Titenare GXL Technologies – Quality Management Services & Support

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Integrated Life Science Service Solutions: (Bio-Pharma, Generics and Devices):

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

Quality Management Services & Support

- Support CEO as the primary and final accountable for effective Quality Management Systems (QMS) as mandated by regulatory bodies (such as FDA/ICH/EMEA/ISO).
- QMS: Create, enhance, maintain end-to-end system aligned with all regulatory guidelines
- Support responsible Quality Designate (such as Qualified Professional in EU)
- Audits:
  > Conduct audits compliant with EDQM/USFDA guidelines
  > Perform gap analyses, follow up with sites for corrective and preventive actions (CAPA) closure
  > Issue report that can be used in regulatory filings
  > Cover sites related to Formulations manufacturing, API, Formulation development, Device manufacturing, Clinical studies
- Manufacturing Systems (contract or inhouse):
  > Creation of SOPs, Work Instructions
  > Quality tracking with global manufacturers
  > Key documents review and creation: SMF, Technical Agreements, Process validation protocol, Specifications
  > Annual Product Quality Review (APQR)
  > Complaints investigations, gap analyses, CAPA closure
  > Batch Release activities:
  → Review of batch records (BMR/BPR)
  → Third party lab coordination
  → Management of country–specific site release procedures as support to Quality Designate
- Qualification & Validation:
  > Development of Qualification protocols
  > Review, develop and documentation of User Requirement Specification (URS)
  > Review of Functional Design Specification (FDS) of equipment
  > Support in different Qualification steps i.e., FAT/SAT/DQ/IQ/OQ/PQ
- Artwork development, working with manufacturers, maintenance via change controls
- Regulatory/Certifications submissions:
  > Related to eCTD, ANDA, DMF, ISO, CE Mark, UL Mark

> Quality sections creation/review

- Manufacturing Site Transfer: Review of alternate sourcing documents
- Formulation Development: Selection, audit of CDO facilities
- Bioequivalence / Clinical Studies: Selection, audit of CRO facilities

FLEXIBLE ENGAGEMENT MODELS

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