



DEVIATION AND CAPA SYSTEMS

DISPELLING SOME MYTHS THAT WILL TRANSFORM YOUR SYSTEM!

If you think you've already read one article too many on this subject, please don't turn the page until you've considered how you feel about the following:

- > When investigating deviations please make sure you don't focus on finding 'root cause'... it simply doesn't exist. The concept of a single root cause is a myth
- > Never treat every incident the same. To do so is actually dangerous!
- > If your policy allows 30 days to 'close out' investigations hang your head in shame...you clearly don't take deviations seriously
- > Do your metrics actually encourage people to report incidents? If so, great...you clearly do understand their importance!
- > If you routinely complete investigations from behind a desk one thing is guaranteed...your diagnosis of the problem and prescription for those CAPAs are probably wrong
- > One last question for those of you involved in deviation investigations...do you really have expert, almost intimate, knowledge of your products and processes? If you don't, investigating 'quality incidents' is a risky business – a bit like a surgeon wielding a scalpel without an expert understanding of human anatomy

'How to Simplify and Improve Your Deviation and CAPA System' is one of NSF's most popular 'in house' courses. Why? Well, our clients tell us they actually get what it says on the tin. Not only do we provide simple tools and techniques that dramatically improve efficiency, we also dispel a few myths. Here is just a sample:

MYTH 1: EVERY DEVIATION HAS A 'ROOT CAUSE'

Fact: There is no such thing as root cause. Most incidents are due to multiple 'contributing factors'

One of the biggest failings in most deviation investigations is the tendency to look just for one 'root cause'. A single event that led to the deviation; 'human error' or 'procedural non-compliance' are two of the most common. This is very rarely the case; there is seldom only one single root cause or single event but rather a number of contributing factors that must queue up in a particular pattern before the incident happens. To prevent the incident happening again you need to remove as many of the contributing factors as possible, not just one 'root cause'.

Contributing factors may include:

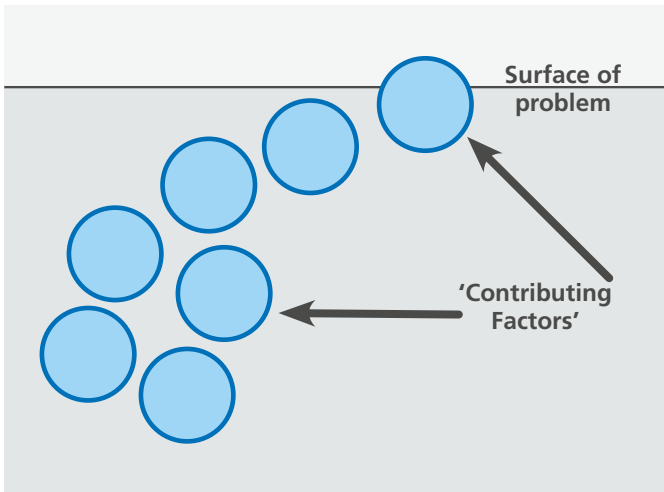
- > Physical (poor plant layout, working conditions, multiple distractions)
- > Procedures that are too long, poorly designed, complex, written for the regulator not the user and therefore totally unworkable
- > People who are poorly trained, managed, demotivated and disengaged
- > Processes that are poorly designed and unreliable

HINTS – SO REMEMBER:

- > Think about multiple contributing factors, NOT one single root cause. Deviations are never that simple!
- > Start digging and don't stop at the first and most obvious contributing factor. The devil really is in the detail
- > First list the contributing factors supported by data or scientifically sound assumptions



- > Is there an obvious sequence of events?
- > Focus your attention on those contributing factors which have the biggest impact, NOT on those easiest to solve
- > Remove the term 'root cause' from your vocabulary and your procedures!



MYTH 2: 'ONE SIZE FITS ALL'. YOUR SYSTEM SHOULD TREAT EVERY DEVIATION THE SAME WAY

Fact: Don't! Deviations must be investigated proportionate to risk

Treat every incident the same and you're likely to suffer from deviation 'blindness', the symptoms of which are familiar to many:

- > Deviation 'overload'
- > Lots of repeat incidents
- > Really important incidents going unnoticed
- > Human error often seen as the most probable and convenient 'root cause'
- > Periodic, corporate-led initiatives such as a 'war on deviations' to close out reports and balance the books. At least for the short term

Failure to 'risk prioritize' incidents is not only inefficient but dangerous. Although you must rally your troops to focus on the 'major' deviations, those that pose greatest risk, you can't afford to ignore those of lesser importance, the 'quality incidents'. They also have to be addressed but in a way that is proportionate to risk.

HINT:

Every incident must be 'triaged' based on risk, and the sooner the better. On our course we demonstrate how this can be done quickly and efficiently using very simple, easy to use, customized 'impact assessments'. Designed with care, these ensure the right questions are asked and data gathered before decisions are made. Our clients tell us this approach has dramatically improved the accuracy and speed of their decision making, vital in the triaging process. The result? Faster, more thorough investigations and less repeat incidents.



MYTH 3: 'CLOSE OUT WITHIN 30 DAYS'

Fact: Allowing 30 days is at least 25 days too long!

Just imagine you're jetting off to your holiday destination, 'ash cloud' permitting. The cabin crew complete their usual welcome and mention a few 'technical problems' to boot. They reassure you that fixes have been identified (CAPAs in pharma speak) and that these will be 'closed out' in 30 days. I think most of us would be running for the emergency exit! In other industries, where deviations and failures can impact on customer safety as well as cost, the number one imperative is to get them sorted, and quickly. The fact that many pharma companies allow the luxury of 30 days is, quite frankly, staggering. A 30 day limit says to people "don't worry, this isn't that important..."



take your time". And they do. In practice we want the complete opposite. Incidents must be investigated sooner rather than later to minimize risk, prevent recurrence and improve the process. All are achievable providing the investigation is done quickly.

HINTS:

- > Make sure every 'quality incident' is reported immediately and triaged within hours using customized impact assessment forms
- > Lower risk 'quality incidents' need to be closed out within hours, 1-2 days maximum, whilst those intimately involved with the incident are around, available and interested. Leave it any longer and both memory and interest fade, resulting in a superficial investigation generating CAPAs that fall way short of the mark
- > Deviations that require a more extensive investigation should be closed out within 3-4 days for the very same reasons. These will clearly take longer since they are broader in scope and potentially present greater risk to your patients and business. Longer yes, but not too long. Remember, the longer the close out period the greater the risk to your business. Memories fade, interest is lost and risk increases. Sometimes dramatically

MYTH 4: METRICS THAT ENCOURAGE PEOPLE TO REDUCE DEVIATION NUMBERS ARE GOOD!

Fact: They are NOT! Such measures potentially encourage the wrong behaviour

We all know that we need accurate 'performance measures' to make the right decisions. What most people don't know is that before selecting any performance measure you must first decide on what behaviour you wish to encourage...then select the most appropriate measure. When encouraged to 'reduce deviation incidents' people usually oblige and incidents appear to decrease in number. Often overnight. Such a measure may encourage under reporting of incidents, particularly if a blame culture is alive and kicking.

HINTS:

- > If you want a good 'performance measure' for deviation systems, one that drives the right behavior, consider one or more of the following:
 - Number of repeat incidents (these should be few and far between)
 - Time taken to raise, report and investigate (the quicker the better)
 - The ratio of 'quality incidents' to 'deviations'. Fix the incidents and the number of deviations will fall...hence the ratio change
- > Change your attitude! Deviations are good news, not bad, providing you learn from the experience
- > If you really want performance measures that drive business improvement, why not consider coming to our course 'KPIs and Performance Measures for Quality Systems'?

MYTH 5: DEVIATIONS CAN BE SOLVED FROM BEHIND A DESK

Fact: They can't! Never, ever

If you want to fix incidents for good you must go to where the action took place and the sooner the better. Although 'desk based' investigations are quick and convenient, the resulting CAPAs are usually based on assumption with a bit of good old fashioned guessing thrown in. The incident ultimately happens again and you end up paying dearly for this false economy.

In Kaizan language the Japanese have a term for this called 'Genchi Genbutsu' ('Go to where the action is'). In North Yorkshire, where people are refreshingly blunt, we call it 'GOYA'.....Get Off Your A*se.



IN SUMMARY

Deviation and CAPA systems exist for two very simple reasons. When 'stuff happens' we rely on the system and the people operating it to assess risk and protect our patients. These unplanned incidents also provide a fantastic opportunity to not only prevent recurrence but to actually learn from the experience and improve business processes. Unfortunately, this is often not the case...some myths seem to have confused our thinking and compromised our ability to manage deviations intelligently.

If you would like help in dispelling a few more myths and dramatically improve the effectiveness of your deviation system, why not give us a call? We can help you to...

- > Prevent incidents happening again
- > Design impact assessments to triage incidents quickly
- > Report and risk prioritize incidents in hours so you focus resources where they are needed
- > Identify CAPAs that hit the mark
- > Close out reports quickly
- > Track and trend open CAPAs to ensure prompt closure of reports
- > Make sure your deviation system drives continuous improvement

If you would like us to come to your company to help you improve your deviation and CAPA program, either by focussed consultancy or through training of your key staff, please call us.

For more information, contact pharmamail@nsf.org or visit www.nsfpharmabiotech.org

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