Make Your Science A Reality

Follow us on Linkedin
Lannett CDMO

Visit our website
www.lannettcdmo.com

Lannett Company, Inc.
1150 Northbrook Drive, Suite 155
Trevose, PA 19053

Joseph Bomba

+1 908-910-0184

CDMO@lannett.com

CDMO
Customer Service
Project Management
Advanced Formulation & Analytical Services
Manufacturing & Supply Chain
Regulatory Support
Serialized Supply Chain
Quality

Lannett Contract Development and Manufacturing

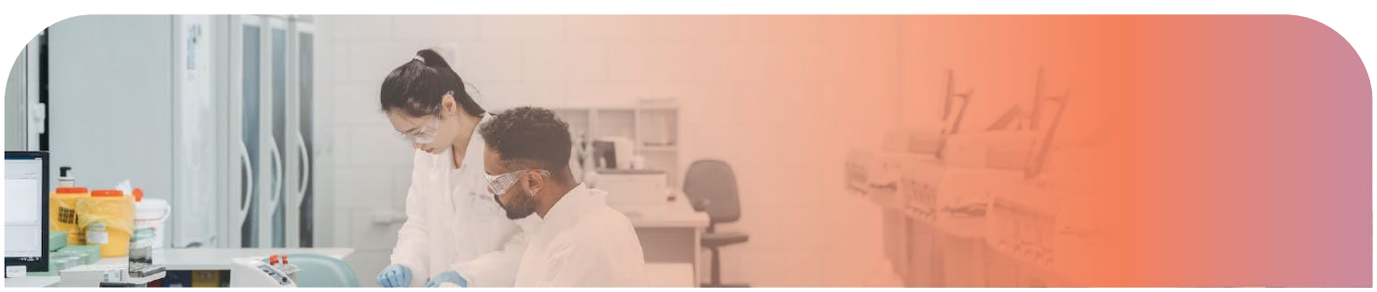
Lannett is your partner, treating your products with as much care as we treat our own.

For 75 years, Lannett has partnered with clients of unique NDA products which have served markets all over the world. As a CDMO, we are able to leverage our deep industry and technical knowledge and provide our clients with the ideal end-to-end solution to suit their needs.

When you work with us, you are assured of a partner who will be highly responsive to your project's needs. We have a proven track record of timeline fulfilment, thanks to our carefully crafted On-time Delivery matrix and Schedule Attainment metrix.

100
unique marketed pharmaceutical products

17
approved product applications since 2019



Making Your Science A Reality

Technology Transfers and Risk Mitigation for Oral Solids and Liquids

Modified Release Technology

Complex Formulations and Reformulation Capabilities

Controlled Substances

Dedicated suites for high potent drugs

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

Seamless scale-up from pilot to commercial scale

Health Canada

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

*

pmda

*

*Re-certification required

MFDS KOREA *

NMPA CHINA

FDA U.S. FOOD & DRUG ADMINISTRATION

Our best work — for you.

At Lannett, people are a priority. Our customer service is recognized as the top in the industry year after year.

As a well-established CDMO, we know everything that a CDMO project demands. Not only are we familiar with your needs—we are equipped to meet them and go further. Our expansive experience drives us to innovate processes that are agile and seamless, thereby becoming increasingly better at achieving targeted delivery.

Based in one location, we are quick to deliver turnarounds and decisive in reacting to market conditions. Proactive describes our culture as we monitor products, analyze markets, attend events, meet and sponsor partners, and stay informed on the industry. All these enable us to help with any ongoing inquiry and pursue excellence in our service to you.

Achievements in Our Customer Service

Consistently achieved a 98% success rate in prompt delivery

Consistently attained the highest scores according to customer satisfaction

High customer retention

Accurate demand planning

Response time usually within 24 hours

Your partner through it all.

Project management is instrumental to the health and success of a project. Having a plan is the first step. Successful implementation of said plan is the next—and just as important.

Our Project Managers are efficient executors and sympathetic mediators, naturals at communicating well with both the client and the team. Committed to transparency, they intentionally forge an environment of trust and collaboration across all aspects and openly discuss risk mitigation.

As your point of contact, our Project Managers make it their job to know all there is to know of a project. They keep informed on the latest regulations, methodologies, and technologies; directly attend to a situation where necessary; and apply whatever they do with a diligent attitude and versatile mindset.

Our Project Managers carry years of experience in leading product development and launch programs. They are skilled organizers, driving the efficiency and efficacy of all involved sectors while keeping to deadlines. In their hands, projects are commonly completed in a shorter time frame than usually stipulated.

In support of our Project Managers, a Project Management Framework is set in place to optimize the following aspects:

- Operational routines
- Governance structure
- Planning and reporting
- Utilization of state-of-the-art Project Portfolio Management (PPM) Solutions

These robust processes work hand-in-hand with our dedicated Project Managers to see to a project's success.

Equipped for your science.

Lannett has the complete capabilities to put science to the test. Our approved SOPs command specific requirements to complete method validation, verification, or transfer of testing procedures to ensure testing procedures provide accurate results.

Test procedures are evaluated every five years and when necessary. Furthermore, we have established sources for common excipients and packaging materials, thereby reducing costs in sourcing and qualifying new materials. Regardless, all materials are tested prior to being used in any product.

Our laboratory team is experienced, consistently trained, and adaptable to any changes in the timeline. Drawing from past experiences, we have successfully performed many tech transfers, able to anticipate all necessary steps and reduce the number of surprises that could impact the success of a project—and at a faster rate than usual.

Flexible & Unique Formulation Development Solutions

We provide cGMP clinical material and commercial products via a variety of technologies.

- 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

We specialize in Oral Solid Dose (OSD) and Liquids, including those for high potent and controlled substances. These include:

- Dry blends filled into capsules or compressed into tablets
- Dry granulation compressed into tablets
- Wet High and Low Shear granulations that are oven or fluid bed dried and filled into capsules or compressed into tablets
- Fluid bed granulations that are filled into capsules or compressed into tablets
- Wurster coated tablets
- Wurster coated beads or microtablets filled into capsules or compressed into tablets
- Non-functional and functional coated tablets
- Laser-drilled osmotic release tablets
- Tablet printing
- Immediate-release, Extended-release, and Delayed Release dosage forms using the technologies listed above
- Solution and Suspension liquid products

Analytical Laboratory Services

Lannett's laboratories are capable of running an average of 1200 stability studies concurrently. Facilities are well-equipped and spacious, and our large walk-in and reach-in stability chambers can be validated at a variety of conditions, the common conditions being:

- Long-term (25°C and 60%RH or 25°C and 40%RH)
- Intermediate (30°C and 65%RH)
- Accelerated (40°C and 75%RH or 40°C and 25%RH)

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
- Physicochemical 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, Mositure Content

ANALYTICAL METHODS

Non-sterile Microbial Tests

- Method suitability Testing
- Raw material and finished product release testing
- Water Activity Testing

Non-sterile Analytical Methods

- Microbiological Examination of Non-sterile Products per USP <60>, <61>, <62>
- Antimicrobial Effectiveness Testing per USP <51>
- Water activity Testing per USP <922>

Reach your market faster.

With Lannett, confidently transition into manufacturing, packaging, and warehousing once you are ready to scale your product to a commercial level.

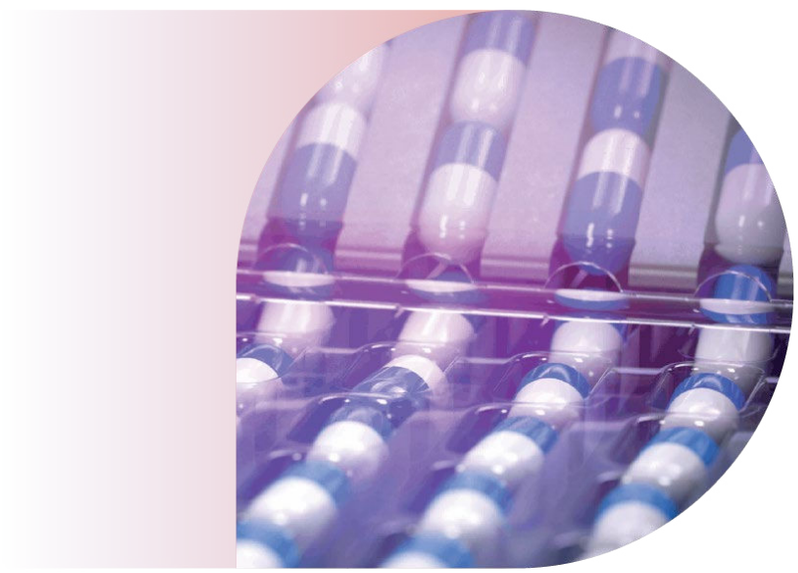
The capabilities of our facilities, seamless processes, and committed team all contribute to a consistent 92-98% success rate in both deliveries and schedule attainment — proving ourselves yet again to be one of the best in this field.

Our prompt deliveries have been distributed as far as:

EUROPE | CHINA | JAPAN | CANADA

Steps we implement for fast scale-up include:

- Integration of a customer's serialization numbering system with ours.
- Utilization of quality tools such as tablet table inspection machines, serialization systems, camera systems to check lot code, expirate dates IP barcoded, and reshipper label verification.
- In-process testing every 15 and 30 minutes of each hour of a process.
- Hourly online audits on packaging.
- KPIs that are tracked and reported daily, weekly, and monthly.
- Automation-Electronic Logbooks, ENG/MAINT - CMMS Infor, QA/QC - LIMS, Chromeleon, Master Control.
- Validation of products/equipment/facilities.
- Supplier quality requirements and specifications.
- Testing of incoming raw materials for dispensing, manufacturing, and packaging.
- Testing of in-process and final product release, with stability testing by our Quality group.



MANUFACTURING & SUPPLY CHAIN

Lannett's main manufacturing site sits in Seymour, Indiana on a total acreage of 30.0 acres (12.4 hectares), and boasts a staff strength of approximately 405. Our capabilities include the following:

- 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

Our specialized equipment helps us continue to be the experts in OSD and Liquids

Products	Capabilities
Oral Solid Dose (OSD) Tablets Capsules	40cc to 1250cc Round and Square Bottles Side-serts and Top-serts
	Blister Pack Uhlmann BEC400 Blister/Cartoner
Liquids	40mL to 1L Round and Square Oblong Bottles

Supply Chain Management, Warehousing, and Logistics

Our superior supply chain management system allows us to continuously meet on-time delivery goals. Electronic monitoring of environmental conditions within our entire Seymour site ensures that the quality of your product is not compomised at any point. The consistent calibration and renovation of our facility allows us to be constantly up-to-date with the latest warehousing and logistical equipment available in the market.

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

Support where you need it.

Regulatory compliance requires vigilance. However, the steps of submissions, approvals, and overall communication with the FDA, if not tackled strategically, can significantly affect a project's timeline.

Lannett offers end-to-end regulatory support to help simplify those procedures. As we are directly responsible for the manufacturing of a product, we are most prepared to provide you with all necessary documentation.

Furthermore, as expertd in their scope, our dedicated team can be consulted to confer clarity and filing strategies at any step, and can assist in communicating with the FDA should it come to that.

We do things at Lannett with heart and commitment, including regulatory support. This translates into a smooth and rapid approval process for you.

Flexible & Unique Formulation Development Solutions

CMC Guidance

Planning and Preparation of regulatory documentation

Post-approval product management

ANDAs and 505(b)(2) submission guidance

Transparency, Accountability and Quality.

Effective November 27, 2023, the Drug Supply Chain Security Act (DSCSA) mandates that prescription drugs have interoperable, electronic tracing.

This new law impacts every stakeholder in the supply chain: Manufacturers, distributors, wholesalers, 3PLs, and dispensers. As one such stakeholder, Lannett CDMO is implementing the necessary to be fully compliant when the time comes.

With the new systems, we will meet the three key requirements:

- Product Identification: NDC, Batch number, Expiration date, and Serial number
- Product Tracing (3Ts): Transaction information, Transactional History (eASN), and Transactional statement
- Product Verification: Every item level to include aggregation

The product identifiers to be installed will be electronically transmitted between authorized trading partners. These will be synced across the supply chain through EPCIS files.

These new efforts promote transparency, accountability, and quality throughout the supply chain. In keeping with this, if we determine a product to be illegitimate, we will promptly report to the FDA within 24 hours.

Our excellence is your assurance.

With more than a quarter of our team dedicated to quality assurance, Lannett delivers reliable data, processess, and systems that are cGMP compliant and effective. Our ICH Q10 Pharmaceutical Quality System ensures that our clients receive only the best from all our teams. Cutting corners is an unrecognizable attribute at Lannett.

For the testing of the products, we utilize different technologies and conduct the tests with conscious consideration of both the client and the anticipated patient.

When you partner with us, we ensure that your product will be realized in its best form.

We determine that:

- The desired product quality is routinely met
- A suitable process performance is achieved
- Quality controls are appropriate
- Improvement opportunities are identified and evaluated
- Our product body of knowledge is continually expanding

Our track record attests to our high standards:

- Zero litigation cases
- Zero warning letter or fine from the DEA
- Zero critical FDA Form 483 observations