

Prescription for success

An EDW remedies headaches in the pharmaceutical industry. *by Lisa Campbell*

Massive changes in the pharmaceutical industry over the past decade have presented myriad challenges to industry executives. Competing demands of providers, payers, consumers and regulatory agencies such as the U.S. Food and Drug Administration (FDA) are causing pain points for pharmaceutical companies. These companies also face fierce competition and an explosion of generic options, which conspire to close the door on years of strong profits.

However, a remedy is available: An enterprise data warehouse (EDW) offers a solution designed to enable these enterprises to easily obtain relevant, accurate and up-to-date information about prescribers, managed care organizations, wholesalers, distributors and consumers.

Physicians' needs

To stay competitive in the industry, a pharmaceutical company must keep its physician customers informed about its drugs and actively motivate them to prescribe those drugs to their patients. This type of interaction demands that the companies' sales representatives are armed with a 360-degree view of physicians' needs and interests. They must know the types of drugs the physicians regularly prescribe—both their company's drugs and those of its competitors—and the types of drugs the physicians might need in the future.

Information about the hospitals the physicians are affiliated with and their patients would benefit a pharmaceutical



company as well. With this in hand, the company can tailor its research and development strategy and its marketing focus to the individual physicians.

The EDW is an important tool that enables a company to capture such information gleaned through interaction with sales representatives, inquiries to the company's call center, participation in company-sponsored clinical studies and activity on company Web sites, to name a few. When disparate data sources are combined into an EDW, all interactions with the company can be easily and efficiently sorted, forming a single view of the physician customers or prospects.

As a result, appropriate messages can be delivered to the right physicians at the right frequency via the right medium.

FDA regulations

In the United States, pharmaceutical firms must meet record-keeping regulations set by the FDA. Known as 21 CFR Part 11, these rigorous requirements govern the use of IT in biopharmaceutical, research and manufacturing operations.

Part 11 requires drug makers, biotech companies, biologics developers, medical device manufacturers and other FDA-regulated industries to implement controls

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for software and systems involved in processing many forms of data as part of business operations and product development. These controls include audits, validation systems, electronic signatures and documentation. A similar regulation exists for pharmaceutical firms in Europe, called the European Annex 11 of the EU Guide.

As a scalable, easy-to-manage relational database management system, an EDW can assist a pharmaceutical company by housing all of its data related to Part 11 or the European Annex 11 regulations. The company will be better equipped to quickly access and monitor this data to comply with the requirements.

Keeping track

Drug counterfeiting is a dangerous and costly concern for the pharmaceutical industry. Whether the counterfeits are fakes, placebos, reduced potency or expired drugs, the top concern is patient safety.

To stem the tide of counterfeiting efforts and illegal distribution of prescription drugs, the FDA released a report in 2003 recommending that pharmaceutical companies implement radio frequency identification (RFID)-enabled ePedigrees to secure the supply chain. These electronic monitoring devices are designed to track a drug along the supply chain, from the manufacturer to the pharmacy, including all transactions relating to the drug.

Pharmaceutical companies initially resisted ePedigrees because of implementation costs, consumer privacy concerns and a lack of RFID and technology standards. However, they are rethinking that stand as

they start to understand that the benefits of tracking their supply chain will make a huge difference to their bottom lines. Not just from the counterfeit drug perspective but also with regard to the ability to improve inventory control, facilitate product recalls and withdraw products with expired dates.

An EDW can enable the integration of data gathered through ePedigrees with existing data sources within the company. Before long, the benefits of the company's investment in RFID ePedigrees can be fully realized.

Research initiatives

In the competitive pharmaceutical industry, a successful company strives to understand its competition so it can win the race to bring new and better drugs to the market.

An enterprise data warehouse (EDW) allows companies to confidently make product and research decisions based on integrated, detailed product and portfolio life cycle data. Integrated physician- and patient-level interaction data from across the company allows pharmaceutical firms to determine the types of drugs to focus its research initiatives on. With this massaged and analyzed data from the EDW, the pharmaceutical firm can make "right time" decisions. It can also gain insight into its market share as well as those of its competitors.

Combining data

Pharmaceutical companies have a growing need to combine the large amounts of their downstream data—such as supply chain or inventory information—with their abundance of sales and marketing data.

This data must be combined for a clear picture of the supply chain and demand to emerge. Once this information is integrated into a data warehouse, the company can make decisions based on the data. For instance, before a big marketing campaign is launched on a particular drug, the enterprise can make certain that retailers have an ample supply of the drug in stock.

Furthermore, when these types of data are combined, the company can ensure that its wholesalers are living up to their trade agreements. Are they supplying the firm with the right amount of product, or are they cutting back? And the pharmaceutical firm can use the data to achieve a clear picture of what drugs are sold and where. Finally, with this information, the company can more accurately forecast and manage its inventory.

The remedy

By putting information from all touchpoints into a single data warehouse system, a pharmaceutical company can have a better understanding of who its customers are, how its products are moving and what new products it should invest in. In short, an EDW cures the headaches of disparate data, making pharmaceutical firms more effective, efficient and profitable. **T**

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