



Leiters.

COMPOUNDING HEALTH™

Helping you deliver
better medicine to
more people.

Better patient care.

At the end of the day that's what it's all about. Partnering with Leiters on your pharmaceutical outsourcing allows you to focus on what matters most...Patient care.

Why Outsource and

Why Now?

During a recent market analysis¹ the following were cited as top concerns with in-house compounding:

- Increasing regulatory pressure
- Drug shortages
- Stability and quality limitations
- Patient risk; medication errors
- Lack of expertise, resources, space & equipment
- Shorter shelf life leads to waste

Combined with the continued need “to do more with less”, high quality pharmaceutical outsourcing is more important than ever.

Your journey to better medicine begins here.

Who is Leiters?

Leiters, founded in 1926, voluntarily registered as a 503B outsourcing facility. Leiters has enjoyed a long and successful history of compounding ophthalmology products out of its San Jose, California facility and serves the hospital market out of its brand new state-of-the-art facility in Denver, Colorado. Physicians and their patients have trusted Leiters for nearly a century with their medication needs. As we expand our markets and services, our unwavering commitment to the health of patients remains our #1 priority.

Elevating the standards in pharmaceutical outsourcing, our solution consists of:

People

Developed by our team of experts

Place

Manufactured in our state-of-the-art facilities

Product

High quality medicines

2
503B cGMP facilities

84,000
sq feet of compounding space

San Jose

24,000 sq feet recently renovated 503B facility in San Jose specializing in ophthalmology services.

★ Denver

60,000 sq feet state-of-the-art 503B facility opened in Denver with a focus on hospital and surgery center services.

Leiters.

A trusted provider of high quality medicines **since 1926**

Why Leiters?

Leiters has been a trusted source of medications for nearly a century. Our multi-disciplinary team consists of quality assurance professionals, cGMP experts, microbiologists, chemists, and pharmacists with deep expertise in sterile pharmaceutical manufacturing, repackaging and compounding. We serve our customers from 2 cGMP facilities, utilizing state-of-the-art technology. In 2016, our Denver facility was built from the ground up and our San Jose facility was completely renovated.



Quality



Reliability



Trusted

Our facilities

- Fully validated, including installation qualification, operational qualification, and environmental monitoring performance qualification activities performed and/or reviewed by industry experts
- Germfree vertical laminar flow hoods offer a high degree of localized control
- Bioquell SeQure™, a fully validated automated biodecontamination system
- Negative-pressure isolators, fume hoods, and biosafety cabinets
- Validated building automation system to alert quality, production, and facility personnel of cleanroom condition changes

Value Added Offering

- Ready to use services
- Single patient dose
- ASTM color standard
- Tall Man lettering
- Bar coding and RFID capable
- Standardization

Providing medicine and services across the continuum of care

Hospitals

Pharmacies

Physician offices

Surgery centers

Our Processes

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- Prior to commercialization, each new product completes a development and validation process including independent laboratory confirmation of identity, potency, and sterility
- Use of fully validated sterile filtration during production to enhance Sterility Assurance Level (SAL)
- Beyond Use Dates (BUDs) established based on product-specific stability testing of both chemical and microbiological characteristics
- Product specific testing may include, but is not limited to, potency, bioburden, endotoxin, and sterility.

What our customers are saying

“...We use Leiters for our compounded ophthalmic drugs, because we feel very good about their quality. Leiters has excellent quality control...”

- **Ophthalmologist**

“...Leiters provides good quality compounded drugs, and I haven't had any problems with their pharmaceuticals. Each batch of drugs we receive from them is tested by a third-party and I have access to the test reports, so I can be sure that their drugs are reliable...”

- **Pharmacy Buyer**

Essential Facts

- Registered with
 - Federal Drug Administration (FDA) as 503B outsourcer
 - US Drug Enforcement Agency (DEA)
 - State Boards of Pharmacy
- ISO7 sterile class clean room
- All sterile preparations are produced following Current Good Manufacturing Practices (cGMP)
- Outsourcing Facility Licenses in 49 states
- Solutions for ophthalmology, hospital and surgery center's
- Sterile to sterile compounding
- Active Pharmaceutical Ingredient (API) to sterile compounding

We invite you to visit our facilities to learn more about how we are elevating the standards in pharmaceutical outsourcing.

Learn more:

leiters.com

[800.292.6772](tel:800.292.6772)

info@leiters.com

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COMPOUNDING HEALTH™

Leiters is an FDA-registered 503B outsourcing provider of high quality ophthalmology and hospital-based services. We are committed to providing healthcare professionals and their patients with high quality medications. Our team of experts in 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 manufacturing facilities to ensure the highest quality products and services. We believe the most important consumers of our products are patients, and patients have trusted Leiters with their health for nearly a century.