

REGULATORY COMPLIANCE SOLUTIONS

DATA INTEGRITY

Raland Compliance Partners is your trusted partner delivering **sustainable** Quality, Regulatory, and Clinical compliance solutions.

Data Integrity (DI) refers to the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be **A**ttributable, **L**egible, **C**ontemporaneously Recorded, **O**riginal or a certified copy, and **A**ccurate (ALCOA).

If Data Integrity isn't one of your top compliance concerns...it should be. The proof that the integrity of your data is a major concern for the FDA is in the increasing number of DI-related Warning Letters and 483s issues by the FDA over the past 10 years and the recently released guidance on Data Integrity and Compliance with Drug CGMP.

Our Data Integrity solutions include the following services:

- DI Assessments and Mock Inspections
- DI Compliance Planning and Risk Management
- Enforcement Action Remediation
- Customized DI Training