



Quality Management Systems  
Operations Management  
Business Planning  
Training

5509 Sefton Avenue  
Baltimore, MD 21214  
(410) 426-2269  
info@qualityedgeconsulting.com  
www.qualityedgeconsulting.com

## Quality Management System Implementation Process

### Task

1	<b>Conduct Gap Analysis and Prepare Report</b>
2	<b>Results Review and Planning Meeting with Management</b>
3	<b>Conduct Executive Overview Training</b>
4	<b>Conduct Implementation/Documentation Training</b>
5	<b>Develop System Process Map</b> <b>Develop required and needed procedures and work instructions</b> <b>Develop Media to provide records of Activities</b>
6	<b>Identify Improvement Opportunities throughout Organization</b>
7	<b>Develop Quality Manual and Release All Documents</b>
8	<b>Conduct Registrar Selection Process</b>
9	<b>Conduct General Personnel Training</b>
10	<b>Monitor Progress Until Certification Audit</b> <b>Conduct Internal Auditor Training and Monitor Internal Audits</b>
11	<b><u>OR</u> Quality Edge Mgmt Consulting Conduct Internal Audits</b>
12	<b>Evaluate Management Review</b>
13	<b>Conduct Preliminary Assessment</b> <b>Review Corrective Actions from Preliminary Assessment or</b>
14	<b>Internal Audit</b>
15	<b>Certification Audit Support</b>
16	<b>Follow-up on Initial Certification Audit Findings</b>

## Description of Tasks

### 1. **Perform Gap Analysis and Prepare Report**

This will involve review of Client's current documents, records and practices to the requirements set forth in the Quality Management Systems Standard or regulation. Interviews with management and all relevant personnel will be required. A complete tour of the facilities will be conducted. At this time, a review of the company's scope of products and services, organizational structure and list of job responsibilities will be performed.

*Deliverables:*

Detailed report on current system status to Standard(s) and/or requirements  
Corrective Action Plan outlining recommendations to achieve compliance  
Draft Project Plan (Gantt chart)

### 2. **Results Review and Planning Meeting with Management**

A meeting with Management is required in order to review the output of the Gap Analysis, discuss and determine specific long term goals or objectives based on the output, define milestones, allocate resources and assign responsibilities to the Project Team to complete the required tasks.

*Deliverables:*

Modified Project Plan  
Task List and Project Team Assignment (consultant is part of project team)

### 3. **Conduct Executive Overview Training and Assist Development of Scope of Certification, Quality Policy and Quality Objectives**

This one-half to one day workshop is designed to provide top management with the information and tools necessary to initiate and actively support the implementation and maintenance of the Standard/Regulation. Workbook exercises will be conducted. A Certificate of Completion will be issued.

*Deliverables:*

The outputs of the workshop will provide a solid basis upon which to build the Quality System and will define and establish the following:

- The Quality Policy
- Key Processes of the Company
- Quality Objectives that will be used when establishing process operations
- Performance measures to the Quality Objectives
- Customer Satisfaction measurements
- Training Effectiveness
- Continual Improvement activities
- Scope Statement for the QMS certification
- Registration requirements

**4. Provide Implementation/Documentation Training to Project Team**

This one day workshop is designed to provide intensive training for the Project Implementation Team in the specifics of implementation and documentation for the Quality Management System. This will involve instruction and practice in the construction of the Quality Manual, flowcharts and procedures, and basic review of the requirements of the Standard. To fully complete this training, the Project Team will construct a process flowchart and/or procedure for a designated process and participate in the development of the Quality Manual. A Certificate of Completion will be issued.

*Deliverables:*

The tools and knowledge to fully implement and maintain the Quality System  
Documentation formats  
Process mapping techniques

**5. Develop a System Process Map and Fill in Gaps**

This step provides the information on how the processes already in place and new processes necessary for compliance to the Standard interact. Management and the Project Team will be required to determine the Key Processes of the organization which form the focal point of all other processes. Upon completion of these tasks, the Quality Manual and procedures can be finalized. This activity is facilitated by Quality Edge Management Consulting, while specific procedural process maps should be developed by the person(s) assigned responsibility.

**a. Identify the processes needed for the quality management system, and their application throughout the organization.**

- 1) This will require determination of the applicability of each of the sections and subsections of the Standard, particularly Section 7.0 Product Realization.
- 2) Identify and describe processes needed for Quality Management System implementation, and apply the PDCA Cycle and Process Approach.
- 3) Identify and describe processes for each specific job function or division and apply the PDCA Cycle and Process Approach.

**b. Determine the sequence and interaction of these processes.**

Develop general "network of interacting processes" flowchart of overall operation. Determine areas of overlap, if any, for further analysis.

**c. Determine criteria and methods required to ensure that both the operation and control of these processes are effective.**

Develop monitoring, measuring, and analysis criteria and methods for gathering data.

**d. Ensure the availability of resources and information necessary to support the operation and monitoring of these processes.**

Define communications channels, data needed, records to establish and maintain.

**e. Measure, monitor and analyze these processes.**

Define types of measurements and methods needed to collect data for analysis.

**f. Implement action necessary to achieve planned results and continual improvement of these processes.**

Define corrective actions required, improvement plans.

*Deliverables:*

Quality System Process map including Level I and Level II activities, with reference as needed to Level III work instruction

**Identify General Improvement Opportunities throughout Organization**

During the development of the Process Map and throughout the implementation effort, we will identify various opportunities for improvement to existing organizational structure and processes. These will be noted and discussed with the Project Team lead and/or Management. This is a complimentary service.

*Deliverables:*

Verbal recommendations for improvement activities

**6. Develop Required Procedures and Specs**

Customized documentation will be developed in conjunction with the Project Team for the processes as determined from Process Mapping and based on the requirements of the Standard. The extent of documentation will be sufficient to ensure the effective operation and control of the company's core processes. Management input is required, particularly in the establishment of the Management Responsibility Clause 5.0, Customer Satisfaction Clause 8.2.1 and Continual Improvement, Clause 8.5.1 for the applicable Standard.

*Deliverables:*

Quality Management System compliant Required Procedures (Level II) and some work instruction (Level III)

**Develop/Acquire Appropriate Media to provide records of Activities**

We will provide and/or evaluate forms, checklists, training guides, software, etc. used for flow-charting, procedure development and record-keeping. This is a complimentary service and various forms are provided with the procedures.

*Deliverables:*

Forms for Corrective/Preventive Action, Non-conforming Material, Management Review, Internal Audits, Training, Design Control and others as needed

**7. Complete Quality Manual and Release all Documents**

The customized Quality Manual defines the intentions (Quality Policy) and commitments (Quality Objectives) of the company to its Quality Management System and is the high-level guidance document from which all other procedures flow down. It will include the System Overview Map and reference to all Level II procedures as they pertain to the elements of the Standard and/or regulation.

*Deliverables:*

Quality Management System compliant Quality Manual and Required Procedures (Level II) and some work instructions (Level III) in electronic format; wpd, pdf, doc

**8. Provide Assistance with Registrar Selection**

We will assist with the evaluation and selection of a registrar as applicable, determination of a suitable certification timetable and scheduling of the assessor.

*Deliverables:*

Provide list of applicable registrars and review final application

**9. Conduct Internal Auditor Training**

This intensive two day course includes a review of the Standard's requirements, the development of audit plans, checklists, and forms, the issuance of nonconformities, the conduct of opening and closing meetings, and practice of communications skills. This training includes a live audit of at least one area of the organization or may be paired with the full audit. Upon completion, the effectiveness of the training will be evaluated, and records generated as evidence. A Certificate of Completion will be issued.

*Deliverables:*

Skills training in the following areas:

- Quality Principles and Practices
- Communications Skills
- Understanding a Process Based System
- Requirements and Interpretation of the Standard
- Documentation Requirements of the Standard
- Introduction to Quality Systems Audits
- Preparing for an Audit
- Audit Planning
- Communications Skills Exercise Review
- Conducting the Audit
- Preparing Findings and Final Report
- Nonconformity Writing Exercise
- Corrective Action and Follow-up Activities
- Practice Audits
- Preparation of Reports
- Review of Audits and Critique

**OR Quality Edge Mgmt Consulting Attend/Conduct Internal Audits**

This activity should be performed primarily by the organization's own Internal Auditors unless Quality Edge Management Consulting has been contracted to perform the audits. We will participate in the initial audits to ensure proper audit management. This is an excellent opportunity for Internal Auditors to become familiar with the overall activities of the organization and discover further ways to streamline processes.

*Deliverables:*

Assistance during audits or complete conduct of audits

**10. Conduct General Personnel Overview Training**

This two to three hours workshop is intended to familiarize all personnel in the concepts, application, requirements, and benefits of the Quality Management System. A short test will be administered to measure the effectiveness of training. All personnel who have not attended any other training course should be included. Those personnel on travel should also be included. A Certificate of Completion will be issued.

*Deliverables:*

Review of Company Quality Policy, procedures and applicable work instructions;  
Orientation Materials

**11. Monitor Progress**

We will make periodic visits to monitor the progress of the implementation and provide assistance as needed. There are generally one to two days on-site visits during the implementation phase of the project and additional phone conference meetings.

*Deliverables:*

Verbal report to Management on current status of Quality Management System, recommendations for change/improvement, revised Project Plan (as required)

**12. Evaluate Management Review**

We will review the Management Review meeting agenda and minutes to ensure all areas are covered and appropriate output is produced. Deficiencies and recommendations for improvement will be noted as needed.

*Deliverables:*

Written evaluation of Management Review activities

**13. Conduct Preliminary Assessment**

NOTE: We will generally perform this only if we have not attended or conducted your Internal Audits. This abbreviated review is conducted in the true style of the actual certification audit. Upon completion of the assessment, a list of findings may be generated and a timeframe established in which these findings should be addressed and corrected. Suggestions will be given on how to address the findings and provide adequate evidence to resolve them.

*Deliverables:*

Assessment Report

**14. Review Implemented Corrective Actions from Preliminary Findings or Internal Audits**

At the end of the allocated time to address the findings, follow-up will be conducted to review any corrective action and objective evidence provided. If the review indicates successful completion of all required activities, recommendation will be made that the organization is ready for Certification audit.

*Deliverables:*

Follow-up and/or closure and production of records for Internal Audit or Preliminary Assessment findings  
Certification Audit Readiness Report

**15. Certification Audit Support**

We will be available off-site during the certification audit to provide support and provide general guidance in response to the registrar's observations. Check-in times will be scheduled with the Management representative (MR).

*Deliverables:*

Assistance during certification audit and observations review with MR

**16. Follow-up on Initial Certification Audit Findings**

If the certification audit conducted by the registrar results in findings, we will provide assistance to develop a corrective action plan to address the findings. We will assist the Client in documenting the findings through the internal Corrective Action process, establishing a timeframe for completion, and providing adequate evidence for resolution.

*Deliverables:*

Recommendations for, review and approval of documented Corrective action plan(s) to address all findings