



CHANGING YOUR QUALITY CULTURE AND IMPROVING GMP BEHAVIORS: WHAT WORKS AND WHAT DOESN'T

by Martin Lush

Ever wondered why 70 percent of change initiatives fail, or why 95 percent of New Year's resolutions are forgotten by February? The same reason traditional training methods have little impact on workplace behaviors, and why the "carrot and stick" (reward vs. punishment) approach to changing behaviors doesn't work. In this article, we detail how to really change your quality culture and improve GMP behaviors.

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

– Plato

To get you thinking, take this article to your next team meeting and ask colleagues these questions (we've provided our thoughts in italics):

1. Can you work any harder? Can you run any faster?

Most people we meet simply can't run any faster.

2. Imagine it's 5 p.m. on a Friday. Do you skip out of the office door buzzing with energy?

Finishing at 5 p.m. on Friday is a luxury for many. As for skipping out the door? I can hear you laughing from here.

3. Is your work-life balance good?

For a vast majority, the balance is firmly tilted towards work.

4. Do you believe in the old saying "If it ain't broke, don't fix it?" In other words, if something appears to be working, leave it alone.

We believe that what worked in 2018 may not work in the future. Many regulations, systems,

practices and behaviors are no longer fit for purpose. Maintaining the status quo is no longer good enough.

5. Do you think 2019 will be the same as 2018, business as usual?

Just look at the news. 2019 will not be the same. It will not be business as usual.

6. Does every day go to plan with no surprises?

Many we meet live in a world of surprises. Some have a dangerous addiction to fire fighting and crisis management.

Fact: 2019 WILL NOT be business as usual.

- > Pressure to make medicines more affordable will intensify
- > Price regulation will become the norm, even in the USA
- > 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 and implemented
- > 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



Fact: 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

Now I'm a glass half full type of person. A born optimist in fact, and I strongly believe that if we embrace challenges then we can achieve prosperity:

Challenges shatter status quo > Adapt and improve > Retain right behaviors > Prosperity

Remember, you can't change cultures without changing behaviors first

WHAT BEHAVIORS MUST WE CHANGE?

To prosper in this unpredictable world, we, the pharmaceutical industry, **MUST**:

- > Move from rules-based **compliance to engagement**. Only engaged passionate people make things happen
- > **Stop training** people and educate them instead. *There's a difference. You train your pets but educate your children. People need to know the why, not just the how*
- > **Stop making the same mistakes** (repeat deviations)
- > **Stop blaming people** for errors and fix the systems that created them in the first place
- > **Get management away from meetings** and emails, and onto the shop floor where they add value
- > Replace our **addiction to firefighting** with one of continuous improvement
- > **Start using science (data)** and common sense to assess risk, not emotion and assumption
- > **Start doing less**, and excel at doing the basics to Ph.D. level
- > **Wage war on complexity**, removing everything that adds no value

- > Move from **CAPA (corrective focus) to PACA**. Prevention must become our priority
- > **Stop "death by measure"** and focus on what really matters
- > **Speed up decision making**
- > **Rebuild trust** with regulators. No trust = no relationship
- > **Put the patient** at the heart of everything

You probably have a few culture change initiatives along these lines already in process. But here's the scary part:

70 percent of change initiatives fail

Ref: MacKinsey & Co and Harvard Business Review

CHANGING BEHAVIORS: WHAT DOESN'T WORK

Focusing on Culture, Not Behaviors:

To change culture you must first change behaviors; not the other way around. Behavioral changes must be small. Big, top-down grandiose statements such as "This is how it's going to be" just don't work. However, focusing on changing small behaviors does.

The small behaviors that matter in reducing repeat problems are:

- > Ensuring **every** investigation takes place at the scene of the incident, not from behind a desk
- > Making sure **every** incident is risk ranked within 30 minutes
- > Completing investigations of minor incidents within four hours and majors within five working days
- > Ignoring the term root cause, and focusing on the error chain instead
- > Making sure 80 percent of actions are preventive (fixing the systems) and 20 percent corrective (immediate risk reduction)



Starting Big or Trying to Change Everything at Once:

When you have no sense of priority. When the goal is big, impersonal and imprecise (such as improving GMP standards), it will be forgotten in weeks. If you want success, focus on changing small behaviors first, such as a commitment to implementing and enforcing '5S' will have a more dramatic impact. It's precise, visual and personal.

Likewise, don't waste time on improving SOP compliance as an initiative. It will fail. Focus instead on applying our rules of 'brutal thinking' (document simplification) and ensuring you have an FC readability score of 80-90. I will cover this on our course. www.nsf.org/training-education/training-entry/changing-gmp-behaviours-1864025

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 on stopping the old. Telling people to stop doing something only reinforces it.

Seeking a Result, Not a Ritual:

When you focus on a result and not the ritual (routine) you will not change behaviors. Remember the Toyota way where "the right process always delivers the right results." Committing to reading more books will soon be forgotten. Implementing a ritual (habit) of reading 20 pages a day stands a better chance of success.

Giving Up Too Soon:

Changing old behaviors (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. Even simple behaviors take weeks to change. Many months of focused effort are required to change complex habits. You have to stick with it.

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.

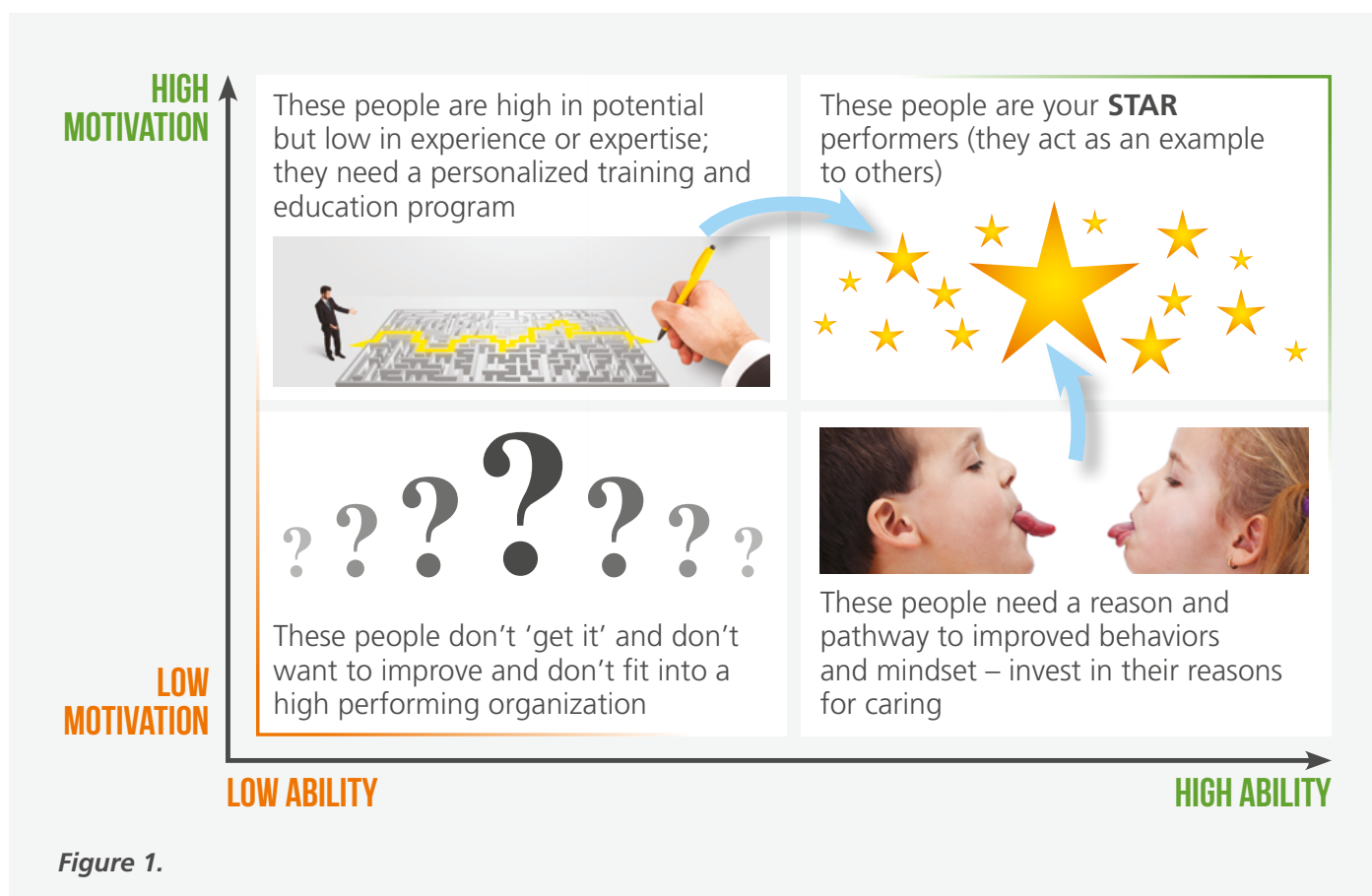


Figure 1.

CHANGING BEHAVIORS: WHAT WORKS

The Fogg Formula: B=MAtH

BJ Fogg, a behavioral scientist at Stanford University, identified three components to behavior: motivation, ability and habit. We have added a fourth component that really helps us in Pharma – the trigger. So, to change any behavior you must:

- > Be intrinsically **m**otivated to do the right thing and know what the right thing is
- > Have the **a**bility 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 **h**abit that you do automatically. This involves having all of the components of the habit loop:
 - A **t**rigger. Something to remind you
 - A simple routine to follow
 - A reward that reinforces the new behavior

Different people have different needs – and our coaching and support needs to be customized to get the most from the people around us. (See Figure 1.) The reality is, however, for some people the disciplines and technology associated with pharma industry simply doesn't jive with them. They may never fit within your high performing team.

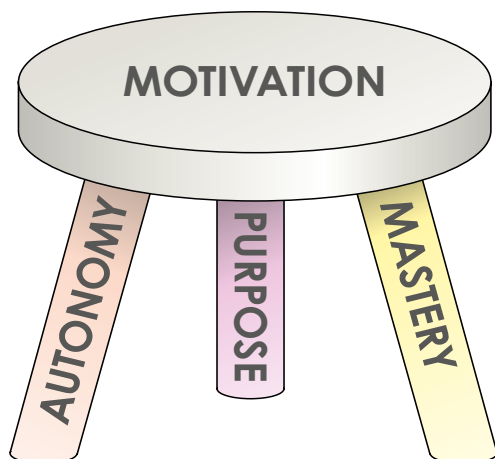


Figure 2.

MOTIVATION

You can't force anyone to do something they don't want to do. People 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, mastery and purpose (see figure 2.):

- > **Autonomy** (freedom) over the task:
 - Treat people as players, not pawns. When you hire good people, just leave them alone. Good people need freedom, not rigid instructions
 - Google employees have one day every week to work on something they choose. Half of Google's new products and offerings come from this day of autonomy
 - Gallup's extensive research on motivation in the U.S. shows 50 percent of employees are not engaged at work. In fact, nearly 20 percent are actively disengaged. The cost of disengagement? Gallup reckons about \$300 billion p.a.
- > **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** toward achieving a greater achievement beyond self or your company. A feeling of self-worth and contribution toward a greater good
 - The behavior must be consistent with their self-image and must not violate personal standards
 - The emotional reaction to performing the behavior must be more positive than negative, and must be more socially acceptable with peers than the old behavior



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 behaviors and reboot habits. The more painful the event, the more effective the reboot.

ABILITY

The key to changing behavior is to make it so easy 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** procedures 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

We all need reminders, signals, indicators and aide-mémoires. We use them consciously (traffic lights) and unconsciously (hunger pains) every day. Help your staff develop the right habits by providing the right reminders, thoughtfully applied and at the right time and place.

HABIT

A habit is formed when people perform the new task automatically. We are all creatures of habit when we act without consciously thinking. Driving to work, brushing your teeth, etc. In fact, 40 percent of the decisions we routinely make are habitual.

- > Habits are vital to our very survival. They free up valuable thinking time for the really important decisions
- > Habits are the product of pure repetition. The more we practice, the stronger the habit.

The number of repetitions depends on the complexity and the person. The greatest gains come from the earliest repetitions. Dedicated practices in the first 20 hours is critical

- > Once formed habits can't be broken, simply replaced with a stronger habit
- > Under conditions of stress, the strongest habit rules supreme

Remember, brutal simplification usually precedes behavior change. The following references will help:

<http://www.nsf.org/info/pbwebinars>

<http://www.nsf.org/newsroom/nsf-pharma-journal-issue-36-2018>

A BEHAVIORAL CHANGE PROCESS THAT WORKS

NSF has developed a unique five-step behavioral change process that works, which we share in our training course:

STEP ONE:

Identify the specific behavior you want to change using our simple diagnostic tools.

STEP TWO:

Understand what drives the old behavior. We will show you how to use the Klein process and other methods.

STEP THREE:

Get people motivated. We will show you how to assess and improve the three levels of motivation (autonomy, purpose, mastery).

STEP FOUR:

Create the ability for the new behavior. You will practice some brutal thinking and other simplification tools and techniques.

STEP FIVE:

Make the new behavior a habit. You will learn how to create memorable triggers, simple routines and rewards that reinforce the new behavior.



YOUR CALL TO ACTION

We have conducted many customized, in-house and residential courses for clients using this five-step process and our behavioral change tool kit. Significant improvements in SOP compliance, housekeeping and dress discipline, right-first-time and deviation investigations were all achieved.

Changing GMP Behaviors

If you want to succeed in changing behaviors and improve your quality culture, this course is a must!

You will leave with:

- > A detailed understanding of what drives behavior
- > A set of tools and techniques that you can use immediately to improve workplace behaviors
- > Access to free NSF resources and support to help achieve success in the workplace
- > The knowledge on how to change your own behaviors and habits
- > All your questions answered. Guaranteed.

Visit our website to learn more about our [pharma training](#) offerings.

Don't miss out!

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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