ENSURING INSPECTION READINESS AT CLINICAL FACILITIES

EARLY PHASE CLINICAL TRIALS

The principles of Good Clinical Practice (GCP) serve to ensure the protection of trial participants and the integrity of the data recorded. Regulations require that all clinical trials be designed, conducted and reported in accordance with these GCP guidelines in order to be acceptable upon submission for marketing approval.

Any site involved in a clinical trial may be subject to GCP inspection by regulatory authorities, including the investigator sites, laboratories, the sponsor's premises, and the contract research organizations acting under arrangements with a sponsor. Clinical research is global, meaning it is increasingly important for sites to pass both FDA and EMA GCP inspections. These may be conducted on a routine basis or occur in response to a specific trigger, and can be related to ongoing or completed studies. Additionally, the inspections may or may not be announced.

The objectives of GCP inspections are to:

- Verify that quality assurance arrangements exist, in compliance with regulatory requirements and GCP
- Ensure the safety of human subjects is preserved and ethical standards are being applied
- Confirm that clinical trial data and results are scientifically valid and accurate

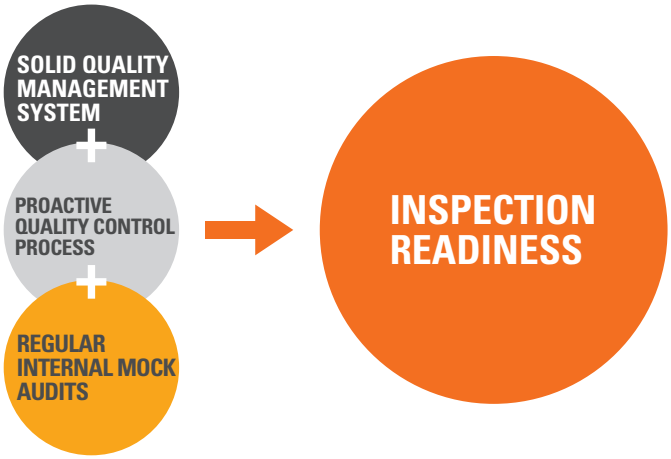
During an inspection, an inspector must be able to wholly reconstruct the clinical trial to confirm that all steps have been performed in accordance with the guidelines, that patients' rights and safety were protected at all times, and that all data is reliable.

For clinical teams undergoing inspection, the process brings with it the burden of administrative tasks and checklists. A

common and recurring issue for a site is that getting ready for an inspection is regarded as a preparatory activity that starts only after notification of an upcoming inspection. This means that the team, headed by the Quality Assurance department, must ensure that all documentation is accessible, accurate and complete by the time the inspector visits the site, often leading to time pressure.

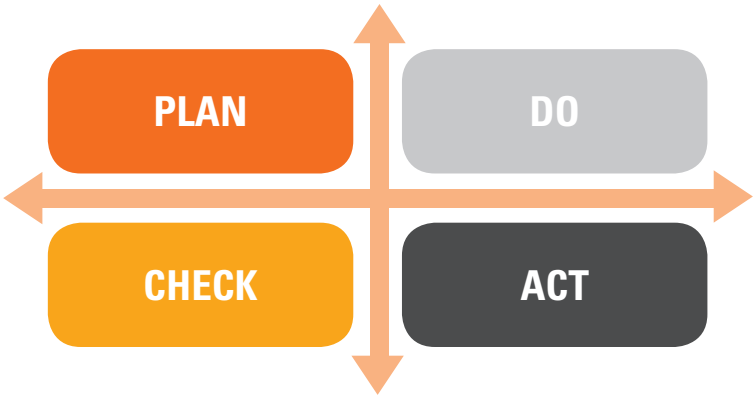
To overcome these last-minute activities leading up to an inspection, facilities can adopt a state of "inspection readiness" whereby the objective is to operate every day at a quality level ready for inspection and is achieved by developing a culture of compliance.

Inspection readiness entails the following activities:



1. Development of a solid Quality Management system, consisting of robust Standard Operating Procedures (SOPs) that cover the required measures to maintain high quality standards
2. Adopting a proactive Quality Control process, that not only checks activities but also aims for continuous improvement. The implementation of digital solutions for data, document and quality management supports this process
3. Carrying out regular, routine internal mock audits and inspections

To foster a culture of compliance, the Quality Management process installs a set of procedures and policies which are monitored and evaluated to highlight where there may be room to improve. Trial activities and collected data are verified against protocol requirements, GCP and GDP regulations and internal procedures, and digitization of these data allows for much simpler review. The verification can be undertaken on all trial data which results in a 100% quality check, however, a more efficient approach may be to spot check only the crucial activities identified during an upfront risk analysis.



The checks need to be reported and interpreted, and whenever a flaw in a system or procedure is detected, its cause needs to be analysed (root cause analysis) to see if any action is needed to correct the fault or to prevent the situation happening again. This corrective and preventive actions (CAPA) process allows for improvement of the facility's overall quality, and its ability to be inspection ready at all times.

The cornerstone of a solid Quality Control approach is described by the Shewart Cycle (adapted by William E. Demming):

- Plan: look at the way of working, define how things can improve and set clear objectives
- Do: implement the planned improvements
- Check: measure results and evaluate if objectives were met
- Act: apply actions for improvement if needed

Internal mock audits and inspections are good tools to evaluate whether the quality system is working as intended, and if the team is indeed inspection ready. These types of self-compliance checks provide valuable opportunities for the identification of deficiencies in documentation or processes long before an inspector arrives, and additionally, help people to be clear, concise and confident when being interviewed.

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