

The Source for Sharing and Learning Since its First Issue in 2005

The Source provides the biopharmaceutical community with timely and critical information on the issues affecting the process of bringing new drug products to the marketplace. Our focus is 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 biopharmaceutical professionals through our newsletter, our website (westthesource-eu.com), our participation at industry conferences and our technical seminars at customer sites. We meet with professionals involved in the drug development process and look at these meetings as an opportunity to share our knowledge and to learn about your delivery system needs. We have published *The Source* EU/AP newsletter since May 2005; each issue is read by more than 1,000 recipients and website visitors who download the current or previous issues from www.westthesource-eu.com. The number of readers is constantly increasing.

Contact us to be added to the mailing list.

Filling Line Choice Dictates Stopper Packaging

One of the important decisions that a biopharmaceutical company must make early in product development relates to the type of filling environment required for the drug. The options include filling in a barrier isolator (aseptic) or filling in a clean room.

The filling environment will dictate stopper processing and the type of packaging in which the stoppers are delivered. For isolator and clean room filling, customers can specify stoppers processed as ready to sterilize or ready to use. The packaging in which the stoppers are delivered should be able to go directly into the controlled environment and should facilitate the transfer of the stoppers into the filling line.

Barrier isolator filling lines help improve the assurance of product sterility, which can reduce production costs and regulatory risk. When isolators are to be used, the method of introducing stoppers into the sterile environment must be considered carefully. Isolators require stoppers to be supplied in packaging that allows for the transfer of the sterile components

directly into the isolator without compromising the isolator's sterile environment or the integrity of the components. STERILIZABLEBAGS™ with rapid transfer ports are used most frequently. These bags generally have a beta port that mates with a compatible alpha port on the isolator. When the seal between the bag and isolator is secure, the stoppers are transferred into the sterile environment.

Vial stoppers used in a clean room filling line are usually delivered in a heat-sealed STERILIZABLEBAGS that can be placed directly into a steam sterilizer. The stoppers remain in the bag for transfer into the filling line. Biopharmaceutical companies should discuss filling line options with their stopper supplier and contract filler to prepare for production scale-up. West works closely with the leading transfer port manufacturers and West currently supplies customers with products in RTP bags.



Solutions for Drug Delivery Systems

Selecting a delivery system for nasal and inhalation drug products may require a custom solution. Such a decision should be made before the drug product goes into Phase I clinical trials. A biopharmaceutical company may need an experienced resource to design and manufacture a multi-material delivery system. The impact of regulatory issues and filing requirements must also be considered.

For years, West has met customers' needs for custom delivery systems. With its subsidiary The Tech Group, West offers a wide range of resources to serve the pharmaceutical markets. West and The Tech Group help customers develop and commercialize drug delivery systems and can supply devices for Phase I, Phase II and Phase III clinical trials. Staff members are knowledgeable with regard to FDA requirements. They have extensive experience in contract manufacturing and work with the world's leading device and pharmaceutical companies.

New Stability Chambers Broaden Capabilities for Frozen Drug Products

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

On-Line Resources

Customers can go on-line to find helpful information regarding industry guidances that address packaging and delivery systems for pharmaceutical and biological drug products. Links to the following draft guidances are available at: westthesource.com/Regulatory/regulatory.asp.

- **Guidance for Industry – Drug Product: Chemistry, Manufacturing and Controls Information**
- **Guidance for Industry – Container Closure Systems for Packaging Human Drugs and Biologics**
- **Guidance for Industry – Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice**

A reference to industry guidances and documents related to the preparation of parenteral packaging components is at westthesource.com/Packaging/Stopppers/westar.asp.

Visit West at these Industry Events

February 26 – 28

PIRA Extractables and Leachables Conference
Munich, Germany

West speaker:

Dr. Mike Schäfers, Vice President, Marketing, Europe

March 4 – 5

APV Prefillable Syringe Seminar
Fichtenau, Germany

West speaker:

Dr. Mike Schäfers, Vice President, Marketing, Europe

March 5 – 6

Rapra Extractables and Leachables Conference
Dublin, Ireland

West speaker:

Heike Schulz, Technical Customer Service Engineer

March 11 – 13

MedTech
Stuttgart, Germany

April 2 – 3

Concept Heidelberg Prefillable Syringe Seminar
Mannheim, Germany

West speaker:

Dr. Mike Schäfers, Vice President, Marketing, Europe

April 24 – 30

Interpack
Dusseldorf, Germany

May 6 – 7

Pharmaceutical and Medical Packaging 2008
Copenhagen, Denmark

May 8 – 9

Prefillable Syringe 2008 Management Forum
London, England

West speaker:

Dr. Mike Schäfers, Vice President, Marketing, Europe

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