

CASE STUDY

Fagron Sterile Services Relies on Charles River for Critical QC Testing



Jason McGuire
Global Quality Director
~ Fagron Sterile Services

Jason is currently the Global Quality Director for Fagron; an international company focused on personalized medicine. He has spent the last several years supporting the pharmaceutical, medical device, and compounding industries providing technical and regulatory guidance. Jason has nearly 20 years of experience serving in many roles with a particular focus on laboratory operations, quality assurance, and regulatory support. He is a microbiologist by education and expertise, and before joining the QA/QC world, he spent time researching and developing anaerobic microbial catalysts for fuel ethanol production.

PRIMARY INTENDED OUTCOME

The pharmaceutical industry is subject to numerous requirements put in place to ensure the safety of patients.

One of those requirements centers around bacterial endotoxin testing (BET). The BET detects unsafe levels of microbial cell wall debris from live or dead Gram-negative bacteria. This bacteria has the potential to cause fever, and in the worse cases septic shock. Utilizing the Limulus ameocyte Lysate (LAL) assay, the BET is a mandatory quality control (QC) release test for injectable pharmaceutical products.

Microbial identification is another mandatory component and requires a hard-to-find level of expertise, specialized and expensive equipment, and robust libraries that cover the specimen spectrum. Confident microbial identification is critical for an environmental monitoring program to ultimately confirm the security of a compounding area.

Fagron Sterile Services (FSS), a leading 503B Outsourcing Facility company, has been able to meet all its needs for both rapid BET and accurate microbial identification through its partnership with Charles River. It's parent company, Fagron, operates in 35 countries, and they leverage Charles River's expertise and equipment to ensure their growing customer base is in safe hands.

Jason McGuire, Global Quality Director at Fagron, has partnered with Charles River since 2003 when he first entered into the contract testing laboratory space.

THE CHALLENGE

Fagron Sterile Services US (FSS), a division of Fagron, is centrally located in Wichita, KS, and operates two FDA and DEA registered and inspected 503B Outsourcing Facilities. FSS has been using Charles River's Endosafe® rapid endotoxin testing instruments and Endosafe® EndoScan-V™, their endotoxin measuring and analysis software for its in-house program for years to achieve more control and better data integrity compliance. As a 503B Outsourcing Facility, quality is critical. FSS complies with all FDA and DEA regulations, cGMP and GDP. For FSS, utilizing a Biotek plate reader in combination with the Endosafe® Kinetic Turbidimetric LAL (KTA) and Endosafe® EndoScan-V™ software has proven

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to be more cost-effective than outsourcing to a contract lab. Charles River provides FDA-licensed LAL reagents, instruments, and tracking and trending software to make endotoxin testing as simple and reliable as possible. Other companies in the Fagron family have also had great success with the Endosafe® nexgen-PTS™ cartridge technology instrument. It is user-friendly, reliable, and quickly delivers consistent results.

As LAL is the most sensitive and specific method for the detection of endotoxins, Charles River has developed and optimized a range of quantitative and qualitative LAL formulations for increased sensitivity and superior interference resistance. Using a combination of these products, FSS has built up a strong and efficient endotoxin testing operation as well as a successful relationship with Charles River. With a new need to explore the services of outsourcing for microbial identification, McGuire knew exactly where to turn.

Testing many varieties and materials in a timely and efficient manner while taking in the consideration the volume and dedicated time of personnel are challenges many 503B facilities experience.

To that end, "it pays to outsource" microbial identification services, McGuire says. Fagron Sterile Services chose Charles River's Accugenix® because "the costs of conducting these tasks in-house, particularly maintaining everything needed for a comprehensive identification program are prohibitive." The equipment alone can cost hundreds of thousands of dollars.

THE DECISION

Charles River acquired Accugenix® in 2012. This acquisition included accurate microbial identifications and strain typing solutions to fill out its quality control program and expand beyond endotoxin testing.

FSS already had "great faith" in the services of Charles River through its experience with Endosafe®. So, "knowing that they acquired this organization gave us extra confidence that Accugenix® was the place to go for environmental identifications and general identifications as well."

Sample management is challenging and intense, he adds. "When you're taking hundreds of samples a day or even a week, it's very challenging to maintain control over those plates and determine whether you need a subculture or not. It's better for us to send it out. Having a reliable partner to handle all of this was key for us. We can be confident about Accugenix® sample management."

Accugenix® has more than 12,000 unique bacterial and fungal species entries in its proprietary libraries for the most robust offering on the market. Accugenix® specializes in bacterial and fungal identification and strain typing of environmental monitoring isolates. They use the latest DNA sequence-based and MALDI-TOF technologies to provide accurate and reliable microbial identification services.

The library, combined with the sophisticated lab management system the company maintains, serves as a powerful data-analysis tool. A customer portal lets clients access their information, submit and check the status of samples, download test results, and more. McGuire uses the tracking and trending tool to see what organisms his company most often encounters over a period of time. This tool allows the team to quickly investigate potential excursions and provide insight to making critical day to day decisions. And, instead of sifting through pages of reports, he and his team can easily crunch the data and use them to improve operations.


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Fagron Sterile Services is a U.S. FDA and DEA-registered 503B Outsourcing Facility that adheres to current Good Manufacturing Practices. All batches are tested for identity, strength, quality, purity, and compliance in its in-house analytical laboratory.

In fact, Accugenix® was started by a process engineer who set up a very controlled workflow to deliver better than 99% on-time delivery. McGuire also notes that Accugenix® has never lost a sample.

THE RESULTS

Partnering with Accugenix® for microbial identification helps FSS maintain compliance. Quality control tests must comply with regulatory requirements enforced by the FDA and other local national health authorities, for instance in Europe. "It can make the regulators feel more comfortable during inspections to be able to see firsthand that you have control over your products. When they see the Charles River brand, they're absolutely comfortable as long as qualified people are using it."

Reliability and ease-of-use is a major component of FSS' partnership with Charles River. "It's easy for us to track and trend our data," says McGuire. They can easily pinpoint the where and when of a problem area in the plant. "We nearly have complete traceability to come up with a root-cause so we can put corrective action in place."

His quality control teams also find the solution very user-friendly, the technology easy to maintain and says its customer service is what "really drove Charles River over the top for me. Being able to call in and speak to a live person every single time and come up with a solution" makes all the difference.

From reliable in-house endotoxin testing solutions with Endosafe® instruments and software, to outsourced microbial identification services through Accugenix®, Charles River has gone above and beyond to meet FSS' QC testing needs.

THE CONCLUSION

Charles River Accugenix® market-leading library and valuable data-analysis tools were yet another factor making FSS decision to expand its relationship with Charles River, simple. McGuire knows that they have the information and ability to make timely decisions on both endotoxin testing and microbial identification.

Charles River's Endosafe® nexgen-PTS™ endotoxin testing system in particular produces results in about 15 minutes, offering faster production, improved sample management, portability and greater accuracy, and reproducibility. Meanwhile, Accugenix® offers a customer portal that allows his colleagues to quickly address anything related to their microbial identification concerns.

McGuire has since spread the word that companies, especially compounders, that don't have the volume to support in-house testing should consider Charles River for both quality and the opportunity for savings. But, they also go beyond that: "For me, the ultimate benefit isn't just cost savings. That's a nice piece of it, but the fact that we could test many varieties of materials and have great integration with the systems we're using on top, made me a believer."

Since Fagron is selling to clients all over the world, "it's important to be able to trust the information," says McGuire. "Charles River is definitely the most reliable company that we've used from an endotoxin testing and microbial identification standpoint."

To learn more about Fagron Sterile Services US, visit fagronsterile.com, or call (877) 405-8066 to set up a free consultation.



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