



charles river

# Charles River Laboratories

Capabilities Overview










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# Our Capabilities

At Charles River, our goal is to accelerate the development 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.

-  Founded: 1947
-  Headquarters: Wilmington, MA
-  Employees: +21,000 worldwide
-  Revenue: \$4.13 billion in Y2023
-  Ownership: Publicly traded (NYSE:CRL)
-  Operations: 150+ facilities in 21 countries
-  Worked on >80% of FDA-approved drugs over the last 5 years and 85% of FDA-approved drugs in 2023 alone.

# Drug Discovery and Development

Supporting >80% of the drugs approved by the FDA in the past 5 years



## Research Models and Services and Cell Sourcing for Human Immune and Stem Cells

Foundational tools that enable clients to discover new molecules



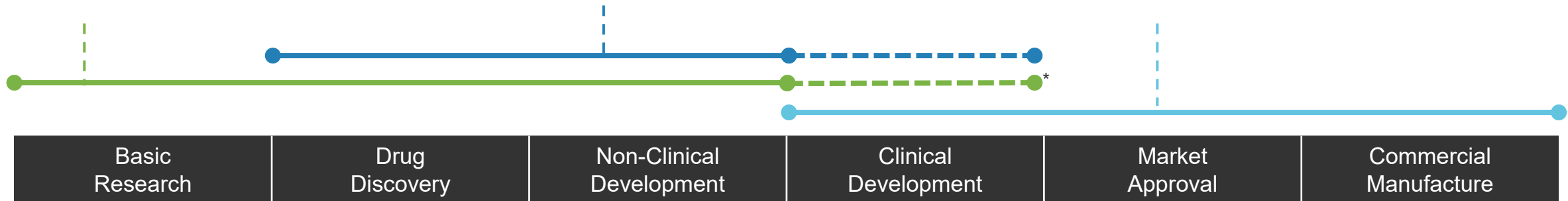
## Discovery Services, Safety Assessment, and Laboratory Sciences

Enabling preclinical success and efficiently advancing ideas into the clinic



## Biologics Testing, CGT CDMO, and QC Microbial Solutions

Ensuring the quality and safety of manufacturing and commercial therapies





# Research Models and Services

Foundational tools that enable the discovery  
of new molecules



# Research Models and Services

With seven decades of experience, our expertise is unmatched, allowing us to provide you with study-ready research animal models via our global network of commercial breeding facilities. Our rigorous biosecurity and genetic standards, and research support services such as surgery, preconditioning, and a comprehensive humanized portfolio allow us to provide you with an animal model to meet your specific research needs.

Our CRADL® contract vivarium space along with staffing and training services for private vivaria provide cost-efficient options to streamline your research operations.

We also offer a broad selection of human immune cells to support both *in vitro* and *in vivo* basic research.

- + **Research Animal Models**
- + **Research Animal Diagnostic Services (RADS)**
- + **Genetically Engineered Models and Services (GEMS)**
- + **Comprehensive Humanized Mouse Model Portfolio**
- + **Surgery and Preconditioning Services**
- + **Genetic Testing Services**
- + **Vivarium Staffing, Training, and Consulting Services**
- + **CRADL® Rentable Vivarium Space**

~1 of 2

Small research models sold North America and Europe for preclinical research come from Charles River

3,600

unique strains are cared for by our genetically engineered models and services staff in an average week



# Cell Sourcing

Providing research-use and GMP-compliant human immune and stem cells



# Cell Sourcing

We are an experienced cell sourcing provider of research-use and GMP-compliant humane immune and stem cells for cell and gene therapies. Our portfolio includes whole blood products, leukopaks, PBMCs, isolated immune cells, hematopoietic and pluripotent stem cells. We also offer bone marrow and cord blood products.

Our custom services include functional immune cell assays, proof-of-concept experiments, custom protocols, and product development.

- + **Human Peripheral Blood Products**
- + **Human Stem Cells**
- + **GMP-compliant Cellular Starting Materials**
- + **Diseased State Biospecimens**
- + **Biopreservation, Cell Freezing Media, and Antigens**
- + **Animal Primary Cells**
- + **Custom Immune Cell and Donor Recruitment Services**

# 25 +

Cell and Gene therapy clients supplied with GMP-compliant cellular starting materials

# 325 +

GMP-compliant products supplied to support clinical-phase manufacturing for the development of allogeneic therapies

# 400K+

Apheresis collections with over 40 years of human cellular material sourcing experience



# Discovery Services and Safety Assessment

Enabling preclinical success and efficiently  
advancing ideas into the clinic



# Discovery Services

Choosing your drug candidates for preclinical development is a big step. Through a strategic approach with clinic efficacy as a guide, we'll drive your programs through a combination of multidisciplinary drug discovery expertise and capabilities in targets, translational platforms, therapeutic areas and across modalities. From target validation through lead candidate selection, you can count on our expertise.

- + **Integrated Drug Discovery**
- + **Logica® Transformative Drug Design**
- + **Antibody Discovery Services**
- + **Chemistry**
- + **Assay Development, Screening, and Profiling Assays**
- + **Pharmaceutical Sciences and Formulations**
- + **Pharmacology Studies**
- + **ADME Drug Metabolism and Pharmacokinetics (DMPK) Studies**

# 490+

patents for specific scientific findings generated for our partners since 2001

# >100

small and large molecules pre-clinical candidates delivered to our clients since 2001

# Safety Assessment

Whether you need a single study or a complete IND-enabling program, we work with you on the design and execution, giving you the confidence that comes from knowing your study will be done right and on time. Determination of a drug's safety profile is perhaps one of the most critical stages of the drug development pathway. Complications and inefficiencies at this late phase of the journey can create costly delays. Our scientists leverage global capacity and multidisciplinary capabilities to design a program around what you value most.

- + **Apollo™ secure cloud-based platform**
- + **Environmental Safety**
- + **IND-enabling Studies**
- + **Nonclinical and Clinical Laboratory Sciences Services**
- + **Pathology Services**
- + **Scientific and Regulatory Affairs Services**
- + **Standard for Exchange of Nonclinical Data (SEND)**
- + **Toxicology Services**
- + **Supported Modalities**
  - **Agrochemicals**
  - **Biotechnology and Pharmaceuticals**
  - **Industrial Chemicals**
  - **Medical Devices**

# 42,000+

Reports delivered in the last 12 months

# 1,500

IND Programs supported in the last 12 months and conduct approximately 300 IND programs per year



# Manufacturing Products and Services

Ensuring safe production and release  
of manufactured products and  
providing GMP-compliant products and  
services



# Biologics Testing

With more than 50 years of experience, our Biologics Testing group has the proven knowledge, expertise, and capacity to address challenging projects for biotechnology and pharmaceutical companies worldwide. Our primary emphasis is on quality, which is enforced through continuous training and internal audit programs, ensuring that our practices are compliant with global regulatory guidelines. No matter your needs, we are unmatched in our ability to provide you with the most progressive, flexible solutions to ensure the safety of your products.

- + **Viral Clearance Studies**
- + **Protein and 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

# 95%

SOW's delivered in under 4 days

# 200+

client audits per year

# Cell and Gene Therapy CDMO Solutions

Cell and gene therapy development is complex, so when you partner with Charles River, you gain access to leading scientific and regulatory guidance along with unmatched portfolio of research, manufacturing, and testing solutions. Through our integrated cell and gene therapy platform, our robust team of scientific experts can help you accelerate and achieve your goals faster.

- + **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**
- + **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**

# 1,000+

cell and gene therapy studies conducted annually

# 20

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

# QC Microbial Solutions

Testing for microbial contaminants is necessary to ensure the safety and quality of pharmaceutical and personal care products, but the process can add costly delays in their release to market. For over 30 years, Charles River has helped customers around the globe streamline testing and mitigate these risks with revolutionary technologies and exceptional services that have changed the way the industries conduct quality control.

- + **Endosafe® Bacterial Endotoxin Testing**
- + **Celsis® Rapid Microbial Detection**
- + **Accugenix® Microbial Identification and Strain Typing**

# >20M+

FDA-licensed cartridges for use with Endosafe® rapid bacterial testing platforms sold since product launch in 2003

# 317+

installations for Celsis® rapid microbial detection systems for bioburden testing in 2023

# 690,000+

environmental monitoring samples processed with Accugenix® microbial identification services around the world in 2023

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# Our Commitment to a Responsible and Sustainable Future

**Our purpose is clear, and our passion is  
strong: together, we create healthier lives**



# Animals in Research

Animals have contributed to nearly every medical breakthrough in recent history, including treatments for cancer, diabetes, and AIDS, and they continue to play an essential role in the development of life-saving therapies for people and other animals. The welfare of animals contributing to research is of utmost importance and a prerequisite for the accuracy, reliability, and translatability of our research.

## Commitment to Humane Care and Well-being of Research Models

Our Humane Care Imperative includes establishing industry best practices and providing education and training to increase awareness of the importance of humane care, fostering animal welfare worldwide. All Charles River employees - whether they work with animals or not - are committed to the highest level of animal welfare. We comply with standards of practice and accepted guidance for the care and use of laboratory animals. Moreover, we participate in voluntary oversight programs, such as AAALAC International that promotes the responsible treatment of animals in science through a voluntary accreditation program, to assess our compliance through in-depth evaluations of our facilities and practices



## The 3Rs Principle

The 3Rs (Replacement, Reduction, and Refinement) was developed over 50 years ago to provide a framework for performing animal research. Charles River has a long and proud history of investing in and embracing the components of the 3Rs principle.

We are committed to leading the industry in adopting the 3Rs, identifying technologies to reduce the use of animals, and supporting efforts by global regulatory bodies to advance solutions that reduce the use of animals while protecting patient safety.

# Advancing Alternatives

With advancements in scientific innovation, adoption of digital technologies, and artificial intelligence, Charles River is uniquely positioned to lead the industry into the next frontier of drug discovery and development. **The Alternative Methods Advancement Project (AMAP)** is dedicated to pursuing scientific and technological innovations that help us collaborate and develop new alternatives methods (NAMs) to animals in testing.



## Advocacy and Strategic Partnerships

- + Created by pursuing [partnerships](#) and relationships with thought leaders, policy makers, and important non-governmental organizations (NGOs)
- + This will provide the opportunity for Charles River to use our voice in the public space to advance the [pursuit of alternatives](#)



## Adopting Alternate Platforms

- + [Endosafe® Trillium® Recombinant Cascade Reagent \(rCR\)](#), our animal-free endotoxin testing solution
- + [Retrogenix® Platform](#), first-in-class in vitro library assesses off-target binding to de-risk *in vivo* studies and support IND
- + [Next Generation Sequencing \(NGS\)](#) for viral clearance testing as a reliable *in vitro* alternative to animal testing methods
- + Our [PathogenBinder™](#) methodology which reduces the need for 1M sentinel rodents annually



## NAMs for Therapeutic Discovery and Development

- + [Virtual Control Groups \(VCGs\)](#), which have the potential to unlock a game-changing new design for safety assessment studies
- + [Human complex \*in vitro\* models](#) for improved translation, early de-risking and partial replacement of animal models
- + Predictive toxicology *in silico* models

**AMAP** will coordinate and track Charles River's goal of investing **\$300M US over the next five years** in a portfolio of technology innovations, partnerships, and advocacy efforts to further enhance this critical mission and drive industry-wide adoption of alternatives.

# Our Commitment to Corporate Citizenship

Our purpose-driven Environmental, Social, Governance (ESG) strategy and sustainability efforts are designed to accelerate the delivery of products and effective treatments to the people and patients who need them. We will deliver on these efforts through our four foundational pillars and the quality outcomes that are fundamental to the patients who rely on the treatments we are helping to develop, to the animals under our care, and to our people and planet.

## Our ESG framework is built on four foundational pillars:

- + Accelerate Accessible Therapies
- + Lead with Integrity
- + Inspire our People
- + Protect our Planet



We've worked on more than 80% of the drugs approved by the U.S. Food and Drug Administration (FDA) over the last five years and 85% of FDA-approved drugs in 2023 alone.



We became a signatory to the United Nations Global Compact (UNGC) and established the Office for Responsible Use of Animals (ORUA), to oversee the responsible utilization and reduction practices, and operating standards of care.



We contributed a total of 29,000 employee volunteer hours in 2023, in support of their local communities.



Ahead of our target goal to deploy 100% renewable electricity across our operations by 2030, we have achieved 92% renewable electricity globally as of December 31, 2023.

# Diversity, Equity, and Inclusion

We are ardent believers in diversity, equity and inclusion – this commitment starts at the top with our CEO and extends into all facets of our business and our relationships with vendors, suppliers and business partners. We are committed to creating a workplace where everyone can succeed and thrive.

**Our focus on diversity, equity and inclusion is anchored in five strategic pillars:**

- + Building Awareness and Understanding
- + Strengthen Belonging and Inclusion
- + Increase Diverse Representation
- + Focus on Equity
- + Partner with our Communities



**Women represented 53% of our total leadership in 2023 (and 52% in 2022), and the composition of women at our Executive Leadership level (VP+) increased to 42% in 2023, up from 38% in 2022.**



**Charles River demonstrated equitable pay practices, with a pay gap of less than 1% by gender (global) and race/ethnicity (U.S) in 2023.**



**Employee Resource Groups (ERGs) have grown to include nearly 4,000 people participating in 11 dedicated global groups at the end of 2023, cultivating a sense of belonging and inclusion.**



**More than 410,000 learning sessions were completed by our employees, representing an average of 19 completed sessions per employee.**

# Data Security and Privacy

As a reflection of our commitment to protecting your data, *Forbes* recently recognized us as one of “**America’s Most Cybersecure Companies**,” and named us the most cybersecure company in the research and development industry.

Recently, we were also granted **ISO 27001 Certification**, the international standard for information security management systems (ISMS). This is a comprehensive framework that helps organizations protect their information assets from a variety of threats, including unauthorized access, use, disclosure, modification, and destruction.

Achieving this certification signifies our ongoing commitment to ensuring that your data is protected by a world-class information security management system.



## Access Control

Our systems ensure that only authorized individuals have access to sensitive data.



## Data Encryption

We use encrypted protocols to further protect data against unauthorized disclosure.



## Incident Response

Our response plans are designed for rapid identification, containment, and recovery.



## Training

We regularly train our teams on information security best practices and specialized products.

  
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