Procedure: Device Recall and Advisory Notices

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Edit this procedure to reflect local regulations and the practices the company employs. Regulatory Affairs (RA) plays a key role in recall procedures. Where there is no RA, this role is assumed by the QA Manager.

# Purpose

This procedure describes a system, provides instructions and assigns responsibilities for the recall of distributed devices and the issue and implementation of advisory notices.

# Scope

The scope of this procedure includes all dispatched, shipped and distributed devices at [Company].

# Responsibilities

|  |  |
| --- | --- |
| Role | Responsibility |
| Chief Executive Officer (CEO) |  |
| Production Manager |  |
| Quality Manager |  |

Amend roles and responsibilities as applicable for your company processes and structure.

# Procedure

## General

Recall of devices involves removal from the market of a distributed device that fails to meet regulatory requirements or has a quality issue that may result in harm to the user. It does not include market withdrawal or stock recovery.

Recalls are necessary when it is determined there is a risk of serious harm or death of the user. Recalls include the return of devices to the supplier, modification by the supplier, exchange or destruction.

An advisory notice is issued to provide information and/or advice on actions to be taken in the use, modification, disposal or return of a medical device.

Market withdrawals and stock recovery are not governed by this procedure.

## Recall responsibilities

The recall committee is responsible for initiating a recall and coordinating related activities. The committee includes the CEO, Quality Manager and Production Manager.

In an emergency or when there is insufficient time to assemble the full committee, the CEO or Quality Manager is authorised to initiate a recall.

Potential recall situations are reported immediately to the Quality Manager. The Quality Manager analyses the product/incident for compliance with specifications and regulatory requirements. The extent of the problem is assessed and reported to the CEO. Where appropriate, a recall committee is convened.

Production and sales are responsible for organising and conducting recall activities including identification of the location of all suspect lots.

## Recall

The recall committee determines if a recall is necessary and determines the:

* extent and nature of health hazard and recall classification
* depth of the recall
* type of notice to consignees (i.e., letter, fax or telephone)
* content of the notice to consignees
* method for verifying effectiveness of recall

When the above data is available, appropriate authorities are notified and given the proposed recall plan.

## Receipt of recalled devices

QA designates and prepares a quarantine area for receipt and holding of recalled devices.

The quantity of devices returned, lot number and source of the return are recorded. This record is used to verify all recalled devices have been located and returned and to prepare any necessary reports.

On completion of the recall, a decision is made regarding the disposition of the recalled devices (refer to Procedure *QP805: Control of Non-conforming Product*).

## Issue of advisory notices

The recall committee determines the need for issuing advisory notices. The process for making this determination is similar to recalls (refer Sections 4.2 and 4.3). Advisory notices are sent via certified mail or other traceable method.

Appendices

Amend as required or delete.

Definitions

Amend as required or delete.

| Term | Definition |
| --- | --- |
|  | Insert terms/abbreviations and definitions for those used within the procedure. Do not include any terms or abbreviations not used within the procedure. |
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Document Information

| Revision History | | | |
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| Revision | Modified by | Change Control No. | Description of Change |
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Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP805 | Control of Non-conforming Product |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

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