Step 2 – Identify Implementation Team


John Seabrooks on facing skeptical questions.

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.

Key Players	Role
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


Trace Custer on setting quality policy and 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."


Trace Custer on setting goals.

Example Objectives & Metrics

Elements of quality policy	**Corresponding quality objectives**	**Corresponding metrics**
Accurate examinations and services	Maintain or improve scores in PT testing	PT results
	Reduction in amended reports	Number or percentage of amended reports
	Reduction in laboratory accidents (e.g., lost in transport, quantity not sufficient)	Number of laboratory accidents
Timely examinations and services	Timely test results	TAT
Meet or exceed expectations of customers and stakeholders	Improved customer survey scores	Survey results TAT for customer complaints Improvement in satisfaction scores or percentile

	Continuously improve and provide state-of-the-art laboratory diagnostics	Initiated new laboratory tests and methodologies completed per year

People often confuse action items with quality objectives. They are not the same.

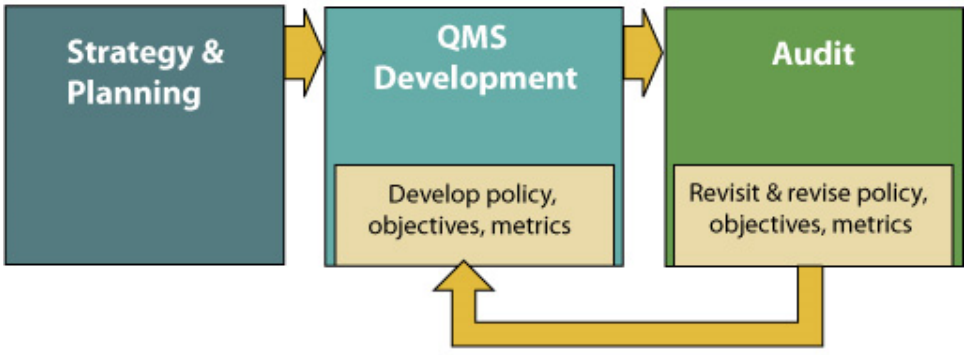
Quality objectives	**Action items**
No beginning and end	Have a beginning and an end
Example: Reduction in amended reports	Example: Complete market survey

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 QM*Ed* online course Quality Manual Development.)


David Wolfe on defining and revisiting goals.


Zuhair Latif on updating preliminary metrics.

Revisiting Objectives and Metrics



Step 17 – Conduct Internal Audit

David Wolfe on checklist approach versus process approach.

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.)

David Wolfe on internal audit review of metrics and follow up.

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 QM*Ed* 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 QM*Ed* 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.

David Wolfe on how to select internal auditors.

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.

Trace Custer on effective internal audits.

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.

PROCESS		WEEK NUMBER									
No.	Title	1	2	3	4	5	6	7	8	9	10
1	Control of Documents	GH									
2	Internal Audit							AF			
3	Management Review								HT		
4	Training						RG				
5	Technical Process A	ER									
6	Technical Process B		RG								
7	Technical Process C			AF							
8	Accommodation and Environmental Conditions	GH									
9	Laboratory Equipment					HT					
10	Purchasing				GH						
11	Complaints							RG			

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: Attended by: Summary:	Audit Record (describe what you did, who you spoke to, what records you examined, etc.)				
Positive Aspects of QMS:					
Opportunities for Improvement:					
Nonconformances:	Corrective Actions (CA) Planned:		Date Action Required by:	Process Owner/ Date:	CA cleared by QM/ Date:
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