Enterprise Architecture Principles Template

# 1. General Information

• Document Owner: EA Team  
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# 2. Purpose

This document defines guiding principles to support consistent and effective architecture decisions across our Life Sciences organization, ensuring regulatory compliance, patient safety, and innovation in R&D.

# 3. Scope

• Applies to: All enterprise systems and solutions in R&D, Manufacturing, Clinical Trials, and Commercial functions.  
• Excludes: Non-regulated marketing pilots and vendor proof-of-concepts.

# 4. Principles

## AP-01: Data Integrity is Paramount

Statement: All systems must ensure ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, Available).

Rationale: Data integrity is a regulatory requirement (FDA, EMA) and essential for patient safety and clinical trial reliability.

Implications:  
- Systems must implement audit trails.  
- Manual interventions must be minimized.  
- Validation is required for GxP systems.

## AP-02: Patient-Centric Design

Statement: All technology solutions must prioritize patient safety, privacy, and user experience.

Rationale: Life Sciences organizations exist to improve patient outcomes, and systems must reflect this.

Implications:  
- Compliance with HIPAA and GDPR.  
- Consent management built into digital platforms.  
- Usability studies for patient-facing applications.

## AP-03: Reuse Before Buy Before Build

Statement: Existing validated solutions should be reused; if unavailable, purchase commercial-off-the-shelf (COTS) before considering custom development.

Rationale: Reuse reduces validation burden and cost while ensuring compliance.

Implications:  
- Repository of validated solutions maintained.  
- Build only when no suitable product exists.