Loft Company

Report: EU GMP Annex 11
Loft Company EU GMP Annex 11 + Core Questions + Advanced + Backup Recovery + Human Oversight + Vendor Management + Third Party Audit

v1.0.2026-11-14

Created: 2026-11-14 00:01
Closed: 2026-11-14 00:16
Answered: 98%

Compliance Score:

97%

(385/394)

Almost all requirements met; very low risk.
A very little uncertainty due to small fraction of measuring points not addressed.

Top Risks:

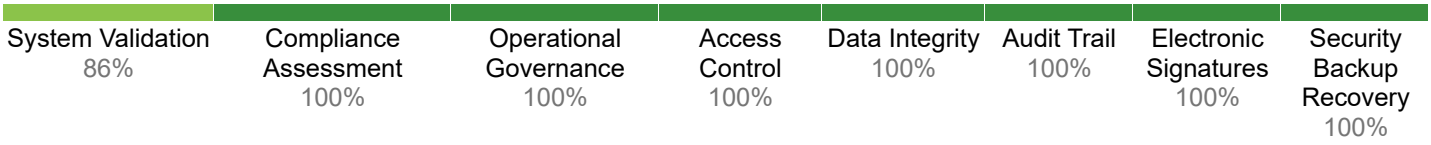
System Validation – 25% Compliant
1. Have test protocols been defined, documented, and approved for system validation activities? Unanswered
Criticality: High

System Validation – 25% Compliant
2. Is there a complete and approved system requirements specification for all computerized systems supporting GMP processes? Partially
Criticality: High

Compliance By Section:

System Validation	86%	Access Control	100%	Audit Trail	100%
Data Integrity	100%	Electronic Signatures	100%	Security Backup Recovery	100%
Operational Governance	100%	Compliance Assessment	100%		

Sections, Weighted



Compliance by Criticality

Criticality	Measurement Points	Yes	Partially	No	Missing	Compliance %
High	39	37	1	0	1	96 %
Medium	40	40	0	0	0	100 %
Total	**79**	**77**	**1**	**0**	**1**	**97 %**

Criticalities, Weighted

Access Control

Access Control covers user authentication, role-based access, temporary/emergency access, offboarding, and monitoring of user accounts.

Are all users uniquely identified and authenticated before accessing computerized systems?	**Yes**

Criticality: High

Is access to functions and data restricted based on defined user roles and responsibilities?	**Yes**

Criticality: High

Is temporary or emergency access logged, justified, and removed after use?	**Yes**

Criticality: High

<< The rest of this section is left out in this sample/preview >>

Recommendations:

System Validation

System Validation includes validation plans, requirement specifications, test protocols, acceptance criteria, and change management for computerized systems.

1. Establish, document, review, and formally approve a complete system requirements specification for all computerized systems supporting GMP processes.

Criticality: High

2. Define, document, review, and approve validation test protocols covering intended use, risks, and GMP-relevant functionality.

Criticality: High

Compliance Score: 97% (385/394)
Almost all requirements met; very low risk.