

<b>AMGEN</b> <sup>®</sup>	Standard Operating Procedure	<b>DOCUMENT NO.</b> GP0095	
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<b>TITLE</b> Global Trade Services Master Data Maintenance and Product Classification			

## 1.0 PURPOSE

The purpose of this Global Standard Operating Procedure (GSOP) is to identify how Global Trade Services (GTS) Master Data is defined, maintained, and used.

## 2.0 SCOPE

This GSOP applies to all customers, products, raw materials, and vendors in all countries, to whom product is sold, or from whom product is purchased.

## 3.0 ROLES AND RESPONSIBILITIES

Role	Responsibility
Senior Manager Import/Export	<ul style="list-style-type: none"> <li>Ensures procedure is followed and staff receives training.</li> <li>Resolves GTS Master Data issues</li> </ul>
Corporate Transportation/Authorized GTS Users	<ul style="list-style-type: none"> <li>Creates, maintains and views GTS Master Data objects and attributes</li> <li>Notifies impacted workstreams of changes to GTS Master Data objects and attributes</li> </ul>
ERP Business COE (Master Data Management)	<ul style="list-style-type: none"> <li>Monitors change management processes for product related or regulated data elements through Change Control Management System (CCMS) workflow</li> </ul>
Basis Team	<ul style="list-style-type: none"> <li>Monitors external data systems</li> </ul>

## 4.0 REFERENCES

This SOP refers to the current version of the following:

GS066 Global ERP Master Data Management

## 5.0 GENERAL

### 5.1 Important Concepts

Corporate Transportation and authorized GTS users create, change, and display various categories of GTS Master Data within Product Master, Customer Master, Vendor Masters, Product Classifications, business partners, Sanctioned Party Lists, country information, licensing information, customs duty rates and tariff codes.

All changes to sanction party lists and embargo restriction lists are maintained in external systems and imported to the global ERP system on a regular basis. Changes to master data (MD) for customer, vendor, and product masters must be approved by the owner of the data prior to making the changes in the global ERP system. Changes to product classification, sanctioned party lists, country information, licensing information like Export Commodity Code Numbers

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(ECCNS) or Harmonized Tariff Schedules (i.e., customs duty rates and tariff codes) will be authorized by the Corporate Transportation prior to being entered.

GTS data is used to authorize or deny shipment or creation of orders or materials to specific countries, businesses, or individuals.

### **CCMS change type classification for GxP data elements**

Creation and maintenance of critical GxP Master Data object data fields that require change control are assigned a change classification rating based on a the level of review and approval required to authorize a change. A CCMS entry is initiated, based on field classification, the change request is routed through the appropriate approval process. Security roles mapping will ensure that access to views will be limited to designated data owner security roles. The change control classifications that are assigned to the critical master data represent the most common classification. However, each change should be evaluated per appropriate site change control procedure. Specific circumstances associated with a particular change may alter the change classification. Changes are classified based on the potential impact to the following:

- Product quality, identity, safety, purity, potency, and efficacy
- Regulatory filings, supplements, and amendments

### **CCMS Change Request Procedure**

For non-critical class one data changes, the end user does not require GxP approval. For class level two and above, a change request must be initiated in the CCMS workflow for approval.

## **5.2 Definitions**

Term	Definition
Export Commodity Code Number	A number that classifies the material and components of which a product is manufactured
Harmonized Tariff Schedule for the US	An organized listing of goods and their duty rates which is used as the basis for classifying imported products and identifying the rates of duty to be charged on them. It is based on the international Harmonized System Convention.
Critical Master Data	Master Data that requires GMP change control per appropriate site change control procedure based on compliance and or business critical impact
Non-critical Master Data	Master Data that does not require GMP change control per appropriate site change control procedure

## **5.3 Abbreviations**

Abbreviation	Definition
CCMS	Change Control Management System
ECCNS	Export Commodity Code Number
GTS	Global Trade Services

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Abbreviation	Definition
GxP	Indicates one of the following: GLP, GCP, GMP, GDP.
HTS	Harmonized Tariff Schedule for the US
MD	Master Data

#### 5.4 Equipment

Not Applicable

#### 5.5 Materials

Not Applicable

#### 5.6 Safety Precautions

Not Applicable

### 6.0 PROCEDURE

The following steps adhere to the GTS Master Data maintenance and product classification procedure in Appendix 1.

#### 6.1 Creation and maintenance of GTS data objects and attributes:

Corporate Transportation and authorized GTS users create, maintain, and view the following data objects and attributes in the ERP system:

- Product Master Product Classification
- Product Master Duty Rates
- Product Master Tariff Code Numbers
- Business Partner Master Data
- Sanction Party List Master Data
- Embargo Data Country Info
- License Maintenance Master Data


#### 6.2 GTS data object and attribute change notification

Corporate Transportation and/or authorized GTS users notify impacted workstream operations teams of proposed changes to shared Master Data objects or attributes.

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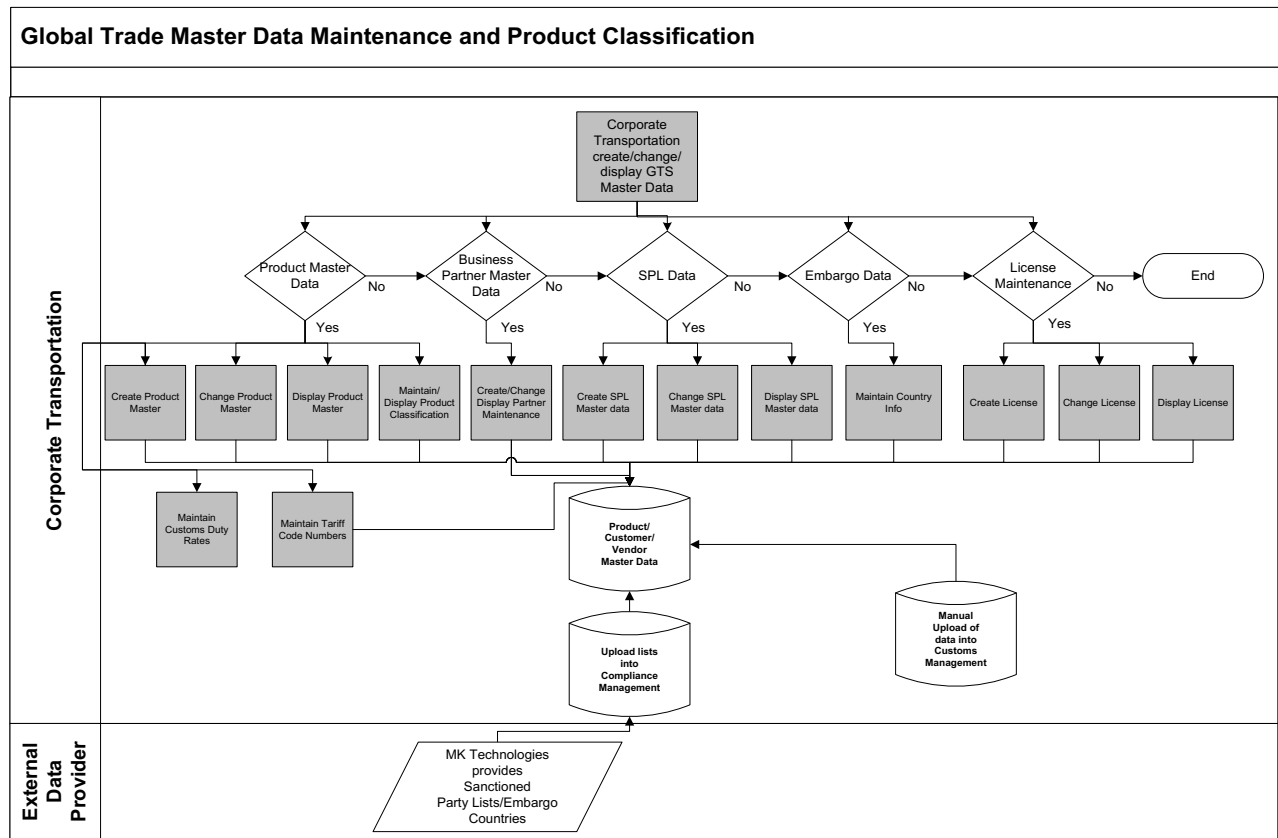
### 6.3 External Data System Monitoring

The Basis Team maintains and controls external data systems including error handling and transmission issues. The Basis Team notifies Corporate Transportation of system status as needed.

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## APPENDIX 1

### Global Trade Master Data Maintenance and Product Classification



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**DOCUMENT HISTORY**

Change	Justification
New	Required for ERP North America implementation