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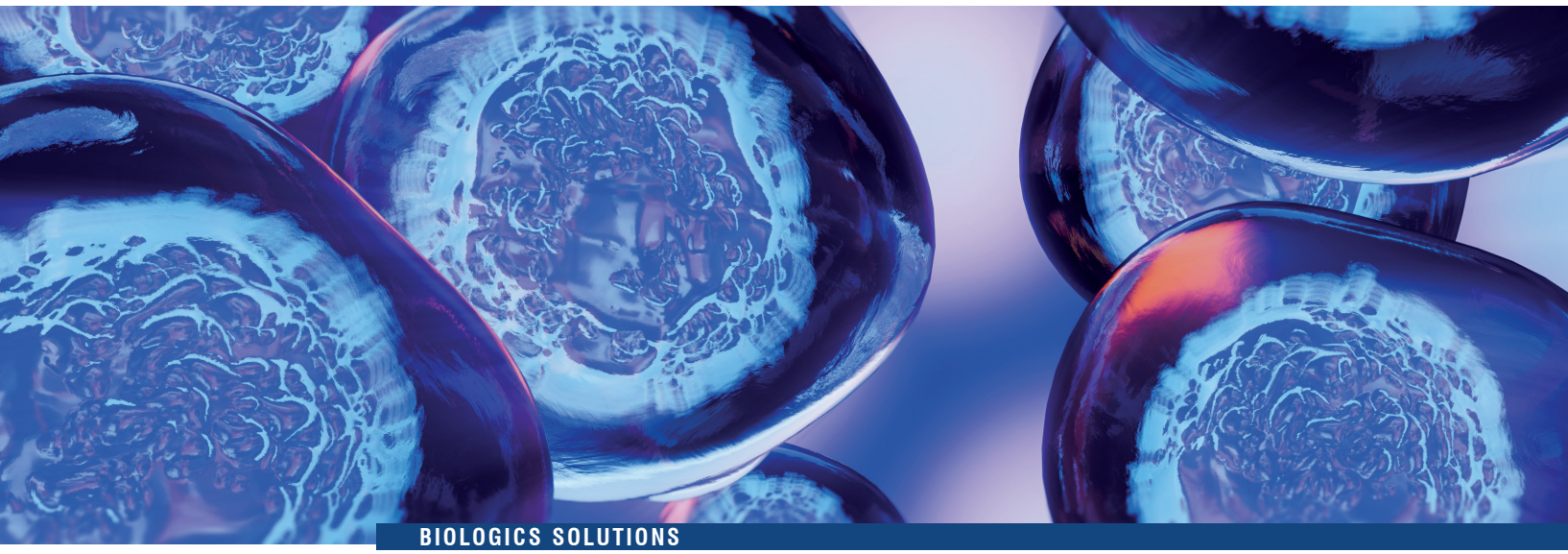

BIOLOGICS SOLUTIONS

Cell Therapy

Contract Development and Manufacturing Services

Click to learn more

Questions for our specialists?
Visit www.criver.com/contact-CRL

Charles River is a trusted partner with the insight and experience to take your cell and gene therapy products from bench to bedside. Our combination of track record, commitment to quality, breadth of services and products, and flexibility provides our customers with a first-in-class, dedicated team focused on the clinical and commercial development of complex cell and gene therapy products. As an experienced commercial-ready CDMO, we know how to accelerate and help you achieve your cell and gene therapy goals.

Our hands-on cell therapy manufacturing services expertise spans a variety of autologous and allogeneic cell types and starting materials, including but not limited to:

- Immune cell populations (i.e. T-cells, NKs, Dendritic cells, etc.)
- Stem cells (i.e. MSCs, HSCs, etc.)
- Other cell types as needed

In addition, we have experience handling TILs, tumors (resections/biopsies/lysate), apheresis material including mobilized, whole blood, and buffy coat.

Development Services

We have a long track record of providing development and manufacturing services for all phases of product development from early comparability lots, engineering runs, toxicity lots, early preclinical and clinical studies, mid-to-late phase trials, and product scale-up, up to commercial manufacturing. Knowing the what, when, and how, we can work with you to streamline your development pathway and put the right tools to work at the right time.

Related Services

- Plasmid DNA CDMO Services
- Viral Vector CDMO Services
- Plasmid and Viral Vector Products
- Viral Vector Packaging Services

Contact Us

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Charles River – Baltimore
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Hanover, MD 21076
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Process Development (PD) and Optimization

Our team is committed to working with you to provide the right PD solutions for your product at the right time in your development lifecycle. Our experience with the latest technology platforms allows us to excel in clinical, pre-commercial, and commercial activities, including process mapping, design, closed systems development, optimization, stability, and scale up.

Assay Development (AD) and Optimization

We can manage AD internally, via a third party, or with some combination thereof, and cover all aspects of product characterization and release testing for cellular products. We offer critical rapid-release testing services for personalized therapies requiring same-day turnaround. Our development team is highly experienced in building, qualifying, and scaling up assays of all types from cell counts to characterization, potency, and release testing. We pride ourselves on working with the latest technologies and methods that can be translated to your process and product release in the timeframes that work for you and your patients.

Why Partner with Us for Your Cell Therapy Manufacturing?

Our teams are skilled in a variety of technology platforms that can be used in the cell therapy manufacturing process. Our years of experience enable us to provide you with insight on best practices and scale-up to not only improve safety, but decrease costs of goods for patients and industry as a whole. Our capabilities include:

- Manufacturing Science and Technology (MSAT) team
- Quality management systems (early phase through commercial)
- Quality control/release testing
- Regulatory support
- Clinical operations and logistics
- Technical operations
- Assay development
- Validation and qualification
- Process development labs

As a trusted cell therapy CDMO, we can manage all aspects of your product development lifecycle and associated supply chain. We manage supply chain integration, scheduling with several parties (i.e. apheresis centers and clinics), temperature, and/or controlled storage before, during, and after shipping with various providers. We also interface on your behalf with additional CDMOs and/or regulatory agencies for global clinical trials and/or product roll-outs, as well as liaise with patient collections facilities and clients CROs.

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