ThermoFisher SCIENTIFIC

PHARMA SERVICES EMEA NETWORK

INTEGRATED NETWORK FROM MOLECULE TO MEDICINE

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

patheon

Katie Shannon
Senior Director of Engineering, Viral Vector Services

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.

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Introduction

Accelerate innovation productivity to get medicines to patients faster.

Welcome to Thermo Fisher Scientific pharma services, your integrated drug development partner. We never lose sight of our shared goal – changing patients' lives for the better. With more than 65 locations around the world, we provide industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers across the globe.

From our EMEA scientists and engineers to our line operators and business professionals, we all take our work personally. Our objective is to help speed your molecule through early phase trials and prepare you for commercial success, faster. That's why our talented EMEA teams – built on experience, insight and the passion to deliver the best possible outcomes – apply heart and science in all they do. Our people pride themselves on solving complex pharmaceutical drug development and supply chain distribution challenges whilst maintaining high quality standards.

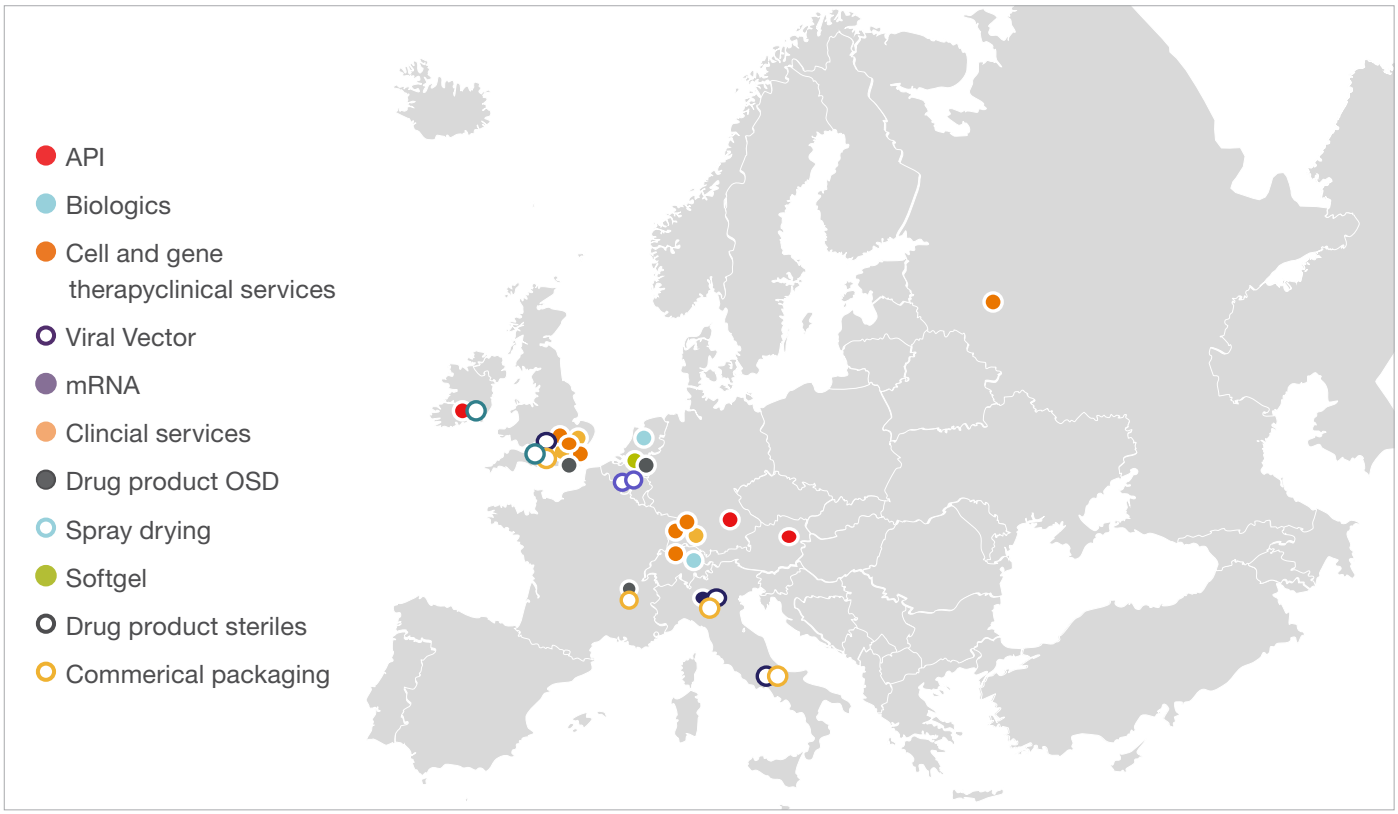
With an increasing demand for our services comes a commitment to continuous improvement, ensuring that we have the capacity, capabilities and expertise to help you achieve success in drug development. That is why we have been making unprecedented investments and enhancing our capabilities across our global network, including our EMEA sites.

In the pages ahead, find out more about our dedication and determination to solve your most complex drug development, manufacturing and clinical supply challenges in EMEA. Learn how our innovative solutions enable our customers to accelerate innovation and productivity to get medicines to patients faster.

"Cooperation with Patheon sites worked well and I like the idea to have the entire supply chain within one company."

— Biopharma company, EMEA

EMEA site network



Location	API	Biologics	Cell therapy	Plasmids	Viral vector	Development	Softgel	Clinical trial solutions	Commercial manufacturing	Specialty warehousing
Basel, Switzerland								●		
Bishop's Stortford, UK								●		
Bourgoin, France						●			●	
Cork, Ireland	●									
Ferentino, Italy						●			●	
Gosselies, Belgium					●					
Groningen, Netherlands		●								
Horsham, UK								●		
Lengnau, Switzerland		●								
Linz, Austria	●									
Milton Park, UK	●					●				
Monza, Italy						●			●	
Moscow, Russia								●		
Regensburg, Germany	●									
Rheinfelden, Germany								●		
Seneffe, Belgium					●					
Stevenage, UK								●		
Swindon, UK						●			●	
Tilburg, Netherlands						●	●		●	
Weil am Rhein, Germany								●		

Investment and innovation

Leverage our investment and innovation to accelerate productivity and speed to market within the region.

The medicines that we develop and deliver to our customers serve one million patients per day. With an increasing demand for our services, expertise and capabilities, comes a commitment to continuously expand our products and services. This is why we have been making unprecedented investments in our network of sites and capabilities around the world, with significant focus on investments in Europe to drive growth and speed to market, to accelerate innovation and productivity and to meet the unique needs of our European customers.

Ferentino, Italy: Expansion includes one new line for high-capacity commercial liquid filling. A new 28,000 sq. ft. development building will include one flexible line for development projects and small-scale commercial manufacturing.

Monza, Italy: Expansion includes three new sterile fill/finish lines, including one high-capacity line for liquid and lyophilized filling for commercial production, one pre-filled syringe/pre-filled cartridge line for medium batch production and one flexible multi-purpose line for low volume filling.

Swindon, UK: Expansion includes the transformation of the 30,000 sq. ft. site into a new full-scale commercial manufacturing site with one line for liquid and one line for lyophilized filling, plus extensive cold chain storage for vaccines requiring ultra-low temperatures.

Lengnau, Switzerland: A state-of-the-art 1.5 million sq. ft. biologics manufacturing facility that leverages highly flexible bioproduction technologies, including both single-use and stainless steel with up to 12,500L bioreactor capacity. This provides biopharma companies with a pathway from development to large-scale production as manufacturing needs evolve.

Rheinfelden, Germany: A new, state-of-the-art 86,000 sq. ft. clinical supply chain facility, providing secondary packaging, storage, logistics services and distribution of clinical supplies to investigator sites across Europe. Featuring highly automated technology in a fully scalable, mixed-use space, the site will serve as a strategic logistics hub for shipping by road or air and its central location will help expedite clinical trial therapies to patients in Europe.

Weil am Rhein, Germany: A new 9,600 sq. ft. cryocenter provides specialized ultra-low temperature, cryogenic storage and cold chain expertise for clinical supply needs for cell and gene-based therapies. With deep expertise in end-to-end cold chain management, the cryocenter will support ultra-low temperature storage, packaging, labeling and distribution required by vaccine and cell and gene therapy innovators. The site will feature -80°C freezers, liquid nitrogen (LN2) cryogenic storage tanks and walk-in 2–8°C and -20°C cold storage technology.

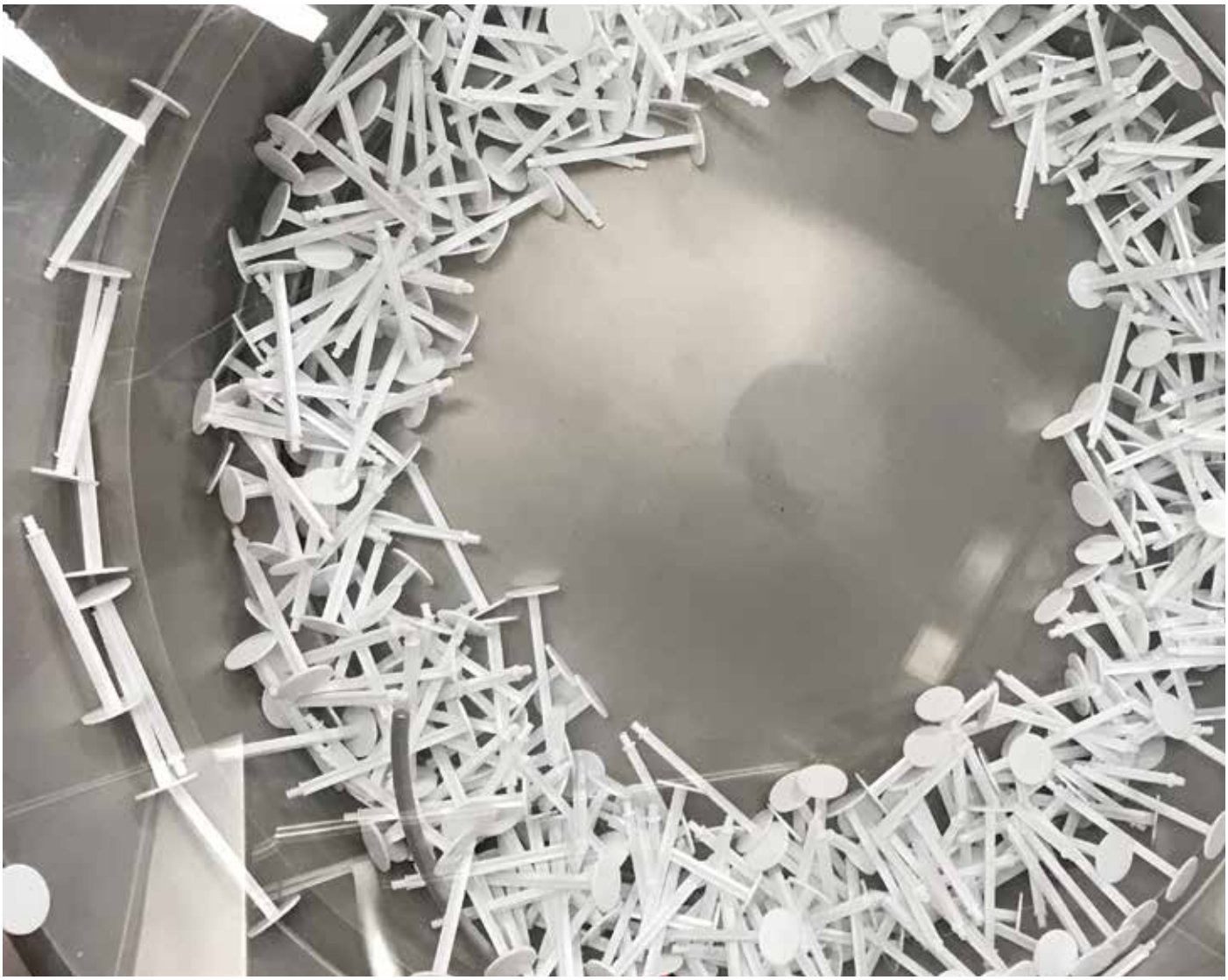
Integrated solutions

Providing solutions and delivering results with expertise in label types, design, and translation management strategies for every trial.

Our integrated solutions and our strategically located drug development and clinical supply distribution centers in EMEA offer outstanding flexibility in the end-to-end supply chain, helping you speed medicines to patients who need them.

By partnering with us you are able to create and customize your own flexible, integrated offering based on your specific needs, all while working alongside our team of EMEA experts to find a solution just for you.

Our fully integrated Patheon™ Quick to Care™ program is an ideal solution for new and emerging companies looking to streamline their drug development. We employ an expert global network to work to reduce your timelines, mitigate risk, simplify your supply chain and get you to clinic sooner. We are committed to simplifying and accelerating the development process.

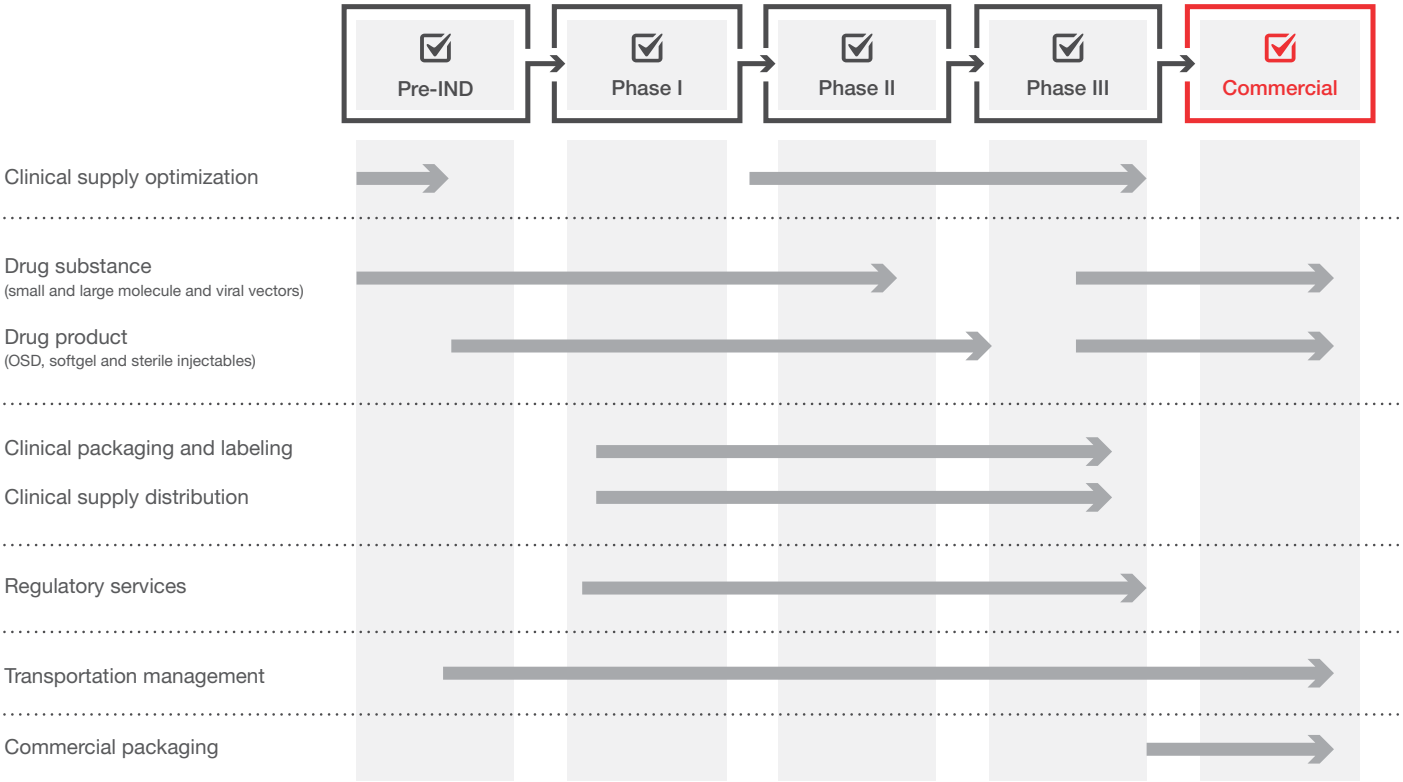


INNOVATION: QUICK TO CARE™

Delivers a streamlined drug development program for new and emerging companies

The Patheon™ Quick to Care™ program delivers a streamlined drug development process, 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.

Quick to Care™ Program – comprehensive, flexible, integrated solution



Supporting every step of journey from development to commercial and from concept to patient

Benefits of Patheon™ Quick to Care™ integrated offering include:

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

Drug substance manufacturing

Avoid rework and costly delays by partnering with us to get your formulation right from the start.

Our drug substance development services can be coupled with our industry-leading complete drug product services range, including pre-formulation screening, formulation, process, analytical development and validation, clinical and commercial supply. We can seamlessly align the development and manufacturing of your small and large molecule drug substance, saving you time and money.

API

Let our API experts help you speed your molecule through early phase trials and prepare you for commercial success, faster.

Whether you need small quantities of **API** for initial development work or many kilograms for a late phase trial, you can reduce risk and raise the bar on quality of small molecule development by partnering with us. Start with us and we'll help you identify a synthetic route suitable for early phase API supply. We'll deliver high-quality API via a seamlessly scalable process that will rapidly achieve your goals at each phase of development while laying a strong foundation for your future success.

Our early development solutions enable you to:

- Overcome complex formulation challenges: bioavailability solubility, stability, process
- Navigate the complex regulatory environment (IND, filing, etc.)
- Build success in early development to enable commercial success
- Shorten timelines to get to market quicker
- Ensure a robust supply chain within a global network

Throughout your journey to market, we offer you:

- Route scouting
- Process development
- Clinical supply manufacturing
- Technology transfer, development and scale up of established processes
- Highly potent API capabilities – handling compounds and controlled substances
- Expertise with structurally complex and difficult-to-manufacture APIs
- Process validation
- Comprehensive analytical services
- Commercial supply manufacturing
- Supply chain management
- Spray drying for early development and commercial scale
- Particle size reduction
- Physical characterization

Partner with us to seamlessly align the development and manufacture of your small molecule API and finished drug product.

"Very reliable, sound expertise, excellent scientific input."

— Clinical-stage biopharmaceutical company, Germany

INNOVATION: QUICK TO CLINIC™ SMALL MOLECULE

Patheon™ Quick to Clinic™ small molecule is an innovative solution for small molecule drug development that accelerates your early development speed while ensuring the critical details aren't overlooked.

Quick to Clinic™ small molecule

API manufacturing and essential solid-state chemistry, drug product development and clinical supply

Our Quick to Clinic™ for Oral Solid Dose can help accelerate your molecule to Phase I/FIH trials. This solution offers essential, quality and efficient services to support Phase I development needs, resulting in:

Key services:

API manufacturing

- Familiarization
- cGMP manufacturing

Solid-state chemistry

- Analysis to support right first-time delivery of a quality drug product

Drug product phase appropriate formulations & manufacturing

- API in a capsule or bottle
- Blend in a capsule or bottle

Clinical packaging and logistics

- Clinical trial supply

"Highly professional from beginning to end. All work was managed very well and followed best practices of project management. Work experience was very interactive, communication was very clear and transparent. The SME demonstrated great subject knowledge throughout the project."

— Biopharma company, EMEA

BIOLOGICS

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

The challenges, costs and risks fo bringing complex large molecule products to market are growing exponentially. We offer flexible, fast, efficient approaches to help your **biologics** discovery through the complex journey to market. We bring deep scientific expertise to every challenge. Our proven track record of developing APIs and scaling up biologics in EMEA helps ensure you gain cost and time savings at every stage of the development process. We offer you the flexibility and speed to help you get ahead of schedule while maintaining the highest quality. We provide biopharma companies with a pathway from development to large-scale production as manufacturing needs evolve.

Our biologics solutions enable you to:

- Meet important milestones with flexibility, speed and strategic guidance
- Gain cost and time savings at every stage of your drug development process
- Leverage flexible solutions, custom built on comprehensive capabilities and experience
- Start with us and stay with us from early development through to large-scale production as your manufacturing needs evolve

We provide:

- Comprehensive development and clinical manufacturing biologics solutions
- Quick to Clinic™ solution for biologics delivering Phase I clinical trial material, fast
- Flexibility, quality and service via process development capabilities
- Upstream and downstream processing capabilities ensuring drug substance is of the highest quality and yield
- Breadth of analytical services to avoid delays and errors and to ensure your molecule is ‘formulation ready’
- Process validation ensuring reliability of supply and consistent quality
- Effective technology transfers for a strategic and financial advantage
- Customized biomanufacturing solutions

“The service provided by Thermo Fisher was very professional and met with expectations. Communication was clear and concise. There was a sense of ownership by the team.”

— Mid-size pharma, EMEA

INNOVATION: PATHEON™ QUICK TO CLINIC™ BIOLOGICS

Patheon™ Quick to Clinic™ biologics is an integrated early development offering designed for biotech companies looking for a dependable solution to scale up recombinant antibodies from discovery to first-in-human (FIH) trials and file for Investigational New Drug (IND) review in as little as 13 months from transfection. Our Quick to Clinic™ biologics solution helps you balance speed, risk and future needs during early development through to commercialization.

Patheon™ Quick to Clinic biologics can save 9 months over a traditional program

DNA to released drug product (months)

Traditional Phase I Program

Quick to Clinic™ Program

- Experience with more than 50 mAb programs
- Strong process development (PD) experience with >80 PD programs completed since 2017
- Drug substance and drug product work in parallel
- Automation: ambr® 15, ambr® 250 Beacon® System, MAM*
- Concurrent, co-qualification of analytical methods
- Pre-qualified vials, contact parts, and closures
- Standardized document templates

WHAT YOU PROVIDE	WHAT WE USE	WHAT WE DO	WHAT YOU GET
Starting material: Gene • DNA sequence – genetic code	• Thermo Fisher Scientific Gibco™ Freedom™ ExpiCHO-S™ Platform • Patheon pharma services' platform process and Thermo Fisher media/feeds with commerically available raw materials	• Cell line development using Berkeley Lights Beacon® System • Evaluation of upstream and downstream platform process using high throughput automation technologies such as ambr® 15 microbioreactor and Tecan miniaturized purification platform • Formulation screening • Analytical method establishment • Toxicology batch • cGMP batch: 500L – 2000L • Viral clearance study • Stability testing	• Early toxicology material • Released drug substance • Released drug product • Minimum 1-month stability date for IND • Templated quality-reviewed reports • Clinical trial packaging and labeling (optional) • Regulatory package for IND preparation

* Multi Attribute Methodology

ADVANCED THERAPIES

Advanced therapeutics, including cell and gene therapies, have the potential to completely revolutionize the stage of healthcare, and speed is of the essence.

We enable emerging biotech and large pharma companies to deliver breakthrough medicines to patients by unleashing the potential of cell and gene therapy. We partner with you to drive the innovation that is needed in this fast-growing market to reach even more patients and treat even more indications.

Our advanced therapies solutions enable you to:

- Seamlessly transition from clinic to commercial with confidence
- Meet critical timelines by leveraging our breadth of services and global network
- Address complex needs of evolving therapies
- Save time and effort with end-to-end solution to get your therapy to market faster
- Efficiently serve patients worldwide via our integrated clinical and commercial cGMP manufacturing and supply chain solutions across advanced therapy modalities including mRNA and cell and gene therapies
- Leverage 20+ years of cGMP advanced therapeutics manufacturing experience with 3,500+ scientists and technicians

Throughout your journey to market, we offer you:

- **GMP plasmid DNA** capacity and expertise to save critical manufacturing time
- **mRNA integrated services** and broad capabilities to support mRNA therapeutics
- Expertise and flexibility to advance **cell therapies** at a rapid pace
- Robust, **clinical supply chain solutions** to maintain speed, temperature and integrity for advanced therapeutics end-to-end
- Experienced **viral vector services** delivering robust support without long queues

Our highly experienced EMEA **Viral Vector** teams provide 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. We accelerate transition from the development laboratory to patients through preclinical and commercial approval, while meeting cGMP standards and industry expectations with high integrity. We provide:

- Viral vector platforms, processes and available cell lines
- Process development, characterization and validation for cell cultures
- A range of assay validation, testing and analytical services
- cGMP manufacturing platforms to support preclinical and human studies through late-phase and commercial programs
- cGMP fill/finish services with a focus on compliance and quality

Let our EMEA drug substance manufacturing experts show you how to speed development and unleash the potential of your discovery.

Product approvals: 74 product approvals for European sites in 2017-2020

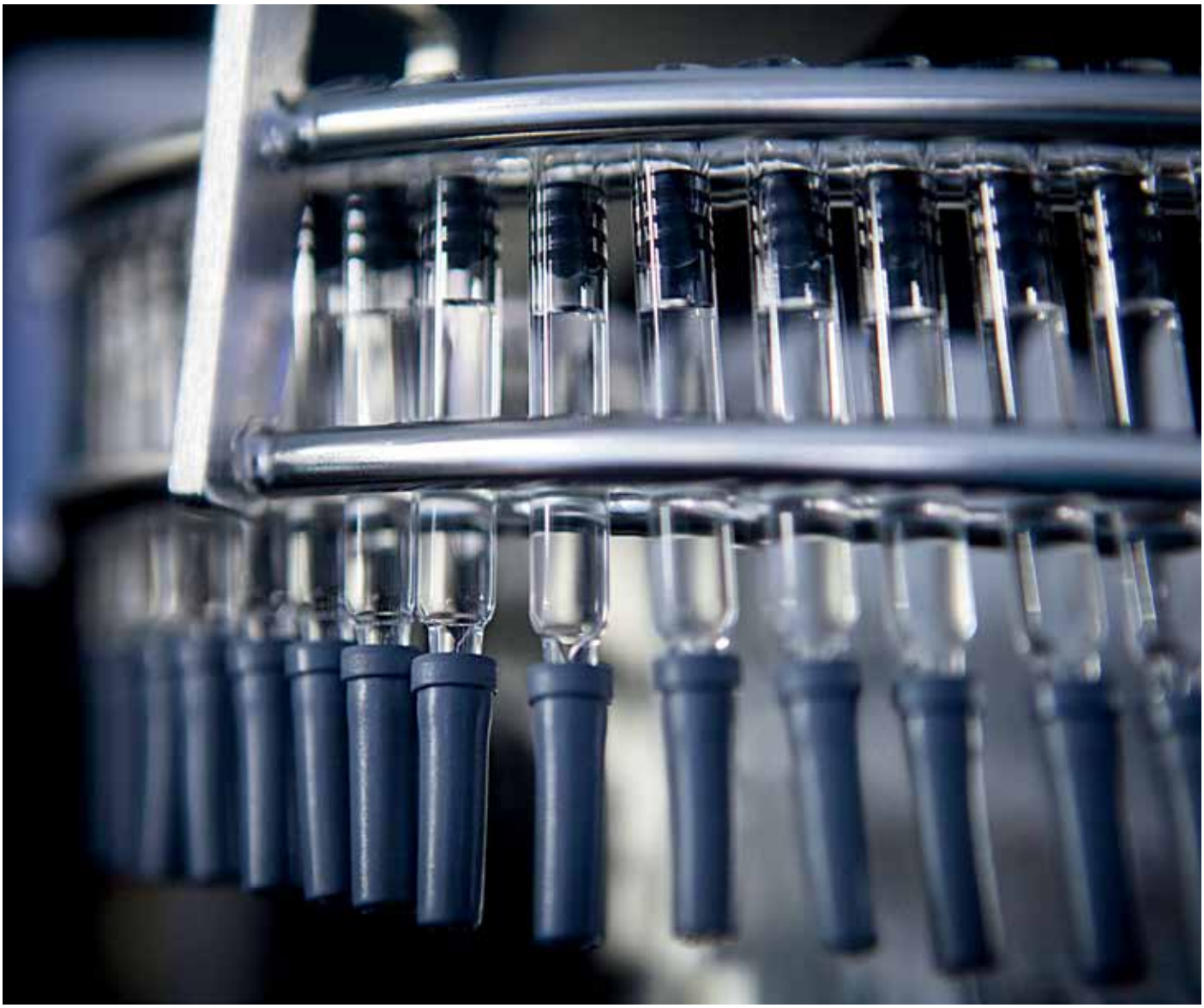
Drug product manufacturing

Every step of the development process brings unique challenges and opportunities.

Time, cost and results are critical. But sacrificing quality is not an option. We have designed a range of flexible solutions and strategies to meet your molecule's unique needs across formulation development, analytical method development, bioavailability enhancement, manufacturing process development and clinical batch manufacturing.

Our EMEA teams 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. Our EMEA professionals – scientists, engineers, project managers and operators – are committed to a culture of problem solving. We help solve complex challenges throughout your product lifecycle.

What's more, working with us from the beginning lets you use early development insights to cut time and costs in later commercial stages.



STERILES

The rapid 10% growth of sterile drug product over the past five years has resulted in the need for capacity and innovative solution within development and manufacturing.

Scaling to commercial manufacturing can be arduous as you try to balance speed, regulatory, quality and your supply chain. To meet this growing demand, Thermo Fisher has further expanded its pharma services footprint in Europe for sterile drug product development and commercial manufacturing of critical medicines, therapies and vaccines. Our investment is not just about adding capacity – it's about enhancing capabilities and expertise across our EMEA pharma services business.

Our steriles commercial manufacturing solutions enable you to:

- Bring your discoveries to market with speed and efficiency
- Access a range of broad solutions to support preclinical, development and commercialization needs
- Accelerate your molecule to Phase 1/FIH trials via Quick to Clinic™ for large molecules
- Leverage clinical and commercial scale capabilities

Throughout your journey to market, we offer you:

- Process development and manufacturing of biologic drug substances at scales from clinical to global commercial
- Breadth of service offering including commercial packaging and logistics support
- A broad range of fill/finish commercial solutions including:
  - Liquid-filled vials
  - Lyophilized vials
  - Prefilled syringes and cartridges
  - Sterile injectables clinical services
  - Biologic and sensitive molecules
- Extensive access to commercial production and clinical trial solutions, end-to-end
- Successful technology transfers whether it's for scaling-up or moving to another facility
- Visibility and collaboration across your product's lifecycle via Patheon™ mysupply platform
- Deep expertise in navigating complex regulatory channels, globally

Regulatory approvals:

Our Pharma Services commercial sites in Europe have been inspected by the FDA and international regulatory authorities 88 times in the past 5 years and are in good standing.

CASE STUDY

Robust processes and clear communication results in successful scale up for commercial launch

SITUATION:

The clinical batches were successfully completed at another in-network site at a small scale and the customer was looking to scale-up batch size. There were a variety of technical challenges that needed to be addressed.

Sensitivities	Hold times	Batch processing
• Oxygen • Stainless steel • Heat • Hygroscopic API	• 6 hours from API addition to completion of pH adjustment • 20 hours from API addition to Lyo start w/IPC • Filling line hold time of 30 hours from SIIP to end of fill	• Nitrogen sparging in disposables • DO measurements • Localized high pH • Active cooling

SOLUTION:

We implemented the following keys to successful registration and validation.

- Constant updates and good communication between operations and QC labs
- Customer on site during proudction allowed for expedited decision making
- Very specific batch record instructions and operator training for highly technical batch

VALUE DELIVERED:

- Three registration batches were successfully completed
- Commerical launch from an additional network site
- Process improvements were made along the way, with a robust process designed and executed prior to PV batch production

"Thermo Fisher is proud to support biopharma, academia and government customers to develop and commercialize both therapeutics and vaccines to fight the COVID-19 pandemic. As the pandemic battle wages on, we also recognize that we must continue to be vigilant in delivering critical non-COVID-19 medicines, because a patient's need for treatments for cancer, genetic diseases and other conditions doesn't stop during a pandemic."

— Michael Shafer, Senior Vice President and President, Thermo Fisher Scientific Pharma Services

INNOVATION: MYSUPPLY

Provides visibility and collaboration across the full product lifecycle

From day-to-day order management and batch tracking to monthly forecasting, this end-to-end digital supply platform, mysupply, provides timely visibility and real-time collaboration tools to enable more efficient ways of working.

mysupply drives attention to where it matters most and helps customers achieve strategic priorities in supply chain optimization.

Customers are also able to identify delays and proactively address critical alerts, as well as traceability of products. mysupply platform provides near real-time data sharing to enhance transparency, build trust and encourage collaboration.

Overview of mysupply

An end-to-end digital supply chain platform

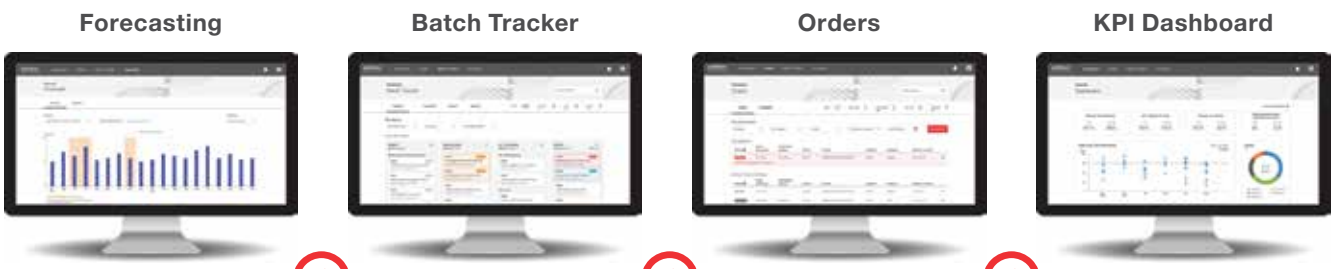
From development to launch, pharma products navigate a dynamic global supply chain with potential changes and delays. To manage these changes, pharmaceutical companies go to great lengths to understand production status, mitigate risk and proactively forecast.

- **Order management and order submission**
- **Change request submission**
- **Live batch tracking and documentation**
- **Quality deviation notifications**
- **Forecast submission and analysis**
- **Shipping information**

Capabilities

mysupply platform provides timely visibility and a real-time collaboration platform to enable more efficient ways of working, from day-to-day order management and batch tracking, to monthly forecasting.

mysupply feature set



ORAL SOLID DOSE (OSD)

Navigating a complex regulatory environment, analytical data, process development and optimization, and on-time delivery are all vital to the success of your OSD drug product

Getting formulation right from the start of early development can help save time and money as you advance through each phase and on to commercialization.

Our early development OSD solutions enable you to:

- Accelerate your project to First-In-Human (FIH) studies with Quick to Clinic™
- Rapidly characterize your drug substance and quickly evaluate formulation options
- Overcome formulation challenges such as low bioavailability
- Gain a clear view of your path through preclinical and clinical studies
- Navigate complex regulatory environment
- Ensure a robust supply chain via our global network

Throughout your journey to market, we offer you:

- Formulation development for all phases to avoid rework and costly delays
- Predictive platform for solubility and bioavailability enhancement – Patheon™ Quadrant 2™
- Solubility enhancement for efficacy of the drug substance or drug product
- Access to broad range of dosage forms to meet your molecule's unique needs
- Analytical method development for all phases to help you with strategic decisions
- Commercial production providing assurance and simpler logistics in your supply chain

CASE STUDY

Meeting milestones and patient needs through expedited delivery of Phase I materials

SUMMARY:

A clinical-stage pharmaceutical company focuses on the development of therapies for patients suffering from genetic mitochondrial disease. The pressure of delivering safe and effective drugs to patients, in a timely manner, is critical—as the quality of patient lives depends on it.

CHALLENGE:

The company needed a way to expedite early testing in order to make informed proof of concept decisions and complete their regulatory submissions. They were looking for a partner that could provide both product development and clinical packaging services.

SOLUTION:

The company collaborated with Thermo Fisher scientists on a program that accelerated the development timeline from API supply through to labelling and packaging for Phase I clinical trials.

IMPACT:

By developing phase-appropriate formulations for oral solid dose forms, the company was able to save both time and money because the speed at which they were able to get to clinic allowed them to generate a proof of concept a lot quicker. In addition, the company was able to eliminate multiple quality agreements and master service agreements by working with Thermo Fisher Scientific under a single contract.

"Working with a CDMO is more about a partnership than a customer-supplier relationship. And I feel that's what we've achieved with Thermo Fisher Scientific."

— Senior Director, Head of Pharmaceutical Development at mid-size pharmaceutical company, EMEA

INNOVATION: PATHEON™ QUADRANT 2™

Predictive platform for solubility and bioavailability enhancement

Poorly soluble compounds often demonstrate lower bioavailability, which can reduce the efficacy of the drug substance or product. Patheon™ Quadrant 2™ predictive modeling is a diagnostic tool for early development, which allows us to see in-silico predictions of formulations.

The results of this diagnostic tool can save time and costs by avoiding trial and error approaches because we can quickly provide a solution to enhance solubility:

- Spray drying
- Lipids
- Particle size reduction
- Hot melt extrusion

This in-silico formulation development approach saves time and cost by avoiding empirical, more traditional trial-and-error approaches

The Quadrant 2™ model analyzes the molecular structure, physical and chemical characteristics of a compound, and predicts the solubility enhancement technology and excipient combination that are most likely to succeed based on:

~80%
of molecules experience bioavailability challenges

300+
molecules analyzed leveraging using Quadrant 2™

*Developed by Thermo Fisher Scientific

CASE STUDY

Biopharma leverages Patheon™ Quadrant 2™ to be first to market

SITUATION:

A biopharma's small molecule needed to quickly address solubility challenges in order to be first to market.

ACTION:

- Leveraged our Quadrant 2™ platform to focus on formulation design and selection using in silico methods that eliminate unnecessary experimentation
- Provided customer with two additional formulation scenarios in case the prepared recommendation did not perform to goal

OUTCOME:

- Advanced molecule formulation development for clinical trials using minimal amounts of API saving time, rework, and costs
- Completed Phase I and IIa with minimal delays due to ample API supply and targeted bioavailability
- Transitioned seamlessly to scale-up and reached market with a price premium advantage

"Very good communication, responsiveness and professionalism. It feels like we are working with a true partner."

— New biotech company, EMEA

"Strong customer focus – high flexibility and commitment. High expertise in solid dosage manufacturing – very collaborative and supportive."

— Large pharma, EMEA

SOFTGELS

Whether your product has solubility issues – like 70% of drugs in development – or requires abuse-deterrent technology, softgels may be the best formulation choice. Innovative softgel technologies help maximize your market potential.

Thermo Fisher brings decades of experience from capabilities spanning development through commercialization. Our EMEA scientists are skilled in developing softgel formulations in early development to overcome bioavailability challenges and speeding new molecules to clinic. We also develop softgel formulations for late-stage lifecycle management, helping our clients retain market share and maximize product lifetime value.

Our softgel solutions allow you to:

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

Throughout your journey to market, we offer you:

- Regulatory support services during development/ pre-approval and post-approval of your drug product
- Solutions for safely handling highly potent compounds
- A range of softgel technologies to meet your molecule's needs
- Dedicated encapsulation facilities and high-capacity output
- Analytical methods to overcome bioavailability challenges and speed new molecules to clinic
- Softgel formulations for late-stage lifecycle management helping you to retain market share and maximize product lifetime value

Let our EMEA drug product manufacturing experts help you accelerate time to market with customized, flexible manufacturing solutions to fit your project's needs.

"Proven track record in production demonstrated via collaboration, high quality, responsiveness, issue resolution."

— Large pharma, EMEA

“Great project execution, attainment of operations plan, high quality and on-time deliveries. Strong leadership in the local management team and strong customer service – true engagement across cross-functional teams.”

— Mid-size pharma, EMEA

“We would highly recommend Thermo Fisher based on reliability, deep technical expertise, flexibility collaboration and positive demeanour.”

— Mid-size pharma, EMEA

“Thermo Fisher delivers on its commitments with high quality output and a strong quality culture across sites. The teams are collaborative and engaging with demonstrated commitment to customer satisfaction, whilst being flexible and accommodating when overcoming issues.”

— Specialty pharma, EMEA

Clinical trial supply solutions

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

As pharmaceutical companies move toward an Investigational New Drug (IND) application and their first human trial, they need to develop comprehensive clinical supply strategies that incorporate the need for flexibility with a balanced risk and cost approach. A reliable clinical supply chain strategy is as essential as a company's discovery program – making it paramount to find a partner who can help guide a comprehensive supply chain strategy and manage day-today supply chain activities.

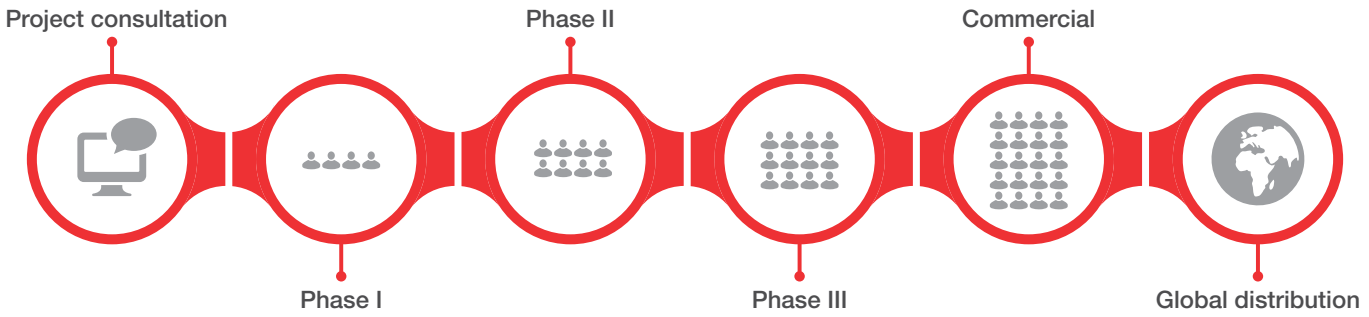
Our purpose-built GMP/GDP-compliant facilities provide clients the flexibility, access and assurance needed for their clinical trial. Our EMEA sites are staffed with highly trained professionals who bring a depth of expertise in managing clinical trials, from protocol design through to investigator site receipt of clinical materials. This expertise, combined with an understanding of local requirements and regulations, language proficiency and established working relationships with key parties across the supply chain, allows us to support the movement, management and delivery of supplies worldwide and across all therapeutic indications.

CLINICAL TRIAL SOLUTIONS

At the center of every clinical trial is a patient waiting for a treatment to arrive safely and on-time.

With unwavering dedication to serving clinical research and patients around the world, we are powered by people with an exceptional commitment to delivering end-to-end, high quality global clinical supply solutions.

Covering all phases of development



Streamlining the clinical supply chain

- Study planning and setup
- Regulatory compliance insights
- End-to-end supply chain and inventory management
- IRT integration
- Label design and translation management

- Over-encapsulation, blinding
- Blister packaging, carding, vials, syringes, auto injectors
- Comparator & ancillary material sourcing
- Global biobanking
- Laboratory services

- Commercial packaging
- Global distribution, with real-time visibility via Global Gateway
- Cold chain network for time and temperature sensitive material
- Global customs and regulatory guidance

"Thermo Fisher will problem solve and think outside the box to ensure tight timelines are met when absolutely critical."

— Mid-size pharma, EMEA

CASE STUDY

Total Transportation Management saves company $10.2M

Total Transportation Management is a unique solution offering. It provides complete oversight of the supply chain processes required to move IMP shipments internationally and within the country of destination.

SITUATION:

A leading pharmaceutical company with an extensive clinical trial pipeline in North America, Asia and Europe, wanted a comprehensive, documented, and fully managed transportation strategy

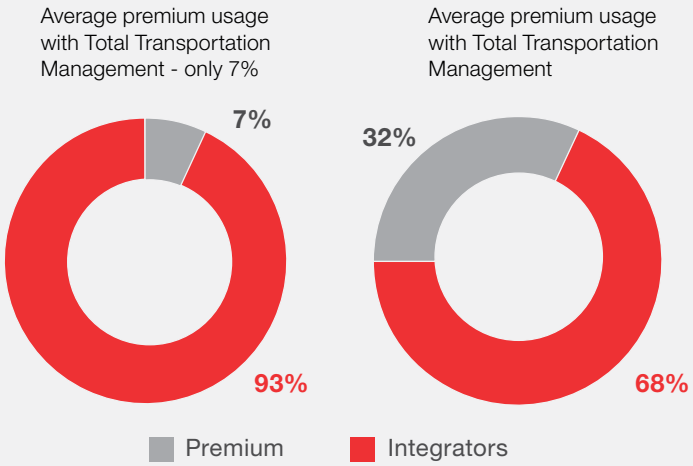
SOLUTION:

- Optimize total transport costs
- Maximize on-time, in-full delivery to all global locations
- Deliver enhanced site satisfaction
- De-risk the supply chain
- Reduce burden on the sponsor's internal study management group

RESULT: Significant cost savings and OTIF efficiencies

Achieved by:

- Leveraging global network of cGMP facilities
- Unique, innovative, data driven logistics expertise
- Sophisticated investigator site support
- Continuous improvement as defined metric of measurement
- Clear communication on revised distribution strategy



COST SAVINGS: $10.2M per year

OTIF: INCREASED FROM 93%–97%

Zero missed dosing events

"Thermo Fisher has been a critical service provider allowing us to meet clinical study supply deliveries."

— Large pharma, EMEA

GMP BIOLOGICS STORAGE AND CELL THERAPY TRIAL SUPPORT

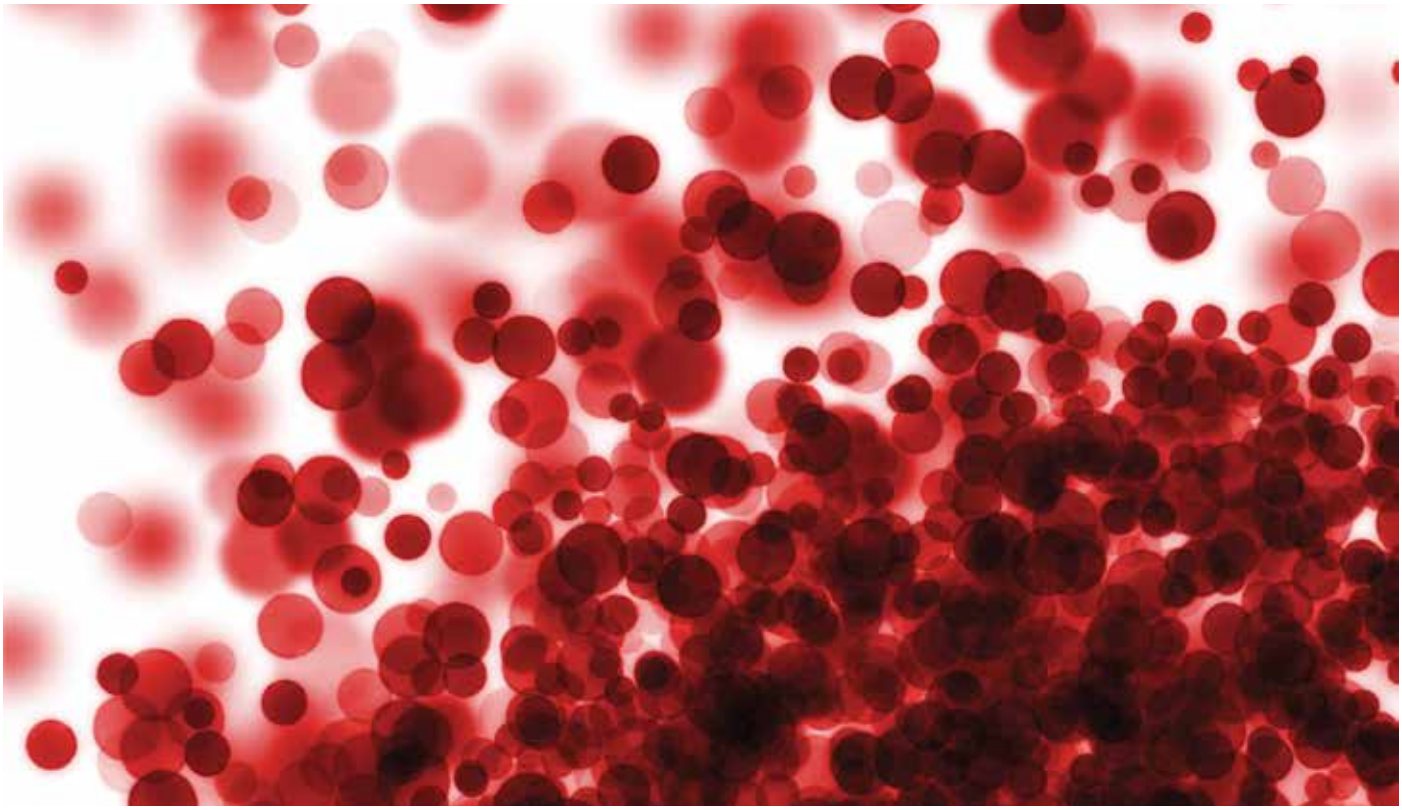
The complex, live structure of biological material is highly sensitive to environmental channels and requires a comprehensive supply chain.

Whether you are preparing vaccines or personalized gene therapies, or safeguarding cell lines for future discoveries, we are committed to protetcing your irreplaceable biologic materials. This type of material not only demands temperature controlled storage and handling, it must also be closely monitored to ensure the material maintains its stability and viability.

We offer:

- Global integrated solutions for biopharmaceutical clinical development and commercialization
- Biorepositories to maintain the integrity of all samples
- Expertise in transporting, storing and handling specialized biological samples and material
- Cyrogenic storage and logistics, combined with proven components and validated procedures, to help meet the specific requirements of individual clinical trials
- Cold chain 24-hour monitoring for both temperature and humidity

Let our EMEA clinical supply experts help you get the right product to the right patient on time and without compromise.



ABOUT US

Thermo Fisher Scientific provides industry-leading pharma services solutions for drug development, clinical trial logistics and commercial manufacturing to customers through our Patheon brand. With more than 65 locations around the world, we provide integrated, end-to-end capabilities across all phases of development, including API, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging. Built on a reputation for scientific and technical excellence, we provide pharma and biotech companies of all sizes instant access to a global network of facilities and experts across the Americas, Europe, Asia and Australia.

We offer integrated drug development and clinical services tailored to fit your drug development journey through our Quick to Care™ program. Our Quick to Clinic™ programs for large and small molecules help you balance speed and risk during early development so you can file your IND quickly and successfully. Digital innovations such as our mysupply platform and Pharma 4.0 enablement offer real-time data and a streamlined experience.

Together with our customers, we're rapidly turning pharmaceutical possibilities into realities.

Supporting large pharma:

Over the last 3 years, Thermo Fisher has worked on projects with ~25 new, large pharma customers in Europe.

Supporting new and emerging pharma:

Thermo Fisher has worked on projects with ~250 new and emerging customers in Europe over the past 3 years.

Partner with our experts in EMEA to help speed your molecule from early development through to commercial success. Contact Us.

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