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Life science *insight*, life-changing *impact*

Thank you for joining us!

It was a pleasure to have you attend our Knowledge Hub Webinar

Are You Ready for the Impacts of ICH GCP E6(R3)

WATCH THE WEBINAR RECORDING

KEY TAKEAWAYS

What are the most impactful changes in ICH GCP E6(R3)?

- Emphasis on a proportionate, risk-based approach to the design and conduct of clinical trials to modernize Good Clinical Practice (GCP) and address the complexities of trials in the modern global regulatory environment.
- Focus on patient centricity, ensuring sponsors are actively seeking feedback and incorporating participant perspectives into the trial design.
- Expanded Data Governance responsibilities with increased expectations for end-to-end data lifecycle management.

How are global regulatory agencies approaching the adoption of the guidance and risk-based principles?

- FDA, EMA, and PMDA are shifting toward a more flexible, efficient, and scientifically grounded approach to clinical trial management and regulatory oversight.
- EMA has set an effective date of July 23, 2025. FDA and PMDA have not yet set a date for implementation.
- With their endorsement of the update, these three agencies emphasize the need for proportionality and recognize the need for innovation in clinical trial design and monitoring, with flexibility to adapt approaches based on trial complexity and emerging technologies.

Where is there the most uncertainty for industry adoption of the new guidance?

- Implementing fit-for-purpose risk-based principles (i.e., demonstration of data integrity processes), maintaining communication and training, and ensuring robust oversight capabilities are in place.
- Operationalizing risk-based quality management across the development lifecycle and how to take a proportionate approach to risk identification and management.
- Aligning processes and systems with the new guideline, and pulling the changes through to SOPs, policies, and systems.

First and foremost, sponsors (and CROs) must understand and get trained on the ICH E6 (R3) Principles!

SPEAKERS

- Sheila Gwizdak, VP, Consulting, Halloran
- Jess Fowler, Associate Principal Consultant, Halloran
- Mamta Puri-Lechner, Senior Consultant, Halloran
- Laura Gilliam, Lead Consultant, Halloran
- Caroline Shannon, Consultant, Halloran

ABOUT HALLORAN

Halloran Consulting Group is a life science consulting firm providing strategic development, regulatory, quality, clinical, and organizational support to industry leaders in the pharmaceutical, biotechnology, and medical device sectors. Our consultants are subject matter experts with technical and strategic expertise, who deliver a tailored approach to each engagement, successfully propelling our clients to their next inflection point.

Contact us to discuss all your Quality and Compliance needs!