



## **BIOLOGICS SOLUTIONS**

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## **Biologics Solutions Facilities and Capabilities**

Questions for our specialists? Visit www.criver.com/contact-CRL We offer a powerful portfolio of testing and contract development and manufacturing (CDMO) services and products in support of the development of a <u>biologic</u> including, antibodies/proteins, <u>cell and gene therapies</u>, <u>vaccines</u>, and <u>biosimilars</u>. As a global organization offering scientific guidance and regulatory expertise combined with ample capabilities and capacity, we give our clients confidence that they can expect exquisite science and on-time delivery. Our reliability is what keeps clients returning to us in support of their programs.

	Alderley Park, UK	Keele, UK	Rockville, Maryland, USA	Hanover, Maryland, USA	Memphis, Tennessee, USA	Pennsylvania, USA	Massachusetts, USA	Ireland	Germany	France
Abnormal Toxicity/General Safety							•			•
Antisera Production								•		•
Biophysical Characterization Studies							•			
Biosafety Testing						•	•	•	•	
Bulk Harvest and End-of-Production Testing						•	•	•	•	
Cell Banking	•	•	•			•				
Cell Line Characterization						•	•	•	•	
Cell Therapy CDMO Services (Autologous and Allogeneic)*				•	•					
Cell Therapy Testing (e.g., safety, purity, identity, potency, POC, microbiology, etc.)*				•	•					
Chromatography and Electrophoretic Methods	•	•	•			•	•	•		
Contamination and Impurity Testing (e.g., mycoplasma, adventitious viruses, residual DNA, etc.)	•	•	•	•	•	•		•	•	
Custom Method Development						•	•	•	•	•
Custom Molecular Cloning*			•							
Cytotoxicity								•		
Disinfectant Efficacy Testing						•		•	•	

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Endotoxin Testing						•		•	•	
Environmental Monitoring Services						•		•		
Genetic Stability Testing						•			•	
Glycosylation/Glycan Characterization							•			
Host Cell Protein Determination						•	•		•	
Identification of Bacterial Isolates						•		•		
Immunopotency/Immunogenicity Testing	-							•		
In Vitro Potency/Bioassays							•		•	
In Vivo Biosafety Testing							•	•		
In Vivo MAP, RAP and HAP Testing							•	•		
In Vivo Potency/Bioassays	-						•	•		
Lot and Final Drug Product Release						•	•	•	•	
Mass Spectrometry Services							•			
Master and Working Virus Seed Production			•			•				
Microbial Cell Bank Testing (e.g., function, purity, identity, impurities, microbiology, etc.)*		•								
Microbial Limits/Bioburden Testing						•		•		
Monocyte Activation Testing (MAT)								•		
Plasmid CDMO Services and Off-the-Shelf Products*	•	•								
Plasmid DNA Testing (e.g., purity, identity, impurities, microbiology, physiochemical, potency, etc.)*	•	•								
Preservative Efficacy Testing								•		
Process- and Product-Related Residuals							•			
Process Characterization (Resin Cycling)						•			•	
Product Characterization*	•	•	•							
Product Release Tests*	•	•								
Protein Characterization						•	•	•	•	
Pyrogen Testing								•		•
QC Release Testing*	•	•	•							
QP Release*		•								

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Raw Material Testing*			•							
Reference Standard Characterization							•			
Shipping Studies*			•							
Spore Count Verification								•		
Stability Testing	•	•	•	•	•	•	•	•	•	
Sterility Testing						•		•		
Typical Residual Impurities Testing (HCDNA/HCP/RNA)*	•	•								
Vaccine Challenge Studies								•		
Vaccine Safety Assays						•	•	•	•	
Viral Clearance Studies						•			•	
Viral Vector CDMO Services and Off-the-Shelf Products*			•							
Viral Vector Testing (e.g. identity, potency, impurities, etc.)*			•							
Viral Vector Packaging*			•							
Water Testing Services						•		•		

\*Supporting our CDMO services

