# Compliance Theater

| Episode # 1 | SOP: Clause and Effect |
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| **Topic:** | Secrets of the SOP |
| **SMEs:** | **Grace Crawford** |
| **Episode Time:** | 09 min., 48 sec. |

**CAST:**
ANNOUNCER/ INVESTIGATOR MOFFIT: Brian Mitchell
MARGIE MARLOW, VP of Clinical Drug Development: Connie Ligman
SAMANTHA PIXEL, the documentation specialist (CRO): Vicki Kunkel
JOHN LINKHOOD, the lead scientist on the project: Mike Hanley
NICOLE APTLY, Clinical review specialist: Terri Orr
NICK NONESSE: Clinical Compliance Officer

**OTHER CREDITS:**
WRITER/PRODUCER/DIRECTOR: Vicki Kunkel
MUSIC: Quin Kempler
SPECIAL SOUND EFFECTS: Amcast Studios

GENRE: Cosy Mystery (with a large dose of spoof mixed in! ☺ Clues are not obvious, to add to the mystery – and suspense – of the story.)

| Character/Audio | Script |
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| SFX: | Door creaking open |
| SFX: | Ominous mystery [*Mystery T19d*. Six seconds.] |
| ANNOUNCER (Investigator Moffit): | *[Use sort of a Dragnet voice style, much in the style of the announcers in the old CBS Radio Mystery shows. Prefer announcer who has a deep voice, but a pleasant raspiness.]*:<br><br>Come in. |
| SFX: | [Mystery organ sting.] |
| ANNOUNCER: | Welcome. I'm Investigator Moffet. |

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| | True compliance crime, more often than not, grows out of seemingly inconsequential, innocent circumstances. It's the product of small mis-steps. Miniscule missed clues. It grows slowly. Almost imperceptibly. It's rarely a glaring gaff, as we'll see in our mystery. And if it starts, it sets off a chain reaction that escalates to the point of ***compliance catastrophe***. |
| SFX: | [Blood-curdling scream] |

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| SFX: | [Mystery music SOT FULL, then fades as we open on the action of the mystery.] |
| ANNOUNCER: | Our story takes place in the bowels of the [COMPANY] campus, in a lower-level conference room, where our characters are discussing a recent FDA violation slapped on the company. The problem? A participant in a phase one drug trial missed a few lab safety check-ins. But those missed appointments were never documented. That means we have a case of PROTOCOL DEVIATION. |
| SFX: | [Murmur of people talking.] |
| SFX: | [Marker squeaking against a whiteboard. "Zapsplat" file] |
| MARGIE MARLOW (Project Manager): | [Audible deep sigh] Okay. There we have it. An outline of the events leading up to the regulatory violation. Anything stand out to anyone? We need to find out what caused the protocol deviation. |
| ANNOUNCER: | That's Margie. VP of Clinical Drug Trials. |
| MARGIE: | Let's go through these events one by one to identify what we missed, and how this could have gotten to the point of an inspection violation. |
| SAMANTHA: [Know-it-all tone of voice.] | Well, because it involves a clinical study, I think we have to look at lab procedures. The lab *was* cited in a separate investigation for a major non-compliant event during the in-vivo experiments before the |

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| | trial. |
| ANNOUNCER: | Samantha's the documentation specialist. Her job is to make sure all documents are properly stored. She clearly thinks she knows who's to blame. |
| JOHN: | Now, *Wait. A. Minute!* |
| ANNOUNCER: | That's John. The lead scientist for drug development. This drug was his baby; he discovered the protein molecule structure that can potentially cure [the disease]. |
| JOHN: | Just because another violation was *cited* in the lab, it doesn't mean lab activities are the *root cause* of *this* problem. As you said: that was a completely separate investigation and has no bearing on this one. |
| SAMANTHA: | If it looks like a duck and quacks like a duck… |
| JOHN:[Angry/exasperated]: | *There were a lot of other ducks quacking in this pond!*<br><br>Take a look at the outline of events up on the whiteboard. [PAUSE.] |
| SAMANTHA: | Yeah. We're looking. So? |
| JOHN: | A string of events lead up to this. First: The study report form was filled out incorrectly. The box stating that our missing study participant had been to all of his lab visits was checked when, in fact, he had missed one. |
| MARGIE: | Yeah. That's odd. Why wasn't that caught during our typical weekly review of all scheduled lab visits? Nick, as head of compliance that falls under your domain. |
| NICK: | [Stammering] Um, well, I didn't know that the reports for that week had been uploaded. |
| MARGIE: | *How*--as head of compliance – can you *not know* when a report is filed?! |

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| NICOLE: | [Sharp, with a bit of an edge to her tone]: Yes, Nick. Please tell us. |
| ANNOUNCER: | Hmmm. Seems as if our procedure review specialist, Nicole, has an axe to grind about something. |
| NICK: | [Sheepishly] I, er, didn't get a notification. Normally, I'm pinged every time there's an upload of a new document in the system, or when a change is made to an existing document. But this time I didn't get an update. |
| MARGIE: | Did it occur to you to find out why you didn't get a notification? |
| JOHN: | [Interrupting] Well, looky there. [Sarcastically] Now…*who* might be in charge of *doc-u-men-ta-tion*?! Let me think…Hmm…Oh, yeah, that would be the [tone turns accusatory] *documentation specialist*! |
| SAMANTHA: | I'm only in charge of document *storage*—which involves cataloguing and retrieval—*not* communicating when changes have been made to a document. I'm just an administrative grunt who doesn't have the permissions to make document status changes. Not like some fancy-pants scientists or managers. Get your facts straight. |
| JOHN: | Well, then, Ms. "I'm-only-in-charge-of-storage," let's look at the *second* event that contributed to our FDA fine. The report was initially stored in the *wrong* Sharepoint folder! No one could find the report for over two weeks. Seems like a cataloging error to me. And, when it *was* found, no one reported it; they just moved it to the proper folder. Now who do you suppose has the 'cataloging' skills to move the document form one storage place to another? That's not a lab mess up; that's a documentation fiasco. |
| SAMANTHA: | [Snorts in disdain] Oh, c'mon. Anyone could have moved that file. Go ahead. Just keep saying whatever you have to say to make yourself feel better. I think we have to look at who has the most to gain by hiding the fact that the study participant was a no-show. |

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| NICOLE: | What are you getting at, Sam? |
| SAMANTHA: | I'm *getting at* that both John and Margie have the most to lose if the clinical trial is a flop and, ergo, the most to gain by hiding anything that might jeopardize the trial. John misses his chance to be the famous scientist who discovered the protein structure that cures [disease], while Margie gets a big fat bonus for all new drugs that go to market. Maybe the two of them were working together. |
| JOHN: | [Enraged]: *Why you little….* |
| MARGIE: | [Interrupting]: *Samantha*, you're out of line. I resent those remarks. |
| SAMANTHA: | [Smirks] What's that matter? Truth hurts? Just sayin'. |
| MARGIE: | [Stern tone, trying to control her anger]: Let's. Get Back. To the issues. At hand. The way I see it, there are three issues. One: The report was initially filled out incorrectly. Why and how did that happen? Two: Why and how was the report stored in the wrong Sharepoint site? And three: How on earth did no one notice the report was missing for over two weeks? |
| JOHN: | Regarding your first point: Have you seen that form? It's very confusing. And that little teeny checkbox to document a no-show is not in the field of view on the computer screen. You have to use the horizontal scroll bar to see it. |
| MARGIE: | That's a good point. The check box is out of sight on a small laptop screen. Even the FDA investigator said he thought not checking the "no-show" box was an unintentional oversight, given how easy it is to miss it on the form.<br><br>Still, we were fined. And our trial took a serious hit. It's now delayed until we can prove to the FDA that we have rectified the problem. |
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| NICOLE: | I think we have rectified it. I know who—and |

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| | what—ultimately caused our FDA citation. There's one thing that could have prevented our violation. And one person who's responsible! |
| SFX: | [Suspense SFX or ORGAN STING] |
| ANNOUNCER: | Nicole—our procedure review specialist-- thinks she has solved the mystery. Can YOU identify the culprit? Think about it, and we'll have an answer after the brief break. |
| BREAK: | [15-second promo for the Bio-Bend regulatory compliance portal. Video file: Biobendpromo.MPEG4] |
| ANNOUNCER: | Our mystery resumes with the resolution to our compliance crime. |
| NICOLE: | This can all be traced back to one thing: the S-O-P—Standard Operating Procedure—for this trial. And there's only ONE person responsible for that, and that person is [pause for suspense] *Nick*! |
| SFX | [ORGAN STING] |
| NICK [Defensive tone] | [Defensive Tone] There is nothing wrong with my S-O-P! I clearly defined the scope of the trial, place of performance, clinical and test requirements, timeline for completion, how to identify non-compliant events and how to document violations. It was air tight. It had all the typical elements of an S-O-P. |
| NICOLE: | But a 'typical' S-O-P doesn't go far enough. It's not just about a *work* plan to *complete the project*. |
| JOHN: | Hmmm…I see where you're going with this… |
| MARGIE: | Well, then, could someone kindly clue me in? |
| JOHN: | An S-O-P needs a treatment plan for non-compliance events as well as infractions that *aren't* violations, but are of *concern*. This SOP didn't have that. |
| NICOLE: | That's right, John. If our reporting S-O-P had included procedures for escalating minor concerns—not just major compliance violations—the issue would have been caught long before any FDA investigation. |
| NICK [snarky tone]: | Hey, Monday Morning Quarterback: Why didn't you |

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| | bring this up during your S-O-P review? |
| NICOLE: | I did. Remember our discussion… |
| SFX: | [Dream sound…going back in time. Soundbible.com/daydreaming] |
| NICK: [ECHO sfx with voice to denote that it was from a conversation in the past.] | Oh, hey, Nicole. How's it going? |
| NICOLE: [ECHO sfx] | I've been reviewing the new S-O-P you wrote for the trial protocol, and I have some concerns. |
| NICK: [Echo sfx] | What concerns? |
| NICOLE [Echo sfx] | It doesn't lay out a process or timeline for escalating non-compliance events that aren't really serious, but that could become an issue if left unchecked. I'm particularly worried about the possibility of reports getting lost, or inadvertently uploaded to the wrong folder. We've had so many complaints from clinicians that our SharePoint filing system is confusing and convoluted, so losing a report is a very real possibility. I think we need to put a timeline on checking when reports are filed, and also a timeline for escalation if we can't find a file or folder. |
| NICK [Echo sfx] | [Dismissive laugh.]<br><br>Oh, don't worry. Those are handled on a case-by-case basis. They're not normally part of an S-O-P. Trust me. |
| NICOLE: [Echo sfx] | But if we identify and escalate events like that, it could prevent a regulatory violation during an inspection. We need to either put that into the S-O-P, or have a stand-alone escalation plan. |
| NICK: [Echo sfx] | [Nick's tone is somewhat annoyed and firm, as he doesn't like being challenged.] Look, you said it yourself: These are *non-serious possibilities*. We're good. I've got this. I've been writing clinical trial S-O-Ps for years. Don't sweat the small stuff. And what |

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| | you're talking about is small potatoes. |
| NICOLE: | [Dejected] Okay, you're the boss, so you have the final say. |
| NICK: | Yes I am and yes I do. |
| SFX: | [Coming out of dream sound. Soundbible.com/magic wand noise] |
| JOHN: | Ha! NOW who's the real quack! |
| SFX: | [Organ sting.] |
| ANNOUNCER: | Nicole was right. Leaving out a clause with a timeline for escalating seemingly minor non-compliant events made this S-O-P a real loser, and led to a regulatory violation. Such crimes of omission never end well. Stand up and fight for details you think need to be included in an S-O-P—or any type of document—even if you think you don't have the right to. Compliance is everyone's responsibility. If you don't speak up when you see issues with documentation, it could lead to inspection violations later on. Omitted clauses have the potential effect of regulatory violations. |
| MUSIC | [FINAL STING and MUSIC THEME.] |
| ANNOUNCER (music theme under): | Tune in for our next episode of our Compliance Mystery Theater series—*Grime and Punishment*—to hear what happens when the odd couple of a lab slob and a scientific snob butt heads as they work together to get the lab ready for an FDA inspection. |
| MUSIC FADES | [Music fades] |