Podcast Transcript

FDA's Current Inspection Focus: What Companies Are Really Getting Cited For

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Kattman: Welcome to Regulatory Horizons, delivering strategic insights for the future of global life sciences regulation. This podcast is your guide to the evolving policies, global frameworks, and innovations shaping the compliance landscape across biotech, pharma, medical devices, and even foods. I'm Amy Kattman, and you're listening to BakerHosts.

Today we're going to talk about FDA's current inspection focus, what investigators are consistently citing, what keeps showing up in FDA 483s and warning letters, and what that means for companies at different stages from early-stage biotech to fully commercial manufacturers.

Kirton: Hello friends. My name is Winston Kirton, and I'm the leader of BakerHostetler's FDA practice, and co-leader of the firm's Life Sciences Industry team, and the host of the Regulatory Horizons podcast. When most people think about an FDA inspection, they think about the moment itself. The investigator showing up, walking the floor, maybe issuing an FDA Form 483 at the end. But perhaps what really matters isn't the inspection. It is what inspections are telling us about where FDA is focused right now. Because FDA inspections are not random, they're not just compliance checklists. They're one of the agency's clearest signals about what it sees as risk, systemic risk, to product quality and patient safety.

Before we get into specific findings, it is important to understand how FDA inspections have evolved. Inspections today are increasingly risk based and data driven. FDA is using inspection history, quality signals, supply chain information, and prior enforcement actions to decide where to spend time. Inspections are

also more targeted. Investigators aren't trying to review everything. They're picking systems, like data integrity, CAPA, quality oversight, and then they're following those threads deeply. And inspections are no longer just on-site events. Remote record reviews, pre-inspection data requests, and follow-up inspections are now part of the normal oversight model.

The bottom line is this: FDA is not asking whether you passed your last inspection. It is asking whether your systems actually work. So, if there is one theme that ties today's inspection together, it is this: FDA is inspecting systems, not snapshots. The agency wants to know whether your quality system, your data controls, and your governance structure consistently produce reliable outcomes, or whether compliance only exists on paper.

Now, the single biggest inspection focus right now is data integrity. Across drugs, biologics, and medical devices, FDA continues to cite weak audit trails, shared user credentials, uncontrolled spreadsheets, incomplete electronic records, and failures to review metadata. What's changed is how FDA views these issues. Data integrity is no longer treated as an IT or documentation problem. FDA is treating it as a quality culture and leadership problem. If analysts can delete or modify data without detection, if audit trails exist but no one reviews them, or if leadership can't explain how data is protected across its lifecycle, FDA views that as a systemic failure. Having SOPs is not enough. FDA expects technical controls that prevent improper actions, not just procedures that assume perfect behavior. What manufacturers should be asking themselves is, can we technically prevent improper data changes? Or are we relying on trust and SOPs alone?

Another major inspection focus is the authority and effectiveness of the quality unit. FDA continues to cite companies where quality units technically exist, but don't function as independent governing bodies. Investigations stop too early. CAPAs close on time but don't address root cause, and the same issues appear inspection after inspection.

From FDA's perspective, a CAPA system that always closes but never prevents recurrence is a red flag, not a success. What FDA is really assessing here is whether quality has real authority or whether it is routinely overwritten by operational or commercial pressure. What manufacturers should be asking themselves is this: Does our quality unit have real decision-making authority?

Sterile and aseptic operations remain a high-risk inspection area as well. FDA is closely scrutinizing environmental monitoring, cleaning validation, and importantly, operator behavior. Investigators are spending less time reviewing procedures and more time observing whether those procedures are actually being followed on the floor. Small deviations, like gowning lapses, unclear interventions, incomplete monitoring responses, are no longer viewed in isolation. FDA is asking whether they reflect a broader lack of control. So, if your practices don't match your procedures, FDA will notice. So, what manufacturers should be asking themselves is this: Would an FDA investigator really observe what our procedures are claiming?

Supplier and CMO oversight has also become a frequent inspection entry point these days. FDA is no longer satisfied with paper qualification or reliance on contracts alone. Investigators are asking how companies actually monitor suppliers, how issues are escalated, and who owns decisions when something goes wrong. This is especially true for global supply chains. FDA expects the same level of oversight regardless of geography. It is important to keep in mind that a problem at your supplier is still your problem, and FDA inspections increasingly reflect that reality. Manufacturers should be asking themselves, how do we know our partners are in control today?

Finally, we're seeing a very basic but very consequential documentation failures. Incomplete batch records, unexplained discrepancies, backdating, and after-the-fact reconstruction continue to appear in inspection findings. FDA does not view these as administrative issues. They undermine the confidence in the entire operation. The principle remains unchanged, and that is, if it isn't documented, it did not happen. Manufacturers should be asking themselves, would our records withstand scrutiny without explanation?

So, a natural question is why some inspections end with a manageable FDA 483, while others escalate into warning letters. Often, it is not the observation itself, it is the response. Superficial investigations, defensive tone, unrealistic timelines, or CAPAs that aren't implemented effectively all signal to FDA that the company either doesn't understand the issue or isn't committed to fixing it. A key takeaway here is, warning letters frequently reflect regulatory frustration, not new discoveries.

So today, let me close with three takeaways. First, FDA inspections are a governance test, not just a compliance exercise. Second, recurring patterns matter far more than isolated mistakes. And third, inspection readiness isn't about passing the inspection. It is about demonstrating control. So, when systems work, inspections are far more predictable. When they don't, FDA is certain to find the cracks.

So, many thanks for listening, and we'll continue to unpack what regulatory signals really mean, not just for compliance, but for business. Until next time, my name is Winston Kirton, and this is Regulatory Horizons. Stay well.

Kattman: Thank you, Winston. If you have any questions for Winston, his contact information is in the show notes. As always, thanks for listening to BakerHosts.