

The background of the image is a dense, overlapping field of numerous pink spheres. The spheres vary in size and are rendered with soft shading, giving them a three-dimensional appearance. The overall color palette is a range of light to medium pinks.

**Quality**

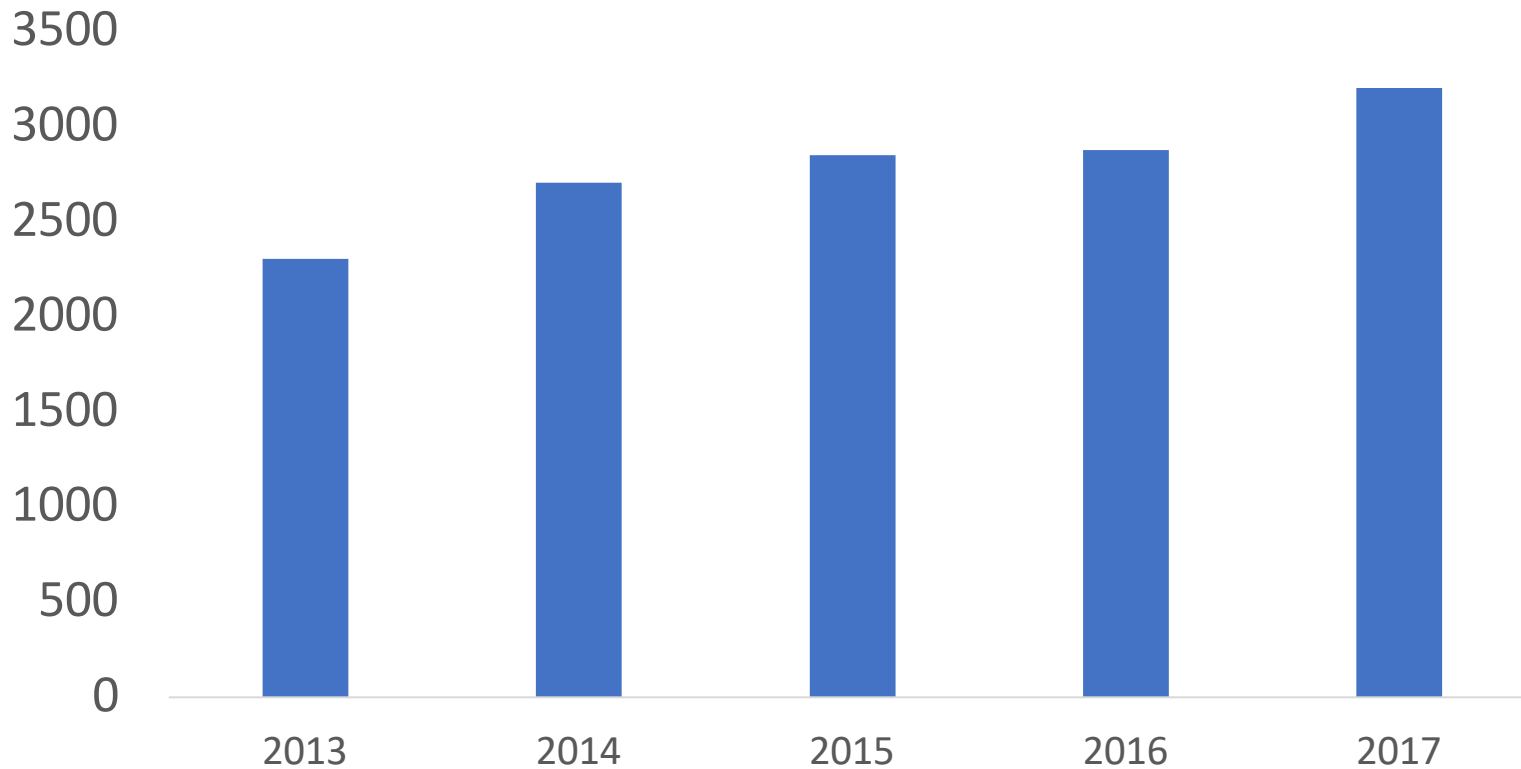
# The impact of poor quality

- Over a 10-year period poor quality medical products have resulted in over 83,000 deaths and potentially over 1.7 million injuries.
- This is despite these products being manufactured under what would be considered very stringent regulations and standards.

International Consortium of Investigative Journalists. "Medical Devices Harm Patients Worldwide as Governments Fail on Safety." [icij.org](https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/) November 25, 2018. <https://www.icij.org/investigations/implant-files/medical-devices-harm-patients-worldwide-as-governments-fail-on-safety/>



## Medical Device Recalls in US by Year



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- We seldom pause to reflect how the products we manufacture, especially if they are in the healthcare sector, can have a transformational if not lifesaving impact on people's lives.
  - Every diagnostic test, every surgical implant, every medical procedure has tangible potential to enhance, reinvigorate or even save a life.



# What this course will do..

- ✓ This course will cover quality and why it is important.
- ✓ It will explain how quality management systems can be transformed to be more balanced, effective and impactful in how they deliver quality and also meet a company's regulatory obligations.
- ✓ It will describe a **step-wise** program that can be used alongside a transformation map to make your QMS and Quality organisation more effective.






## Quality v quality

- In this session we will cover the many aspects around quality as an attribute.
- These encompass features as wide ranging as whether the product meets specifications, to how it looks and feels.
- The concept of quality is also relevant to organisational culture. It covers whether individuals have pride in their work, understand the impact of their actions and also the ability of them to proactively improve how their jobs are performed.
- To avoid any unnecessary confusion we will use the word *quality* to indicate the concept of value, and the word *Quality* to indicate the functional organisation tasked with implementing, managing, and maintaining the quality management system.

# Which organisation is yours ?

- X The quality system is focused on compliance rather than quality.
- X Metrics are disconnected from customer needs.
- X Technology is put before process.
- X The Quality department is disconnected from the needs of the business.
- X A culture of quality is absent.
- ✓ The quality system supports all the needs of the business.
- ✓ Metrics measure your ability to meet customer expectations.
- ✓ Technology supports effective and efficient processes.
- ✓ The Quality organisation is aligned with the needs of its business partners.
- ✓ There is evidence of quality in everything you do.



**So what is “  
quality “ ? and  
why it matters to  
your business.**

Dictionary definition of quality is:-

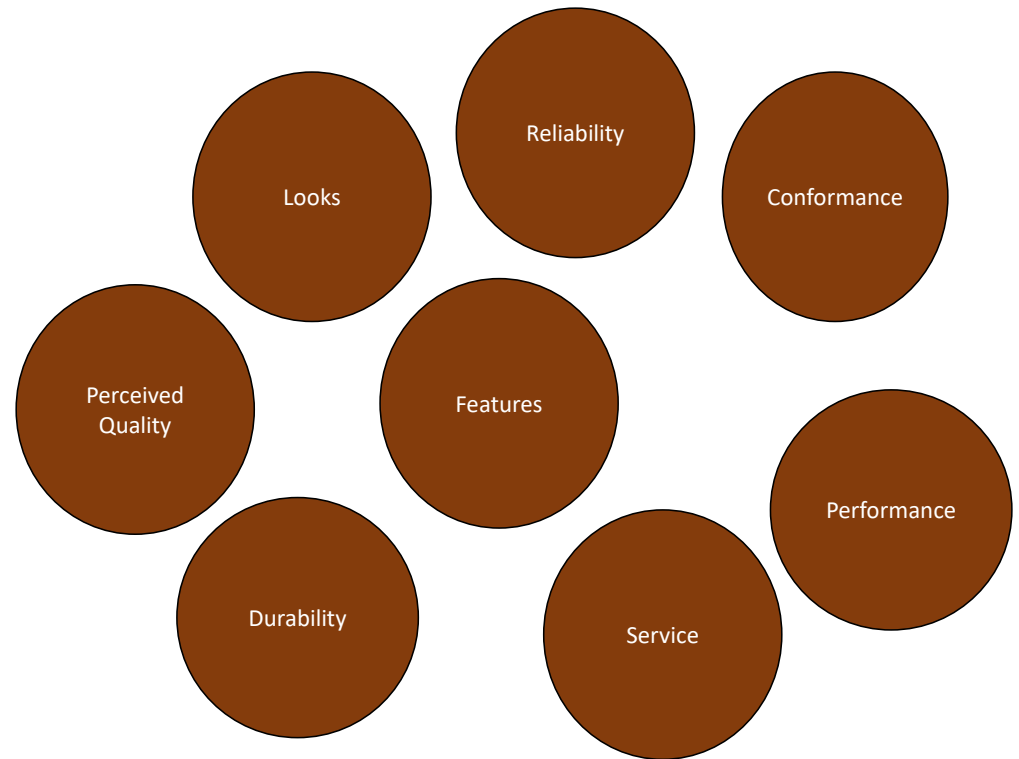
*“The totality of features  
and characteristics of a  
product or service that  
bear on its ability to  
satisfy stated or implied  
need.”*

# Garvin, 1987

Garvin in 1987 in his  
Harvard Business  
Review article:

*Competing on the Eight  
Dimensions of Quality*

broke down quality  
into..



# Performance

- In modern parlance, products and services need to do what they say on the tin.
- How they perform is crucial. In many ways it is an attribute that any successful organization must deliver on. Failure to deliver on performance expectations will generally result in loss of business



# Conformance

- There are expectations that goods and services conform to the specifications defining their manufacture and this has a direct link with performance.
- This is far easier for goods than the services, and consequently there is a strong emphasis within quality management around quantitative aspects of quality that are easy to measure: size, material, weight, etc



A Sharp microwave oven with a stainless steel finish. The door is closed, showing a black mesh window. On the right side, there is a control panel with a digital display showing '88:88' and a temperature of '9°C'. Below the display is an 'AUTO MENU' section with buttons for A1 through A10, labeled with various food items like Reheat, Potato, Meat, Vegetable, Fish, Pasta, Soup, Cake, Pizza, and Chicken. The Sharp logo is visible in the top left corner.

**SHARP**

# Features

- Today, businesses must straddle the line between offering new and shiny features as not to be left behind, but not distract themselves from their core offering, ensuring it is still relevant and delivering on this.

# Reliability


- Reliability is a measure of the probability that the product will perform as intended.



# Durability

- Durability describes how long you can use a product before it needs replacing.



A close-up photograph of a young woman with blonde hair, wearing a grey button-down shirt and a black headset with a microphone. She is smiling warmly at the camera, with her hand near the microphone. The background is a soft, out-of-focus grey.

# Customer service

Exemplary customer support is a key attribute that businesses forget at their cost.

# Looks

- The product just looks very well made from the packaging to the components to the marketing literature.

# Perceived quality

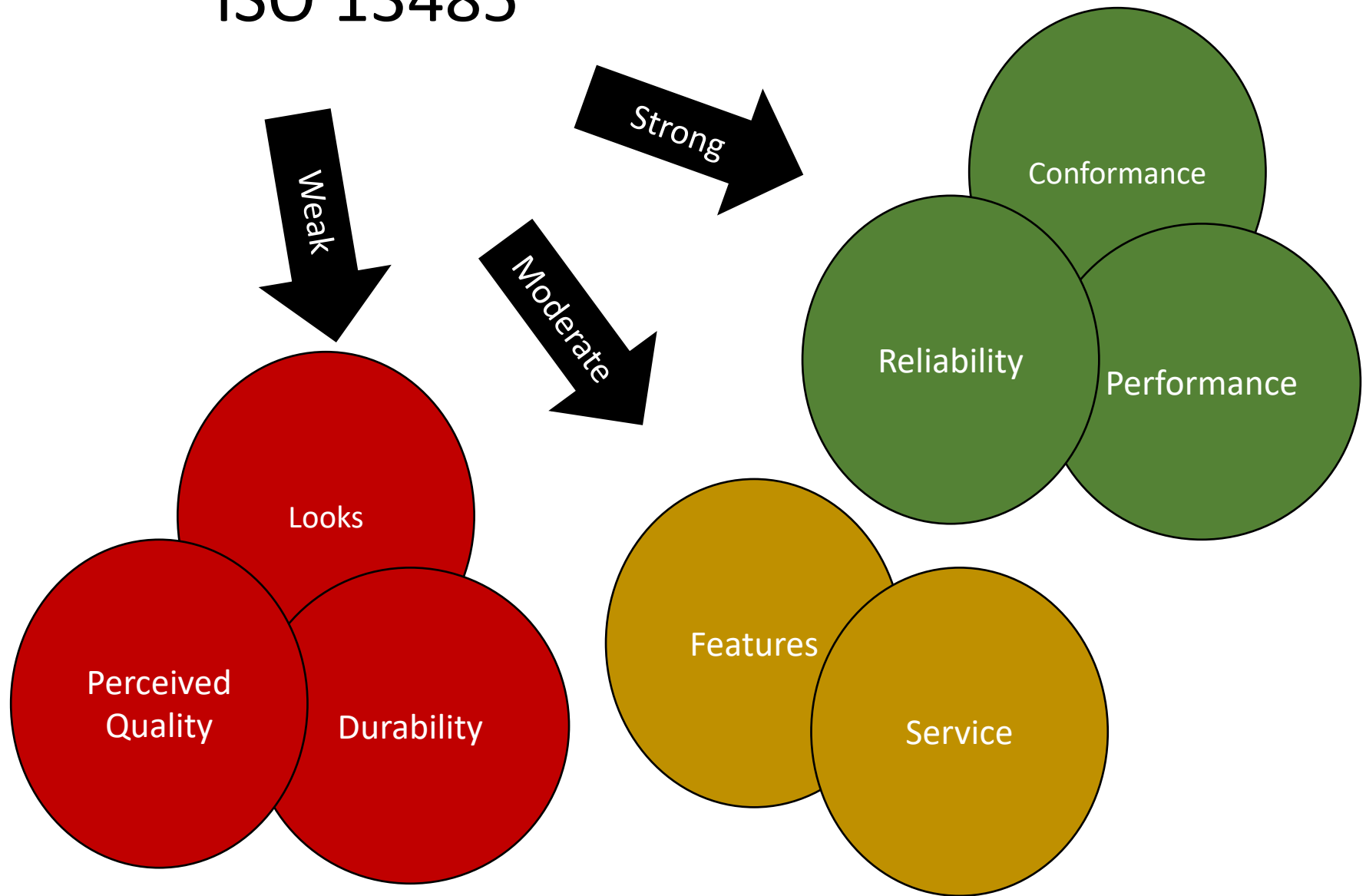
Perception is reality



# An holistic view of quality ?

- The question for Quality organisations is are you equally focused in all the dimensions of quality ? Or do you focus on aspects that are easier to measure or those traditionally viewed as being within the jurisdiction of the Quality organisation such as specifications and tolerances ?
- The obvious question is if you aren't considering these less obvious, though critical aspects of quality, who within your organisation is ?

# ISO 13485



The regulations have not always protected the customer



IVDR / MDR

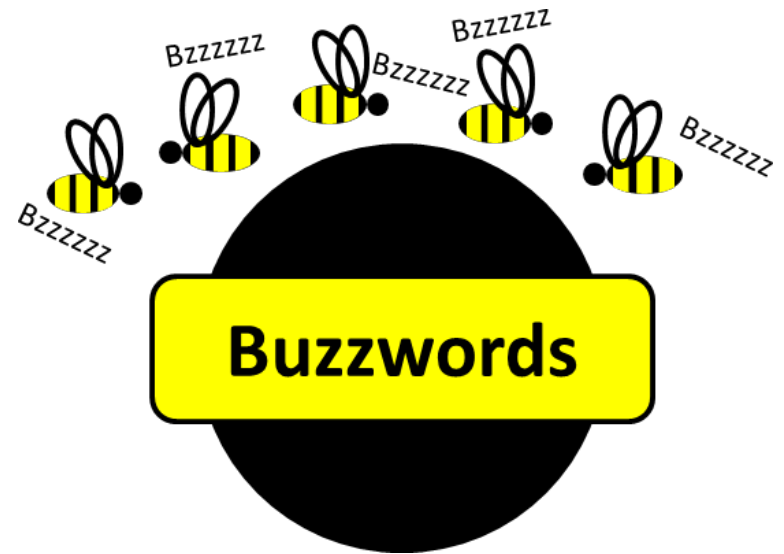
In the UK **one in five** products are expected to be removed from the market over the next five years and **one in ten** companies are halting all innovation activity.

[www.abhi.org.uk](http://www.abhi.org.uk)

# Does quality really matter anymore to businesses?

- If you look at the top ten medical device companies selling products and services intrinsically connected to patient health and safety, approximately half have no explicit mention of the importance of product quality on their corporate websites. The remaining have a collection of generic statements buried in text extolling the virtues and importance of quality.
- Poor quality costs industry around \$5 billion per year. A significant recall can cost as much as \$600M. It has also been calculated that a company moving from average to good quality can increase its revenue by 4 percent\*.

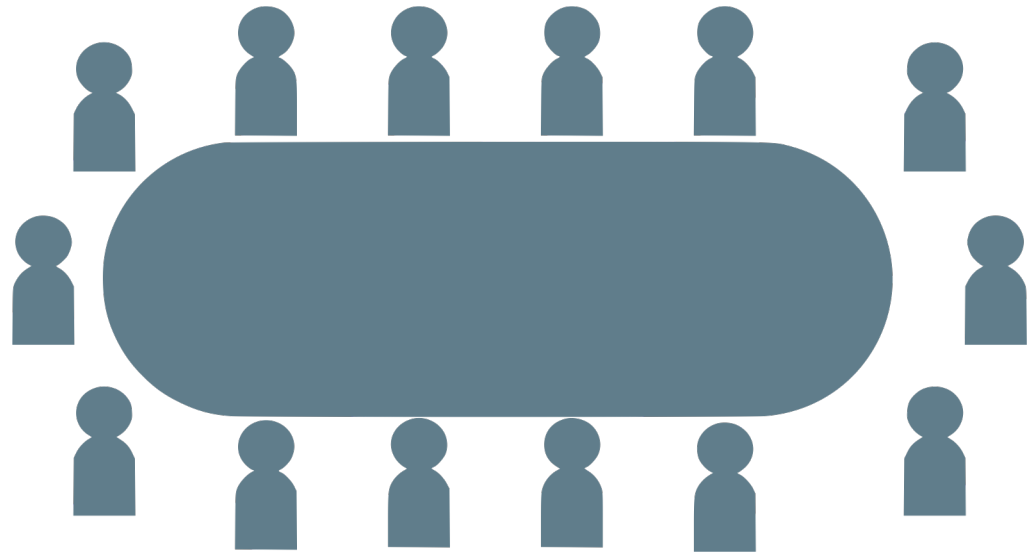
\* Fuhr, Ted, Katy George, and Janice Pai. "The Business Case for Medical Device Quality." mckinsey.com October 2013.



# Have we lost our focus on quality ?

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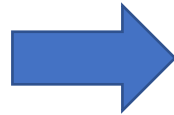
- Quality has taken a backseat to the more fashionable aspects such as sustainability, protection of the environment, diversity, and more general corporate social responsibility?
- If you look at the makeup of the executive boards of these top ten companies, half do not have an Executive Director on the board specifically called out being responsible for quality.





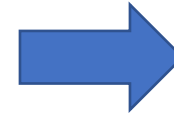
Control

QMS



Change

Lean  
Six Sigma



Innovation

Breakthrough  
thinking

### Change highly controlled

- Consistency of manufacture
- Compliance
- Documentation
- Regulatory control

### Change within discrete boundaries

- Variability reduction
- Waste-removal
- Flow driven by customer demand
- Cost reduction

### Change without boundaries

- New markets
- New customers
- Disruptive technology

## Opposing Views on Quality

Negative

Positive



- *I don't feel the impact of poor quality directly. Why does it matter ?*
- *As long as customers keep paying, what's the problem ?*
- *Customers are so far away. Why should I care ?*

- *Quality is my number one priority.*
- *Customers are central to everything we do.*
- *Customer feedback is key.*

Positive

**Extrinsic  
(Public facing)  
Views**

Quality is a façade. Vision and mission statements that do not reflect reality.	Pride in ones own work. Shame in poor performance. I am able to make change.
Cowboys, rogue traders and scammers	Pockets of excellence. Monopolies.

Negative

Positive

**Intrinsic  
(Personal) Views**



- Control
- Order
- Regulations
- Compliance

- Freedom
- Disorder
- Creativity
- Innovation

How do you satisfy **both** extremes ?