



Fundamentals of Quality Management Systems

12 Quality System Essentials (QSE)



QSE 1: Organization and leadership – Plays a vital role in a laboratory’s success in implementing a Quality Management System (QMS). When leadership promotes and communicates the benefits of a QMS, employees are more likely to embrace it. Key aspects of QSE organization and leadership encompass defining job roles, setting quality objectives, documenting the QMS, fostering a culture of quality, allocating resources, and overseeing process management.

How is QSE 1 implemented in your laboratory?



QSE 2: Customer focus – Involves identifying and meeting customer expectations by soliciting input and ensuring ongoing satisfaction. Key QSE 2 elements include identifying customers, determining expectations, measuring satisfaction through feedback analysis, and managing complaints.

How is QSE 2 implemented in your laboratory?



QSE 3: Facilities and safety management – Aims to create a safe and efficient laboratory environment. Key QSE 3 elements involve optimizing laboratory design for safety and efficiency, managing access, maintaining clean work areas, and implementing a comprehensive safety program covering PPE, SDS, hazardous waste and more.

How is QSE 3 implemented in your laboratory?



QSE 4: Personnel management – Involves all laboratory staff and their qualifications, this crucial QSE is needed for a successful QMS and maintaining high-quality standards. Key elements include job descriptions, onboarding/exiting plans, training plans, competence assessment, professional development support, performance evaluation, and personnel record maintenance.

How is QSE 4 implemented in your laboratory?



QSE 5: Supplier and inventory management – Acquiring and maintaining laboratory supplies to ensure the quality of materials used for laboratory operations. Key aspects include setting purchase criteria, evaluating incoming materials, and establishing appropriate stock levels.

How is QSE 5 implemented in your laboratory?



QSE 6: Equipment management – Maintains laboratory equipment that performs accurately and reliably. Key QSE elements encompass equipment qualification, verification/calibration, prevention maintenance, unscheduled maintenance, and decommissioning.

How is QSE 6 implemented in your laboratory?



QSE 7: Process management – Involves planning, managing, and documenting interconnected laboratory processes or effective operations. Key QSE elements include workflow analysis, specimen management across pre-analytical, analytical, and post-analytical stages, process documentation, validation, verification, and performance monitoring.

How is QSE 7 implemented in your laboratory?



QSE 8: Documents and records management – Creating, controlling, and maintaining laboratory policies, procedures, and records. Effective management is vital for streamlined laboratory workflow. Key QSE elements encompass documents, a document management system, records, and a records management system.

How is QSE 8 implemented in your laboratory?



QSE 9: Information management – Ensures quality by addressing information needs, maintaining confidentiality, managing data access, and ensuring data integrity throughout its lifecycle. Key QSE elements include managing information flow, confidentiality, data access, integrity, and reporting complete and accurate results.

How is QSE 9 implemented in your laboratory?



QSE 10: Nonconforming event management – Detects and tracks deviations from policies or requirements and addresses process gaps. Key QSE elements include identifying, reporting, investigating, and documenting nonconforming events, implementing corrective actions after root cause identification, and tracking and evaluating corrective action outcomes.



QSE 11: Assessments – Assessment protocols, for both internal and external monitoring, ensure compliance with regulatory requirements and evaluate the effectiveness of processes within the QMS. This involves conducting audits, proficiency tests, and quality assurance reviews.

How is QSE 11 implemented in your laboratory?



QSE 12: Continual improvement – Involves enhancing activities and processes for customer and organizational benefit. Key QSE elements include empowering all staff for improvement, identifying opportunities (e.g., assessments, feedback, and NCE analysis), considering values, strategies, customer needs and risks, generating solutions, implementation, evaluating effectiveness, and integrating sustained improvements into laboratory process.

How is QSE 12 implemented in your laboratory?

Resource: Clinical & Laboratory Standards Institute - [CLSI Guidelines](#)

This job aid is a component of the free, on-demand CDC training course “Fundamentals of Quality Management Systems” Find the course at <https://reach.cdc.gov>. V23328