1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe process for returning products to an Amgen facility.

2.0 SCOPE

This SOP applies to all Amgen facilities to which product can be returned.

3.0 ROLES AND RESPONSIBILITIES

Role	Responsibility
Trade Operations	• Manages and processes returns • Contacts customer • Coordinates the carrier, local Amgen facility, and the customer • Credits the customer account according to the appropriate return policy • Informs the customer about his responsibility when returning a product • Checks the outstanding returns once a week and follows up with the carrier and the customer
Warehouse	• Verifies the content of the return against the shipping and ordering documentation • Contacts Trade Operations with discrepancies and acceptances

4.0 REFERENCES

This SOP refers to the current version of the following:

- GS066 Global ERP Master Data Maintenance

5.0 GENERAL

5.1 Important Concepts

Not applicable

5.2 Definitions

Term	Definition
Business decision	Choice to determine the dollar value of the credit applied to the customer's account when product is returned. The decision is based on a variety of factors.
Customer	Approved pharmacy, hospital, wholesaler, specialist center, etc.

Term	Definition
Delivery Note	Document that contains all sales order detail along with batch number
Returns	Amgen products that the customer sends back to the company for disposition

5.3 Abbreviations

Abbreviation	Definition
PGI	Post Goods Issue
QA	Quality assurance
RMA	Return material authorization
RO	Return order
TO	Trade Operations

5.4 Equipment

Not applicable

5.5 Materials

Not applicable

5.6 Safety Precautions

- Store returned products separately and, when applicable, under temperature-controlled conditions.
- Use an approved biomailer for SureClick devices.

6.0 PROCEDURE

The following procedures require appropriate master data as described in GS066 Global ERP Master Data Maintenance.

A product may be returned for only two reasons:

1. Delivery issue (e.g., late, wrong order, damaged packaging, and so on) for destruction
2. Quality issue

6.1 Customer Returns Products to an Amgen Facility without Reference

The following steps refer to the Returns without Documentation Process in Appendix 1.

6.1.1 Trade Operations (TO)/Customer Care (Canada) returns the product to an Amgen site without reference to an outbound shipment. The warehouse staff contacts

TO/Customer Care (Canada) to inquire if the product returned meets any open requests.

6.1.2 If no return order exists for the product, the warehouse staff creates a return delivery note without reference.

6.1.3 Facility staff receives the product into a return location.

6.2 Customer Product Return to an Amgen Site with Reference

The following steps refer to the Product Returns with Reference Process in Appendix 2.

6.2.1 TO receives a request to create a return order from a customer or facility staff with reference to a customer shipment.

6.2.2 Facility staff creates return delivery note for the return order. After the creation of the delivery note, the warehouse staff confirms that the batch and quantity in the delivery note matches the physical receipt.

6.2.3 If the batch and quantity of the physical return match the return delivery note, the facility staff receives the product into a return location.

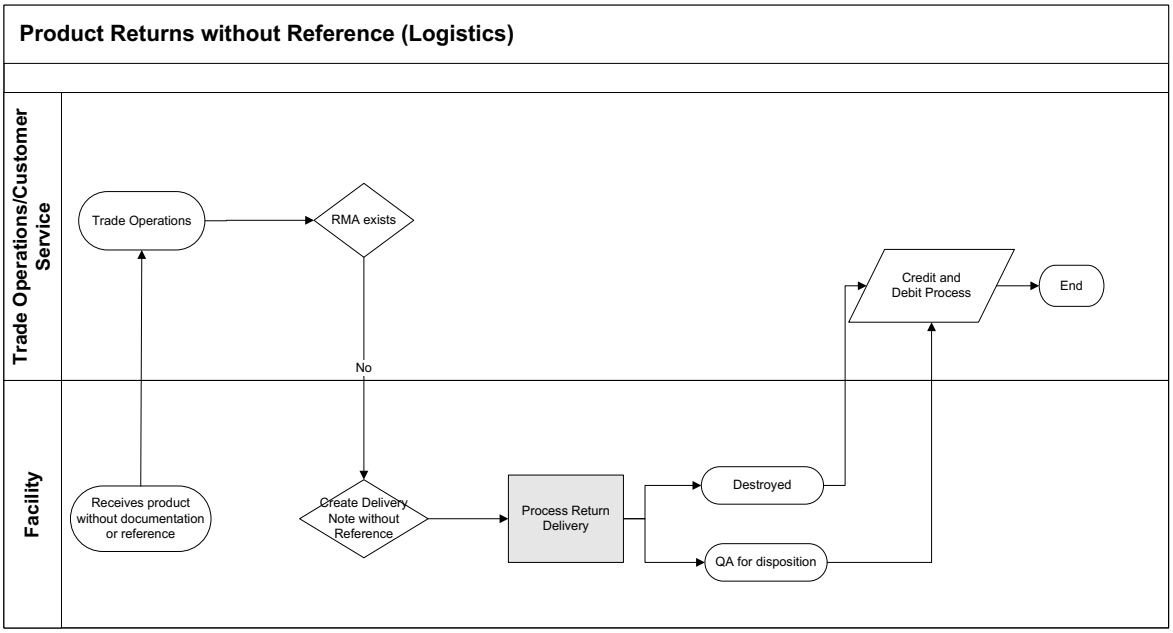
6.2.3.1 If the returned product quantity or batch does not match the delivery note, then the facility staff notifies TO of the discrepancy. TO corrects the return order and the warehouse staff creates a new delivery note. (Warehouse staff then follows from step 6.2.3)

6.2.3.2 After return delivery is confirmed, TO creates an RMA and starts the customer credit process.

6.3 Return Product Status

6.3.1 After a return delivery note is complete and post goods receipt occurs, the product is returned to either Quality Inspection or destruction status in the global ERP system.

Appendix 1
Product Returns without Documentation Process



Appendix 2

Product Returns with Reference Process