To fail to prepare is to prepare to fail

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Can there be anything worse than the idea of a regulatory inspection? Well, yes – an unannounced inspection! However, both are equally stressful and are usually detrimental for a company if it is not adequately prepared. So, what does it take to be "inspection ready"?

Firstly, there is no excuse for not being "reasonably" ready for an inspection, regardless of its GxP nature. The focus of any inspection will be on processes and systems, and the advent of key systems and technologies over the past two decades – for instance, document management systems – has made the jobs of preparing, reviewing, and storing critical documents easier, regardless of budget. Many of these systems also have the added advantage of ensuring that each document review and subsequent activity is recorded, and there are even companies to whom the filing and maintenance of key documents can be totally outsourced (eg, in the case of clinical trial master files). Of course, the old adage of, "If it isn't documented, it wasn't done", will always ring true. With this basis, it's "simply" a case of tracking changes, keeping up to date with legislation, and ensuring issues/problems are noted, managed and addressed in a timely fashion (easy, right?).

But why is all of this so important? The answer is patient safety: be it ensuring that a product is consistently produced and controlled to an appropriate quality standard (GMP), that the process and conditions for the conduct, monitoring and reporting of nonclinical studies are suitable (GLP), or that trials of human subjects are designed, conducted and reported according to accepted ethical and scientific standards (GCP).

So, with this in mind, what should one do when faced with an inspection notice (clue: the right answer doesn't involve panicking)? The first thing to accept is that you may never fully be "inspection ready"; findings will always depend on the type of inspection, the inspector(s) themselves, and the current environment. That's not to say that companies should not prepare – far from it. The right team undertaking the right preparation work will go a very long way towards a ensuring a successful outcome, both in terms of patient safety and also reducing the risk associated with related regulatory activities (eg, licensing applications or ongoing clinical trials) for sponsors. Having the right team(s) for an inspection is critical, and just as importantly, the team must be led by an individual with the required characteristics and traits – the most qualified person on paper may not be the right person to guide the team.

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Of course, the job of this individual is made easier when an organisation is in a constant state of inspection readiness and understands again that there will always be "gaps" – but those gaps have been identified and corrective actions/plans are planned or ongoing to address these. The main piece of advice from regulators is transparency: don't try to hide something! This is just one of the messages we hear in this issue from the EMA's Dr Fergus Sweeney, who shares his many years of experience in building, shaping and leading the Agency's inspection group, which has increasingly become a global partner for many other regulatory agencies. We also hear from two experts on GMP and GCP inspection readiness, who between them share many hints and tips for approaching inspections. In addition, the emphasis on teamwork and ensuring that the right individuals are involved is highlighted in our final focus article, which also emphasises the key role that the "back room" team plays during the inspection itself.

Our other articles this month include a summary of the challenges of conducting clinical trials in rare diseases; a view on how opportunities for close interaction between stakeholders can result in better access to medicines for patients; and a look at emerging regulatory policies as drivers of acceleration to market in Asia.

Hopefully, with the advice imparted in this issue, the road to inspection readiness will be more direct for all of us!