PROGROW PHARMA PARTNERS

A Team with All Essential Elements to Execute Strategic Challenges of Healthcare Space!

ABOUT US

We are an advisory firm with a team of professionals having 20+ years of experience in serving the Pharmaceutical Industry.

Our exclusive focus and knowledge of the Global Biotech, and Healthcare sector enables us to offer advisory services to healthcare companies (Market leaders, Innovators, Generic Players CROs, and others) and its Investors (Private Equity investors, Venture Capitalists, HNIs, and others)

Our dedicated team brings together scientific expertise, financial know-how, and industry experience to understand the science and challenges associated with innovation, drug development, clinical trials, patents & litigations, and competition across geographies.

DOMAIN KNOWLEDGE AND SERVING DIVERSIFIED PHARMA CLIENTS SET US APART

OUR MISSION

Our mission is to become the recognized advisor in its target market for providing healthcare and service tailored to each client’s needs and expectations.

OUR SERVICES

TRANSFORMING BUSINESS CHALLENGES INTO GROWTH OPPORTUNITIES

Strategic Advisory

Strategic Partnership, Joint Ventures, and Tie-ups

We mediate JV/ Collaborations by identifying products /companies /facilities in different geographies that align with a client's business

Investment and Divestment

Helping to find right candidate for mergers and acquisitions – Our team can assist in brand acquisition/divestment, total or partial sale of manufacturing facility etc. to create long term value for the business.

Licensing

Tracking approval and development of new drugs of Pharma companies across the Globe, our team identifies In-licensing/ Out-licensing opportunities of innovative drugs (Small molecules/ Biologics) suitable to our client's need.

Financial Services

With domain knowledge – Technical and Financial under one platform, we use appropriate valuation methodology to assist clients in their investment decision.

- Investment opportunity assessment of sub sectors, API, formulations
- Assist investment banks in identifying opportunities in Pharma and co execute the projects
- Third party Technical and commercial due diligence
- Business evaluation of start-up pharma companies

Feasibility Studies

We provide market and techno-commercial feasibility studies to pharma companies and/or investors.

- Market study and product selection
- Required Cost Calculation (Investment, Operating, Factor, and Input costs)
- Financial Forecast (Income Statement, Balance sheet and Cash flow)
- Feasibility Analysis

Industries focus –

- API and Intermediate
- Finished Dosage
- Biologics/Biosimilars/Bio-better
- OTC, Nutraceuticals, Herbal / plant extracts
- Animal/ veterinary products
- FMCG- Disinfectant, sanitization products

We cover all markets –

- **Regulated Markets:** USA, EU, Japan, Australia
- **Semi- regulated Markets:** India, ASEAN- countries, China, Brazil, etc.
- **Non-Regulated Markets:** Sri Lanka, Bangladesh, East Africa, etc.

OUR SERVICES

TRANSFORMING BUSINESS CHALLENGES INTO GROWTH OPPORTUNITIES

Quality Support & Compliance

Our experienced team provides process validation services for the continued verification of manufacturing processes that help clients maintain quality and compliance for cGMP regulated products.

- **Computer System Validation** – Team leverages the latest risk-based Computer System Validation (CSV) technique to ensure that our clients' systems are ready for inspections from the regulatory authorities (FDA, EMA, MHRA, etc).
- Our consultants have extensive experience in various applications-
  - Cloud-based (SaaS and PaaS) applications; Configured Off-the-Shelf (COTS) applications – Laboratory Information Management System/ LIMS (HP ALM, LabVantage) and Manufacturing Execution Systems /MES (PAS-X and TULIP); On prem and cloud-based (IaaS) infrastructure
- **Part 11 and Annex 11 Compliance** – Team has expertise in Compliance with FDA 21 CFR 11 Electronic Records; Electronic Signatures and EU Annex II Computerized Systems which have become new essentials in pharma industry.
- **GxP Audits** – Our team is proficient in conducting mock inspections, internal audits, vendor and supplier auditing, and gap assessments.
  - GMP Audit - Evaluating the system and manufacturing facility in compliance to the regulatory expectation and quality standards.
  - GAP Audit – To assess their level of compliance with requirements of Desired Regulatory Agencies
  - Others GxP – Qualified team has a breadth of expertise across the entire development and regulatory spectrum (GCP, GLP, GCLP, GPV, ISO-13485, etc.).
  - Vendor qualification/ assessment Audit – To evaluate and qualify the vendors for procurement of the critical supplies
- Strategic assistance in international regulatory submissions like DMFs ASMFs, Technical Dossiers

SELECT PROJECTS EXECUTED

Strategic Advisory

- Out-licensing of Innovative preoperatory products – Vaccines
- Assisting US –based company in Formulation development of its patented NCE molecule
- Strategic Advisory to the India pharma company – In-Licensing of NCE/ NME molecule for Domestic Market
- Identify buyers or strategic investor/ partner for existing injectable facility, Biotech start-up, multi-specialty hospitals, etc.
- Market Potential assessment of Novel Peptide-based products in various indications, and Strategic Advisory for Out-licensing of them
- Evaluation of Business Plan and Marketing Strategy of a New Venture (International subsidiary) of India Pharma Company
- Global Market Assessment and In-Licensing & Out-licensing of NCE, NME, NDDS products

SELECT PROJECTS EXECUTED

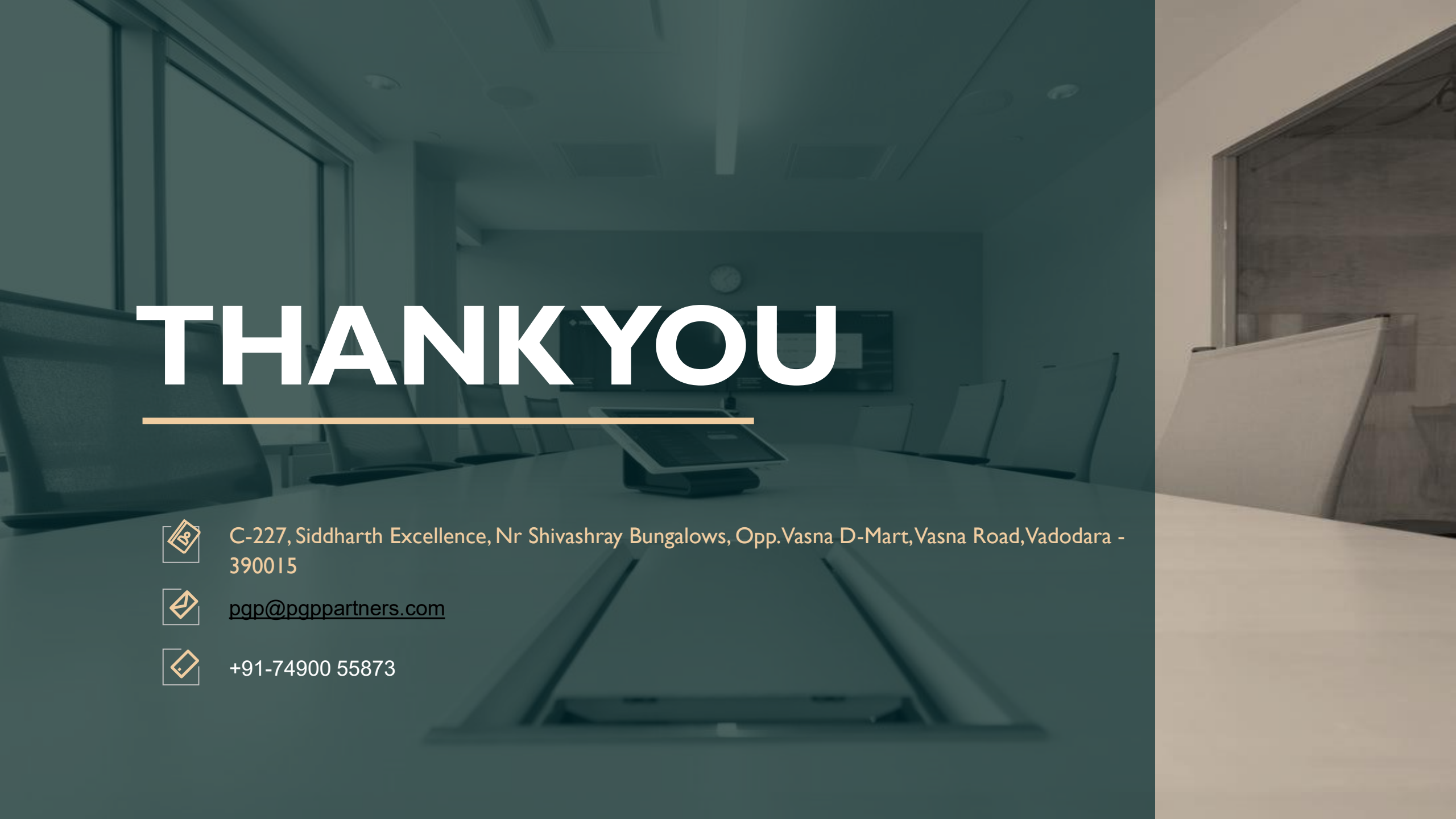
Financial Services

- Business Evaluation for Biopharma Start-up focusing on developing an Innovative New Chemical Entity for Metabolic and CNS diseases
- Fund raising for Biotech Start-up focusing on Drug Repurposing, and developing New Molecular Entity
- JV partnership for Biotech Start-up focusing on the development and manufacturing of Low-cost and High-quality Natural Peptides
- Valuation of Biotech Company – Evaluate the pipeline, Technology platform and its IP assets
- Third party and/or Independent Business and Technical Due Diligence and/or Valuation of companies, such as, CRO, Nutraceutical companies, API & Finished Dosage manufacturer, Preclinical CROs, Vaccine, etc.

SELECT PROJECTS ONGOING /EXECUTED

Quality Support and Compliance

- Developed and reviewed CSV-Laboratory System (LabX, LIMS Labware) in quality control laboratories and for Manufacturing Execution Systems (PAS-X and TULIP) at one of the International Pharmaceutical Company as per FDA 21CFR part 11, CFR par 210 and/or other GxP regulations
- Authored and reviewed configuration specifications, user requirements, validation protocols, instrument qualification documents, traceability matrix RTM, validation summary reports, SOPs.
- Assist in risk analysis and risk assessment process
- Assisted clients by guiding product development in line with the country specific requirements, data generation, document compilation for submission to various Regulatory Agencies all over the world, responding to the queries and finally obtaining the approval or registration of the product
- Third party regulatory/vendor auditor for reputed Indian MNC



THANK YOU

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