Table of Contents

Forms Index

1. PURPOSE

The following procedure defines various change control options, notification processes, and their interactions according to the Risk Management Based Approach.

2. SCOPE

This procedure applies to products, components (via Vendor Initiated Changes), facilities, utilities, equipment, processes, and software. It also includes and covers Customer Change Notification and business continuity modification or improvements.

3. RESPONSIBILITIES

3.1 **Quality management** is responsible for ensuring changes are controlled per the appropriate change control process.

3.2 **Change Coordinator**: Is the owner of the change control, monitors the change control portfolio, can provide training on the change control process and tools to the different stakeholders. It's responsible for maintaining defined metrics for the change control process. QA Engineers are the change coordinators for their respective areas.

3.3 **Change Leader or Requester**: Is responsible for the management of the dedicated change, including risk assessment/impact analysis and follow-up of actions required for implementation.

3.4 **Delivery Team**: Group of individuals from different departments, responsible for the execution of action items and deliverables defined in the Change Request.

3.5 **Change Control Committee**: Group of individuals from different departments (Quality is mandatory) which reviews the Change request and which decides for execution or not. The group constitution is flexible and will be established accordingly the Change Control Committee Members.

4. DEFINITIONS

4.1 Change: A change is defined as a planned and lasting change of a product or a process characteristic which may affect the safety, the quality, or the performance of an item:

4.1.1 Product-related changes, as apply:

- 4.1.2.1 Raw materials and components
- 4.1.2.2 Labeling, packaging
- 4.1.2.3 Product specifications
- 4.1.2.4 Sterilization, depirogenation, GAMMA, ETO, etc.

4.1.2.5 Customer-related documents (drawings, instructions For Use, validation guides, certificate of release)

4.1.2.6 Suppliers, vendor changes and qualification modifications

4.1.2 Process related changes:

4.1.2.7 Supplier processes and locations

4.1.2.8 Manufacturing processes.

4.1.2.9 Packaging processes.

4.1.2.10 Incoming processes.

4.1.2.11 Inspection processes.

4.1.2.12 Shipping and distribution processes.

4.1.2.13 Equipment (installations of new equipment, devices, supply systems, lab and production, computerized systems)

4.1.2.14 Hardware and Software, firmware, configurations

4.1.2.15 Procedures (manufacturing, in-process, QC and release)

4.1.2.16 Facilities and utilities (manufacturing and warehouse locations, storage conditions)

4.2 **Action before commercial use:** implementation of activity as a precondition for the commercial use of the change, initiated after approval of a change request (e.g. training, procedural changes, validation, etc).

4.3 **Action after commercial use**: implementation of an action as a precondition for the closure of the change request (e.g. regulatory approval, customer approval, etc.).

4.4 **Customer Change Notification:** Process which guarantees the information to customers of those changes to be implemented by the company or its suppliers with potential impact on product safety, quality, identity, purity, fit, form or function. The notification letter is the only official mechanism for change communication to customers.

4.5 **ECR:** Engineering Change Request which contains all relevant information to describe the change and the impact of the change.

4.6 **ECO: Engineering Change Order** contains all defined action items to be executed before the implementation of the change.

4.7 ***Emergency Change Control:*** When an unexpected situation occurs that a change is needed immediately to ensure continued operations. This change must be expedited in the fast track to obtaining its authorization and approval before implementation using the one-page form A2. Full change control is subsequently filed for evaluation no later than (2) two business days from execution. Impacted items are withheld from further use pending such evaluation.

4.8 ***Implementation Plan:*** A description of activities necessary to support the integration of the change into operations. The plan may include the initiation or revisions in the documentation.

4.9 ***Like-for-Like change***: Instruments or parts that perform the same function have the same characteristics and specifications but may be produced by different manufacturers. These may be approved for use as replacement instruments or devices if the validated state is not altered. Also referred to as a replacement in kind or functionally equivalent instruments or parts.

4.10 ***Major change:*** Those changes that may affect adversely GMP requirements and the critical attributes of a system, facility, apparatus, material, product, procedure or process. In addition, these changes may have the potential to cause any type of impairment, damage or weakening of the product quality or process reliability.

4.11 ***Minor change:*** Those changes that unlikely have an adverse impact on the GMP or quality attributes of the product, process, material or procedure on its validated state. Changes with non-adverse impact on the GMP requirements shall not require a change control.

4.12 **PMF: Product Master File** according to the definition of *21 CFR Part 820* Device Master Records.

4.13 ***Temporary Change:*** A temporary change is a change approved based on a predetermined limit, such as a specific number of units of production (lots) or for a defined time. At the end of the specified deadline, the changed process or system must be returned to its normal state. A temporary change may be converted to a permanent change with appropriate approval.

4.14 ***Change control revision or amendment:*** Changes made in the change plan or forms prior to or during the execution of that plan. A new version number will be assigned in increments of one digit to keep the document control***.***

4.15 ***IT –*** Information Technology

5. DESCRIPTION & CLASSIFICATION OF ITEMS SUBJECT TO CHANGE CONTROL

Items subject this procedure will be handled according to the scope and impact of the change. Changes and events will be defined as a site or business division specific and then managed per the applicable procedure. Any changes specific to the site will be handled by company local procedures. Changes specific to a business corporate division will be handled according to the applicable global procedures or policies.

5.1.1 Quality Documents

5.1.1.1 Quality documents applicable only to the local site will have changes controlled by the Quality System Management.

5.1.2 Products

5.1.2.1 All cGMP product changes applicable to the site will be handled by the corresponding business division process.

5.1.3 Vendor/Supplier Initiated Changes

5.1.3.1 Vendor/Supplier initiated changes applicable to the site will be controlled by this procedure and communicated to other business divisions as needed.

5.1.4 Facility, Utility, Equipment, Process and Software Changes

5.1.4.1 Changes to facilities, utilities, equipment, process and software will be controlled by this procedure.

5.1.4.2 Changes to process and software applicable to this site will be controlled by this procedure.

5.1.4.3 Process and software changes applicable to this site will be controlled by this procedure.

5.1.5 Customer Notification

5.1.5.1 Requirement and method of customer notification will be determined by Quality, dependant on the impact of the change using input from the notification matrices for each business division.

5.1.5.2 Determination and timing of customer notification will be controlled per this procedure.