An Overview of the Function and Activities of the Pharmaceutical Quality Knowledge Management System (PQ KMS) Working Group

Background

Regulators and the pharmaceutical industry face many challenges to ensure the continued supply and availability of medicines in an increasingly globalised and dynamic environment. Changes to pharmaceutical manufacturing processes, innovation and new knowledge, altered supply chains and changes to general operations are just some examples of the many issues affecting the availability of medicine required to meet patient needs. Companies manage these changes within their pharmaceutical quality systems and/or seek timely regulatory review when changes require prior approval. Regulatory agencies have sought to achieve greater levels of operational agility to better respond to a dynamic and complex operating environment by leveraging global intelligence and knowledge sharing capabilities to facilitate the timely review of applications to support changes in pharmaceutical quality and manufacturing of critical medicines. Indeed, ICMRA supports the prioritization of efforts to leverage collective information, expertise and knowledge sharing among ICMRA member authorities and key stakeholders for the protection of public health[1].

To this end, ICMRA supports the development of a collective Pharmaceutical Quality Knowledge Management System (PQ KMS) capability. The envisaged PQ KMS capability aims at strengthening international collaboration to support the global development, manufacture and supply of medicines, respectively. A PQ KMS capability will enable further reliance and collaboration in the field of inspections and more convergence regarding regulatory evaluation of pharmaceutical quality. Together, this will facilitate manufacturing agility, addition of new manufacturing sites to support increases in capacity, and strengthen the resilience of global supply chains. A key enabler for delivering the full benefits of a PQKMS capability is an enhanced product and process knowledge coupled by a mature on-site pharmaceutical quality system (PQS). Another key enabler supporting a PQ KMS capability is the availability of an IT solution(s) that would enable simultaneous submissions by industry of the same information between regions using standardised formats, definitions and naming conventions. This would enable rapid sharing and analyses of pharmaceutical quality information amongst regulators to support enhanced risk-based oversight of manufacturers. Such IT solution(s), coupled with enhanced product/process knowledge, a mature on site PQS and stronger convergence in assessment and inspection practices, are key pillars towards a PQ KMS capability.

Following an initial period of consultation with the broader ICMRA membership, the ICMRA Executive Committee formally established a PQ KMS Working-Group (WG) with specific responsibility for advancing efforts needed to develop a PQ KMS capability. The current overview outlines the structure, function and ongoing work coordinated by the WG to realise ICMRA's broader strategic vision concerning the development of a global PQ KMS capability. The current overview is subject to change as new work streams commence over time.

Structure and Function

The WG is currently co-chaired by the Health Products Regulatory Authority of Ireland and US Food and Drug Administration and includes representatives from the broader ICMRA membership. In addition to engaging and communicating with external stakeholders, the WG, on behalf of the broader ICMRA membership, is responsible for providing leadership, strategic vision, and coordinating work needed to progress the development of a PQ KMS capability. The WG meets on a monthly basis to review updates from different working groups on progress relating to specific initiatives needed to drive the development of a PQ KMS capability. Current supporting efforts

[1] Global Pharmaceutical Quality Knowledge Management: Enhancing Regulatory Reliance and Agility

include the oversight of two sub-working groups, each tasked with progressing complementary work contributing to the strategic vision of establishing a PQ KMS capability.

Figure 1 provides an overview of reporting structures and ongoing projects coordinated by the PQ KMS WG. Importantly, the proposed reporting structure does not represent a fundamental change to existing governance arrangements already established within each external organisations (i.e. ICH, IPRP and PIC/S). Rather, the proposed reporting structure is designed to help coordinate harmonisation work proposed by each organisation to facilitate the development of a PQ KMS capability.

Coordination of Projects to Progress a PQ KMS Capability

PAC Sub-WG: Operationalise Collaborative Pilots

Following an ICMRA-Industry virtual workshop on enabling manufacturing capacity during the COVID-19 pandemic[2], the PAC Sub-WG was tasked with operationalising two pilot projects focusing on i) collaborative assessments of Chemistry and Manufacturing Controls (CMC) related Post-Approval Change (PAC) assessments and ii) collaborative remote hybrid inspections. Each pilot aims to identify commonalities and differences among regulatory authorities in working towards a common assessment approach. Lessons learned and data collected during each pilot will serve as a starting point for future international convergence of regulatory actions and complement the harmonization work undertaken by external organisations. A number of pilot projects are planned throughout the coming year that will build on previous experiences. Further details concerning each pilot are available on the ICMRA website[3].

JRP Sub-Working Group: Development of a Joint High-Level Reflection Paper

Harmonization efforts needed to support the development of structured and standardized data elements must be progressed through well-coordinated efforts undertaken by existing and highly experienced international regulatory harmonization and information-sharing bodies, including, the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), International Pharmaceutical Regulators Programme (IPRP), and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Therefore, the PQ KMS WG convened an additional working group (Joint Reflection Paper [JRP] Sub-WG) including representatives from ICH, IPRP and PIC/S to develop a high-level reflection paper (RP) outlining the key priorities and general sequence of harmonisation work that each organisation will progress to facilitate the development of a PQ KMS capability. This high-level RP will provide a strategic vision that will shape the development of each organisations future work. Once the RP is drafted, the WG will provide final endorsement prior to publication.

External Organisations: Engagement and Coordination

Once the RP developed by the JRP Sub-WG is published, it will be the responsibility of the organisations (i.e. ICH, IPRP and PIC/S) to develop their respective detailed work plans and timelines to align with the priorities and venues for harmonisation work set out in the RP. To ensure a coordinated approach across each organisations' multi-year work plan, the PQ KMS WG will continue to engage with representatives from each organisation. Moreover, the PQ KMS WG will arrange time during regular ICMRA Summit and Plenary sessions (at least annually and potentially biannually) for report-outs on the progress of each organizations relative to their proposed work plans.

Future Communication and Engagement

[2] https://www.icmra.info/drupal/sites/default/files/2021-10/covid-19_manufacturing_capacity_ws_report.pdf
[3] https://www.icmra.info/drupal/en/strategicinitatives/pqkms

To ensure key stakeholders are fully aware of all ongoing and future projects coordinated by the WG, and how this work coalesces with ICMRA's broader strategic vision concerning pharmaceutical quality management, regular communications will update on the current status of both collaborative pilots. Specifically, communications will be issued once key milestones related to these projects are achieved. Additional communications will include announcements for conferences and/or workshops organised by WG, which will provide an opportunity for all stakeholders to engage and communicate their views on the development of a PQ KMS capability. The PQ KMS WG sets the aspiration to conduct a public meeting at least once per year with industry and other external stakeholders to present and discuss the work under way, review future work plans, and gather stakeholder input.

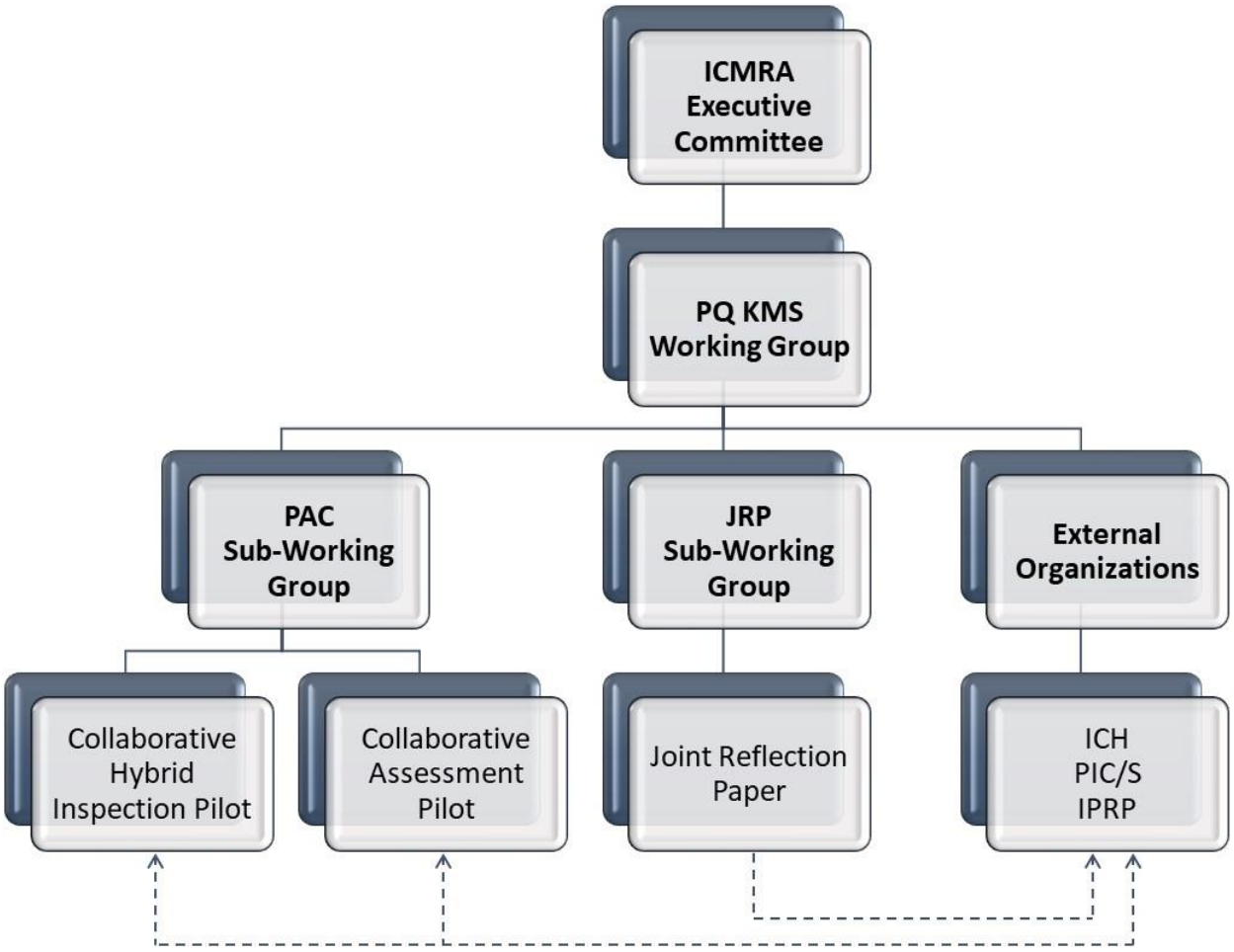

Figure 1: *Overview of the reporting structure and ongoing work coordinated by the PQ KMS Working Group, as mandated by the ICMRA Plenary, for the purposes of establishing a PQ KMS capability. Dashed line indicates the flow of information and engagement between groups that will inform and guide harmonisation work and pilot projects needed to support a PQ KMS capability. PAC: Post-approval change; JRP: Joint reflection paper*