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#### 1.0 PURPOSE

The purpose of this standard operating procedure (SOP) is to describe the material maintenance process. Material maintenance describes which products can or cannot be sold to or shipped to specific customers based on the country, customer group, and order type. It also describes the process for substituting materials at the package or product level.

#### 2.0 SCOPE

This SOP applies to all Amgen products and customers.

# 3.0 ROLES AND RESPONSIBILITIES

Role	Responsibility
Trade Operations (TO)	<ul> <li>Creates material listing</li> <li>Changes material listing</li> <li>Displays material listing</li> </ul>
External Data Provider	Provides current and continually updated information regarding the Sanctioned Party List and embargo restrictions

#### 4.0 REFERENCES

This SOP refers to the current version of the following:

BP0066\_MDM Global ERP Master Data Management Business Practice Standard

#### 5.0 GENERAL

# 5.1 Important Concepts

Not applicable

#### 5.2 Definitions

Not applicable

#### 5.3 Abbreviations

Term	Definition
MDM	Material Data Management
NDC	National Drug Code
OTC	Order to Cash
QA	Quality assurance

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Term	Definition
Sanctioned Party List	An official list of individuals or organizations that are denied certain trade privileges or with whom trade is banned

# 5.4 Equipment

Not applicable

#### 5.5 Materials

Not applicable

# 5.6 Safety Precautions

Not applicable

#### 6.0 PROCEDURE

Refer to appendix 1 for the following procedure.

# 6.1 Inventory Management

Creates, changes, and displays material listing by the following categories:

- 6.1.1 Commercial Goods
- 6.1.2 Clinical Study
- 6.1.3 Geography
- 6.1.4 Miscellaneous Service

# 6.2 Customer Service

Substitutes materials by the following levels:

- 6.2.1 Pack level NDC
- 6.2.2 Product level NDC

Refer to appendix 2 for the following product substitution strategies procedure.

# 6.3 Quality Assurance

- 6.3.1 Receives new product/material
- 6.3.2 Studies logistics of the substitution
- 6.3.3 Forwards the information to Order to Cash (OTC) department

# 6.4 OTC (Logistics MDM)

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6.4.1	Creates the batch search strategy
6.4.2	Changes the batch search strategy
6.4.3	Displays the batch search strategy

Refer to appendix 3 for the following material listing exclusion procedure.

# 6.5 QA

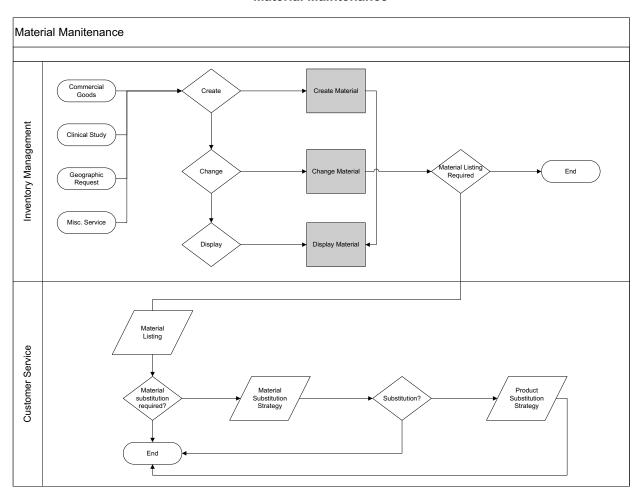
- 6.5.1 Receives the new item/material
- 6.5.2 Studies the logistics of the exclusion

# 6.6 OTC (Logistics MDM)

- 6.6.1 Creates the material listing/exclusion
- 6.6.2 Changes the material listing/exclusion
- 6.6.3 Displays the material listing/exclusion

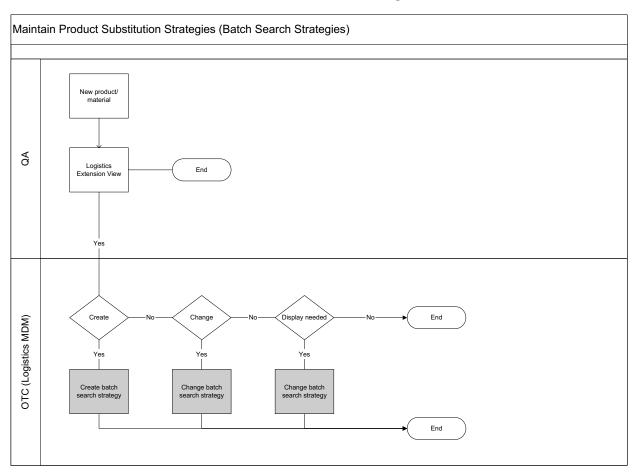
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Appendix 1
Material Maintenance



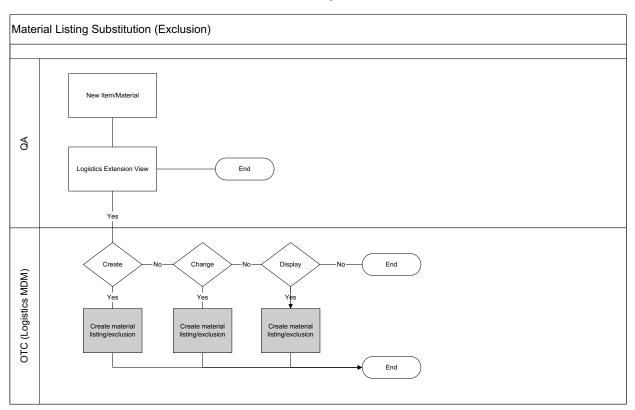
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# Appendix 2 Product Substitution Strategies



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# Appendix 3 Material Listing Exclusion



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# **DOCUMENT HISTORY**

Change	Justification
New	Required for NA go-live