

Gabriele Schwarz

Any pitfalls in RBM implementation? The perspective of the Regulators

The pending ICH E6 Addendum asks the sponsor to develop a systematic, prioritized, risk-based approach to monitoring and allows varied approaches as long as they improve the effectiveness and efficiency of monitoring. The sponsor may choose on-site monitoring, a combination of on-site and centralized monitoring, or, where justified, centralized monitoring alone. However, there should be a documented rationale for the used monitoring strategy. This rationale should be based on a thorough risk identification and risk evaluation process which is undertaken by a multidisciplinary team during protocol design and project development.

Furthermore, risk-based monitoring (RBM) requires efficient communication of the decided monitoring strategy and its rationale to those who are involved in or affected by these activities as well as a periodic review of risks and monitoring results to ascertain whether the implemented monitoring remains effective and relevant, taking into account emerging knowledge and experience.

The presentation will address a number of success factors as well as pitfalls in respect to risk-based monitoring.