Titenare GXL Technologies: R&D Projects, Contract Development Organization (CDO) Management Services

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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

R&D Projects, Contract Development Organization (CDO) Management Services

- Provide access to a large product pipeline which are under development: Titenare GXL has a network of large number of CDOs and access to their development pipelines for API, formulation, and device. Our goal is to ensure collaborative success for pipeline expansions for all partners.
- Provide market insights into the market potential for the products, launch dates, etc.
- Identification and selection of CDOs aligned with Client criteria and nature of studies
- Manage R&D projects and CDO's of various types:

  > Development only with technology transfer, or

  > Full ANDA/eCTD/510K with BE/Clinical studies, and up to commercial supplies
- Technical and commercial due diligences of the selected CDO sites as per latest regulatory guidelines
- Negotiations on scope of work, commercial and technical agreements
- Preparation of entire management and quality systems for the management of CDOs
- Audit of CDO sites as per target regulatory standards for USFDA, EUGMP, ROW, ISO
- Comprehensive monitoring of studies at multiple CDO sites
- Intermediate assessment of data and progress during product developments
- Assistance in review and finalization of study reports consistent with regulatory guidelines
- Drive significant cost savings; keep Client's internal headcount down

FLEXIBLE ENGAGEMENT MODELS

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