



QUALITY CULTURE FOR THE 21ST CENTURY

IS YOUR QUALITY CULTURE FIT FOR PURPOSE? WANT TO FIND OUT?

by Martin Lush

If you Google 'culture' be prepared for days of reading. Let's just say, for the sake of expediency, that culture is defined by the actions taken, under pressure, when nobody is looking. Like a moral compass, your Quality Culture keeps you heading in the right direction no matter how stormy and unpredictable the weather. With Consent Decrees, Warning Letters, fines and prosecutions running into \$billions, the Quality Culture of some pharma companies, including some big

players, is not what it needs to be. Their compasses are clearly pointing in the wrong direction. So how is your compass? Do you have a Quality Culture capable of navigating a chaotic and unpredictable 21st century?

To find out, grab a few colleagues and complete the following tasks. They will only take a few minutes. Tackle each as if your jobs depended on them. You never know...

TASK ONE: TIME FOR REFLECTION

Let's start with a 'Quality Culture Health Check'. Answer the following with a simple yes/no:

Frustrated by your hierarchy?	Yes <input type="checkbox"/> / No <input type="checkbox"/>	SOPs and documents complex and impossible to follow?	Yes <input type="checkbox"/> / No <input type="checkbox"/>
Suffocated by your bureaucracies?	Yes <input type="checkbox"/> / No <input type="checkbox"/>	Do crisis and fire fights dictate your agenda?	Yes <input type="checkbox"/> / No <input type="checkbox"/>
Exhausted by internal politics?	Yes <input type="checkbox"/> / No <input type="checkbox"/>	Absence of visible and approachable leadership on the shop floor?	Yes <input type="checkbox"/> / No <input type="checkbox"/>
Management not walking the talk?	Yes <input type="checkbox"/> / No <input type="checkbox"/>	Suffering from initiative overload, trying to do too much?	Yes <input type="checkbox"/> / No <input type="checkbox"/>
Decision making ponderous and slow?	Yes <input type="checkbox"/> / No <input type="checkbox"/>	Staff turnover or attrition greater than 5%?	Yes <input type="checkbox"/> / No <input type="checkbox"/>
Insufficient training budget?	Yes <input type="checkbox"/> / No <input type="checkbox"/>	30-day time limit for closure of deviations?	Yes <input type="checkbox"/> / No <input type="checkbox"/>
Management obsessed by profit alone?	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
Suffering from 'death by measure'?	Yes <input type="checkbox"/> / No <input type="checkbox"/>		
Change control system slow, complex and unwieldy?	Yes <input type="checkbox"/> / No <input type="checkbox"/>		

A 'yes' to any and your culture is probably not fit for purpose. A 'yes' to many? Well, your compass (Quality Culture) is taking you in the wrong direction. You need to read on, your job may depend on it...

So, what does a good Quality Culture 'feel like'? Since NSF are lucky enough to have some of the finest consultants around, we asked 10 of our most experienced colleagues "what does it feel like when you walk into a company with a good Quality Culture?"



TASK TWO: THE HONESTY TEST

This is what their combined 330 years' experience has taught them to expect. How do you measure up?

- > A genuinely warm welcome from security and reception
 - > Demonstrable pride and ownership in everything at every level (the workplace, engineering workshop's documentation, the cafeteria). Everything says 'we care'
 - > An environment where people REALLY matter – contractors and agency staff as well as full-timers
 - > Minimal levels of hierarchy and bureaucracy
 - > A clean and well maintained plant. Not necessarily state of the art... just well looked after. From the toilets to the Class 100
 - > Leaders who are modest, visible, approachable, passionate, and informed. Leaders who care about what they do beyond the profit and loss account
 - > A culture that is open, transparent and focussed on excellent face-to-face communications
 - > Rigorous discipline. After all, when you have disciplined people, you don't need hierarchy, bureaucracy or excessive controls
 - > Excellence in the basics of GMP
 - > Patient-centric thinking at every level with excellence in risk-based decision making
 - > A very strong health and safety culture and ethos. GMP and health and safety are different sides of the same compliance coin. Both depend on positive behaviors and habits
 - > Low rates of turnover, typically less than 5%. People feel valued, engaged. They want to stay
 - > Confidence in junior staff and operators, the true custodians of quality. Clear accountability and ownership
 - > Total integration of QA on the shop floor. QA staff who understand the process and operators who understand the Pharmaceutical Quality System (PQS)
- > Total congruency in objectives, actions, measures, rewards. No contradictions that confuse and drive the wrong behavior. 'Quality is non-negotiable'
 - > An obsession with right first time and a passion for simplicity. An intolerance of waste and complexity
 - > Mistakes are genuinely seen as good opportunities for learning, personal development and improving profit
 - > Suppliers and third parties are considered 'one of the family'. An extension of the production line. Treated with respect and valued, not taken for granted

BEST-IN-CLASS PRACTICES

Over the last 27 years NSF has worked in partnership with many clients to make their Quality Culture fit for the future, not the past. A 21st century Quality Culture doesn't just evolve or happen by accident. It is a product of disciplined focussed effort from the top down. As one of our clients put it: "it's 98% perspiration, 2% inspiration". The gurus reckon 4-5 years of disciplined, painstakingly focussed effort is needed. Minimum. Although there is no such thing as a quick fix, we can help make your journey as painless as possible. During our many years of experience we have identified how the best-in-class created a Quality Culture fit for the 21st century.

HOW THE BEST BEAT THE REST

The following is a summary of how the best achieved success. You can find out more at our seminar on 'Quality Culture for the 21st Century' (see page 14). For now just ask yourself how you compare with the behaviors and practices of market leaders:

1. Leadership: Those leading the way:

- > Really 'get it'. They see the PQS as a business management system that extends across the product lifecycle, the entire business. It's considered a profit not a cost center. The PQS is the engine that drives efficiency and improves quality as well as profit



- > Firmly believe that if you do the right things profits will follow. Bad things happen to those who focus on profit alone
- > Have a strong, visible CEO who demonstrably supports the PQS with the total commitment of their site leadership. Walking the talk is more important than emails
- > Management are honest about where they are and where they need to be. Not, 'we've passed the last inspection...we're OK'. More, 'we were very lucky, now let's fix it'
- > They have a broad understanding of the product lifecycle, not just the \$ numbers
- > Leaders who have a 'Value of Quality Story' they share at every opportunity. One that is personal, meaningful
 - 'Patients depend on us'
 - 'Take pride in making a difference'
 - 'Consequences of getting it wrong'
- > They take a mature and intelligent approach to riskbased decision making
- > They avoid the 'pendulum swing' when faced with a crisis. From doing too little to doing too much. They stay on course
- > Accept full accountability. The buck stops here
- > Standardize and then 'localize'. Set standards that provide a rules framework and then encourage local ownership by allowing local interpretation

"Avoid bureaucracy and hierarchy by creating a culture of discipline, accountability without fear and ownership. Create a culture around freedom within a framework, rather than rules issued by central office that are inappropriate for most. Fill the culture with self-disciplined people. Disciplined people, disciplined thought, disciplined action"

– George Rathman, cofounder of Amgen

- > Demonstrate (role model) the leadership behaviors they expect from others
 - > They invest in developing very strong local supervision
- > Ensure there is a direct link between quality performance, incentives and rewards
 - > Success is celebrated and achievements rewarded, large and small

2. Company culture

- > Open and blame-free. Problems are surfaced and sorted quickly, not hidden
- > There is a 'see it, say it, solve it' mentality
- > Attitude that quality extends across the product lifecycle. They design quality in from the start for their products, processes, systems and documents
- > Transparency not secrecy
- > 'Greater good beyond pure profit', not profit at all costs
- > Excellent communication of the quality agenda supported by positive feedback on performance:
- > Face-to-face briefings for the entire workforce
- > Team approach to deviation investigations and continuous improvement
- > Congruency. Behaviors, actions, measures and rewards all driving the right behavior
- > A culture of continuous improvement, not continuous fire fighting

3. Do the basics to PhD level with a focus and passion for simplicity

- > User involvement in the creation of user-friendly documents. SOPs with more pictures and schematics than words
- > Batch records that are thin and functional with fewer check signatures
- > Change control systems that are simple and fast
- > A focus on simplifying the lives of the users, not the system administrators
- > The KISS principle reigns supreme. Keep It Simple Stupid!



4. Organization and people

- > The best-in-class recruit people with the right values, attitudes and beliefs. 'You can train in the skills, it's difficult to change mindset'
- > Induction process that gets across the vital importance of what they do
- > Cross-functional career development. Manufacturing spend time in QA and vice versa
- > QA representation on the executive board. After all quality is business critical
- > Cross-functional teams and meetings. Manufacturing, QA, QC, Engineering, Technical support, Registration, Commercial etc. One team, with one purpose. No silos, fiefdoms or turf wars are tolerated
- > Excellent internal customer/supplier relationships. People understand what others do
- > Risk-aware across all activities. Everyone understands the consequence of 'getting it wrong'. Accountability for product quality, without fear
- > Engagement of the entire workforce in quality improvement
- > Extensive process expertise and knowledge

5. Company mantra 'we can always do better'. A hunger for continuous improvement across all business activities

- > Mistakes are seen as learning opportunities, not an inconvenience
- > Systems in place for sharing knowledge and 'lessons learned', the successes and the failures
- > Acceptance of new ways of working, not 'we've always done it this way'

6. Risk management: intelligent, mature, integrated

- > Mature approach based on process and product expertise not blind, risk-averse compliance. Best-in-class focus on the real risks rather than those imagined

- > A standardized and fully integrated risk management process. Not one 'bolted on'
- > Risk management is central to every business decision. From equipment calibration to due diligence
- > Decisions based on science

7. Excellent change management: to focus resource, stay in control, and say NO!

- > Change control is seen as core business competency, not a compliance activity
- > Used to focus resource on the 20% of initiatives that contribute 80% benefit to quality and business performance
- > Ensures a 'measured' rate of change. Not a chaotic stampede

8. Surveillance and escalation systems. Sensitive, robust, fast

- > Governance structures in place to oversee performance and enforce standards
- > Systems in place that allow data to be collected, interpreted and acted upon quickly. Hours not days, weeks not months to ensure action is taken before it's too late: data relating to
- > Audits and self-inspections
- > Deviation and CAPA
- > Customer complaints
- > Product quality reviews
- > Batch rejects
- > Reworks and reprocessing

9. Systems and measures that reinforce and habituate the desired behaviors

- > Performance measures that drive the right behavior
- > Structures, processes and systems that reinforce desired behavior, not destroy it
- > Audits that offer solutions, not just criticism



- > People encouraged to raise deviations, not punished
- > SOPs that encourage compliance rather than making it impossible
- > Focus on education, not training. Coaching, mentoring, not telling
- > Internal 'Quality Leadership'
- > Education for key decision makers
- > Executive GMP education for senior executives
- > Executive briefings. Staying up-to-date and ahead of the game

10. Education and development: good quality people = good quality products

- > Strategic investment and planning in education
- > Education budget protected no matter what

KEY POINTS

- > A company's Quality Culture is like its compass. It serves to guide it safely through an unpredictable world to a successful future, no matter how bad the weather
- > Those suffering regulatory censure have Quality Cultures that are no longer fit for purpose. Their compass has taken them in the wrong direction
- > Changing your Quality Culture takes strong leadership, company-wide engagement and disciplined execution
- > The commercial and regulatory weather conditions are changing fast. Changing culture takes time and this precious commodity is fast running out. For the sake of all your stakeholders, don't get left behind!
- > The good news is that others have done it. If you want to know more about their problems and pitfalls as well as their successes come along to our 'Quality Culture for the 21st Century' seminar. We will help you learn from the best
- > Having the right Quality Culture will ensure that the Quality of your product remains non-negotiable, no matter what

"Quality is not an act. It is a habit." – Aristotle

ABOUT THE AUTHOR



Martin Lush has over 30 years' experience in the pharmaceutical and healthcare industry. He has held senior management positions in QA, manufacturing, QC and supply chain auditing and has conducted audits and education programs for many hundreds of companies in over 25 countries.

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