



West Pharmaceutical Services, Inc.
Policy on Change Notification

January 1, 2018

Objectives

The objective of the West change management process is to assure that every proposed change to a West provided product is evaluated to determine its likely impact to material of composition, design, form, fit or function, and therefore its potential impact on the safety, quality, identity or purity of the products supplied to West's customer.

Policy

West recognizes that customers should be notified of important changes in the products we supply to avoid potential risk to customers' products and, ultimately, the patients they serve. West follows established risk-based change control procedures to evaluate, process and track all changes within West's manufacturing network and to notify affected customers so that the impact of the change can be evaluated in a timely fashion. West evaluates changes based on three established categories:

- **Major Change** - A change that alters the product's physical and/or chemical properties outside of established specifications or is likely to impact the performance or quality of the West product. Examples of a Major Change are a change in manufacturing facility location or material meeting the aforementioned criteria.
- **Moderate Change** - A change that may alter the product's physical and/or chemical properties outside of established specifications or may impact the performance or quality of the West product. Examples of a Moderate Change are a change in test method that is not compendial in nature or a change in manufacturing method or process outside of the current validated state.
- **Minor Change** - A change that is unlikely to alter the product's physical and/or chemical properties outside of established specifications or unlikely to impact the performance or quality of the West product. Examples of a Minor Change are a change to a more stringent product specification, a like-for-like material change or a change in quality control laboratory location using the same methods.

Timing of Notification

West will provide written notice to customers as follows:

- **Major Change** – one year, wherever possible, but no less than 90 days prior to the change.
- **Moderate Change** – at least 90 days prior to the change.
- **Minor Change** – at the discretion of West.

A handwritten signature in blue ink, appearing to read "Andy Polywacz", is written over a horizontal line.

Andy Polywacz
West Vice President of Quality and Regulatory Affairs