



# Single-use biomanufacturing



## The growth of biologic medicine

# The Journey Begins

### Sources

#### Past

1. PAREXEL Biopharmaceutical R&D Statistical Sourcebook 2015/2016 2. BioPlan Associates, Inc. 13th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production 3. Evaluate Pharma

#### Present

1. Evaluate Pharma 2. Deloitte report - <https://www2.deloitte.com/uk/en/pages/life-sciences-and-health-care/articles/measuring-return-from-pharmaceutical-innovation.html> 3. BioPlan Associates, Inc. 13th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production

#### Future

1. Bioplan Associates 13th Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production 2. GE Biopharmaceutical Trends Study 2017

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

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## PAST



### Market Trend

- >40% # biologic molecules in R&D: **5,979** in 2003 ↑ to **8,617** in 2010<sup>1</sup>
- >70% Process titers: **1.96** in 2008 ↑ to **3.41** in 2015<sup>2</sup>
- 400% Biologic product revenues: **\$50M** in 2003 ↑ to **\$200M** in 2016<sup>3</sup>



### Industry Need

- Flexibility, efficiency, speed
- Lower cost at smaller scale

Single-use technology emerges



### GE Solution

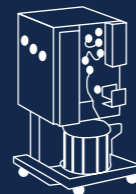
#### Industry's First



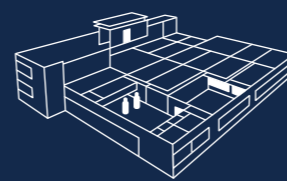
**WAVE Bioreactor™**  
Rocking single-use bioreactor platform



**Xcellerex™**  
Stirred tank single-use bioreactor platform



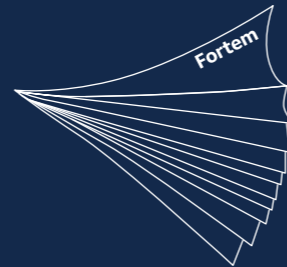
**ÄKTA™ ready & ReadytoProcess™ chromatography columns**  
Disposable chromatography purification solution



#### Industry's First



**KUBio™ and FlexFactory™**  
Modular facility solution for cGMP mAb production utilizing the FlexFactory single-use platform



**Fortem™ single-use film**  
GE's single-use platform film built for bioprocess

## PRESENT

**1,501**<sup>1</sup> # biologics in phase II and III



Large pharma R&D ROI: ↓ **70%** from 2010<sup>2</sup>

Mid-tier biopharma R&D ROI: ↓ **43%** from 2013<sup>2</sup>

### Use of single-use technologies

#### Clinical manufacturing



#### Commercial processes



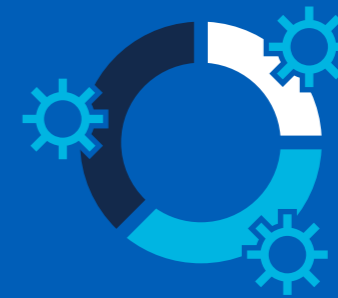
- Greater productivity
- Accelerated drug development
- Risk-mitigated biomanufacturing capacity

Single-use technologies used in clinical and commercial processes

## FUTURE



% of industry that thinks manufacturing capacity constraints exist: **17.3%** in 2009 ↑ to **27.2%** in 2016<sup>1</sup>



**37%** of industry survey respondents have already invested in automation and are investigating additional solutions

- Clinical and commercial capacity
- Improved consistency and productivity
- Improved business performance

Single-use technologies will continue to create value for the biopharmaceutical industry



GE BioPark

#### Industry's First



**GE BioPark** introduces a biomanufacturing campus that consists of four KUBio facilities supported by GE owned and operated warehouse, media and buffer hydration, utilities, and support services



PREDIX

Digital biomanufacturing - **GE's Predix platform** coupled with GE's expertise in bioprocess applications and technologies enables biopharma manufacturers to improve operational productivity by reducing unplanned downtime, predicting potential adverse manufacturing events, identifying process bottlenecks, and optimizing asset performance