



## MADISON, WI

# New Biomanufacturing Center of Excellence and Your Strategic Partner for Biologic Drug Development

Spring 2013

**Our new, state of the art facility, with expanded mammalian cell line engineering and biomanufacturing capabilities utilizing single use systems, offers increased flexibility and manufacturing scale to support our customers' growth.** We offer a broad range of integrated formulation and analytical services to solve your most difficult development challenges in Biologics.

### **Our new Madison facility services include:**

Process development focus with extensive non-GMP and GMP experience, laboratories and support functions

Solutions for difficult to express proteins

Flexible cGMP production scale from 10 L to 1000 L

Extensive use of single use technologies to eliminate cross contamination

Unidirectional flows throughout facility

Growing to 100,000+ square feet and 100+ employees

### **Catalent Biologics key solutions:**

Bioassay Development

Mammalian Cell Line Engineering

Process Development

Viral Clearance Studies

cGMP Manufacturing

Assay Qualification

Formulation Development

Stability Studies

Fill/Finish

Regulatory support



DEVELOPMENT



DELIVERY



SUPPLY



### Benefits for our Customers:

Equipment flexibility and scale  
Expansion space available for Phase III and commercial manufacturing  
Single use equipment eliminates product cross contamination

Integrated analytical, formulation development, viral clearance and fill finish supply  
GPEX® technology for the greater stability and higher expression cell lines

### Expertise with Biologics:

GPEX® cell line technology platform expressed in over 300 cell lines  
Proven with master cell banks and bulk drug substance  
Track record of cell line development through cGMP production supporting Phase I and II clinical trial material  
Completed multiple programs from cDNA through drug product release in approximately 14 months

Experienced and cohesive team running your cGMP program from development through Process development scale production  
Phase I and Phase II clinical material has been completed for use in clinical in US and Europe  
World-class on-time delivery

## Why Catalent Biologic Solutions?

### Fastest path from gene to clinic utilizing our GPEX® technology

GPEX® proprietary technology creates stable, high-yielding mammalian cell lines with high speed and efficiency getting your drug development to clinic in one-third the time of traditional approaches. The advantages of applying GPEX® technology to your product's development span from early feasibility studies, to clinical manufacturing, to commercial scale production.

### Broadest global development expertise

Our unique technologies, deep expertise and proven track record of global regulatory and commercialization execution provides the support to solve your most difficult drug development challenges and achieve optimal molecule form and therapeutic profile for virtually any dose form.

## Integration Ensuring Your Gene to Market Success

We are your strategic partner for biologic drug development success. With our expanded biomanufacturing capabilities and our broad range of integrated services we provide fast innovative solutions from formulation development to biomanufacturing and analytical services, to clinical and commercial fill/ finish supply.

### Discover more solutions with Catalent.

Call: + 1 888 SOLUTION (765-8846) Email: [solutions@catalent.com](mailto:solutions@catalent.com) Visit: [www.catalent.com](http://www.catalent.com)

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better treatments.  
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### Catalent Pharma Solutions

14 Schoolhouse Road  
Somerset, NJ 08873 USA  
F + 1 732 537 6480