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SAP Segmentation for Pharmaceutical Manufacturing: A Solution for Regulatory Compliance and Supply Chain Efficiency

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Abstract: ***Pharmaceutical manufacturing, with its unique compliance requirements and highly regulated environments, faces significant challenges for global distribution. Varying regulations related to ingredients, production sites, and packaging create hurdles that can complicate planning and inventory management. SAP Segmentation functionality offers an efficient solution to these challenges, enabling the alignment of supply chain operations with regulatory needs. This research paper explores the SAP Segmentation functionality in the context of a global pharmaceutical manufacturing firm, outlining its implementation, advantages, and the potential for optimization within the pharmaceutical supply chain. Drawing on industry insights and real-world examples, this paper details how SAP Segmentation can resolve the operational inefficiencies of manual planning and regulatory mismatch.***

Keywords: SAP, Segmentation, Pharmaceutical Manufacturing, API

1. Introduction

In the global pharmaceutical industry, manufacturers face the dual challenge of producing high-efficacy medications while complying with diverse regulatory standards across multiple markets. Each country that a pharmaceutical manufacturer distributes to has its own set of requirements across supply chain aspects such as the sourcing locations of active pharmaceutical ingredients (APIs), the manufacturing process, and the packaging of finished goods. Failure to meet these standards can result in stockouts in key markets, excess inventory, or even non-compliance penalties. Traditional planning methods, such as lot-by-lot or attribute-based planning, often fall short of managing this complexity effectively.

SAP Segmentation provides a structured and automated approach to align inventory with market-specific regulations. In this paper, we will explore the challenges of segmentation in pharmaceutical supply chains, the limitations of traditional planning methods, and how SAP Segmentation, combined with tools like SAP S/4HANA, can revolutionize compliance-driven planning and improve overall business efficiency.

Overview of Segmentation Challenges in the Pharmaceutical Industry

The pharmaceutical industry is heavily regulated, with strict requirements governing everything from API sourcing to bulk/brite production and distribution. These regulations often differ from market to market, which further exacerbates supply chain challenges for pharmaceutical companies operating on a global scale. For instance, a single medication might be approved in one country only if it is sourced from a specific API manufacturer, while another country might require the product to be packaged at a local facility. Managing such nuances manually not only increases the likelihood of errors but also strains operational efficiency and results in mismatches between available stock and regulatory requirements. Thus, one of the primary challenges for the industry players is the need to separate stock based on specific attributes. This level of segmentation is essential because different markets often have strict regulations that require specific compliance standards for each of these attributes. Failing to meet these regulations can result in significant delays, stockouts, or regulatory penalties.

Additionally, pharmaceutical companies must segment customer demand based on market-specific attributes. Markets may require products that meet distinct regulatory conditions, such as sourcing from approved vendors, compliance with local production regulations, or specific quality standards like potency. This requires a detailed approach to managing and categorizing demand to ensure the right products are available for each market. Aligning these requirements with supply chain processes is a significant challenge without the proper segmentation tools in place. Moreover, businesses must drive their supply chain based on an optimal matching logic between demand and supply attributes. This means ensuring that available stock—classified by regulatory requirements, production sites, and ingredient sources—matches market demand without error. Balancing these variables manually by supply/ demand planners is not only time-consuming but also prone to mistakes, leading to inefficiencies and compliance risks. The challenge is further amplified by the need to fulfill customer demand in compliance with demand and supply attribute matching requirements, which involves aligning each order with the correct product segment to meet both customer expectations and regulatory conditions [1].

Another significant challenge is the need to execute the supply chain at all levels—execution, tactical, and strategic—based on optimal demand and supply matching. At the execution level, this means ensuring that the right stock is picked and shipped based on segmentation characteristics. At the tactical level, it involves planning production runs that meet segmented demand, ensuring regulatory compliance while optimizing resource usage. Strategically, pharmaceutical companies must plan for the long term, forecasting demand based on market segmentation and aligning supply strategies to meet these expectations efficiently.

The pharmaceutical industry's reliance on lot-by-lot and attribute-based planning highlights the inefficiencies of manual interventions. Attribute-based planning involves tagging products with characteristics, such as batch number, manufacturing site, or API source. While this may seem logical at first, this technique creates manual dependency on planners who must manually reconcile lots with market-specific regulations. Planners often rely on Excel sheets for offline planning, bypassing system algorithms, and creating disconnected processes. This manual approach is highly prone to errors and consumes valuable planning time, leading to unreliable plans. Moreover, attribute-based planning ignores the system's ability to optimize automatically, leading to stock imbalances. For example, stockouts may occur tightly regulated markets because lots suitable for that market are inadvertently sent to less regulated markets. This further burdens the supply chain, as excess inventory accumulates in markets with looser regulations. Traditional planning systems struggle with ensuring regulatory compliance while maintaining operational efficiency. This is where SAP Segmentation's role becomes crucial.

Aspects of SAP Segmentation Tailored to the Pharmaceutical Industry

The implementation of SAP Segmentation in the pharmaceutical industry requires careful configuration of segmentation structures, strategies, and master data to ensure that product lots meet regulatory compliance across different global markets. SAP Segmentation enables firms to automate compliance management, inventory allocation, and production planning, making it a vital tool for optimizing the pharmaceutical supply chain.

In the context of SAP segmentation for pharmaceutical manufacturing, the first step is to define segmentation characteristics. These characteristics are the specific attributes that will differentiate and classify materials. In a pharmaceutical scenario, characteristics may include factors like the source of the active pharmaceutical ingredient (API), the quality grade, production site, or even the packaging facility. Each characteristic helps define how materials will be managed and tracked throughout the supply chain to meet regulatory or market-specific requirements.

Next, a segmentation structure is established by grouping these characteristics together. This structure forms the framework through which the materials are categorized. For example, a segmentation structure in pharmaceutical manufacturing could combine attributes such as API, API supplier, and manufacturing/primary packaging/ secondary packaging site codes. The structure allows the system to treat each unique combination of characteristics as a distinct segment. This ensures that materials are tracked and managed according to specific regulatory standards.

Once the segmentation structure is in place, the segmentation strategy is defined. The segmentation strategy outlines how customer demands (requirement segments) are matched to the appropriate stock (stock segments). This strategy governs how inventory is allocated based on regulatory needs and market demand. For instance, if a specific region only accepts products manufactured with APIs from certain approved sources, the segmentation strategy will ensure that only compliant inventory is allocated to that region's orders. By automating the matching of customer demand to available inventory, the segmentation strategy simplifies planning and execution, ensuring compliance and improving operational efficiency [3].

SAP Segmentation is very cross functional cutting across various standard SAP functionalities and modules spanning the entire supply chain from procurement to production, distribution, and financial management. Within the Material Master module, segmentation enables the detailed classification of pharmaceutical materials at all stages of production such as bulk, brite or finished products. In the area of Materials Management, pharmaceutical companies can control the procurement, and transfers of materials based on segmented requirements that align with specific market or regulatory standards, ensuring that the sourced or transferred materials meet the quality or compliance needs of the destination market. SAP allows for segment-level control in purchase requisitions, purchase orders, and goods receipts, ensuring that only compliant materials are brought into the procurement process. In the Sales and Distribution module, segmentation can be leveraged to manage customer requirements at the sales order level which can be aligned with specific business- defined segments, ensuring that products with the correct API source, production site, or packaging type are allocated to meet customer demand. This ensures timely and accurate fulfillment of orders while maintaining compliance with regional regulations, improving customer satisfaction and reducing the risk of non-compliance. In the Production Planning module, segmentation ensures that production orders for finished goods, for example, consume the correctly segmented britestock or bulk batches. This ensures that goods produced meet the regulatory needs of each market segment [2].

This approach to segmentation within SAP helps pharmaceutical companies manage their supply chains more effectively, ensuring that only compliant products reach their intended markets while reducing the complexity of inventory management.

Pharmaceutical Business Scenarios in SAP Segmentation

In practice, SAP Segmentation can be applied to a variety of business scenarios in the pharmaceutical industry. One common scenario involves managing stock for multi-market distribution, where products are produced at different manufacturing sites during various stages of production and need to meet the regulatory requirements of various markets. Using SAP Segmentation, manufacturers can configure the system to match stock with the correct market based on regulatory compliance. If a finished product is primary or secondary packaged at multiple locations, SAP Segmentation ensures that only stock produced at approved sites is available for sale in markets with stringent regulations. This reduces the risk of stockouts in key markets while preventing the buildup of non-compliant stock in other regions.

In another scenario, SAP Segmentation can be used to manage API sourcing for different markets. For instance, if one market requires a local API source, the system can be configured to ensure that only lots produced with the locally sourced API are available for sale in that market. This

improves supply chain efficiency and ensures compliance with local regulations.

By integrating segmentation strategies with production planning, sales orders, and stock transport orders, pharmaceutical manufacturers can ensure that their supply chain is optimized for compliance and efficiency. The system automatically adjusts production and distribution processes based on segmentation rules, reducing manual effort and improving overall supply chain performance.

Business Benefits

The incorporation of SAP Segmentation into a pharmaceutical organization's systems landscape delivers substantial business benefits across the entire supply chain, from planning to execution and distribution. Segmentation enables the business to streamline operations, reduce complexity, and enhance regulatory compliance, which are critical in an industry driven by stringent market requirements. One of the most significant benefits is the ability to segment customer demand based on regulatory requirements. This capability allows pharmaceutical companies to match customer demand to the right stock segments, ensuring that only products compliant with the relevant market regulations are allocated to each customer. For instance, markets with specific API sourcing regulations can be matched to compliant lots, reducing the risk of non-compliance. By automatically categorizing stock, SAP Segmentation eliminates the need for manual interventions in the allocation process, significantly improving the accuracy and efficiency of inventory distribution. Another notable advantage is the reduction in the number of material codes required. Previously, companies might have created different material codes to account for various regulatory, manufacturing, and packaging differences across markets. However, SAP Segmentation allows for these variations to be handled at the segmentation level, drastically reducing the need for multiple material codes. This simplification of material master data translates into fewer master data variants to manage, reducing the complexity of manufacturing and streamlining production processes. As a result, companies can focus on improving operational efficiency without needing to juggle multiple material codes for the same product. SAP Segmentation also leads to reduction or complete elimination of manual batch determination effort. In traditional systems, the warehouse picking team would have to manually determine which batch to ship based on characteristics such as the API ingredient used, the site of bulk manufacturing, and regulatory approvals. This manual effort was both time-consuming and prone to errors, increasing the risk of incorrect shipments. With SAP Segmentation, batch characteristics are automatically determined based on the batch master's stock segment, allowing the system to match the right batch to the corresponding order seamlessly. This automation reduces the workload on the warehouse team and ensures that the correct batch is shipped every time, enhancing overall accuracy and efficiency.

Thus, it is evident that the segmentation solution leads to overall reduction in supply chain planning complexity. By leveraging ERP segmentation-based planning, companies can rely on the system to forecast demand and plan inventory based on business defined segmentation attributes. This reduces the effort required by supply chain planners to manually forecast for different market needs, freeing up resources for more strategic decision-making. The system's ability to handle multiple segmented planning strategies ensures that the right stock is produced and allocated based on demand forecasts for each region, reducing the risk of stockouts or excess inventory in markets with regulatory restrictions.

2. Conclusion

SAP Segmentation offers a robust and effective solution for addressing the unique and complex challenges of pharmaceutical manufacturing and distribution. By seamlessly integrating across various SAP modules, segmentation enables pharmaceutical companies to manage compliance, streamline operations, and enhance the accuracy of inventory and supply chain processes. Through precise classification of materials, automated allocation of stock to meet regulatory and market-specific requirements, and optimized planning and production strategies, SAP Segmentation helps reduce manual interventions, improve regulatory compliance, and increase operational efficiency. As the pharmaceutical industry continues to evolve and face new regulatory and operational challenges, the implementation of SAP Segmentation stands as a key strategy for ensuring sustainable, compliant, and efficient global operations.

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