

# Elevating the Standards in 503B Pharmaceutical Outsourcing

Leiters Health is a trusted FDA-registered 503B outsourcing provider of ready-to-administer compounded sterile preparations committed to providing healthcare professionals and their patients with the highest-quality medications.

| President & CEO: | Joseph C. Cosgrove      | Leiters 🔅 Health              |
|------------------|-------------------------|-------------------------------|
| Founded:         | 1926                    | QUALITY COMPOUNDING FOR LIFE" |
| Employees:       | 375                     |                               |
| Toll-Free Phone: | (800) 292-6772          |                               |
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|                  | Englewood, CO 801       | 12                            |
| Website:         | www.leiters.com         |                               |

## **Company Background**

Leiters Health, founded in 1926, is an FDA-registered 503B outsourcing provider of high-quality compounded sterile preparations and pharmacy services. We have a long history of evolving and innovating to meet the latest regulatory requirements and market needs.

All sterile preparations are produced under Section 503B of the FD&C Act (503B Guidance), follow current Good Manufacturing Practices (cGMP), and USP <797>. Our facility consistently upholds all standards based on the audits conducted by the FDA, the states of California and Florida Boards of Pharmacy, multiple health systems, group purchasing organizations, and other independent accreditation organizations.

Our team of experts in sterile pharmaceutical manufacturing, repackaging, and compounding provide a sophisticated understanding of what it takes to elevate the quality and consistency of supply in pharmaceutical outsourcing. We combine a highly experienced team, with robust processes, in stateof-the-art outsourcing facilities to ensure delivery of the highest quality products and services.

As part of our ongoing commitment to quality, compliance, and sterile manufacturing excellence, we continue to invest in our state-of-the-art 503B facilities, including two existing facilities in Denver, Colorado, and a new facility in Buena, New Jersey, which will be operational in 2024. We stand ready to support the needs of the healthcare community now and in the future.

# **Product Overview**

Leiters Health provides ready-to-use compounded sterile preparations and pharmacy services across the continuum of healthcare, including hospitals, surgery centers, physician offices, and clinics.

#### Hospital and Surgery Center Products and Services

- Prefilled syringes, vials, and bags.
- Ready-to-administer Pain Services portfolio to support ERAS and opioid reduction strategies.
- Pharmacy fill service for the Avanos Medical opioid sparing ON-Q<sup>\*</sup> Pain Relief System (bupivacaine HCl and ropivacaine HCl).

#### Ophthalmic Products and Services

- Prefilled syringes, vials, and dropper bottles including: injections, antibiotics, and dilating agents.
- FDA-Compliant Repackaged Avastin<sup>®</sup> Service. Multiple presentations available based on physician preference.

### **Key Business Partners**

Leiters Health is partnered with many market leading innovative healthcare companies that compliment what we do. The products and services offered by these companies may provide additional value to your organization. Our key business partners include: Angels for Change, Avanos Medical, Besse Medical, Bluesight, Cardinal Health, End Drug Shortages Alliance, Eye Connect International, Prodigy Health, and The Academy.

## **GPO Affiliations**

Leiters Health provides our products and services to many leading health systems, community hospitals, clinics, and physician offices. In addition, we currently have national contracts with: AmerisourceBergen, Captis, Cardinal Health, EyePro, Healthtrust, Premier, US Retina, and Vizient. Please contact us for additional information regarding our contracts.

# **Collaborating With Leading Health Systems**

Leiters Health is committed to new product development in collaboration with its customers to meet evolving market needs. We work closely with our nine strategic health system investors to evaluate, create, and deploy solutions that enable pharmacy efficiencies. Pharmacy leaders from each of our investor health systems hold a seat on the Leiters Health Strategic Pharmacy Advisory Board. We meet with this group regularly to understand and nimbly respond to pharmacy challenges with real-world, innovative solutions. This allows us to offer a meaningful portfolio across the continuum of care to all of our customers and ultimately ensure that healthcare providers and their patients have a continuous supply of critically needed drugs.

# Site Visits

We don't want to simply tell you about what we do, we want to show you! We invite you to visit our facility to better understand the cGMP regulations, sterile manufacturing processes, and automation we use to elevate the quality of our products and services. Come join the growing list of organizations who have visited our facilities. To schedule a site visit please visit www.leiters.com.

COMPOUNDING HEALTH<sup>™</sup> is a registered trademark of Leiters. Avastin<sup>\*</sup> is a registered trademark of Genentech, Inc. ON-Q<sup>\*</sup> is a registered trademark of Avanos Medical, Inc., or its affiliates. IBUD is from date compounded, <sup>†</sup> Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry https://www.fda.gov/downloads/drugs/guidances/ucm434176.pdf