DATA INTEGRITY PROGRAM

GRANTEK

CONSULT
DESIGN
DELIVER

Grantek offers a suite of services to help Life Sciences manufacturers identify compliance gaps and Data Integrity risks that could result in failure to retain adequate records and/or potential regulatory agency observations.

WHAT?

FDA guidance describes Data Integrity as maintaining the completeness, consistency, and accuracy of data throughout its lifecycle

WHO?

While the general principles of Data Integrity can apply to all manufacturers, they are ***embedded within the regulations*** of the ***Life Sciences*** industry

WHY?

To assure that Life Sciences products are manufactured in a way that protects patient safety, product quality, and data integrity

DATA INTEGRITY FOCUS

Data Integrity goes above and beyond 21 CFR Part 11 requirements. Manufacturers must ensure that recordkeeping requirements for completeness, consistency, and accuracy of production data are maintained throughout a product's lifecycle.

Regulatory agencies are focusing on:

- Shared user logins
- Missing or disabled audit trails
- Incomplete collection, retention, and review of data
- Testing into compliance
- Lack of basic access control
- Lack of contemporaneous recording of activities
- Failure to investigate data discrepancies
- Overwriting or deletion of original data
- Data falsification
- Unauthorized changes

Email **info@grantek.com** to learn how your operations could benefit from Grantek's Data Integrity Program

WHY CHOOSE GRANTEK

Grantek's Data Integrity audits cover more than 21 CFR Part 11 compliance; we assess the computerized systems using checklists and methodologies that follow ISPE GAMP guidelines to ensure that we evaluate your systems against all applicable regulatory controls.

GRANTEK'S COMPLETE SOLUTION FOR DATA INTEGRITY CAN PROVIDE:

COMPLIANCE ASSESSMENT

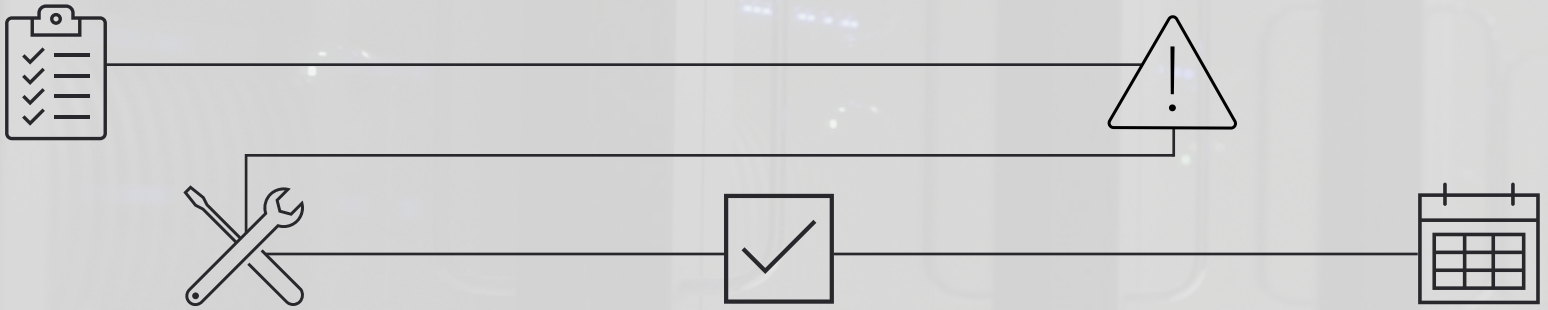
- Checklist template tailored for each customer based on the architecture of the target systems
- Data is evaluated for each stage of production, from the machine PLCs, all the way up to the enterprise systems
- The assessment includes a compliance risk rating for each item

RISK REDUCTION PLAN

Designed to help prioritize corrective actions and to determine a remediation plan per identified risk

Including:

- Administrative
- Configuration
- E-record
- Record Storage
- Security
- Date & Time synchronization
- 3rd-party vendor



DESIGN SOLUTIONS

Grantek will help to design remediation solutions and estimated costs for risks identified including:

- Projects
- Procedures
- Standard documentation for future systems

VALIDATION

Grantek may assist in validating a data integrity risk remediation solution through:

- Developing qualification documentation
- Change management documentation
- Performing system tests

CONTINUOUS IMPROVEMENT

An internal auditing plan should be developed and include:

- Proactive compliance checks
- Remediation projects reviews
- New projects that may alter plans or provide new data