

Quality Goals and Objectives

Auditing Platform

October 2023

This issue of *QMS BP* is dedicated to quality management and leadership responsibilities for building effective quality management systems for clinical research infrastructures. In this article, the SCTO's Auditing Platform highlights common QMS issues observed during its audits and formulates best practices when setting quality goals and objectives for your organisation. Each article draws from the platform's extensive auditing experience across various organisations.

Why are quality goals needed?

- Quality objectives are measurable quality control methods. Their assessment is used to focus the goal(s) from the quality policy into plans for improvement.
- In accordance with requirements set out in the SCTO's Guidelines for Good Operational Practice (GGOP), quality objectives should be defined and be consistent with a CTU's quality policy.

Audit observations: What was missing?

1. Quality goals and objectives were not formally documented, defined, or managed.
2. No process was in place to ensure that quality goals are set and followed up on during the review period.

Recommendations

1. Document and formalise a defined process in an SOP.
2. Ensure that quality objectives are established and planned in advance based on all relevant functions, levels, and processes.
3. Formalise (annual) quality goals in a controlled document (incl. milestones, timelines, and progression).
4. Maintain an overview document that allows the completion of objectives to be logged and tracked.

5. Review the completion and/or non-adherence of quality objectives in the annual quality management review.

- Extra tips:
 - Ensure quality goals are directly or indirectly measurable.
 - Ensure that their continuous improvement is based on a risk-based approach and their achievement supports the vision of the CTU's quality policy.