Titenare GXL Technologies – Regulatory Affairs Services & Support on-Demand

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Integrated Pharma Business, Development and Commercial Solutions:

Highest Quality at affordable Cost & Collaboration Connected

BUSINESS SOLUTIONS AND SERVICES

Access to right Products & Funding	*Access to integrated Services*	*Access to right Markets*
BUSINESS DEVELOPMENT ➢ New Product Strategies ...R&D, Inlicensing, Outlicensing ➢ Global Supply Chain management ➢ Mergers & Acquisitions ➢ Advisory Services ➢ Turnkey project solutions ➢ Fund raising support	TECHNICAL SERVICES ➢ Facilities Design & Engineering ➢ Regulatory Affairs – Drug & Device ➢ Quality Management Systems ➢ Development Services – Product/Analytical ➢ API Development Monitoring Support ➢ Technology/Site transfers ➢ Third Party Audit and Compliance ➢ ISO//CE Mark/UL certifications ➢ Global supply chain management ➢ Intellectual Property	MARKETING & SALES ➢ Market Assessment ➢ Competitor Differentiation ➢ Pipeline Prioritization ➢ Competitor and customer perspectives ➢ Complete organization value maps ➢ Implementation planning and support ➢ Market access: India, EU, US, RoW

Regulatory Affairs Services & Support on-Demand

- Competent team to undertake complete requirements for the Client's geography
- Review of documents from R&D, Bioequivalence studies, API manufacturer and formulations manufacturing for NDA, sNDA, ANDA/eCTD readiness; 510K/CE/UL/ISO/IATF readiness, gap analyses and gap closure advisory.
- Compilation of NDA, sNDA, ANDA/eCTD, 510K/CE/UL with necessary coordination with various entities
- Submission of eCTD for EU, ANDA's for USA, or any other geographic filings. Work with specific, compatible database tools
- Running Centralized procedures like Centralized/MRP/DCP (EU)
- Running of procedures for ANDA, and DCP/MRP, national phases
- Advisory on optimum filing strategies to reduce approval time and costs, filings & queries management, with customer as front end
- Guidance to R&D team during product development stages to ensure streamlined ANDA/eCTD/510K/CE/UL approvals
- Management of post approval changes / variations, renewals, and optimum strategies
- Review of active substance Drug Master File and actions closure
- Screening of in-licensing dossiers for registration success
- Coordination with Manufacturing, R&D, Quality, Artworks, Pharmacovigilance, and other functions for smooth integration of all ANDA/eCTD/510K/CE/UL documents to ensure regulatory compliances.
- Regulatory budget setting and costing based on Client product pipeline plans.
- Optimum regulatory planning for site transfer and technology transfer projects; establishing, gathering, and compiling documents for filing variations and new sourcing strategies

FLEXIBLE ENGAGEMENT MODELS

- Specific project based
- Rent-a-resource: Monthly retainer based
- Resource placement at the manufacturing sites