

Organization - People

Part 1 of 1

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How are Quality organizations structured ?

What people and skills to you need ?

What does the Quality organization of the future look like ?

How should you lead this organization ?

Agenda

- People
- A peek into Quality organisations of the future



Differing Voices – Transforming a Quality Organisation

How you organise your Quality organisation will depend essentially on who you ask. There are many stakeholders with vested interests and opinions on this matter.

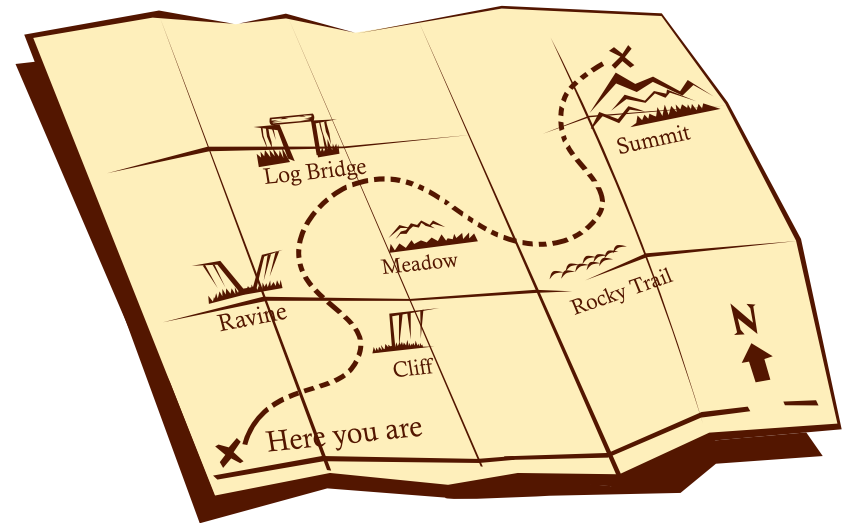
- Continuous improvement industry
- Your business partners
- Traditional flavours of Quality that have arisen from the Total Quality Management movement.
- Vendors selling you eQMS applications

The approaches described here are based on extensive experience, review of academic literature, an aspect often not considered in modern organisations, and **practical** application.



Current state

It is worth reflecting on how Quality organisations currently look. Understanding how we got here helps immensely in understanding where you need to go, and the challenges you will face.



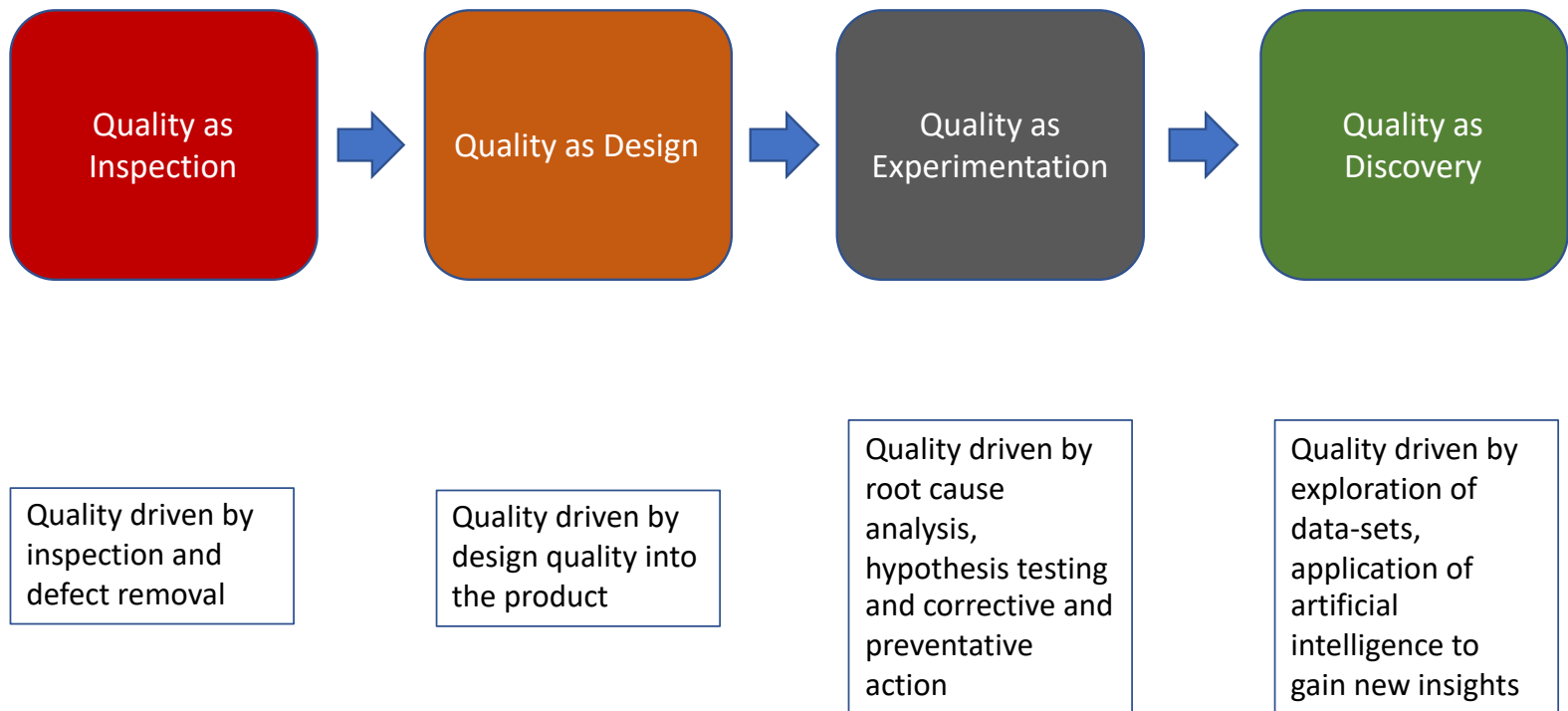
How we got here..

- Royal Cubit
- Master craftsmen
- Taylorism
- Total Quality Management
- Six Sigma

Quality has always changed and the expectation is it will continue to do so...

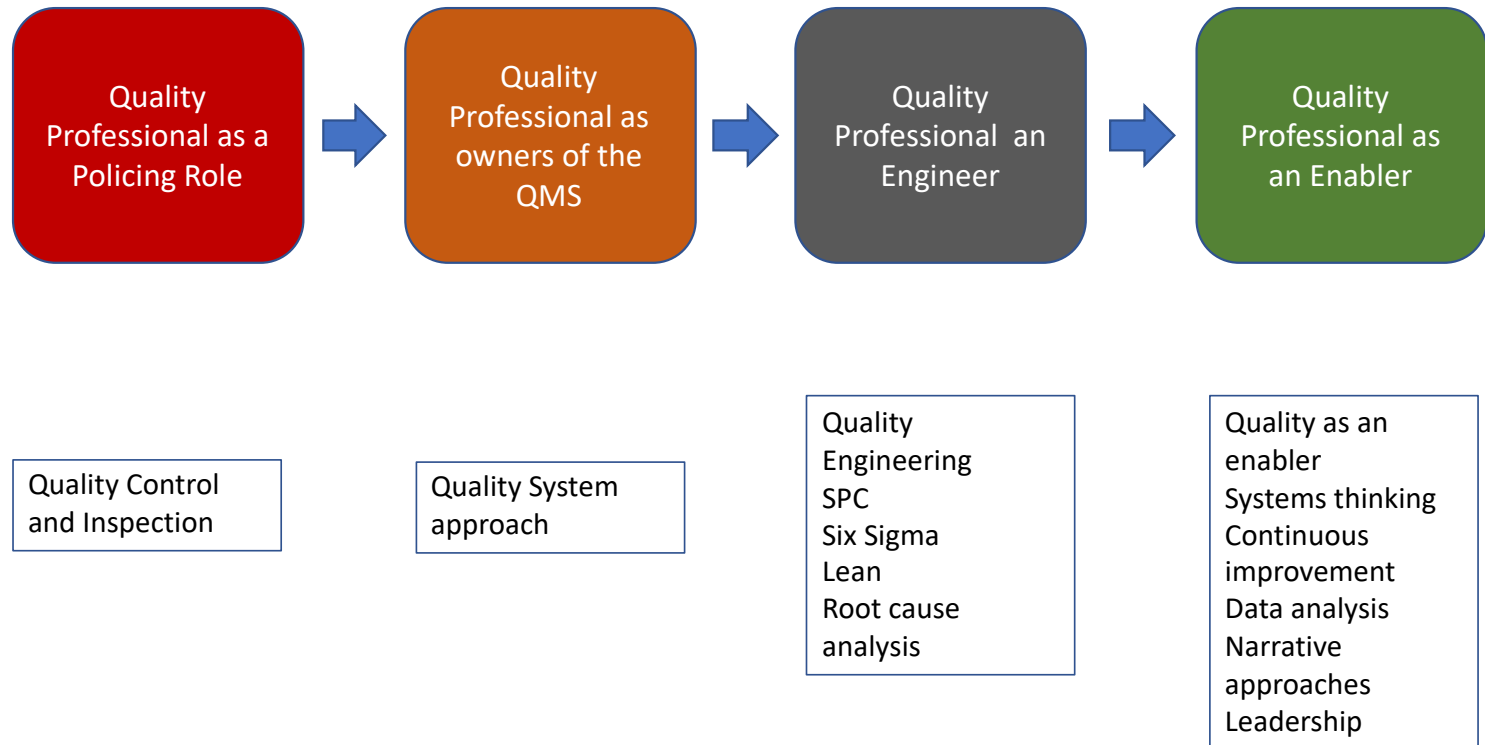


Quality of the Future...



Evolution of approaches to Quality (Adapted from Radziwill, 2018).

The changing role of the Quality Professional...



It's not the Wild-West but...

- There are currently few rules on how you approach it or how you structure your organisation.
- In certain industries that the Quality function must be independent of manufacturing and an individual appointed to oversee the organisation.
- Aside from that there is no regulatory mandate that dictates how a Quality organisation is organised either, in its size structure or the skill-sets it has within it.



Flavours of Quality

Supplier Quality

Regulatory

Compliance

Documentation
Control

Change Control

Validation

Quality Control

Quality
Assurance

Quality
Engineering

With specialisation comes lack of flexibility
and frustration of Operational partners who
may only see one flavour of Quality



Quality Engineering

- The role and purpose of this group will be highly dependent on which organisation you look at.
- In certain organisations they are akin to custodians of the quality management system. In others, this function focuses on controlling non-conforming product and in other organisations they have a more continuous improvement role. This same group across different businesses may look very different.
- You need to decide what you want your groups to do and be consistent in your messaging.
- You will need to cover all the bases.



You have a broad canvas to paint on..

- This aspect of differing roles, range of qualifications gives those that work in the Quality arena a somewhat weak sense of self-identity, compared with other professions. This has been long noted for a while by those that look at organisations.
- Entry into the Quality is generally not via professional certification, such as seen in other occupations such as finance and law. This has resulted in a variability of approach in a field that itself can be interpreted multiple ways.

QUALIFICATION



- Few children grow up to want to work in Quality.
- Most in the function come from other disciplines.
 - Manufacturing, R&D, Engineering, etc
- Your organisation is probably skewed to towards engineering and natural sciences v arts and humanities.
- Whilst degrees and diplomas in Quality are available and are becoming more popular, certainly within the healthcare industry it is somewhat uncommon for leaders within the Quality organisation to have formal qualifications in the discipline

➤ Qualifications



So, the world of work is changing - or is it?

- One of the consistent messages in businesses today is that virtually all modern organisations operate in what is known as a 'knowledge-based economy'.
- Organisations compete for individuals with the best intelligence and qualifications, and through these 'knowledge workers' the business gains competitive advantage. This has led to the belief that information itself is the key currency and we are all beaver away in this new knowledge driven landscape.

This is patently not true.

The under-utilisation of talent (The 8th Waste)

- Whilst such aspirations are laudable – using the intellectual power of your staff – most workers generally do not use their intelligence or creativity on a day-to-day basis. Often, they are asked to perform tasks well below their intellectual ability and qualifications.
- Do not let this happen.



- As a leader responsible for a Quality organisation does this matter ?

Yes.

- As a leader you should question whether all the positions within your jurisdiction are making valid contributions to delivering customer value.
- Are they doing tasks that add value for the customers' of the QMS ?
- Are they using the skills appropriately ?
- Are they being suitably developed ?



STAFF



CAREER
COMPETENCY



RECRUITMENT
&
SELECTION



TRAINING
&
DEVELOPMENT



PERFORMANCE
MANAGEMENT



MULTISOURCE
FEEDBACK



CAREER
DEVELOPMENT



SUCCESSION
MANAGEMENT



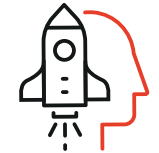
HR PLANNING



TEAMWORK



PROJECT
MANAGEMENT



KNOW-HOW



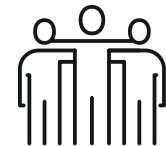
EMOTIONAL
INTELLIGENCE



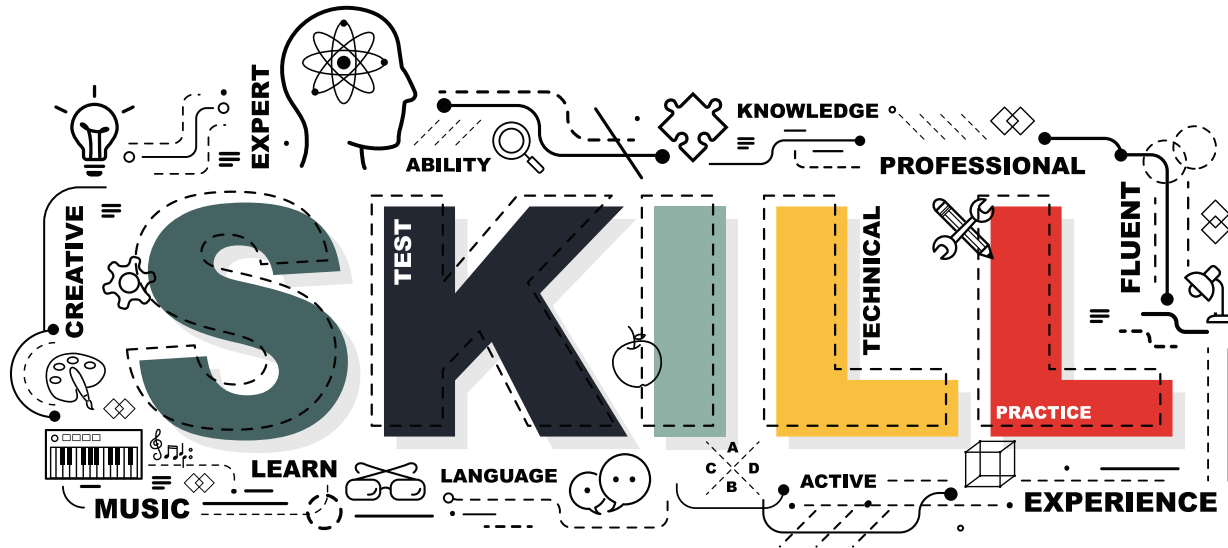
EMPOWERMENT



TECHNICAL
KNOWLEDGE

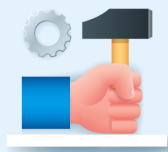


COMMUNICATION



Skills and competencies you'll need

- Those with direct experience using your products as customers.
- Those from other non-technical disciplines.
- Those from other functions in the organisation.
 - Consider the benefit of rotating individuals between different departments, even bringing in those from different functions.
- There are also competencies which are fields of expertise in their own right, ones that do require formal qualification. These include statistics, data analysis and information technology etc.
- Bring together different perspectives and often challenging new opinions will help you make better decisions, with access to the skills you need.



HARD WORK



SOCIETY



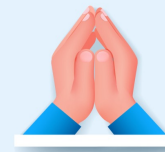
DETERMINATION



MORALITY



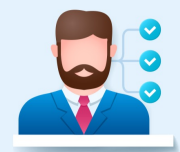
PERSEVERANCE



BELIEF



DISCIPLINE



CHARACTER

WORK ETHIC

Behaviours

- Inquisitive
- Collaborative
- Pragmatic
- Level-headed
- Committed
- Big picture orientation
- Attention to detail
- Self-aware
- Empathic

You are going to need a mix of different personality types

New thinking is needed.

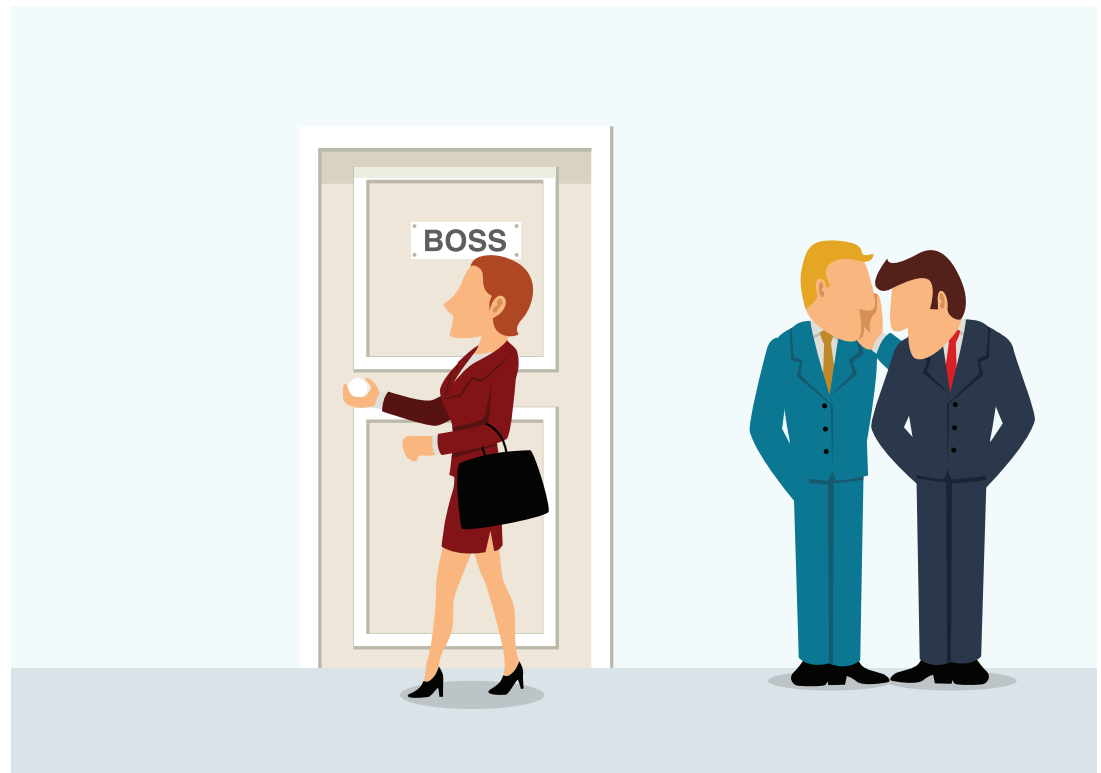
Behaviors of the Quality Professional	
Old	New
Factory facing	Customer facing
Process thinking	Systems and complexity thinking
Dispassionate	Passionate
Enforces	Mentors, coaches, teaches
Ability to understand data	Ability to humanise data
Comfortable with limited data	Comfortable with Big Data
Uncomfortable with uncertainty	Flourishes in times of uncertainty
Puts compliance first	Puts your customers first
Polices stakeholders	Partners with stakeholders

'Moral Mazes'

Robert Jackal, 1988

Based on analysis of US corporate life. Rules for managerial success..

- Never go around your boss.
- Even when your boss claims they want diverse and dissenting views, essentially always tell your boss what they want to hear.
- If your boss wants something to stop happening, it stops happening.
- Anticipate your boss's needs, such that they do not have to behave as a boss.
- Do what the job needs and at times simply keep your mouth shut.





Training,
training,
training...

- Having simple processes that are clearly described is not enough.
- This is especially the case for steps that are critical within the manufacturing process which impact the quality and safety of your products.
- You will need to train individuals in how to execute processes and as importantly they need to demonstrate understanding and the ability to carry out tasks appropriately.



Training within Industry (TWI)

The importance of effective training can be traced back to initiatives such as Training Within Industry (TWI) developed during the Second World War and as such these approaches are experiencing a degree of resurgence.

The TWI approach to training is characterised by four attributes:

1. **Simplicity.** There is particular focus on getting the job done.
2. **Focus.** The training should involve the minimum of training time.
3. **Learning by Doing.** Training focuses on hands-on demonstration of the training being applied.
4. **Cascaded.** There is an expectation that those trained provide training to others in a 'cascade effect'.



Proportionality based on risk..

- Not every change to every document requires extensive training and assessment. If this were the case your organisation would collapse under the sheer weight of training.
- For procedures that do not impact product directly / changes to policies whilst it might be important to deliver training, there is generally no need to assess competence of understanding.
- Furthermore, minor changes to documents may only require the document be read and understood and do not require a formal training exercise.
- You need to pragmatically decide the level of training based on, again, the risk.

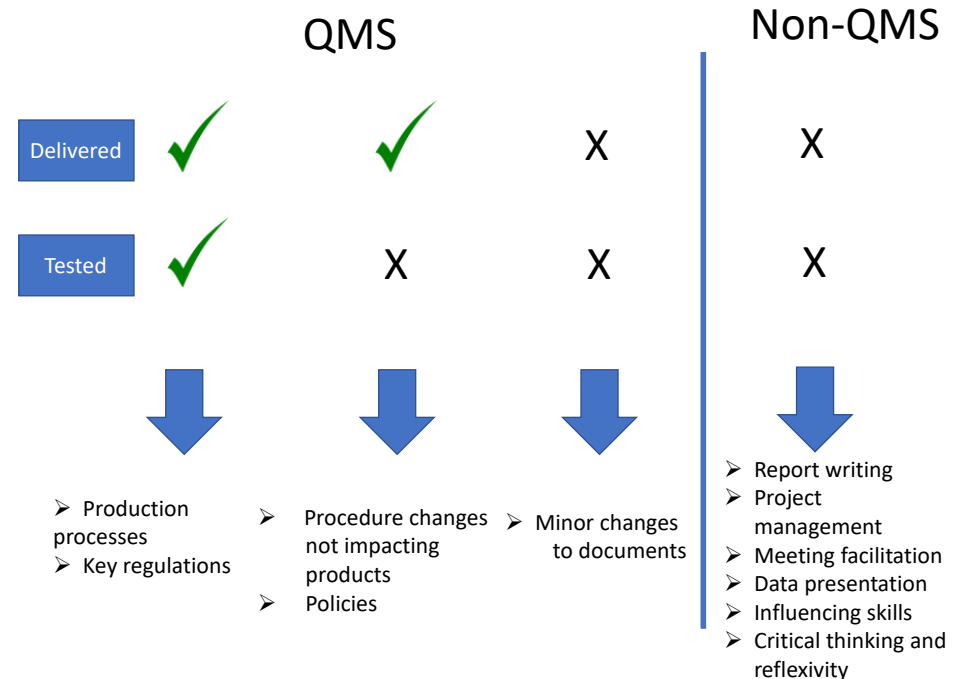


Use multi-media

- Videos
- Pictures
- 1:1 sessions
- On-line training
- VR training
- Document review

➤ Skills needed..

- Job skills
 - Skills to complete tasks
 - Practical risk management
- Technical skills
 - CAPA
 - Change Control
- Non-Technical skills





Non-technical skills

- These include the ability to write clear and concise reports, the ability to manage projects effectively and the ability to facilitate meetings and present data efficiently.
- In addition, there are competencies such as soft skills, like the ability to influence and cognitive skills such as critical thinking and reflexivity.
- Do not underestimate the value of incorporating these areas into your training programme.

It all starts with you..

- As a Quality leader you have huge influence on how people behave.
- You will get what you tolerate.
- Through your words and actions you have massive influence on whether there is an restless focus on satisfying your customers, or not.

**A Balanced
Quality
System**



**Managing
Change**



**Balancing
Risks**



**A Quality
Mindset**



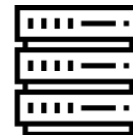
People



Process



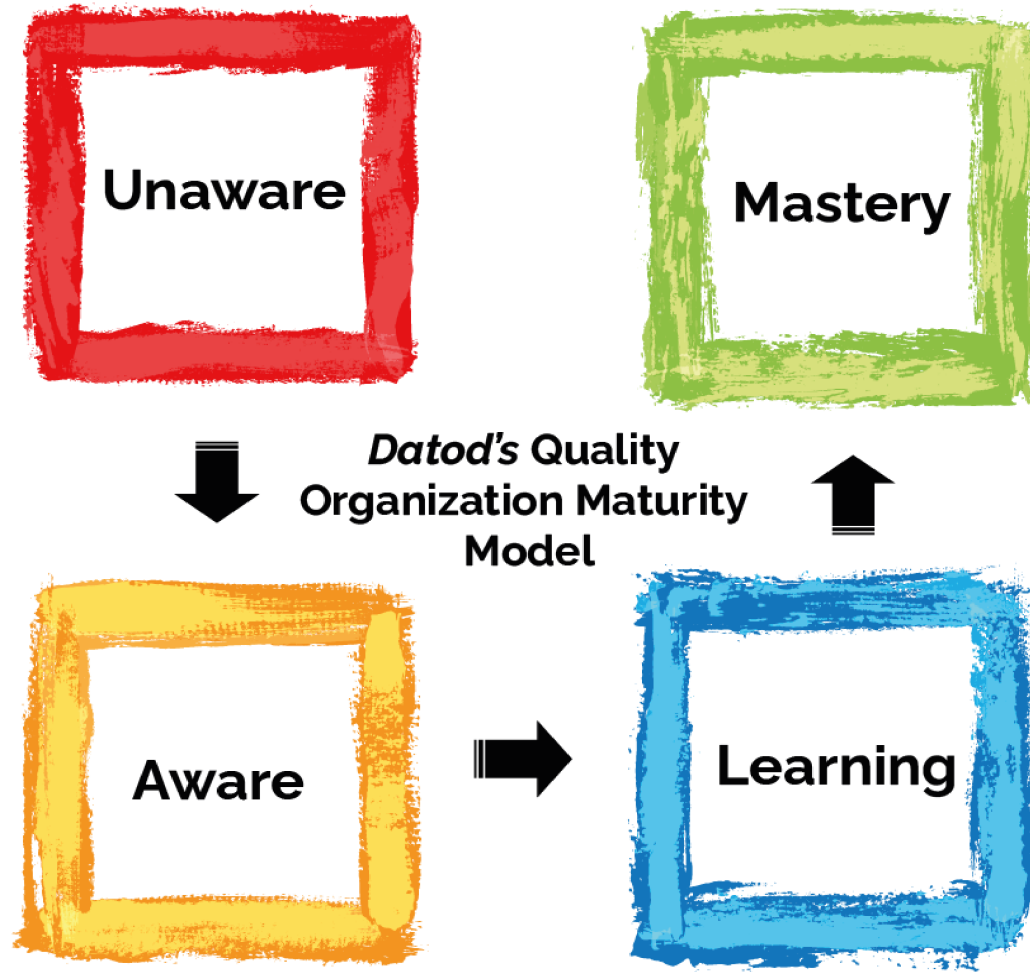
Technology



**Making the
QS work
for you**



Let's look at **People** through the 4 maturity levels.





Your score indicates that you may be struggling in leveraging the power of your most powerful resource: your people. The individuals in your organisation are all very similar in terms of back-grounds and views, or you may be unaware of their backgrounds. This can result in a lack of diverse perspectives when it comes to decision making. Additionally, staff turnover is either very low and staff stay for too long in the Quality organisation or very high and you struggle to replace them.

The general view of your Quality organization is it is introverted and inwardly looking.

Individuals tend to progress up through the ranks within your Quality group. This can limit upward mobility for talented individuals who come from outside the function.

The ability of individuals to to make effective decisions is poor. Decisions often move up the management chain, which can lead to frustration and a lack of ownership among employees.

All individuals are generally unquestioning of the Quality System, which can stifle improvements.

Individuals learn through on-the-job training. Whilst there are generic job descriptions for each role, training plans are not always tailored to individual's needs and personal development. There is no succession plan in place, which can lead to a loss of institutional knowledge and experience when key employees leave. You need to become better at understanding your organization and its capabilities and strengths and begin to actively shape it for the needs of your customers.



- Quality is comprised of individuals that are predominantly a single skill set or behavioural type.
- Onboarding training is generally on the job as individuals learn from others.
- Quality leadership has arisen by progression from within the Quality function of the same organisation.
- There is no concept of succession planning.
- Individuals tend to focus on their own skills and unique competencies. Movement within Quality is limited or even actively discouraged.
- Decisions are moved up the management chain if they are believed to be above a certain pay-grade.
- Generally the mindset may be pessimistic.

Next steps:

- Create a skills audit within Quality to identify skill, competency, and behavioural gaps.
- Clearly define the Roles and Responsibilities of all individuals that work in the Quality function ensuring these link back to customers' needs.
- Approach how you onboard, train and develop staff with more formal approaches.



Your ability to leverage the power of your people is still poor. The individuals in your organisation tend to have very similar in back-grounds and views. Lack of diversity is still a problem. Staff turnover is low. When individuals do leave, replacing them is a challenge. Loss of expertise is a problem. Individuals tend to progress up through the ranks within the Quality organisation. Individuals do not often come from outside the Quality group or move to other groups. You do not have the expertise or capabilities you need.

Individuals often move decisions move up the management chain to validate decisions they have made and to share risk. The level of accountability is generally low.

All individuals accept the Quality System as is, but can become frustrated and do not understand how it can be improved.

Individuals learn from on-the-job training against a generic training plan. Job descriptions are generic for each post. There is a very reactive ad-hoc succession plan in place. As turnover is low, it may be difficult to inject new blood into the organisation without causing disruption. It is essential to have a plan in place for when key personnel leave, in order to avoid any loss of expertise or institutional knowledge.

A more tailored approach to staff training and development will lead to better performance from employees. Finally, consider encouraging movement between different departments and groups within the company, in order to create a more cohesive workforce.



- Leadership is aware of the predominance of single skill-sets within Quality but there are limited examples of this changing when key posts are filled.
- Truly autonomous decision-making is limited.
- Newcomers from outside the business quickly mimic the organizational culture within Quality.
- There is limited awareness that the Quality System is a framework that can be improved to meet user needs.

Next steps:

- Develop an active and maintained succession plan for the Quality organization.
- Bring in individuals into the Quality organization with different backgrounds and experiences.
- Rollout training on making risk based decisions down through the organization



The way you manage talent is becoming effective. Whilst individuals in your organisation tend to have very similar in back-grounds and views, there is evidence of new blood entering the group. Staff turnover is the same as other groups. There is evidence of individuals joining Quality from other groups, and individuals leaving to join other functions.

There is evidence of accountability at the appropriate level of the organization. Individuals are able to make decisions but know when to escalate and get additional perspectives. The ability to make risk-based decisions is becoming evident at all levels.

All individuals give active feedback on ways to improve the Quality System, which is seen as an aspect that can be improved to make jobs easier in order to better serve the customer.

Individuals learn from on-the-job training against a person specific training plan. Job descriptions are tailored for each post. Gaps in skills and competencies are known and documented. This is yet to develop into a formal succession process. Despite this you are starting to develop both depth and breadth in your talent pool, with both generalists and specialists.

There is a feeling of growth and renewal within the Quality organization, leading to one of optimism.

To further develop formalize how you approach succession planning. Proactively rotate individuals throughout the business to bring in needed new perspectives and talent.



- There is evidence that the composition of Quality is becoming more diverse.
- Individuals are recruited with needed expertise that is absent. Movement across functions is actively encouraged and more visible.
- Most individuals still have predominantly similar view-points : technical, engineer etc but more diverse transferable skills are being added.
- There are still individuals who struggle with the more holistic role of Quality they are having less influence with time.
- There is potentially a feeling of growth and renewal within Quality and generally one of optimism.

Next steps:

- Roll out training in the Cynfin framework to better aid decision making.
- Actively second individuals in and out of the Quality organisation to and from other functions.



Your ability to manage talent is excellent. The Quality organization has a diverse makeup including individuals with varying experiences and perspectives. Staff are actively seconded to other functions to ensure staff are developed across the business.

Individuals are able to confidently make risk-based decisions at the appropriate level. In addition, they know when to act and when to understand an issue more. Additional perspectives are always sought. Individuals are continually looking at improving the Quality Systems.

A true commitment to developing people has been made by ensuring that staff members have what they need to succeed in their roles. A plan for succession is in place so that the talent pool is always full. New hires undergo a comprehensive onboarding program that sets them up for success from day one. These initiatives have resulted in a highly skilled and engaged workforce.

A person specific training and personal development plan, considering both current and future needs, is in place for each individual. Job descriptions are tailored for each individual. Gaps in skills and competencies are known, documented and form the basis for a formal succession plan that is regularly reviewed by leadership. Internal and external training against this plan takes place on an ongoing basis, ensuring that staff have the skills they need to excel.

This commitment to employee development helps to create a motivated and engaged workforce that is able to meet the ever-changing needs of the business. There is great optimism in the business.



- The Quality organization is diverse and continually being refreshed with new talent.
- Gaps in skills are actively being addressed through a visible commitment to succession planning.
- Job requirements are clear and there is commitment to staff training and development.
- Risk based confident decision making is evident at all levels of the organization.

Next steps:

- Continually reassess your gaps in skills and competencies to ensure they are relevant to the current and future challenges of the business.

Summary

- Seek diversity but allow individuals to play to their strengths.
- Focus on training, training, training...
- Invest in your people.

