

Quality Mindset

Part 1 of 3
Systems





**How do you and your organization see the whole around
your ?**

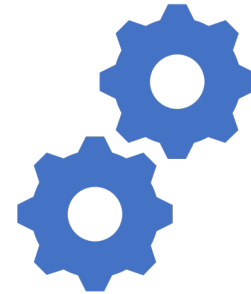
How do you view your Quality organization ?

As importantly, how do others see your organization ?

Agenda



Word-views:-



Systems in action

World-views

Order



- Events are predictable
- Path forward is unambiguous

Non-order



- Events are unpredictable
- Path forward is always unclear

Where would you position..

1: Your organisation ?

2: Your world-view ?

1: Is your organization in the place you predicted and planned for 5-10 years ago ?

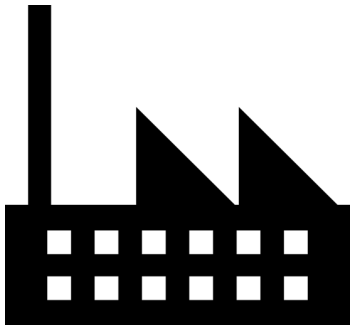
2: Is your life in the place you predicted and planned for 5-10 years ago ?

World-views

Order ←————→ Non-order



Organizations



Ourselves



World-views

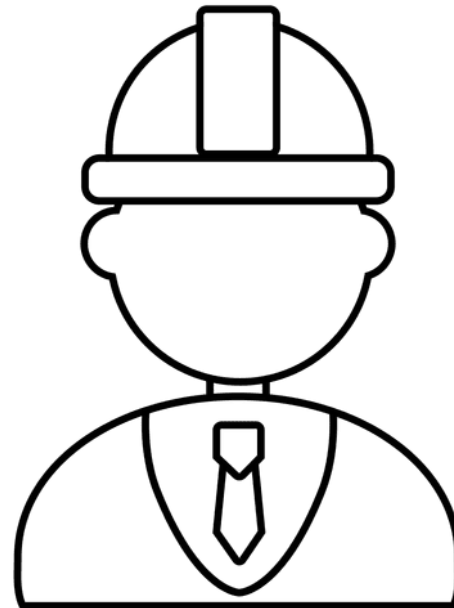


“ We’ll cross that bridge
when we come to it ! ”

How do you feel about this statement ?

It gives a big clue where you are on this
spectrum, either as an organization or as
an individual”

- An engineer will always approach such challenges with this reductionistic mindset, one that has been re-enforced through a lifetime of training and experience.
- Though is this really the case ? Do organizations really act like machines ?
- Do people act like machines ?





Different approaches

- This module explores where an engineering view of the world helps and is extremely valuable...

..... and when it doesn't and at times can actually hinder your ability to see and influence the world.

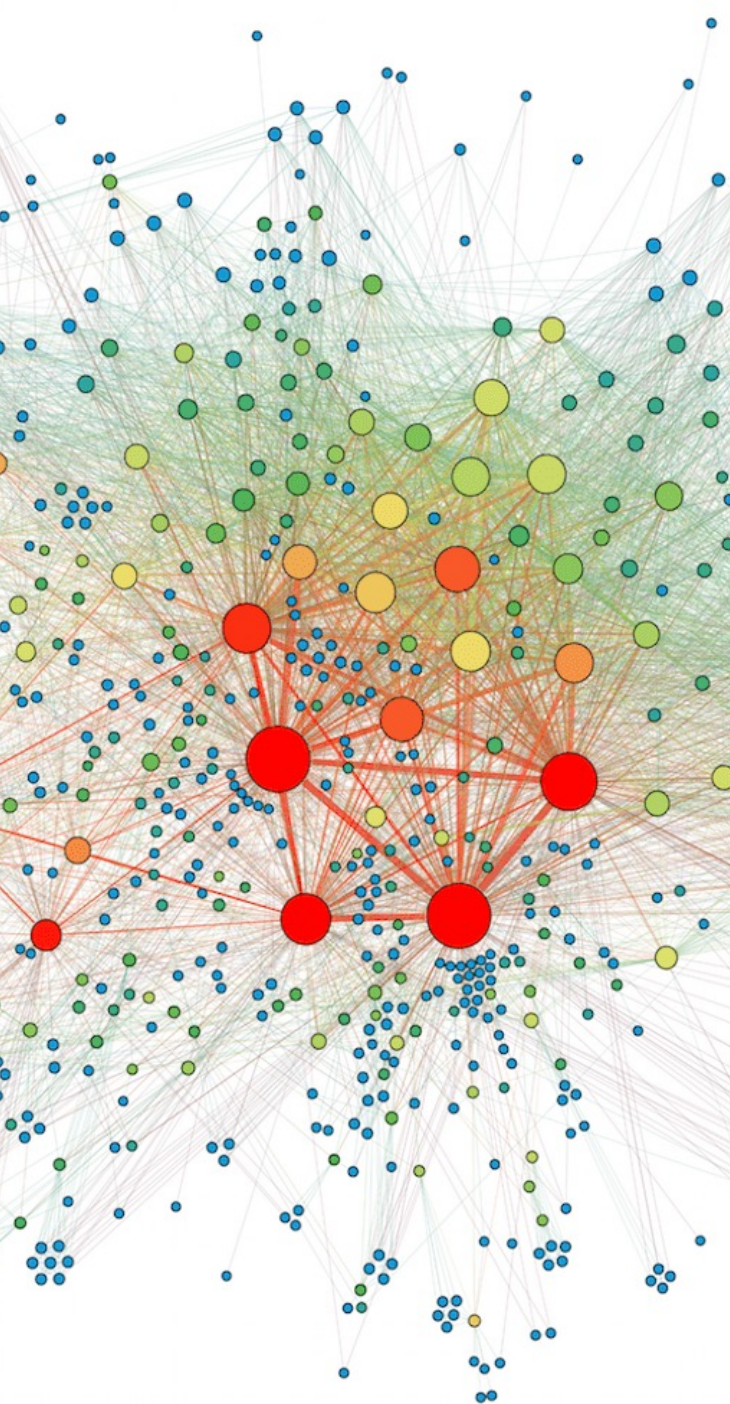
As a leader
we want
conflicting
things.

Diversity

Agility



Predictability

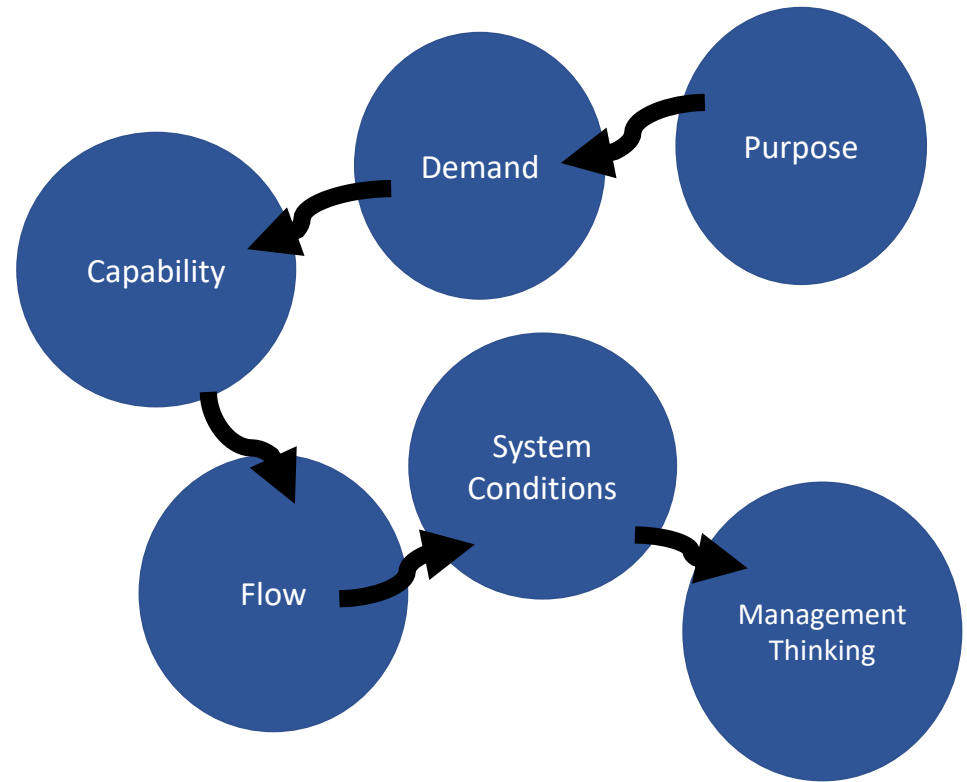


Systems

- Over the years, ways of looking at processes has evolved into a more systems approach. Since its inception in the 1990s systems thinking has been applied to settings ranging from healthcare to social challenges.
- A fundamental principle of systems thinking is that improvement cannot be made unless the underlying system is addressed.
- A system is not just a collection of processes. A system is holistic, and you cannot understand the system without looking at the totality of the system. By its very definition a quality management system is a system, but rarely viewed as such.

How do systems behave ?

- In 2003 John Seddon proposed a model for checking a system and offers some structure to helping comprehend one in action.
- The model comprises of 6 steps



Cause and effect

- Though basic systems may be complicated and harder to understand but – generally the relationship between cause and effect holds.
- You can model the system.
- Unlike complex systems covered in the next model.
- The effect may be unexpected.
 - ie: Unintended consequences which with hindsight were obvious.



Purpose

- **What is the purpose of the system ? What are the purpose of the sub-systems ?**
- For example, is the CAPA system in place to fix and prevent errors and to continually improve the QMS, or to create documents to demonstrate to an auditor you have a CAPA process that meets the regulations ? These are two different things, though often confounded.



Demand

What are the demands on the system ?

- Every system has demand put on it. The QMS is no different. There are two types of demand, *Value Demand* which is demand aligned with the purpose of the system and *Failure Demand*.
- *Failure Demand* is demand caused by failure to deliver something right for the customer. Errors in manufacturing records are a form of Failure Demand and cause unnecessary rework in other parts of the system.
- Incomplete or poorly defined customer design inputs create Failure Demand during product development, as product is potentially redesigned before launch.

Types of Failure Demand

Call Centres can be good examples of failure demand.

- In some organisations work generated by the QMS can give the illusion that the system is working but is completely delinked and detracting from final customer needs.
- **The system creates its own work.**
- Reports are created that are never read. Data compiled that is never reviewed or data reviewed with no decision reached.
- Ask yourself the question how much activity on a daily basis within your QMS is delivering against customer expectations requirements for Compliance, Business Health and Customer Experience ?





Capability

- **Is the system capable of meeting the load put on it ?**

How will your quality system meet peaks of demand or events such as product recalls or external audits that put sudden urgent stress on the system and its human resources ?

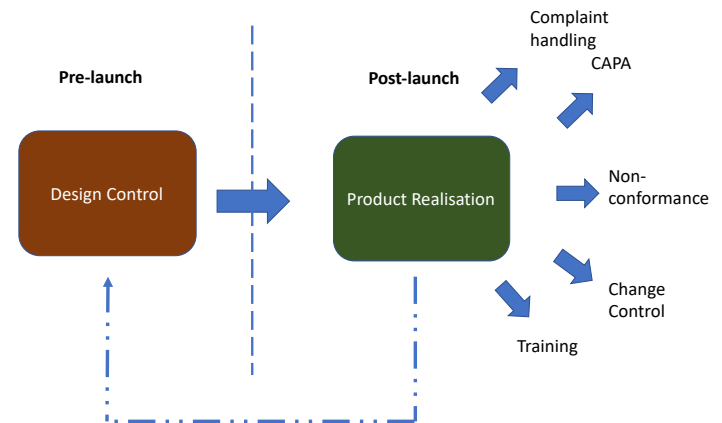
Flow

How does the system flow to meet demand ?

- The system is not static but needs to flow to meet demand.
- During the product realisation process within the QMS, how do your records and documents flow with the product ?
- How is this fully managed if different systems, such as electronic batch records, ERP and eQMS as well as the physical product and paperwork need to move in unison ?
- To a great extent managing flow with different applications, each with often different business owners has decreased the ability to manage flow effectively.

System conditions

- **What causes the system to behave as it does ? How are the sub-processes linked ?**
- Often sub-systems are not aligned. One example of system conditions causing outputs that are not in line with customer needs can be with the two subsystems of the QMS, Design Control and Product Realisation





Management Thinking:-

Are your managers focussed on the customers or just satisfying your needs ?

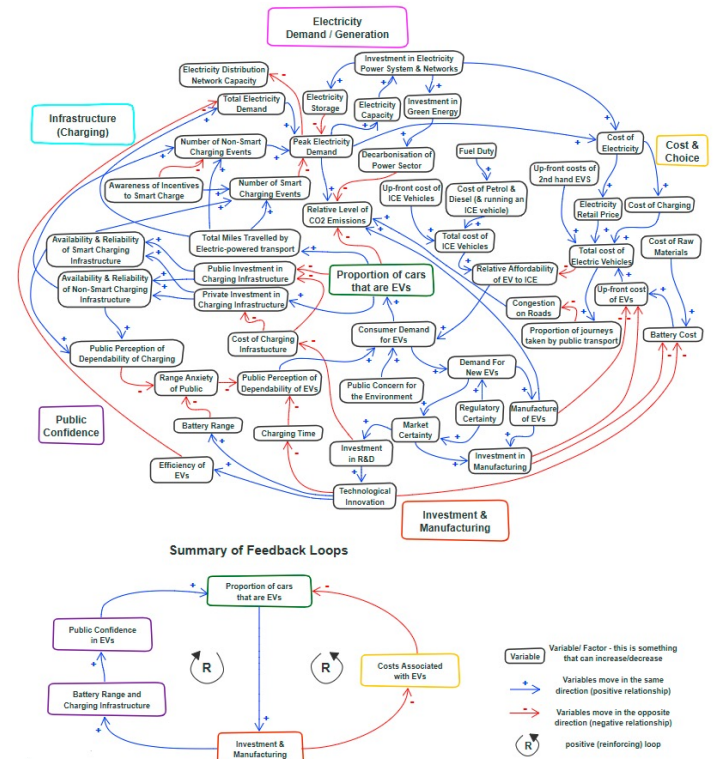
- Systems, generally, do not operate on their own.
- They take people and people are driven by beliefs and behaviours that make up organisational culture. Often what is seen as an aberration and behaviour of the system is simply a function of those who run and manage it.
- This comes down to the culture, and the more nebulous aspects of the QMS that form the foundation how it behaves and is executed. Aspects that are difficult to measure often have a huge impact.

Covid-19

- [illegible]

Electric Vehicle Use

- In October 2021 the UK government published *Net Zero Strategy: Build Back Greener* - detailing how it would act in its contribution to the effort to stem global warming by reducing net CO2 to zero.
- Systems thinking was a key component in the document and overall strategy around decarbonisation. It also was a concrete example that systems thinking is now a standard concept in how organisations, businesses or even governments view the world and how they manage change.



FDA Opioid Response

- Policy maker's initial tack was to reduce the availability of the prescription drugs. It made the situation worse. Patients went to extreme means to obtain medication by legal and often illegal means and another wave of addiction to heroin and illicit drugs ensured.

THE OPIOID EPIDEMIC BY THE NUMBERS



70,630

people died from drug overdose in 2019²



10.1 million

people misused prescription opioids in the past year¹



1.6 million

people had an opioid use disorder in the past year¹



2 million

people used methamphetamine in the past year¹



745,000

people used heroin in the past year¹



50,000

people used heroin for the first time¹



1.6 million

people misused prescription pain relievers for the first time¹



14,480

deaths attributed to overdosing on heroin (in 12-month period ending June 2020)³



48,006

deaths attributed to overdosing on synthetic opioids other than methadone (in 12-month period ending June 2020)³

SOURCES

1. 2019 National Survey on Drug Use and Health, 2020.
2. NCHS Data Brief No. 394, December 2020.
3. NCHS, National Vital Statistics System. Provisional drug overdose death counts.

Updated February 2021. For more information, visit: <http://www.hhs.gov/opioids/>



Opioid Crisis in US

- **Heterogenous:-** The social, physiological and organisational interactions were hard to predict and the underlying mechanism difficult to fully understand. Machine thinking was not appropriate.
- **Multiple stakeholders are involved:-** No single authority had complete jurisdiction and "*Ineffective coordination can result in unintended consequences.*"
- **There is are delays between actions and effects:-** In the real world there is a delay in system between any intervention and impact of the intervention.
- **There are unintended consequences of actions:-** Sometimes interventions result in outcomes that were unexpected and counter to the result predicted and hoped.
- **The crisis is evolving:-** The system was not static.
- **Data gaps limit understanding of knowledge:-** At times we don't know what we don't know.

FDA's Opioid Systems Modeling Effort



The opioid crisis is a complex problem with a lot of unknowns and an ever-changing landscape. There is no one-size-fits-all solution to the problem, so regulators and policy makers like FDA need a toolkit of approaches to questions and decisions about the crisis.

Systems modeling and systems thinking are important elements of FDA's toolkit.

In 2017, the National Academies of Science, Engineering, and Medicine recommended that FDA employ a systems approach to help understand the ripple effects that FDA actions may have on the opioid crisis. FDA's systems modeling effort, which kicked off in 2018, combines **dynamic simulation modeling** with **systems thinking principles**.

The goals of the effort are:

1. Identify strategies and actions that may have the greatest positive impact on the crisis,
2. Assess the potential for unanticipated consequences of actions, and
3. Identify important areas for further research.



System dynamics modeling helps map the crisis with quantitative insights.

SOURCE (Simulation of Opioid Use, Response, Consequences, and Effects) is at the center of FDA's modeling effort. SOURCE simulates the national population's transitions through opioid use, use disorder, treatment, and recovery, and influences on those transitions. The model provides both qualitative and quantitative insights about potential effects of changing one or more parts of the system.

FDA conducts research to update and enhance SOURCE and to provide other fit-for-purpose modeling tools. These efforts include researching specific components of the crisis, adding system outcomes to SOURCE, building interactive interfaces, diagramming, and developing models collaboratively with stakeholders.



Systems thinking helps maximize the utility of modeling to stakeholders.

FDA's modeling team is incorporating a supporting analysis service that can guide FDA stakeholders through their systems-based assessments of potential opioid-related policies. This facilitative process helps analysts and decision-makers determine when modeling may add value and support them as they refine their policy questions, articulate their assumptions, and interpret model results with an understanding of context, framing, assumptions and caveats. It also helps FDA decision-makers place modeling findings within the broader set of information available to support decision making. The analysis service emphasizes interdisciplinary collaboration and creates opportunities for engagement throughout the modeling process.

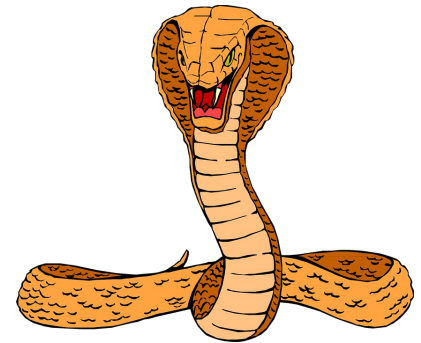
FDA works with academics and colleagues across HHS to share learnings.

Want to learn more about our approach? Check out our white paper, publications, and partnerships.

2022 | Center for Drug Evaluation & Research | Office of Strategic Programs | Office of Program & Strategic Analysis

Unintended consequences – The Cobra Effect

- The term originated from the concern during British rule of India in the 1800s of the number of snake attacks taking place. The authorities offered a bounty for every dead cobra handed in.
- This reward encouraged some to breed the snakes to obtain the reward. On realising the authorities immediately abandoned the practice of paying for dead snakes.
- Left with snakes that they were unable to sell, breeders simply released them into the wild, resulting in an explosion in the snake population, an outcome completely opposite to the one originally hoped for.



Applying systems thinking to the QMS

- The FDA also understands your organisation is a system, your business is a system and your QMS is a system.
- The approaches that the FDA are taking will eventually translate into an expectation of organisations to use such strategies to protect the consumer and ensure that products are manufactured that are safe.
- Now is the time to start applying such systems thinking to quality management.



A Systems Approach to Quality Management of Healthcare

One area that systems thinking has been attempted to be applied is in quality management within the healthcare setting, as poor quality has real potential for patient harm through human error or inappropriate application of medicine or procedures.

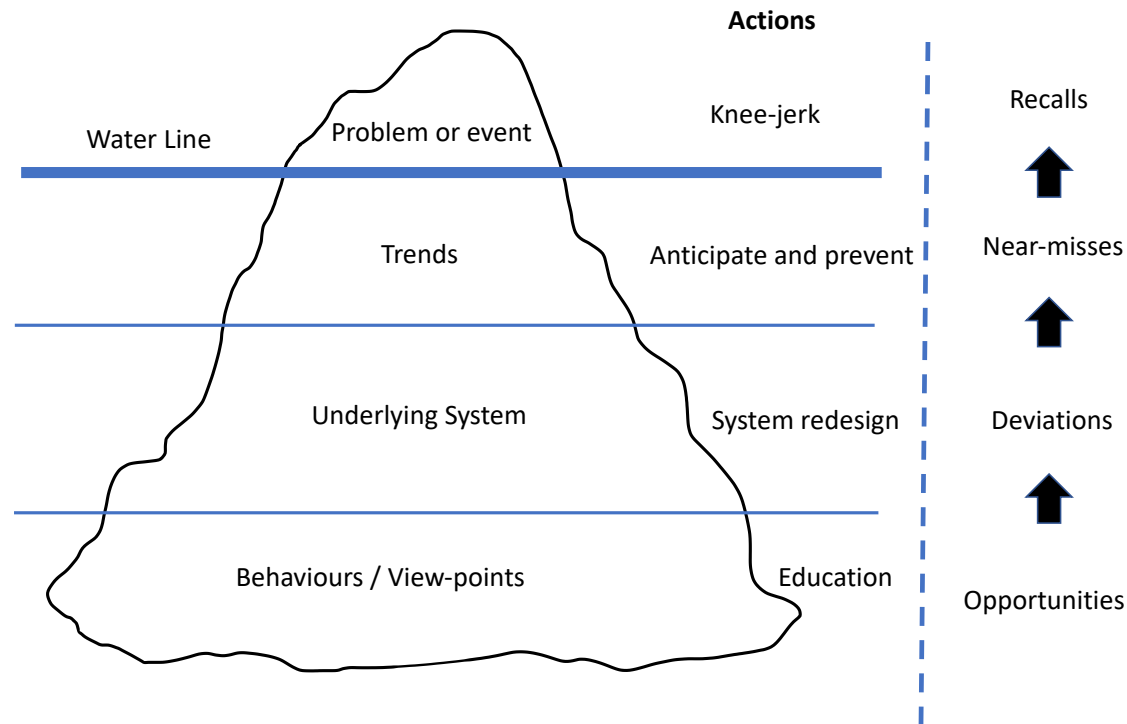
The healthcare setting has been described as well suited to the application of systems thinking due to:-

- **The multiple groups and handover of critical information between them.**
- **Often no one area has ownership of a process.**
- **Often the absence of a natural team that would encourage collaborative working.**

Sound like your Quality organisation ?

Some aspects of systems thinking in healthcare.

Underlying causes that are driven by the system





Unintended consequences of target driving the wrong behaviours.

- An absolute focus on metrics is they can drive the wrong behaviours, sometimes with these unintended consequences. One much publicised example is the UK government's 4-hour accident and emergency (A&E) target set in 2000.
- With creditable intentions to improve patient care a maximum of 4 hours was set between a patient arriving at a hospital emergency department and either admission, transfer to another department or discharge from the hospital. Attempts to meet this target were widely abused by several hospitals.
- Despite over £820 M being spent on A&E departments between 1998 and 2007 it was concluded that the 4-hour target had **no impact** on overall patient care.

Poor targets caused..



- **Tunnel-vision**:- A focus away from other areas which though important were not measured.
- **Adverse selection**:- Avoiding treating the most ill patients who would require excessive amounts of care.
- **Bullying**:- Intimidating staff to achieve targets.
- **Erosion** :- Undermining professional motivation.
- **Ceiling effect**:- _Removing incentives for further improvement beyond the target.
- **Gaming** :- Distorting the data.
- **Distraction**:- Denying data that supports underperformance.

Don't think this applies to your Quality organisation ?

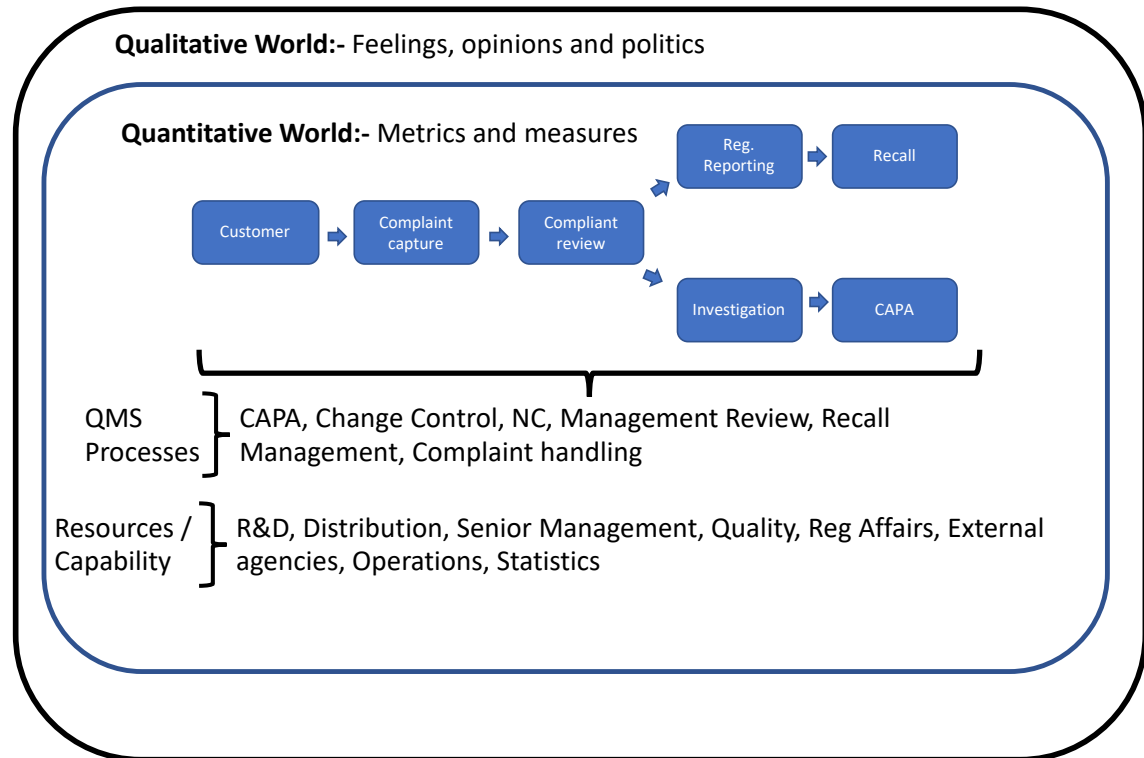
Cobra Effect in the QMS.

- Tracking non-conformance numbers by area often results in under-reporting of issues and driving quality issues under-ground.
- Measuring CAPA cycle time encourages weak investigation and poor corrective actions in the race to close out an issue.
- Monitoring complaint closure rate results in customers whose concerns are never truly satisfied, but whose complaint is closed and therefore 'compliant'.
- Internal audits held for compliance reasons resulting in true deficiencies being hidden, only exposed when the external inspectors arrive.
- End-of-year inventory targets that result in lots being manufactured and shipped that customers do not need or want.

A system under stress

A product recall.

Recall Management Process

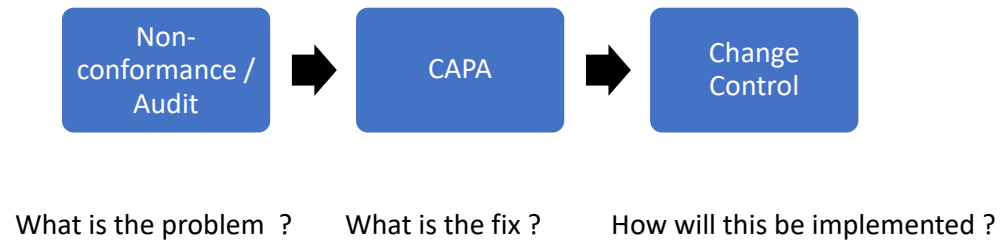


Anyone who thinks that organisations and processes act as machines to live in the daily caldron of a recall investigation. Doing so, they will appreciate that the qualitative world of feelings and opinions is often more powerful than metrics and logic.

Practical tips for dealing with systems

Look at the whole, act on the whole

- You need to see the QMS not as separate systems, but as a whole. In practice it is useful to divide the QSM into constituent parts for ease of analysis, but always have a clear understanding that parts of the QMS are connected, some more than others.



- This is especially important when we cover **Quality System Management Review** in a later module

Is this a problem or symptom ?

- Things to consider include questioning whether the presentation of an issue is the real problem, or are there are more foundational causes hiding below the waterline you need to understand and address ?
- Conversely if the solution is obvious and a delay in not justified, don't get wrapped in the methodology unduly.

The 5 Whys



Try and understand

- You will need to understand the problem, and this will involve asking questions. Questions you don't know the answers to. Not to validate your own views but to truly comprehend. Is this view an opinion or fact ? Can it be verified independently ?
- You need to get to the truth, whether it is an opinion or a measurable fact.
- Perception is reality.
- Listening not to fix but to see.



PERCEPTION



COGNITION



UNDERSTANDING



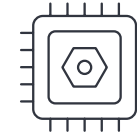
VISION



REALITY



KNOWLEDGE



MEMORY



SENSORY SYSTEM

Does this matter ?

- If you conclude an issue is a real problem it helps if you take a step back and ask yourself does it **really matter** ? You can only answer this question if you put yourself in the customer's shoes.
- As we have covered previously there are potentially many different customers you will need to consider. In addition by satisfying one customer are you dissatisfying another ?
- Conversely you may need to implement changes in one area that may have little benefit, or even have a detrimental impact on this system, but need to be implemented for the greater good of the organisation or another process.
- Your job as a quality leader is to articulate this bigger picture view.





Look for patterns

- When you take systems approach you are looking for patterns in the data that may not tell you much in isolation but may give you an indication of a more, well, systemic issue.
- For example, are errors or defects across the subsystems driven by patterns that may be related to ineffective training. Is there commonality? Are patterns related to seasons linked to staff turn-over or end of year or financial year deadlines?
- The individual data points may not be telling you much but your challenge as a leader is to connect the dots.

Wait for results

- We live in an age of instant gratification, where reward is immediate. This expectancy also pervades business often reinforced by share expectations and the hope of a change of personal or process will create instant success.
- This isn't what happens in a system view of an organisation. Actions take time to take effect and changes bed in, and teething problems to be resolved.
- With the interconnected nature of systems, it may take time for the impact of changes to work through all the subsystems.



Summary

- Treat the quality system for what it is, a system and not a collection of isolated processes.
- Do not expect to influence one part of the system without perturbing another.
- Try to truly understand the system before acting. Look for underlying causes.
- Beware of the unintended consequences of your actions.