WEST ANALYTICAL SERVICES FOR CELL AND GENE THERAPY

As a result of our deep understanding of materials and their compatibility with the drug product, West can assist you in designing studies and in navigating the challenging and evolving regulatory landscape.

R&D LAB

West has a lab focused on Advanced Therapies inclusive of a Viral Vector and Cell Culture Lab, Lyophilization Lab, Gene Delivery Lab, and a Refrigerator/Freezer Room. It includes infrastructure for the handling of Bio-Safety Level 1 (BSL1) Biological material & Bio-Safety Level 2 (BSL2) Biological material.

CONTAINER CLOSURE INTEGRITY

West has an extensive portfolio of CCI techniques and analysis for various packaging and delivery systems to meet the needs of pharmaceutical, biotech, and medical device manufacturers. We have the understanding and capabilities our customers need to ensure efficiency, reliability, and safety, from concept to patient.

FUNDAMENTAL TESTING

West's Analytical Services team has vast expertise and experience in the requirements of compendial analysis for important components in drug product packing, from elastomers to glass and plastics. In addition, the West team can evaluate the effects of sterilization on elastomer moisture content and identify an elastomer for compatibility.

PACKAGING & DEVICE COMBINATION PRODUCT TESTING

A thorough understanding of current regulations enables West to create and execute robust study designs. These studies cover syringes, cartridges, vials, and all related components, devices, and combination products. West's Analytical Services Laboratory follows ISO testing standards and supports customers with USP <382> testing needs. West also offers Design Verification Testing (DVT) studies and can customize performance testing for customers.

EXTRACTABLE & LEACHABLES

Regulatory agencies are focusing on E&L in pharmaceuticals. Providing E&L information is expected. West Services and Solutions partners with our customers to help navigate the challenging regulatory landscape. West uses guidances such as USP <1663> "Assessment of Extractables Associated with Pharmaceutical Packaging/ Delivery Systems" and <1664> "Assessment of Drug Product Leachables Associated with Pharmaceutical Packaging/Delivery Systems" when planning and performing extractables and leachable studies. We offer a holistic approach for your container closure system, device, or combination product.

PARTICLE TESTING

Due to the impact on patient safety, particles are a regulatory concern and a focal point of the pharmaceutical industry. West's Analytical Services Particle Laboratory provides testing with the ability to count and size sub-visible and visible particulate using technologies such as Light Obscuration (LO), microscopy, and light microscopy/ image analysis (LM/IA) for automated particle detection. Services such as USP <788> and USP <789> testing are available for primary and secondary packaging.

CONTACT US

TO LEARN MORE VISIT
WESTPHARMA.COM/SERVICES/ANALYTICAL-SERVICES