

Flexible Solutions for Pharmaceutical Components Westar[®] Component Processing

It's an age-old dilemma. How can pharmaceutical manufacturers keep up with rising quality expectations while reducing processing costs? In-house processing requires space, validations, equipment maintenance and more. All of which affect cost. But is outsourcing the right answer?



CUT COSTS WITHOUT CUTTING QUALITY

In-house processing of components – including washing, siliconization and sterilization processes — requires expertise and incurs a multitude of costs. Such processes may not be your core capability, which can affect quality. Outsourcing may seem too risky and expensive.

LEGACY OPERATIONS DON'T MEET TODAY'S EXPECTATIONS

Many in-house component processing lines use legacy procedures, inadequate validations, and older equipment. In extreme cases, these validations may be out of compliance. Investments required to meet today's quality expectations can be costly and a source of regulatory scrutiny in your operations. Per the FDA, quality management failures led to 50% of sterile injectable drug shortages in 2011.¹





VARIABILITY AFFECTS QUALITY

Not only do older processes and equipment cost money to maintain or upgrade, they may cause variability or even failures in component quality. Such processing issues can add cost while affecting operational performance and reducing drug quality, putting patients at risk.

REDUCE RISK WITH AN INDUSTRY LEADER

Quality risks and regulatory issues associated with in-house washing, siliconization and sterilization can be reduced by outsourcing component processing to the experts. The Westar Drug Master File is one of the most often accessed in the industry.





MEET QUALITY EXPECTATIONS AND REDUCE COSTS

Industry proven Westar ready-to-sterilize and ready-to-use components reduce the cost associated with component processing operations. Westar components meet international pharmacopeia standards and specifications, reducing quality variability and increasing your peace of mind.

Talk to your West representative and choose the right option for your product, and ultimately, for your patients' health.

Reference: 1. FDA drug shortages: fundamental problems in the inability for the market to observe and reward quality. Policy & Medicine website. April 12, 2013. http://www.policymed.com/2013/04/fda-drug-shortages-fundamental-problem-is-the-inability-for-the-market-to-observe-and-reward-quality.html. Accessed September 29, 2015.



Westar[®] Component Processing

Leverage Expertise in Ready-to-Use and Ready-to-Sterilize Components

\mathbf{z} Reduce Cost — \mathbf{z} Increase Quality

Westar Components Can Streamline Your Manufacturing Process

- Reduce testing and validation studies
- Increase throughput
- Reduce labor and maintenance costs
- Improve regulatory compliance and quality assurance
- Available in a wide range of packaging formats

Ready-to-Sterilize Components

- Clean components that comply with applicable pharmacopeia standards
- Consistency of preparation
- Process validation for quality assurance

Ready-to-Use Components

- Sterilized components delivered to your door in integrity-tested packaging systems
- Minimize variability in sterile operations
- Eliminate component preparation from your manufacturing process

Visit West today at www.westpharma.com to learn more.

West Pharmaceutical Services, Inc. 530 Herman O. West Drive, Exton, PA 19341

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