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Implementing an Effective Return Material Authorization Program

Implementation of an effective Return Material Authorization (RMA) Program is relevant to organizations where medical devices may be returned. An RMA Program can support a compliant Quality Management System (QMS) and provide a means for appropriate product status identification, once returned from the field. It can help manage Quality aspects of returned materials as well as support appropriate Accounting and Customer Service for those returned items.

This White Paper focuses on Return Material Authorization for Medical Devices per ISO 13485:2016 § 7.5.8 and 21 CFR 820.60. It includes discussions on the application of an effective RMA Program, including an example Return Material Authorization Form.

Why is a Return Material Authorization Program Relevant?

An RMA program can help to support the QMS, as well as enable compliance to ISO 13485:2016 § 7.5.8 and 21 CFR 820.60 for product returned from the field. Through the RMA process, returned product can be appropriately identified and distinguished from conforming product to prevent mix-ups. The RMA Program can also provide a method for the organization to receive and process returned product.

What Does an Effective Return Material Authorization Program Consist Of?

An effective Return Material Authorization Program addresses regulatory requirements as outlined in ISO 13485:2016 § 7.5.8, which states:

> "The organization shall document procedures to ensure that medical devices returned to the organization are identified and distinguished from conforming product".

As well as 21 CFR 820.60, which states:

> "Each manufacturer shall establish and maintain procedures for identifying product during all stages of receipt, production, distribution, and installation to prevent mix-ups."

The program may include an inspection to determine the current status of the product (unopened / undamaged, damaged / nonconforming, etc.) in order to identify how to process it accordingly. In cases where product is unopened / undamaged, there is potential to return it to inventory. Of course, this requires assessment of expiration dates and the shelf life remaining on the product. In cases where the product is damaged, it requires segregation / quarantine to investigate and determine an appropriate disposition (rework / return to vendor / scrap, etc.). This can be tied to the organization's Nonconforming Materials Program. The disposition may also be communicated to the Accounting group to allow for credits / charges to the customer, according to company policy. In turn, this can aid in Customer Satisfaction.

Creation of an RMA Log

An RMA Log may be created and utilized as a tool to help support and manage the RMA process. This can provide a method to assign RMA tracking numbers, monitor RMA processing times, and capture any additional information that may be useful for tracking and trending purposes. The use of an RMA Log should be tied to the established RMA process and procedural requirements.

Use of an RMA Form

In order to accommodate appropriate RMA documentation requirements, the creation of an RMA Form is applicable. This may include space to capture details of the returned material(s), including the associated investigation and disposition results. As always, it's important to tie the RMA Form (and RMA Log) to the RMA procedure and ensure that it is aligned with the defined procedural requirements.

An example form is provided below:

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[Company Logo]	RETURN MATERIALS AUTHORIZATION FORM			
		Effective Date:	Revision:	Form Number:

SECTION #1		
RMA #	Date:	Customer ID:
Company Name:	Customer Contact Name:	
Customer Address:	Contact Phone #:	
	Customer email:	
Part # (S):	Lot # (S):	
Description:	Expected Quantity:	
Detailed Description of reason for return:		
RMA Issued by (Print):	Signature:	Date
RMA Authorized by (Print):	Signature:	Date

SECTION #2		
Date recieved:		
Part # (s) recieved:	Lot # (s) recieved:	
Quantity per lot returned received:		
☐ Inspection revealed no nonconformities, with expiration greater than 12 months (Return to inventory) Quantity Acceptable: ☐ Inspection revealed nonconformity, damaged product or expiration less than 12 months **Issue NCMR #:** Comments:		
Print:	Signature:	Date

SECTION #3		
Original PO/Invoice#	Credit Memo #	
Credit Product: Yes ☐ No ☐	Credit Freight: Yes ☐ No ☐	Service Charge: Yes ☐ No ☐
Print:	Signature:	Date

SECTION #4		
☐ No NCMR issued release to finished good	☐ NCMR issued and closed (attach copy of NCMR)	
Print:	Signature:	Date

Summary

Establishment, implementation and maintenance of an effective Return Material Authorization Program can support a compliant Quality Management System and allow for proper identification and traceability of returned product. Not only will an RMA Program serve as a useful Quality Management tool, but it will also benefit other departments in the company. RMA can tie back to the accounting process to ensure that customer credits / refunds are being appropriately captured and processed, which also plays an important role in Customer Satisfaction.

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