

# TRAINING AND EDUCATION: DATA INTEGRITY



Our services in training and education provide cutting edge, innovative and dynamic training and education on contemporary topics of interest and value to our clients. Our staff of industry experts with real-world experience combines global regulatory knowledge with industry best practices to help clients increase their knowledge and implement pragmatic solutions to improve and enhance their operations.

## DATA INTEGRITY IS CRITICAL

Recent actions by FDA and global regulators have uncovered that data integrity is a topic of concern and prevalence in the pharma biotech industry. Lack of data integrity can jeopardize regulatory compliance, patient health and safety, and company reputation. Our Data Integrity course is designed to reduce risk in all of these areas and helps attendees have a clear line of focus on the importance and impact of data integrity.

### The two-day course helps attendees to:

- > Understand the concept of data integrity across the lifecycle and within different aspects of the operational spectrum
- > Recognize, identify and consider potential root causes that may lead to data integrity issues
- > Grasp the impact that data integrity has on processes, product, patients and regulators
- > Utilize approaches for setting up data integrity surveillance and governance processes and conduct risk assessments to proactively identify where data integrity risks exist
- > Understand the link between data integrity and the quality management system and what steps should be taken to integrate data integrity into a robust QMS process to ensure sustainability



## WHAT YOU'LL LEARN

### DAY 1

Instructional and participative exercises on day 1 define what data integrity is and help attendees identify areas throughout the lifecycle where data integrity is applicable and needs to be managed.

Additionally, attendees learn to identify and understand the drivers and potential root causes that can lead to data integrity issues, including causes related to culture of quality factors. By thinking through and discussing potential root causes, attendees will be able to determine patterns and themes that can help them and their organizations mitigate or prevent these issues in the future.

The learning on day 1 will also help attendees understand the likelihood and impact of data integrity on processes, product, patients and regulators. This session will reinforce and prioritize the patient focus and impact to ensure attendees have an emotional connection to the criticality and importance of this topic.



### DAY 2

Instructional and participative exercises on day 2 assist attendees in understanding how to properly set up data governance and a surveillance process, and how to utilize risk assessment in evaluating both paper and electronic documentation processes.

Attendees will also gain information on the link between data integrity and the QMS and how to properly integrate these concepts with the objective of continuously managing data integrity and achieving sustainability in data validity and compliance.

## OUR TRAINING AND EDUCATION SERVICES

We provide training and education services to pharmaceutical, biologics and biotech companies and offer training and education that meets the most pressing and current topics in the industry. We ensure the quality and sustainability of our educational services by ensuring that our courses include lectures, team work, case studies and discussions that engage course attendees.

Our training and education services are designed to build capability and ensure that course attendees are provided with pragmatic, effective and powerful tools and tactics so that they can leverage their ability to influence their organization and serve as change agents to drive innovation and continuous improvement.

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