Monitoring and GCP Compliance
Nashville, TN (November 2026)

Upon completion of this conference, participants will be able to:

1. Understand the purpose of clinical trial monitoring and the regulatory requirements.
2. Apply Good Clinical Practice principles during monitoring activities and monitor prep.
3. Evaluate participant safety and data integrity through monitoring practices.
4. Describe risk-based monitoring approaches.
5. Identify, document, and manage non-compliance findings.
6. Utilize monitoring as a key component of inspection readiness and overall quality management.

Agenda

Day 1 Overview: Will answer three important questions: Why does monitoring exist? What do monitoring review? How does monitoring protect subjects and data?

8:30 – 8:45 am	**Welcome**
8:45 – 10:00 am	**Why Monitoring Exists: Protecting Participants and Ensuring Compliance** Monitoring is not simply a regulatory requirement, it is a critical mechanism for ensuring participant safety, data reliability, and compliance with GCP and protocol requirements. This session will include the purpose of monitoring, regulations for sponsor oversight, how monitoring protects the participants, the different types of monitoring, and the responsibilities of both the sponsor and the site. **Discussion with participants:** • What could happen if monitoring did not exist? • Real-world examples of monitoring findings
10:00 – 10:15 am	**Break**
10:15 – 11:00 am	**GCP Principles Applied to Monitoring Visits** Good Clinical Practice principles are the foundation of every monitoring activity. This session will be interactive, demonstrating how monitors assess compliance through routine review activities. It will be an overview of the GCP principles, how these requirements are translated into monitoring activities, common findings related to non-compliance of GCP, and regulatory documentation expectations. This session will include an interactive workshop: "think like a monitor" activity where participants will be asked to identify GCP violations, documentation deficiencies, participant safety concerns, and data integrity issues.

11:00 am – 12:00 pm **Presenter: Jennifer Kinsey**	**Monitoring for Participant Safety and Data Integrity** Monitoring serves as a critical safeguard for both participant protection and credible study results. This session will include ALCOA+ principles review, source documentation review, source data verification, source data review, query generation and query resolution, adverse event review, eligibility verification, and ICF review. There will be a small exercise where participants will be asked to evaluate sample source documents and identify documentation issues that could impact data integrity and subject safety.

12:00 – 1:00 pm	**Lunch**
1:00 – 1:45 pm	**Monitoring Visit Lifecycle: Preparation, Conduct, and Follow-Up** This will outline the monitoring visit from focused preparation through evidence-based review, reporting, and closure. Participants will review how to prioritize safety and critical data, communicate findings, assign follow-up actions, and build a visit plan using sample site concerns.
1:45 – 2:45 pm	**Expanded Source-Document Review Workshop** Participants will review six fictional record excerpts as one participant story, tracing consent, eligibility, safety, medication, investigational product accountability, and documentation issues across source records, logs, and EDC. Groups will identify the impacts, determine the evidence needed to clarify findings, and propose appropriate queries, follow-up, or escalation.
2:45 – 3:00 pm	**Break**
3:00 – 3:45 pm	**Protocol Deviation Assessment and Escalation** This portion introduces a four-step framework for confirming deviation facts, assessing participant and data impact, identifying recurring patterns, and applying study-specific escalation criteria. Participants will work through six scenarios to practice documenting

	the rationale, determining appropriate follow-up, and identifying evidence needed for closure.
3:45 – 4:45 pm	**Integrated Mock Monitoring Visit** Teams will practice a monitoring visit session. They will conduct a simulated monitoring visit at a fictional site with consent, safety-reporting, data, and accountability concerns. Through preparation, evidence review, site discussion, and close-out, participants will develop the findings log and action plan that distinguishes urgent escalation from routine follow-up and specifies owners, due dates, and closure evidence.
4:45 – 5:00 pm	**Debrief and Day 1 Recap** Participants will reflect on the mock visit, discussing how evidence shaped their assessments, which findings required escalation, and what made follow-up actions clear and defensible. The recap reinforces the day's key lessons on GCP, ALCOA+, source review, deviation assessment, and documented resolution of monitoring findings.

Day 2 Overview: will discuss modern monitoring practices, how sites can manage noncompliance and how monitoring contributes to inspection readiness.

8:15 to 8:30 am	**Welcome**
8:30 – 10 :00 am	**Risk-Based Monitoring and Risk-Based Quality Management** As clinical trials become increasingly complex, monitoring strategies continue to evolve from 100% review models to risk-driven approaches. This session will explain risk-based monitoring and risk-based quality management. Discussing critical quality factors, centralized monitoring, and ICH E6(R3) updates. There will be a short discussion where participants will be asked to weigh in on how risk-based monitoring strengthens GCP compliance. Participants will be asked to do a group exercise of developing a risk-based monitoring plan for a sample study.

10:00-10:15am	**Break**
10:15-11:15 am **Presenter: Emily Sheesh**	**Monitoring Visits: Detecting and Managing Non-Compliance** Monitoring plays a key role in identifying issues before they escalate into serious compliance concerns. This session will review the identification of protocol deviations and violations, repeated non-compliance from the site, root cause analysis, and corrective and preventative actions. There will be a short exercise where participants will be given an example and have to determine the recurring GCP violations. The exercise will give them practice on what findings a monitor should document, what should be escalated, what warrants a CAPA, and identifying appropriate follow-up monitoring actions.
11:15am – 11:45am	**Inspection Readiness Begins with Monitoring** Review of FDA inspection trends, what inspection readiness means throughout the study lifecycle, monitoring reports as evidence of sponsor oversight, audit trails and documentation expectations, and common inspection findings. This session includes a short discussion with participants on how routine monitoring activities improve inspection readiness.
11:45 AM – 12:15 PM	**Monitoring as a GCP Tool: Bringing It All Together** This session will tie everything together. Discussing the three objectives of monitoring: protecting participants, ensuring data integrity, and demonstrating compliance. The closing session will include a short exercise where participants will be asked to match monitoring actives with the GCP objectives they support.