accelerated global approvals
- Assessment outputs support reliance in low- and middle-income countries

Pilot extension

Based on positive results and feedback, pilots have been extended for 1 extra year.

- A detailed report is now publicly available

ICMRA website

Summary Report

Scope includes:

- ✓ High impact changes for medically important treatments
- ✓ Innovative manufacturing technologies
- ✓ PACMPs that impact supply
- ✓ Generics and biosimilars

- Applicants are encouraged to contact the PQKM Pilot Coordination Group to discuss potential applications
- **Informal discussions** are welcomed prior to application
- The application process is simple – just a 2 page form

Email contacts for queries
icmra-pac-pilot@fda.hhs.gov
icmra-pac-pilot@ema.europa.eu
icmra-pac-pilot@pmda.go.jp

Ongoing activities

- 5 applications submitted in Q2/Q3 2025
- 2 have been accepted, 1 rejected and 2 under evaluation
- The first pilot in phase 2 will start in September
  - Transfer of DS manufacturing site
  - EMA lead (DE Rapp), FDA, SwissMedic, and MHRA participating
  - NMPA, China will be an observer
- Efficiencies identified during the first phase will be introduced

Collaborative Hybrid Inspection Pilot (CHIP)

- A collaborative hybrid inspection is a joint inspection by two authorities with one lead authority on site and one authority participating remotely.
- Goal of the CHIP was to enable a CMC submission that would undergo a single hybrid inspection that would be accepted by participating authorities.
- Scope limited to pre-approval inspections and to selected products (e.g. PRIME & Breakthrough). Aim to increase manufacturing capacity and supply.

CHIP - Proposals Accepted and Regulatory Authorities

Applicant	Lead 'Onsite' Authority	Remote Authority	Observers
Roche	Swissmedic	FDA	EMA and Health Canada
Gilead*	FDA	Health Canada	PMDA, Swissmedic, MHRA, MoH Israel, EMA, HPRA

* Using a CMO

- 3 collaborative hybrid inspections completed without technical difficulties
- Survey of participants was positive – CHIP approach did not add regulatory burden and can benefit patients and industry
- Good operational outcomes and good communication and interaction between authorities and with the manufacturer and sponsor
- But a collaborative hybrid inspection required a significant increase in workload compared to a normal inspection

CHIP Achievements

- Positive and productive collaborations with supporting tools developed
  - Regulators - Joint Inspection Protocol with agreed timetable for inspections
  - Sponsors & Facilities – Industry Expectations Guidance and timely communication and response to deficiencies.
  - Sponsors achieved approvals with sites securing CGMP Compliance Status.
- Lead and Remote Regulatory Authorities aligned on inspection procedure and findings
  - Agreement on deficiencies, significance and post-inspection activities.
  - Harmonized approach towards unfavourable compliance status in participating regions with no supply from facility pending resolution. Achieved in different ways.
- Continuous communication among the RAs
  - Use of IT platform to securely share information between participating inspectorates before, during and post inspection.

Next Steps

- **CHIP is open for applications**
- CHIP Report published on ICMRA Website
- Updated information for stakeholders will be published on ICMRA Website
- A model inspection plan
- A model document list
- Continue to improve process

ICMRA website

Summary Report

Email contacts for queries
icmra-pac-pilot@fda.hhs.gov
icmra-pac-pilot@ema.europa.eu
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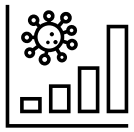
How can collaborative assessments and hybrid inspections become more sustainable in the medium to long term?

Possible scope for future activities



Post-approval changes impacting supply

- Collaborative assessments or hybrid inspections supporting increased manufacturing capacity for important medicines

Innovative manufacturing technologies

- New technologies e.g. continuous manufacturing
- Process models
- Artificial intelligence
- Advanced process control etc.

→

Types of submissions that could be considered

- Pre-submission scientific advice?
- Post-approval supplements/variations?
- Initial marketing authorization applications?
- Pre-approval hybrid inspections?

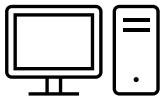
Enablers of longer term sustainability

Principles

- Voluntary participation - regulators aim to align assessment outcomes within their legal frameworks, but are not bound by decisions of other authorities
- Comparable data protection and conflict of interest standards are upheld
- Regulators apply comparable assessment standards, including implementation of ICH guidelines

Administrative support

- Long-term secretarial and administrative support is available to sustain collaboration



IT support

- Regulators can securely access and share relevant documents, such as assessment & inspection reports
- Sponsors can authorize access to their regulatory submissions and confirm identical submissions have been provided to all participating agencies

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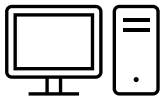
Administrative s

- Long-term secr ration

ICMRA Executive Committee currently considering how to ensure the long-term sustainable future of the collaborative assessment and CHIP initiatives



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Acknowledgements


Larry Lee, FDA


Evdokia Korakianiti, EMA


Theresa Mullin, FDA


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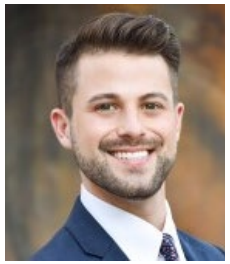
Brendan Cuddy, EMA


Sean Barry, HPRA


Susan Polifko, FDA


Will Lewallen, FDA


Michael McDonald, HPRA


Magda Joseph, Health Canada


Karin Boon, MHRA


Derek Smith, FDA


Susan Rosencrance, FDA


Evangelos Bakopanos, Health Canada

Industry Presentation
"ICMRA PQKMS Pilots – industry perspective"

Markus Goese, F. Hoffmann-La Roche Ltd

ICMRA PQKM pilots – industry perspective

ICMRA PQKM Virtual Stakeholder workshop
Sept. 19, 2025

Markus Goese, F. Hoffmann-La Roche Ltd, on behalf of Industry

Presentation outline

1. Recap: industry participants in first round of PQ KMS pilots
2. Industry Reflections on collaborative PACMP pilot
3. Industry Reflections on collaborative hybrid inspection pilot (CHIP)
4. ICMRA PQ KMS Pilots - Outlook and Recommendations
5. Benefits of the Pilots in a Nutshell – Why we (Roche) applied again
6. ICMRA PQ KMS Pilots - Conclusion & Next Steps

1. Recap: Companies in first round of ICMRA PACMP pilots

(in alphabetical order)

Table 2. Participating sponsor companies and regulatory authorities

Applicant	Lead Authority	Participating Authorities	Observers
AstraZeneca	FDA	EMA	PMDA, Health Canada, HSA, ANVISA
Gilead	FDA	EMA, MHRA, Swissmedic	Health Canada
Merck Healthcare KGaA	PMDA	FDA, EMA, MHRA, Swissmedic	HSA, Health Canada, TGA
MSD	EMA	FDA, PMDA, Health Canada	HSA, Swissmedic
Roche	EMA	FDA	PMDA

Note: Roche's first pilot project was a drug substance and drug product manufacturing site transfer PACMP for an oncology monoclonal antibody, and our second project (accepted by ICMRA into the extension of the pilots in June 2025) is a multi-product PACMP for a drug substance manufacturing site transfer for another oncology MAb.

1. Recap: Companies in first round of ICMRA CHIP pilots

Table 3 Participating companies and regulatory authorities

Applicant	Lead Inspectorate	Participating Inspectorates	Observers
Gilead	US FDA	Health Canada	EMA HPRA PMDA MOH Israel MHRA
Roche	Swissmedic	US FDA	EMA Health Canada Regierungspraesidium Tuebingen
Gilead	US FDA	Health Canada	No observer

2. ICMRA PQ KMS Collaborative (PACMP) Assessment Pilot

Industry thanks ICMRA for publishing the collaborative assessment and CHIP pilot reports, which summarize experiences and learnings, and clearly highlight the benefits of these collaborative initiatives for both, regulatory agencies as well as the pharmaceutical industry.

- **Benefits of Collaborative PACMP Assessment:**
  - Simultaneous approval by participating National Regulatory Authorities (NRAs) for post - approval changes, plus potential of faster approval of variation even with health authorities not directly involved in pilot but relying on ICMRA outcome
  - Advanced alignment on data expectations and harmonized information requests
  - Transparent dialogue and enhanced collaboration between regulators and industry

- **Identified Improvements:**
  - For extension phase in 2025, clarify timelines regarding deadline for application to the pilot/ expected date for dossier submission
  - Streamline submissions through a single platform to multiple NRAs
  - Facilitate communication and sharing of assessment reports and final decisions through a single IT repository.

3. ICMRA PQ KMS Collaborative Hybrid Inspection Pilot (CHIP)

- **Benefits of CHIP:**
  - One facility inspection instead of multiple NRA engagements, reducing on -site inspectorate days, enabled by hybrid inspection methodologies
  - Opportunity to align inspection approaches among different agencies and foster harmonization
  - One list of observations, one single inspection report that can be leveraged by co - inspectors & observers (ICMRA members)
  - Remote inspectorate benefits from local/leading inspectorate being at site e.g., for site tour , and document review, leading to aligned observations

- **Identified Enhancements:**
  - Improving inspectorate coordination and further harmonization leveraging existing inspection approaches (e.g., PIC/S for operationalization)
  - Use one working framework incl. defined R&Rs, process, template (e.g., PIC/S), IT platform as enabler for one inspection report including follow -up of CAPAs.
  - Scheduling inspection within the overall assessment timeframe of the different jurisdictions (e.g., US-PAI requirements vs. other NRA procedures)

4. ICMRA PQ KMS Pilots- Outlook and Recommendations

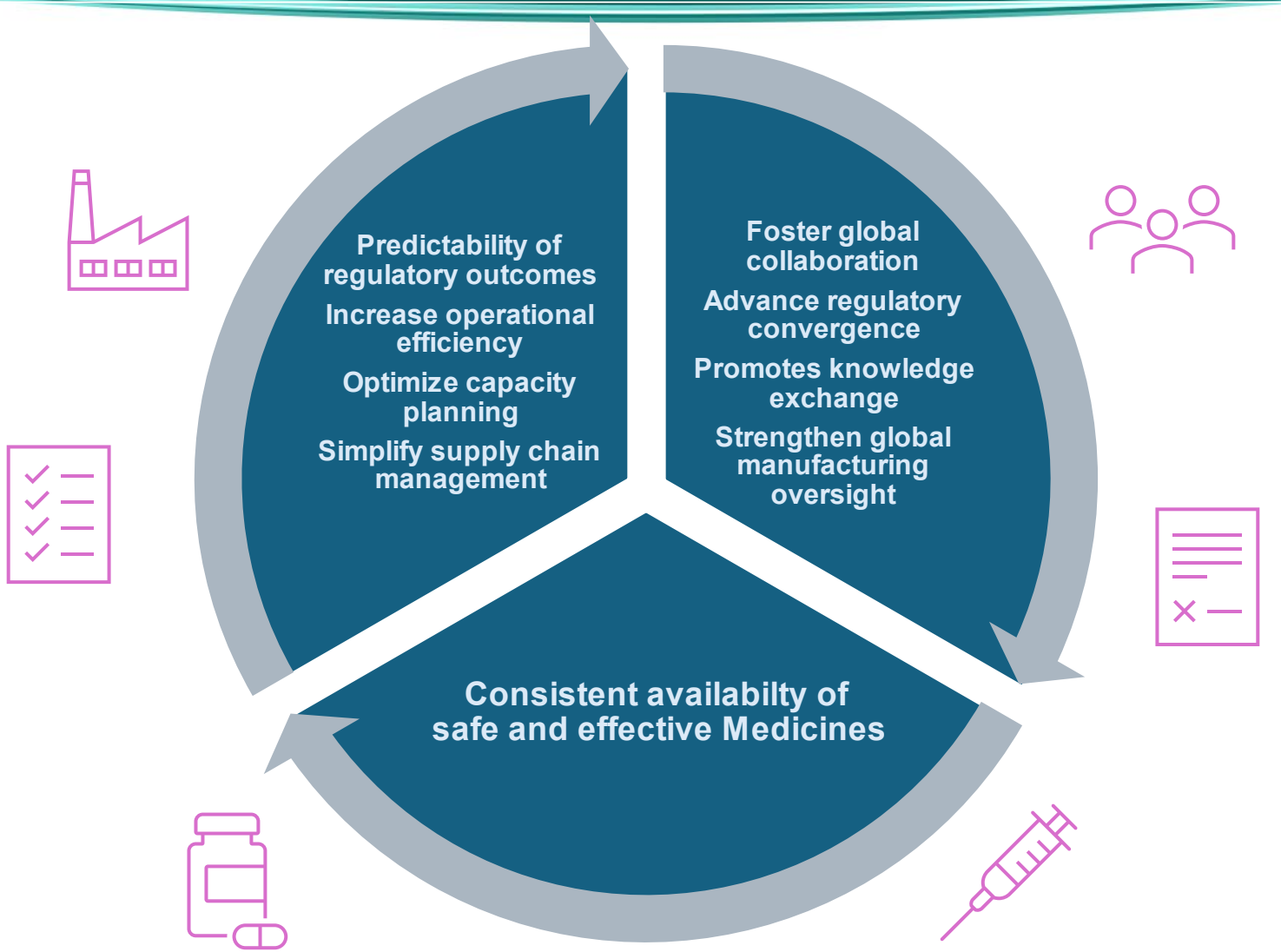
- **Key Objectives:**
  - Streamline and facilitate post-approval changes review and inspections collectively amongst ICMRA Members and beyond
  - Gain broader acceptance across both industry and NRAs
  - Embed reliance and promote regulatory convergence by relying onassessment and inspection outcomes

Industry believes the benefits of collaborative activities clearly outweigh challenges and hopes these pilot results become routine practice and improve patient access

- **Current Industry Challenges to join pilots:**
  - uncertainties about return on investment (future outlook), resources allocation, business priorities

- **Further Developments:**
  - Appreciation for the recent extension of the pilots, as well as expansion in scope, incl. to innovation in manufacturing, and allowing PACs in addition to PACMPs
  - Consider more flexibility in approach, e.g., expand scope to PACMP step -2, involve ICMRA members beyond the core working group more closely; consider engaging observers in the procedure early on and with a more active role (especially in assessment phase)
  - Establish a wider, more formal process for collaborative assessment and inspections beyond the pilot scope (with a list of participating countries) to pave the way for routine reliance and collaboration practice.

5. Benefits of the Pilots in a Nutshell – Why we (Roche) applied again



6. ICMRA PQ KMS Pilots- Conclusion & Next Steps

Industry welcomes further in-depth conversations with ICMRA, to identify areas for industry input and support of the long-term goal of global convergence, collaboration, and reliance

Panel 1: Pilot of Collaborative Assessment of post-approval change management protocol

Co-moderated by Janis Bernat, IFPMA, and William Lewallen, FDA

Panelists: Regulators

- Sau (Larry) Lee, FDA
  Deputy Director of Science, Office of Pharmaceutical Quality
- Yasuhiro Kishioka, PMDA
  PhD, Review Director, Office of Cellular and Tissue-based Products
- Evdokia Korakianiti, EMA
  Head of Quality and Safety, Human Medicines Division
- Seán Barry, HPRA
  Senior Pharmaceutical Assessor (Biologicals)
- Evangelos Bakopanos, Health Canada
  Manager, Biotherapeutics Quality Division 2, BRDD, CORR

Panelists: Industry

- Mark Pellett, *AstraZeneca*
  Executive Director and Section Head, CMC Regulatory Affairs
- Wan-Li LIAO, Merck KGaA
  GRA CMC Regulatory Intelligence Associate Director
- Sarah Miksinski, Gilead Sciences Inc.
  Executive Director, CMC Regulatory Affairs
- Lisa Little-Tranter, Merck/MSD
  Senior Director, CMC Biologics Global
- Markus Goese, F. Hoffmann-La Roche Ltd
  Head EU CMC Regulatory Policy
- Nick Cappuccino, *IGBA*
  Chair, IGBA Science Committee
- Ramesh Potla, *Takeda*
  Senior Technical Regulatory Advisor - Biologics, Global Regulatory Affairs CMC

Panel 2: Collaborative Hybrid Inspection Pilot

Co-moderated by Sérgio Cavalheiro Filho, IFPMA and Michael McDonald, HPRA

Panelists: Regulators

- Brendan Cuddy, EMA
  Scientific Senior Specialist, Quality & Safety of Medicines Department (H-QS)
- Magda Joseph, Health Canada
  Regional Manager of GMP Inspections, Regulatory Operations and Enforcement Branch
- Christian Schärer, Swissmedic
  Head of Inspectorate
- Lane Christensen, FDA
  Branch Chief - Chemistry, Manufacturing & Controls
- Roberto Conocchia, EMA
  GMP Technical Lead

Panelists: Industry

- Stephen Mahoney, Gilead
  Executive Director, Head of Quality Policy & Advocacy
- Andrea Kurz, F. Hoffmann-La Roche Ltd
  Lead External Advocacy Europe, Quality Policy & Advocacy

Industry Concluding Remarks

Ginny Beakes-Read, IFPMA

ICMRA Concluding Remarks

Theresa Mullin, FDA


ICMRA
International Coalition of Medicines Regulatory Authorities