

MEDICAL DEVICE DEVELOPMENT PHASES AND FUNCTIONAL ACTIVITIES

	Tasks / Functional Groups	PHASE 0 Evaluation / Opportunity & Risk Analysis	PHASE 1 Demonstration / Concept & Feasibility	PHASE 2 Design & Development / Verification & Validation	PHASE 3 Final Validation / Product Launch Preparation	PHASE 4 Product Launch & Post-Launch Assessment	
1	Cross-Functional Management	Financial Review	Project Core Team Selection	Cross-Functional Project Management	Cross-Functional Project Management	Cross-Functional Project Management	
		Business Model Development	Hire Specialists for Expertise Gaps	Budgeting / Fundraising Activities	Business Development	Budgeting or Fundraising Activities	
2	Markets & Marketing	Market Analysis	Customer Input / VOC	Customer Prototype Evaluation	Product Branding	Market Launch Plan / Forecast	
		Competitive Assessment "PRD" (1)	Customer Prototype Evaluation	Customer Prototype Evaluation	Product Branding	Market Launch Plan / Forecast	
3	Writing and Publications	Business Plan & Presentations	Business Plan & Literature Search Updates		Meta Analysis White Paper	Meta Analysis White Paper, Publish Peer Review Papers	
		Literature Search	Business Plan & Literature Search Updates		Data Summary, Analysis White Paper, Publish Peer Review Papers	Data Summary, Analysis White Paper, Publish Peer Review Papers	
4	Research & Development	Early Risk Assessment & Concept Approach	Early Concept Prototype Design & Build	Prototype Evaluation	Update Design Per Review & Analysis / Multiple Discipline Input Driven	Sustaining Engineering / Product Improvements as Needed	
			Initiate & Maintain Design History File (DHF)	Initial Design Risk Analysis (dFMEA)	Update Design Per Review & Analysis / Multiple Discipline Input Driven		DHF Completion
5	Design Documentation	Quick CAD Layouts, Prelim. Engineering Specs	CAD Models, Minimum Drawing Set, Engineering Specification		Full Released Documentation Per ISO13485		
6	Industrial Design	Sketches, Renderings (Paper, Digital)	Renderings, Size / Feature Mockups, Appearance Models (Hard Foam, RP (2) Methods)		"Looks-Like / Works-Like / Made-like" Cosmetic Refinement, Pre-Production Units, Packaging, (Production Methods)		
7	Legal / IP	Legal / IP Analysis, Clearance Opinion	IP Landscape Review & Review of Filings		Final Patent Review with R&D		
8	Regulatory	Regulatory Path	Initial Regulatory Strategy		Regulatory Strategy Update		
9	Reimbursement	Reimbursement Path	Initial Reimbursement Strategy		Pursue Reimbursement		
10	Manufacturing & Operations	Manufacturing plan	Initiate DFM (Tooling, Fixturing)		Manufacturing / Operations Scale Up		
			Initiate DFM (Tooling, Fixturing)		Detailed Productivity Analysis	Supplier Collaboration	Manufacturing & Process Engineering
11	Quality	Quality Plan	Initiate Quality Management System (QMS) / Document Control		Begin Process IQ / OQ / PQ / PPQ		
12	Pre-Clinical	Pre-Clinical Path	Pre-Clinical Tests		Biocompatibility Testing (If Possible)		
13	Clinical	Clinical Path	Assemble SAB & MAB	Determine Endpoints & Variables	Clinical Validation Plan		
14	Data and Statistics	Market Forecast	Survey Analysis	Pre-clinical Data Analysis	Survey Analysis	Literature & Data Meta Analysis	
15	Sales	Sales Path	Sales Plan		Recruit Sales Team		
		GATE 0 DECISIONS		GATE 1 DECISIONS		GATE 2 DECISIONS	
16	Market Opportunity	Tech, Regulatory, IP Approach Feasible	Value Proposition Viable & Sustainable	Product Risks Acceptable	Commercialization Readiness	Design Freeze	Final Validations
			Value Proposition Viable & Sustainable	Product Risks Acceptable	Commercialization Readiness	Design Output Meets Targets	
17	Basis for Competition	Manageable Risk & Executional Gaps	Technical Feasibility Proven & Optimized	Manufacturing & Value Chain Confidence	Risk Mitigation Confirmed	Risk Mitigation Confirmed	Regulatory Submission, Testing Complete
							Sales Launch, Business Launch Plan Adjust

GATE 0 — Product Definition Acceptance / Concept Charter

GATE 1 — Feasibility Demonstrated / Initial Design Acceptance

GATE 2 — Final Design Acceptance

GATE 3 — Product Launch Acceptance / Launch Readiness



1) PRD = Product Requirements Document 2) Rapid Prototyping 3) Design For Manufacturability & Assembleability © 2010 Optimum Technologies, Inc.