



Australian Government

Department of Health

Therapeutic Goods Administration

Driving a GMP / Quality Culture to provide supporting evidence of better business outcomes

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Overview

- What is Quality Culture?
- Why is it the new buzz item?
- Change (Why we have a love / hate relationship)
- Behaviors (we all have them)



Introduction

- Ever wondered why 95% of New Year's resolutions are forgotten by February.
- It is the same reason traditional training methods have little impact on workplace behaviors
- Why the “carrot and stick” (reward vs punishment) approach to changing behaviors doesn't work.



Human behavior flows from three main sources: desire, emotion and knowledge
- Plato



Quality culture – The what

- Quality culture starts with leadership that understands that human behavior and motivations are critical to meeting ongoing quality requirements, and naturally emphasizes continuous improvement of processes.
- Defined as the shared beliefs, values, attitudes, and behavior patterns that characterize the members of an organization.



Business WILL NOT be as usual

- Pressure to make medicines more affordable will intensify.
- Speed to marketplace must improve. Development pipelines will come under intense pressure to make new medicines available faster.
- New science and technology must be embraced.
- Lots more new regulations to comply with? **You Bet!**
- The acute shortage of skilled and experienced people will start to bite hard.
- Uncertainty is here to stay. The unpredictable impact of political and socioeconomic changes, extreme weather conditions, urbanization and globalization will all have dramatic effects.



Why is quality culture so Now...

- The Regulatory Quality Metrics initiative has raised questions about the role of quality culture in driving behaviors vis-à-vis metrics collection and decision making.
- Recent rash of Data Integrity problems discovered by regulators.
 - FDA (15 WLs), EMA (1)
- PDA recent conducted a survey on Quality Culture and has started workshops on the topic.



Change conditions

- When conditions change, so must our behaviors
- You don't have to believe this; survival isn't compulsory
- Those who believe in the old saying
 - “If it isn't broken, don't fix it” are in for a really tough time
- Challenge shatter status quo
 - > Adapt and Improve > Retain Right Behaviors > Prosperity
- Remember, you can't change culture without changing behavior first



Are you too busy to improve?





So WHAT behaviors must we change

To prosper in this unpredictable world, We, Pharmaceutical Industry, Regulators MUST

- Move from rules-based compliance to engagement. Only engaged passionate people make things happen.
- Stop training people and educate them instead. Yes there is a difference. You train your dog but educate your children. We need to know the why, not just the how.
- Stop making the same mistakes (repeat deviation, repeat findings).
- Stop blaming people for errors and fix the systems that created them in the first place.



So WHAT behaviors must we Change

- Get management away from meeting and emails, and onto the shop floor where they add value
- Japanese Genba or Gemba -
- In business, genba refers to the place where value is created;
- In manufacturing the genba is the factory floor.
- In lean manufacturing, the idea of genba is that the problems are visible, and the best improvement ideas will come from going to the genba.
- The genba walk, much like the management by walking around (MBWA), is an activity that takes management to the front lines to look for waste and opportunities to practice genba kaizen, or practical shop floor improvements.



So WHAT behavior must we change

- Replace the addiction to firefight with one of continuous improvement
- Start using science (DATA) and common sense to assess risk, not emotion and assumptions
- Start doing less and excel at doing the basics to Ph D Level
- Wage war on complexity, removing everything that adds no value (all those years of small changes away from what was working when we changed because an operator made a mistake)
- Move from CAPA (corrective focus) to PACA prevention must become the priority
- Stop “death by measure” and focus on what really matters (all those hours pulling the management review data together which doesn’t get looked at)
- Speed up decision making - strike while the iron is hot
- Rebuild trust with regulators No trust = no relationship, more A1 compliance rating and less A3
- Put the patient at the heart of everything (remember you could be that patient)



WHAT doesn't work

Focusing on Culture, not behaviors

To change culture you must first change behaviors; not the other way around

Behavior changes must be small

Those BIG, TOP DOWN grand statements as
“This is how it's going to be” just don't work

Focus on changing small behavior does.





WHAT doesn't work

Small behaviors that matter in reducing repeat problems are:

- Ensuring every investigation take place at the scene of the incident, not from behind the desk. (imagine what would we think if the police detectives did this)
- Making sure every incident is risk ranked within 30 minutes if not straight away (within 1 business day is the industry standard)
- Completing investigation of minor incidents within four hours and majors within five working days (Wow I hear you saying the industry level is 30 days and some even longer)
- Ignoring the term root cause (potential, concurrent) and focusing on the error chain instead
- Prato rule: Making sure 80% of actions are preventive (fixing the system) and 20% corrective (immediate risk reduction) (wow I hear again in Industry it is the other way around, how many preventive actions are in your systems)



Starting BIG or trying to change everything at once

- Our Iceberg is Melting by John Kotter
 - On the surface, our iceberg is melting is a simple story of a colony of penguins facing a dilemma. But contained within the story and the characters is a powerful message about the fear of change and how to motivate people to face the future and take action.
- No sense of priority
- Goal is big
- Impersonal
- Imprecise (such as improving GMP Standards)
 - These changes will be forgotten in weeks



Change for success

- Focus on changing small behavior first
- Such as a commitment to implementing and enforcing “5S” will have a more dramatic impact. It’s precise, visual and personal.
 - 5 S is the name of a workplace organization method that uses a list of five Japanese words
 - § Sort (Seiri)
 - § Set in Order (Seiton)
 - § Shine / Sweeping (Seiso)
 - § Standardize (Seiketsu)
 - § Sustain (Shitsuke)



Trying to Stop an old behavior, rather than start a new one

- Behaviors and habits, over time, become hard-wired
- They can't be removed, only replaced by stronger habits
- The best way to do this is to focus on the new, not stopping the old
- Telling people to stop doing something only reinforces it



Seeking a Result, not a ritual

- When focusing on a result and not the ritual (routine) you will not change behavior.
- Remember “the right process always delivers the right result”.
- Remember all those process validations to verify and have process that is consistent for the products. We follow them don't we.
- Example: Committing to reading more books will be soon forgotten. Implement a ritual (habit) of reading a chapter a day stands a better chance of success.



Giving up to soon

- Changing old behavior (and eventually culture) is hard
- We rely on habits to survive, they are ingrained
- Most people expect immediate results and give up when they don't happen



Not Changing the environment

- Behaviors are dramatically affected by the environment which includes systems, procedures and measures.
- Unless these change, old behaviors will quickly return.
- There are normally three components to Behavior: Motivation, Ability and Habit and just because we in the Pharma industry like to be different we add the Trigger.



So to change any behavior you must

- Be intrinsically motivated to do the right thing and know what the right thing is
- Have the ability to change
 - This means the new behavior must be simpler than the old one. It must take less effort (physical and mental) and less time, otherwise why bother?
 - You must know in detail how and why change must happen.
- The new behavior must then be practiced until it becomes a habit that you do automatically. This involves having all of the components of the habit loop:
 - A Trigger. Something to remind you
 - A simple routine to follow
 - A reward that reinforces the new behavior



Motivation

- Can't force anyone to do something they don't want to do.
- They have to believe that the advantages (benefits and anticipated outcomes) of the new behavior outweigh the disadvantages of sticking with the old behavior.
- Changing any behavior is easy providing people are intrinsically motivated and the new behavior is simple.
- True motivation is intrinsic. It's personal, emotional and deep-seated. Intrinsic motivation requires
 - Autonomy (freedom) over the task
 - § Treat people as players, not pawns
 - Mastery: the desire to continuously improve at something that matters and to make a difference
 - § Mastery is achieved by deliberate practice, repetition and constant, critical feedback
 - Purpose: towards achieving a greater achievement beyond self or your company. A feeling of self-worth and contribution towards a greater good.



Motivation

- When it comes to motivation, timing is everything. As the old saying goes
 - “Never let a good crisis go to waste”.
- A bad regulatory inspection, a product recall, warning letters and other big events are great opportunities to change behavior, reboot habits and improve processes.
- The more painful the event, the more effective the reboot.



Ability

- The key to changing behavior is to make it so easy for people just can't say no.
- Ability means:
 - Having the knowledge and context: the reasons why
 - Having the tools needed to perform the task: equipment, simple procedure and simple systems
 - Removing any barriers that prevent the adoption of the new behavior
 - § Barriers can be tangible (time, money, old procedures and systems, equipment and plant) or psychological (anxiety, discomfort, peer pressure)



Triggers and habits

- We all need reminders, signals, indicators and aide memoires.
- We use them consciously (traffic lights) and unconsciously (hunger pains)
- A habit is formed when people perform the new task automatically.
- We are all creatures of habit when we act without consciously thinking.



A Behavior Change Process that Works

- The following are some of the key ingredients that result in measurable, lasting and meaningful improvements in a GMP / Quality Culture:
- A strong management commitment towards maintaining and improving quality culture. The commitment must be visible to employees at all levels in the organization.
- A safe, fair, trusting and open environment between management and employees about all aspects of Quality Culture.
- An open, feedback environment that is learning and not blame based that allows employees to learn and grow.
- Awareness and encouragement among employees to question why they do what they do.
- A focus on quality desired practice and at risk practice ensuring that focus is not on the lagging quality Indicators.
- A strong, consistent, timely reaction to the discovery of at risk acts, whether they result in defects/noncompliance or not.
- At risk quality incidents are viewed as opportunities to learn, improve and grow.
- A commitment to improving the profile and attitude towards Quality/GMP.
- Increased employee engagement.



Questions

- Time for Questions before I leave you with a quick summary.



5 Main ingredients for quality culture

- Ingredient 1: A mentality of “we’re all in this together” (the company, suppliers, and customers)
 - The company not just as the building, assets and employees, but also customers and suppliers. The goal is consistently win-win-win for all parties.
- Ingredient 2: Open, honest communication is vital
 - An important way to encourage truth-telling is by creating a culture where people listen to one another. This is a culture where open, honest communication is understood as necessary for people to function best.
- Ingredient 3: Information is accessible
 - Information accessibility is at the heart of the work we do. Business leaders should be open about sharing information on the company’s strategic goals because this information provides direction for what we will do next and – more importantly – direction for how to improve



5 Main ingredients for quality culture

- Ingredient 4: Focused on processes
 - Everyone should move away from a “blame the person” mentality to a “blame the process and let’s fix it” approach to problems and improvement.
- Ingredient 5: There are no successes or failures, just learning experiences.
 - An important insight is that failure and success are always value judgements we form after the fact. We can never predict with certainty whether what we do will end up as a success or a failure (or a mistake). We do the best we can based on our current experience, information, and understanding, and something happens.



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