WAY 11

ARL Bio Pharma – USP 795, 797, and 800 Testing Services

Ensure your health-system's compounded drug products and facilities consistently meet quality standards.

President & CEO: Thomas C. Kupiec, PhD
Founded: 1998
Employees: 300+
Toll-Free Phone: (800) 393-1595
Phone: (405) 271-1144
Email: info@arlok.com
Address: 840 Research Parkway, Suite 546
Oklahoma City, OK 73104
Website: www.arlok.com

Company Background

ARL Bio Pharma is a contract laboratory that provides analytical and microbiological testing for health-system pharmacies. Since 1998, ARL has supported the industry-wide commitment to deliver high-quality drug products by providing guidance and test services for all phases of the product lifecycle following USP and FDA guidelines. ARL is ISO 17025:2017 accredited, FDA-registered and audited, and DEA licensed for Schedules I through V.

Service Overview

USP standards are critical for health-system pharmacies to produce safe and effective compounded medications. Incorporating these standards into compounding practices promotes patient safety and quality preparations, while minimizing the risk of hazardous exposure.

ARL offers comprehensive testing services for health-systems to quickly and easily meet industry standards.

- **Analytical Testing:** qualifies drug substances, excipients, and drug products to meet pharmacopeia specifications.
- **Microbiology Testing:** offers the highest quality in USP-required microbiology testing for non-sterile and sterile preparations.
- **Personnel and Environmental Monitoring:** evaluates plates and media fills for incubation and observation.
- **USP 800 Surface Wipe Sampling:** measures the level of hazardous drug surface residue to ensure workplace safety.

Beyond Use Dating and Stability Studies

Health-system pharmacies may want to extend a beyond use date (BUD) on a drug product to increase compounding efficiencies and reduce drug waste. USP 795 and 797 require the BUD assignment to be supported by a stability-indicating analytical method.

ARL's stability indicating methods meet the requirements set by USP and FDA. To ensure that a product retains its quality characteristics throughout its BUD, it is important to also evaluate the physical, chemical, and microbiological properties. ARL has extensive experience in stability studies, and will guide health-systems through the entire process from understanding goals and helping design the study, to providing results and interpreting the data.

Ordering Information

Request A Quote: info@arlok.com

ARL Bio Pharma Client Portal: portal.arlok.com

ARL's client portal allows users to submit samples online, receive test results in real-time, and analyze test data trends.

ARL Bio Pharma Core Values

- **Scientific and Technical Competence:** ARL Bio Pharma delivers comprehensive and exceptional analytical and microbiological solutions to help our customers meet quality standards.
- **Customer Service:** ARL Bio Pharma is committed to understanding our customers' needs and strives to make every touch point a positive experience.
- **Quality:** ARL Bio Pharma is committed to compliance with regulatory requirements, laboratory standards of practice, and continuous improvement.
- **Integrity:** ARL Bio Pharma is committed to honesty, reliability, and transparency.
- **Collaboration:** ARL Bio Pharma is committed to engaging internal and external stakeholders to produce optimal outcomes.