Regulator Vision for ICH Q6 Review and Revision

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In accordance with its 2019 remit, the ICH Quality Discussion Group developed an effective approach and a list of priorities to modernize ICH Quality guidelines and enable innovation. The ICH Management Committee endorsed recommendations to update and consolidate stability guidelines and modernize guidance for setting specifications for drug products and drug substances in accordance with science and risk-based concepts described in ICH Q8 - Q12.

These topic revisions are intended to clarify regulatory expectations, address contemporary approaches to assess quality risks and introduce criteria to accommodate and enable innovative technology. In particular, revisions of ICH Q6A & 6B are expected to reinforce the holistic and integrated approach for setting specification criteria in accordance with a drug product control strategy, consider clinical relevance, platform experience and prior knowledge and accommodate continuous evolution through the product's lifecycle.

Recent surveys and anecdotal examples suggest that extent of ICH implementation remains a significant challenge. It is imperative that ICH guideline modernization, especially with respect to setting specifications, is accompanied by reliable regulatory application and alignment to ensure consistent global harmonization.