# NAVIGATING REGULATORY AND RESOURCE CHALLENGES WITH THE RIGHT PARTNER FOR YOUR COMBINATION PRODUCT

You are facing challenges as drug development becomes more complex. Regulatory requirements are challenging and resources that understand bringing together both the drug and device development can be limited. You can de-risk your filing process by addressing regulatory and resource challenges upfront, thus allowing you to achieve more timely drug development and regulatory submission.

## Your journey to a robust testing program for your drug product starts with the components during pre-clinical through phase 1 of your drug development process

### Components: vials/stoppers/seals:

- Chemical Compatibility (UV, pH, IR, etc.)
- Particulate (USP <788>, <789>; Ph. Eur 2.9.19)
- Extractables (USP <1663>, ISO 10993-18)
  - VeriSure® Technical Package (4432, 4023, 4040 formulations)
  - Material Characterization*
- Elemental Impurities (USP <232>, <233>, ICH Q3D)
- Silicone oil analysis
- United States, European, and Japanese Pharmacopoeia for elastomeric closures, glass, and plastic

*Completed material characterization documents available for select West products.

## As the drug product is introduced and components are assembled, your vial system requires testing during phase 1 to 2 of your drug product development

### Assembled vials/stoppers/seals:

- Leachables (USP <1664>, ISO 10993-18)
- Elemental Impurities (USP <232>, <233>, ICH Q3D)
- Simulation Studies
- $E_2L$
- Glass Delamination Testing
- Particulate (USP <788>, <789>; Ph. Eur 2.9.19)
- Container Closure Integrity (USP <1207> & <382>)
  - Helium Leak Detection
  - Vacuum Decay
  - Laser-Based Gas Headspace Analysis
  - Dye Ingress
- Packaging and Delivery System Performance Testing (ISO, USP <382>)
  - Dimensional Analysis
  - Seal Leakage
  - Coring and Fragmentation
  - Penetration Force
  - Needle Self-Sealing Capacity
  - Spike Retention and Sealability
  - Flip-Off Cap Removal
- Fractography analysis*
- Residual Seal Force

*Third-party support for fractography analysis

**As trends move toward home healthcare and increased patient compliance, utilization of administration systems for at home care requires testing during phase 2 of your drug product development to help ensure patient safety and compliance**

### Administration systems:

- Packaging and Delivery System Performance Testing (Design Verification Testing/Essential Performance Requirements)
  - Compatibility with Vials/ Syringes/Cartridges
  - Total Attachment Force
  - Leakage and Sealability
  - Vial Deliverable Volume
  - Luer Connectivity and Leakage
  - Reconstituted Dosage Concentration
  - Residual Volume

**STABILITY: Your vial system, or combination product if an administration system is added for at-home care, requires stability testing at phase 3 of your drug development process once all testing methods are validated and required specifications are set.**

### Examples of stability testing/EPRs:

- Leachables
- Container Closure Integrity
- Attachment Force

As the material scientists that help develop injectable packaging and devices using expertise in ISO standards, USP chapters, FDA guidances, MDR article 117 requirements and other pertinent regulations, we can help you achieve timely drug development and regulatory submission. When you work with West, you can de-risk your combination product development and regulatory strategies throughout drug-device development.

## YOUR SUCCESS IS OUR SUCCESS!

CONTACT WEST ANALYTICAL SERVICES TODAY TO DE-RISK YOUR DRUG PRODUCT DEVELOPMENT.

Important product and safety information and warnings at:
**https://www.westpharma.com/products/vial-adapter-systems/mixject**

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