Doc. no. / Rev	QV0200456 Ver. 1.0
Valid from	8 January 2024
Page	1

Standard for Cytiva Change Control and Notification process for Pall Medical products

For External Use

Table of Contents

Standard for Cytiva Change Control and Notification process for Pall Medical products

1. INTRODUCTION

A process for change control is required for medical devices products.

As a supplier of products often used in a in a regulated environment, Cytiva acknowledges that change control is a critical process in the quality management system and necessary to fulfil the obligations to supply products with a consistent quality to our customers.

Changes will be informed of in a way that will not disclose IP or business critical information. More detailed information may be shared with customers during audits.

2. PURPOSE

The purpose of this document is to provide an overview of the change control process and notification content for Pall Medical products.

Detailed procedures and instructions that are in compliance with this document are used at the local Cytiva sites and can be reviewed during audits.

This document may be used to introduce the Cytiva change control process and notifications to customers or other external organizations or individuals.

3. SCOPE

This standard applies to all Pall Medical products supplied to the medical device industry and intended for use in a regulated environment, that are available for subscription to change control notifications and thus are listed on the Cytiva Regulatory Support web page: www.cytiva.com/rsf.

Notification for products not available for subscription on the Regulatory Support web site, will be considered and sent through sales channels.

4. DEFINITIONS

Change control: Management of all planned changes associated with the design or manufacturing of marketed products.

Design changes: Any modification to a product that may impact design form, fit or function.

Form: The unique and relevant physical characteristics of a part, defining the “look” of the part or item, e.g. shape, size, dimensions, colour, mass and/or other visual parameters which uniquely characterize and distinguish the part.

Fit: Fits intended application; The ability of a part to physically interface, connect with, or become an integral part of another part or assembly, includes for example tolerances. Whether the physical dimensions of a part fit into the product it was designed to go into. It must adhere to the specifications set in the design phase.

Function: The action(s) that an item is designed to perform, what the product actually does, product performance.

Indication: the indications or intended use of a Pall Medical product is the use for which the device is intended according to the information provided by a manufacturer in the product labelling or promotional materials, and which is cleared, approved or otherwise authorised by a relevant Health Authority within the respective country in which the product is placed on the market.

Safety/Performance characteristics: attributes that ensure the device designed, developed, produced and packaged is suitable for its intended purpose.

Pall Medical product: includes branded devices as well as bulk filters and membranes

5. STEERING PRINCIPLES

Each manufacturing unit has a change control process team with relevant representatives from functions or sites involved with proposed changes. The representatives are on an organizational level that gives authority to take decisions.

The representatives are responsible for:

- assessing all aspects of proposed changes
- assessing the output from risk management
- deciding on the extent of verification/validation
- determining if a customer notification is required, by reviewing approved Quality Assurance Agreements
- reviewing and approving design and manufacturing changes

6. CUSTOMER NOTIFICATION

For changes listed below in points 6.2-3, customers are always notified. Any effective Quality Assurance Agreement prevails.

The listed points reflect customer input over many years, through many types of interactions (e.g. interaction regarding quality agreements, customer audits, customer feedback to notifications etc.), and are adopted to fit the product area characteristics and needs.

6.1. Changes subject to customer notification, and time frames

Notification is given for products available for subscription to change control notifications listed on the web page www.cytiva.com/rsf, according to this Standard.

The pre-notification time frames in signed Quality Assurance Agreements with customer are those that Cytiva aims to fulfil. However, there may be extraordinary situations where Cytiva may have to inform with shorter notice, and Cytiva reserves the right to inform with shorter notice than described below.

6.2. Changes for which Cytiva will send a notification

Note that some information and/or data is considered proprietary. For such material not all details are disclosed. Cytiva confidentiality of proprietary information takes precedence over custom product transparency.

Changes for which notification is given without notice:

- Regulatory certification status

Changes for which notification is given 3 months prior to implementation:

- New edition of this change control standard (in the event of Cytiva reducing the stringency laid out in this document, a new edition of this change control standard will be notified minimum 6 months prior to implementation)
- Change of company name or legal entity
- Change to label and certificate content
- Change in specific product release testing
- Change concerning shelf life
- Changes in packaging
- Changes that could impact the indication, performance, or safety of a medical device

Changes for which notification is given 6 months prior to implementation:

- Change of critical subcontractor (manufacturing, finished product release testing)
- Change of test method for finished product release test
- Addition of manufacturing site – like for like equipment and processes
- Change in raw material grade (not including packaging)
- Addition of new raw material manufacturer, except for proprietary information/data

Changes for which notification is given 9 months prior to implementation:

- Significant manufacturing changes (if form, fit or function are impacted)
- Change of manufacturing environment (reduction in classification)

Changes for which notification is given 1 year prior to implementation:

- Addition of manufacturing site – not like for like
- Change in product specification
- Change in raw material type

6.3. Discontinuation Policy

Should Cytiva decide to discontinue any products covered by this Standard, customers registered for change control notifications shall be notified typically 12 months in advance.

However, there may be extraordinary situations due to external or internal factors where Cytiva may have to inform of a discontinuation with shorter notice. Cytiva reserves the right to inform with shorter notice than described in situations when non-standard events occur.

7. SUBSCRIPTION TO CHANGE NOTIFICATION

Products subject to change control notification are listed on www.cytiva.com/rsf. Registration at the Regulatory Support web page is required for notification. To receive change control notifications, customers need to register at this web site and subscribe to CCN for the product they buy. Each product for which notification is required must be selected.

7.1. Notification Content

The notification contains the following information:

- identity of product (product name, article/code number)
- description of the change
- reason for change
- impact of change
- supporting data (when applicable)
- updated specification when applicable
- timeline for the change
- where to request additional information

8. DOCUMENT OWNER

Customer Regulatory Support Director

9. REVISION HISTORY

Revision Number	Section(s) Changed	Changes	Updated by
01	N/A	New document	Ondina Åsberg

End of Document