



Company overview

OVERVIEW

Leiters Health, founded in 1926, is a trusted FDA-registered 503B outsourcing provider of high-quality compounded sterile preparations and pharmacy services.

THE PROBLEM

Healthcare providers today are challenged to do more with less while trying to improve patient care. Healthcare organizations that perform sterile drug compounding in-house continue to face new, heightened quality and patient safety requirements and intensive regulatory oversight to assure compliance with regulatory guidelines.

As regulations continue to evolve, it is becoming more difficult for hospitals, surgery centers and clinics to safely and effectively compound drugs in house. They face additional in-house challenges as well such as:

- Continuing drug shortages and escalating drug costs.
- Shorter in house shelf life can lead to medication waste.
- Costly investments in equipment and staff training to ensure compliance.

Due to these in-house challenges, many healthcare providers are choosing to outsource their compounding to FDAregistered 503B outsourcing providers. However, not all 503B vendors are the same. The selection of a 503B provider is an important decision that requires thoughtful assessment and vetting of any potential vendor. Pharmacy leaders must do their due diligence to fully assess the quality, safety and track record of any potential 503B partner.

THE SOLUTION

Leiters Health provides hospitals, surgery centers, clinics and physician offices access to high-quality compounded sterile preparations. Our team of experts in cGMP, sterile pharmaceutical manufacturing, repackaging, and compounding provide a sophisticated understanding of what it takes to elevate quality and consistency of supply in outsourcing. We combine our team, our robust processes and our state-of-the-art outsourcing facility to ensure the highest quality products and services.

THROUGH 3 KEY PILLARS, PEOPLE, PLACE AND PRODUCT, LEITERS HEALTH IS ELEVATING THE STANDARDS IN PHARMACEUTICAL OUTSOURCING.

PEOPLE

- Highly trained multifunctional teams of pharmaceutical experts ensure quality and regulatory compliance for all released product.
- Relevant industry experience with sterile injectable pharmaceutical companies, hospital pharmacies, and academia.
- Our customer experience team of regional based account representatives, account managers and customer service specialists work together to provide you with consistent and reliable service.



PLACE

- FDA-registered and inspected, cGMP compliant 503B outsourcing provider.
- Licensed to ship to all 50 states (+ the District of Columbia).
- State-of-the-art equipment and automation is used throughout our sterile manufacturing process.

PRODUCT

- All sterile preparations are produced under 503B of the FD&C act (503B Guidance), following current Good Manufacturing Practices (cGMP) and meet or exceed USP <797>.
- Full microbiological and chemistry testing is completed prior to each batch being released. This includes sterility, endotoxin, potency, identification, impurities, particulate (subvisible), visual appearance and pH testing.
- A batch specific Certificate of Analysis (CoA), detailing all the testing performed, is provided with every shipment.

Leiters 🔅 Health

OUR PRODUCTS AND SERVICES

Leiters Health provides medicines and pharmacy services across the continuum of care including hospitals, surgery centers, clinics and physician offices.

HOSPITAL AND SURGERY CENTER PRODUCTS AND SERVICES

- Prefilled syringes including PCA (patient-controlled analgesia).
- IV bags and vials.
- Surgical Pain Services portfolio including opioid free medications.
- Pharmacy fill service for the Avanos Medical ON-Q* Pain Relief System.

OPHTHALMIC PRODUCTS AND SERVICES

- Prefilled syringes, vials, and dropper bottles.
- Injections, antibiotics and dilating agents.
- FDA-Compliant Repackaged Avastin[®] Service.

KEY PARTNERS

We are partnered with many market leading innovative healthcare companies that compliment what we do here at Leiters Health. The products and services offered by these companies may provide additional value to your organization.



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