Compliance to Performance

How to optimise your
Organisational Culture and
Quality Maturity for Success

Executive Summary

Optimising organisational culture and quality maturity is crucial in promoting consistent, reliable business processes and to minimise supply disruptions. This involves understanding the visible and invisible aspects of culture, and their impact on the quality system.

Organisational culture change requires time, effort, commitment, and alignment with the organisation's vision. Organisations with lower Quality Management Maturity often exhibit outdated procedures, lack of innovation, and high levels of unplanned work, among other traits. To avoid stagnation, leaders must identify early warning signals and take corrective actions. Changing course requires recognition that the organisation is indeed off course, identification of mis-alignments across the organisation that are driving undesirable behaviours, seeking out root causes, and developing and implementing a corrective and preventative plan. This process requires sustained leadership commitment and coordinated effort across the organisation. Implemented well, will drive desired behaviours and culture, enhanced employee experience and as a result, high organisational performance.

Introduction

It is well recognised that regulatory authorities are delving more into the reasons for ongoing supply disruptions caused by quality system issues. There are clear signs and agreement from industry and regulators alike, that the reason for such ongoing challenges needs to be understood and resolved. A number of the regulatory authorities have highlighted culture and behaviours as a clear factor. Indeed, the US FDA has been considering[i] the best mechanism to operationalise its Quality Management Maturity (QMM) Assessment as part of its regulatory oversight of the sector.

US FDA describe[ii] QMM is "the state attained when drug manufacturers have consistent, reliable, and robust business processes to achieve quality objectives and promote continual improvement", but where does culture fit in?

Schein's definition of organisational culture is often referred[iii] to as three levels:

- "artefacts that may reflect culture (for example, symbols and language)

- norms and values about appropriate attitudes and behaviours (espoused or real)

- underlying assumptions and beliefs (conscious or unconscious)."

In short, the visible and the invisible.

If not everything is visible, it is perhaps difficult then to consider what the impact of organisation culture might be on an organisation's quality system, its effectiveness and robustness, even its maturity state. Furthermore, how would an organisation measure the impact of these cultural attributes or go about improving culture to enhance quality maturity?

Why getting it right is important?

What is apparent, is that organisations and regulators alike, understand that there is a very clear link between people within an organisation, their behaviours, and the compliance level, and subsequently the performance of an organisation. This in turn has a bearing on the organisation's success and the cost of quality, but importantly it is a factor in supply chain disruptions and therefore impacts patient outcomes.

Organisational culture change is not something that is developed overnight, or implemented via a set of instructions, nor is it something that can be changed by some minor adjustments to a few people's behaviour. It takes time and effort. Most importantly it takes sustained commitment, unwavering dedication to an aligned approach, robust and constructive challenge to minimise distractions and rapid management of any activities that are out of alignment with the culture transition.

The focus should be on a patient-centric organisation taking collective accountability for quality, driving forward a positive quality culture, underpinned by inspirational leadership and an enhanced employee experience.

Impact on maturity levels

We already know that organisations with lower levels of Quality Management Maturity[iv] tend to exhibit certain traits or characteristics, such as out of date procedures not being adequately or correctly followed, little to no proactive work on continuous improvement, minimal innovation, low level of creativity and higher than average levels of unplanned work resulting from deviations and excursions. Importantly, we have observed organisations in this maturity level to also have a fragmented culture (e.g. hierarchical fractures), lower levels of staff morale and higher levels of attrition.

Furthermore this has, on occasion, resulted in a perceived (or perhaps real) risk of lower levels of fairness, inclusion and/or equality. The link between low quality maturity and poor EDI (Equity, Diversity & Inclusion) staff survey results is a relatively new, but understandable finding resulting from NSF's experience of deploying the QMM Assessment. A concerning state which can often be difficult to get out of.

Spotting the doldrums

When a successful organisation finds themselves in a period of stagnation, much like a sailing ship in a race becoming stuck in the windless waters, it is important to first be able to recognise this within your organisation.

As with all elements of Quality Maturity, leadership is critical in identifying this looming risk. A ship's Skipper for example will be actively scanning the water conditions, the weather and the performance of the vessel and crew, looking out for risks, but in particular looking to avoid the doldrum water belt of listlessness.

The Skipper will be looking for any early warning signals, watching the tell-tales on the mainstay, they will be looking at the performance of other ships in the water ahead, they will be rallying the crew to identify any unexpected changes in activity or performance – working cohesively together to keep the ship operating in an optimal state and on track for success.

To ensure that an organisation does not get into the doldrums in the first place, organisation and quality leadership must identify the early warning signals, the tell-tales, or leading indicators.

These then must form part of the metrics that are considered, monitored and importantly any shifting trends scrutinised. Any indication of the organisation going of course, must be corrected with definitive actions that are well communicated and changes mobilised, inclusively, through teams.

Getting out of the doldrums

Unfortunately, even with active intervention, some may still find themselves sailing far too close to the windless channel, or indeed stuck floating through a period of uneasy calmness, with performance seemingly stalling.

How then can an organisation change course and find the best co-ordinates to sail back to success?

There are a number of steps an organisation needs to take, much like any good investigation:

1. Identification and Recognition

2. Analysis and Assessment

3. Consideration of Root Cause(s)

4. Develop & Implement a Corrective and Preventative Plan

5. Monitor and Check Effectiveness

Sounds simple, and a process most will be familiar with, so why is it so hard to do?

Getting an organisation out of the doldrums, is not just about correcting a process and procedure, although this may also be necessary. It is about changing culture, mindset, the way the organisation works, looks and feels. It is about alignment of the rudder, sails and crew to the Skipper's vision, instructions, and ambitions.

Recognising that an organisation is in the doldrums is perhaps the easy part. Getting it out takes sustained leadership commitment, co-ordinated effort across the organisation and long term dedication from everyone to the agreed end goal.

Getting into the detail

Full analysis and assessment of the organisation's current state is critical to getting the desired outcome. Without fully understanding where the challenges lie, will make it difficult to rectify the situation. Equally, only partial analysis or a segmented view, could result in the organisation following a different and perhaps better than the current course, but still off course for full success.

How much analysis is enough?

This of course is the open-ended question. The answer though is primarily one of scope, not scale.

NSF Experts are experienced practitioners and can obtain a good overview of an organisation and its challenges by taking a broad look (scope). The level of depth (scale) required, may be dependent on a number of factors, such as size and complexity of the organisation or further depth may be needed where corrective action is required. It should be noted that the analysis, is not a compliance review, audit or inspection – although non-compliances or risks should not be ignored – this is a holistic review of an organisation; how it operates, not what it does.

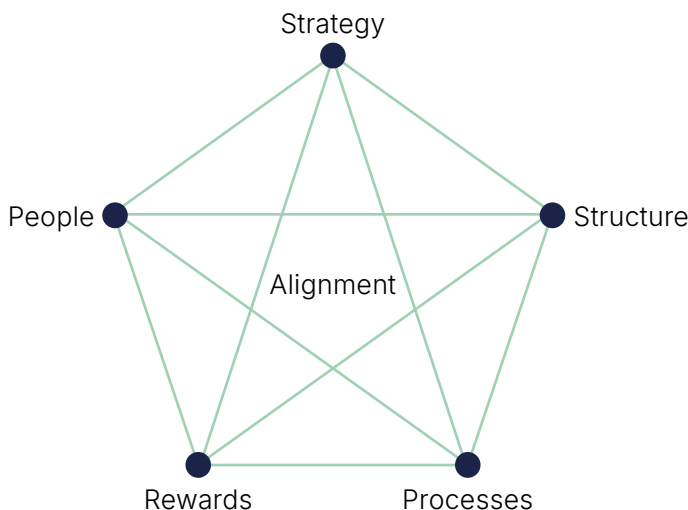As a high-level framework, Galbraith's Star[v] is a useful starting point.

**Figure 1: Galbraith's Star Model[iv]
(Author's adaptation of original).**

- **Strategy** – is about direction. What are the corporate and strategic goals, and how do these drive direction?

- **Structure** – refers to organisational design, authority, and empowerment, but ultimately who has decision-making powers.

- **Processes** – relates to information flows and how they are set up to enable your desired business model.

- **Rewards** – drives motivation and incentivises employees in the direction of your desired business model, vision and outcomes.

- **People** – considers the skills, capabilities, and capacity requirements to support your desired business model.

The aim of the analysis and assessment is to look for alignment, or more importantly, mis-alignment.

First, however, the organisation and its leadership must be absolutely clear on the direction, vision and objectives (business and culture) for the future of the organisation. There must be no doubt on the golden star that the ship is following. This should flow like a golden thread through the organisation – from the vision and mission, through to the organisation and quality strategies, into team and personal objectives. Critically, it must be the guiding light that informs the analysis and assessment.

Work then should commence. NSF has seen many examples of mis-alignment and the following are two examples where clear tensions exist between elements of Galbraith's Star model:

Organisation 1 – Tension between Strategy and Rewards

This organisation had a Corporate Strategy and objectives for high performance and levels of high compliance. In order to manage this, the organisation had implemented metrics to monitor quality activities and leading indicators. One of the measures was "zero tolerance to human error". However, it is well understood that humans make errors. Humans tend not to be perfect, and many strive to be better, especially where a reward is associated to this. As such, metrics and measures such as this one, will unfortunately drive some individuals to potentially hide errors or manage the errors in a non-compliant manner. As a result, compliance issues are hidden, awaiting an inspector to potentially identify them.

Key Learnings:

- Measures and metrics drive behaviours, in this case hiding errors. Behaviours drive culture, in this case driving a non-compliant culture.

- Measures and metrics need to align to the organisation's strategy and objectives. A better metric than zero tolerance to human error, would be to have a team objective/reward strategy to identifying positive initiatives that drive lower levels of human error. In this way accountability is moved from individuals to teams, removing competition between individuals. The reward strategy relates to positive change and behaviours which will lead to a more positive quality culture.

Organisation 2 – Tension between Structure and People

This organisation had been working to enhance and mature its quality culture. It was as an embryonic organisation moving from start up, into the regulatory landscape. As a result, it had invested in a significant number of highly talented individuals to help catapult the organisation into the market. However, the organisation was hampered by slow decision making, backlogs and low staff morale. This was impacting engagement, performance, and importantly creativity and dynamism. Following analysis, NSF identified that the decision making

was still undertaken primarily by the senior leaders of the organisation, organisational structure had not adapted appropriately with the growth and staff development plans were not adequately considered.

There were low levels of delegation and trust in the workforce. The staff engagement data demonstrated that the workforce believed that there was a them and us mentality (i.e. a cultural fracture across organisational hierarchical layers), they felt there were little to no opportunities to exceed or progress within the organisation, and that the few opportunities available, were unfairly managed.

Key Learnings:

- When an organisation is growing rapidly, alignment of the Star model elements needs to be scrutinised more closely and organisational activities and approaches adapted in an agile manner to align to business growth.

- An organisation recruitment strategy to onboard talent, needs to be coupled with, and aligned to, development and retention strategies, that not only look at individual talent growth, but also the environment that the individual's are operating in. It is important to understand what environment is best for individuals to thrive – for example exploring options for delegation, empowerment, moving decisions to the lower levels, supporting risk appropriate innovation and career paths.

Direction setting for success

With a plan of actions identified to create alignment across the organisation, the journey must begin.

It is important to recognise that the leadership – in its role taking collective accountability for the organisation's success – should take seriously any area that has difficulty in maintaining alignment to the desired business performance levels, culture objectives or golden star. The leadership team as a collective should investigate, seek solutions, and work cohesively to resolve any issues or deviations observed. These solutions should be communicated to the organisation and clearly demonstrate that the entire leadership team supports the direction of travel.

Cohesion and unity are paramount when it comes to leadership action and communication.

It may be advantageous to identify role models, to serve as an example of the behaviour and attributes desired from staff within an organisation. Leadership roles naturally place individuals in this role model position. Role modelling provides a basis to set the culture and climate of an organisation.

Role modelling requires those who undertake the role to accept a level of accountability that they demonstrate the culture and values of the organisation. This is critical when in going through a state of flux or change to re-engineer an organisation back to full alignment. How leaders and role models behave impacts the employee perception of the organisation. It can create a sense of empowerment by supporting the establishment of trusted relationships.

It can enhance employee experience, and therefore engagement, within an organisation. It is well recognised that a higher employee satisfaction, leads to higher levels of performance.

In summary

Building a strong quality culture is essential for organisations striving for excellence in performance, compliance, and patient outcomes. It requires a sustained commitment from leadership, a collective accountability for quality, and a comprehensive analysis and assessment of the organisation's current state. By recognising the signs of stagnation, implementing effective strategies, and fostering role modeling and alignment, organisations can navigate the doldrums and set sail towards success.

Learn more about NSF and how we can work with you at www.nsf.org/contact-us
For more information, please contact us at : healthsciences@nsf.org

i   March 2023. Fiscal Year 2022 Report on the State of Pharmaceutical Quality. (2023).
     Available at: https://www.fda.gov/media/169611/download [Accessed 5 Jul. 2023].

ii   Research, C. for D.E. and (2022). CDER Quality Management Maturity. FDA. [online]
     Available at: https://www.fda.gov/drugs/pharmaceutical-quality-resources/cder-quality-management-maturity [Accessed 5 Jul. 2023].

iii CIPD. (n.d.). CIPD | On this page. [online] Available at:
     https://www.cipd.org/en/knowledge/factsheets/organisation-culture-change-factsheet/. [Accessed 5 Jul. 2023].

iv   "NSF's Quality Management Maturity (QMM) Assess model. [online] Available at: https://www2.nsf.org/qmmwhitepaper[Accessed 12 Dec. 2023].

v   Galbraith, J. (2002). The star model. [online] Available at: https://www.jaygalbraith.com/images/pdfs/StarModel.pdf [Accessed 12 Dec. 2023]

The US FDA has been considering the best mechanism to operationalise its Quality Management Maturity (QMM) Assessment as part of its regulatory oversight of the sector.

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