Charles River Laboratories

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Location: San Francisco Bay Area

Manufacturing and Testing Facilities Footprint & Capacity:

16 Aseptic Manufacturing Suites "Riverside" 4600 East Shelby Dr, Memphis, TN (325sqft)
Validated ISO 7 Grade B production (US FDA and EU Annex 1 compliant for cell culture or viral transduction)

9 Aseptic Manufacturing Suites "Bluff City" 4600 East Shelby Dr, Memphis, TN (625 sqft)
ISO 7 Grade B production (US FDA and EU Annex 1 compliant for cell culture or viral transduction)
Commercial Building Global Drive facility (120,000 sqft)
Fully modular clean room space with ballroom capability. Anticipated Q4 2023.

Rockville, MD (GMP MFG & PD)
4 GMP Suites and all PD labs

Keele/Alderley Park, UK (GMP plasmid MFG & PD)
10 GMP production suites and 4 HQ (GMP-like) suites

358 Technology Drive Malvern, PA 19355
11 cGMP cleanroom suites for cell bank manufacturing and biosafety testing

466 Devon Park Drive Wayne, PA 19087
Cell line characterization, biosafety testing, viral clearance studies, potency assays, cell-based bioassays, lot release programs, and stability studies.

Max-Planck-Straße 15A, 40699 Erkrath, Germany
Potency assays, cell-based bioassays, cell line characterization, biosafety testing, custom HCP ELISAs, lot release programs, and stability studies.

Gottfried-Hagen-Straße 20, 51105 Köln, Germany
Viral Clearance Studies

Carrowntreila, Ballina, Co. Mayo, Ireland
Analytical testing, cell line characterization, biosafety testing, lot release programs and stability studies.

Modalities / Tech Platforms Supported:

Manufacturing: Cellular Therapies(Stem Cell, MSC, iPSC, DC, NK, T-cell, B-cell, Tumor cells (TILs, MILs) Macrophages, Fibroblasts) AAV, Lentivirus, Retrovirus and Adenovirus production. Plasmid production. Mammalian and Microbial Master and Working Cell banks and Virus/vaccine manufacturing.

Testing: All Cell-derived modalities supported including: Cell therapies, Gene therapies, Viral Vectors, Plasmids, Recombinant Proteins, Enzymes, large molecule, etc.

Process & Analytical Development Capabilities:

Gene Therapy: Process development scales include shake-flasks, 3L and 10L bioreactors. Cellstack 10s and Hyperstacks for adherent processes. For our standard suspension based process: Vicell XR is used to monitor viability and vcd (samples are taken in triplicate). Vicell Metaflex is used to monitor pH, metabolites such as glucose pCO2 and pO2. Online parameters such as pressure, weight, temperature, pH, DO, sparging, and overlay are available on the XDR.

Cell Therapy: PD/AD development in Hanover, MD and cGMP Manufacturing in Memphis, TN. Process Development is typically conducted in 3 stages: Process Evaluation, Process Optimization (if needed), and Process Confirmation. Note if a process meets all targets, CQAs, and GAP assessment criteria during the Process Evaluation phase, then those studies can suffice as Process Confirmation. AD consists of a similar process: Methods Evaluation, Reproduce/Develop Method (assure GMP compliance), and Fit for Purpose. Both sides are trained on and transferred down to Memphis MS&T to prepare for clinical manufacturing.

GMP Manufacturing Capabilities:

Integrated Cell and Gene Therapy Contract Development and Manufacturing Organization (CDMO) Solutions including testing and quality control

Cell Therapy, Viral Vector, and Plasmid DNA Production, Mammalian and Microbial Master and Working Cell banks and Virus/vaccine manufacturing.

Research, High Quality (HQ), and GMP Grade Materials

Cell Sourcing for Research-use and GMP-compliant Human Cells

Plasmid and Viral Vector Products

Custom Cloning

Scientific and Regulatory Affairs Services

Accelerated development through site-to-site shared systems and tech transfers

20 FDA-approved cell and gene therapies supported between 2013-2023

1,000+ cell and gene therapy studies conducted annually

Analytical / Testing Capabilities:

Viral Clearance Studies

Cell Line Characterization

Cell Banking

Contamination and Impurity Testing

Lot and Final Drug Product Release Testing

Stability Testing

Bioactivity and Impurity Testing

Anti-Infective and Vaccine Challenge Studies

40,000 biologic testing reports sent annually, supporting +40 commercial client compounds

Track Record:

Viral Vector and Plasmid Manufacturing: 40+ pDNA batches manufactured annually (HQ and GMP). 25+ AAV GMP batches. 10 Ad GMP batches. 3 LVV GMP batches. 5 RVV GMP batches.

Cell Therapy Manufacturing:
2-commercial clients, 1 auto gene edited, 1 allo ctl- Together produce approx 100 batches annually.
1-phase 3 allo epi-approx 50 batches annually
1- phase 1 auto TIL-approx 20 batches annually
4-technology transfer

Biologics Testing:
Supported 86% of drugs approved by FDA in 2023
Supported 10 of the 20 FDA-approved CGT products
Deliver 20,000+ reports and perform 100,000+ tests per year
100% of viral clearance studies submitted and accepted by regulatory authorities (150 total in 2024 with 20 for Gene Therapy products)

Value Proposition:

At Charles River, our goal is to accelerate the development, production, and safety of discoveries, drugs, and products. We actively collaborate with academia, biotech, pharma, and governments to provide research solutions. Our extensive portfolio includes in vitro and in vivo studies, drug discovery support, safety assessment, manufacturing, and more. Through collaborations, we contribute to patient safety and drug efficacy by advancing vital treatments and therapies.

Because of the depth and breadth of our scientific reach, we know that we owe a tremendous responsibility to our clients, to patients, to ourselves, and to the scientific community in achieving this goal. It's a responsibility that guides every decision: continuously maintaining best-in-class solutions, innovating and pushing the boundaries of science, championing openness and integrity at every step, and balancing each decision through our singular focus – patient safety and drug efficacy.