

Accelerate your product's speed to market — right from the start

Phase I sterile clinical development and manufacturing services

Innovation. Flexibility. Experience. Catalent brings them all to your Phase I clinical trials with a full range of sterile formulation development and manufacturing solutions.

When you partner with Catalent, you have access to a strong set of analytical chemistry resources available to the pharmaceutical and biotechnology industries. You also benefit from the ability to seamlessly transition your product from the Phase I development and manufacturing stage to Phase II trial support—without spending time and resources on a complex technology transfer to another facility.



A history of exceptional clinical support

We have provided sterile products to support clinical trials for more than two decades—from first-in-humans studies through registration and global marketing. And we employ pharmaceutical CGMPs to ensure the highest levels of quality and safety.

Catalent's Pharmaceutical Product Development Services

	Pre-clinical	Phase I	Phase II	Phase III	Launch	Commercial/Phase IV
Analytical Services	GLP toxicology study support; MD/MV for Phase I clinical supplies	Clinical supply release/stability for clinical supplies	MD/MV for Phase III clinical supplies; support scale-up	Tech transfer to commercial site; support process validation; registration specifications	Validation batch release and stability	Troubleshooting/method remediation
Structural Chemistry	Isolate active; structural proof of active for IND; polymorph screening/selection	Impurity profiling	Reference standard characterization; structural proofs for NDA	Extractables and leachables		Counterfeit analysis; litigation support; impurity/contaminant ID/characterization; process improvement
Stability Services	Toxicology study support	Formulation support; clinical batch stability	Formulation support; clinical batch stability	NDA stability; expiration dating; CMC documents	First 3 post-approval lots	Post-approval changes; annual lot(s)
Microbiology	Toxicology study and preservative formulation support	Clinical supply release/stability	Method qualification; clinical supply testing; support scale-up	Process validation support; registration specifications	Validation batches release and stability	Sterility release



Catalent offers an unmatched range of development services from pre-clinical to Phase IV/commercialization.

- **Analytical services** — Our scale, infrastructure and scientific expertise enable us to solve your most difficult analytical challenges, with comprehensive services including GLP toxicology study support, MD/MV for Phase I clinical supplies and support process validation.
- **Structural chemistry** — We offer specialized equipment, full spectroscopy services and internationally recognized expertise in extractables and leachables characterization.
- **Stability services** — Catalent leads the contract industry with laboratory and chamber capacity, operational excellence, on-time delivery of reports and effective regulatory assessment—helping to ensure advancement of your product through development, registration and commercialization.
- **Microbiology** — We provide quality testing services with rapid data turnaround, including method qualification (Rapid Microbial Methods) and process validation support.
- **Global regulatory services** — Catalent's regulatory services group has an extensive consulting portfolio across a wide range of therapeutic areas. Our services include regulatory submissions at investigational and marketing stages, regulatory electronic publishing, and training workshops.

The Catalent advantage

- Sterile formulation development and filling combined in one convenient package of services
- Seamless transition from Phase I development and manufacturing/filling to Phase II trials
- Innovative biologic cell-line development using our proprietary GPEX[®] technology for rapid development and increased yield
- Specialized services including DEA license (schedules I-V); potent compound handling; light-sensitive compounds; and low-humidity environment requirements
- A full continuum of global integrated drug development, manufacturing and packaging services for the pharmaceutical, biotechnology and health care industries

Catalent is well positioned to serve you wherever you do business. Contact us today.

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Printed by Catalent Pharma Solutions,
Moorestown, NJ.
Lit. No. ST-PHI-SS (10/08)

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