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What Constitutes a Site Quality Management System?

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Excellent clinical research sites deliver high-quality work with respect to patient safety, data integrity, and regulatory compliance. High-quality performance requires three components:

- A leadership team that is committed to high-quality performance
- A work environment (office space, technology, equipment, etc.) that supports high-quality performance
- A quality management system (QMS) that provides structure for consistent, high-quality performance that meets internal, customer and regulatory requirements:
    - A system for hiring, onboarding and developing competent and motivated personnel
    - Standard operating policies and procedures (SOPs) and work instructions, which, if followed, will deliver high quality outcomes
    - A training program so that personnel know how to follow the SOPs
    - A quality control program to ensure that the SOPs are followed
    - Metrics to measure performance against the SOPs, detect issues to be addressed, and drive improvement

Components of a Site Quality Management System

The essential components of a QMS are as follows:

1. **Capable Personnel**
    a. Suitable qualifications, experience, training and motivation
    b. Well-defined and communicated quality expectations
    c. Objective performance goals, measurement and feedback
    d. Management commitment and attention to quality
2. **Standard Operating Policies & Procedures (SOPs) and Work Instructions**
    a. Clinical trial conduct (GCP)
    b. Human subjects protection program
    c. Research compliance program
    d. Safety and security program
    e. Conflict of interest (financial and non-financial)
    f. Training program
    g. Other, as appropriate
3. **Initial and Continuing Education**
    a. Topics specific to clinical research
        1. Good Clinical Practice (GCP)
        2. Investigator responsibilities
        3. Reportable events
        4. Recruitment and screening procedures
        5. Informed consent requirements
        6. Good Documentation Practice (GDP) and recordkeeping
        7. Study-specific training

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8. Other, as appropriate

b. Topics not specific to clinical research
    1. Patient privacy
    2. Information security
    3. Biohazards
    4. Chemical hygiene
    5. Electronic Health Records (EHR)
    6. Other, as appropriate
c. Assessments to ensure knowledge and competence
d. Professional certifications

4. Quality Control System

a. Internal compliance oversight and quality control
    1. Informed consent process
    2. Randomizations according to eligibility criteria
    3. Drug accountability
    4. Other, as appropriate
b. External monitoring and auditing
    5. Sponsor monitoring
    6. Sponsor audits
    7. IRB/ethics committee inspections (local IRBs and ethics committees)
    8. Government inspections (FDA, OHRP, EMA, etc.)
c. Corrective and preventive action (CAPA) plans

5. Metrics

a. Key performance indicators (KPIs) and standards
b. Key risk indicators (KRIs) and standards
c. Benchmarking against other sites
d. Measurement and reporting
e. Corrective action when required

An effective QMS does not just satisfy a checklist of these elements but includes substantive implementations of them. The QMS at a large site is typically more complex than one at a small site. QMS systems can vary for other reasons, but all the above elements should be covered.

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