

CASE STUDY

Achieving 503A+



JSD Pharmacy Sets the Gold Standard for Super Sterile



Deborah Larison, PharmD
Director of Pharmacy
~ JSD Pharmacy

Deborah J. Larison, Pharm.D., C.Ph. is currently the Director of Pharmacy at JSD Pharmacy in Evansville, IN. Dr. Larison has served the compounding pharmacy industry for over 20 years and obtained her QP503A™ Certification. Dr. Larison is a visionary and dynamic clinical pharmacist with broad-based experience in Pharmacotherapy, Pharmacy Practice, and Pharmacy Regulatory and Compliance matters.

PRIMARY INTENDED OUTCOME

The lightbulb moment happens when you realize the choice of system and methods for your compounding pharmacy enable you to become a top tier 503A facility. Deborah Larison, Director of Pharmacy at JSD Pharmacy, advocates that with the right microbial solutions and data tools, the organization can achieve – what she calls "503A+." This case study analyzes Dr. Larison's approach, motivations, and expectations in elevating a 503A compounding pharmacy.

"I ask my team; do you want to be average or outstanding?" states Dr. Larison. "I consider the baseline acceptance criteria for adhering to USP guidelines as our worst-case scenario. If we are not going above and beyond the minimum high-risk USP expectations, we are not outstanding."

Dr. Larison's mantra is that a 503A compounding pharmacy should exceed regulatory requirements. Pharmacists can do this by putting patient safety at the center of everything and mitigating all risks to them. No compromises exist in her microbiological testing methods. Dr. Larison is a perfectionist, but if you ask her for a descriptor, it would be patient protector. She had a constant awareness for increased safety even before USP made it mandatory.

For example, regulatory guidelines indicate that the facility should sample once every six months. This means a facility only takes two snapshots of their bioburden each year. If there are contamination events, the facility will not have enough data to precisely find and eliminate these invisible invaders. Leaders of high-risk compounding facilities need to know daily risk.

Heavy emphasis on processes and monitoring will result in safer product development and improved manufacturing. Dr. Larison delivers on these goals with the help of Charles River's QC Microbial Solutions – offering Endosafe® cartridge technology for rapid endotoxin detection, Celsis® rapid microbial detection, as well as Accugenix® microbial identification and strain typing. Charles River provides the JSD team with reliable and relevant data to fuel confident decisions on product quality and bioburden control. Without this strict control, the pharmacy risks more than just its reputation; patient lives are at stake.

THE CHALLENGE

Reputation isn't everything, but one pharmacy's wrongs can have a multiplying effect. The industry still reels eight years later from one of the worst public health catastrophes when 64 people died and 753 were sickened from a fungal meningitis outbreak, which stemmed from contaminated, deficient, and deadly drugs at The New England Compounding Center.¹ This horrific incident led to increased regulations for compounding pharmacies, which in turn encouraged the FDA to divide these entities into 503A and 503B facilities.²

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Googling pharmacy compounding incidents now still shows more unacceptable cases of near deaths³, loss of eyesight, and excruciating wounds.⁴ These recent reports reinforce Dr. Larison’s commitment to performing more than minimum requirements from the state and Federal government. Charles River aids JSD Pharmacy in those efforts to never lose focus on product quality and bioburden control.

Dr. Larison is a realist on many fronts, as she recognizes first that pharmacists are not microbiologists, and second that it is unreasonable that 503A pharmacies be compared to 503B regulations. But every 503A pharmacy should strive for 503 “A+.”

Time management, cost control, and automated reporting are practical needs that require solutions to run an efficient operation. “When I open the lab door for the day, I look around that room and think, what’s the risk today and how can we mitigate it?” Dr. Larison conveyed. “To mitigate any risk, I need a system that instills confidence.”

THE DECISION

Initially, Dr. Larison looked for a provider to perform genus/species ID in a new lab. However, in working with her team and striving for outstanding, she knew that to transform her lab into “A+”, she needed more than a tactical tool. Dr. Larison required strategic vision and a system for long-term gains. Detailed below are four criteria that led Dr. Larison to Accugenix® and Microbial Solutions from Charles River.

SAVE TIME, ENSURE QUALITY

Before using the Accugenix® Customer Web Portal, the team at JSD Pharmacy had to manually analyze copious amounts of data for either pass or fail for every sampling event. If the possibility of a germ existed, a new system had to make a difference in uncovering the likely scenario for its presence and accelerating identification, freeing up time to focus on compounding.

CONVENIENT TESTING

Charles River also provides proprietary Endosafe® FDA-licensed LAL cartridge technology for bacterial endotoxin testing that produces a 15-minute quantitative result and can be used right on the manufacturing floor.

FIND AND IDENTIFY EVERYTHING

“We do most of our testing at the end of the day when the team has completed compounding medicines for the patients and all the traffic in and out of the lab has subsided and the lab is at its dirtiest,” said Dr. Larison. “Charles River makes it simple for us to submit sample requests online. Established metadata help to filter sample results and give insight into the state of control of the facility.”

DRILL DOWN ON DETAILS

More than a nicety, the team needed the most environmentally relevant library in the industry to accurately identify all organisms recovered. Accugenix® provides clients various tools in the form of tracking and trending reports that assist in drilling down on specific organisms and where they came from in the facility.

Charles River compares results of unknown organisms to industry-relevant databases that contain entries for bugs discovered globally. The Accugenix® team processes more than 450,000 environmental isolates every year, which enables the R&D team to know what to add to build the most robust libraries available to the industries we serve.

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“We receive data that allow us to take action on questions like: Do we need to reclean, change processes, check kill efficacy, or address gowning and garbing?” stated Dr. Larison. “With Charles River, it’s problem solving to the nth degree and foreseeing and determining a trend before it becomes an out of specification.”

SUPPORT STAFF

From client engagement specialists who onboard clients to account managers and a customer care team, Charles River is an extension of the pharmacy. They are the microbiologists providing white-glove service.

“I knew Charles River had a strong reputation in the industry and had more than 16,000 employees to support clients. But it came down to the one-on-one with an expert microbiologist that solidified our choice,” said Dr. Larison.

THE RESULTS

For JSD Pharmacy, the outsourcing of microbial identifications coupled with tracking and trending features provided the accuracy and advancements that elevated the team’s work. By making a concerted effort to set the bar higher, JSD Pharmacy is well prepared for both internal and external audits and evaluations. They even conduct mock FDA evaluations with a third party.

The push for “503A+” means an added protection level for the patient and JSD’s reputation. These high standards for super sterile compounded medications help ensure safe medicines for patients with acute and chronic conditions. Charles River also receives an “A+” for delivering on the criteria; their support and tools strengthen the oath we take to protect every patient.

THE CONCLUSION

Patient need for compounded medicines will grow because customized medicines make a difference in quality of life. The medical field that develops these complicated pharmaceuticals will remain highly regulated. In response, pharmacists not only require precision at every stage involving prepping, mixing, assembling, altering, packaging, and labeling, but they also must be hypervigilant about their bioburden in the controlled environment to ensure no harm to anyone. Pharmacists realize they are not microbiologists, which only adds to the need for exacting tools and subject-matter experts who support them from start to finish.

Currently, under FDA guidelines, 503B pharmacies have more requirements to meet than 503A in terms of manufacturing practice (CGMP) compliance. JSD decided that it was doable to go above the 503A standards. Today, with the help of Charles River, JSD Pharmacy stays ahead of the curve in preparation for the opportunities of tomorrow.

1. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/press-releases/december-13-2018-owner-and-four-former-employees-new-england-compounding-center-convicted-following#:~:text=BOSTON%20%E2%80%93%20An%20owner%20and%20four,caused%20by%20a%20pharmaceutical%20drug>.
2. <https://www.congress.gov/bill/113th-congress/house-bill/3204>
3. <https://www.kvue.com/article/news/investigations/defenders/54000-higher-austin-woman-almost-dies-after-pharmacys-dosage-mistake/269-d1bf71e7-025b-44d4-b8ec-8a45e108b8b8>
4. <https://www.kvue.com/article/news/a-pharmacy-error-left-a-hole-in-a-womans-arm-the-size-of-a-golf-ball/269-03e58e22-40ca-4dfc-9888-ec0548484433>

FIND THE *Aspergillus* BEFORE YOUR PATIENT DOES.



Making sure a contaminated product never reaches patients means being proactive about quality control. Trust Charles River's portfolio of FDA-licensed, CGMP-compliant products and services to maintain control and consistency in your compounding facility. Gain peace of mind from raw materials to final product release, and prevent the avoidable when providing patients the products on which they depend.



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& SERVICES



DISCOVERY
SERVICES



SAFETY
ASSESSMENT



LABORATORY
SCIENCES



BIOLOGICS TESTING
SOLUTIONS



QC MICROBIAL
SOLUTIONS

For more information, visit us at www.criver.com/compounding


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