

# Ensuring Authenticity for Certificates of Analysis (COAs)



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## **FDA Public Meeting: Implementation of Drug Supply Chain Provisions of Title VII of FDASIA**

July 12<sup>th</sup> 2013

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# Purpose and Scope

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## Purpose

- ✓ The purpose of the July 12th meeting is to provide an overview of Title VII, discuss how FDA plans to implement it and hear public comment about those provisions that specifically address imported drugs and importers. Under Title VII FDA is authorized to require that importers submit information demonstrating that their drug complies with applicable requirements of the Federal Food, Drug and Cosmetic Act before their products can enter the United States. In addition, commercial importers must register with FDA and meet good importer practices. These authorities apply to both human and animal drugs.

## Scope

- ✓ 8. Should FDA require that importers submit certificates of analysis (COAs) to the Agency as a condition of admission under section 801(r) of the FD&C Act? If so, how could an importer demonstrate a COA's authenticity?

- ✓ **Protecting the Patient**
  - The problem can go back to the API
- ✓ **What Six Degrees Counterfeit Prevention can offer**
- ✓ **COA Content, Encryption, Decryption, and Authentication**
- ✓ **Demonstration**
- ✓ **Challenges**
  - Is the data secure?
- ✓ **Benefits**

## Scope of Drug Counterfeiting

- ✓ The World Health Organization (WHO) estimates that counterfeit drug prevalence rates fall between 10% and 30% in the developing world, as compared to 1% or less in developed countries.
- ✓ The global anti-counterfeit packaging market is expected to be worth \$79.3 billion by 2014, growing at an estimated CAGR of 8.6% from 2009 to 2014. This opens up a significant market potential for track-and-trace management (barcoding) product authentication solutions for the pharmaceuticals industry.

- Source: [The Financial Express, Feb 11, 2013](#)

# Protecting the Patient

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## THE ECONOMICS OF COUNTERFEIT DRUGS

When you take a prescription drug, you're seeking relief from an ailment. Whatever that ailment may be, it's interfering with your daily life, your productivity, and your general wellbeing. So if you take a prescription drug that isn't what you thought it was, and it doesn't give you relief—maybe it even makes you feel worse—what's to blame? Learn about the prevalence of counterfeit and substandard drugs, what they're made of, where they're coming from and what is being done about it.



### HOW MANY DRUGS ARE COUNTERFEIT?



**10%** of medicines/pharmaceuticals in the United States.



**25%** of medicines/pharmaceuticals in developing countries—this includes substandard medications.



**50%** of medicines/pharmaceuticals sold through websites.

### WHAT IS IN COUNTERFEIT DRUGS?



Source: [Carrington College](#) and the [World Health Organization \(WHO\)](#) - 2011

# The Problem Can Go Back to the API

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In 2008, more than 80 people in the U.S. allegedly died from dosages of blood thinner Heparin. It turned out counterfeit ingredients traced back to China made their way into supplies in 10 countries, including the UK, Australia, Canada, and France.



Source: [Business Insider - Dangers of Counterfeit Drugs - 2012](#)

# What 6DCP Can Offer

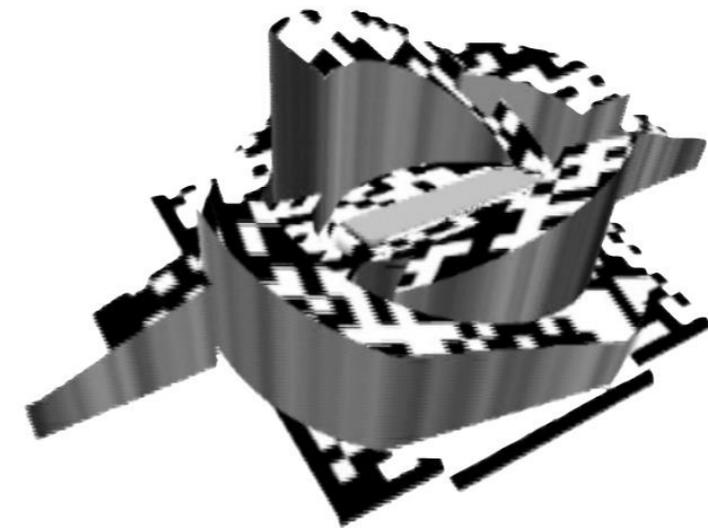
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Six Degrees Counterfeit Prevention, LLC is a leading provider of the world's first non-mathematical encryption method.

The encryption was developed in Israel over a span of 10 years in order to make it the most powerful counterfeit protection, grey market detection, track and trace and marketing acceleration solution on the market today.

A Sophisticated & Powerful  
Encrypted Barcode



The Only Non-Mathematical  
Encryption in the World

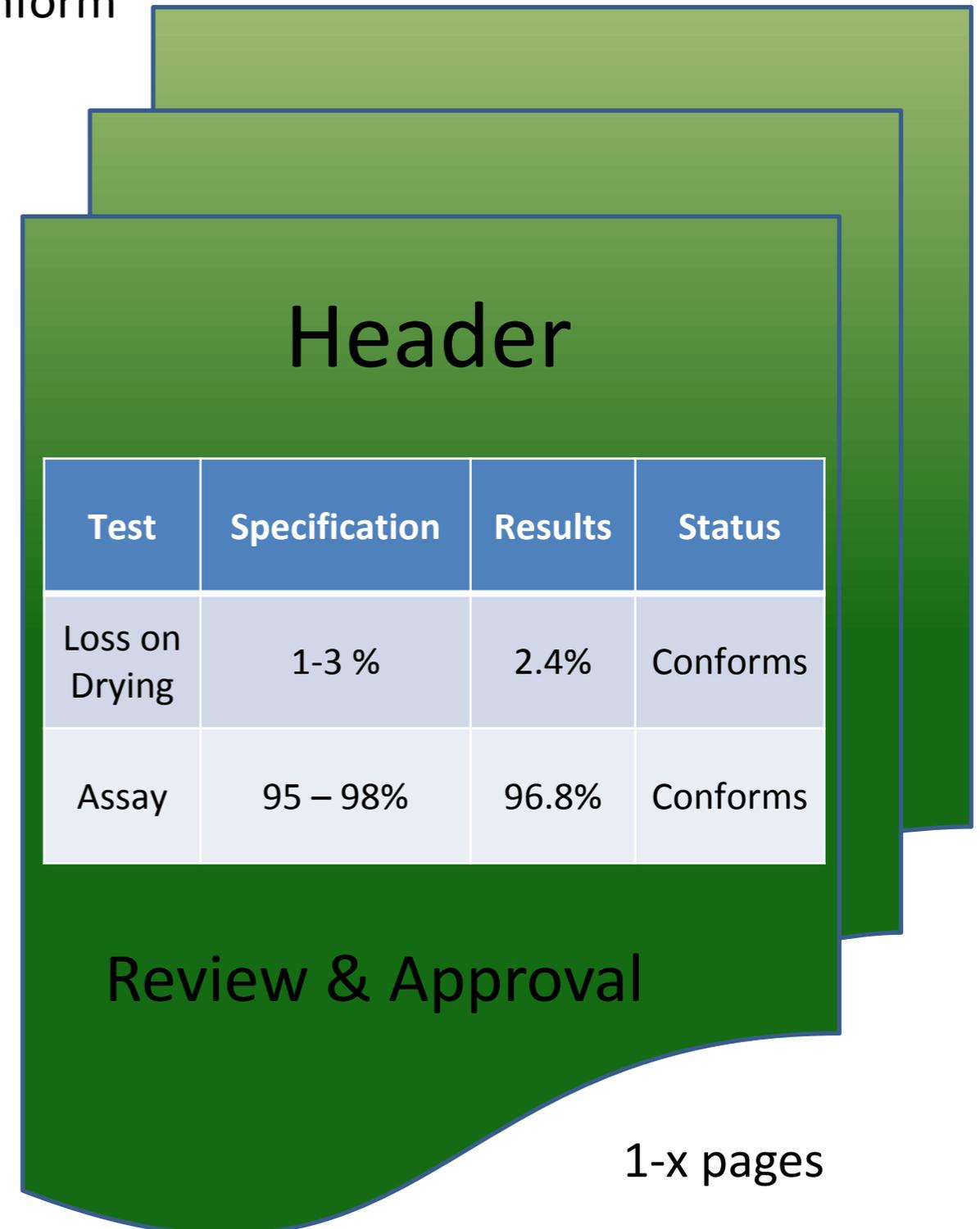
# COA Content



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- ✓ Each batch of product will be required to conform to laboratory test specifications.
- ✓ No two batch test results are the same.
- ✓ The typical Certificate of Analysis consists of three main sections.
- ✓ Header:
  - Company Logo
  - Company Name
  - Address
  - Item Number
  - Item Description
  - Batch
  - Date of Manufacture
  - Expiration Date
  - Destination Market
  - COA Version Number
- ✓ Body:
  - Master Data: Test, Specifications, Test Method
  - Variable Data: Results, Status
- ✓ Review and Approvals:
  - Compiled by
  - QC review by
  - QA approval by

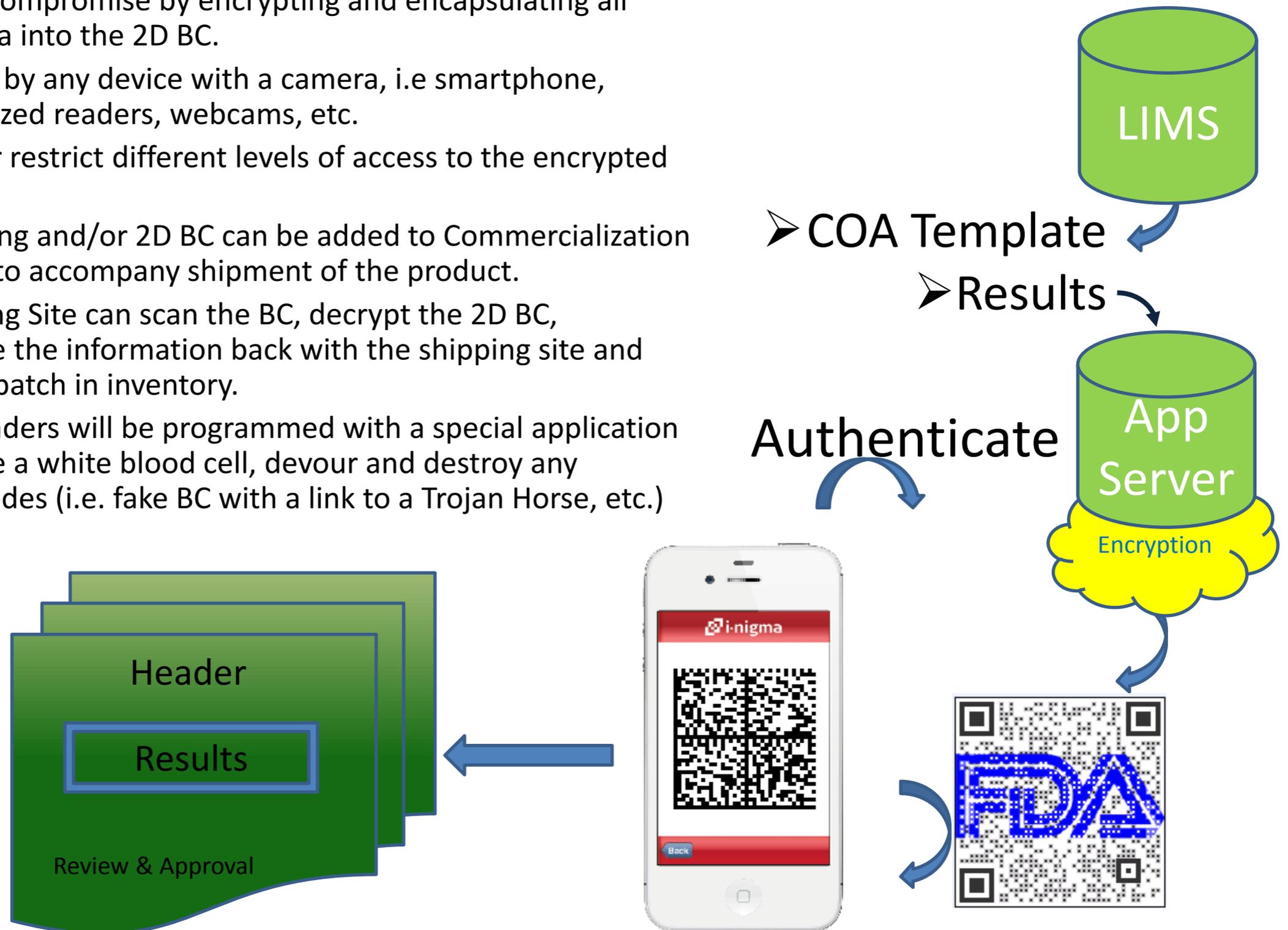


# COA Encryption, Decryption, & Authentication



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- ✓ Avoid data compromise by encrypting and encapsulating all relevant data into the 2D BC.
- ✓ Can be read by any device with a camera, i.e smartphone, commercialized readers, webcams, etc.
- ✓ Can allow or restrict different levels of access to the encrypted content.
- ✓ The URL string and/or 2D BC can be added to Commercialization documents to accompany shipment of the product.
- ✓ The Receiving Site can scan the BC, decrypt the 2D BC, authenticate the information back with the shipping site and receive the batch in inventory.
- ✓ Certified readers will be programmed with a special application that will, like a white blood cell, devour and destroy any malicious codes (i.e. fake BC with a link to a Trojan Horse, etc.)



# Demo



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Document security demo:

**State Bank of India**  
Guarantee Register Authentication

Guarantee Number:  (6)  
Date of Issue:  -  -  (DD-MM-YY)  
Applicant Name:  (18) **1**  
Applicant Account Number:  (6)  
Beneficiary Name:  (18)  
Guarantee Amount:  (8)  
Type of Guarantee:   
Expiration Date:  -  -  (DD-MM-YY)  
Last Claim Date:  -  -  (DD-MM-YY)  
Confirmation Email:  (EMAIL)  
**Generate Guarantee Stamp** **2**

**State Bank of India**  
Guarantee Register Authentication

**4**

Guarantee Number:   
Date of Issue:  -  -   
Applicant Name:   
Applicant Account Number:   
Beneficiary Name:   
Guarantee Amount:   
Type of Guarantee:  **Performance Guarante**  
Expiration Date:  -  -   
Last Claim Date:  -  -

[HTTP://RS.2CQ.CO/?A76597913695564B841368CF8253A0C315ECB09C598C1640D34E1C3D6008ECA8B87BF330076CA3E4CDE202B7A5B90316DDC851CC8010E2D2DCA26FDE5A5A163DEDDAA46297DADBCE111D001A8A4D](http://RS.2CQ.CO/?A76597913695564B841368CF8253A0C315ECB09C598C1640D34E1C3D6008ECA8B87BF330076CA3E4CDE202B7A5B90316DDC851CC8010E2D2DCA26FDE5A5A163DEDDAA46297DADBCE111D001A8A4D)

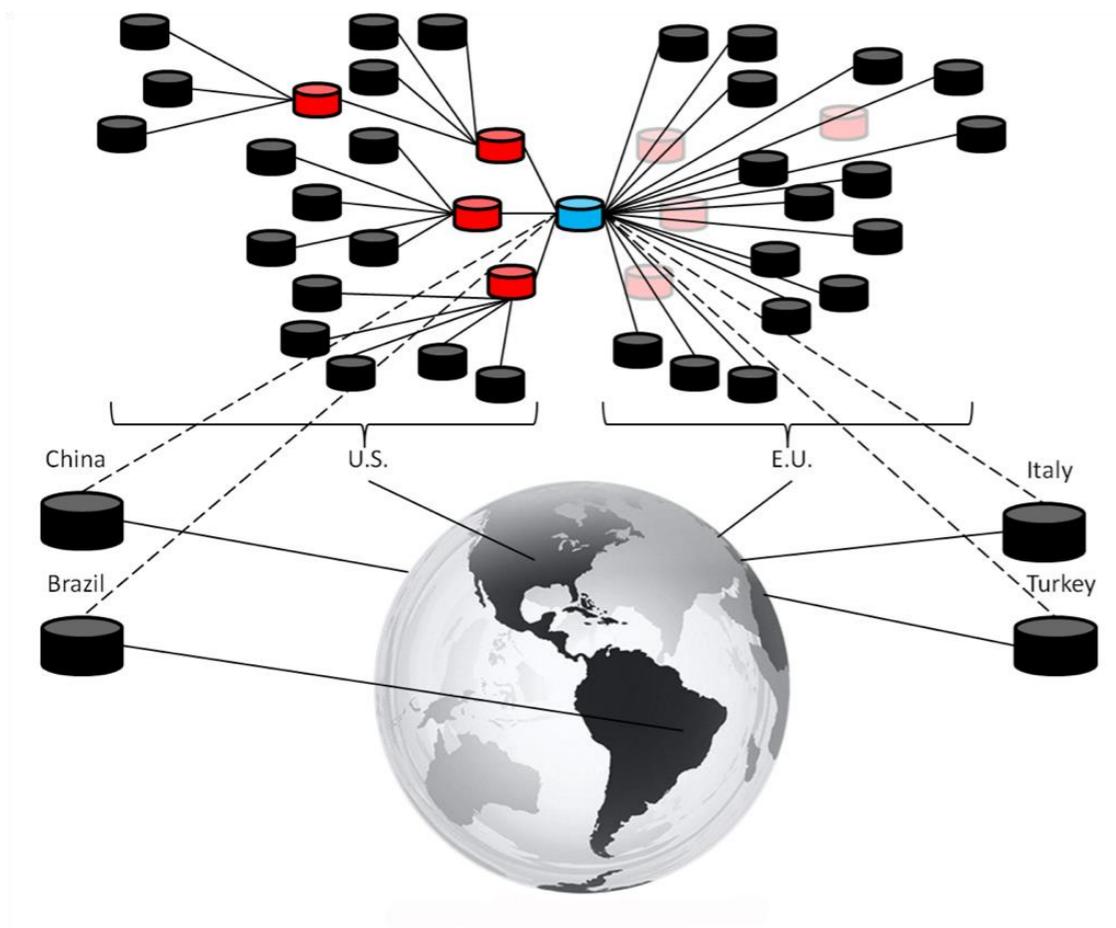
**3**

# Track & Trace

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- ✓ Track & Trace each product independently from manufacturing to the end user in real time
- ✓ Each scanning event captures three aspects to “geo-locate” the scan:
  - IP address
  - Nearest cell tower
  - GPS coordinates
- ✓ Supply chain data is stored in a log file to be used for analyzing logistics, White Listing, locations, etc.
- ✓ In regions where there is no or limited access to the internet, use **SMS network**



Even digital signatures have recently been compromised:

## [UNCOVERING ANDROID MASTER KEY THAT MAKES 99% OF DEVICES VULNERABLE](#)

“[...] discovered a vulnerability in Android’s security model that allows a hacker to modify APK code without breaking an application’s cryptographic signature, to turn any legitimate application into a malicious Trojan, completely unnoticed by the app store, the phone, or the end user. The implications are huge!”

Written By Jeff Forristal, Bluebox CTO

**In our opinion, it is a devastating hit to an E-SIGN document !**

**With 6DCP/Cryptocodex, we do not sign a document but capture the entire content and safeguard it.**

# Is the Data Secure? Cyber-attacks will be a Risk



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## ✓ Cybercrime in the pharmaceutical industry: a booming business

- **Being prepared - locking the door before the horse has bolted...** "The first step is knowing where your data is. Often companies secure their structured data sources - databases etc, but the challenge is that data is often scattered across unstructured sources 'in the wild' of an organization.

## ✓ RSA: Cyber-attack could put customers at risk

- Information about RSA's SecurID authentication tokens used by millions of people, including government and bank employees, was stolen during an "extremely sophisticated cyberattack," putting customers relying on them to secure their networks at risk, the company said today.

## ✓ Why Digital Signatures Are Not Signatures

- "The problem is that while a digital signature authenticates the document up to the point of the signing computer, it doesn't authenticate the link between that computer and Alice. This is a subtle point. For years, I would explain the mathematics of digital signatures with sentences like: "The signer computes a digital signature of message  $m$  by computing  $m^e \bmod n$ ." This is complete nonsense. I have digitally signed thousands of electronic documents, and I have never computed  $m^e \bmod n$  in my entire life. My computer makes that calculation. I am not signing anything; my computer is."

# Challenges (cont'd)

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- ✓ Not all COA's are digitally signed and validated. Some are manually signed, scanned and/or faxed
  - We have the capability to provision readers from authorized personnel responsible for signing these documents with an “approval” or “denial” function. So when they scan the code, they not only verify that the content is original, they can “approve” or “deny” as well. The scanning event is logged in the system that the authorized user approved the certificate. It will also record the date, time, and reader/scanner ID.
- ✓ One central system vs. distributed systems
- ✓ Enforcement of one process, one technology, one standard

# Benefits

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- ✓ Security of the COA results
- ✓ Cyber-security expertise
- ✓ Authentication by the issuer of the COA
- ✓ Military Grade encryption
- ✓ Inter-operability - No special equipment
- ✓ Relevant information about the reading device can be captured with each scanning event and stored in a log file.
- ✓ Can be integrated with LIMS, ERP, Serialization (SNI), or other transactional systems
- ✓ Can be the foundation for Track & Trace for raw materials, API, excipients, drug products, and finished goods
- ✓ Data compression ensuring fast data retrieval, Decryption, and authentication.
- ✓ Cost effective solution
- ✓ GS1 compliant, if necessary
- ✓ We will customize a fully secure, cloud based system to meet the regulatory requirements of the FDA.

# Thank You



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Website: <http://www.6dcp.com/>

Presentation: <http://www.6dcp.com/FDA>



**For Additional Information**  
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# Backup Slides

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# Backup Slides

# Examples of 2D BC's from the Demo

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# Examples of URL's from the Demo



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## FDA (Use FDA logo)

[HTTP://RS.2CQ.CO/?A76597913695564B841368CF8253A0C315ECB09C598C1640D34E1C3D6008ECA8B87BF330076CA3E4CDE202B7A5B90316DDC851CC8010E2D2DCA26FDE5A5A163DEDDAA46297DADBCE111D001A8A4D](http://RS.2CQ.CO/?A76597913695564B841368CF8253A0C315ECB09C598C1640D34E1C3D6008ECA8B87BF330076CA3E4CDE202B7A5B90316DDC851CC8010E2D2DCA26FDE5A5A163DEDDAA46297DADBCE111D001A8A4D)

[HTTP://RS.2CQ.CO/?C7C512BE626ADC188005A7C83BFF0F75FEE7D37B673E54104C9195A74614A1909A0662317228BCF86291DBD6DE47350E80C8B5DFAC055160EB4B29CA835E33C80DE8BECBB0E2BD19039C0001AB1B](http://RS.2CQ.CO/?C7C512BE626ADC188005A7C83BFF0F75FEE7D37B673E54104C9195A74614A1909A0662317228BCF86291DBD6DE47350E80C8B5DFAC055160EB4B29CA835E33C80DE8BECBB0E2BD19039C0001AB1B)

[HTTP://RS.2CQ.CO/?03F08BFF340ACD6D1BEDFC6B73998F93BCDE4C274AEDAD5B0875247A0C3D16C70473354A39A28FC50B19F9B032AB3B097E885BC7CFAFDC1357793A7A501C41FB2DEFC090E0F667B00C02000C5B6A](http://RS.2CQ.CO/?03F08BFF340ACD6D1BEDFC6B73998F93BCDE4C274AEDAD5B0875247A0C3D16C70473354A39A28FC50B19F9B032AB3B097E885BC7CFAFDC1357793A7A501C41FB2DEFC090E0F667B00C02000C5B6A)

[HTTP://RS.2CQ.CO/?A39363275153C96D8BD2B53A73C0FB8AACD62D9B96CB27CC3C27FC4172C36EE12B8A78773E156D7AA76E4C4E04B405CAA402674F03E16FFED9E197A178B48D79807E4B18730347221BCB004D3281](http://RS.2CQ.CO/?A39363275153C96D8BD2B53A73C0FB8AACD62D9B96CB27CC3C27FC4172C36EE12B8A78773E156D7AA76E4C4E04B405CAA402674F03E16FFED9E197A178B48D79807E4B18730347221BCB004D3281)

[HTTP://RS.2CQ.CO/?054F2B2665933E1108571B757190C1D7DE9B73233BEDE74F70A13A36920481E3F5513328795CFB0FACF3EE8A9D747BBB0EA57878E81E2836858D2D067DFDE2AEB4B9701BE8D67EC71213004F7F4D](http://RS.2CQ.CO/?054F2B2665933E1108571B757190C1D7DE9B73233BEDE74F70A13A36920481E3F5513328795CFB0FACF3EE8A9D747BBB0EA57878E81E2836858D2D067DFDE2AEB4B9701BE8D67EC71213004F7F4D)

[HTTP://RS.2CQ.CO/?078E7B11025564133A4B828F2A689E9B4FB21FD5EA161F44ED72D0632EF11BA54DED251E42B148C926535C1F5D5BC0EFBF9CD8D90814DCE6641E64E422B3D58AA1AC10491C7BBC6C1CAF00101689](http://RS.2CQ.CO/?078E7B11025564133A4B828F2A689E9B4FB21FD5EA161F44ED72D0632EF11BA54DED251E42B148C926535C1F5D5BC0EFBF9CD8D90814DCE6641E64E422B3D58AA1AC10491C7BBC6C1CAF00101689)

[HTTP://RS.2CQ.CO/?6E4DF5132AFA176BA2711C3B65C4545332343A4621532DC8AD7FBD56A5942B92BBA2075532CB8EE8B007921FA262381051B6F1ECA2D0463011DE9A54C77D62E8439F3AAA4336ACA3122800567C38](http://RS.2CQ.CO/?6E4DF5132AFA176BA2711C3B65C4545332343A4621532DC8AD7FBD56A5942B92BBA2075532CB8EE8B007921FA262381051B6F1ECA2D0463011DE9A54C77D62E8439F3AAA4336ACA3122800567C38)

[HTTP://RS.2CQ.CO/?AFF30505BCDDC0DAE733A8F7A355553C0434A3A846C793B98D7AE2825CE178FC0CD930CE1C1486A663DD24CB392D693599AD7E1FAD1DF475209F01F81690DF50E443A65500E923DC047D0015A330](http://RS.2CQ.CO/?AFF30505BCDDC0DAE733A8F7A355553C0434A3A846C793B98D7AE2825CE178FC0CD930CE1C1486A663DD24CB392D693599AD7E1FAD1DF475209F01F81690DF50E443A65500E923DC047D0015A330)

[HTTP://RS.2CQ.CO/?6FE258AB6C81C95722127A141662E961082EF54FC270203122E49761C8A73DABFB8B10D158F57BCD3DC806AF7FC745B0563E5DA0D02B3854F0837CEBE3FCE2CB82363136E40051F4114700420325](http://RS.2CQ.CO/?6FE258AB6C81C95722127A141662E961082EF54FC270203122E49761C8A73DABFB8B10D158F57BCD3DC806AF7FC745B0563E5DA0D02B3854F0837CEBE3FCE2CB82363136E40051F4114700420325)

# Examples of Decrypted 2D BC's

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**State Bank of India**  
Guarantee Register Authentication

Guarantee Number: 606060  
Date of Issue: 04 -07 -13  
Applicant Name: Laboratory ABC  
Applicant Account Number: 712980  
Beneficiary Name: USFoodandDrugAdmin  
Guarantee Amount: 990999  
Type of Guarantee: 1 **Performance Guarante**  
Expiration Date: 04 -07 -14  
Last Claim Date: 04 -07 -14

**State Bank of India**  
Guarantee Register Authentication

Guarantee Number: 606060  
Date of Issue: 04 -07 -13  
Applicant Name: Laboratory DEF  
Applicant Account Number: 712980  
Beneficiary Name: USFoodandDrugAdmin  
Guarantee Amount: 990999  
Type of Guarantee: 2 **Tender Guarante**  
Expiration Date: 04 -07 -14  
Last Claim Date: 04 -07 -14

**State Bank of India**  
Guarantee Register Authentication

Guarantee Number: 606060  
Date of Issue: 04 -07 -13  
Applicant Name: Laboratory GHI  
Applicant Account Number: 712980  
Beneficiary Name: USFoodandDrugAdmin  
Guarantee Amount: 990999  
Type of Guarantee: 3 **Advance Payment Guarante**  
Expiration Date: 04 -07 -14  
Last Claim Date: 04 -07 -14

**State Bank of India**  
Guarantee Register Authentication

Guarantee Number: 606060  
Date of Issue: 04 -07 -13  
Applicant Name: Laboratory JKL  
Applicant Account Number: 712980  
Beneficiary Name: USFoodandDrugAdmin  
Guarantee Amount: 990999  
Type of Guarantee: 4 **Retention Guarante**  
Expiration Date: 04 -07 -14  
Last Claim Date: 04 -07 -14

**State Bank of India**  
Guarantee Register Authentication

Guarantee Number: 606060  
Date of Issue: 04 -07 -13  
Applicant Name: Laboratory JKL  
Applicant Account Number: 712980  
Beneficiary Name: USFoodandDrugAdmin  
Guarantee Amount: 990999  
Type of Guarantee: 5 **Payment Guarante**  
Expiration Date: 04 -07 -14  
Last Claim Date: 04 -07 -14

**State Bank of India**  
Guarantee Register Authentication

Guarantee Number: 606060  
Date of Issue: 04 -07 -13  
Applicant Name: Laboratory MNO  
Applicant Account Number: 712980  
Beneficiary Name: USFoodandDrugAdmin  
Guarantee Amount: 990999  
Type of Guarantee: 6 **Facility Guarante**  
Expiration Date: 04 -07 -14  
Last Claim Date: 04 -07 -14

# Examples of Decrypted 2D BC's (cont'd)



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 **State Bank of India**  
Guarantee Register Authentication

Guarantee Number:

Date of Issue:  -  -

Applicant Name:

Applicant Account Number:

Beneficiary Name:

Guarantee Amount:

Type of Guarantee:  **Maintenance Guarante**

Expiration Date:  -  -

Last Claim Date:  -  -

 **State Bank of India**  
Guarantee Register Authentication

Guarantee Number:

Date of Issue:  -  -

Applicant Name:

Applicant Account Number:

Beneficiary Name:

Guarantee Amount:

Type of Guarantee:  **Customes Guarante**

Expiration Date:  -  -

Last Claim Date:  -  -

 **State Bank of India**  
Guarantee Register Authentication

Guarantee Number:

Date of Issue:  -  -

Applicant Name:

Applicant Account Number:

Beneficiary Name:

Guarantee Amount:

Type of Guarantee:  **Shipping Guarante**

Expiration Date:  -  -

Last Claim Date:  -  -