



West Pharmaceutical Services, Inc.
Statement on Change Notification for Components

30 June 2020

Objectives

The objective of the West change management process is to ensure 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.

Statement

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 four established categories:

- **Major Change** - A change that poses a significant impact to a known West or customer Regulatory filing or strategy, alters the product's physical and/or chemical properties outside of established specifications or is likely to impact the performance, safety, effectiveness 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 impact a known West or customer Regulatory filing or strategy, alter the product's physical and/or chemical properties outside of established specifications or may impact the performance, safety, effectiveness 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 1B Change** - A change that is applicable to more than one West facility and is unlikely to impact a known West or customer Regulatory filing or strategy, alter the product's physical and/or chemical properties outside of established specifications or unlikely to impact the performance, safety, effectiveness or quality of the West product. Examples of a Minor 1B Change are a change in quality control laboratory location using the same methods or a transfer of a West-owned tool from one plant to another plant.
- **Minor 1A Change** - A change that is only applicable to one West facility and is unlikely to impact a known West or customer Regulatory filing or strategy, alter the product's physical and/or chemical properties outside of established specifications or unlikely to impact the performance, safety, effectiveness or quality of the West product. Also, typically used for Like-for-Like changes. Examples of a Minor 1A Change are a change of machine location within the same room classification or a like-for-like material change.

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 1B Change** – at the discretion of West.
- **Minor 1A Change** – at the discretion of West.

Andy Polywacz
West Vice President of Quality