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REVIEW ARTICLE

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A Deep Dive into Material Types used in the Pharmaceuticals Industry

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ABSTRACT

This research article aims to provide an overview of various materials and material groups that are employed in the manufacturing lifecycle of a pharmaceutical product. These groups may vary from raw materials, packaging material, active pharmaceutical ingredient and other intermediates that contribute towards the formulation of a finished drug. From a business perspective, such a classification of materials is necessary to simplify business processes such as inventory management and procurement as well as enabling effective decision making in supply/demand processes. The article also dives into how these materials can be classified and managed through standard, off-the-shelf solutions provided by a complex and feature-rich configurable Enterprise Resource Planning (ERP) system such as SAP.

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Introduction

The pharmaceutical manufacturing process is an intricate business process that employs a multitude of material types across various hierarchies to ensure the safety and efficacy of the final product. Appropriate classification of these materials in various groups allows the manufacturer to apply appropriate process control on materials with similar data attributes such as during procurement, inventory management, storage, supply or demand planning and distribution. It allows the business to effectively manage regulatory and compliance requirements for similar materials and maintain documentation and traceability.

Like most Enterprise Resource Planning (ERP) systems, SAP provides a way to systematically classify groups of materials that have identical attributes [1]. This allows a pharmaceuticals manufacturing organization to manage independent rules for various categories of materials that are a part of day-to-day business viz. finished goods, semi-finished goods, packaging materials and many more. This paper aims to dive deeper into some of the commonly used material types used in the pharmaceuticals manufacturing industry and to understand their purpose, behaviors and configuration options in an SAP system.

Materials Management in an SAP

In the extremely feature-rich ecosystem provided by SAP, materials and material types hold a very foundational place in the solution design for any business. Materials are the basis on which various other business processes rely for execution - sales to customers, finance to generate profit & loss statements, procurement to buy materials from suppliers amongst many others. From an ERP systems perspective, accuracy and completeness of materials data/ configuration enables downstream data and aforementioned processes. Multiple other data objects such as batches, inventory, purchase/sales orders, source lists, purchase information records, customer material information records etc. rely on material data as the foundation to build upon. Thus, it is imperative that there is a strong understanding of cross functional business processes in the scope of an SAP implementation project, and that understanding is accurately translated into data requirements for types of materials and their respective attributes.

To this end, the concept of SAP Material Type helps a business group together and manage materials with similar attributes. These groups of materials are highly dependent on the nature of business and can vary between industries and domains. The choice of material type for a material created in SAP can influence several things including:

- The specific purpose of the material, for example, a process material or a configurable material.
- Whether the control on the material number will be internal or external.
- Definition of the number range from which material number can be assigned.
- The views of material master and the data attributes within can be configured based on material type.
- Whether the material is valuated i.e. changes in value of a material are considered in financial accounting.
- The GL accounts changed by material movement across plants or warehouses.

As briefly stated before, the choice of a material type along with the underlying configuration for a material has a downstream

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impact on multiple business processes. For example, an indirect MRO material can be configured to not be sold to customers. Consequently, a bad assignment of a material type to a material can also have negative impact on business processes since it is not possible to overwrite the material type attribute in SAP once material is in use and has transactions posted against it. For example, if a finished good was wrongly assigned the material type for a raw material, business may not be able to use for the intended purposes of shipping it to customers for sales. Such a scenario may require a workaround to create an entirely new material (with the correct material type of a finished good) altogether resulting in inefficiencies across the supply chain processes of demand/supply planning, manufacturing, and sales. Hence, decision of material types to be used in SAP implementation project is a very high visibility activity during the design phase of the project.

Types of Materials used in Pharmaceuticals Manufacturing

The end-to-end pharmaceutical manufacturing process involves a complex series of steps to ensure the production of safe and effective drugs. An API material undergoes synthesis to yield the core therapeutic component and is combined with other excipients to create various dosage forms which is followed by other unit operations like granulation, compaction, coating, packaging etc. to ultimately formulate a finished drug product [3]. Below is a list of commonly used categories of materials employed in this process.

1. **Raw materials:** This category comprises of starting materials, reagents, solvents, auxiliary materials (e.g. chromatographic supports, drying agents, inert gases etc.), consumables (e.g. filters, filter media, bags, scoops, funnels etc.), excipients and other inactive ingredients, containers, and closures used in the manufacture and packaging of active pharmaceutical ingredients (APIs), API intermediates or drug products (DP), and formulated media used in the production of DP.

2. In-Process materials: As the name suggests, these products or substances are obtained at the intermediate stages of either APIs or DP manufacturing process. Some examples are

a. Spray dry dispersions (SDDs) for both clinical and commercial use and solid dispersion bulk powder (SDD Bulk powder).

b. Powder blend, wet granulation, bulk gels, compressions, coatings etc. which are employed prior to primary packaging of the product.

c. Partially synthesized clinical APIs and API Intermediates, in-process active or placebo clinical drug products

1. API/ drug substance is the biologically active component used in drugs which is directly linked to the intended outcome of the drug. These are typically complex chemical compounds that are either synthetic (also known as small molecules) or natural APIs used in making biologics [2].

2. Secondary and tertiary components are non-labeling components that are used in the formulation of a drug product but are present in relatively small quantities as compared to the primary (API) and secondary (fillers, binders, liquids etc.) components. These are generally not essential to the therapeutic action of the drug.

3. Bulk material includes all bulk tables/ liquids or capsules/ hydration bulk or generally any other form of solid/sterile dosage that is the result of a manufacturing process and has not undergone packaging processes. Also included is purified active biological bulk drug ingredient formulated with specific excipients, sterilized by filtration, and filled into appropriate containers.

4. Primary packaging materials are packaging materials that hold and come in direct contact with the drug material. These can include vials, bottles, blister packs, syringes, sachets etc. depending on the type of drug.

5. Brite stock essentially refers to filled, unlabeled products that have undergone primary packaging processes i.e. it is held in its appropriate primary container/ closure system (primary packaging) and stored in inventory for future secondary packaging processes. Keeping Brite stock inventory on hand enables better utilization of primary and secondary packaging equipment as well as increased availability of the product [4].

6. Secondary packaging refers to the packaging material in which primary packed material resides. Examples include labels, cartons, packaging inserts etc.

7. Shipper materials are used to transport bulk pharmaceutical products between sites or to customers. This can include containers such as plastic lined fiber drums, bulk boxes, corrugated boxes with liners, air pillows, insulated foam coolers, absorbents etc.

8. Finished goods are fully packaged and labeled products that can be sold to a customer. It usually has demarcation based on product name, dosage form, dosage strength and unit, count/ fill size etc. and is usually restricted to being sold in certain markets only due to regulatory and compliance requirements. Finished products can also belong to the clinical research stage which are essentially packaged labeled drug products or assembled patient kits. These are also known as investigational medicine products (IMPs). Other examples of this kind include packaged or labeled active and placebo drug products or commercial comparator products sourced for clinical supplies.

9. Any other non-valuated items which are expensed at receipt but are inventory tracked

10. Medical devices may be required as a category even for pharmaceutical manufacturers who do not manufacture any traditional medical devices. There may be other devices in this category that accompany the drug product e.g. plunger, syringe/ prefilled syringe, nebulizer etc.

11. Service materials may be required by business to represent unique services that are procured to support manufacturing, packaging, testing of APIs/ drug products or intermediates. These are non-physical materials.

Standard Material Types offered by SAP S/4 HANA

To encapsulate the requirements for the various kinds of materials described in the previous section, SAP offers the below Material Types with multiple configuration options.

1. Material type FERT is used to classify finished goods ready

for sale or distribution, manage inventory, plan manufacturing, or run supply/demand heuristics on. The standard configuration of this material type is done with the understanding that they are produced in-house and cannot be purchased [5]. However, if the manufacturing firm is working with contract manufacturing organizations (CMO), then finished goods might need to be setup for a subcontracting purchase.

2. Material type HALB is used to generally categorize semi-finished products i.e. products that are currently in intermediate stages of production and are expected to be a part of an assembly/ bill of materials on their way towards a finished product. In general, materials in this category might not be setup for sales but exceptions can be made based on business scenarios.
3. ROH is the material type for raw materials which are usually purchased from qualified suppliers. These materials are fed into the manufacturing process to fabricate a finished product. It is highly unlikely that a raw material is sold, hence the standard material type configuration aligns with that.
4. VERP material type is used to capture various packaging (both primary and secondary packaging) and shipper materials.
5. Material type DIEN is provided to categorize services that can be procured both internally and externally [5]. These are non-physical goods that cannot be tracked through inventory but only through a financial price/value associated with them. Managing these materials involves creating purchase orders, receipt of services, , quality check on the services received and invoice management and closure with the supplier.
6. SAP material type NLAG is used to manage non-stock materials i.e. materials that are not managed on an inventory basis even though they are physically stored materials. Pharmaceutical manufacturers may choose to classify consumable materials such as filters, cleaning chemicals, steriles, tubings, gloves, films etc. that are usually employee in the manufacturing process. Inventory management is not activated for these materials either on a cost or value basis.

Mapping of Pharmaceutical Material Types vs Standard SAP Material Types

Following is a proposed mapping of how a project implementation team might look to line up materials required in day-to-day business transactions against standard material types offered out-of-the-box by SAP.

S. no.	Type of Pharmaceutical Material	Proposed SAP Material type
1	Raw materials	ROH
2	In process materials	HALB
3	API	Either HALB or ROH depending on whether it is internally manufactured or procured externally
4	Secondary/ tertiary components	NLAG/ ROH depending on the value of the product
5	Bulk	HALB
6	Primary/ secondary packaging materials	VERP
7	Shipper materials	VERP
8	Brite stock	HALB
9	Finished goods	FERT
10	Non-valuated materials	NLAG
11	Medical devices	Since these are used in the manufacture of a finished product, it can be categorized in either ROH or HALB.
12	Service materials	DIEN

It should be noted that each organization tends to have very specific requirements on material management and material types. The above table is only a proposed, high-level guide. Specific business scenarios must be probed in great detail during focused design workshops held as a part of the SAP implementation project's design/ requirements gather phase before finalizing any such mapping.

Conclusion

The complexity of the pharmaceutical manufacturing business gives rise to a number of material types that are required for successful synthesis of a finished drug. A highly configurable and flexible ERP system such as SAP is able to address specific requirements for each of these material types through standard material types that are pre-configured in the system. However, each organization has its own nuances of day-to-day transactions and the SAP implementation team, which is ideally a combination of business and SAP experts, should make further adjustments to standard configuration after deeper discussions on specific business scenarios.

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