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SERVICES

QUALITY SYSTEMS - PROJECT MANAGEMENT - REGULATORY AFFAIRS



Aseptic Fill & Finish

- · Bausch & Stroebel Variosys filler that is highly flexible and modular.
- Capable of filling bulk and nested vials, syringes, ampoules, and cartridges.
- 100% non-destructive IPC with redosing ensures zero underfilled units.
- SKAN isolator technology that is leading the industry.
- · Flexible formulation suites to accommodate Phase 1 through commercial



Laboratory Services

- · Development and validation of stability indicating UPLC and HPLC assays
- · Residual solvents
- Microbiological: sterility, bioburden, B/F, and endotoxin
- · Stability testing that meets ICH guidelines.



Project Management

Let our seasoned project management teams guide you through every step of the Contract Manufacturing process, from technology transfer through ongoing commercial production support.



Regulatory Support

Our team of regulatory experts has decades of experience with agencies around the world.



