



## BIOSAFETY TESTING

### Science, credibility and quality to keep you on track

**Integrated services generating fast results** Catalent provides the biotechnology industry with an unparalleled range of integrated product development and testing services designed to speed your product development from bench to clinic.

#### Added Value for Every Development Phase

**Complete viral clearance** In keeping with regulatory requirements, our experts will help you validate the capacity of key process steps to provide viral clearance by designing scientifically sound studies that accurately demonstrate the virus inactivation or removal potential of your manufacturing process. We include all appropriate controls, use high-titer virus stocks and perform validated infectivity assays to evaluate samples in real time.

**Robust In-process and lot-release testing** Catalent performs assays for all stages of biopharmaceutical manufacturing, including in-process tests for contaminating agents, cGMP-compliant lot-release testing for biocontaminants, testing for host-cell proteins, bioassays for potency and analytical assays for structural and contaminant determination.

**Rapid cell bank characterization** Our staff and technologies can facilitate all characterization of assays required by the FDA and other regulatory agencies, worldwide, for mammalian Master and Working Cell banks including:

- Virus detection by infectivity, electron microscopic, enzymatic and PCR-based assays
- Identity by isoenzyme analysis and karyotyping
- Detection of microbial and other adventitious agents by sterility and mycoplasma assays

**World class stability services** Catalent's biological testing expertise is completely integrated into our stability protocols. We offer all ICH conditions to support standard stability studies, photostability and stress testing.

**Expert method development and validation** Catalent's expert scientific team can develop and validate complex release assays for products in Phase I through commercialization. We work with recombinant proteins, therapeutic viruses and attenuated bacterial vaccines—and help you design the right path that best meets the accuracy, linearity, precision and specificity guidelines set by regulatory agencies.



DEVELOPMENT



DELIVERY



SUPPLY

## Custom Viral Clearance Studies to Meet Your Needs

Biopharmaceuticals require viral clearance studies to validate the removal of potential viral contaminants. Catalent can design and perform custom viral clearance studies for recombinant and nonrecombinant protein therapeutics including:

- Custom validation of manufacturing processes to inactivate or remove the virus
- Validation of scale-down model of the manufacturing process
- Custom client laboratories for performance of studies
- Well-characterized, high-titer virus stocks
- Validated assays
- Quantification of virus inactivation and clearance
- Controls to ensure accurate and precise scientific results
- qPCR assays for virus removal steps

### MOLECULAR BIOLOGY

- Detection of residual host DNA
- Virus detection by PCR
- Product-enhanced reverse transcriptase assays
- Restriction map analysis
- Plasmid copy number determination
- Plasmid retention by selective marker sensitivity

### VIROLOGY

- Validated infectivity assays
- Characterized, high titer virus stocks for viral clearance
- Screening for retroviruses and other adventitious viruses

### MICROBIOLOGY

- Sterility testing (USP, 21 CFR)
- Mycoplasma testing (PTC direct method, indirect method, PCR)
- Endotoxins (LAL by gel-clot or Kinetic-chromogenic method)
- Bioburden

### CELL BIOLOGY

- Milling, solution and slurry modes
- Crystal engineering

### ANALYTICAL

- Gas chromatography (GC)
- High-performance liquid chromatography (HPLC)
- Amino acid analysis (AAA)
- Glycan analysis
- Structural analysis
- Mass spectroscopy

Contact Catalent today and let our expert team tailor a biosafety program to fit your needs.

more products.  
better treatments.  
reliably supplied.™

[www.catalent.com](http://www.catalent.com)

### Catalent Pharma Solutions

14 Schoolhouse Road  
Somerset, NJ 08873  
**T** + 1 732 537 6200  
**F** + 1 732 537 6480  
[solutions@catalent.com](mailto:solutions@catalent.com)

### Catalent Pharma Solutions

160 Pharma Drive  
Morrisville, NC 27560  
**T** + 1 919 465 8155  
**F** + 1 919 481 4908  
[solutions@catalent.com](mailto:solutions@catalent.com)