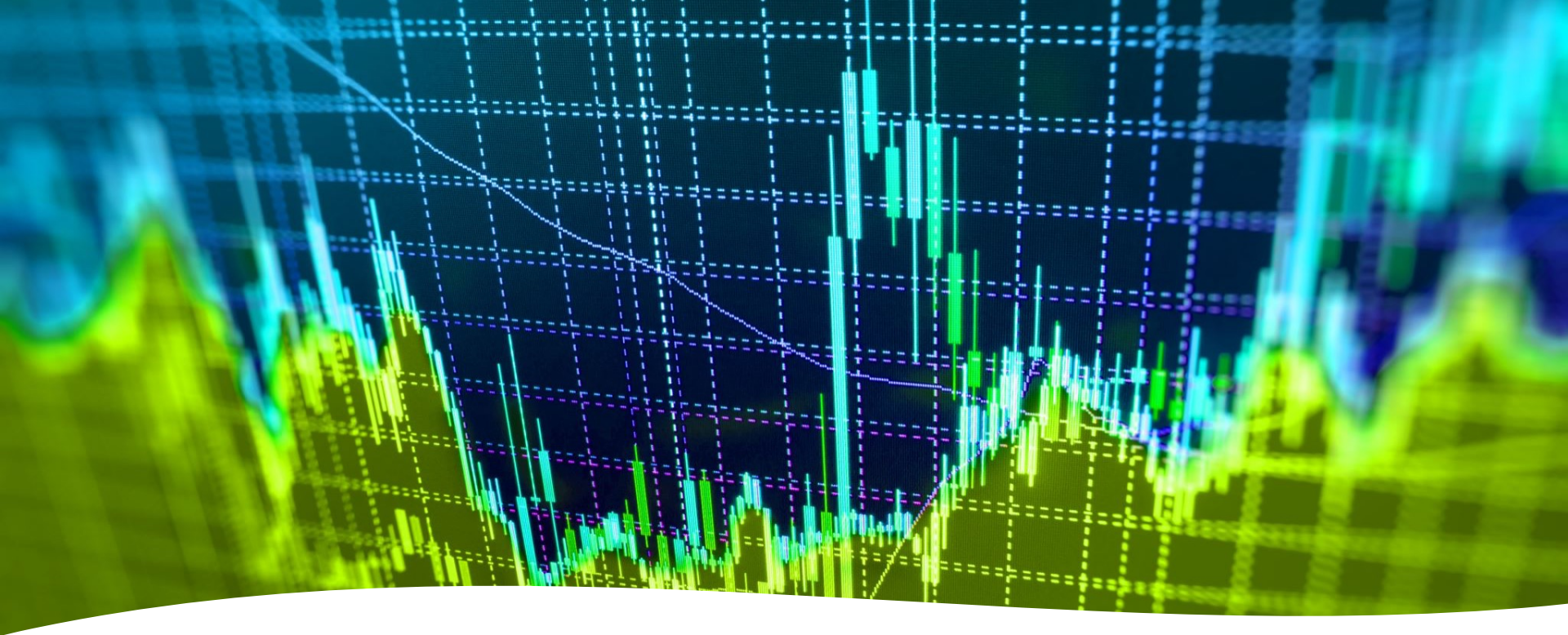




**Making the
QMS work for
you.**





The QMS is a **business tool.**

- It should work for **all** those that have to interact with the QMS and deliver positive value for its three customers.
 - Customer experience
 - Regulatory compliance
 - Business health

Connecting the dots



Implementing it, maintaining it and developing it is all about making the correct decisions based on the correct data with input from the correct stakeholders.

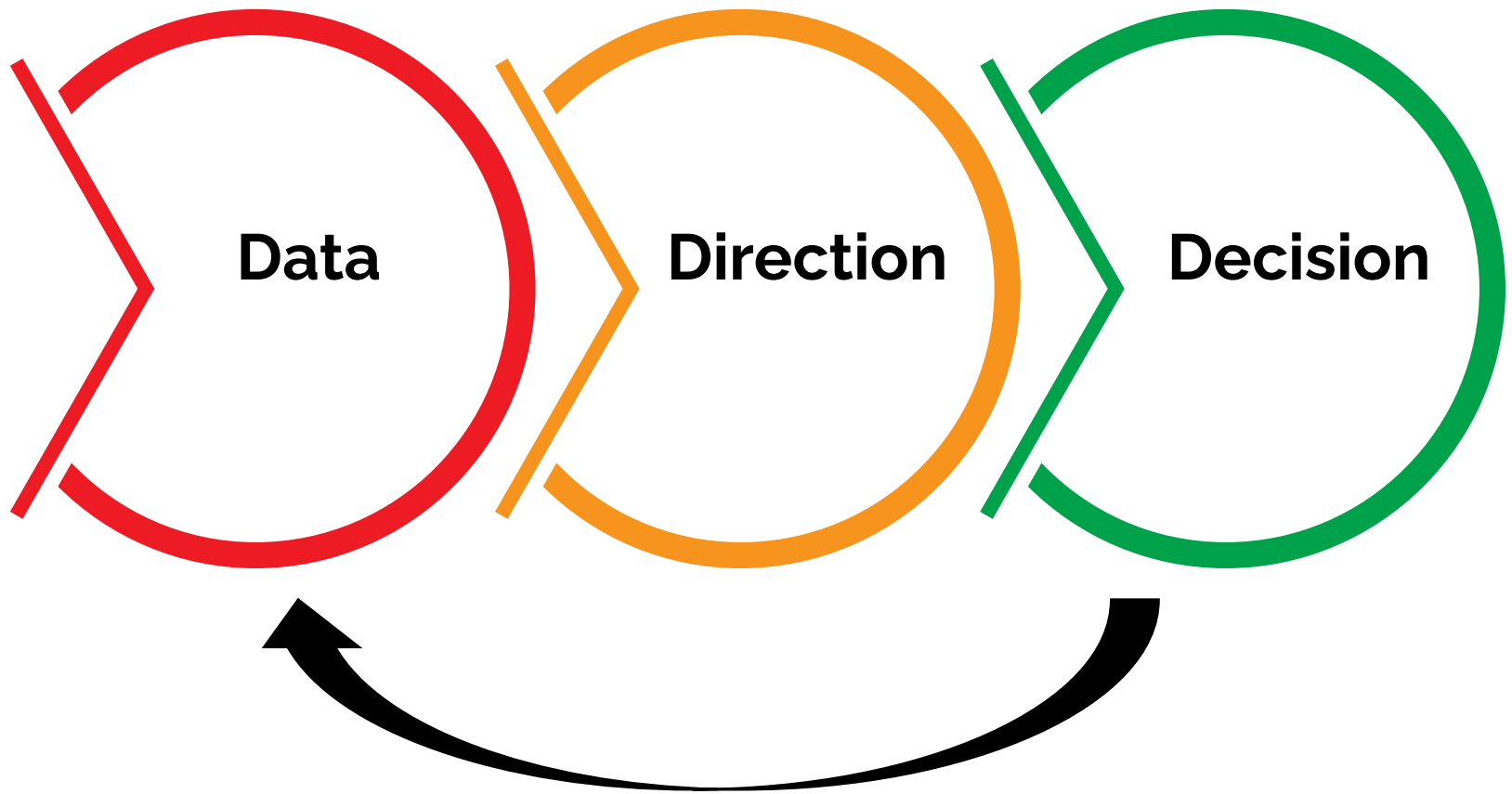


It is about seeing the **fine detail** and the **big picture** simultaneously.



Primarily it is about all of the business: Showing up and taking action.

The 3 Ds





Data

- You are going to need access to the correct Quality data.
- The data needs to be checked for integrity and validity.
- Identify owners accountable for managing this data.
eg: non-conformances numbers, scrap, open CAPA events, etc.



Automation

- Look to automate how this data is generated and presented.
- Leverage eQMS systems that will do this automatically.

Direction

- You as a leader will have to decide what is important and which metrics you need to track and focus on.

They should be a mixture of metrics

- a) that are related to directly the output of the QMS you want to see.
- b) Metrics that measure the mechanics of the QMS.

Develop **true** customer centric performance metrics

- ❑ Improving and moving in the **right** direction is often **more important**.
- ❑ Slow progress over time is **more** effective than setting an **unachievable** goal.
- ❑ All metrics **must** be linked to customer needs or your ability to execute the QMS.
- ❑ Measuring the mechanics of the Quality System eg: No. of CAPA, NCs, Change orders etc is **not good enough**.

Creating a Dashboard

- The metric should link directly with an aspect the customer deems important.
- The metric should be widely visible.
- The metric should be clearly understandable by everybody in the organisation

Metric	Clarity
(Number of change orders per month per shift per headcount) / days in the month	Poor
The average number of non-conformances per 100 production lots	Better

Area	Metric	Why	Metric	Score (example)
Customer	Complaints per test	Key metric of satisfaction from normal manufacturing	+10 = complaints decreasing, 0 = stable, -10 complaints increasing (3month rolling average)	0
Customer	Field Actions / customer correction notices	Key metric of dissatisfaction from atypical manufacturing	+ 10 = FA decreasing, 0 = FA stable, -10 FAs increasing (6 month rolling average)	-10
Customer	Customer service rate	Are customers' happy with support ?	+10 = support service rate improving, 0 = no change, -10 support service rate getting worse (3month rolling average)	+10
Regulator	Internal / external audit ratio	Need to find issues internally and fix rather than through external inspections	+ 10 = In > Ex, 0 In same as Ex, -10 In < Ex. (6 month average normalised to person days of audit)	0
Regulator	Critical observations or greater through external inspection	External regulators should not be finding issues	+10 = none or decreasing, 0 = no change in observations, -10 = increasing, -30 = Warning letter	+10
Business	Scrap	Indicator of defects	+10 = none or decreasing, 0 = no change in scrap, -10 = increasing (3 month moving average)	+10
Business	Products launched on time	Product delays = lost sales	+10 = ahead of plan, 0 = on plan, -10 = late (6 month moving average)	0
QMS Execution	Timeliness to plan RCIs	Are we solving problems on time ?	+10 = ahead of plan, 0 = on plan, -10 = late (3 month moving average)	0
QMS Execution	Timeliness to plan CC	Are we applying fixes to problems on time ?	+10 = ahead of plan, 0 = on plan, -10 = late (3 month moving average)	+10
QMS Execution	Effective CAPA	Are the fixes working ?	+10 = > 90% effective , -10 = < 90%,)	-10

Max possible score = 100

Total =

20

Min possible score = -120

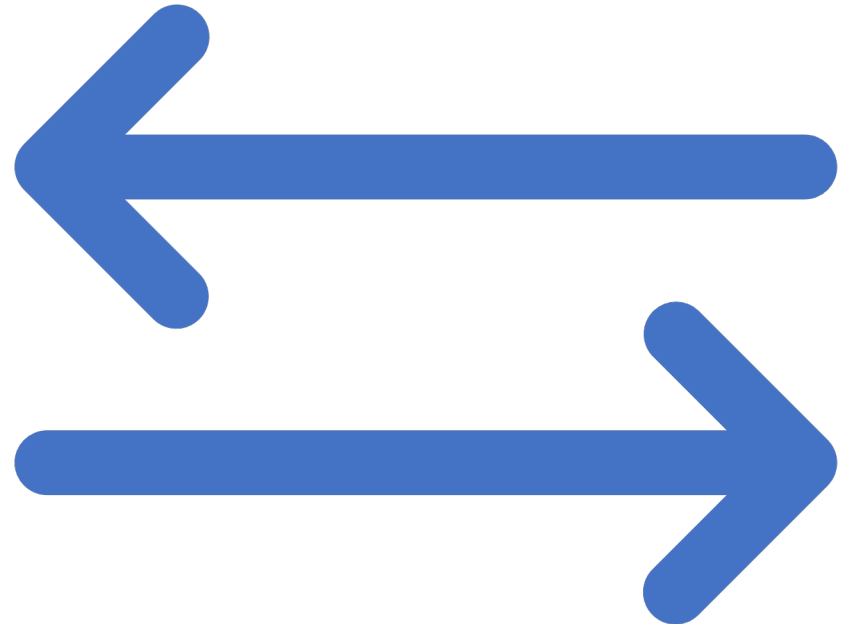
-120 ↔ < - 40

- 40 ↔ < + 30

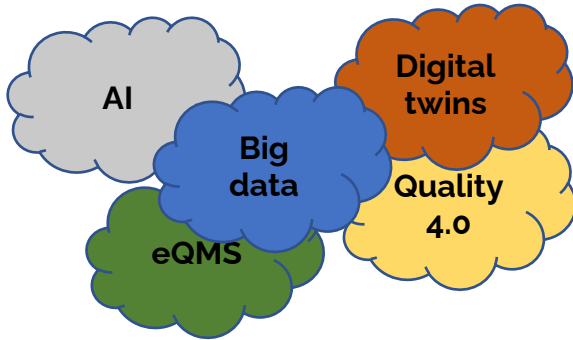
< + 30 ↔ + 100

Direction

- Direction is also about where you want to go and positioning the QMS and the Quality organisation for the future.
- We have touched on the future of Quality Management, let's look in more detail.



The **future** of Quality Management depends on who you listen to....



- Vendors
- Consultants
- Media



2019: Summit of Quality professionals to determine the future research **themes** for Quality management, looking towards a date line of **2030**.

Themes from SWEDISH INSTITUTE FOR QUALITY SIQ

**Take a Systems
Approach**

Treat the Quality organisation and QMS as a system.

**Control
v
Change**

Manage the need to stay the same but also innovate.

Sustainability

Manage the impact of quality on the end-end supply chain and broader environment.

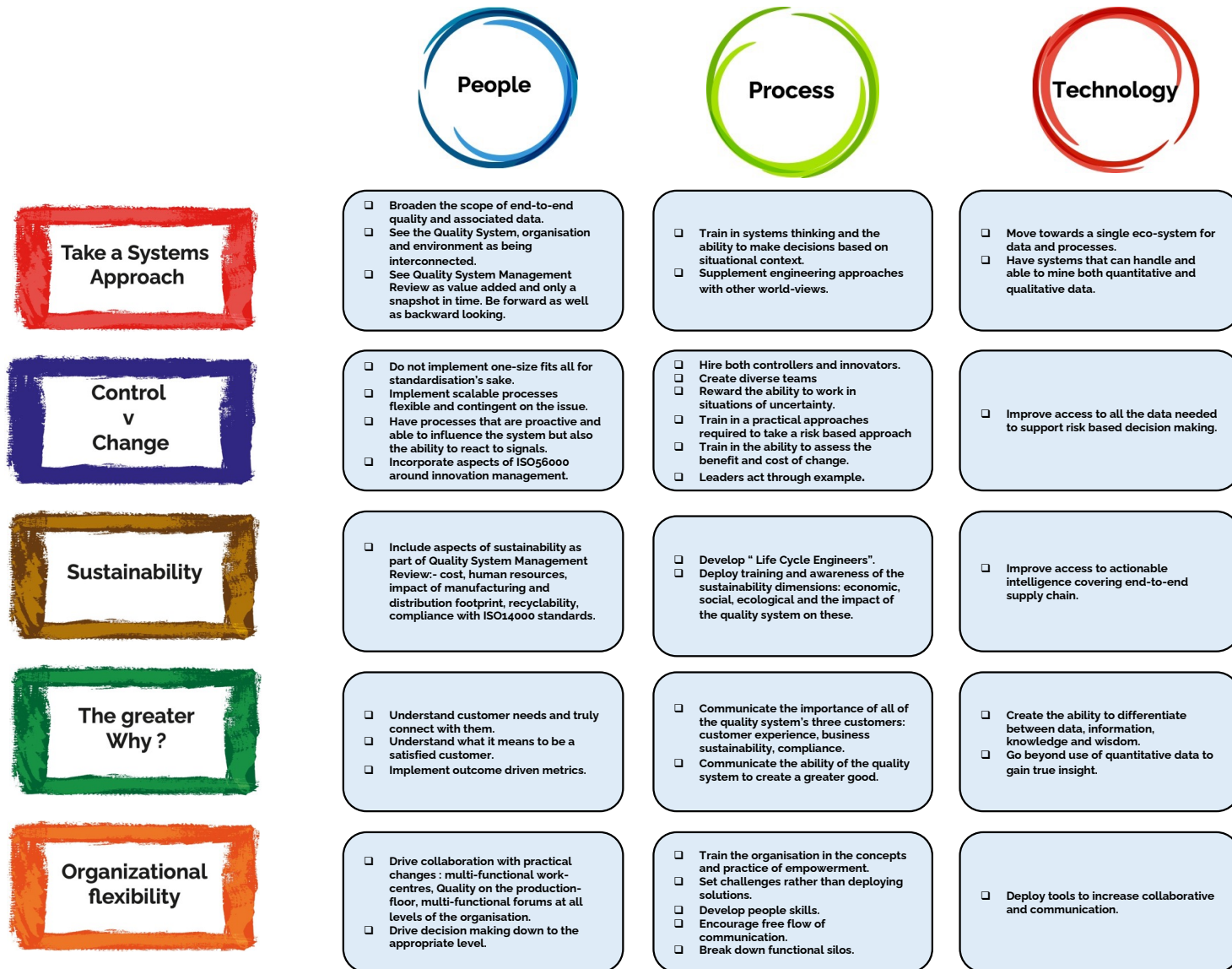
**The greater
Why ?**

Understand and articulate the greater purpose of managing quality.

**Organizational
flexibility**

Build a flexible and agile organisation.

Get your Quality function ready for the **future** demands of the business, **now**



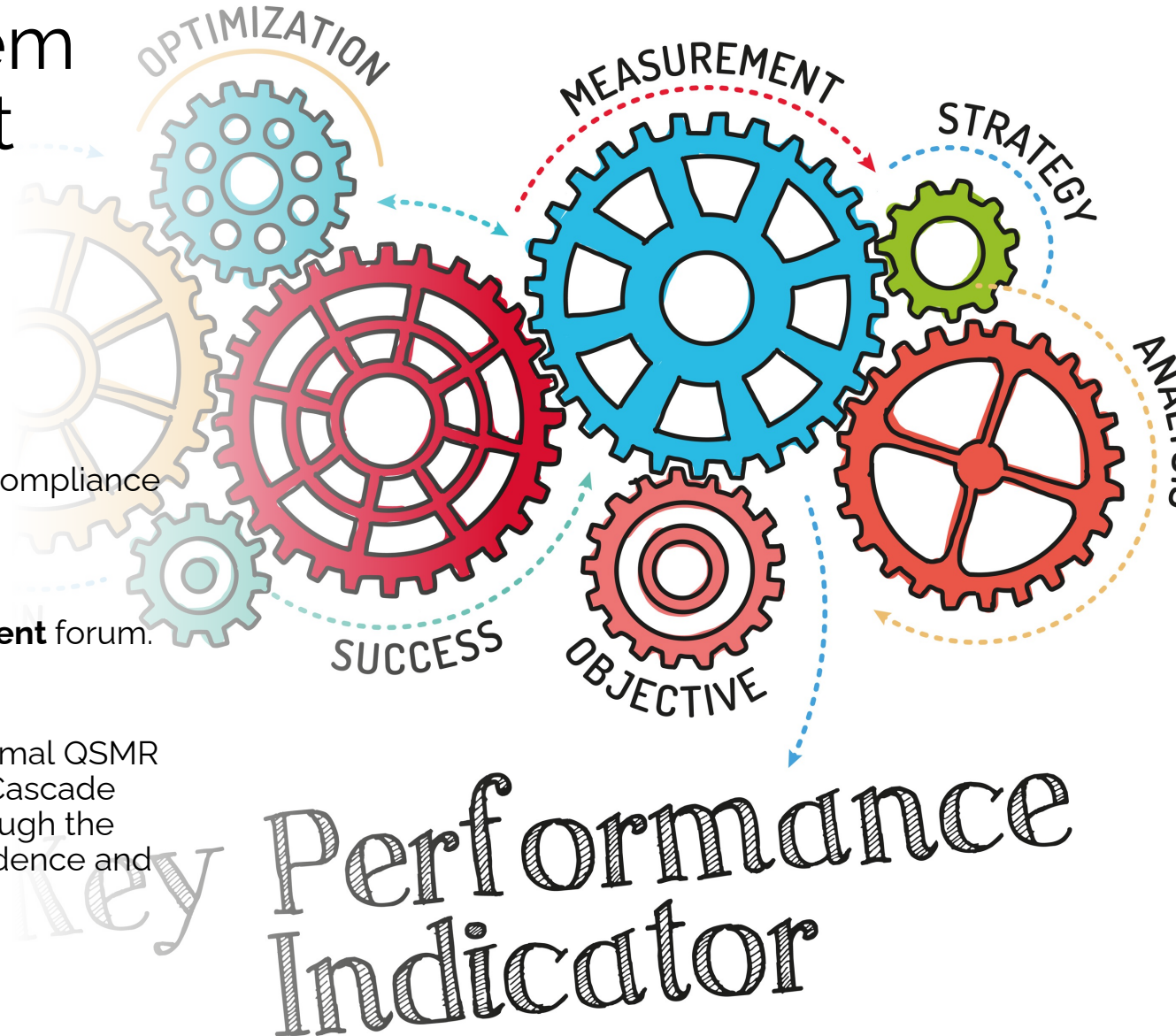
Decisions

- You will need to make key decisions based on the data and direction you want to go.
- Use the Quality Planning process to define Quality objectives aligned with commitments made in your Quality Policy.



Quality System Management Review

- A **key** forum is QSMR.
- This is **not** just to meet a compliance / regulatory obligation.
- It is a **business improvement** forum.
- Whilst you may have a formal QSMR at intervals eg: quarterly. Cascade forms of QSMR down through the organisation at greater cadence and with greater granularity.



Tips for QSMR

1: Involve all functions

The quality system crosses the whole of the business. If you just involve the Quality organization and it becomes just an internal perspective, then you are a best not getting other viewpoints and a worst undermining the system.

- Most quality system reviews involve Operations and R&D but other functions need the opportunity to attend, contribute and understand the quality system.
- How many reviews have Human Resources, Finance, IT or Marketing in attendance? These functions have a huge role in how the organization performs and whether the QMS is meeting all customer needs. Involve any function you think has a role to play in supporting this endeavor.

Tips for QSMR

2: Explain the power the group has

- You will need to do more than just explain the purpose of the meeting from it being a regulatory requirement.
- You will need to articulate the power the meeting has to shape the QMS and assess that it is doing its job for the business.
- You need to explain why attendees are there, the contribution they need to make and the importance of agreeing the allocation of resources to address identified issues or opportunities.

Tips for QSMR

3: Create a dialogue and decide

- In essence, QSMR is reviewing data that supports whether all aspects of the quality system are meeting all customer needs. Each area needs a clear conclusion of whether the data supports a well-functioning system. QSMR should not be death by PowerPoint. It should be focusing on areas that need help and not focus on areas that are in control.
- Many organizations do not want to put any negative data in presentations that would indicate to an auditor you have an area that needs improvement. This defeats the main purpose of the meeting.
- This will involve having an **active conversation** about what the data is telling you. There should be differences of opinion as you move towards hopefully a consensus. QSMR is something you are part of, rather than something you have done to you.

Tips for QSMR

4: Document it well

- QSMR is your window into the quality system. It is also a window for how internal agencies will view your QMS. These documents however they are presented, will be closely reviewed by others.
- Review them closely through their eyes. Do they tell an adequate story? Are they clear? Does the data support your conclusions? What actions are you prioritizing?

**A Balanced
Quality
System**



**Managing
Change**



**Balancing
Risks**



**A Quality
Mindset**



People



Process



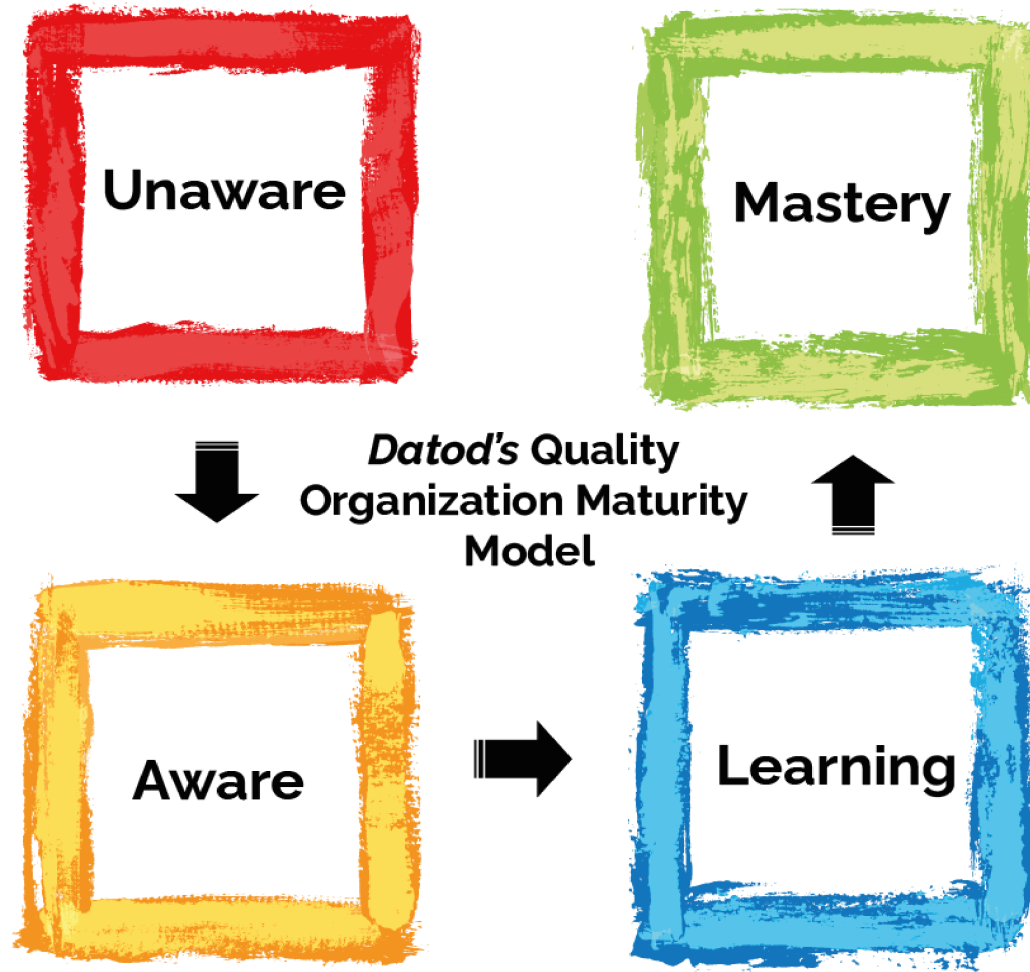
Technology



**Making the
QS work
for you**



Let's look at **Making the QS Work for You**
through the 4 maturity levels.





Your Quality System is not working for you. The metrics measuring performance have no relationship to the output desired or the needs of the customer. The Quality organization may be too focused on measuring itself.

Key outputs of the Quality Systems are either unknown or moving in a negative directions ie: customer complaints, field actions. In addition, your internal audit process is failing to identify issues prior to external inspection.

Identify true KPIs and actions that will move them in a positive direction and benefit your customers.

Your ability to investigate problems is poor. Many corrective actions that are implemented are ineffective.

New products are either launched late or not at all. Individuals' performance goals are disconnected to the objectives the organization is attempting to achieve.

You must address these issues and provide a path forward that is tied to organizational objectives. All individuals need to understand the impact of their work and efforts on meeting customer needs and put in place systems to encourage collaborative working to ensure objectives are being met.

You need to gain a better understanding of whether your Quality organization and Quality System is delivering for your customers and stakeholders. You need to proactively address any areas where their needs are not being met based on sound data and analysis.



- Your Key Performance Indicators are not linked to the outcomes you are desiring.
- Your Quality System is not achieving the outcomes you need for its customers.
- Individuals' performance goals are disconnected from the outcomes your business needs.

Next steps:

- Start building an inventory of metrics that measure truly what the customers of the Quality System consider value.
- Explore ways to translate these KPIs into meaningful goals for individuals and groups.



Your Quality System is still not working for you as effectively as it could be and you are still unaware of how the system is functioning. You recognize this gap in knowledge. The metrics measuring performance have little relationship to the output desired and largely measure transactional steps of the Quality System mechanics. The Quality organization may still be too focused on measuring itself.

Key outputs of the Quality Systems whilst stable are not improving ie: customer complaints, field actions. In addition, your internal audit process is not always predictive of performance during external inspection.

Whilst you are able to investigate problems on time the corrective actions implemented are still not always as effective as you expect.

Whilst new products are launched on time the development process is still too slow and onerous.

Individuals' performance goals are still disconnected to the objectives the organization is attempting to achieve.

You need to gain a better understanding of whether your Quality organization and Quality System is delivering for your customers and stakeholders. You need to proactively address any areas where their needs are not being met based on sound data and analysis.



- Whilst Quality System performance is stable it is not improving outcomes for the customer.
- You are still measuring Quality System activity rather than output.



Next steps:



- Improve your internal audit process and make sure it is truly effective in uncovering potential problems.
- Make sure that your corrective actions are appropriate and actually address the root cause of problems.
- Streamline your new product development process so that it is more efficient and less costly.
- Realign individual's performance goals with the overall objectives of the organization.



Learning

Your Quality system is starting to be effective and efficient. The metrics measuring performance have a direct link to the outputs you are desiring around improved compliance and customer satisfaction, though not always linked to financial profitability of the business.

Key outputs of the Quality Systems are improving ie: customer complaints, field actions. In addition, your internal audit process is identifying issues before they are detected during external inspection. You are able to investigate problems more quickly and your corrective actions are more effective.

New products are launched more quickly than before and the process is less onerous. Individuals' performance goals are connected to objectives the organization is attempting to achieve.

Your Quality System working for you in this way creates opportunities to focus less on "fire fighting" and more on continuous improvement projects which can have a real impact on the financial profitability of the business.



- Quality System performance is improving outcomes for the customer.
- Individual goals are linked to the objectives of the business.



Next steps:

- Focus on ways that the Quality System can help the business be more cost effective.
- Explore performance that encourage cross-functional collaboration.



Mastery

Your Quality system is highly effective and efficient. The metrics measuring performance have a direct link to the outputs you are desiring across all key areas: regulatory compliance, customer satisfaction and financial health.

Key outputs of the Quality Systems are either improving ie: critical audit deficiencies, field actions etc, or at an incidence too low to measure. As a result, you are able to investigate problems more quickly and your corrective actions are highly effective. Importantly when they are not, you quickly learn from them.

This allows you to effectively manage new products being launched extremely rapidly and with superior performance in the field.

Individuals' performance goals are connected to objectives the organization has set allowing for comprehensive quality goal setting. In addition, functions work effectively towards collective goals ensuring that no one goal is overlooked. Your Quality System is working for you in every way !

- The Quality System is improving outcomes for all its customers.
- All in the Quality organization are working towards shared goals that are linked to success of the complete business.



Next steps:

- Continue to be unrelenting in your pursuit of understanding customer needs and translating these needs into individual and collective actions to meet them.

A hand is pointing at a bar chart displayed on a tablet screen. The chart consists of several white-outlined bars of varying heights. The background is a blurred image of a person in a blue shirt.

Summary

- The QMS will only improve through active effort.
- This effort if clear, focused and structured will:-
 - Improve compliance.
 - Financial performance.
 - Help grow your business through the sale of safe goods and services.