DATA INTEGRITY

Ensuring compliance with the evolving Data Integrity guidelines from the MHRA/FDA and other regulatory bodies is a major challenge for Pharmaceutical Manufacturers, Contract Organisations (Manufacturers, Research, Laboratories etc) and system suppliers.

Each impacted organisation must be able to demonstrate compliance during regulatory or client/customer inspection.

Clarity Compliance Solutions can be your Data Integrity partner and we can lead you through the whole Data Integrity Program activity.

Data Integrity Program Support

We have a team of highly experienced professionals to support you:

- DI Subject Matter Experts
- DI Program Leaders
- DI Assessment Leaders
- DI PMO Support

Combined with our Data Integrity Training Courses ensures we can deliver a cost effective pragmatic compliant solution.

Clarity Compliance Solutions have been helping clients comply with Data Integrity for a couple of years, building up a wealth of clients' Inspection experiences. We have developed our own approach to implementing Data Integrity, including a Data Integrity Toolkit and our approach to developing a Data Governance Framework.

Data Governance Framework:

Regulatory Requirements Business Operation & Continuity Needs

Strategic Planning & Data Integrity Programme

Organisation
Leadership | Culture and Human Factors | Responsibilities | Awareness
Policies | Ownership | Training
Procedures

Controls
Behavioural | Procedural | Technical

Supporting Processes
Auditing Metrics Classification Validation

Business Processes

IT Architecture & Infrastructure

Data Lifecycle Management

Regulatory Compliance Risk Managed Ongoing Business

Our approach would include:

Data Integrity Auditing – Understand your DI exposure

- DI Site Audit (Benchmarking and assessment)
- DI Program Audit (Ongoing DI program vs best practice)

Data Integrity Training – Ensuring competency of your team

Data Integrity Toolkit – Leverage and tailor our tools

- DI Policy, DI Strategic Plan & DI Project Definition
- DI Assessment Checklist & Procedure
- DI Implementing Positive Quality Culture
- DI Standard Operating Procedure (SOP) Review
- DI Risk Management Tools
- DI Reporting Tools
- DI into New Project Development Lifecycle
- DI Project Handover Criteria

Our goal is to help our clients achieve Data Integrity compliance by building a strong and robust Data Integrity Program that is woven into the fabric of the client organisation and through its Data Governance Framework is sustainable in its delivery and operation.

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Training is a critical element in the development, implementation and operational delivery of a Data Integrity Program.

During Regulatory inspection your organisation will need to demonstrate that your staff had a suitable level of Data Integrity knowledge and were competent to develop key components and deliver the key activities.

Our courses can help ensure your staff are suitably trained.

Training Courses are provided in three formats, these being:

- **In-House Course** Held at a convenient location, tailored to meet the specific needs for your organisation, allowing you to work through real issues in the privacy of your own team.
- **Open Forum Course** Held across various locations, with multiple company attendees, allowing excellent networking opportunities.
- **Online Training** Accessed over the internet using desktop computers, laptops, tablets and smartphones.

Our Data Integrity training courses include:

Data Integrity for Management (½ day)

Aimed at senior and departmental management. The course provides an overview of DI threats and issues posed within paper/electronic systems and explains the management obligations required to resource (budget and staff), implement and deliver a DI Governance system in order to comply with regulatory requirements.

Data Integrity for Practitioners (Full or ½ day)

Aimed at staff involved with development and implementation of a DI Program. The course provides an overview of DI threats and issues posed within paper/electronic systems and explains the key deliverables and tasks required to plan, develop, implement, monitor and roll-out a successful DI Program in order to comply with regulatory requirements.

Data Integrity for Operational Staff (Full day)

Aimed at staff in an operational capacity taking on roles such as Process Owner, Data Owner, Data Custodian, System Owner, Data Steward, Data User and exploring their roles and responsibilities in order to comply with regulatory requirements.

Data Integrity for Staff (Online)

Aimed at organisations, new starters and existing staff. The course provides a high-level overview of Data Integrity threats and issues posed within the paper and electronic systems and how to comply with regulatory requirements and expectations.

Bespoke Training Data Integrity Courses

Our courses come as standard modules, but we can customise the courses to meet your specific requirements. This could include:

- Increased number of practical exercises
- Exercises based on your organisation and its challenges
- Discussions based on your companies equipment

Mix & Match - Training & Consulting

We can deliver our courses and include an element of ad-hoc Data Integrity Consulting or high-level system assessments. Many of our clients have found adding ad-hoc consulting very beneficial for their team.

Why Clarity Compliance Solutions?

With an integrated risk based approach to Data Integrity, Clarity Compliance Solutions can deliver a tailored solution to ensure you achieve Data Integrity compliance by benchmarking your current position, training your team, helping you implement a governance system and then supporting you through assessments to remediation and ongoing operational Data Integrity compliance.