

Data Integrity and Governance Workshop

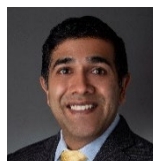
September 9–10, 2024 | Ahmedabad

September 12–13, 2024 | Hyderabad

Instructors:



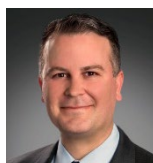
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The Stage 1 workshop is focused on developing a solid understanding of the foundations of GMP data governance and data integrity assurance. In this two-day workshop we discuss current regulatory expectations and guidance, including the ALCOA principles, with the goal of developing a comprehensive understanding of how to operate efficiently within a GXP regulated environment. The workshop is designed as 75% lecture and 25% hands-on case studies where participants will be tasked with working in small groups to evaluate various DI scenarios, followed by group presentations.

Day One – Regulatory Requirements and Good DI Practices	
8:00 am – 9:00 am	Registration, Networking, and Coffee/Tea
9:00 am – 11:00 am	Session 1: Current State – Regulatory developments, 483 and WL examples <ul style="list-style-type: none">FDA expectations and recent 483 examplesUpdates to GAMP 5 and Annex 11Recent developments in regulatory DIRecent update to ICH Q9, QMM
10:00 am – 10:30 am	Networking Break
10:30 am – 12:30 pm	Session 2: Solutions – An Introduction to Risk-Based Data Governance

	<p>Data governance is a principled approach to managing data during its life cycle, from acquisition to use to disposal. This session will discuss how the concept of data governance applies to the manufacture of pharmaceuticals.</p> <ul style="list-style-type: none"> • Data Governance • Data Mapping • Data Ownership
12:30 pm – 1:30 pm	Networking Lunch
1:30 pm – 3:00 pm	<p>Session 3: Data Mapping Case Study</p> <p>This session will discuss several practical case studies and how the practice of data mapping will assist in determining possible compliance risks.</p> <p>5 different case studies – 1 study for 2 groups</p> <ul style="list-style-type: none"> • EM plates • Sample prep • Integration • Production Monitoring Forms • Batch record review
3:00 pm – 3:15 pm	Networking Break (Tea/Coffee)
3:15 pm – 5:00 pm	<p>Session 4: Risk based approaches to good Data Integrity controls in production and laboratory</p> <p>This session will examine the various risk-based approaches to addressing data integrity controls from the acquisition of data and review of the data as well as lifecycle approaches to ensuring that the data that was generated is preserved on legacy systems.</p> <ul style="list-style-type: none"> • A demonstration of Risk Management tools used to develop data integrity control strategies • DI in CDS (e.g., Empower 3) • Good Documentation Practices for Paper-based Systems • Audit trail review strategies • DI aspects for managing hybrid and legacy systems in production (DCS, SCADA)
5:00 pm – 5:30 pm	Session 5: Q&As

Day Two – Critical Thinking and DI Investigations	
7:30 am – 8:00 am	<i>Networking, and Coffee/Tea</i>
8:00 am – 9:00 am	<p>Session 1: Critical thinking</p> <p>This session will discuss how critical thinking is essential in determining risk associated with data integrity breaches and the importance of how critical thinking can be utilized in investigations.</p>
9:00 am – 11:00 am	<p>Session 2: Robust Data Integrity Investigations: from initial event to final CAPA: a systematic and risk-based approach</p> <p>This session will evaluate the expectations for conducting data integrity investigations and the best practices for conducting internal audits to detect data integrity breaches.</p> <ul style="list-style-type: none"> • DI investigation expectations • DI Internal audit tips and tricks
11:00 am – 11:15 am	Networking Break (Tea/Coffee)
11:15 am – 12:15 pm	<p>Session 3: Case Study – Data Integrity Investigations: A systematic and risk-based approach</p> <p>This session will provide practical case study examples of data integrity breaches and the various ways to address these possible breaches. This will be a hands-on and interactive session discussing possible scenarios of data integrity investigations and how to address these issues.</p> <p>5 different case studies – 1 study for 2 groups</p> <ul style="list-style-type: none"> • EM Data • OOS • Laboratory CDS System • Batch record falsification • Scratch papers

12:15 pm – 1:15 pm	Working Lunch (Participants to continue their case study discussion and prepare presentation)
1:15 pm – 2:15 pm	Session 4: Case Study Presentations and Discussion
2:15 pm – 2:30 pm	Networking Break (Tea/Coffee)
2:30 pm – 3:30 pm	<p>Session 5: Computer Software Assurance (CSA) & CGMP – points to consider when embracing a risk-based validation approach</p> <p>This session will discuss the concept of computer software assurance and how this concept may be used for leveraging resources and priorities during computer system validation.</p>
3:30 pm – 4:15 pm	<p>Session 6: Management Responsibility and Regulatory and Legal Risks Due to DI Issues</p> <p>This session will discuss the role of management oversight and awareness regarding data integrity issues. This session will also discuss maintaining a complaint data integrity culture at the site.</p> <ul style="list-style-type: none"> • Regulatory and legal Risk due to DI issues • Management responsibility
4:15 pm – 4:30 pm	<p>Session 7: Wrap-up and What's next!</p> <p>This session will discuss vendor management tools, quality metrics, and future applications of Pharma 4.0 concepts in pharmaceutical manufacturing.</p> <ul style="list-style-type: none"> • Advanced data management systems (e.g., clouds, dashboarding, QI) • Vendor management