

FROM MOLECULE TO MEDICINE

ONE INTEGRATED PARTNER FOR
EVERY STEP OF YOUR DRUG
DEVELOPMENT JOURNEY

- API
- BIOLOGICS
- VIRAL VECTOR SERVICES
- EARLY & LATE PHASE DEVELOPMENT
- CLINICAL TRIAL SOLUTIONS
- LOGISTICS SERVICES
- COMMERCIAL MANUFACTURING

Mike Pearson
Staff Program Manager,
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Welcome to Thermo Fisher Scientific, your integrated drug development partner who never loses sight of our shared goal — improving patients' lives.

Our Thermo Fisher Scientific Pharma Services business was created by combining the CDMO capabilities of Patheon and the clinical trial capabilities of Fisher Clinical ServicesSM. With other recent additions like Patheon Viral Vector Services (formerly Brammer Bio), we have simplified our branding by aligning all CDMO and Clinical Service offerings under the Patheon brand. We are an integrated force and stronger than ever. Built on a proven foundation of quality systems and commitment to continuous improvement, we have the capabilities and expertise to help you achieve success in drug development.

Everything we do is focused on making certain that your molecule can become what it was meant to be—a discovery that can change patients' lives for the better and make the world healthier, cleaner and safer. All of us—from our scientists and engineers to our line operators and business professionals—take our work personally. We are firm in our belief that all people deserve a healthier life. That's why our trusted team, built on experience, insight, and the passion to deliver the best possible outcomes, apply heart and science in all they do.

In the pages ahead, find out how we can solve your most complex drug development and manufacturing challenges.



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Unmatched, fully integrated global site network.



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SMALL MOLECULE DRUG SUBSTANCE CAPABILITIES

Meet the people who make it right the first time from grams to tonnes.

Our people pride themselves on solving your unique challenges. We optimize processes to speed your molecule through early phase trials and apply initial learnings to prepare you for commercial success faster. But whether you start with us in early phase or late, we draw on years of experience and deep expertise to keenly focus on superior delivery performance.

Whether you need grams of API for an in-house project or kilo after kilo for a late phase trial or commercial supply, you can reduce the risk and raise the bar on quality by working with a partner whose reputation stands on both quality and excellence in chemistry. In addition, our high-quality APIs and intermediates are made in the same facilities and to the same stringent standards. So you can rest assured that your molecule is surrounded by quality and care.

Get to market fast with integrated API solutions.

DISCOVER EXPERTISE AND GLOBAL REACH FROM CLINICAL TO COMMERCIAL API PRODUCTION

Thermo Fisher Scientific gives you a complete range of solutions and services at world-leading facilities in Europe and North America. Start with us early and we'll help you scout a manufacturing route forward. Join us in later phases and get the insight and quality that leads to success faster. Throughout your journey to market, we offer:

- Route scouting
- Process development
- 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
- Commercial supply manufacturing
- Supply chain management
- Spray drying
- Micronization
- Physical characterization

A COMPREHENSIVE RANGE OF CHEMISTRY AND MANUFACTURING TECHNOLOGIES

Providing the right chemistry and technological capabilities are the basis for today's API development and manufacturing. Thermo Fisher offers you cutting-edge technology from start to finish in multi-step chemical synthesis, and from traditional to complex manufacturing. We're also ready to help determine what is both technically and financially feasible for your project. Our breadth of capabilities includes:

Microreactor Flow Chemistry

Get the efficiency, flexibility and scalability of microreactor flow chemistry. We run continuous processes on small reactor scales to deliver improved product quality and higher yields. The same process is used for early phase batches and late phase/commercial batches, simplifying scale-up.

Today's advanced catalysis discoveries can require complex, multi-step chemical synthesis, making it difficult to prove viability quickly. Thermo Fisher makes more of these discoveries feasible with advanced catalysis technologies that can reduce timelines from years to months. You'll have access to interdisciplinary route scouting expertise, chemocatalysis and biocatalysis, proprietary biocatalytic processes, and experience with large-scale complex processes that development-only labs do not offer.

Polymers

With over 20 years of experience, we lead the way in polymeric API technology. This lets you create completely unique products by combining proprietary process technologies, polymer science, advanced synthesis and large scale cGMP expertise.



CLINICAL AND COMMERCIAL BATCH MANUFACTURING—QUALITY, SPEED AND SCALE

Early-stage clinical supplies of API are produced at state-of-the-art cGMP facilities in Europe and North America. A team of experts will surround your discovery with a full range of technologies and analytical services to not only run the project with the highest degree of flexibility, but also deliver on time with exceptional yields and superior quality.

In late-stage trials and beyond, your drug substance will be manufactured at a cGMP commercial production facility where a team of experts works continuously to optimize processes, increase outputs and reduce timelines.

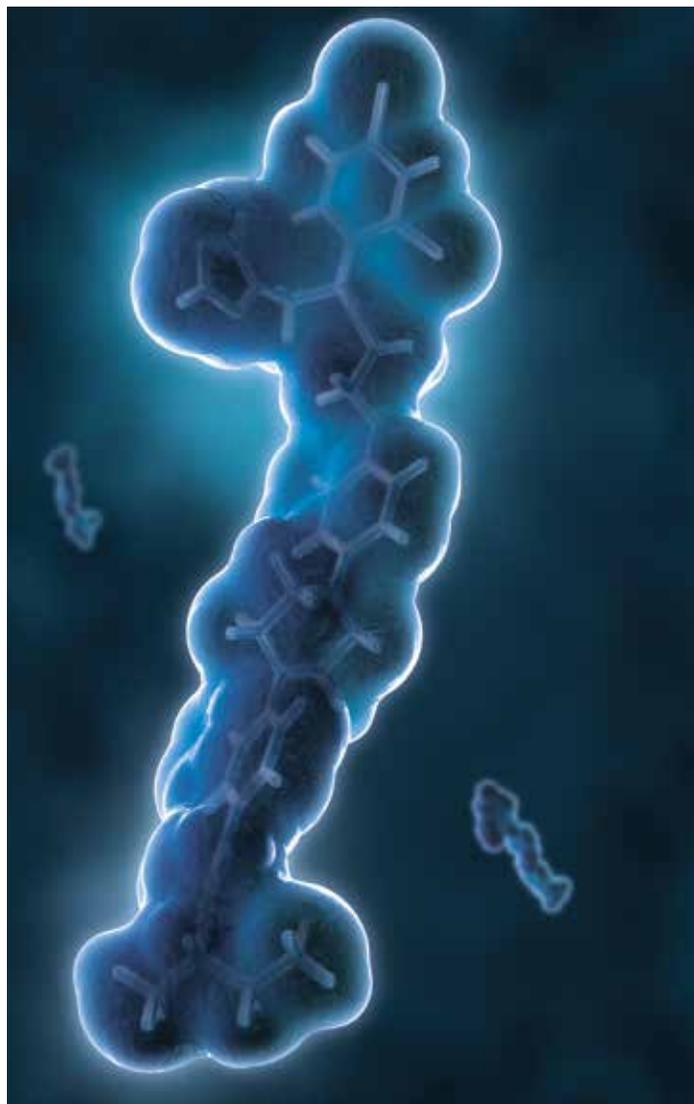
Our clinical and commercial batch manufacturing capabilities include:

- A comprehensive array of technologies, services and solutions
- Flexible manufacturing solutions
- Scalable processes
- Dedicated teams and multiple facilities for clinical and commercial scale manufacturing
- Total capacity in excess of 800,000 L with reactors as large as 16,000 L
- Access to a streamlined end-to-end supply chain
- Full regulatory support with CMC documentation
- Regulatory approvals to work with controlled substances and highly potent compounds

PROCESS VALIDATION—ENSURING A RELIABLE COMMERCIAL SUPPLY

In clinical phases and as part of the establishment of your commercial supply of API, we provide a complete validation package according to regulatory and cGMP guidelines, including:

- Quality by Design (QbD) and Proven Acceptable Ranges (PAR)
- Process validation with critical parameters
- Validation of analytical assays
- Release testing
- Stability studies at required ICH conditions
- Container shipment studies
- CMC documentation in CTD format



END-TO-END SOLUTIONS FOR THE SMALL MOLECULE CHALLENGES AHEAD

We have the science, methods, breadth of services and technology to solve the most complex small molecule challenges. The proven ability to make it Right-The-First-Time, every time. Scale from grams to kilos to tonnes. A superior regulatory track record. A faster, seamless path from early API development to scale-up and commercialization. Global reach and scale.

These are just a few of the reasons to choose Thermo Fisher for your API production. Yet, the most compelling reason is our people: The scientists, engineers and experts who surround your discovery with the sharpest minds in the business. So you can maximize the true potential of your molecule and deliver it to the patients who need it most.



Jeff Hou, Ph.D.
Manager, Cell Culture Development,
Pharma Services
Princeton, NJ

LARGE MOLECULE DRUG SUBSTANCE CAPABILITIES

Let our biologics experts show you how to speed development and unleash the potential of your discovery.

Your molecule has the power to change lives and shape the future. Thermo Fisher Scientific is the company that offers the flexibility and speed to help you get ahead of schedule while maintaining the highest quality. We bring scientific expertise to every challenge and our proven track record of scaling up biologics helps ensure you gain cost and time savings at every stage of the biologic development process.

Just as important, our people understand the long and complex journey ahead, and are as committed to your success as you are. We are driven by science and have the experience to solve complex large molecule challenges.

Discover flexible solutions, custom built on comprehensive capabilities and experience.

UNLOCKING SUCCESS WITHOUT LOCKING YOU IN

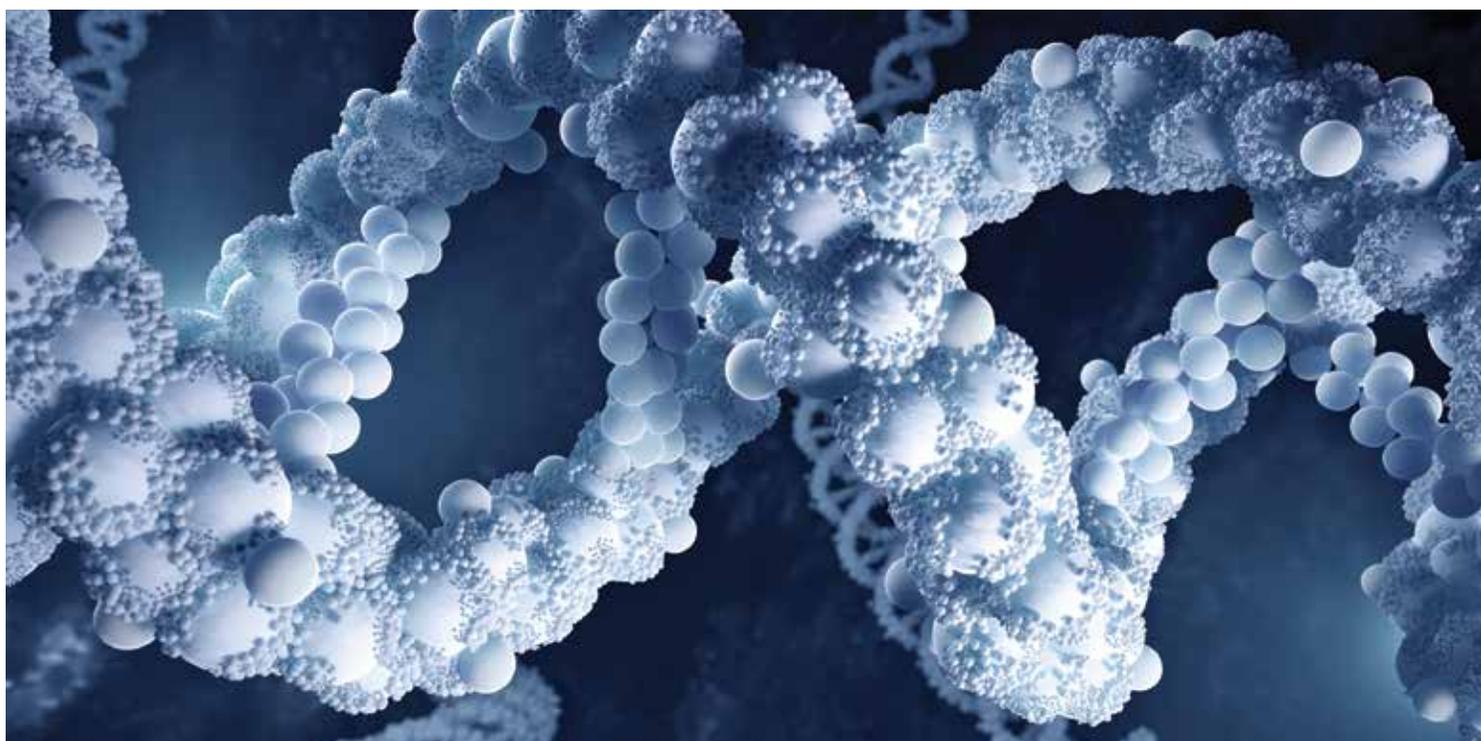
We pride ourselves on our ability to create flexible options for our clients. We understand the uncertainty associated with forecasting demand. We think strategically to offer bio-manufacturing options that meet the unique needs of your molecule, and can work with your cell lines. Our contracts are individualized to meet your requirements, we do not require you to use proprietary technology, and we do not charge royalties. Our strong reputation is built on successfully transferring complex molecules.

QUICK TO CLINIC™ FOR BIOLOGICS DELIVERS PHASE I CLINICAL TRIAL MATERIAL, FAST

The pressure to file an IND makes accelerated Phase I safety testing a priority. With the Quick to Clinic™ program, Thermo Fisher Scientific can deliver your large molecule released drug substance and drug product for First-in-Human studies in as little as 14 months. Now you can meet important milestones such as filing the IND, or securing additional funding, with confidence. Our Quick to Clinic™ program for Biologics is made with speed and flexibility because we understand the importance of reducing the time it takes to get your discovery to the patients who need it.

PROCESS DEVELOPMENT CAPABILITIES— FLEXIBILITY, QUALITY AND SERVICE

We apply our process development skills to significantly increase the batch yield and reduce processing time for your molecule. Applying Design of Experiment (DoE) methodology to both Upstream and Downstream processing, we define the CPPs and CQPs that enable robust processes, maximize yields, and optimize throughput. For Upstream processing, we utilize the Sartorius ambr® 15 and 250 platform as well as 0.5 L, 1 L, and 10 L single-use bioreactors to define optimal feed and processing conditions.



UPSTREAM PROCESSING CAPABILITIES

With a fully integrated global network of cGMP facilities across Europe, North America, and Australia, we are a leader in manufacturing monoclonal antibodies and recombinant proteins using single-use technologies. Our expertise spans multiple commercial cell lines including CHO. We also specialize in fed-batch and perfusion cell culture processing.

Fed Batch Processing

We can achieve stable reliable production at titers >5 g/L.

Perfusion Processing

We can achieve high productivity and manufacture of unstable proteins.

Single-Use Technology

We can help you reduce technology transfer and scale-up risks and eliminate cross-contamination concerns. We offer multiple single-use bioreactor platforms and scale: 250 L, 500 L, 1000 L, and 2000 L.

DOWNSTREAM PROCESSING CAPABILITIES

Thermo Fisher offers a range of purification processes that ensure your drug substance is of the highest quality and yield, including:

- Depth filtration
- Tangential and alternating tangential flow filtration
- UF / DF development
- Chromatography development
- Nanofiltration and virus inactivation
- Viral clearance studies
- Final product formulation
- Robustness studies

ANALYTICAL SERVICES THAT MEASURE WHAT IS MOST IMPORTANT TO YOU

Our analytical capabilities include rapid identification and characterization of your recombinant protein or antibody, development and implementation of cGMP methodologies and data generation for regulatory submissions. Analytical methods are developed in process development by the same teams that will use them in manufacturing, to avoid delays and errors created by handoffs. Our breadth of analytical services and capabilities include:

Analytical Methods and Method Validation

- Glycan profiling
- ELISA assays for product and impurity assessments
- Gel and capillary based electrophoresis
- Gel and capillary based isoelectric focusing
- Residual DNA detection
- Cell-based bioassays
- Immunologic and colorimetric assays
- Mass spectrometry
- ICH stability testing

PROCESS VALIDATION—ENSURING RELIABILITY OF SUPPLY AND CONSISTENT QUALITY

In late clinical phases, and as part of the establishment of your commercial supply, Thermo Fisher provides a complete validation package according to regulatory and cGMP guidelines. BLA / PPQ-enabling process characterization and validation activities include:

- Process characterization
- Validation of process and analytical methods
- PPQ campaigns
- Container shipment studies
- CMC documentation in CTD format

PERSONAL ATTENTION TO THE DETAILS

At Thermo Fisher Scientific, you'll be assigned a project manager who will serve as your main point of contact, as well as a cross-functional team dedicated to designing a process that meets the needs of your discovery and your business. If you are a consultant, we also understand your unique role and can offer customized, flexible solutions aligned to your clients' needs.

TECH TRANSFER FOR A STRATEGIC AND FINANCIAL ADVANTAGE

Technology transfers, either for a scale-up or a move to another facility, are part of the normal course of business. If the transfer is urgent, our team has a proven track record of quick, effective executions to get your project back on track and preserve product supply. In all cases, we are driven by your deadlines, flexible in our approach and determined to get it Right-The-First-Time, every time.

Flexible, end-to-end solutions for development and commercial production.

Work with one partner for both drug substance and drug product manufacturing at the development and commercial scale. Our knowledge of formulation development and bio-processing ensures that your molecule is "formulation ready" regardless of the stage you are at.

CUSTOMIZED BIOMANUFACTURING SOLUTIONS

We offer a range of versatile solutions to overcome capacity restraints while meeting the highest quality and regulatory standards.

Global Network

Take advantage of our manufacturing locations in the US, EU and Australia for simplified logistics and R&D tax advantages.

FROM TRADITIONAL CAPACITY TO CUSTOMIZABLE MANUFACTURING MODULES.



Dedicated Capacity

Allocate capacity for each of your products and transfer capacity in and out of the line.



Fractional Ownership

Sharing a line or facility lowers cost while allowing you to achieve flexibility and scalability.



Flexible Network Access

Get anytime access to a specific type of capacity within our global network.



Condominium Capacity

A fully customized solution that includes everything from design services to operational management.



Enterprise

For clients who own facilities, we offer operational improvements and repurposing of existing equipment.



A SCIENCE-DRIVEN APPROACH TO REDUCING RISK AND REALIZING THE REWARDS

We offer a depth and breadth of innovative biologic capabilities from development to commercialization. We pioneer new technologies to improve the manufacturing process. Our teams focus precisely on every step, but never forget the end goal. We think strategically to offer flexible, fast, efficient approaches to helping your discovery through the complex journey to market.

The scientists, engineers and professionals of Thermo Fisher Scientific apply a science-driven, risk-based approach to every step of the biologic development and manufacturing process. They draw on years of experience and partner with you at the stage of development that is most advantageous for your business. Because this is the best way to make certain your discovery lives up to its promise for the patients who need it most.



Nicole O'Brien
*Sr. Director of Technical
Program Design*
Alachua, FL

From process development to commercial supply, we offer the viral vector expertise necessary to help clients deliver innovative cell and gene therapies.

Cell and gene therapies are generating positive clinical results at an accelerating rate, with multiple products in late-stage development and expected to be licensed in the near future. The gene and cell therapy markets are growing rapidly at about 25 percent per year, and the FDA predicts that by 2025, 10 to 20 new gene therapy products will be approved each year. These novel, life-saving therapies are treating diseases that were, until recently, untreatable.

Viral Vector Services (VVS) provides process and analytical development along with clinical and commercial supply of viral vectors for *in vivo* gene therapy and *ex vivo* gene-modified cell therapy. With over 12 years of experience, we accelerate the transition from development laboratory to patients. From pre-clinical and clinical development, to commercial approval, our expertise enables us to meet both cGMP standards and industry expectations with high integrity. We are enabling biopharma customers to deliver breakthrough medicines to patients by unleashing the potential of gene therapy.

We have experience working with a broad range of viral vectors products (AAV, AV, LV, HSV, and RV), serotypes and pseudotypes. We have completed over 100 projects using a variety of manufacturing technologies in the delivery of over 150 lots of clinical trial material, including commercial lots. Our team of more than 600 innovative employees is focused on serving the needs of clients and patients.

The design and recent expansion of our cGMP-compliant, state-of-the-art, multi-product facilities and use of single-use equipment allows maximum flexibility for manufacturing platform, scale and project scheduling, while ensuring product quality. As we strive to exceed expectations, our collaborative approach ensures that our clients are involved, engaged, and well informed throughout the project.

Viral vectors are complex and require deep expertise to analyze and manufacture. VVS has long established this capability. Combined with Thermo Fisher's GMP production expertise, we are uniquely positioned to partner with our clients to drive the evolution of this incredibly fast-growing market.



VIRAL VECTOR

DEVELOPMENT & MANUFACTURING

<p>Services</p>	<ul style="list-style-type: none"> • Single cell and virus cloning and screening • cGMP cell and virus banking • Process development, characterization and qualification • Analytical method development, qualification and validation • Pre-clinical, clinical and commercial viral vector production • State-of-the-art clinical and commercial aseptic fill and finish services • QC release and stability testing • Clinical/commercial state-of-the-art warehouse 	
<p>Suspension Manufacturing Platforms</p>	<p>PRECLINICAL 200L</p>	<p>COMMERCIAL 4x200 L 1,000 L 2,000 L</p>
<p>Adherent Manufacturing Platforms</p>	<p>PRECLINICAL Flatstock iCELLis® 500</p>	<p>COMMERCIAL Flatstock iCELLis® 500</p>

AAV

<p>Adherent + Suspension</p>	<p>Producer cell line + Ad</p>	<p>Suspension + HSV</p>	<p>Suspension + Baculovirus</p>
<p>Mammalian cells transient transfection</p>	<p>Mammalian cells infection</p>	<p>Mammalian cells infection</p>	<p>Insect cells infection</p>

ADENOVIRAL

<p>Adherent + Suspension</p>
<p>Mammalian cells infection</p>

LENTIVIRAL

<p>Packaging/ Producer cell line</p>	<p>Adherent + Suspension</p>
<p>Mammalian cells</p>	<p>Mammalian cells transient transfection</p>

RETROVIRAL

<p>Packaging/ Producer cell line</p>	<p>Adherent + Suspension</p>
<p>Mammalian cells</p>	<p>Mammalian cells transient transfection</p>

HERPESVIRAL

<p>Adherent + Suspension</p>
<p>Mammalian cells infection</p>

Sanjay Konagurthu, Ph.D.
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EARLY & LATE PHASE DEVELOPMENT CAPABILITIES

Our experts anticipate problems before they even start, improving your chances of success at every stage of drug development.

Your discovery has the potential to shape the world. Thermo Fisher Scientific has the proven experience, scientific expertise and problem solving skills to make certain your molecule—small or large—lives up to its greatest potential. We work with you to meet the requirements of every step and phase faster, more efficiently and cost effectively. And our proven track record scaling from one development phase to the next helps ensure the therapies we make together have the best chance to reach the patients who need them most.

THE RIGHT ROUTE FOR COMPANIES OF EVERY SIZE

At Thermo Fisher Scientific, your molecule comes first. Whether your company is emerging or a giant in the industry, our people are dedicated to identifying the best path forward for your molecule. They are ready to guide you through our flexible, agile and scientifically driven development services from the very early stages of development through late stage trials and beyond. What's more, working with us from the beginning lets you use early development insights to cut time and costs in later development stages.

The people and the capabilities to meet your toughest development challenges.

Every step of the development process brings unique challenges and opportunities. Time, cost, and results are critical. But sacrificing quality is never an option. As a result, we have designed a range of flexible solutions to meet your molecule's unique needs across formulation development, analytical method development, solubility enhancement, manufacturing process development and clinical batch manufacturing.

As important, all our professionals—scientists, engineers, project managers and operators—are committed to a culture of problem solving. Bringing deep scientific insight, real-world development experience and always a “safe pair of hands” to your project. No one has touched more molecules than we have.

CHOOSE FROM A BROAD RANGE OF ORAL SOLID AND STERILE DOSE FORMS TO MEET YOUR UNIQUE NEEDS

Flexibility, speed, expertise, and experience are needed to advance your oral solid and sterile injectable drug products from the preclinical phase to approval. Let us help you transform your discovery into a drug product with the best chance for approval by leveraging:

- Flexible approaches to maximize speed and minimize cost
- Formulation and process development
- Optimization for cost and quality
- Proven technology transfer experience
- Scalability to commercial manufacturing
- Strong regulatory track record

With extensive experience, we understand the unique challenges of developing oral solids and sterile injectables. We offer a broad range of capabilities to address the specific needs of your drug product including:

Sterile Dose Forms

- Small and large volume parenterals
- Liquid filled vials
- Lyophilized vials
- Extensive range of vial sizes including ISO standard
- Pre-filled syringes and cartridges

Oral Solid Dose Forms

- Tablets
- Capsules
- Layered technologies
- Beads/microtablets
- Modified release profiles

SOLVING SOLUBILITY ISSUES BEFORE THEY BECOME PROBLEMS

Over 80% of molecules experience solubility challenges. If not solved early, these issues can derail early phase trials, and lead to higher costs and missed deadlines in later stages. As a result, Thermo Fisher offers broad technological capabilities, including:

- Spray drying
- Lipid formulations
- Hot-melt extrusion
- Coated beads
- Size reduction (e.g. micronization)
- Cyclodextrin complexes

A BREAKTHROUGH IN TAKING THE GUESSWORK AND TIME OUT OF FORMULATION

It's called Quadrant2® and it is a one-of-kind, computational modeling tool. Designed exclusively for Thermo Fisher clients, this innovative program rapidly accelerates early formulation development and cuts the costs of trial and error experimentation.

Quadrant2® analyzes the molecular structure, and physical and chemical characteristics of a compound, and predicts the solubility enhancement technology and excipient combination that are most likely to succeed based on:

- API chemical structure
- Physicochemical properties
- Full-scale molecular modelling based on Quantum and Molecular Dynamic simulations
- Exclusive excipient descriptor database developed by Thermo Fisher

The proposed solubility enhancement technology and excipient combination are confirmed via a cross verification/model validation approach with more than 70 commercially available molecules, and has proven to be over 90% accurate for technology selection and over 80% accurate for excipient selection.

PRE-FORMULATION AND ANALYTIC CAPABILITIES AT A GLANCE

We give you access to a broad, proven range of formulation and analytic capabilities to take your molecule from Pre-clinical to Phase I clinical studies and beyond. Each of our development and manufacturing sites have cGMP labs staffed by highly experienced scientific teams.

Pre-Formulation Capabilities

- Chemical purity analysis
- Physicochemical properties
- Solid form definition and analysis
- Excipient compatibility testing
- Amorphous vs. crystalline solid-state testing
- Aqueous and solvent solubility
- Solution and solid-state stability
- Vehicle screening for ADME and toxicology

Analytical Capabilities

- Physical and chemical definition analysis
- Method development and validation
- Impurity tracking
- In-process production support
- Stability testing for various ICH climatic zones
- Genotox studies
- PAR studies



QUICK-TO-CLINIC™ ACCELERATES THE TIME TO PHASE I CLINICAL TRIALS

In as few as 14 weeks, the Quick-to-Clinic™ program for oral solid dose delivers high-quality Phase I material and the data you need to support your Phase I clinical trials. This program delivers:

- Phase appropriate analytical method development and validation
- Phase appropriate simplest of dosage forms (API in a capsule, tablet or bottle)
- Bulk packaging or simple in-house HDPE bottles
- One-month stability testing
- Product development summary report

GAINING AN EARLY ADVANTAGE AND PREPARING FOR THE FUTURE

Working with Thermo Fisher in early development means taking advantage of a full range of fast, flexible Clinical Batch Manufacturing services. Our years of experience, an industry-leading inspection record and our 95% Right the First Time performance give you confidence that your molecule is prepared for success. In addition, our integrated services position you for the fastest and most efficient path to market in later phases.

Our Clinical Batch Manufacturing Services include:

- cGMP manufacturing at all scales
- Small molecules and biologics
- Oral solid, sterile and softgel dosage options
- Quality by Design (QbD) process development
- Full analytical support and stability testing
- Over-encapsulation and matching placebos
- Materials for dose escalation studies
- Registration batches
- CMC documentation for regulatory submissions

CHOOSE FROM A BROAD RANGE OF STERILE DOSE FORMS TO MEET YOUR UNIQUE NEEDS

Flexibility, speed, expertise, and experience are needed to advance your sterile injectable drug product from the pre-clinical phase to approval. Let us help you transform your discovery into a drug product with the best chance for approval by leveraging:

- Flexible approaches to maximize speed and cost
- Formulation and process development optimization for cost and quality
- Single-use, disposable technology
- Proven technology transfer experience
- Scalability to commercial manufacturing
- Strong regulatory track record

With extensive sterile injectables experience, we understand the unique challenges of sterile injectable development and offer a broad range of capabilities to address the specific needs of your drug product including:

- Small and large volume parenterals
- Liquid filled vials
- Lyophilized vials
- Extensive range of vial sizes including ISO standard
- Pre-filled syringes and cartridges

TECHNOLOGY TRANSFER—THE OPPORTUNITY FOR PROCESS & PRODUCT IMPROVEMENT

While many CDMOs see technology transfer as a complex process that often goes wrong, we see it as a way to capture an advantage. In fact, we believe that when planned for and executed correctly, it can lower manufacturing costs and improve process robustness and efficiency.

THE FINAL PUSH FOR REGULATORY APPROVAL STARTS AT THE BEGINNING

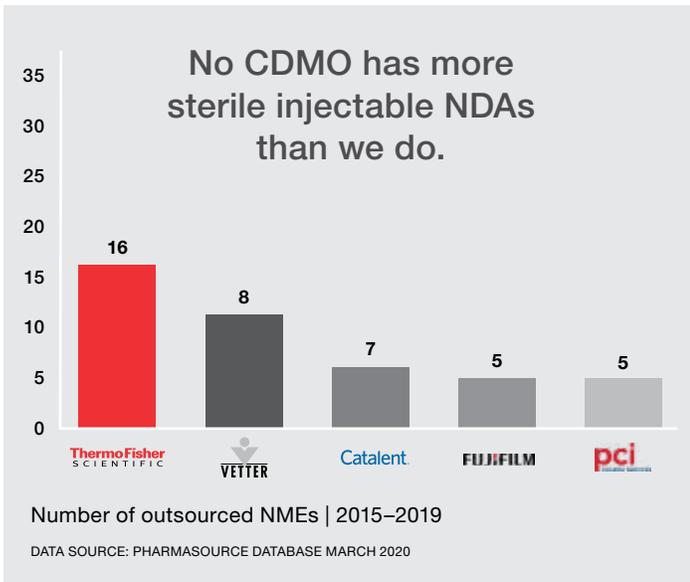
Depth of expertise and resources. Responsiveness and flexibility. Dependable quality. Parallel active pharmaceutical ingredient (API) and finished dose development. Right First Time/On-time reliability.

That’s what our experts bring to your project. And it also explains why from 2015–2019 we helped our clients earn 16 new drug application (NDA) approvals for sterile injectables. More than any other CDMO.

Achieving a fine balance of speed, efficiency and scale at every stage.

The journey from early stage through Phase IIb/III clinical trials and ultimately to commercialization is long, complex, and costly. But there are people who understand your molecule and the road ahead. They know speed is critical, that risk must be managed at every stage, and that each challenge must be overcome before it becomes a problem.

These are the scientists, engineers and professionals of Thermo Fisher Scientific. Who apply a science-driven, risk-based approach to every stage and phase of the development process. Who draw on years of experience. And who partner with you from the earliest stages of formulation development to maximize the potential for early approval success while ensuring your manufacturing processes are scalable all the way to commercialization. Because they believe this is the best way to make certain your discovery lives up to its promise to the patients who need it most.



QUICK TO CARE™ INTEGRATED OFFERING

Integrated drug development and clinical services for new and emerging pharma.

The path through drug development is marked by detours, roadblocks and very few shortcuts. At times you may feel that you're the only person keeping your molecule on its critical path. Unexpected delays can lead to missed milestones, rework and delayed timelines—all setbacks that no one wants to explain to their investors.

Coordination across multiple vendors is extremely complex and requires constant attention. Multiple agreements must be negotiated. Multiple and differing quality procedures have to be reconciled. Getting multiple vendors, some of whom are competitors, to coordinate their activities into a single project can be challenging.

Also, in a multi-vendor scenario, who really “owns” and absorbs your program's risk? Who among your multiple vendors is thinking creatively about ways to mitigate your project's risk across the entire development process?

Give your molecule the best shot at success.

The Quick to Care™ service offering delivers a streamlined drug development program, designed specifically for new and emerging companies. This program combines your drug substance and drug product development, clinical manufacturing, forecasting, demand planning and clinical trial supply chain into a single solution to accelerate your discovery to approval.

Benefits of Patheon Quick to Care™ Integrated Offering include:

- Acceleration of development timelines
- Simplified supply chain
- Reduced risk

Time savings of 14 weeks have been accomplished by having integrated timelines, cross-site collaboration and the elimination of duplicative work. Simplicity is achieved by establishing a streamlined supply chain with a single partner, having combined and integrated proposals, a single MSA, harmonized quality agreements, consolidated invoicing and vendor managed transportation. Reduced risk focuses on having a central focal point and accountability, expertise and experience leveraged across the network and centralized logistics and storage with enhanced liability coverage.

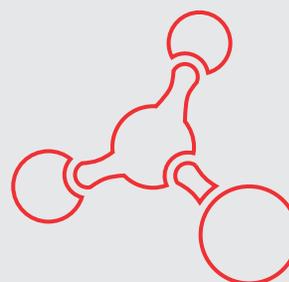
HOW IT WORKS

Comprehensive program management with a single point of contact

Your Quick to Care™ Program Manager is your single point of contact who manages all communication and your molecule's critical path. They create, oversee and actively lead a collaborative Molecule Team of scientific and process experts across drug substance and drug product areas. All quality, safety, technology, and logistics issues flow through the Program Manager. This role was designed specifically for new and emerging pharma companies that run lean.

Assurance of supply means reduced risk

An additional service offered within the Quick to Care™ offering is our end-to-end demand planning which calculates the need for Drug Substance, Drug Product and Clinical Demand. This decreases the risk of stock-out situations which can put development timelines at risk.



14–20 weeks saved from large molecule development

Whether your project is starting at chemical synthesis or formulation, we're ready to bring new molecules into our industry-leading, single-vendor drug development and clinical supply solution. Contact us today and let us show you how our Quick to Care™ service offering can give your molecule the best shot at success.

Holli Carlson
Client Services Director,
Pharma Services,
Mt. Prospect, IL



The drug development landscape has changed. Our commitment to best-in-class clinical trial solutions has not.

Nowhere is this more evident than in clinical supply management. Companies are recognizing the strategic importance of clinical supplies in ensuring drug development risks and costs are well understood and anticipated. Upfront planning has become a critical component in executing a streamlined, efficient and nimble clinical supply chain. As such, clinical supply professionals are playing a more active role in development and study planning, managing mission critical activities, forecasting and mitigating operational risk.

For over 30 years the Thermo Fisher Scientific team has been committed to helping clients of all sizes develop comprehensive clinical supply plans that incorporate the need for flexibility in trial execution with a balanced risk and cost approach. From complete clinical supply plans, to comparator sourcing strategies, distribution strategies and packaging design recommendations, our experts are on hand to meet any of your strategic planning requirements.



Robust Fisher Clinical ServicesSM supply chain solutions to meet your clinical trial needs

PACKAGING DESIGN & PRODUCTION

Keeping the patient in mind is key to identifying the optimal packaging configuration for your trial. Our team of project managers, in combination with our packaging engineers, can assist you in identifying the most suitable packaging for your clinical trial in order to ensure patient safety and compliance.

Services include: Primary, Secondary, Over-encapsulation, Pre-filled syringe, Tamper-evident, Blinding, Climate-controlled (including Cold Rooms)

LABELING

Whether needing to implement an Approved Phrase Library (which has been shown to shorten label cycle times by more than 50 percent) or determining the appropriate label type, text and strategies for your trial, our experienced and dedicated label project management teams can help you build the strategy that will deliver results both long and short term.

Services include: Booklet, Single & Multi Panel, Digital, Alternative Translation & Label Approval System (ATLASSM)

BIOSERVICES

Ensuring a seamless workflow which connects the sponsor, bio-manufacturer, clinical center, and patient into a well-coordinated chain of custody is our specialty. As the leader in managing critical biological material, we provide our customers with customized solutions to store, package, and transport their valuable material.

Services include: Biobanking & Biorepository, Laboratory Processing, Qualification / Validation, Kit Production, Cold Chain Logistics

GLOBAL DISTRIBUTION

Given the ever-expanding global nature of today's clinical trials, sponsors demand and deserve the assurance that their needs will be met regardless of location, and in accordance with a consistent global quality standard. Our 20 purpose-built cGMP/GDP compliant facilities, supported by over 30 partner depots—located across five continents—provide the global presence, information systems and quality standards to provide clients the flexibility, access and assurance needed for their clinical trial.

Services include: Ambient, Refrigerated & Cold Storage, Controlled Substance Storage, GDP Distribution Services to over 150 countries

TOTAL TRANSPORTATION MANAGEMENT

Managing the transportation of life science shipments has become increasingly complex over the years, with patient pools expanding, often to remote locations across the globe. In addition, the growth of biologics creates additional supply chain challenges due to cold chain handling, storage and distribution requirements. Our logistics specialists and teams of in-country experts can simplify the complexity associated with transportation planning and monitoring and, as a result, optimize transportation performance and costs across the supply chain.

Services include: Supplier Qualification, Mode Optimization, Courier Selection & Management, Customs & Regulatory Guidance, Importer of Record, Cold Chain Supplies Management, Dispatch Services, Proactive Track & Trace, Data-Objective Monitoring & Reporting, and Consolidated Billing

COMMERCIAL DRUG SOURCING

Sourcing comparator, rescue medication, or co-medication for clinical trials is not merely a purchasing or procurement exercise. Applying a strategic approach, evaluating every sourcing factor and creating a customized plan with multiple options results in an optimal comparator sourcing strategy.

Services include: Comparator, Co-medication, Rescue medication sourcing

CLINICAL SUPPLY OPTIMIZATION

Leveraging the expertise of a dedicated supply chain team, proprietary technology tools and an extensive cGMP network, we provide proactive guidance in the development of supply strategies, as well as overarching simulation, forecasting and cost management. This team of professionals can assist you in identifying the optimal packaging configuration, establishing and verifying IRT setup, forecasting patient clinical supply requirements by country and identifying the regulatory hurdles you will face based upon your current country selection.

Services include: Forecasting, End-to-End Supply Chain Management, Centralized Project Management, Consolidated Reporting

CLINICAL ANCILLARY MANAGEMENT

It's easy to forget about ancillaries when immersed in the details of a global clinical supply chain. Our dedicated team of clinical ancillary project managers can help you develop a complete ancillary strategy that will ensure your sites are appropriately stocked at time of First Patient In and in accordance with regulatory requirements.

Services include: Sourcing, Inventory Management, Distribution, Ancillary Returns Management

QUALIFIED PERSON SERVICES

For strategic planning purposes, our team of QPs are available to provide advice on your expiry strategy, including the most current conditions required by regulatory authorities.

Services include: Regulatory Oversight, Compliance Guidance

A black and white portrait of Marcus Roberts, a Black man with a goatee, smiling and standing with his arms crossed. He is wearing a dark zip-up sweater over a light-colored checkered shirt. The background features a stylized world map with a light gray color scheme.

Marcus Roberts
Senior Manager, Quality,
Pharma Services
Memphis, TN

Partner with our team of logistics experts to take on your toughest challenges.

When storing and transporting pharmaceutical products and materials there are significant, non-negotiable requirements: temperature management to protect product integrity, mandated licenses and certifications, systems and processes that conform to regulatory guidelines, and end-to-end security of the supply chain.

For over 30 years, we have provided industry-leading logistics services with impeccable quality standards to satisfy and protect our clients and the patients they serve. We help our customers deliver a risk controlled and efficient supply chain between development and manufacturing sites, clinical investigators and patients worldwide. Given this extensive background in managing pharmaceutical products, our clients trust us to execute clinical trial and commercial product deliveries on time, every time. We find the most cost-effective option to ensure product integrity, regulatory compliance and shipment security while maintaining impeccable end-to-end quality standards.

Specialized logistics services to make your most complex supply demands more efficient.

SPECIALTY WAREHOUSING

Whether storing bulk API, commercial drug marketing samples or specialized trade product, our GMP/GDP-compliant Distribution Centers are specifically designed to meet the demanding needs of today's pharmaceutical companies.

We ensure optimal quality and capacity by employing advanced automation, including pick-to-light / put-to-light systems and RF technology. We have made significant investments in support of the increased demand for cold chain services by expanding our refrigerated/frozen storage and providing zero Time Out of Environment (TOE) pick and pack solutions. Our continued investment in cold chain storage and distribution mirrors the industry's evolution towards complex cold chain therapies.



Our distribution centers are highly secure and fully climate controlled, featuring:

- A validated Warehouse Management System
- cGMP, GDP, PDMA and Drug Supply Chain Security Act (DSCSA) compliant processes
- Licensed per 21 CFR 205.4, 205.5 and 205.6 to distribute prescription drug products
- Wholesale distribution licenses to all 50 US states
- DEA Class III – V, TSA and VAWD certification
- Designated areas for quarantined/high-level security storage
- Managed environments for ambient (15°C to 30°C), refrigerated (2°C to 8°C) and frozen (-25°C to -10°C) storage

Services include: Comprehensive Environment & Security Management, Validated Warehouse Management System, Ambient through Frozen Storage, Zero Time Out of Environment Cold Chain Pick & Pack and Designated Secured Areas for Quarantined & Controlled Substance Storage

COMMERCIAL DRUG MARKETING SAMPLE PROGRAMS

For over 30 years, life science companies have partnered with us for commercial sample distribution because of our logistics expertise and unmatched track record of delivery to representatives in the field or directly to healthcare practitioners.

We are the industry leader for the delivery of samples, managing the largest sample-send programs in North America. We facilitate over 8,500 daily life science shipments, including DEA controlled substances and cold chain product. We have managed over 3 million annual direct-to-practitioner shipments with over 53 million individual product units picked. Our track record includes a pick accuracy over 99.9%, 99%+ on-time service and 99% of shipments delivered without damage or loss.

Services include: Sample Request Processing, Order Management, Fulfillment & Distribution Services, Transportation Management including Appointment-Based Deliveries, Proactive Track & Trace for Cold Chain Shipments, Acknowledgement of Contents and Signature Verification Services and Returns Management.

GLOBAL TRANSPORTATION SOLUTIONS

Pharmaceutical companies require that their life science shipments be transported with the highest possible security while ensuring product integrity. We leverage a global network of quality-vetted providers to deliver specialty logistics solutions that effectively leverage available resources of air, ocean and surface transportation. Our GDP-compliant services span the entire product development life cycle, from bulk active pharmaceutical ingredients and clinical trials materials, to product commercialization samples and finished goods.

We provide a consultative solution design focused on defining client and situation-specific needs, driving cost savings and reducing time-in-transit. We provide a cost-effective service through the flexibility of our offerings and by leveraging corporate resources and carrier/supplier agreements. Industry certifications include:

- GDP Certified
- C-TPAT Certified
- IATA Accredited Cargo Agent
- TSA-certified Indirect Air Carrier
- US DOT Registered Hazmat Carrier
- World Cargo Alliance (WCA) First Member & Pharma Member

Services include: Air, Ocean, Ground and Parcel, Ambient through Ultra-Cold Temperature Management (15°C to 25°C, 2°C to 8°C, -20°C, -80°C and LN2), On-Line Status Visibility Including GPS Tracking, 24/7/365 Support and Quality-Vetted Life Science Specific Provider Network



Jessica Morin
Portfolio Services Manager,
Pharma Services,
Whitby, Ontario

Jigal Shah
Business Manager,
Pharma Services,
Whitby, Ontario

Our experience and expertise can make your most complex discoveries a commercial reality.

Your molecule has proven itself, cleared innumerable hurdles and now it's time to introduce it to the world. This is no time to take risks. First and foremost, Thermo Fisher Scientific offers you a trusted partnership. People, facilities and processes that have built a reputation for quality and innovation for over 40 years.

These are the people who deliver more than 75% of all dosage forms. Who are focused on the client experience—delivering on time and Right-The-First-Time.

INNOVATIVE CAPABILITIES FROM BUSINESS MODELS TO MANUFACTURING TECHNOLOGY

Thermo Fisher puts you on the frontier of new technologies and business models which include offerings such as continuous manufacturing and condominium manufacturing suites. And we provide a smooth transition from early development all the way to commercialization and product lifecycle management.

ORAL SOLIDS

We provide access to a wide range of conventional and specialized oral solid dosage form capabilities and scale. Further expand your options with innovative combinations of these forms and a variety of controlled-release technologies. All these choices are executed with expansive scientific resources, expertise in complex formulations such as solubility enhancement and capabilities for highly potent compounds and controlled substances.

SOFTGELS

Discover the many clinical and technical advantages of softgels with a host of patent-protected specialized technologies. These include advanced solutions for enhancing solubility and bioavailability, as well as unique controlled-release and oral delivery technologies. Our experience covers both development of prescription (Rx) products and ideation sessions to ensure brand sustainability for over-the-counter (OTC) products. Create a product that stands out in the marketplace with a broad palette of shapes, sizes and colors.

STERILE INJECTABLES

Gain access to extensive pharmaceutical development and manufacturing capabilities at all scales. We offer specialized expertise in formulation development, lyophilization, cycle development, process development and scale-up. We provide a broad range of equipment that easily scales from small quantities for early development clinical trials and small-volume commercial products, to large-volume clinical trial material and commercial products. Options include disposable (single-use) manufacturing technologies as well as traditional stainless steel equipment are available. You'll also have access to state-of-the-art, cGMP manufacturing capabilities for prefilled syringes and cartridges.

COMMERCIAL PACKAGING

Collaborate with one end-to-end supply chain provider from manufacturing to clinical through commercial. We have packaging lines throughout our global network, with the flexibility to support small or large volumes. Our experience and expertise adds value throughout the packaging life cycle. Our broad capabilities include bottle, blister, sachet, vial, ampoule, syringe and kit assembly.



SPECIALIZED ORAL SOLIDS

	Bilayer Tablets	2 IRs or IR+CR/SR fixed-dose combination.
	Trilayer Tablets	3 IRs or IR+placebo+CR/SR fixed-dose combination.
	Microtablets	IR or CR/SR, low-dose tablets; via device, capsule or sachet.
	Tablets in Capsules	IR or CR/SR, over-encapsulation for blinded clinical supply.
	Chewable Tablets	IR or CR/SR, single or bilayer fixed-dose combinations. Ideal for pediatrics and high-dose compounds.
	Fast-Dispersible Tablets	IR, disintegrates/disperses as suspension in water, divisible into 4 parts for titration. Ideal for pediatrics.
	Sublingual Tablets	IR, single-layer tablets for sublingual administration.
	Beads in Hard-Shell Capsules	IRs and/or CRs/SRs fixed-dose combination, uncoated or polymer coated; extrusion, spheronization or drug layering.
	Liquid-Filled Capsules	IR or CR/SR, hard shell, options to improve solubility, bioavailability and absorption. Ideal for Phase I and beyond.
	Laser-Drilled Controlled-Release Tablets	CR/SR, osmotic, zero-order, controlled-release over a defined time period.
	Hydrophilic Gel Matrix	Controlled-release technology.
	Polymer Matrix	Controlled-release technology.
	Wax Matrix	Controlled-release technology.
	Pulsatile Release	Controlled-release technology.
	Polymer Coating	Controlled-release technology.
	Tablets	IR or CR/SR, single-layer tablets, coated or uncoated, with or without break line or embossing, range of shapes and sizes.
	Powder-Filled Capsules	IR, two-piece gelatin or HPMC capsules in a range of sizes and multiple color combinations.
	Powders, Granules, Coated Beads and Multiparticulates	IR, packaged in bottles and sachets of varying dimensions and fill weights.

CONVENTIONAL ORAL SOLIDS

STERILE INJECTABLES

	Liquid-Filled Vials	<ul style="list-style-type: none"> • Aseptic Filling, Terminal Sterilization when required. • Extensive range of vial sizes, including ISO standards. • Batch sizes to meet product demand. • Disposable (single-use system) manufacturing options. • Glass or polymeric vials available.
	Lyophilized Vials	<ul style="list-style-type: none"> • World-class scientific expertise to develop and optimize lyophilization cycles. • Disposable (single-use system) manufacturing options. • Extensive range of vial sizes, including ISO standards. • 800 m²+ of global lyo capacity.
	Prefilled Syringes and Cartridges	<ul style="list-style-type: none"> • Aseptic Filling, Terminal Sterilization when required. • Broad range of sizes and configurations. • Disposable (single-use system) manufacturing options. • Small and large batch sizes available. • Glass or polymeric options available.
	Sterile Injectables Clinical Services	<ul style="list-style-type: none"> • PFS plunger and backstop assembly. • Needle safety device assembly. • Auto-injector assembly. • PFS and reference material blinding.
	Biologic and Sensitive Molecules	<ul style="list-style-type: none"> • Peristaltic pumps. • Cold chain storage and distribution. • Assembly, packaging, and labeling at 2°C - 8°C. • Filling under nitrogen.

STERILE DOSAGE FORMS COMMERCIAL AND DEVELOPMENT

	GREENVILLE, NC, USA	FERENTINO, ITALY	MONZA, ITALY	GREENVILLE, NC, USA	FERENTINO, ITALY	MONZA, ITALY
	Development			Commercial		
Liquid Vials	2 ml – 20 ml	2 ml – 100 ml	2 ml – 100 ml	2 ml – 65 ml	2 ml – 500 ml	2 ml – 100 ml
Lyophilized Vials	2 ml – 20 ml	2 ml – 20 ml	2 ml – 100 ml	2 ml – 65 ml	2 ml – 25 ml	2 ml – 100 ml
PFS / Cartridges	0.5 ml – 20 ml		0.5 ml – 20 ml	0.5 ml – 20 ml		0.5 ml – 20 ml

1. ISO and Non-ISO vials can be accommodated.
2. Additional vial sizes available and can be shared by a Thermo Fisher representative.
3. Development scale manufacturing capabilities suitable for clinical trial material manufacturing.
4. Disposable (single-use system) manufacturing options available.
5. New capabilities are continually being added. A detailed list of current capabilities can be made available on request.

GMP LYOPHILIZATION CAPABILITIES

	GREENVILLE, USA		FERENTINO, ITALY		MONZA, ITALY	
	Development	Commercial	Development	Commercial	Development	Commercial
	1 x 2 m ² 2 x 7 m ²	1 x 25 m ² 5 x 28 m ² 2 x 30 m ² 1 x 60 m ²	2 x 7 m ²	1 x 10 m ² 2 x 20 m ² 1 x 33 m ² 1 x 42 m ²	2 x 7 m ²	2 x 29 m ² 2 x 33 m ² 2 x 37 m ² 4 x 40 m ²
Total	16 m²	285 m²	14 m²	125 m²	14 m²	358 m²

SOFTGELS

	Softgel Capsules	<ul style="list-style-type: none"> • Immediate-release soft gelatin capsules. • Clinical development scale production. • 13.7B capsule commercial manufacturing capacity. • Extensive range of sizes, colors and imprinting options.
	Soflet® Gelcaps	<ul style="list-style-type: none"> • Patented technology enrobes tablets. • Broad array of color and imprinting choices. • Safely encases highly potent compounds. • Perfect for clinical trial blinding.
	EnteriCare® Enteric Softgels	<ul style="list-style-type: none"> • Enteric properties are integrated into the gelatin shell. • Reduces risk of reflux and gastric irritation. • Protects acid-labile compounds. • Compatible with SMEDDS, hydrophilic and viscous fills.
	Chewels® Chewable Gels	<ul style="list-style-type: none"> • Chewable for patient comfort and convenience. • Rapid onset of action and relief of symptoms. • Ideal for pediatric and geriatric markets. • Patented technology. • Available in lozenge form.
	Twist-Off Softgels	<ul style="list-style-type: none"> • Precise unit dosing for oral liquid and topical products. • Hermetic seal helps preserve API. • Portable convenience improves patient compliance. • Consistent dosing for reliable results in clinical trials.
	Versatrol™ Controlled-Release Softgels	<ul style="list-style-type: none"> • Unique matrix system to fine-tune release. • Controlled-release capabilities integrated into fill. • Lipophilic and hydrophilic formulations. • Suitable for compounds with low solubility.
	Solvatrol™ Enhanced Solubility Softgels	<ul style="list-style-type: none"> • Enhances solubility and bioavailability. • Lipophilic and hydrophilic formulations. • Provides a stable solvent delivery system. • Reduces plasma level variability.
	LiquiSoft™ Chewable Liquid-Filled Softgels	<ul style="list-style-type: none"> • Solid dose for oral liquid formulations. • Soft, chewable shell with a pleasant burst of liquid. • Enhances performance of poorly soluble compounds. • Flavors and aromas mask unpleasant tastes and odors.

SOFTGEL SHAPES AND SIZES

		CAPSULES		REQUIRED CONTAINER SIZE (CC) BY FILL COUNT			
		Size	Fill Volume Range (CC)	60 Count	100 Count	250 Count	500 Count
OVAL	2	0.089-0.111	60	60	75	150	
	3	0.182-0.228	60	75	120	200	
	4	0.209-0.261	60	100	150	250	
	5	0.312-0.389	75	100	150	300	
	6	0.318-0.397	75	100	150	400	
	7.5	0.386-0.482	75	100	225	400	
	9	0.469-0.586	100	120	300	600	
	10	0.567-0.709	100	120	300	600	
OBLONG	3	0.181-0.227	75	75	200	350	
	4	0.243-0.304	100	120	250	400	
	5	0.285-0.356	100	120	300	750	
	6	0.338-0.422	100	120	400	750	
	8	0.452-0.564	120	200	500	950	
	14	0.863-1.079	200	300	750	1250	
ROUND	2	0.073-0.123	60	60	75	150	
	3	0.138-0.183	60	75	120	200	
	4	0.173-0.244	60	100	150	250	
	5	0.195-0.305	75	100	150	300	
	6	0.279-0.367	75	100	150	400	
	7	0.305-0.428	75	100	225	400	
	15	0.737-0.922	150	225	500	750	

Other shapes and sizes available. Formulation can affect options.

A WORLD OF DOSAGE FORMS

		NORTH AMERICA							EUROPE					
		Bend, USA	Cincinnati, USA	High Point, USA	Greenville, USA	Toronto, Canada	Whitby, Canada	Manati, Puerto Rico	Bourgoin, France	Monza, Italy	Ferentino, Italy	Milton, Park, U.K.	Swindon*, U.K.	Tilburg, Netherlands
ORAL SOLID DOSAGE FORMS														
SPECIALIZED	Bilayer Tablets		•		•	•	•		•					
	Trilayer Tablets		•				•							
	Microtablets	•	•			•			•			•		
	Beads in Capsules	•	•		•				•			•		
	Coated Beads	•	•		•	•						•		
	Tablets in Capsules	•	•			•	•		•			•		
	Fast-Dispersible Tablets	•	•			•	•	•	•			•		
	Laser-Drilled Controlled-Release Tablets		•											
	Liquid-Filled Capsules	•	•			•						•		
	Biphasic Liquid-Filled Capsules		•			•								
	Bilayer Chewable Tablets		•		•	•	•							
	Beads in Liquid-Filled Capsules	•	•											
	Hydrophilic Gel Matrix	•	•			•	•	•	•			•		
	Polymer Matrix		•		•	•	•	•						
	Wax Matrix				•	•								
	Pulsatile Release	•	•			•	•					•		
	Polymer Coating	•	•		•	•	•			•		•		
Sublingual Tablets	•	•		•	•	•			•		•			
CONVENTIONAL	Uncoated	•	•		•	•	•	•	•			•		
	Coated	•	•		•	•	•	•	•			•		
	Powder-Filled Capsules	•	•		•	•	•	•	•			•		
	Powders and Granules	•	•		•	•	•	•	•			•		
	Multiparticulates	•	•		•							•		
	Spray Drying**	•										•		
SOFTGELS	Softgel Capsules			•										•
	Twist-Off Softgels			•										•
	EnteriCare® Enteric Softgels			•										•
	LiquiSoft™ Chewable Liquid-Filled Softgels			•										•
	Versatrol™ Controlled-Release Softgels			•										•
	Solvatrol™ Enhanced Solubility Softgels			•										•
	Soflet® Gelcaps			•										•
	Chewels® Chewable Gels			•										•
STERILE DOSAGE FORMS														
Liquid-Filled Vials				•					•	•				
Lyophilized Vials				•					•	•				
Prefilled Syringes				•					•					
Prefilled Cartridges				•					•					

* Our Swindon site is a Condominium site that builds customized facilities to meet client needs for a variety of dosage forms.
 ** Commercial capabilities in Florence, SC



PHARMA SERVICES

PACKAGING CAPABILITIES

	NORTH AMERICA						EUROPE			
	Allentown, PA, USA	Cincinnati, OH, USA	Greenville, NC, USA	Toronto, ON, Canada	Whitby, ON, Canada	Manati, Puerto Rico	Bourgoin, France	Monza, Italy	Ferentino, Italy	Horsham, UK
ORAL SOLID DOSAGE FORMS										
Blister	•	•	•	•	•		•			•
Bottle		•	•	•	•	•	•			
Blister Carton Wallet	•									•
Pouch / Sachet			•		•		•			
Powder in Bottle				•		•				
Liquids in Bottle		•			•					
KIT ASSEMBLY	•									•
STERILES										
Pre-filled Syringe Assembly	•		•					•		•
Syringe Labeling & Packaging	•									
Vial / Ampoule Labeling and Packaging	•		•					•	•	•
AUTO-INJECTOR										
Assembly & Packaging	•									•
SERIALIZATION	•	•	•	•	•	•	•	•	•	•

PROCESS VALIDATION—ENSURING A RELIABLE COMMERCIAL SUPPLY

To help your discovery reach the patients who need it most, on time, we deliver complete process validation in accordance with regulatory and cGMP guidelines, including:

- Process validation with critical parameters
- Validation of analytical assays
- Hold time studies
- Stability studies at required ICH conditions
- Container shipment studies
- Release testing
- CMC documentation in CTD format

LIFE CYCLE MANAGEMENT—EXTENDING THE POTENTIAL OF YOUR PRODUCT

Make the most of your investment by maximizing your existing product's lifespan and reach. With the experience of more than 50 successful life cycle management projects, we can quickly and cost-effectively help you achieve your goals.

- **Enhance Clinical Benefits:** Modified release technologies to improve patient compliance and clinical benefits
- **Reformulate:** A new dose form or strength to unlock new markets and indications
- **Synergistic Combinations:** Combine your API with other drugs to simplify patient compliance or address unmet clinical needs

Unlike other CDMOs that tie you to a limited number of solutions and services, Thermo Fisher gives you access to a broad range of dosage forms, formulation methods and specialized technologies to create a successful new product while extending your exclusivity.

CONTINUOUS MANUFACTURING—THE NONSTOP ROUTE TO LOWER COSTS AND HIGHER QUALITY

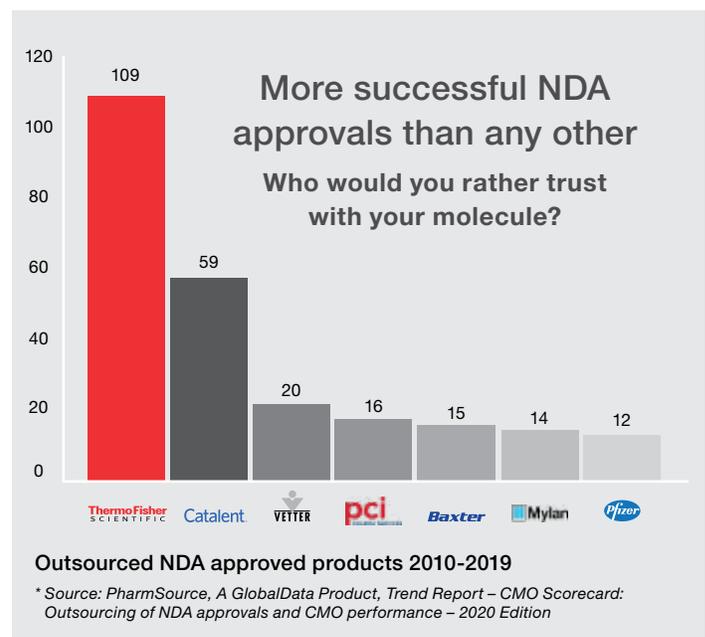
Today, Thermo Fisher Scientific is revolutionizing how OSD medicines are made through continuous manufacturing. In this process, the raw materials are fed into the process train and the final product is produced continuously without interruption via an integrated series of unit operations. Our modular

designed, nonstop, fully integrated process is not restricted to batch size and offers a range of advantages, including:

- Maximum flexibility to meet unique client product and capacity needs
- Real-time monitoring and adjustment to maximize process control, producing consistent and high quality products, and minimizing batch rejections
- Removing the need for scale up studies and lowering the costs of product development
- Smaller facility footprint compared to conventional batch processing equipment

Dosage forms tailored for your molecule and your patients.

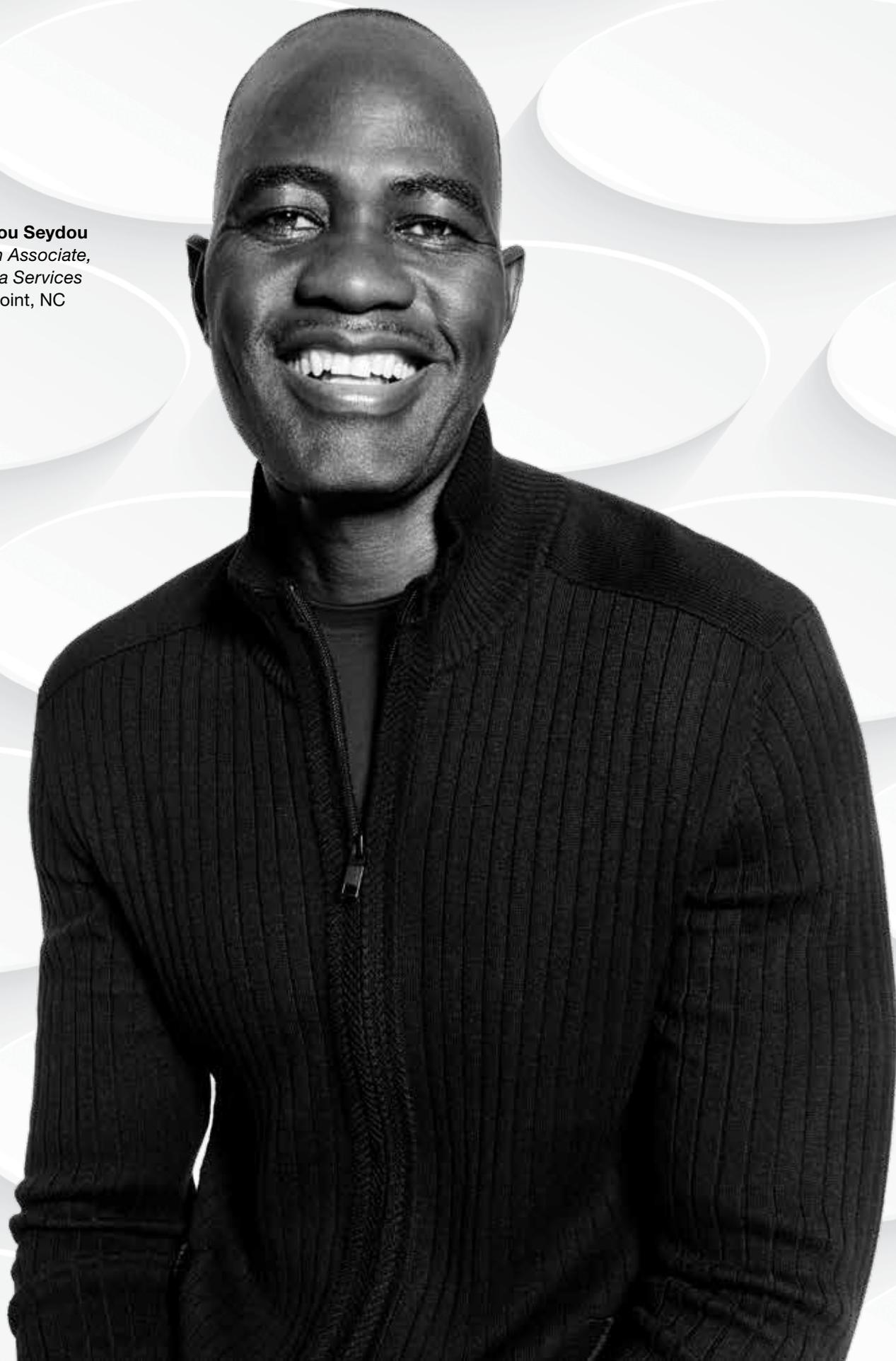
Access to comprehensive dosage forms. A reputation built on 40 years of experience. More NDA approvals than the next three leading CMOs combined. A seamless path from early development and scale-up of even the most complex molecules to commercialization. Innovative business models and technology from condominium manufacturing suites to continuous manufacturing. The right form for every patient.





Isabelle Lafosse
*Director, Global Technology
Transfer, Pharma Services,
Cincinnati, OH*

Adamou Seydou
Gelatin Associate,
Pharma Services
High Point, NC



SOFTGEL TECHNOLOGIES FOR RX AND OTC

Innovative softgel technologies that maximize your market potential: Where ideation and expertise come together.

Softgel technologies are becoming an increasingly popular dosage form in both the Rx and OTC markets. With decades of experience and capabilities spanning development through commercialization, our softgel experts understand what it takes to maximize the potential of your product in either market. From our scientists who are skilled in developing softgel formulations in early development to overcome low solubility challenges, to our manufacturing operators who are relentless about making the manufacturing process more efficient, you can count on our team to help your project achieve success through ideation and partnership.

Your flexible partner from development to commercial.

Thermo Fisher Scientific offers development and manufacturing capabilities for specialized products including highly potent drugs, hormones, DEA-controlled substances (schedule I-III) and abuse-deterrent products.

And when existing Rx products need new revenue streams, product and brand managers can tap into our softgel expertise and proprietary technologies for new softgel product formulations. We offer cost-effective and flexible business models ranging from fee for service, to licensing of existing products and co-development of proofs of concepts.

Thermo Fisher brings value to pharmaceutical and consumer health care companies through ideation sessions and flexible business models that can:

- Develop product proof of concept to confirm market interest
- Provide innovation for product lifecycle management
- Provide solutions for Rx, OTC and tablet to softgel switches
- Enhance bioavailability to obtain quicker onset of action
- Provide formulation options for specific patient populations including pediatrics and geriatrics



Access a range of proprietary technologies with proven market success.

Chewels®



Chewels® chewable gels are approved for pharmaceutical use and are ideal for pediatric and geriatric populations. They are also well suited for people who find swallowing difficult and are looking for a convenient dosage form for administration. The chewable gels have a soft texture and can be chewed within a minute. No water is needed. The technology provides an opportunity for taste masking, adding another element to patient acceptance and compliance.

LiquiSoft™



LiquiSoft™ softgels are particularly suitable for liquid fills that require a fast onset of action and/or buccal absorption. The technology enhances the performance of poorly soluble compounds and is an accurate, convenient dosage option for oral liquids. LiquiSoft softgels come in a variety of flavors that mask bad tastes and odors, adding to patient appeal.

Sofgel®



Sofgels® technology is suitable for liquid formulations, applications requiring faster onset of action, low-dose products and those with poor bioavailability that would benefit from a lipid system. These capsules are easy to swallow, and twist-off options are available.

Soflet® Gelcap



Soflet technology is an excellent choice to safely encase highly potent compounds and is particularly suitable for clinical trial blinding. A broad palette of colors and imprinting choices are available.

EnteriCare®



With the **EnteriCare®** patented technology, the enteric properties are integrated into the gelatin shell, not a coating. The result is an elegant, clear capsule that targets delivery to the small intestine, reducing risks of reflux, gastric irritation, and transformation of acid-labile compounds. EnteriCare enteric softgels allow for the delayed release of your compound with the clear-dosage form consumers prefer.¹

Ask your Thermo Fisher representative about our portfolio of products and technologies available for out licensing.

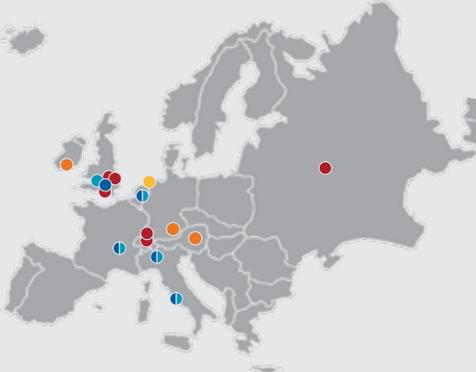
¹ Quantify Consumer Perceptions and Preferences Relative to Oral Product Dosage Forms in OTC Pharmaceutical and Nutritional.

GLOBAL SITE NETWORK

North America



Europe



Asia



South America



Africa



Australia



A FULLY INTEGRATED GLOBAL NETWORK



- API
- Biologics
- Viral Vector
- Development
- Clinical Trial Solutions
- Commercial Manufacturing
- Specialty Warehousing

	API	Biologics	Viral Vector	Development	Clinical Trial Solutions	Commercial Manufacturing	Specialty Warehousing
Ahmedabad, India					•		
Alachua, Florida, USA			•				
Allentown, Pennsylvania, USA					•		
Basel, Switzerland					•		
Beijing, China					•		
Bend, Oregon, USA				•			
Bishop's Stortford, United Kingdom					•		
Bogota, Columbia					•		
Bohemia, New York, USA					•		
Bourgoin, France				•		•	
Brisbane, Australia		•					
Buenos Aires, Argentina					•		
Cambridge, Massachusetts, USA			•				
Cincinnati, Ohio, USA				•		•	
Cork, Ireland	•						
Ferentino, Italy				•		•	
Florence, South Carolina (East), USA	•						
Florence, South Carolina (West), USA	•						
Franklin, Massachusetts, USA					•		
Frederick, Maryland, USA					•		
Greenville, North Carolina, USA				•		•	
Greenville, South Carolina, USA	•						
Groningen, Netherlands		•					
High Point, North Carolina, USA				•		•	
Horsham, United Kingdom					•		
Indianapolis, Indiana, USA					•		
Lexington, Massachusetts, USA			•				
Lima, Peru					•		
Linz, Austria	•						
Manati, Puerto Rico						•	
Memphis, Tennessee, USA							•
Mexico City, Mexico					•		
Milton Park, United Kingdom				•			
Monza, Italy				•		•	
Moscow, Russia					•		
Mt. Prospect, Illinois, USA					•		
Plainfield, Massachusetts, USA*			•				
Pretoria, South Africa					•		
Princeton, New Jersey, USA		•					
Regensburg, Germany	•						
Rheinfelden, Germany*					•		
Rockville, Maryland, USA					•		
Santiago, Chile					•		
Sao Paulo, Brazil					•		
Seoul, South Korea					•		
Singapore					•		
Somerville, Massachusetts, USA			•				
St. Louis, Missouri, USA		•					
Stevenage, United Kingdom					•		
Suzhou, China					•		
Swedesboro, New Jersey, USA							•
Swindon, United Kingdom						•	
Tilburg, Netherlands				•		•	
Tokyo, Japan					•		
Toronto, Ontario, Canada				•		•	
Vacaville, California, USA					•		
Weil am Rhein, Germany					•		
Whitby, Ontario, Canada				•		•	

*Opening soon

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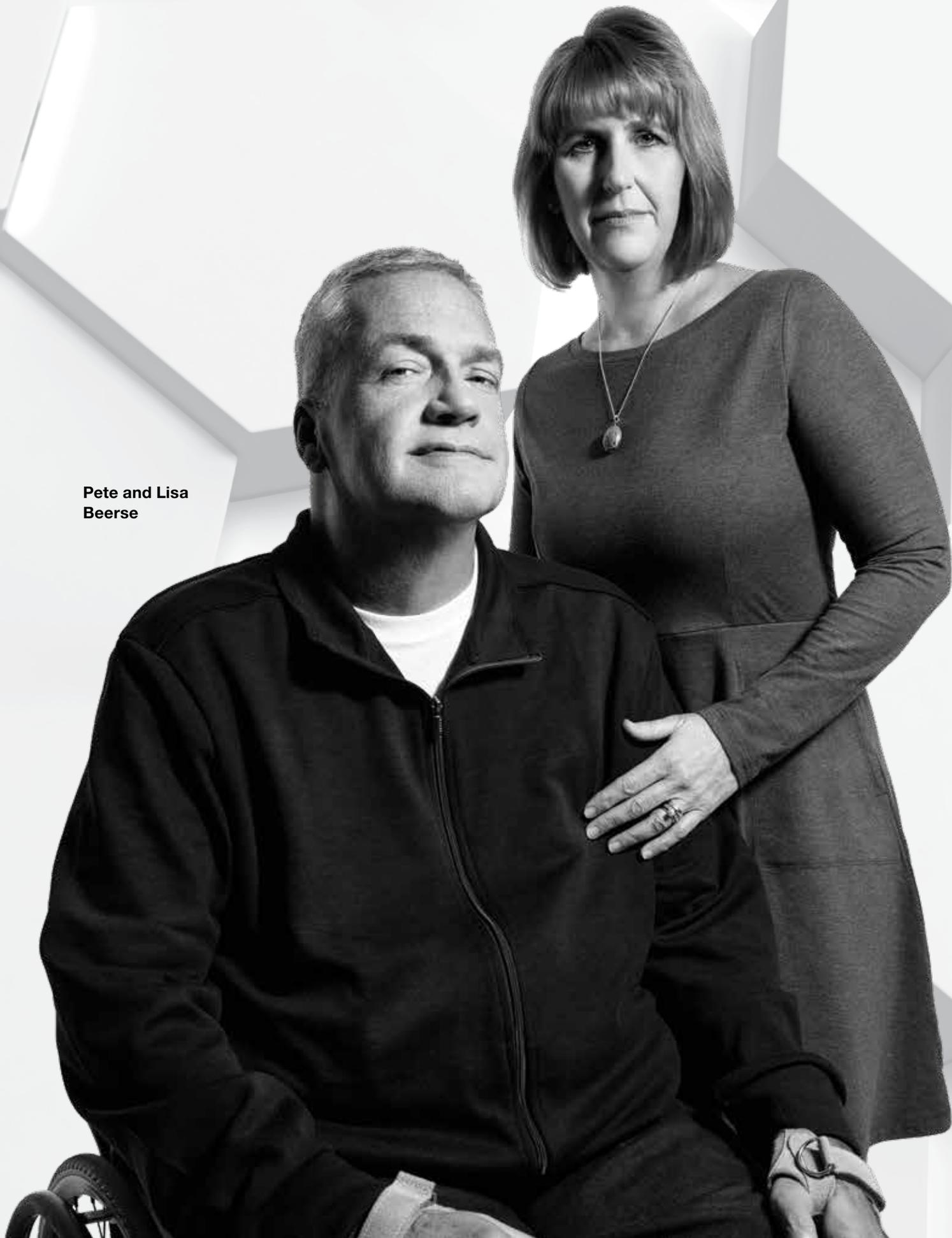
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**Pete and Lisa
Beerse**



MADE FOR

TRIALS & TRIUMPHS

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 came 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."

Find out more at thermofisher.com/patheon

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