Strategy	Specifications + Planning	Development	Verification + Validation	Transfer
Human Factors + Usability				
Systems Engineering				
Core Technology Research IP development Feasibility User Needs / VOC Human factors User experience Product features Market Opportunity Product line strategy Competitive analysis Freedom to operate Reimbursements Business Model Business plan Financing Supply chain Risk Project risk Hazards Regulatory Plan	Project Plan Product development plan Team roster Risk management plan Design Inputs User needs / intended use Marketing requirements System requirements Hazards analysis UI requirements Cost requirements Traceability matrix Service plan	Architecture System - Operational model Industrial design / human factors Software Component selections Cost modeling Design Mechanical engineering Electrical engineering Ul design + simulations Breadboards + prototypes Subsystem test SQA / bug tracker / defect log Engineering analysis DFM / DFA / DFS Design for reliability Integration + Debug Prototype + build Functional testing Usability testing (device / GUI) Software test and verification Agency prescreen Design Outputs Test results Design reviews FMEA / FMECA Updated requirements BOM, dwgs, ass'y dwgs Gerber data, sw code, build envnmt. Verification Protocols + Test Plans	IFU Product graphics Packaging Training materials Manufacturing Equiv. Units Procurement Inspection Build Verification to Requirements Bench Agency Sterilization Biocompatibility Reliability analysis Validation to User Needs Protocols Usability testing Pre-clinical studies Clinical studies Clinical studies DMR + DHF Control Regulatory Submission Manufacturing Readiness Supplier + process ID Supplier qualification Readiness review	Manufacturing Supply chain implementation Pilot tooling + build Training First article qualifications Production tooling validation Process validation, IQ, OQ, PQ

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