Commonly Used QM Definitions

Quality Management (QM): The overall system that includes all activities involved in quality assurance and quality control, including the assignment of roles and responsibilities, the reporting of results, and the resolution of issues identified during the review.

Quality Control (QC): The real time ("day-to-day") observation and documentation of the sites work processes to ensure that accepted procedures are followed. Quality control (QC) is a subset of the quality assurance (QA) process. It is comprised of the following activities:

- Detection and measurement of the variability in a clinical trial
- Detection and measurement of the characteristics of clinical trial data generated
- Corrective responses to discrepancies found during the conduct of a trial

Quality Assurance (QA): Covers all policies and systematic activities implemented within a quality system. QA ensures that data are recorded, analyzed, and recoded in accordance with the protocol and GCP. The use of GCP guidelines ensures ethical and scientific quality standards for the design, conduct, recording, and reporting of IRB approved clinical trials that involve research participants.

Clinical Quality Management Plan (CQMP): A written document, in this case, specific to a clinical research setting, which encompasses both Quality Assurance and Quality Control procedures and details the responsibility, scope, indicators measured, sample size, and frequency of these activities.

ICH Good Clinical Practice Definition of Quality Assurance
The planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented, and recorded in compliance with Good Clinical Practice and applicable regulatory requirements. (ICH GCP 1.46) Within the quality assurance system, several operational techniques and activities help to verify that the requirements for quality of trial related activities have been fulfilled. (ICH GCP 1.47)

Key Quality Indicators
Clinical trial quality requires consistent adherence to measurable and verifiable standards to achieve uniformity of output that satisfies specific customer or user requirements. Key quality indicators during the conduct of clinical research include, but are not limited to, the following:

- Patient eligibility criteria
- Informed consent process
- Serious Adverse Events (SAE) & Adverse Events (AE) ascertainment and management
- Scheduled tests and procedures
- Missed visits, tests, and procedures
- Recording of concomitant medications
- Use of prohibited medications
- Study drug or device administration

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