SCTO PLATFORMS

Quality Management Review

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 developing a quality management review (QMR) for your organisation. Each article draws from the platform's extensive auditing experience across various organisations.

Why is a quality management review needed?

- The aim of the QMR is to assess the organisation's quality management system for its adequacy or sufficiency, suitability to purpose, and effectiveness.
- In addition, a QMR allows the CTU to decide what next steps are needed to improve the current quality approach.
- In accordance with requirements set out in the SCTO's Guidelines for Good Operational Practice (GGOP), each CTU needs to ensure ongoing efficiency and quality performance.

Audit observations: What was missing?

1. There was either no or an inadequate annual quality management review (QMR) in place to assess the overall efficiency and performance of a CTU and/or the effectiveness of its quality management system (QMS).

Recommendations

1. Define a QMR process to ensure that processes and services are adequate.
2. Define and document the acceptance criteria for KPIs.
3. Conduct and formally document a QMR with the appropriate CTU management (e.g. director, executive board, or quality management team).
4. Define and collect key performance indicators (KPIs) addressing, for example, the following areas:
    - changes within a CTU (regulatory, business-related, etc.)
    - results of internal (and possible external) audits/assessments

- customer feedback and complaints
- opportunities arising from risk review and nonconformity.