QMS-125

Appendix1: **Activities Included for Each Change Type**

Appendix 1 – Activities Included for Each Change Type

Change Type	Included Activities
Documentation	A **Documentation** change covers a change to any registered document including but not limited to: • Registered Specifications
Facility / Utility / Equipment	A **Facility / Utility / Equipment** change covers any modification to the equipment, or the environment of equipment operation (e.g. Relocation, modification, new equipment, new components or consumables) and facility changes in the manufacturing area or office area. The changes include, but are not limited to: • Manufacturing equipment (blenders, tanks, mills, sieves, compressing machines, encapsulators, etc.) • Packaging equipment (vision systems, cappers, labellers, shrink tunnels, pharmacode readers, etc.) • Equipment PLC's • Tooling (compressing and packaging) • Water system • Test equipment (Analytical instruments, calibration instruments) • Environment (HVAC, pest control, etc.) • Construction • Demolition
IT Systems	An **IT Systems** change covers any change to a GMP computer system, including: • Hardware • Software • Data integrity • Operation • Storage / back-up • Traceability
Manufacturing Process	A **Manufacturing Process** change covers any change to a Blend, Tablet, Capsule or Liquid production or packaging process including, but not limited to: • Manufacturing process instructions (processing times, order of addition, critical parameters) • Packaging process instructions (set up, critical parameters) • Cleaning processes (time, temp, agent, method) • Introduction of new products • Deletion of products • Transfers of products into, or out of, the facility. • Lot traceability • Storage requirements

Change Type	Included Activities
Materials	A **Material** change covers any change to an active or an excipient including: • Grade • Supplier (new) • Manufacturer (new) • Manufacturing site • Manufacturing process • Storage / delivery containers
Packaging / Labelling / Artwork	A **Packaging** change covers any change to: • New components • Format / Dimensions • Materials • Artwork
Process Change	A **Process Change** covers any change to a manufacturing or packaging process.
Process Control System	A **Process Control System** change includes changes to: • Changes to the BMS • Changes to any system that monitors processes
Specification / Test Method	A **Specification** change covers any change to a specification or limit including, but not limited to: • Raw material specifications • Bulk / Finished Goods specifications • In-process test limits • Packaging specifications (excluding artwork) • Formulation Order • Sample or standard preparation • Instrument parameters • Chemical reagents

2