

DESIGN FOR COMPLIANCE. LAUNCH WITH CONFIDENCE.

Embedding quality and regulatory requirements into the design & development of your medical device.

Create robust device designs backed by clear, consistent and compliant technical documentation.

YOUR CHALLENGES



DESIGN CONTROL COMPLEXITY How do you ensure design activities, changes, risks, and outputs remain controlled and traceable?



REGULATORY REQUIREMENTS How do you translate ISO 13485:2016 and EU MDR 2017/745 requirements into practical design controls and processes?



TECHNICAL DOCUMENTATION & COMPLIANCE How do you keep design evidence and technical documentation complete, consistent, and inspection-ready?

OUR APPROACH

01 ASSESS

- Comprehensive review of existing documentation and design inputs
- Regulatory gap analysis against ISO 13485 and EU MDR requirements
- Risk management considerations
- Prioritized execution roadmap



02 IMPLEMENT

- Advanced 3D CAD modeling, stack-up tolerance analysis, and assembly drawings
- Rapid prototyping and hands-on mechanical integration support
- Full compilation of Design History Files (DHF) and technical dossiers



03 ASSURE

- On-demand technical design & regulatory compliance hotline
- Direct support for verification, validation, and Notified Body audits

YOUR BENEFITS



CONTROLLED DESIGN PROCESSES

Strengthen design controls with clear requirements, responsibilities, change management, and traceability.



REGULATORY-ALIGNED DEVELOPMENT

Embed ISO 13485:2016 and EU MDR 2017/745 requirements into practical, consistent processes built for smooth auditor approval.



INSPECTION-READY DOCUMENTATION

Build complete, coherent technical documentation with the evidence and traceability needed to demonstrate compliance.

**READY TO BUILD STRONGER
DESIGN CONTROLS**
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Committed to **Excellence**