DATA INTEGRITY REMEDIATION PLAN

Company:	*[Company Name]*
Assessment Date:	*[DD.MM.YYYY]*
Prepared by:	*[Name, Title]*
Approved by:	*[Name, Title]*
Version:	1.0

1. Executive Summary

[Provide a brief summary of the data integrity gap assessment findings and the overall remediation approach. Include the number of critical, major, and minor findings, and the estimated timeline for remediation.]

2. Remediation Phases Overview

Phase	Timeline	Focus	Expected Outcome
Phase 1: Quick Wins	0-4 weeks	Immediate risk reduction, low effort actions	Critical gaps addressed
Phase 2: Short-term	1-3 months	System configurations, procedural improvements	Major gaps closed
Phase 3: Long-term	3-6 months	Major system changes, validation projects	Full compliance achieved
Phase 4: Continuous	6-12 months	Monitoring, trending, sustained compliance	Culture change embedded

3. Phase 1: Quick Wins (0-4 Weeks)

Actions that can be implemented immediately with minimal resources to reduce critical risks.

#	Action	Owner	Due Date	Status
1.1	Enable audit trails on all GxP-critical systems	[IT Admin]	[Date]	☐ Open
1.2	Disable or remove generic/shared login accounts	[IT Admin]	[Date]	☐ Open
1.3	Create individual user accounts for all lab personnel	[IT Admin]	[Date]	☐ Open
1.4	Protect audit trail settings from modification	[System Admin]	[Date]	☐ Open
1.5	Implement password policy (complexity, expiration)	[IT]	[Date]	☐ Open
1.6	Conduct data integrity awareness training for all staff	[QA/Training]	[Date]	☐ Open
1.7	Lock down Excel files with access controls	[IT]	[Date]	☐ Open
1.8	Implement Good Documentation Practice (GDP) training	[QA]	[Date]	☐ Open

4. Phase 2: Short-term Actions (1-3 Months)

Actions requiring moderate effort and planning, addressing major compliance gaps.

#	Action	Owner	Due Date	Status
2.1	Implement periodic audit trail review process	[QA]	[Date]	☐ Open
2.2	Develop and deploy Data Integrity Policy (SOP)	[QA]	[Date]	☐ Open
2.3	Configure automatic logout/session timeout	[IT]	[Date]	☐ Open
2.4	Implement backup verification testing	[IT]	[Date]	☐ Open
2.5	Migrate GxP Excel files to controlled environment	[IT]	[Date]	☐ Open
2.6	Establish user access review process (quarterly)	[QA/IT]	[Date]	☐ Open
2.7	Integrate standalone equipment with LIMS/network	[IT/QC]	[Date]	☐ Open

5. Phase 3: Long-term Actions (3-6 Months)

Major projects requiring significant resources, planning, and validation effort.

#	Action	Owner	Due Date	Status
3.1	Complete validation of critical spreadsheets	[CSV Team]	[Date]	☐ Open
3.2	Upgrade LIMS to 21 CFR Part 11 compliant version	[IT/QC]	[Date]	☐ Open
3.3	Implement electronic signature capability	[IT/QA]	[Date]	☐ Open
3.4	Deploy Document Management System (DMS)	[IT/QA]	[Date]	☐ Open
3.5	Implement NTP time synchronization across all systems	[IT]	[Date]	☐ Open
3.6	Develop disaster recovery and business continuity plan	[IT/QA]	[Date]	☐ Open

6. Phase 4: Continuous Improvement (6-12 Months)

Sustaining compliance through monitoring, trending, and culture change.

#	Action	Owner	Frequency	Status
4.1	Conduct quarterly data integrity self-assessments	[QA]	Quarterly	☐ Open
4.2	Track and trend data integrity metrics/KPIs	[QA]	Monthly	☐ Open
4.3	Include data integrity in management review	[QA/Mgmt]	Quarterly	☐ Open
4.4	Conduct annual data integrity training refresher	[Training]	Annual	☐ Open
4.5	Perform annual comprehensive gap assessment	[QA]	Annual	☐ Open
4.6	Update procedures based on lessons learned	[QA]	Ongoing	☐ Open

7. Resource Requirements

Resource Type	Estimated Effort	Notes
IT Support	[X] hours/week for [Y] months	System configurations, access management
QA Support	[X] hours/week for [Y] months	SOP development, training, reviews
CSV/Validation	[X] person-days	Spreadsheet validation, system upgrades
Training	[X] hours per employee	Initial + annual refresher
External Support	[If applicable]	Consultants, software vendors

8. Budget Estimate

Item	Estimated Cost	Phase
Software licenses/upgrades	€ [Amount]	Phase 3
Hardware (if required)	€ [Amount]	Phase 3
External consulting	€ [Amount]	Phases 1-3
Training (external)	€ [Amount]	Phases 1-2
Internal labor (estimated)	€ [Amount]	All Phases
TOTAL ESTIMATED BUDGET	**€ [Total]**	

9. Success Metrics

- 100% of GxP systems have audit trails enabled and protected
- 0% generic/shared login accounts in use
- 100% of critical spreadsheets validated
- 100% of staff trained on data integrity
- Overall ALCOA+ compliance score ≥90%
- Zero critical data integrity findings in audits/inspections

10. Approval

Role	Signature	Date
Prepared by:		
Reviewed by (QA):		
Approved by (Management):		

Based on PIC/S PI 041-1, FDA Data Integrity Guidance, and WHO TRS 1033