

The way forward

Helping accelerate biotherapeutic
commercialization in a
highly dynamic world

The way forward



The ever-dynamic biotherapeutics and vaccine market has evolved significantly in recent years. Novel vaccines and therapeutics are emerging at previously unthinkable speeds. Biomanufacturers are facing increasing competitive pressure to adapt and innovate. New treatments are demonstrating the ability to address more rare diseases. Biosimilars are gaining rapid acceptance, providing access to life-saving medicines for new geographies and patient populations. And promising new approaches like cell and gene therapies offer even greater potential for patients in the years ahead.

Bringing such medicines to market requires masterfully balancing innovation in process design, performance, and efficiency with speed and cost—while never compromising quality. Successfully meeting these needs requires new approaches and ways of thinking.

At Thermo Fisher Scientific, we recognize the challenges you face and the increasingly critical role we play as your supplier. We are fully devoted to supporting your need for high-quality and innovative products, a stable supply chain, and robust risk-mitigation strategies. We take these responsibilities very seriously. In today’s fast-moving industry, we collaborate with our customers to solve problems across a range of technical and operational spheres, including process development and optimization, technical transfer, co-innovation, demand planning, and regulatory consultation.

We are committed to your success and the lasting impact your work has for patients and families worldwide. We can’t wait to get started with you on your journey. Together we can reach new frontiers and make the world healthier.

A handwritten signature in black ink that reads "Daniella".

Daniella Cramp, President, BioProduction
Senior Vice President, Thermo Fisher Scientific

Contents

Creating supply chain resiliency	<u>5</u>
Streamlining workflow processes	<u>11</u>
Collaborating to commercialize	<u>19</u>

The dawn of a golden age in biotherapeutics

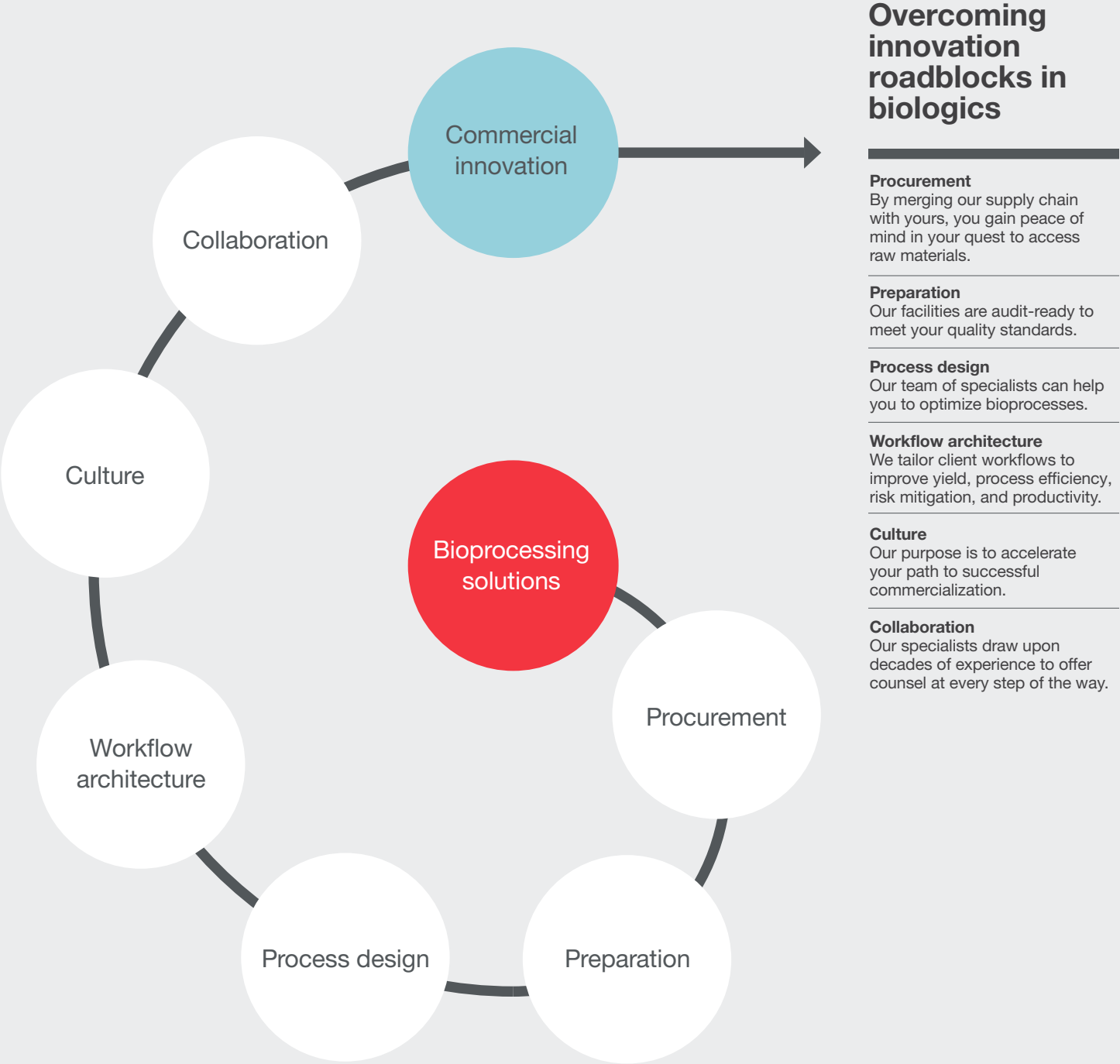
As damaging as the coronavirus crisis has been to all facets of industry and society, it may one day be remembered as the dawn of a golden age. From a scientific perspective, the development of safe and highly effective vaccines at unprecedented speed is cause not just for celebration but also for optimism.

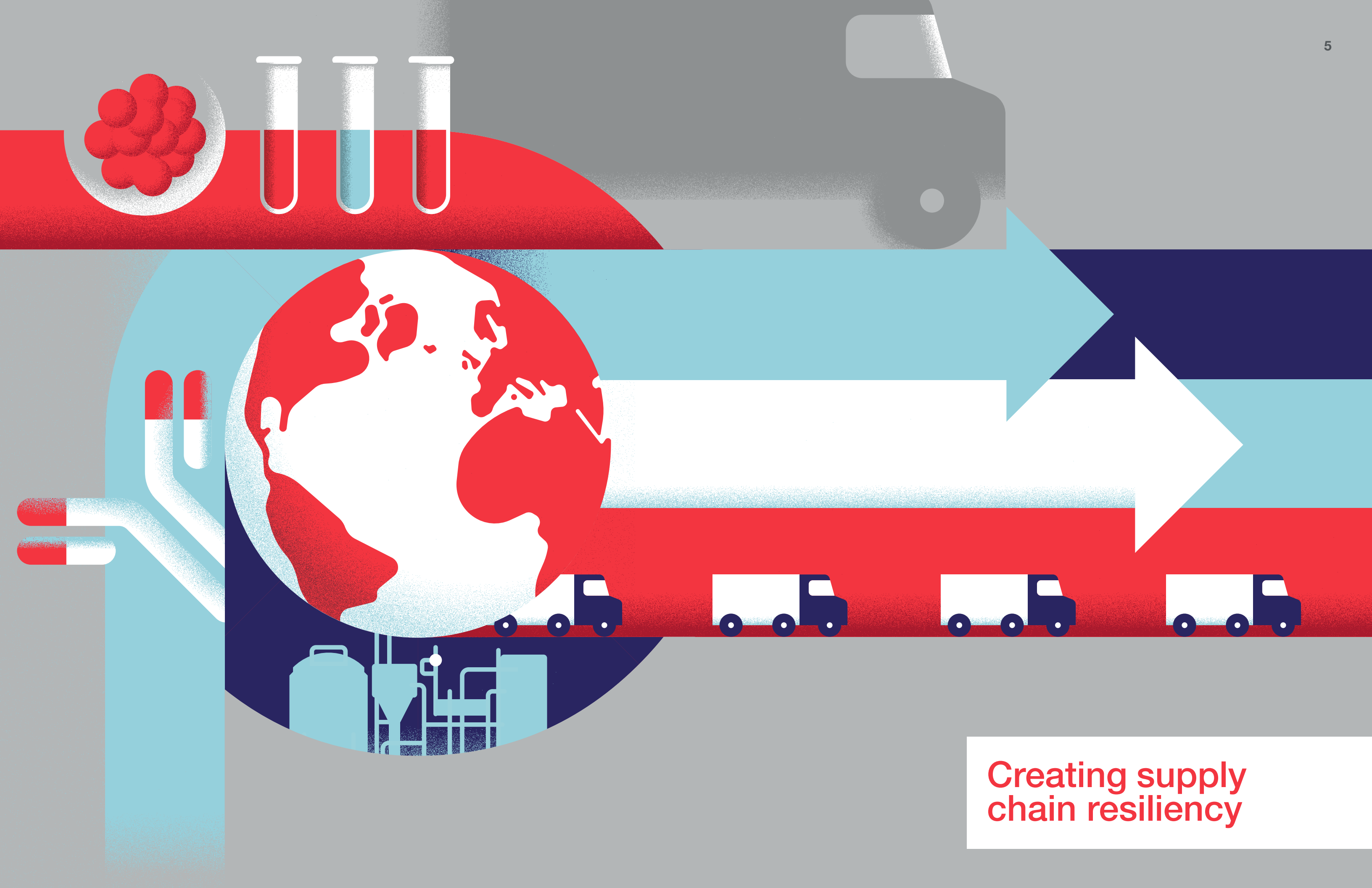
Thermo Fisher Scientific is proud to play a key role in supporting pioneers in their development of vaccines, an approach that we believe can serve as a model going forward. Our command of manufacturing systems combined with our global footprint, technical expertise, and strong relationships can likewise help drive commercialization of other world-changing, innovative drugs. With our capabilities, this can be done safely and efficiently in multiple biologic modalities, including antibody, gene, cell, and nucleic acid therapies.

Not that it will be easy. Even in normal times, bioprocessing is highly complex and dynamic. Every project has unique challenges, and the industry is being hampered by unprecedented constraints in procuring materials. The supply chain will eventually stabilize—but not as quickly as anyone would like. Until it does, it's more important than ever to choose partners wisely.

At Thermo Fisher, we have spent decades building out the systems and expertise necessary to successfully guide customers through every stage of production. Our industry veterans and scientists around the globe are backed by processes, technology, and infrastructure that together can help anticipate and overcome any roadblocks that might hamper the commercialization of your next-generation vaccines and therapies.

We've created this showcase to make you aware of our unparalleled breadth of assets and our uniquely collaborative approach. We're eager to help bring your innovative ideas to fruition and fully realize the power of the science and technology at our disposal.





Creating supply
chain resiliency

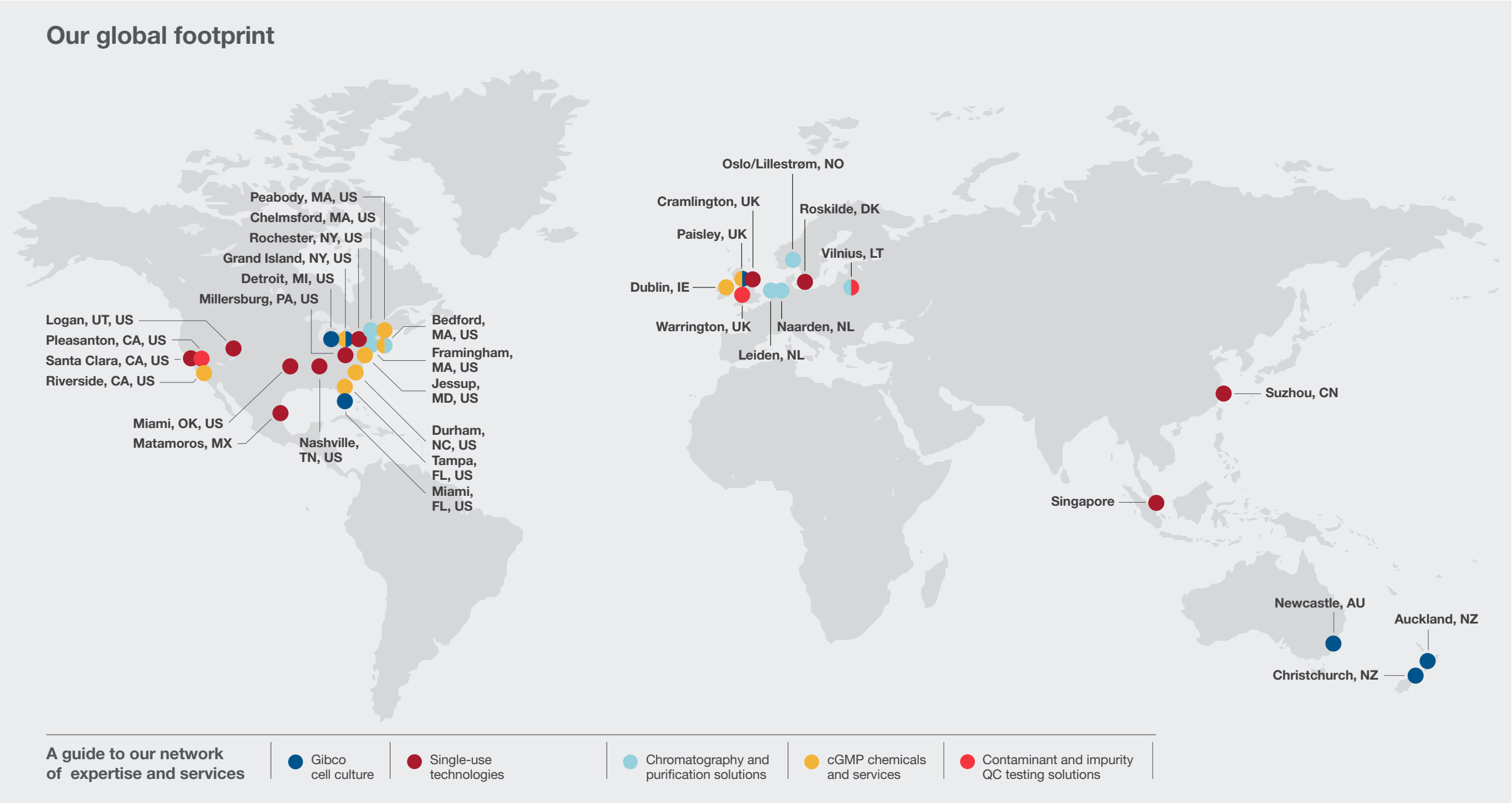
Supply chain constraints won't diminish any time soon — choosing the right suppliers can help

Thermo Fisher has been investing in bioprocessing capacity, capabilities, and innovation for decades. But we became especially aggressive during the virus crisis, spending more than \$650 million on upgrading our facilities and expanding our manufacturing capacity to support customers with a reliable supply of raw materials.

To reduce the risks associated with materials supply, we created redundant manufacturing sites across more than a dozen locations in North America, Europe, and Asia, enabling more regional and in-country sourcing strategies. We are standardizing raw materials, processes, equipment, and finished product testing throughout our network to enable equivalency across manufacturing sites and reinforce our network to minimize disruptions.

Now more than ever, we're anticipating and planning for materials shortages before they happen. We qualify suppliers and secure secondary or dual sourcing to help make sure that raw materials and components meet manufacturing specifications. We're sparing no expense on these efforts to help ensure that your resources will be available when and where you need them.

Our global footprint



Quality control is vital during every phase of design, development, and manufacturing

Quality is our priority.

We maintain robust quality control measures in all facets of manufacturing, from sourcing and testing raw materials to our supplier qualification regimen and our ongoing risk mitigation program.

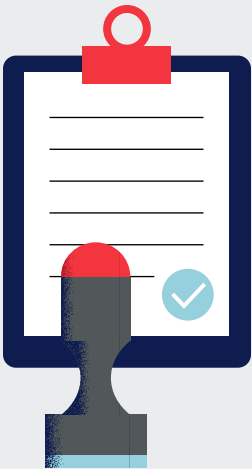
Our state-of-the-art facilities are ISO-certified and audit-ready. We host hundreds of customer site audits every year. We also use industry-standard quality management software to help ensure compliance with global regulations and standards.

Our systems are in a continual state of what we refer to as Practical Process Improvement. We’re constantly upgrading our products and services to stay ahead of customer needs.

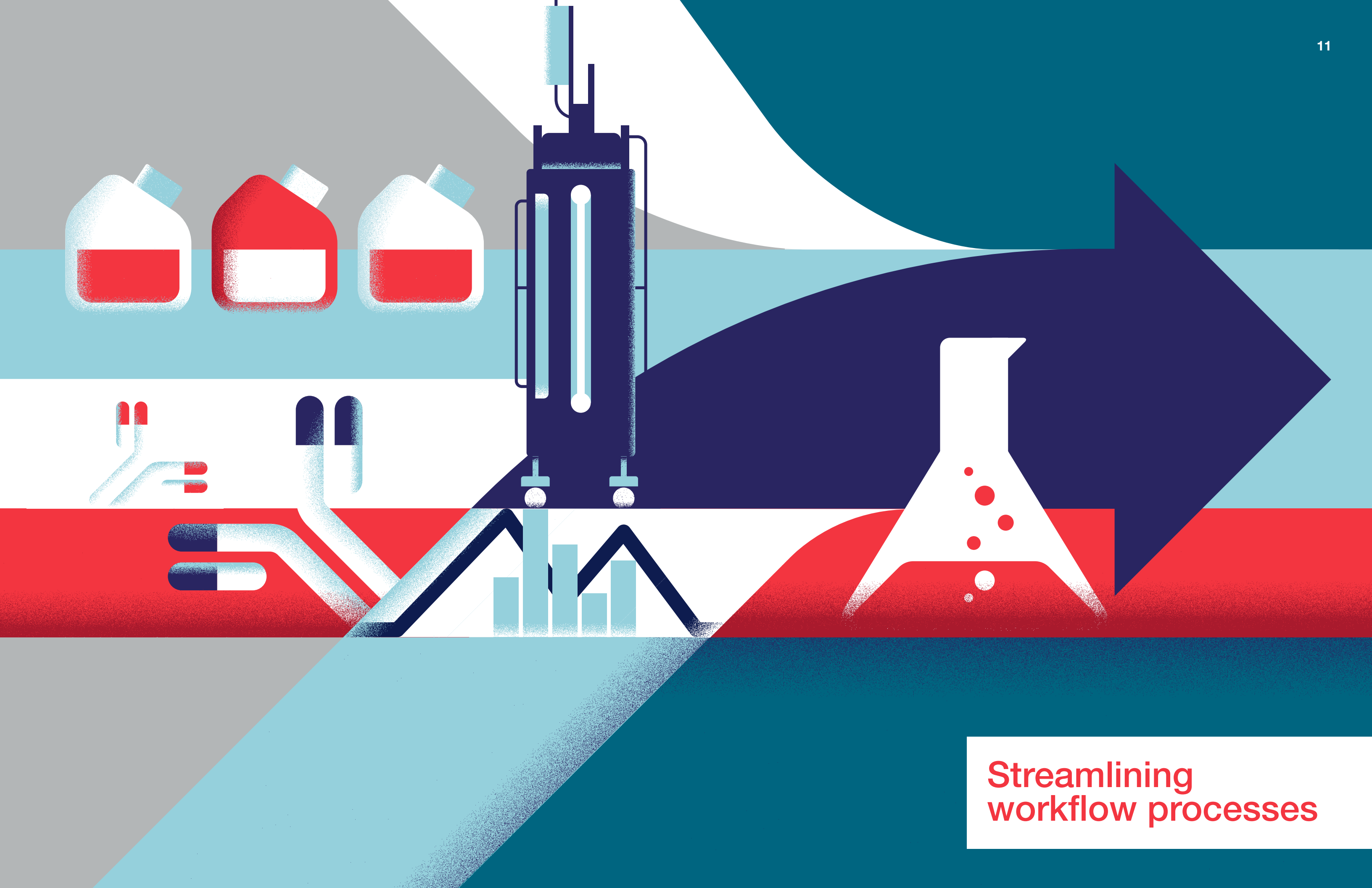
When our supply chain is part of your supply chain, we’re fully invested in the effort to maximize quality and reduce disruptions in materials and chemicals.

Our goal isn’t merely to help you through a project. We’re aiming for long-term business continuity.

Our end-to-end focus on quality



Supplier qualification process		Quality assurance assets and procedures	
✓	Technical questionnaire	✓	Our QMS and facilities are all ISO certified. Most facilities meet the highest QMS standard, ISO 13485.
✓	Raw material qualification testing	✓	Our bioprocessing technologies include a certificate of quality assuring that product has been tested and accepted in accordance with specifications.
✓	Supplier quality management system (QMS) audits	✓	Applied Biosystems™ analytical testing to help ensure quality and safety of pharmaceutical products
✓	Ongoing supplier monitoring program	✓	Certified clean rooms with traceability and rigid environmental specifications to minimize contamination
		✓	Systematic raw material supply chain risk-management program
		✓	We host more than 200 site audits per year, and in 2021 we hosted 51 regulatory or registration audits with no major or critical findings.
		✓	1.5 million bioprocess containers inspected per year



**Streamlining
workflow processes**

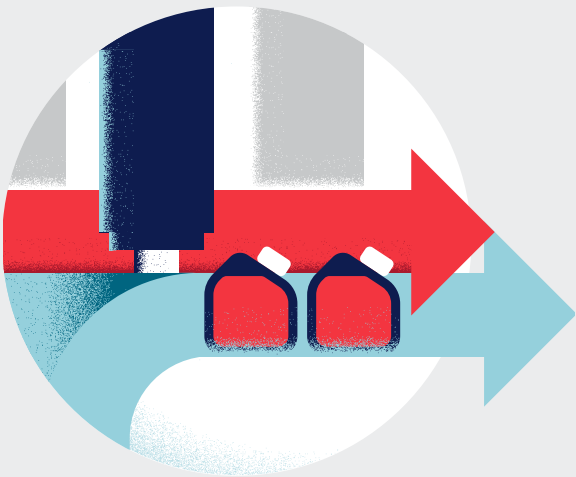
We help customize workflows by matching best practices with your specific needs

The first step toward commercializing any new therapeutic is to formulate an effective production strategy.

Robust, verified, and efficient biomanufacturing workflow processes can greatly reduce manufacturing costs, improve product quality, and accelerate the journey to market.

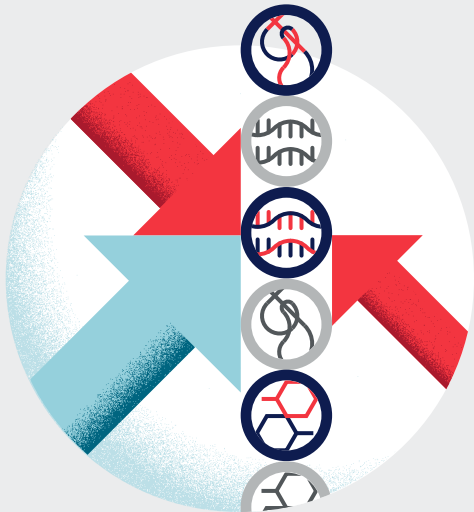
Whether you are a startup developing your first molecule or an established manufacturer branching out to novel therapeutics, we have the products, services, and expertise to help transform your processes. We can help build a custom platform—and we can assist with transitions and upgrades.

Process development and optimization



Improved manufacturability

We provide a range of services to help accelerate development, including design and optimization consultations from professionals with experience in cell culture media. We also offer purification solutions to help process developers tailor downstream purification according to their specific needs. To progress your molecule advancement, we can help you identify optimal raw materials.



Process characterization

We help maximize cell-line potential with multiomics media development services by applying deep data interrogation, which yields a more advanced media design and optimization path to achieve higher performance. Our integrated bioreactor systems automate data collection and provide measurement, control, and data management for seamless transfer to pilot and cGMP manufacturing. During clinical trial preparation, we also can help to identify optimal cGMP raw materials and offer a risk-based approach and redundant materials supply to help ensure long-term success.



Analytical methods

We offer the methods and tools to inform process analytics, enabling our customers to make rapid quality assessments to reduce risk to patient safety and improve process design. Multistage contamination and product purity data analysis enables you to get the information you need faster.

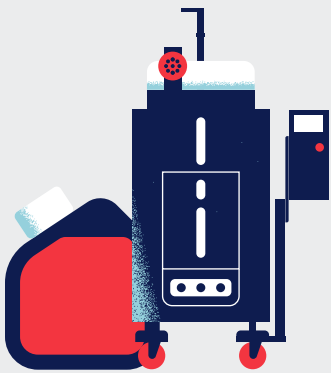
We've been pioneering innovation in upstream processes for decades

At Thermo Fisher, we've helped hundreds of biomanufacturers accelerate the development, scale-up, and cGMP manufacturing of life-changing medicinal products. Our clients have access to our unique combination of in-depth sourcing, testing, and manufacturing experience. And we make it a priority to simplify and optimize upstream processes to accelerate your path to distribution.

The goal is not merely to be first with innovations, like chemically defined cell culture media or single-use bioreactors and fermentors. We push for a state of continual innovation. While we may be incredibly proud of how our 5,000 L single-use bioreactor changes the economics of upstream biomanufacturing, it's not an excuse for complacency. We're already working on next-generation upstream innovations.

Whatever the scope of your project, our portfolio of upstream technologies provides consistent, scalable solutions to help keep you at the forefront. We offer unmatched technical and manufacturing process experience to simplify and optimize upstream processes that can help get you more quickly to clinic and manufacturing.

A look at our upstream capabilities



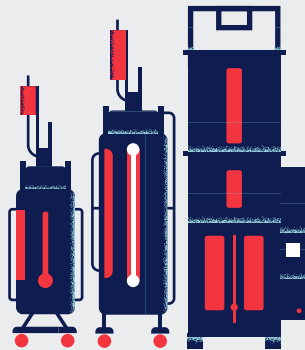
Innovative technologies

Our modern cell culture systems produce notably higher titers and speed the transition from bench to bioreactor. Thermo Scientific™ HyPerforma™ single-use bioreactors provide higher mixing turndown ratios to meet the demands of specific cell culture processes.



Process simplification

We simplify workflows by limiting resource-intensive steps. The AGT™, or Advanced Granulation Technology™, media format exceeds performance compared with other dry powder cell culture media formats, while reducing complexity and inconsistency. We also offer a range of fluid transfer products to reduce the number of components that need to be sourced and assembled.



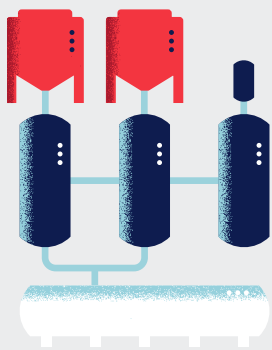
Scalability

Our suite of single-use technology solutions seamlessly integrates systems and data from bench to pilot to cGMP manufacturing—and accelerates production facility buildouts.



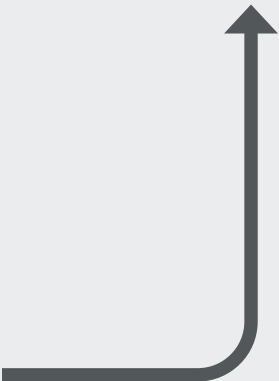
Quality and safety

We provide contaminant and impurity QC testing solutions for microbial, mycoplasma, and viral detection. Our rapid molecular methods can replace cell-based assays, shaving weeks off testing time. Our regulatory consulting services can help the quality and speed of submissions.



Technology transfer enablement

Advanced automation and process control systems manage process data and documentation from development through manufacturing or between manufacturing sites.



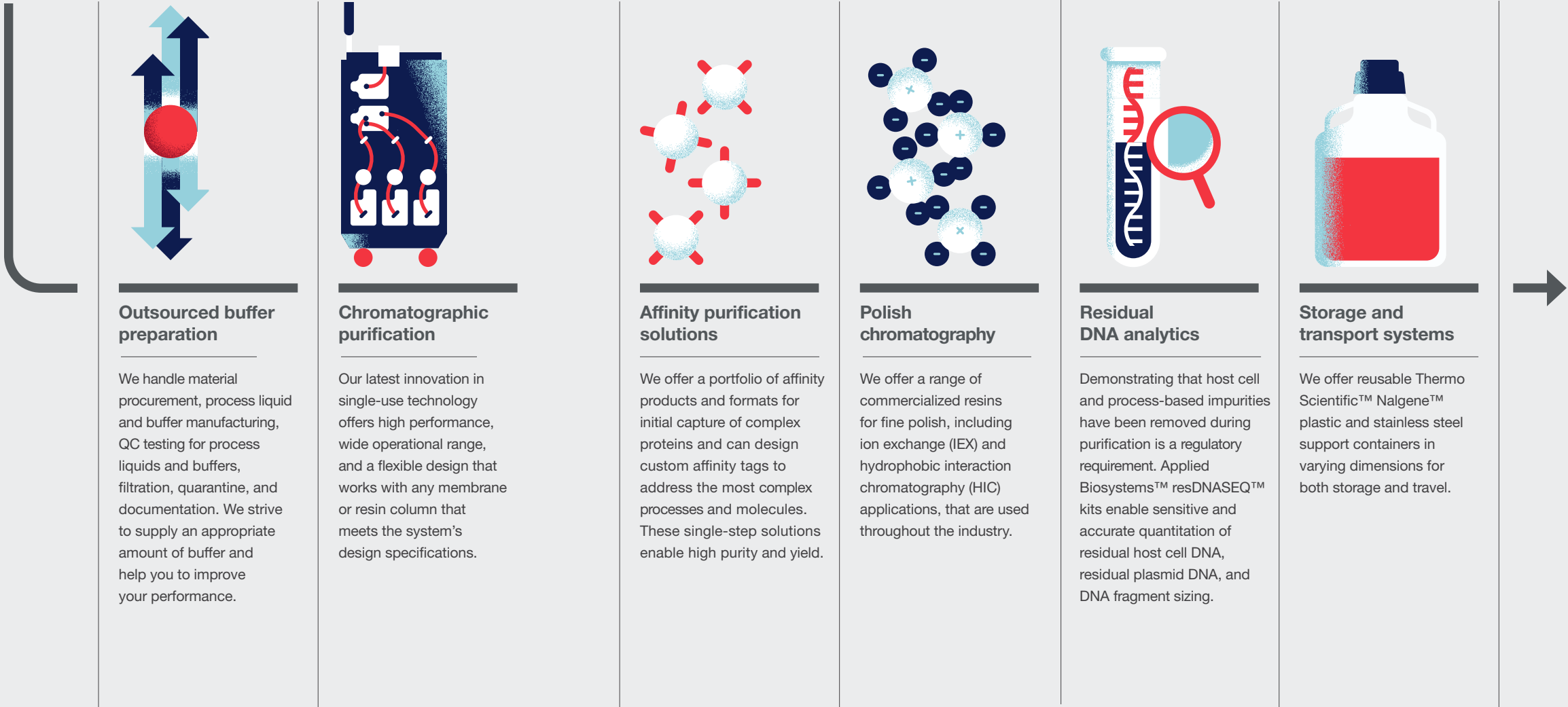
We have the tools and experienced professionals to mitigate downstream bottlenecks

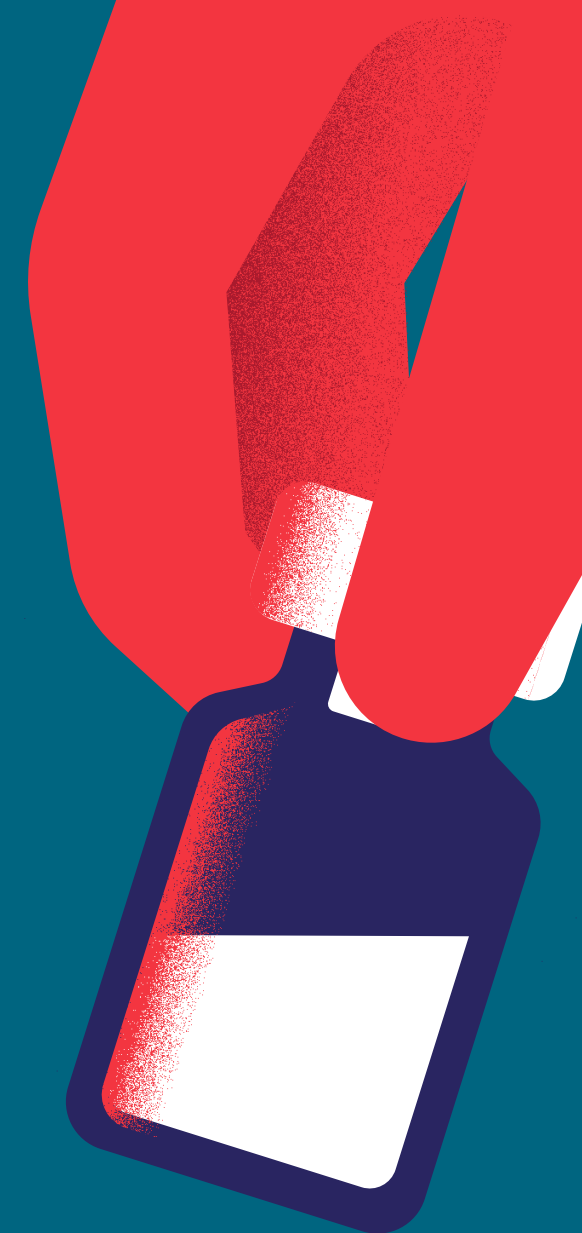
Bottlenecks can hinder downstream development at any phase. Insufficient buffer supply can stall processes before they start. Additional chromatographic purification steps can increase costs and cause delays. Contaminants or impurities may impact product quality or even bring a program to a full stop.

Buffers require significant resources and coordination. We can help maximize manufacturing flexibility by simplifying buffer preparation—whether through in-house single-use mixing systems or complete outsourcing models. Our resins also offer high resolution and excellent capacity to mitigate pressure from increasing titer upstream, enabling you to achieve high purity and high yield.

Meanwhile, our affinity resin technology and customization capabilities provide purification solutions for a range of emerging modalities, including fusion proteins, antibody fragments, antibody drug conjugates, nucleic acids, exosomes, and virus particles. We also provide sensitive, accurate, and reproducible analytical methods to enable purification process characterization and demonstrate clearance of residual DNA.

We help streamline your downstream





**Collaborating to
commercialize**

We’re dedicated to helping accelerate your journey to commercialization

We collaborate during every phase of production to get your innovation to market.

Our technical specialists around the globe are dedicated to understanding your needs and exploring options for streamlining based on industry best practices and state-of-the-art technologies. They will coordinate a workflow assessment—a Process Walk, or Gemba Walk—to identify potential areas of waste and risk within your workflow.

Our bioprocess design centers offer hands-on training with single-use instruments in our advanced facilities that are devoted to optimizing your process development.

Our educational seminars and webinars provide the latest information about product training, applications, and process optimization.

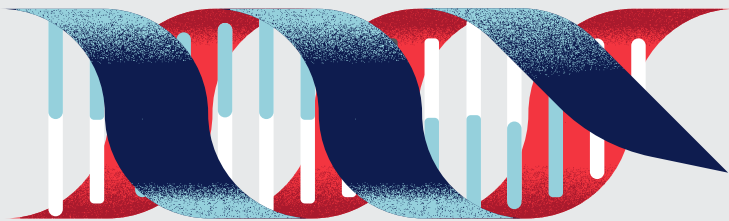
We offer dedicated technical support at every step as well as regulatory consulting services across biologic modalities.

The way forward to delivering life-saving innovations

Regardless of modality, we have the expertise to support your workflow.

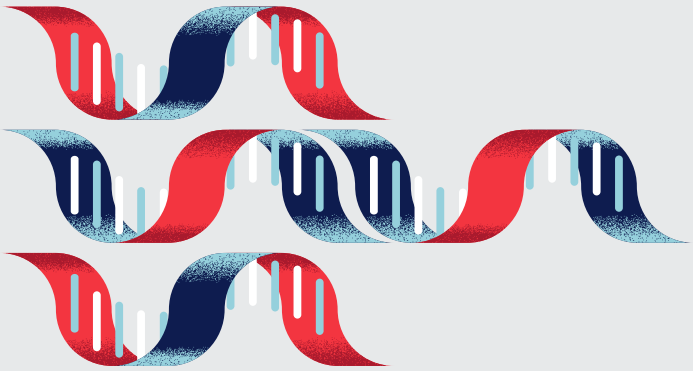
Gene therapy

Helping to enable high upstream productivity and novel solutions to address challenges of viral vector purification, and providing assays that help ensure quality and safety to meet in-process and lot-release testing needs



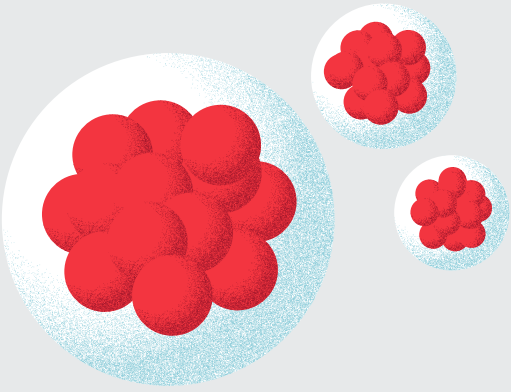
Nucleic acid therapy

Innovating to adapt to the evolving landscape with the rapid development of affinity purification solutions to support mRNA-based vaccines and therapies



Cell therapy

Providing solutions utilized in numerous FDA-approved and EMA-approved chimeric antigen receptor T-cell (CAR T) therapies, including the first commercially approved CAR T therapy



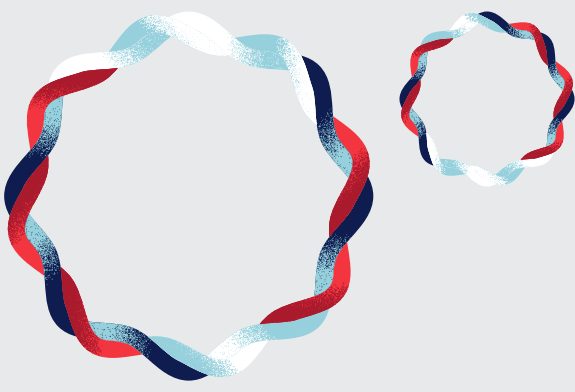
Antibody therapeutics

Products integrated into hundreds of traditional mAb clinical and commercial pipelines and innovative solutions to support the next generation of emerging mAb therapeutic derivatives



Plasmid production

Designing solutions with the first single-use system specifically engineered for microbial fermentation and the first chemically defined microbial media



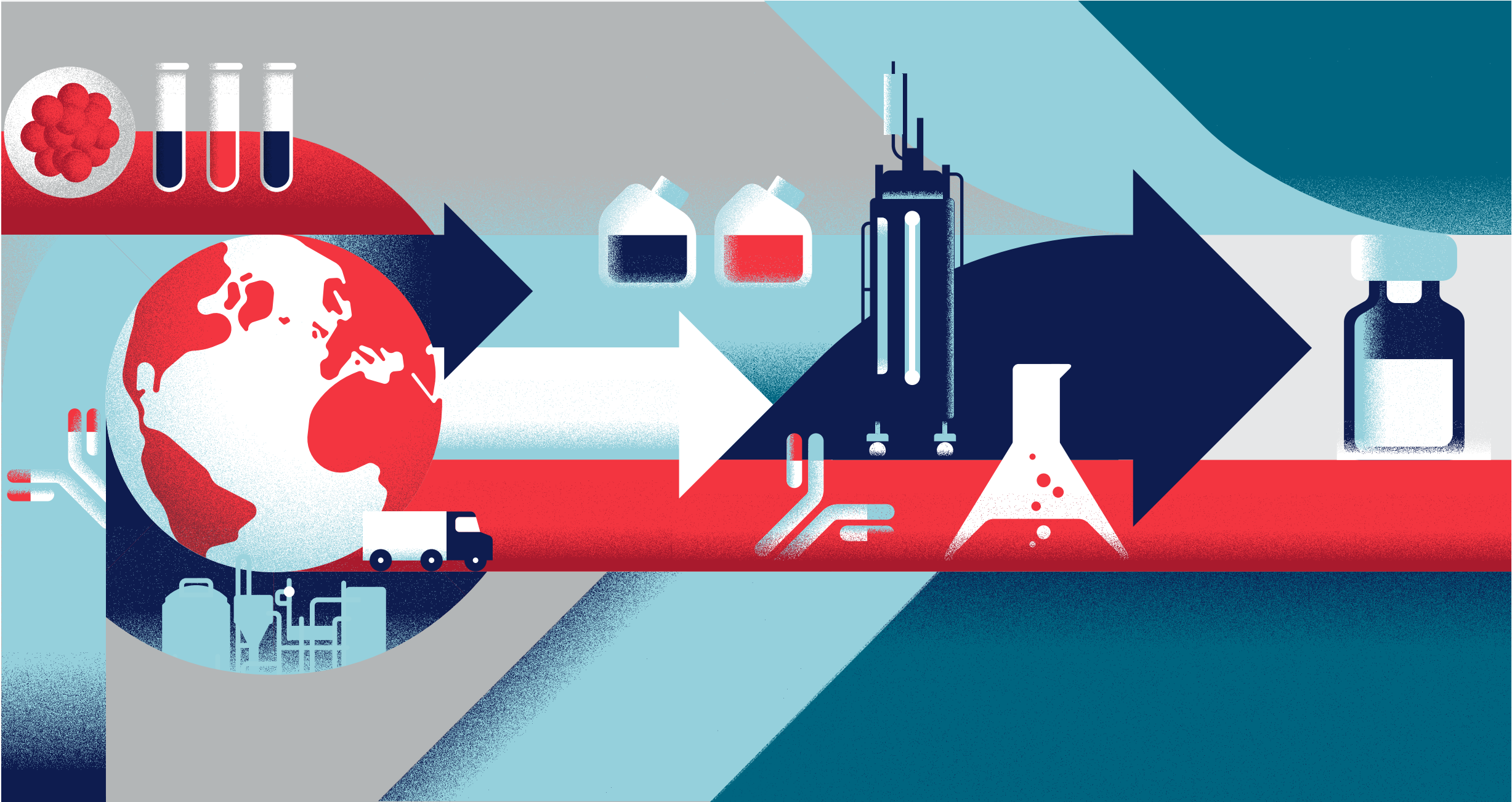
We're the industry leader in bioprocess innovation—and we're here for you

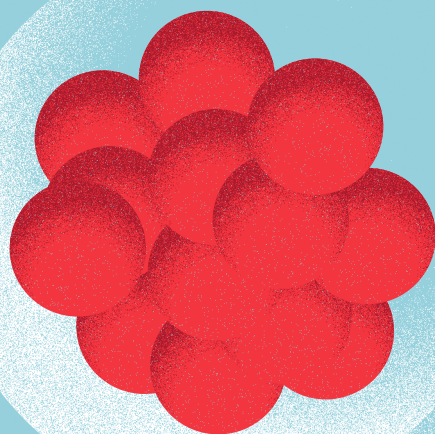
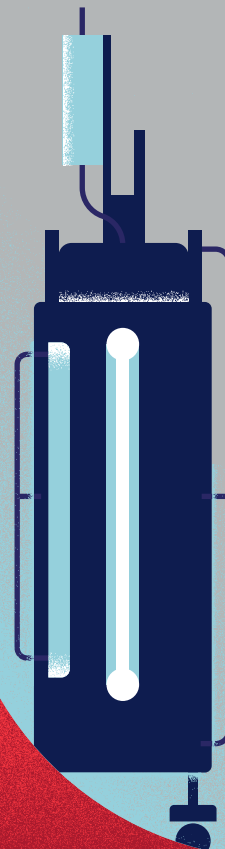
You have a program. We have a way to get you there.

Remarkable advances in new areas of medicine, from gene and cellular therapy to antibody therapies and mRNA technologies, offer the promise of a new golden age of biologics innovation. But the potential of these exciting fields is being hampered by increasing production complexity.

At Thermo Fisher, our Mission is to enable our customers to make the world healthier, cleaner and safer. This can be a high bar to clear during such uncertain and dynamic times, but we've spent decades investing in the infrastructure and building the technical knowledge to prepare us. We're confident that we have the talent and technology to help you successfully commercialize your medicines, now more than ever.

We believe that the best way forward is together. We're eager to get started.





Learn more at thermofisher.com/bioprocessing
Ready to speak to a rep? [Click here.](#)

Intended use of the products mentioned in this brochure varies. For specific use statements, please refer to the product label.
© 2022 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified. **EXT2419 0522**