Global Serialization Markup Language
A Standardized Non-Proprietary Data Format and Architecture

Agenda

- Legislation
  - Serialization Definition
  - Pedigree Definition
- Technology of Serialization
- XML Language
- GDSML Development and Implementation
- Conclusions and Questions

Problem

Drugs that are:

- Counterfeited
- Diverted
- Sub-Potent
- Substandard
- Adulterated
- Misbranded or
- Expired

Situation

- Importing from countries with less rigorous regulatory standards and systems

- Increased Outsourcing

- Supply Chain Complexity

- Economic Misrepresentation

Legislation

FDA has issued a guidance "Standards for Securing the Drug Supply Chain"

Standardized numerical approach to be applied to a prescription drug at the point of manufacturing and repackaging

- Package or Pallet Level
- Validation
- Authentication
- Tracking and Tracing

New Requirements

- States such as California and Florida – Implementing Pedigree Requirements
- Countries such as Italy and France – Implementing Serialized National ID coding to products exported and imported into their receptive countries

Serialization

Serialization is the process done at the point where the drug is produced and packaged to provide a unique number or code by which the "unit" can be tracked in the pedigree process. Serialization typically is done to the unit level which may be a bottle or even, in some cases, a single dose.

Pedigree

A pedigree means an electronic record containing information regarding each transaction resulting in a change of ownership of a given prescription drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the prescription drug.

Serialization Technology

- Bar Coding
- 2D Data Labeling
- RFID Tracking
- Visual Optical Imaging

Outcome

- Globalization in Supply Chain Process increased opportunity for fraud

- State, Federal and International efforts are being made but slow

- Pedigrees and serialization are two tools for tracking and tracing drug shipments

Serialization

- Youtube Video

XML

- Is a text based language designed for structuring data.

- Developed for information exchange

- Uses human readable language as opposed to computers which use binary and ASCII code.

- Specifically developed to enable information exchange among different systems.

XML (continued)

- Resembles HTML but XML features influence the development of other languages and lead to better standardization of formats.

- Is a group of technologies with a long history and is a license free platform that is well supported.

- Supports W3C.org Encryption standards

GDSML Development and Implementation

- Simplicity through a defined serialization schema – based on XML standards!

- Supported by hundreds of third party applications though standard XML parsers

- Standard understood by thousands of XML developers

- Should work on existing IT infrastructure

Conclusions

- Global Problem Requires a Global Solution
- Accountability Through the Supply Chain
- Serialization and Pedigree are tools for tracking and tracing drug shipments
- Need to continue to harmonize and developing of the process globally

Questions???