Scapa Regulatory Compliance Services
Your one-stop strategic outsource partner

Taking on your Regulatory Service challenges.

Scapa Healthcare, your strategic outsource partner, has expanded its turn-key solutions to offer you a more comprehensive one-stop-shop.

Our new Regulatory Compliance Services are part of our Product-Life Cycle Management process, offering full-service and support from submission to clearance and market surveillance. Our regulatory experts provide efficient and consistent regulatory and compliance support for Class II & III medical devices.

- Full-service regulatory support
- Enable you to more easily make significant design changes
- One-stop-shop for regulatory planning & services—design, manufacturing, logistics, and post market surveillance
- Scapa experts update your products status and communicate the regulatory climate

scapahealthcare.com
For more information: Americas ScapaUSregulatoryservices@scapa.com | Europe ScapaEUregulatoryservices@scapa.com
Learn more at: scapahealthcare.com/capabilities/regulatoryservices

Scapa Healthcare

At Scapa Healthcare, we listen to our partners. You've requested regulatory assistance. We are now pleased to offer full-service regulatory compliance services & post market surveillance.

Pre and Post Audit Support

- Offer pre-audit advice for: FDA, ISO 9001, ISO13485, Quality Assurance, Supplier, & OEM audits
- CAPA responses & implementation
- cGMP implementation & training

Design Plan Development

Creation of formal design plan for component and finished medical devices for FDA Class II & III before formal development process begins:

- DHF (Design History File Contents) 820.30, ISO 13485 Clause 3, FDA 820.181, ISO 13485 7.3
- Quality practices & verification
- Risk assessment & methods

Creation & Management of Design History Files

As part of the Design Plan Development, Scapa will manage and document your design history files.

- FDA Sec 820.30 and ISO Clause 3
- Device Master & History Record
- Biological Evaluation Testing
- Stability Data
- FDA Correspondence & submissions
- Design Dossier

Documenting & Executing Protocols / Testing for Validation

- Qualification of Scapa Healthcare manufactured components
- Ongoing documentation of outputs: Design concepts, Design planning, Product Design, Process capability, Design verification, Design validation, Equipment commissioning, and Design transfer.

Safety Regulatory Information

Upon request, offer safety regulatory information and updates for components and parts such as:

- US Consumer Product Safety
- Phthalates
- Food Allergy
- Proposition 65
- EU REACH
- Substance of Very High Concerns (SVHC)
- Conflict Minerals
- Solvents & ISO 10993

Document Preparation for Regulatory Submissions

- Preparation of necessary documents for: FDA 510k, STED, EU Technical File & CE mark submissions.

Navigating Regulatory Pathways & Notification of Changes

- Advise the best pathway to regulatory clearance for commercial distribution
- Conduct conformity assessment and identify all viable options

Post Market Surveillance Services

- Product compliance monitoring & tracking
- Post-market surveillance 21 CFR Part 822
- Root cause analysis of critical product complaints
- Maintain documentation of reportable events
- Medical device or component reliability monitoring

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