

SMALL MOLECULE API SOLUTIONS

TAKING A BIG PICTURE APPROACH

• API

• BIOLOGICS

• VIRAL VECTOR
SERVICES

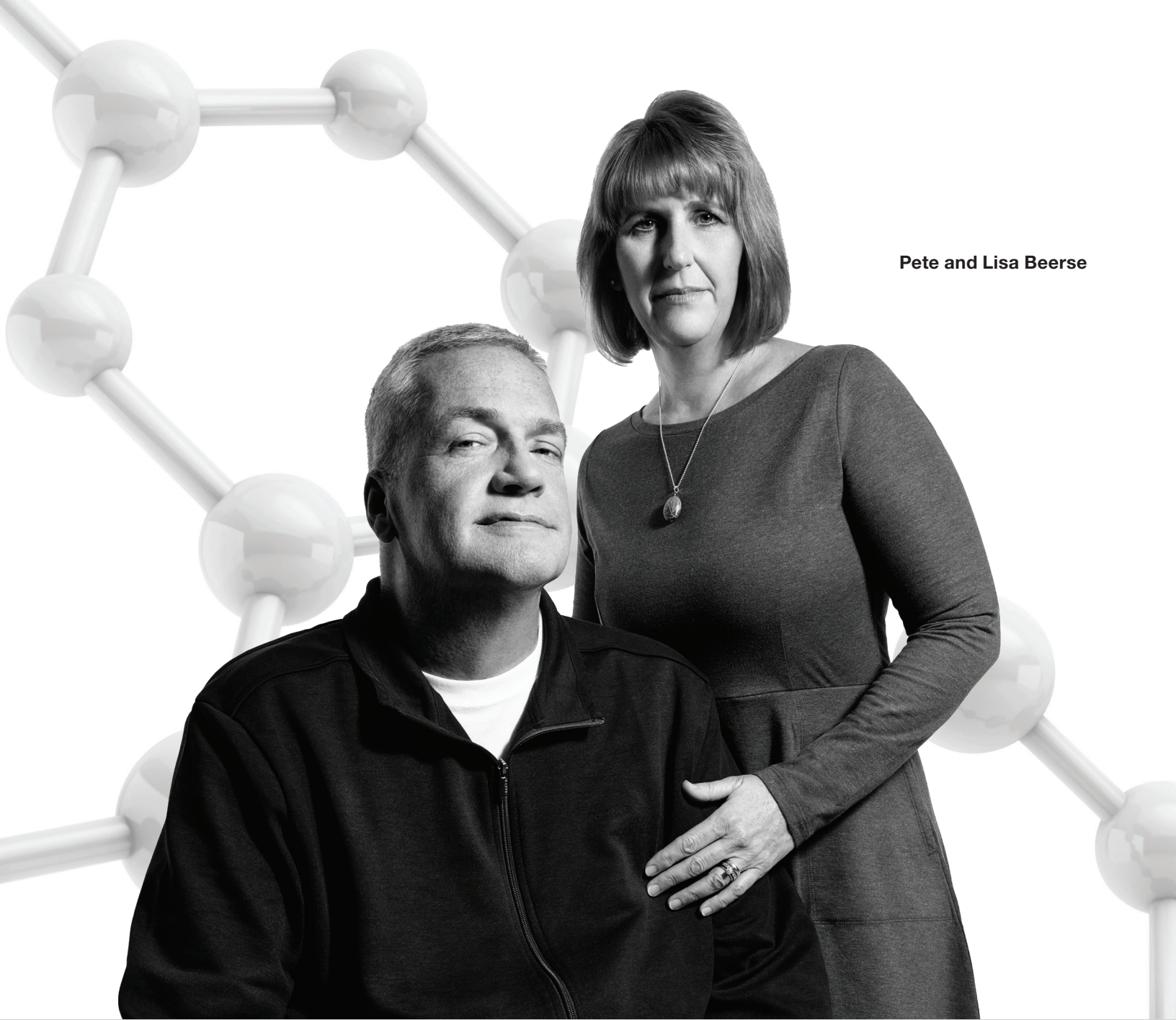
• EARLY & LATE
PHASE DEVELOPMENT

• CLINICAL TRIAL
SOLUTIONS

• LOGISTICS
SERVICES

• COMMERCIAL
MANUFACTURING

patheon



Pete and Lisa Beerse

HOW A COMBINATION OF MEDICINES HELPED ONE MAN TAKE BACK HIS LIFE, AND INSPIRE US ALL.

On a quiet Sunday afternoon, Pete and his wife Lisa took a moment to sit on a porch swing and relax. A small piece of wood holding the chain broke and they fell backwards causing Pete to break his neck. Now, this father of eight who had been a college athlete had to face life in a wheelchair, requiring assistance for even his most basic needs. Pete says while the physical toll was tremendous, the emotional and mental toll was even worse. In addition to dealing with his body having to understand its lack of function – from mobility to heat regulation – there was the depression and anxiety that also comes with watching his wife and kids step in to care for him. But Pete and Lisa did not give up. They worked for over a year with doctors to find the right mix of medications. Though it was a grueling process, eventually they got it right. Pete credits these medications with saving his life and giving him the strength to persevere. Together, Pete and Lisa look forward to the future: their daughter’s wedding, time with friends and family, even their first trip on an airplane since the accident. As Pete says, “We’ve been married 32 years. Not long enough.”

Fifty-eight percent of medicines in development are small molecules—many of which feature highly potent molecules.

Additionally, 70% of drugs in development have solubility issues, requiring special attention to formulation. With competitive options for API outsourcing in all geographical regions, it can be difficult to choose the right partner for your project, regardless of its complexity. Thermo Fisher Scientific offers the expertise and capabilities to partner with pharmaceutical companies of all sizes and in all stages of development.

Making your API right the first time: From grams to tonnes

Time is indispensable and quality is critical when it comes to the development and manufacture of your small molecule API. Getting to your next milestone doesn't have to be a journey you navigate alone. Thermo Fisher Scientific Pharma Services offers a full range of scientific and regulatory services to help get you to clinic quickly and find your runway to commercial.

Take advantage of the expertise of our world-class chemists and our global network of development and manufacturing facilities. We offer a broad range of chemistries and our ability to integrate drug substance and drug product development with clinical services gives you the ability to scale your project under one roof.

GLOBAL NETWORK AND UNMATCHED SCIENTIFIC EXPERTISE

We support API development at six sites within the United States and Europe—two locations in Florence, South Carolina, and one site each in Greenville, South Carolina; Cork, Ireland; Linz, Austria, and Regensburg, Germany. Within our network, we have more than 370 PhD and Masters degrees dedicated to refining, optimizing, and launching your API project.

We have over 50 years of manufacturing experience for small molecule API and offer key capabilities from preclinical to commercial.

***“High quality facility, management,
and technical team.”***

— Clinical-stage biopharmaceutical company, USA

“Outstanding technical ability, strong communication and team leadership.”

— Small molecule biotechnology company, USA

API drug substance sites



OUR SOLUTIONS

From early process optimization work all the way to commercial-scale development, we provide key services across all phases of development to get your project to market:

- Route scouting
- Solid-state chemistry
- **Process development:**
Work directly with scientists with deep chemistry knowledge and many years of experience in successfully supporting early and later phase clinical development programs. Our experts offer you cutting edge technology from start to finish in multi-step chemical synthesis and from traditional to complex manufacturing.
- Clinical supply manufacturing
- Tech transfer and scale-up of new and existing processes
- Continuous improvement of existing processes
- Expertise with difficult-to-manufacture APIs
- Innovative solutions to manufacture your complex API
- High potency compounds and controlled substances
- **Comprehensive analytical services:**
To support route scouting and process development activities and accelerate your clinical programs, we provide a comprehensive range of analytical services. Our analytical development and quality control teams have in-house access to a comprehensive range of state-of-the-art analytical techniques and extensive experience
- Commercial supply manufacturing
- Supply chain management
- **Spray drying:**
Address bioavailability challenges with our spray drying expertise and technologies, with solutions from preclinical to commercial scale. Move to your next milestone efficiently by scaling through our integrated drug substance and drug product network.
- Micronization
- Physical characterization

“Very reliable, sound expertise, excellent scientific input.”

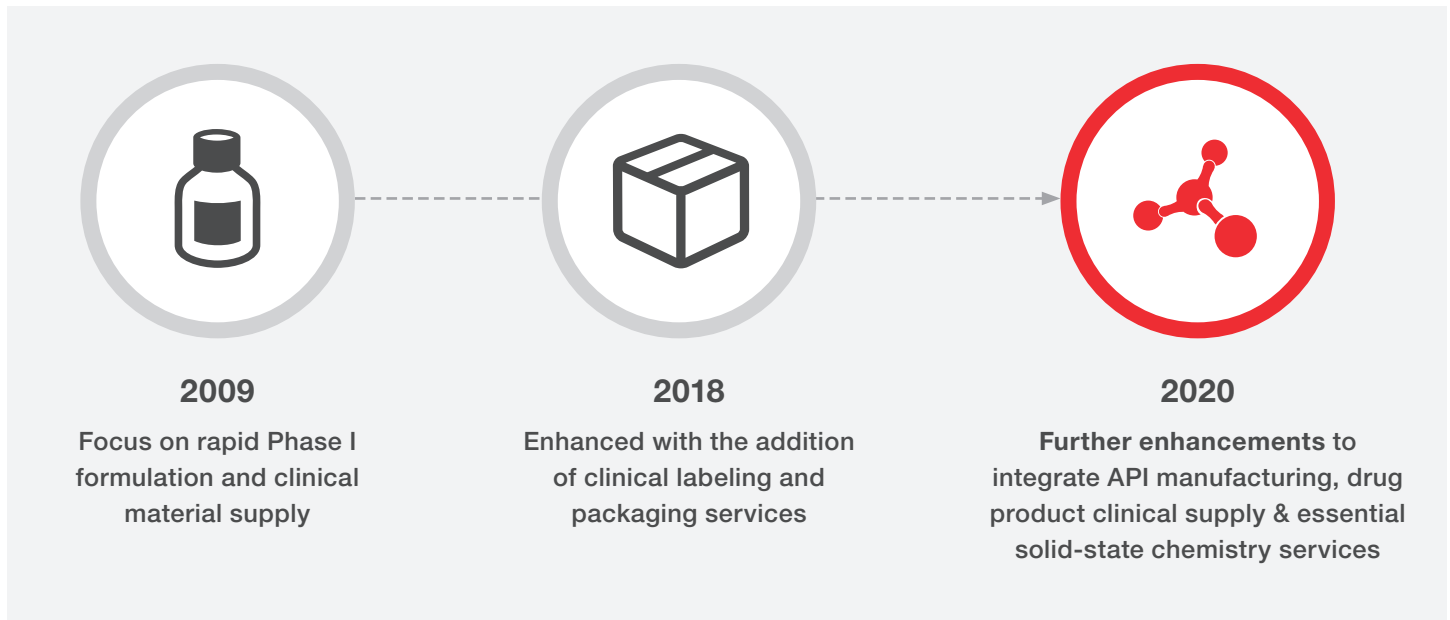
— Clinical-stage biopharmaceutical company, Germany

Early development: Achieve molecule milestones faster with Patheon™ Quick to Clinic™ small molecule

Our goal at Thermo Fisher is to always innovate and expand our offerings in order to enable our clients to reach their goals. This innovation includes our newly enhanced Quick to Clinic™ program for oral solids. This service offers expert API and drug product manufacture, as well as clinical

services, supported by phase-appropriate formulation and essential solid-state work to allow clients to quickly reach their Phase I milestones. The integrated approach allows you to save time, simplify your supply chain, and make investments for future milestones. Our unmatched expertise allows clients in early development to reduce their risk as they move into clinic.

Evolution of the Quick to Clinic™ offering



Harness the power of an integrated network with Quick to Care™

Patheon's Quick to Care™ suite of services delivers a streamlined drug development program. This offering combines your drug substance and drug product development, clinical manufacturing, forecasting, demand planning, and clinical trial supply execution into a single solution to accelerate your discovery to proof of concept. Save time and money on your development journey with:

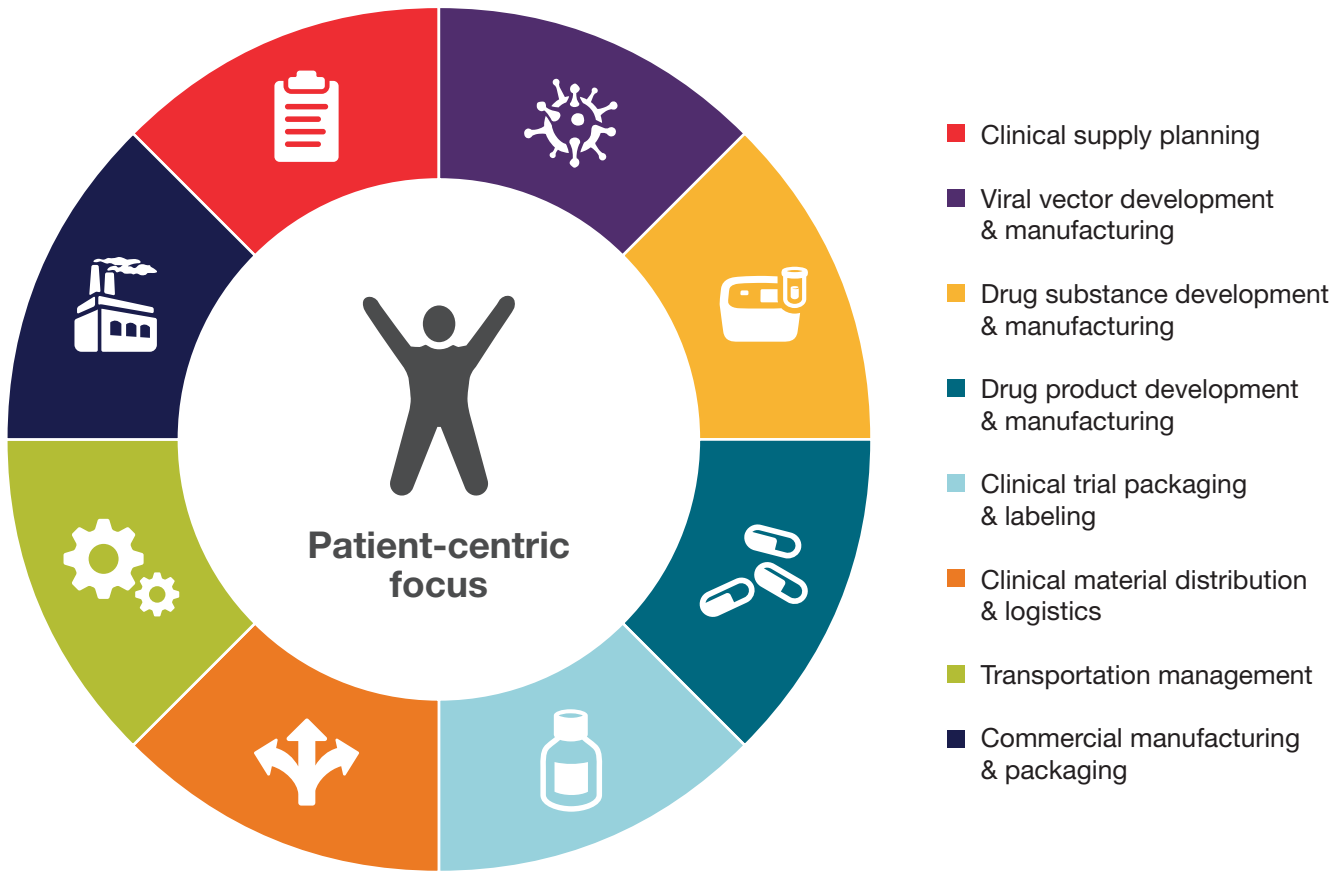
- Comprehensive program management with a single point of contact
- Scientific insight to speed every step
- Assurance of supply
- Simplified contract and administration
- Optimized tech transfers

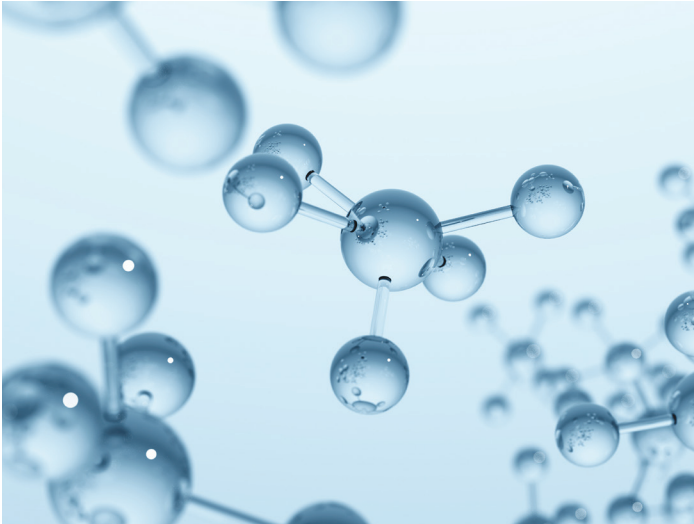
109
new drug applications in the last decade
(2X the nearest competitor)

50+
years of experience manufacturing cGMP API

95%
average right-first-time rate in 2021

~275
small molecules worked on in 2021





Runway to commercial: Scale with a trusted partner

Thermo Fisher Scientific offers commercial API manufacturing under full cGMP conditions with speed, efficiency, and exceptional quality. We bring flexibility to adapt to changes in your market and mission and will never stop working to optimize your process to increase outputs while reducing timelines. As your trusted partner, we are committed to providing you with:

- Global capacity
- Technical expertise
- High containment and regulatory compliance
- Continuous innovation
- Commitment to quality
- Spotless reputation

When you're ready for the next step in drug development, our drug product and clinical services experts can help with [formulation](#), [packaging](#), [labelling](#), [distribution](#), and more.

Drug product development

Every step of the drug development process brings unique challenges and opportunities. We have designed a range of flexible solutions to meet your molecule's unique needs across formulation development, analytical method development, bioavailability enhancement, manufacturing process development and clinical batch manufacturing.

Clinical supply services

Once your product is ready for clinical trials, we can assist with the logistics. Whether you need primary or secondary packaging of your clinical drug, storage, distribution, logistics, cold chain management, or comparator and ancillary sourcing, our global team can meet the needs of every trial regardless of size, phase or therapeutic area. We also offer import/export services, including Importer of Record (IOR) capability in more than 25 countries to date, and best-in-class direct-to-patient services.

We are committed to delivering the highest possible value while ensuring adherence to the highest level of quality, performance, reliability and sustainability standards.

***Learn more about our extensive API development and manufacturing offerings.
Contact us today.***

