CONSULTING SERVICES

Life Cycle Services for Pharmaceuticals

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:

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

Integrated Clinical Supply Chain Development & Management: Process optimization, fill/finish, project management, automation, sterilization, supplier auditing, and cross-functional collaboration.

Drug Development: Method development, validation, and qualification; concept, formulation, design, process characterization and development; packaging design and development, protocol design for product and stability testing; and structured electronic drug development record.

Product Submission/Registration: IND, NDA, labeling, and due diligence for ICH, EMA, and FDA products, including oral solid dosage, tableting, API, and aseptic

Post-FDA Approval Production & Comprehensive Packaging: Packaging design, manufacturing, sterilization, quality engineering, chromatography, purification, formulation, filtration, automation, process optimization, fill/finish, equipment and cleaning validation, stability testing, cell culture, CIP, and SIP

Technology Transfer & Collaboration: Training, knowledge transfer, and document management, from formulation to production

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

Integrated Quality & Risk Management: Pharmacovigilance, risk analysis, drug regulatory harmonization, cGMP compliance, quality audits, CAPA, shelf life, LIMS, calibration, computer systems, CIP, and SIP

Quality Engineering & Quality Assurance: QMS Development, GMP, CAPA, Master Batch Records (MBR), LIMS, risk assessments, supplier QA, GCP, calibration, quality audits, cost control, and facility auditing

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

INFO
www.southsix.com
info@southsix.com
(774) 425-4434

LOCATIONS
Massachusetts
Texas
Washington

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