Loft Company

Report: US 21 CFR Part 11
Loft Company US 21 CFR Part 11 + Core Questions + Advanced + Backup Recovery + Human Oversight + Vendor Management + Third Party Audit

v1.0.2026-11-10

Created: 2026-11-10 09:20
Closed: 2026-11-10 09:35
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:

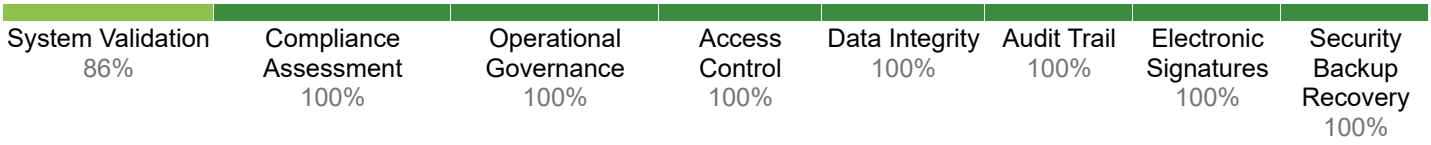
System Validation – 25% Compliant
1. Have test protocols been defined, documented, and approved to verify that systems perform as intended for Part 11-regulated electronic records? Unanswered
Criticality: High

System Validation – 25% Compliant
2. Are documented and approved system requirements in place for all computerized systems that create, modify, maintain, or transmit electronic records subject to Part 11? 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 individuals uniquely identified and authenticated before accessing systems that manage Part 11 electronic records? **Yes**

Criticality: High

Is system access restricted to authorized individuals based on assigned roles and responsibilities? **Yes**

Criticality: High

Is temporary or emergency access controlled, 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. Document, approve, and maintain system requirements for all computerized systems that create, modify, maintain, or transmit Part 11 electronic records.

Criticality: High

2. Define, document, and approve validation test protocols to verify that systems perform as intended for Part 11 electronic records.

Criticality: High

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