Roundtable Session 2 – Table 10 - How to Move From Pilot Initiatives to Sustainable Programs

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Abstract:
Regulatory divergence for Post-Approval Changes (PACs) remains a significant challenge while managing a global supply chain, driving the need for harmonized processes. Recent global health authority pilots, notably the International Coalition of Medicines Regulatory Authorities (ICMRA) Pharmaceutical Quality Knowledge Management System (PQ KMS) program, successfully demonstrated the feasibility and benefit of synchronized assessments and collaborative inspections. These initiatives confirmed the long-sought vision of having one dossier, one assessment, and one outcome for a PAC and reduced duplication of effort. However, challenges with regional requirement differences, IT platforms, and upfront resource allocation must be systematically addressed. This roundtable will explore the ongoing efforts to strengthen global regulatory convergence and reliance for PACs, and discuss the key roadblocks to transition these pilot initiatives into sustainable programs.

Discussion Questions:

1. When regulators collaborate, differences in baseline expectations (like timelines or regional requirements) can emerge. What foundational regulatory agreements are needed to ensure consistent cooperation and establish true mutual reliance between agencies?

2. How can reliance based on collaborative assessment and inspections be balanced against the individual sovereignty of national health authorities?

3. Sustainability requires shared commitment between industry and regulators. Beyond participating in pilots, what proactive role must industry play—such as harmonizing internal data standards or engaging in policy advocacy—to help transition these initiatives from pilots to sustainable frameworks?

4. What additional scope or types of submissions must be integrated into collaborative programs to make the initial effort and resource investment worthwhile for more companies?

5. As the initiative considers expanding to more complex submissions and more regulators, what specific technical barriers must be preemptively addressed to ensure the efficiency seen in the pilots is scalable?

Notes:

- Foundational regulatory agreements needed for mutual reliance include Mutual Recognition of Standards, which is formal acceptance of common quality and technical baselines. This is complemented by Harmonized Procedures, which are standardized protocols for collaborative assessments, inspections, and joint decision-making, and a Formal Reliance Commitment, which involves policy documentation to accept and act on the regulatory findings of collaborating agencies
- Balancing reliance on collaborative assessment and inspections with the individual sovereignty of national health authorities is achieved through a structured framework. This framework involves establishing clear scope and conditions for reliance, ensuring national authorities retain the right to a final review and veto to align findings with national legal requirements. It also requires transparency and information exchange to build trust, and the use of formal agreements (like MOUs) to legally define the limits of cooperation, dispute resolution mechanisms, and the boundaries of shared authority.
- To make the initial effort and resource investment worthwhile for more companies, collaborative programs must integrate additional scope and types of submissions. This expansion should move beyond simple Post-Approval Changes (PACs) to include more complex PACs (like changes in manufacturing or facility location) and a wider range of routine Chemistry, Manufacturing, and Controls (CMC) submissions. Furthermore, integrating the Quality Module of initial drug applications and focusing on submissions related to platform technologies or generic applications would benefit a larger volume of companies globally by leveraging a single, collaborative assessment for resource-intensive and recurring quality life-cycle management activities.
- As the initiative considers expanding to more complex submissions and more regulators, the efficiency seen in the pilots is scalable only if key technical barriers are preemptively addressed. These barriers center on data and IT infrastructure, primarily requiring IT Platform Interoperability and Standardization to ensure diverse regulatory systems can seamlessly exchange high-volume data. This must be coupled with Standardized Data Formats and Semantics across all regions to prevent automated review tools from failing due to inconsistent data. Finally, a Secure and Scalable Information Exchange system is critical to handle the increased volume of sensitive data while meeting the varied, stringent security and audit requirements of every participating national health authority.