Wilmington PharmaTech by the numbers

20 + years
of cGMP manufacturing

300 + API
candidates developed

30 + patents
filed for clients

> 180
IND submissions, and counting...

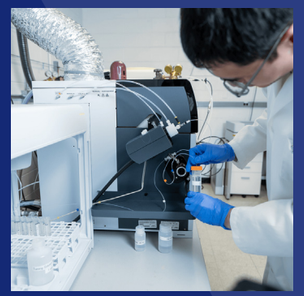
A dedicated and experienced team...

We provide fast, local access to scientists with a wealth of expertise and a combined 20+ years of experience developing more than 300 API candidates, plus agile U.S.-based project management.

...and World-Class Facilities

Our deep heritage is there for all to see. We have invested in our already well-equipped ex-DuPont/Merck laboratories and cGMP suites to include continuous flow chemistry capabilities and a dedicated pilot plant.

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

WILMINGTON PHARMATECH

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WILMINGTON PHARMATECH

Better Science, Faster Results.

Comprehensive small molecule drug substance development and cGMP manufacturing in Delaware, USA.

Lead Generation | API Development | Complex Synthesis | Solid State Chemistry | cGMP Clinical and Commercial Manufacturing | High Potent | Specialty Starting Materials

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 and seamless support from medicinal chemistry to methods and process development, analytical services, and US-based cGMP API supply.

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.

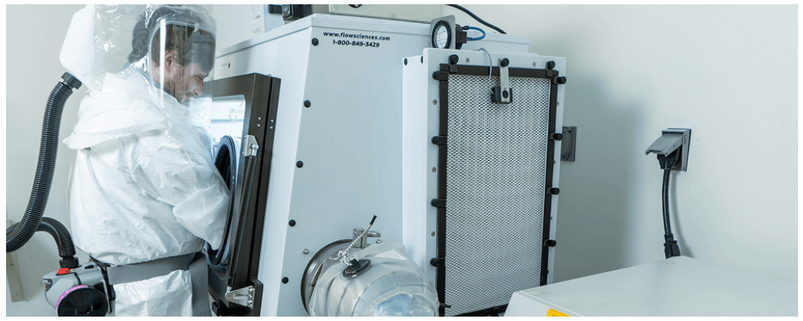
About us

With deep scientific experience developed across hundreds of molecules, Wilmington PharmaTech provides flexible sourcing and support options coupled with close attention to each client's objectives and each molecule's needs.

Our customers choose Wilmington PharmaTech because for over 20+ years, we have demonstrated we have the science and the capabilities to help make their projects real. Our customers value our flexibility in finding ways to accelerate their projects: our proven quality management system (QMS) and our history of delivery excellence.

Our 54-acre, FDA-inspected, Delaware campus features state-of-the-art cGMP-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

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 substance (CDS), and peptides.
Our 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 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.

cGMP 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. Our 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.