

Compliance

21 CFR Part 11



EasyMatch® QC with Electronic Record Keeping 21 CFR Part 11 Compliance Checklist

| Subpart | Subject | Compliant? |
|--------------|---|------------|
| § 11.10 (a) | System validation | ✓ |
| § 11.10 (b) | Accurate and complete copies of records | ✓ |
| § 11.10 (c) | Protection of records | ✓ |
| § 11.10 (d) | Limiting system access | ✓ |
| § 11.10 (e) | Computer-generated audit trail | ✓ |
| § 11.10 (f) | Operational system checks | ✓ |
| § 11.10 (g) | Authority checks | ✓ |
| § 11.10 (h) | Device checks | ✓ |
| § 11.10 (i) | Education and training of personnel | SOPs |
| § 11.10 (j) | Personnel accountability | SOPs |
| § 11.10 (k) | Control of documentation | ✓ |
| § 11.30 | Controls for open systems | N/A |
| § 11.50 (a) | Electronic signature contents | ✓ |
| § 11.50 (b) | Electronic signature controls | ✓ |
| § 11.70 | Electronic signature linking to records | ✓ |
| § 11.100 (a) | Unique electronic signatures | ✓ |
| § 11.100 (b) | Identity verification | SOPs |
| § 11.100 (c) | Certification of electronic signature use | SOPs |
| § 11.200 (a) | Electronic signature components | ✓ |
| § 11.200 (b) | Biometric electronic signatures | N/A |
| § 11.300 (a) | Unique IDs/passwords | ✓ |
| § 11.300 (b) | Password aging | ✓ |
| § 11.300 (c) | Loss management | SOPs |
| § 11.300 (d) | Transaction safeguards | ✓ |
| § 11.300 (e) | Testing of biometric devices | N/A |

✓ = Compliant when configured as described in the Validation and Compliance Notebook.

SOPs = Must be handled through company procedures.

N/A = Not addressed.

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Specifications subject to change without notice

11/07