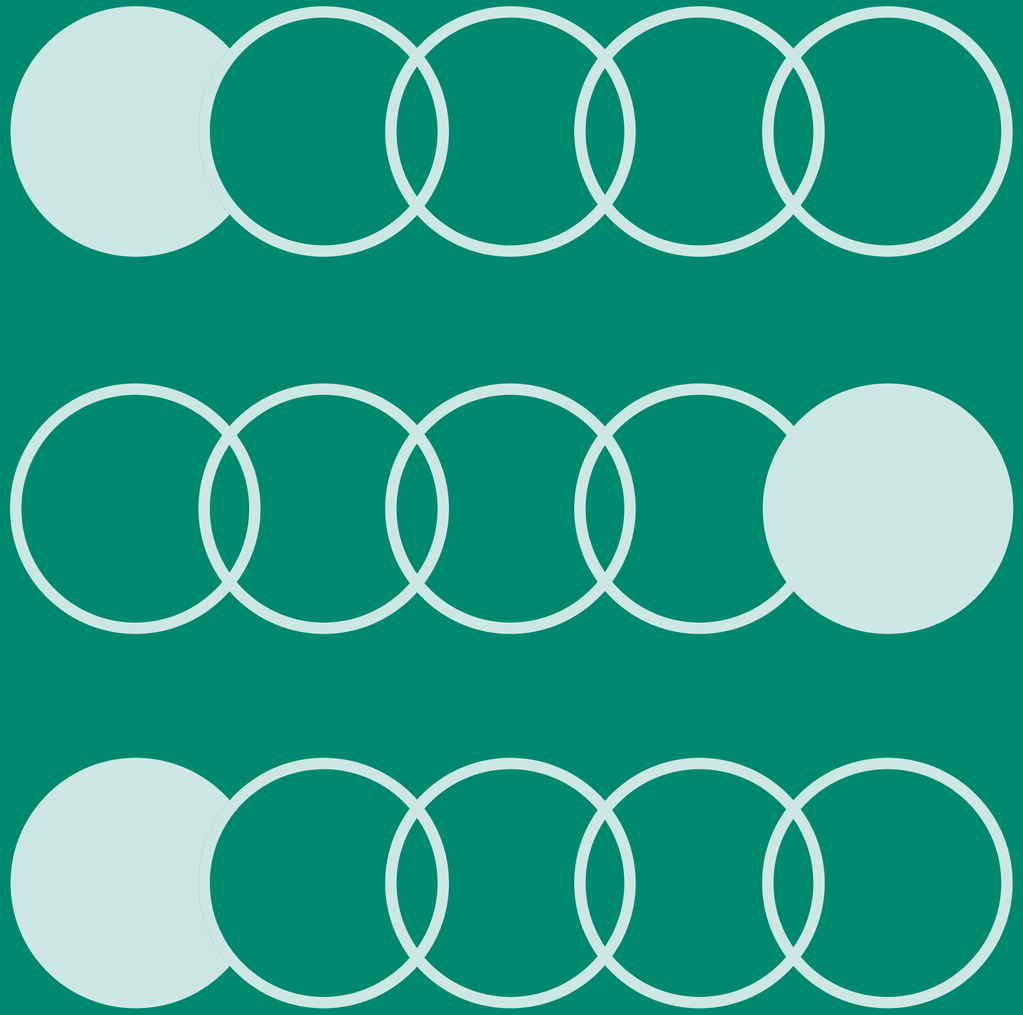
Fast Trak Services:
From molecule to market



cytiva

At the speed of Fast Trak

Whether you're looking to launch a new molecule, enhance existing capacity, or bring biosimilars to emerging markets, in today's fast-paced and highly competitive environment, *speed to market* is critical.

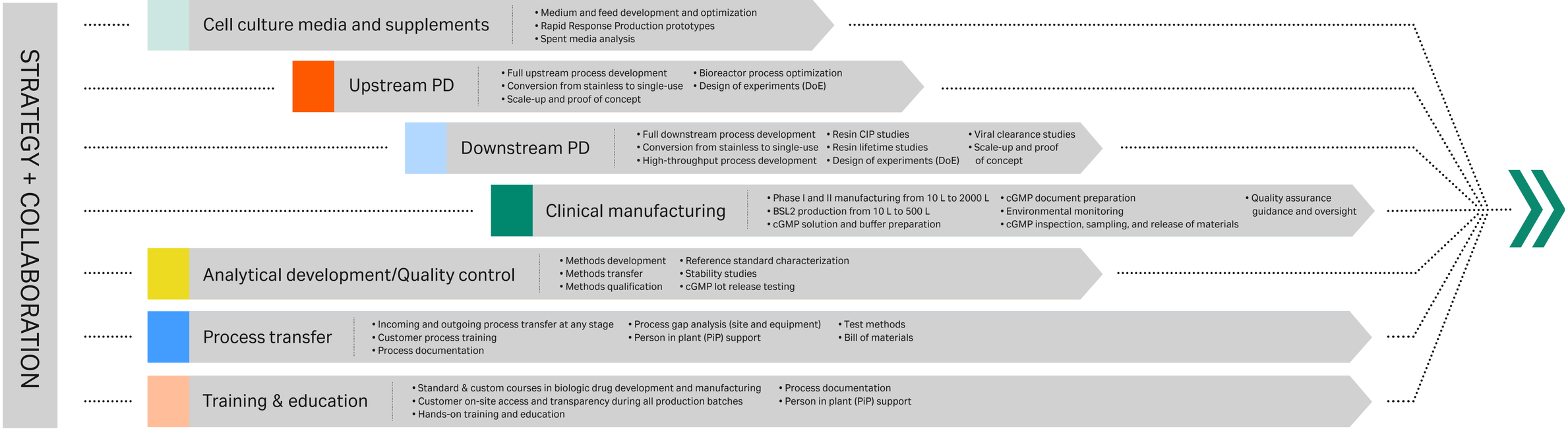
Our Fast Trak™ portfolio of services is designed to take you from molecule to market — and anywhere between — in the shortest time possible, while reducing costs, accelerating robust outcomes, and mitigating risk, all with full transparency.

In 1981, I started my first job in a biomanufacturing company and I have spent the years since then developing processes and building facilities to speed molecules to the clinic and to market faster and with less risk. My early experiences gave me insights into the pains and pressure points when developing a drug and what is needed to succeed. Many of our scientists have a similar background to my own and are driven by the mission to speed medicines to desperate patients. In fact, there are hundreds of FTE-years of accumulated development and manufacturing experience in the Fast Trak team, which leads to a solid understanding of how to maximize performance, outcome, and project speed for a variety of biologics and expression systems. These are some of the many reasons we call our services Fast Trak.

Parrish M. Galliher
Chief Technology Officer, Upstream, Cytiva

At the speed of parallel processing

Integrated process development, manufacturing, and training



Speed to market isn't just a matter of taking faster steps. It's also important to know how and when to take steps in parallel.

Our high-throughput processes and flexible single-use technologies let you step up the pace both upstream and downstream. Moreover, the many complex, interrelated phases that comprise process development can often be performed simultaneously, significantly reducing cost and time to market.

In addition to the efficiencies that come with a deep understanding of all parts of the manufacturing process, Fast Trak also gives you the flexibility to use those services comprehensively or à la carte according to your needs.

At the speed of proven expertise

Expertise lies in knowing what needs to be done and, equally important for reducing time to market, in knowing what doesn't need to be done.

At Fast Trak, we've learned from many years of experience how to minimize trial and error and get it right the first time. For nearly 30 years, we've been a trusted partner in cell culture media, process development, and education and training. In addition, we have over a decade of experience in manufacturing biologics, having completed numerous production and cGMP campaigns for Phase I and II clinical trials.

Our expertise encompasses process development, analytical development, process scale-up, and cGMP manufacturing across a broad range of expression systems, including mammalian, microbial, and insect. It's backed by leading cell culture media formulations, single-use technologies, purification columns, systems, resin, and advanced control platforms.

The Fast Trak leadership team fields a combined 300 years of industry experience.

Fast Trak services experience

Biologic molecules	Expression systems	
Monoclonal antibodies & antibody fragments	CHO K1	*Pichia*
Biosimilars	CHO S	*Saccharomyces cerevisiae*
Virus	CHO DG44	Hybridomas
Virus-like particles	CHO M	S2
Subunit vaccines	CHO-GS	SF9
Hormones	NS0	Per.C6™
Fusion proteins	*E. coli*	Vero
Enzymes	*Pseudomonas*	HEK

At the speed of full transparency

Our goal at Fast Trak isn't just to solve your biomanufacturing challenges. It's to empower *you* to solve them, too.

From the start, we foster a relationship built on total transparency. Along the way, we share not just information, but space. Customers have on-site access during all production batches. And when the milestone for technology and process transfer is reached, we share *your space:* our person-in-plant program puts Fast Trak experts in your cleanrooms for startup support to ensure that production begins as soon as possible.

Reinforcing transparency with education, we provide hands-on and classroom training for all participants including new equipment operators.

Transparency and Customer Access

- Customer is actively involved in all project phases
- Process development lab for proof of concept and scale-up studies
- Customers have on-site access during all production batches
- Person-in-plant (PiP) support
- Hands-on training
- Regulatory and site safety training
- Online and classroom education

At the speed of global reach

With Cytiva's worldwide footprint, you not only go faster to market, you can also go further.

Cytiva Fast Trak is a global organization with over 80 scientists. These, in turn, have access to hundreds more Cytiva scientists and technology experts in related bioprocess fields, potentially giving you early access to innovations that may further speed you to market.

Fast Trak has regional centers in the USA, Sweden, India, and China, along with satellite centers in Turkey, Japan, Singapore, and Korea. While each contributes its own area of expertise, they also serve as a common training and education center for local operations.

Global centers

One of the most rewarding aspects in my career has been working with customers and Cytiva teams who are driven by the same mission — to improve human health. Throughout this journey, I've seen our teams accumulate a wealth of experience and expand to meet customer needs around the globe. We're proud to have a successful partnership history, whether it is solving scale-up challenges, being an extra set of hands and teachers, or partnering on total process outcomes — we walk in this journey together.

Umay Saplakoglu
PhD Fast Trak Global Leader

At the speed of end-to-end solutions

Cell culture media

Before beginning lab work, we carefully study your cell line and molecule requirements, specifications, goals, and needs, and collaborate with you to develop a robust cell culture strategy.

We give you access to our comprehensive library of reference formulations, a resource reflecting HyClone laboratories' nearly 30 years of cell culture media experience.

- Medium development and optimization:
  - Basal and feed media screening/optimization
  - *De novo* cell culture medium
  - Metabolic Pathway Design process
- Analytical services
  - Spent media analysis
- Rapid Response Production: non-GMP rapid prototyping of customized media and reagents within 7 days

PD/Upstream

With over 30 years experience in developing processes for multiple cell lines, we've learned the importance of selecting the best technology solutions for your needs and cost structure.

- Conversion from stainless to single-use
- Technical transfer
- High-throughput clone screening
- Process scale-up and proof of concept
- Bioreactor process optimization
- Process design
- Process (raw material) simplification

PD/Downstream

Developing purification processes is a complex task that involves balancing the purity of your product with process robustness and the minimum number of unit operations needed for maximum economy.

- Design of experiments (DoE)
- High-throughput process development (HTPD)
- Selection of traditional or single-use
- Process scale-up and proof of concept from 10 L to 2000 L
- Viral clearance studies
- Bulk drug formulation
- Resin cleaning in place (CIP) studies
- Resin lifetime studies

Analytical development/Quality control

Every successful performance testing platform begins with a strategy. It is critical to have the right analytical tools at every stage of your project, and the purpose of analysis is different at each. At Fast Trak, process development, manufacturing, and quality experts work together to deliver that strategy with full understanding of one another's needs, following well-established processes that minimize confirmation runs without cutting corners on quality.

- Methods development
- Methods transfer
- Methods qualification
- Reference standard characterization
- Stability studies
- Lot release testing
- Raw material inspection and testing
- Environmental testing

Clinical manufacturing

To save time, we conduct equipment testing and process verification before deployment at your facility. Our manufacturing teams focus on quality outcomes from the earliest stage of your project — reducing contamination risk, improving the quality of the process and the end product, and providing regulatory robustness on a standard platform.

Phase I and II clinical manufacturing

- cGMP — from 10 L to 2000 L
- BSL2 — from 10 L to 200 L
- cGMP document preparation
- cGMP solution and buffer preparation
- cGMP inspection, sampling, and release of materials
- Quality assurance guidance and oversight

Technology transfer

We work closely with you to transfer your upstream and downstream processes and analytics to your manufacturing site, or that of a CMO designated by you, while being sensitive to your culture and cost structure. We provide on-site support, with both upstream and downstream scientists.

- Customer process training
- Process documentation
- Process gap analysis (site and equipment)
- Person in plant (PiP) support

Training and education

To further empower you, we provide hands-on training and education, both on-site and off-site, to all participants including new equipment operators. Training and educational courses can also be held at Fast Trak regional centers around the globe.

- On-site access during all production batches
- Process development lab for proof of concept and scale-up studies
- Fast Trak support staff at customer site for start-up activities
- Process, equipment, and regulatory training
- Site safety training
- Classroom, on-site, and online education
- Courses held at regional centers around the globe

Turnkey biomanufacturing solutions

In today's market, the ability to respond rapidly to demands on your manufacturing footprint is critical. Cytiva turnkey solutions provide flexibility and security with proven results.

FlexFactory™ is our single-use bioprocessing platform that accelerates your market access by deploying versatile systems within existing plants.

- Installed at your site within 12 months
- Integrates single-use equipment and consumables with centralized monitoring and control

KUBio™ lets you construct new facilities using pre-engineered manufacturing modules, produced in parallel then assembled and qualified on-site.

- Operational anywhere in the world in 14 to 18 months
- Incorporates FlexFactory single-use platform

A KUBio/FlexFactory combination delivers the rapid response and operational flexibility you need to realize *speed to market* anywhere in the world.

cytiva.com/fasttrak

For local office contact information, visit cytiva.com/contact

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