

THE DELTACUBE[™] MODELING PLATFORM

De-risk your approach to container-closure selection

The pharmaceutical and biotech industries can face many challenges when selecting the appropriate vial, stopper and seal combination for their drug product. These include:

- Timeline and budget constraints to be able to perform thorough studies
- Data constraints for components
- Limited or lack of container-closure expertise
- The need to justify their container closure system to regulatory authorities.

In addition to these challenges, not understanding the parameters that can affect your vial, stopper and seal combination can lead to container closure integrity (CCI) issues, which puts your container closure system (CCS) at risk for sterility problems. These issues can arise due to many different variables such as:

- Improperly matched components
- Poorly designed, controlled or even defective components
- Lack of process monitoring and control



The more you understand your components, your component fit and your processing, the less likely you are to have these types of issues.

West's DeltaCube[™] Modeling Platform was developed to help customers mitigate these issues during the early phase of their component selection. This online, subscription-based modeling tool provides you with a data-driven approach to guide your vial, stopper and seal combination selection.



REDUCE RISK

- Container closure modeling based on large data sets, across a range of West materials and sizes
- West data continually added to increase accuracy
- Upload non-West data for your CCS comparison

ACCELERATE DEVELOPMENT

- Make a fast determination for your CCS based on visualization of actual data points
- Narrow CCS prototypes that you need to test in early development for residual seal force (RSF) and CCI

REDUCE REWORK:

• Understand component variability and impact on CCI related to component fit.

CHOOSE A SUBSCRIPTION PLAN THAT MEETS YOUR CCS DEVELOPMENT NEEDS

	Basic	Advanced	Premier
# of CCS	2	4	Unlimited
Timing	12 months	12 months	12 months
# of Users	1 Admin 3 Users	1 Admin 5 Users	Unlimited Admin Unlimited Users

West also provides testing services to support CCS capping studies and performance as well as <u>CCI testing method development and validation</u> according to USP <1207> and USP <382> for your specific product.

Visit the webpage for the DeltaCube[™] Modeling Platform to learn more.

Contact West Pharmaceutical Services today to learn more about the only online vial system integrity modeling platform designed to help developers make more confident decisions about their container closure system utilizing big data for components.

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