YOUR GUIDE TO CHANGING REGULATORY REQUIREMENTS AND ANALYTICAL TESTING NEEDS 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: plungers/cartridges/syringes/seals:

- Chemical Compatibility (UV, pH, IR, etc.)
- Particulate (USP <787>, <788>, <789>)
- Extractables (USP <1663>, ISO 10993-18)
  - VeriSure® Technical Package (4432, 4023, 4040 formulations)
  - Material Characterization*
- Elemental Impurities (USP <232>, <233>, ICH Q3D)
- Silicone 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, evaluation of your combination product is required during phase 1 to 2 of your drug product development

Prefilled syringes/cartridges*:

- Leachables (USP, <1664>, ISO 10993-18)
- Elemental Impurities (USP <232>, <233>, ICH Q3D)
- Simulation studies
- E2L
- Particulate (USP <787>, <788>, <789>)
- Container Closure Integrity (USP <1207> & <382>)
  - Helium leak detection
  - Vacuum Decay
  - Laser-based Gas Headspace Analysis
  - Dye Ingress
- Package and Delivery System Performance Testing (ISO, USP <382>)
  - Break Loose and Extrusion/Glide
  - Needle Pull-Out Force
  - Needle Penetration Force
  - Needle Shield Pull-Off Force
  - Residual Volume
  - Deliverable Volume/Dose Accuracy
  - Liquid Leakage Beyond Plunger
  - Plunger Movement at simulated altitude
  - Plunger Rod Retention Force
  - Closure System Forces and Torques
    - › Luer Lock Collar Pull-Off Force
    - › Luer Lock Collar Torque Resistance
    - › Luer Lock Tip Cap Unscrewing Torque
    - › Tip Cap and Needle Shield Pull-Off Force
  - Luer Connectivity
  - Luer Cone Breakage Resistance
  - Burst Resistance
  - Dimensional Analysis
  - Flange Breakage Resistance
  - Seal Leakage
  - Coring and Fragmentation
  - Needle Self-Sealing Capacity

*Cartridges will be used for pen injectors or medical devices (see below)

As trends move toward home healthcare and increased patient compliance, testing is required during phase 2 of your drug product development to help ensure patient safety and compliance

Autoinjectors/pens/on-body devices:

- Packaging and delivery system performance testing (Design Verification Testing/Essential Performance Requirements)
  - Actuation Force
  - Free Fall and Breakage
  - Dose Accuracy
  - Injection Time
  - Needle Shielding/Hiding Length
  - Needle Shield Over-Ride Force
  - Needle Extension Length
  - Cap Removal Force
  - Needle Attach/Detach Torque
  - Last Dose Accuracy Testing
  - Injection Force
- Particulate (USP <787>, <788>, <789>)

STABILITY: Your combination product requires stability testing at phase 3 of your drug development process once all testing methods are validated and required specifications are set.

Conditions*

- 25C°/60% RH
- 40°C/75% RH
- 30°C/65% RH
- 2-8°C Refrigerated
- -20°C
- -80°C

*Other conditions available upon request

Examples of EPR tests:

- Leachables
- Container Closure Integrity
- Dose Accuracy
- Injection Force

RELEASE: With your drug product commercialized, you require release testing for your essential performance requirements (EPRs).

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/self-injection-platforms/selfdose**

Important product and safety information and warnings available at: **https://www.westpharma.com/products/self-injection-platforms/smartdose/smartdose-10**