

Approaching Quality Management Differently

Matthew Wictome

Managing Director - Datod



Datod Consulting Ltd

Building sustainable change



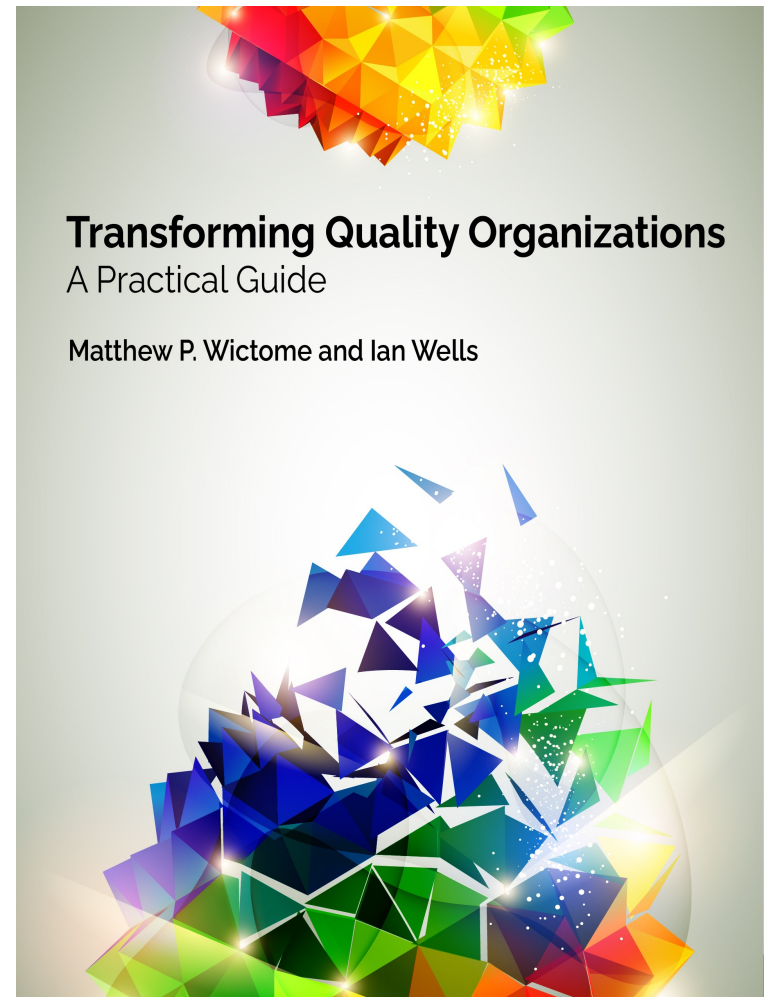
Agenda

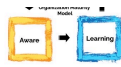


- This presentation covers at a **high** level the contents of a 18 module curriculum that is part of Datod's Quality Organisation transformation package.
- It will cover how it can **transform** how your organisation manages quality for your patients with **proven** results.

Content

- Is **aligned** with the contents of the book: *Transforming Quality Organizations: A Practical Guide* (Business Expert Press, New York, 2023)
- Is **additional** to the book and contains **much** material that didn't get into the book.
- It covers in much **more** detail how to **practically apply** some of the **thinking** described in the publication.





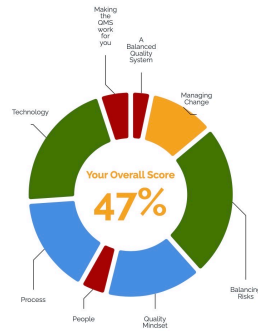
Thank you for taking the Quality Organization and QMS Assessment Tool

Your **results** and link to the **full** report have been emailed to matt.wictome@datod-consulting.co.uk. [Change email address](#)

Here is your section by section report !

Below you will find your score for each one of the attribute categories and tips on how to improve for next time.

● UN-AWARE ● AWARE ● LEARNING ● MASTERY



We've scored you based on the following key areas.

Here is a quick summary for each of the dimensions. Much more in the final report !

A BALANCED QUALITY SYSTEM MANAGING CHANGE BALANCING RISKS QUALITY MINDSET PEOPLE PROCESS
TECHNOLOGY MAKING THE QMS WORK FOR YOU

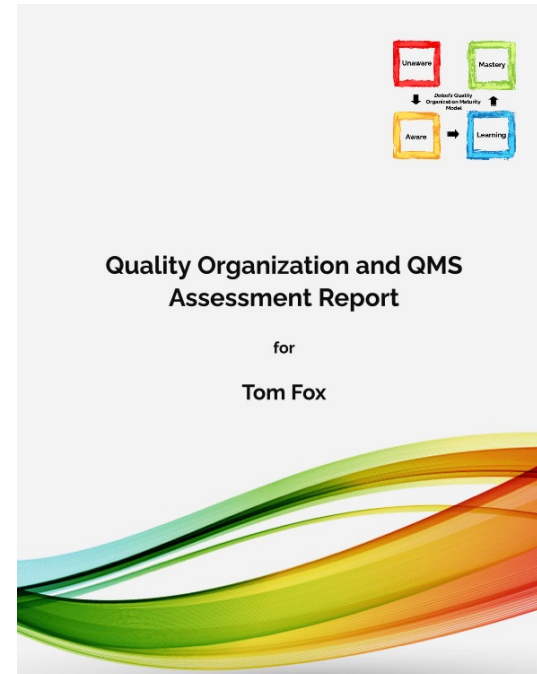


A Balanced Quality System - Unaware

11%

Is your Quality System balanced to meet the expectations of all of its customers and do you know who they are ?

Your score indicates that your Quality System is unbalanced! It is unaware of who its customers are



Thank you for taking the
Quality Organization and QMS Assessment Tool

Here's a reminder how you scored:

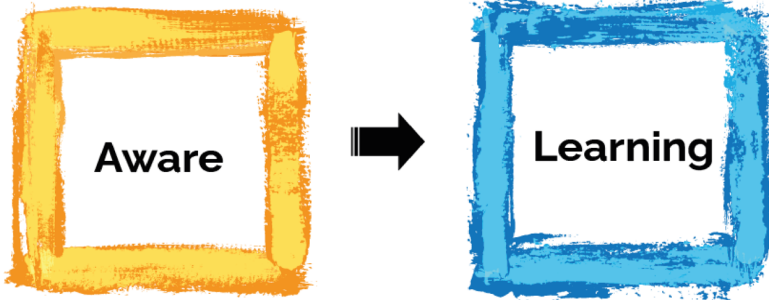


www.transformyourqms.com

It's completely free for a **limited period** only !!



**Datod's Quality
Organization Maturity
Model**



Your Quality Organization is more balanced and at Learning. It has an understanding of who its customers are and whether they are being satisfied. No one customer type is dominating.

The Quality organisation is more committed to all its customers. Data describing the Quality System is now includes data that truly begins to measures its output and effectiveness not only transactional data. Quality System Management Review now includes a broader audience and is driving data-driven decisions to improve the Quality System and increase customer satisfaction.

You are putting an increased understanding of customer needs into action. Your next step is to focus on delivering value by reducing waste and streamlining your processes. By making this shift, you will be well on your way to becoming a high-performing organization that provides real value to its customers.



- Quality organization is unaware of who its customers are or whether their needs are being satisfied.
- The Quality organization is centred around itself.
- The Quality organization is focused on meeting compliance needs rather than the needs of its other customers.

Next Steps:

- ✓ Start viewing the Quality System more holistically with multiple customers that need satisfying:- **Regulatory Compliance, Business Health** and **Customer Experience.**
- ✓ Start building an inventory of performance indicators that provide true *Value* for each customer segment.
- ✓ Define which indicators are *Meeting, Exceeding* or *Not Meeting* customer expectations.
- ✓ Reposition Quality System Management Review to add value to the whole business with inputs from the wider organization.

Your Quality Organization is still largely unbalanced but you are more aware of this deficiency. It is working to connect better with both the end-customer and the financial needs of the business. Metrics that are used to assess the Quality System are still largely transactional but there is more awareness of the need to measure aspects customers consider important.

Your Quality System Management Review is beginning to involve other stakeholders, but there is still a focus on the perspectives of senior management. Your Quality Organization is still largely disconnected from both the end-customer and the financial needs of the business, but there is self-awareness around this deficiency. With increased involvement from other stakeholders and a focus on customer satisfaction, your Quality organization will be able to better serve the needs of the business.

To improve your Quality organization, continue identifying your customers and better understanding their needs. Then, align your Quality System to meet those needs and establish metrics to track progress.

Importantly continue to refocus your management review process and ensure it engages with all relevant stakeholders in order to drive appropriate continuous improvement. By taking these steps, you can continue to close the gap between your Quality organization and your customers, and better position yourself for success.

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Current course content...

- Content will be **continually** added based on new material becoming available and user requests.

| Title | Content |
|---|---|
| Balancing the Quality System. | How do you build a QMS that satisfies all its customers ? |
| Quality ? | What do we mean by quality ? |
| Balancing the Quality System - Part 1 | Customers, balancing the QMS. |
| Balancing the Quality System - Part 2 | 5S approaches, 8 wastes of the QMS, QMS Maturity levels. |
| Managing Change - Part 1 | Change, Quality planning, objectives and data, KPIs, regulations. |
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| Quality Mindset - A Quality Perspective - Part 3 | Approaches to improve the perception of your QMS and Quality organization to get better results, now and in the future. |
| Organization - People | What are the skills and behaviours you need for now and the future. |
| Organization - Process & Technology | Building effective customer centric processes and leveraging technology. |
| Building a Transformational Map | The practicalities of building an effective Quality Transformation Map. |
| Making the QMS work for you | Making the QMS work for you and your customers. |

Putting its customers central to the Quality System...



WHAT DO WE MEAN BY
THAT ?



HOW TO LOOK AT QUALITY
MANAGEMENT A BIT
DIFFERENTLY.



THE SIGNIFICANT BENEFITS
OF REBALANCING YOUR
QMS.

Approaches that work..

The approaches described during the course have been applied at medical device companies **large** and **small** over 20 years resulting **significantly improved** KPIs.

- ✓ Product recalls rates cut by **50 %**.
- ✓ New product development cycle time cut by **50 %**.
- ✓ **Significant** cost savings in Quality System execution.
- ✓ **Significant** improvements in customer satisfaction.

A photograph of a diverse group of people, including an older man, a young man, a woman holding a baby, and a young girl, all sitting in a row in what appears to be a medical waiting area. They are all looking towards the left. The background shows a reception desk and a clock on the wall.

It starts and ends with patients
like you and me...

How effective are our
healthcare systems in
delivering for **patients** like
you and me ?

At times they are really, really effective..



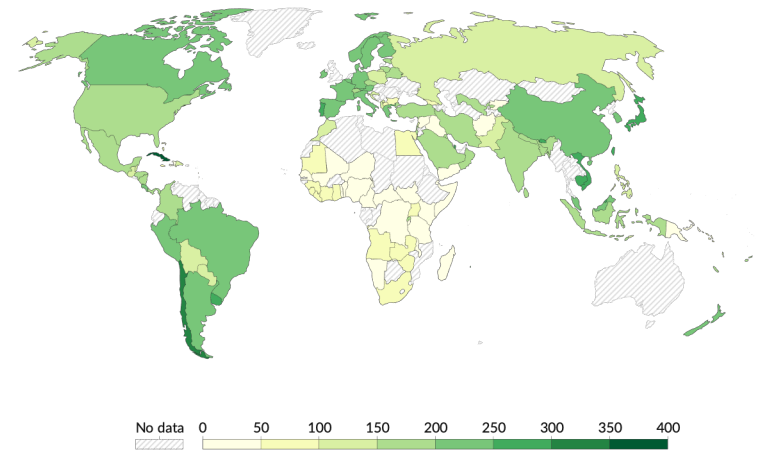
> 68% of the world population has received at least one dose of a COVID-19 vaccine.

> 12.9 billion doses have been administered globally.

WHO

Total COVID-19 vaccine doses administered per 100 people, Nov 2, 2022
All doses, including boosters, are counted individually.

Our World
in Data



Source: Official data collated by Our World in Data - Last updated 3 November 2022

OurWorldInData.org/coronavirus • CC BY

At times they are really, really bad..



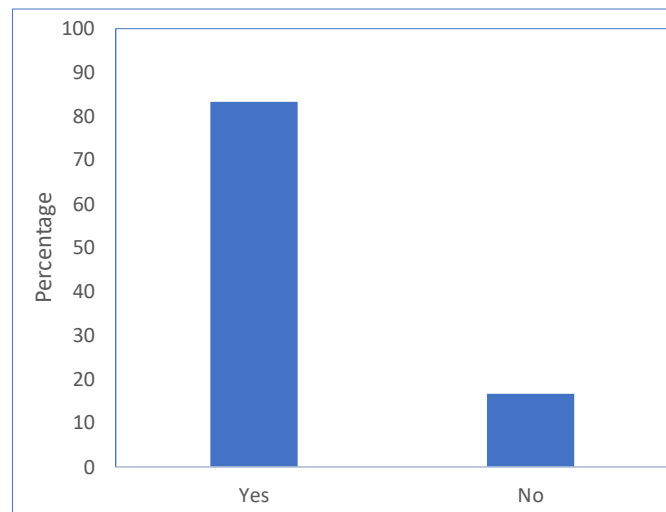
IVDR / MDR

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

LinkedIn Poll of Quality Professionals were asked

*“Over the last few years in the medical device industry there has been **more** focus on meeting regulations **rather** than meeting patient needs ?”*



Healthcare companies need to do **both**.

ie: Meet the regulations **and** meet patient needs.

This is not a criticism of regulations

- Regulations help ensure **consistency** and help ensure products are **safe**.
- This is more a discussion of balancing resources and effort appropriately.
- A product that is **compliant** may not be necessarily **good**.
- Quality and compliance are not the same things.



As well as regulators,
and end-customers,
there is **another** group
you need to satisfy.

Business Health

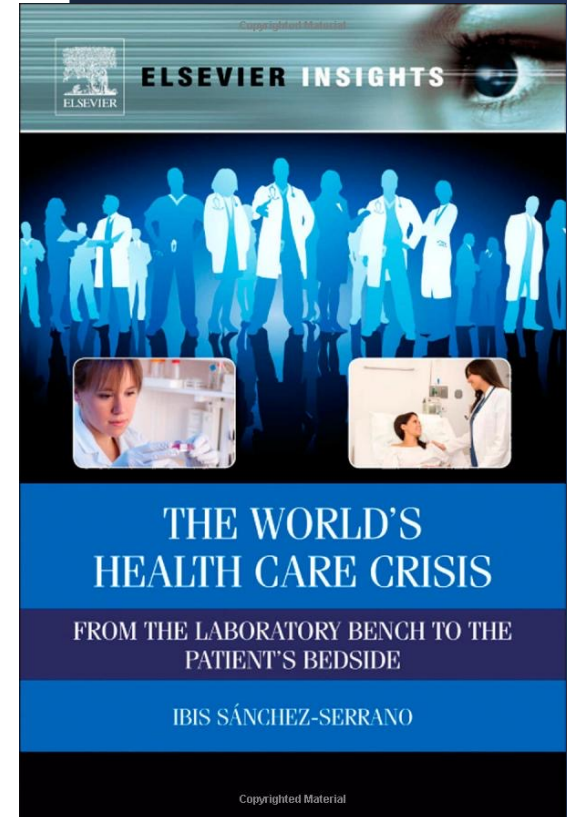
Businesses need to be
profitable, grow and
meet their shareholders'
expectations.



Other challenges are specific to **now..**

- ❑ **Innovation v Control.**
- ❑ Healthcare systems under **strain.**
- ❑ **Skills gap.**
- ❑ **Technological advances** – AI, Machine learning.

Quality organisations and Quality Systems need to be more **efficient**, **effective** and more **impactful**.



A close-up photograph of a person's hands holding a white rectangular sign. The person is wearing a dark suit jacket and a white shirt. The sign has the text 'Who are Your Customers?' written on it. 'Who are Your' is in black, and 'Customers?' is in red.

Who are Your Customers?

So **who** does your Quality organisation
and QMS need to satisfy ?

The **three customer** groups any Quality organisation and the Quality System **must satisfy** to be truly effective.





You need to obey the regulations and adhere to the standards applicable to your products.



You need to meet your customers expectations with respect to quality, cost, safety and delivery.



Your business needs to be profitable.

**Your QMS and Quality organisation
has huge influence on all 3 areas.**

All three meet the **true** definition of a customer...

They can **take** their business **elsewhere**.



Regulators / Notifying bodies can **refuse** to approve your Quality System.



Customers can purchase from **other** suppliers.



Shareholders can invest in **other** businesses.



Your Quality System needs to be **balanced**.

- ❑ Compliance is an attribute the customer simply expects as a given.
- ❑ It will **not** differentiate you in the marketplace.
- ❑ Quality organisations will need to ask themselves what is their true **purpose**, beyond ensuring compliance ?



or



Handing out speeding tickets

Helping build more beautiful cars

Datod was set up in 2019 to help organisations **rebalance** their Quality organisations.

Datod is the welsh word for "unravel".

Our Mission:

To be the **go-to** partner for medical device companies who want to **transform** their Quality organisations to better **serve** their patients and **grow** their businesses.

But How ?



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Building sustainable change

Tools to build a **customer centric** Quality System

- ❑ Leverage lean methodology to understand each customer group's perception of **value** and work **relentlessly** to deliver it.
- ❑ Deliver only what your customer decides is important, **not** what you think is important.
- ❑ The customer decides whether you are doing this effectively, **not you**.

You need to view the QMS from multiple perspectives





Perspective

We don't see things as they are. We see things as we are.

Expectations..



Compliance



Satisfaction and Safety



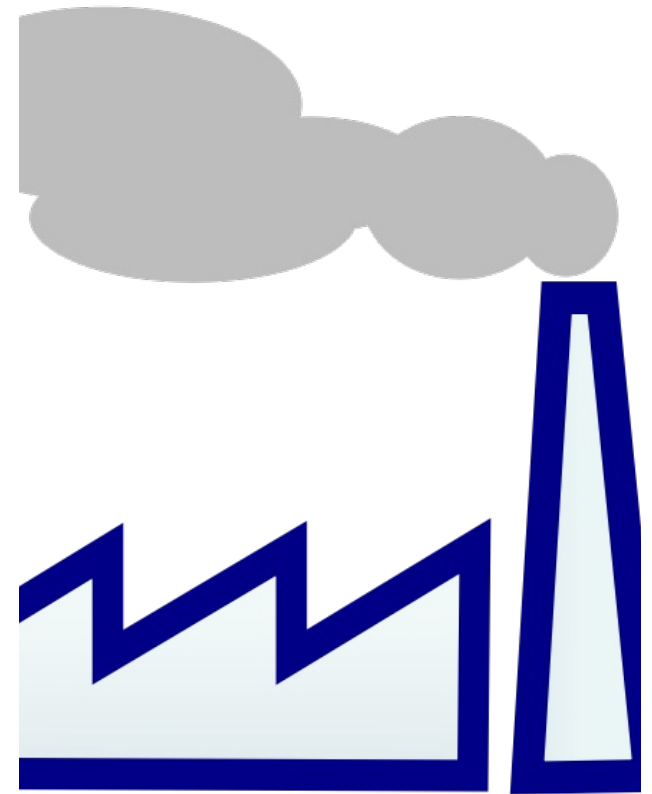
Cost

These expectations are often in conflict.

This course will show you how to satisfy all expectations.

Lean thinking applied to the Quality System

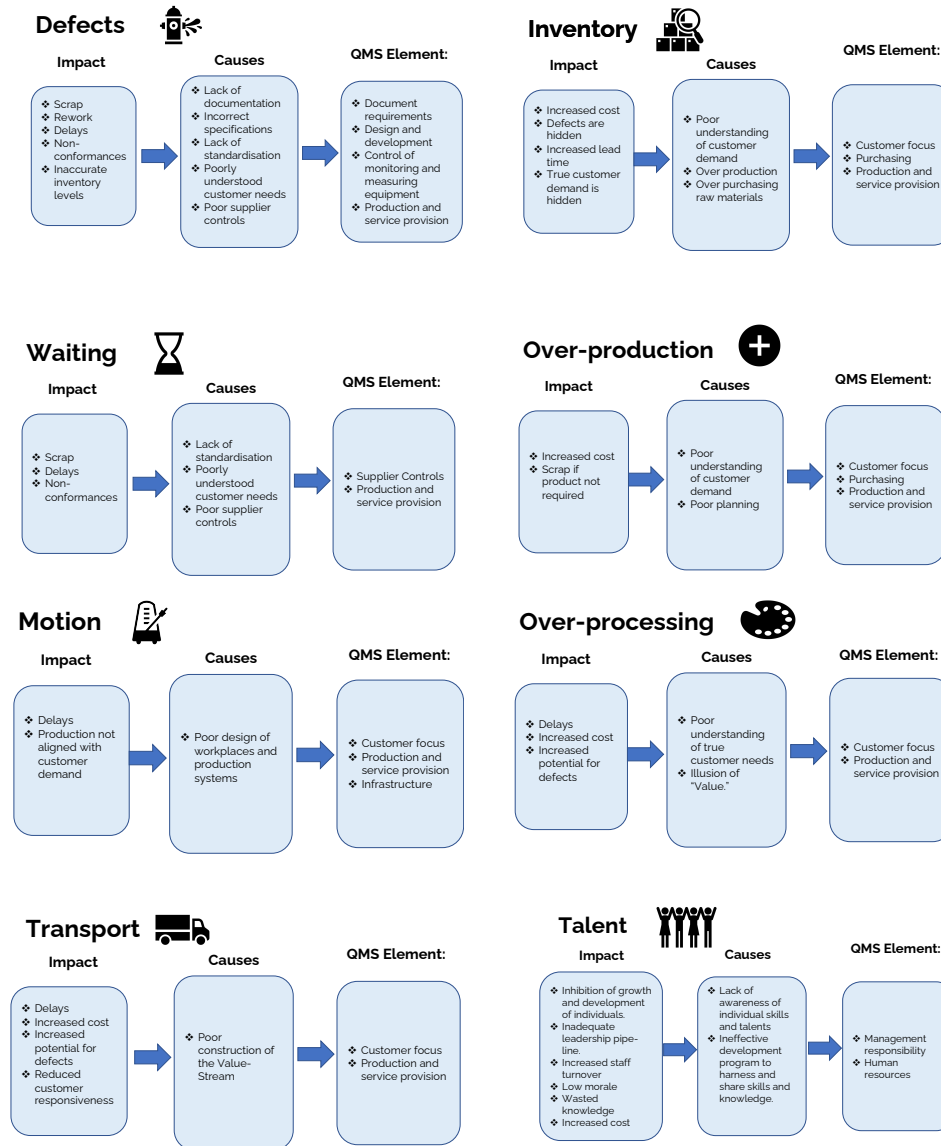
- ❑ Lean methodology originated in Toyota and has **transformed** the efficiency of modern manufacturing plants.
- ❑ Leverage the power of lean thinking applied to the **transactional processes** of the Quality System.
- ❑ Key is putting the Quality System's **customers** central to your thinking.



A close-up photograph of a person's hand dropping a green plastic bottle into a recycling bin. The bin is made of grey plastic with yellow and blue slots. The background is a blurred green field.

Remove waste from your
Quality System and make it
flow.

The 8 Wastes applied to the Quality System



This waste is **preventing** you satisfying your customers.

It is **preventing** your Quality System from being effective.

Work **tirelessly** to remove !

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**.

| 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

Drawbacks in lean thinking

- Manufacturing approaches have not always delivered their **full** potential in healthcare organisations. *
- Organisations are complex, changing and evolving systems and **not** machines.
- Your Quality System is a complex adaptive system.
- You will need to apply **newer** thinking around how Quality Systems and organisations **actually** behave to **improve**.

* Kaplan GS, Patterson SH, Ching JM, *et al* Why Lean doesn't work for everyone *BMJ Quality & Safety* 2014;**23**:970-973



We will cover how to manage change of the QMS

- Organizations and People do not behave like machines however much we want them to.
- You need to start with a plan...
-but accept that it will change.



Planned Change

| |
|---|
| Diagnosis |
| Vertical governance |
| Project start and endpoint |
| Linear plan |
| Control uncertainty |
| Hierarchical leadership |
| Learning through quantitative data |

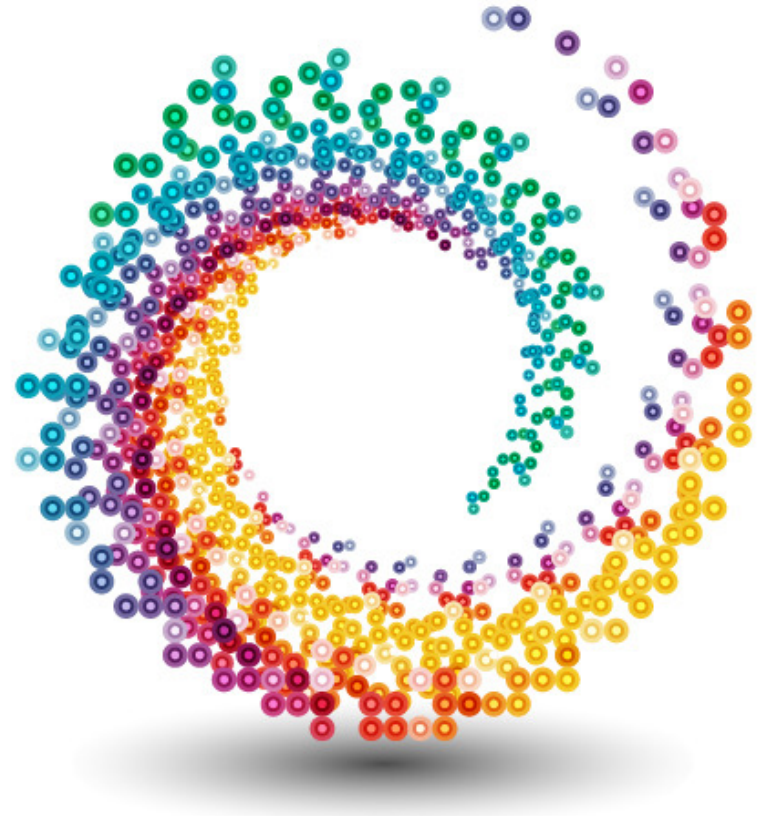
V

Emergent Change

| |
|-----------------------------------|
| Dialogue |
| Horizontal governance |
| No beginning or end |
| Non-linear plan |
| Embrace uncertainty |
| Distributed leadership |
| Learning through narration |

Embracing complexity

- ☐ Complex systems are changing, evolving and hard to predict.
- ☐ Think, shoals of fish, economies, crowds...
- ☐ Cause and effect does not always hold.
- ☐ Your Quality organisation and Quality System is a **complex** system.



Complex is not the same as Complicated



A car key
is **Simple**



A car is
Complicated



How traffic behaves
is **Complex**

Your Quality System is at times a: Complex Adaptive System



Designing quality management systems as complex adaptive systems

Petter Øgland

Department of Informatics, University of Oslo, Norway

Abstract

Complex adaptive systems research adds to the theory of how to design systems that are resilient to change in turbulent environments. This paper reports a case story about using complex adaptive systems theory for designing a quality management system in a politically turbulent organization. The story explains how the quality management system evolved rapidly, exploiting the turbulence of the organization, but collapsed after six years. Through an analysis and discussion of what went

Quality management systems from the perspective of organization of complex systems

Alba N. Zaretsky

Dosimetría de Radiaciones Ionizantes, Comisión Nacional de Energía Atómica, Presb. Juan González y Aragón 15, (B1802A1A) Ezeiza, Prov. de Buenos Aires, Argentina

Received 6 April 2007; received in revised form 13 October 2007; accepted 26 December 2007

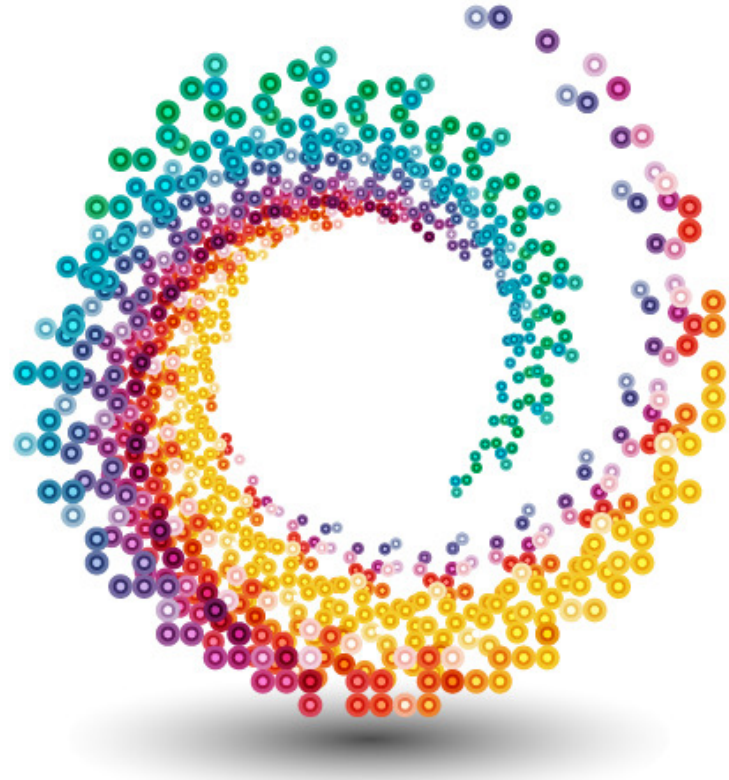
Abstract

The aim of this model is to analyse quality management systems from the standpoint of the organization of complex systems introduced by Robert Rosen. The concept that an organized system, under certain conditions, can be modelled as a living system introduces unsuspected tools to analyse its behaviour. The model is oriented towards the understanding of the implications of

Treat it as such

How **complex** systems behave....

- ☐ Systemic
- ☐ Path-dependent
- ☐ Sensitive to context
- ☐ Emergent
- ☐ Episodic



As your QMS is at times a **complex** system, this is the reason..

In systems that are complex and changing there is often no such thing as a root cause.

- Your non-conformances haven't reduced to zero.
- Your complaints haven't been completely eliminated.
- Your human errors haven't been eradicated.

Even after **1000s** of hours of investigation and effort.



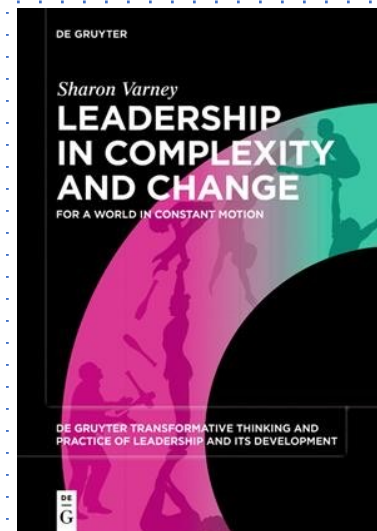
Supplement our approach..

- It's not that we haven't been applying **enough** effort.
- Maybe we've been applying the **wrong** effort in the **wrong** way ?



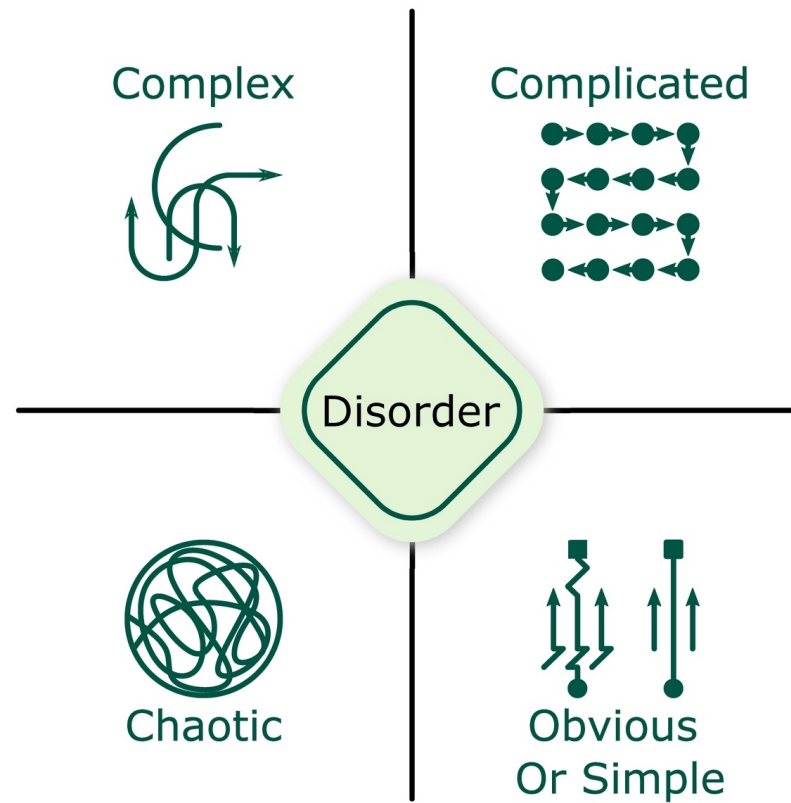
This aspect of successfully changing a complex system will be covered in depth in the course.

Recommended reading



How does this help me in practice ?

Cynefin Framework

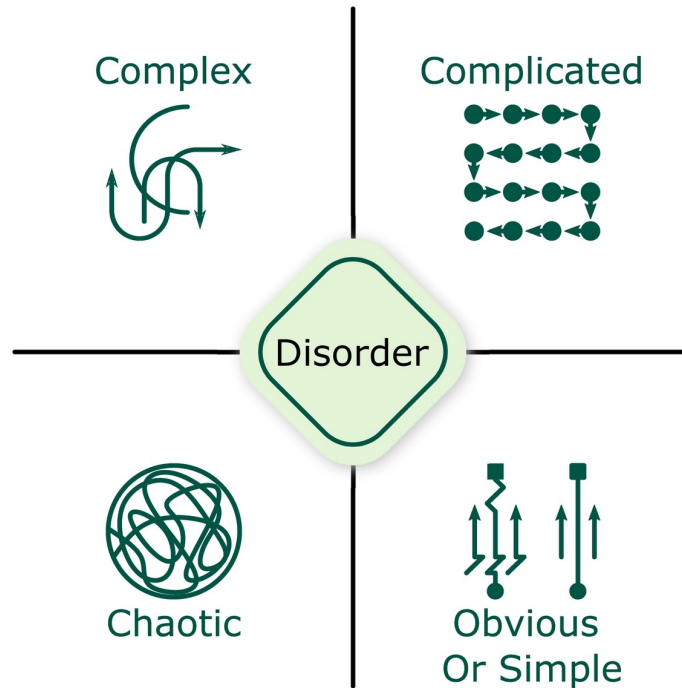


A Quality System example

Solutions obtained through examining patterns that emerge and evolve.

- ✓ What is the culture of quality ?
- ✓ What are the behaviours ?
- ✓ Who are the stakeholders of influence ?
- ✓ Flagrant breaches of GDP and GMP

Gain control



Solutions are through expert knowledge eg: Regulatory Affairs, External consultants

- ✓ IVDR / MDR compliance
- ✓ Regulatory requirements for new markets



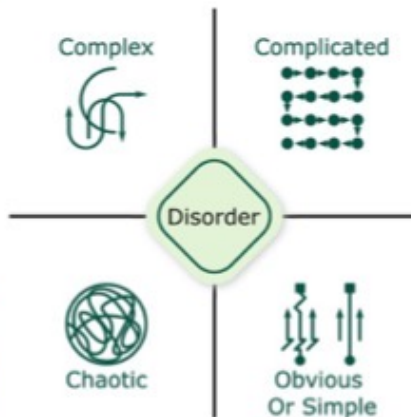
- ✓ Reduce variability, waste
- ✓ Improve control
- ✓ Improve OTIF / LIFR



Solutions are best practice eg: lean, PEx etc

QM as an holistic approach

QM as a systems approach



QM as a "hands-off" approach

QM as a process approach

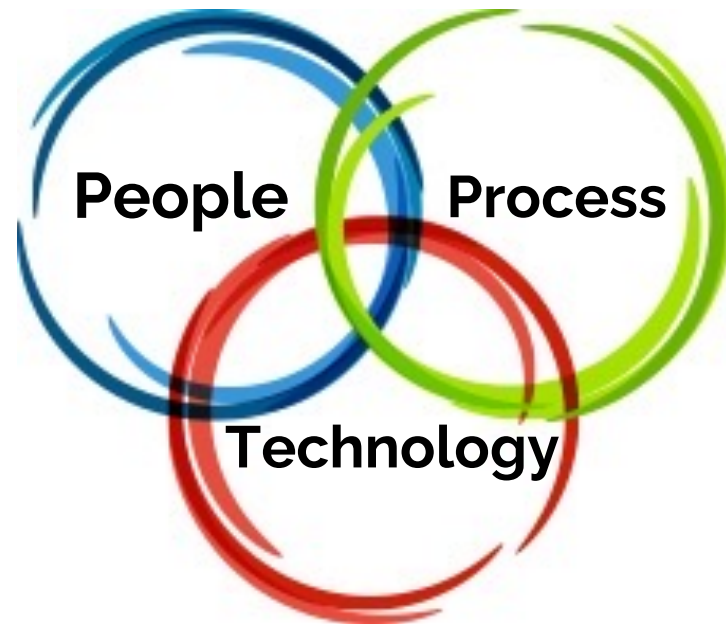
Innovation

Effective Quality Management depends on **context** and what you are trying to **achieve**.

Control

Building a more **effective** Customer Centric Quality System

Areas you need to consider:





Do you the right people with the right skills and behaviours ?

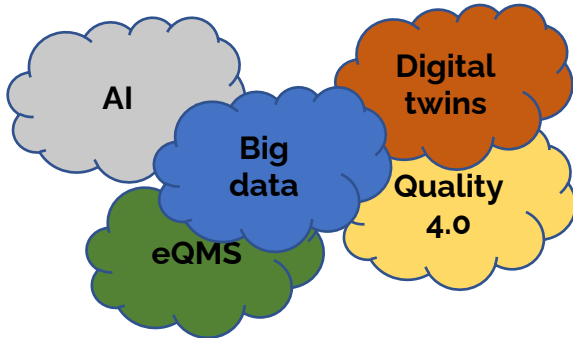


Do you have the right processes focused on serving your customers and built around user needs ?



Are you leveraging technology to better serve your patients and grow your business ?

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.

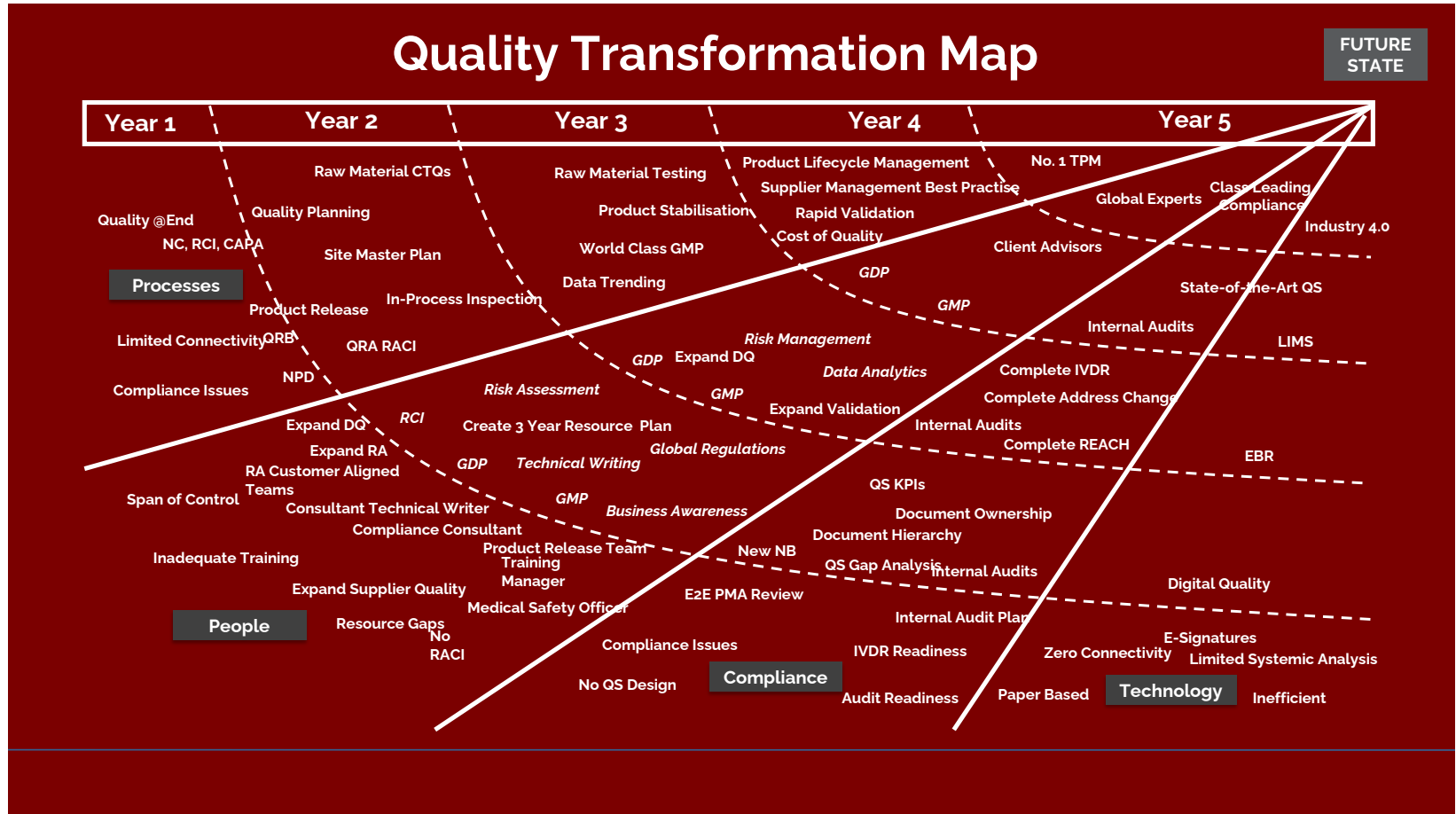
**Organizational
flexibility**

Build a flexible and agile organisation.

Building a **transformation** map for your Quality System and organisation.

- Applying basic approaches will only get you **so far**.
- It will not position your organisation for the **future success**.
- You will need a **plan**.

What one looks like..



Final thoughts..

QUALITY IMPROVEMENT

Changing how we think about healthcare improvement

Complexity science offers ways to change our collective mindset about healthcare systems, enabling us to improve performance that is otherwise stagnant, argues **Jeffrey Braithwaite**

For all the talk about quality healthcare, systems performance has frozen in time. Only 50-60% of care has been delivered in line with level 1 evidence or consensus based guidelines for at least a decade and a half¹⁻⁵; around a third of medicine is waste, with no measurable effects or justification for the considerable expenditure⁶⁻⁹; and the rate of adverse events across healthcare has

adaptive system, meaning that the system's performance and behaviour changes over time and cannot be completely understood by simply knowing about the individual components. No other system is more complex: not banking, education, manufacturing, or the military. No other industry or sector has the equivalent range and breadth—such intricate funding models, the multiple moving parts, the complicated

make it hard to impose order. And health systems are indeterministic—meaning that the future cannot be predicted by extrapolating from the past. They are also fractal and self similar, often looking alike in, for example, organisational culture in different places and at different points in time.

How then is a system as complex and seemingly dynamic as healthcare

Braithwaite J. Changing how we think about healthcare improvement *BMJ* 2018; 361 :k2014 doi:10.1136/bmj.k2014

*“ [A] note of caution goes to the proponents of today's most popular strategies: it's time to stop thickening the rule book, reorganising the boxes on the organisation chart, and introducing more key performance indicators—and to do **something more sophisticated.** ”*

As Quality professionals we can do better..

- meeting regulations in a more effective and efficient way.
- protecting and delivering value to our customers.
- ensuring our businesses are profitable.

In the following sessions we will cover how.

Course content...

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Transforming Quality Organizations: About the authors



- ❑ **Ian Wells**, PhD, is currently a Vice President of Quality Assurance and Regulatory Affairs for Trinity Biotech. Over the past thirty years, he has worked in R&D, Operations and Quality/Regulatory for a range of companies in the Pharmaceutical & Medical Device fields. His focus has been the implementation of small and large change programs to drive the removal of non-value adding processes from quality systems and provide enhanced customer outcomes. He holds a PhD and graduate degree in analytical chemistry and chemometrics. Ian is passionate about finding and developing the best talent, is a trained coach and has spent a large proportion of his professional life working in a variety of countries and cultures. Through experience, he has developed a methodology of strategic quality change based around the concept of the transformation map and its use to bring out the best in people and process and the technology used to support them.



- ❑ **Matthew P. Wictome**, PhD, is Managing Director and founder of Datod Consulting. Datod specialises in building better and more effective Quality organisations. Over the past thirty years he has worked closely with a wide range of companies implementing impactful change to better serve the customer, benefit the shareholder, and improve regulatory compliance. As well as holding qualifications in lean & Six Sigma he is an ISO 13485 Quality System lead auditor. He holds a PhD and graduate degree in Biochemistry and an Executive Masters in Strategy, Change and Leadership with the University of Bristol. He is passionate in designing and implementing quality systems that are effective, efficient and outcome driven. His interests include how organisations function in the real world and the role of organisational culture has on the management of quality.

How to contact us..

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Datod Consulting Ltd

Building sustainable change