

Better API Science. Reliable American Supply.

Best-in-class drug substance (API & HPAPI) development and GMP manufacturing for complex chemistries and accelerated timelines, from preclinical through commercial supply.

Integrated contract research, development and manufacturing organization (CRDMO) for better results, faster.

Superior small molecule drug substance development and manufacturing in the USA for all our complex and accelerated discovery, clinical, and commercial needs.

Custom synthesis for small molecule projects, including peptides, with integrated, end-to-end support, from lead generation to method and process development, process scale-up, and GMP manufacturing.



Specialized Expertise

Including your challenging complex chemical synthesis. We rescue promising molecules that others cannot.



CMC Capabilities

Continuous flow, complex chemistry, HPAPIs, controlled drug substance, ADCs, and Peptides.



Unique Catalog of RSMs

Large-scale, difficult-to-synthesize starting materials.



Analytical Expertise

Both integrated and stand-alone.

About Us

With deep scientific experience developed across hundreds of molecules, Wilmington From our DuPont/ Merck roots and through 20+ years of experience with over 200 INDs, thousands of clinical and commercial batches, and multiple commercial products, as well as recent lab, manufacturing, and HPAPI expansions, Wilmington PharmaTech is ready to solve your complex challenges and accelerate your projects.

Our 54-acre, FDA-inspected, Delaware campus features state-of-the-art GMP-compliant API manufacturing capacity for clinical, specialty-scale, and commercial demand, plus dedicated facilities, including:

- ✓ Facilities dedicated to development- and clinical-scale manufacturing, with full analytical support
- ✓ A building dedicated to late stage/larger capacity clinical and commercial supply, with state-of-the-art HPAPI suites operating to occupational exposure band (OEB) 5 level



Lead Generation

Our seasoned team of medicinal chemistry experts have decades of specialized experience in solving the most complex synthetic challenges. For more than 20 years, we have designed hundreds of compound analogs and facilitated the synthesis of thousands of variants in support of target identification through lead optimization across therapeutic areas. Wilmington PharmaTech has participated in rescuing many promising molecules that other contract providers could not develop.

API Development

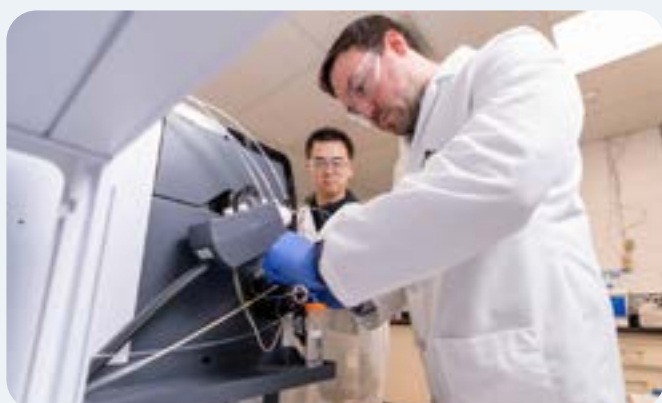
We provide better science, faster! For more than two decades, Wilmington PharmaTech has invested in creating deep scientific experience in chemical development for IND-enabling, seamless support. This includes process development and scale-up through cGMP supply.

Our facility capabilities are purposefully designed to handle the full range of drug substance challenges, including multi-chiral center, OEB 5 HPAPI (e.g., for cytotoxic compounds and antibody-drug conjugate (ADCs)), continuous-flow processing, controlled drug substances (CDS), and peptides.

Capabilities include:

- ✔ API synthesis
- ✔ Dedicated HPAPI suites
- ✔ Process development and optimization
- ✔ Process scale-up
- ✔ Analytical method development, validation and ICH stability programs
- ✔ API impurity services
- ✔ Robust IND-enabling services

We continuously invest to keep our laboratories and cGMP suites current and well-equipped, including the recent addition of scalable purification solutions for the chiral and achiral separations. Our advanced purification services include racemates and atropisomers with the same cycle used for the purification of both chiral and achiral molecules.



GMP Manufacturing

Proven expertise to accelerate your discovery program through target identification, scaffold synthesis, and lead optimization.

- ✔ IND-enabling to small-scale commercial pilot plant for API production
- ✔ HPAPI Handling
- ✔ Capacity from large-scale cGMP labs to pilot suites

Analytical Testing

Whether for in-process, release, or stability testing, Wilmington PharmaTech provides a comprehensive suite of analytical testing capabilities, including:

- ✔ Analytical method development and validation
- ✔ Full cGMP release for both clinical and commercial API
- ✔ Non-GXP and GLP testing
- ✔ Reference Standards, including preparation, qualification, and distribution for intermediates and APIs
- ✔ Identification of impurities and preparation for qualification, including the distribution of impurity standards
- ✔ Full ICH stability studies, including trace impurity analysis
- ✔ Designated QA office and documentation storage
- ✔ Genotoxicity impurity services

Solid-State Chemistry

With a wealth of expertise and a combined 20+ years of experience, Wilmington PharmaTech provides comprehensive solid-state chemistry support to optimize your API's form.

Services include:

- ✔ Salt selection and polymorph screening
- ✔ Crystallization optimization

Specialty Starting Materials: Large Scale

At the request of many clients, Wilmington PharmaTech has created a unique catalogue of difficult to synthesize starting materials and analogues available at kg scale to facilitate discovery and IND enabling activities. A PDF list of these compounds is available upon request.

Wilmington PharmaTech by the numbers



20+

years of cGMP
manufacturing



1000+

API candidates
developed



160+

patents filed
for clients



200+

IND submissions,
and counting

A dedicated and experienced team...

We provide fast, local access to scientists with a wealth of expertise and a combined 20+ years of experience developing more than 1000 API candidates, plus agile U.S.-based project management.



...and World-Class Facilities

Wilmington PharmaTech's FDA-inspected Delaware campus, a former DuPont/Merck site, combines discovery and development labs, scalable manufacturing through commercial scale, advanced analytics, and HPAPI-ready suites to support fast-moving and complex small-molecule programs.

Better Science, Faster.



"Our business has been built upon trusted performance, creating long-term relationships with many large pharma companies, and dozens of smaller innovators."

HARRY LI, PH.D.
CEO & FOUNDER OF WILMINGTON PHARMATECH COMPANY