独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

APAC 13th
MQS session
Apr 23, 2024

Activities of ICMRA PQKMS

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Office of International Programs, PMDA

Today's outline

- ICMRA
- Pharmaceutical Quality Knowledge Management System (PQKMS)
- ICMRA-ICH-PIC/S-IPRP Joint Reflection Paper
- Post-Approval Change(PAC) Sub-WG
  - ✓ Collaborative Assessment Pilot
  - ✓ Collaborative Hybrid Inspection Pilot
- Technology platform to support PQKMS
- Collaborative Work with ICH
  - ✓ ICH M4Q(R2)
  - ✓ Structured Quality Data Submission

ICMRA (International Coalition of Medicines Regulatory Authorities)

A voluntary, executive-level, strategic coordinating, advocacy and leadership entity
(39 regulatory authorities)

- Current/emerging regulatory & safety challenges
- globally
- strategically
- on-going, transparent, authoritative and institutional manner

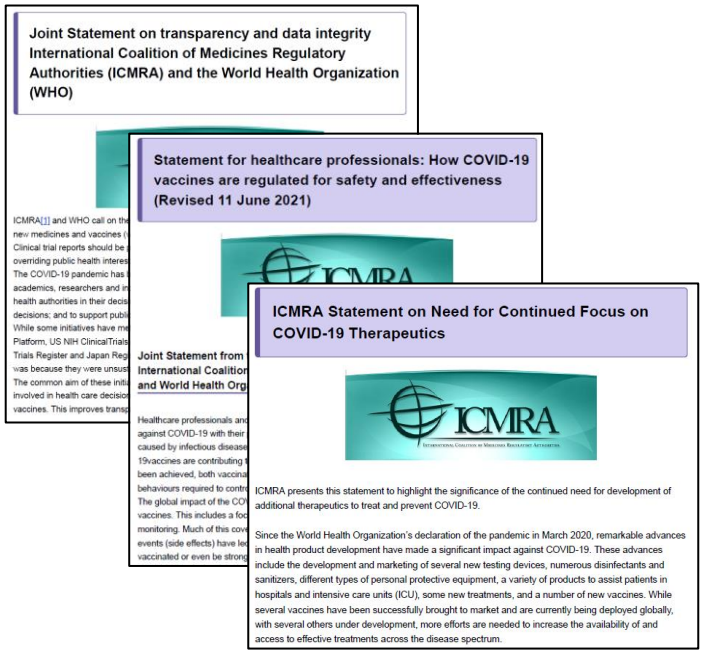
- Direction for areas/activities common to regulators etc.

Chair
- **Ms. Emer Cooke**
  EMA

Vice Chair
- **Dr. Yasuhiro Fujiwara**
  PMDA
- **Dr. Antonio Barra-Torres**
  ANVISA (Brazil)

ICMRA's Activities to Tackle COVID-19 Pandemic

- **High Level** Information Exchange
- **Working Level** Information Exchange
- **Specific Area Communication**
  - Vaccine Vigilance Network
  - Pregnancy and Lactation
  - Regulatory Agility
  - Communication with Industries
  - Virus Variants
  - GMP・GCP inspection etc.



https://www.icmra.info/drupal/en/covid-19

Pharmaceutical Quality Knowledge Management System (PQKMS)

Background

Agility to maintain

- **robust supply chains**
- **continually update manufacturing processes**

to incorporate changes and improvements

☐ **Implementation of changes: Potential delay**

Pharmaceutical industry : highly regulated/globalized

- ***approvals*** *from multiple national regulatory bodies with different timeframes*

☐ **Common procedures, guidelines, requirements, interoperable infrastructure**

- *timely information sharing among regulators on changes occurring within the supply chain*

Pharmaceutical Quality Knowledge Management System (PQKMS)

Aims

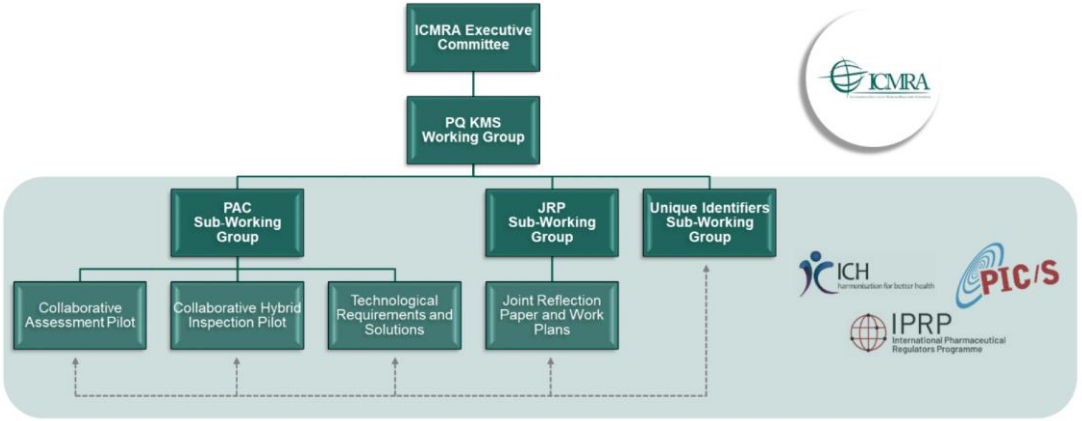
leverage **collective resources/information sharing**
on pharmaceutical quality between regulatory agencies

Alignment : regulatory requirements (post-approval setting)
- data submissions and regulatory assessments
- inspections

Goals

- **Regulatory reliance, agility, effectiveness, and efficiency**
- **Harmonization: data submissions, regulatory expectations, assessments, inspections**
- **Acceleration: global availability of quality medicines**

Pharmaceutical Quality Knowledge Management System (PQKMS)



- Collaborative Assessment
- Collaborative Hybrid Inspection
- Technological Requirements and Solutions
- Unique Identifiers

ICMRA-ICH-PIC/S-IPRP Joint Reflection Paper

A Regulatory Pharmaceutical Quality Knowledge Management System (PQ KMS) to Enhance the Availability of Quality Medicines

ICMRA-ICH-PIC/S-IPRP Joint Reflection Paper
Version Dated: 21 July 2022

Background and Rationale

Changes to pharmaceutical manufacturing processes, technological innovations, and altered supply chains are just some examples of the many issues requiring operational agility that affect the availability of medicines required to meet patient needs. Whether pursuing continuing improvement in manufacturing a novel therapeutic based on post approval experience, or routine updates to operations, equipment, suppliers, and other post approval changes (PACs) later in a product life cycle, manufacturers are expected to proactively manage pharmaceutical quality using existing frameworks outlined in the internationally harmonized guidelines. Specifically, this includes ICH Q10 Pharmaceutical Quality System[1], building on the guidance in ICH Q8 Pharmaceutical Development[2], while applying the principles in ICH Q9 Quality Risk Management[3], and utilizing the enablers and tools outlined in the ICH Q12 guideline on Lifecycle Management[4].

While companies manage these PACs within their pharmaceutical quality systems (PQS), the current operating environment requires prior approval by the regulatory authority of each region and country individually. For a product to be globally available to patients, this can translate to numerous and often duplicative regulatory review processes and time frames. This presents regulatory complexity that can significantly constrain manufacturer agility in addressing challenges such as supply chain disruptions, or the need to significantly scale up production to meet urgent needs for critical therapies in multiple regions that could directly impact on the supply of critical medicines.

ICH harmonisation for better health

1. M4Q (R2): Common Technical Document on Quality Guideline
2. New guideline on structure product quality submissions

IPRP International Pharmaceutical Regulators Programme

1. IPRP quality assessment tools and best practices
2. Convergence of quality post-approval changes/variations
3. Implementation of ICH Q12

PIC/S

1. Structured data format for inspection reports
2. Tools and templates for PQS assessment for inspectors and associated training
3. Promotion of use and reliance on GMP inspectional information

Post-Approval Change(PAC) Sub-WG

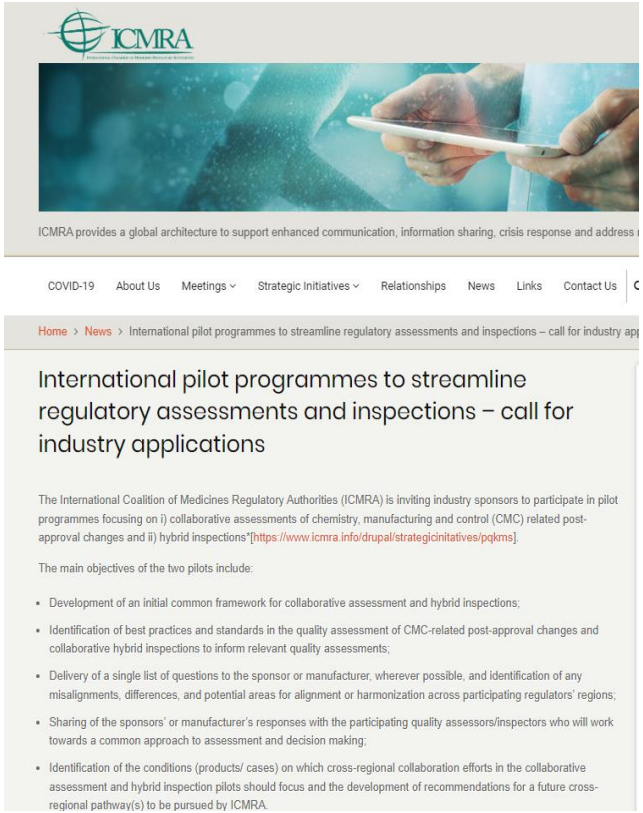
Activities

Initiate two regulatory collaboration pilots

- Facility inspections
- CMC
- PAC submission assessments
- Related regulatory actions

Two pilots are ongoing

- ☐ Collaborative Assessment
- ☐ Collaborative Hybrid Inspection



Post-Approval Change(PAC) Sub-WG
Collaborative Assessment Pilot

Scope

post-approval CMC changes including PACMPs

Objective

- **Platform: Multiple regulatory agencies** for a collaborative assessment
- **Questions: Single list** to the applicant
- **Regulators: Common approach** to the application assessment/decision making
- **Learnings: Share** to build further collaborations in assessment

Post-Approval Change(PAC) Sub-WG
Collaborative Hybrid Inspection Pilot

Scope

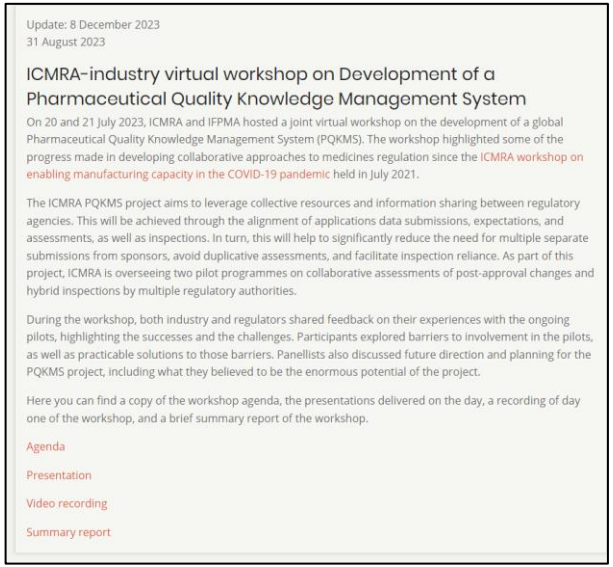
Pre-approval and pre-license inspections

Objective

- **Hybrid inspection approach: <u>How stakeholders in site inspections (Regulators and Industry) can engage to allow evaluation of a facility</u>**
  - ➢ Combination: on-site inspectorates at a facility / virtual technology
- **Identify: <u>Misalignments, differences, potential areas for harmonization</u>** in GMP expectations
- **Develop: <u>Aligned protocols/reports for hybrid assessments</u>**

Post-Approval Change(PAC) Sub-WG

ICMRA-industry virtual workshop on a Development of PQKMS (20-21 July, 2023)



Update: 8 December 2023
31 August 2023

ICMRA-industry virtual workshop on Development of a Pharmaceutical Quality Knowledge Management System

On 20 and 21 July 2023, ICMRA and IFPMA hosted a joint virtual workshop on the development of a global Pharmaceutical Quality Knowledge Management System (PQKMS). The workshop highlighted some of the progress made in developing collaborative approaches to medicines regulation since the ICMRA workshop on enabling manufacturing capacity in the COVID-19 pandemic held in July 2021.

The ICMRA PQKMS project aims to leverage collective resources and information sharing between regulatory agencies. This will be achieved through the alignment of applications data submissions, expectations, and assessments, as well as inspections. In turn, this will help to significantly reduce the need for multiple separate submissions from sponsors, avoid duplicative assessments, and facilitate inspection reliance. As part of this project, ICMRA is overseeing two pilot programmes on collaborative assessments of post-approval changes and hybrid inspections by multiple regulatory authorities.

During the workshop, both industry and regulators shared feedback on their experiences with the ongoing pilots, highlighting the successes and the challenges. Participants explored barriers to involvement in the pilots, as well as practicable solutions to those barriers. Panellists also discussed future direction and planning for the PQKMS project, including what they believed to be the enormous potential of the project.

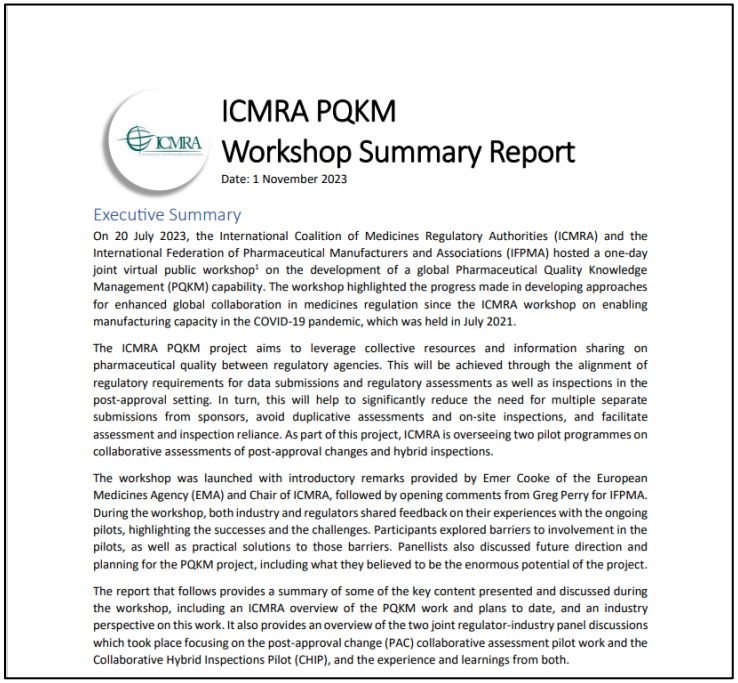
Here you can find a copy of the workshop agenda, the presentations delivered on the day, a recording of day one of the workshop, and a brief summary report of the workshop.

Agenda

Presentation

Video recording

Summary report



ICMRA PQKM
Workshop Summary Report
Date: 1 November 2023

Executive Summary

On 20 July 2023, the International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) hosted a one-day joint virtual public workshop[1] on the development of a global Pharmaceutical Quality Knowledge Management (PQKM) capability. The workshop highlighted the progress made in developing approaches for enhanced global collaboration in medicines regulation since the ICMRA workshop on enabling manufacturing capacity in the COVID-19 pandemic, which was held in July 2021.

The ICMRA PQKM project aims to leverage collective resources and information sharing on pharmaceutical quality between regulatory agencies. This will be achieved through the alignment of regulatory requirements for data submissions and regulatory assessments as well as inspections in the post-approval setting. In turn, this will help to significantly reduce the need for multiple separate submissions from sponsors, avoid duplicative assessments and on-site inspections, and facilitate assessment and inspection reliance. As part of this project, ICMRA is overseeing two pilot programmes on collaborative assessments of post-approval changes and hybrid inspections.

The workshop was launched with introductory remarks provided by Emer Cooke of the European Medicines Agency (EMA) and Chair of ICMRA, followed by opening comments from Greg Perry for IFPMA. During the workshop, both industry and regulators shared feedback on their experiences with the ongoing pilots, highlighting the successes and the challenges. Participants explored barriers to involvement in the pilots, as well as practical solutions to those barriers. Panellists also discussed future direction and planning for the PQKM project, including what they believed to be the enormous potential of the project.

The report that follows provides a summary of some of the key content presented and discussed during the workshop, including an ICMRA overview of the PQKM work and plans to date, and an industry perspective on this work. It also provides an overview of the two joint regulator-industry panel discussions which took place focusing on the post-approval change (PAC) collaborative assessment pilot work and the Collaborative Hybrid Inspections Pilot (CHIP), and the experience and learnings from both.

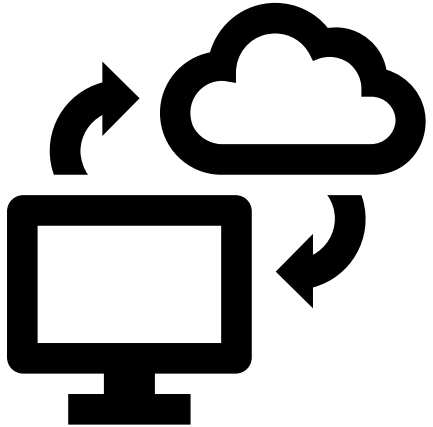
Latest updates of the pilots in the report

Technology platform to support PQKMS

ICMRA PQKMS Technology Platform sub-Working Group

PQKM Platform Governance Reflection paper

- Governance
- Technical capabilities to support PQKM objectives
- Data and system security and privacy
- Financing and procurement



ICH PQKM Technology Platform Taskforce

- Possibility: ICH's role of governance/oversight

Collaborative Work with ICH

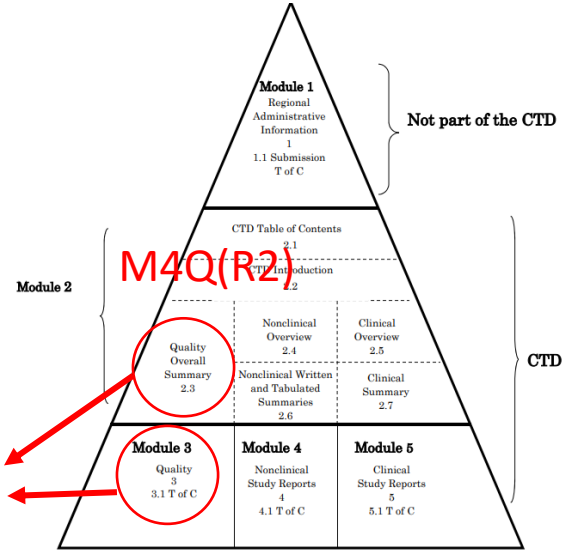
1. M4Q (R2): Common Technical Document on Quality Guideline
2. New guideline on structure product quality submissions

Objectives of M4Q(R2)

1. Global convergence of science- and risk-based regulatory approaches
2. Organization and positioning of information for Modules 2 and 3.
3. Communication between regulators and applicants
4. Lifecycle and knowledge management
5. Embracing product and process innovation.
6. Efficient use of digital tools
7. Elucidating regulatory expectations and supporting efficient assessments, decision-making and actions

Structured data submission

After M4Q(R2) reached Step2



Take home messages

Activities under ICMRA PQKMS includes

- **Pilot: Collaborative Assessment & Collaborative Hybrid Inspection**
  - ➡ **Collaboration among multiple regulators**
- **Technology platform: Support PQKMS**
  - ➡ **Cloud-based assessment**
- **ICH: M4Q(R2) and Structure Product Quality Submission**
  - ➡ **Change of dossier format and submissions**

Thank you!