



BTI's Patented Patient Safety Assurance Solutions Give Peace of Mind

Pharmaceutical companies are all retooling to comply with regulatory agency bar coding requirements on pharmaceuticals. While the minimal requirement may be met with a simple UPC bar code, BTI has harnessed its portfolio of patented intellectual property to address the unique needs of the pharmaceutical, biotechnology, and medical device industries.

All three industries are facing unique challenges in the traceability and integrity of their supply chains. Manufacturers of innovative drugs are particularly challenged by a rising tide of counterfeit and diverted products. Moreover, lack of traceability with regard to storage temperature parameters artificially shortens product shelf life.

Standard UPC bar code offers little help in this regard. BTI's proprietary deployments of GS1 Databar offer unique solutions that promise increased profitability and decreased liability for valuable pharmaceutical franchises.

BTI's pharmaceutical assurance solutions practically guarantee that a pharmacist who complies with the program will not be able to unknowingly dispense a counterfeit or diverted drug. BTI's proprietary encryption techniques ensure that simply copying a legitimate bar code and reproducing it on the label of a counterfeit or diverted product will not enable counterfeit and diverted goods to be dispensed in a legitimate pharmacy. These same technologies were developed for and have passed the highest level of scrutiny for national security applications within the United States, China, and elsewhere.

Among BTI's advisors are former Secretaries of Defense, Homeland Security, and NSA. Additional BTI technology can be added to pharmaceutical packaging to provide the same assurance that the product has not been stored outside of its permitted storage parameters. Others may offer some of the same security features as BTI; however, those technologies rely on holograms and other

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costly manufactured devices. BTI's technology leverages standard printers, ink, and proprietary knowledge and software.

Generally regarded as ending at the pharmacy, the pharmaceutical supply chain in reality ends at the consumer, i.e. the patient. The cost of medical error in terms of morbidity, mortality, and financial toll is well documented, as is the need for bar code based solutions to solve those challenges. BTI's Managing Director for Healthcare and Life Sciences, Dr. Jonathan Javitt, drafted the original White House report entitled "Revolutionizing Healthcare through Information Technology," and served as a special assistant to the FDA commissioner in finalizing the bar code regulations. Dr. Javitt has worked with BTI to ensure that the company is able to offer its pharmaceutical clients the most cost-effective solutions that safeguard both valuable brands and also the consumers whose future lives depend upon those brands.

GS1 Databar in Depth

From the plant to the patient, the requirement of drug safety, authenticity and traceability depend on individual unit label to contain much more information than before. Bar codes need to be denser in order to contain valuable information such as lot number, expiration date, serialized number, concentration, dosage, etc. in a very limited space.

2D bar codes were developed to fill this need. In fact, they have been optimized to provide pharmaceutical supply chain with distinct values:

- Print on a very small area
- Hold a large amounts of information
- Easy to read
- Resist tampering
- Provide redundancy for reliability

There are several types of 2D bar codes on the market, such as GS1 Databar (formerly known as RSS), Data Matrix and PDF417. However GS1 Databar stands out for its ability to mitigate costly and complex adoption overhead. The most important advantage of GS1 Databar is that it works with existing standard bar code scanners and wands instead of the more expensive sweeping laser scanner or CCD camera capturing device.

BTI's Patented Patient Safety Assurance Solutions Offers Peace of Mind

GS1 Databar — Intelligent Supply Chain Investment

Hundreds of characters can be encoded in a GS1 Databar symbol that's smaller than half the size of a standard UPC code.

Transition to GS1 Databar is a painless upgrade to the existing system, i.e. install printer driver and add composite component to UCC.EAN.

An entirely new 2D bar code implementation would render thousands of systems, including Point-of-Sale and Point-of-Use, obsolete and cause a chaotic transition.

Less expensive sweeping lasers can read GS1 Databar symbols. Data Matrix must be scanned by camera-like devices.

Data Matrix standard does not include a human-readable element — the text that goes along with the bar code symbol

GS1 Databar allows manufacturers to add additional information during production, e.g. labels with preprinted bar codes for NDC numbers can add lot and expiration data.

GS1 Databar creates minimal impact to the existing production process.

BTI's proprietary pharmaceutical technologies include:

Holobar® — bar code in holographic labels

Medibar™ — bar code used to ID patients to prevent wrong site surgery

IPC codes™ — thermo-sensitive bar codes

Virtual Bar code™ — bar code printing on irregular surfaces

RSS Bearer Instruments — Bar coded financial instruments (coupons, rebates) which are transported on credit card network

Inline Bar Code — bar code added to single dose medications on a production line

Medipak™ — single dose medication packaging

Broadcode™ — bar code used to label products with embedded logo or message

Supplytrace™ — track and trace proposition

Blisterpack — software for labeling single dose medications using RSS bar code

BIVACC™ — two part bar coded labels for medication labeling

	Process	Production Line Impact	Hardware	Software
GS1 Databar ✓	Existing	Minimal	Existing	New
Data Matrix	New	High	New	New

Copies of US patents available on request.

