ClinDMO

Where Clinical Innovation Meets Manufacturing Excellence

ALTASCIENCES

DRIVING FASTER, SMARTER, AND MORE FLEXIBLE CLINICAL DRUG DEVELOPMENT.

We offer adaptive formulation and GMP compounding during study conduct, enabling sponsors to **pivot on emerging data**, and make **informed decisions** before committing to full-scale manufacturing.

Instead of producing large, fixed batches up front, we manufacture only what is necessary—such as a small cohort of 15 capsules—to support early dosing. Through real-time data review and formulation adjustments, this strategy ensures efficient, cost-effective scale-up while minimizing waste, conserving valuable APIs, and accelerating development timelines.

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ONE VISION, ONE PARTNER

Altasciences Aligns Clinic and CDMO for Smarter Solutions

As drug candidates progress into clinical development, the need for high-quality clinical trial material (CTM) becomes critical. Our contract development and manufacturing capabilities seamlessly integrate with our clinical operations to deliver tailored drug products that support efficient, reliable clinical studies.

- We specialize in manufacturing a wide range of dosage forms, including:
  - solid orals (tablets, powder- and liquid-filled capsules)
  - oral liquids (solutions, suspensions)
  - topical products (gels, creams, ointments)
  - specialized forms (IV, ophthalmic formulations)
- We can conduct small-scale spray drying of GMP materials (in milligram to gram quantities) and in-clinic testing to evaluate bioavailability techniques.
- Our drug product services cover all clinical phases (Phase I to IV), commercial drug production, and smooth tech transfers, ensuring consistent supply and quality throughout drug development.

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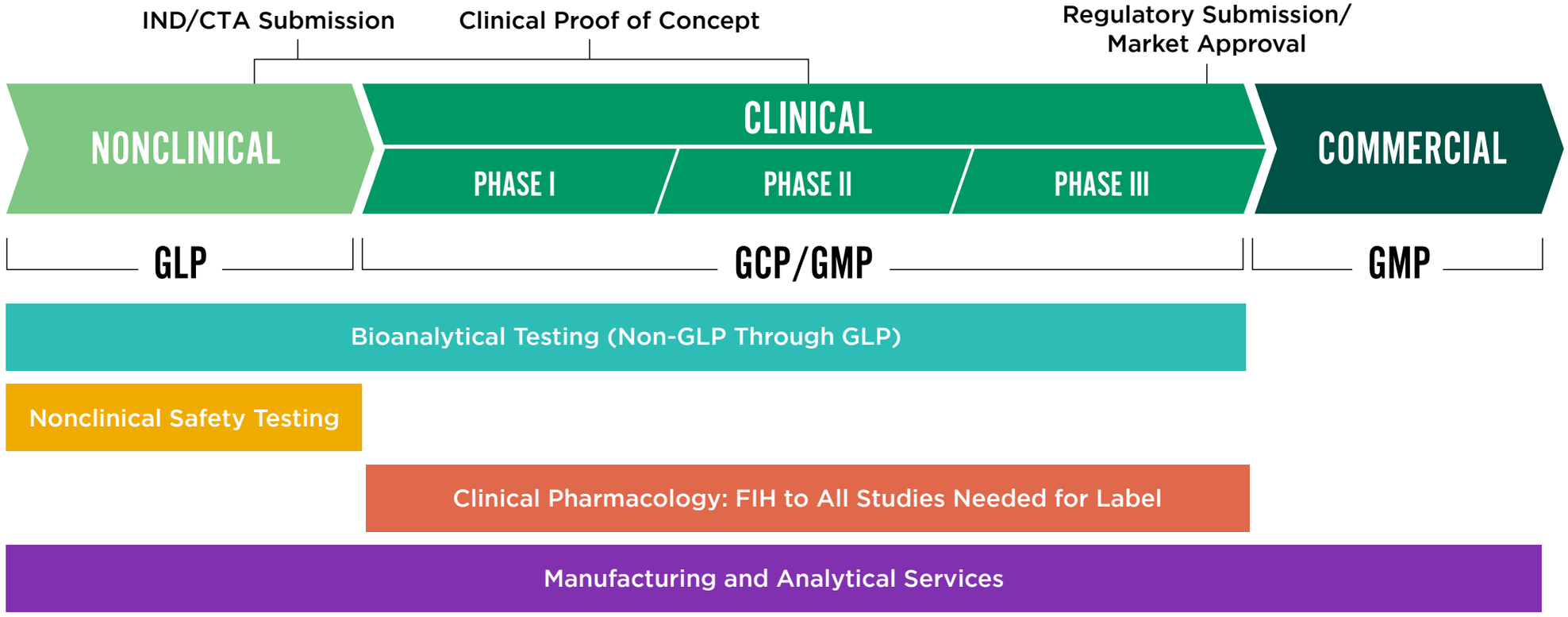
BRIDGING GLP, GCP, AND GMP FOR FASTER DRUG DEVELOPMENT

Integrating Services and Phases

Our integrated pathway combines preclinical, clinical, bioanalytical, and manufacturing expertise to advance your molecules.

By following GLP, GCP, and GMP standards, we ensure a smooth transition from early GLP studies to GCP-driven clinical trials and full GMP production. This minimizes handoffs, speeds up timelines, and facilitates a straightforward progression from research to market.



CDMO: THE CLINICAL CONNECTION

Our CDMO team goes beyond formulation and large-scale GMP manufacturing by offering tailored clinical support services designed to create a synergistic approach to your clinical trials. This close alignment between the CDMO and clinic ensures drug products are ready when and where you need them.

- **Over-encapsulation:** Maintaining blinded studies by encapsulating existing dosage forms.
  - **Combination Capsules:** Adding one tablet or capsule into another with backfilling excipients to meet upcoming or ongoing study requirements.
- **Placebo Manufacturing:** Producing matching placebo forms (liquid vehicles, powder-filled capsules, tablets, and more) for use in blinded or control arms.
- **Re-labeling of Drug Product:** GMP-compliant re-labeling to meet study-specific packaging and regulatory needs.

OPTIMIZING FORMULATION AND DOSING STRATEGIES

The Challenge

Many sponsors face uncertainty early on in the process: the optimal formulation or dosing strategy may not yet be defined for drug product in humans. This frequently leads to the production of excess drug products, consuming valuable APIs and expending unnecessary money, time, and resources.

Our Solution

We deliver GMP services directly at the clinical site, where the product can be:

- manufactured under GMP conditions
- dosed to participants
- analyzed in real-time
- adjusted in formulation or dose, with the ability to repeat as needed

This **on-demand approach** accelerates decision-making and conserves critical resources to streamline adaptive clinical trials.

FLEXIBLE PHARMACY AND MANUFACTURING FOR EARLY-PHASE AND BEYOND

With comprehensive CDMO capabilities, we can support every stage of your drug's life cycle, from early development to commercialization. We streamline the transition from preclinical to clinical phases with customized small-batch preparations and adaptable GMP manufacturing. Comprehensive CMC services and scale-up strategies ensure a smooth path to market, effectively driving your product's advancement.

Accelerating Time From Manufacture to Clinic

- Tailored small-batch preparations
- Advancing preclinical formulations to clinical
- Narcotics licensing
- Specific formulations for study objectives
- Change of route of administration/tolerability

Early-Phase Appropriate

- Complex on-site pharmacy compounding
- Adaptable formulations during first-in-human trial design
- Small-scale GMP manufacturing
- Development, validation, stability, QC/QA release
- Drug product dispensing

Final Product Through Commercialization

- Final formulation
- Seamless CMC
- Stability program
- Clinical manufacturing
- Packaging, labeling, and distribution
- Scale up to commercialization
- Tech transfers/backup

CLINIC-READY WITH SMART MANUFACTURING

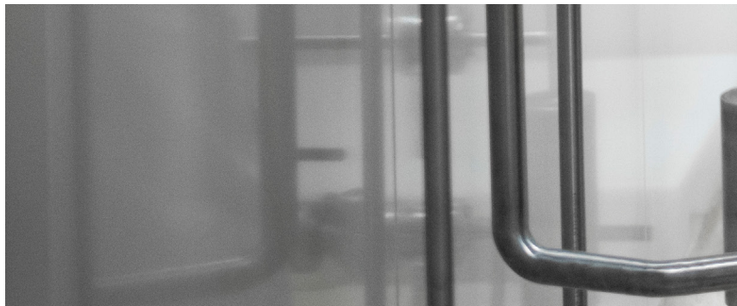
By marrying R&D formulation expertise with on-demand manufacture at the start of clinical programs, we dramatically accelerate the time from production to patient dosing.

- **Seamless Formulation Adaptation:** Transition preclinical formulations into clinical use with minimal risk, ensuring safety and compliance. We can:
  - Continue preclinical formulations into first-in-human studies to safeguard subject safety.
  - Adapt formulations to meet specific study objectives.
  - Adjust for the changes in route of administration.
- **Tailored Formulations:** Adjust for study-specific needs, such as route of administration, tolerability, bioavailability, and pharmacokinetic profiles.
- **Short-Term Stability Focus:** Only the stability data required for intended dose range and study duration is needed, allowing for flexibility to adjust the dose strengths prior to or during the clinical trial.
- **Real-Time Manufacturing:** Avoid delays from supply chain bottlenecks, securing IP supply so that it is never a rate-limiting step.
- **Scalable Solutions:** Maintain a clear path to commercial GMP manufacturing with robust tech transfer capabilities.

CLINIC-INTEGRATED GMP MANUFACTURING

Providing adaptive in-clinic manufacturing and GMP pharmacy presence across all North American clinics delivers unmatched benefits.

- Fast turnaround times and real-time coordination within the same time zones.
- Simplified logistics and compliance by collaborating with the same trusted North American provider for both clinical and CDMO services.
- Access to USP <795> and <797> compounding pharmacies alongside GMP manufacturing, providing a unique blend of speed, flexibility, and cost-efficiency.



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CONNECTED CLINICS. INTEGRATED CDMO.

580+ BEDS IN NORTH AMERICA

265	180	140
Montréal	Los Angeles	Kansas City

CLINICAL FACILITY
Kansas City, KS

CLINICAL FACILITY
Montréal, QC

Preclinical and Bioanalytical Facility
Seattle, WA

Bioanalytical and Research Facility
Laval, QC

Preclinical Facility
Scranton, PA

Preclinical Facility
Sacramento, CA

Preclinical and Bioanalytical Facility
Columbia, MO

CLINICAL FACILITY
Los Angeles, CA

CDMO FACILITY
Philadelphia, PA

ACCELERATED MAKE-TEST-SHIP CYCLE

Our CDMO facility in Philadelphia, PA, serves as the hub for adaptive clinical manufacturing, enabling rapid formulation, testing, and delivery of study material. Streamlined processes and close integration allows us to **produce, test, and ship material to our clinical sites within 7 to 14 days** for agile dosing strategies and faster study progress in Phase I trials.

Philadelphia, PA (U.S.A.)
Manufacturing and Analytical Services Facility

Make-Test-Ship
(7 - 14 Days)

Clinical Pharmacology Unit
Montréal (Canada)

Clinical Pharmacology Unit
Los Angeles (U.S.A.)

Clinical Pharmacology Unit
Kansas City (U.S.A.)

CDMO SERVICES AND CAPABILITIES

We can support every stage of your development, from early formulation and analytical support, to Phase I to III clinical supply and full commercial batching. With GMP manufacturing, integrated stability testing under ICH conditions, and regulatory guidance for global submissions, we ensure quality, compliance, and scalability throughout the entire process.

R&D (GMP Abbreviated)

Formulation and analytical development for GLP studies.

Clinical Supply

Phase I, II, and III GMP manufacturing and testing for GCP studies in IND/CTA.

Commercial Supply

GMP manufacturing and testing for commercial NDA/MAA.

Stability Support

- ICH at 25°C/60%RH, 30°C/65%RH, 40°C/75%RH
- Chambers at 2 - 8°C

Regulatory Support

ICH CTD module III (IND/NDA, CTA/MAA).

CDMO SITE DETAILS

64,000
square-foot facility

50+
staff members

200+
projects completed

- High-potency OEL I to IV and grade C (ISO7) suites
- Controlled unclassified (non-sterile) GMP suites

- US FDA registration (CDER/CDRH)
- PA board of pharmacy
- PA DEP environment, health, safety
- DEA controlled schedule I to V

Platform Technology:

- Liquid-filled capsules
- Oral solutions/suspensions
- Nanonsuspensions/nanomilling
- Tablets coated/uncoated
- Terminally sterilized liquids
- Drug device combinations
- Spray drying technology

THE POWER OF INTEGRATION

Altasciences brings clinical and CDMO expertise together to accelerate your development programs. By combining adaptive formulations, small-batch GMP manufacturing, and seamless integration with our clinical units, we give you the flexibility to make informed decisions in real time, without wasting valuable API or slowing timelines.

With responsive teams, strategically located facilities across North America, and proven experience from early-phase through commercialization, we are committed to helping you reduce risk, conserve resources, and bring therapies to patients faster.

Are you ready to start your next clinical manufacturing program? **Contact us today**.

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ADDITIONAL RESOURCES

Fact Sheets

Manufacturing and Analytical Services

Pharmaceutical Analytical Services

Webinars and Podcasts

From Concept to Market: Overcoming the Challenges of Manufacturing and Clinical Trials

High-Potency Manufacturing Solutions

Infographics

Shaping the Future of Medicine: Pharmaceutical Formulation Development

Nanomilling: Enhancing Drug Solubility and Bioavailability

The Benefits of Liquid-Filled Capsules (LFCs)

Case Studies

Rapid Development of a Liquid-Filled, Hard-Shell Capsule Formulation of Cannabidiol

Evaluating Milling Conditions for Scaling Up a Nanosuspension Drug Product

Manufacturing With a Highly Potent API for an Ophthalmic Indication

ABOUT ALTASCIENCES

Altasciences is a forward-thinking, mid-size contract research organisation offering pharmaceutical and biotechnology companies a proven, flexible approach to **preclinical** and **clinical pharmacology** studies, including **formulation, manufacturing, and analytical services**. For over 30 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include **preclinical safety testing**, **clinical pharmacology and proof of concept**, **bioanalysis**, **program management**, medical writing, **biostatistics**, clinical monitoring, and data management, all customizable to specific sponsor requirements.

We help sponsors get better drugs to the people who need them, faster.

CONTACT US **LEARN MORE**

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