Ewan Norton IPA Conference Presentation Summary (November 2018)

Overview

Organisational culture can have a massive impact on a company. Can impact the way you dress, talk, act and even think. We all want to fit in and it can change the way we deal with situations in work and with our friends or when we're in a team. Example shown is outside work e.g. hipsters - despite all being individuals and wanting be trend setters and individualistic, they all end up looking the same!

There's a famous quote from Peter Drucker about Organisational Culture eating Strategy that is very true. If you get the wrong culture for your company, it can ruin any strategy that you have. Gave an example of how a company has good excellent analytical systems and good data integrity, but senior member of staff told person to not take the cleaning sample correctly (in a highly potent facility). The 'data integrity' would look perfect, but the 'data authenticity' would not be there and patient safety would be risked.

Companies have to work hard to get the right culture, you can't just state that this is going to be your culture and expect it to happen. Google had a company motto of 'Don't be Evil' and you can decide for yourselves how successful they were in achieving that.

How YOU Impact Your Organisation's Culture

You can argue that if you work for a large company you may not be able to change the culture, but you can change the culture within your sphere of influence….

Video of inspection planning sketch.

The video was filmed on my smart phone in my brother's house and features my brother, my wife and my 8 year-old nephew and I edited it on some software I downloaded from the internet. I'd like to thank my family for their help.

Just think about the signals that you send out – your staff get their lead from you and if you just appear to be paying lip-service to quality and trying to get round it at any opportunity, then do you really expect them to have integrity when it comes to their interactions with their staff or do the right thing when no-one is watching?

But if you do the right thing, you can influence the culture in the area around you and your staff will be more likely to follow your lead.

You should know that every action proposed in the video has happened during an inspection…

It does need senior management guidance to change the overall company culture, but that shouldn't stop you making a difference in your local area.

Using the data, you can get to Knowledge and then maybe even on to Learning i.e. knowing what will happen next and how to deal with it.

- **Don't Do It Again!**

Human error as a root cause should be infrequent. If you have lots of deviations with that root cause, it means that you've not been investigation properly. All you're doing it going for an easy route and blaming the person. Nobody comes to work to do a bad job and most likely there will be a process, procedural or systems based error

that leads to the mistake. If you come up with a 'Human Error' root cause, all you are doing is blaming the person and 'white-washing' over the issue. But as you didn't fix the issue, it will happen again… you'll tell the person 'Don't do it again!', but it's just more white-wash, and it'll happen again! Then the person will be on a written warning and they'll possibly lose their job for something that's not their fault. So you'll probably drive them to hide issues and that can lead to serious data integrity and cultural issues in your organisation.
There should only be a handful of deviations that have a 'Human Error' root cause.

When you assign a root cause as 'Human Error', all you're doing is making the person a Scape Goat. In the Jewish religion, a Rabbi could ceremonially transfer the sins of the people onto an (innocent) goat and then send it out of the village into the wilderness (to die).
All you are doing when you blame a person, is transferring the *sins of the company* onto an innocent person and ultimately you may end up sending them out in the wilderness as well…

A lot of companies are starting to look at Error Chains during investigations. Your process can be sailing along without any issue, but little do you know that somewhere below the surface a significant problem is developing. It's only when it break the surface that you are aware of it and your process runs aground. If you look at the chain of events that has caused the issue, you'll see that the last couple of items in the chain are related to humans (as they're the ones actually doing the process). But if you do a proper investigation, you'll see that the issue was probably caused by poor processes, systems or procedures… but if you really delve deep you'll see that often the real root cause was in fact the 'Culture and Leadership' of the company. A review of plane crashes that I'd read highlighted between 6 and 13 links in the chain that lead to these crashes… any one of them being fixed would have prevented the accident. You can stop an issue happening by breaking any of the chains. However, the further down the chain you break it, the more issues you ultimately prevent!

We then watched a PowerPoint slide show about a packaging line with 100 containers going past at about 1 a second. The test involved everyone and they had to watch the slides and record the number of poor prints, the number of batch number errors and the number of expiry date errors. Typically no-one got all the results correct and I took the easy route and blamed the people and gave everyone a formal written warning and told them 'I was disappointed with them and not to do it again!!!'. The truth of the matter was not that the person was to blame, but actually they were asked to do something that was physically impossible as the human mind can only retain 7 (+/-2) bits of information at a time and this 'test' required you to retain about 14. Therefore the process was itself was to blame, not the people.
I'd like to thank Martin Lush from NSF for this test and if you'd like advice on how to generate one of these that's specific to your own company, then please contact me on ewan.norton@mhra.gov.uk.

A common thing that is being seen now is a questionnaire that makes a person have to answer a significant number of questions before a human error can be assigned (sometimes up to around 7 pages). What happens is that it is so much effort to identify a deviation as a root cause, you might as well just investigate the deviation properly in the first place. When I see this applied properly at a site, it gives me confidence that they are trying to get to the proper root cause.

When you stop blaming the person and look for the real causes (or links in the error chain), you end up with good fixes to the problems, little or no recurring errors, a workforce that knows that fixes will be made and they are confident that they are valued. This leads to a much better culture within the company and a better working environment.

- **Education *(not training!)***

  We are a generation of people that don't like to wait to get the information we're looking for. We have been brought up to get information almost immediately and aren't used to search too hard to find it… asked audience to think of the amount of time they'd wait on a website to load and also how long a delay to the loading of website pages cost Nordstrom 11% of sales. The answers are - 3 seconds and 0.5 seconds respectively.

  We're so used to getting information fast – if you do a Google search for Knowledge Management, Organisational Culture and MHRA you see how many hits you get and how fast it took, especially considering that they are ranked according to what they system thinks you want. Important to note that the searches are so good that you will almost certainly get what you're looking for in the top ten hits!

  Only 50% of people look beyond the third hit on the google search results and only 9% go to page 2…

  There was an internet meme on the best place to hide a dead body… page 2 of Google search results. We're a generation of people that has the information they want at their fingertips.

  We like the path of least resistance and don't like having to go out of our way to get what we want - as evidenced by the little shortcuts we take when walking that can only save a second (if that)!

  It's useful to realise that only 20% of what's needed by people to do their jobs is written down. The other 80% is in our heads. We're also dealing with a generation of people that have never read a manual and rarely read anything longer than 140 characters. British chef Rick Stein has written 26 books but when he wanted to learn how to make an apple strudel - he looked up YouTube. That is what most young people do these days.

  I have seen a situation where one person had read 87 SOPs on a single day and signed to say they had understood them all! When you bring new people or 'on-board' them as some companies call it, don't lock them in a room and shove SOP after SOP down their throats. That's not learning, it's not even training it's more akin to 'water-boarding' than 'on-boarding'.

  Think about going to a restaurant – how many times have you asked what the soup is and the person goes 'I don't know – I'll just to check' or if you ask if there's an ingredient in that you're allergic to, or can't eat for religious reasons and they go 'I don't know', or 'I *think* you'll be okay'! Everyone in the kitchen knows what the soup is, or what the ingredients are - so why don't the people at the front of the house know?

  Then compare that to a restaurant where the person can recommend things to go with what you're having, they know what each item is and can tell you what they taste like and whether you'll be full if you just have the main… The food tastes exactly the same, but the whole experience is better and you have much more confidence about the evening.

All the restaurant has done is have sessions at the start of the day where the chefs and the waiters get together and they taste the food and explain what's in it and what each element is. The waiters enjoy themselves more, are more engaged, you're happier with the experience and will spend more money and will probably come back and recommend it to other people.

Now imagine that analogy to your workplace…

Knowledge (*swinging lightbulbs*) should flow from one person to another, but knowledge is actually quite sticky!! It won't travel far from you if you're not given the opportunity to share it. It's not that you don't want to share it… it's just that you don't have the time to do it as you've got other priorities. But if you give your staff times to meet with each other on a regular basis to discuss specific items, the knowledge flows naturally. Otherwise it just sticks in the same place… We have done this in the MHRA over the last few years by introducing compulsory monthly team meetings and giving people topics to educate others on and a forum to share their issues and experiences with the other inspectors. I can honestly say that I now know more, enjoy my job much more, am more confident and am a better inspector because of this.

- **Management Review**

As inspectors, we are trained to take 'data', convert it into 'information', then knowledge and if then the panacea would be to take it to 'learning'. We expect the site to have done this with their data, but very often they never go beyond the 'information' stage and so you see management reviews with pretty graphs with nice colours that say things like 'there has been a 16% reduction in Minor deviations and therefore we are doing much better'. But this doesn't take into account what the deviations were, what were repeats, whether they show trends i.e. whether they are on a particular product, or shift, or item of equipment, whether the root causes were similar etc etc. The sites are just not generating Knowledge that they can act upon and therefore try to improve things for the workforce. It sometimes appears that the management review data is being gathered because there is a regulatory requirement to do this, not because the benefit to the company and patients is understood!
We also see tick-box exercises for self-inspection (internal audits), where each time someone just goes around with a list and ticks off each item e.g. desks clean… bins empty…. computer screens locked etc etc. They aren't encouraged to look around, ask questions or try to understand the process. When I see I tick-box self-inspection form during an inspection, I begin to anticipate that there will be issues observed… Y

When people work for a company that understands the benefit of the information available to them, they see improvements being sought out and happening and aren't left dealing with the same issues day-in/day-out and are motivated to raise issues and believe that the company will strive to improve.

Real Life Examples

- **Example 1**
The slide was presented and then the attendees were asked what classification of deficiency the MHRA would give if:
    i) The MHRA identified this and the company hadn't?
    ii) The site had identified it and handled it appropriately?
The attendees were also asked what they would do if they found this issue. It was expected that the initial step would be to raise a deviation to investigate the issue.

It was explained that in case i), it would probably be identified as an 'Other' deficiency – the lowest classification.
In case ii), if the site had raised a deviation and investigated it appropriately then there would be no deficiency at all.

The approach actually taken by the company was explained: multiple people from a number of departments were found to have falsified records in an attempt to cover up that the issue had ever happened. This resulted in a Critical deficiency being raised.

This is a particularly powerful example of the impact of Organisation Culture - in this case, it would have been easier and quicker to do the correct thing and it was actually harder and involved more effort, to do the incorrect thing!

- **Example 2**
  This company had serious difficulties and a poor inspection history due to the items presented. It would have been easy to identify individuals as the root cause for the issues identified, but a more detailed review would suggest the organisation culture was not appropriate.

- **Example 3**
  Integrity was hit for '6'.
  A very recent independent report (October 2018) was issued on the ball tampering issue by Australian cricketers whilst playing against South Africa.
  The report highlighted themes that are common from above… Cricket Australia (the governing body) paying lip service to culture, when the issue was found the staff were punished, Cricket Australia placed too much emphasis on winning.
  The parallels to the points covered so far are clear…

  Interestingly the report states that the cricketers were asked to sign a 'Players Pact' to respect the game's tradition. It says that similar initiatives in the past have not been successful. It was highlighted that when a company identifies data integrity issues that one of the first things they typically do is to get staff to sign a document saying that they won't day anything like that… however, unless that is accompanied by significant efforts from the senior managers to change the culture, all that is happening is that the people are being blamed again for the issues…

Conclusions

The conclusions are as presented. It was noted that it can take a number of years e.g. 3 to 5 change the culture of a bad company and this requires serious commitment over that period from senior managers.

Thank You

Thank you for listening.