

## West Scientific Insights Lab

Drug development programs should aid customers in the successful mitigation of technical and regulatory risks to ensure drug products move swiftly through the regulatory approval process and into commercialization. West's Scientific Insights Lab experts provide service and support to help pharmaceutical and biopharmaceutical manufacturers Simplify the Journey™ from molecule to market.



**Polymer Material  
Science**



**Interfacial Chemistry  
& Surface Science**



**Biologic  
Drug Products**



**Injectable Container Closure  
Systems & Drug Delivery**

### Offers Customers Early R&D Support for:

- Container components/system screening/selection with biologics
- Drug excipient selection and formulation optimization
- Silicone/tungsten impact on biologics
- Understanding API and excipient interaction with delivery
- Vial CCS application research (e.g. spike/stopper compatibility, system modeling, etc.)

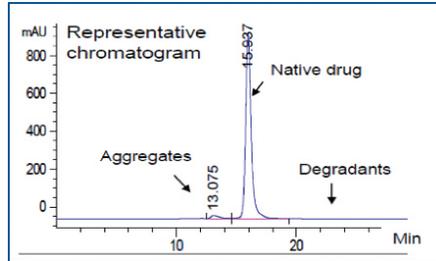
#### **Primary Containment Compatibility & Selection**

#### **Understanding Formulation Impact on Functionality & Delivery**

#### **Primary Research Confirmation Testing**



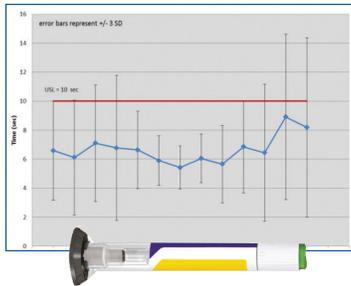
**Case Study 1** West conducted testing for three different syringe systems to determine the materials best suited for the drug product.



**Case Study 2** To understand how excipients/drug formulation impacts functionality, West conducted testing to determine the cause behind injection time failures in autoinjector, modeled impact and provided results.

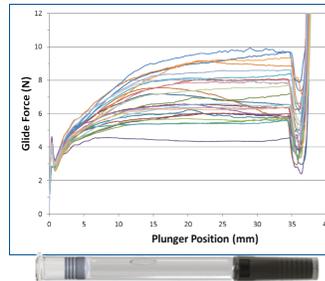
### Problem

AI injection time failed specification limit



### Causal Factor

Syringe glide force variability increases over time

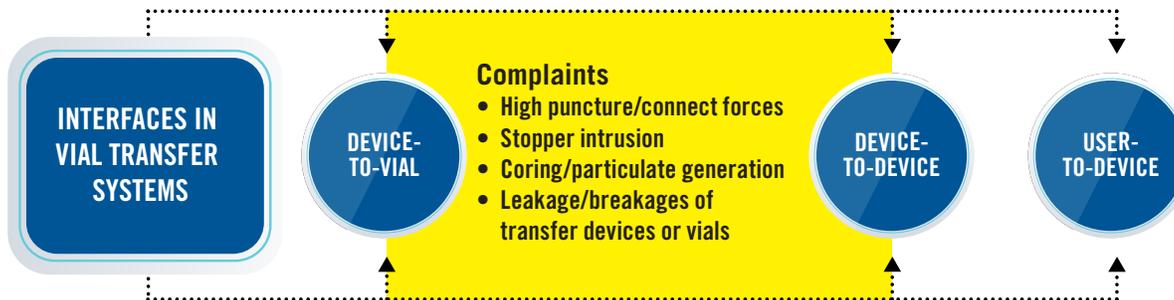


## Our Capabilities Include:

- SE-HPLC (size exclusion liquid chromatography)
- cIEF (capillary isoelectric focusing)
- Hydrophobic Interaction Chromatography (HIC)
- CEX (cation exchange chromatography)
- PAGE (polyacrylamide gel electrophoresis)
- Flow Imaging
- ELISA (enzyme linked immunosorbent assay)
- SLS (static light scattering) and DLS (dynamic light scattering)
- Protein quantitation
- Mass spectroscopy (outsourced)
- UV/VIS/Fluorescence Spectroscopy
- RP-HPLC



**Case Study 3** Container closure application research can help to determine the source of a variety of issues, including breakage, leakage or other containment and delivery issues. This also includes performance test development to address the challenges of USP <800>.



\*Source: Cathy Zhao, Approaches to Address Challenges at the Device-to-Vial Interface, 2019 PDA India Chapter Container Closures For Injectables: Technologies, Properties And Practices Workshop, Pune

For more information about West's Integrated Solutions program, contact West today. [WestAnalyticalServices.com](http://WestAnalyticalServices.com)

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