GCP DIRECTIONS

Virtual Education & Networking Week
July 28-31, 2025

Simplifying Clinical Compliance Together

Join clinical compliance leaders, innovators, and peers for a virtual week packed with insights, connection, and collaboration.

***GCP Directions** is designed to tackle the real-world challenges of Good Clinical Practice head-on—offering practical strategies, expert perspectives, and interactive sessions that move the conversation forward.*

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Agenda

Monday, July 28 – Regulatory Updates	
10:00 AM ET	**Welcome and Review of Platform**
10:15 AM	**ICH E6(R3) – WHAT'S CHANGING, WHAT IT MEANS** **Navigate the Most Impactful Updates and Learn How to Future-Proof Your Clinical Compliance Strategy** - Anchor your risk assessments in critical-to-quality factors that drive meaningful outcomes - Embed quality by design and stakeholder alignment into early trial planning - Strengthen oversight by formalizing vendor management and documentation practices - Build a clear data governance model to support validation and system compliance - Apply risk-proportionate thinking to monitoring plans that scale with trial complexity
10:45 AM	**BEYOND ICH E6(R3): WHAT ELSE MATTERS?** **Break Down the Latest Regulatory Guidance Shaping GCP Compliance—and What It Means for Day-to-Day Operations** - Prepare for BIMO inspection readiness with updated FDA expectations on inspection processes and planning - Understand how FDA guidance on Digital Health Technologies is reshaping data collection and protocol design - Apply the latest thinking from FDA's Protocol Deviations Draft Guidance to improve documentation and reporting - Align with new submission standards from FDA's BIMO Planning Guidance for CDER - Unpack the October 2024 FDA Guidance on Electronic Systems, Records, and Signatures, a major update modernizing expectations for data governance and oversight
11:15 AM	**LIVE AND UNFILTERED: SPEAKER Q&A SESSION** *Get face-to-face (virtually) with the previous speakers in an exclusive, live-only Q&A. This is your chance to ask the real questions—the ones you've been dying to ask but never see on a slide.* *No slides. No recordings. No judgment. Just candid conversation, behind-the-scenes insights, and the space to dig into what really matters.*
11:30 AM	**PANEL DISCUSSION: PUTTING R3 INTO PRACTICE** **Real-World Perspectives on How Clinical Teams Are Adapting for the R3 Era**

	Join a candid conversation with clinical leaders on how their organizations are translating the ICH E6(R3) guidance into action across clinical operations, systems, and culture. • Have you already started making changes? What's been the most impactful so far? • Which operational shifts are proving necessary to align with R3 expectations? • How are you prioritizing the elements of R3—and what advice would you offer to those just starting their compliance journey?
12:15 PM	**INTERACTIVE DISCUSSIONS: CHOOSE YOUR TOPIC** **Engage with Quality-Driven Clinical Professionals and Exchange Insights on the Topic of Your Choice** *This session is not recorded and only available for LIVE participation.* 1. **Who's Interpreting R3 at Your Company?** Discuss the cross-functional dynamics of implementing R3—who's driving the conversation, and are they the right ones? 2. **Oversight or Overkill?** Debate the fine line between effective vendor oversight and unnecessary documentation burdens. 3. **QbD or Buzzword?** Get real about how (and whether) quality by design is actually being implemented in trials. 4. **The Protocol Is the Problem.** Unpack how outdated or overcomplicated protocols are at the root of compliance issues. 5. **Who Owns the Data Now?** Navigate the murky waters of data governance, especially in decentralized and tech-heavy trials.
1:00 PM	Day Concludes

Tuesday, July 29 – Operational Alignment	
10:00 AM ET	**Welcome and Review of Platform**
10:15 AM	**ENSURING OPERATIONS FIT THE TRIAL** **Proactively Align Systems, Processes, and Resourcing to Avoid Downstream Risk** - Identify the hidden risks of operational misalignment—before they impact compliance or timelines - Conduct a structured assessment to evaluate whether processes and systems meet trial demands - Uncover gaps that could lead to data integrity issues, safety risks, or regulatory delays

	- Leverage findings to strengthen oversight, optimize procedures, and reduce unnecessary deviations - Align operational capabilities with trial scope to support efficient, compliant execution
10:45 AM	**CHANGE MANAGEMENT THAT STICKS** **Maximize the Impact of New Systems and Processes by Managing the People Side of Change** - Support employees through clinical and compliance changes by focusing on the human side of adoption - Identify common change resistor profiles and strategies to address resistance early and effectively - Leverage tools like change impact assessments, stakeholder mapping, and communication plans - Apply a structured change management model to bridge the gap between implementation and sustained results - Use training plans, performance metrics, and feedback loops to drive adoption and long-term engagement
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11:30 AM	**PANEL DISCUSSION: OVERSIGHT & RELATIONSHIP MANAGEMENT** **How Sponsors Are Rethinking Partnerships in Light of Increased Oversight Expectations** *Join clinical leaders for an open discussion on how organizations are navigating evolving oversight requirements while maintaining strong, productive relationships with CROs and vendors.* - Explore the strengths and challenges of your current partnership model - Share how ICH E6(R3) is reshaping expectations for oversight and accountability - Discuss whether current models are built for true collaboration—or just compliance - Examine the growing trend of sponsors **taking back ownership of the TMF**—and what it means for oversight and control - Identify the critical questions to ask when selecting a partner in today's compliance landscape

12:15 PM	**OPEN MIC DISCUSSIONS: COLLECTIVE COMPLIANCE—What We're REALLY Doing** *This open engagement format encourages participants to bring their challenges and best practices, so we can discuss, share, and recognize you are part of a tribe. This session is not recorded and only available for LIVE participation.* Choose your preferred topic area 1. **That Seemed Like a Good Idea....** Lessons from compliance initiatives, process changes, or tech rollouts that didn't go as planned—what was learned, and what you'd never do again. 2. **TMF Therapy** Open up about the struggles (and small wins) of managing your Trial Master File—from vendor oversight to version control to inspection panic moments. 3. **Oversight Overload** How much oversight is too much? Share what's working (or not) in managing vendors, documenting oversight, and balancing trust with compliance. 4. **Whose Process Is It Anyway?** Talk through the chaos of overlapping SOPs, unclear ownership, and cross-functional misalignment—plus what you've done to bring order to the madness.
1:00 PM	Day Concludes

Wednesday, July 30 – Inspection Readiness	
10:00 AM ET	**Welcome and Review of Platform**
10:15 AM	**THE STORY OF YOUR STUDY** **Identify Compliance Gaps by Aligning Your Study's Narrative Across Plans, Processes, Systems, and Documentation** - Identify misalignment between procedural documents, study plans, and the study team's narrative that could impact inspection outcomes - Detect inconsistencies between TMF content, trial conduct, and operational workflows that create compliance risks - Review supporting documentation to assess how well your TMF tells the complete and accurate story of the study - Evaluate systemic gaps that could compromise inspection readiness and regulatory compliance - Develop a targeted action plan to address inconsistencies and prepare for successful inspections - Gain confidence that your TMF and operational processes present a compliant, auditable record, prepared for an inspection

10:45 AM	**CLOSING THE GAPS: PROACTIVE GCP COMPLIANCE** **Maintain Compliance and Mitigate Risk with Ongoing Remediation and Oversight** - Identify and remediate process gaps that could undermine long-term compliance and inspection outcomes - Establish continuous oversight practices to ensure ongoing alignment between study plans, processes, and documentation - Implement routine quality checks and audits to proactively detect and address emerging risks - Strengthen vendor oversight by formalizing processes that document decision-making and accountability - Foster a culture of continuous compliance that adapts to evolving regulations and inspection expectations
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11:30 AM	**PANEL DISCUSSION: GCP INSPECTION GOSSIP** **Insights and Lessons from Recent Regulatory Inspections to Strengthen Your Inspection Readiness** - Hear real-world experiences from panelists about recent GCP inspections—what surprised them and what they'd do differently - Understand the key areas of focus across different regulatory authorities and how these differences impact inspection preparation - Identify emerging trends, common findings, and shifting expectations that could affect your next inspection - Discuss which agencies or inspection areas present the greatest challenges and how to stay ahead of evolving requirements - Gain practical tips and advice to fine-tune your inspection readiness strategy based on firsthand insights
12:15 PM	**INTERACTIVE: MORE INSPECTION GOSSIP** **Spill the Tea on Your Latest Regulatory Inspection Experiences and What You've Heard from Others** *Open engagement format allows for face-to-face interaction and a real opportunity to candidly share and learn from one another. This session is NOT recorded and only available for LIVE participation.*

1:00 PM	Day Concludes

Thursday, July 31 – Future-Ready Compliance	
10:00 AM ET	**Welcome and Review of Platform**
10:15 AM	**GENERATIVE AI: THE FUTURE OF INSPECTION READINESS** **Unlock the Power of AI to Automate, Analyze, and Elevate GCP Compliance** - Recognize the game-changing impact AI will have on clinical compliance through automation - Discover how AI-driven insights can transform how you predict risks and manage inspection readiness - Explore the possibilities of a self-analyzing TMF that anticipates inspector questions before they arise - Envision how virtual inspection co-pilots could reshape how teams locate, interpret, and present study data - Consider the role AI could play in delivering continuous inspection readiness instead of reactive preparations
10:45 AM	**GENERATIVE AI – WHAT IT MEANS FOR CLINICAL COMPLIANCE TODAY** **Lay the Foundation for Seamless AI Adoption and Maximize Immediate Impact** - Evaluate how your clinical infrastructure must evolve to integrate AI and next-gen compliance tools - Identify the critical steps to prepare for AI adoption while maintaining inspection readiness - Understand the challenges of implementing AI — and where to find opportunities for early wins - Discover how strategic AI pilots can generate actionable insights and build internal momentum - Determine how to source the right expertise and partners to guide your AI transformation journey
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11:30 AM	**PANEL DISCUSSION: THE COST OF NON-COMPLIANCE – CAN YOU AFFORD TO FALL BEHIND?**

	Uncover What's at Stake and Learn How to Secure Leadership Buy-In for Innovation in Clinical Compliance - Examine the financial, operational, and reputational risks of maintaining outdated compliance systems - Explore how manual processes and lack of automation contribute to regulatory findings and inspection failures - Understand how AI-powered compliance tools can mitigate risk and reduce costly remediation efforts - Learn how to frame the **ROI of compliance innovation** to gain executive buy-in and support - Hear firsthand stories of inspection challenges that could have been avoided through technology adoption - Discover proven strategies for building internal momentum and positioning compliance innovation as a business imperative
12:15 PM	**ASK ME ANYTHING: EXCLUSIVE LIVE SESSION WITH DONNA DOROZINSKY** **A No-Holds-Barred Q&A on Clinical Compliance, GCP, and Inspection Readiness** *Participation is limited to trial sponsors only. Bring your toughest questions and get unfiltered insights directly from Donna Dorozinsky, Founder & CEO of Just in Time GCP.* • **No topic is off-limits**—ask about GCP challenges, inspection pitfalls, vendor oversight, or AI adoption • **Get personalized guidance** on navigating compliance complexities and staying ahead of regulatory changes • **Participate in a candid, interactive conversation** where you set the agenda • **Live and unrecorded**—this session is available only to those who attend in real time
1:00 PM	Conference Concludes

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