GCP INSPECTION INSIGHTS

Real-World Inspection Insight to Help Clinical Trial Sponsors Anticipate Risk and Stay Prepared

Virtual Education and Engagement
Thursday, March 26, 2026 | 11 AM – 2:30 PM ET
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GCP Inspection Insights brings together experienced quality and operations leaders for an honest look at how inspections are actually unfolding today. With a deliberate focus on FDA-driven transparency trends, real inspection data, and firsthand perspectives across regulatory authorities, this program goes beyond guidance to examine what clinical trial sponsors need to anticipate, adjust, and prioritize to remain inspection-ready.

Agenda

Thursday, March 26, 2026	
11:00 AM ET	**Welcome and Audience Demographics** • Review data collected from registration to understand who is in the audience • Discuss patterns and trends and benchmark where you stand
11:15 AM ET	**SCIENCE UNDER PRESSURE** ***Preparing Your Inspection Readiness Strategy Amid Regulatory and Political Change*** *Melissa Cabuang, Senior Director, Quality Assurance Program Head, GENENTECH*

	• Understand how FDA staff turnover, leadership changes, and shifting political priorities are already influencing clinical trial inspections • Anticipate increased scrutiny and evolving inspection models, including hybrid and unannounced visits • Identify practical ways sponsors can maintain inspection readiness amid shifting regulatory enforcement priorities and scientific uncertainty
11:45 AM ET	**FDA TRANSPARENCY IN PRACTICE** ***What Increased Inspection Visibility Means for Your Risk, Oversight, and Accountability*** *Niloy N. Shah, Vice President, R&D Quality, REPLIMUNE* • Understand how the FDA's increased transparency initiatives are changing the visibility of inspection outcomes and compliance history • Explore how publicly available data can be used to inform oversight, site and vendor selection, and inspection readiness strategies • Apply practical approaches to manage inspection readiness in an environment where findings and Form 483 trends are more visible, and more durable, than ever
12:15 PM ET	**OFF THE RECORD: LIVE Q&A*** *A Candid Conversation with the Previous Speakers* • Stay for an unrecorded, unfiltered discussion with our first two speakers as they respond to your toughest questions • Bring your questions, insights, and skepticism, nothing's off-limits except the recording **This session is not recorded and available to live attendees only*
12:30 PM ET	**BREAK** *Step away for a few minutes to recharge.* Grab a fresh cup of coffee, check your email, or get some air, whatever helps you reset and refocus for the next session.
12:45 PM ET	**CASE STUDY: USING ANALYTICS TO STRENGTHEN INSPECTION READINESS**

	How Data-Driven Insights Shift GCP Inspection Readiness from Reactive to Risk-Proportionate *Sofija Krivokapić, Data Science Lead, Clinical Quality, ASTRAZENECA* • See a real-world example of how inspection data is analyzed to reveal risk patterns and readiness gaps • Learn how predictive scoring can help teams prioritize inspection preparation and resource focus • See how analytics-driven insights shifted post-inspection follow-up from reactive response to proactive quality management • Take away practical steps to integrate inspection data analytics into your broader GCP readiness framework
1:15 PM ET	**EXPERT PANEL: INSIDE TODAY'S GCP INSPECTIONS** ***What Regulatory Investigators Are Asking Now, and What's Catching Even Experienced Teams Off Guard*** *Moderator* *Donna Dorozinsky, Founder & CEO, JUST IN TIME GCP* *Panelists* *Shola Jhanji, Associate Director/Quality Program Lead, GENENTECH* *Samelyse Lees, Director, Inspection and Intelligence Lead, GSK* *Sarah Silvers, Head of Clinical Quality Assurance, ORCA BIO* • Hear candid, firsthand global inspection experiences from trial sponsors across FDA, EMA, MHRA and more • Understand how expectations differ, and where they're converging, across regulatory authorities • Compare notes on how peers handled the unexpected: new questions, surprise requests, and evolving inspection styles • Gain perspective you won't find in guidance documents or conference decks, insight drawn directly from recent, real-world inspections
2:15 PM ET	**OFF THE RECORD: LIVE Q&A*** *A Candid Conversation with the Previous Speaker and Panelists*

	• Stay for an unrecorded, unfiltered discussion as the previous speaker and panelists respond to your toughest questions • Bring your questions, insights, and skepticism, nothing's off-limits except the recording **This session is not recorded and available to live attendees only*
2:30 PM ET	**LIVE CONFERENCE CONCLUDES** • Unless otherwise indicated, sessions are recorded and available for on-demand viewing in the Event Hub.