



# An Enduring Partnership From First Idea to Finished Product



# Pegasus Laboratories, Inc



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## Mission Statement

**Pegasus Laboratories is committed to the development and manufacturing of a wide range of R<sub>x</sub> and OTC products to meet the contract manufacturing and private label needs of our customers who provide distribution and service to the pharmaceutical marketplace.**

**Our mission is to continually improve our manufacturing capabilities and services to provide our customers – our partners in business – with competitive strategies that support their ultimate goals from concept to commercialization.**

## Vision

**Our vision and focus is to develop, secure and foster long-term relationships and contracts with a limited number of customers that look upon us as their manufacturer of choice for developing and producing their products.**

## An Overview

- Based in Pensacola, Florida
- Founded in 1986
  - Acquired by PBI/Gordon Corporation in 1999
- Contract development and manufacturing organization
  - Human health products
  - Animal health products
- Turn-key technical services
- cGMP facility
- Physical plant
  - Currently 81,500 sq. ft.
  - Onsite space for over 100,000 sq. ft. future expansion
- Personnel expansion
  - 83 Total Employees (89 w/Temps) as of 3/23/15
  - Approximately 30 are in QA, QC and Technical Services

## Contract Development and Manufacturing Organization

- cGMP, DEA approved facility producing non-sterile pharmaceuticals
  
- Dosage forms
  - Solid
  - Semi-solid
  - Liquid
  
- Packaging options
  - Bottles
  - Tubes
  - Pens
  - Airless metered dose containers
  - Wipes
  - Foil pouches
  - Syringes

## Operational Areas

Technical  
Services

Quality Services  
and Regulatory  
Support

Manufacturing and  
Packaging



## Technical Services

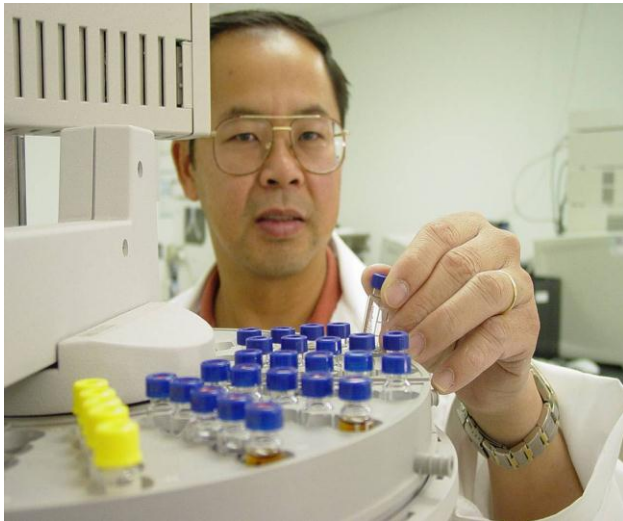


## Technical Services

- Formulation development
- Analytical method development
- Process development
- Validation
- Commercial scale-up
- Final packaging
- On-going studies

## Technical Services

- Formulation and process development batch sizes for pilot scale and clinical studies from 1kg up to 220 kg
- Experienced staff of professionals in formulation development and analytical methods development
- Experienced management and tracking of complex projects to meet client goals



## **Pegasus' Technical Services Team of Chemists, Scientists, and Engineers provide turn-key product development services including:**

- Formulations Development
- Technology Transfer
- Analytical Methods Development and Validation
- Process Development and Validation
- Process Scale-up
- Excipient and Container Closure
- Compatibility Studies
- Stability Studies, ICH Conditions
- Clinical Trial Supplies

## **Quality Systems and Regulatory Support**

## Quality Systems and Regulatory Support

- GMP facility with a successful compliance history
- DEA licensed facility
- State-of-the-art laboratories for development and quality control
- Complete validation services including process, cleaning, equipment, analytical methods, packaging

## Quality Systems

- Validations & Qualifications
- Manufacturing & Packaging
- Finished Product Testing
- Raw Material Testing
- Stability Testing
- Documents Control
- GMP Training
- Fully Equipped Labs for Project Support

## Regulatory Group

- Drug Listings (FDA-SPL)
- Annual Product Reports
- Chemistry, Manufacturing and Controls
- Labeling
- Assisting with NADA/NDA filings
- Vendor Audits
- Stability Data System

## Quality Control Laboratory and Analytical Services Laboratory

Equipment includes:

- Multiple HPLCs with PDA and MS Detectors
- FTIR
- GC
- AA
- UV Spectrophotometer
- Friabilator
- Hardness Tester
- Autotitrator
- Dissolution Apparatus with auto sampler
- Particle Size Analyzer
- Stability Chambers (25°C, 30°C, 40°C)

## **Manufacturing and Packaging**



## **Creams, Ointments, Gels, Suspensions and Lotions**

- Custom formulations designed to client requests
- Process scale-up and engineering
- Pilot studies and clinical batch production
- Full validation services
- Accelerated, intermediate, and long term stability studies
- Compounding, individual lot sizes up to 4,000 kg
- Custom packaging in tubes, bottles, pouched wipes, pens, metered-dose containers, and vials
- Intrinsically-safe manufacturing & packaging area

## Manufacturing Area



- 1,000 gallon jacketed mix tank with three agitators designed for high viscosity products
- 400 gallon jacketed mix tank with agitator for low viscosity products
- 150 gallon jacketed mix tank with agitators for high viscosity products
- 150 gallon mix tank with agitator for low viscosity products
- 60 gallon jacketed mix tank with two agitators designed for high viscosity products
- 40 gallon jacketed mix tank with agitator for low viscosity products
- An RO water system for the generation of USP purified water

## Pegasus' Commercial Production Team and cGMP facility offers a wide range of specialized manufacturing and packaging

### Specifically:

- Tubes ranging from 3 gram to 300 grams
- Wipes and foil pouches in various sizes
- Bottles ranging from 1 ounce to 1 gallon
- Pen applicators in various sizes
- Vials from 1.4 mL to 30 mL
- Metered dose containers in various sizes
- Various other specialty packaging configurations



## Tablets

- Custom formulations designed to client requests
- Process scale-up and engineering
- Pilot studies and clinical batch production
- Full validation services
- Accelerated, intermediate, and long term stability studies
- Compounding, individual lot sizes up to 400 kg
- Custom packaging in up to 1,000 count bottles

## Tablet Manufacturing Equipment

- 10-20 cubic foot stainless steel ribbon blenders
- 20-100 cubic foot stainless steel v-blenders
- Tablet presses with rated capacities up to 4,000 tablets / minute (depending on product profile)
- Metal detectors



## Tablet Packaging Equipment

- Bottle feeding turntable
- Tablet counter
- Cotton stuffer
- Automatic capper
- Labeler with coder
- Induction sealer
- Collection table
- Case sealer
- Rated capacities vary with package sizes and product profiles



## Oral Solutions and Suspensions

- Custom formulations designed to client requests
- Process scale-up and engineering
- Pilot studies and clinical batch production
- Full validation services
- Accelerated, intermediate, and long term stability studies
- Compounding, individual lot sizes up to 3,000 kg
- Antibiotic solution/suspension area manufactures up to 780 gallons.
- Custom packaging in bottles, syringes, and other packaging configurations

Oral solutions, suspensions, and syrups processing and packaging area supports production of specialized containers.

## Liquid Processing Equipment

- Mix tanks (40 to 800 gallon scale)
- Reverse osmosis (RO) water system

## Liquid Packaging Equipment

- Automatic fillers with filling capabilities from 5 mL to 1 gallon containers





# **Next Steps for an Enduring Partnership From First Idea to Finished Product**

