Step 2 – Identify Implementation Team

QMS development is a unique project, and it needs to be staffed with the right people. You will need to identify or hire an individual responsible for oversight of quality management activities, who will champion the cause and steer individuals in the organization to help with the implementation and ongoing activities.

<table>
<thead>
<tr>
<th>Key Players</th>
<th>Role</th>
</tr>
</thead>
</table>
| Quality Manager/Project Lead | • Interface with top management and ensure that the organization gets the resources it needs to create and maintain the QMS  
• Develop plan and schedule for implementing the standard  
• Assess time and resource needs  
• Monitor progress and adjust plans based on progress and obstacles  
• Coordinate mapping of core processes  
• Serve as lead internal auditor |
| Implementers/Deputies        | • Assist in mapping out core processes  
• Serve as internal auditor  
• Assist with ongoing maintenance once QMS is established |
| Technical Writers/Documentation Specialists | • Create easily readable processes and procedures |

In addition, you will need to appoint a committee that is responsible for oversight of the implementation progress and that will meet at regular intervals throughout to monitor progress. Members should include key leadership, management, appointed QA manager, and deputies (i.e., internal auditors).
Step 8 – Set Quality Policy, Objectives, & Metrics

Once you know your market, you must formulate a concise statement of how you will serve that market. What are you here to do?

Example Quality Policy – Laboratory serving a large oncology population:

“To ensure accurate and timely examinations and services for our oncology patients and health care providers and to continuously meet or exceed the stated or implied expectations of our clients and stakeholders.”

Example Objectives & Metrics

<table>
<thead>
<tr>
<th>Elements of quality policy</th>
<th>Corresponding quality objectives</th>
<th>Corresponding metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accurate examinations and services</td>
<td>Maintain or improve scores in PT testing</td>
<td>PT results</td>
</tr>
<tr>
<td></td>
<td>Reduction in amended reports</td>
<td>Number or percentage of amended reports</td>
</tr>
<tr>
<td></td>
<td>Reduction in laboratory accidents (e.g., lost in transport, quantity not sufficient)</td>
<td>Number of laboratory accidents</td>
</tr>
<tr>
<td>Timely examinations and services</td>
<td>Timely test results</td>
<td>TAT</td>
</tr>
<tr>
<td>Meet or exceed expectations of customers and stakeholders</td>
<td>Improved customer survey scores</td>
<td>Survey results</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TAT for customer complaints</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improvement in satisfaction scores or percentile</td>
</tr>
</tbody>
</table>
People often confuse action items with quality objectives. They are not the same.

<table>
<thead>
<tr>
<th>Quality objectives</th>
<th>Action items</th>
</tr>
</thead>
<tbody>
<tr>
<td>No beginning and end</td>
<td>Have a beginning and an end</td>
</tr>
<tr>
<td>Example: Reduction in amended reports</td>
<td>Example: Complete market survey</td>
</tr>
</tbody>
</table>

The policy, objectives, and metrics you write at this stage are helpful in focusing your work moving forward, but they are not permanent; they can be changed. Once you develop and implement your QMS, you will learn a great deal about whether they are realistic or whether they represent the right things. For this reason, the Roadmap has a step in the audit phase that recommends revisiting these items. You can then retest the system with the revised items. It is a continuous loop of improvement. (See CAP QMEd online course Quality Manual Development.)

Revisiting Objectives and Metrics

David Wolfe on defining and revisiting goals.

Zuhair Latif on updating preliminary metrics.
Step 17 – Conduct Internal Audit

Several months after the documentation has been written, trained auditors should carry out internal audits covering all processes and activities of the QMS. (If you chose to use the “Segmenting Work by Process” approach, you would audit only those key processes that you developed. See Step 4 – Develop Implementation Plan, for description of this approach.)

The audit determines whether processes are being carried out in accordance with the organization’s quality plans and whether the quality system is effective. (See CAP QMEd online course Internal Auditing.)

To do an effective job, the auditor needs to understand the process in terms of its inputs, value added, resources, outputs, and resulting metrics. See the graphic below.

The processes and procedures created in Step 12 – Map and Develop Processes and 14 – Create Documentation define how the organization’s quality system should work. These are the quality plans. The audit seeks to determine whether the plans are being carried out and whether they are working. Here is a simplified way to look at this:

| Processes, Procedures, and Work Instructions: | Say what you do |
| Implementation: | Do what you say |
| Internal Audits: | Show me you do what you say |
Each audit requires a written report, which is reviewed with the quality manager and stakeholders. The report identifies nonconformances and areas for corrective action to bring the actual practices in line with the quality system, as well as potential improvements in the system. Management is responsible to make sure the corrective actions are effective. The report also includes positive aspects of the QMS, enabling future auditors, external assessors, and management review teams to ensure that these positive elements do not slip. (See CAP QMEd online course Management Review.)

External ISO assessors use the internal audit results to understand if and where the organization is acting to correct and improve its operations.

Internal auditors need to be independent of the function being audited. However, there is a strategic advantage to selecting auditors whose departments’ processes relate to the areas they are auditing. For instance, a chemistry technologist could audit phlebotomy and outpatient collections, and a microbiologist could audit hematology or contract review.

Employing one or two full-time people to audit all the processes might seem an attractive alternative, but full-time auditors may develop a certain tunnel vision regarding the organization’s operations and may lack the status of a management-based audit team. They also may lack the status of someone who performs daily work within the organization.

Regardless of the auditor pool’s size, having a strategy for selecting auditors will go a long way toward guaranteeing the audits’ overall effectiveness and, more importantly, the management system's effectiveness and improvement. The auditors must not have responsibility within areas they are auditing.

The quality manager normally prepares and distributes the actual audit plan to all members of the audit team and function heads. It typically comprises a simple time-based program by week, with weeks across the top and processes/areas to be audited up the side.
<table>
<thead>
<tr>
<th>No.</th>
<th>Title</th>
<th>WEEK NUMBER</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Control of Documents</td>
<td>GH</td>
</tr>
<tr>
<td>2</td>
<td>Internal Audit</td>
<td>AF</td>
</tr>
<tr>
<td>3</td>
<td>Management Review</td>
<td>HT</td>
</tr>
<tr>
<td>4</td>
<td>Training</td>
<td>RG</td>
</tr>
<tr>
<td>5</td>
<td>Technical Process A</td>
<td>ER</td>
</tr>
<tr>
<td>6</td>
<td>Technical Process B</td>
<td>RG</td>
</tr>
<tr>
<td>7</td>
<td>Technical Process C</td>
<td>AF</td>
</tr>
<tr>
<td>8</td>
<td>Accommodation and Environmental Conditions</td>
<td>GH</td>
</tr>
<tr>
<td>9</td>
<td>Laboratory Equipment</td>
<td>HT</td>
</tr>
<tr>
<td>10</td>
<td>Purchasing</td>
<td>GH</td>
</tr>
<tr>
<td>11</td>
<td>Complaints</td>
<td>RG</td>
</tr>
</tbody>
</table>

**Representation of Audit Program Schedule**

A best practice is to record the results of an audit on a standard report form. No ISO standard requires this; an organization could simply write audit reports on a plain sheet of paper. However, a form helps the auditor, prompts follow-up action, simplifies record keeping and control, and enables external ISO assessors to determine what has happened.
Quality System Internal Audit Report

Date: | Process #: | Revision: | Process Name:
---|---|---|---
Auditor(s): | Responsible Person: | Areas Audited:

Pre-Audit meeting
Date: | Audit Record (describe what you did, who you spoke to, what records you examined, etc.)
Attendee by: | Summary:

Positive Aspects of QMS:

Opportunities for Improvement:

<table>
<thead>
<tr>
<th>Nonconformances:</th>
<th>Corrective Actions (CA) Planned:</th>
<th>Date Action Required by:</th>
<th>Process Owner/Date:</th>
<th>CA cleared by QM/Date:</th>
</tr>
</thead>
</table>

Signed by Auditor: | Process/procedure Change Required? | If yes, does process owner agree?

Sample Internal Audit Report Form

A management representative should brief auditors prior to the audit. The briefing will prepare the auditors and ensure the audit is complete and effective by reviewing issues, areas to cover, and numbers of records to examine. At this briefing, management should examine previous audit results with the auditor. The audit will verify that corrective actions have been implemented and are effective.

Implementation Roadmap

Strategy & Planning
- Establish Stakeholder Commitment
- Identify Implementation Team
- Plan Change Management Activities
- Conduct Readiness Assessment
- Conduct Initial Staff Training

QMS Development
- Develop Implementation Plan
- Set Preliminary Goals for Metrics
- Reassess Market
- Map and Develop Processes
  - Core
  - Support
- Set Quality Policy Objectives, and Metrics
- Identify Needed Support for Processes
  - Documentation
  - Training
  - Competencies
- Enhance Document Control and Records Control
- Provide Training on Process Development
- Create Documentation
  - Processes
  - Procedures
  - Work Instructions
- Assemble Quality Manual

Audit
- Conduct Internal Audit
- Perform Root Cause Analysis and Corrective Action
- Conduct Management Review
- Conduct Internal Surveillance Audits
- Provide Audit Phase Training

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