

# 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.

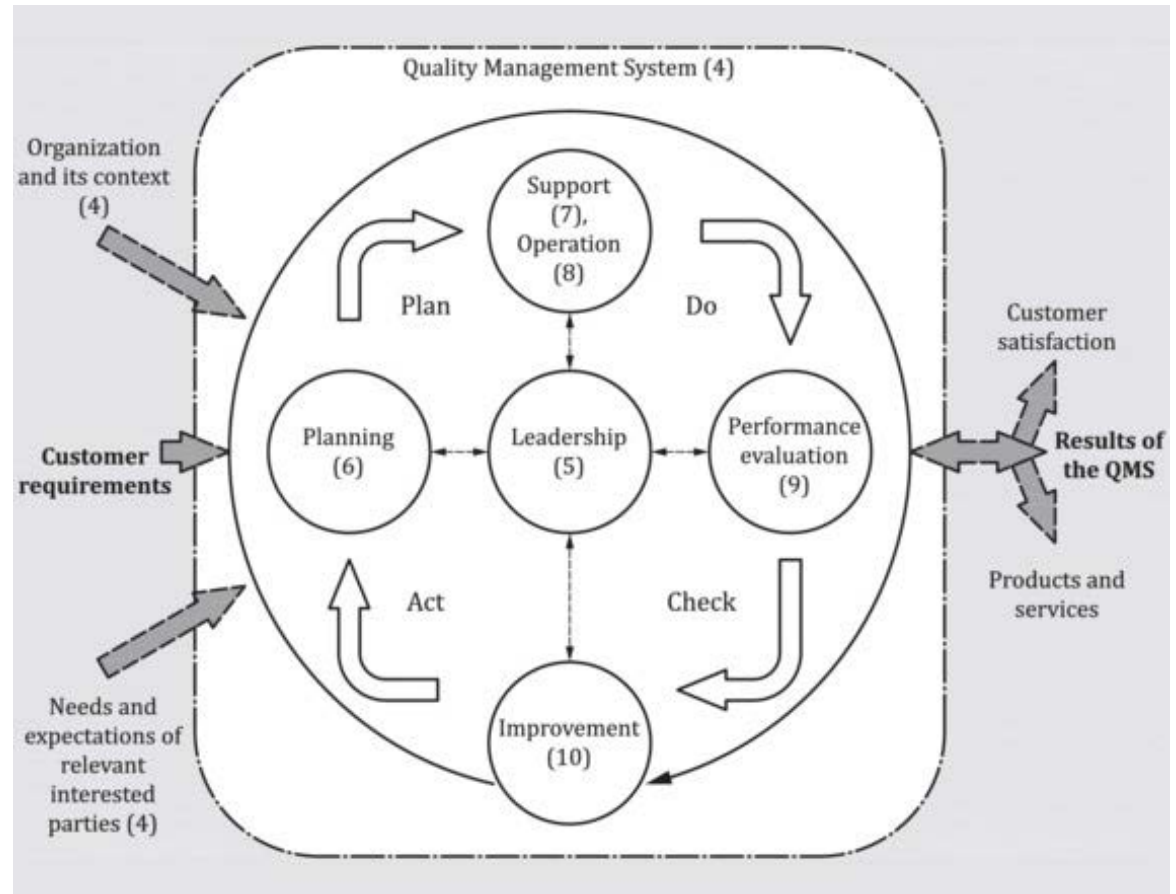
The new ISO 9001 expects top management to adopt a more proactive approach to quality management.

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**

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

- Leadership est au centre de l'architecture

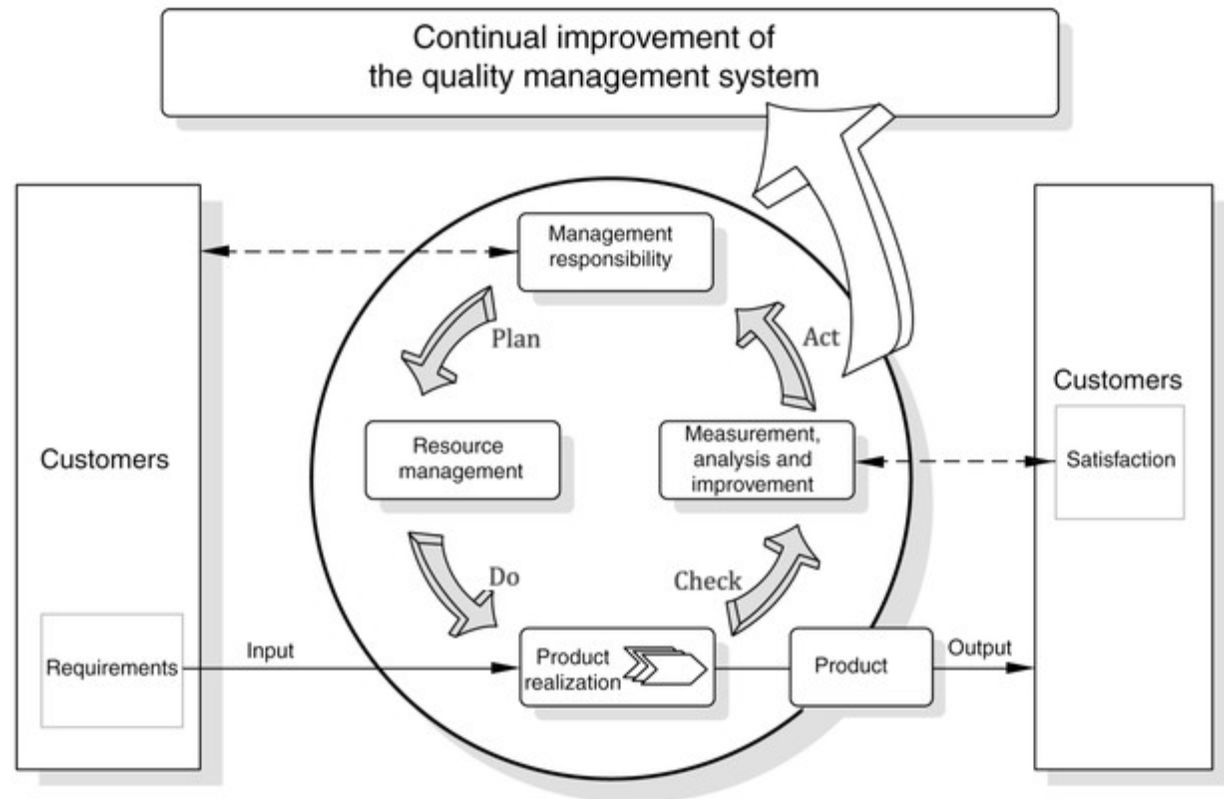


must also ensure QMS effectiveness and efficiency

# 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