APPENDIX A-02

Segregation of Duties (SoD)

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1. Purpose

This appendix defines the Segregation of Duties (SoD) matrix to ensure that no single individual has control over all phases of a critical process. This reduces the risk of errors, fraud, and non-compliance with FDA regulations (21 CFR Part 11 and Part 820).

Something is here to check

2. Scope

This SoD matrix applies to all software development, quality management, and laboratory operations processes within the organization.

3. Key Principles

- **No single person can initiate AND approve a change**
- **Development and Quality Assurance must be independent**
- **Code review requires at least 2 approvers (not including author)**
- **Production deployment requires Quality Manager approval**
- **Document approval requires segregation between author and approver**

4. Segregation of Duties Matrix

The following table defines which roles can perform which actions. = Allowed, = Prohibited

Action	Dev Lead	Developer	QA Lead	Quality Mgr	SRE Lead	Product Owner
Create Change Request						
Approve Change Request						
Write Code						
Approve Pull Request (Code Review)		*				
Merge to Main Branch						
Deploy to Production						
Approve SOP Document						
Execute Lab IQ/OQ/PQ						
Approve Lab Results						

* *Developer can approve Pull Request only if they are NOT the author*

5. Critical Requirements

- **Minimum 2 approvers required for all Pull Requests**
- **Quality Manager must approve all production deployments**
- **No developer can approve their own Pull Request**
- **Branch protection must be enforced on main/production branches**
- **All changes must go through Pull Request process (no direct commits to main)**

6. Approvals

This document requires electronic signature approval via DocuSign (21 CFR Part 11 compliant).

Role	Name	Signature & Date
Author	[Name]	[DocuSign Field]
Reviewer (QA Lead)	[Name]	[DocuSign Field]
Approver (Quality Manager)	[Name]	[DocuSign Field]