10 Things You Can't Miss

to Ensure your Device Makes it to Market

C3 Medical Device Consulting

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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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