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Turning Your Inspection Fears into Actionable Readiness Steps

As a clinical trial leader, being inspection ready is critical in the success of navigating a regulatory authority inspection and thus obtaining investigational product approval. Recently, more than 100 industry leaders gathered to discuss how to best prepare organizations for inspections, what strategies to employ, and how to mitigate risks. As regulators are taking significant strides towards modernizing clinical trials, being prepared can trip up even the most experienced clinical research professionals. Ultimately, decreasing cost and ensuring investments made for months, if not years, can result in clearing an FDA inspection and moving your organization towards market availability.

Top Inspection Fears:


Data monitoring and surveillance


Inability to adequately tell the story of the trials


Investigator/Site and vendor readiness

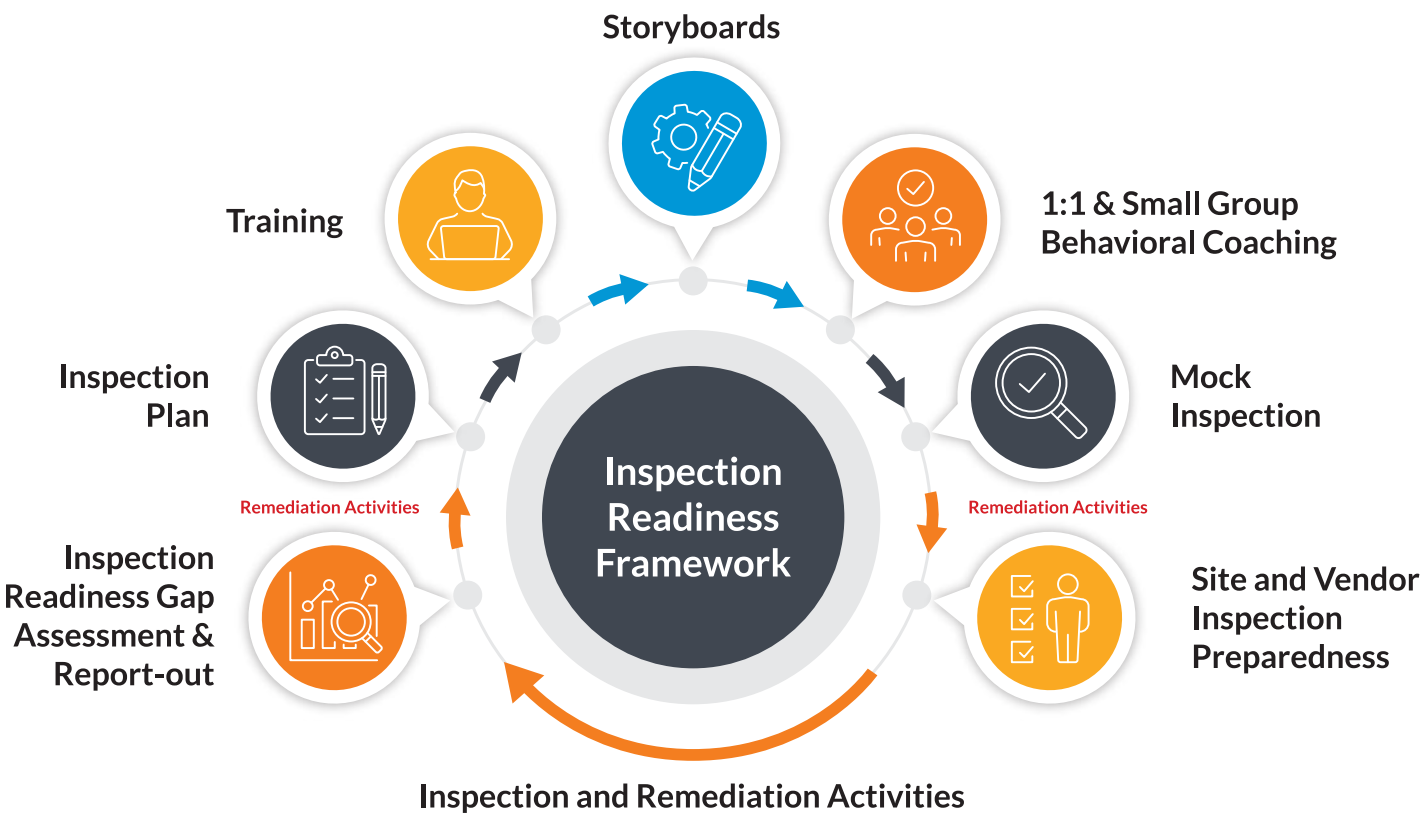

Receiving inspectional observations/ findings


Subject matter expertise confidence


Incomplete or inadequate records and documentation

> ***Our biggest fear is jeopardizing the drug approval process if the inspection does not go well. Our challenge is shifting a mindset, keeping inspection readiness at the forefront from the start. Ensuring strong documentation of issues, identifying risks, and being prepared with plans and processes. An inspection finding that negatively impacts our path to commercialization results in additional time and resources we may not be able to support.***
>
> \- CORE East Workshop Attendee

Seven Step Inspection Readiness Process



Preparation is vital to ensure study teams are equipped with knowledge to pass a successful inspection, which can lead to marketing approval without unnecessary steps or repeat processes. Sponsors need to establish an ongoing efficient process that demonstrates compliance and gives confidence to regulators that data controls are in place to ensure a product is safe and effective to yield a product approval.

> *Internally we have become so fearful of the inspection that we are not taking risk-based approach over our quality systems; not all risk is created equally. Not being ready because everything is a priority is a losing strategy. As a small biotech, we need help, especially with limited time and resources.*

Halloran offers virtual or on-site inspection and audit readiness engagements to assist clients in preparing for regulatory inspections from agencies such as the FDA, EMA, MHRA, PDMA, and CFDA. These engagements may include mock inspections, storyboard preparation, behavioral interview training, and coaching. We guide clients through immediate remediation efforts by crafting responses, strategies for remediation, and developing corrective and preventative action plans (CAPA).

The contents of this infographic are drawn from an on-site workshop, "Turning Your Inspection Fears into Actionable Readiness Steps," held during Halloran's CORE East program. More than 100 participants spent three days discussing clinical development approaches and best practices. Through the active exchange of ideas attendees shared valuable insights, applying them to their respective organizations. This event offers unparalleled access to industry leaders, decision-makers, and engaged participants who are enthusiastic about life sciences and drug & device development. We thank the participants for their contributions.

Our Experts

Elizabeth Bodi, Principal Consultant, has over 32 years of experience in the biopharmaceutical and medical device industries. Liz has expertise in quality and compliance with a primary focus on clinical operations and clinical quality assurance activities to ensure excellence and compliance across phase I-V clinical trials. Specific experience in the management of clinical quality assurance programs including site, vendor, and process audits. Additionally, skilled in the implementation of quality system initiatives – such as developing SOPs, conducting gap analyses and remediation, establishing and/or managing quality groups, conducting inspection readiness activities including behavioral coaching and mock inspection, hosting regulatory authority inspections, and the development and delivery of training courses in clinical research management and GCP.

Meaghan Marchand, Senior Consultant, has over 10 years of experience in the pharmaceutical and biotechnology industries. Her career has focused on clinical quality assurance activities to ensure excellence and consistency across phase I-V clinical trials. Meaghan also has specific experience in the management of clinical quality assurance programs including site, vendor, and process audits. She has deep expertise in inspection readiness strategies and is also skilled in the implementation of quality system initiatives including QMS assessments, developing SOPs, conducting gap analyses, remediation of compliance gaps, and conducting behavioral coaching in preparation for inspections.

To learn more about our inspection readiness services visit our website at **hallorancg.com**

Halloran Consulting Group, Inc.
@HalloranConsult
Halloran
A ProductLifeGroup Company
hallorancg.com
info@hallorancg.com