Integral Healthcare Solutions

FDA QMSR Document Control and Governance Support

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What to have ready

Each item ties to the QMSR text or FDA's QMSR pages. The regulation and your licensed copy of ISO 13485 govern.

1. A licensed copy of ISO 13485:2016(E), Third edition, the edition Part 820 incorporates (21 CFR 820.7(b) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/section-820.7]).
2. Access to ISO 9000:2015(E) Clause 3 for the definitions the regulation incorporates (21 CFR 820.7(a) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/section-820.7]).
3. A list of the finished devices you intend to commercially distribute (FDA QMSR page [https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr]).
4. A statement of which activities you perform: design, manufacture, packaging, labeling, storage, installation or servicing (21 CFR 820.1(a) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/section-820.1]).
5. Your documented quality management system: the quality manual and current procedures (21 CFR 820.10(a) [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/section-820.10]).
6. Your control-of-records procedure, checked against ISO 13485 Clause 4.2.5 (21 CFR 820.35 [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/section-820.35]).
7. The added record content 820.35 requires in certain records, mapped to where each item is captured (21 CFR 820.35 [https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-820/section-820.35]).
8. An inspection-readiness plan written for Compliance Program 7382.850, not QSIT (FDA QMSR page [https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr]).
9. If you are audited under MDSAP, your MDSAP audit reports (FDA MDSAP page [https://www.fda.gov/medical-devices/cdrh-international-affairs/medical-device-single-audit-program-mdsap]).