ALTASCIENCES

PHARMACEUTICAL CONTRACT MANUFACTURING SERVICES

We provide proof of concept, R&D, non-clinical, clinical, and commercial manufacturing that includes liquid-filled capsules, band/sealing technologies, powder and over-encapsulated capsules, topical formulations, and clinical and blister packaging. All manufacturing is done in our purpose-built facility, equipped with continuous monitoring of temperature, humidity and pressure, with real-time notification.

SERVICE OFFERINGS

- Formulation development and manufacture of drug product for your API from development through commercialization
- Cost effective, scale optimization experience from small prototype batches to commercial scale
- In-house analytical testing to drive and support formulation success
- Receipt, storage, manufacturing, release, and distribution capabilities
- Clinical supply and commercial manufacturing for Phase I-III
- DEA License for Schedule I-V, including pallet positions for Schedule III-V and vaults for Schedule I-II
- Clinical packaging
- Bottle and blister packaging capabilities
- Package design capabilities
- Primary and secondary packaging

contact@altasciences.com
altasciences.com

ALTASCIENCES

PHARMACEUTICAL CONTRACT MANUFACTURING SERVICES

Our highly trained staff ensures the release of quality batches, the first time, and every time. Our strength lies in efficient procedures, state-of-the-art equipment, and deep expertise for any of your formulation needs – we have manufactured nearly every available dosage form on the market today.

NANO MILLING

The latest, state-of-the-art equipment for the wet milling of APIs to reduce particles to nano size. Vial filling from 0.3 ml to 500 ml, and packaging services after vial filling, for a comprehensive solution.

CAPSULE OPTIONS

- Liquid-filled
- Powder-filled
- Gelatin
- Quali-V® (hypromellose, made from plant-derived materials)

BLINDED STUDY MATERIALS

- Over-encapsulation — blinding of a solid dosage form, such as a capsule or tablet into a capsule shell
- Removal of commercial logo and/or identifier from the tablet or capsule
- Over-printing with confusion print
- Other blinding options upon request

POTENT HANDLING CAPABILITIES

- Segregated, flexible, Grade C and D clean room suites with dedicated air handling for potent compounds
- Room sizes and equipment capabilities to scale your project from clinical through commercialization

GRADE C INJECTABLE DRUG PROCESSING

Grade C, cGMP suites, inspected by both FDA and European Union Quality Personnel, permit a high guarantee of product sterility with heat, gamma, or e-beam exposure.

TERMINAL STERILIZATION

A convenient, cost-sensitive alternative that decreases development time and expense versus aseptic sterilization.

OTHER MANUFACTURING

Our team has delivered turn-key solutions and developed formulations, designed equipment trains, validated processes, developed and validated analytical methods, and obtained regulatory approvals for nearly every pharmaceutical dosage form, including:

- Liquids and semi-solids
- Various capsule formulations (powders, pellets, beads, liquids, etc.)
- Proprietary dispersions
- Creams/gels
- Packaging

LICENSING AND REGISTRATIONS

- Pennsylvania Department of Health Prescription and Non-Prescription Drug and Medical Device Manufacturer, Distributer and Wholesaler
- U.S. Food and Drug Administration Drug Establishment FEI 3007884119/Labeler code 75969
- Analytical DEA License Number RA0396831 for Schedules I - V
- Manufacturer DEA License Number RA0403078 for Schedules I - V
- FDA Food Facility Registration Number 13781101748
- All FDA Inspections have yielded approvable recommendations with no 483s
- EU QP Inspected

contact@altasciences.com
altasciences.com