RECEPTOPHARM

A NUTRA PHARMA COMPANY

CONTRACT RESEARCH SERVICES

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CONTRACT RESEARCH SERVICES

ReceptoPharm has installed the pathways to develop, produce and supply clinical material for Phase I and II studies at the highest levels. In 2008, the Company began offering services catering to small and start-up biotechnology companies.

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Partnering with ReceptoPharm

As a clinical stage company specializing in biologics, ReceptoPharm has cleared many of the hurdles that face emerging biotech companies. Below are the top reasons that companies choose to partner with ReceptoPharm as its CRO:

1. Therapeutic experience encompassing infectious disease, autoimmune conditions, neurological disorders and oncology indications.

2. A renowned team of scientists, led by Dr. Paul Reid, specializing in human and veterinary regulatory affairs for the United States, Canada, and Europe, and drug applications (pre IND, IND and Orphan), drug production, new drug development, clinical trial design, patient monitoring, and experimental design.

3. Significant investment in establishing a production facility to meet US and EU standards, including the installation of quality systems to meet GMP standards and ISO Class 5 certification.

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A Global View on Drug Development

ReceptoPharm prides itself on taking a global view on drug development; whether it's preparing submissions, protocols, formulations, or organizing clinical trials internationally.

ReceptoPharm has invested heavily in establishing its own production facility to meet US and EU standards, including the installation of quality systems to meet GMP standards. Its commitment to maintaining the highest quality standards can now be used as a resource by other biopharmaceutical companies.

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Top-Rated Drug Production Facilities

Establishing and maintaining a qualified drug production facility can represent a significant drain on a small company's resources.

ReceptoPharm understands that its investment in manufacturing and its first-hand knowledge in drug discovery and development can be very valuable assets to small companies that do not have these resources or capabilities in-house. Working with ReceptoPharm through its ISO class 5 and GMP certified facilities will allow these companies to avoid considerable clinical development expenses and allow them to focus on a more important task, expeditiously getting their products to the next stage.

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Contract Research Services

Pre-Production Studies

- Stability Studies
- Formulation
- Adventitious Viral Testing
- Preservative Efficacy Testing
- Assay Development/Potency Testing
- Methods Development

US & EU Regulatory Support

- FDA Drug Applications, IND Preparation
- EU Submissions, IMPD Preparation

Sterile Filling Capabilities

ReceptoPharm can manually fill a variety of drug products for your clinical development projects in the US and EU. While ReceptoPharm specializes in biologics, including MAbs, natural, recombinant and synthetic proteins, it can also prepare and fill pharmaceutical products in its ISO class 5 cleanroom facilities.

Contract Manufacturing Services

- Drug Formulation
- ISO 5 Sterile Filling Suite, Single and Multi-Dose Liquids for Injection
- Clinical Trial Supplies to FDA & EU Requirements
- Packaging and Shipment to Sites
- Release Testing and Certification

Quality Systems/GMP Certification

- Installation of Quality Systems Using Our SOPs
- GMP Audits
- GMP Training
- QA Function
- IQ/OQ/PQ
- Validations (Equipment and Processes)

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