New / existing medical device manufacturer

Is product SaMD / AI-ML?
21 CFR 820 + FDA SaMD guidance

Yes — SaM

SaMD extra reqs
IEC 62304 lifecycle
FDA AI/ML TPLC
Cybersecurity plan

No — standard MD track

Phase 1 — Management responsibility · § 820.20 / ISO 13485 §5

Top management commitment
Quality policy · quality objectives · management representative
ISO §5.1–5.5 · § 820.20(a–e)

Quality policy
Documented, signed
ISO §5.3 · § 820.20(a)

Customer focus
Regulatory + patient req.
ISO §5.2 · § 820.20(b)

Management review
Planned intervals, records
ISO §5.6 · § 820.20(c)

Phase 2 — QMS documentation & planning · § 820.5 / ISO 13485 §4

QMS documentation framework
Quality manual · SOPs · work instructions · forms · records
Device master record (DMR) · device history record (DHR)
ISO §4.2 · § 820.181 / § 820.184 · document control § 820.40 / ISO §4.2.4

Risk-based QMS process approach
ISO §4.1 · ISO 14971 risk mgmt · § 820.30(g) · outsourced process controls
QMSR § 820.4 — risk-based approach explicitly required

Phase 3 — Resource management · § 820.25 / ISO 13485 §6

Human resources
Competence, training
awareness records
ISO §6.2 · § 820.25

Infrastructure
Facilities, equipment
calibration § 820.72
ISO §6.3 · § 820.70

Work environment
Contamination control
sterile device rules
ISO §6.4 · § 820.70(c)

Phase 4 — Design & development controls · § 820.30 / ISO 13485 §7.3

Design planning
Stages, reviews, V&V activities, responsibilities · ISO §7.3.2 · § 820.30(b)
Design & development file (DDF) opened · ISO §7.3.10 · § 820.30(j)

Design inputs
Functional, performance, usability, safety req. · regulatory standards
ISO 14971 risk outputs · ISO §7.3.3 · § 820.30(c) · IEC 62366-1 usability

Design outputs
Specifications, drawings, acceptance criteria · traceability to inputs
ISO §7.3.4 · § 820.30(d) · DMR / Technical File update

Design review
Formal multi-discipline
records with attendees
ISO §7.3.5 · § 820.30(e)

Design verification
Outputs meet inputs
test protocols & reports
ISO §7.3.6 · § 820.30(f)

Design validation
Intended use confirmed
clinical / perf. eval.
ISO §7.3.7 · § 820.30(g)

Design transfer & change control
Transfer to mfg verified · design changes reviewed, V&V, approved
ISO §7.3.8–7.3.9 · § 820.30(h–i) · QMSR change impact assessment

Phase 5 — Purchasing & supplier controls · § 820.50 / ISO 13485 §7.4

Continual improvement feedback loop

Supplier qualification & approved supplier list (ASL)
Evaluation criteria proportionate to risk · written quality agreements · change notifications
Purchasing info & spec. verification · ongoing monitoring & re-evaluation
ISO §7.4.1–7.4.3 · § 820.50(a–b) · QMSR §820.50 — outsourced process controls §4.1.5

Phase 6 — Production & service provision · § 820.70 / ISO 13485 §7.5

Process controls
Production SOPs
in-process checks
DHR records
ISO §7.5.1 · §820.70

Identification
UDI assignment
traceability system
lot / serial records
ISO §7.5.8–9 · §820.60

Process validation
Sterilization val.
software validation
IQ OQ PQ records
ISO §7.5.6–7 · §820.75

Preservation & install
Packaging, labelling
storage conditions
installation records
ISO §7.5.11 · §820.130

Phase 7 — Measurement, analysis & improvement · § 820.100 / ISO 13485 §8

Feedback & complaint handling
Post-market surveillance · MDR reporting
FDA MDR 21 CFR 803 · ISO §8.2.1–8.2.3
QMSR — management review now inspectable

Internal quality audit
Planned program, impartial auditors
ISO §8.2.4 · § 820.22
QMSR: FDA may now inspect audit rpts

Control of nonconforming product
Identify, segregate, evaluate, disposition · concession process
ISO §8.3 · § 820.90 · advisory notice procedures · rework records

Corrective & preventive action (CAPA)
Root cause analysis · action plan · implementation · effectiveness check
ISO §8.5.2–8.5.3 · § 820.100 · timely without undue delay
QMSR: corrective action must not adversely affect safety & performance

Phase 8 — Post-market & regulatory reporting · 21 CFR 803 · ISO §8.2.3

FDA reporting (US)
MDR 21 CFR 803 — death/injury
Field safety corrective actions
21 CFR 806 recall reporting
UDI in GUDID · QMSR §820.198

Global regulatory reporting
EU MDR Art. 87 vigilance / FSCA
EUDAMED registration
Health Canada MC/VP reporting
CDSCO Form 45 · PMDA reporting

Phase 9 — Data analysis & management review · ISO §8.4 + §5.6

Data analysis inputs to management review
Feedback · complaint trends · NCP rates · audit results · supplier performance
PMS data · corrective actions · new / revised regulatory requirements
ISO §8.4 + §5.6.2 · QMSR §820.20(c) — mgmt review reports now FDA-inspectable

Phase 10 — Continual improvement · ISO §8.5 · § 820.100

Continual improvement cycle
Quality policy review · objective setting · system updates · process improvements
Regulatory horizon scanning — FDA QMSR / ISO 13485 revision monitoring
ISO §8.5.1 · SaMD TPLC updates · AI/ML algorithm change protocol

Records retention & record control
Min. device lifetime + 2 yrs · confidential health info protection · § 820.180
ISO §4.2.5 · QMSR §820.180 — internal audit & mgmt review now FDA-inspectable

QMS compliance maintained