**IBM**

# IBM Solution for Pharmaceutical Track & Trace: Supply chain visibility drives overall performance
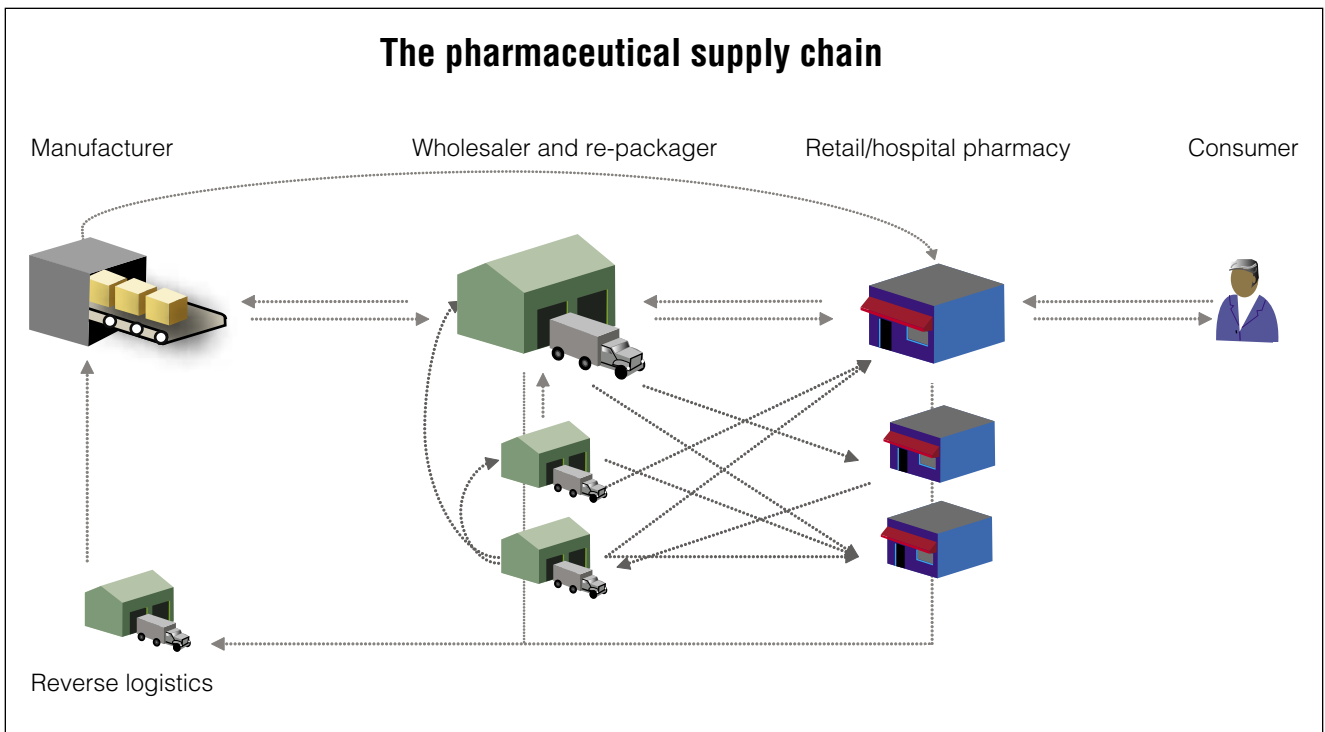


## Highlights

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

- *Ensure patient safety and compliance with government mandates*

- *Reduce vulnerability to counterfeiting and diversion*

- *Drive return on investment through more effective anti-counterfeiting and more efficient recall management, chargeback resolution, expiry management, forecasting and planning*

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

- *Protect brand value*

**Lack of product visibility in pharmaceutical supply chains**

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

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. Without data sharing across the supply chain, it becomes difficult to authenticate product or to effectively manage business processes related to the supply chain. This lack of product visibility helps make counterfeiting possible. It also leads to cumbersome and, at present, costly, labor-intensive business processes that raise the price of pharmaceutical products for the consumer.

# The pharmaceutical supply chain

Manufacturer | Wholesaler and 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.*

Linking item-level serialization with track and trace capabilities by uniquely identifying and tracking the unit of sale through the supply chain enables suspicious products to be flagged, and significant events can be responded rapidly to. These capabilities address both the underlying cause and visible symptom. Additionally, many everyday tasks can be automated. All of which helps you protect your customers and improve business operations.

The World Health Organization estimates that counterfeit drugs account for approximately one percent of the supply in developed countries and as much as 10-30 percent[1] in developing regions. Yet, even one percent represents millions of prescriptions every year in the United States alone.

What follows is an overview of other common challenges facing pharmaceutical companies, worldwide.

### Counterfeit products

*The U.S.-based Center for Medicines in the Public Interest estimates that US$75B will be lost in worldwide pharmaceutical sales by 2010, up 90 percent from 2005; countless people may be harmed.[2]*

Counterfeiters can produce fakes that look identical to the genuine product, exactly duplicating packaging and reproducing identifying information such as bar codes, lot numbers and expiration dates.

Increasingly, governmental legislation worldwide will require supply chain participants to maintain chain-of-custody records that prove the origin and authenticity of each product.

## Diversion and theft

*In addition to problems with counterfeiting, pharmaceutical companies must also worry about diversion and theft which are estimated to cost the industry up to US$1B annually.*[3]

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 percent 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 lower prices. The manufacturer then reimburses 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 percent of sales in safety stock.*

Drug prices tend to change 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

*Because it is difficult to identify sellers and initial process for items returned to manufacturers, as many as 40 percent may have discrepancies and many may be over-credited.*[4]

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 the original price 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 serialization and pedigree requirements continue to mature. With an underlying mission to create a safer and secure supply chain for patients, state and federal governments have developed serialization or 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 traveled a legitimate path throughout the supply chain.

**IBM Solution for Pharmaceutical Track & Trace**

Item-level serialization and track and trace capabilities enable better supply chain visibility, which can reduce counterfeiting and improve business performance. The IBM Solution for Pharmaceutical Track & Trace enables anti-counterfeiting regulatory compliance, diversion detection, automated chargeback resolution, safety stock reductions and accurate returns processing. These benefits, in turn, help protect patients and your brand, and improve your customer service.
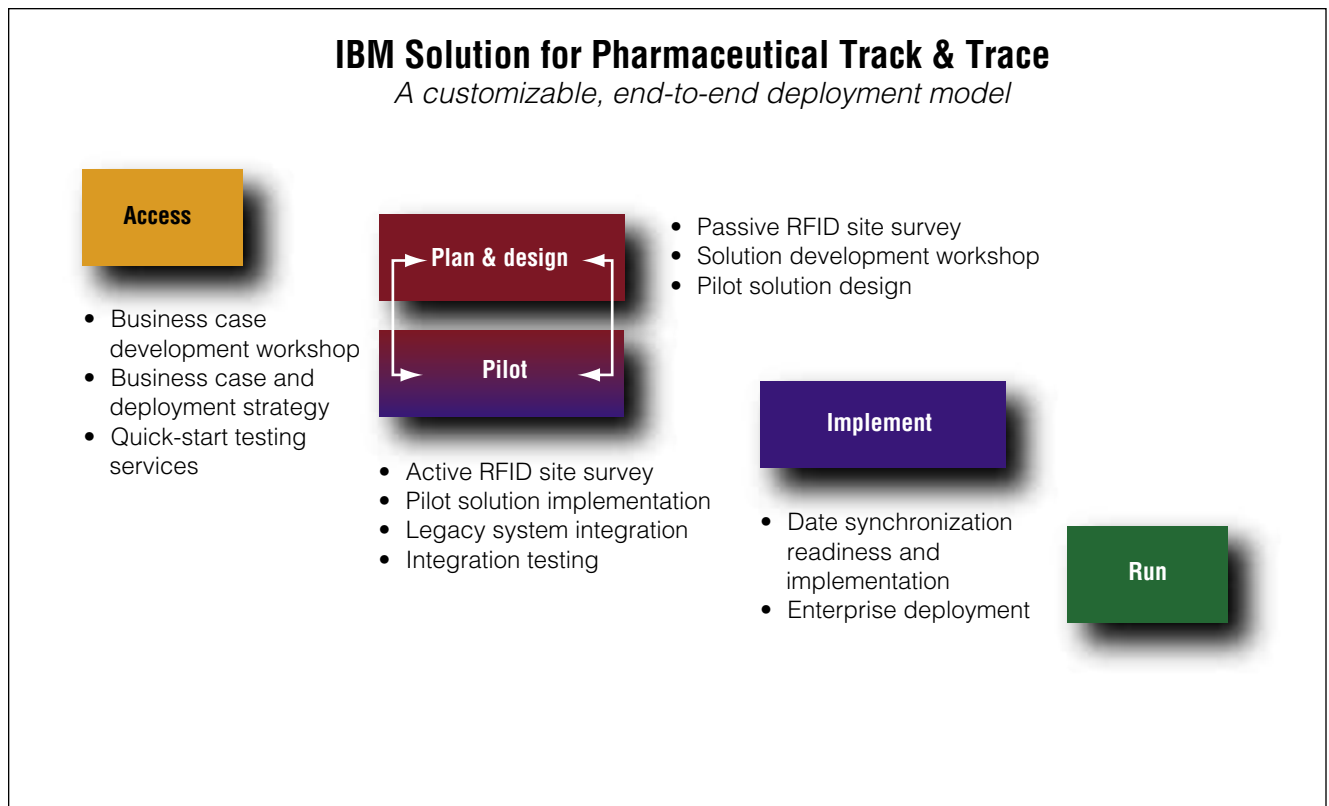
With supply chain visibility you can realize not just regulatory compliance, but also a significant return on investment (ROI) through improved business intelligence.

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 across multiple industries for years. We can

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## 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**

**Pilot**

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

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

**Implement**

- Date synchronization readiness and implementation
- Enterprise deployment

**Run**

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?*
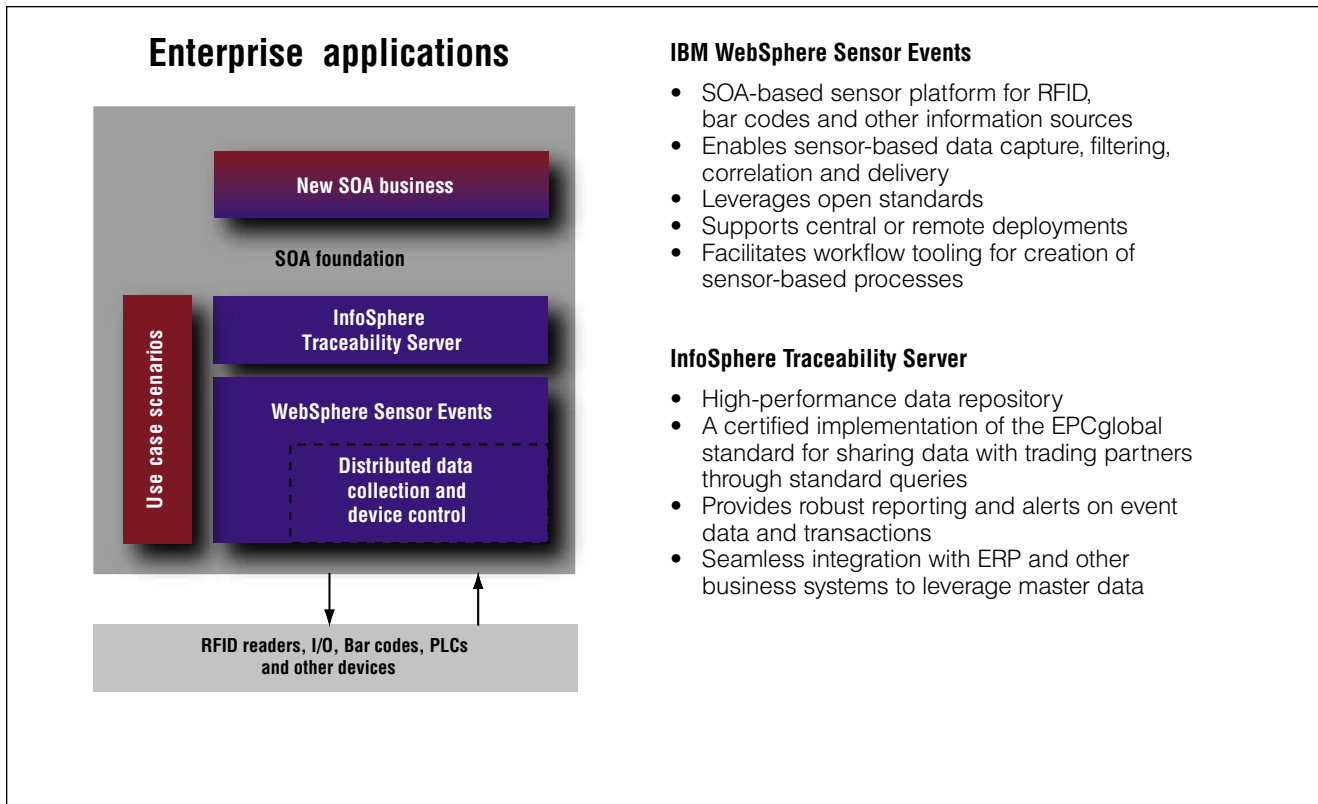- *What is the deployment strategy and how do we manage it?*

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 ranked IBM the worldwide leader in the application-management services market based on the company's growth and flexibility in evolving a management practice that supports discrete and embedded application management solutions.[5]

The IBM Solution for Pharmaceutical Track & Trace is based on tightly integrated products from the IBM WebSphere® software platform and IBM InfoSphere™ software platform – a service-oriented architecture (SOA)

that enables you to integrate with other business applications such as ERP systems and build new tools and applications more quickly and at a lower cost. The key platform components of the solution include IBM WebSphere Sensor Events and the IBM InfoSphere Traceability Server, which enables collecting and sharing – in a secure manner – sensor-based information such as bar code or RFID information.

IBM WebSphere Sensor Events supports data collection from all forms of passive RFID and/or 2D bar codes in order to serialize each item, case, tote and pallet.



**Enterprise applications**

New SOA business

SOA foundation

InfoSphere Traceability Server

WebSphere Sensor Events

Distributed data collection and device control

Use case scenarios

RFID readers, I/O, Bar codes, PLCs and other devices

**IBM WebSphere Sensor Events**

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

**InfoSphere Traceability Server**

- High-performance data repository
- A certified implementation of the EPCglobal standard for sharing 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

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 lets IBM 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 labeling equipment, at production speeds, and with Six Sigma read reliability. This capability can stand alone or can be integrated with existing enterprise or manufacturing execution systems to automatically obtain information to meet pedigree requirements – such as batch numbers, lot numbers, expiration dates and purchase order numbers.

IBM's InfoSphere Traceability Server 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, the InfoSphere Traceability Server enables trading partner collaboration through secure, standards-based queries – making on-demand pedigree, shipment verification or automated chargeback resolution possible. In addition, the InfoSphere Traceability Server 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.

*IBM has leading pharmaceutical industry expertise, and consultants who have provided support to 75 percent of the top 40 major pharmaceutical manufacturers in over 750 pharmaceutical engagements in the last seven years.*

**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 bar codes or 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.

IBM has leading pharmaceutical industry expertise, and consultants who have provided support to 75 percent of the top 40 major pharmaceutical manufacturers in over 750 pharmaceutical engagements in the last seven years. IBM is also a leader in pharmaceutical track and trace expertise. Through a proven, scalable pharmaceutical track and trace solution that includes a complete pre-integrated software stack, IBM offers pharmaceutical companies a low-risk approach to secure and automate their supply chains – an approach which is already in use by major manufacturers and wholesalers. In addition, the IBM solution is certified by EPCglobal under Drug Messaging and EPCIS Standards and will interoperate with other systems supporting these leading global standards.

Lastly, IBM's approach offers you flexibility. With the IBM Solution for Pharmaceutical Track & Trace you can start small and scale as needed. IBM's unique combination of capabilities include experienced services teams, software and partners – such as sensor or bar code infrastructure partners – and can help you chart out and implement a path toward regulatory compliance and improved supply chain efficiency.

**Find out more**

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/sensors

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[1] "Counterfeit Medicines," Fact sheet No. 275, World
Health Organization, (November, 2006).

[2] Ibid.

[3] Katrina Megget, "Drug theft costs industry up to
$1bn a year," *in-pharmatechnologist.com*, October
2, 2007, http://www.in-pharmatechnologist.com/
Industry-Drivers/Drug-theft-costs-industry-up-to-
1bn-a-year (accessed November 24, 2008).

[4] "Life Sciences Supply Chain Evolution," Health
Industry Insights, (June 2008).

[5] Rona Shuchat, "Zooming Out to Capture the
Broader Application Outsourcing Opportunity:
2007 Integrated and Discrete Views," IDC,
(September 2008).