

Systems to Promote Safe, Efficacious Drug Administration

Why We Travel

On October 11, West hosted more than 50 biopharmaceutical professionals from 19 companies in the San Diego area for a free Educational Series seminar on the technology of parenteral packaging.

Since October 2004, West has presented three seminars for biotech companies. The Educational Series is one tool we use to help biopharmaceutical companies avoid the risks associated with new product packaging. The seminars provide West's technology experts with an opportunity to learn about customers' parenteral packaging needs and to share their knowledge.

Our technical experts will continue to travel around the country to meet with biotech professionals. See the back page for details of West's participation in the AAPS National Biotechnology Conference on June 18 in Boston.

We hope to see you at a seminar in your community.

In the meantime, you can read previous issues of *The Source* posted at westthesource.com. Call us or send an email and we will add you to the mailing list.

Many biopharmaceutical products approved for market – and many in the development pipeline – are processed as lyophilized or dry powder drugs. The dry form of the drug protects its potency and extends its shelf-life. Prior to administration, the drug must be prepared as a liquid through reconstitution. Further, some drugs must be transferred between vials and other systems of administration.

Biopharmaceutical companies developing lyophilized or dry powder drugs will have to consider systems and devices that will provide the end user with safe and efficacious administration. West Pharmaceutical Services can help with this process. West, through its subsidiary Medimop Medical Projects Ltd., is a leader in the world market for transfer, mixing and administration systems for injectable pharmaceuticals. West's systems and devices help to safely and efficiently connect, interface, mix and filter injectable drugs in vials, bags and syringes.

West offers a variety of products to meet drug formulation and disease-specific needs. These systems and devices promote safe and simple product handling and can help reduce medication errors and improve patient compliance. The products are 510K approved by the United States Food and Drug

Administration and carry CE certification for European markets.

- *Clip'n'Ject® provides end users with all the necessary components for drug reconstitution in a single package. The system accepts existing drug vials for currently marketed products.*
- *MixJect® is the ideal solution for preparation of powder drugs to be reconstituted by a diluent prefilled syringe.*
- *Mix2Vial™ is a dual-sided device that allows rapid transfer of a diluent into vacuum powder vials. The device may incorporate an inline filter.*
- *Vial adapters permit quick and safe transfer from vials, allowing convenient, optimal quantity aspiration. Vial adapters are available with venting and inline filter options.*
- *The needleless transfer device facilitates the rapid transfer of a diluent into vacuum powder vials. The mixed drug can be aspirated through a filter into a syringe for injection.*

For information about West's reconstitution systems, call Brian Brucker or Adrienne Williams at 1-800-231-3000.



FDA Amends Rules for Combination Products

The Food and Drug Administration issued a final rule in the August 25, 2005, Federal Register to amend its definitions of "mode of action" and "primary mode of action" for combination products. A combination product is one that consists of a drug and device, a drug and a biologic or a device and a biologic.

These definitions, along with an accompanying algorithm, are used by the Agency's Office of Combination Products (OCP) to determine which center within the FDA has primary jurisdiction for the product. The rule requires sponsors to recommend which center should have primary jurisdiction using the definitions. With the new rule, the FDA hopes to simplify the designation process by providing a defined framework.

The rule, effective November 23, 2005, is online at <http://www.fda.gov/OHRMS/DOCKETS/98fr/05-16527.pdf>.

Examples of combination products where the components are physically, chemically or otherwise combined:

- *A monoclonal antibody combined with a therapeutic drug*
- *A device coated or impregnated with a drug or biologic*
- *Prefilled syringes, insulin injector pens, metered-dose inhalers, transdermal patches*

Examples of combination products where the components are packed together:

- *A drug or biological product packaged with a delivery device*
- *A surgical tray with surgical instruments, drapes and lidocaine or alcohol swabs*

Examples of combination products where the components are separately provided but labeled for use together:

- *A photosensitizing drug and activating laser/light source*
- *An iontophoretic drug delivery patch and controller*

The agency has issued a draft Guidance for Industry and FDA Current Good Manufacturing Practice for Combination Products September 2004; online at www.fda.gov/cder/guidance/OCLove1dft.htm.

AAPS Symposium on Biotech Packaging

Biotechnology packaging will be the subject at a half-day symposium, Parenteral Packaging of Biotech Drug Products, on June 21, 2006. The symposium is part of the National Biotechnology Conference presented by the American Association of Pharmaceutical Scientists. The three-day conference begins on June 18 at the John B. Hynes Veterans Memorial Convention Center in Boston.

The symposium topics include:

- *Proper Selection of Parenteral Packaging - Brian Brucker, West Pharmaceutical Services*
- *Regulatory and Technical Issues - Fran DeGrazio, West Pharmaceutical Services*
- *Processing Issues - Bob Nase, West Pharmaceutical Services*
- *Characteristics of Glass Vials and Prefilled Syringe Systems - Rob Swift, Amgen, Inc.*
- *Container Closure Integrity - Dana Guazzo, RPH, PhD, RxPax, LLC*

Information is available online at www.aapspharmaceutica.com/meetings/biotec/bt06/index.asp.

Free Poster Summarizes Leachables Analyses

Leachable analyses have become an important issue with pharmaceutical regulatory agencies. To support customers with information on this topic, West periodically tests elastomeric closures.

Adrienne Williams, biotech technical account manager, presented one such series

of tests in a poster, Evaluation of the Effect of Sterilization on the Leachable Profile of Elastomeric Closures, at the American Association of Pharmaceutical Scientists annual meeting in November.

The poster summarizes results for laminated and non-laminated stoppers

in aqueous based drug product (pH 7.0) and 20 percent ethanol using screening methods and specific monitoring for potential extractables.

To request a copy, send an email to Adrienne.Williams@westpharma.com or phone 610-594-3160.

To learn more, contact adrienne.williams@westpharma.com (610-594-3160) or brian.brucker@westpharma.com (610-594-3334)

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