



## Life Cycle Services for Medical Devices

South 6 offers a complete suite of medical device life cycle services, from individual consultants to project teams to strategic outsourcing. Our consultants can fill knowledge gaps on current teams, or work independently under our clients' direction as product development engineers, manufacturing engineers, quality assurance professionals, regulatory and clinical affairs associates, validation engineers, and more.

South 6 has the largest database of highly skilled consultants with expertise within the following areas:

**Product Research & Development:** Design engineering, design control, material review, DHF/DMR/DHR development, concept development, packaging design, and packaging development

**Preclinical & Clinical Testing:** Raw materials testing, reliability testing, analytical testing, biocompatibility testing, and assessment

**Clinical Research/Clinical Affairs:** Biometrics, clinical operations, clinical systems, and medical affairs

**Submission & Registration:** 510(k), PMA, IDE, CE mark, labeling, design dossier, and due diligence for both medical and combination devices

**Post-FDA Approval Production & Comprehensive Packaging:** Packaging design, product transfer, manufacturing, sterilization, quality engineering, automation, lean manufacturing, Six Sigma, PFMEA, and facilities expansion

**Validation:** Cleaning, Master Validation Plans (MVP), equipment, process, computer systems, packaging, shelf life, test method, and sterilization

**Quality Engineering & Quality Assurance:** QMS development, SOPs, audits, remediation management, CAPA, supplier management, warning letter responses, 483 responses, consent decree consultation and solutions, inspections, complaint handling, complaint review, document control, medical device reporting (MDR), post-market monitoring and surveillance, product recall, change control, and device EOL management

**Facilities Compliance & Expansion:** Facility and utilities design, set-up, inspection, construction management, facility and equipment commissioning, HVAC, manufacturing environment, cleanroom, and cost control

**Technology Transfer & Collaboration:** Training, knowledge, and document management, from design to production

INFO  
[www.southsix.com](http://www.southsix.com)  
[info@southsix.com](mailto:info@southsix.com)  
 (774) 425-4434

LOCATIONS  
 Massachusetts  
 Texas  
 Washington

CONNECT WITH US ON  
 LinkedIn: south-6  
 Facebook: @south6inc