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Research Article

Understanding the Rules Determining Country-of-Origin for Pharmaceutical Products Along with a ERP Based Solution

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ABSTRACT

This article aims to understand the depths, complexities and some of the recent trends involved in the rules as stated and interpreted by various customs agencies around the world for determining the country-of-origin of finished/ semi-finished pharmaceutical products as they are traded across international borders multiple times on their journey to the patient. It is imperative for pharmaceutical manufacturers, distributors, freight forwarders and other supply chain stakeholders to understand and implement these rules in their business processes to be able present accurate information as expected by customs agencies around the world. The article also dives into a proposed Enterprise resource planning (ERP) based solution that may help a business automate the derivation of the country-of-origin based on historical transactions that may take place in the procurement, manufacturing and global trade business units.

Keywords: Active Pharmaceutical ingredient (API), ERP, country-of-origin, contract manufacturing organizations (CMOs), United States Customs and Border Protection (CBP), Food and Drug Administration (FDA)

1. Introduction

Global pharmaceutical supply chains are a complex ecosystem of suppliers, manufacturers, logistics partners, and distributors from many countries. In the modern pharmaceuticals supply chain, materials are sourced, processed and transformed in multiple countries using both domestic and foreign materials and equipment. The figure below captures a hypothetical high-level depiction of a typical end to end supply chain for a product whose components/raw materials/ intermediate products traverse through multiple countries throughout the manufacturing process.

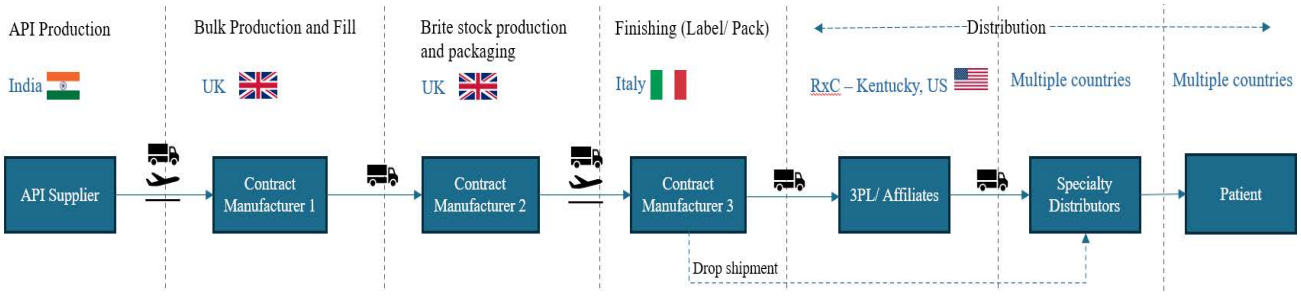

Figure 1: Simplified example of a global pharmaceutical supply chain.

The pharmaceutical product starts its journey as an Active Pharmaceutical Ingredient (API) which is the biologically active component mostly responsible for the intended therapeutic effect of the drug. Multiple countries have developed extensive manufacturing expertise and market share in this space led by India, China, Italy, South Korea and Germany amongst others. Through the process of Bulk production, APIs are formulated into the dosage form as intended for the drug such as oral solid doses, injectables etc. through often complex and specialized, environment-controlled processes by Bulk manufacturers. Due to reasons of cost, expertise, availability of labor, capacity and equipment amongst others, pharmaceuticals manufacturers must partner with multiple suppliers and contract manufacturing organizations (CMOs) across the world to optimize a product's supply chain. It is often uncommon for a single pharmaceutical manufacturer to have all the required expertise. Bulk material is then transformed into Brite Stock material which refer to pharmaceutical materials that have undergone primary packaging and exist in the forms of bottles, vials, blisters and pouches. The origins of this term belong to the food industry where filled and unlabeled canned products were stored in inventory for future labeling, final packaging and distribution. Brite Stock pharmaceutical material typically undergoes further packaging steps of labeling, printing, carton inserts, cartons and finally placed into an appropriate unit of measure such as cases, cartons, bundles or pallets [3] before being distributed as finished product to 3rd party logistics partners, affiliate organizations and specialty distributor on their way to patients located in different countries.

As can be seen, the interpretation of country-of-origin of a finished/ semi-finished product by a customs agency importing/ exporting the product can get highly complicated as it crosses multiple international borders along the way. Pharmaceutical manufacturers are scrutinized on the accuracy of country-of-origin on a product by various stakeholders involved at various milestones in the lifecycle of a finished/ semi-finished pharmaceutical product such as in the manufacturing process of labeling a product or during the commercial process of importing or exporting a product or selling it to the Federal Government in the US. Inaccurate representation of the country-of-origin on a customs invoice can lead to heavy civil or criminal penalties under the Trade Agreements Act (TAA) and False Claims Act (FCA) [1]. To cite an instance from recent years, a global medical devices manufacturers opted to an $8.3 million settlement to resolve a lawsuit alleging it violated the FCA when it improperly certified a certain batch of products as being of 'US origin' in process of selling them to the Department of Veterans' Affairs (VA) [2]

2. The rules for Country-of-Origin Analysis for Pharmaceuticals

The question of country-of-origin of a pharmaceutical product however has long been in contention. It is a complicated question, and the answer often depends on a myriad of factors including the customs agency in question. Regulatory agencies from different countries may employ different standards for country-of-origin, and hence the same product with the same supply chain nodes can often mean different country-of-origin for different agencies [1]. As per the 'VEIS and Intrastat traders' manual version 12' provided by the Revenue office of Irish Tax and customs department, 'Goods whose production involved more than one country shall be deemed to originate in the country where they underwent their last, substantial, economically justified processing resulting in the manufacture of a new product or representing an important stage of manufacture' [4]. In this context, the site of Bulk production site qualifies the last site of substantial transformation where API material is further processed with additional excipients and undergoes blending, granulation, compression, coating steps to produce a transformed Bulk product. In the hypothetical supply chain depicted above, the country-of-origin as interpreted by Irish customs would be UK.

However, the understanding and the precedence laid out by the United States Customs and Border Protection (CBP) and the Food and Drug Administration (FDA) is a bit more complex and looks a step deeper into the manufacturing process. As per the day-to-day historical business transactions performed by CBP, the agency determines that the process of Bulk manufacturing does not result in a substantial transformation of the API product, unless there is a specific change in the product's chemical composition [5]. Therefore, in such a scenario where the essential characteristics of the finished/ semi-finished batch emulate those of the API batch, CBP would consider the country-of-origin to be the site of API manufacturing i.e. India. However, a recent February 2020 ruling in Acetris Health, LLC v. United States by the U.S. Court of Appeals for the Federal Circuit (CAFC) creates a dichotomy by upholding a decision that the finished pharmaceutical product (tablets) procured by the VA is not "wholly the … manufacture" of India and is not "substantially transformed in India,". The court concluded that a U.S.-made end product may be maybe manufactured in the United States even though it may be comprised of foreign made components and that the source of the API was irrelevant when evaluating the country-of-origin for the purposes of the Federal Acquisition Regulations (FAR) and TAA. Even though a government request for a formal reconsideration of this decision is anticipated, it remains to be seen which direction is taken by the CBP towards the broad interpretation of the concept of 'substantially transformed' [6].

3. A proposed solution towards the derivation of country-of-origin from an ERP standpoint

Pharmaceutical manufacturing firms use a single or a combination of integrated, feature-rich and complex ERP systems to manage the day-to-day business operations of procurement, manufacturing, regulatory compliance management, supply/ demand planning and many more. Through standard, out-of-the-box features or through business specific enhancements, ERP systems can be setup to incorporate the aforementioned rules to derive various data attributes including country of origin of a material, or a batch of a material during the execution of a business process. The following text covers only one of the many ways in which an ERP system such as SAP can be setup to automatically derive the country of origin on a finished/semi-finished pharmaceutical product.

3.1. Proposed master data/ configuration setup

All finished/ semi-finished materials in the scope for country-of-origin determination require a flag for identifying if they are comprised of a Single or Multiple API materials. This identification flag may be built as a characteristic in the SAP material master classification data of the respective materials.

SAP Suite for Hana provides the ability to store the country of origin in a standard field in the material master international trade import or export views (table MARC, field HERKL). However, if the business is not using the functionality associated with these views, then a custom characteristic may be built in the classification data for the material master for API materials to hold the country-of-origin of the API material. This country will be the country of the approved supplier of the API material as noted in the product specification of the respective API. If the business requires multiple suppliers for the API product, then the placeholder for country-of-origin may be placed at the batch master level of the respective API batch procured. For the country-of-origin derivation logic to work, it is essential that this master data for API supplier countries exists in the system.

All batches of finished/ semi- finished materials may have two placeholders for country-of-origin – one for import/export from the United States (US COO), and another one for import/ export for Rest of the World (RoW COO). The standard field provided by SAP in the batch master for the purposes of country-of-origin (table LOBM, field HERKL) may be used as one placeholder while another custom field can be easily built as a placeholder into the batch master classification data.

3.2. Use cases and logic for derivation

Case 1: When the batch for which country-of-origin being derived is a finished good/ Brite material comprised of multiple API materials, the country-of-origin as inferred by customs agencies both for United States and Rest of the World is the same i.e. the country of Bulk production. The site of Bulk production, whether internal or CMO, is where the finished material last underwent 'substantiative transformation' and the respective country becomes the country of origin.

Case 2: When the batch for which country-of-origin is being derived is a finished good/ Brite material with a single API material in its genealogy, the country-of-origin as inferred by RoW customs agencies is the country of Bulk production as detailed in the previous case. However, US customs will go a step further in the manufacturing genealogy to look at the country of API manufacturing as the true country-of-origin. For this purpose, the system logic must drill down a step further into the finished/semi- finished batch genealogy to derive the respective API batch used in manufacturing. The procurement history of the API batch will provide the details of the approved supplier and its respective country.

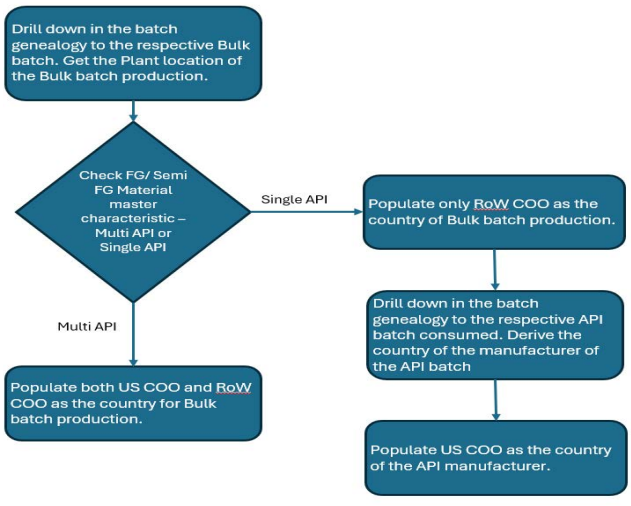

Figure 2: Logic for derivation of country-of-origin.

4. Post ERP implementation governance process

Any changes in qualified API suppliers and contract/ internal manufacturing sites for Drug product formulation require a change in product marking/labeling. Hence, it is recommended that there is a strong change management and communication protocol in place between various organizational units such as global trade and tax which are consumers of data pertaining to country-of-origin and other units such as procurement, supply planning, and manufacturing execution teams which have relevant transactional details to accurately validate the derived country-of-origin to prevent any fees and penalties associated with inaccurate country-of-origin on global trade documents/ reports such as customs invoice and Intrastat reports.

5. Conclusion

Although the country-of-origin associated pharmaceutical material/ batch may not be Good Manufacturing Practice (GMP) relevant data, it is very critical that manufacturers get it right lest they should risk paying heavy duties and fines to customs agencies. With modern pharmaceutical supply chains being increasingly complex with each supply chain node possibly located in a different country, manufacturers must keep a track of the rules of determination as defined by customs agencies around the world and establish development and governance processes to keep their ERP systems solutions abreast of these requirements. Appropriate logic must be developed in the ERP system to be able to print and report this data accurately to customs agencies.

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