

Quality Management System

Quality management is the overall process of setting standards, supervising activities and using systems to make sure products and services consistently meet set quality levels and customer expectations. In clinical trials, quality management involves designing and implementing clear and effective clinical trial protocol, including tools and processes for running the trial and handling data, to protect participants' rights, safety and well-being while ensuring the trial results are reliable.

Quality Management Pyramid



The quality management pyramid is a layered structure for organizing Quality Management System documents, starting with the Quality Policy at the top, which guides the Quality Manual, procedures, work instructions and records, forms below it.

Policy: Policy is the highest-level document, created by top management, that states the organization's commitment to quality and serves as a guiding principle for the whole quality management system.

Manual: A quality manual is a comprehensive document that explains the quality policy, quality goals, scope of the quality management system and how key procedures are connected.

Standard Operating Procedures: Standard Operating Procedures in a quality management system are written instructions that explain how to do routine tasks the same way every time to ensure quality and consistency.

Thus, Standard Operating Procedures ensure uniformity in the performance of activities by clearly outlining who does what, when and how, helping to prevent errors, maintain quality and comply with regulatory requirements.

Typically, Standard Operating Procedures cover:

- **Purpose**
- **Scope**
- **Responsibilities**
- **Procedure**
- **List of Forms and templates to be used**
- **References**

Different stakeholders involved in a clinical trial, including Sponsors, Study Sites, Contract Research Organizations and Ethics Committees are required to maintain their own Standard Operating Procedures to ensure clear responsibilities, consistent processes and compliance with regulatory and ethical standards throughout the study

Work Instructions: Work instructions in a quality management system are clear, step-by-step guides that show exactly how to do specific tasks within a procedure

Records and Forms: A form in a Quality Management System is a blank template that shows what information needs to be collected like checklists, logs. When this form is filled out, it becomes a record. The record acts as proof that a process was done correctly and the goals were met such as training