

PRODUCT DESCRIPTION · COPYRIGHT 2026

Med Journey AI



A medical-device commercialization platform built to the standard of the most aggressive FDA reviewer — at any scale, from a single founder to a multinational CMO running hundreds of programs.

A solo entrepreneur with one device idea faces the same regulatory mountain as a multinational contract manufacturer running 200 active programs.

Different scale, identical rigor required. Med Journey AI is the platform that serves both — on the same architecture, with the same artifact quality, and the same guidance from people who have lived through 510(k) clearances, FDA inspections, MDSAP audits, and EU Notified Body assessments.

The platform organizes work around a hierarchy FDA reviewers recognize: a Company owns a Quality System; a Program represents a device family; each Component within a Program carries its own Design History File per 21 CFR §820.30. Every artifact — Design Inputs, Verifications, pFMEAs, Batch Records, 510(k) sections — produces in the structured language regulators expect, with version control, audit trail, and signature workflow built in from day one.

Med Journey AI is what happens when consultant-grade rigor stops being a \$80,000–\$250,000 line item and starts being the default substrate of a workspace.

What you get is not a document generator. It is a project-based commercialization platform with three tracks (Medical Device, Manufacturing Automation, Business & Legal), a unified Documents Vault, a semantic search index across every artifact you produce, an Early Warning System that monitors FDA recalls and competitive filings against your program, and AI affordances that refuse to draft downstream work without their upstream inputs in place. Each capability is described in the pages that follow.

Built for the spectrum

TIER 1 · THE SOLO FOUNDER

One device. One workspace. Concept to clearance.

You know your technology. The platform provides the regulatory, design-control, quality, and capital scaffolding — in the language reviewers, payers, and investors recognize. AI drafts grounded in your own data, never speculation. When you ask the platform to draft a Design Transfer before Verification exists, it declines and tells you exactly what to populate first.

Typical workspace: 1 Company · 1 Program · 1–3 Components.

TIER 2 · THE SMALL QMS SHOP / RA CONSULTANT

Three to thirty programs. Shared QMS spine. Role-based access.

A consultant managing programs across multiple founder-clients runs each one as its own Program inside a shared Company. The QMS substrate (controlled documents, training records, SOPs) is reused; client-specific work stays isolated. Customer-review workflows let the consultant send a snapshot — say, the URS — to the client's engineering lead for sign-off, with the response logged into the document's permanent audit trail.

Typical workspace: 1 Company · 5–25 Programs · multi-role membership.

TIER 3 · THE MULTINATIONAL CMO (MNCMO)

Hundreds of concurrent programs. Five-tier tenancy. C-suite dashboards.

An organization running hundreds of programs across customer enterprises gets a five-layer model: Tenant → Org Units → Programs → Sub-Projects → Documents. An executive dashboard rolls up pipeline percent-complete by pathway, Early Warning Index by program, and regulatory risk by tenant. From the C-suite roll-up, three clicks drill into an individual Component's dFMEA. From there, the audit trail reconstructs every change that artifact has seen — including who reviewed it, when, and what they said.

Typical workspace: 1 Tenant · 10–50 Org Units · 100–1,000+ Programs · per-customer isolation enforced by RLS.

Components - SurgiPath Line 5

COMPONENT - PROCESS FLOW

Primary device

Instrument — fields autosave on blur; click Save to force-commit + reload from the server.

STEPS

5

CYCLE TIME

1h 27m

SETUP TIME

32m

BLENDED YIELD

94.0%

DESIGN CONTROLS

PROCESS CONTROLS

Design Plan

System Inputs

URS

Outputs

Reviews

Verification

Validation

dFMEA

Transfer

Changes

Traceability

DHF Index

User Requirement Specifications — the contract every downstream phase (Process Flow - Equipment - Engineering studies - IQ/OQ/PQ) verifies against.

Save to Document Vault

FUNCTIONAL 1 REQ

+ ADD FUNCTIONAL

FR-001

The device shall perform its intended function (as described in the project record) within specified parameters.

ACCEPTANCE CRITERION

Functional bench testing demonstrates 100% pass on a sample of n>=30 with 95% confidence.

VERIFICATION

Test

PRIORITY

Must

SOURCE

customer

NOTES

Portfolio Dashboard — enterprise rollup with project pipeline by lifecycle stage and at-a-glance health buckets (green / yellow / red). C-suite + operations VPs land here for the active picture.

WORKSPACE - MNCMO SUMMARY

Portfolio Dashboard

100 projects across 5 facilities

Enterprise-wide rollup. C-suite + operations VPs land here for the active picture. Drill into any stage / facility / customer for the underlying project list.

MNCMO Summary

Global

China

Ireland

India

United States

GLOBAL VIEW

100 PROJECTS

Project status (lifecycle)

Project status (lifecycle)

Count of projects per lifecycle stage

active

40

on_hold

18

closed

17

archived

13

cancelled

7

draft

5

Drill from MNCMO Summary into Global / China / Ireland / India / United States — same metrics scoped to a single facility. The pivot is one click; the underlying project list is two.

Platform depth • the work behind the cards

Every artifact lives in a unified Documents Vault with full audit trail. Every AI affordance is grounded in your project's own data — and refuses to speculate when upstream inputs are missing. Every saved document is searchable across your entire DHF semantically (by what you mean, not by what file it lives in).

01

Per-Component DHF

Each Component carries its own URS, Design Outputs, Reviews, Verifications, Validations, Transfer, dFMEA, and Traceability Matrix — the structure expected under 21 CFR §820.30. Mirrors how FDA thinks about a device family.

02

Process Controls Stack

Process Flow with decision diamonds and rework loops (not just linear lists). pFMEA, Engineering Studies, Metrology Plan, IQ/OQ/PQ Qualification Runs, and an FDA-formatted Batch Record skeleton that drafts from the upstream stack.

03

Documents Vault • Audit Trail

Every snapshot is versioned, every state transition logged, every customer response captured. Reconstruct the chain of custody on any artifact across its full lifecycle — substrate for 21 CFR §820.40 and Part 11 readiness.

04

Semantic Search

Vector embeddings on every document in your Vault. Find the right requirement, test report, or risk control by semantic meaning — not by filename. Auto-indexes on creation; no manual tagging.

05

Multi-Reviewer Approval

Send any snapshot to one or twenty customer reviewers in a single call. Each reviewer receives a magic-link; aggregate state resolves automatically. One veto rejects; all-approved finalizes — the right posture for regulated artifacts.

06

Early Warning System

Five-dimension monitoring per program: FDA (recalls, MAUDE, 510(k) clearances), USPTO patents, scientific literature, industry press, and social signal. Weekly scoring with stage-weighted aggregation.

07

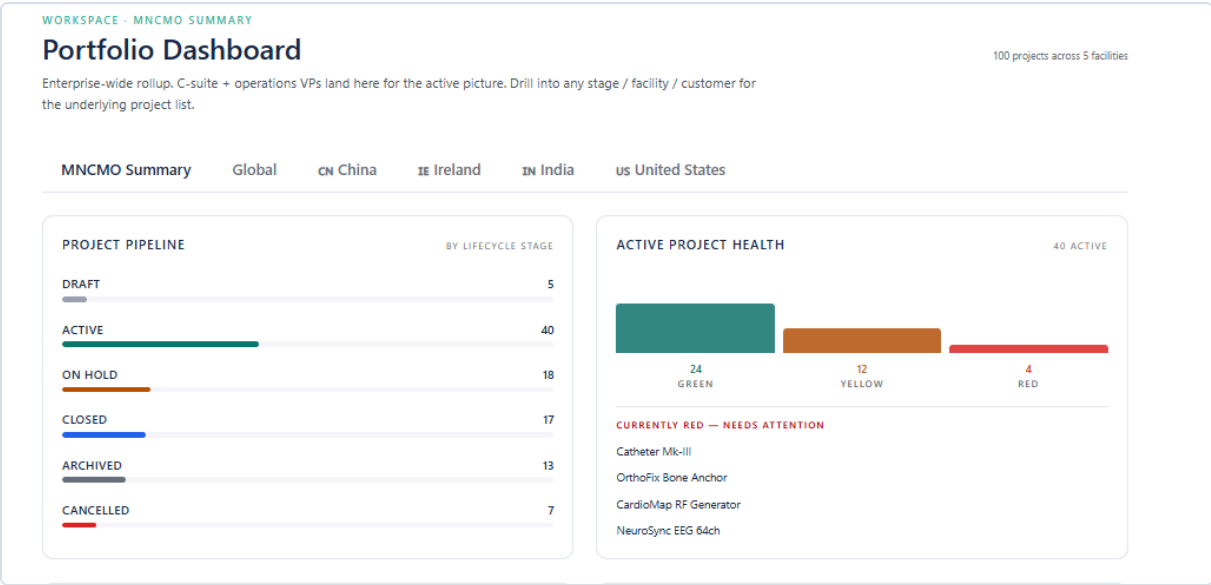
Submission Readiness

08

AI That Refuses to Guess

Per-pathway checklists (510(k), De Novo, PMA, HDE, Exempt) score the project against every required artifact. Applicability toggles (sterile, software, animal study, clinical, EMC, implantable) exclude items that don't apply.

Every AI affordance lists its upstream inputs. Try to draft a pFMEA without a Process Flow, or a Design Transfer without Verification, and the platform declines and tells you exactly what to populate first. No speculative output.



Component drill-down — Design Controls tab bar (Design Plan · System Inputs · URS · Outputs · Reviews · Verification · Validation · dFMEA · Transfer · Changes · Traceability · DHF Index) with cycle-time / setup / blended-yield rollups, viewing a single Primary device's URS section.

Regulatory pathways covered

One classification engine, two regulatory regimes, fifteen distinct pathways — each with its own artifact checklist, applicability gates, and submission package.

US FDA

- **510(k)** Traditional, Special, Abbreviated
- **De Novo** Class I/II reclassification
- **PMA** Class III premarket approval
- **HDE** Humanitarian Device Exemption
- **510(k)-exempt** Class I / select Class II

EU IVDR (2017/746)

- **Class A** self-declaration
- **Class B** Notified Body QMS audit
- **Class C** per-device technical review

EU MDR (2017/745)

- **Class I** self-declaration
- **Class Is / Im / Ir** sterile · measuring · reusable
- **Class Ila / Ilb** Notified Body conformity assessment
- **Class III** incl. implantable, with SSCP & CECP

QUALITY SUBSTRATE

- **21 CFR 820 & ISO 13485**
- **ISO 14971** risk management
- **21 CFR Part 11** e-records

- **Class D** EU Reference Lab verification
 - **21 CFR §820.40** document controls
 - **21 CFR §820.30** design controls
-

The standard of evidence

Every artifact produced by Med Journey AI is built to pass review by the most aggressive FDA reviewer in the room. Predicate research uses live, web-grounded queries against the FDA 510(k) database — never hallucinated K-numbers. Risk analysis structures map directly to ISO 14971 Annex C. Submission packages mirror the eSTAR template structure and the RTA checklist. Clinical evaluation reports follow MEDDEV 2.7/1 Rev 4 for the EU side.

The AI does not guess. When an upstream prerequisite is missing — say, a Design Transfer is requested without prior Verification — the system refuses to draft, surfaces the missing input, and points to where it lives in the workspace. The cost of refusing to speculate is occasional friction; the cost of speculation is invalid downstream work that reviewers eventually catch. The platform makes the right trade.

What “built to the standard of an aggressive reviewer” means in practice: predicate K-numbers are real FDA records. Substantial-equivalence arguments reference the predicate's indications verbatim. Risk control measures trace to specific hazardous situations. Design Verifications reference the requirements they verify by ID. Process Flows show every decision and rework path explicitly. Batch Records carry calibration-due-date checks. Document state transitions are timestamped, attributed, and immutable.

Next step

Start a 14-day trial at **app.bollong.ai/upgrade**. Bring an active program, or walk through the seeded MNCMO demo set — ten enriched programs across five pathway types, ready to drill into from Company-level dashboards down to individual Component dFMEAs.

About Bollong.AI. Bollong.AI builds the workspaces and infrastructure that medical-device entrepreneurs, RA consultants, and contract manufacturers use to take products from concept to commercial reality. Med Journey AI is the flagship medical-device platform; Entrepreneur's Journey covers business formation; MedValidator provides anonymous predicate-search as a lead-magnet. The architecture supports five-tier multi-tenancy out of the box, isolated per-app data, and a unified cross-app audit trail.

