

Spreading the Word

In the past two years, West has presented seminars in Boston, San Francisco, San Diego and Baltimore on the subject of parenteral packaging for biotech companies. The free seminars attract an average of 50 biopharmaceutical professionals, representing a variety of disciplines and range of companies from emerging to established.

At the most recent seminar in Baltimore, a number of participants asked for information about pharmaceutical vials. We addressed their questions with presentations on cyclic polyolefin and glass. This issue of *The Source* presents the benefits of each.

Our technical experts will continue to present seminars for biotech professionals. See the back page for details of West's participation in the AAPS National Biotechnology Conference on June 21 in Boston.

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.



Vial Material is an Important Factor for Biotech Drugs

One of the important considerations for biopharmaceutical drug packaging is the material composition of the drug vial. For liquid and lyophilized drug products, the choice is usually between vials manufactured from a cyclic polyolefin or from glass.

A cyclic polyolefin such as Resin CZ® is the preferred vial material for an oncologic or toxic drug where glass vial breakage is a concern. Resin CZ vials, manufactured in Japan by Daikyo Seiko, Ltd., are 100% optically inspected and hold extremely tight dimensional tolerances and visual attributes. Resin CZ passes all major compendia including the physicochemical and biological tests of the USP and JP. It also meets physicochemical tests for Ph.Eur. for polyolefins.

Resin CZ provides the following benefits:

- **Durable**
- **Non-flaking**
- **Highly transparent**
- **Very low in extractable ions**
- **Compatible with a wide pH range**
- **Resistant to high heat**

The conical vial design promotes complete drug removal, reducing product waste and disposal concerns. Resin CZ vials are designed with a blowback feature compatible with readily available stoppers and seals, a feature that helps maintain container closure integrity over the drug's shelf life.

Glass vials for pharmaceutical use are generally produced entirely from Type I borosilicate tubing glass, which provides outstanding chemical durability. It is particularly suited to pharmaceutical vials that require long-lasting, constant characteristics. These vials provide hydrolytic resistance in conformance with the current USP and Ph.Eur. Their inert surface minimizes interactions between the drug product and the container system.

Type I glass vials are generally available in 13mm and 20mm neck sizes and can contain volumes ranging from 1mL to 100mL. Glass vials are designed with the blowback feature.

To discuss the most appropriate vial container for your drug product, call Brian Brucker at 610-594-3334 or Adrienne Williams at 610-594-3160. You may also send email to brian.brucker@westpharma.com or adrienne.williams@westpharma.com.

Resin CZ is a registered trademark of Daikyo Seiko, Ltd.



The Cold Facts about Frozen Storage

Some liquid drugs developed by biopharmaceutical companies must be shipped and stored frozen to maintain product stability. Companies developing these drug products must be aware of the phenomenon of glass transition of elastomers, a critical consideration for pharmaceutical stoppers.

Glass transition occurs when cold temperature transforms an elastomer to a glass-like state. The hardened material loses its elasticity, the property that creates a tight seal between the stopper and the glass vial. This change to the stopper could affect the seal. As the drug package returns to ambient temperature, the stopper regains any lost elastic properties. By then, however, a breach in the seal may allow contaminants into the drug vial.

The glass transition point for butyls is typically about -50° C. Drugs usually reach these low temperatures during shipping. Storage temperatures tend to be higher. Nonetheless, a seal integrity breach contaminating the drug could occur during shipping or storage.

Further, frozen drugs packaged with a gas such as argon in the headspace could lose that blanket of protection if the seal is breached. The headspace is the area of the vial between the drug and the stopper. Gas is sometimes used to fill this area to replace air because oxygen may affect the drug.

Biopharmaceutical companies developing drugs that will be shipped and stored frozen should adopt a testing procedure to demonstrate that the cold temperature has not caused a breach of seal integrity.

A Wealth of Knowledge

The subject of extractable and leachable analyses is an important issue for pharmaceutical companies. West's global regulatory compliance program helps to ensure that the company's packaging components meet the rigorous standards demanded by the pharmaceutical industry. Further, West's staff members are knowledgeable regarding the industry guidances for packaging and they work closely with customers to help them meet regulatory challenges.

West's experts share their knowledge by speaking at industry conferences and contributing articles to trade journals. One such

article, "The Importance of Leachables and Extractables Testing for a Successful Product Launch," was recently published in North America and Europe. Written by Fran DeGrazio, Vice President, Marketing and Quality Assurance, the article discusses the impact of the Food and Drug Administration's June 1999 Container Closure Guidance on the requirements for extractable and leachable testing of container/closure packaging components.

To request a copy, send an email to one of the individuals listed below.

Free Symposium Offered at AAPS Bio

West Pharmaceutical Services has been invited to present the symposium "Parenteral Packaging for Biotech Drug Products" at the AAPS National Biotechnology Conference, June 21, in Boston. The symposium, number 1721, will be from 9:00 a.m. to 11:30 a.m. at the Hynes Convention Center. West's technical experts will be available to answer questions related to packaging for parenteral biopharmaceuticals.

The symposium is free to conference attendees. West will also exhibit parenteral packaging for biotech drug products, at booth number 513.

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 – Wayne Curry, 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 about the conference is available online at www.aapspharmaceutica.com/meetings/biotec/bt06/index.asp.

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

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