



Managing Change Part 1 of 4



Is your organization managing change efficiently and effectively ?

Are you applying the correct fixes to the right problems ?

Are you able to manage your pipeline of change ?

Does senior management have clear visibility of the extent of change across the organization ?

Agenda

What do we mean by change management ?

Why these sessions are different

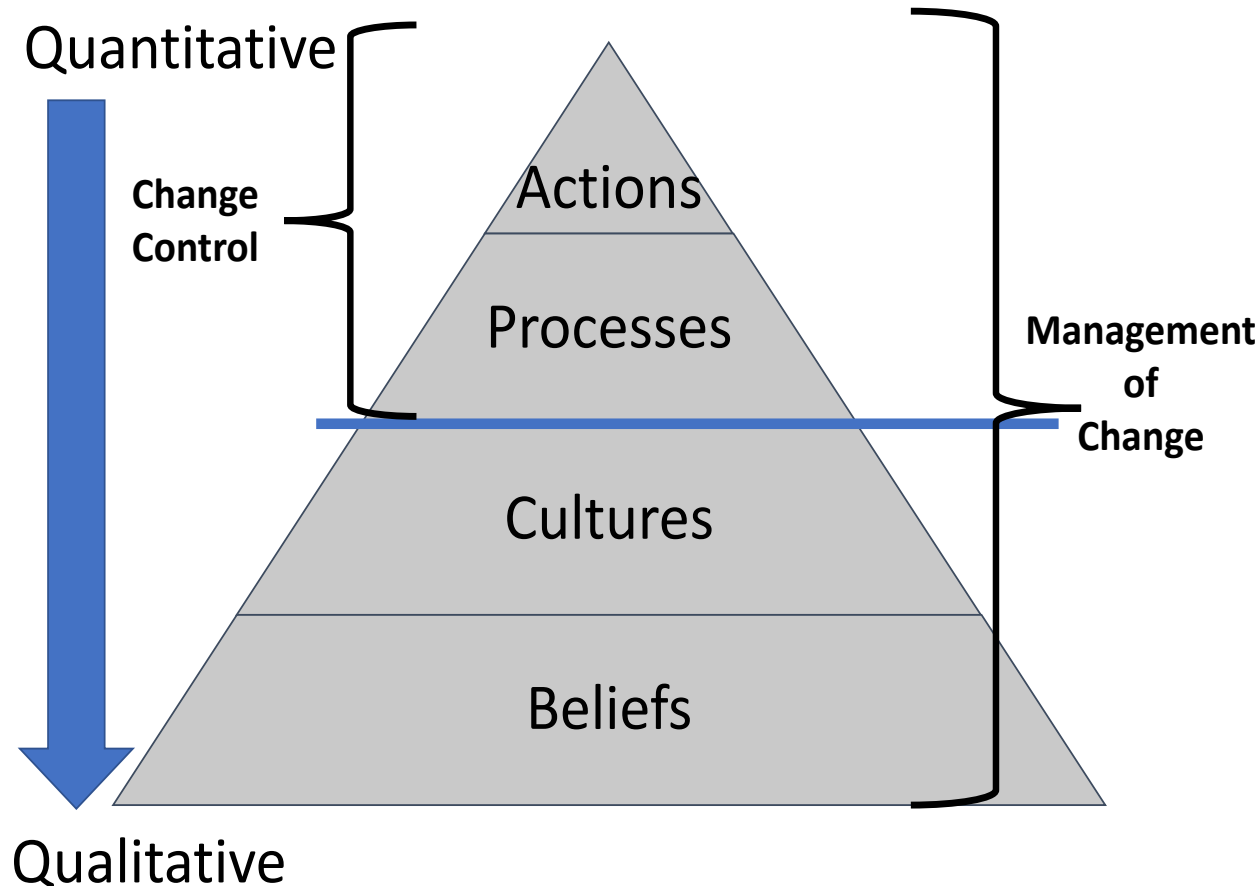
Scope of change

Root cause analysis – practical help

CAPA

Practical help to manage the change process

Change management v Change Control v Document Control.





Change can come from many directions. These are essentially driven by the three customer expectations of the QMS.

Compliance

Change may be driven by the need to make changes to meet the requirements of changing or current regulatory requirements or standards.

Business Health

Change may be the result of the need to improve the efficiency of the business to ensure its viability and the ability to reinvest resources to drive business growth and support existing or new markets.

Customer Experience

Change may be driven to improve the customer experience of the product, with respect to performance and reliability. Change may be driven by technological improvements to reduce risk associated with the manufacturing process. Change may also be the result of new customer requirements.

Change management

- Google search of 'Change Management' yields 6.4 Billion hits.
- There's a lot of advice out there.
- This session differs in other material on change management in 2 **important** ways.

1: Don't put the cart before the horse

This approach puts greater focus on asking the question

“ Am I fixing the right problems with the right fixes ? “

- ✓ Root cause investigation approaches
- ✓ Types of CAPA
- ✓ Prioritising change

2: In the real world stuff happens. You will not be as in control as you want to be.

There are many change models
eg: Kotter's 8 Step Model which
infer that the change leader always
has control over events.

In reality the change leader is
embedded in the change process.

More of this is the session on
Organizational Complexity



Models are a **simplification** of the real world.

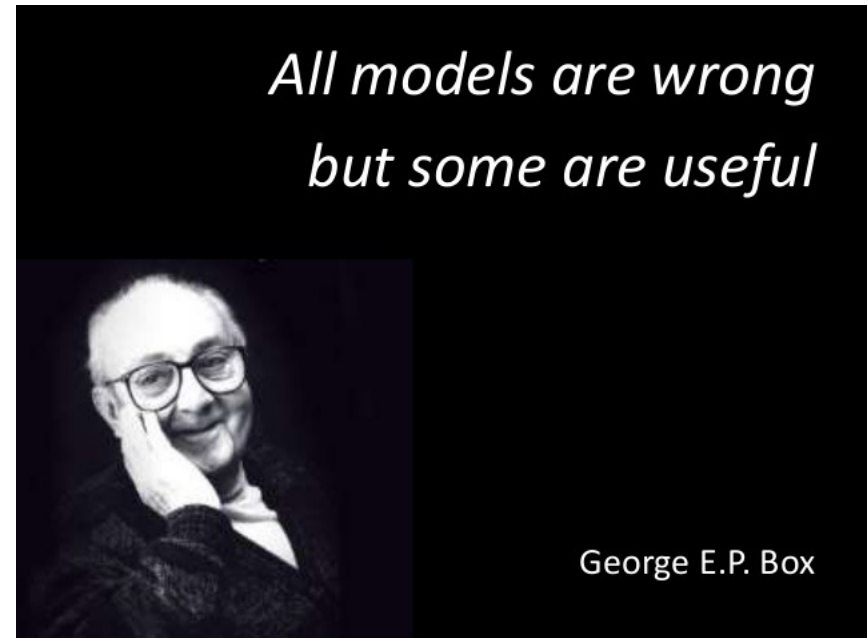
They can help, when they are 'roughly right.'

Which is better than being 'precisely wrong.'

The same applies to **all other** change methodologies


Six Sigma, lean, scrum, agile...

Do not use them dogmatically....





Making sure you address the
correct problems...

A pair of binoculars with black barrels and red-rimmed objective lenses is resting on a weathered wooden post. The background is a soft-focus sunset or sunrise over a body of water, with a warm orange and yellow glow. The text "What is the scope of the changes you want to make ?" is overlaid in white, sans-serif font, centered over the binoculars.


What is the scope of
the changes you
want to make ?

Clue: It's not everything.

You are focussed on the
Quality Organization and
by extension the **Quality
System**.

You should be focused on
what **Quality Data** is
telling you.





—

You need a
proactive
process..

That process is called

Quality Planning

Quality Planning



Quality Planning is the process used to identify **Quality Objectives** that meet the expectations of the **Quality Policy**.



Quality Planning is carried out to maintain compliance with regulations and to continuously develop the Quality Management System.



Analysis of Quality Data is used to derive appropriate Quality Objectives and Key Performance Indicators.

Quality Planning

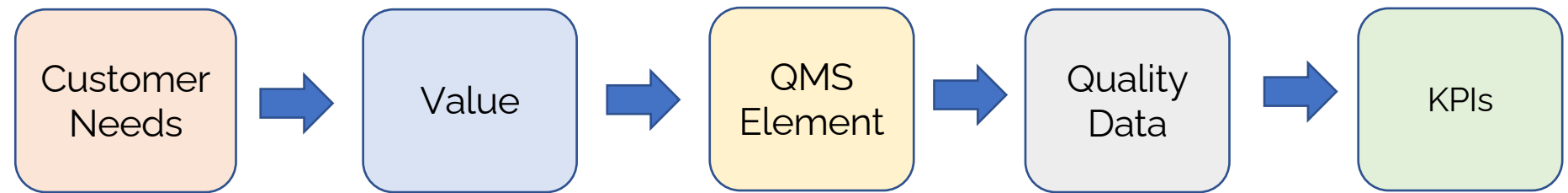
ISO13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes

5.4.1 Quality objectives

Top management shall ensure that **quality objectives**, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. **The quality objectives** shall be measurable and consistent with the quality policy.



Link between Customer Needs and Key Performance Indicators (KPIs)



Understanding Customer Needs and translating these needs into Key Performance Indicators is crucial to organisational success.

Quality System Elements

Customer	Value	Quality System Element ISO13485:2016
Finance (Business Health – Financial Profitability)	Scrap low.	8.3 Control of nonconforming product
Human Resources (Business Health – Staff Moral)	Adequate resources.	6.1 Provision of resources
Internal and External Audit (Compliance)	Document controls present.	4.2 Documentation requirements
Internal and External Audit (Compliance)	Design controls present.	7.3 Design and development
End-user (Customer Experience)	Manufacturer resolves complaints to satisfaction of the customer.	8.2.2 Complaint handling
End-user (Customer Experience)	Product meets expectations regarding quality and reliability.	7.3 Design and development

[illegible]

❖ What is Quality Data ?

- Quality Data is data generated through execution of the Quality Management System.
- Quality Data can be Quantitative (numerical) or Qualitative (non-numerical).

The importance of Quality Data

- ❖ The integrity of Quality Data is **critical**. Its analysis is used to base-line performance of the QMS and determine whether improvements are needed through the deployment of Quality objectives.
- ❖ Quality Data is used as the basis of data driven decision making. As such, Quality data require specific controls on how the data is collected, presented, analysed and verified as accurate.



Examples of Quality Data

Data	Type
Number of non-conformances per month	Quantitative - discrete
% of product scrapped per month	Quantitative - continuous
Bottle height assessed against a specification	Quantitative - continuous
Customer satisfaction survey	Qualitative
Number of open change orders	Quantitative - discrete
Customer complaint rate per month	Quantitative - discrete
% of production orders completed on time.	Quantitative - continuous
Process map	Qualitative / Quantitative

Quality Data Extraction and Presentation

- ❖ Quality Data may be extracted from a number of systems. They may be electric applications and the information downloaded or they may be paper-based and the data manually transcribed.
- ❖ Care should be taken for manually transcribed processes that errors are not introduced during the transcription process.
- ❖ Quality Data should be appropriately presented in visual manner to aid understanding and support any conclusions derived from the dataset.



ANALYSIS & DATA

Examples of data collection and presentation tools

Tool	Use
Check Sum	When collecting data on the frequency or patterns of events, problems, defects, defect location, defect causes, etc..
Control Charts	When predicting the expected range of outcomes from a process.
Pareto Chart	When there are many problems or causes and you want to focus on the most significant
Scatter Diagram	When trying to determine whether the two variables are related, such as when trying to identify potential root causes of problems.
Stratification	When data come from several sources or conditions, such as shifts, days of the week, suppliers, or population groups
Flow charting	To develop understanding of how a process is done.
Histogram	When analysing what the output from a process looks like.

Quality Data Analysis

- Unless the conclusions are obvious, Quality data should be analysed with the appropriate statistical methodology.
- Based on the output of the statistical analysis it may be necessary to employ root cause methodology and experimentation to test whether any hypothesis based on the data is supported.



Common statistical tools

Test	Purpose
Analysis of Variance (ANOVA)	Comparing means between independent groups
Correlational	Comparing association between variables
Chi-square	Test of strength of association between two categorical variables
T-test	Testing differences between populations
Regression analysis	Test of whether a predictor variable predicts an outcome variable.

Quality Data Verification

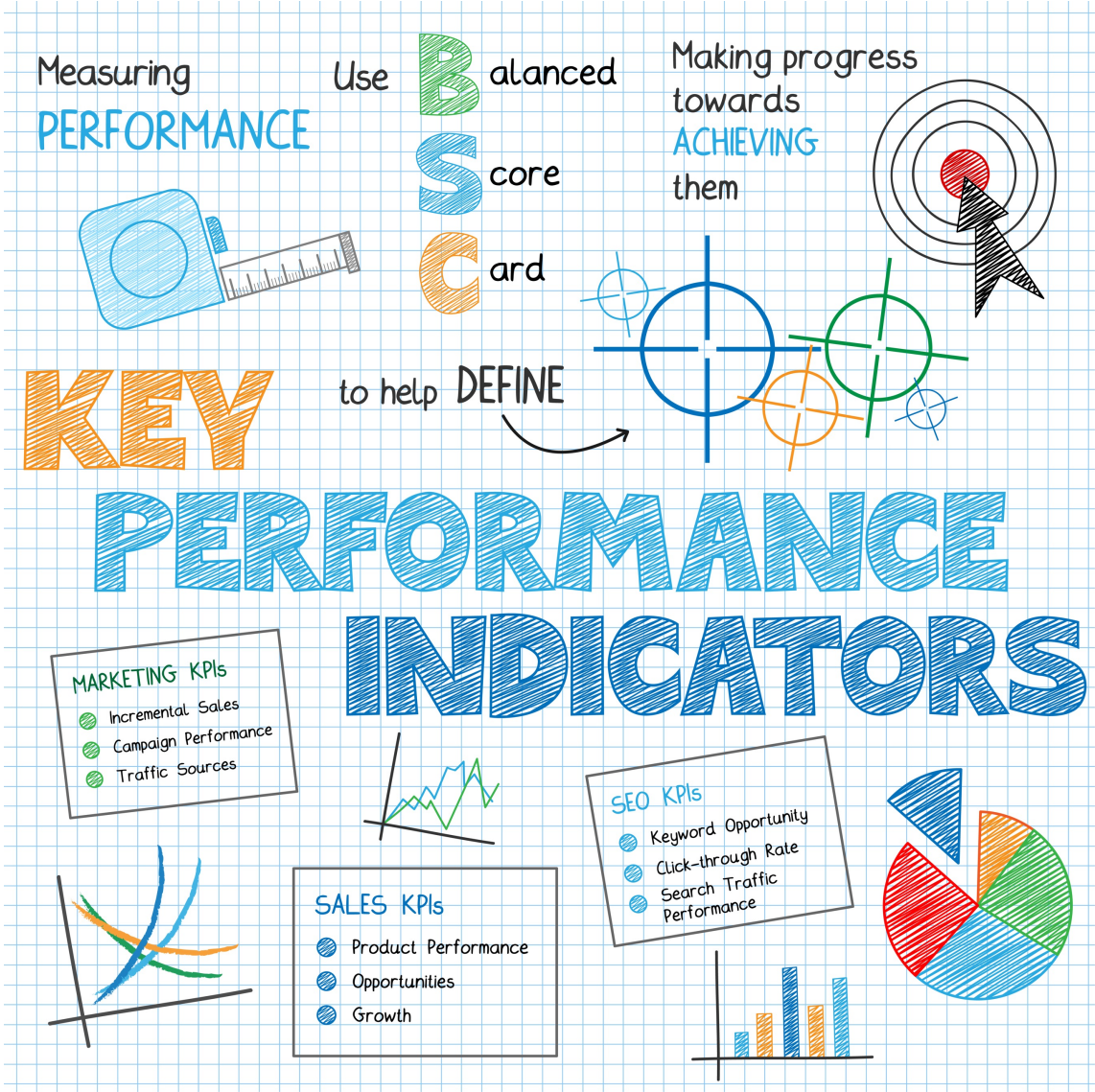
- ❖ As the analysis of Quality Data informs decisions around the effectiveness of the QMS and its ability support the manufacture of safe and effective products for end users, it is important that the accuracy and integrity of the data be independently verified.
- ❖ The data should be verified before it is used in the decision-making process eg: departmental meeting or Quality System Management Review and when no further data manipulation will occur.

Quality Data Verification

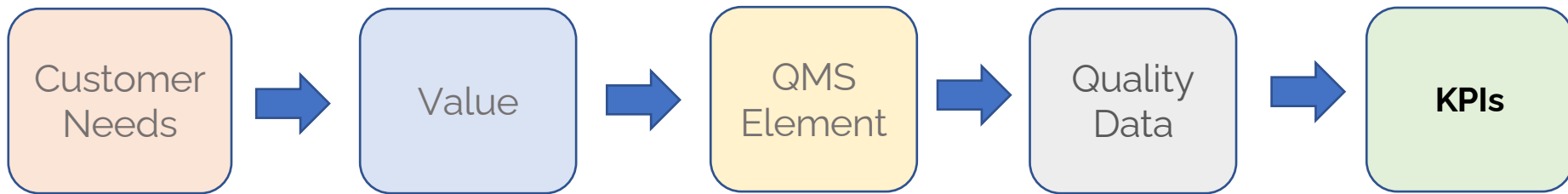
- ✓ Is the dataset large enough to support any conclusions ?
- ✓ Has any relevant data been excluded ?
- ✓ Has the most appropriate method to display the data been used ?
- ✓ Is the integrity of the data supported ie: Has any data been lost in the extraction, transcription or manipulation process ?
- ✓ Has the most appropriate statistical tool been employed ?
- ✓ Is there sufficient information documented around how the data has been manipulated eg: normalisation ?
- ✓ Is there sufficient information around where the raw data is located such that the final data package can be rebuilt in the future if needed ?



Key Performance Indicators



Key Performance Indicators (KPIs)



It is not practical to track and use **all** Quality Data in the assessment of the effectiveness, efficiency and compliance status of the QMS.

Key Performance Indicators

- ❖ KPIs are measures that demonstrate how effectively an organisation is achieving its key business objectives.
- ❖ KPIs should be used to assess the QMS.
- ❖ **It is up to you to decide based on the Quality Data which part of the QMS needs improving.**



KPIs should connect **Strategy** with **Specific Outcomes**

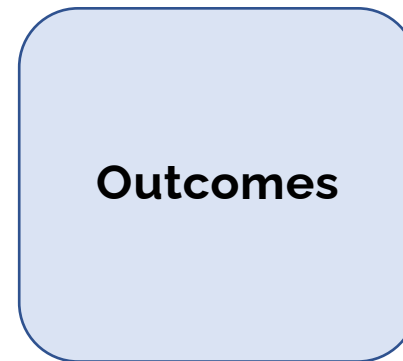
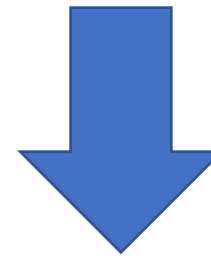
Organisational strategy and purpose

- ❖ Increased sales
- ❖ Increased products
- ❖ Improved compliance etc



Specific outcomes

- ❖ Functional goals and objectives
- ❖ Projects
- ❖ Individual goals and objectives
- ❖ Behaviours



Development of KPIs is an opportunity to build employee engagement

Joint development of KPIs is an opportunity to connect everybody in the organisation with the organisation's purpose.



Common mistakes in setting KPIs

KPIs that measure **status** or **activity** but not linked to **outcome**

Examples:-

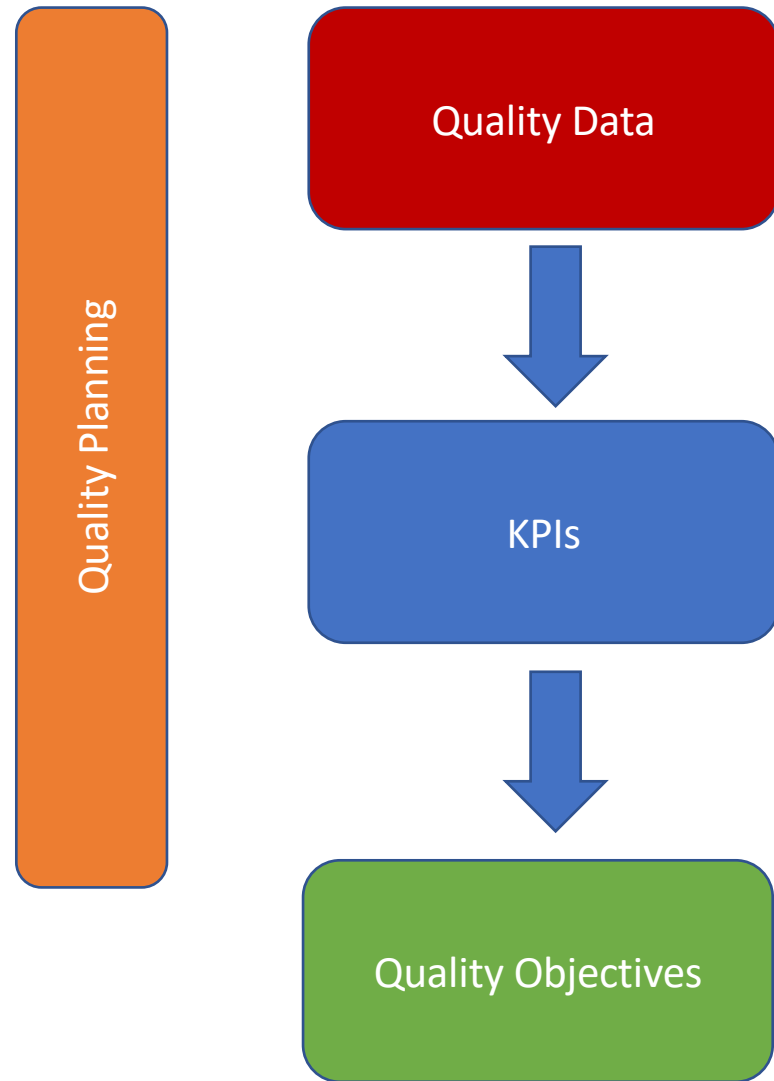
Status or Activity based (Poor KPI)	Outcome based (Better KPI)
Customer complaints closure rate	% customer complaints closed to the satisfaction of the customer
Customer complaints per month	Net Promoter Score *
% corrective actions closed on time	% of corrective actions that are effective
Cost of scrap	% of raw materials scrapped off during production
Head-count	Staff turnover as a %
Number of Change Orders open per month	% of non-conformances related to Change Control
Number of external audit observations	Ratio of external to internal audit observations

* Measurement of customer satisfaction

Outcomes are not linked to the Customer's perception of "Value"

KPI	Value	Customer
% customer complaints closed to the satisfaction of the customer	Customer satisfaction	Customer Experience
Net promoter score	Customer satisfaction	Customer Experience
% of corrective actions that are effective	Effective CAPA system	Compliance
		Business Health
% of raw materials scrapped off during production	Productivity	Business Health
Staff turnover	Staff moral	Business Health
% of non-conformances related to Change Control	Compliant Change Control	Compliance
Ratio of external to internal audit observations	Effective internal audit process	Compliance

KPIs should support
the **Quality
Objectives** through
the process of
Quality Planning



SMART Quality Objectives



Specific:-

The objective should be specific and narrow as possible to ensure effort is focussed on what is required.



Measurable:-

You need to define exactly how you will measure that the objective has been achieved.



Attainable:-

The objective needs to have a reasonable chance of success such not to demotivate.



Relevant:-

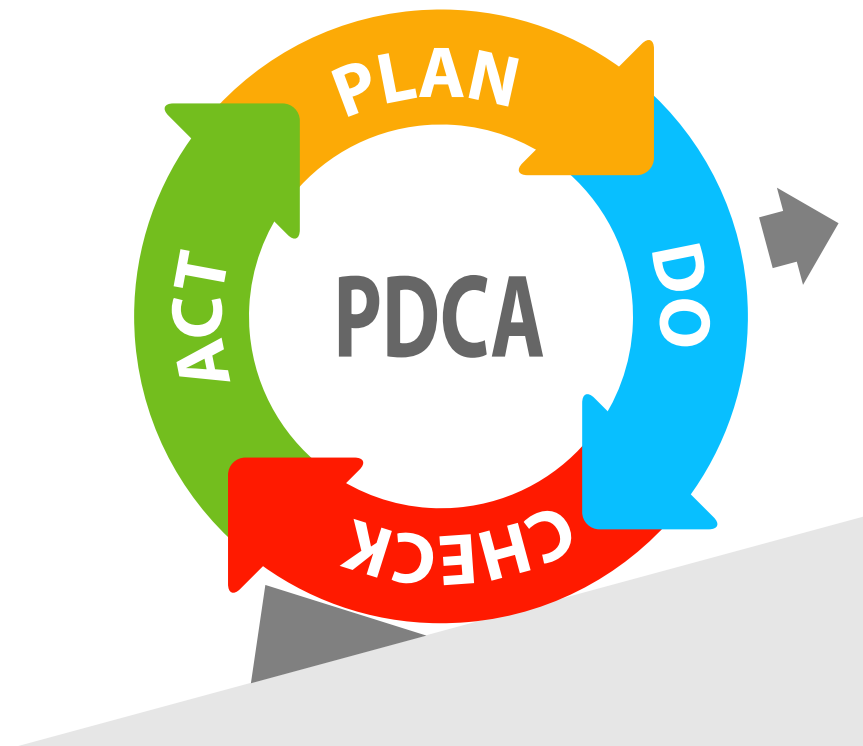
The objectives should be relevant to the organisational objectives that link to the goal.



Time based:-

The goal should have a date it is expected to be delivered.

Monitoring the progress of Quality Objectives



- Progress on Quality Objectives should be monitored at intervals to assess progress and determine whether objectives should be modified as circumstances change.
- Delivery of Quality Objectives should form part of **Quality System Management Review**.

- ❖ As the QMS matures it generally moves to a position where it is broadly compliant and meets customer needs.
- ❖ This status is maintained and monitored through internal audit and independently verified via external audit and certification.
- ❖ Does the QMS need to be continually improved further ?

**Is “good
enough”
good
enough ?**

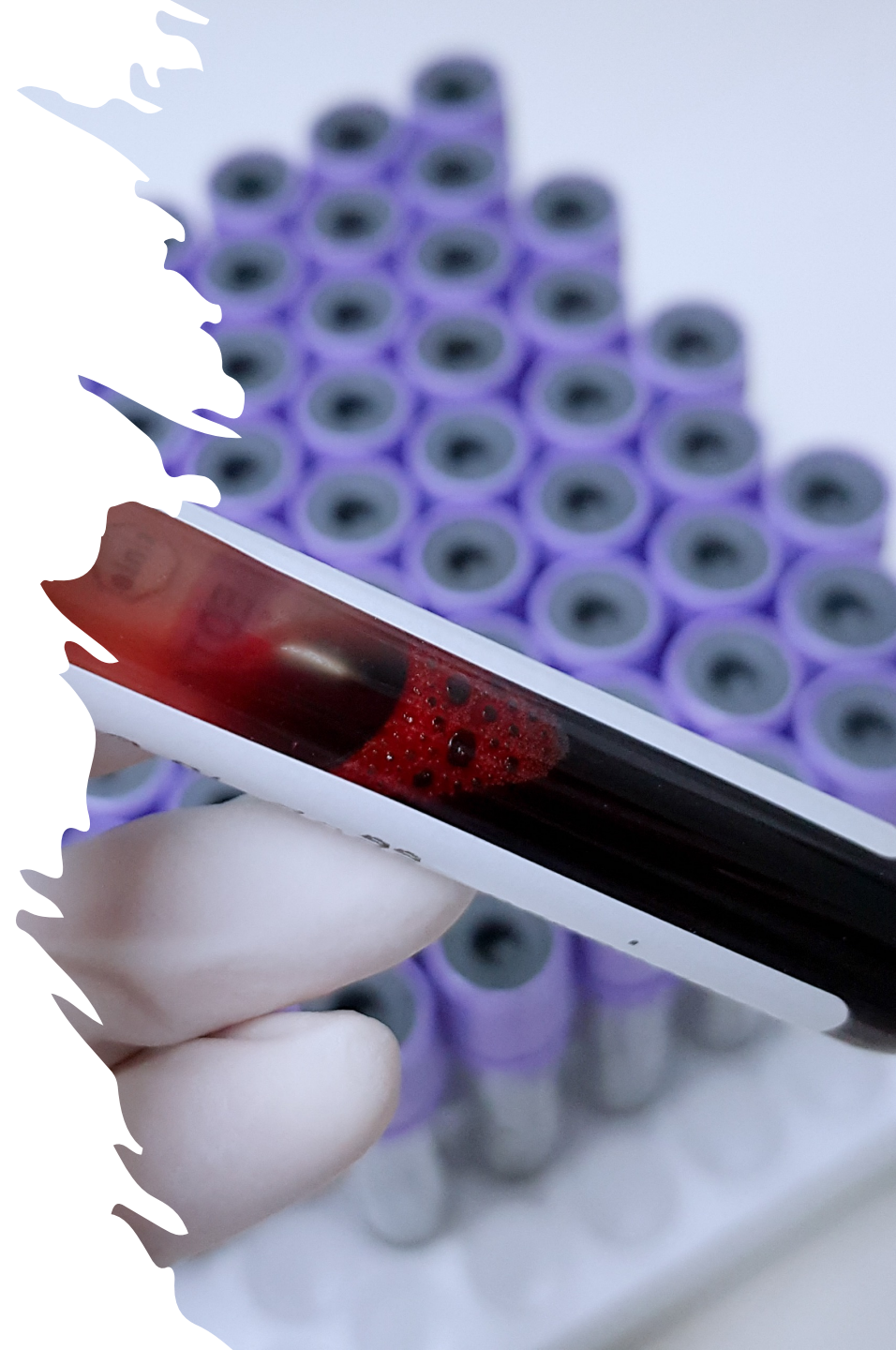
ISO13485:2016, ISO9001:2015 and MDR / IVDR: 2017

ISO13485: 2106 - Medical devices — Quality management systems — Requirements for regulatory purpose

Section 8.5 Improvement

“ The organization shall identify and implement any changes necessary to ensure and **maintain** the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review. “

ISO13485 is focused on ensuring that the QMS maintains the status of the registered medical device and its continued ability to meet end user expectations and regulatory requirements.



ISO13485:2016, ISO9001:2015 and MDR / IVDR: 2017

ISO 9001:2015 -Quality management systems — Requirements

10.3 Continual Improvement

“ The organization must **continually improve** the suitability, adequacy, and effectiveness of the quality management system. The organization must consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that must be addressed as part of continual improvement.. ”

ISO9001 has a strong focus on continuous improvement of the QMS.

Many device manufactures have stopped being certified to ISO9001 and only support ISO13845.



Yes

- ❖ The EU Medical Device Regulations [MDR] (Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009) and In Vitro Diagnostics Regulations [IVDR] (Regulation (EU) 2017/746) entered into EU law and was approved by the European Parliament on 27th May 2017.
- ❖ These regulations are legal requirements and put **special emphasis** on the need to **continually improve** the QMS.

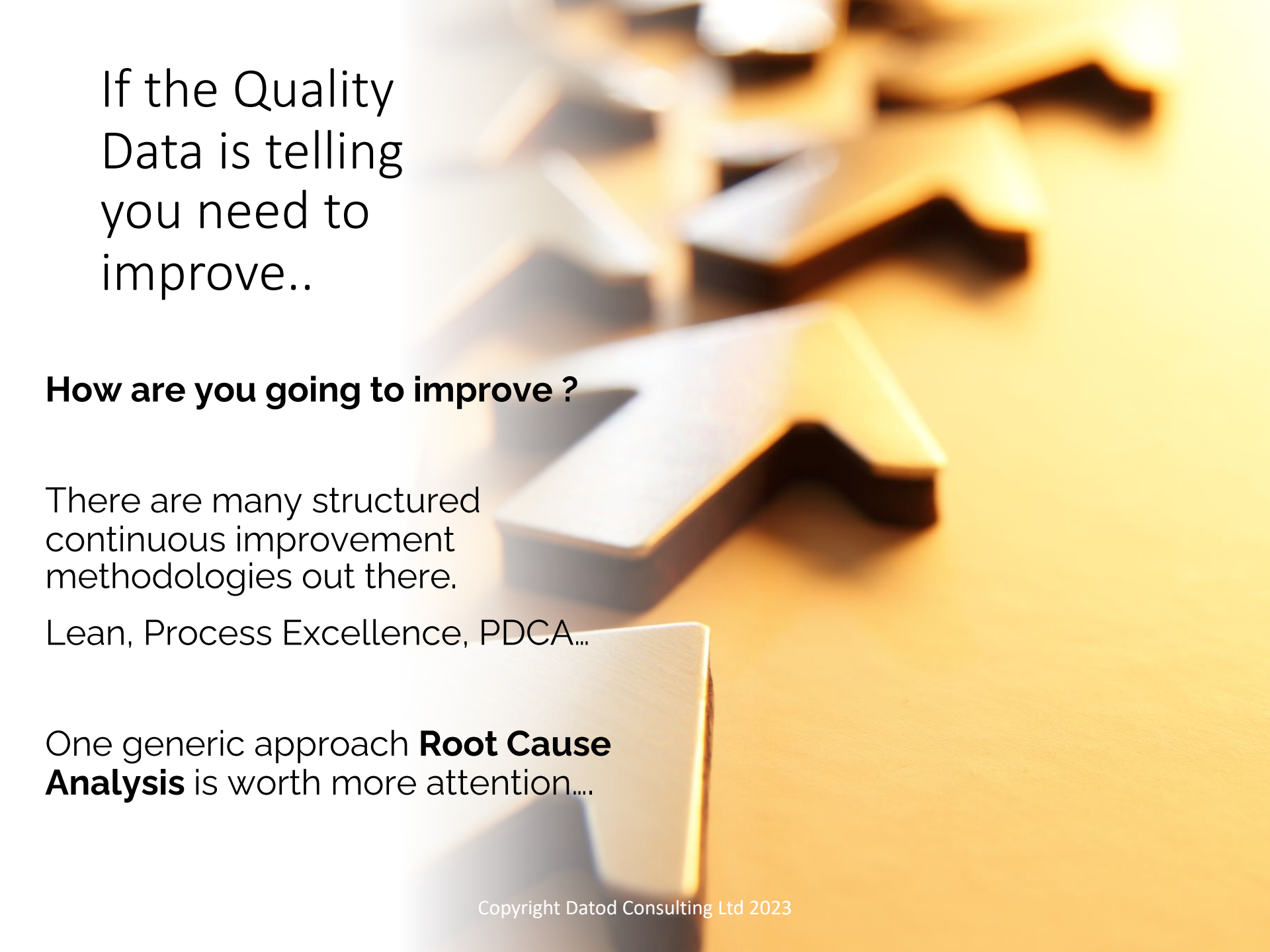




IVDR Article 10 Section 8:-

"Manufacturers of devices...shall establish, document, implement, maintain, keep up to date and **continually improve a quality management system.**"

Going forward, simply maintaining a QMS will not be sufficient to meet the regulatory requirements for product sold in the EU.



If the Quality
Data is telling
you need to
improve..

How are you going to improve ?

There are many structured
continuous improvement
methodologies out there.

Lean, Process Excellence, PDCA...

One generic approach **Root Cause
Analysis** is worth more attention....