Radio Frequency Identification (RFID) in Pharmaceuticals - Supply Chain Security Concerns Provide Impetus for RFID Adoption

Radio Frequency Identification (RFID) in Pharmaceuticals - Executive Summary

GBI Research’s report on the markets for RFID in the pharmaceutical industry provides a comprehensive analysis on the applications of RFID technology in the pharmaceutical supply chain. The market for RFID hardware, software and services is forecast for seven years and the key factors driving or restraining the market are analyzed. Analysis on regulations and mandates provides valuable insights into the key trends that drive the growth of RFID in the pharmaceutical industry.

Pharmaceutical Industry’s Pressing Need to Regain Lost Reputation and Revenues Due to Counterfeit Drugs Will Drive the Growth of RFID Market

GBI Research finds that there is a growing need for the pharmaceutical industry to secure their distribution channels from counterfeit drugs. RFID solutions provide the ideal identification method by which pharmaceutical industry can counter fake drug issues. While pharmaceutical companies, distributors and wholesalers are on a continuous look out for these fake drugs, counterfeiters find innovative ways to introduce fake drugs into legitimate supply chains. The use of RFID solutions can avoid the loss of investor confidence and a consequent decline in share prices due to such counterfeiting incidents. Also, increased supply chain security and operational efficiency will help the pharmaceutical industry improve their reputation in the delivery of safe drugs. Hence, increasing concerns over the safety of supply chains and the health of patients have forced companies to think big and adopt RFID solutions. A steady increase in the adoption of RFID hardware, software and services in the pharmaceutical industry is expected to drive the growth of these solutions.

Impact of Counterfeit Zyprexa on Eli Lilly’s Share Prices, Oct 2001 – Jul 2004

Source: GBI Research
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5.6 Markets for Counterfeit Drugs

Counterfeit drugs are one of the key challenges facing pharmaceutical supply chains and the safety of patients. It is estimated that the global market for counterfeit drugs was $XX billion in 2006 and is expected to grow to $XX billion by 2010.

Counterfeit drugs are those drugs which are sold under a product name without authorization and which are sold with the intention of misleading the customer into believing that the drug is original. Counterfeiting is one of the major problems facing healthcare systems across the world. It is more prevalent in developing countries where there is limited control over the flow of drugs through the supply chain.

Counterfeiting thrives in developed countries where the movement of goods in the supply chain is not strictly regulated. In the developing countries of Africa, Asia and Latin America, counterfeit drugs constitute nearly XX% of the total pharmaceutical market.

Figure 13: RFID in Pharmaceuticals, Number of Counterfeiting Cases Opened by the US FDA, 1997-2006

Source: GBI Research, US Food and Drugs Administration (FDA)

In developing countries counterfeit drugs are estimated to account for approximately XX% of the total pharmaceutical market.
7 Radio Frequency Identification (RFID) in Pharmaceuticals – Market Characterization

7.1 Market Forecasts for RFID in Pharmaceuticals

The global market for RFID solutions in the pharmaceutical industry will grow rapidly due to the expected increase in awareness and the alleviation of concerns regarding implementation. The global market for RFID solutions in the pharmaceutical industry was valued at $XXm in 2008. It is expected to grow to $XXm in 2015 at a compound annual growth rate of XX%.

![Graph](image)

**Figure 32: RFID in Pharmaceuticals, Global, Revenue Forecasts ($m), 2008-2015**

<table>
<thead>
<tr>
<th>Year</th>
<th>2008</th>
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<td>Revenue ($m)</td>
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Source: GBI Research

A lack of awareness about RFID technology and the lack of a proof-of-concept for returns on investments have hampered the growth of the market for RFID in pharmaceuticals. Although RFID technology has been implemented in industries such as the automotive industry, its implementation rate in the pharmaceutical industry has been slow. The pharmaceutical industry is reluctant to make large investments in RFID implementation as it is unsure about the efficiency of the technology in real-time functions. One of the key concerns raised is the lack of standardization across the supply chain that could lead to the inefficient functioning of RFID systems. Although RFID technology is being deployed in closed-loop systems, where tags can be reused, deployment in open-loop systems will require an increase in awareness and proof-of-concept studies. The effectiveness and reliability of RFID systems in open-loop systems need to be demonstrated to encourage industry participants to adopt RFID technology.
9 Radio Frequency Identification (RFID) in the Pharmaceuticals – Regulatory Landscape

9.1 Regulations in the US Encourage RFID Adoption in the Pharmaceutical Industry

9.1.1 The Prescription Drug Marketing Act of 1987 (PDMA)

The Prescription Drug Marketing Act of 1987 (PDMA), as modified by the Prescription Drug Amendments of 1992, amended sections 301, 303, 503, and 801 of the Federal Food, Drug, and Cosmetic Act (the Act) to establish the requirements related to the wholesale distribution of prescription drugs. One of the primary purposes of the PDMA was to increase safeguards to prevent the introduction and retail sale of substandard, ineffective, and counterfeit drugs in the US drug supply chain.

9.1.2 California Pedigree Legislation’s Deadline has been Postponed on Multiple Occasions Due to the Challenges Faced in RFID Implementation

According to the California pedigree legislation, a “Pedigree” means a record, in electronic form, containing the information regarding each transaction resulting in a change of ownership of a given dangerous drug, from the sale by a manufacturer, through to the acquisition and sale by one or more wholesaler, manufacturer or pharmacy, until the final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.
12 Appendix

12.1 Market Definitions

Pharmaceutical manufacturer – Manufacturer’s of traditional chemical drugs and biopharmaceuticals are classified as pharmaceutical manufacturers.

Trading partners – Authorized wholesalers, secondary wholesalers, distributors, retail pharmacy chains and pharmacies are classified as trading partners.

Authorized wholesalers – Authorized wholesalers buy drugs directly from the pharmaceutical manufacturers and have an ongoing relationship with the manufacturer.

Secondary wholesalers – Secondary wholesalers buy from authorized wholesalers and sell to retail, hospital and individual pharmacies.

Radio Frequency Identification – it is an automatic identification technology used to store and remotely retrieve data using devices called RFID tags or transponders.

RFID Solutions Market – The scope for RFID solutions market includes the markets for RFID hardware, software and services.

Service providers – RFID service providers include the players who offer services such as installation, integration, maintenance, IT support and training.

One-stop solutions – This type of RFID solution includes a single industry participant or a collaboration of industry participants which offers a combination of hardware, software and services for complete implementation and integration.

12.2 Abbreviations

ADR  Authorized Distributors
API  Active Pharmaceutical Ingredient
ASN  Advance Shipment Notice
CAGR  Compound Annual Growth Rate
CCPA  Coalition for Community Pharmacy Action
DTP  Direct-to-Pharmacy
EAN  European Article Number
ECJ  European Court of Jurisprudence
EMEA  European Medicines Agency
EPC  Electronic Product Code
ETSI  European Telecommunication Standards Institute
EU  European Union
FDA  Food and Drugs Administration
HDMA  Healthcare Distribution Management Association
HF  High Frequency
IS  Information Services
ISO  International Standards Organization
LBT  Listen before Talk
LF  Low frequency
MAH  Market authorization holder
ONS  Object Naming Service
PDMA  Prescription Drug Marketing Act of 1987
PhRMA  Pharmaceutical Research and Manufacturers of America
12.3 Research Methodology

GBI Research’s dedicated Research and Analysis Teams consists of experienced professionals with a pedigree in marketing, market research, consulting background in the medical devices industry and advanced statistical expertise.

GBI Research adheres to the Codes of Practice of the Market Research Society (www.mrs.org.uk) and the Society of Competitive Intelligence Professionals (www.scip.org).

All GBI Research databases are continuously updated and revised. The following research methodology is followed for all databases and reports.
12.3.1 Coverage

The objective of updating GBI Research’s coverage is to ensure that it represents the most up to date vision of the industry possible.

Changes to the industry taxonomy are built on the basis of extensive research of company, association and competitor sources.

Company coverage is based on three key factors: revenues, products and media attention/innovation/market potential.

- The estimated revenues of all major companies, including private and governmental, are gathered and used to prioritize coverage; and
- Companies which are making the news, or which are of particular interest due to their innovative approach are prioritized.

GBI Research aims to cover all major news events and deals in the pharmaceutical industry, updated on a daily basis.

The coverage is further streamlined and strengthened with additional inputs from GBI Research’s Expert Panel (see below).

12.3.2 Secondary Research

The research process begins with exhaustive secondary research on internal and external sources being carried out to source qualitative and quantitative information relating to each market.

The secondary research sources that are typically referred to include, but are not limited to:

- Company websites, annual reports, financial reports, broker reports, investor presentations and SEC Filings;
- Industry trade journals, scientific journals and other technical literature;
- Internal and external proprietary databases;
- Relevant patent and regulatory databases;
- National government documents, statistical databases and market reports;
- Procedure registries; and
Radio Frequency Identification (RFID) in Pharmaceuticals -
Supply Chain Security Concerns Provide Impetus for RFID
Adoption

12.3.3 Primary Research

GBI Research conducts hundreds of primary interviews a year with industry participants and
commentators in order to validate its data and analysis. A typical research interview fulfills the
following functions:

- It provides first-hand information on the market size, market trends, growth trends, competitive
  landscape, future outlook etc;
- Helps in validating and strengthening the secondary research findings; and
- Further develops the Analysis Team’s expertise and market understanding.

Primary research involves e-mail correspondence, telephone interviews as well as face-to-face
interviews for each market, category, segment and sub-segment across geographies.

The participants who typically take part in such a process include, but are not limited to:

- Industry participants: CEOs, VPs, marketing/product managers, market intelligence managers
  and national sales managers;
- Hospital stores, laboratories, pharmacies, distributors and paramedics;
- Outside experts: investment bankers, valuation experts, research analysts specializing in
  specific medical equipment markets; and
- Key opinion leaders: physicians and surgeons specializing in different therapeutic areas
  corresponding to different kinds of medical equipment.

12.3.4 Expert Panel Validation

GBI Research uses a panel of experts to cross verify its databases and forecasts.

GBI Research expert panel comprises marketing managers, product specialists, international sales
managers from medical device companies; academics from research universities, KOLs from
hospitals, consultants from venture capital funds and distributors/suppliers of medical equipment
and supplies etc.

Historic data and forecasts are relayed to GBI Research’s Expert Panel for feedback and adjusted
in accordance with their feedback.

12.4 Contact Us

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