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Inspection Readiness - are we there yet?

(or 'How to avoid that heart sinking moment when you know that an inspection is imminent')



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Tower Mains Training
20 November 2018

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Objectives

- To ensure:
 - That participants are aware of:
 - What they should prepare
 - How they should prepare
 - When they should prepare
 - Can we do it? YES, WE CAN!



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The Boy Scouts are taught to be prepared at all times. They carry a pocket knife and a piece of string, just in case they ever need one. I do remember my son aged 10 being picked up at Scout camp on our way to go on holiday. He'd been at the camp for 2 weeks and over that period he and his fellow Scouts hadn't changed their clothes ever and they only pretended to get washed and clean their teeth. You try sitting in a car for 600 miles in the middle of summer with a boy who has had the same socks on for 2 weeks. We had to stop at the first garage we came to, bought a pack of baby wipes and he was instructed to go the toilet, take off his clothes and double bag them, clean himself all over with the baby wipes and get dressed in clean clothes. Despite all that we still had to drive with the windows open in order to breathe. I'm not entirely sure what he thought he was preparing for...

So, preparation for an inspection

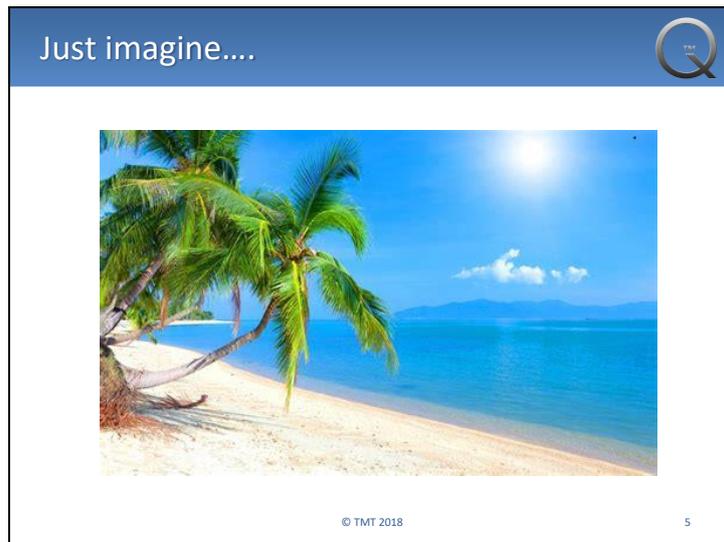
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What to prepare

- When a company is getting ready for an inspection folk rush around writing SOPs, creating forms, reviewing TMFs and completing Notes to File, etc
- It's a stressful time for everyone
- The Inspectors aren't fooled by all this activity
- So, if you feel stressed.....

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Just close your eyes and imagine yourself lying on this beautiful tropical beach with the sun warm on your body and not a care in the world. You can hear the waves as they come to shore and move away. Waves of relaxation and peace. Just breathe in that beautiful, tranquil air. Just feel those negative ions going into your lungs and then to every cell in your body and finding your brain and your body relaxing.... And open your eyes.

How would you like to feel this relaxed, knowing that you were about to be inspected.

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- Accountability
 - Each process and activity is a named person's responsibility
 - Planned oversight of activities (sponsor or vendor) is proactive and reactive
- CAPA result is quality improvement rather than just resolution of an issue
- All important issues are storybooked
- Handovers are documented
- We control removal/addition of documents to TMF

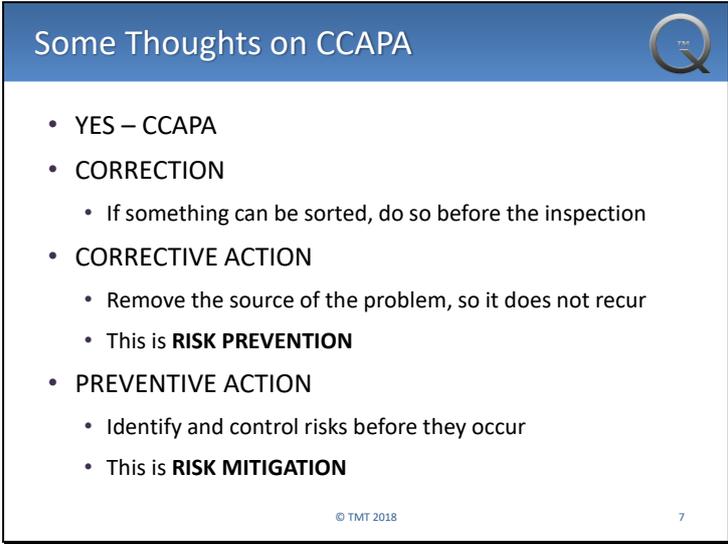
If we make named persons responsible for tasks, activities, whole or part processes, documentation and the collection, reviewing, reporting and filing of said documentation and we give them training and we give them clear instruction and pathways on which to move forward then we are half way there. So, what stops us? Poor communication, too much work, not enough clarification of responsibilities, poor handovers, poor management skills,

not enough appreciation for a job well done and people leave. I read somewhere recently that a CRAs term of employment with a company is around 14 months. How can we know what we need to know if the person with all the details has gone without passing these details on? We can try to reconstruct details but that's not the hard evidence that the inspectors are looking for. So, what can we do about that? We can ensure that all important issues or events are captured in detail – always thinking about what we might need tomorrow rather than just today. We can ensure, as far as possible that handovers are documented before a team member leaves, even if the new replacement hasn't yet arrived. We empty their heads of everything we need or are likely to need and we document it.

Completing information on issues and filling in the holes uses up a huge amount of resources when preparing for an inspection, so it really pays off to get this information beforehand.

When an issue occurs and becomes the focus of a CAPA we generally aim to resolve that CAPA and to ensure that it can't happen again. However, this is only about blocking holes in our processes or activities and is not really about improvement. Every CAPA is an opportunity to improve what we do and to give us a more robust Quality Management System.

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Some Thoughts on CCAPA

- YES – CCAPA
- CORRECTION
 - If something can be sorted, do so before the inspection
- CORRECTIVE ACTION
 - Remove the source of the problem, so it does not recur
 - This is **RISK PREVENTION**
- PREVENTIVE ACTION
 - Identify and control risks before they occur
 - This is **RISK MITIGATION**

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Preparing for an inspection is part of risk management. Preparing well in advance of an inspection should be part of the Risk Management Plan.

Planning for an inspection should start with the protocol summary.

Preparation is everything 

- Not just having all your documentation in good order
- Not just having your processes effective and efficient
- Not just having a robust Quality Management System
- Not just having a ready-to-roll inspection team
- Not just having read all the regulations
- Not just having your Training Records up-to-date
- Not just having a current GCP certificate

WHAT ABOUT THE PEOPLE?

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Preparation is everything and if you're not prepared then you're not going to have a great inspection. We are told that we should have sustained inspection readiness. In other words, be ready for an inspection at any time. A bit like a sword of Damocles constantly hanging over your head. Not sure when or if it's going to fall.

In order to maintain sustained inspection readiness you can keep the hamster wheel turning on perpetual motion as you put all the processes in place that you think you will need and many companies spend many hours/days/weeks/months, even years getting on top of the documents and trying to have a perfect TMF or perfect SOPs or perfect training records. But that's not all they do, they paint walls and woodwork, hide things away in cupboards, weed the car park; give the receptionist a new uniform. Is that going to do it? Is that going to be the difference between a 'good' inspection and a 'bad' inspection?

The inspectors want to know that the trial is in safe hands, that your processes and supporting documentation are robust. They want to see evidence of that. They want to see evidence that shows them that what you said you would do in your protocol, your submission documents and your SOPs actually happened, on time, on spec and that you've adequately documented this.

You can prepare THINGS. You can set up and test processes, you can validate computerised systems, you can review the content of your TMF but if you don't prepare the people who're going to be interviewed then it can all fall down, and sustained inspection readiness goes out the window. People get stressed prior to, during, closing out and following up an inspection. Even if they have a minor role, it can be a very stressful situation.

How would you like to turn it into a golden opportunity to show your boss how well you do your job and the inspectors how confident they should be in your abilities to perform your trial-related tasks. That sounds like something we could put efforts into because we all win in that scenario.

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Interfaces

“An interface is a catalytic surface on which problems can develop”



- You know your processes
- They know their processes
- How do these interact?
 - Gaps
 - Overlaps
 - Confusion

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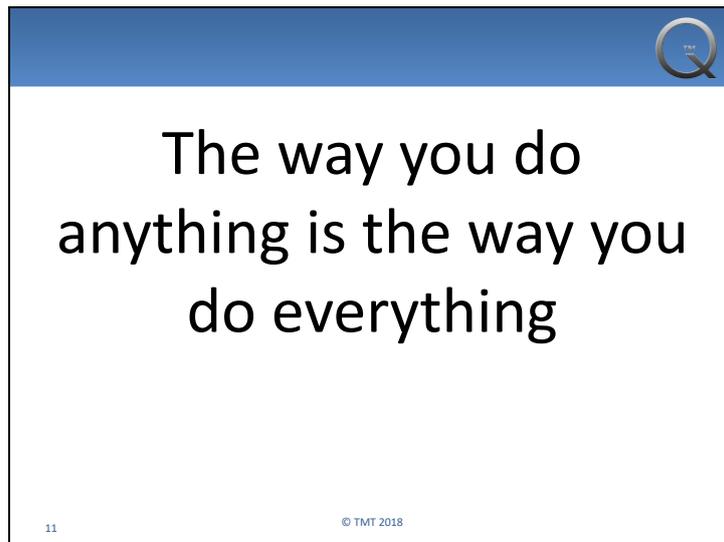
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Symptoms

- Can't think straight
- Can't remember things that they do every day
- Find it difficult to answer questions concisely
- Don't give good eye contact
- Hands sweat
- Lose confidence,
- Don't sleep well
- Get headaches
- Get pins and needles in their fingers
- Get indigestion
- May get unwell
May have chest pain
- Muscles tighten up and it affects their breathing
- Lose their cool
- Look pale or flushed and uncomfortable

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Can a person in this state have a good interview? Can they instil confidence in the inspectors?

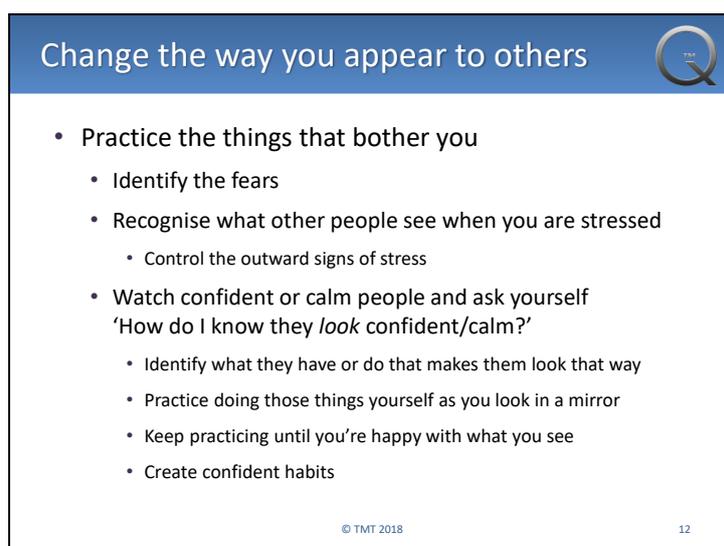


The way you do anything is the way you do everything

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If you look confident and in control, then the inspectors may feel that that is how you do your job. If you sound as if you can't string two words together, your memory fails you when you are asked a simple question that you know the answer to and you look as if you would rather be anywhere else than sitting in an inspection with the MHRA then that is how they may think you do your job. They know that people get nervous, but some people become debilitatingly nervous and it really impacts on their performance at interview. It's difficult to sound confident about your abilities when you look and sound like a nervous wreck

So, what are we going to do about the people?



Change the way you appear to others

- Practice the things that bother you
 - Identify the fears
 - Recognise what other people see when you are stressed
 - Control the outward signs of stress
 - Watch confident or calm people and ask yourself 'How do I know they *look* confident/calm?'
 - Identify what they have or do that makes them look that way
 - Practice doing those things yourself as you look in a mirror
 - Keep practicing until you're happy with what you see
 - Create confident habits

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Copying others who do a job well in order to learn how to do the job well yourself is how Neuro-linguistic Programming (NLP) started. Doctor Richard Bandler who is the originator of NLP wanted to train people to be confident, so he looked at confident people to see how they behaved and he then taught others to be confident by first looking confident and that led to feeling confident.

Here are his seven ways to face your fears.

1. Don't waste your time. How you work with someone with a fear of heights is different to how you would work with someone with a fear of spiders. But the major thing that I get people to focus on is what's important. In most cases, the phobias have been made into such a big deal that people think about them all the time, which is such a waste of their energy. I ask them to evaluate how much time they've spent worrying about their phobia per day. Even if it's just a half an hour, then that's three and a half hours a week. Over ten years you're going to waste a couple of thousand hours worrying, when you could be having fun. That's when people start to think 'enough is enough'. When you get there, you know it's time for a change.

2. Phobias are in your mind. Regarding phobias, most people are afraid whether the object's there or not. Just the other day a woman told me how afraid of spiders she was, and she was shaking in her boots while she was explaining to me. I replied: "excuse me, there are no spiders here. Why are you afraid now?" The truth is, she wasn't afraid of spiders. She had a huge picture of spiders in her head, and she could barely look at it. She just felt the way she would feel if this huge, imaginary giant spider was there.

3. See the alternative. I have people look and see themselves holding a spider in their hand, and I say: "Do you want to be this person? Wouldn't you like to be this fearless person? When you look at that don't you feel, i want that?" It's all about choice and the direction they want to be headed.

4. Curious creatures. Curiosity beats the alternative. If you're not curious you're not exploring the world you're living in. The fittest organisms are the ones that adapt – and adaptation requires curiosity. Fear is the absolute opposite of curiosity. It's where you don't look at things, you don't find out what works, you don't find out what's dangerous. The great thing about curiosity is it blasts fear out of the way.

5. Picture this. Most height phobics get near the edge and start making pictures of themselves jumping off. And that's why they have fear. If they stop making those pictures and instead make pictures of themselves being relaxed and comfortable and staying away from the edge they'll be a lot better off. If it's done in just the right way, it starts to happen unconsciously and automatically.

6. Reverse engineering. To reverse fear, I get people to find the way a direction feels like it's spinning in their body. Then I get them to reverse the spin. Often, not always, it's in the guts – the entemic nervous system, which scientists are only just beginning to realise has its own neurology. You reverse that spin, you reverse the feeling, literally.

7. Think. I don't cure anybody because I don't think they're sick. If someone learned to be afraid, it just means they're dependable. All I have to do is get them to be dependable in a new way. One way is to reverse a memory. When you run an old scared memory backwards, it flattens out the neurons, because those neuro-cortical pathways are selected by size and

fired by a chemical charge. Now, here's the trick to personal change: you create a void and fill it with something better, then it doesn't go back to what it was.

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Preparing yourself for interview

- Read your job description and know your responsibilities
- Read the trial protocol and know the main elements
- Know the parts of the regulations that pertain to your responsibilities
- You already know the questions they will ask
 - They are all about your responsibilities and the part you played in a particular trial
- They're asking you because you know the answers

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- If the inspectors want to know about your background what will you tell them? You'll give them a potted and relevant history that shows you are qualified and have the right experience and expertise to do the job.
- If they want to know your responsibilities in a particular trial, then you give them a fairly high-level overview and if they want more then they will ask you for it.
- If they want a concise and comprehensive overview of the trial, you may be the best person to give them that. Practice beforehand in the mirror or with a friend or colleague.
- Storyboard any known issues so that you can talk about them confidently
- If they ask about a particular issue, then be transparent and honest – don't dwell on the issue itself but rather on how quickly it was identified, assessed, mitigated or resolved and what has been put in place as a quality initiative to prevent it happening again. In this way you cast the company in the best light and the inspectors are told about the robust risk management processes that you have.
- If you don't understand the question, then ask for clarification or ask them to repeat it if you didn't hear correctly
- Stop when you've answered the question, don't keep talking to fill up space or you may get caught in bear traps of your own making

During the interview 

- Wait for the inspectors to speak
- Sit in a way that allows you to move a little and that won't cause your muscles to get too tight
- Give good eye contact
- Think before you answer a question – don't rush in
- Don't forget to breathe
- If pauses develop, let them
- Start with a high level answer – if they want more they'll ask

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Check out the room beforehand as it is less stressful if you are not going into an unknown set-up.

Make sure that the back office know where you are, leading up to the interview. If you need to go to the loo, then tell the back office beforehand and let them know when you come back.

Don't take anything in to the room with you – particularly your phone, notes, etc. If you do want to take anything in with you that might help you to answer their questions, then it must be reviewed by QA beforehand.

Introduce yourself at the start and thank them at the end. Gather anything you took in with you and leave quietly.

After the interview 

- There should be a de-brief by QA before you speak to anyone else
- Don't tell anyone the questions you were asked – it won't help them and may cause stress
- Don't tell colleagues that it was terrible or anything else negative – it may cause stress
- Learn from this experience
 - What could you have done better?
 - What did you do that you're proud of?



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Preparing for the next inspection

- When it's all over.....
 - Have a 'lessons learned' legacy meeting
 - Discuss what went well and what didn't and discuss quality improvements based on this
 - Make plans for sustained inspection preparation
 - Create a task force with representatives from relevant functional areas
 - Create a Master Inspection Preparation Plan
 - Aligned to the Risk Management Plan
 - Delegate tasks and activities to named individuals or groups
 - Report and review progress at agreed intervals

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Summary

- Prepare! Prepare! Prepare!
 - Prepare yourself and your staff
 - Reduce stress
 - Increase confidence
 - Questions and Answers
 - Review your documents, SOPs and TMF
 - Ensure all documents complete and present or explained in NTF
 - Ensure practice is reflected in SOPs
 - Audit TMF and resolve CAPAs
 - Ensure control of removal /addition of TMF documents




**KEEP
CALM
AND
BE
HAPPY**

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The end.... 

- Slides and discussion notes available
- Storyboarding infographic and additional storyboarding information available.
- Any questions?

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