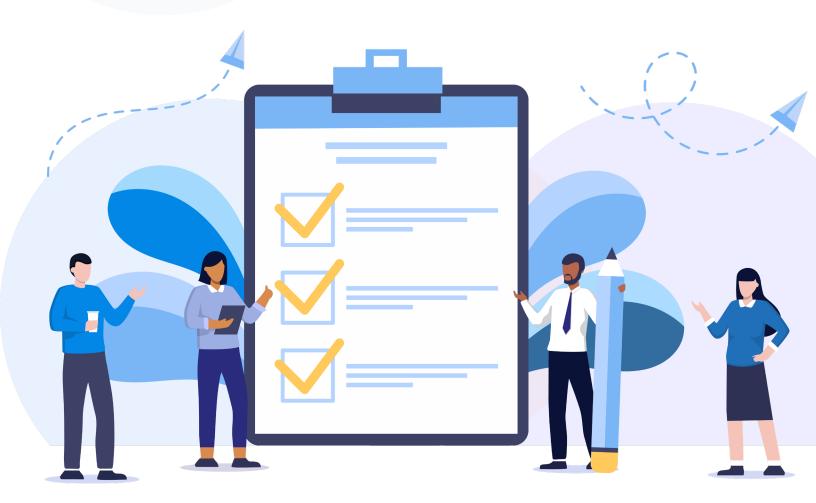
## 10 Things You Can't Miss

to Ensure your Device Makes it to Market





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Risk Assessment		
	Is there a Risk Analysis Document in accordance with ISO 14971:2019?  Is there a list of potential hazards which include a rating of likelihood of occurrence and severity?  Is there a Risk Control Chart which clearly defines a Risk Priority Number, RPN, which is As Low As Reasonably Practicable, ALARP?	
Software Requirements		
	Is there a complete Software Requirements Specification with unique, testable requirements?  Is there a functional state/flow diagram in the Software Requirements Specification?  Are there a IEC or equivalent standards referenced in the Software Requirements Specification?	
Software Architecture and Detailed Design Documents		
	Is there a system/sub-system diagram in the Software Architecture Document?  Are each of the software functions and parameters (Input, output, return value) described in the Software Detailed Design Document?  Are the function algorithms described in the Software Detailed Design Document?	
Source Code		
	Are details on the Development Environment provided?  Is the Source Code readable, including named functions and well commented?  Does the Source Code include unit tests, free from empty states, dead code, and include sufficient memory allocation (>50% free)?	
Hardware Requirements		
	Is there a complete Hardware Requirements Specification with unique, testable requirements?  Is there a functional block diagram in the Hardware Requirements Specification?  Are there a IEC or equivalent standards referenced in the Hardware Requirements Specification?	

Schematic Design, Printed Circuit Board Layout and Gerber Files		
	Is the Schematic Design and Layout created in a standard toolset (Altium, OrCAD, DX Designer, etc.)?  Do the Schematic Design components have complete parameter fields (Manufacturer, Manufacturer Part Number, Part Type, Tolerance, Rating, etc.)?  Does the PCB Layout and Gerber files have appropriate fabrication notes?	
Bill of Materials		
	Is the Bill of Materials complete with Manufacturers and Manufacturer Part Numbers?  Does the Bill of Materials include only qualified manufacturers parts?  Are the Bill of Materials key components in stock, readily available and reviewed for obsolescence?	
Hardware Design Document		
	Does the Hardware Design Document include details on all the functional blocks?  Does the Hardware Design Document include details on the key components (Description, Part Number, Supply Voltage, Inputs/Outputs, etc.)?  Does the Hardware Design Document include design rationale and calculations for component values?	
Design	Failure Mode and Effects Analysis	
	Are the DFMEA Occurrence and Severity levels clearly defined?  Are the DFMEA BAR ("Broadly Acceptable Region") and ALARP ("As Low As Reasonably Practicable") values clearly defined?  Are all the DFMEA ALARP failure modes mitigated?	
Design Verification		
	Is the Design Verification Plan Complete?  Is the Design Verification Protocol Complete?  Do each of the Design Verification Protocol tests trace to a hardware requirement?	



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