ALLIANCE
CONTRACT PHARMA
An Altasciences company

Manufacturing and Analytical Services

We provide proof of concept, R&D, clinical and commercial manufacturing that includes liquid-filled capsules, band/sealing technologies, powder and over-encapsulated capsules, topical formulations, and clinical and blister packaging which are manufactured in our purpose-built facility including state-of-the-art ISO 7 and ISO 8 cleanrooms. In addition to our DEA license for controlled substances, we have a full analytical laboratory, ICH stability chambers, cGMP warehouse, and shipping capabilities to help you in every aspect of your project.

FACILITY

Our 30,000-square-foot facility features:

- 9,500-sq.-ft. warehouse
- 3,300-sq.-ft. manufacturing area
- 2,500-sq.-ft. segregated ISO7/8 manufacturing area (capable of handling potent compounds)
- 1,500-sq.-ft. R&D formulations lab
- 3,000-sq.-ft. analytical lab.

We have manufactured and/or tested nearly every currently available pharmaceutical dosage form.

MANUFACTURING SERVICES OFFERING

Product Development and Manufacturing Capabilities

- Formulation and development
- Process optimization
- GMP clinical supply manufacturing (Phases I-IV)
- Scale-up and engineering batch manufacturing
- Validation batch manufacturing
- Commercial batch manufacturing

Controlled Substance Manufacturing Capabilities

- DEA Manufacturing License (Schedules I-V)

Additional Client Support Services

Facility expansion capabilities, including dedicated space and equipment, as required to meet project demands.

- Man-in-plant
- Perform supplier audits

Dosage Type and Process Capabilities

- Liquid-filled hard shell capsules
- Capsule banding
- Particle size reduction (wet milling/nano-milling)
- Powder blending
- Powder-filled capsules
- Over-encapsulation
- Injectable vial filling (pre-sterilized)
- Solutions and suspensions
- Gels and creams
- Clinical packaging (bottles and blisters)
- Potent product handling

Simplifying Contract Services

ANALYTICAL SERVICES OFFERING

Development and Validation of Critical Methodologies

- Cleaning methods for the detection of API on manufacturing equipment
- API methods for assay/related substance
- Finished dosage products (assay/degradation, dissolution)

Stability Testing

- ICH environment stability chambers

Controlled Substance Testing

- DEA analytical license (Schedules I-V)

Drug Product Release Testing

- High Performance Liquid Chromatography (HPLC) and Ultra Performance Liquid Chromatography (UPLC)
- Dissolution and disintegration
- Moisture analysis (Gravimetric and Karl Fischer [KF] Titratron)
- Spectroscopy (Ultraviolet/Visible [UV/VIS] and Infrared [FTIR])
- Total Organic Carbon (TOC)
- Viscosity
- Particle size analysis
  - Malvern
  - Horiba
  - AccuSizer (USP<788>)

QUALITY ASSURANCE SERVICES

Quality Systems

- Product release
- Standard Operating Procedures (SOPs)
- Equipment and facility qualification documentation
- GMP audits
- Regulatory inspections

Data Management Systems

- Agilent enterprise content management (OpenLab ECM) and chromatography data system (CDS)
  - Secured client portal for 24-hour off-site access to data and documentation

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