



The Art of Preparing for Regulatory Inspections

Those of us who have worked within the pharmaceutical industry for a reasonable length of time would have been involved in FDA, MHRA, and various other regulatory inspections at sometime in some shape or form. For those of us coming out of it unscathed (and with a good result) then we can be excused for feeling pleased with ourselves. Why then does the notification of a forthcoming regulatory inspection still make our blood run cold?

The answer often is that we know there are non-compliances within our work place and we would rather not “air our dirty linen” in public. Of course, Murphy’s Law will prevail and the inspector(s) will find them! We all have non-compliances that we know about and can be guilty of not doing enough to resolve them in a timely manner. This article is not about how to manage or resolve these issues but rather about how we can use the art of preparation to help influence a better inspection outcome. It is not the author’s intention to suggest that inspectors should be misled.

Preparing for a regulatory inspection is both science and art. Let’s compare it to a game of chess, not only do we need to know the rules of the game and the capabilities of each piece (this is the technical knowledge and is the science) but in order to get to “check mate” and win the game we need to have a strategy, to understand and appreciate the importance of the movements not only of each piece but collectively as a whole game (this is the art). Similarly, we can all be trained systematically about the structural aspects of an inspection, for example: observations, 483s, opening and closing meetings, warning letters etc (this is the science) but there is no hard and fast rules about the actual preparation. For example, the strategy on inspection core team (fronters and back room control) selection, control room layout, management of personnel/facility during an inspection etc (this is the art). Indeed how do you go about training someone to have a “nose for it”?

I have come across many companies spending a small fortune on the science part of inspection preparation but little attention on the art of inspection strategy and the selection of a brilliant core team. Often, core teams members are thrown together because of their availability or their job position rather than because of their aptitude and natural flair to host and manage inspections.

Personally, I believe a successful inspection outcome is influenced by the art of choosing the correct strategy and the right members for the inspection core team.

The strategy will largely depend on the objective(s) of the inspection (GMP, PAI, Quality Systems, For Cause etc) and it is of paramount importance to select the inspection core team members accordingly. The inspection core team must fully understand the company culture and objectives so that these can be integrated in the preparation. The members should be humble, graceful, assertive and yet knowledgeable about all the relevant issues. They need to understand and appreciate when/how to act, what with, why and with whom.

Apart from the art of getting the right strategy and inspection core team, there is the art of creating the right atmosphere during the inspection. This is not just in the inspection front room but the entire site. Imagine how the inspectors would feel coming out of the controlled

calm of the front room only to be greeted by the panic experienced by all on their way to the wash room? Not to mention the stress levels of all the staff. A controlled and calm environment will influence a better final outcome compared to misunderstandings and errors caused by an atmosphere of panic.

Naturally, all wise men and women in the industry would know that preparing for regulatory inspections is an on-going art. However, art alone without current sound technical knowledge is not nearly enough to provide a successful outcome. Just like the balance between body and soul, ying and yang, the science and art should work to compliment each other.

For those of us who have somewhat failed in understanding the art, or achieving the science and got a less than desired inspection outcome, there is always a last resort.....the art of praying!

About This Article

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