Premier Pharmacy Labs is an industry leading 503B Outsourcing Facility providing sterile and non-sterile compounding services to hospitals, surgery centers, clinics, researchers & patients nationwide.
Our Mission

at Premier Pharmacy Labs is to supply exceptional pharmaceutical preparations to the global healthcare market. We accomplish this by using technology, state of the art facilities, and an unmatched quality assurance program that complies with FDA cGMP regulations.
Our team is committed to providing the highest level of patient safety and product quality in all of our preparations and services. We aim to partner with clients in an effort to provide a dependable drug supply chain that introduces cost savings and efficiency.

**About**

Premier Pharmacy Labs is a leading FDA registered and inspected 503b Outsourcing Facility that provides sterile, non-sterile, and admixture compounding services to hospitals, surgery centers, clinics & research institutions nationwide.

Premier aims to be the elite provider of compounding services in the marketplace with an unwavering commitment to patient safety through adaptive quality assurance and training processes.

**Corporate Vision**

- To be a timely and efficient supplier of high quality pharmaceutical preparations with a focus on patient safety, automation, and technology
- Expand CMO capabilities with IND and early stage development partnerships to bring new products to market
- Utilize FDA guidelines and Pharmaceutical GMP advisors to become a model for the outsourcing industry
On November 27, 2013, the Drug Quality and Security Act (DQSA) was signed into law, which increases FDA oversight of some types of compounding. The law created the outsourcing facility category under a new section titled 503B of the Food, Drug & Cosmetic (FD&C) Act. This designation requires compliance with cGMP and enhanced reporting to the FDA.

**Premier Commits to 503B**

Premier Pharmacy Labs has invested substantial capital and created robust processes to meet 503B and cGMP regulations. Premier is proud to be part of this new designation and our customers will continue to benefit from our ongoing investments in this market.

**FDA Recommendation**

The FDA is encouraging all hospitals, surgical centers, universities and ophthalmologists to utilize the services of a registered and inspected 503B outsourcing facility to meet their admixing, repackaging and compounding needs. As the laws continue to evolve, only 503B facilities, like Premier, will be able to fill your medication supply needs.
Why Use Premier

Premier is committed to addressing some of the greatest challenges in the healthcare market. Our guiding principles make it easy to see why we are a leader in outsourcing pharmacy.

Who We Are

- **503B Outsourcing facility** specializing in sterile injectables and other medication preparations
- **FDA cGMP compliance**—same standards as FDA registered pharmaceutical manufacturers
- **Robust FDA reporting** requirements down to the API level
- **Full tracking**, tracing, and accountability on all compounded preparations
- **In house analytical laboratory** for quality assurance and rapid turnaround times
- **Sterilization** and audit checkpoints for enhanced safety
- **Automation** with validation—same equipment and processes pharmaceutical manufacturers leverage
- **Customer Service** with a live human means immediate help when you need it

Corporate Vision

To be a timely and efficient supplier of high quality pharmaceutical preparations with a focus on safety and technology

Expand CMO capabilities with IND and early stage development partnerships to bring new products to market

Utilize FDA guidelines and Pharmaceutical GMP advisors to become a model for the outsourcing industry
Premier provides safe, effective, and innovative solutions to help our customers navigate the challenges of today’s medication supply chain.

Capabilities & Services

**Sterile, non-sterile & admixture compounding services** performed in a quality controlled, automated environment.

- Sterile Compounding
- Non-Sterile Compounding
- Admixture Services
- Repackaging
- Clinical Trials

**Our Customers**

- Hospitals
- Medical Centers
- VA Health Systems
- Surgical Centers
- Universities
- Specialty Clinics
- Research Institutions

**What We Supply**

- Injectables
- Oral formulations
- Topical formulations
- Nasal Sprays
- IV bags
- Urology formulations
- Ophthalmology formulations
Cutting edge technology and equipment are at the foundation of our operations and facilities.

State-of-the-art cleanrooms & HEPA airflow hoods

- **ISO7, ISO5, and Hazardous clean rooms** provide ample space for compounding activities
- **Regular independent inspection** and certification of our clean rooms, laminar flow hoods and biological safety cabinets
- **Minncare® Dry Fog System** provides an additional layer of sterility assurance

⚠ **MET ONE Particle Counter System**

- **Real time monitoring** of cleanroom particle counts with automated alerts and visual indicators

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- **Refrigeration and freezing** down to -80°F with automated temperature monitoring and alerts

Chemunex Chemscan RDI Rapid Scan

- **The ChemScan RDI laser scanning cytometer** delivers counts of viable microorganisms within 3 hours after sampling, with sensitivity down to a single cell; without the requirement for a growth phase while the standard growth plate method takes up to 14 days to deliver counts of culturable organisms
- **Provides total traceability** for each analyzed sample
Non-Sterile to Sterile Protocol
The Difference is in the Process

Active Pharmaceutical Ingredient (API) arrives and is placed in quarantine

Return API to Distributor/Manufacturer

In-Process testing for potency check

Infrared Spectrophotometer for quick identification of API

API to quality control/quality analysis

API passes identification

API fails identification

Packages of finished preparation

Preparation sent to quality control for analysis

Preparation passes in process testing

Preparation fails for potency

Samples held in quarantine until final preparation is released from quality control

Dispersing

Sent back to compounding for adjustment

Final preparation testing is reviewed

Preparation passes testing

Preparation fails either microbiology or potency

Preparation sent to reverse distributor for destruction
With the technology and quality assurance of a pharmaceutical company, choose Premier Pharmacy Labs as your sterile outsourcing partner of choice.

**People, Process, Product**

At Premier Pharmacy Labs, there isn’t one reason that explains our advantage. Like the industry, it’s complex and multi-factorial. Our highly trained staff, state-of-the-art facilities and product quality assure we can meet the requests of our clients.

**Culture of Excellence**

Quality is more than just set of rules and standards. It’s a way of thinking. Every employee and partner that comes on board is trained in our quality approach and culture.

**Grow with Us**

Our philosophy has always been do what is right by our customers. Time after time, this has resulted in a mutually beneficial relationship beyond just supplying product. Partner with Premier and let’s grow together.