

West Facility in Germany Celebrates 50 Years

On September 18, 2010, West's employees and their families in Germany celebrated the 50th anniversary of the founding of Pharma Gummi, the predecessor company of West's operations in Germany. Pharma Gummi was founded in 1960 by Hans Wimmer. The company became a part of West in 1967.

The celebration included an open house for employees and their families at both the Eschweiler and Stolberg plants. In the evening, West hosted a public celebration in the Eschweiler market square that featured music and food. The square was packed with some 3,000 people, including many West employees and their families.

A highlight of the day was a visit by Mr. Wimmer, who, with his family, enjoyed the plant tour and the evening celebration.

The anniversary celebration not only marked 50 years, it also focused on helping the community through West without Borders. Employees raised money for Kinderschutzbund Eschweiler, an organization that provides services and support for children in need.



The large crowd at the open house enjoyed food and music.



Guests enjoyed a showcase of West's products.

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West and Daikyo Receive Johnson & Johnson Global Pharmaceutical Supplier Excellence Process Award

At a meeting on September 23, 2010, at West's European Headquarters in Eschweiler, the Johnson & Johnson Global Pharmaceutical Supply Group presented an award to West and Daikyo Seiko, Ltd. for their commitment and participation in the supplier excellence process. West supplies Johnson & Johnson Cilag, located in Schaffhausen, Switzerland, with FluroTec® lyo stoppers for REMICADE® vials. REMICADE is used to treat rheumatoid arthritis. West also supplies 1mL long and 1mL standard FluroTec plungers for PROCRT® syringes that are used to treat hemophilia, and plungers for diluent syringes for RISPERDAL® CONSTA® (risperidone), which is used for the treatment of schizophrenia and for the longer-term treatment of Bipolar I Disorder. Cilag considers West a strategic partner/supplier and uses West products for development work.

From left to right:

Igor Proglhof, Director,
Global Packaging, J&
GPSG; Marc Klinkenberg,
Sales Director, Central
Region Europe, West;
Peter Breugelmans,
Sourcing Manager,
Marketed Products, J&
GPSG; Laurent Frechin,
Vice President, Sales
Europe, West; Daniel
Abischer, Purchasing
Manager, Stock
Purchasing, J& GPSG;
and Patrick Radermacher,
Area Sales Manager, West



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RISPERDAL® CONSTA® are registered trademarks of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

West Launches www.WestPFSolutions.com

Central to West's core is the goal of providing prefillable syringe (PFS) systems and components along with technical expertise and services designed to bring pharmaceutical and biopharmaceutical products to market safely, reliably and with the integrity you've come to expect from West. To support customers' needs, West has launched www.WestPFSolutions.com, a web site dedicated to prefillable syringe solutions, services and support. The site provides information that is applicable globally.

"The WestPFSolutions web site connects customers to the technical and regulatory support they need to help get their product to market quickly," said Mike Schaefer, Vice President, Marketing, Europe. "This web site highlights our expertise in and solutions for prefillable syringe systems."

The site contains detailed information about prefillable systems, including the first-in-class Daikyo Crystal Zenith® 1mL long insert needle syringe system, a silicone-oil-

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Learn more about West's prefillable solutions, including the Daikyo Crystal Zenith 1mL Long insert needle syringe at www.WestPFSolutions.com.

tungsten- and glue-free prefillable system made from a highly break-resistant cyclic olefin polymer. The site features components for prefillable syringes, services, technical and regulatory support and complementary drug administration systems such as the West ConfiDose® auto-injector system. There is also a library of resources that includes technical reports, scientific papers and links to global regulatory and standard-setting web sites.

"West's PFS experts are available around the world to meet our customers' specific challenges with regard to their unique needs," said Schaefer. "This site is the first link in partnering with our customers to provide solutions to their PFS challenges."

The web site is available at www.WestPFSolutions.com.

The **West Ready Pack® System** – A Convenient One-Source Solution

A major challenge in laboratory, clinical and small-volume manufacturing environments is the ability to find low-risk packaging components that are easy to use and can help mitigate concerns with container closure integrity. The West Ready Pack system is the solution. Each sterile Ready Pack system comes with West stoppers, Flip-Off® seals and your choice of glass or Daikyo Crystal Zenith® resin vials; these components have a track record of successful commercial application.

World-Class Components

The Ready Pack system is suitable for low-quantity filling of high-value drugs. The stopper components are conveniently packaged in quantities of 500 each (20mm finish) or 1,000 each (13mm finish). Stoppers are available for both serum and lyophilized drugs.

Vial options include sterile Daikyo Crystal Zenith and glass from Type I borosilicate glass, a standard for packaging drug products.

Manufactured from a break-resistant cyclic olefin polymer, Crystal Zenith vials are ideally suited for packaging high-value biopharmaceuticals or those requiring low-temperature storage or shipping. In addition, Crystal Zenith vials can help keep your drug pure by reducing exposure to leachables and silicone oil.

In addition, West Flip-Off seals help maintain container closure integrity and are engineered to provide tamper-evident packaging. Ready Pack Flip-Off seals are also available in a copolymer formulation for low-temperature applications.

The sterilized components are delivered in packaging appropriate for aseptic filling and terminal sterilization, if needed. Because the components are delivered ready to use, you can eliminate component preparation from your processing, saving time and money.

The Ready Pack system includes ready-to-use vials, stoppers and seals.



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No matter what configuration you choose, West Ready Pack components provide a solution for risk mitigation, change control strategies and Quality by Design initiatives, so you can rest assured that your drug product and its packaging maintain a consistent profile from clinical stages through commercial development.

For more information visit www.westpharma.com and enter keyword/search "Ready Pack".

Continuous Improvement... Exceeding our Customers' Expectations

Westar® RS particle Specification is tightened to 2.5 PCI Score

The Westar RS (ready-to-sterilize) process represents the pinnacle of cleanliness and value for elastomeric components for vials and syringes. Westar RS components comply with current regulatory requirements and international standards.

As part of our ongoing commitment to continuous improvement, West is pleased to inform you that the global particle specification for Westar RS components has been tightened to ≤ 2.5 PCI (Proved Clean Index) score.

After a comprehensive data review and analysis of the four West facilities around the world that provide Westar RS processing, it was determined that West could consistently meet a PCI score specification of ≤ 2.5 . Further, this specification is achievable without changing the production process or the analytical test method. This significant specification enhancement is the result of the excellent consistency and repeatability of the Westar RS process. The improved Westar PCI score specification exemplifies West's commitment to enhance product quality.

Additionally, to allow direct interpretation of our certified value without calculations, the particle specification will also be expressed and reported in maximum number of particles per 10cm² for each particulate size range on the certificate of analysis.

	Current	New
> 25µm but ≤ 50µm	not specified	≤ 13 particles / 10cm ²
> 50µm but ≤ 100µm	not specified	≤ 3.5 particles / 10cm ²
> 100µm	not specified	≤ 0.9 particles / 10cm ²
PCI	≤ 3.4	≤ 2.5

Every washload will be tested and acceptable results for all four values (each of the three size categories and PCI) will now be the release criteria for particle levels on Westar RS products.

As of October 29, 2010, manufactured Westar RS products are now tested, certified and released according to this new tighter specification.

For more information, please contact your Account Manager.

Syringe Components Free of Dry Natural Rubber

The issue of dry natural rubber (DNR) or "latex" content in pharmaceutical components such as needle shields and tip caps for prefillable syringes has been the focus of recent discussion among pharmaceutical companies, pharmaceutical component suppliers and authorities.

Consequently, West would like to emphasize that its two synthetic polyisoprene formulations, 7025/65 grey and 7028/55 grey, developed for tip caps and needle shields for prefillable syringes, are DNR-free (latex free).

Customer certifications are posted in the Technical section of our [West PFS solutions](#).



web site. In addition, the formulation characteristics, which are also posted on the web site, list DNR content at 0.0%. If you would like to have a certification specifically for your company, please contact your West sales or Technical Customer Service representative who will forward your request to the West Regulatory department.

Formulation 7028/55 grey is West's most recent innovation for tip caps and needle shields. West recommends 7028/55 grey for all new drug applications in the prefillable syringe format. The characteristics of Formulation 7028/55 grey are:

- High resistance to ozone cracking
- Free of dry natural rubber, nitrosamine and pre-cursors
- Compatible with steam, gamma and EtO sterilization
- Non-cytotoxic (ISO 10993-5 test)
- Low coring properties
- Low in extractables
- No MBT and derivatives
- Low susceptibility to frosting and hazing

West's Podcast Examines Glass Delamination

Recent drug product recalls have been caused by issues associated with glass, including breakage, delamination and particulate formation. These issues could adversely affect the health of patients and create a serious financial burden on the drug manufacturer.

To provide information on glass delamination, West has posted a new podcast on this subject to its web site, www.westpharma.com.

The podcast discusses general glass vial manufacturing processes and the chemical reactions that can lead to problems such as delamination. It features West's Eugene Polini, Senior Technical Account Specialist, who has a background in analytical chemistry, biology and international business and has been with West for more than 26 years. During the podcast, Polini also talks about viable alternatives to glass, including cyclic olefin polymers.

According to Polini, "The use of polymeric containers can eliminate the risk of issues such as delamination. Particulate matter injected intravenously can cause harm to the body so there is a definite patient safety issue when any glass particulate is detected."

The launch is part of a series of podcasts aimed at providing the pharmaceutical and biotechnology industries with valuable information to assist in minimizing their risk as they move from drug discovery to commercialization.

The podcast is available at www.westpharma.com search keyword: Podcasts and can also be reached by going to the What's New page.



If there are any questions or comments, please feel free to contact:
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