West Pharmaceutical Services, Inc.

Statement on Change Notification for Medical Devices/Contract Manufacturing

30 June 2020

West change management for medical devices/contract manufacturing is based on, and supported by, a risk-based approach.

West has an internal change control procedure / system in place to manage and track all changes within the West medical device/contract manufacturing network.

Changes are evaluated based on risk and then categorized into one of the three classifications as outlined below:

Change Classification	Change Description	Customer Notification or Requests for Change Approval
Major Change (3)	A significant impact to a 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.	Communicated to customers with 1 year notification, when possible, but no less than 90 days notification prior to the change, providing adequate time for evaluation and approval of the change.
Moderate Change (2)	A potential to impact a 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.	Communicated to customers with approximately 60 days of notification prior to the change and, as defined per Quality Agreements, approval of the change.
Minor Change (1B/ 1A)	Is unlikely to impact a 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. which applies to multiple sites (1B) or to a single site (1A).	Notification to customers, for changes with an unlikely impact on the product or process, will be at the discretion of West medical device / contract manufacturing site (as applicable).

Changes initiated by West's customers will be additionally reviewed against current process capabilities, current inventories (as applicable), and categorized as above. A mutual change implementation plan will be developed.

The goal of the West medical device/contract manufacturing change process is to ensure that every change is evaluated to determine if there is a potential risk to the product, in conjunction with our customer's evaluation of the potential impact on end users.

West reserves the right to proceed with minor or moderate changes if no response to the change request is received within 60 days of notification.

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West Vice President of Quality

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