DATA INTEGRITY

TYPICAL INSPECTOR QUESTIONS

This document contains 44 typical questions that GMP inspectors (FDA, EMA, national authorities) ask during inspections regarding data integrity. Use this to prepare your team and verify your compliance status.

1. Governance & Policy (10 Questions)

#	Question	Preparation Tip
1	Do you have a data integrity policy? Can I see it?	Have SOP-DI-001 ready
2	Who is responsible for data integrity in your organization?	Name your DI Officer/Coordinator
3	How do you train employees on data integrity?	Show training records, curriculum
4	When was the last data integrity training conducted?	Have dates and attendance lists
5	How do you assess data integrity risks?	Show risk assessment methodology
6	Do you have a data integrity risk assessment? Show me.	Have completed assessment ready
7	How do you handle data integrity deviations?	Explain escalation process
8	How is data integrity included in your self-inspection program?	Show audit schedule, checklists
9	How does management review data integrity status?	Show management review minutes
10	What metrics do you track for data integrity?	Have KPIs/dashboard ready

2. Electronic Systems & Audit Trails (12 Questions)

#	Question	Preparation Tip
11	Show me a list of all GxP computerized systems.	Have system inventory ready
12	Is the audit trail enabled on this system? Show me.	Know how to access audit trail
13	Can the audit trail be disabled? By whom?	Explain protection controls
14	How do you review audit trails?	Show review procedure, forms
15	Show me the audit trail for this batch record.	Be able to retrieve quickly
16	Do you use any generic or shared login accounts?	Ideally answer NO with evidence
17	How do you manage user access rights?	Explain role-based access
18	When was the last user access review?	Show review documentation
19	What happens when an employee leaves or changes roles?	Show account deactivation process
20	Are failed login attempts logged?	Show example in audit trail
21	How are passwords managed?	Explain policy (complexity, expiry)
22	How do you ensure time stamps are accurate?	Explain NTP synchronization

3. Specific Systems (8 Questions)

#	Question	Preparation Tip
23	Do you use Excel for GxP calculations? Show me.	Have list of GxP spreadsheets
24	How are these spreadsheets validated?	Show validation documentation
25	How do you prevent unauthorized changes to Excel files?	Explain access controls
26	Do you have standalone equipment not connected to a network?	List standalone systems
27	How do you ensure data integrity on standalone equipment?	Explain backup/transfer process
28	How is data transferred from equipment to LIMS?	Demonstrate data flow
29	Show me your LIMS. How does it capture original data?	Be able to demonstrate system
30	Can results be deleted or overwritten in your LIMS?	Explain controls preventing this

4. Data Handling & Investigations (6 Questions)

#	Question	Preparation Tip
31	Show me how you investigate OOS results.	Have OOS SOP and examples
32	How do you ensure all test results are reported, including failures?	Explain complete data policy
33	Can analysts repeat tests? Under what conditions?	Explain re-analysis rules
34	How do you prevent selective reporting of results?	Explain review/approval process
35	Show me a data integrity deviation from the last year.	Have example ready to discuss
36	What corrective actions were taken for this deviation?	Show CAPA documentation

5. Backup & Recovery (4 Questions)

#	Question	Preparation Tip
37	How do you back up GxP data?	Explain backup schedule, media
38	When was the last backup restoration test?	Show test documentation
39	How long do you retain GxP data?	Know retention requirements
40	Where are backups stored?	Explain off-site storage

6. Paper-Based Systems (4 Questions)

#	Question	Preparation Tip
41	How do you ensure entries are made contemporaneously?	Explain GDP requirements
42	Show me how corrections are made in paper records.	Demonstrate proper corrections
43	How do you control blank forms?	Show form control procedure
44	How are original paper records protected?	Explain storage, access controls

Preparation Checklist

Before an inspection, ensure you can demonstrate:

☐	Preparation Item
☐	Data Integrity Policy/SOP is approved and current
☐	Training records show all staff trained on DI
☐	System inventory is complete and current
☐	Can demonstrate audit trail access for any system in <5 minutes
☐	No generic/shared login accounts exist (or documented exception)
☐	User access review documentation is current
☐	GxP spreadsheets are listed and validated
☐	Backup restoration has been tested in the last 12 months
☐	DI metrics/KPIs are tracked and can be presented
☐	Recent DI deviation examples are prepared for discussion
☐	SMEs for each system are identified and available
☐	Management has reviewed DI status in last quarter

Key Documents to Have Ready

Document	Location
Data Integrity Policy (SOP)	[Document location]
System Inventory / Risk Assessment	[Document location]
Audit Trail Review SOP	[Document location]
Training Records	[Document location]
User Access Review Records	[Document location]
Validated Spreadsheet List	[Document location]
Backup/Recovery Test Records	[Document location]
DI Deviation Examples	[Document location]
Management Review Minutes	[Document location]

Based on FDA, EMA, and PIC/S inspection observations (2020-2024)