DATA INTEGRITY WORKSHOP

BOOK

YOUR

SLOT

Book this data integrity training to up-skill your company! The training can be scaled, and the content is customizable for your needs!

Contact us: https://www.gxp-cc.com/contact/
info@gxp-cc.com

About the course

Data integrity failures in the pharmaceutical industry are a recipe for disaster which could compromise the security of patients, the trust of regulators and the quality of the product. This workshop will provide insights into the key processes and concepts enabling data integrity. We will explain core data integrity principles and provide real-world examples and case studies. We will discuss current regulatory expectations, best industry practices, and hands-on interactive exercises to maximize the learning progress.

KEY TOPICS

- Key principles for data integrity
- Quality culture and the human factor
- Data retention
- Third party management and supply chain oversight
- Segregation of duties
- Paper and hybrid records
- Data and metadata reviews
- Implementation strategies

YOUR SPEAKER

Ulrich Köllisch, PhD

Dr. Ulrich Koellisch has been on the forefront of the data integrity initatives and has supported many organizations in the pharmaceutical and biotech sectors executing Data Integrity campaigns. Ulrich has experience in consulting for audit preparation and GMP/ GCP areas, co-leads the PDA interest group "Data Integrity", and is an active participant in other industry knowledge groups.

Your Course Program

DAY 1

Perspectives on data integrity	• Historical perspectives • Regulatory perspectives	0:30 h

Introduction and hot topics	• Key concepts
	• Terms and definitions
	  ◦ Interactive Exercise
	• The human factor and quality culture
	• Data life cycle
	• Requirements and guidelines - an overview
	• Hot topics and recent regulatory action
	  ◦ FDA 483 trends and how to learn from them
		1:30 h

Coffee Break		0:30 h
Data flow mapping	• Data flow maps • Data Integrity Risk Assessments (DIRA) • Interactive exercise data flow (customizable!)	1:30 h
Q&A session day 1		

DAY 2

Data and Audit Trail Review	• Data and metadata review • Audit Trail requirements • Audit Trail Review Strategy • Hands-On Audit Trail Review Exercise	2:00 h
Coffee Break		0:30 h
Third Party Management	• Regulatory Overview • Current cases • Hands-On Exercise	1:30 h
QnA Session Day 2		

Your Course Program

DAY 3

Access Control and Segregation of Duties	• Least priviledges concept • Access control strategy and requirements • Regulatory case studies	1:00 h
Data Retention	• Data Retention requirements • How to create a Data Retention concept • Hands-On Example	1:00 h
Coffee Break		0:30 h
From Data Integrity to Quality Intelligence	• How to handle outdated systems ◦ Paper Records and Hybrid Records • Enablers for Informed Decision Making: Data Integrity, Knowledge Management and Advanced Data Analytics	1:30 h
QnA Session Day 3		0:30 h

Who should attend?

Pharmaceutical and Life Science Companies:
Quality assurance; manufacturer; validation and qualification engineers; compliance and quality control, contract manufacturing organisations (CMOs).

Presentation slides will be provided along with a **digital GxP-CC course certificate!**

Any Questions or suggestions?

We are flexible in customizing the workshop, e.g., focusing on specific areas like quality control, manufacturing or incorporating other regulatory areas (e.g. GCP, CMC).

Please feel free to send any questions and discussion topics to: info@gxp-cc.com