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WHITE PAPER

Ready for Our Closeup: GCP Inspection Readiness

A Limited Run

Not so long ago, the buzzword for inspection readiness was "Inspection Ready Every Day." But anyone who has survived a Good Clinical Practice (GCP) inspection knows that inspection is theater; thankfully, a limited-run performance.

The script is crafted to tell a gripping story. The director blocks the action, the actors rehearse their lines, and the stage crew practice handling props and moving scenery before opening for a small but important audience. As with any performance, what goes on behind the scenes is critical to success.

Step Right Up

A team is ready to host an inspection when

- The Trial Master File either documents compliance with the protocol, regulations, and GCPs, OR…
- Where non-compliance occurs, it also documents the quality cycle at work
- Team members can speak knowledgeably about the study, whether they were part of the study team from the beginning or not
- Team members can produce any Trial Master File document on demand

Using our theater analogy, let's look at each element.

The Script

The Trial Master File is the script that the inspection team uses to present the story of the investigational product. Every good story has a beginning, middle, and end. The International Council on Harmonization Good Clinical Practice (GCP) guidance helpfully provides requirements for the minimum set of documents that fulfill those three plot elements. The DIA Trial Master File Reference Model gives a more complete picture of every possible document.

The inspection team's first task is to map their Trial Master File to those references. This map has two purposes: First, to identify the location of each document; then, to determine how each location is controlled.

Essential documents—those specified by GCP—are typically easily mapped and well-controlled in either a paper document room or a dedicated electronic Trial Master File. Mapping the rest of the documents in the DIA Reference Model usually leads the team to realize that the Trial Master File is more widely dispersed than they thought. Regulatory submission documents and communications might be in a regulatory information management system; safety documents might be attached to cases in the safety database; contracts might be in a contracts repository; oversight documents for vendors that the sponsor oversees might be on a shared drive. Mapping all these documents is the first step to being able to retrieve them.

Rewriting the Script

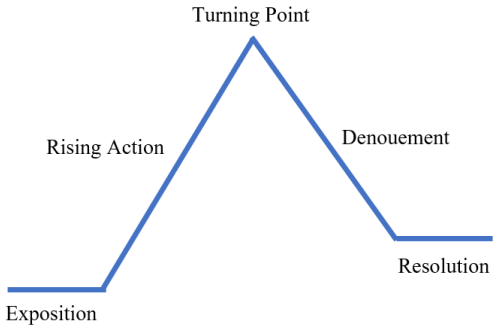
Most scripts need fine-tuning, and the TMF is no exception. The team must review the TMF for plot holes and confusing or misleading information. An auditor can serve as a useful proxy "audience" for this gap analysis, but wherever possible, the team that will speak about the study and retrieve documents during the inspection should participate—they are the ones who need to be most familiar with the "script."

Some gaps can be mended – the team may be able to locate missing information and file it. In other cases, documents may be lost, or activities may not have been documented. Regulators tend to frown on the practice of post-hoc documentation via notes to file. Instead, the inspection team can write storyboards that they can use to practice explaining these "plot holes" in interviews. Storyboards can also be used to prepare explanations for quality issues that arose during a study.

Dramatic Structure

A good storyboard presents an issue in a way that is pleasing to the audience.

- **Exposition**: Identify the SOP or plan that governs the activity in question; identify the roles involved.
- **Rising action**: Recount the oversight measures that led to identification of the issue.
- **Turning Point**: Describe the issue.
- **Denouement:** Detail the root cause and corrective and preventative actions taken to ensure the issue did not recur.
- **Resolution**: Happily ever after! Show how the problem was solved.



Inspectors expect errors to occur, but a well-told story gives confidence that the study team has an appropriate process for responding to issues and making improvements.

Off Book

It's not enough to write a compelling storyboard. The inspection team must be able to deliver the story in a convincing way—even more challenging when the team being inspected is not the same team that conducted the trial.

Some teams spend a lot of time compiling extensive dossiers or writing lengthy storyboards. These typically benefit the team members gathering the information, but not anyone else who might be interviewed. It's better to capture a few bullet points for each issue that interviewees can memorize. If the inspector asks for specific details, these can be retrieved by the inspection team.

A layered approach to rehearsal works best:

- First, have interviewees practice reading questions and answers off the storyboard.
- Next, ask interviewees questions and have them practice locating the response on the storyboard and then reading it.
- Then, do the same exercise "off book," without the storyboards.
- Finally, mix it up: Ask questions out of order; ask off-topic questions; throw in some challenges and requests for specific details.

Stage Crew

No show can go on without the technical crew – the folks who man the lights, move the scenery, and modulate the sound. In an inspection, your "front room" and "back room" teams are that crew, and the systems they use to capture and track inspection requests and deliver documents are their tools.

Some teams favor a paper process, with requests handwritten on forms and documents physically run back and forth from team to inspector. Others use a combination of spreadsheets for logging requests, messaging for communicating between rooms, and shared drives for moving electronic documents.

Whatever system you choose has to be **easy to use**, because your stage crew doesn't do this every day. They need to be a well-oiled machine from the start.

Your system should permit the inspection team to **visualize** the status of each request at a glance.

It should facilitate **communication** among the whole team – front room, back room, and vendors too—regardless of whether they're on site or remote, with a sponsor email account or without.

Finally, tools should be as **integrated** as possible, so the team doesn't spend valuable time switching apps.

Setting the Stage

Ready Room in an inspection management solution that manages inspection requests from ask to delivery. Generate requests, assign them to team members, attach documents, and release them to the inspector with one easy drag-and-drop workflow. Integrated chat and comments keep your whole team connected.

Ready Room can help your "stage crew" shine. Call us at (978) 880-3242 or email at info@synclinical.com for more information.

Get ready.

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