

Project Charter

Example Project Name

Element	Details
Project Name	Medical Device Equipment Development
Sponsor	[Name of Sponsor/Executive]
Project Manager	[Name of Project Manager]
Objective	Design, build, and validate a new piece of equipment for medical device manufacture, ensuring compliance with regulatory standards and optimizing production efficiency.
Scope Statement	This project covers requirements gathering, design, prototyping, testing, validation, and documentation for the new equipment. Excludes post-market surveillance and ongoing maintenance.
Resources Required	- Engineering team - Quality assurance specialists - Regulatory affairs experts - Manufacturing technicians - Budget: €XXX,XXX - Facilities: R\&D lab, manufacturing floor - Equipment: CAD software, prototyping tools, testing apparatus
Key Milestones	- Project kick-off - target - Design freeze - target - Prototype completion - target - Validation testing - target - Regulatory submission - target - Project closure - target
Deliverables	- Design documentation - Validated prototype - Test reports - Regulatory submission package
Assumptions	- Annual output of 100,000 widgets per year, with 5days x 24hr shift pattern - Regulatory requirements will not change significantly during the project - Stakeholder support remains consistent
Constraints	- Budget limitations - Timeline: [insert duration] - Compliance with [insert relevant standards, e.g., ISO 13485, FDA 21 CFR Part 820]
Risks	- Delays in regulatory approval - Technical challenges in design - Resource availability issues
Approval Signatures	Sponsor: _____ Project Manager: _____