



ENSURING REGULATORY COMPLIANCE ICH E6 (R2) ADDENDUM OPTIMIZING QUALITY RISK MANAGEMENT

TOP 50 GLOBAL BIOPHARMACEUTICAL COMPANY



INDUSTRY CHALLENGE AND OPPORTUNITY

The recently revised ICH E6 (R2) Addendum provides both a challenge and opportunity for GCP organizations to modernize their **QRM approaches**.

By building quality in - starting with **critical data & processes** during protocol development, using **centralized and study risk-based monitoring**, strengthening **risk mitigation** - organizations can better manage risks resulting in increased clinical and operational data quality, speed of decision making, and patient safety.

Our client, a global Biopharma company, needed to quickly come up to speed to both ensure compliance and optimize value, by implementing new QRM practices and supporting tools, in an **efficient and effective** manner.



AGILE ASSESSMENT AND DEVELOPMENT

TayganPoint assembled a team of **domain experts** (Clinical Operations, ICH, RBM), program, and **change management** professionals to assess the current state compliance and areas of opportunity for improvement.

Working with a **cross-functional** Sponsor team, recommendations and detailed designs were developed around Process Improvements and Enabling Tools, SOP Development, Training and Communication.

An implementation plan allowing for **Fit-For-Purpose** solution development and rollout to the client's Americas, Europe, and Asia-Pac regions was developed.



INCEPTION TO EXECUTION IN LESS THAN 12 MONTHS

Implementation included:

- > Developing **new ways of working** with Investigators and CROs in overseeing quality.
- > Leveraging **Industry Standards** and Tools to Optimize existing Quality Management Systems and Processes for Human Subject Protection, Trial Results Reliability, and Operational Efficiencies.
- > Adopting a **Centralized and Risk Based** approach to not just site monitoring but whole study monitoring.
- > Adopting a Risk-Based approach to computer systems validation.
- > Refining CAPA and RCA processes and tools to support the overall new QRM approach.