

The Source for Sharing and Learning

Since its first issue in 2004, *The Source* has provided the biopharmaceutical community with timely and critical information on the issues affecting the process of bringing new drug products to the marketplace.

Our focus has been on helping you select the appropriate delivery and packaging system for your new drug. By doing so, we can help you reduce some of the risk associated with drug development.

We have initiated a dialogue with biopharma professionals through our newsletter, our website (westthesource.com), our participation at industry conferences and our Educational Series. We have met with thousands of professionals involved in the drug development process.

We look at these meetings as an opportunity to share our knowledge and to learn about your delivery system needs. One of our recurring discussions relates to the required steps for delivery system and drug packaging selection. In this issue, we'll take a look at a testing program that will help advance the container closure selection process.

Previous issues of *The Source* are posted at westthesource.com. Contact us to be added to the mailing list.



Container Closure Selection: Test Before You Choose

Bringing an innovative biopharmaceutical drug to the market requires years of work and testing. Along the way are many important decisions that impact critical time lines. Among these is choosing a suitable container and closure for sensitive biopharma drug products.

During initial package selection, data generated by screening and compatibility studies can be used to help select an appropriate container closure system. The compatibility of the closure system with the drug product is critical; performing a screening of the container closure system with the drug product will reduce the risk of incompatibility of the product and the packaging later in the development process. You should conduct screening and compatibility studies in the first phase of selecting an appropriate container closure system.

FDA guidances recommend that extractables/leachables testing be performed on a drug product's packaging and delivery systems. Leachables are chemical species that migrate from packaging or other components into the drug product under normal conditions or use, or during stability testing of the drug product. It is important to test for leachables because they may:

- **Interfere with drug product assays**
- **Interfere with medical diagnostic tests**
- **Increase the total impurities to unacceptable levels**
- **React with other drug products, vehicles or excipients**
- **Increase the toxicity of the drug product**

Screening and extractables/leachables studies will require time and money that must be built into the qualification and stability studies early in the product development cycle. Planning for and performing this testing minimizes risk and contributes to a successful product launch.

West Monarch Analytical Laboratories is equipped to conduct compatibility studies and extractables/leachables testing in Phases I - IV. The laboratory facilities in Ohio and Pennsylvania are FDA-registered, GMP-compliant, licensed to handle controlled substances and can handle cytotoxic drugs.

By relying on West's analytical expertise, pharmaceutical companies can focus their resources on what they do best—discovering and developing new drugs—without expending valuable resources to establish their own methods for testing extractables/leachables.



New Stability Chambers Broaden Capabilities for Frozen Drug Products

As part of its emphasis on continually expanding services offered to customers, West Monarch Analytical Laboratories recently installed a new stability chamber capable of operating to -85°C. Because many of today's biotech-based drug prod-

ucts require storage at low temperatures, the availability of the chamber at West provides customers with additional study options for their drug products. The new stability chamber is undergoing validation and will be connected through West's Kaye

Monitoring System. This addition is one of many expected to be incorporated into West's services throughout the year.

The chamber is located at West Monarch's facility in Lionville, Pa.

West Studying Moisture Absorption of Lyophilized Drugs

West Pharmaceutical Services is performing a study on elastomeric stoppers to determine their effectiveness in protecting a lyophilized drug product from moisture absorption. The study uses vials filled with lyophilized lactose; lactose was chosen because of its inherent hygroscopic properties.

To provide a comparison for the impact of the drying cycle after sterilization, stoppers were autoclaved and then dried at three durations. The study will monitor the moisture content of the stopper after initial autoclave sterilization and drying and at each time point over the three-year study. West will also evaluate the moisture levels in the lactose over the same three-year time period.

On the Road Again

West the Source is an outreach program that includes an ambitious schedule of trade events and industry conferences.

The importance of these meetings was evident last fall at the Parenteral Drug Association's forum on prefilled syringes. West's technical experts were present with an exhibition of the company's solutions for prefillables, a scientific poster on how ozone affects sterilization of elastomeric components used with syringes and a conference presentation on packaging solutions for prefilled syringe systems. The size of the crowd attested to the interest in the topic and the many conversations West's representatives had with customers emphasized the value of personal relationships.

You can meet with West representatives dedicated to biopharmaceutical companies at these events in the coming months:

Interphex

New York City, April 24 – 26
Visit West at Booth 315, Level 3.

Pharma Med Device

New York City, April 24 – 26
Visit The Tech Group, West's custom injection molding company, at Booth 311, Level 1, Exhibit Hall 1B.

Hyaluron Contract Manufacturing Open House

Burlington, MA, May 7
For information, go to hyaluron.com/openhouse.htm.

AAPS National Biotech Conference

San Diego, June 24 – 27

In addition, West will host an Educational Series seminar in the Philadelphia region for biopharmaceutical companies on May 16. To register, go to westthesource.com.

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Visit West at westthesource.com

