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## On Tour With the Global Track & Trace Initiative

*by Wayne McDonnell*

I had the pleasure of coordinating a panel discussion back in November 2009 at the first roundtable meeting of the Global Track & Trace (GTT) Initiative. Its ultimate goal is to provide a forum for manufacturers, wholesalers, and technology companies to not only discuss the issues associated with track and trace, but to develop actionable solutions.

The event was hosted by **Excellis Consulting** and **Axway** on the regal grounds of the Aronimink Golf Club in Newtown Square, PA. On a crisp fall day, just off Philadelphia's Main Line, I lamented not hauling my golf clubs through airport security for an early morning round. As I prepared to lead a panel discussion with industry executives, I couldn't help but draw parallels between the average weekend golfer and track and trace. In both cases, we strive to bring our best game to every round, on every hole, with one or two successful shots enough to keep us coming back for more. Still, though, it's hard to improve our score beyond double bogey.

### The inaugural roundtable

The meeting assembled executives from manufacturing, wholesale, and technology companies to discuss the current state of track and trace. The co-founder of the GTT and host for the roundtable event Brendan Shaw opened the conference with a welcoming and provocative message for the attendees: "GTT is meant to be a medium for the industry's collective voice and an opportunity for the industry to collaboratively solve global regulatory, technical, and business issues relating to track and trace."

Following that call to action, the first half of the roundtable included presentations by **GS1 US**, **AmerisourceBergen**, and **Bracco Diagnostics**.

These discussions provided attendees with insights from the standards as well as legislative, wholesaler, and manufacturing perspectives. Executives from **AmerisourceBergen**, **Genzyme**, **Johnson & Johnson**, and **Schering-Plough** then joined me for an extensive panel discussion. At the conclusion of the event, attendees completed a track-and-trace survey that provided invaluable insights.

### A tale of three perspectives

Bob Celeste, director of healthcare for GS1 US, delivered the first presentation. His overview of the regulatory and business implications of track and trace can be summarized in one word—complexity.

Manufacturers have a multitude of track-and-trace regulations with which to decipher and comply around the world. The healthcare value chain is replete with a multitude of product identification and location coding schemes. Mr. Celeste cited examples where the same item from one manufacturer was traded with nearly 10 different alphanumeric identifiers. To help reduce complexity across the value chain, GS1 is working with the industry and the Food and Drug Administration (FDA) to implement a Global Location Number (GLN) standard by the end of 2010 and a Global Trade Item Number (GTIN) standard by the end of 2012.

Heather Zenk, director of integration solutions for

AmerisourceBergen, delivered the wholesaler perspective. A wholesaler's ability to effectively deploy track-and-trace technology depends first on its own ability to rapidly transact large volumes of data, and secondly on the capability of its trading partners to effectively use that data.

Consider the wholesalers' position in the value chain. They are brokers of the "many-to-many" relationships between life sciences manufacturers, retail pharmacies, and healthcare providers and dealers of serialized data and pedigrees. Therefore, wholesalers recognize the criticality of globally harmonized regulations, the establishment of a shared data network, and an industry-wide agreement on a data sharing model.

Barry DeDominicis, associate director of technical operations for Bracco Diagnostics, shared the manufacturer perspective. Bracco Diagnostics, like other manufacturers, learned through its initial track-and-trace efforts that labeling items with serial numbers is relatively easy, but sharing and make effective use of the data with contract manufacturers and downstream trading partners is the hard part. Therefore, it's difficult for manufacturers to make progress with their track-and-trace initiatives beyond the packaging line or warehouse. This is precisely one of the key points of "The Track-and-Trace Paradox: Will the Healthcare Value Chain Be Ready To Comply Globally?" a report on the state of track and trace across the healthcare value chain.

### The data don't lie: Track and trace is stuck in neutral

At the conclusion of the roundtable meeting, attendees completed a survey to allow the GTT Initiative to collect quantitative data from this small, informal, yet representative population. The following is a summary of the key findings:

- **Serialization strategies**—90% of respondents have a plan to serialize products.
- **Funding**—In 2009, 60% had a budget of at least \$500,000 to support their serialization and/or track-and-trace programs.
- **Technology selection**—80% have selected 2D barcodes to apply serialization at the item level.
- **Standards**—70% of respondents are members of GS1, so presumably they at least recognize the criticality of data standards if they haven't already adopted the GS1 data models.
- **Progress to date**—Only 30% have serialized their products on a large scale. Most respondents have limited serialization to products sold in countries where they need to comply with existing legislation.
- **Compliance with existing legislation**—In the countries where serialization or pedigree legislation is enacted, 50% of respondents have met those requirements solely with their own capabilities. The other half leveraged local, third-party capabilities to comply.

### The driver and the putter

The most compelling result from the survey of GTT roundtable attendees was that all respondents identified compliance as the No. 1 driver of their track-and-trace initiatives. Furthermore, only one respondent identified ROI as being at the top of the list of top-five drivers.

Again, these results are consistent with our research on the state of track and trace. Healthcare companies consider compliance as the main driver of their initiatives. There are a few companies willing to discuss and identify real business value from their track-and-trace investments, but even these companies consider ROI to be a putter in the bag, not the driver.

Since the last delay of California's e-pedigree legislation, companies have limited investments and implementations in the countries where serialization or pedigree are required by law. Without data sharing models and agreement on data-capture technologies, will manufacturers be ready to comply with global track-and-trace regulations? Will they be able to extend serialization and pedigree upstream to contract manufacturers or downstream to wholesalers or direct customers? If manufacturers rely on third parties to comply with local regulations in the near term, will third-party logistics providers develop more comprehensive track-and-trace products as standard offerings? Hopefully the GTT Initiative will provide the value chain with the forum required to define real technology selections, share data and information, and jointly share risks and rewards.