

Company Name: [type here]

Project Name: [type here]

Project Leader: [type here]

Project Description: [type here]

Product Development Project Phase	Deliverable	Location	Check if Completed & Documented
<b>Planning:</b> To identify scope of the project; define user needs and corresponding design inputs.	"Bootstrap" Quality System	Company Quality System	<input type="checkbox"/>
	Proof of Concept	Project File	<input type="checkbox"/>
	Research Results	Project File	<input type="checkbox"/>
	User Needs	Design History File	<input type="checkbox"/>
	Product Description	Project File	<input type="checkbox"/>
	Regulatory Strategy & Plan	Project File	<input type="checkbox"/>
	Design & Development Plan	Design History File	<input type="checkbox"/>
	Risk Management Plan	Risk Management File	<input type="checkbox"/>
	Project Schedule & Plan	Project File	<input type="checkbox"/>
	Business Strategy & Plan	Project File	<input type="checkbox"/>
	Quality Plan	Project File	<input type="checkbox"/>
	Design Inputs	Design History File	<input type="checkbox"/>
	Design Review	Design History File	<input type="checkbox"/>
	Planning Phase Review	Project File	<input type="checkbox"/>
<b>Design &amp; Development:</b> To establish product design and detailed specifications; to identify design outputs and verification methods.	Design Outputs	Design History File	<input type="checkbox"/>
	Risk Analysis (hazard identification)	Risk Management File	<input type="checkbox"/>
	Risk Evaluation	Risk Management File	<input type="checkbox"/>
	Risk Assessment(s)	Risk Management File	<input type="checkbox"/>
	Design Verification Plans	Design History File	<input type="checkbox"/>

	Human Factors	Project File	<input type="checkbox"/>
	Sales & Marketing Strategy	Project File	<input type="checkbox"/>
	Working Prototypes	Project File	<input type="checkbox"/>
	Define Regulatory Path	Project File	<input type="checkbox"/>
	Design Review	Design History File	<input type="checkbox"/>
	Design & Development Phase Review	Project File	<input type="checkbox"/>
<u>Design Verification:</u> To demonstrate the product meets the design inputs.	Design Verification Reports	Design History File	<input type="checkbox"/>
	Design Validation Plans	Design History File	<input type="checkbox"/>
	Manufacturing Plan	Project File	<input type="checkbox"/>
	Risk Control	Risk Management File	<input type="checkbox"/>
	Residual Risk Acceptance	Risk Management File	<input type="checkbox"/>
	Sterilization Validation (if applicable)	Design History File	<input type="checkbox"/>
	Software Validation (if applicable)	Design History File	<input type="checkbox"/>
	Design Review	Design History File	<input type="checkbox"/>
	Design Verification Phase Review	Project File	<input type="checkbox"/>
<u>Design Validation:</u> To demonstrate the product meets the user needs.	Regulatory Submission	Project File	<input type="checkbox"/>
	Revised Manufacturing Plan	Project File	<input type="checkbox"/>
	Design Validation Reports	Design History File	<input type="checkbox"/>
	IDE Clinical Trial	Project File	<input type="checkbox"/>
	Risk Management Report	Risk Management File	<input type="checkbox"/>
	Prove Market Is Receptive	Project File	<input type="checkbox"/>
	Prove There Are Buyers	Project File	<input type="checkbox"/>
	Prove Pricing Models	Project File	<input type="checkbox"/>
	Design Review	Design History File	<input type="checkbox"/>

	Design Validation Phase Review	Project File	<input type="checkbox"/>
<u>Market Release:</u> To launch product into manufacturing and marketplace.	Regulatory Clearances	Project File	<input type="checkbox"/>
	Reimbursement Codes	Project File	<input type="checkbox"/>
	Sales & Marketing Plans	Project File	<input type="checkbox"/>
	Production & Post-Production Risk Management	Risk Management File	<input type="checkbox"/>
	Revised Risk Management Report	Risk Management File	<input type="checkbox"/>
	Finalize Quality System	Company Quality System	<input type="checkbox"/>
	Transfer to Manufacturing Design Review	Design History File	<input type="checkbox"/>
	Market Release Phase Review	Project File	<input type="checkbox"/>