
Track and Trace in the Cold Chain

According to the US Food and Drug Administration (FDA), more than 10 percent of the worldwide drug supply is counterfeit, and in some countries more than half the drug supply is suspect. Industry analysts have estimated that counterfeit drugs have cost the industry approximately \$2 billion in the U.S. alone and an additional \$7 billion has been lost to drug re-importation in 2003. The number of FDA counterfeit investigations has quadrupled since 2000.

In February 2004, the FDA issued a report on 'Combating Counterfeit Drugs', which has triggered significant interest and activity in the mass serialization of pharmaceutical products and, in particular, radio-frequency identification technology (RFID). In that report the FDA recommended a combination of **track and trace** and **product authentication** technology to secure the pharmaceutical supply chain. The report specifically states that, "The adoption and common use of reliable track and trace technology is feasible in 2007, and would help secure the integrity of the drug supply chain by providing an accurate drug 'pedigree', which is a secure record documenting the drug was manufactured and distributed under safe and secure conditions."

Tracking involves knowing the physical location of a particular drug product as it moves through each segment of the supply chain. **Tracing** is the ability to generate a detailed transaction history for a particular product including the physical location, the time spent at each location, record of ownership, packaging configurations and environmental storage conditions. The resultant detailed transaction history of a specific product is the product **pedigree**. **Authentication** is the ability to ensure a particular product is not counterfeit or adulterated as well as to determine the current status of that product including whether it has expired, been recalled or previously discarded at any prior point in the supply chain.

Cold Chain Complications

For a track, trace and authentication program to be truly successful the solution must offer visibility and protection from the point of manufacture to sale to the consumer. The ideal solution will not only ensure the identity, strength and purity of the drug but also the quality and efficacy. The quality of drug products that require temperature controlled storage conditions can be adversely affected if they are not carefully managed and distributed within required temperature guidelines. An otherwise authentic temperature-sensitive drug product may become ineffective if exposed to inappropriate temperatures in the supply chain. As a result, environmental storage conditions become a critical component of the Track, Trace and Authentication technology for cold chain products.

The number and volume of temperature-sensitive products is increasing rapidly. The Biotechnology Industry Organization has estimated that the growth in temperature-sensitive products will outpace the rest of the industry with average growth estimated at 15% per year. The FDA has approved approximately 130 biotechnology products and vaccines (most are temperature sensitive) - nearly 70% of those products were approved in the last six years. In addition, there are more than 370 biotechnology products and vaccines currently in clinical trials.

To address the growing demand, the FDA formed Team Biologics, a partnership between the Center for Biologics Evaluation and Research (CBER) and the Office of Regulatory Affairs (ORA), to focus on inspection and compliance issues in the biologics area. Field inspectors are increasingly scrutinizing temperature-sensitive materials within the cold chain, from manufacturers' plants through the distribution network. The Team Biologics' inspections have led to longer inspection times and to more thorough FDA reviews of good manufacturing practices. At least seven 483 citations have been issued for temperature related practices.

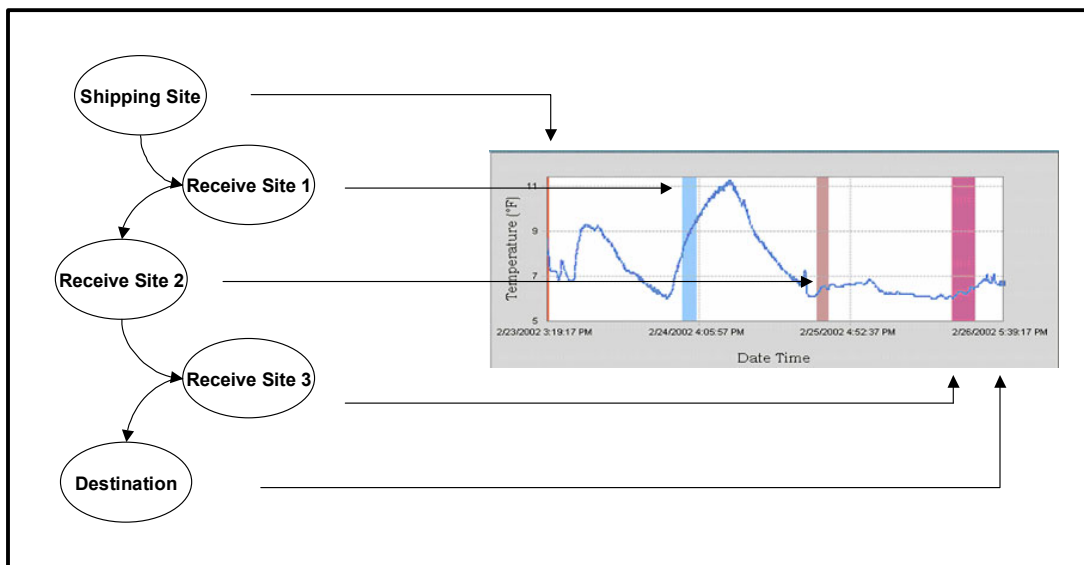
Active RFID Tags Provide Additional Information and Control

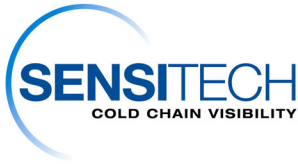
Comprehensive track, trace and authentication solutions will ultimately reduce patient risk by giving manufacturers, wholesalers, carriers, pharmacies and regulators a systematic method to detect and control counterfeiting, drug diversions and product mishandling. The solutions will ultimately ensure the right product, in the right place, at the right time, in the right condition.

The best-in-class pharmaceutical manufacturers of temperature-sensitive drug products are already tracking temperature through the major segments of their supply chains. Their cold chain products typically receive special attention and handling, including formal monitoring programs with existing standard procedures and protocols.

Active RFID tags with temperature capabilities will complement the data, currently compiled through the use of traditional temperature monitors, with detailed product location data providing a solid foundation for product tracking and tracing (*see chart below for example*). These RFID techniques and related systems would address challenges with both cold chain and non-cold chain products. The active tags will enhance the collection and increase the accuracy of temperature, time, and location related data. Recipients no longer need to unload pallets of product and locate devices buried deep within the shipment before they are able to determine if temperature or supply chain abuses occurred.

Traditional Time & Temperature Data Augmented with Location Detail





White Paper

Sensitech partnered with Ember Corporation to jointly develop an active RFID temperature tag. The active tag will provide detailed information regarding the location of the device as it moves through the cold chain as well as detailed information regarding the ambient storage temperature conditions in which it travels. Sensitech's active tags coupled with Ember's network hardware enable users to implement an RF program while maintaining a substantially lower investment in hardware infrastructure costs.

Sensitech is currently piloting this new technology with a limited number of key customers, in each of their vertical markets.

About Sensitech

Sensitech is the leading provider of cold-chain information and analysis that enable global leaders in food and pharmaceuticals to protect the integrity, freshness and efficacy of their temperature-sensitive products. In the past decade, Sensitech has protected more than \$200 billion of its customers' assets around the globe. The company is based in Beverly, Massachusetts, and has offices in Redmond, Washington, Fresno, California, Canada and Amsterdam with service and distribution offices around the world. For additional information about Sensitech, call 978-927-7033 or visit www.sensitech.com.