Lannett CDMO
Making Your Science A Reality

Founded in 1942, Lannett Company, Inc. has an extensive history of manufacturing various unique pharmaceutical indications including over 100 currently distributed products. As a long-established CDMO, we utilize our deep industry knowledge and provide our clients with ideal end-to-end solutions that meet their needs.

Safety, quality, and productivity are of the utmost importance when choosing a manufacturing partner. Understanding this, our dedicated staff utilizes in-house talent and manufacturing capacities (3.5B Oral Solid doses and 2.0M liters of liquids per year) to ensure that these business objectives are met.

U.S. FOOD & DRUG ADMINISTRATION

Health Canada

NMPA CHINA

EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH *

pmda *

MFDS KOREA *

*Re-certification required

Your Strategic Partner for Success

Lannett CDMO specializes in Oral Solid Dose (OSD) and Liquids, including high potency and DEA controlled substances. No matter the scope of your project, we deliver — streamlining product formulation and manufacturing from concept to commercial scale.

Technology transfers and risk mitigation for Oral Solids and Liquids

Modified release technology

Complex formulations and reformulation capabilities

Controlled substances

Dedicated suites for potent drugs

Capability to handle compounds with OELs ranging from greater than 500 µg/m^3 to as low as 0.1 µg/m^3(Category 1-3B)

Seamless scale-up from pilot to commercial scale

Flexibility and Service All in One Place

Our world class drug product development and manufacturing space spans approximately 400,000 square feet, including R&D, analytical development and quality control labs, manufacturing, packaging, warehousing and distribution.

A Flexible Unique Formulation Development Solutions

We use a variety of approaches to provide cGMP clinical material and commercial products.

- Dosage forms to support PK and tox studies
- Optimization of existing formulations
- Process development and scale-up
- Excipient compatibility and dosage form design
- Improved safety and efficacy
- Reverse engineer formulation

B Analytical Laboratory Services

With our team's in-depth technical understanding, we successfully customize solutions for your complex products to ensure your product meets the highest quality standards.

Analytical Tests

- Method development and validation
- Raw material, packaging material, in-process, and finished product release testing
- Full ICH stability finished product storage and testing
- Physiochemical testing
- Elemental impurities
- Residual solvents
- Extractables/leachables

Analytical Methods

- Chromatography: HPLC/UPLC with UV/RI/Conductivity/CAD, GC, TLC
- USP dissolution apparatus 1, 2 and 7 testing
- ICP-MS testing
- UV-VIS spectroscopy
- Atomic absorption spectroscopy
- Particle size testing: sieve, laser diffraction
- Total Organic Carbon (TOC) testing
- Physical properties: refractive index, specific density, viscosity, polarimetry, moisture content

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C Non-Sterile Microbial Testing and Methods

- Method suitability testing
- Raw material and finished product release testing
- Water activity testing
- Microbiological examination of non-sterile products per USP <60>, <61>, <62>
- Antimicrobial effectiveness testing per USP <51>
- Water activity testing per USP <922>

D Regulatory Support

To ensure a smooth and rapid approval process, we can assist with end-to-end filing strategies.

- CMC guidance
- Planning/preparation of regulatory documentation
- Post-approval product management
- 505(b)(s) guidance

E Superior Manufacturing and Packaging at Every Stage

When your product is ready to be scaled-up, we provide smooth transition to the next level with the following capabilities.

- Blending
- Compression
- Encapsulation
- Tablet coating
- Fluid-bed coating
- Rotary granulation
- Spray granulation
- High-shear granulation
- Laser drilling
- Primary and secondary packaging
- Bottle, blister, and packaging

F Supply Chain Management, Warehousing and Logistics

We provide end-to-end services to maintain the safety and integrity of your pharmaceutical products.

- DSCSA-compliant serialization services
- Material sourcing
- Domestic and global distribution
- VAWD accredited

Third-party options:

- Specialized vault and cage for DEA substances
- Optimum ambient storage conditions for freezers and coolers

G Quality Assurance

Our Pharmaceutical Quality System is ICH Q8, Q10 and FDA cGMP compliant to ensure desired product quality is met, suitable process performance is achieved, appropriate process controls are in-place, improvement opportunities are identified, and product body of knowledge is continually expanded.

Why Lannett

Safety —
Average safety rate of 1.4 recordables per year

High Quality Standards —
History of no critical 483 observations

Demonstrated Speed to Market —
17 approved product applications since 2019

Best in Class Customer Service —
Over 95% schedule attainment;
Average product yield rate of 96%

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SCHEDULE A CALL