

QUALITY MANAGEMENT

Understanding the importance of quality management in clinical trials.

KEY LEARNINGS

Quality management is implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

- Roles and responsibilities of quality management at site
- Difference between quality control and quality assurance
- Quality management responsibilities
- Difference between inspections and audits
- Implementation of different levels of quality control and management.



AUDITS VERSUS INSPECTIONS

Audit

A systematic independent examination of trial related activities and documents, to determine whether the evaluated trial related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's SOPs, GCP, and the applicable regulatory requirement

ICH-GCP 1.6

Inspection

The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or CRO facilities, or at other establishments deemed appropriate by the regulatory authority

ICH-GCP 1.29