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THE BOLLONG.AI PRODUCT SERIES · MEDICAL DEVICES

MJAI · *Med Journey AI*

Revolutionize Document Generation for Medical Device Commercialization.

Med Journey
BELIEVE, ACHIEVE, REALIZE

Medical devices don't ship on flowery vision statements. They ship on 21 CFR 820, on ISO 13485, on the 510(k) predicate that survives an FDA reviewer's questions. The people who bring new devices to market are ***engineers first*** — but the artifacts they have to produce (the DHF, the risk management file, the traceability matrix, the Q-Sub package) sit in a regulatory language they didn't sign up to write.

MJAI was built to close that gap. Every artifact drafted with ***inline citations back to source*** so a reviewer verifies rather than authors from a blank page. Every persona — regulatory, quality, biocompatibility, human factors — reads YOUR device record first, not a generic template. ***You review. The dossier assembles itself.***

WHO IT'S FOR

Medical-device founders taking Class II devices to 510(k), De Novo, or PMA — where regulatory + quality overhead used to eat 15–30% of program cost.

Service organizations (consultants, CMOs, design-support firms) hosting multiple client programs under one MSA — recursive tenancy so each client's DHF stays isolated.

Investors with medical-device portfolios who want oversight into program health — cross-portfolio rollups showing DHF completeness, submission timelines, and post-market friction, without asking the founder for a Friday status update.

DESIGN CONTROLS · 820.30

REQUIREMENTS TRACEABILITY

DHF · SPRINT-HPV Cartridge

USER NEEDS	14 · linked
INPUTS	42 · traced
OUTPUTS	38 · verified
V&V	31/38 executed

Compile DHF ✓ Cited to source

SUBMIT · Q-SUB COMPILE

PRE-SUBMISSION PACKAGE

Q-Sub · 510(k) pathway

Persona: Regulatory Affairs SME · 3 cited predicates

> *"Cleared predicates: K221847 (Cepheid Xpert HPV), K183456 (Roche cobas 4800). Substantial equivalence argument drafted; awaiting your review on analytical performance section."*

Open in Vault Refine

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CONCEPT → CLEARANCE → POST-MARKET

Complete Device History File, generated by you.

MJAI is the operating system for a medical-device program. Every artifact carries a citation to source (21 CFR, ISO, FDA guidance, published predicates); every persona reads your actual device record before drafting; every review lands in the Vault with an immutable version. **Generate your own content and save both time and money.**

DESIGN CONTROLS	**21 CFR 820.30**from first user need through V&V. Requirements traceability, inputs / outputs, dFMEA, verification + validation records. Every link cited.
PROCESS CONTROLS	Manufacturing validation — IQ / OQ / PQ, in-process controls, pFMEA, first-article inspections. Ties to Design Controls via device-record cross-reference.
SUBMIT	510(k) / De Novo / PMA / General & Special Controls compile. Q-Sub / Pre-Sub drafter with cited predicates. Deficiency-response workflow.
MONITOR	Post-market surveillance, complaint intake, MDR / IVDR reports, cybersecurity Sec 524B (2023), 5-dimension novelty tracking. **See friction before it costs you.**
BUSINESS LAYER	MSA + client-hosting for service orgs. Multi-tenant with recursive rollups — each client's DHF stays isolated under shared QMS scaffolding.
SME PERSONAS	Regulatory Affairs · Quality · Biocompatibility · Human Factors · Cybersecurity · Clinical. Each reads YOUR device record before drafting.
DOCUMENT VAULT	Versioned, watermarked, immutable snapshots of every draft. **Regulatory-grade permanence.**Every artifact traceable to the persona's rationale.
CROSS-APP ROLES	SAML · OIDC · SCIM. One login — role travels from MJAI to enterprise console to EJ. Console rollups across 10 → 1,000+ programs.

WHAT YOU STOP BUYING

*Greenlight Guru · Qualio · MasterControl · Veeva Vault RIM · Matrix Requirements · Ketryx · ETQ Reliance · Sparta TrackWise · **RA consultant retainers at $400–$800/hr** · offline QMS binders no reviewer can audit.*

See bollong.ai for details. Free classification + predicate map at MedValidate before you commit to the pathway.