

**HEALTHCARE & LIFE SCIENCES**  
PHARMACEUTICALS & MEDICAL DEVICES



***Counterfeiting and Adulteration are complex risks—together we can solve them.***



## Counterfeiting & Adulteration— The Invisible Threat

In itself, fake packaging doesn't harm patients—it's the counterfeit and adulterated medicines that they contain. Sadly, today, even authentic packaging is no guarantee of authentic contents, due to theft and recycling of authentic materials.

Unlike most consumer products, the integrity of pharmaceuticals and their distribution is not only a matter of brand protection and corporate integrity—it's a matter of patient welfare and even national security. It is for this reason that a major goal of the FDA is the protection of pharmaceuticals and their distribution. The efforts of Authentix provide a significant advance in supporting that goal.

### Simplifying a Complex Process

The integration of a comprehensive authentication program can be a complex process. For example, deciding whether to mark the product as well as the packaging and selecting the appropriate technical platform can be a daunting task in itself and that's only the beginning. The integration of the technology into your business processes, maintaining its security, testing for authentication features in the field, and providing chain of evidence custody, also need to be considered—all within the context of your return on investment. The decisions are difficult and ones that detract from your principal objective of developing and marketing pharmaceutical brands.

As an accountable partner, Authentix provides the leadership, support and full program management skills to ensure an effective solution with minimal disruption to your business.

## What Makes Authentix® Different

There are 4 key differences that set Authentix apart—individually they are important, collectively they are unsurpassed:

### 1. We Invented, Developed and Applied the Technology.

Underpinning all that we do is a foundation of world-class technical experience. Many of the covert marking technologies in use today were invented, developed and applied commercially for clients by members of our senior management team. With such depth of experience, Authentix can design and implement effective authentication solutions whatever the circumstances.

### 2. We Deliver Commercial Outcomes for Clients.

Our clients don't have technology needs. They have commercial problems which technology may help solve. In an industry awash with niche technologies we never forget this. Our principal goals are to define your issues, design and install the most appropriate solution, manage the program and most importantly, deliver the commercial return.

### 3. We Structure Ourselves to Serve our Specialist Industries.

As a client focused service provider, we structure ourselves in industry teams. Within each team, we have the depth of commercial and technical experience to understand your specific industry issues and tailor a practical, sustainable program to meet your needs.

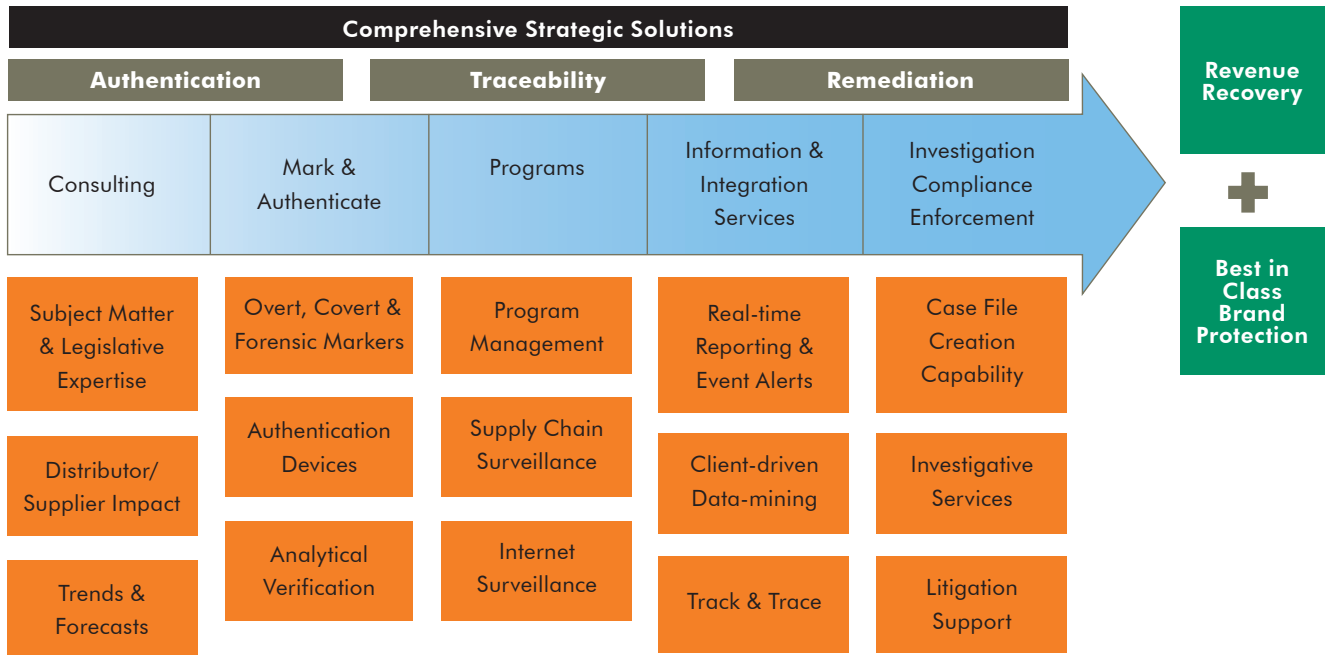
### 4. We Deliver Complete Solutions.

Authentix is unique in the industry in being able to authenticate products as well as their packaging. Even if the product is ingestible, such as a food, drink, or pharmaceutical, we have a range of FDA approved markers, which can authenticate the product, without impairing it in any way. In combining product and packaging authentication, together with a range of serialization options and support services, we provide the most comprehensive authentication and tracking service in the industry.



## Comprehensive Strategic Solutions

In designing a pharmaceutical authentication program, Authentix begins with the end in mind—the protection of patients, together with risk avoidance and commercial return for clients. The seamless process of product marking, field and web surveillance, data warehousing and reporting, provides clients with key event knowledge and unequivocal case file support to ensure distribution compliance.



## Program Design and Installation

Typically, Authentix would adopt the following approach in developing pharmaceutical brand protection programs for clients:

### Initial Consultation

- Risk analysis, Quantification of the issue, Assessment of options
- Project scope and deliverables
- Risk mitigation and revenue recovery

### Technology Selection

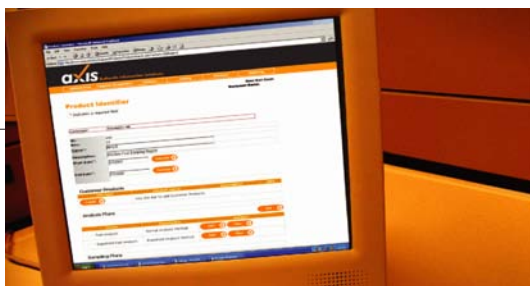
- Specification of layered technology platform
- Definition of field surveillance requirements
- Installation by trained in-house operators
- Local training
- Program auditing

### Surveillance

- Web monitoring to identify sites suspected of selling illicit medications
- Product purchase and testing for authenticity and source
- In-market testing for packaging and in-product authentication features
- Collection of samples for further laboratory analysis as required

### Data Management & Reporting

- Online access to up to the minute field surveillance results
- Event reporting, tracking and management
- Trend analysis and planning of target re-sampling points
- Chain of evidence custody
- Quantification of revenue recovery and risk mitigation





## Package Authentication

Authentix has one of the largest portfolios of proprietary authentication technologies in the industry. This combined with our deep expertise in integrating authentication technologies with print inks enables us to formulate effective solutions for even the most demanding production and packaging environment.

Through the creative combination of overt, covert and forensic features we provide client specific authentication fingerprints. Our in-house design and fabrication of web-enabled field authentication devices ensure solution integrity and continuity while providing for easy, fast and reliable field authentication.

## Legal Defensibility

Field authentication of products and packaging with Authentix technology is of significant value in enforcement efforts. In addition, we provide forensic validation of marker fingerprints to ensure confidence when taking legal actions against criminals. When field and analytical based authentication is combined with our desktop Program Management tools, total cycle time from field authentication to forensic validation can be as little as 24-36 hours. Our Program Management tools provide security of samples and documentation to ensure legal defensibility of the authentication process. This level of confidence has significant impact on the protection of product in the market and in the distribution pipeline when its authenticity is called into question.

## Product Authentication

Authentix is unique in the industry in providing authentication markers that are placed directly in or on drug products and providing a method for field authentication that is quick, easy and delivers a very high degree of confidence. Our marker systems are designed to provide client-specific fingerprints that can not only confirm authenticity, but also identify the manufacturing site and line to aid in identifying diverted product. Our markers are FDA accepted and we have successfully marked product coatings, formulations and active ingredients of products now in distribution throughout the world.

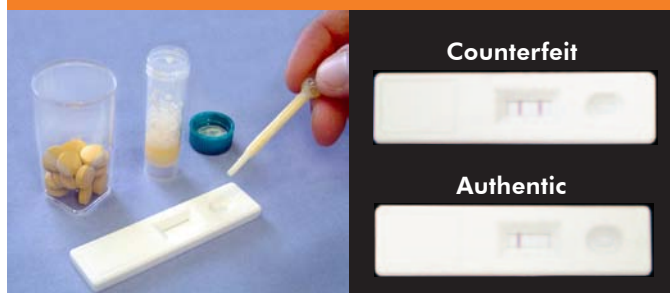
### Markers

- Listed in CDER inactive ingredient guide
- Simple organic GRAS compounds
- Used in CDER approved products
- Used at trace levels (ppm to ppb)
- Easily inserted via coatings, inks, excipients, or API

### Marker Detection

- Add tablet to liquid in vial
- Shake briefly
- Read results
  - 1 line = authentic
  - 2 lines = counterfeit

*Inactive ingredients become high security taggants*



# Tracking & Tracing Products Through the Supply Chain

The incorporation of secure authentication features, coupled with a program of regular inspection, ensures that counterfeits are excluded from your supply chain. The prevention of diversion and the tracing of individual single unit packs requires more, however. The key is having a sound technological approach to product coding and a well developed data management system. Through a combination of overt and covert serialization, whether 2D, Electronic Product Code (EPC) or other symbology, brand owners can be assured that critical tracking information can be recovered when necessary.

The development of improved Radio Frequency Identification Tags (RFID) and the establishment of an EPC will be of significant value in supply chain management and product tracking. However, current

limitations in the cost and accuracy of this technology, at the unit level, will limit its broad application for many years. Through the use of covert codes (alphanumerics or barcodes), in isolation, or in combination with RFID at case and pallet levels, Authentix will address your unit tracking needs with state of the art technology that can be implemented today.

Applied during packaging operations, each dispensing unit receives a unique 'licence plate' which can be matched to production lots, outer cases, pallets and customer shipments. By relating individual unit codes to customer shipments, diverted product can be traced to its source. In addition, the traceability of individual packs can be of significant value in limiting the scope of product recalls.

A brief overview of the key elements is as follows:

## Manufacturing

Serialized codes are applied during manufacturing, read in-line automatically, and uploaded to a central server. Individual covert unit codes are linked to overt codes and nested to case and pallet codes.



## Warehousing

Pallet codes are matched to those of shipping cases and individual product units. Printable and RFID codes can be matched.

## Distributor

Product cases are scanned upon receipt by the distributor and matched to retail customer data upon dispatch.



## Shipping

Customer destination details are recorded at point of dispatch.

## Retailer

Products can be scanned at retail outlets to ensure authenticity and check source.



## Centralized Data Management System

Our proprietary middle-ware can interface with all operating platforms. Central storage of unit codes, together with field inspection data supports legal action against illicit traders where required.

## Secure Web Access

Via a wireless PDA or Internet enabled PC, field inspectors can access the database remotely to check a products' authenticity and source from any point in the supply chain.



## Case Study: Packaging



### The Problem.

Counterfeit copies of a major pharmaceutical brand were discovered in the US market. With no security measures in place to allow patients, care givers and inspectors to readily distinguish authentic from counterfeit product, both patient welfare and the manufacturers reputation were under threat. Given such risks, the \$1 billion of authentic product, which was in the distribution pipeline, could not be sold without a means of authenticating the product, from the manufacturers warehouse to the point of care.

### The Solution.

Product was relabelled and repackaged to include a variety of authentication features that could be identified by patients, care givers and inspectors, both in the field and in the laboratory. These included:

- Overt color-shifting ink, which could be readily distinguished by patients and care givers.
- Covert, machine-readable inks, which could be detected by inspection staff with appropriate readers in the field.
- Forensic markers that could only be detected under laboratory analysis.

The printed solutions were applied to packaging, labels and other components using a variety of printing methods. Moreover, the solution was developed by Authentix and approved by the client and the FDA within 4 weeks.

### The Outcome.

The strategic solution developed provided a secure means of distinguishing authentic from counterfeit product, thereby restoring confidence in the brand among physicians, pharmacists and patients. With a secure means of authentication in place, the manufacturer has mitigated the risk of potential lawsuits. Furthermore, the \$1 billion of product frozen within the supply chain was released for sale and the expense of a full product recall was averted.

## Why Our Solutions Are So Secure

In building an authentication solution, Authentix adopts a secure, multi-layered approach. While overt features are visible to the patient, access to covert features is restricted to authorized inspectors. In combination with forensic features, the presence and identity of which is closely guarded, our solutions are both effective and sustainable.





## Case Study: In-Product

### **The Problem.**

The active ingredient of a range of OTC preparations was manufactured by the patent owner and sold for formulation into tablets and capsules. Consumption statistics exceeded output by the manufacturer, indicating that formulators and distributors were violating supply agreements and patents, by using API from unauthorized sources. This resulted in loss of revenue to the patent holder and increased exposure to false liability claims from product formulated with illicit active ingredient.

### **The Solution.**

An inactive, FDA, GRAS status marker was incorporated into the API at trace levels at point of manufacture, following the development of short-term stability data. The marked API was supplied to formulators whose products were then inspected in the marketplace. Routine field monitoring and auditing implemented.

### **The Outcome.**

Regular sampling of formulated product at retail level identified product without marker, indicating that the API had not been sourced from the patent holder. The absence of forensic marker in retail stock enabled the patent holder to confront rogue formulators and take remedial action. A proactive monitoring and enforcement program has now been in place since 1998.

## Case Study: Patent Expired

### **The Problem.**

An established, patent expired product that still commands a leading market share and premium price compared to generic products, was heavily targeted by counterfeiters. The required authentication solution had to integrate with other existing security features as part of a technology migration strategy.

### **The Solution.**

Optically variable device with multiple covert and forensic features was introduced. These could be identified by field reps at the point of retail and in the laboratory. The multi-layered solution enables quick authentication in the field and provides a second line of defense to audit distributors and wholesalers.

### **The Outcome.**

With a secure means of distinguishing authentic product from counterfeit, and a sustained policy of IP enforcement, the revised program has resulted in numerous legal successes and a reduced incidence of counterfeiting. The client has now begun a process for reviewing and implementing new technologies to ensure continuous enhancement of the solution.

***If it's not Authentix® — it's not secure.***

**About Authentix**

Authentix® is the global leader in authentication solutions for brand protection and fiscal recovery. As the inventor and developer of many of the leading nano-scale authentication solutions in use today, we have a world-class technology portfolio. Moreover, our skills in applying those technologies to solve counterfeit, adulteration and smuggling issues for clients, ensures that we are a trusted partner of many of the world's leading brand owners and governments. In the last three years we have recovered over \$3 billion in lost revenues in the petroleum, pharmaceutical and consumer goods industries alone. In addition, our expertise in the fields of valued documents, currency and homeland security applications helps protect the very fabric of our society.

If you would like further information on Authentix or wish to discuss a commercial application in confidence, please call us toll free at +1 (866) 434 1402 or contact us via our website at [www.authentix.com](http://www.authentix.com)

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