Quality Policy

Auditing Platform

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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 defining a quality policy for your organisation. Each article draws from the platform's extensive auditing experience across various organisations.

Why is a quality policy needed?

- CTU's quality policy plays an important role in how its QMS functions and thus its overall operations. It provides the highest-level objective for a system's function and thus the direction for each action and decision made by team members.
- In accordance with requirements set out in the SCTO's Guidelines for Good Operational Practice (GGOP), each CTU needs to ensure that a quality policy is established, implemented, and maintained.

Audit observations: What was missing?

1. There was no evidence that the commitments stated in an organisation's quality policy are addressed by its existing QMS.

Recommendations

1. A quality policy needs to consider all legal, ethical, and customer/service requirements.
2. Define objectives that are appropriate to a CTU's purpose and context and that support its strategic direction.
3. Formulate the policy precisely to reflect the commitments that can be made based on the processes defined in the QMS.
4. Example: If regulatory compliance is a stated objective, do the following:
    - define a process to review and document regulatory changes in order to assess any impact before changes are made.

- evaluate all QMS processes against listed regulations, policies, etc.