IBM

IBM Solution for Pharmaceutical Track & Trace

Highlights

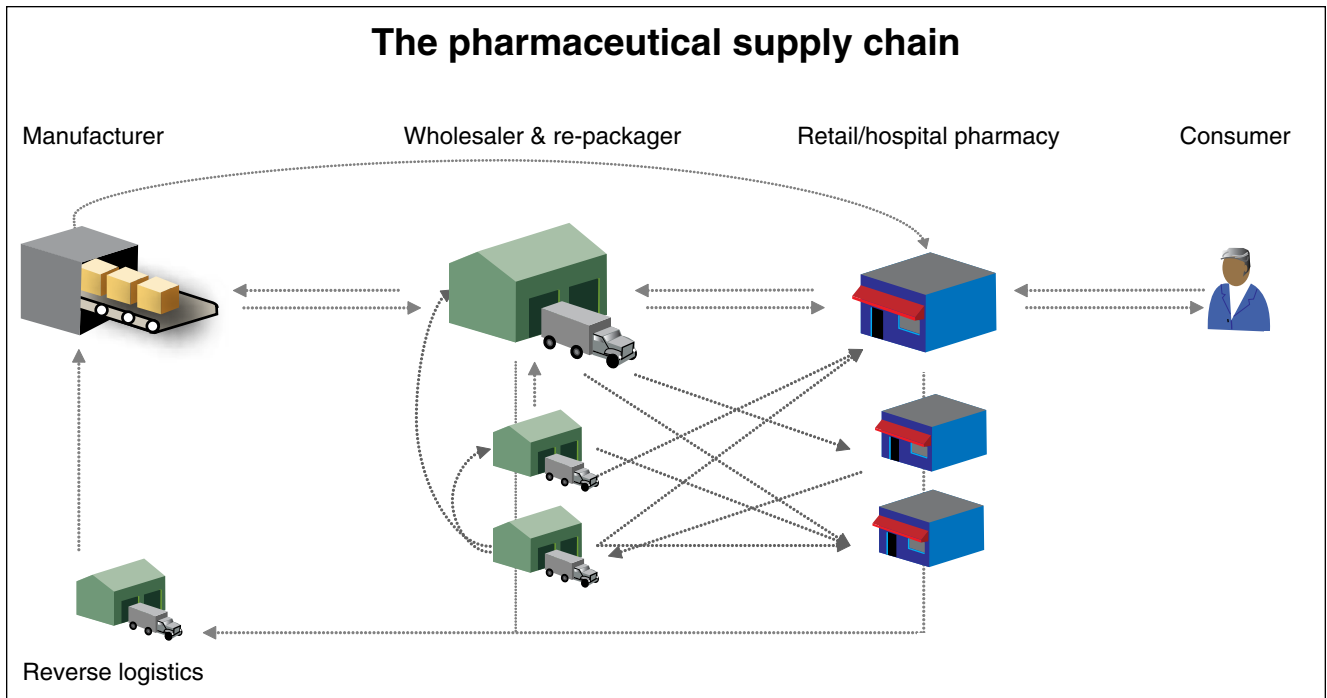
■ *Improve supply chain visibility through item-level serialization*

■ *Ensure patient safety and compliance with government mandates*

■ *Reduce vulnerability to counterfeiting and diversion*

■ *Drive ROI through more efficient recall management, chargeback resolution, reverse logistics, expiry management, forecasting and planning*

■ *Integrate real-world events with business applications and processes*

■ *Protect brand value*

The underlying problem: Complexity in the pharmaceutical supply chain

At its core, the pharmaceutical industry is about improving the quality of people's lives. But today's life-saving drugs are often small, high-value items which are easily stolen or diverted. Nearly impossible to authenticate by the end user, they have become an attractive target for counterfeiters and incidents of counterfeit drugs are on the rise.

But counterfeit drugs are only one visible symptom of a deeper issue. The distribution network used to bring drugs to us is intensely complex – products change hands as many as 10 times on the way to the consumer. This complexity helps make counterfeiting possible. It also leads to cumbersome and expensive business processes that only raise the cost of pharmaceutical products for the consumer.

Linking item-level serialization with track and trace capabilities can address both the underlying cause and visible symptom. By uniquely identifying and tracking the unit of sale through the supply chain, we can help flag suspicious products, enable rapid targeted responses to significant events, and automate everyday processes. This helps you protect your customers and improve business.

The pharmaceutical supply chain

Manufacturer · Wholesaler & re-packager · Retail/hospital pharmacy · Consumer

Reverse logistics

The pharmaceutical supply chain is complex and faces challenges from counterfeiting, diversion and theft, chargebacks, stock safety, and returns.

Symptoms of a complex supply chain

Counterfeit products: $40B is lost each year in worldwide pharmaceutical sales; countless people are harmed.

The World Health Organization estimates that counterfeit drugs account for as little as 1% of the supply in developed countries and as much as 10 – 30% in developing regions. But even 1% represents millions of prescriptions every year in the United States alone.

More importantly, counterfeiters can produce products that look identical to the genuine product, exactly duplicating packaging and reproducing identifying information such as bar codes, lot numbers and expiration dates. The industry has responded with unique packaging technologies such as holograms to help customers recognize authentic products. Now, many governments require supply chain participants to maintain chain-of-custody records that prove the origin and authenticity of each product.

Diversion and theft: Are estimated to cost the pharmaceutical industry $40B in lost annual sales.

Drug diversion is the simple act of taking a product that was contractually obligated to a certain market at a given price and selling that product on the open market. While diversion is often used to exploit pricing differences

between countries, it also happens across markets within countries. With products changing hands up to 10 times in the distribution channel, there are ample opportunities for diversion and outright theft.

Manual chargebacks: A typical pharmaceutical manufacturer pays out up to 10-15% of annual sales to wholesalers in refunds.

While manufacturers sell products to wholesalers at one price, the manufacturers agree to sell their products to other markets – government organizations, nursing homes, hospital chains, etc. – at different prices. The manufacturer will reimburse the wholesaler for the difference between the initial fee and the pre-negotiated rate; this is a chargeback. Currently, wholesalers maintain a large staff to process and submit these claims. In turn, the manufacturer has its own staff to manually validate and process the refund requests. Inefficient and expensive, this process also opens the door to inadvertent duplicate refunds as diverted products can find their way back into the primary chain.

Excessive safety stock: It is estimated that the average manufacturer holds 10% of sales in safety stock.

Drug prices tend to increase frequently – some as often as every six months. As a result, wholesalers and retailers often engage in binge buying, trying to beat the next jump. With the complex pharmaceutical supply chain, it is very difficult to distinguish binge buying from a hot product. Therefore, every party in the chain – down to the retailers – maintains excessive safety stock, tying up capital that could be more productive in other places.

Overpayment on returns: Three percent, or $15B, of pharmaceutical products get returned each year worldwide – and almost all are over credited.

When a product is returned to a manufacturer or wholesaler, they typically refund the current list price not the original paid price. Since prices change frequently and products often have a shelf life measured in years, it is almost impossible to know what was originally paid for any returned item without item-level serialization. This is especially challenging for wholesalers who have razor-thin margins.

Regulatory requirements: An increasing number of U.S. and European pedigree requirements continue to mature.

With an underlying mission to create a more safe and secure supply chain for patients, state and federal governments have developed pedigree laws that require pharmaceutical manufacturers, distributors and pharmacy retailers to track items throughout the supply chain. A pedigree contains critical information about a product as well a trace history of each change of ownership of that drug. This enhances regulators' and consumers' confidence that the drug prescribed is from a trusted source and has travelled a legitimate path throughout the supply chain.

How to manage the complex supply chain: Supply chain visibility
Item-level serialization and track and trace capabilities enable better supply chain visibility – which can raise the bar for counterfeiters and improve business performance. The IBM Solution for Pharmaceutical Track & Trace makes possible anti-counterfeiting regulatory

compliance, diversion detection, automated chargeback resolution, safety stock reductions and accurate returns processing. These benefits, in turn, help protect patients, your brand and improve your customer service. With supply chain visibility, you can realize not just pedigree compliance, but also ROI.

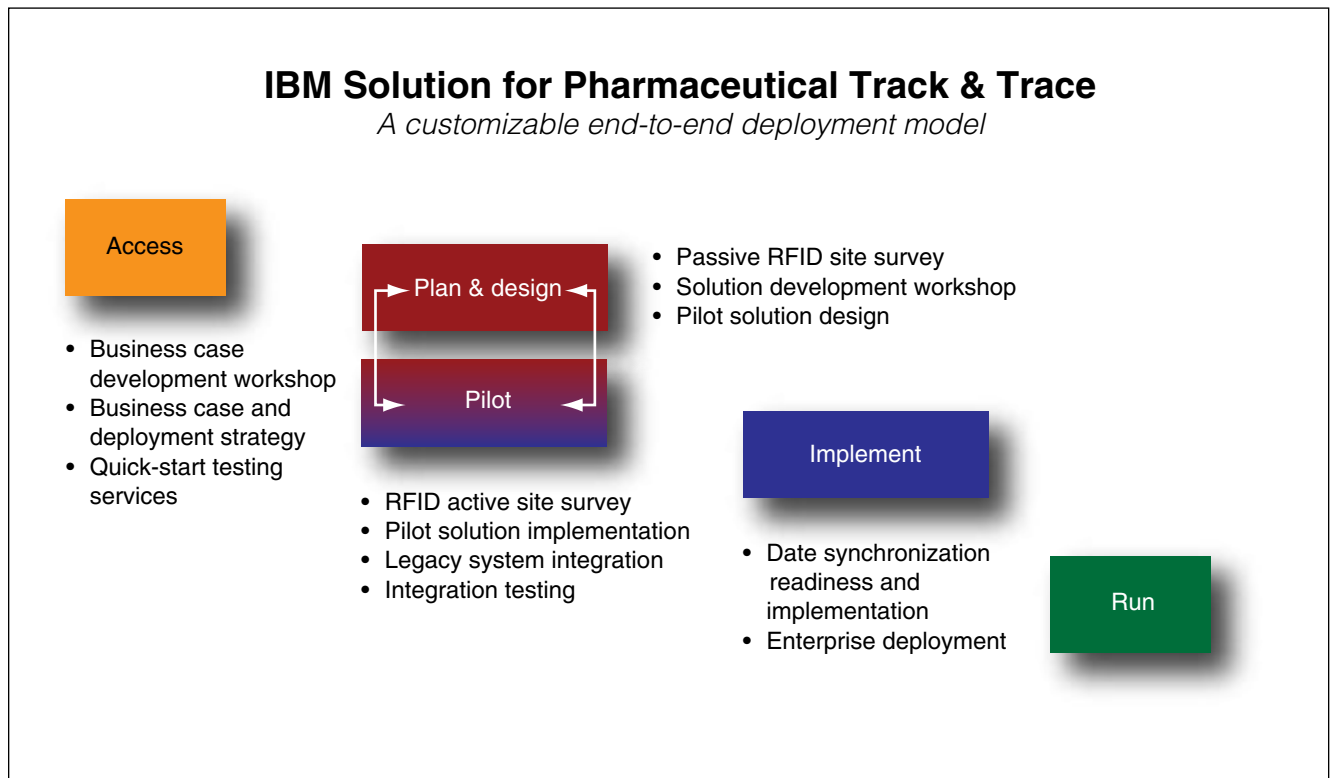### The Solution: IBM Solution for Pharmaceutical Track & Trace

The IBM Solution for Pharmaceutical Track & Trace is a low-risk, proven approach to integrate item-level serialization and track and trace capabilities in your business. It consists of the following:

- *Business consulting services to identify serialization strategy*
- *Technical consulting and implementation services*
- *A pre-integrated, robust, high-performance software infrastructure*
- *Business services that automate processes and drive ROI*

- *A dynamic partner ecosystem supporting multiple forms of data collection capabilities*

IBM Global Business Services has a long history in the pharmaceutical industry, including a dedicated practice supporting 22 of the top 25 manufacturers on major re-engineering and systems implementation projects. Moreover, IBM has been actively involved in item-level serialization and RFID projects

IBM Solution for Pharmaceutical Track & Trace
A customizable end-to-end deployment model

Access

- Business case development workshop
- Business case and deployment strategy
- Quick-start testing services

Plan & design

- Passive RFID site survey
- Solution development workshop
- Pilot solution design

Pilot

- RFID active site survey
- Pilot solution implementation
- Legacy system integration
- Integration testing

Implement

- Date synchronization readiness and implementation
- Enterprise deployment

Run

across multiple industries for years. We can bring this expertise to bear to help you develop an item-level serialization strategy addressing questions such as:

- *What do I need to do to comply with state and federal regulations?*
- *Which products does it make sense to start with?*
- *Which business processes offer the greatest potential for return?*
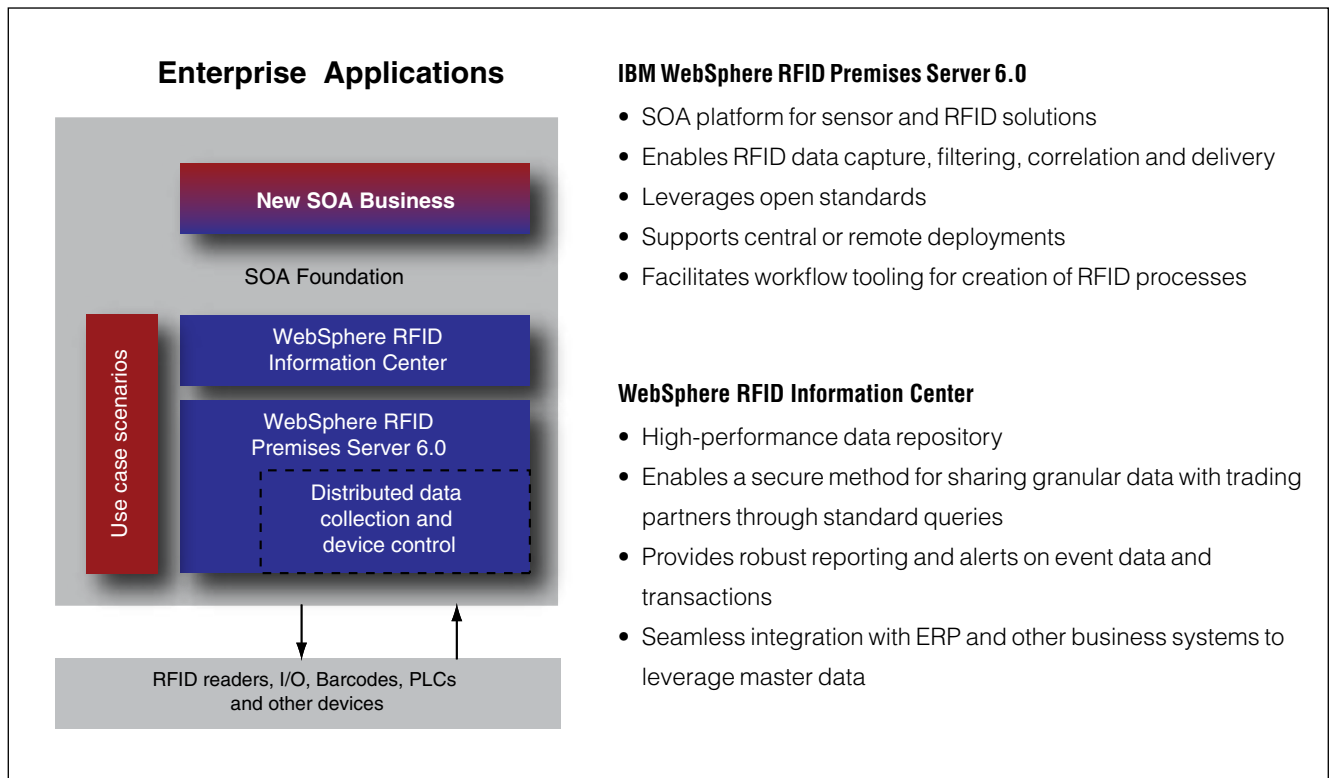- *What is the deployment strategy and how do we manage it?*

IBM Global Technology Services (GTS) can help you design, build, test and deploy your track and trace solution on a global scale. In addition, GTS offers maintenance services, software help desks, remote monitoring and management, on-site services and business continuity and recovery services. IDC has named IBM Global Services as the top market share leader in network consulting and integration services revenue each year since 1996.

The IBM Solution for Pharmaceutical Track & Trace is based on the IBM WebSphere® software platform –

a Service Oriented Architecture that enables you to reuse existing assets and build new tools and applications more quickly and at a lower cost. The key platform components of the solution include the IBM WebSphere RFID Premises Server and the IBM WebSphere RFID Information Center (RFIDIC).

The IBM RFID WebSphere Premises Server supports data collection from all forms of passive RFID and/or

Enterprise Applications

New SOA Business

SOA Foundation

Use case scenarios

WebSphere RFID Information Center

WebSphere RFID Premises Server 6.0

Distributed data collection and device control

RFID readers, I/O, Barcodes, PLCs and other devices

IBM WebSphere RFID Premises Server 6.0

- SOA platform for sensor and RFID solutions
- Enables RFID data capture, filtering, correlation and delivery
- Leverages open standards
- Supports central or remote deployments
- Facilitates workflow tooling for creation of RFID processes

WebSphere RFID Information Center

- High-performance data repository
- Enables a secure method for sharing granular data with trading partners through standard queries
- Provides robust reporting and alerts on event data and transactions
- Seamless integration with ERP and other business systems to leverage master data

2D bar codes in order to serialize each item, case, tote and pallet. IBM provides pre-packaged use cases which embody common workflows that IBM has enabled across multiple pharmaceutical engagements – such as packaging, distribution center and pharmacy operations. These software assets simplify deployment, reduce implementation costs, and let us focus on what's unique about your business – rather than re-creating the wheel.

For example, RFID tags can be applied to items in line, with standard labelling equipment, at production speeds, and with Six Sigma read reliability. This capability can stand alone or be integrated with existing enterprise or manufacturing execution systems to automatically obtain information to meet pedigree requirements – batch numbers, lot numbers, expiration dates, P.O. numbers, etc.

IBM's WebSphere RFID Information Center is a high-volume, high-performance data repository that holds serialized item-level information. This includes the changing association between cases, totes, and pallets as well as the business context (what, where, when and why) each time an item is read. As IBM's implementation of the EPCglobal Information Service (EPCIS) specification, RFIDIC enables trading partner collaboration through secure, standards-based queries – making on demand pedigree, shipment verification or automated chargeback resolution possible. In addition, RFIDIC also provides features which use the serialized data stored in each company's EPCIS to execute and automate business process in the middleware. This allows your legacy applications to take advantage of the new functionality without requiring expensive changes to existing systems.

Partner ecosystem, industry standards and hardware support
IBM has partnered with the premier leaders in hardware and software technologies to construct a robust solution for the pharmaceutical industry. IBM supports major industry standards for sensor data exchange and sensor hardware components, such as RFID tags and readers. Together with our Business Partners, IBM can provide the needed hardware, software and services to deliver a competitive, industry-leading sensor-based solution.

Why IBM
In June 2006, the U.S. FDA Report identified RFID as "the most promising technology for implementing electronic track and trace in the drug supply chain," recommending that "stakeholders move quickly to implement this technology." Putting our experience and solution set to work for you, IBM – in concert with a range of Business Partners – can design customized, scalable solutions

for multiple manufacturing facilities, distribution centers and warehouses and help ensure a virtually seamless fit with your existing infrastructure.

- *IBM is a leader in RFID technology and solutions through active participation and leadership in standards organizations and as a developer of original patents that support tag and reader technology.*
- *With worldwide RFID Test and Solution Centers, IBM offers unrivaled international support for serialization in real business environments.*
- *IBM consultants represent both functional and technical specialists, who have provided support to 75% of the top pharmaceutical firms.*
- *IBM Research is an RFID technology pioneer.*

IBM recognized the value of RFID early on and continues to invest in research and professional development around RFID and RFID solutions. Our approach is to develop a customized plan focusing on your business requirements to align with your strategic business initiatives.

Call on us

Learn more about how IBM can help you develop and implement business use cases. Let us help you define an overall serialization implementation plan that meets your unique business requirements. Please contact your IBM representative or visit us online at:

ibm.com/solutions/rfid
or at
ibm.com/solutions/sensors

IBM®