bioproduction

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Bioprocessing by Design

Driving performance through collaboration

ThermoFisher SCIENTIFIC

The demands of biomanufacturing: innovation, performance, and efficiency

The biotherapeutics market is increasingly dynamic. Novel biologics are coming to market, bringing new treatments to more diseases. Biosimilars are gaining rapid acceptance, providing access to lifesaving medicines for new geographies and patient populations. And promising new approaches like cell therapies offer even greater potential for patients. Bringing these medicines to market requires an increased focus on balancing innovation in process design, performance, and efficiency with speed and cost. While navigating this evolving landscape, one value that can never be compromised is quality.

Successfully meeting these needs requires new approaches and ways of thinking.

70%
of drug approvals are expected to be **biologics by 2025**

Dynamic biologics landscape

Emerging geographies

$35 billion
in **global revenue for biosimilars** and follow-on biologics by 2020

>85%
of biopharma manufacturing seed trains use **single-use systems**

Single-use systems drive modular facilities

Process efficiencies intensify

10x increase
in **platform cell titers** over the last decade

65%
of all drug shortages are caused by **manufacturing and quality issues**

Evolving regulatory environment

Biologics are complex and every process is unique.
Successfully meeting demand for both productivity and cost control requires simultaneously addressing performance and efficiency in your specific bioprocess.

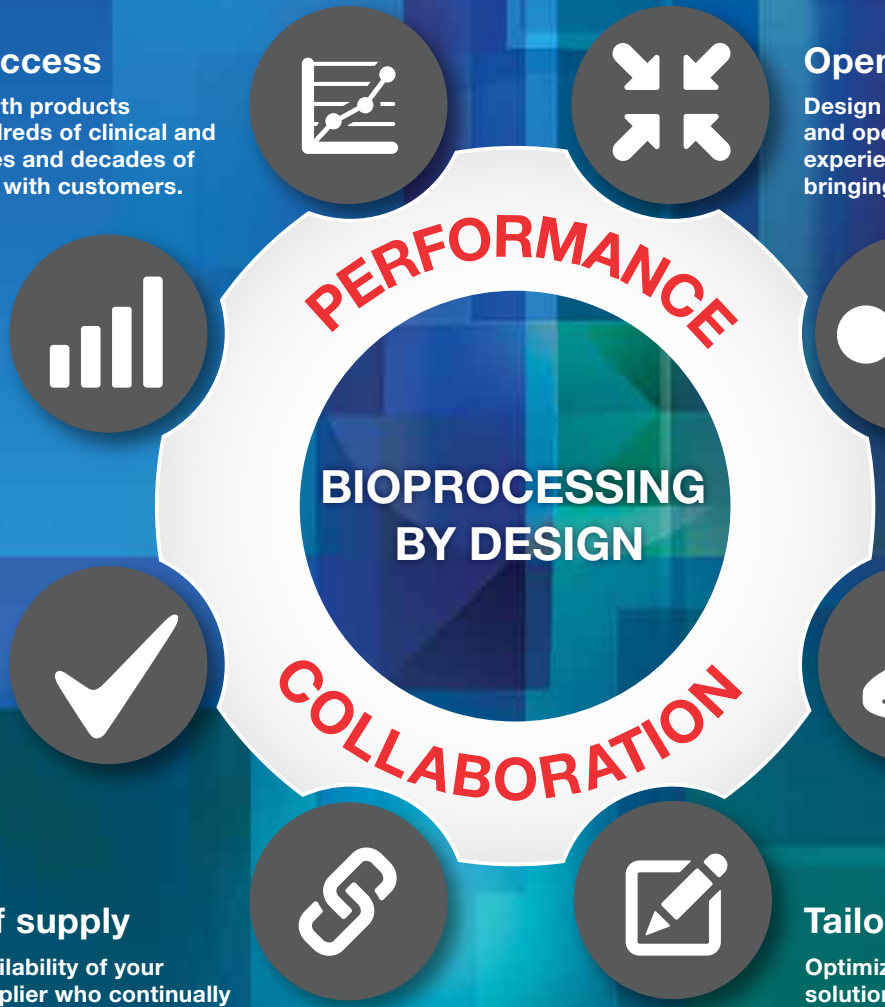
Driving performance through collaboration

To meet the increasing demand for biologics worldwide, you need to expect more from suppliers. It isn't just about the products we deliver, but how we do business together.

With a collaborative approach that is grounded in our technical knowledge, we work with you to achieve optimal bioprocessing outcomes. Committed to identifying the technologies and services that address your needs, from drug development through large-scale commercial production, we provide integrated and tailored solutions that improve the overall biomanufacturing experience. If a solution doesn't exist, we'll build it—together.

And while we are flexible in our approach, we are uncompromising in our pursuit of performance. Through technical engagement, innovative product design, and strategic sourcing programs, we deliver productivity, quality, and assurance of supply so that you can have complete confidence in the efficiency and speed of your biologic development and manufacturing processes.

That's our commitment to you and it's what we call Bioprocessing by Design.



Record of success

Rely on a partner with products integrated into hundreds of clinical and commercial pipelines and decades of experience working with customers.

Open architecture

Design optimal systems for your applications and operations with the support of experienced professionals capable of bringing the right technologies together.

Productivity

Find the right solutions to help increase yields, remove or reduce workflow steps, manage costs, and simplify your process and operations.

Adaptive innovation

Tackle the challenges of increasingly molecule- and application-specific processes with a pioneer who drives innovation in the industry.

Quality and safety

Expect products that perform consistently day to day, lot to lot, and year to year, with rigorous QC practices that help ensure product performance and integrity.

Holistic approach

Leverage the breadth of our capabilities to support your needs, including process development, regulatory support, supply chain management, and lean manufacturing.

Assurance of supply

Help ensure the availability of your products with a supplier who continually invests in manufacturing redundancy and business continuity strategies.

Tailored solutions

Optimize your workflow with unique solutions that fit your needs—from upstream and downstream bioprocessing to supply chain services.

Upstream

Upstream bioprocessing has made great productivity gains over the last decade. Modern cell culture systems are now producing notably higher titers while also decreasing the time from bench to production bioreactor. Thermo Fisher Scientific has helped pioneer significant technological advances that have driven these performance gains, including improved cell lines and expression systems, cell culture media optimization, the development of single-use technologies, and improved process automation. While these advances will continue to be critical in driving upstream efficiency, the adoption of approaches like continuous bioprocessing holds even greater potential.

Achieve optimal outcomes in your upstream bioprocess

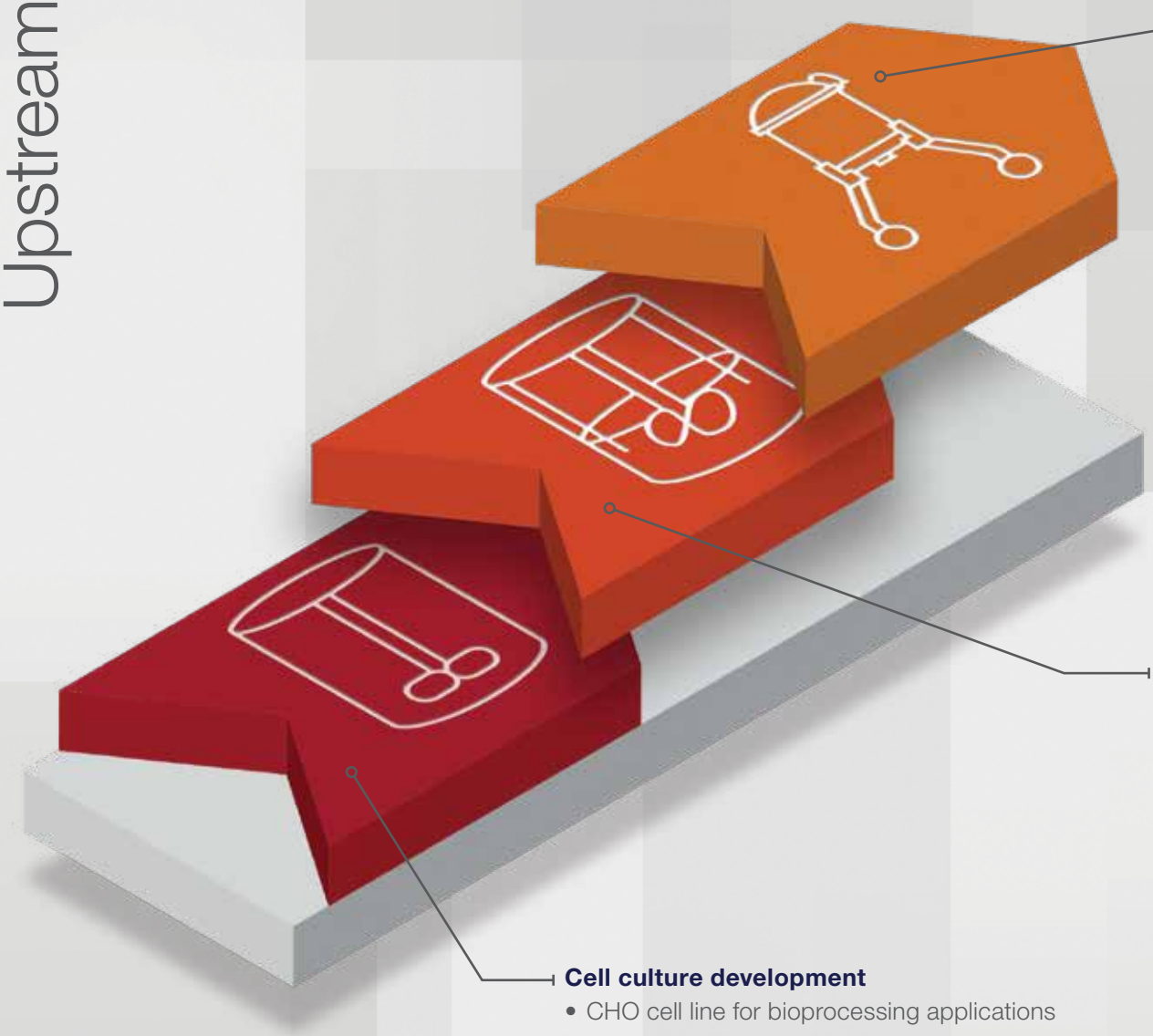
Increase cell culture titers and quality
Utilize our media and feeds, including custom media services, to drive optimal titers without compromising on product quality.

Simplify upstream scale-up to production
Combine our configurable control systems with single-use bioreactors from benchtop- through production-scale, to intensify the process of getting into production.

Design your process for efficiency
Explore solutions that can improve your process efficiency by matching the right cell culture media and supplement formats with single-use mixing and liquid-handling technologies tailored to your process.

Enable faster product release with validated, real-time mycoplasma testing
Reduce your QC testing timelines with a PCR-based mycoplasma testing method that is accepted by regulatory agencies for accelerated lot release of multiple therapeutic modalities.

Upstream



Harvest and collection

- Simplified connectivity between bioreactors and harvest devices
- Storage and transport solutions for single-site and multisite connectivity
- Microbial identification solutions for process and environmental monitoring control platforms

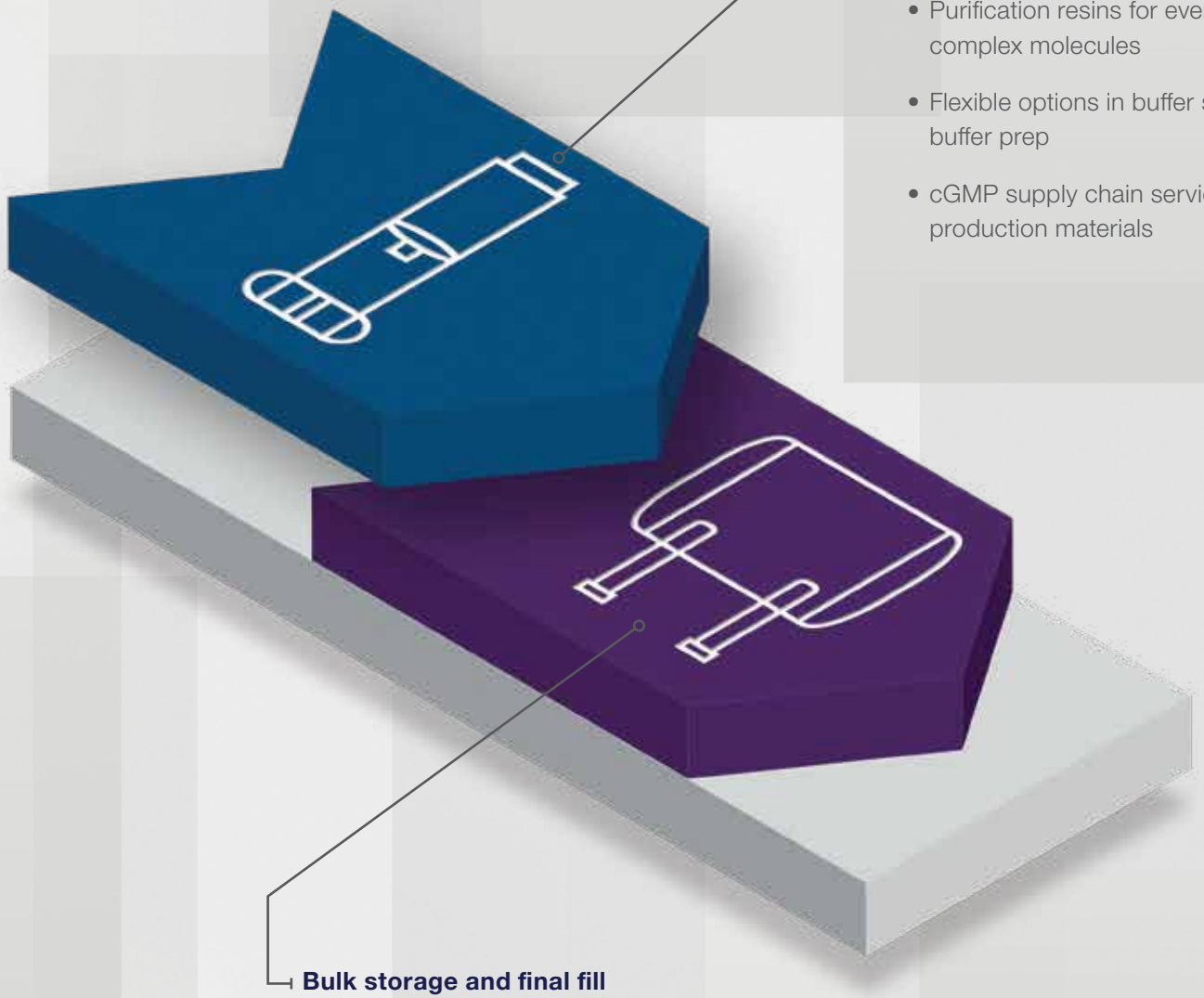
Scale-up and production

- Process development and optimization services and solutions
- Integrated single-use systems for scale-up and production
- Configurable measurement and control platforms

Cell culture development

- CHO cell line for bioprocessing applications
- Media, feeds, and services that drive high titers and biologic quality
- High-throughput glycan analysis platform with high data quality

Downstream



Purification

- Purification resins for even the most complex molecules
- Flexible options in buffer supply or in-house buffer prep
- cGMP supply chain services for direct production materials

Bulk storage and final fill

- Proven contaminant and impurity QC testing for drug substance samples
- Single-use containment for processing and storage of critical products
- Procurement, warehousing, and manufacturing preparation services

Downstream

Advances in upstream processing have led to downstream bottlenecks—particularly during chromatography purification. While many gains have been made in chromatography resin–binding capacity, there are still challenges with labor-intensive buffer preparation processes and steps for cleaning traditional equipment. We have developed multiple solutions for downstream buffer preparation and supply, and are integrating single-use technologies into downstream workflows to drive process simplification. Additionally, the connectivity of integrated operations and innovations in continuous bioprocessing are expected to deliver efficiency gains. To stay ahead of future downstream needs, we are focusing on novel purification platforms to address new molecules and therapies in your pipeline, and on process analytical testing to ensure removal of product- and process-related impurities, including host cell components and leached proteins.

Achieve optimal outcomes in your downstream bioprocess

Devise purification strategies for even the most complex molecules and processes
Discover products that offer the highest specificity for their target molecule, enable purification of novel biologics, and are capable of operating at flow rates that support continuous applications.

Ensure process and product safety with rapid analytical methods
Detect impurities and identify contaminants, like residual host cell DNA, with molecular techniques that are quickly becoming the standards for pharmaceutical analytics worldwide.

Reduce costs and gain productivity in buffer preparation
Utilize multiple options to simplify buffer preparation—from in-house single-use mixing systems to complete outsourcing models—designed to maximize manufacturing flexibility.

Rely on high-quality single-use delivery systems for processing and storage of critical liquids
Choose from our broad offering of flexible and rigid bioprocess containment and transfer systems that can be optimized for your process—with the industry's largest component library to support your custom designs.

Integration brings it all together

The biomanufacturing industry is undergoing a major shift—from single-product processes and stainless steel infrastructure to flexible, multiproduct facilities using single-use technology. Though single-use systems are being widely adopted, there is still a lag in the adoption of process automation, which will enable you to capitalize on the aggregation and management of real-time and historical process data to ensure consistency and repeatability of every process step.

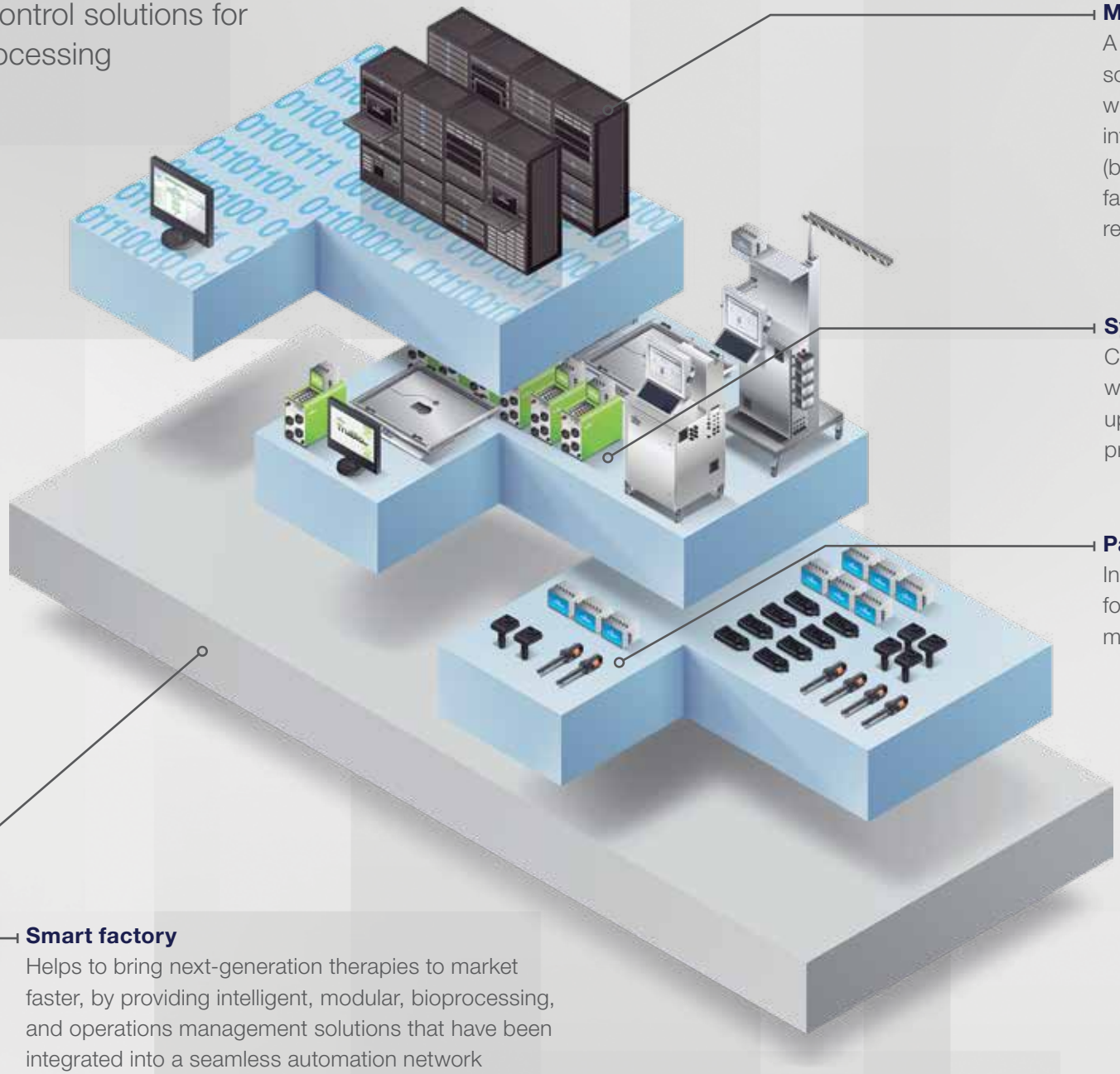
Automation will play a major role in facilitating semicontinuous and continuous processing strategies. It will enable more efficient dosing and feeding in the bioreactor, pH changes in the process, and the creation of gradients in chromatography. In a continuous process, automation will allow facilities to dilute concentrated buffers in-line to avoid sizeable liquid storage. For complex testing for impurities and contaminants, we offer integration of multiple analytical assays into offline platforms for both high-throughout process development and automated QC methods.

Many facilities have a mix of old and new equipment, often running independently on custom software. Intensified processes require a higher level of automation and often call for the rapid addition of sensors, pumps, and other peripherals. Regulatory directives are driving an increase in data collection, including a move toward comprehensive electronic batch records and increased security protocols around data integrity. And efficient facility management demands integration of the overall process within a plant manufacturing execution system (MES).

Our universal automation platform provides highly configurable solutions that enable you to design the optimal systems for your operations, with the support of experts capable of bringing the right technologies together. We can help automate your processes and data collection; control and harmonize equipment from multiple suppliers; and provide sensors, controllers, and bioreactors.

Integrated solutions

Comprehensive measurement and control solutions for bioprocessing



MES
A process management solution that optimizes plant-wide resource utilization, integrates manufacturing (batch) information, and facilitates training and validation record management

Systems
Combines universal hardware with flexible software to enable upstream and downstream processes at any scale

Parts
Intelligent components for modular bioprocess measurement and control

Smart factory
Helps to bring next-generation therapies to market faster, by providing intelligent, modular, bioprocessing, and operations management solutions that have been integrated into a seamless automation network

Upstream services

- Cell line and media development
- Spent media analysis
- Process optimization and scale-up
- Conversion to single-use with validation support
- Bioprocessing liquid manufacturing
- Analytical methods, IQ/OQ/PQ, and implementation services

Downstream services

- Custom ligand development and resin prototyping
- Process optimization and scale-up
- Validation and regulatory-support packages
- Downstream buffer manufacturing
- Engineering of single-use handling systems
- Custom assay development services

Production supply chain services

Supply and order management | Material handling and logistics | Safety stock programs | Custom labeling and barcoding | Pallet transfer and container recycling | Sampling | Material QC inspection | Production materials release | Virtual consignment

Support

Service and support plans | Customer care | Field support | Operations and training services | Practical Process Improvement (PPI)

A holistic approach to services and support

Biologic developers and manufacturers are increasingly looking to outsource services that supplement existing capabilities or allow resources to focus on core competencies. Outsourcing options have become attractive for a variety of reasons, from speed of development and managing cost to demands for flexible and lean operations. Whether you need support with short-term projects or are seeking long-term strategic alternatives, we offer solutions across the biomanufacturing workflow. When you partner with us, you gain access to a team of experienced professionals that help partner with you to develop strategies for improving the performance of your manufacturing process.

Consider how we can support you in every step of your bioprocess

Simplify your supply chain and improve logistics

Engage our supply chain solutions to streamline the procurement of production materials—enabling you to redeploy resources to higher-value activities, all while meeting your quality requirements and improving your On Time In Full (OTIF) supplier rates. We can also increase material readiness for the production suite with advanced services like barcoding, labeling, sampling, and vendor managed inventory/consignment.

Utilize our lean management system to gain efficiency and reduce cost

Partner with our trained professionals, who have extensive continuous improvement experience applying our Practical Process Improvement (PPI) business management system, to help optimize your operations. Using methods like Gemba walks, we focus on streamlining your process for greater efficiency and cost reduction.

Investment in quality and assurance of supply

Today's biotherapeutic producers are transforming lives by making better therapies more accessible. As a result, ensuring the safety and availability of these medicines is paramount. In addition to responding to evolving regulatory requirements, biomanufacturers are adopting comprehensive strategies to ensure product supply and long-term business continuity. We recognize that as a supplier into your process we play an increasingly critical role to support your need for high-quality products, a stable supply chain, and robust risk mitigation strategies.

Product quality you can rely on

Quality is our top priority and it begins with our raw materials, supplier qualification, and ongoing risk mitigation program. We've built our systems through rigorous QC practices, including testing of in-process and finished goods, to ensure consistent product performance and integrity that you can depend on day to day, lot to lot, and year to year.

Worldwide manufacturing network

Our worldwide manufacturing network supports bioprocessing customers in more than 100 countries on six continents. These state-of-the-art facilities are ISO-certified and meet rigorous quality standards. Our sites are audit-ready; we host hundreds of customer site audits per year.

Risk mitigation strategies to help meet your production demands

Our supply chain is part of your supply chain—a responsibility we take seriously. We utilize multiple risk mitigation strategies and offer enhanced supply chain services to make sure you get the quality product that you need, when you need it—without disruption.

Cell culture

Grand Island, NY, US
Inchinnan, UK
Auckland, NZ
Christchurch, NZ
Newcastle, AU

Single-use technologies

Logan, UT, US
Cramlington, UK
Millersburg, PA, US
Matamoros, MX
Santa Clara, CA, US
Rochester, NY, US
Fairpoint, NY, US
Roskilde, DK
Miami, OK, US
Suzhou, CN

Purification

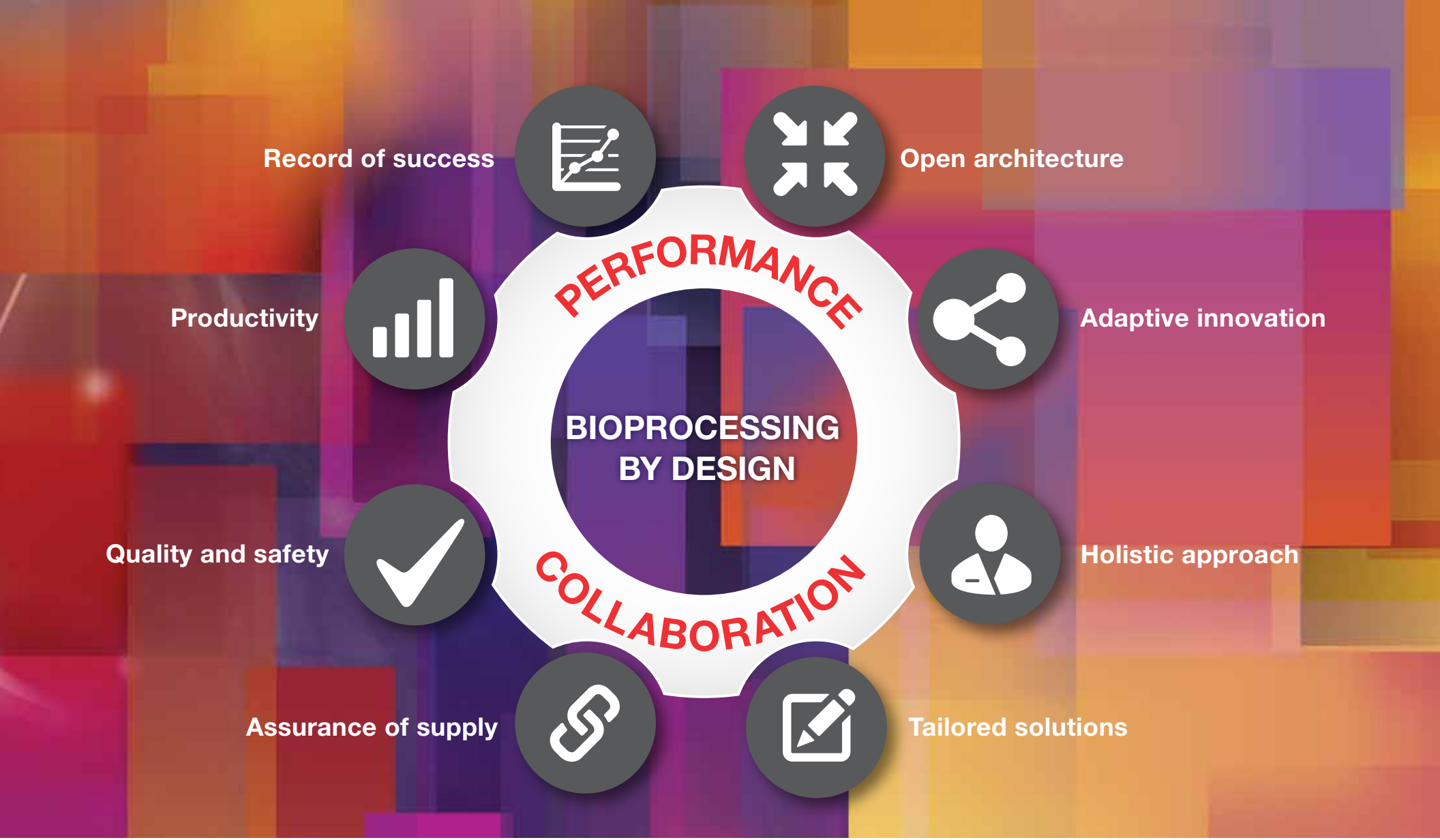
Bedford, MA, US
Framingham, MA, US
Naarden, NL
Leiden, NL
Oslo/Lillestrøm, NO

Analytical methods

Vilnius, LT
Pleasanton, CA, US
Warrington, UK

cGMP supply chain

Durham, NC, US
Peabody, MA, US
Jessup, MD, US
Tampa, FL, US
Riverside, CA, US
Dublin, IE



Find out more at **thermofisher.com/bioprocessing**

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