



Pharmaceutical Systems Division

### Policy for Customer Notification of Changes

West Pharmaceutical Services (West) Policy for Customer Notification of Changes requires West to evaluate effects of changes and provide advance notification to customers of any change in the manufacturing processes or raw materials that could have a substantial or significant potential to adversely effect the identity, quality, purity or functionality of the component as it relates to its safety or effectiveness. A risk assessment of the change on the closure/component and its potential to increase risk as it relates to safety or effectiveness of the drug/biologic/device product it may come in contact with is also considered. Changes subject to advance notice via a formal Customer Change Notification include, but are not limited to:

- ◆ Changing from a natural derived raw material to a synthetic version of the material
- ◆ Change of a product specification
- ◆ Change in the location of manufacture of the finished closure/component
- ◆ Potential implication to a customer's regulatory filings

West may also communicate to its customers minor changes or operational changes that have a minimal potential to adversely affect the component/closure. Minor changes or operational changes that may be communicated via a Customer Communication Letter include, but are not limited to:

- ◆ New equipment technology
- ◆ Facility changes (e.g. expansions, layouts, etc.)
- ◆ Secondary product packaging or shipping requirements

West has an internal change control procedure and systems in place to centrally manage and track all changes in each major geographic region of the globe.

Every effort will be made to provide such notice at least 60 days in advance of the change. Typically, West notifies customers a year or more in advance of this target and will actively work with you to assure supply of pre-change product for use during your change assessment and implementation period, whenever possible.

This Policy has been updated in an effort to clarify West's position relating to changes and to more effectively address the needs of our customers.

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