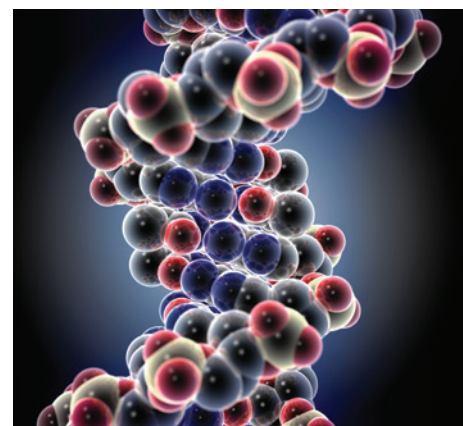


GE Healthcare

# Evolve with flexibility

Single-use bioprocessing





## **Biomanufacturing: an evolving industry**

The biopharmaceuticals landscape is undergoing unprecedented change.

As more and more biologics go off-patent and new treatments emerge, drug pipelines are becoming increasingly diverse. At the same time, developing new drugs at lower cost has become imperative. Moving efficiently from idea to product creates benefits for both biomanufacturer and patient. Rare diseases, personalized medicine, localized manufacturing, and the ability to adapt quickly to market demands are the order of the day. In this ever-changing world of biopharmaceuticals, economies of scale have given way to economies of agility.

If you're a biomanufacturer, what is your path through this new landscape?





Evolve with  
*efficiency*

In today's marketplace, it pays to be agile.

Single-use technologies provide the operational and strategic flexibility needed for success in a marketplace of continuous change. Comparing single-use with traditional technologies in a representative mAb-based model reveals the differences.

Single-use technologies enable shorter time to market at lower capital expenditure. They allow substantial reductions in labor, based on elimination of cleaning and sanitization in place (CIP, SIP) and related testing. Single-use technologies require a changeover

period of hours, as opposed to the days or weeks required for stainless steel, enabling significantly higher throughput. In addition, single-use technologies reduce your manufacturing footprint, enabling smaller facilities with less cleanroom space and resulting in lower costs for utilities, heating, ventilation, and air conditioning.

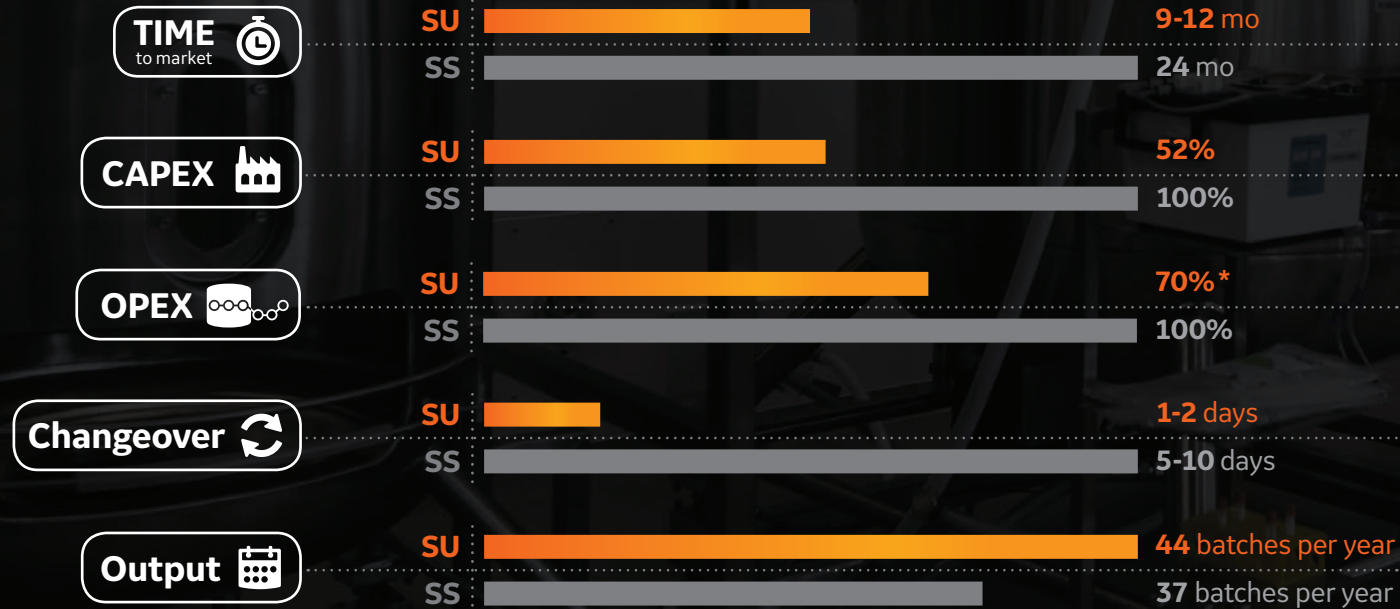
There is little question that single-use will be a part of every biomanufacturer's strategy moving forward. What part will it play in yours?

Single-use vs. stainless: *process economy*

Process economy study

We used GE's proprietary simulation tools to model this 2 × 2000 L mAb process and analyze key variables.

The simulation compares a single-use process train (SU) with a comparable stainless steel-based process train (SS), both modeled in a traditional, stick-built facility.



\*Industry reports vary: 70% - 120%



# Evolve with *flexibility*

Your road to future biomanufacturing success starts here.

Our goal is to help get you where you need to go in the evolving world of biopharmaceuticals. We understand that the path you take will be unique.

Perhaps you're looking to implement single-use at the instrument level, creating an island of automation around a single unit operation. Perhaps you're looking to integrate single-use technologies with existing equipment for a hybrid solution. Or maybe you've set your

sights on deploying single-use across your entire production train, controlling every part of your facility from a distributed control system.

Whatever your strategic objective, at GE, we offer you something unique in return: the ability to bring together all the pieces you need to execute a single-use strategy, whether it's for one application, for your entire facility, or for anything in between.

## Single-use Products Technologies Solutions

- ÄKTA™ ready chromatography system
- ReadyMate™ aseptic connectors
- ReadyCircuit™ bags and tubing
- Xcellerex™ bioreactor and mixer systems
- WAVE Bioreactor™ systems
- HyClone™ large-volume process liquids
- ReadyToProcess™ chromatography columns
- FlexFactory™ manufacturing platform
- KUBio™ prefabricated manufacturing facility

## Experience Expertise Collaboration

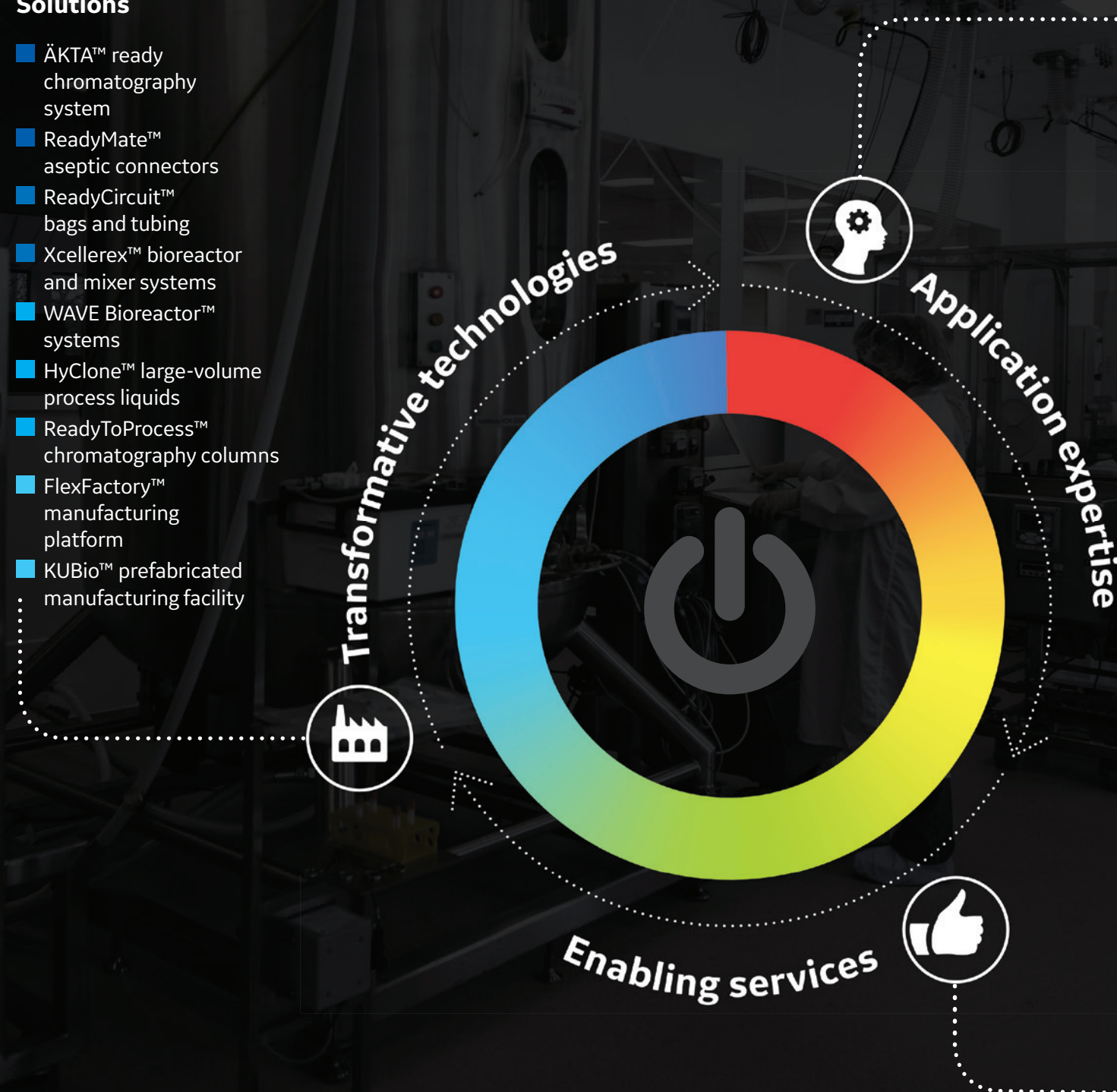
- Process development
- Analytical development
- Medium development and customization
- cGMP manufacturing
- Upstream unit operations
- Downstream unit operations
- Local / global regulatory
- Quality by design (QbD)
- Material science
- Leachables and extractables
- Security of supply
- Sustainability
- Automation
- Facility design

## Fast Trak services

- Process development
- Cell culture medium optimization
- Analytical services
- Chromatography resin screening
- Bridge manufacturing
- Training and education
- Technology transfer
- Regulatory support: international and local

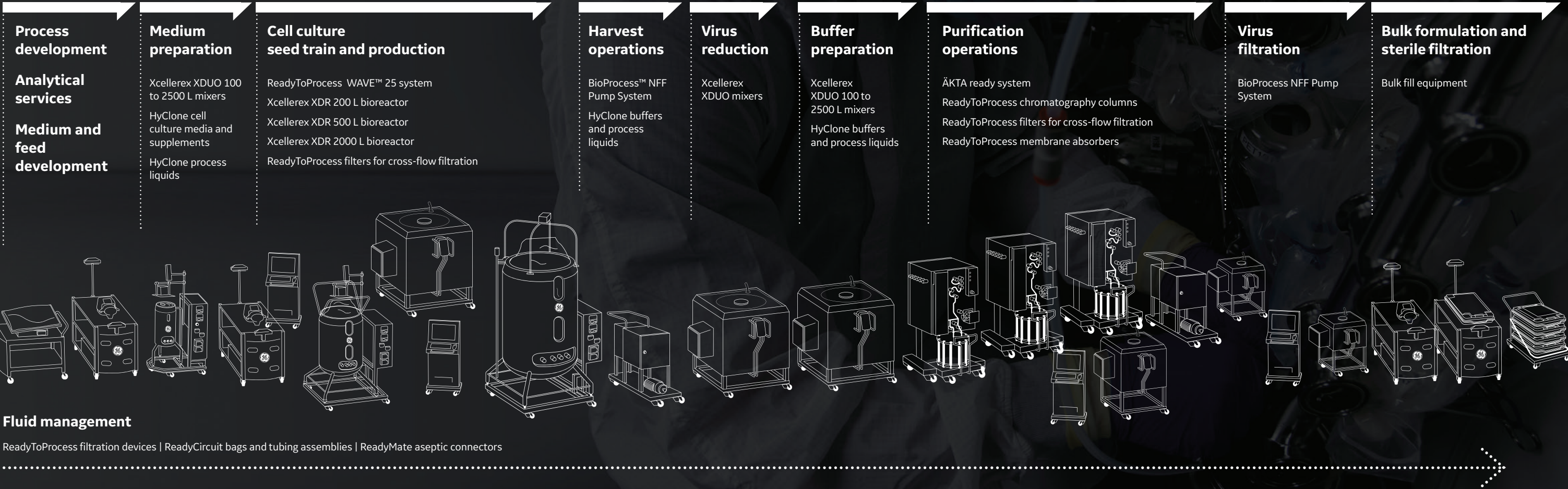
## SiteCare services

- System health check
- Lifecycle management
- Parts advisory services
- Global logistics





SINGLE-USE PORTFOLIO across the bioprocess spectrum



Evolve with

***transformative technologies***

We have all the transformative pieces you need for your chosen single-use strategy. Even the walls.

Walk down a GE single-use production train and you'll pass game-changing technologies. They include everything from prepacked ReadyToProcess columns and patented ReadyMate aseptic connectors to innovative systems like our Xcellerex XDR-500 MO microbial fermenter and our ÄKTA ready chromatography system with disposable flow path. They're the building blocks of your single-use strategy. You can combine

them to fit your scale today and adapt them to meet your needs tomorrow. You can convert unit operations from stainless steel to single-use, or enhance existing capacity with turnkey solutions like our FlexFactory single-use biomanufacturing platform or our KUBio prefabricated single-use facility. **Automation/integration:** Data consolidation and integration are critical for streamlined operations.

Our automation approach is highly flexible, offering integration support at the unit, process, or plant operations level for your product lifecycle management. Our UNICORN™ automation software provides real-time equipment monitoring while meeting quality and cGMP documentation requirements. We also enable central control at the process train level and distributed control at the facility level through DeltaV™ and Wonderware™ platforms, as well as others.

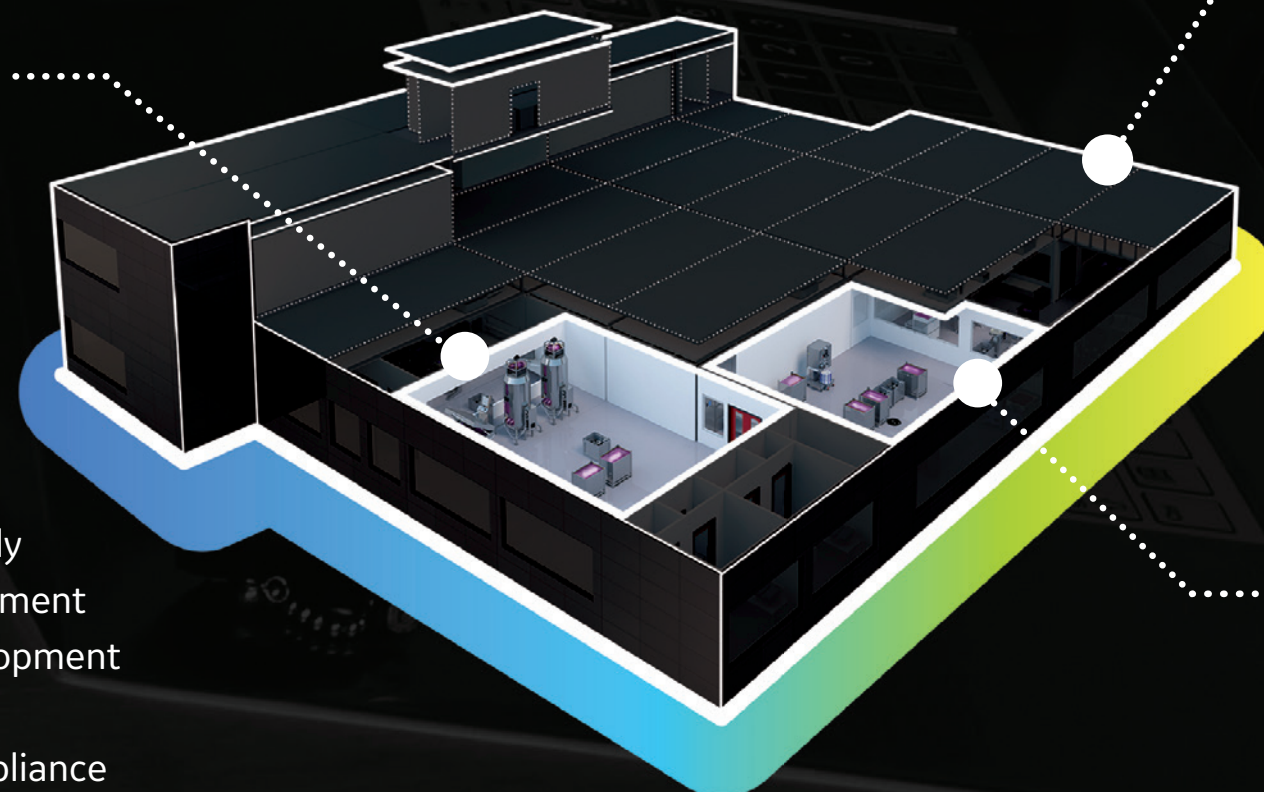




## Upstream

Bioreactor production

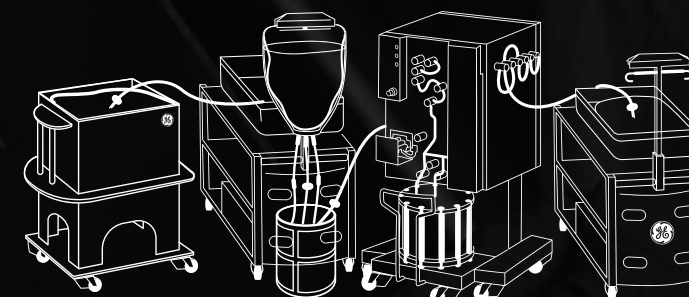
- Material science
- Security of supply
- Process development
- Analytical development
- Facility design
- Regulatory compliance
- Site support



**KUBio**   
cGMP facility

**FlexFactory**   
Single-use platform

*Our KUBio and FlexFactory single-use solutions are agile and configurable, enabling you to reduce risk and realize capacity faster, minimizing infrastructure and improving operational efficiency. We manage your project and provide end-to-end services from design through qualification and beyond.*



## Downstream

Chromatography purification

Evolve with

# *outcomes-based expertise*

Single-use isn't solely a technology. It's also a mindset.

At GE, that mindset grows out of a deep functional understanding of every area of single-use biomanufacturing, and the ability to deploy that knowledge for your needs.

It requires a range of expertise in everything from analyzing the impact of polymers on cell culture outcomes to looking deep into the supply chain to manage materials and suppliers.

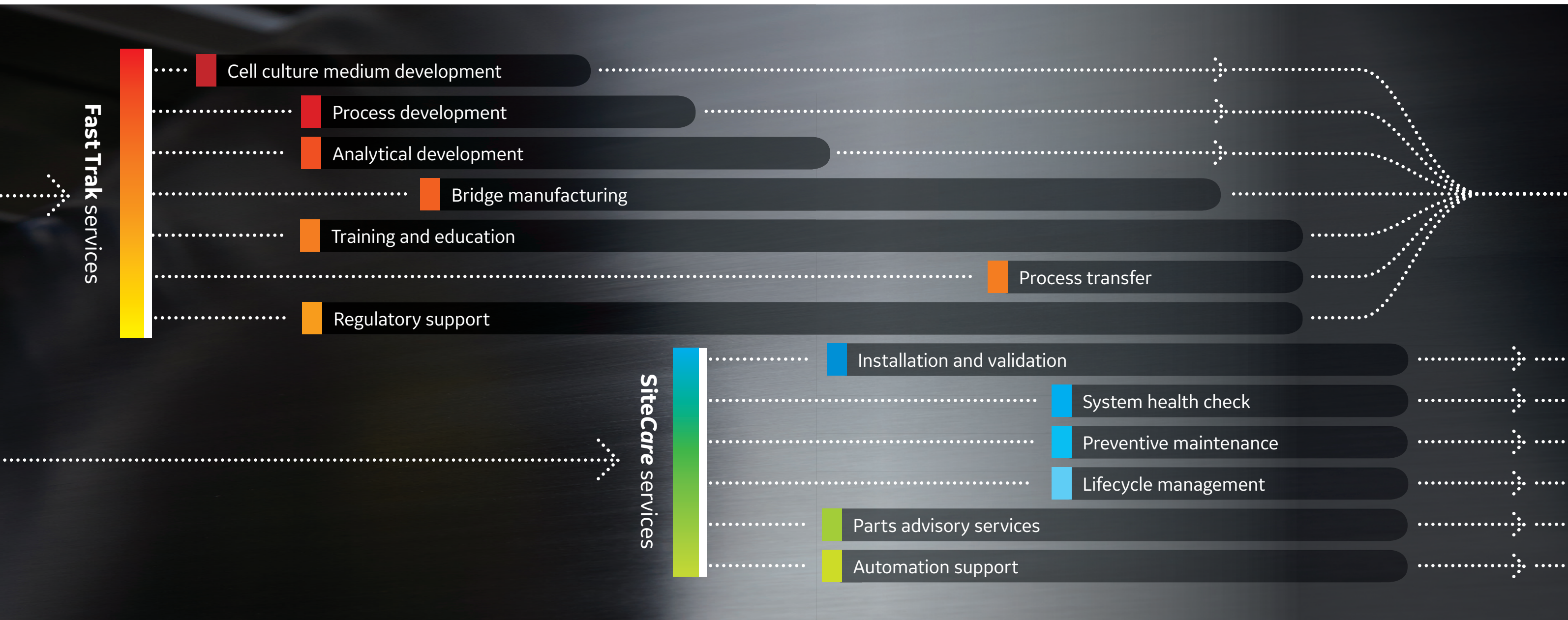
It requires intimate knowledge of the workflow, upstream and downstream: how to save thousands of dollars on something as simple as a phosphate buffer, and how to achieve incremental efficiencies in chromatography by increasing resin performance and variety of column sizes.

It requires the big-picture understanding needed to design a biomanufacturing facility from the ground up that fully realizes

the benefits of single-use, and to negotiate the complex local regulatory landscape in order to place a turnkey facility in the region of your choice.

How do we know these things? Because we've done them. At GE, we understand the many transformative pieces of single-use technology better than anyone. Above all, we know how to bring them together for you.





Evolve with  
***enabling  
services***

No two biomanufacturers' single-use strategies are identical.  
Neither is their need for support.

To help implement your unique strategy, we offer a complete range of support services to take your molecule to market. All are performed with open collaboration and complete transparency.

You have support options for clinical manufacturing, scale-up, conversion from stainless steel to single-use, and the complexities of local and international regulatory

compliance. You can draw on GE's expertise in chromatography resin screening and in cell culture medium development, with access to GE's comprehensive HyClone library of reference formulations. Upstream and downstream, we can help you select the best technology solutions for your needs and cost structure, optimizing your process to achieve the minimum number of unit

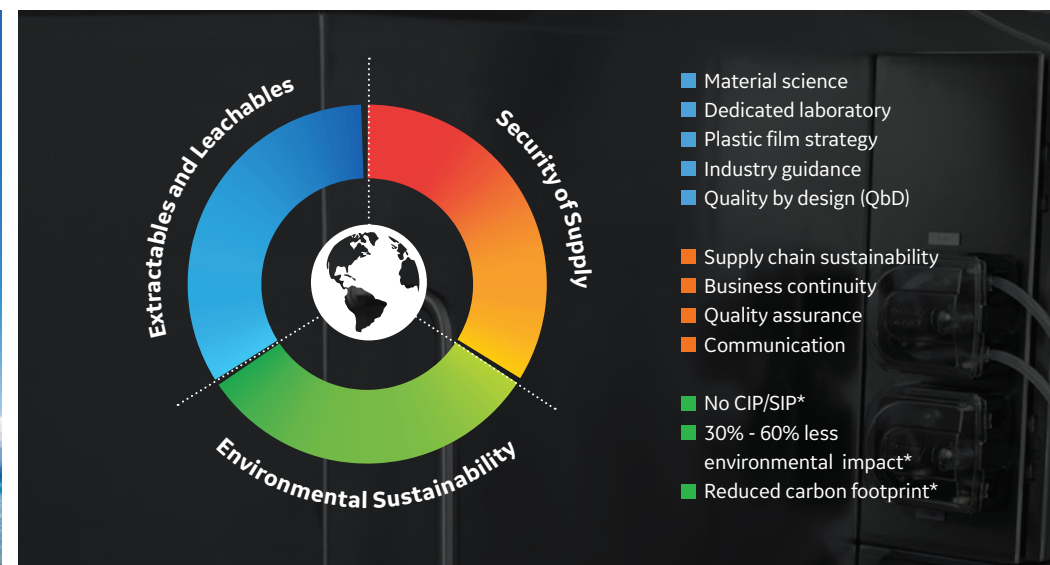
operations required for maximum economy while maintaining purity of your product.

Because people are an equally important part of your single-use strategy, we also offer hands-on training and education, both on-site and off-site, to all participants including new equipment operators.



# Keep *evolving*

Our goal is to help you move forward with single-use technology.  
We're making sure that your journey is safe, secure, and sustainable.



GE has been at the forefront of developing, commercializing, and helping to shape the future of single-use technologies from the beginning. We know that single-use technologies are right not only for you, but also for the industry, the patient, and the planet.

## **Extractables and leachables:**

Our extractables policy is comprehensive and applies material science to understanding different impacts on bioprocess performance. It yields a wealth of in-depth, relevant data that customers can use in validation work for regulatory submissions. We have a laboratory in Uppsala, Sweden, dedicated to scientific understanding of extractables and leachables, and we actively participate with industry associations to help define the future of extractables guidance.

## **Security of supply:**

At GE, we take security of supply seriously. We deploy risk mitigation strategies along with a QbD approach for sourcing and quality. This entails strict controls in supplier management and product quality, and tailored business continuity plans for our sites and product lines.

**Sustainability:** A technology shift of the magnitude of single-use has potential implications for sustainability. Our lifecycle assessment (LCA) study is a formally accredited methodology that furthers customer and industry understanding by quantifying the environmental impact of different bioprocess technologies. It lets us compare the effects of single-use versus stainless steel in terms of energy consumption, water use, and carbon footprint. Single-use exhibits lower environmental impact in all three areas. \*

\* The LCA study was performed in accordance with ISO 14040-44 standards and was reviewed by a third-party critical panel.

Find out more at:  
[https://www.gelifesciences.com/gehcls\\_images/GELS/Related%20Content/Files/1384357132198/litdoc29085317\\_20131114224350.pdf](https://www.gelifesciences.com/gehcls_images/GELS/Related%20Content/Files/1384357132198/litdoc29085317_20131114224350.pdf)

Journal of Cleaner Production:  
<http://digitalreprints.elsevier.com/t/61300-els-d88676-jcp>

*"Security of supply and business continuity of key manufacturing components is top of mind for our customers in the biopharmaceutical manufacturing industry. Being one of the first companies in the bioprocessing field to achieve ISO certification in business continuity reflects our commitment to minimizing risk and any potential impact of unforeseen disruptive incidents. We are actively working to certify our other BioProcess manufacturing sites to the ISO 22301 standard, including single-use technologies, cell culture media, and bioprocess hardware."*

**— Jan Makela**  
General Manager, BioProcess,  
GE Healthcare





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***[gelifesciences.com/singleuse](http://gelifesciences.com/singleuse)***

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