hgLearn

Create. Empower. Hone.

Topic	Duration	Delivery*
NEW! Data Culture This is an Introductory course to the topic of Data Culture in Health Authority Regulated environments. This course establishes the current Regulated landscape in context with Digital Transformation, Advanced Digital Technologies, and Data Analytics.	60-90 minutes	• onsite • remote • hybrid
Data Governance for Leadership This is a 60-minute training course designed for Executive Management and Management with responsibilities for Data Integrity Assurance. Learning objectives include: • Data Governance fundamentals in context with applicable global Regulations, Guidance, industry standards and best practice. • Management responsibilities for Data Governance and Data Integrity Assurance • Data Governance System Review	60 minutes	• onsite • remote • hybrid

Foundations in Data Integrity Assurance
This is a comprehensive course for all personnel responsible for assuring the integrity of GxP information and data.
 	
Learning Objectives include:
• Overview of Regulations, Guidance, and Industry standards
• Data Governance + Data Integrity Principles + Requirements (ALCOA+ and GoodDocPractices)
• Data Integrity Assurance: Controls for Prevention, Detection and Correction
  ◦ Self-Inspection
  ◦ Data Review/Audit Trail Review
  ◦ DI Investigations + CAPAs
• Case Studies
	4-6 hr workshop	• onsite

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Topic	Duration	Delivery*
AccelerateDI This is an introductory course with a focus on fundamental data integrity and Good Documentation Practice requirements. This course is suited for start-up organizations that are operating at scale as a precursor to additional training.	60 minutes	• onsite • remote
Data Governance Program Development This course provides an overview and methodology for developing and implementing a Data Governance Program. • Data Governance Overview • Data Integrity Master Plan(s) • DI Policies + Procedures • Data Integrity Risk Assessments • DI Training Curriculums • DI Metrics • Quality Culture and Data Integrity	60-90 minutes	• onsite • remote • hybrid

Data Integrity Assurance Workshop
This is a hands-on workshop for individuals to build competency in data integrity assurance through exploration of methodology, tools, and interactive case studies.
 	
Learning objectives include:
• Overview of Data Governance and data integrity assurance in context with applicable Regulations, Guidance, Industry Standards, and best practice
• Data Governance + Data Integrity Principles + Requirements (ALCOA+ and GoodDocPractices)
• Data Integrity Assurance: Controls for Prevention, Detection and Correction
  ◦ Self-Inspection
  ◦ Data Review/Audit Trail Review
  ◦ DI Investigations + CAPAs
• Data Integrity Risk Assessments:
  ◦ Interactive Data Process Mapping and DI Risk Assessments
  ◦ Data Integrity Control Strategies for DI Monitoring + Continuous Improvement
	3-day workshop	• Onsite ILT only

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Data Integrity Investigation Training This training provides an overview of data integrity investigations to include the unique regulatory requirements and expectations for investigating data integrity issues. The overview includes examples, methodology and tools. Data Integrity Investigation workshops include in-depth discussions, case studies, and breakout sessions wherein participants conduct an E2E data integrity investigation based on real world examples.	Intro Module: 90-min -or- 4-hr workshop	• onsite • remote
Data Integrity Audits and Self-Inspection This training provides an overview of data integrity audits and self-inspection to include audit preparation, methodology, techniques, and oversight of CAPAs and remediation for DI risks and non-compliance. Topics span internal and external audits, and inspection techniques across manual, hybrid, and electronic processes and records. Data Integrity Audit and Self-Inspection workshops include in-depth discussions, case studies, and breakout sessions wherein participants conduct an E2E data integrity audit and inspections based on real world examples.	Intro Module: 90-min -or- 4-hr workshop	• onsite • remote

Inspection Readiness
This course provides a comprehensive approach to inspection readiness strategy that engages all levels of the organization from manufacturing operators to senior level employees.
 	
Learning objectives include:
• The role of FDA in protecting the public health
  ◦ History of FDA
  ◦ Jurisdiction and Authority
  ◦ Enforcement Tools
• The process of Inspection Management
  ◦ Roles + Responsibilities during inspections
  ◦ Do's + Don'ts during Inspections
  ◦ Managing requests and records
  ◦ Responding to issues
• Proactive and Effective Preparation: Training, Walk Throughs, Mock Inspections
	4 hours	• onsite
		• remote
		• hybrid

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Topic	Duration	Delivery*
Audit Trail Review, Data Review • **Laboratory** • **Manufacturing** This training provides an overview of data and audit trail review to include types of data and associated audit trails, audit trail functionality, and the regulatory requirements and expectations for effective data and audit trail review. The training includes examples, methodology and tools to support meaningful data and audit trail review for all types of data.	90-min	• onsite • remote
Good Manufacturing Practices This training provides an overview of the Regulations: • 21CFR 210/211: Current Good Manufacturing Practices for Finished Pharmaceuticals • 21 CFR 600/610: Biological Products • 21 CFR 1271: Human Cell Tissue • 21CFR 820: Quality System Regulation for Medical Device • ISO13485: Medical Devices	Intro Module: 90-min -or- 2-3 day workshop	• onsite • remote
Quality Management Maturity This course provides a comprehensive introduction Learnings Objectives include: • Overview of Quality Management Maturity and Regulatory Expectations • Assessment, Measurement + Quality Metrics	2 hours	• onsite • remote • hybrid

Certifications

Upon successful completion of these programs, a Certificate of Qualification is granted to each participant.

Topic	Duration	Delivery*
Data Integrity Auditor Qualification Program This qualification program provides auditors with the right perspective and practical tools to establish audit programs and build capability in auditing against data governance and data integrity requirements. This overview will include a deeper dive into data review strategies, interview techniques, and documentation of audit findings to get the most out of data integrity audits. Case studies will be used to demonstrate proficiency in detection of data integrity breaches.	upon request	
Data Integrity Investigator Qualification Program This qualification program provides investigators with an overview of the regulatory expectations for data integrity investigations and the methodology to conduct meaningful investigations that achieve root cause and sustainable corrective action. Workshops will include strategies for containment and immediate actions, interviews, data review, impact assessment and effective CAPA as well as explore contributing factors such as individual and organizational behaviors and values.	upon request	
Data Integrity Data Reviewer Qualification Program This qualification program provides data reviewers with the right perspective and tools to perform effective data review on a routine basis. The workshop will include regulatory expectations for data review, and the role of the data reviewer. Topics include identifying, accessing, and reviewing manual, electronic and hybrid data and managing corrections and escalations.	upon request	

Certifications *continued*..

Upon successful completion of these programs, a Certificate of Qualification is granted to each participant.

Topic	Duration	Delivery*

Data Integrity Certification:
This certification program is a comprehensive course for personnel assuring the integrity of GxP information and data. The course will cover foundations in data integrity and offer advanced data integrity topics specifically designed to reflect your organization and demonstrate consistency and proficiency of understanding.
 	
Learning Objectives include:
• Overview of Regulations, Guidance, and Industry standards
• Data Governance + Data Integrity Principles + Requirements (ALCOA+ and GoodDocPractices)
• Data Integrity Assurance: Controls for Prevention, Detection and Correction
  ◦ Self-Inspection
  ◦ Data Review/Audit Trail Review
  ◦ DI Investigations + CAPAs
 	
This program can be designed for:
• Laboratories
• Manufacturing Operations
• Quality Assurance
	upon request	

Data Governance and Data Integrity for CSV/CSA Practitioners	upon request	
Deviation, Investigation, CAPA Management	upon request	
ICH Q10	upon request	
Quality Risk Management (ICH Q9)	upon request	