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

What are the main services you provide?
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 the microbial data and minimising the risk to patients. Like our customers, patient safety is at the core of what we do.

What additional solutions do you provide?

Endosafe endotoxin detection
As cGMP and FDA-approved and licensed therapy manufacturers, the organisation our customers partner with for their solutions must also 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.

Accugenix microbial identification and strain typing
Consistent and diligent EM practices are some of the best strategies to achieve operational improvements that eliminate risk to patient health. Our proprietary DNA sequencing and MALDI-TOF organism libraries are continuously optimised to maximise 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.

Celsis rapid microbial detection
When it comes to critical assays such as final product sterility, confidently finding nothing ultimately means everything. Celsis rapid microbial detection determines a product’s sterility by providing a definitive yes or no answer to the most critical of decisions. Through reagent-catalysed 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 the QC workflow and a new level of confidence in the safety of our customers’ products.

What makes your company stand out in the field?
At Charles River, we support developers and manufacturers from discovery through product release to deliver therapeutics to the patients who need them most. 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 to keep you ahead of the curve. Our solutions are designed to streamline workflows, ensure the integrity of test data, and allow job completion with the confidence of total quality control.

COMPANY DETAILS
NAME: Charles River Microbial Solutions
CONTACT: Melancolie Spedito-Jovial
EMAIL: askcharlesriver@crl.com
WEB: www.criver.com/whatsatrisk