Renejix®

PHARMA SOLUTIONS

Your Molecule, Our Mission.

April 2024

E2E Services - Our Capabilities Overview

Small Molecule API

- Manufacturing, process development, scale-up and optimization of APIs
- Solid State Characterization and API assessment
- Alternative Partners available in USA, Europe, & Asia

GLP Labs

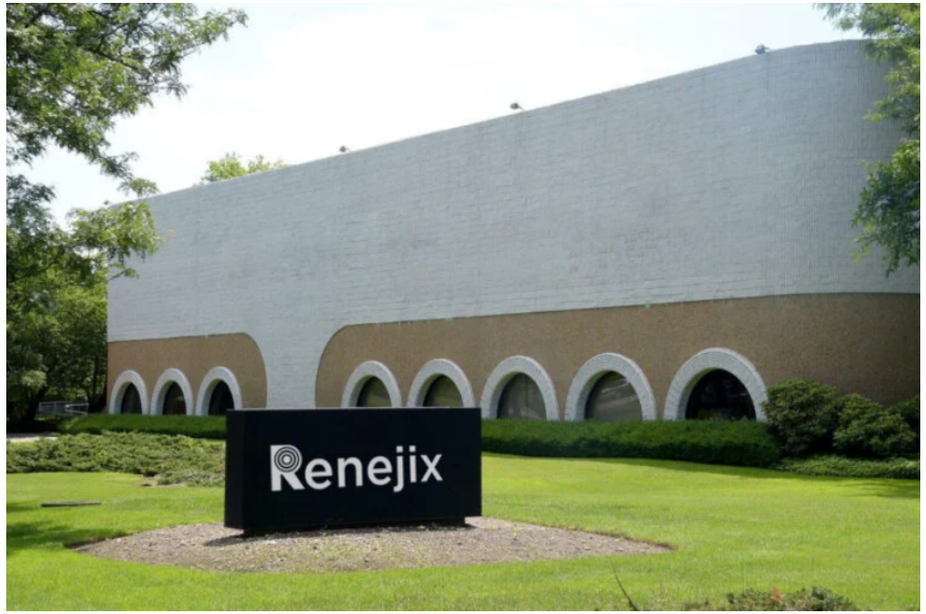
- Toxicology, Carcinogenicity
- Efficacy
- Discovery
- Regulatory
- Invitro and invivo animal studies
- PK/PD
- R&D Early Stage Support

Finished Dosage Development & GMP Manufacturing (USA)

- R&D (for all small molecule dosage forms) & Manufacturing across Preclinical - Phase III & Commercial
- Phase I-III & Commercial Supply for all non-sterile dosage forms (oral solids, tablets, capsules, films, powders/granules, suspensions & solutions, topicals, semi-solids, softgels, emulsions, creams, transdermals)
- High Potency Handling (OEB 5 up to .1µg/m^3)
- Controlled Substance I-IV Handling
- Specialized Containment Suites
- Wide variety of Formulation Technologies & Delivery Systems
- Development across all small molecule dosage forms.
- 300+ instruments and equipment and 350+ staff
- CPO Packaging, Labeling & Marketing Design

cGMP CERTIFIED

Facilities



Established in Jan. 2017

Total area ~110,000 sq. ft.
Manufacturing Area 18,000 sq.ft
Warehouse Area 64,000 sq.ft
Lab area 6,500 sq.ft
R&D area 5,000 sq.ft
Utility & Mechanical 4,500 sq.ft
Office & General area 12,000 sq.ft

Brand New Facility became operational from Feb. 2018

Total area ~309,000 sq. ft.
Manufacturing Area 90,000 sq.ft
Warehouse Area 117,000 sq.ft
Lab area 12,000 sq.ft
R&D area 4,650 sq.ft
Utility & Mechanical 50,750 sq.ft
Office & General area 24,700 sq.ft

Dosage Forms

- Full manufacturing capacity for all non-sterile dosage forms
- Development expertise and capabilities for all dosage forms

Learn more about our dosage forms.

Specialized Technologies

Learn more about our formulation technologies

Patient Centric Solutions

Complex Drug Products

Differentiated delivery systems

» Customized Drug Release (High dose, IR, CR, XR/ER)

» unique release profile drugs can be combined in a single dosage form

Optimize Therapeutic Effect

» Bioavailability Enhancement

» Improve onset of action, variability of absorption between patients, and food effects variation

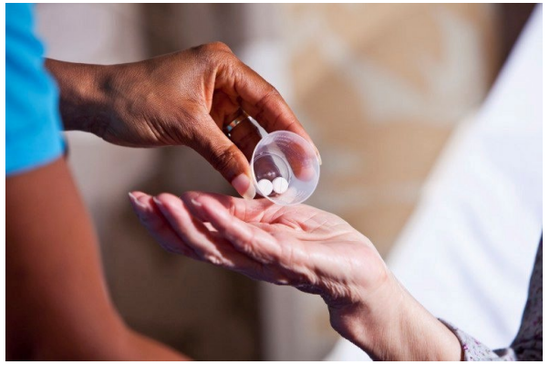
»Optimize efficacy, safety, and dosing frequency

Increase Acceptance

» Pediatric, Geriatric, and Dysphagic Friendly

» Taste Masking

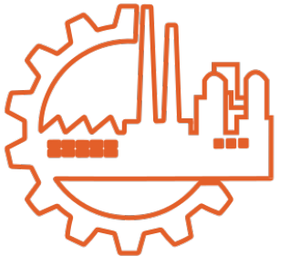
» ODTs, ODFs, Chewables, Emulsions, mini-softgels



Equipment (Central Islip, NY)

- High speed tablet presses with part 11 compliance
- Bi-layer, Tri-layer and Tablet in Tablet, tablet presses part 11 compliance
- Granulators at different capacities from 5 litre to 1200 litres
- Blenders from 50 litres to 3000 litres
- Glatt Coating machines to handle 1 kg to 1200 kg
- Glatt fluid bed dryers and Fluid bed processors with top and bottom spray, pro 30, 60 and 300
- Hard Gelatin Encapsulation machines
- Sky Soft Gel Manufacturing machines with different capacities
- Transdermal patch machine both drug loading and pouch to handle both commercial and R&D sizes
- Laser drill machine to handle both R&D and commercial scale
- Hot melt extruder both R&D and commercial scale
- Imprinting machine
- High speed packing lines with liquid filling capability
- Gelatin melting tanks to handle 1.5 billion capsules per year
- DIRS Water System with online TOC Analyzer
- Stability Chambers (25°C, 30°C & 40°C) with required %RH
- Walk-in Stability Chamber (25°C) with required %RH
- Controlled drug Vault and cage to store C I-V drugs

*Complete equipment list can be provided upon request



Equipment (Hauppauge, NY)

- High speed tablet presses with part 11 compliance
- Granulators at different capacities from 5 L to 1400 L
- Blenders from 50 L to 3000 L
- Coating machines to handle 1 kg to 1000 kg
- Fluid bed dryers with top spray with capacity to handle 25 kg to 250 kg
- Hard Gelatin Encapsulation machines
- High speed packaging line
- DIRS Water System with online TOC Analyzer
- Stability Chambers (25°C, 30°C & 40°C) with required %RH
- Walk-in Stability Chamber (25°C) with required %RH
- Controlled drug Vault and cage to store C I-V drugs

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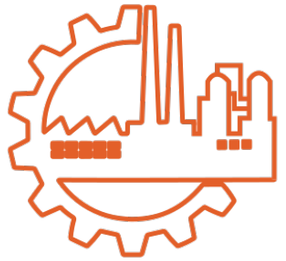


Analytical Equipment (Central Islip, Hauppauge)

- HPLC with UV, RI and PDA detector , GC with FID and TCD detector , FTIR with Omni chem.
- UPLCs
- UV Spectrophotometer and Dissolution Apparatus (USP-I, II & IV)
- Particle size Analyzer (Malvern)
- KF Titrator (Metrohm)
- X-RD(Bruker/XRD D2 phaser)
- Polarimeter
- All other Laboratory Instruments

*Complete equipment list can be provided upon request

Technical Staff - Overview

Hauppauge, NY

Total # of employees: ~60

Central Islip, NY

Total # of employees: ~290

- Head of Formulation, Head-Quality, Head-QC and Head –Manufacturing with over 20+ years of experience.
- Quality Control personnel with over 20 years of experience.
- Quality Assurance personnel with average of 18 years of experience.
- C-Suite that previously sold Invagen Pharmaceuticals to Cipla in 2016

Regulatory

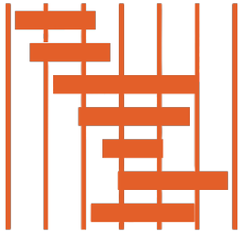
Proven expertise in regulatory and quality

- Experts in international protocol and standards Global regulatory strategy (US, EU, LATAM, ASIA (Japan, China, and South Korea, India)
- Substantial experience in all aspects of regulatory submissions, support, and filings for 100+ ANDAs, NDA filing, 505(b)(2) filings, and orphan drug designations applications.
- Support for a complete filing or for CMC section filing, depending on need
- Support in maintaining approved submissions globally
- Harmonized quality system certified and periodically verified by the major regulatory bodies
- Environmental Accreditation
- Compliant handling of controlled substances, highly potent materials, and solvents

Project Support

Project Management

- Site-Based Point of contact for R&D phase programs
- Extensions of your development team
- From project proposal to delivery accurate supply chain forecasts
- Full continuity through your program from proposal to development to commercialization
- Sense of urgency to and strict adherence to timelines.



Operations

- Site-Based point of contact for Clinical and Commercial phase programs
- Adaptable, on demand Manufacturing
- Highly-responsive service via phone, text and email
- Follow project from proposal to delivery