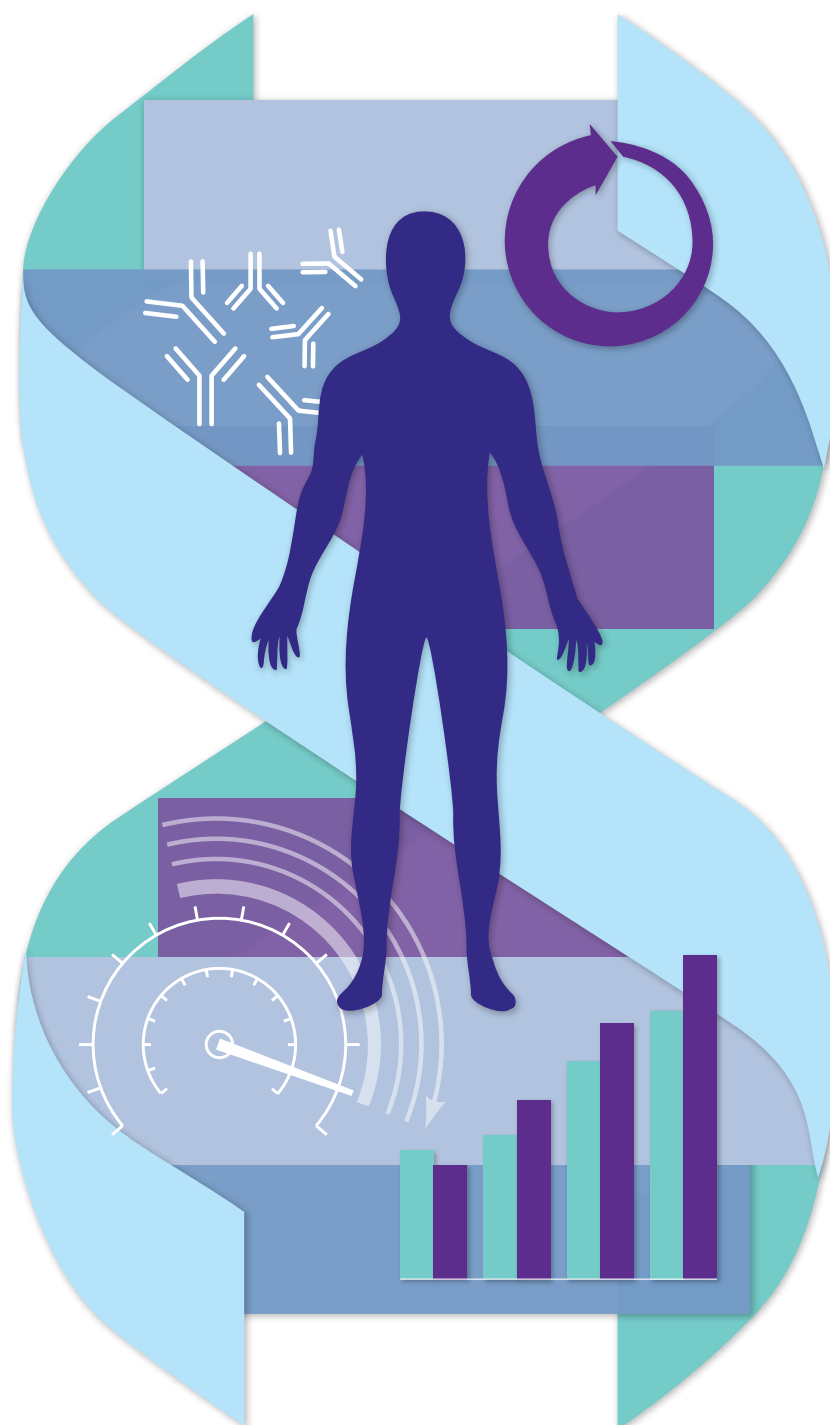


advanced  
biologics solutions.  
faster to market.



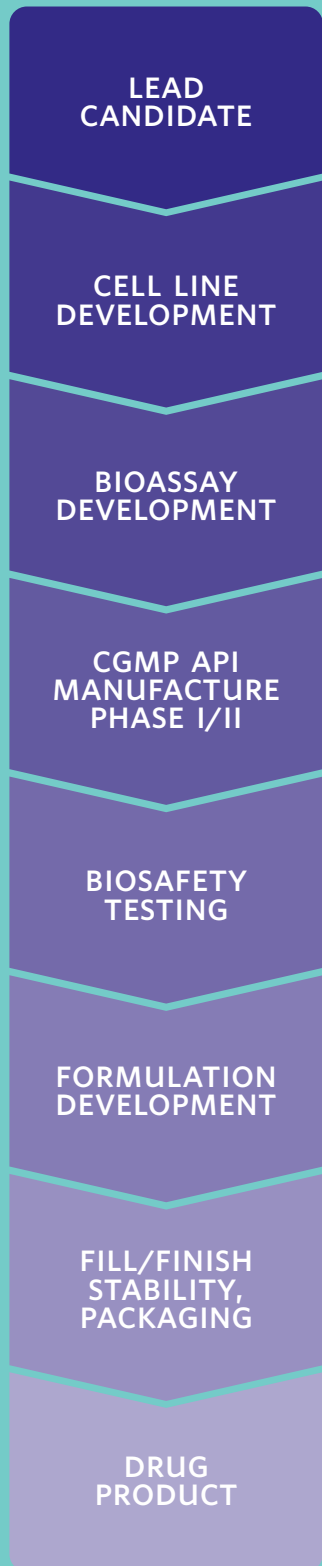
DEVELOPMENT



DELIVERY



SUPPLY



We are your strategic partner for biologic drug development success. With our GPEX<sup>®</sup> technology for mammalian cell line development and our broad range of integrated services, we provide fast, seamless solutions from development to biomanufacturing and analytical, to fill/finish and packaging.

## OUR UNIQUE GPEX<sup>®</sup> TECHNOLOGY

Catalent's proprietary Gene Product Expression (GPEX<sup>®</sup>) technology sets a new standard in mammalian cell line engineering. GPEX<sup>®</sup> technology can ensure that genetically-stable cell lines are produced 100% of the time.

### FAST

GPEX<sup>®</sup> technology is fast with high expression levels. We can take you from cDNA to master cell bank candidate in less than 5 months (FIGURE 1).

### RELIABLE

GPEX<sup>®</sup> technology is reliable with unmatched stability (FIGURE 2). We provide consistent expression stability and high productivity levels with no need for selection.

### PROVEN

GPEX<sup>®</sup> technology is proven, with customers in five continents and an established regulatory path.

- Material produced with GPEX<sup>®</sup> technology is being used for human clinical trials throughout the world for asthma, cancer, heart disease, fibrosis, lysosomal storage diseases, sepsis, MS, and other indications.
- Using GPEX<sup>®</sup> technology, we have generated cell lines expressing hundreds of different proteins.
- Commercial products made from GPEX<sup>®</sup> cell lines are currently sold in Asia and South America.

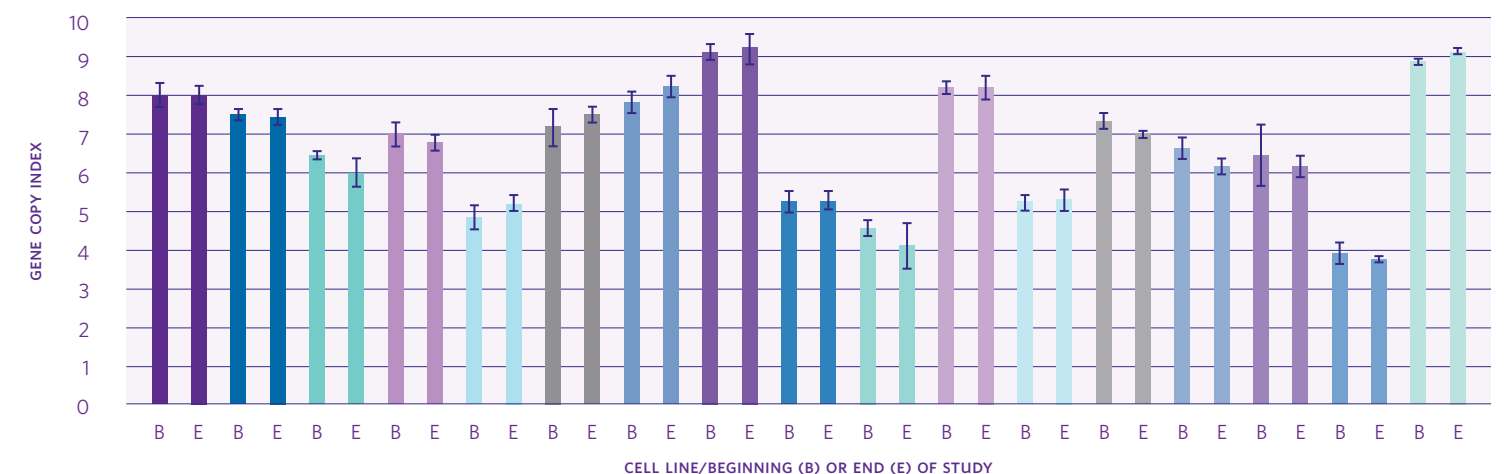
### GREAT VALUE

Because of Catalent's favorable intellectual property, GPEX<sup>®</sup> technology maximizes value compared to competitive technology.

FIGURE 1 GPEX<sup>®</sup> technology is fast with high expression levels



FIGURE 2



\*Experiment details: 17 different cell line stability studies were performed over 40 to 60 cell generations. A master cell bank vial (B) was compared to cells that completed the 40-60 cell generations in culture (E)

## HIGH QUALITY BIOMANUFACTURING

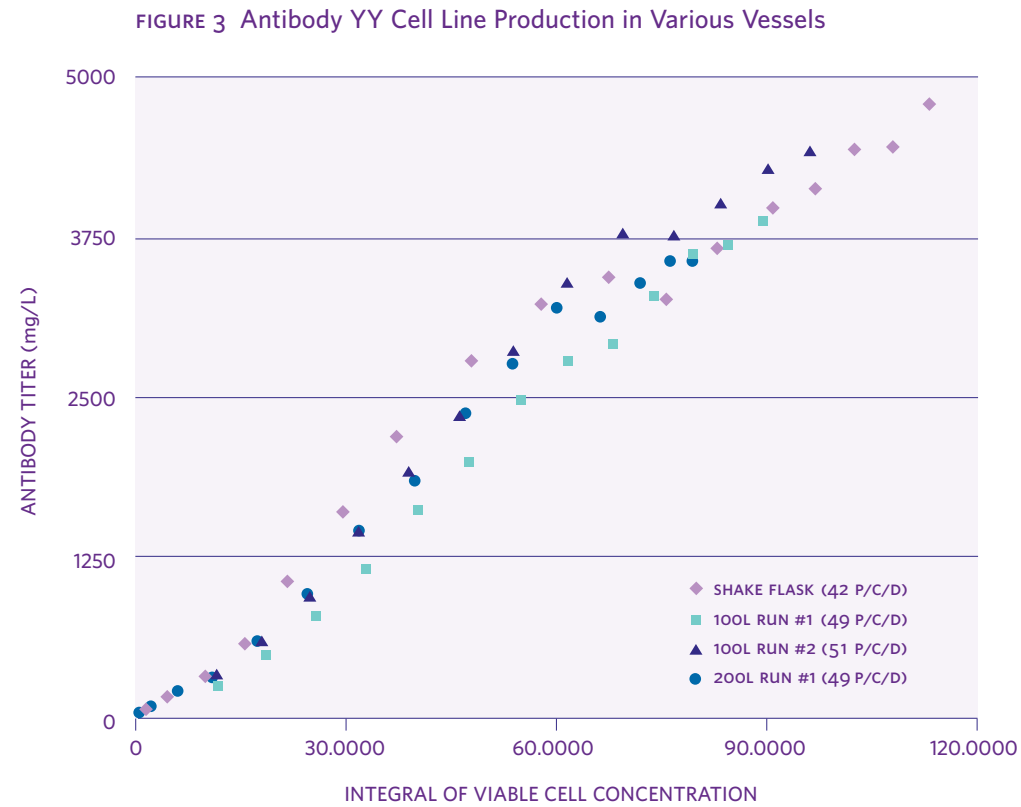
Whether you are using a Catalent GPEX® technology-based cell line or your own mammalian cell line, we can easily transfer your project to our manufacturing plant and provide you with a high quality product.

### BIOMANUFACTURING

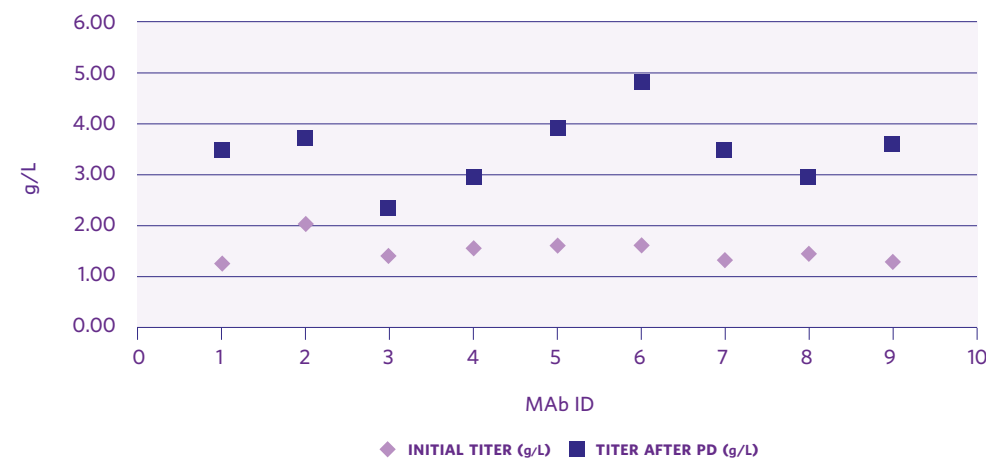
Our reputation is founded on the reliable generation of master and working cell banks with consistently maintained yields, even during scale-up. (FIGURE 3) Whether you are using a Catalent GPEX® technology-based cell line or your own mammalian cell line, we easily transfer your project to our manufacturing plant.

Catalent's biomanufacturing capabilities include:

- Rapid cell culture optimization in shake flasks through 10L bioreactors to give high titer processes (FIGURE 4)
- Accelerated and efficient protein purification development from milligram to 100s gram scale
- Non-cGMP production (up to 100L) in disposable and stainless bioreactors
- cGMP manufacturing of Phase I / Phase II material in product-dedicated suites up to kilogram scale



**FIGURE 4** Fed-Batch Shake Flask Antibody Productivity Before and After One Process Development Cycle



## EXPERT BIOLOGIC DEVELOPMENT SUPPORT

With over 20 years in the industry and a proven track record supporting biotech and pharmaceutical companies with analytical and regulatory consulting services, we help you build a smooth path to product filing.

### REGULATORY CONSULTING

Catalent Regulatory Consulting provides creative regulatory strategies, targeted product development plans, and operational excellence to reduce risk and enhance speed to market for a wide variety of biologic products.

#### EARLY STAGE SERVICES

- Strategic Biologic (NME, Biosimilars, Biobetters) and Biologic/Device Combination Development Planning
- Gap Assessments and Remediation Plans
- IND Submission Preparation and Filing
- FDA Meeting Support

#### LATE STAGE SERVICES

- Pivotal Clinical and CMC Development Planning
- NDA/BLA Submissions Preparation and Filing
- FDA and Advisory Meeting Support
- NDA/BLA Maintenance
- Post-approval CMC Changes

### BIOASSAY DEVELOPMENT

Our rigorous standards and state-of-the-art equipment are designed to provide the most creative solutions. We have developed and validated bioassays for proteins and peptides, therapeutic viruses, attenuated bacterial vaccines, aptamers and more.

We can help you demonstrate that your biopharmaceutical product is active by testing it in a system that appropriately reflects its clinical indication. Our cell-based assays, immunoassays, and purity assays are robust in all applications.

#### LOT-RELEASE TESTING OF BIOLOGIC MATERIAL

#### STABILITY-POINT TESTING

#### VERIFICATION OF STRESS-POINT TESTING

#### PROCESS OR FORMULATION

#### CHANGE SUPPORT

### BIOSAFETY TESTING

Our testing services bring added value to every phase of biopharmaceutical development.

#### CELL BANK CHARACTERIZATION

#### CELL BANKING & MAINTENANCE

#### VIRAL CLEARANCE TESTING

#### ADVENTITIOUS VIRUS DETECTION

#### METHOD DEVELOPMENT & VALIDATION



## TAKE YOUR PRODUCT TO CLINIC AND BEYOND

Our broad range of fill/finish manufacturing capabilities, innovative packaging solutions, and a global supply chain network can help you to take your product seamlessly to clinic or market.

### CLINICAL SUPPLY SERVICES

Catalent is a leading global clinical supply services provider. We can help you reduce your timelines and gain peace of mind, through integrated, innovative solutions and deeper expertise in project management and global supply chain. For your planned clinical trials, Catalent provides:

- COMPARATOR SOURCING
- CLINICAL MANUFACTURING & BLINDING
- CLINICAL PACKAGING & LABELING
- GLOBAL WAREHOUSING & DISTRIBUTION

### FILL/FINISH MANUFACTURING

Your specialized manufacturing challenges, our tailored solutions. From clinical through commercial scale, we have the global network and the extensive manufacturing, analytical, and packaging capabilities to provide you with customized options and reliable supply.

- BLOW/FILL/SEAL
- STERILE LIQUID PRODUCT
- PREFILLED SYRINGES
- VIAL AND SYRINGE FILLING (SMALL SCALE FOR DEVELOPMENT)
- LYOPHILIZED PRODUCT (SMALL SCALE FOR DEVELOPMENT)

### INJECTABLE PACKAGING SOLUTIONS

#### SPECIAL HANDLING EXPERTISE

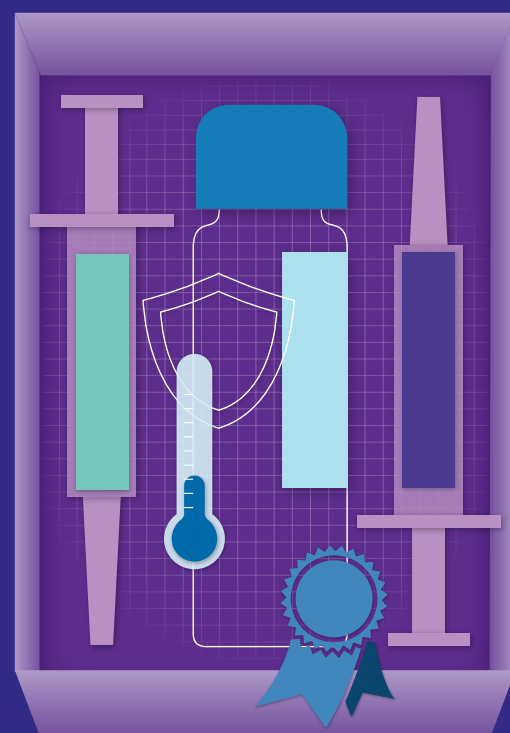
Our unmatched cold-chain handling and storage capabilities improve speed to market and minimize financial and regulatory risks

#### CUSTOM PACKAGING SOLUTIONS

With our wide range of formats, unique adherence solutions, and investment in automation, we work with you to design packaging and kitting specific to your customers' needs.

#### RELIABLE QUALITY & SUPPLY

Our extensive expertise and commitment to quality ensure reliable supply, and we have a proven track record of supporting pandemic or seasonal demand.



**Catalyst + Talent.** Our name combines these ideas. From drug and biologic development to delivery technologies and supply solutions, we are the catalyst for your success. With over 75 years of experience, we have the deepest expertise, the broadest offerings, and the most innovative technologies in brand and generic pharmaceuticals, veterinary medicine, consumer health, and biologics. Whether you are looking for a single, tailored solution or multiple answers throughout your product's lifecycle, we can improve the total value of your treatments—from discovery to market and beyond. **Catalent. More products. Better treatments. Reliably supplied.™**

-  **DEVELOPMENT**
- BIOLOGICS
  - PRE-FORMULATION & FORMULATION
  - SOLID STATE SERVICES
  - PHARMACEUTICAL & BIOPHARMACEUTICAL LAB SERVICES
  - REGULATORY CONSULTING

-  **DELIVERY**
- SOFTGEL
  - ZYDIS® & LYOPAN® FAST DISSOLVE
  - CONTROLLED RELEASE
  - INHALATION
  - INJECTABLES

-  **SUPPLY**
- CLINICAL SUPPLY
  - MANUFACTURING
  - STERILE FILL/FINISH
  - PACKAGING SERVICES & DELIVERY SOLUTIONS

To learn more about Catalent Biologics, contact us today.

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