

Promoting Global Collaboration to Enable Manufacturing Capacity in the COVID-19 Pandemic and Beyond: ICMRA Pilot for Collaborative Hybrid Inspection¹

This is a high-level proposal aiming to outline the objectives, overview, and deliverables of a pilot for collaborative hybrid inspection. Further details on the scope and implementation strategy (e.g., type of engagements among different regulatory agencies) will be further determined with active consultation of the participating regions, once ICMRA Executive Committee endorses this proposal.

OBJECTIVES

- Develop a Pilot Program that describes how stakeholders in site inspections (Regulators and Industry) can engage to allow evaluation of a facility via a hybrid inspection approach. The scope of the pilot will initially be targeted to inspections where multiple regulatory agencies have an interest in the facility and products to be covered by the on-site inspectorate.
- Conduct collaborative facility assessment by a combination of using of on-site inspectorates at a facility and utilizing virtual technology to allow participation of other inspectorates in the GMP inspection.
- Identify best virtual platforms and information technology (i.e., video) to facilitate concurrent on-site inspection and distant assessment.
- Identify best practices to prepare and conduct the hybrid inspection to ensure that both on-site and distant inspectorates obtain the desired information to complete respective assessments and meet their objectives.
- Develop a framework to accommodate time zone differences between the facility location and the distant inspectorates.
- Identify misalignments, differences, and potential areas for alignment or harmonization in GMP expectations – one area of focus here might be in how the inspection is reported and how deficiencies are classified.
- Provide collaboration and dialog opportunities for industry participants to understand the impact of the hybrid approach on industry.
- Develop aligned protocols and reports for performing such hybrid assessments so that the information can be easily shareable and useful to other interested ICMRA inspectorates.
- Develop methodologies for allowing easy and quick access to the final reports from those distant assessments.

¹ A hybrid inspection refers to a facility assessment performed using a combination of on-site inspection and distant assessment using a virtual technology. This term could be modified by the working group in developing this pilot program to accommodate different regulator legislative laws on the definition of "inspection".

PILOT PROGRAM OVERVIEW

The proposed pilot program will use a combination of on-site inspectors in the facility and distant inspectors (through a virtual platform) to conduct a hybrid inspection where multiple regulators are interested in the facility and products to be covered. Facility inclusion in the pilot will be based on the mutual interest of regulators, voluntary participation by the manufacturer and its facility, and the facility having the technology capable to support distant assessment. Key features of this program include:

- Regulators can overcome travel logistic challenges created by the pandemic and leverage local inspection teams to obtain necessary information to support regulatory decisions that would otherwise be delayed due to travel issues.
- Potential for collaborative assessment of facility when marketing applications submitted to multiple regulators, therefore avoiding multiple inspections or facility assessments by different regulatory agencies for the same product and facility.
- Rules of engagement will be developed to describe interactions amongst participating authorities.
- Evaluation of the inspection outcome and any enforcement action if needed should remain a matter for each participating authority to decide and conclude under their own legal framework.
- The pilot is voluntary for regulators and industry.
- The duration of the pilot is anticipated to require one year but may be extended based on ICMRA members' ability to execute the deliverables.

PILOT PROGRAM DELIVERABLES

The proposed pilot program will deliver the following:

- A protocol that describes on how to execute the hybrid inspection will be developed. The protocol will include information on how to prepare, execute and report the hybrid inspection. It will include criteria for participation, confidentiality, facility selection, roles of participants, engagement with the facility, conduct and organization of the teams involved in the hybrid inspection.
- Once the protocol is approved, the Working Group will apply the Protocol to evaluate at least 3-5 facilities with at least two Regulatory Agencies involved in the hybrid assessment. After each assessment, a report with findings will be issued.

After the completion of the pilot program with evaluation of 3-5 facilities, the Working Group will issue a report to ICMRA Executive Committee, summarizing the outcome of pilot program with implementation recommendations, including as applicable protocols and reports to be used for executing hybrid inspections.