# PROGROW PHARMA PARTNERS

A unified team, strategically equipped to navigate the complex challenges of healthcare

# ABOUT US

At ProGrow Pharma Partners, we envision a future where innovation and compliance converge seamlessly to accelerate global healthcare progress.

With over two decades of expertise, we stand as trusted advisors—combining deep scientific insight, financial strategy, and regulatory mastery to transform complex challenges into strategic opportunities.

Our risk-based validation approach, aligned with GAMP 5 standards, ensures robust, efficient, and future-ready systems across pharmaceutical, biotech, nutraceutical, and life sciences domains.

We partner with innovators, generic manufacturers, CROs, suppliers, and investors to deliver bespoke solutions that empower bold decisions, unlock growth potential, and set new benchmarks for excellence in the pharmaceutical ecosystem.

**LEVERAGING DEEP EXPERTISE TO DRIVE STRATEGIC GROWTH ACROSS PHARMA SEGMENTS**

# OUR MISSION

We aspire to redefine advisory excellence in the pharmaceutical sector—empowering our clients with innovative, tailored solutions that anticipate challenges, unlock opportunities, and set new benchmarks for growth and success.

# SERVICES

## Transforming complex challenges into strategic growth opportunities

### Strategic Advisory

#### Strategic Partnerships & Collaborations

Drive innovation through alliances and joint ventures aligned with your growth vision.

#### Investment & Divestment Advisory

Maximize value with expert guidance on acquisitions, divestments, and restructuring.

#### Licensing Solutions

Secure global in-licensing and out-licensing opportunities for breakthrough molecules.

### Comprehensive Feasibility & Market Studies

**From cost modelling to financial forecasting, we provide end-to-end feasibility analyses—covering regulated, semi-regulated, and non-regulated markets worldwide.**

#### Industry Focus

- APIs & Intermediates
- Finished Dosage Forms
- Biologics, Biosimilars & Bio-betters
- OTC, Nutraceuticals & Herbal Extracts
- Veterinary & Animal Health Products
- FMCG: Disinfectants & Sanitization Solutions

#### We cover all markets –

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

# SERVICES

## Validating Systems, Safeguarding Wealth

### Financial Services

**With our combined technical and financial expertise, we apply robust valuation methodologies to help clients make informed investment decisions. We:**

- Assess opportunities across diverse sub-sectors, APIs, and formulations
- Partner with investment banks to identify and co-execute projects within the pharmaceutical industry
- Conduct independent technical and commercial due diligence
- Evaluate business potential for emerging pharmaceutical and biotech start-ups

### Computer System Validation (CSV)

**We help life sciences organizations meet stringent guidelines like US FDA 21 CFR Part 11 and EU GMP Annex 11. Comprehensive solutions to ensure systems meet regulatory expectations. Validation deliverables:**

- Tailored validation plans on risk level.
- Documented use requirements and functional specifications.
- IQ, OQ, and PQ protocols for system functionality testing.
- Inspection-ready documentation for regulatory compliance.
- Ongoing support and training on SOPs and validation templates.

# SERVICES

## Ensuring Integrity, Driving Excellence

### Regulatory Consulting Services

**We deliver proven strategies and best practices to strengthen compliance and safeguard patient health in a cost-effective manner.**

**Our expertise includes:**

- Regulatory Submissions: Preparation and submission of documentation for approvals.
- Regulatory Strategy: Comprehensive planning for successful submissions and compliance.
- Compliance Audits: Internal audits to ensure adherence to global standards.
- Regulatory Intelligence: Staying ahead of evolving regulations and industry updates.

### Quality Assurance & Validation Services

**With hands-on experience in project management, risk assessment, and validation, we guarantee top-tier quality and compliance.**

**Key offerings:**

- Quality system audits: Assessing compliance with US CFR Part 210/211, ICH, and EU GMP.
- Quality Management Systems (QMS): Designing and maintaining systems for deviations, investigations, CAPAs, and change controls.
- Training: Empowering teams with knowledge of Quality control and Regulatory guidelines.
- Risk management: Identifying and mitigating potential risks proactively.

# RELEVANT EXPERIENCE

# 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 the 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.

# Financial Services

- Business Evaluation for Biopharma Start-up focusing on developing an Innovative New Chemical Entity for Metabolic and CNS diseases
- Assist in the 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.

# Comprehensive Feasibility & Market Study

| No | Client | Project Description | Scope of services | | | | Completion year |
|---|---|---|---|---|---|---|---|
| | | | Market study | Financial feasibility | Technical feasibility | Business analysis | |
| 1 | Public-listed biotech (Confidential), USA | Business valuation and Market feasibility of novel, patented, proprietary technology platform and product portfolio. Targeted market- Global | Y | Y | | Y | 2025 |
| 2 | Confidential/ SPV, India | Techno- Commercial feasibility study to set up sterile injectable (SVP and LVP) manufacturing facility in India | Y | Y | Y | | 2025 |
| 3 | New Life therapeutics, Singapore | Business valuation and Market feasibility of novel, patented, proprietary formulations of an approved product portfolio. Targeted market- ASEAN countries | Y | Y | | Y | 2023 & 2020 |
| 4 | DAL Medical Service company ltd, Sudan | Concept Design, Costs Related to Civil Work & Operation and Financial Project Feasibility Analysis For Setting Up A Finished Dosage Form Manufacturing Facility | | Y | Y | | 2022-23 |
| 5 | NU Life, Sri Lanka | Commercial Feasibility study for Finished Dosage (Sterile inj.) Manufacturing Facility | | Y | Y | | 2022 |
| 6 | Maliban, Sri Lanka | Commercial Feasibility study for Finished Dosage (Biosimilar) Manufacturing Facility | | Y | Y | | 2022 |
| 7 | Erris Pharmaceuticals, India | Market analysis and Techno-Commercial Feasibility study for Bulk Drug Manufacturing Facility | Y | Y | Y | | 2021 |
| 8 | Lesous Lifesciences, India | Detailed Project Report on Market analysis and Techno-Commercial Feasibility study for Bulk Drug Manufacturing Facility | | Y | Y | | 2020 |
| 9 | Independent Buyer, India | Business Analysis of Bulk Drug and Intermediates Manufacturing Facility | | Y | Y | Y | 2020 |

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| No | Client | Project Description | Scope of services | | | | Completion year |
|---|---|---|---|---|---|---|---|
| | | | Market study | Financial feasibility | Technical feasibility | Business analysis | |
| 10 | Vamsi Labs, India | Business Analysis of Bulk Drug Manufacturing Facility (Potent compounds) | | | | Y | 2019 |
| 11 | Blue Nile Pharmaceuticals Manufacturing S.C/ L BLUPHAR, Ethiopia | Market Feasibility Study to set up a Finished Dose Manufacturing Facility for Human and Veterinary therapeutics, Ethiopia | Y | Y | Y | | 2018 |
| 12 | Issar Pharmaceuticals, India | Market analysis of patented, approved and pipeline products (Collagen & Peptide) and Business valuation | Y | | | Y | 2018 |
| 13 | Cellix Bio, India | Market analysis of select drugs [505(b)2] in different therapy areas, Assessment of market potential, and Business Evaluation | Y | | | Y | 2017 |
| **Relevant projects done by ProGrow Pharma Partners' team in past** | | | | | | | |
| 14 | Shilpa Medicare, India | Market analysis, Feasibility analysis and Pipeline prioritization of Oncology products, India | Y | | | Y | 2015-2016 |
| 15 | Impact capital, Ethiopia | Financial Feasibility Report for Product portfolio provided by an Ethiopian local investment advisory and management company | | Y | | | 2015 |
| 16 | Sunshine Healthcare Lanka, Sri Lanka | Private and Hospital market analysis, selection of products, and techno-commercial feasibility study of finished dosage manufacturing plant in Colombo | Y | Y | Y | | 2014-2015 |
| 17 | Orchid Pharmaceuticals, India | Market analysis and Feasibility Study of Marketed and Pipeline products | Y | Y | | | 2013-2014 |

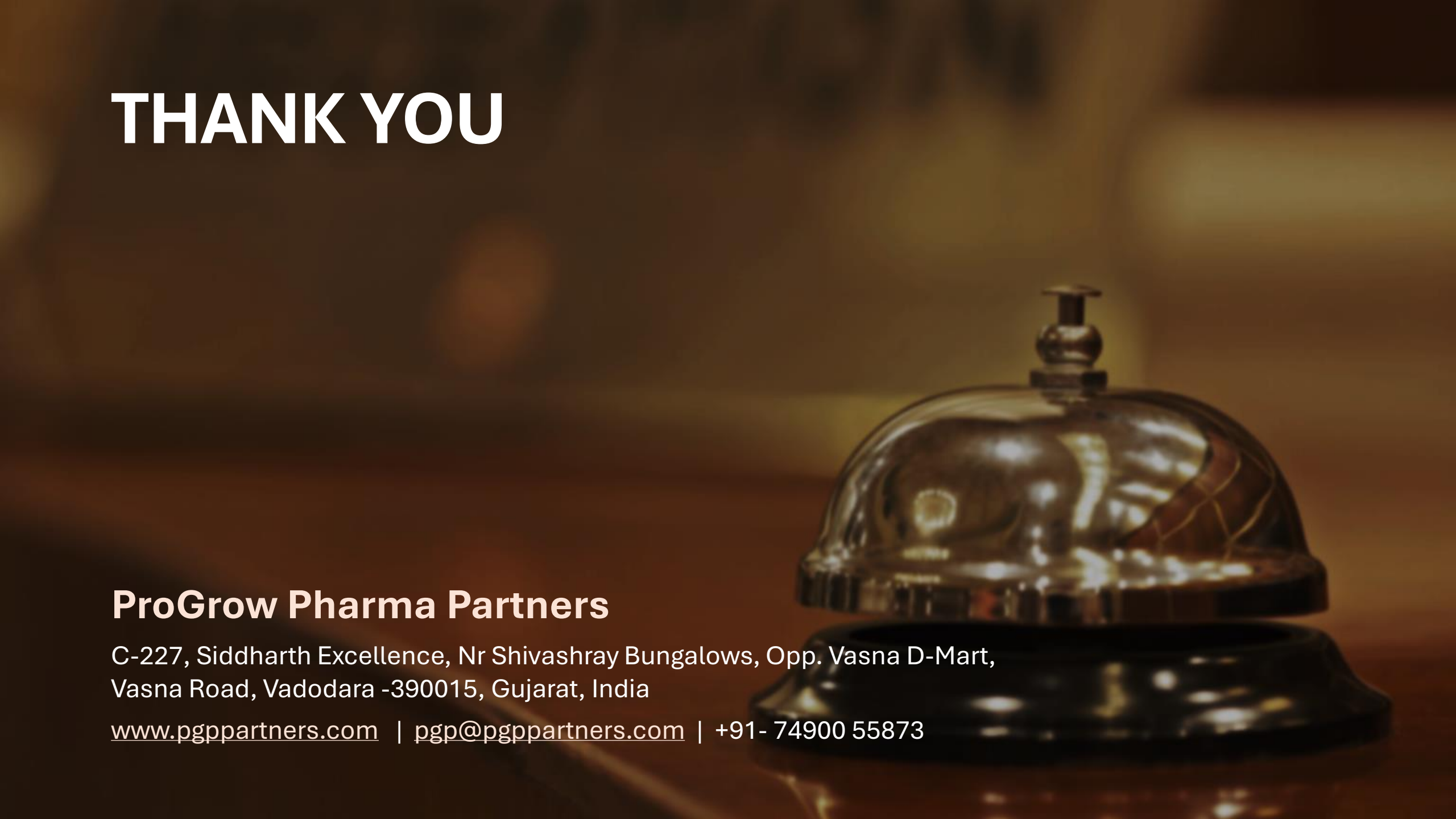
# Quality Support & Compliance

- Led the development and review of CSV for key laboratory and manufacturing systems, including **LabX, LIMS (LabWare), PAS-X, and TULIP,** ensuring alignment with **FDA 21 CFR Part 11, CFR Part 210**, and global GxP requirements.
- Authored and reviewed **critical documentation** such as configuration specifications, user requirement specifications, validation protocols, qualification reports, traceability matrices, validation summary reports, and SOPs.
- Performed **comprehensive risk analysis** and **risk assessment to ensure system integrity**, data reliability, and regulatory compliance.
- Supported and participated in **third-party regulatory** and **vendor audits** for a leading Indian multinational pharmaceutical company.
- Prepared **pharmacovigilance documentation** for semi-regulated markets, including **Risk Management Plans (RMPs) and Periodic Safety Update Reports (PSURs).**

# Quality Support & Compliance

- Collaborated with clients to align product development with country-specific regulatory requirements, supporting:
  - Data generation and evaluation strategies
  - Document compilation for regulatory submissions
  - Dossier preparation for different markets (EU, US, ROW, WHO PQ)
  - Gap analysis to identify and resolve deficiencies before filing
  - Lifecycle management of regulatory documents
  - Coordination with cross-functional teams including R&D, Quality Assurance, and Regulatory Affairs
  - Preparation of labelling components (SmPC, PIL, carton/leaflet artworks)
  - Compilation of Chemistry, Manufacturing, and Controls (CMC) documentation
- Maintained regulatory databases and handled version control for all submission-related correspondence and documentation.

# THANK YOU

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