FACT SHEET

Developing a Proactive Framework for Audit and Inspection Readiness

Industry Challenge

In a world of increasing partnerships, the number of audits and inspections required is increasing. Health Authority scrutiny has increased, as evidenced by a substantial increase in regulatory inspections in recent years, even in the face of risk-based target selection, and we expect that trend to continue. The broader use of vendors throughout the drug development lifecycle requires an evolving skillset and organizational mindset to effectively manage these critical activities while maintaining a state of readiness. With the added pressure of compressed timelines and more focus on efficiency, the stakes are higher than ever; it is increasingly critical to get it right the first time and minimize the time people spend to support audit and inspection activities. Companies need audits and inspections to run smoothly in order to build auditor confidence and to expedite approvals.

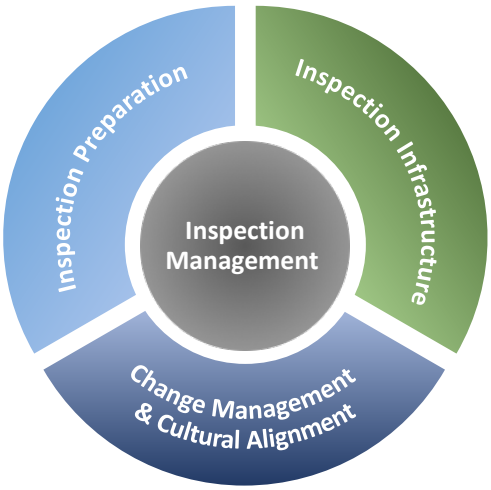
The TriRadial Solution

At its core, developing a state of readiness is all about demonstrating that your operations are executing consistently and that all outputs are compliant, well managed and well organized. At TriRadial, we have identified three essential components for an Audit and Inspection Readiness capability: ***Inspection Management, Inspection Preparation and Inspection Infrastructure***. The first two components go hand-in-hand within the lifecycle of a specific product, while the third helps ensure not only consistent processes, tools and roles across all sites and regions, but also continuous learning and improvement. Implementing all three components effectively also requires ***cultural alignment*** and a rigorous ***change management*** program to ensure the right mindset for maintaining the appropriate state of readiness in a diverse outsourcing environment.

> ***A well-run inspection or audit, supported by a sustainable, integrated framework, can help reduce the severity of a finding or sometimes avert one altogether***

Inspection Management:

Of the three components, Inspection Management is the most visible and critical to demonstrating how well you operate and how well you manage key issues. In this phase of activity, we help you define specific roles, SOPs, communication channels and tracking mechanisms to ensure a smoothly run and efficient audit or inspection. This is what the health authorities will see and how they will largely gauge your ability to control and monitor your business; it is one of the clearest reflections of your operations and first impressions are critical. A well-run inspection or audit can help reduce the severity of a finding or sometimes avert one altogether.



Inspection Preparation:

Having the processes and roles in place to manage audits and inspections is one thing, but preparing the organization so they are truly ready when an event happens is another …and typically where most companies fall short. Once the underlying mechanics of managing an audit or inspection are defined, the various teams involved must be trained and prepared for how to quickly and efficiently engage, react and respond. To help prevent the otherwise inevitable "fire drill" once an audit or inspection is announced, it is important to identify study-specific risks and to have clear explanations for and evidence of how those risks are managed. We can help assess responsiveness and employ storyboarding as an effective tool for discussing different types of risks and underlying issues.

Inspection Infrastructure:

The reality of drug development today is that companies and teams operate on a global basis, engaging with many partners, both internal and external. The ability to clearly demonstrate consistent and repeatable outcomes in that environment is increasingly complex, but nonetheless a critical requirement. How an inspection is managed in one country should be consistent with the next. The ability for a company to learn and continuously improve across organizational and regional boundaries can further demonstrate the company's global state of control. The right set of proactive metrics, highlighted in global dashboards, provides early insight to potential problems and help companies to mitigate risks before they become unavoidable problems that can derail an audit or inspection. Global procedures, roles and tools should also include continuous improvement mechanisms that help not only improve audit and inspection readiness, but also to avoid known risks.

The Results

Every audit or inspection host team wants to be in a position to welcome the investigator, whenever the event takes place. With the right process, tools, roles and preparation, management can rest assured that teams will come together quickly and efficiently, and that regulators will be supplied with information that clearly demonstrates an appropriate level of control over the drug development process. Teams can then focus on the science and not be unnecessarily burdened by fire drills and time spent scrambling to find answers.

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