Streamlined Solutions. Dependable Service. Technical Expertise.

Supporting your combination product development from concept to market.

ZEBRASCI
Combination Product Experts

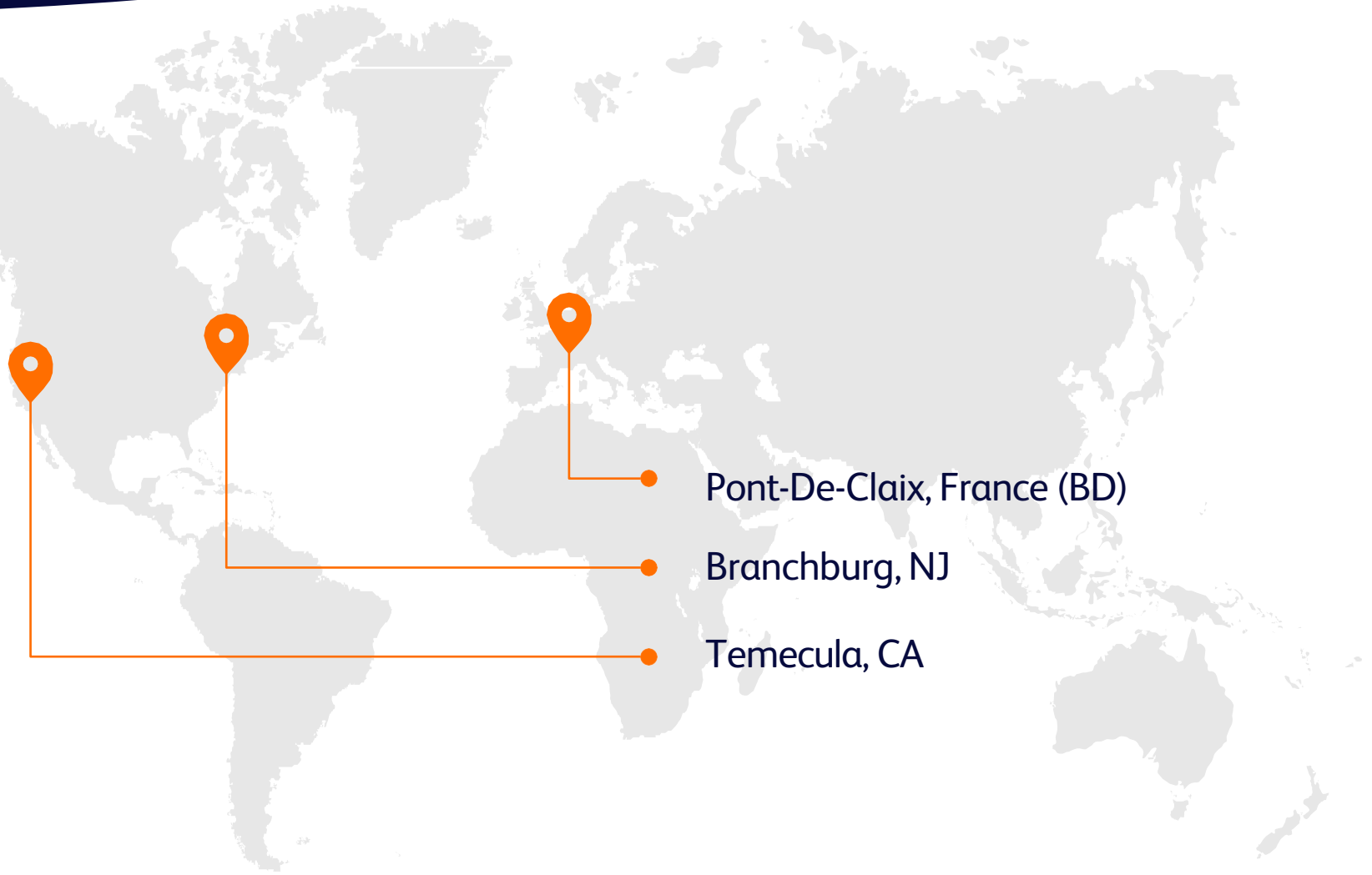
ZebraSci is available coast to coast in the United States with presence in Europe

Global presence for lab, filling, and assembly

NJ & CA are FDA Registered & Audited

GMP Quality System, ISO 17025:2017 Accredited (CA Only), & ISO 13485:2016 Certified

France is ANSM and FDA registered and audited, accredited 210/211 GMP



ZebraSci is a BD company and operates as an independent platform

ZebraSci can support the development of drug-device combination products with both BD and non-BD devices

Confidentiality of customer data and data on non-BD products is of utmost importance to maintain customers' trust where data sharing is not desired

Specific customer testing results, protocols and results managed by ZebraSci are safeguarded from the BD organization to protect customer confidentiality

ZebraSci Service Offering

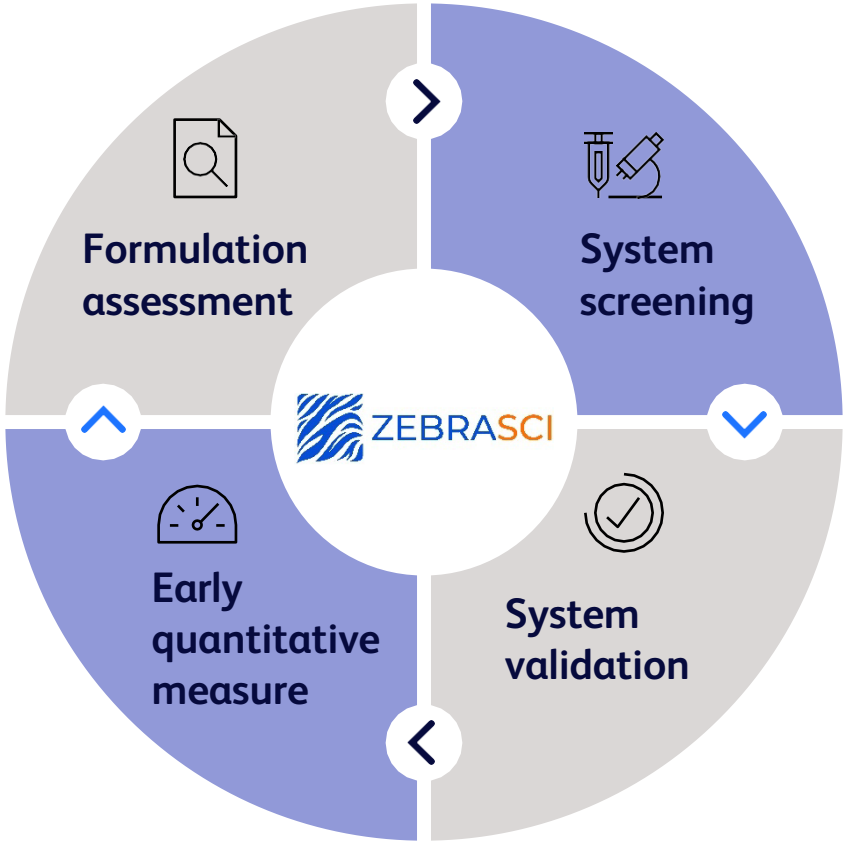
Expertise and capabilities to support your needs

Primary container & device selection and evaluation

Formulation optimization and compatibility assessment

Early rapid silicone sensitivity assessment

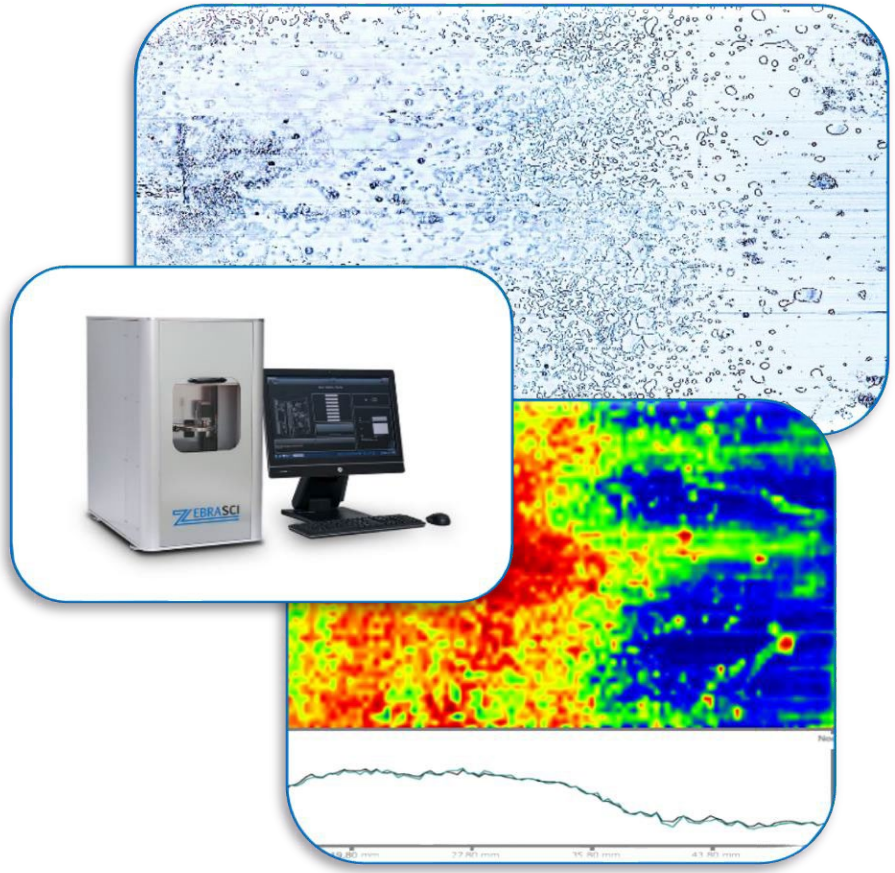
Quantitative representation of performance



Accelerated selection protocol in a system

System-based data for filing

Silicone Layer Characterization

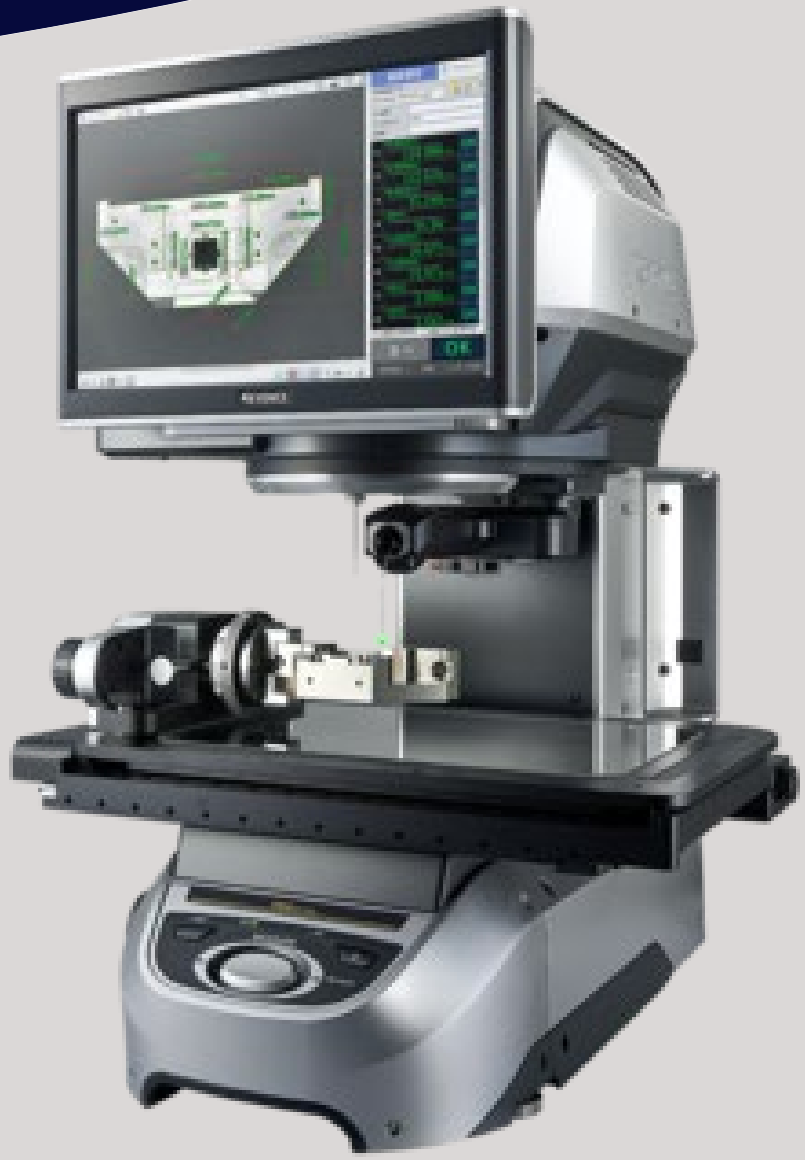


ZebraSci FlexHD Lubricant inspection platform which non-destructively characterizes the amount of container lubrication. This enables one to:

- Predict device performance
- Limit drug interaction
- Assist root cause investigations

Functional Dimension Analysis

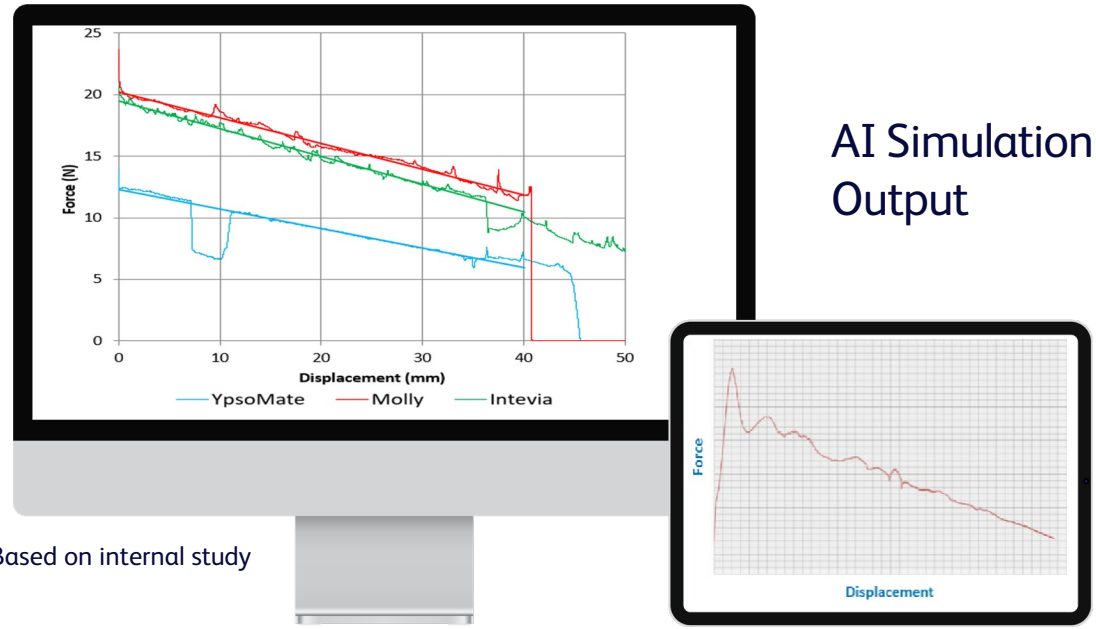
Assess robustness and reliability of the system



Mechanical Performance Testing

Autoinjector Simulation Study using Instron ElectroPuls

Characterize Power Pack Spring Forces (empirical determination)



AI Simulation Output

Based on internal study

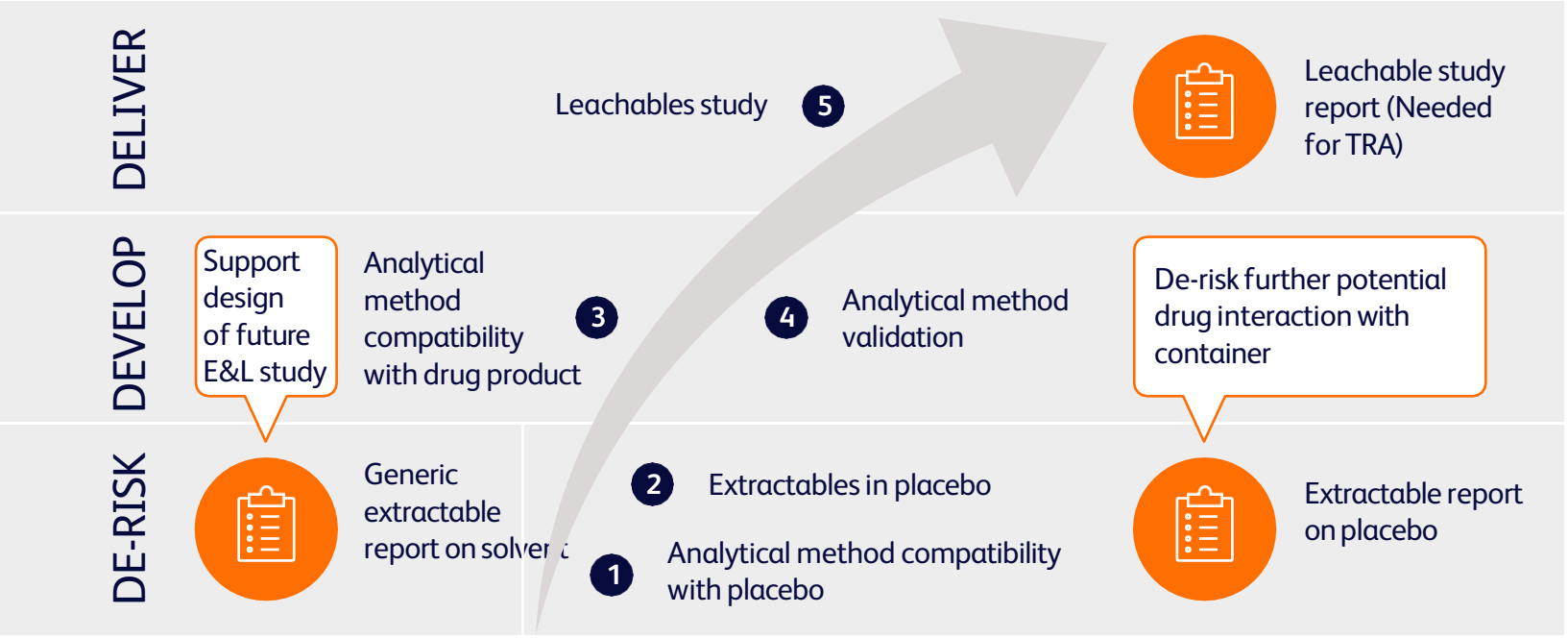
Slope = spring constant
Y-intercept = initial force of Power Pack

Drug combination product design verification testing

Extractable & Leachable (E&L) studies with Toxicological Risk Assessment

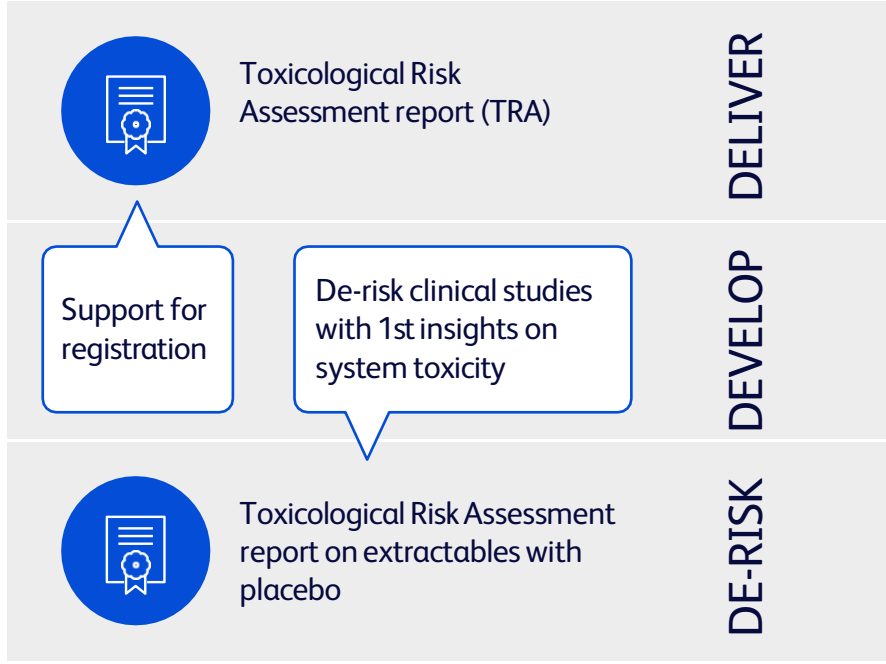
E&L study

Assess what compounds from the primary container could migrate into a drug product formulation**



Toxicological Risk Assessment

... and the associated potential toxicological risks



*Extractable testing as per USP 1663 and 1664 **under normal conditions of production, storage and use

Functional testing capabilities (non exhaustive list)

Prefilled Syringe + Needle Safety Device*	Cartridge + Pen*	Prefilled Syringe + Autoinjector*
Needle Shield Removal Force	Min Dose Accuracy (Pen)	Autoinjector Cap Removal Force
Activation Force	Mid Dose Accuracy (Pen)	Activation Force
Breakloose & Glide Force	Max Dose Accuracy (Pen)	Injection Time
Delivered Dose	Visual Appearance (Pen)	Injection Depth
Separation Force	Injection Force (Pen)	Deliverable Volume
Needle Safety Shield Override Force	Plunger Force Lock (Cartridge)	Needle Safety Shield Override Force
Syringe Leakage within Safety Device	Resealability (Cartridge)	
	Coring of Rubber Component (Cartridge)	

*Not limited to samples seen below

Container closure integrity testing (CCIT)

- Laser Headspace Analysis
- High Voltage Leak Detection
- Helium Leak Detection
- Vacuum Decay Detection
- Dye Leak Detection

* For more information : August 2016 revision of United States Pharmacopeia (USP) Chapter <1207>, “Package Integrity Evaluation—Sterile Products”

Small-scale fill / finish & assembly

Product complaint management & root cause investigation

Combination product incoming to lot release testing

How can we partner with you to serve your combination product development needs?

ZEBRASCI
Combination Product Experts

zebrasci.com

sales@zebrasci.com