PharMEDium®
AmerisourceBergen

FDA REGISTERED & INSPECTED 503B OUTSOURCING FACILITIES

Confidence.

It's the product of many components.

Visionary leadership and effective management of highly-skilled teams

Unmatched redundancy and capacity for consistent supply

Rigorous operating standards and testing to cGMP requirements

A Visual Guide to PharMEDium's Sterile-to-Sterile Compounding Process

Only FDA-approved* sterile drugs and FDA-cleared medical devices are used to produce our ready-to-use Compounded Sterile Preparations (CSPs)

* FDA-approved drug products include otherwise legally marketed sterile drug products in finished dosage form. Such commercially available drugs are produced in FDA-registered facilities subject to FDA inspection.

1 **CSP Accuracy** starts with careful technology-enabled validation, verification and batch preparation.

STAGING ▶

Batch-specific sterile drugs and components are identified and picked from inventory.

SCANNING ▶

Components, labels and associated batch documentation are re-verified and scanned.

PASS THROUGH ▶

Sanitized batch components are passed into the cleanroom for use in compounding.

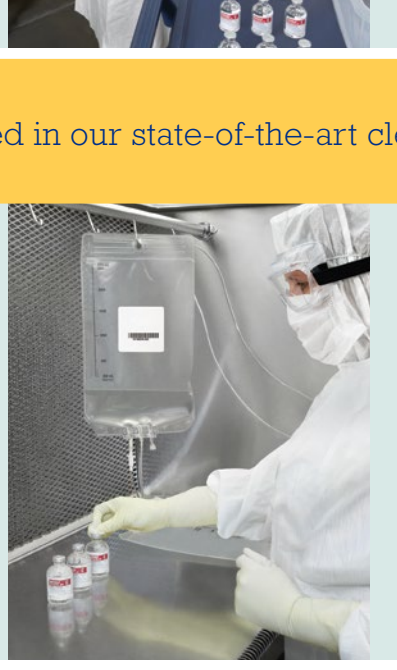
2 **CSP Sterility** is maintained in our state-of-the-art cleanrooms.

ISO Class 5 laminar flow hoods and ISO Class 7 cleanrooms are monitored for pressure, humidity and temperature.

CERTIFIED PHARMACY TECHNICIANS

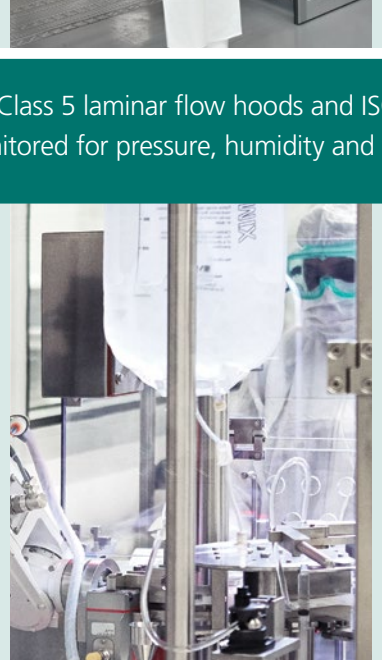
Regularly re-certified for proper sterile gowning/gloving and aseptic manipulation.

Our Quality Assurance team performs extensive, real-time environmental monitoring of our personnel, equipment and cleanroom facilities.



COMPOUNDING ▶

FDA-approved sterile injectable drugs are compounded with FDA-approved sterile diluent to the final concentration.



FILLING ▶

CSPs are accurately filled into final containers.

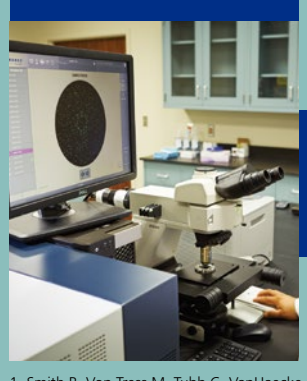
3 **CSP Batch Release Testing** is performed using the most advanced technology and validated methods.

Finished product samples are pulled for rigorous testing.

Validated rapid microbiological[1] and chemical test methods are utilized according to current industry guidance, regulatory requirements and Standard Operating Procedures (SOPs).

We utilize validated sterility[1] and endotoxin test methods.

STERILITY



ENDOTOXIN

POTENCY

Redundant technology and software systems support our Quality Control personnel as they conduct laboratory testing and verify test results.

1. Smith R, Von Tress M, Tubb C, VanHaecke E. Evaluation of the ScanRDI® as a rapid alternative to the pharmacopoeial sterility test method: comparison of the limits of detection. *PDA J Pharm Sci and Tech*. 2010;64:356-63.

Finished CSP lots are quarantined while qualitative and quantitative testing is performed according to United States Pharmacopeia (USP) requirements.

LABELING

PACKAGING

STAGING

4 **CSP Release to Shipping** occurs after the batch has passed ALL quality tests.

Quality Assurance verifies all documentation and test results.

WE PUT PATIENT SAFETY FIRST.

100% of PharMEDium CSP Batches are Tested

because you are expecting only the highest quality CSPs with optimum expiration dating.

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