



## **Data Governance in Pharma: A Pragmatic Approach to Data Integrity**

By: Mahasti Kheradmand

# Table of Contents

- Data Governance .....2
- Data Integrity .....2
  - Approach .....6
  - Purpose .....6
  - Scope .....6
  - Roles and Responsibilities.....6
  - Assessment Approach.....7
  - Remediation Planning.....7
  - Governance.....8
  - Continuous Improvement .....8

This white paper presents a comprehensive Data Governance framework for pharmaceutical organizations, with particular emphasis on Data Integrity as a critical compliance element. While multiple governance models exist, this paper outlines a pragmatic, risk-based approach that integrates 5 core elements: data architecture foundation, organizational structure, data integrity by design, business process integration, digital evolution and innovation.

The framework emphasizes the interconnection between governance and integrity, demonstrating how a well-structured governance program enables effective data integrity management. The paper then deep dives into Data Integrity implementation, providing practical guidance for assessment, remediation, and continuous improvement. This approach helps organizations navigate regulatory requirements while driving operational excellence through data-driven decision making. Special attention is given to standalone systems and manual processes, which often present the highest data integrity risks in GMP environments. The model presented can be scaled and adapted based on organizational maturity and specific business needs.

## Data Governance

Data Governance in pharmaceuticals is a strategic, enterprise-wide framework that ensures the availability, usability, integrity, and security of data across Manufacturing, Quality, Supply Chain, Engineering, and Data Science functions. It encompasses the people, processes, and technologies required to manage and protect critical data assets throughout their lifecycle, enabling compliant and efficient operations while supporting data-driven decision making.

Enterprise data governance framework is comprised of the following elements:

### 1. Data Architecture & Technology Foundation

- Cloud-based data infrastructure with validated security controls
- Enterprise data model and standardized taxonomy
- Technology stack integration (e.g., Veeva Vault, ERP, LIMS, MES)
- Data lifecycle management from acquisition to archival
- Data flow concepts
- AI/ML readiness and validation framework

### 2. Organizational Structure & Accountability: Clearly defined roles and responsibilities:

- Data Owners (Business Process Owners)
- Data Stewards (Subject Matter Experts)
- System Owners (Technical Leads)
- Quality Oversight (Compliance Champions)
- Cross-functional Data Governance Committee
- Metrics and KPIs for data quality and process effectiveness
- RACI matrix for data-related decisions

- Training and certification program

### 3. Data Integrity by Design

- ALCOA+ principles implementation
- Risk-based data criticality assessment
- Data integrity controls in computerized systems
- Review by exception framework
- Audit trail review strategy
- Data integrity verification in CSV/CSAQ activities
- Paper to digital transformation roadmap
- Data backup and disaster recovery

### 4. Data Domains & Business Process Integration

Critical data mapping across:

- Product Development & Technology Transfer
- Manufacturing Operations & Equipment Performance
- Quality Control & Product Testing
- Product Release & Supply Chain
- Complaints & Post-Market Surveillance
- Regulatory Submissions & Commitments
- Equipment Maintenance & Calibration
- Environmental Monitoring & Facility Control

### 5. Digital Evolution & Innovation

- AI/ML governance framework
  - Model validation approach
  - Training data quality assurance
  - Performance monitoring
- Predictive analytics implementation
- Real-time data visualization
- Process automation opportunities
- Data science capability building
- Innovation pipeline management
- Regulatory compliance for emerging technologies
- Performance Benchmarking
  - Industry best practices assessment
  - Peer company performance comparison
  - Technology adoption maturity evaluation
  - Operational excellence metrics

- Regulatory compliance benchmarking
- Digital transformation progress measurement

## Supporting Elements

- Standard Operating Procedures
- Training Materials
- Assessment Tools
- KPI Dashboards
- Risk Assessment Templates
- Audit & Inspection Readiness
- Change Management Strategy
- Continuous Improvement Process

## KPIs Across Framework Components

### 1. Data Excellence Index (Foundation & Architecture)

**Composite Score (0-100%)** measuring:

- System integration effectiveness (% successful data transfers)
- Data availability (uptime/accessibility)
- ALCOA+ compliance rate
- Error detection rate
- Data integrity incidents **Target:** 95%+ with monthly trending

### 2. Governance Effectiveness Score (Organizational Structure)

**Monthly Assessment (0-100%)** tracking:

- Training completion rate
- SOP compliance
- Data review timeliness
- Issue resolution time
- Cross-functional meeting effectiveness **Target:** >90% compliance with quarterly review

### 3. Process Integration Health (Process & Digital Maturity)

**Weekly Dashboard** monitoring:

- Batch release cycle time
- Right-first-time rate

- Data-driven decision rate
- System adoption rates
- Cross-functional data utilization **Target:** 30% improvement in cycle times year-over-year

## 4. Innovation Impact Score (Innovation & Automation)

**Quarterly Assessment** measuring:

- Automation implementation rate
- Predictive model accuracy
- Process improvement ROI
- AI/ML solution effectiveness
- Digital initiative success rate **Target:** 25% efficiency gain per implemented solution

## 5. Business Value Realization (Performance Management)

**Monthly Business Review** tracking:

- Cost savings from data initiatives
- Quality event reduction
- Compliance rating
- Productivity improvements
- Resource optimization **Target:** \$X million annual savings, zero critical findings

## Data Integrity

While Data Governance provides the overarching framework for managing data assets across the organization, Data Integrity deserves particular attention in the pharmaceutical industry due to its direct impact on product quality and regulatory compliance. Among the five elements of our Data Governance framework, Data Integrity stands out as a critical cornerstone that demands detailed examination, especially in GMP operations.

The following section deep dives into a pragmatic approach to Data Integrity, focusing specifically on pharmaceutical systems and processes where data directly impacts product quality decisions. This approach addresses the unique challenges posed by both integrated and standalone systems, paper-based processes, and the increasing complexity of digital transformation initiatives in regulated environments.

### Approach

To set up a framework for Data Integrity, you must ensure, at a minimum, that you have established a high-level Policy and Standard Operating Procedure (SOP) within your Quality System, regardless of whether the system is on-premises or cloud-based. The

policy and SOPs should demonstrate how regulatory requirements related to Data Integrity are instituted, practiced, managed, and continually evolved in your organization.

Start with a pragmatic approach. The highest risks typically lie with stand-alone laboratory and manufacturing computerized systems that are not integrated into your Manufacturing Distributed Control System (DCS) or Manufacturing Execution System (MES) or IT infrastructure. These systems pose risks such as data being stored on different personal laptops, printouts from devices being lost, data not being backed up, access control management gaps, data manipulation, data overwrite, and lack of control.

Establish a risk-based approach and document your methodology. Partner early with the Quality organization to create a fit-for-purpose approach. Right-size the strategy to address the most significant risks effectively and efficiently.

The SOP needs to include the following elements at a minimum to comply with various regulatory bodies and effectively present your strategy and approach during regulatory audits. Data Integrity is a continual effort and needs to evolve over time.

## Purpose

This guideline outlines a risk-based approach to assess an organization's Good Manufacturing Practices (GMP) computerized systems for data integrity compliance gaps and develop remediation plans.

## Scope

The scope covers computerized systems directly impacting Good Manufacturing Practices (GMP) activities that produce GMP records or data used to determine product quality. Non-GMP, research/development, and paper-based record systems require data integrity assessment but are not included in this guideline. System and process data (automated or paper based) should comply with ALCOA+ principles.

## Roles and Responsibilities

- **Data Governance Lead (Business Process Owner):** Establish Data Governance strategic framework.
- **Data Steward:** Oversees assessments, assigns resources, obtains approvals, compiles reports.
- **Subject Matter Experts or System / Data Owner:** Provide system expertise to support assessments.
- **Assessor:** Conducts system evaluations, identifies gaps, proposes remediations.
- **Approver:** Reviews and approves assessment outputs (technical and leadership roles)
- **Quality Assurance:** Reviews and approves assessment documentation.

# Data Integrity Assessment Approach

1. **Data Integrity Maturity:** Establish and perform a data integrity maturity assessment to baseline the organization's current state and set target maturity levels aligned with company Objectives and Key Results (OKRs) and IT roadmaps.
2. **System Inventory:** Compile a list of in-scope GMP computerized systems.
3. **Risk Prioritization:** Prioritize systems based on criticality and potential product quality impact.
4. **Data Criticality:** Evaluate systems considering data type criticality leveraging SISPQ (Safety, Identify, Strength, Purity and Quality) and ALCOA+ principles.
5. **Requirements Evaluation:** Use a standardized questionnaire to assess systems against data integrity requirements (e.g., user access, audit trails, backups).
6. **Gap Analysis:** Identify gaps against requirements and categorize based on data integrity risk.
7. **Endorsement:** Present the assessment approach to Quality Councils and Leadership forums for endorsement and alignment with objectives.
8. **Quality Mindset:** Advocate a culture where data integrity is embedded in systems, processes, and behaviors.
9. **Training:** Implement multi-tier training to build data integrity awareness and expertise across the organization.
10. **Governance:** Establish a governance board to discuss trends, requirements, share information, and escalate issues to management.

## Remediation Planning

A sense of urgency and continuous improvement is essential in demonstrating a strong culture of Data Integrity from leadership to the shop floor. Creating a culture of transparency, escalating data integrity risks, and continually resolving issues are key in any organization.

1. **Immediate Corrections:** Any identified data integrity failures require prompt investigation and correction per quality management processes. Promote transparency and reward accountability.
2. **Gap Remediation:** Develop remediation proposals based on:
  - o **Gap Criticality:** Impact on GMP data/product quality
  - o **Severity:** Degree of manual data handling and product quality impact
  - o **Complexity:** Projected remediation effort
3. **Prioritization Scoring:** Use a risk priority number (RPN) based on the above factors to prioritize remediations.
4. **Quality Approval:** Obtain approval for the assessment approach for visibility during regulatory audits.

## Visual Metrics



Visual metrics (e.g., Objective and Key Results, OKR) should be used to monitor and display data integrity performance. Data integrity gaps must be included in the Quality Risk Register and be part of ongoing monitoring. Driving pragmatic OKRs aligned with the business, operational, and people processes is crucial. This framework should include rewarding individuals who are change agents, take ownership, and drive resolution of issues.

## **Training**

Implement comprehensive training on data integrity principles and controls for personnel involved in operating, supporting, or using GMP systems. Begin with introductory Data Integrity training for the entire organization to build a foundational understanding. Then, establish targeted expert training tailored to specific functions and roles. Avoid overwhelming the organization with unnecessary training; instead, tailor the training content to match the role and responsibilities of everyone.

## **Governance**

Establish a data integrity governance program with management oversight, defined processes, quality controls, and metrics.

## **Continuous Improvement**

Periodically review and enhance the program based on findings, guidelines, technological advancements, and changes to systems or processes.

In conclusion, Data Integrity must be deeply embedded within the design of Data Lifecycle processes and systems, both automated and manual. It is essential that data management is not treated as an afterthought but integrated into every aspect of an organization's operations. This integration should be exemplified by leadership and embraced by all personnel. By fostering a culture where Data Integrity is prioritized, organizations can ensure compliance, improve operational efficiency, reduce human error, and meet regulatory requirements. Ultimately, this commitment serves the goal of manufacturing high quality products for patients.

## Advantages of Partnering with BioTechData

At BioTechData, we offer tailored Data Integrity solutions that align with regulatory requirements and integrate seamlessly into your operations. We will work closely with your organization to develop a fit-for-purpose Data Integrity Framework, ensuring compliance and operational efficiency. By embedding regulatory standards into every aspect of your processes, we help you mitigate risks and enhance the quality of your data management practices.

Partner with BioTechData to benefit from our extensive industry experience and commitment to excellence. Visit our [business site](#) for more information.