



Charles River Launches Helper Plasmid to Streamline Adeno-Associated Viral Vector Manufacturing

March 9, 2023

Off-the-shelf pHelper simplifies gene therapy supply chains with immediate availability

WILMINGTON, Mass.--(BUSINESS WIRE)--Mar. 9, 2023-- Charles River Laboratories International, Inc. (NYSE: CRL) today announced the launch of its off-the-shelf pHelper offering, which is designed to secure supply and streamline adeno-associated virus (AAV)-based gene therapy programs from early discovery through commercial manufacturing. It is available immediately in Research Grade (RG), High Quality (HQ), and Good Manufacturing Practice (GMP)-grade.

Helper plasmids are the latest in a comprehensive collection of contract development and manufacturing organization (CDMO) products and services developed to simplify complex supply chains and safeguard viral vector packaging in cell and gene therapy programs. This plasmid product is reliably manufactured and released with Chemistry, Manufacturing and Controls (CMC) information and a Certificate of Analysis (COA) to support regulatory filings and approval applications.

Using standard off-the-shelf plasmids such as pHelper AAV-based gene therapy developers can both accelerate production timelines and reduce costs while leveraging significant features and benefits:

- Immediate, reliable supply
- Fit-for-purpose, consistent quality
- Kanamycin antibiotic resistance
- Animal component-free production
- License and royalty-free, from research to commercial
- History of use in AAV production for a range of serotypes, therapeutic trans-genes, and scales

Gene Therapy Spotlight Launch

Charles River will officially launch its ready-to-use, off-the-shelf helper plasmid offering during an invite-only showcase event on March 13, [Gene Therapy Spotlight: Investment, Regulatory and Development Perspectives](#), held in conjunction with the [Advanced Therapies Congress](#), London, UK.

Alongside a wealth of expert speakers and panel discussions, Ramin Baghirzade, PhD, Senior Director, Global Head Commercial, Gene Therapy CDMO Services will present: The Role of Plasmid DNA in Expediting Gene Therapy Manufacturing and Beyond.

Plasmid DNA CDMO Services

The addition of pHelper plasmids follows the launch of the [eXpDNA™ plasmid manufacturing platform](#) established over decades of plasmid DNA CDMO scale-up experience, which significantly reduces plasmid production turnaround time for advanced therapy medical product (ATMP) and vaccine developers.

In recent years, Charles River has significantly broadened its cell and gene therapy portfolio with several acquisitions and [recent expansions](#) to simplify complex supply chains and meet growing global demand for plasmid DNA, viral vector, and cell therapy services. The Company offers end-to-end support and supply chain simplification for cell and gene therapy developers. Combined with the Company's legacy testing services, Charles River offers an industry-leading "concept-to-cure" solution for advanced therapies.

For more information, register for Charles River's upcoming GEN webinar on March 30, in which Andrew Frazer, PhD, Associate Director, Scientific Solutions, Gene Therapy CDMO Services explores Advancements in Manufacturing for Rapid Delivery of pDNA Starting Materials: <https://bit.ly/41KDrDM>

Approved Quotes

- "The launch of Charles River's pHelper plasmids are the first in the off-the-shelf plasmid product portfolio aimed at supporting AAV-based gene therapy programs. By reducing program development costs and simplifying supply chains, pHelper will help accomplish our ultimate goal of delivering safe, effective therapies to patients faster." – Kerstin Dolph, Corporate Senior Vice President, Biologics Solutions, Charles River
- "We are committed to supporting advanced therapy developers with a rapid supply of critical plasmid DNA starting materials to expedite their programs. The addition of in-stock packaging plasmids for RG, HQ, and GMP grade plasmids, combined with Charles River's established plasmid and viral vector CDMO capabilities, will help to both accelerate timelines and ensure the highest quality product with one partner." - Andrew Frazer, PhD, Associate Director, Scientific Solutions, Gene Therapy CDMO Services

About Charles River

Charles River provides essential quality products and services to help pharmaceutical and biotechnology companies, government agencies and leading academic institutions around the globe to accelerate their research and drug development efforts. Our dedicated employees are focused on providing clients with exactly what they need to improve and expedite the discovery, early-stage development and safe manufacture of new therapies for the patients who are in-need of them. To learn more about our unique portfolio and breadth of services, visit www.criver.com.

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Source: Charles River Laboratories International, Inc.