★ **EXAMPLE DOCUMENT** ★

This is a completed example for illustration. Replace with your own data.

DATA INTEGRITY GAP ASSESSMENT

Company:	**PharmaPro GmbH**
Location:	Munich, Germany
Employees:	45 (12 in QC Laboratory)
Products:	API Manufacturing (Small Molecules)
Regulatory Status:	EU GMP certified, FDA-inspected (2022)
Assessment Date:	15 January 2026
Assessed by:	Dr. Maria Schmidt, Data Integrity Officer

Executive Summary

This gap assessment evaluated 7 GxP-relevant systems against ALCOA+ criteria. The overall compliance score is **62% (CRITICAL)**, indicating significant gaps requiring immediate remediation.

CRITICAL FINDINGS (Immediate Action Required):
- LIMS audit trail DISABLED - no tracking of changes
- Generic login 'Lab' used by 8 analysts - no attributability
- Excel batch records unprotected - anyone can modify

Systems Assessed

ID	System	Type	GAMP	GxP	Score	Status
SYS-001	ChemStation LIMS	LIMS	4	Critical	42%	**CRITICAL**
SYS-002	SAP S/4HANA	ERP	4	Supporting	92%	OK
SYS-003	Excel Batch Records	Spreadsheet	-	Critical	25%	**CRITICAL**
SYS-004	Mettler Balance XPE	Equipment	1	Critical	58%	MAJOR
SYS-005	Paper Logbooks	Paper	-	Critical	75%	MAJOR
SYS-006	MasterControl DMS	DMS	4	Critical	89%	OK
SYS-007	Outlook Email	Email	3	Non-GxP	N/A	N/A

Overall Weighted Score: 62% - CRITICAL (Target: ≥90%)

Detailed Findings by System

SYS-001: ChemStation LIMS (CRITICAL - 42%)

ALCOA+ Criterion	Score	Finding
Attributable	0/3	Generic login 'Lab' used by all 8 analysts. No individual accountability.
Legible	2/3	Data readable but some reports difficult to interpret.
Contemporaneous	2/3	Generally recorded at time of test, minor delays noted.
Original	2/3	Raw data retained but metadata incomplete.
Accurate	2/3	Calculations correct but limited verification.
+Complete	1/3	Failed injections can be deleted without documentation.
+Consistent	2/3	Generally consistent but some sequence gaps noted.
+Enduring	2/3	Backup exists but restoration never tested.
+Available	2/3	Data accessible but audit trail export limited.
Audit Trail Protected	0/3	AUDIT TRAIL DISABLED! No change tracking.

SYS-003: Excel Batch Records (CRITICAL - 25%)

Finding	Severity	Details
No Access Controls	CRITICAL	Files stored on shared network drive with no restrictions. Any employee can modify.
No Validation	CRITICAL	Spreadsheets contain complex formulas but no validation documentation.
No Version Control	MAJOR	Multiple versions exist with no clear version history or control.
No Audit Trail	CRITICAL	Changes not tracked. Excel Track Changes feature not used.
Local Copies	MAJOR	Staff save copies to local drives, creating uncontrolled duplicates.

Remediation Priority Summary

#	Action	Owner	Est. Cost	Due
1	**Enable LIMS audit trail IMMEDIATELY**	IT Admin	€0	24h
2	**Create individual LIMS user accounts**	IT Admin	€500	1 week
3	**Move Excel to SharePoint with access controls**	IT Lead	€2,000	4 weeks
4	Validate critical spreadsheets	CSV Team	€5,000	3 months
5	Integrate balance with LIMS	QC Manager	€8,000	6 months
6	Implement periodic audit trail review	QA	€200	2 weeks
	TOTAL ESTIMATED BUDGET		**€15,700**	

Sign-Off

Role	Signature	Date
Prepared by:	[Signature] Dr. M. Schmidt	15.01.2026
Reviewed by:	[Signature] J. Weber, QA Manager	16.01.2026
Approved by:	[Signature] K. Mueller, Site Director	17.01.2026

★ END OF EXAMPLE DOCUMENT ★