

Advancing TDD quality

The leading targeted drug delivery (TDD) solutions provider, AIS Healthcare does more to put patient safety first. Throughout our two 503A specialty compounding pharmacies, we take extra steps and make extra investments to go beyond industry requirements and produce medications of the highest quality and sterility.

Going beyond the expected

From order entry to shipping, AIS Healthcare has facilities and procedures designed to advance the quality of every syringe. With our proven, proprietary process that combines aseptic processing with terminal sterilization, we are able to achieve unprecedented sterility assurance and extended Beyond-Use Date.



100%

THIRD-PARTY TESTING

of all stock solutions¹



21-45

DAY BUD AT ROOM TEMPERATURE

(average 34 days) for all formulary medications²



1:1,000,000

STERILITY ASSURANCE LEVELS

(versus 1:1,000 sterility assurance levels with aseptic processing alone)

Doing more of what matters

With industry-leading pharmacies in Dallas, Texas (our headquarters), and Ridgeland, Mississippi, AIS Healthcare has a fully redundant TDD operation designed to produce medication of the highest quality.

- ✓ 120,000 patient-specific prescriptions produced annually
- ✓ Licensed in all 50 states
- ✓ PCAB-accredited for sterile compounding
- ✓ Regularly inspected by pharmacy boards, the DEA and the FDA (no 483 observations on the last inspection)
- ✓ Our Chief Medical Officer and all Medical Advisory Board members are renowned physicians in the spinal neuromodulation space
- ✓ Three distinct services to improve care delivery
- ✓ 24/7 support for patients and providers

AIS Healthcare is dually accredited by URAC and the Accreditation Commission for Health Care (ACHC).



ACCREDITED
Specialty Pharmacy
11/01/2022



Your partner in patient care

We're focused on creating efficiencies and improving outcomes throughout the care continuum.

Going above and beyond for providers

- ✓ We work with patients and payers to secure authorizations and complete needed paperwork
- ✓ Our pharmacies compound and ship medication with overnight delivery to all 50 states
- ✓ Your AIS Healthcare representative is your single point of contact for anything you may need

Optimizing your TDD service line

Different financial models are available:

- ✓ Direct bill
- ✓ Buy and bill
- ✓ Home Connect in-home refills and maintenance

Prescribe with ease

Use your Surescripts-certified EHR software to send orders directly to AIS Healthcare (find us by our SPI number, 2531401). For providers in states without e-prescribing mandates, orders can be faxed directly to AIS Healthcare at 888.298.2220.

You can also securely e-prescribe, manage patient prescriptions, track your orders and more with our physician portal, MyAIS Connect.

myAIS Connect™

Get started today.

Contact your AIS Healthcare representative to learn more or get started.

aiscaregroup.com | 877.443.4006

FOR HOSPITALS

Doing more to put patient safety first

AIS Healthcare goes above and beyond industry standards to compound prescriptions of the highest quality and sterility



 AIS Healthcare

Advancing quality. Improving lives.

¹All patient-specific dispenses within maximum concentrations (based on AIS Healthcare in-house data for 120,000 aseptically processed and terminally sterilized patient-specific prescriptions in 2019)

²Third-party testing for pH, sterility, potency, endotoxins and particulate matter

Exceeding USP <797> standards

All 503A specialty compounding pharmacies like ours must meet United States Pharmacopeia (USP) guidelines along with all state and local regulations. In many ways, we far exceed these requirements, doing more to put patient safety first.

Compounding processes

AIS HEALTHCARE QUALITY STANDARD	USP <797> GUIDELINES	EXCEED STANDARDS
Our USP-grade active pharmaceutical ingredients all come from FDA-registered manufacturers. An outside, independent lab tests all bulk ingredients for potency and endotoxins.	Requires packages of bulk ingredients to be compliant with their USP monographs.	✓
AIS Healthcare performs vendor audits of all critical suppliers.	No specific guidelines	✓
All stock solutions are prepared by a licensed pharmacist and tested by an outside, independent lab for sterility, potency, particulate matter, pH and endotoxins before use in compounding.	No specific guidelines	✓
We conduct multiple 0.22-micron sterilizing-grade filtration steps, including filter integrity testing, to ensure medication sterility.	Only one 0.22-micron sterilizing-grade filtration step required.	✓
We combine aseptic processing with terminal sterilization to achieve unprecedented sterility assurance and extended Beyond-Use Date.	No specific guidelines	✓
Throughout the entire compounding process, including terminal sterilization, our independent internal quality department reviews our work and methods to help us continually improve safety and quality. This team reports directly to our CEO and COO. We also work with industry leaders to help us find new ways to go above and beyond.	No specific guidelines	✓

Our pharmacists

AIS HEALTHCARE QUALITY STANDARD	USP <797> GUIDELINES	EXCEED STANDARDS
Compounding of patient-specific prescriptions is done only by licensed pharmacists.	Compounding can be done by pharmacy technicians with oversight by a pharmacist.	✓
All of our pharmacists are specially trained in high-risk sterile compounding. Written competency exams and media-fill procedure and aseptic technique testing are administered every six months, and unannounced glove fingertip testing is conducted monthly.	All compounders must pass a written exam annually and aseptic technique, media-fill procedure and glove fingertip testing semi-annually.	✓
AIS Healthcare's more than 30 pharmacists have more than 400 years of combined experience.	Compounding pharmacists should be adequately skilled, educated, instructed and trained.	✓
Our Pharmacists in Charge are QP503A certified by Eric Kastango and CriticalPoint.	No specific guidelines	✓

Cleanroom facilities

AIS HEALTHCARE QUALITY STANDARD	USP <797> GUIDELINES	EXCEED STANDARDS
Each of our pharmacies has multiple controlled rooms that exceed the required ISO standards for cleanliness and air quality.	Pharmacies need two ISO-validated rooms.	✓
There is a positive pressure differential from the buffer room outwards, which helps to prevent airborne contamination from contacting critical sites and entering the compounding areas.	Facilities must be designed so that air quality improves with movement through the operational areas.	✓
Audible and visible alarms are located in all compounding areas to immediately alert staff when the pressure drops.	No specific guidelines	✓
All interior doors allow for hands-free access, preventing the spread of any contaminants on hands or gloves.	No specific guidelines	✓
Lines of demarcation are present in all anterooms—embedded in the floor, not taped, to avoid any contaminants in the adhesives.	Lines of demarcation are required in all anterooms, but do not need to be embedded.	✓
Enhanced contamination control procedures, including full-body sterile garb for cleanroom personnel. All staff members put persistent germicidal on their hands and two sets of sterile gloves—one white pair over one green pair—to immediately detect rips.	Only one pair of sterile gloves is required for cleanroom personnel.	✓
In the anteroom, all staff members wash their hands for 30 seconds with 105°F water (timed with a digital clock on the wall) and clean underneath their fingernails with a nail pick.	Requires staff to wash their hands with warm water for at least 30 seconds with disposable soap.	✓
Staff members have dedicated facility shoes, and use a hands-free shoe barrier applicator to prevent any cross-contamination. Before they enter the anteroom, staff members remove their shoe coverings using a hands-free, externally vented, pneumatic shoe cover remover. Then, upon entry into our anteroom, everyone immediately steps onto a Dycem® contamination control mat.	Shoe covers are required (do not need to be sterile).	✓
A state-of-the-art facility management system continuously monitors temperature and pressure, and creates a daily log.	Manual daily log of pressure and temperature, at minimum.	✓
An integrated laminar airflow bench enables more than 500 air changes per hour in the direct compounding area.	Requires compounding rooms to have 30 air changes per hour.	✓

Cleanroom facilities (continued)

AIS HEALTHCARE QUALITY STANDARD	USP <797> GUIDELINES	EXCEED STANDARDS
The direct compounding area is disinfected at least every 30 minutes as well as before and after compounding. AIS Healthcare uses only sterile cleaning products and uses sporicidals every day; industry standards only require these agents to be used monthly. This is in addition to thorough morning, midday and evening cleanings and weekly cleanings of walls. All stainless steel materials in the compounding room (and throughout the pharmacy) have been custom fabricated to be consistently cleaned.	All ISO 5 spaces must be cleaned and disinfected at the beginning of every shift, every 30 minutes, before each batch, after spills and when any contamination is suspected. Pharmacies must clean and disinfect all surfaces and areas monthly, and use sporicidals monthly (non-sterile cleaning products acceptable for routine cleanings).	✓
Four independent cleanroom certifications are completed per year.	Only two required per year	✓
Non-viable particle count is done 12 times per year; combined viable air and surface sampling done no fewer than 50 times per year.	Non-viable particle count and viable air sampling required twice per year; surface sampling required periodically.	✓
AIS Healthcare performs preventive maintenance on its cleanrooms and conducts HEPA filter leak tests quarterly.	Requires semi-annual cleanroom preventive maintenance.	✓

Take a tour.

See how we go above and beyond industry standards on a tour of our compounding pharmacies in Dallas, Texas (headquarters), and Ridgeland, Mississippi.

Can't visit in person? Take our virtual tour at tour.aishhealthcarepharmacy.com.

