
ThermoFisher
SCIENTIFIC
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
patheon

Mike Pearson
Staff Program Manager,
Pharma Services
Bend, OR

HOW LEVERAGING A GLOBAL NETWORK DELIVERED BIG RESULTS.

Mike's team in Bend, OR was only supposed to optimize the spray drying process for a particular medication while another, much larger, facility would handle the large-scale manufacturing. However, the other facility's equipment wouldn't be available in time to meet the client's aggressive IND filing schedule. It was time to leverage the power of the Thermo Fisher Scientific global network and Quick to Care™ program to offer the client their best chance for success. Through incredible effort and intensely coordinated activities, the team in Bend delivered nearly two orders of magnitude more material than typical projects before transferring the product to other Thermo Fisher sites to test, fill, and deliver to patients. Despite the change in plans, the right team stepped in to ensure all deadlines were met, and the client got a critical medicine to the patients who needed it most.

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 Services℠. With other recent acquisitions and continued expansions to provide end-to-end solutions, 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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Emily Anderson, PhD
Analytical R&D,
Pharma Services
Florence, SC

Jessica Floyd
QC Lab Supervisor,
Pharma Services
Florence, SC

HOW, IN A CULTURE OF KNOWLEDGE SHARING, A MENTOR PAVED THE WAY TO SUCCESS FOR THEIR MENTEE.

At Thermo Fisher Scientific, we believe that knowledge belongs to everyone. So, years ago, when Emily worked with her intern, Jessica, in the analytical department, she taught her all she could, as freely as possible. Today, Jessica leads her own team in quality control. Because of her past experience, she is uniquely qualified to identify issues that might have otherwise been missed and everyone benefits. This unique culture of knowledge sharing is a big part of how we get medicine into the hands of patients faster.

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 tech-nologies that can reduce timelines from years to months. You'll have access to interdisciplinary route scouting expertise, chemo-catalysis and biocatalysis, proprietary bio-catalytic 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

In as little as 14 weeks from receiving your API, you can have your Phase I product manufactured, labeled, packaged and delivered to the clinic with Quick to Clinic™ small molecule. That's up to 1 month faster than most standard timelines.

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, PhD
Manager, Cell Culture Development, Pharma Services
Princeton, NJ

HOW A SMALL STARTUP WAS ABLE TO SCALE UP, WITHOUT LOSING THEIR PRECIOUS MATERIAL.

Jeff faced a dilemma: how to complete a large biomanufacturing scale up with the very small amount of material his client gave him. And the stakes were high. His client had spent a lot of time and money developing this potentially revolutionary Alzheimer's treatment. Any wasted material would put the execution of the clinical trial at risk, and possibly risk the future of the entire program. Jeff knew the process needed to be perfect. So, his team worked tirelessly to find ways to improve the cell culture performance. They examined key process parameters and even completed additional work in the process development laboratory to ensure success. The result was a flawless scale up and, most importantly, a potentially breakthrough drug was able to get into the clinic.

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

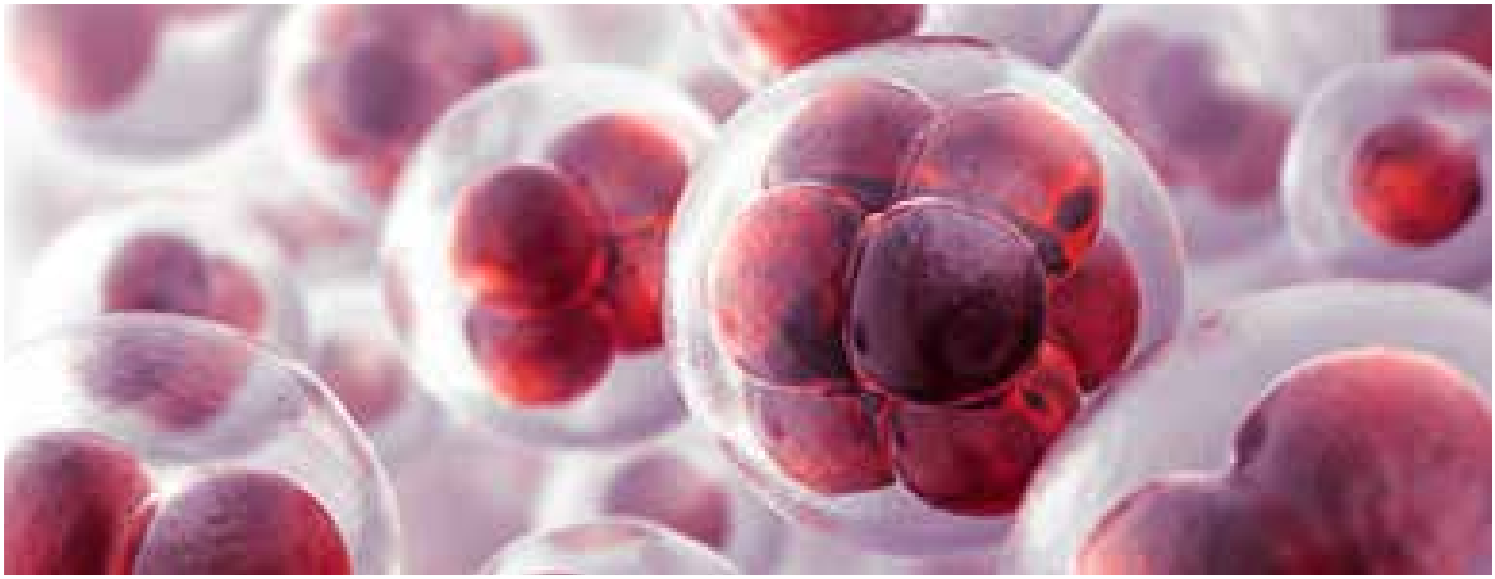
We pride ourselves on our ability to create flexible options for our clients. We understand the uncertainty associated with forecasting demand. We think strategically to offer bio-manufacturing options that meet the unique needs of your molecule, and can work with your cell lines. Our contracts are individualized 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™ BIOLOGICS HELPS YOU BALANCE SPEED, RISK, AND FUTURE NEEDS DURING EARLY DEVELOPMENT

The pressure to file an IND makes accelerated Phase I safety testing a priority. With the Quick to Clinic™ biologics program, Thermo Fisher Scientific can deliver your large molecule released drug substance and drug product for First-in-Human studies in as little as 13 months. Now you can meet important mile-stones 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) meth-odology 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 Asia-Pacific, 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 North America, Europe, and Asia-Pacific 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

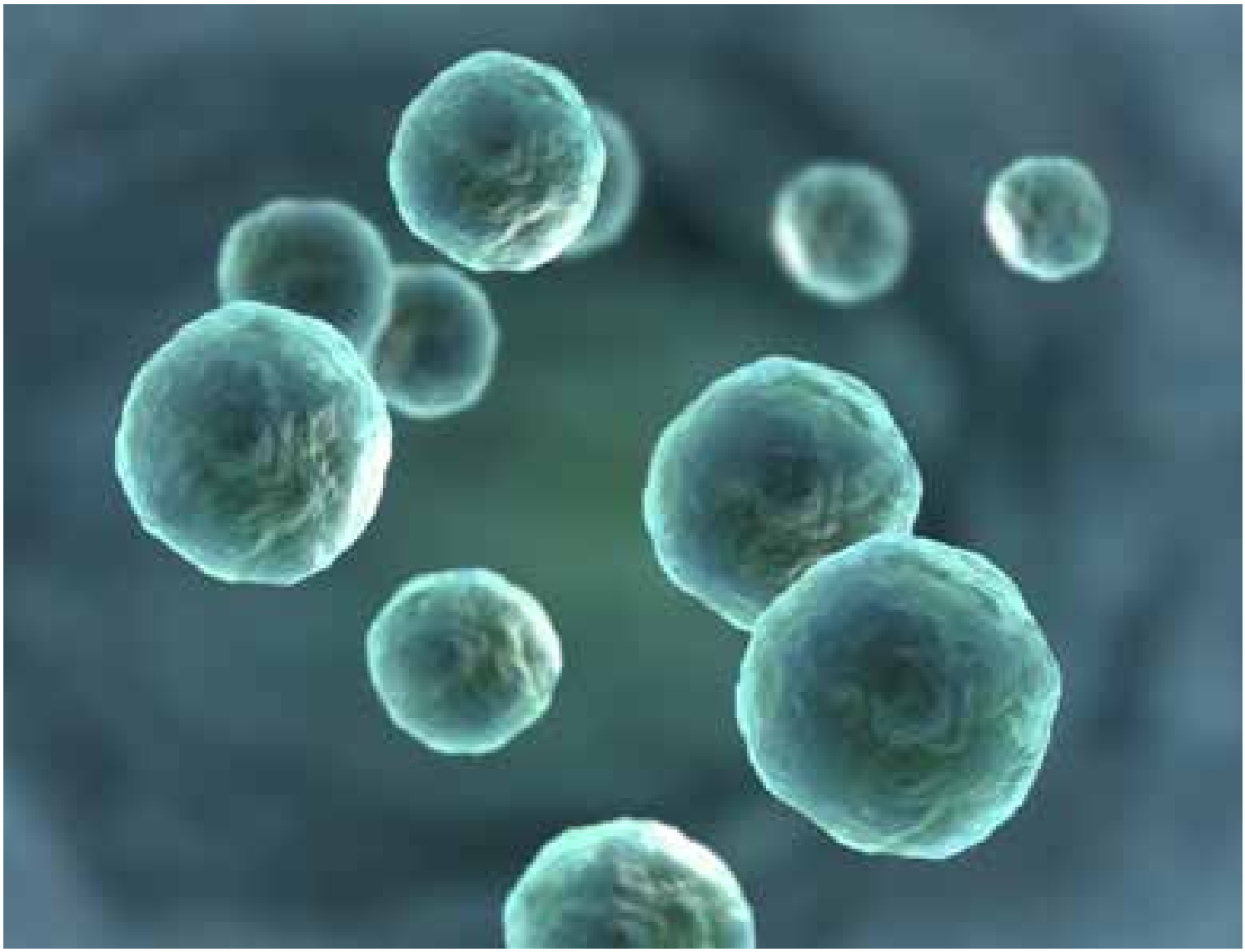
Get anytime access to a specific type of capacity within our global network.

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.

Katie Shannon
Senior Director of Engineering,
Viral Vector Services
Cambridge, MA

HOW VIRAL VECTOR TECHNOLOGY IS RAPIDLY SCALING UP TO ENABLE ONE MIRACLE AFTER ANOTHER.

The promise of viral vectors has been pursued for over two decades. But in the last few years, this transcendent technology that's targeting over 200 diseases has finally started to create real treatments and possible cures. This sudden momentum has put Katie and her team to the test. With major capital investments, they've built out Thermo Fisher's Viral Vector capacity in just under 30 months, across three locations. Katie has had to customize these locations to the new and innovative technology, and constantly shifting demands. As she says, "we've literally had to move walls while we're in the middle of building them." But nothing stops her and her team. Not even 50 tons of boulders discovered beneath a construction site. In spite of the obstacles, she and her team build for maximum flexibility, even with the demands of the most precise science on the line. With three viral vector manufacturing sites and more on the horizon, engineers like Katie and her team are paving the way for pharma and biotech companies to bring new treatments to market, and potentially save millions of lives.

ADVANCED CELL AND GENE THERAPY SOLUTIONS

Get your advanced therapy to market faster.

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.

Advanced therapeutics, including cell and gene therapies, have the potential to completely revolutionize the state of healthcare, and speed is of the essence. A partner that has the expertise, capacity, and global supply network is increasingly critical to seamlessly transition from clinic to commercial with confidence. Thermo Fisher Scientific offers the confidence of partnering with an experienced CDMO, combining scale with breadth of services and support network to meet your critical timelines.

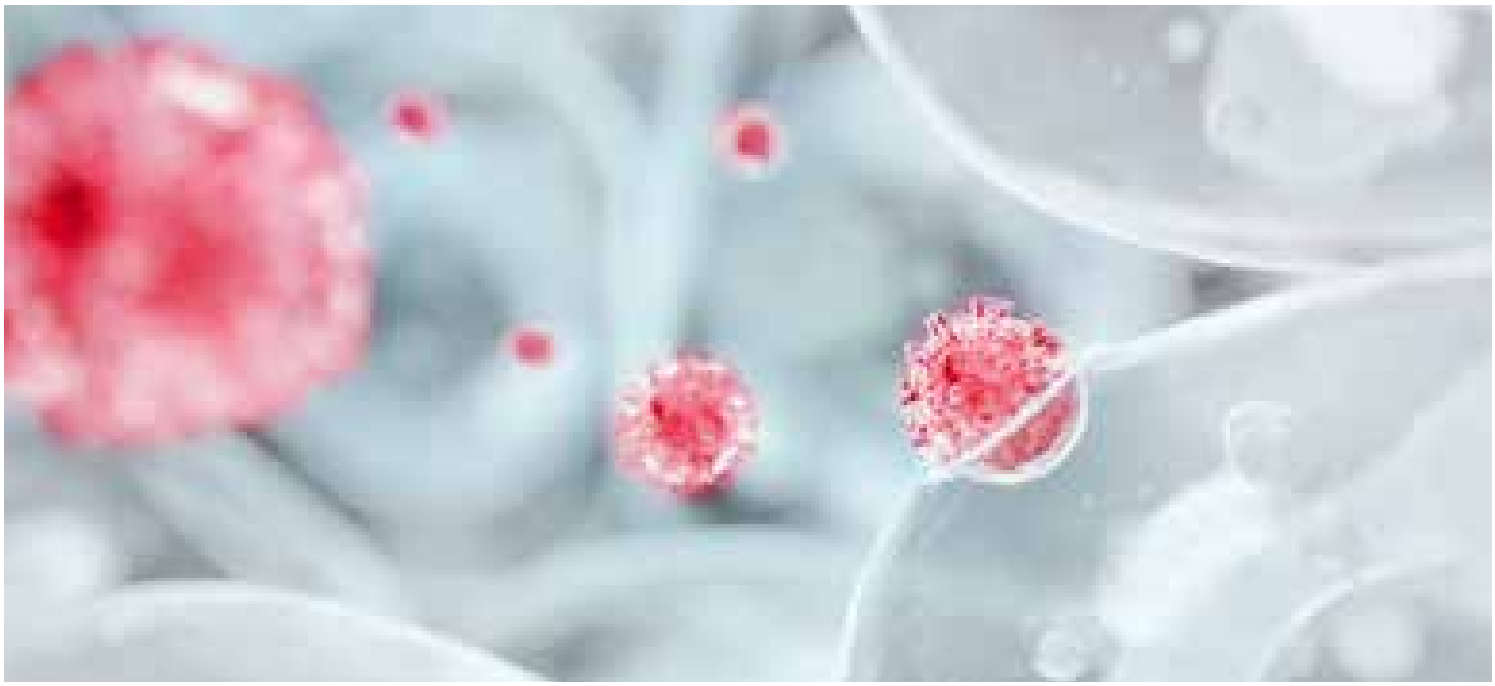
Experienced viral vector services deliver robust support without long queues.

Viral Vector Services 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 20 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 break-through 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 130 viral vector projects completed using a variety of manufacturing technologies in the delivery of over 500 viral vector cGMP clinical and commercial lots. Our team of 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. We have 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

Services	• 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 • regulatory services	
Suspension manufacturing platforms	**PRECLINICAL** 200L	
	CLINICAL 4x200 L 500 L WV 200L	**COMMERCIAL** 4x2000 L 1,000 L 2,000 L
Adherent manufacturing platforms	**PRECLINICAL** Flatstock iCELLis® 500 iCELLis® nano	
	CLINICAL Flatstock iCELLis® 500	**COMMERCIAL** Flatstock iCELLis® 500

AAV

Adherent + Suspension	Producer cell line + Ad	Suspension + HSV	Suspension + Baculovirus
Mammalian cells transient transfection	Mammalian cells infection	Mammalian cells infection	Insect cells infection

ADENOVIRAL

Adherent + Suspension
Mammalian cells infection

LENTIVIRAL

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

RETROVIRAL

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

HERPESVIRAL

Adherent + Suspension
Mammalian cells infection

AVOID TRANSITIONS IN MATERIAL QUALITY AND SAVE CRITICAL MANUFACTURING TIME WITH COMMERCIAL-QUALITY GMP PLASMID DNA

Plasmid DNA forms the genetic foundation for many therapeutic strategies, and the growth of cell and gene therapies as well as the rapid emergence of the mRNA vaccine market has created intense pressure on manufacturing of plasmid DNA. Thermo Fisher Scientific has responded to the call by expanding capacity and service offerings so you can get to market faster. Services include:

- Process development and optimization
- Master cell banking
- Scale up to GMP for clinical and commercial
- Critical raw material or drug substance
- In-Process and release testing
- Stability testing and storage

LEVERAGE EXPERTISE AND FLEXIBILITY TO ADVANCE CELL THERA-PIES AT A RAPID PACE

Cell and gene therapies have been quickly gaining traction with many market approvals anticipated yearly. Speed is of the essence, which is why having a partner who knows what's expected in regulated environments, has the flexibility to serve your unique needs, and can assist across your entire value chain is so important. Thermo Fisher Scientific has the expertise and flexibility you need to continue moving at a rapid pace. Services include:

- Process and method development and optimization
- Master cell banking
- GMP for clinical
- Sterile Fill/Finish of DS
- Cryopreservation
- Stability

INTEGRATED SERVICES AND BROAD CAPABILITIES TO SUPPORT MRNA THERAPEUTICS

The emergence of mRNA therapeutics including the development of new vaccines and gene therapies has created a market constraint on access to critical raw materials and technical expertise. Thermo Fisher Scientific knows nucleic acids and pharmaceutical services and has worked to integrate our capabilities across the operational value chain to enable you to move your mRNA therapeutic from development to commercialization. Services include:

- Process development and optimization
- Clinical mRNA scale
- Scale up to GMP for clinical and commercial
- Full scale mRNA
- Upstream ingredient supply

MAINTAIN SPEED, TEMPERATURE, AND INTEGRITY FOR ADVANCED THERAPIES ACROSS YOUR SUPPLY CHAIN

With experience maintaining the integrity of millions of samples in our global network of biorepositories, we are the experts in transporting, storing, and handling specialized biological samples and material, from ambient to cryogenic temperatures. Consistent quality. Global network. Dedicated to you. Services include:

- GMP biologics management – ambient to cryogenic storage globally
- Continuous monitoring
- Specialty courier services
- Clinical to commercial distribution
- Clinical site receipt and administration

Sanjay Konagurthu, PhD
Sr. Director, Science & Innovation, Pharma Services
Bend, OR

HOW TAKING THE EDGE OFF A CRYSTAL GAINED AN ADVANTAGE.

Sometimes, even if your job focuses on data, you have to look beyond it. That's why Sanjay and his team at Thermo Fisher Scientific don't just apply data to solve formulation challenges. They look beyond the data for other potential roadblocks. In the early phase trials of a complex API molecule, his team recognized that dagger shaped crystals were inhibiting flow during production. While short-term workarounds for trials were at hand, they knew that in future scale ups, this would become a significant problem. So they collaborated with teams who modified the API process in advance. Smoothed the crystal. And solved the problem before it became one.

EARLY AND 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

An estimated 70-90% 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 tech-nological 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 Patheon™ Quadrant 2™ 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.

Quadrant 2™ 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 200 commercially available molecules, and has proven to be over 90% accurate for technology selection and over 80% accurate for excipient selection.

PRE-FORMULATION AND ANALYTICAL CAPABILITIES AT A GLANCE

We give you access to a broad, proven range of formulation and analytical 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

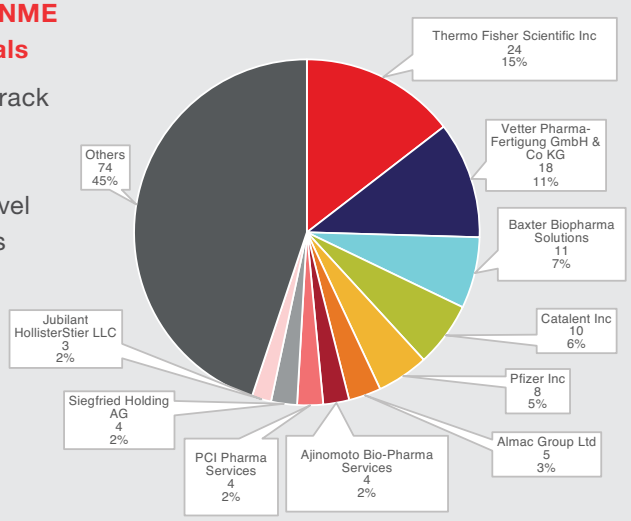
In as few as 14 weeks, the Quick to Clinic™ small molecule delivers high-quality Phase I material and the data you need to support your Phase I clinical trials. This program delivers:

- 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

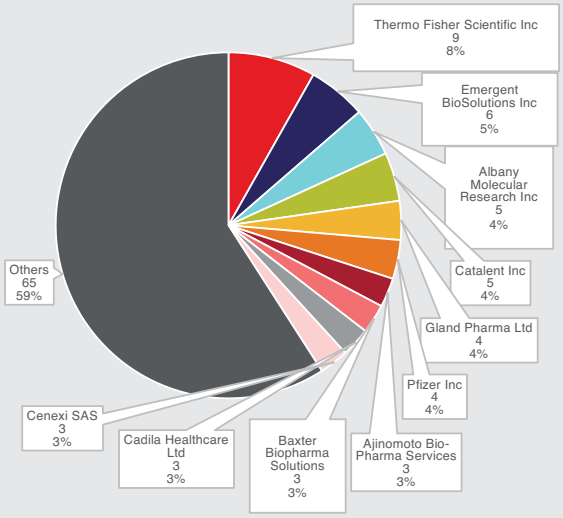
Thermo Fisher injectables is the leader in both NME & NDA approvals

Demonstrated track record with the FDA in securing approvals of novel drugs for clients

CMO market share of parenteral NME approvals, 2011-2020



CMO market share of parenteral non-NME NDA approvals, 2011-2020



Source: GlobalData New Drug Approvals and Their Contract Manufacture – 2021 Edition

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 89% 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 AND 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 2011-2020 we helped our clients earn 24 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

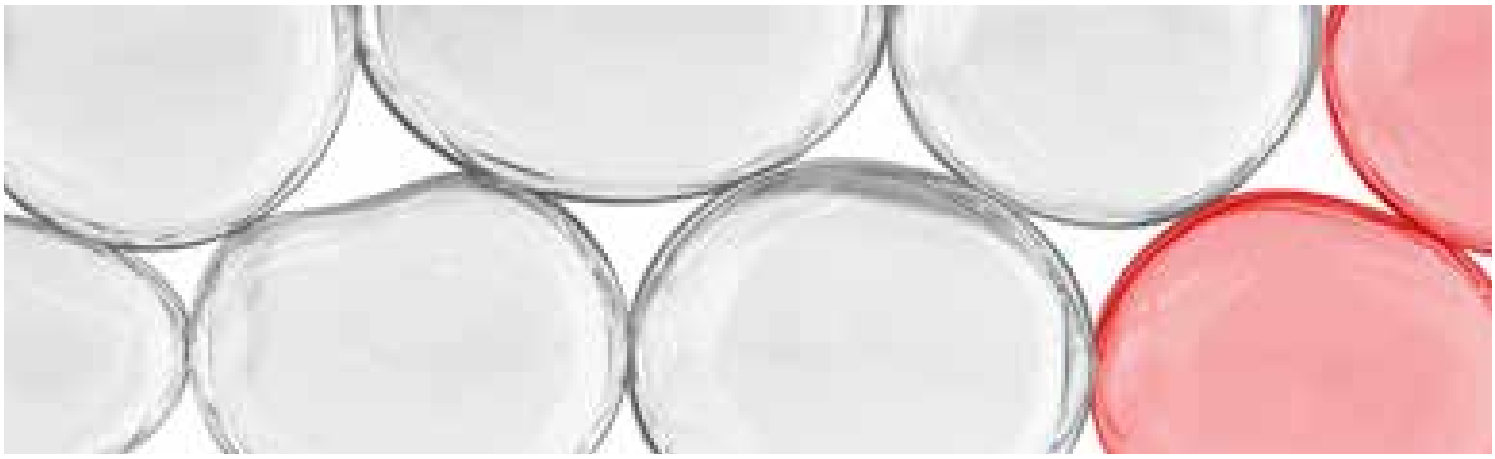
Integrated drug development and clinical services for new and emerging pharma.

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?

The solution? Our Quick to Care™ program.



Give your molecule the best shot at success.

The Patheon™ Quick to Care™ program 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 account-ability, 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.

On average, Quick to Care™ clients saved 14 weeks off drug development timelines.

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™ program can give your molecule the best shot at success.

Holli Carlson
Director, Commercial Solutions, Pharma Services
Mt. Prospect, IL

HOW SPRING BREAK HAD TO WAIT A LITTLE LONGER, SO A BABY COULD HAVE A BETTER SHOT.

After a long night of packing for her family's spring break vacation, Holli woke up at 4:40 AM Saturday morning. She noticed a text message on her phone. A six-day-old baby experiencing violent seizures needed a client's medication immediately. Vacation was going to have to wait. By 5:20 AM, Holli was on the phone with the client to identify a solution. By 7:30 AM, she and her team were at the site (normally closed on Saturdays). The client had received an emergency Treatment IND from the FDA the night before. Next, through Thermo Fisher's Total Transportation Management capability, they were able to arrange same-day shipment from their TSA-certified warehouse. No red tape. No delay. No package opening at the airport. The package went directly on a commercial flight, and was hand delivered to the hospital 12 hours after Holli received that text. Best of all, when every moment mattered most, a baby in urgent need could be treated with the client's medication in hours instead of days.

CLINICAL TRIAL SOLUTIONS

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 Patheon™ Fisher Clinical Services℠ 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 29 purpose-built cGMP/GDP-compliant facilities, supported by over 45 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 and 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

Angie West
Global Relationship Director, Pharma Services
Allentown, PA

HOW A COMBINATION OF TEAMWORK, HEART, AND SCIENCE ENSURED THOUSANDS OF PATIENTS AROUND THE GLOBE DIDN'T GO WITHOUT MEDICINE.

Angie will never forget the day she got a call from a client with a packaging and logistics challenge of global proportions. They needed her help figuring out how to get an oncology drug labeled for 60,000 patients in 35 countries every month. And they needed that solution to fit in a four week cycle – half the time typically required to turn around a trial of that scale. So, Angie pulled together a team of experts across 10 departments to break down every step of the process. They worked long hours and explored every possible opportunity to increase efficiencies and take time out of the process. Then they set up an operator training lab to ensure everyone on the team could deliver the new solution as planned. The result was a 55% reduction in cycle times and thousands of patients around the world received the life-saving medication they needed.

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 and security management, validated warehouse management system, ambient through frozen storage, zero time out of environment cold chain pick and pack and designated secured areas for quarantined and 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 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 and 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

Jigal Shah
Business Manager,
Pharma Services
Whitby, Ontario

Jessica Morin
Portfolio Services Manager,
Pharma Services
Whitby, Ontario

HOW DIGGING DEEP INTO CANADIAN REGULATIONS GOT A CLIENT'S MEDICATION ONTO SHELVES IN BRAZIL.

A medication made in Thermo Fisher's Whitby, Canada site needed to be on shelves in Brazil by July 4, or the client would lose the right to sell the medicine in that country entirely. But the delivery vendor made a mistake and delivered the product to Mexico instead. Jessica and Jigal teamed up to work through the options. They could do another production run in Canada on short notice, but it still wouldn't meet their deadline. They couldn't ship from Mexico to Brazil because Mexican customs would delay the process for too long. So, they took a step back and looked deeper into the regulations to find a better and quicker solution. The 10% of the run that had been kept at the plant in Canada was able to be shipped to Brazil by the deadline and still comply with Brazil's regulations. The product arrived on shelves in Brazil by the end of June, and the client was able to deliver this life-changing medication to patients that never had access to it before.

COMMERCIAL MANUFACTURING

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 50 years.

These are the people who deliver more than 100 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 pro-duct 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.

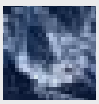
SPECIALIZED ORAL SOLIDS

	**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.

CONVENTIONAL ORAL SOLIDS

	**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.

STERILE INJECTABLES

	**Liquid-filled vials**	• 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**	• 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 m^2+ of global lyo capacity.
	**Prefilled syringes and cartridges**	• 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**	• PFS plunger and backstop assembly. • Needle safety device assembly. • Auto-injector assembly. • PFS and reference material blinding.
	**Biologic and sensitive molecules**	• 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	2ml – 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 m^2**	**285 m^2**	**14 m^2**	**125 m^2**	**14 m^2**	**358 m^2**

SOFTGELS

 **Softgel capsules**	• 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**	• Patented technology enrobes tablets. • Broad array of color and imprinting choices. • Safely encases highly potent compounds. • Perfect for clinical trial blinding.
 **EnteriCare® enteric softgels**	• 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**	• 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**	• 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**	• 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**	• Enhances solubility and bioavailability. • Lipophilic and hydrophilic formulations. • Provides a stable solvent delivery system. • Reduces plasma level variability.
 **LiquiSoft™ chewable liquid-filled softgels**	• 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
	16	0.975-1.218	250	400	950	1500
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, Nether-lands
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				●					●				

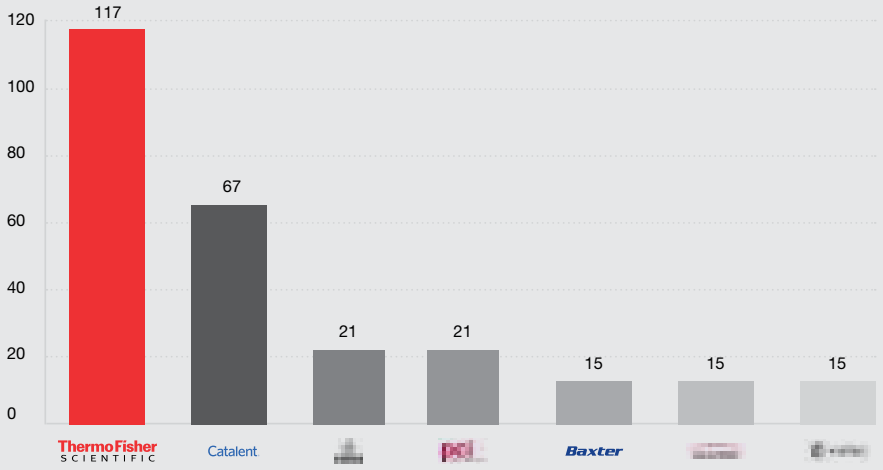
* Our Swindon site is a Condominium site that builds customized facilities to meet client needs for a variety of dosage forms.
** Commercial capabilities in Florence, SC

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										
Blisters	●	●	●	●	●		●			●
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	●	●	●	●	●	●	●	●	●	●

More successful NDA approvals than any other CMO.

WHO WOULD YOU RATHER TRUST WITH YOUR MOLECULE?



Dose outsourcing: NDA approved products 2011-2020
Source: GlobalData – New Drug Approvals and Their Contract Manufacture – 2021 Edition
Data does not include NDA approvals for non-therapeutic drugs.

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 50 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.

Adamou Seydou
Gelatin Associate,
Pharma Services
High Point, NC

HOW WASTED MATERIAL INSPIRED SAVING TIME AND MONEY.

When it comes to manufacturing softgel dosage forms, nobody knows more about operating the equipment that makes them than Adamou. He's relentless about finding new ways to make the manufacturing process more efficient. So, when he saw the amount of scrap material being produced during a specific manufacturing process, he was determined to find a way to decrease it. He enlisted the help of a team of experts who supported his cause and they worked after hours and weekends until they found a solution. The result is a new process that greatly reduces scrap, delivers savings to customers, and most importantly, helps to lower the cost of medicines for the patients who need them.

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 formu-lations. 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®

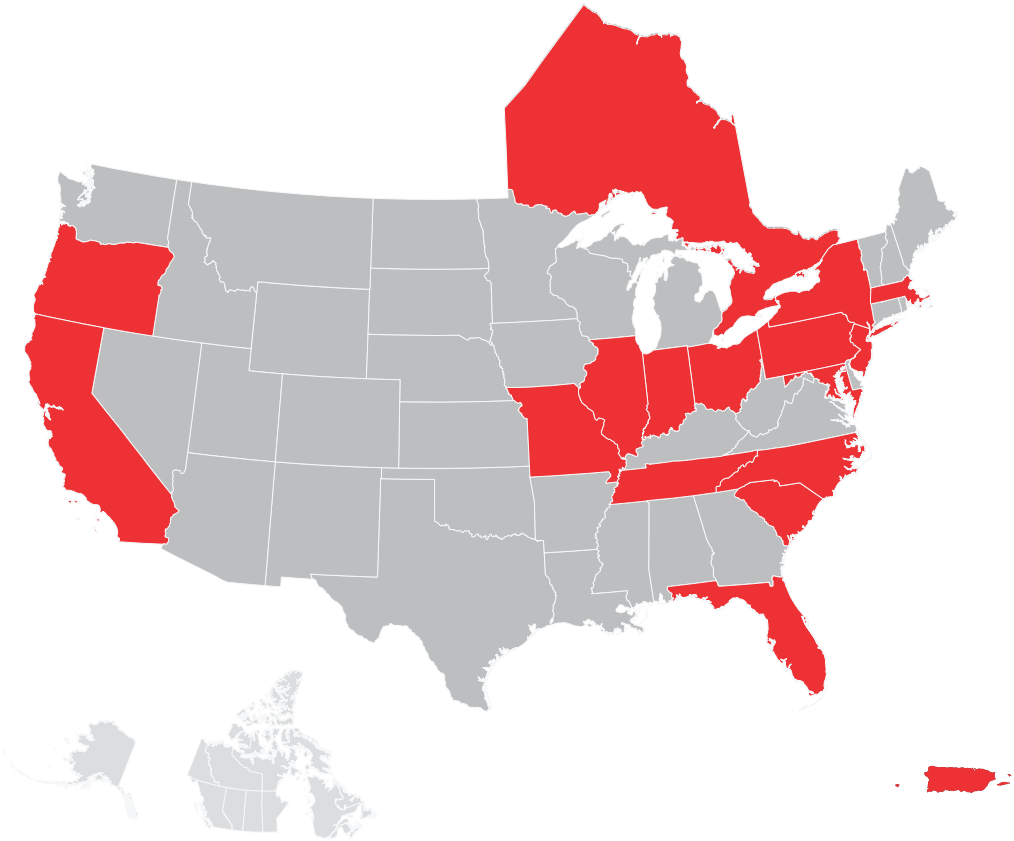
With the **EnteriCare®** patented technology, the enteric properties are integrated into the gelatin shell, not a coating. The result is an elegant, clear capsule that targets delivery to the small intestine, reducing risks of reflux, gastric irritation, and transformation of acid-labile compounds. EnteriCare 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



	API	Biologics	Cell Therapy	Plasmids	Viral Vector	Development	Softgel	Clinical Trial Solutions	Commercial Manufacturing	Specialty Warehousing
Alachua, Florida, USA					●					
Allentown, Pennsylvania, USA								●		
Bend, Oregon, USA	●					●				
Bohemia, New York, USA								●		
Cambridge, Massachusetts, USA					●					
Carlsbad, California, USA*				●						
Cincinnati, Ohio, USA						●			●	
Florence, South Carolina (East), USA	●									
Florence, South Carolina (West), USA	●									
Franklin, Massachusetts, USA								●		
Frederick, Maryland, USA								●		
Greenville, North Carolina, USA						●			●	
Greenville, South Carolina, USA	●									
High Point, North Carolina, USA						●	●		●	
Indianapolis, Indiana, USA								●		
Lexington, Massachusetts, USA					●					
Manati, Puerto Rico									●	
Memphis, Tennessee, USA										●
Mt. Prospect, Illinois, USA								●		
Plainville, Massachusetts, USA					●					
Princeton, New Jersey, USA		●	●							
Rockville, Maryland, USA								●		
San Francisco, California, USA*			●							
Somerville, Massachusetts, USA										●
St. Louis, Missouri, USA		●								
Swedesboro, New Jersey, USA										●
Toronto, Ontario, Canada						●			●	
Vacaville, California, USA								●		
Watertown, Massachusetts, USA				●		●				

GLOBAL SITE NETWORK

South America

	API	Biologics	Cell Therapy	Plasmids	Viral Vector	Development	Softgel	Clinical trial Solutions	Commercial Manufacturing	Specialty Warehousing
Bogota, Columbia								●		
Buenos Aires, Argentina								●		
Lima, Peru								●		
Santiago, Chile								●		
Sao Paulo, Brazil								●		

GLOBAL SITE NETWORK

Europe

	API	Biologics	Cell Therapy	Plasmids	Viral Vector	Development	Softgel	Clinical trial Solutions	Commercial Manufacturing	Specialty Warehousing
Basel, Switzerland								●		
Bishop's Stortford, United Kingdom								●		
Bourgoin, France						●			●	
Cork, Ireland	●									
Ferentino, Italy						●			●	
Gosselies, Belgium					●					
Groningen, Netherlands		●								
Horsham, United Kingdom								●		
Lengnau, Switzerland		●								
Linz, Austria	●									
Milton Park, United Kingdom	●					●				
Monza, Italy						●			●	
Moscow, Russia								●		
Regensburg, Germany	●									
Rheinfelden, Germany								●		
Seneffe, Belgium					●					
Stevenage, United Kingdom								●		
Swindon, United Kingdom						●			●	
Tilburg, Netherlands						●	●		●	
Weil am Rhein, Germany								●		

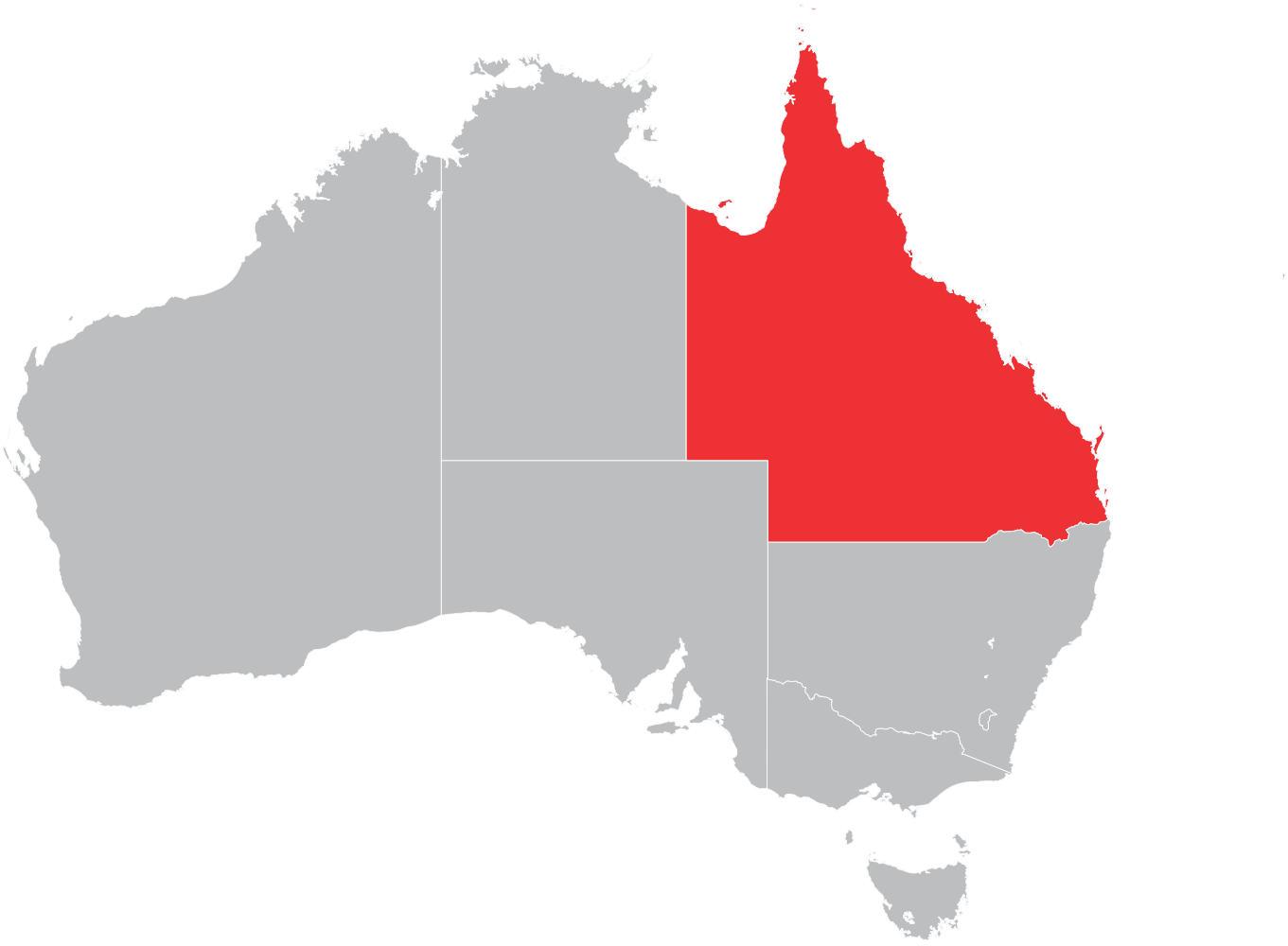
GLOBAL SITE NETWORK

Asia

	API	Biologics	Cell Therapy	Plasmids	Viral Vector	Development	Softgel	Clinical trial Solutions	Commercial Manufacturing	Specialty Warehousing
Ahmedabad, India (Domestic Tariff Area)								●		
Ahmedabad, India (Special Economic								●		
Beijing, China								●		
Hangzhou, China		●				●		●	●	
Seoul, South Korea								●		
Singapore (Site I)								●		
Singapore (Site II)*						●			●	
Suzhou, China								●		
Tokyo, Japan								●		

GLOBAL SITE NETWORK

Australia



	API	Biologics	Cell Therapy	Plasmids	Viral Vector	Development	Softgel	Clinical trial Solutions	Commercial Manufacturing	Specialty Warehousing
Brisbane, Australia		●								

GLOBAL SITE NETWORK

Africa

	API	Biologics	Cell Therapy	Plasmids	Viral Vector	Development	Softgel	Clinical trial Solutions	Commercial Manufacturing	Specialty Warehousing
Pretoria, South Africa								●		

Linda
Heart transplant patient

HOW ONE BRAVE PATIENT WENT FROM THE HEART TRANSPLANT LIST TO CLIMBING THE MOUNTAIN TRAILS.

“It felt like getting kicked in the chest by a horse.” That’s how Linda described the shock she received from her implanted defibrillator when she had one of her yearly “mini heart attacks.” Her once active life was getting smaller and smaller as her heart continued to fail. Unable to even walk to meetings at her office without fatigue, she waited 2 ½ years on the heart transplant list, until one day there was finally a match. But there was a twist. Linda would receive her new heart from a brave woman who was expecting a lung and heart transplant of her own. So Linda proceeded to the hospital for one of the rarest procedures in surgery – a domino transplant. Hours later, with the donor heart beating steadily in her chest, Linda could feel a strong, healthy pulse for the first time in 15 years. At first the road to recovery would be challenging, managing over 40 doses of medications each day. But now, thanks to new, innovative drug products, she relies on just a few – many of which are manufactured by Thermo Fisher. And a year later, she hiked to the top of Angel’s Landing in Utah, with nothing but a backpack, a bottle of water and healthy heart full of possibilities.

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