



FACILITY OVERVIEW

Shanghai, China

Our Microbial Solutions site in Shanghai, China 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 February 2019
- Microbial Solutions product distribution and service site within China

Laboratories and Facilities

- Covers an area of approx. 1,100 square meters

Staff

- 11 employees

Product and Service Offerings

Accugenix® Microbial Identification and Strain Typing Services

- Prototypic identification [MALDI-TOF]
- Genotypic identification [DNA Sequencing]

Celsius® Rapid Microbial Contamination Detection

- Customer evaluation testing and troubleshooting

Endosafe® Bacterial Endotoxin Testing

- Customer evaluation testing, method development, and troubleshooting Training Lab
- Dedicated lab designed to facilitate hands-on LAL training and workshops

Compliance, Certifications, Accreditations and Professional Affiliations

Operates in compliance with

- ISO 9001
- ISO 17025

Quality and Process Initiatives

- Quality system is organized to monitor processes and operations throughout the microbial identification, instrumentation, and technical services activities.
- Performance of self-assessment audits, error management, and customer feedback, facilitating continual improvement and ensuring impartiality of the activities performed.

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.

EVERY STEP OF THE WAY

