CONSULTING SERVICES

South 6

Regulatory Affairs: Writing submissions, documentation, and remediation including 510(k) submissions, AER's, PMA's, IDE, remediation/resolution management, technical papers and complaint handling Quality Assurance &

Quality Engineering: Development of complete quality systems, including complaint management, deviation management, CAPA, change control, training, and document management and control. Methodology, policy, and procedure development. Gap/Risk assessment. Recalls, MDR's and complaint handling. Auditing to determine compliance with applicable regulations, guidelines, procedures, and policies for Part11, quality systems, vendors, and IT compliance.

Validation: Developing Standard Operating Procedures (SOP), validation protocols (IQ, OQ,PQ), and validation master plans. Conducting validation executions and writing validation reports. Computer systems, software, process, cleaning, methods, facilities and utilities, equipment, IT infrastructure, and 21 CFR Part 11.

Statistical Analysis: Statistical design and analysis for all phases of clinical trials, from the beginning planning stages through study completion and report preparation.

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