Titenare GXL Technologies: BE Studies / CRO Management Services

Dr. Ashwani Kumar,
Director & Partner
+ 0091 9740644880
ashwani.kumar@titenaregxl.com
www.titenaregxl.com
Corporate Office:
No. 815, 5th Cross, 9th Main, HRBR Block I,
Kalyan Nagar, Bangalore 560043, INDIA

Mr. Thomas J. Brya,
Managing Director USA
+01-847-337-6557
tom.brya@titenaregxl.com
Corporate Office:
222 W. Merchandise Mart
Plaza, Suite 1230
Chicago, IL. 60654 USA

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

BE Studies/CRO Management Services

- Identification and selection of CROs aligned with Client criteria and nature of studies
  > TGXL has access to several CRO sites
  > Drive significant cost savings
  > Review of CRO/CDO SOPs, quality assurance and quality controls
  > Approved by USFDA and EU Health Authorities, with successful NDA, sNDA, ANDA/CTD submissions
- Technical and commercial due diligences of the selected CRO/CDO sites
  > March 2018 ICH Good Clinical Guidance driven unified standards for US, EU, and Japan
  > Good Engineering Practices (ISO14971) for medical device
- Negotiations on scope of work, commercial and technical agreements
- Preparation of entire management and quality systems for the management of CROs
- Audit of CRO sites as per target regulatory standards for USFDA, EUGMP, ROW
- Comprehensive monitoring of studies at multiple CRO/CDO sites
  > Risk assessment of recent computerized system validations
  > Risk assessment of medical device product as per ISO14971
- Assistance in preparation of study guidelines and protocols creation. Medical device risk assessment review
- Intermediate assessment of data and progress during studies
- Assistance in review and finalization of study reports consistent with ANDA/CE Mark/IEC6060-1 guidelines

FLEXIBLE ENGAGEMENT MODELS

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