

## MEMBER PROFILE



Purdue Pharma is a mid-sized pharmaceutical manufacturer based in Stamford,

CT. They have several manufacturing and distribution facilities producing their pharmaceutical product lines. A leader in the development of long-acting medicines, Purdue has long been known for its pioneering research on persistent pain. Purdue has also applied its expertise to other areas such as respiratory diseases, oncology and bacterial infections.

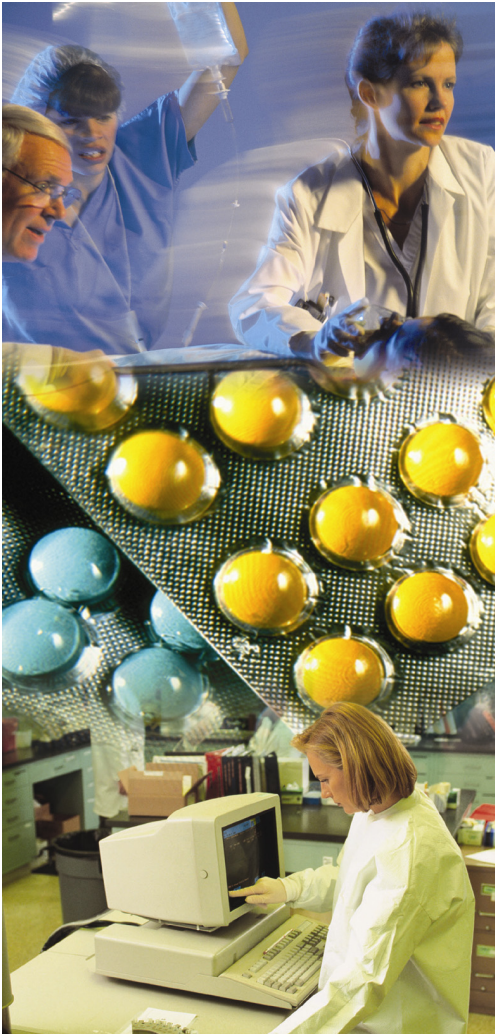
## GS1 STANDARDS USED

### GS1 Serialization

Serialized Global Trade Item Number (SGTIN)  
Serial Shipping Container Code (SSCC)

### GS1 Data Carriers

Item: GS1 EPCglobal RFID UHF Gen2 (SGTIN)  
Case: GS1 EPCglobal RFID UHF Gen2 (SGTIN)  
Pallet: GS1 Linear Barcode (SSCC-18)



# A GS1 Healthcare US™ Success Story:

## Purdue Pharma Expands & Enhances Serialization & EPC/RFID Programs Using GS1 EPCglobal Gen2 Standard

### Synopsis

In June 2006, Purdue Pharma initiated an ambitious program to upgrade and expand their Electronic Product Code™/Radio Frequency Identification (EPC/RFID) and serialization programs using GS1® standards. This effort established RFID serialization for bottles containing OxyContin® Tablets by collecting item to case to pallet data relationships to support item level track and trace through the supply chain. This program had four objectives:

- Item level tagging using GS1 EPCglobal UHF Gen2 technology
- Case level tagging using GS1 EPCglobal UHF Gen2 technology
- Target all domestic bottles and cases of OxyContin
- Collect and aggregate tag data: item>case>pallet

By June 2007, Purdue Pharma was manufacturing and shipping bottles and cases of OxyContin Tablets using GS1 EPCglobal UHF Gen2 standard, placing them ahead of the curve in complying with customer and regulatory requirements, and laying the foundation for addressing problems like diversion and counterfeit drugs.

One of the most comprehensive programs in the pharmaceutical industry, Purdue Pharma has tagged and collected data for over 4 million bottles of OxyContin to date using GS1 standards.

### Customer Background

Purdue Pharma has long believed in the importance of serialization (i.e., *the unique identification of items at the lowest saleable unit*), and has been working with RFID since 2004, when they manufactured and shipped their first batch of RFID-tagged bottles containing OxyContin Tablets using the GS1 EPCglobal UHF Gen1, Class 0 standard. In 2006, Purdue Pharma sought to upgrade and expand their serialization and RFID programs with an eye toward developing item level track and trace capabilities.

Ultimately, track and trace is a collaborative supply chain solution that requires trading partners to work together. In collaborating with their trading partners both then and now, Purdue has found that standards are absolutely essential for ensuring that trading partners can work together and that their systems are interoperable, accurate and reliable.

Therefore, it was no surprise when Purdue once again looked to GS1 standards, the most widely implemented supply chain standards in the world, to support their expansion efforts. Implementing GS1 standards ensured that Purdue could leverage their investments in serialization and RFID for item level track and trace to better secure their products and to combat the problem of diversion.

### Business Challenge

Diversion of drugs from the pharmaceuticals supply chain is a top of mind concern for drug manufacturers. Diversion is the sale of drugs outside the distribution channels for which they were originally intended. Diversion involves an event (like theft) in which drugs are removed from their legitimate supply chain and eventually sold to consumers through alternate channels. Those illegitimate alternate channels are the source of much legitimate concern.

**“Diversion creates a false market that is not regulated or well controlled -- the perfect environment for introducing counterfeit drugs.”**

- Richard Widup  
Senior Director of Corporate Security, Purdue Pharma

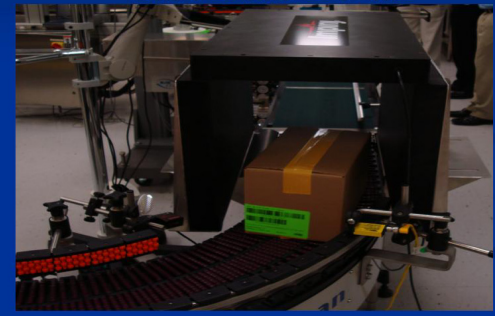
“Gen2 made encoding simpler & more controllable, and management of the whole process much easier.”

- Mike Celentano  
Purdue Pharma

**In-line Label Verification**



**Case Read Portal**



**Serialized/Verified Tagged Product**



**RESULTS**

Purdue Pharma has tagged & collected data for over 4 million bottles of OxyContin to date using GS1 standards.

Post-packaging tag read rates of 99.988% approaches Six Sigma results.

**WHAT'S NEXT FOR PURDUE?**

- Evaluate serialization path for remaining Rx
- Build pedigree/track & trace platform

Diversion introduces “the unknown” into the route from the manufacturer to the consumer: Have they been altered? Have they been tainted? Were they handled properly to ensure efficacy (e.g. temperature; humidity; etc.)? As these questions illustrate, diverted drugs can be compromised and pose serious risks to patient safety. Nonetheless, those drugs are still sold to the public under the manufacturer’s brand name – giving the consumer a false sense of security about a drug that took an uncertain route to their medicine cabinet. Pharmaceutical manufacturers operate in a zero-fault environment where safety issues are of paramount concern. The importance of maintaining consumer confidence in the brand cannot be overstated. Diversion directly undermines that effort.

**Opportunity**

Purdue believes that serialization is the key to securing their products. Serialization provides a unique way to identify each individual instance of a product and provides the foundation for tracking and tracing each individual instance of a product as it travels through the supply chain. Such visibility is essential to security. Therefore, beyond meeting regulatory and customer requirements, Purdue sees their serialization and RFID programs as part of the on-going effort to better secure their products, and pursues any opportunity to enhance their security.

Although Purdue’s existing programs were also based on GS1 standards, Purdue’s Associate Director for Supply Chain Systems & RFID, Mike Celentano, saw the ratification of the GS1 EPCglobal Gen2 standard as a milestone that provided tremendous opportunity. With Gen1 Class 0, EPC tags could only be encoded by the EPC tag manufacturers. As a result, the manufacturers of Purdue’s product labels needed to add pre-encoded EPC tags to the labels they manufactured as a separate step in the label production process. But, with Gen2, Purdue’s label manufacturers could encode EPC tags themselves – enabling them to integrate the EPC tag encoding process right into the label manufacturing process. This simplified Purdue’s serialization and RFID programs. “And with Gen2,” Celentano noted, “there are more tag vendors available, so we can multi-source & control costs better.”

**Solution**

Under their new (Gen2) program, Purdue uses the GS1 GTIN with serial number as the unique identifier for items and cases, and the GS1 SSCC as the unique identifier for pallets. For data carriers, Purdue uses GS1 EPCglobal UHF Gen2 RFID tags for items and cases, and the GS1 linear bar code for pallets. GS1 standardized identifiers are well established and globally acceptable, and their use promoted confidence in Purdue’s program. And, with the advancements in Gen2, Purdue has been able to get their new program up and running quickly with minimal impact to their production lines.

Purdue’s label manufacturers encode serialized EPC tags as part of the label production process. Those item labels are then affixed to bottles as part of the packaging process at Purdue manufacturing facilities. For cases, Purdue encodes its own EPC tags on the production line, and attaches them to cases during the packaging process. EPC-tagged cases are then filled with EPC-tagged bottles, and the aggregated data for each case and its contents are read and stored in the system at the end of the line. Pallets are built at Purdue’s distribution center. Purdue assigns an SSCC, prints a bar code label, and affixes it to each pallet. Pallets are then built with the serialized cases, and the aggregated data added to the system to promote accuracy and security in order fulfillment and receiving.

Today, Celentano remains enthusiastic about Gen2. The Gen2 tags are robust and have held up well against the rigors of packaging. In addition, interoperability across vendors has been good and tag supply has been able to keep up with Purdue’s availability and lead time requirements. “With the performance characteristics and product commoditization we’re seeing with Gen2, you can see the foundation for a critical mass capability starting to take shape.”

**BENEFITS**

- Simplified encoding process
- Streamlined label production process
- Improved cost control through in-house encoding & multi-sourcing
- Collection of aggregated data right on packaging line
- Collection of item level data throughout supply chain without disturbing packaging