BIOLOGICS OVERVIEW BROCHURE

FLEXIBLE BIOMANUFACTURING SOLUTIONS

Patheon

fisher clinical services

ThermoFisher SCIENTIFIC

• API • BIOLOGICS • EARLY & LATE PHASE DEVELOPMENT • CLINICAL TRIAL SOLUTIONS • LOGISTICS SERVICES • COMMERCIAL MANUFACTURING

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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 you the flexibility and speed to help you get there ahead of schedule while maintaining the highest quality. We bring deep 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.

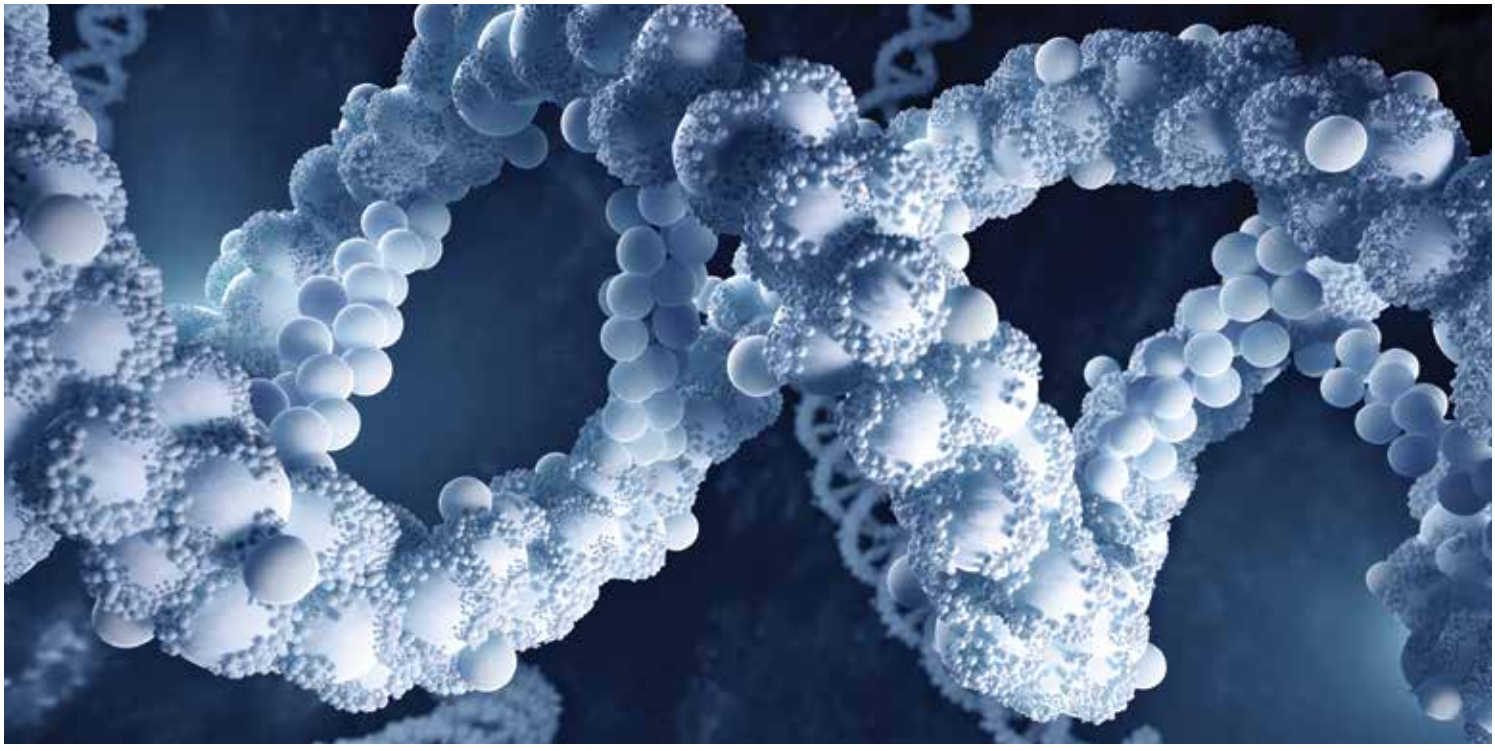
We pride ourselves on our ability to create flexible options for our clients. We understand the uncertainty associated with forecasting demand. We think strategically to offer biomanufacturing options that meet the unique needs of your molecule. We can work with your cell lines. Our contracts are individualized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

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

The pressure to file an IND makes accelerated Phase I safety testing a priority. With the Quick to Clinic™ program, Thermo Fisher Scientific can deliver your large molecule drug substance for First-in-Human studies in as little as 12 months. Now you can meet important milestones – such as filing the IND – or secure additional funding with all the confidence your project needs, and we can supply. Because helping you reduce the time it takes to get your discovery to the patients who need it matters, our Quick to Clinic™ for Biologics is made with speed and flexibility.

PROCESS DEVELOPMENT CAPABILITIES – FLEXIBILITY, QUALITY AND SERVICE.

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



UPSTREAM PROCESSING CAPABILITIES.

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

Fed Batch Processing

Achieve stable reliable production at titers >5 g/L.

Perfusion Processing

Achieve high productivity and manufacture of unstable proteins.

Single-Use Technology

Reduce technology transfer and scale-up risks and eliminate cross-contamination concerns. Multiple single-use bioreactors: 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'S 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:

- Validation of analytical methods
- ICH stability studies
- 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. We also understand the unique role of consultants and offer custom, 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. Even when 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

Manufacturing locations in US, EU and Australia. Take advantage of 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 operation management.

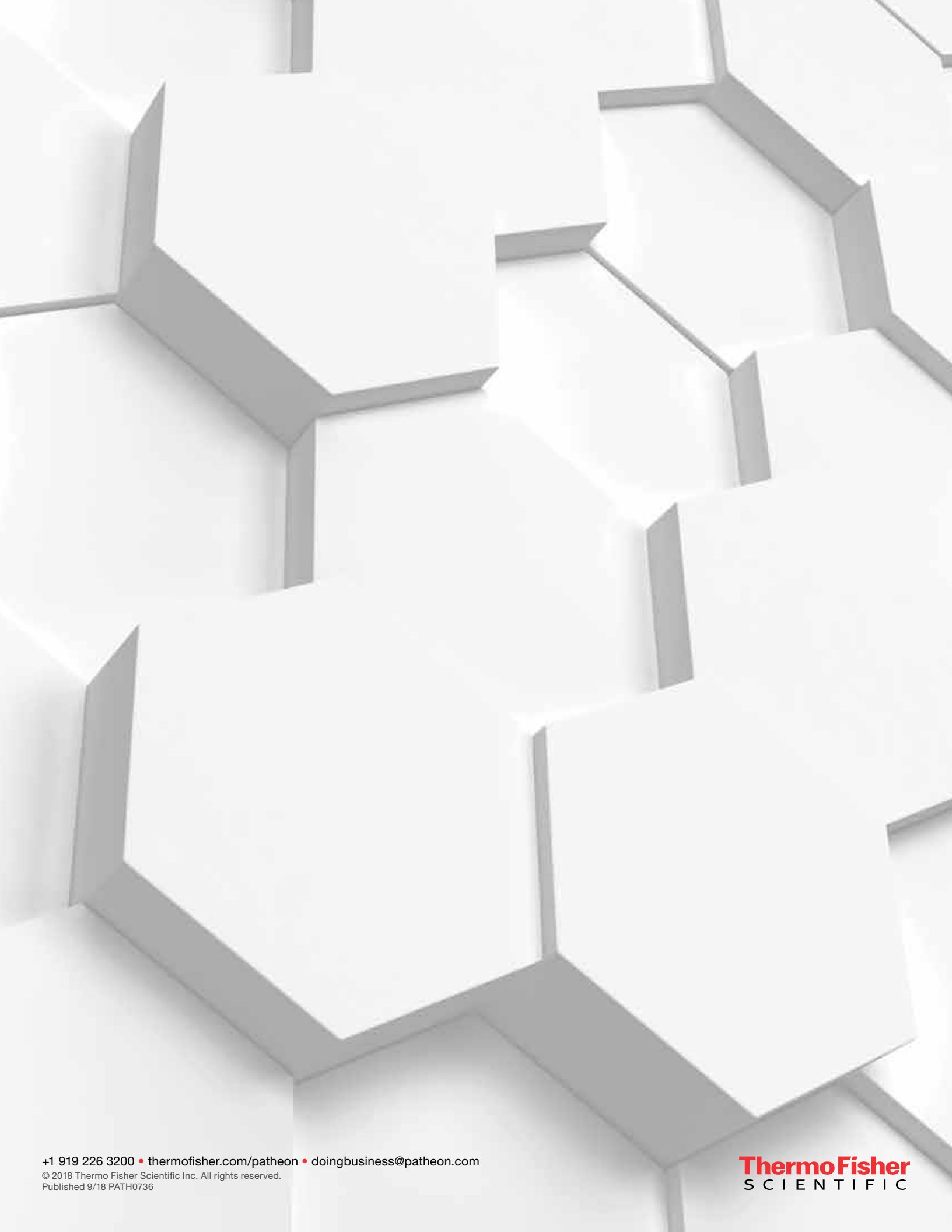
Enterprise

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.

Offering a depth and breadth of innovative biologic capabilities from development to commercialization. Pioneering new technologies to improve the manufacturing process. Focusing precisely on every step, but never forgetting the end goal. Thinking strategically to offer flexible, fast, efficient approaches to helping your discovery through the complex journey to market.

These are the scientists, engineers and professionals of Thermo Fisher Scientific. Who apply a science-driven, risk-based approach to every step of the biologic development and manufacturing process. Who draw on years of experience. And who partner with you at the stage of development that's most advantageous for your business. 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.



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