GSMS, Incorporated aims for safer drugs with a pioneering drug track and trace system

Overview

- ***Business Challenge***
  With the threat of drug counterfeiting growing and new regulations on the horizon, GSMS, Inc. sought to leverage its critical role in the pharmaceutical distribution chain by offering drug track and trace capability to its trading partners.
- ***Solution***
  Teaming with IBM, GSMS deployed an ePedigree solution capable of detecting counterfeit or otherwise unknown drug products from the manufacturing line to the pharmacy counter, enabling a major leap in consumer safety.
- ***Key Benefits***
  - **For customers:** *Increased consumer safety through reductions in drug counterfeiting and faster product recalls*
  - **For trading partners:** *Faster compliance with imminent state and federal drug traceability requirements*
  - **For GSMS, Inc.:** *Increased revenues and the addition of new trading partner and customer accounts*

GSMS, Inc. is a contract manufacturer, wholesaler, distributor, and repackager of pharmaceuticals. Operating out of a 95,000-square-foot facility in Camarillo, California, GSMS employs one of the industry's first ePedigree systems as well as some of the most sophisticated packaging equipment available today.

When it comes to consumable products such as food and prescription drugs, the average American citizen has largely taken his/her safety for granted. This mindset attests to the success of watchdog agencies such as the U.S. Food and Drug Administration in maintaining the integrity of the supply chain through a comprehensive set of process guidelines, rigid monitoring and strict enforcement. Up to this point, the fabric of measures taken to ensure the public safety has been largely proactive and preventative in nature, aimed at detecting and heading off problems upstream in the supply chain, at or near the point of production. While these safety measures remain critically important, the ongoing evolution of production, packaging and distribution

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>
> – *Jim Stroud, President and CEO, GSMS, Incorporated*

Business Benefits
For customers
• Increased consumer safety through reductions in drug counterfeiting and faster product recalls
For trading partners
• Faster compliance with imminent state and federal drug traceability requirements • Reduction of potentially billions of dollars in lost revenues and brand equity due to counterfeiting • Reduced compliance costs
For GSMS, Inc.
• Increased revenues • Addition of new trading partner and customer accounts

practices—especially in the area of pharmaceutical drugs—has led to the emergence of a new set of vulnerabilities within the supply chain, the biggest of which is the threat of drug counterfeiting. Around the world, revenue from counterfeit drug sales—growing twice as fast as the pharmaceutical market as a whole—is projected to exceed $70 billion by 2010.

The rise in drug counterfeiting coincides with—and is likely affected by—big changes occurring at all levels of the global pharmaceutical market. In the U.S., the most fundamental trend is an overall increase in prescription drug consumption, driven on the demand side by the aging and longevity of the population, and on the supply side by the availability of new classes of drugs. As the volume and diversity of pharmaceutical commerce has grown, the industry's value chain has also become more globalized and complex.

To reduce costs, for instance, large pharmaceutical manufacturers are increasingly turning to smaller suppliers—both domestic and offshore—for commodity manufacturing. Competing on versatility, many of these so-called contract manufacturers also provide specialized services such as pressing pills from "bulk" powder and packaging them at specific dosage levels. Wholesale distributors also tap contract manufacturers to break down bulk volumes into smaller batches before distributing them to retailers. Increasing globalization and complexity are also evident in the industry's changing distribution model. While sales through traditional pharmacies still account for the largest share, the cost and flexibility advantages of Internet and mail order channels are propelling their rapid growth.

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Dynamism breeds opportunity

For the industry as a whole, a key impact of these changes is that pharmaceutical shipments are likely to follow much more diverse and convoluted paths than before—making it harder to validate the point of origin, or pedigree, of each shipment. It was in this challenge that GSMS, Incorporated (www.gsms.us), a fast-growing, progressive contract manufacturer with an expertise in packaging, saw opportunity. With regulators moving to require the electronic tracking of a drug's origin—a capability known commonly as ePedigree—across the distribution chain, GSMS sought to bring its own offer to market first. It saw IBM's technology, process expertise and market credibility as a strong foundation for the success of its groundbreaking initiative.

In the 20-plus years since it was founded as a contract manufacturer, GSMS had distinguished itself by a steady stream of drug packaging improvements, each conceived from a deep knowledge of the market needs and executed with agility.

These include the introduction of "unit-of-use" packaging, which, by distributing pills to pharmacies in 30-, 60-, and 90-count containers, reduces dispensing errors and improves pharmacy efficiency by eliminating the need for manual counting. Like this practice, the company's ePedigree solution was an early response to a burgeoning need among the industry's key stakeholders. What makes GSMS especially well suited to deploying an ePedigree solution is operational versatility, which enables GSMS to perform multiple roles in the drug distribution chain—from manufacturing to wholesaling to repackaging—each of which represent important touch points in the ePedigree process flow.

As the company introducing ePedigree to its trading partners, GSMS needed to deploy a system that was flexible enough to accommodate the labeling systems used by all pharmaceutical manufacturers. To that end, it worked with IBM to design a system capable of scanning both 2-D barcodes and RFID tags. The ePedigree cycle begins at the point of manufacture, at which point each individual container (or "unit of use") is scanned or tagged with its pedigree data, including country of origin, manufacturer, lot number and expiration date. Leveraging the functionality of IBM WebSphere® Premises Server, the captured data is then sent to IBM InfoSphere™ Traceability Server (formerly IBM WebSphere RFID Information Center), the cornerstone of the solution, where the ePedigree record is stored in a secure repository, running on IBM DB2®. Once the initial profile has been established, it is updated each subsequent time the unit ships from one location to another, providing traceability all the way back to the point of manufacture.

Rigorous demands

Because it effectively functions as the nerve center for product tracking across the entire distribution chain, InfoSphere Traceability Server needed to meet a demanding set of requirements. At a basic level, this includes ensuring granular access security, such that each trading partner can only see what it is supposed to see—even though all access the same core repository. From a business value perspective, InfoSphere Traceability Server's biggest strength is its ability to embed event-driven intelligence into business processes through alerts and reporting. If, for example, an unrecognized product makes its way into the distribution chain, InfoSphere Traceability Server will flag that product as unrecognized and automatically issue an alert. The same capability can be used to identify and isolate other "flagged" items such as expired batches or products subject to recall.

In terms of process flow, the distribution side of the pharmaceutical value chain is highly diverse, with manufacturers, wholesalers and contract manufacturers performing different functions under different relationship models, each of which has its

Solution Components

Software

- IBM WebSphere Premises Server
- IBM Tivoli® OMEGAMON® XE
- IBM Tivoli Composite Application Manager for Web Resources
- IBM InfoSphere Traceability Server
- IBM DB2

Services

- IBM Software Group Lab Services

Smarter Wholesale Distribution

With its pioneering introduction of drug track and trace capability, GSMS, Inc. has laid the groundwork for end-to-end transparency of the entire pharmaceutical drug distribution chain. Through a system of automated alerts, the entry of counterfeit drug products can be detected at any point in the chain, thus increasing consumer safety and preventing damage to manufacturers' brands.

own set of process flows and requirements. In the course of designing the solution, the IBM team—relying on its deep knowledge of pharmaceutical industry processes—generated detailed models of each flow. The team then used these insights to design these flows into the business logic and security parameters of the solution. To manage the solution, GSMS also deployed an IBM Service Management solution that helps maintain high application availability. Using IBM Tivoli Composite Application Manager and IBM Tivoli OMEGAMON XE for DB2, staff can proactively and quickly identify and respond to problems before customers are impacted.

A path to compliance

By enabling ePedigree capability across its trading partner relationships, GSMS is laying the groundwork for achieving the ultimate goal of increased consumer safety. With the first ePedigree regulations scheduled to take effect in 2011 in California—and broader action likely to soon follow—GSMS is providing a cost-effective way for pharmaceutical manufacturers and wholesalers to comply. On a more strategic level, the solution will provide these manufacturers with a powerful tool for thwarting counterfeiting activity, thereby preventing the loss of billions in revenue and incalculable damage to their brand. But as president and CEO Jim Stroud points out, ePedigree is about more than stopping a bad thing. "The peace of mind customers get from knowing where their drugs come from generates goodwill across the entire value chain—from the pharmacy where they pick up a prescription to the manufacturer whose name is on the label," says Stroud. "That's why we see ePedigree as a tremendous benefit for the entire pharmaceutical value chain."

For GSMS as a company, Stroud sees its new drug traceability solution as an important source of competitive differentiation in the catalyst for even faster growth. "We're committed to the safety of consumers using our pharmaceuticals," says Stroud. "With IBM's proven track and trace solution, we're ahead of the curve in serialization regulation and expect to attract more trading partners because of it."

For more information

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