



Biotechnology Product Lifecycle Services

South 6 Life Sciences offers a complete suite of biologics/biotechnology lifecycle 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 process engineers, quality assurance professionals, regulatory affairs associates, validation engineers, genetic engineers, microbiologists, biomedical engineers, molecular biologists, biochemists, and more.

South 6 recruits highly skilled consultants with expertise within the following areas:

Personalized Drug Development : Concept development, assay development and qualification; method development, qualification, and validation; formulation, fermentation, scale-up, and analytical development; and packaging design and development

Preclinical & Clinical Development: Safety pharmacology, immunotoxicology, biocompatibility testing and product assessment

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

Submission & Registration: IND and BLA, labeling and due diligence for ICH, EMA, and FDA products, including injection and vial

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

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

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

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

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