

# Balancing the Quality System –Part 1 of 3





**How balanced is your Quality System ?**

**Does it know all its customers ?**

**Does it know whether it is meeting their needs ?**

**Have your end-customers been forgotten in the need to  
be compliant ?**

**Are your shareholders getting what they expect from your  
Quality organization ?**

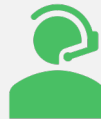
# Agenda



What do we mean by a balanced QMS ?



The importance of being customer centric



The customers of the QMS



Approaches to becoming more customer centric

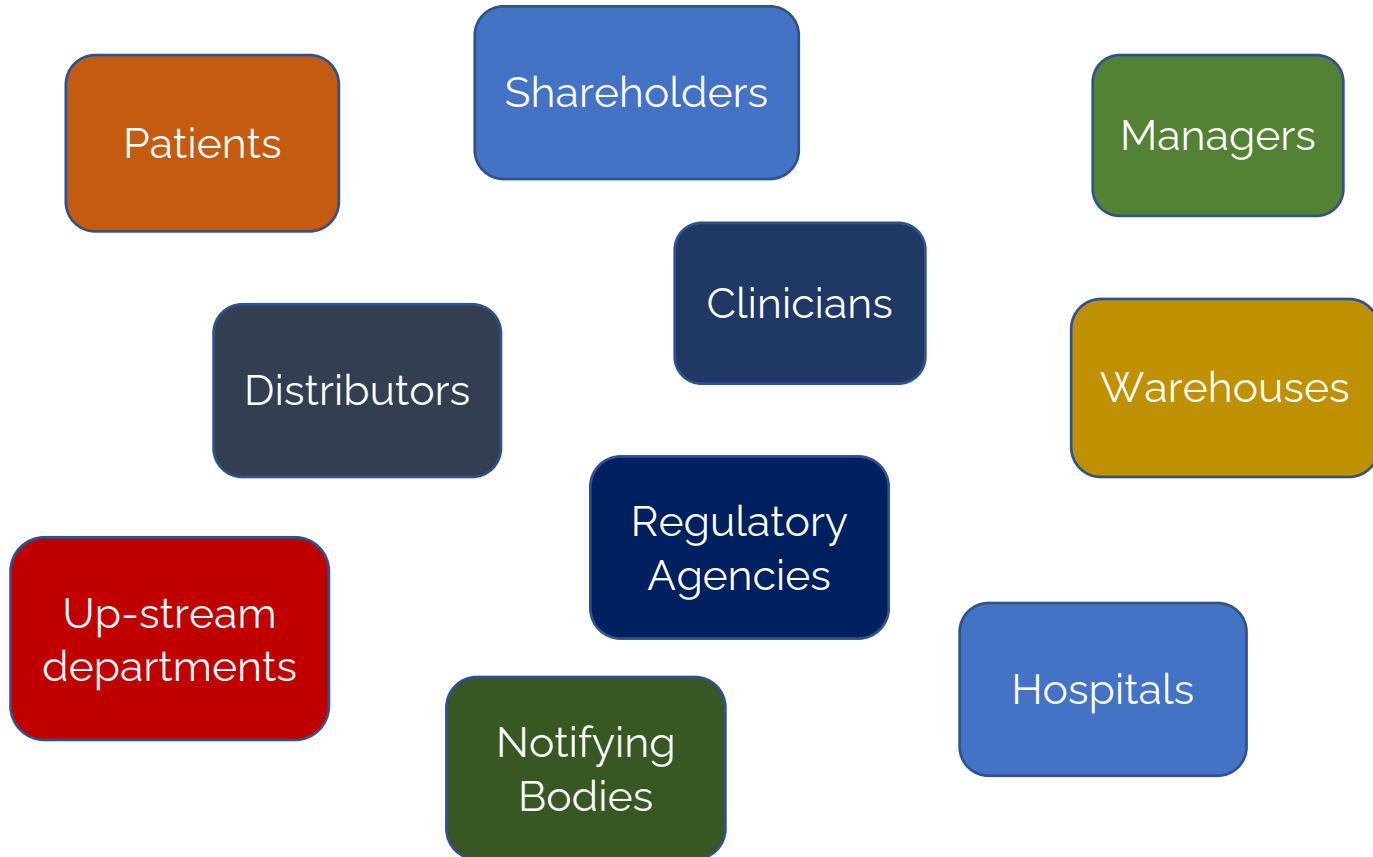
# What do we mean by a balanced QMS ?

It all starts and finishes with customers.



Often we think – quite rightly – of patients

# Others types of customers ?



**Are these all customers ?**

# What is a customer ?

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The dictionary definition of a customer is generally something like.

**' A person who buys goods or services from a business. '**



# Attributes of a customer

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Customers hold a unique relationship with their suppliers in that:-

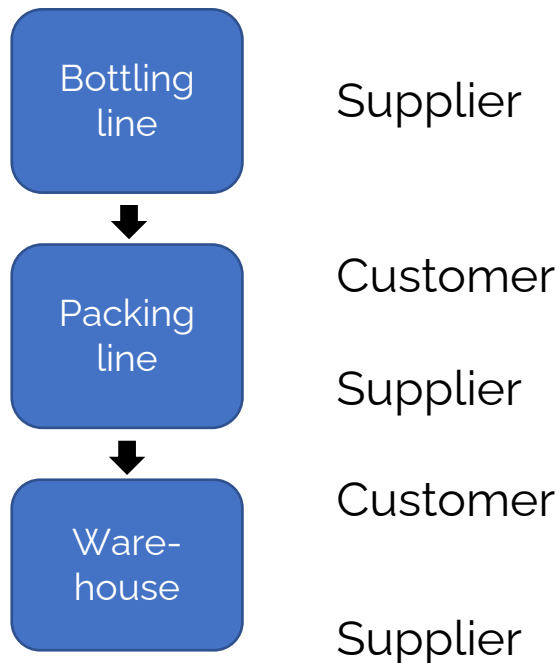
- 1) The relationship is never subordinate to the supplier.
- 2) The customer can take their business elsewhere if needed.



# The myth of the 'internal' customer

Modern manufacturing approaches have increased the concept of 'internal customers'.

Departments are both customers and suppliers. This has driven a need for internal supplier agreements.





**Suppliers**

Who  
supplies  
the raw  
materials ?

**Inputs**

What  
materials are  
needed ?  
What other  
resources are  
needed ?

**Process**

What are  
the steps?

**Outputs**

What is  
created ?

**Customers**

Who are  
the  
customers ?

# The pros and cons of 'internal' customers as a concept

## Advantages

- ✓ Drives need to understand whether you are satisfying your customers needs.
- ✓ It is satisfying to be considered a customer.

## Disadvantages

- ❖ Can prevent areas working as holistically for the overall benefit of the company ie: reinforces silos.
- ❖ Can reinforce focus on local targets.
- ❖ Can allow defects to pass downstream if they do not impact an area.
- ❖ Drives incorrect relationships between areas.
- ❖ Dilutes from understanding the real end-customer's needs.



Peter Drucker

One of the pioneers of quality management was less supportive of the idea of there being internal customers and in his view the only customer that existed was the external customer who paid the bills.

# Who are the customers of the QMS ?

**The quality management system exists to ensure that customers receive product that is safe, reliable and meets all their expectations.**

What about the regulators ?

What about the share-holders ?

The **three** groups any Quality organisation and the Quality System **must satisfy** to be truly effective.





You need to ensure you **meet** all applicable regulations and expected standards.



Your end customers – those who buy your products – need to be **satisfied**.



Your business needs to be **financially** viable.



You need to demonstrate with **objective evidence** – that you are meeting the requirement of the appropriate standard or regulation.

- ✓ Management of change.
- ✓ Control of measuring and test equipment.
- ✓ Document management.
- ✓ Design controls.
- ✓ Data driven decision making.



The end customer is primarily concerned around these three aspects of the goods or services that you provide:-

- ✓ Quality and safety
- ✓ Availability
- ✓ Price

A business that is compliant but not **satisfying** the customer will **fail**.



Your business needs to be **financially** viable.

- ✓ Bottom line profit
- ✓ Sales
- ✓ Market share
- ✓ Share price

A business that is compliant, satisfying the customer but **unprofitable** will **fail**.

All three meet the **true** definition of a customer...

They can **take** their business **elsewhere**.



Regulators / Notifying bodies can **refuse** to approve your Quality System.



Customers can purchase from **other** suppliers.



Shareholders can invest in **other** businesses.



Your Quality System needs to be **balanced**.

- ☐ The regulations will eventually settle down.
- ☐ Compliance is an attribute the customer expects as a given.
- ☐ It will **not** differentiate you in the marketplace.
- ☐ Quality organisations will need to ask themselves what is their true **purpose**, beyond ensuring compliance ?



or



**Handing out speeding tickets**

**Helping build more beautiful cars**

# Concept of **value** and the role of perspective.

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**Value** has a very specific meaning related to how the product is changed and whether the customer would be willing to pay for this change.

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It involves concepts such as '**value added**' and '**non-value added**' activities and '**mapping the value stream.**'

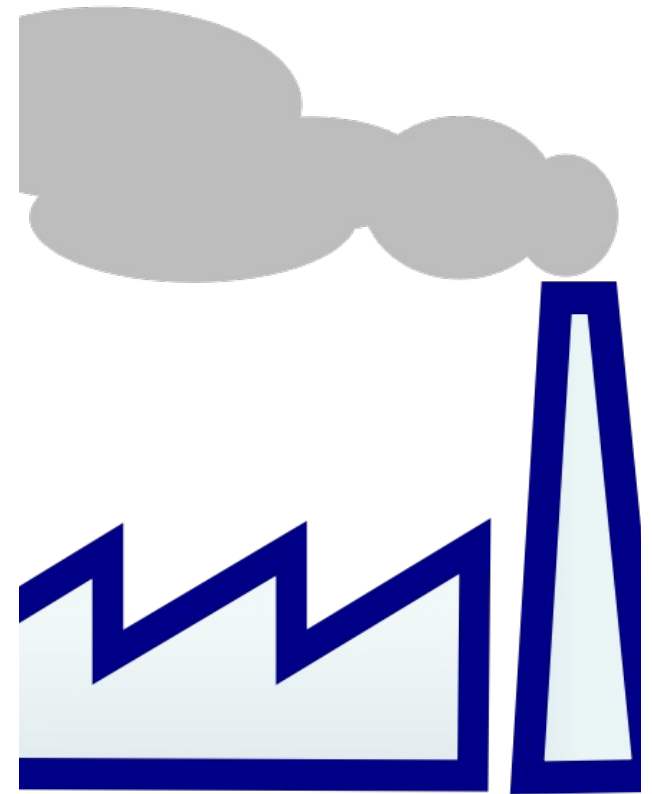
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Different customers will consider different aspects of the QMS more important than other depending on their perspective.

# Lean thinking applied to the Quality System

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- ❑ Lean methodology originated in Toyota and has **transformed** the efficiency of modern manufacturing plants.
- ❑ Leverage the power of lean thinking applied to the transactional processes of the Quality System.
- ❑ Key is putting the Quality System's **customers** central to your thinking.



# Outcomes

- You need to focus on **outcomes** that your customers care about.
- Ideally measured through aspects that demonstrate you are satisfying **multiple** customers.
- KPIs in **harmony**.

## Customer facing metrics - Does the customer really care about these ?

- ☐ The average time to close a complaint.
- ☐ The number of staff without approved training plans.
- ☐ The number of CAPA events open in the quality system.
- ☐ The number of open service orders with customer



- ✓ The % of complaints closed to the customer's satisfaction.
- ✓ The number of deviations in manufacturing system the result of poor training as the cause.
- ✓ The number of ineffective CAPA events implemented.
- ✓ The % of customers with equipment that cannot be used due to equipment failure.

## Customer facing metrics



- ✓ Orders delivered on time and of the correct quality.
- ✓ Product has clear instructions.
- ✓ Product meets expectations regarding quality and reliability.
- ✓ Company responds to questions in a timely manner.
- ✓ Company resolves complaints to the satisfaction of the customer.



## Customer facing metrics

- ✓ Scrap levels
- ✓ Inventory levels
- ✓ Appraisal and inspection costs
- ✓ Raw material costs

You need to view each QMS element from **multiple** perspectives





# Perspective

We don't see things as they are. We see things as we are.

# Example

## Control of Non-Conforming Product



Regulators / Notifying bodies are **only** concerned do you meet the regs and standards.

**Can you demonstrate control ?**



Customers are **only** concerned that they are getting the product they want.

**Is defective product preventing this ?**



Operations are only concerned that you make a swift and **appropriate** decision to scrap or release.

**Are you wasting company money ?**



# Tools to build a **customer centric** Quality System

- Leverage lean methodology to understand each customer group's perception of **value** and work **relentlessly** to deliver it.
- Deliver only what your customer decides is important, **not** what you think is important.
- The customer decides whether you are doing this effectively, **not you**.