What’s at risk?

Microbial Solutions from Charles River
In the fast-paced world of biotech, it can be hard not to count minutes in dollars. You may be on a tight production schedule, or perhaps you’re racing to market against your competitors. Meanwhile, patients are fighting a different clock – balancing doses and appointments with dreams and future plans, wondering how they can add years to their lives.

What you have in common is understanding the importance of that final quality check – the critical moment when all the precision and care of your production team can be negated. If a fragment of contaminant slips through during a rushed release putting patient lives on the line, the only turnaround time that will matter is how quickly you can pull your product from the shelves.

Those who work in QC know that their job is more than a box to be checked, and that job can’t be done effectively without confidence in the results they report. Tight timelines, regulatory demands, and stringent data integrity standards can make it hard to focus on what’s really at stake in your QC process: the safety of your product and the lives of your patients.

Give your team and your patients the peace of mind they need. Choose microbial testing solutions that offer the efficiency, objectivity, and accuracy necessary to confidently deliver a safe therapeutic on time, every time.

Our Microbial Solutions portfolio of Endosafe® endotoxin testing, Celsis® rapid microbial detection, and Accugenix® microbial identification and strain typing products and services facilitate confident and objective decision making, ensuring the integrity of your microbial data and minimizing the risk to your patients. Like you, patient safety is at the core of what we do.
Some call her strong-willed, others say she’s spunky. But today, in the emergency room with a stomach bug that’s left her severely dehydrated, baby Harper is not herself. She hasn’t slept more than a two-hour stretch all week, so when she gets IV fluid therapy and finally sleeps through the night, her parents are relieved. They trust that the sterile needle and the 20 mL/kg of pure isotonic fluids that have just been administered are safe and free of harmful bacterial endotoxins. And it’s because of the manufacturer’s stringent endotoxin testing methods that tomorrow Harper will wake up and will take on the world.

The ability to detect all environmental Gram-negative bacterial endotoxins is a critical element of safe pharmaceutical production, medical device manufacturing, radiological health, and dialysis water testing fields. As these medical techniques, treatments, and therapies sustain the lives of thousands of patients, highly sensitive and exquisitely specific in vitro assays are necessary to ensure these products are safe for release.

Alternative, non-compendial assays can return false negatives, potentially subjecting patients to a fatal pyrogenic reaction. In the more than 40 years that LAL has been in use alongside the rabbit pyrogen test, not one FDA-confirmed pyrogenic response in a patient has been documented due to a false-negative result. Since its discovery, LAL has been continually recognized as the most sensitive method available for endotoxin detection, and the fact that the public regards intravenous injection, medical device implants, and other related therapies as routine practice stands as a compelling testimony to the efficacy of the LAL assay and the core values of our Endosafe® brand.

As a cGMP and FDA-approved and licensed therapy manufacturer, the organization you partner with for your solutions should be held to those same standards. Our portfolio of FDA-licensed LAL products for rapid and traditional bacterial endotoxin testing solutions reduces retest rates, decreases variability, and improves turnaround times, enabling prompt, confident decisions about product safety.
Without confidence in your environmental monitoring (EM) data, you can never be completely sure that your products are free from unwanted microorganisms. Consistent and diligent EM practices are some of the best strategies to achieve operational improvements that eliminate risk to patient health.

Accurate and timely microbial identification is crucial for tracking and trending EM data that guide critical decisions and protect you from releasing contaminated products. The accuracy of each sample ID relies on using appropriate methodology as well as relevant organism databases to find the closest match.

Many phenotypic identification methods depend on visual reads of the assay with variable, subjective human interpretation of the final result. Errors or misinterpretation in phenotypic assay readouts can lead to incorrect conclusions, mislead root-cause investigations, and ultimately jeopardize product quality. Even DNA sequencing and MALDI-TOF can fall short of giving the right answer if appropriate data analysis is not performed or relevant, comprehensive databases are not referenced.

Our proprietary DNA sequencing and MALDI-TOF organism libraries are continuously optimized to maximize the accuracy of species-level identifications. We identify over 100,000 environmental isolates every year, enabling us to expand our organism libraries based on real samples frequently recovered from QC labs around the world and to create the most relevant database for the pharmaceutical and medical device industries.
While traditional methods have delivered results for decades, they don’t help you release product faster, detect contamination sooner, or eliminate all doubt when answering the question “is it safe?” In an industry that relies on cutting-edge technology to improve patient lives, assays that require a visual read for final sterility confirmation are no longer acceptable. After all, some of these tests have not changed substantially since the 1930s. Rapid microbiological methods (RMMs) are effective at modernizing the laboratory by transforming subjective decisions into unambiguous results.

When it comes to critical assays like final product sterility, confidently finding nothing ultimately means everything. Celsis® rapid microbial detection determines your product’s sterility by providing a definitive yes or no answer to the most critical of decisions. Through reagent-catalyzed amplified ATP-bioluminescence rapid detection, our technologies can detect even the lowest levels of microbial contamination a week faster than the traditional method, unlocking new efficiencies to your QC workflow and a new level of confidence in the safety of your product.

Currently treating rheumatoid arthritis, and the travel bug.

Frank has made careful plans. He and his wife will travel by rail on their vacation this fall. It will be easier on his joints if he can walk the length of the train, and his wife will enjoy the foliage along the way. He’ll take his knee injection beforehand. Frank trusts his medicine to do its job — and it will, because it is sterile. The steroid manufacturer’s sterility testing was able to rule out the presence of pathogens that would have immobilized Frank in a matter of days. Because of the confidence he has in his treatment’s safety, Frank is able to swap worry over a trip to the hospital for anticipation of the adventures that lie ahead.

Celsis® Rapid Microbial Detection

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Microbial Solutions

At Charles River, we support developers and manufacturers from discovery through product release to deliver therapeutics to the patients who need them most. We know the immeasurable work that goes into creating vital treatments – and we know just how quickly that work can be undone during a failed quality check.

As quality issues persist as a driving force behind product shortages, recalls, and FDA warning letters, it is imperative that we identify ways to improve the quality control process. For more than 30 years, the Charles River Microbial Solutions team has continued to cultivate a portfolio of leading-edge technologies and services that keep you ahead of the curve. Our solutions are designed to streamline your workflows, ensure the integrity of your test data, and allow you to complete your job with the confidence of total quality control.

With a growing list of laboratory locations in the Americas, Europe, and Asia Pacific offering technical and customer support in multiple languages and time zones, we can help you harmonize your microbial QC testing needs with an array of products and services. Our goal is to be the one you trust to deliver solutions that reduce risk, build efficiency, and improve your bottom line.

You can count on our team’s commitment to in-depth, individual assistance, from our very first conversation to the delivery of service and beyond.

For a list of worldwide locations or to obtain product literature or technical documentation, please visit our website at www.criver.com/MicrobialSolutions.

You made a promise to your customers and patients to provide them safe, effective therapies. Let us help you keep that promise.