



FACILITY OVERVIEW

Charleston, South Carolina

Our Microbial Solutions site in Charleston, South Carolina offers a progressive portfolio of quality control testing solutions for the pharmaceutical, medical device, and consumer care industries to help bring products to market safely and efficiently. Our products and services are designed to streamline workflows and supply chains, ensure the integrity of test data, and allow you to release products with the confidence of total quality control.

Background

- Founded as Endosafe® in 1987
- Acquired by Charles River in 1994

Laboratories and Facilities

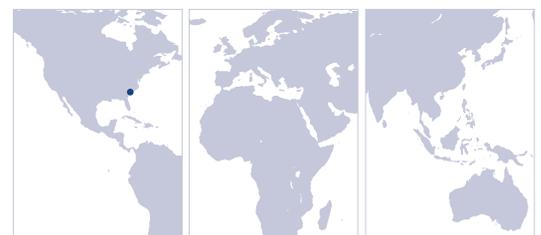
- Extensive site security and monitoring systems
- 44,000 square foot (4,088 m²) GMP manufacturing facility with supporting laboratories
- Technical service laboratory
- Contract bacterial endotoxin testing services
- 6,000 square foot (557 m²) facility dedicated to collection of crude lysate from the Atlantic horseshoe crab (*L. polyphemus*)
- Sustainability: Solar power generation in 2020 with the addition of a new General & Administrative building

Staff

- Over 300 employees

Product and Services Offerings

- Manufacturing of Endosafe® LAL products and accessories
 - Endosafe® cartridge technology
 - Kinetic chromogenic LAL Endochrome-K™
 - Kinetic turbidimetric LAL KTA and KTA²
 - Endpoint chromogenic reagents
 - Gel-clot LAL
 - Contract endotoxin testing
 - Product validation and release testing
 - Informational testing of samples
 - On-site training
- Rapid Microbial Detection
 - Production of Celsis AMPIscreen® pharma reagents
 - Customer sample feasibility and evaluation testing, through:
 - Celsis® sample effects testing
 - Celsis® spiking study testing
 - Customer test method development and ongoing support
 - On-site instrument demonstrations and training



EVERY STEP OF THE WAY

Compliance, Certifications, Accreditations and Professional Affiliations

Charles River's Charleston facility operates in compliance with the following regulatory agencies or accredited organizations:

- Food and Drug Administration (FDA) License Number #1197
- South Carolina Department of Natural Resources (SCDNR)
- South Carolina Board of Pharmacy (Non-Dispensing Drug Outlet)

Quality and Process Initiatives

- Current good manufacturing practices (cGMP)
- Quality System based on 21 CFR Part 820, compliance through Biological License Agreement on file with the FDA
- Routine FDA surveillance (CBER and CDER)
- On-site IT support, customer and technical services, and operations engineering team
- Excellent history of regulatory compliance

Achieving Sustainability Through the 3Rs Imperative

- Reducing the use of animals in pharmaceutical testing is a well-established initiative influencing the industry. The 3Rs (Replace, Reduce, Refine) are fundamental principles for driving ethical research, testing, and education using animals. We are firm in our commitment and compliance to the 3Rs initiative, as these principles are being incorporated into legislation, guidelines, and practice.
- As an LAL manufacturer, Charles River has helped alleviate pressures on horseshoe crab populations through conservation and animal welfare practices.
- We have developed new models and tools based on the latest innovative technologies that use 95% less raw material than traditional endotoxin testing methods through our Endosafe® cartridge technology.
- This technology significantly reduces the amount of LAL per test, minimizes the need for retesting that is often necessary with traditional methods, and ensures the safety of an FDA-licensed method.
- If all global endotoxin tests shifted to cartridge technology, Charles River alone could meet the global supply from our current annual quota. This technology would allow us to reduce the numbers of horseshoe crabs collected, yet still keep conservation in place.