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Pharmaceutical drug launch and its readiness in enterprise systems

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Abstract: ***This paper makes an honest attempt to describe the process of drug launching and information system and infrastructure readiness after FDA approval. The drug development process is critical because it contains information needed to launch a drug in the market properly [1]. During the drug development process, the company and its researchers already have in mind the drug's target customers. Having a persona for the potential customers will help the marketing team design advertisements and campaigns after the drug has been successfully formulated and approved by the Food and Drug Agency or FDA. New technologies and accurate clinical trial results are making drug development process more efficient and higher chance of approval. There are multiple IT applications involved in every stage of product development which carries their specific functionalities. These systems should be connected to each other for data processing, validations, and result analysis. Some systems functions at site level for data recording, activities and others are at corporate level for drug reports and analytics.***

Objective: This study intends to empirically describe the process of pharmaceutical drug launch and its readiness in enterprise systems.

Keywords: Enterprise system, pharmaceutical drugs, clinical trial, SAP, ERP, Cloud system.

I. INTRODUCTION

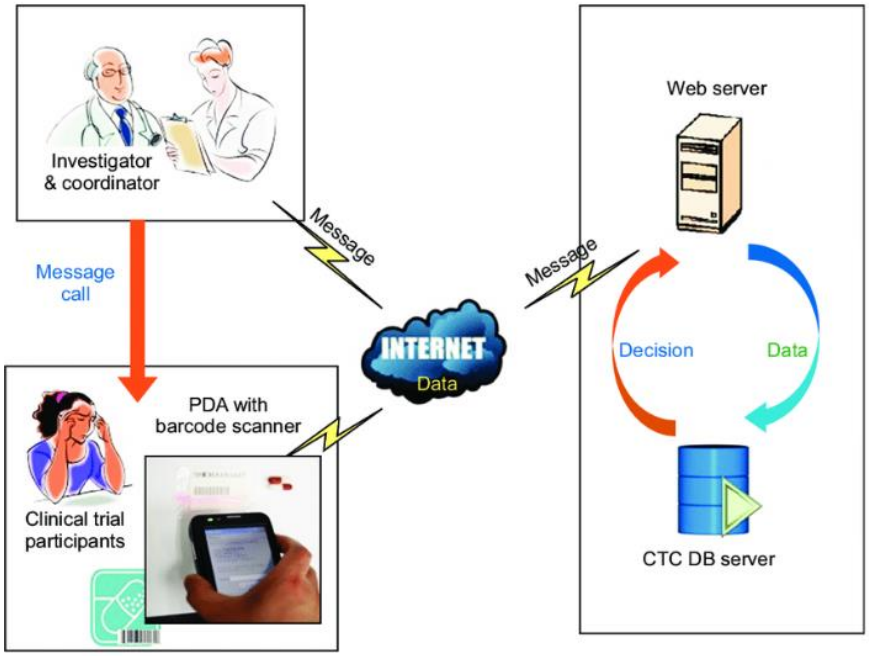
Drug development is a complex and lengthy process which involve multiple stage wise activities. Each stages requires certain validations and needs to adhere FDA compliances and GxP standards.

GxP compliance is an essential component within the life science industries created to ensure that food, medical devices, drugs and other life science products are safe and effective. These companies use numerous enterprise systems based on need, ease of use and compliance reasons. In order to ensure seamless supply chain of the new drug being launched, it need to be available in the production environment of these systems and the business and IT team get together to run business processes associated to the new drug.

II. CLINICAL TRIALS

Clinical trials are done to gather information regarding the effectiveness and safety of new drugs and medical devices. There are various stages and steps of clinical trials in the drug development process. There are many reasons why clinical trials need to be performed and managed. In one way, it's necessary to make sure the new drug works before using it on a large scale. The clinical trials stage is also the most expensive. Many companies have used clinical trials phase as an opportunity to begin introducing a new drug to the masses. Some companies have transformed clinical trials experience by providing necessary information to the participants and the public regarding the drug and what it can do to help people.

A Clinical Trial Application provides comprehensive information about the investigational medicinal product(s) and planned trial, enabling regulatory authorities to assess the acceptability of conducting the study. Health authorities' assessment covers the investigational medicinal product properties, the benefit/risk ratio of the study, the quality of the information provided to the trial subjects, and the suitability of the clinical sites and investigators. Information technology (IT) platforms have been applied to the implementation and conduct of clinical trials to improve efficiencies in several medical fields, and these platforms have recently been introduced [3]



III. Drug Manufacturing and Marketing Strategy

- **Marketing – Salesforce**

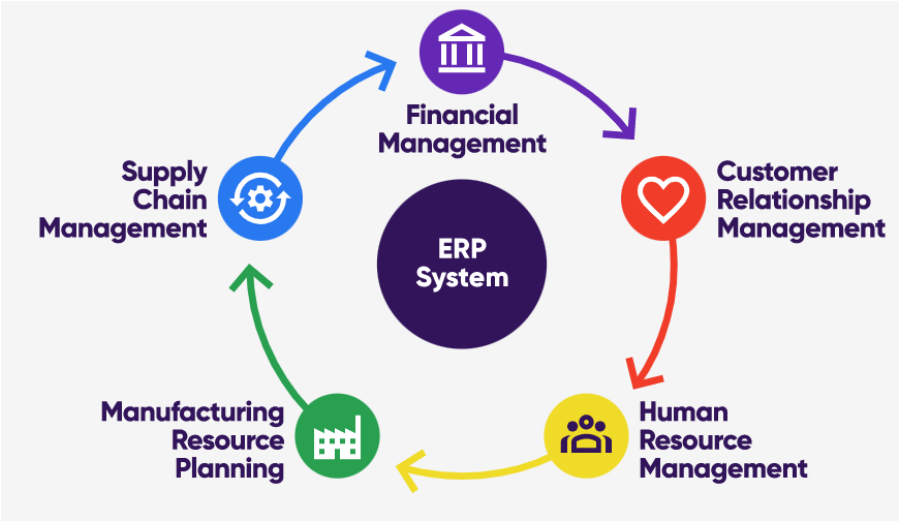
  After getting approval from the FDA, marketing and advertising of the new drug is the next essential step in its launch. The marketing team can generate strategies on how to introduce the product to the market and reach its target customers from the data gathered from the product development and clinical trials. Launching a new drug is almost the same as launching a new product in different media, like television and the Internet. Pharmaceutical companies also use various advertising and marketing methods, like building a website and sharing information through social media channels. Pharmaceutical companies use marketing solutions such as Veeva Salesforce for distributing Samples to Doctors, Hospitals and pharmacists.

- **Sales support strategy - SAP Hybris**

  For launching drug in the market, organizations make effective strategy to promote drug among pharmacies, doctors, and healthcare professionals. SAP Hybris is a digital commerce platform enables pharmaceutical industry to sell products, solutions, and services digitally – either through a typical online store or other digitally connected devices, such as mobile phones, online pharmacy, connected cloud systems, and IoT devices. It also allows pharma industry to include their physical stores in digital commerce strategy, especially for Omni channel fulfilment scenarios.

- **Setup Enterprise Resource Planning System - SAP S/4 HANA**

After Drug approval from FDA, Business makes strategy to forecast product expansion and manufacturing at enterprise level. S/4HANA is a future-proof and stable enterprise resource planning (ERP) system from SAP. Like all ERP platforms, it unites all pharma industry's business data in one place and accelerates pharmaceuticals business processes. SAP's latest S/4 Hana platform raises the standard benefits of ERP to a new level. With the addition of artificial intelligence (AI) such as machine learning (ML) and advanced analytics, S/4HANA can discover insights, identify trends, make predictions, and therefore help with data-driven decisions and business transformation for drug launching. [4] The result is a platform that allows pharma industry to easily manage large data sets, connect to new technologies and has an intuitive interface, paving the way for Pharmaceutical practices.



- **Data reporting and analytics**

During drug development, all clinical trial data for further product development and improvement is required. Sometime data structure become complex and enormous size. With the SAP Analytics Cloud solution, pharmaceutical companies can bring together analytics and planning with unique integration to SAP applications and smooth access to heterogenous data sources. As the analytics and planning solution within SAP Business Technology Platform, SAP Analytics Cloud supports trusted insights and integrated planning processes enterprise-wide to help pharmaceutical industry to make decisions.

- **Setup Warehouse Management System**

  Based on the drug type, required storage criteria and geographical locations, pharma industry creates drug storage and logistics plan. SAP EWM (Extended Warehouse Management) is a best-of-breed and best-in-class Warehouse Management System (WMS) product by SAP. This WMS product has the strong pedigree of its parent, it offers a great potential for life science and pharmaceutical companies to leverage upon inherently strong WMS capabilities to meet the process and functional requirements.

- **Compliance and Customs Application – GTS**

  Drug distribution is another main task for pharmaceutical industry. Selling and distribution required pharma industry to adhere compliance and regulation. SAP GTS helps pharma industry to efficiently manage its foreign trade processes and assert in the global competition. The solution ensures that pharma industry comply with legal requirements, facilitating smooth customs and foreign trade management, including electronic communication with the customs authorities. It reduces financial risks and reliably ensures that pharma industry always benefit from any privileges and discounts available in foreign trade. SAP GTS Compliance Management helps pharma industry to monitor all processes related to the import and export of goods. In doing so, full compliance with legal regulations along the entire process chain can be achieved. Boycott list check, embargo check as well as import and export control are of central importance in this context. Checking and screening processes can be seamlessly integrated in existing systems, helping to minimize risk, penalties, and fines. An automatic check of state embargoes is performed for incoming and outgoing goods. The system also enables the determination and application of the required approval regarding the dual-use regulation, licensing, and other compliances.

- **Data warehousing system for mid to senior level reporting**

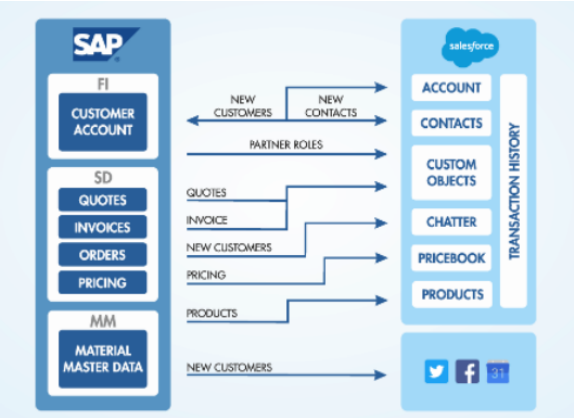
  After drug approval, all clinical trial data for further product development and improvement is required. Sometime data structure become complex and enormous size. With the SAP Analytics Cloud solution, pharma industry can bring together analytics and planning with unique integration to SAP applications and smooth access to heterogenous data sources. As the analytics and planning solution within SAP Business Technology Platform, SAP Analytics Cloud supports trusted insights and integrated planning processes enterprise-wide to help pharma industry make decisions. Pharma industry uses SAP Data Warehouse Cloud system for all data warehousing use cases. This SaaS (Software-as-a-Service) is based on SAP HANA Cloud. It combines data, and analytics in a cloud solution that offers data integration, database, data warehouse, and analytics services. This enables customers to realize the full potential of a data-driven business. To improve the integration with SAP ERP systems, the SAP BW bridge enables ABAP-based data extraction and staging capabilities within SAP Data Warehouse Cloud Within SAP BW bridge, customers can implement data extraction and staging scenarios up to the Composite Provider level. In other words, it is not possible to create new queries within the SAP BW bridge environment. In this regard, within the SAP BW bridge, there is no support for OLAP engine, and functionality dependent on OLAP (e.g., analysis authorizations, query as info provider, query execution). Front-End tools do not have the possibility to access SAP BW bridge artefacts directly.

- **Master data Management**

  Master data is the core data of pharmaceutical industry that exists independently of specific business transactions and is referenced in other business processes. It builds the foundation for the smooth execution of business processes and well-informed business decisions. Master data represents business objects rather than

business transactions and is rarely changed over a long period of time. The following objects are among pharma industries most important master data objects:

- Product
- Customer
- Supplier
- Employee
- Product recipes
- Price masters
- Relevant taxes
- Discounts/Rebates for trade promotions



IV. CUSTOMER SUPPORT

Good customer support or customer service system is critical in a product and a pharmaceutical company's success. [2] As much as it's true that technology drives the industry, it also makes sense that customers' support is equally essential for a company's survival and a successful product launch. The final process of launching a new drug is providing a broader array of information sources found online. These information sources are different from the ads people see on television or the Internet. More physicians tend to recommend a drug to their patients, not only because of its efficacy, but also based on overall customer experience with the brand. To effectively launch a drug, companies must be able to provide answers to medical questions. They should also be able to identify patients and connecting physicians with other doctors in the field.

SAP's experience management products can enhance every aspect of pharma business, from Sales to Marketing, Commerce, Customer Data, and Service. These cloud applications can be deployed individually or in combination. [5]

V. CONCLUSION

Pharmaceutical marketing is critical in launching a new drug in the market. To understand the entire process of launching a new product in the pharmaceutical industry, pharma industry needs to start at the very beginning—from the drug development until the customer support. Understanding the different processes will help pharma industry create better strategies to market their drug and introduce it to the market. There are increasing number and variety of IT platforms were available to assist in the planning and conduct of clinical trials. Product launching required many legal formalities and trade approvals including submission of GMP inspections reports and creating Standard operating procedures (SOP's) for manufacturing processes. Once Compliance related regulatory work completed and required applications submitted for product labeling, business setup organization structure in their enterprise structure. Based on product type, geographic location, marketing strategy and regulatory requirements, business decide new organizational structure which include creating new financial reporting unit, sales unit, manufacturing unit, warehouse, and distribution models. Business also strategies if product must manufacture internally entirely or manufactured by contract manufacturing unit. Procuring raw material, API and packaging material are decide based on batch quantities as per production schedules. Once all setup is done then business create pilot project to validate production capacity and manufacture sample size batch. In this pilot project multiple teams involve performing their department specific functions. Multiple documents created including installation qualifications, operational qualification, and performance qualifications. These protocols are necessary to test business requirements against configurations and scenarios developments. Multiple regression, stress and performance testing needs to perform to validation functions of different departments. Once test completed, documented, and approved by business, master data and cutover strategy must execute for uploading data into production environment. Production environment readiness will be completed once cutover and master data activities completed and release for business use.

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