Smart Decisions Behind a Successful FDA Inspection

Chesapeake Research Group's FDA Inspection with Complion

Chesapeake Research Group, LLC is a multi-specialty clinical research site dedicated to improving health outcomes by conducting rigorous and efficient clinical studies for medical drugs and devices.

When the FDA inspector came knocking at Chesapeake Research Group (CGR), Neal Surasky wasn't surprised. "It was something we knew was going to happen at some point," says Neal, Director of Compliance at CRG. "It seems like every other year we're getting an FDA inspection. It's just the nature of the trials we're conducting."

While this certainly wasn't the first FDA inspection Neal had experienced at CRG, this was the first after the implementation of Complion's eRegulatory

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solution. "All the other studies we had done involved paper binders," Neal says. "All of our documents were filed under certain tabs so that an inspector or an auditor could go through the regulatory binder and find exactly what they needed."

In most cases the inspectors knew exactly what they were looking for, so it was a simple matter of directing them to a particular document.

Preparation: Think Through the Details

> *"My job as a director of compliance and regulatory specialist was to make sure that our regulatory system was ready..."*

"The Complion system made it really, really simple," says Neal. "But we had some decisions we needed to make ahead of time." Planning was critical. Neal and his team had to determine how the inspectors and auditors would access the regulatory binder.

One option was to provide the inspector with access to the Complion regulatory system. Doing so, however, would require the inspector to view a short training video to access the system.

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A second option was to print out hard copies of the entire regulatory binder. But that seemed unreasonable, according to Neal. "It defeats the entire purpose of the electronic regulatory system." So Neal and his team opted for a third option, compiling the binder into a PDF document that was then provided to the inspector for review.

"This was something that our team and Complion had already thought through as we had developed our SOPs for our eRegulatory binder. Our SOP for our binder states that in the event of an inspection or an audit, the inspector or auditor would be provided with a PDF copy of the regulatory binder in order to perform that part of their task."

With that plan in place, Neal and his team knew exactly what they were going to do when the FDA called. "In addition to reviewing all of our source documents for completeness and ensuring everything was in order, we also refreshed our memories to the conduct of the trial," Neal says. "My job as a director of compliance and regulatory specialist was to make sure that our regulatory system was ready, and that included compiling the binder."

Based on previous experience with audits by sponsors and CROs, Neal was aware of the potential issues related to the sheer size of the PDF file to be provided to the FDA inspector.

Instead of compiling the entire binder into a single PDF, Neal compiled each section of the regulatory binder separately. He then saved it to a flash drive and provided it to the auditor. Each section of the binder corresponded to a tab in a paper regulatory binder, allowing the inspector to easily find what they were looking for, and "the PDFs were easy to open and navigate through."

Based on the success of that strategy, Neal and his team decided they would handle the current inspection in the same manner.

Another decision to be made was what to include in the documents to be provided to the inspector. "I thought to myself, if I was going to give this inspector the entire regulatory binder, what would be in it? It would include every single protocol, Informed Consent Form (ICF), amendment and revision. It would include every version of everything that we did, and that gave me a little bit of a pause for thought," Neal says.

Chesapeake Research Group uses the archive function in the Complion system. Neal's intention was to compile active and archived files into the binder. This would essentially recreate a paper binder in an electronic form, where all the versions and all the different forms of the documents would be available for review," Neal explains.

"The inspector went through nearly every section of the regulatory binder, and had no problems navigating the individual sections."

But upon the first attempt, the archived files didn't appear. The Complion team jumped into action. "They enabled us to make the archived files downloadable," Neal says. "We archived everything that needed to be archived and it compiled just like all the other active

files, and we gave that to the inspector. Once we had done all that, he was ready to do his inspection."

The Inspection: A Positive Impression

Neal is happy with the outcome. "I feel the inspection went really well," he says. "I don't think it could've gone much better." The inspector went through nearly every section of the regulatory binder, and had no problems navigating the individual sections. "If he asked me where a particular document was, I was able to pinpoint for him exactly where it had been filed."

"Having the system designed for our site made it easy to tell him where to find everything. The inspector was very impressed with that"

"One of the benefits to the Complion system is that we were able to incorporate our own binder template. The system enforced the organizational structure we defined. If the inspector wanted to know where to find something, having the system designed for our site made it easy to tell him where to find everything. The inspector was very impressed with that."

Having gone through FDA inspections before, Neal understood that PI oversight is a huge consideration during any FDA inspection. At CRG, PI oversight was documented using electronic signatures with respect to monitoring and follow-up letters. "The fact that we had moved toward electronic signatures seemed to make the inspector pretty happy", stated Neal. "eSignatures were a good way to provide PI oversight, and the fact that he didn't comment any further was a good thing."

"What I think really got him on to our side was when we explained how we were transitioning from paper delegation authority to electronic delegation authority in the Complion system. He was really happy with how we were going to be using the Complion system for our delegation of authority. It seemed to say to him that this would prevent issues related to oversight."

Post-Inspection: Worth the Effort

"Complion was amazing and very responsive."

The inspection went well. "Overall, it was a great learning experience. I believe it helped streamline some of our processes," Neal observes, and "Complion was amazing and very responsive. They worked with us to ensure we had the appropriate training and documentation during implementation and they were available to answer questions and provide support throughout the process. Their efforts contributed to our success. We did not end up with any 483s or warning letters," Neal says. "It was a no-findings inspection, which was great!"

Complion's mission is to transform the way clinical trial documentation is maintained. We seek to centralize, standardize, automate the regulatory process so you can become more efficient and productive. That's why we developed the first 21 CFR Part 11 compliant eRegulatory system designed specifically for clinical research sites. Learn why Complion is the trusted standard for over 60+ sites, health systems, Academic Medical Centers and Cancer Centers.

Contact us today!

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