Pharmacies that prepare individualized dosages of sterile, high-risk drugs for patients must meet stringent requirements and standards to assure patient safety. Because aseptically compounded preparations are often administered to immunocompromised individuals, proactive quality control is critical to ensuring that a bad product does not transfer risk to the patient. Charles River offers FDA-licensed products and cGMP-compliant services to maintain control and consistency in your compounding processes, from in-process testing to batch release.

**Endotoxin Testing**

Bacterial endotoxin tests (BETs) detect 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®-PTS™ is a handheld spectrophotometer that utilizes FDA-licensed disposable cartridges to deliver accurate, convenient endotoxin results in 15 minutes at the point of sample collection. This rapid, on-site solution eliminates bottlenecks, improves sample management and, most importantly, assures that your products are free of endotoxin (pyrogen) within limits set by the Pharmacopeia. To ensure that you get the most out of the Endosafe®-PTS™, Charles River offers additional support through method development and training.

**Microbial Identification for Your Environmental Monitoring Program**

Confident microbial and particle measurement is critical for your environmental monitoring program to ultimately confirm the security of your 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 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 & Bioburden 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. Charles River performs this testing for clients according to global regulatory guidelines.