

**PADT MEDICAL DEVELOPMENT PROCESS**

<b>PHASES</b>	<b>1 CONCEPT DESIGN</b>	<b>2 PLANNING</b>	<b>3 DETAIL DESIGN</b>	<b>4 VERIFICATION</b>	<b>5 VALIDATION</b>	<b>6 TRANSFER</b>
<b>ACTIVITIES</b>	Define user needs Evaluate concepts Perform feasibility studies Evaluate IP landscape Initiate risks assessment	Formulate product specs Prepare design plan Prepare risk mgt plan Prepare supply chain plan Update risk assessment  <b>Design Review # 1</b>	Refine product specs Document design/processes Build & test prototypes Update risk assessment Evaluate & select suppliers  <b>Design Review # 2</b>	Build GMP prototypes Verify functionality Design and verify packaging Verify biocompatibility Verify sterilization  <b>Design Review # 3</b>	Prepare validation plan Validate product Validate processes Production scale up Clinical studies  <b>Design Review # 4</b>	Collect design outputs Finalize PRD, FMEA, RMF Finalize DMR Finalize DHF/DHR Transfer materials & files  <b>Design Review # 5</b>
<b>INITIATED DOCUMENTS</b>	Product Requirements Doc (PRD) Failure Modes & Effects Analysis	Risk Management Plan (RMP) Design History File (DHF) Product Dev. Plan (PDP) Design Review Report	Device Master Record (DMR) Bill of Materials (BOM) Manufacturing Specs Work Instructions (WIK) Engineering Studies Design Review Report	Verification Protocol Verification Report Engineering Studies Review Review Report	Design Val. Plan & Report Process Val. Plan & Report Engineering Studies Design Review Report	Design Transfer Report Engineering Studies Design Review Report
<b>RECORDS</b>	Concept Design File	Design History File (DHF)				
		Risk Management File (RMF)				
		Device Master Record (DMR)				
						Device History Record (DHR)
<b>PROCEDURES</b>		Document Controls (SOP # 05001)				
		Design Controls (SOP # 05002)				
		Risk Management (SOP # 05010)				
		Purchasing Controls (SOP # 05037)				
						Identification and traceability (SOP # 05022)
						Production & Process Controls (SOP # 05042)
						Acceptance Activities (SOP # 05021)
						Records (SOP # 05004)
						Handling & Storage of Products (SOP # 05020)