Do we really need quality manager?

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Perhaps the most important change that ISO 9001 2015 brought was about top management:

1. The move from ‘Management responsibility in the 2008 version’ to ‘Leadership in the 2015 version’

2. No need for top management to appoint a quality management representative (QMR).
The changing role of the quality management representative (QMR) However, this change does not mean that the role of QMR will become superfluous.

In fact, the function will be embedded in a more supportive environment, as the new standard assigns more responsibility to top management.
The new ISO 9001 expects top management to adopt a more proactive approach to quality management.

In the future, top management is to take more **accountability for the effectiveness** of the quality management system.

In other words, top management **not only needs to provide the resources necessary for a functioning quality management system** (QMS), but must also ensure QMS effectiveness and efficiency.

**Representation of the structure in PDCA cycle of QMS for ISO 9001:2015**

- Leadership est au centre de l’architecture
Extended model of a process-based quality management according to ISO 9001:2008

Top Management is **ONE** part of the puzzle in the system.

She’ll wait for the results of analyzes of measures to take action and plan actions.
Top Management!

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• In the future, top management is to take more accountability for the effectiveness of the quality management system.

• In other words, top management not only needs to provide the resources necessary for a functioning quality management system (QMS), but:

  ➔ Must also ensure QMS effectiveness and efficiency
• During much of my career in the “quality field”

• The one problem that I've observed in all those years is that nobody really knows what the quality manager should do.

• Why the confusion?
To start with, the title of quality manager is a problem.

– Manufacturing makes things, ...
– Engineering designs things, ..
– Nurses draw blood,..
– MD select blood donors,..
– and purchasing buys things.
So, does the quality department quality things?

I don’t think so, and that’s part of the problem.
• So then, what should the quality manager and the quality Department do?

• While there are no direct requirements for a quality manager in ISO 9001:2015,

• there are many required activities that fit well with the traditional role of a quality manager.
Understanding the needs of interested parties: Clause 4.2 (4. Context of the Organization)

• Requires that the blood centre determine who the interested parties of the QMS are, such as customers and suppliers, and determine what the requirements of these interested parties are.

• Performing this task and keeping the information up to date is one task that is often within the job description of the quality manager.
Establishment and continual improvement of the QMS processes: clause 4.4

- Once the blood centre processes and their interactions are determined and implemented, these processes need to be maintained and improved.

- Maintaining an overall process integration flow is one activity that many quality managers perform.
Customer focus and product conformity: When looking at customer focus in clause 5.1.2

- There is a need to determine the risks and opportunities that can affect product conformity.

- Managing the risks and opportunities for product quality could be one of the tasks of the quality manager,
Monitoring the quality objectives (clause 6.2)

• Quality objectives: that have been established and reporting them to top management is another traditional role of the quality manager.

• Having one person focus on the management of this important activity is a good idea to provide focus and direction.
Internal and external communication: Communicating with customers (clause 7.4)

• Communicating with customers on quality matters is most easily done if you have one point of contact such as a quality manager.

• This way your customers know the best person to call to get answers when problems occur, rather than taking time to find the right person.

• Likewise, it is best if your employees receive QMS information from one source.

• A quality manager is ideal to fill these roles.
Release of products and services: In section 8.6

- The requirements ask that you determine the planned arrangements to verify the products and services and indicate that the products and services have successfully met the requirements.

- The people who perform these inspections often report to a quality manager,

- So the quality manager would direct and control these operations within your blood centre.
Internal audit planning & management: clause 9

• Managing the internal audit most easily fit into the traditional role of a quality manager.
• Having one overall person responsible for this activity can once again focus the resources to perform the auditing role within the company.

• The quality manager can provide this focus, direction, and control for QMS audits.
Nonconformity and corrective action: clause 10.2

• This is another traditional role of the quality manager.
• With one owner, these processes that are used throughout the blood center can be better controlled.
• so that one process is used everywhere and best practices are incorporated by everyone.
In summary:

• quality managers are supposed doing much more than gathering and reporting performance data.
• 1- They are partnering with others to create valid and reliable measures of quality and blood safety.
• 2- They are answering meaningful quality questions by collecting, analyzing, and making sense of performance data.
Skills you will need as Quality Manager:

1. A deep knowledge of a blood center's processes and operations
2. Communication skills
3. The ability to persuade
4. Interpersonal skills
5. Problem-solving ability
6. Organizational and planning skills
7. Skills in numerical and statistical analysis
8. The ability to work as part of a team