APPENDIX A-01

Roles & Responsibilities

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1. Quality Manager

Responsibilities:

- Final approval of all SOPs and quality documentation
- Approval of production deployments
- Approval of lab results and IQ/OQ/PQ protocols
- Management of CAPA and deviation processes

2. Development Lead

Responsibilities:

- Technical leadership and architecture decisions
- Code review and Pull Request approvals
- Merge authority for main branch
- Change Request creation and technical assessment

3. QA Lead

Responsibilities:

- Independent quality assurance and testing
- Approval of Change Requests
- Lab procedures execution (IQ/OQ/PQ)
- Final approval of lab results

4. SRE/DevOps Lead

Responsibilities:

- Infrastructure and deployment management
- Production deployment execution
- Merge authority for main branch
- Lab equipment setup and validation support

5. Product Owner

Responsibilities:

- Product requirements and prioritization

- Change Request initiation

- Stakeholder communication (no approval authority)