MED JOURNEY AI · WORKFLOW MAP

From idea to submission — in 7 stages.

How MJAI is organized · companion to the Platform overview & Attachment A (Coverage Map)

ATTACHMENT B

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MJAI's workspace is laid out the way a medical-device program actually runs — in **seven stages**, in the order a founder hits them. Each stage groups the cards that belong together; every card is wired to a specific FDA or EU regulation and produces submission-ready output. You don't pick a methodology; you pick your pathway, and the workflow assembles itself.

01 Project

Set up the program — name it, describe it, enumerate its assemblies.

Overview — program dashboard: status, progress, next action, owner.

Details — intended use, indication, target population, anatomical site, novelty statement. Drives every downstream card.

Assemblies — components & parts: BOM, materials, mass properties. Direct Onshape import.

02 Foundation

Determine your regulatory class & commercial position before drafting anything.

Classification FDA — AI predicts class, product code, and pathway per 21 CFR 860.

Predicates FDA — AI mines the 510(k) database for substantial-equivalence candidates.

Product & Specs — OCR engineering drawings; live Onshape CAD integration.

03 Risk & Quality

Identify hazards before they cost you a year in re-work.

Risk Management ISO — ISO 14971:2019 plan + file; risk acceptability criteria, methods, roles.

System Risk ISO — Hazard analysis, DFMEA roll-up, residual risk vs benefit per §7.4.

Traceability TRACE — User Need → Design Input → Verification → Validation matrix.

04 Compliance

Draft the regulatory submission packages your pathway requires.

General Controls FDA — Registration, Listing, UDI, MDR SOP, Recall SOP, Labeling.

510(k) Builder FDA — Sections 1–20 drafted from your DHF + predicates. eSTAR-ready.

Clinical IDE — Evidence plan, Investigator Brochure, ICF, IRB submission.

EU Pathway CE — MDR Annex II/III TD, IVDR performance evaluation, CE infrastructure, PMS/PMCF/PSUR.

05 Repository

Everything MJAI generates lands here — versioned, indexed, inspection-ready.

Document Vault SOT — Auto-snapshot every AI draft. FDA-arranged repo with version history.

Templates DRAFT — Upload your QMS templates; AI fills them with project context.

Documents — Local uploads (drawings, IFUs, test reports) anchored to the program.

06 Project Mgmt

Keep the people, dates, and decisions visible alongside the regulatory work.

Stakeholders — Internal team, consultants, advisors, investors.

Timeline — Milestones (510(k) submit, NB audit, first revenue) with dependencies.

Notes — Free-text journal — meeting notes, FDA call summaries, design decisions.

07 Company

Company-wide systems that span every program.

QMS CO — Quality system anchored to ISO 13485 / 21 CFR 820. Shared across all programs.

EWS PREM — Early Warning System: cross-customer signal detection on adverse trends, recalls, FDA actions.

Community — Other founders & consultants in your pathway. Anonymized comparisons.

HOW THE STAGES FLOW TOGETHER

Foundation sets your pathway → **Risk & Quality** feeds hazards into **Compliance** drafts → **Repository** stores every AI output as the inspection record → **Project Mgmt** tracks who does what when → **Company** ties multiple programs to one QMS. *You don't need to follow the order strictly — but the workflow assumes the upstream answers exist, and warns you when they don't.*