



Lecture 1: Definitions – What does Quality mean?

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Quality

What is it?

Why is it important?



QUALITY

The word '**QUALITY**' has its origin in a Latin word - "**Qualitas**". It means '**general excellence**' or a **distinctive feature**'.

Oxford Reference Dictionary defines quality as: "A standard of how good something is as measured against other similar things."

If we try to analyze this definition we come across some key words:

- Standard
- Goodness
- Measurement
- Comparison

<https://drpotdar.wordpress.com/2008/02/21/basic-concepts-of-pharmaceutical-quality>

QUALITY

In manufacturing, a measure of excellence or a state of being free from defects, deficiencies and significant variations.

It is brought about by strict and consistent commitment to certain standards that achieve **uniformity of a product** in order to satisfy **specific customer or user requirements**.

ISO 8402-1986 standard defines quality as "**the totality of features and characteristics of a product or service** that bears its ability to satisfy stated or implied needs."

<http://www.businessdictionary.com/definition/quality.html>

QUALITY IN A PHARMACEUTICAL SENSE

ICH Quality Guideline Q6A Specifications

Quality: The suitability of either a drug substance or drug product for its intended use. This term includes such attributes as the **identity, strength, and purity.**

ICH Quality Guideline Q9 Quality Risk Management

Quality: The degree to which a **set of inherent properties** of a product, system or process **fulfills requirements.**

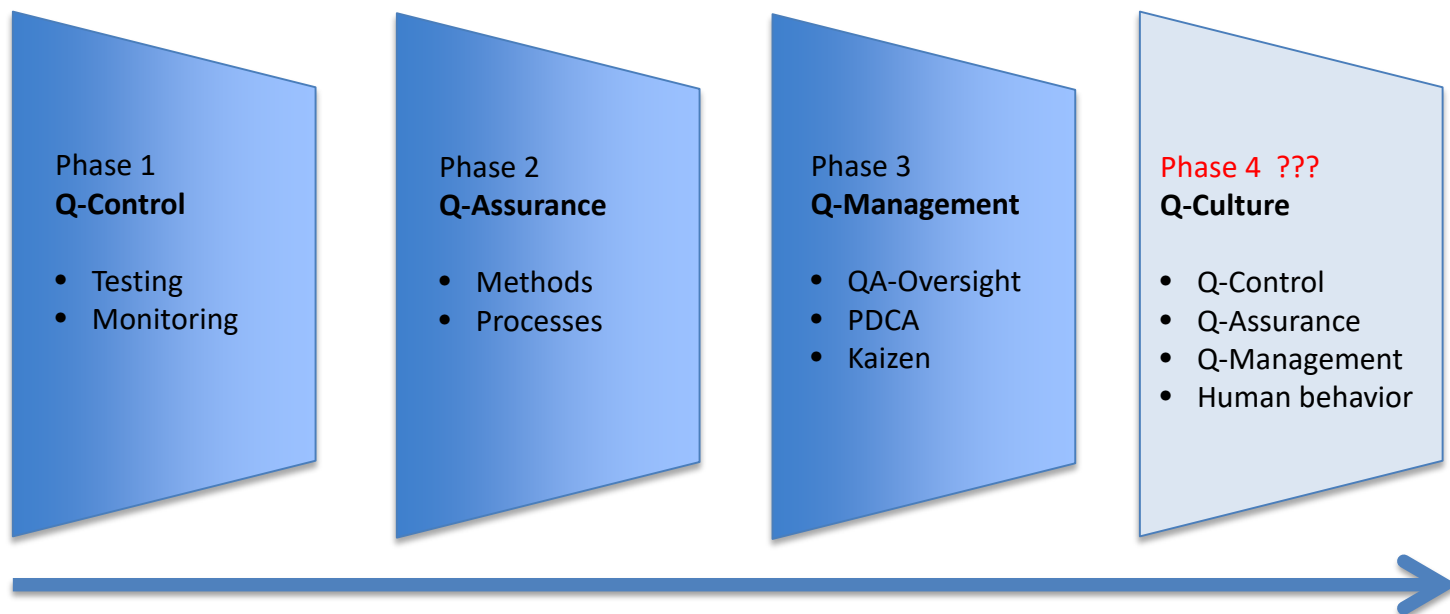
COMPETING ON 8 QUALITY DIMENSIONS

- Performance
- Features
- Reliability
- Conformance
- Durability
- Serviceability
- Aesthetics
- Perceived Quality

These dimensions can serve as a framework for strategic analysis. Some of these are always mutually reinforcing; some are not. The challenge to managers is to compete on selected dimensions.

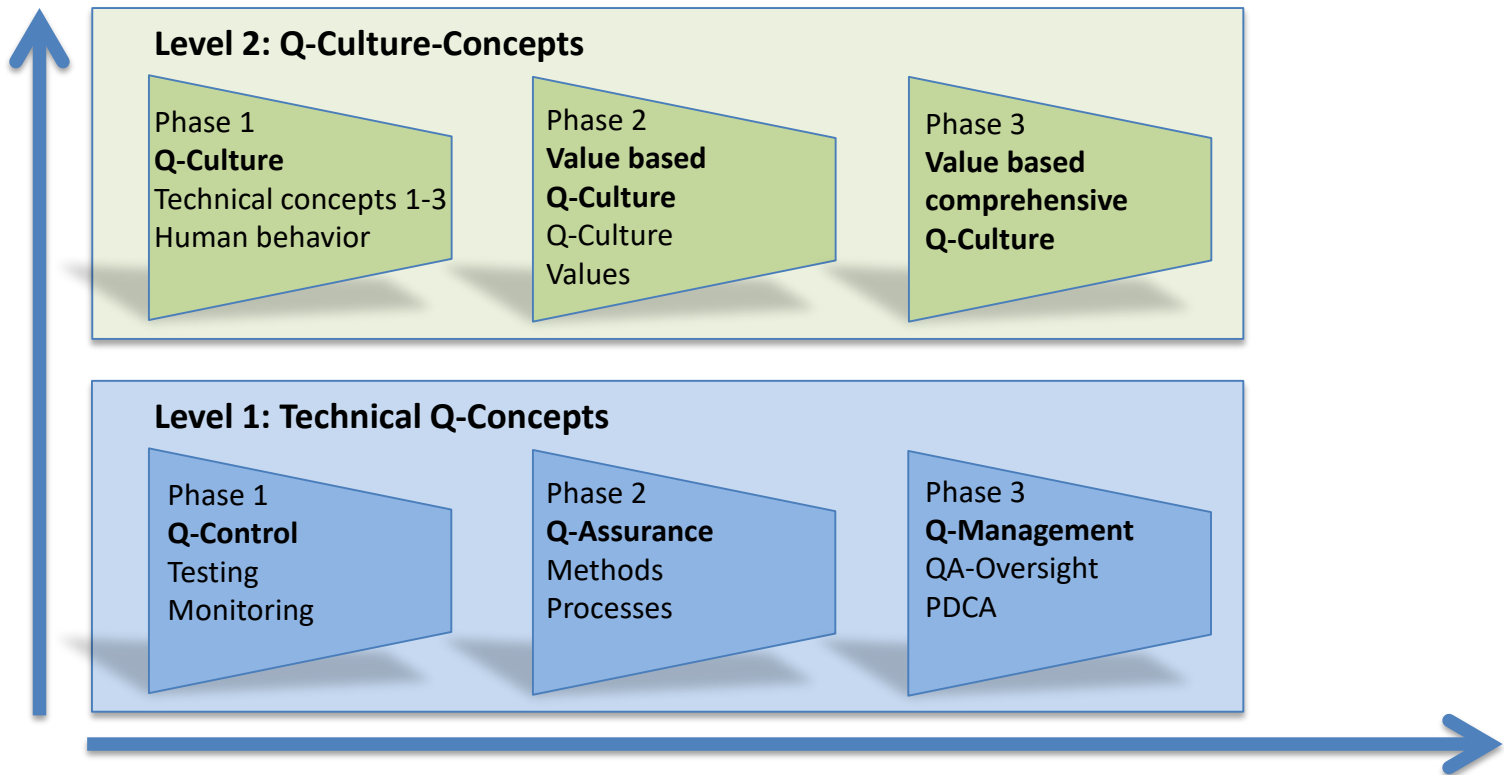
David A. Garvin, Harvard Business Review

DEVELOPMENT OF PHARMACEUTICAL QUALITY CONCEPTS



Quality Culture combines the technical aspects of „What we have to do“ (Phases 1-3) with the psychological aspects of human behavior.

DEVELOPMENT OF PHARMACEUTICAL QUALITY CONCEPTS



Quality Culture opened a new dimension in Quality Concepts.

Let us discuss the following questions:

1. How do you identify Quality Culture?
2. Where do you find Quality Culture?
3. How can you detect a high level of Quality Culture?

QUALITY CULTURE

is a set of group values that guide how improvements are made to everyday working practices and consequent outputs.

<http://www.qualityresearchinternational.com/glossary/qualityculture.htm>

Quality Culture combines two components: QUALITY and CULTURE. Quality Culture reflects people's quality thinking and quality awareness.

Quality awareness determines the value of a product or a service for the client. Therefore, quality awareness is the secret of success of any Quality Management System.

QUALITY CULTURE: Explanatory context

A quality culture is, arguably, a set of taken-for-granted practices that encapsulate the ideology of the group or organisation.

Quality culture is a specific aspect of organisational culture, which is defined, for example by Robbins (2001) as 'the social glue that helps to hold an organisation together'.

Schein had suggested that 'the culture of an organisation is made up of many variables - modes of interaction, assumptions, rituals, membership, structures, control mechanisms and so on'.

<http://www.qualityresearchinternational.com/glossary/qualityculture.htm>

QUALITY CULTURE: Explanatory context

Harvey and Green (1993) outlined the nature of quality culture, which was seen, at the time, as a function of manufacturing industry:

A culture of quality is one in which **everybody** in the organisation, not just the quality controllers, **is responsible for quality**. A central feature of such organisations is that each worker or team of workers is both a customer of, and supplier to, other workers in the organisation:

they form a **chain of internal customers and suppliers**.

It is the responsibility of each unit to ensure the quality of their own work.

The emphasis is on ensuring that things are **'done right first time'**.

When they are not then the process that has led to an unsatisfactory output is analysed so that corrections can be made in the process to ensure that the problem does not arise again.

QUALITY CULTURE: Explanatory context (continued)

In a perfect quality culture there might be no need to check final output, as individual responsibility and self-control of everyone's own results are basic requirements for a high performance quality culture.

A final check of results against specifications, KPIs, etc. by others, is to shift responsibility away from those involved at each stage.

However, Quality Control is one of the central parts of GMP. It has the responsibility to check products manufactured by others.

→ Quality Culture has to deal with and solve this conflict!



BEHAVIOR

1

a : the manner of conducting oneself

b : anything that an organism does involving action and response to stimulation

c : the response of an individual, group, or species to its environment

2

the way in which someone conducts oneself or behaves

3

the way in which something functions or operates

<https://www.merriam-webster.com/dictionary/behavior>

QUALITY BEHAVIORS

Quality behaviors are observable or countable actions (in doing or saying) of an individual or a group, that positively determine or influence the quality of a product or service.

Definition by Thomas Krieger and Martin Haerer, 2017

QUALITY BEHAVIOR

Quality behavior is relevant in all tasks of our daily business:

- Perform a manufacturing step
- Perform an analytical test
- Write an SOP or instruction
- Train you new colleague
- Investigate a deviation or complaint
- Recrute new employees
- Coach your employee
- Chair a meeting or participate in a meeting
- Call someone on the phone
- Write an e-mail
- ...

VALUE BASED COMPREHENSIVE QUALITY CULTURE

