WAY 19

Microbial Solutions for Compounding Pharmacists From Charles River

Charles River offers FDA-licensed products and GMP-compliant services for compounding pharmacists to help maintain control and reduce risks associated with manufacturing in an aseptic environment.

President & CEO:	James C. Foster
Founded:	1947
Employees:	11,000+ Worldwide
Stock Symbol:	CRL
Toll-Free Phone:	(877) CRIVER-1
Fax:	(978) 988-9236
Website:	www.criver.com
Email:	askcrl@criver.com

Company Background

Charles River is a global provider of comprehensive, innovative microbial QC product and testing solutions. We can help you meet the necessary global regulatory requirements to get to market and get your products to the patients and consumers that need them the most. We offer full-service solutions, including rapid endotoxin testing, microbial detection and identification, and strain typing to ensure safe manufacture and timely product release. We are committed to providing precision, confidence, and robustness in QC testing and methods to help manufacturers meet their standards for product safety and customer confidence. Our investment in new product research and development is matched by our high-quality standards and dedication to client-focused problem solving.

Product Overview

We lead the market with products and services that meet the diverse needs of the compounding pharmacy industry. Our unique combination of Endosafe® endotoxin testing, Celsis® rapid microbial detection, and Accugenix® microbial identification and strain typing services keeps your manufacturing operations running efficiently and smoothly, lowers your cost to manufacture, and protects your reputation.

Additional Product Lines

Bacterial Endotoxin Testing

The BET detects unsafe levels of microbial cell wall debris from live or dead Gram-negative bacteria that cause fever and symptoms of septic shock. Until now, BET required skilled analysts and manipulation of cumbersome reagents.

The Endosafe® nexgen-PTS™ is a handheld spectrophotometer that utilizes FDA-licensed LAL cartridges to deliver accurate, real-time endotoxin results in 15 minutes at the point of sample collection. The USP/BET compliant cartridges require no microbiology training, eliminate the need to prepare endotoxin standards, and are compatible with suitable dilutions of all common compounded sterile products. This rapid, on-site solution eliminates bottlenecks, improves sample management, and most importantly assures that products are free of endotoxin (pyrogen) within limits set by the Pharmacopeia. To ensure that our clients get the most out of the Endosafe® nexgen-PTS™, Charles River offers additional support through method development and training.

Microbial Identification for Environmental Monitoring Programs

Confident microbial and particle measurement is critical for an environmental monitoring program to ultimately confirm the security of the compounding area. Accurately identifying an organism to the species, and many times to the strain level, facilitates tracking of the potential origin of the contamination and prevents delays in product release and completion of investigations.

Charles River offers comprehensive contract microbial testing services from our FDA-registered, cGMP-compliant laboratories. We have supported QC testing for over 1,000 global facilities within the biopharmaceutical, medical device, and nutraceutical industries with our Accugenix® bacterial/fungal identification and strain typing services. Offering a 98% accurate identification rate and 99% on-time delivery, we have tested and identified more microorganisms than any other company or service laboratory in the industry.

Sterility Testing

Sterility testing is used to demonstrate the presence or absence of extraneous viable contaminating microorganisms in samples. This testing should be applied to substances, preparations, or articles which, according to the Pharmacopoeia, are required to be sterile.

Charles River provides sterility testing through our Celsis® ATP-bioluminescence technology that is compliant with the requirements of the USP, EP, and current FDA regulations. Sterility testing is conducted by direct inoculation or membrane filtration methods and can be performed in an isolator or cleanroom environment. In conjunction with the sterility test, a bacteriostasis/fungistasis test is performed to assess whether the test article is inhibitory to the growth of microorganisms.

Microbial Limits Testing

Microbial limits testing is performed on pharmaceutical products and medical devices in order to monitor the levels of microbial organisms present during processing and handling. The information provided by this test can be used to help determine the sterilization dose for the product or device. This assay is designed primarily to allow quantitative enumeration of bacteria and fungi that may grow under aerobic conditions. Our Celsis® rapid microbial method reduces the long incubation times necessary for a quantitative assay with a qualitative, ATP-based bioluminescence automated analysis, a proven gold standard for product screening and rapid release.