

Transformations in biomanufacturing

# Enterprise Solutions

KUBio | FlexFactory | Services





In biomanufacturing the only certainty is risk and the only constant is change. Technology is pushing new frontiers, new markets are opening up across the globe, and new competition is creating new levels of urgency — all under the ever more watchful eye of regulators.

Industries in transformation demand transformative solutions. In today's global biomanufacturing environment, a total solution is a must-have, but it is not enough. That solution needs to be built from new ways of thinking and structured around new ways of doing.





# Biomanufacturing transformed

Enterprise Solutions is our end-to-end platform that is revolutionizing biologics production with powerful and innovative modular approaches. Cytiva's biopharma expertise and global resources address the enormous complexity of biomanufacturing.

You may be a startup launching a new molecule for the first time, an established player bringing biosimilars to emerging markets, or an international powerhouse moving toward distributed manufacturing. Whatever your goals, Cytiva provides you with new options to achieve and maintain them at every level of biomanufacturing: process, capacity, equipment, automation, and human competencies — all managed from one point of contact.

## FastTrak Services

- Cell culture media development and optimization
- Full upstream & downstream process development
- Analytical services
- Clinical manufacturing
- Technology transfer
- Training & education

## Business Consultation

- Financing guidance
- Connection with credit export & multi-lateral agencies

## Program Management

- From concept to realization
- One-point-of-contact project management
- Logistics management
- Full qualification documentation
- Local building code and agencies compliance

## KUBio

Over 100kg mAbs/year

- Pre-engineered cGMP-compliant optimized biomanufacturing solution

## FlexFactory

mAbs + Vaccines

- Integrated upstream & downstream single-use or hybrid platform

## SUPPORT

### Process Support

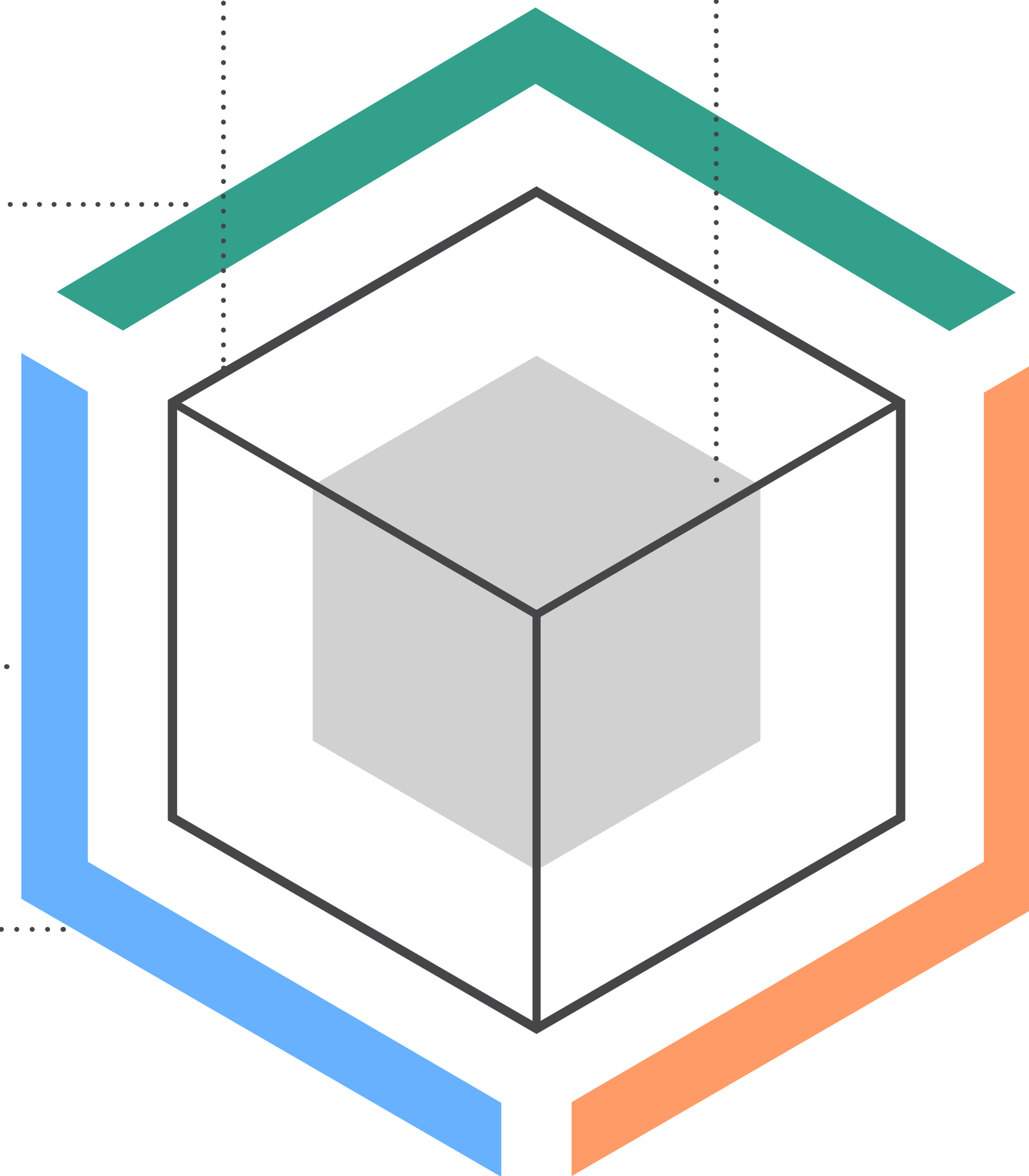
- Site-wide system health check
- Process efficiency & compliance
- Flexible block of hours

### Product Support

- Life cycle management
- Parts advisory service
- Maintenance analysis scorecards
- Qualification
- Preventive maintenance

### People Support

- Placement services
- Ongoing technical training
- Ad hoc workshops



# Timelines

transformed

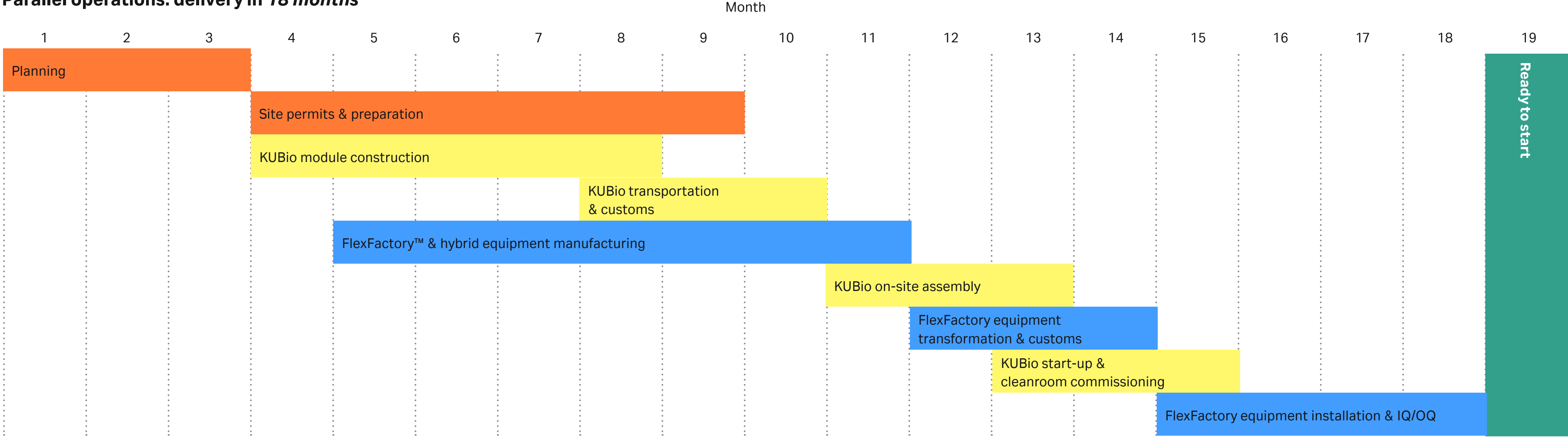
Speed to market isn't just about rapid access. It's also about risk — understanding when to take it and when to let others.

Modularity played out on a global stage delivers unprecedented speed to market. Case in point: KUBio™, our turnkey cGMP-compliant process and facility solution for mAb production. A dedicated stainless steel solution typically takes 5 years from concept to realization at a capital expense of as much as \$300 million. With KUBio you can be up and running in just 18 months at a fraction of the cost.

That's excellent news if you're someone with an approved molecule looking for market access, where just a single day's delay can amount to millions of dollars in lost revenue.

It's even better news if you're someone with a molecule in development and need manufacturing capabilities. The longer you can defer committing to the capital expenditure of a plant, the lower your investment risk, all while deploying a solution that can get you to market quickly.

### Parallel operations: delivery in 18 months

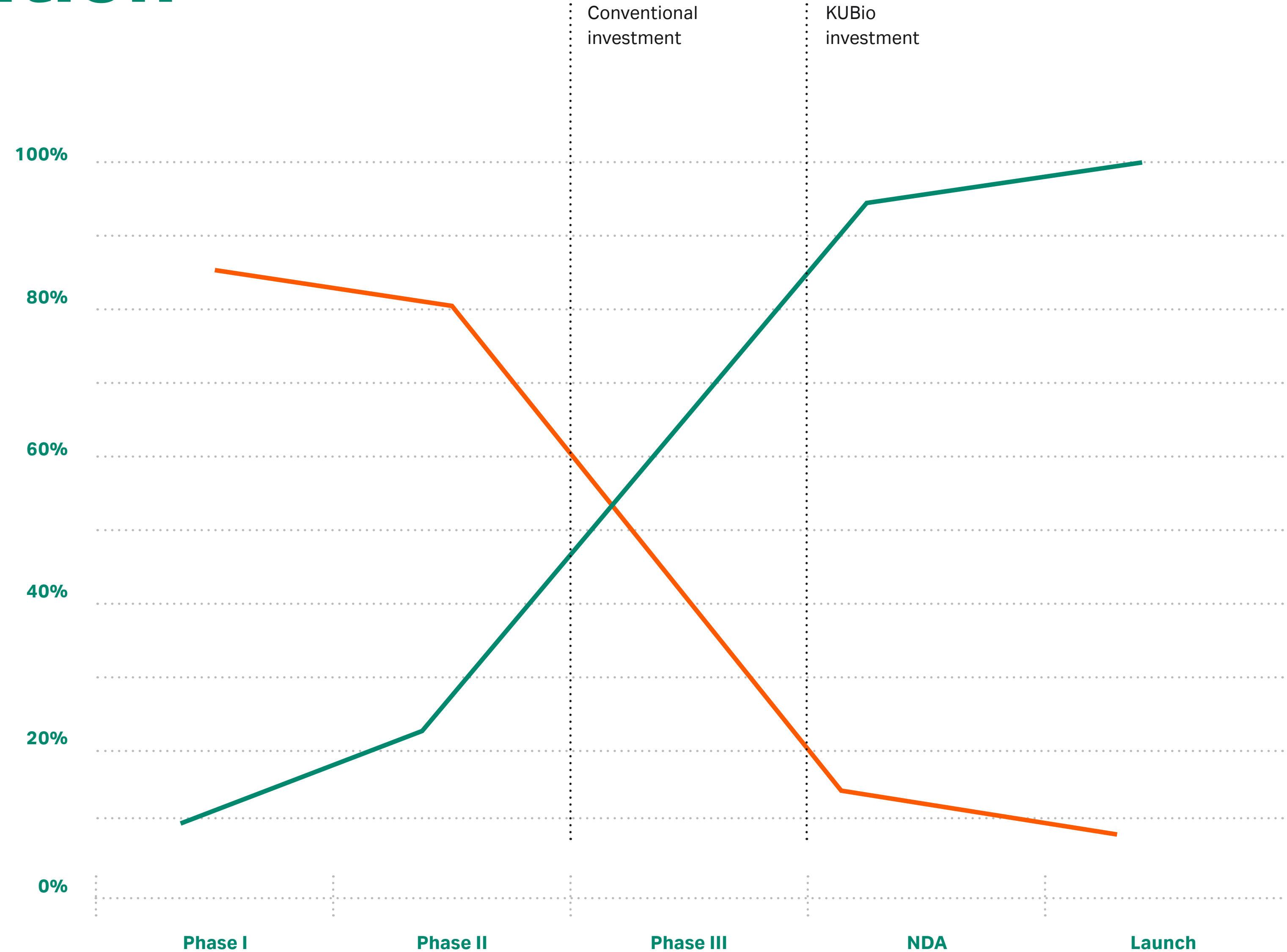


# Real options valuation

## Deferred investment

A KUBio not only frees up your capital but also substantially mitigates your risk.

Investment in a traditional plant must be made five years ahead of FDA approval — during late Phase II clinical trials, when a molecule's success rate is low. With KUBio, you can defer that decision until after Phase III, when the success rate is high.



# Flexibility transformed

At first glance, *modular* and *standardized* seem at odds with *flexible* and *customized*. But therein lies the secret to unprecedented speed and agility in biomanufacturing. When you standardize the parts, a solution becomes configurable and can be rapidly customized.

## **The Enterprise Solutions Configurator**

At Cytiva, we've synthesized our many years of biomanufacturing into a configurable "design space." Within this space, we have defined dozens of process-level configurations, each with hundreds of item-level configurations down to the individual article number.

Because we have already calculated the mass balances on every unit operation and the many factors that affect them, we can optimize those configurations to your desired volume, titer, lead time, equipment, consumables, maintenance, labor, mix of stainless steel versus single-use, and mix of capex versus opex. When you move within this design space, you enjoy the time and cost savings of a preverified, prequalified solution. Your process design is virtually done before you begin.

## **Post-installation flexibility**

The principle of optimal configurability doesn't stop at the design phase. It's just as productive when it comes to operational flexibility within the factory: single-use technologies provide the agility needed for successful multibatch and multidrug production.

Configurability also enables flexibility between factories. It allows you to transfer drug line processes and equipment, and to optimize consumables, parts inventories, and human competencies on a worldwide basis.



## Configurator App: a number of optimized configurations

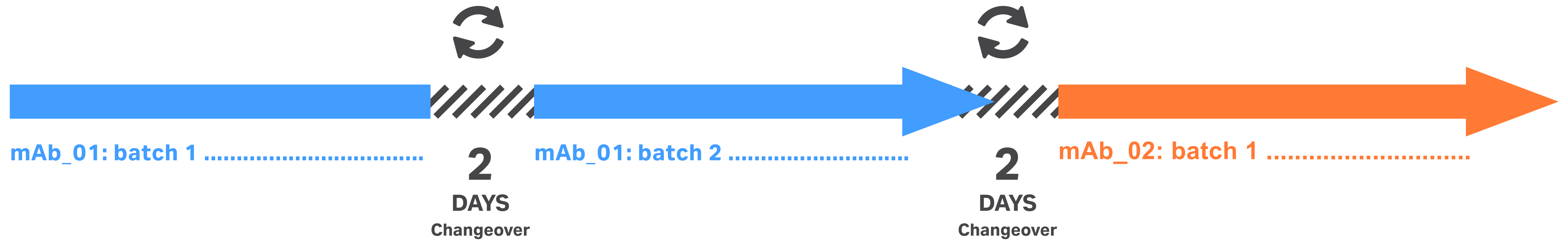
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### Example configuration: 2 × 2000L

Time to Market	16 mo
Titer	3.8 g/L
Utilization	18 × 7
Qualified state	YES
Yearly mAb output	150 kg
Financial (USD/G)	\$64

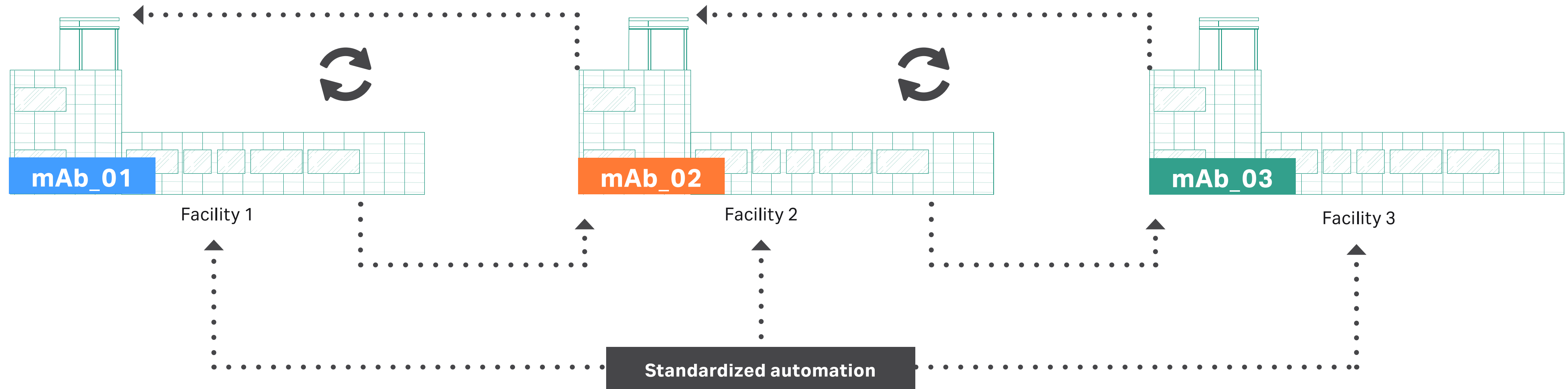


## Production line flexibility: multi-product, multi-batch



## Global scale/multi-facility setup: a factory of factories

Reproducible: drug line processes, equipment, parts, staff, training, and support





# KUBio

## The production environment transformed

KUBio is our turnkey cGMP-compliant process and facility solution for mAb production that dramatically reduces time to market.

Thanks to its modular construction, KUBio can be made operational in only 18 months. Pre-engineered manufacturing modules equipped with our FlexFactory platform are produced in parallel, then assembled and qualified at your choice of site anywhere worldwide. Because KUBio is a predesigned solution, your investment is known and fixed from the start of the project.

One KUBio is already fully operational and productive in China, and we are continuing to implement others. Cytiva will manage nearly every stage of your KUBio project, including off-site construction, transport, logistics, insurance, local labor and regulatory compliance, final construction, and qualification.

cGMP  
ISO  
DIN  
EN  
VDE

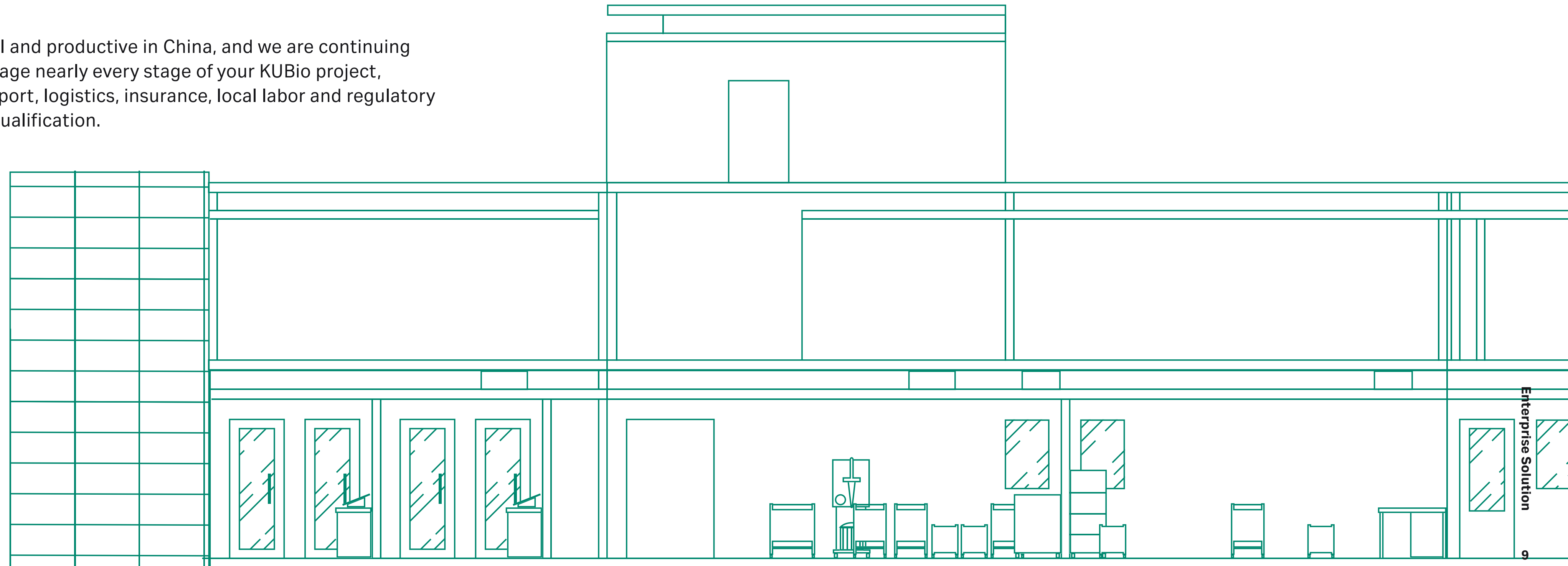
## KUBio deployed in 18 months

mAb output capacity per bioreactor (kg)

	Titer		
	2.0	3.0	4.0
2 × 500 L	28	42	56
2 × 1000 L	56	84	112
2 × 2000 L	112	168	224
4 × 2000 L	224	336	448

Assumptions: 70% recovery through purification  
20 batches per year, per reactor

	Building footprint	Total space
2 × 500 L	1200 m <sup>2</sup>	2200 m <sup>2</sup>
2 × 2000 L	1350 m <sup>2</sup>	2400 m <sup>2</sup>
4 × 2000 L	1500 m <sup>2</sup>	2650 m <sup>2</sup>





# FlexFactory

The production workflow transformed

FlexFactory is our integrated single-use or hybrid platform. It gives you rapid access to cGMP manufacturing capacity while providing flexibility in your production process for when your needs change.

Processing steps are integrated via single-use tubing sets, open automation allowing equipment that you specify to be included, and a centralized monitoring and control system that enables you to optimize the performance of your bioprocessing equipment in real-time. When not housed in a new facility, FlexFactory can be tailored to meet your needs in an existing one.

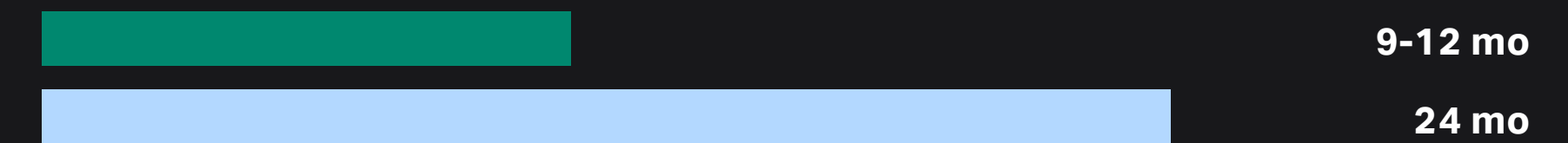
Numerous FlexFactory platforms have been installed worldwide since the concept was first pioneered by Cytiva's Xcellerex brand. Our process experts and engineers will work with you to prevalidate, transfer, and install your process equipment with complete transparency.

## Process equipment may include

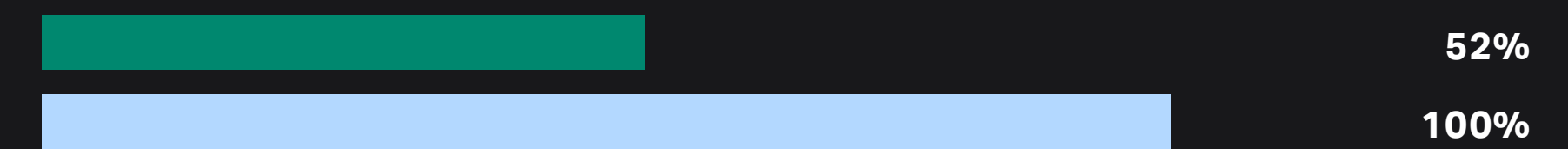
- WAVE Bioreactors/cell culture seed train
- XDR Bioreactors/cell culture expansion
- XDUO and XDM Quad mixing systems
- Harvest pump skid and filter holder
- ÄKTA Chromatography skids
- Viral filtration pump and filter holder
- TFF/UFDK skid for final concentration
- Automation hardware and software
- ReadyToProcess disposables

## Single-use vs Stainless: *process economy*

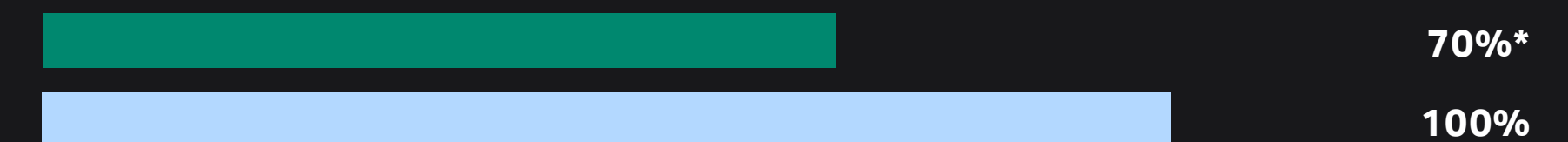
### Time to market



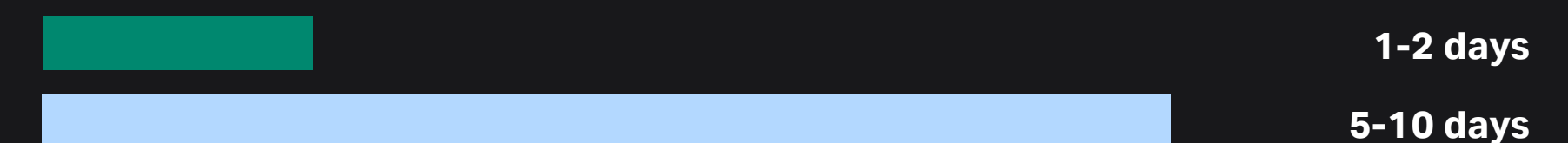
### CAPEX



### OPEX



### Changeover



### Output



\*Industry reports vary 70% - 120%



# Support

## Production services transformed

Successful biomanufacturing isn't just about achieving a qualified solution, it's also about sustaining one. To that end, we provide a continuum of services from concept to realization and beyond.

We manage almost every aspect of your FlexFactory or KUBio project from initial development through final construction and assembly — including unloading huge manufacturing modules dockside and providing support through customs.

Our global team of Cytiva's financial experts can assist you with advisory and arrangement services for loans and leases. Their specialized industry knowledge and local financing expertise often open doors to attractive financing solutions.

Our Fast Trak experts work openly and collaboratively with you throughout your project from analytical development, through upstream and downstream process development, tech transfer, installation, and start up, as well as training and education.

We provide a complete suite of tools for preventive maintenance, placement services, and life-cycle management. Recently, we've introduced a radically new concept in support: *Flexible Blocks of Hours* that allow you to leverage Cytiva's global expertise for all your post-installation needs.

### Project management

Single point of contact and integrated control

### Continuous support

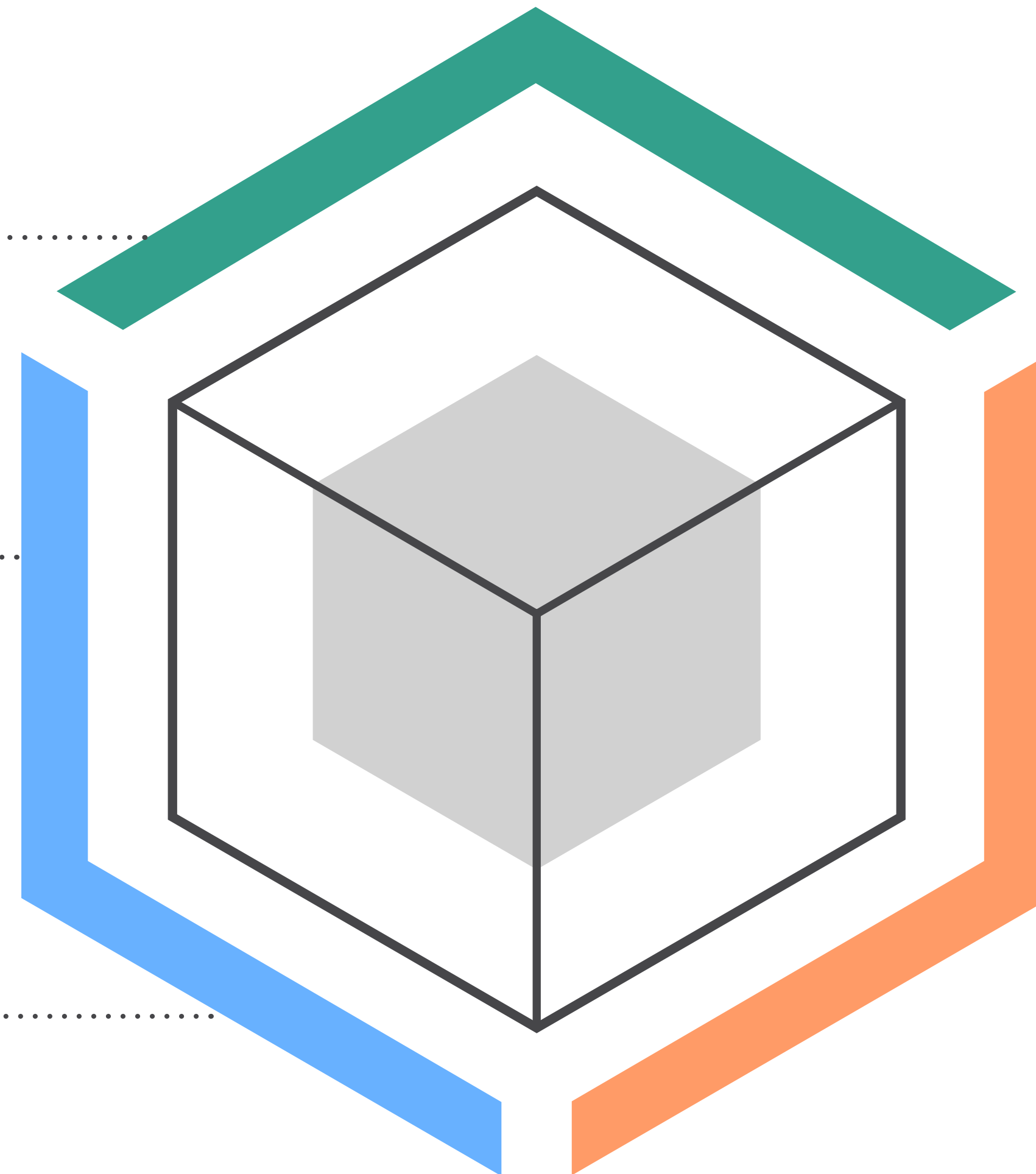
Site-wide bioprocessing and engineering support, flexible blocks of hours, flexible response times, person-in-plant, preventive maintenance, life cycle management, and placement services

### Fast Trak

Rapid process development, scale-up, clinical and cGMP manufacturing, installation services, education, training, and tech transfer

### Financial consultation

Industry insight combined with a global team of financial experts





# Borders Transformed

## Global solutions require global reach.

Enterprise Solutions is part of Cytiva, serving biopharma companies, governments, and healthcare professionals in over 100 countries.

We bring that global understanding to every step of your manufacturing process in many different forms. It includes the commitment of hundreds of sourcing, quality, and manufacturing professionals working behind the scenes to provide security of supply for the consumables you use at your facilities worldwide.

It also encompasses pooled Cytiva scientific expertise, localized knowledge and relationships, and the logistical ability to move entire factories across continents.



### Global centers

#### United States

Arlington Heights, IL  
Issaquah, WA  
Lafayette, CO  
Logan, UT  
Marlborough, MA  
South Plainfield, NJ  
Westborough MA  
Niskayuna, NY  
Van Buren, MI  
Oklahoma City, OK

#### Brazil

São Paulo  
Rio de Janeiro

#### United Kingdom

Amersham Place  
The Grove Centre  
Cardiff

#### Ireland

Cork

#### Austria

Pasching

#### Norway

Oslo  
Lindesnes

#### Turkey

Istanbul

#### Germany

Braunschweig  
Cölbe  
Dassel  
Munich

#### Sweden

Umeå  
Uppsala  
Staffanstorp

#### The Netherlands

Eindhoven

#### Saudi Arabia

Dharhan

#### Israel

Tirat Carmel

#### India

Bangalore

#### China

Shanghai

#### Japan

Tokyo

#### Singapore

#### Australia

Melbourne  
Rydalmere

#### New Zealand

Tauranga

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