

PHARMACEUTICAL TRACK AND TRACE

**MOVING TOWARDS
NEW STANDARDS**



COGNEX

TOTAL TRACEABILITY, E-PEDIGREE AND SERIALIZATION

- What is ePedigree, and why is serialization necessary?
- Which countries have ePedigree regulations?
- How does ePedigree contain counterfeiting?
- How does serialization improve Overall Equipment Effectiveness (OEE)?
- What are the GS1 coding and marking standards for serialized products?
- What do I need to know about ISO 15415 or 15426?

If you are looking to better understand these issues and want to learn more about the context, regulations, and standards related to your industry, Cognex can help. Discover how you can benefit from implementing a track and trace solution and improve your productivity through our **Unique Value Proposition**

BUSINESS ISSUES & OPPORTUNITIES

With new regulation and legislation coming into effect in countries around the world, track and trace solutions are becoming a high priority. It is pertinent for the pharmaceutical industry to understand the challenges related to track and trace but it is even more important to foresee the opportunities that lay within.

REGULATION & LEGISLATION

Mass Serialization will impact ALL pharmaceutical plants

An increasing number of countries around the world are, or will be, adopting sophisticated tracking infrastructures mainly because of local regulations. The increasingly concentrated pharmaceutical industry has, for some time now, established specialized plants to produce fewer products but for an increasing number of countries. International corporations that want to continue exporting their products to countries with ePedigree regulations will have to adapt their product packaging and labeling to conform to these regulations.

Countries having regulatory deadlines

- Turkey : Partially implemented, full deployment January 1st, 2010
- France : January 1st, 2011
- United States (State of California) : January 1st, 2017

Countries having entered regulatory negotiations

- Spain
- Germany
- Italy
- Bosnia
- China
- Brazil

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Some of the implications.

Each individual primary and/or secondary item package (box, tube, vial, etc.) must be marked and must carry a unique identifier. A 2D Data Matrix code is the preferred data carrier, and must show GTIN Number and include the following data:

- Country Identifier
- Company Identifier
- Product Identifier
- Control Key
- Lot Number
- Serial Number
- Expiration Date

Each code must be readable at the final consumer level distribution point (pharmacies, clinics, hospitals, etc.). Data must be collected and stored in a format accessible to the regulation control organizations for a minimum period of five years.

INDUSTRIAL IMPACT

ePEDIGREE, MASS SERIALIZATION AND TOTAL TRACEABILITY.

The purpose of item-level serialization is to create an electronic health record (EHR) for every item at every stage of the supply chain, and to upload the EHRs to a secure, globally accessible database.

The aggregation of EHRs creates a complete history, or ePedigree, of each item. The goal is to allow all interested parties throughout the supply chain – from distribution to the local pharmacy – to be able to access the ePedigree for an item to verify its authenticity, thus ensuring patient safety.

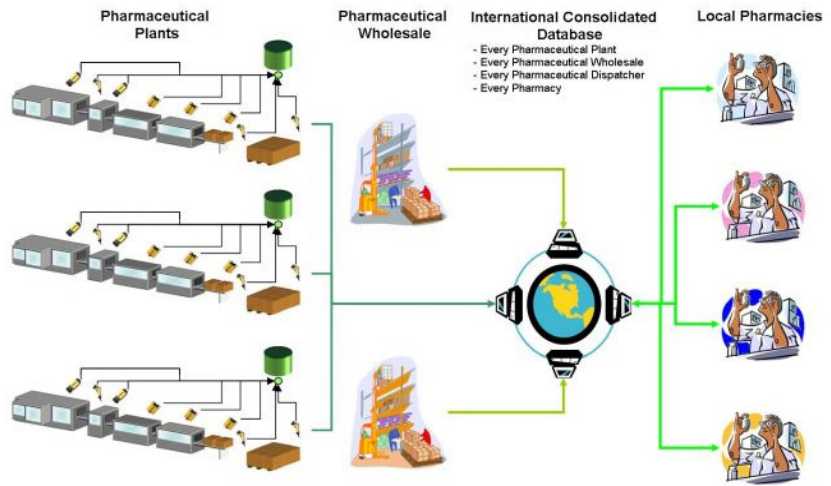
Though this vision for total traceability is in its early stages, countries will begin to adopt these principals as they move forward with ePedigree regulatory framework.

REQUIRED PROCESS MODIFICATIONS AND ENHANCEMENTS.

In order to meet GS1 standards, it is strongly recommended to upgrade existing productions lines and to examine investment plans in new lines in light of the most recent specifications. Typically this approach requires reviewing the following processes:

PRODUCT MARKING

GS1 standards should be kept in mind when investing in marking systems or retrofitting existing equipment for 2D Data Matrix marking capability.



DATA ACQUISITION & DECODING

Data acquisition at plant level is a three step process and requires to be in line with GS-1 standards and recommendations to review the following operations :

- Code grade verification

Data Matrix code grade verification is the first step. The use of the Cognex® DataMan® 100V Data Matrix code verifier for verification to ISO 15415 is necessary in order to guarantee code readability throughout the entire supply chain. Code verification is an off-line procedure that takes place according to internal SPC rules and is generally conducted by the QC Lab.

- On-line grading and OCV

Statistically controlling code grade quality is not sufficient when it comes to high volume production. In this case it is strongly recommended that 100% of production be monitored to avoid printing out of Data Matrix codes of poor quality and readability. Furthermore, printed text on pharmaceutical packaging must also be controlled in

production to ensure accuracy and human readability. The Cognex In-Sight® vision system family is designed to provide real-time process control on all characteristics of a Data Matrix code according to the ISO 15415 specification and can also handle Optical Character Verification (OCV).

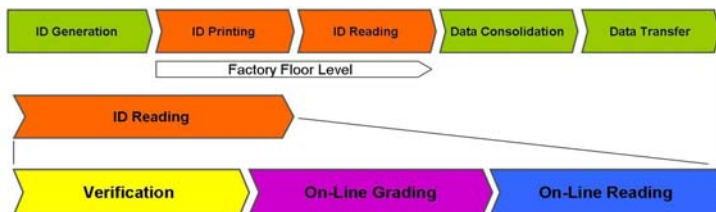
Ideally, online Data Matrix quality grading and OCV are performed at every critical process point of the production line. It is especially recommended that online grading and OCV be performed immediately after printing to prevent further process handling of items with poorly printed codes and text on the packaging.

The Cognex® In-Sight® family

is designed to provide real-time process control on all characteristics of a DataMatrix code according to the ISO 15415 specification and can also handle OCV (Optical Character Verification).

- On-line reading for factory floor data collection

Every serialization solution must have Data Matrix readers at all strategic production operations, for example when consolidating single items into bundles, or at the end of the line when grouping cartons onto pallets. At every step, Cognex® DataMan® industrial ID readers provide unmatched code reading performance with the option for a handheld or fixed-mount product. DataMan ID readers should also be considered for intermediate operations, such as product picking for QC. With high yield fixed readers and robust handheld units, products can be tracked all the way through the packaging process to shipment.



Process Type	Off-Line	On-Line	On-Line
Location	QC Lab	Factory Floor	Factory Floor
Speed	NA	Up to 400 parts/mn	Up to 400 parts/mn
Inspection Type	DataMatrix decoding and verification	DataMatrix decoding, grading and readable text verification OCV	DataMatrix and/or bar code decoding
Volume of Products Considered	Statistical Product Picking	100% of production	100% of production
Specifications	100% compliance to ISO 15415.	Quality drifts on ISO 15415 characteristics	NA
Environment	Strict environment variation control to met ISO Standard	Steady environment variation control.	Limited Environment variation control.
Read Expectations	NA	Very High First Pass read yields	Very High First Pass read yields

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VALUE YOUR INVESTMENTS

How do you value investments that are made to satisfy regulators? Legislation aimed at securing patient safety rarely takes into account the cost and constraints imposed on manufacturers and the supply chain. Fortunately, ePedigree legislation, while it imposes a burden on the pharmaceutical industry, presents numerous benefits to manufacturers that will allow them to experience a high return on investment. Specifically, ePedigree will make it far more difficult for counterfeit products to enter the supply chain for authentic products to be diverted for unauthorized uses, or into unauthorized markets. Furthermore, the consolidation of factory floor data enables a very detailed analysis of the use of industrial assets. The implementation of a track and trace system can deliver productivity gains through better internal management of resources – gains that can preserve margin at a time when the patents for several highly profitable “blockbuster” drugs are expiring. And when viewed from the perspective of the pharmaceutical contract laboratories, the traceability system can become a valuable tool for increasing bottom line profitability through lean management of capital equipment and resources.

CONTACT YOUR LOCAL COGNEX SPECIALIST

Do you have specific issues relative to counterfeit containment or OEE you would like to discuss ? Please feel free to contact your local Cognex Specialist to help you review your needs.

EFFECTIVE COUNTERFEIT PREVENTION

The World Health Organization (WHO) estimates that overall sales of counterfeit medicines represent 10% of global sales, or approximately \$35 billion US dollars or 26 billion Euros! The percentage of counterfeit drugs sold can in some countries is as high as 25% to 30%, and can even reach 50% in developing countries!

There many costs of counterfeiting, which are felt by both patients and pharmaceutical manufacturers alike:

- **Patient safety:** Treatment failure, intoxication, and even death
- **Legal Liability :** Who is legally responsible?
- **Financial:** Loss of income, profitability, and intellectual property rights
- **Company image and brand :** What is the cost in terms of bad publicity?

Mass serialization, marking Data Matrix codes on packaging, and enabling authenticity verification through the use of ePedigree are the best strategies available for preventing counterfeiting products from entering the supply chain.

OEE IMPROVEMENTS = BOTTOM LINE IMPROVEMENT

As in any manufacturing industry, pharmaceutical companies need to be constantly vigilant to eliminate inefficiencies in production. By implementing mass serialization, manufacturers will be able to identify process bottlenecks, minimize equipment downtime and maintenance, and most of all, to carry out corrective actions that will increase productivity and optimize production resources.

When each product has a unique serial number, its processing time can be precisely calculated, making it easier to identify areas where a reallocation of human resources and equipment improvements will produce the most significant return on investment.

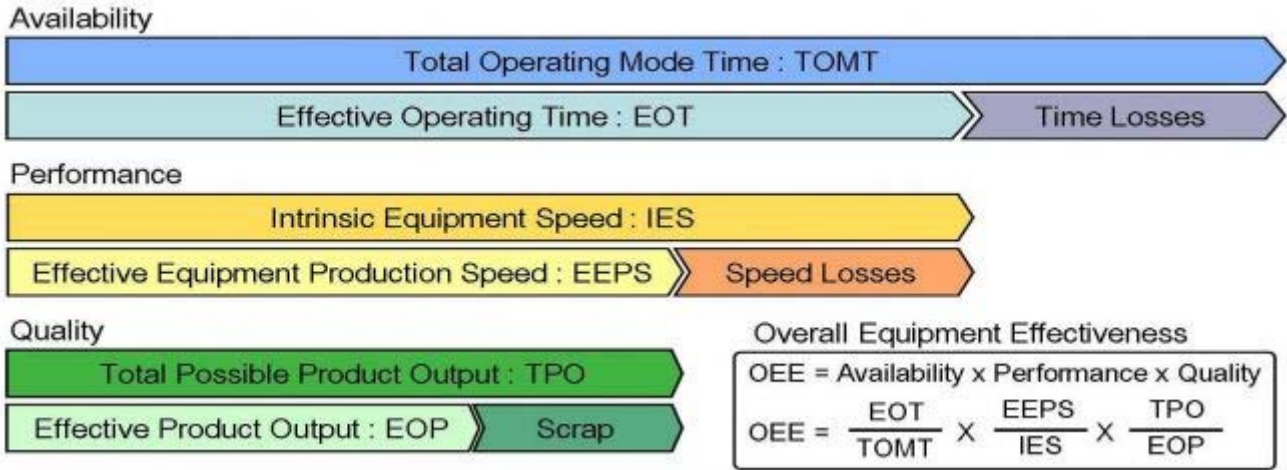
Ultimately, by using data readily available through track and trace procedures, every pharmaceutical production site can implement an Overall Equipment Effectiveness (OEE) program that will directly contribute to improving the company's bottom line.

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OVERALL EQUIPMENT EFFECTIVENESS

Overall Equipment Effectiveness (OEE) is the measure of the overall productivity a company is experiencing with its manufacturing resources. OEE takes in account the three following items: availability, performance, and quality. Unfortunately, many companies only have a very approximate idea of their OEE and often limit their analysis to averaging their throughput. The pharmaceutical industry is no exception to this rule.

The following formula will help you understand the concept.



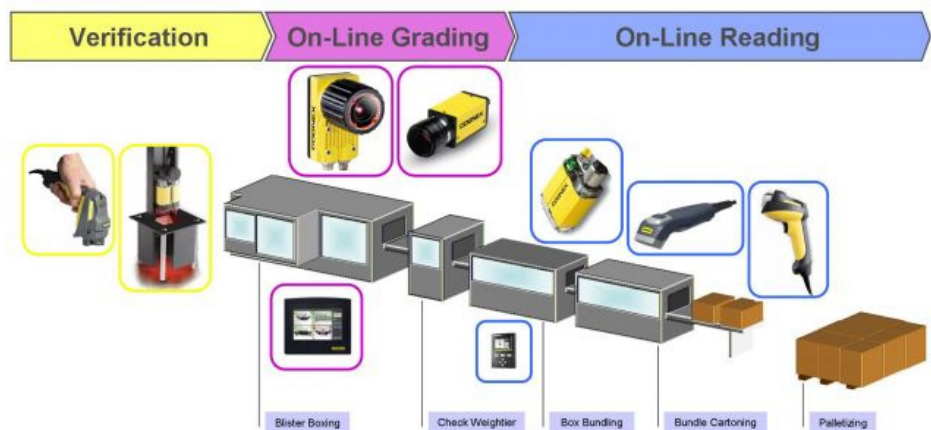
IMPROVE YOUR OEE WITH MINIMAL INVESTMENT

Many industries have OEE levels of 40% to 50%. Even if you are running at a higher OEE than 40-50%, there is almost always opportunity for improvement. Consider a line that produces 200 parts per minute. An OEE increase of just 2% would result in the production of an additional 1.4 million products per year – for a single line!

Cognex, by providing reliable information to your IT platform, will help to improve your processes by communicating valuable information to other equipment on the factory floor, thus enabling proactive and reactive process and yield improvements. And the most exciting thing about OEE is that there is little or no investment required to improve it !

COGNEX'S GLOBAL TRACEABILITY SOLUTION HELPS IMPROVE PRODUCTIVITY

For traceability and verification in all of your manufacturing, packaging and shipping processes, you need a full range of solutions to choose from. From fixed mount readers and cordless handheld readers to complete vision systems capable of performing inspection, ID and verification, Cognex can help you dimension a cost-effective track and trace solution to deliver the performance you need.



CASE STUDY

1 Standard and high performance solution

Customer

Large Multi-Site Laboratory in France.

Background

Customer was investigating solutions relative to investments related to CIP 13 and track and trace. The system had to be deployed on all lines before end of December 2010.

Customer Constraints & Process Details

- Marking Technology : Ink Jet Cartridge Printing Technology
- Max. Throughput : 400 ppm
- Linear Conveyor Speed : up to 40m/mn
- Communications : Ethernet TCP/IP and I/O.
- Data Format : TCP/IP Protocol via ASCII format
- *Grade Verification : Statistical picking*
- *Dynamic Grading : According to characteristic in ISO 15415*
- *Text Verification : As an option (approx. 40 characters)*
- *Fixed Mount Decoding : At each reconciliation step.*
- *Handheld Decoding : For palletizing, pick and extraction points*

Customer Expectations

- Highest first pass yields
- Lowest false reject rates
- Standard off-the-shelf product
- Hardware and software compatibility
- Worldwide support network

Cognex Configuration Selected by Customer :

After thorough trials and benchmarks customer finally selected Cognex as its global supplier and choose the following configurations:

Code Grade Verification

- Fixed mount verification system: DataMan DM-100V

Post Marking - Dynamic Grading & Character Verification

- Camera: In-Sight Micro 1400

Accessories: Cables, I/O Box, Lighting, Lensing & filters

Process traceability & reconciliation

- Camera : In-Sight Micro 1110

Accessories: Cables, I/O Box, Lighting, Lensing & filters

Paletizing, picking & extraction

- Handheld Reader: DataMan 7550LR



2 Customer benchmarks Cognex and replaces all existing units!

First pass read yield is the ability for a decoding system to read code upon first try. At speeds that now come close to 400 or 500 parts per minute, this ratio can be the fine line between profit and loss.

To improve packaging yields, a customer tested the DataMan DM 100X on a run of over 1.3 million parts and achieved a first pass read yield of 99.987% thus improving their throughput and productivity.

The customer's previous decoding systems rejected 108.000 parts per year, parts that had to be handled in default mode increasing all unit level costs. As of today, they have had 15 times less false rejects amounting to 15 times less rework!

Customer benchmarks Cognex and ... replaces all existing units!

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3 Machine builder chooses Cognex for high performance applications and unbeatable price.

A large European machine builder needed to benchmark several vision systems for its new print and read machine. The application consisted of reading Data Matrix codes, 100% online grading of the codes, and verifying printed text (40 characters on 4 lines) at a speed of over 400 parts per minute!

After thorough testing, Cognex was qualified as the undisputed leader with read rates significantly above expectations. While most other systems had high false reject rates, Cognex equipment preserved packaging yields with the lowest false reject rate of the benchmark. Furthermore, the In-Sight solution for track and trace gave an extra edge to the Cognex offering. What finally decided it for the customer was Cognex' wide range of products and worldwide support network that would solve and support applications in over 140 countries!

ASK US ABOUT IN-SIGHT TRACK AND TRACE SOLUTIONS.

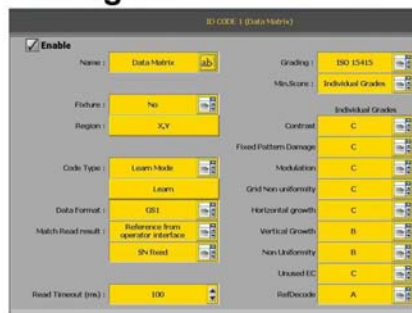
We are confident that we can help you implement the most cost effective, reliable track and trace solution available. If you are considering new identification systems — or even if you are satisfied with your existing systems - let our team show you how a track and trace solution for In-Sight smart cameras can improve your yields and maximize your return on investment. Contact our European organization or submit your application today!

The Global Healthcare User Group (GS1 HUG™) “strongly recommends investing in camera-based” systems for automatic identification. As pharmaceutical manufacturers around the world begin preparing for the coming ePedigree requirements, they are discovering that camera-based systems are not only recommended, they are essential for a successful track and trace program.

Fortunately, In-Sight vision systems are ready for ePedigree today, equipped with all of the capabilities you need to automatically identify and verify the integrity of information printed on primary and secondary pharmaceutical product packaging:

- **High performance reading of all GS1-standard Data Matrix codes and 1D barcodes.**
- **On-line grading of Data Matrix code quality.**

Configure



Produce



- **Highly reliable verification of printed text (commonly known as “Optical Character Verification”, or OCV).**

Plus, the compact, all-in-one In-Sight vision systems are easier to integrate, maintain and validate for 21 CFR Part 11 compliance than PC-based vision systems. With dozens of available models offering multiple performance levels, there's an In-Sight vision to meet the requirements of any application.

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HOW TO GET STARTED

Learn more

With almost three decades of vision experience and thousands of pharmaceutical installations throughout the world, Cognex has developed the most complete line of solutions available. Whether you need fixed-mount readers to complete factory floor data collection or a more powerful solution giving you on-line grading and OCV capabilities, or if you are looking to verify grade quality in your QC lab or by sampling products off the line, Cognex does it all!

Serialization application support

Cognex offers a worldwide support network (34 Cognex offices and over 300 official partners in the world) can help you address every aspect of your serialization project.

By simply registering for your FREE personalized **traceability demonstration** you can get a first look at our track and trace solution for pharmaceutical serialization. Within a few minutes, you'll see your codes (2D and/or OCV) being read, displayed, and data transferred. You can also choose to submit your application online to our engineering staff which will tailor a first approach according to your production specifications.

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OTHER PHARMACEUTICAL APPLICATIONS

Cognex offers a wide range of solutions for most your pharmaceutical needs :

- ID code reading, verification and grading
- OCV (Optical Character Verification)
- Blister Inspection
- Fill Level Verification
- Package inspection
- Robot guidance for pick and place applications



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COGNEX VALUE PROPOSITION

When it comes to Pharmaceutical track and trace, Cognex has the most complete Value Proposition available. Contact us at www.cognex.com to have a Cognex expert contact you and have him detail the following advantages.



• Limit Capital Expenditure

Cognex is significantly less expensive than other providers offering inferior solutions. In some cases, a Cognex solution can deliver up to 42% budgetary savings.

• Preserve your Packaging Yields

Using Cognex readers on your line can cut rework up to 15 times compared to competitive equipment by reducing false rejects. Gathering the right information right from the start is a critical issue when it comes to collecting factory floor data that will be collected and analyzed at the plant IT level.

• Reduce Total Cost of Ownership

With Cognex's complete product range—from Verification to simple handhelds—you have one supplier with worldwide support and a common philosophy. Our systems handle existing, interim, and future applications.

• Compliance and Standards

Cognex solutions align to GS1 recommendations when it comes to serialization and CIP 13, and comply, where necessary, to code quality standards such as ISO 15415, ISO 15426-2 and ISO 16022. Furthermore, Cognex can offer FDA 21 CFR Part 11-ready solutions, making it easier to validate compliance for the installed system.

• Printing Quality readiness throughout value chain

Cognex can detect print quality issues at any stage of production and packaging, from verification through hand held reading at the end of the line.

• Factory floor On-Line Data Collection

Cognex provides seamless integration for efficient data collection, formatting, and transmission to systems used for data analysis and archiving.



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Companies around the world rely on Cognex vision to optimize quality and drive down costs.

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