DOMINO

From Compliance to Competitive Advantage

Serialization for Pharma Manufacturers

2026 Guide

Domino. Do more.

"Serialization is the single greatest challenge the printing industry has faced in recent decades. We have created this guide to help you understand, implement, and optimize serialization to ensure compliance, traceability, and patient safety. Have questions? Just ask – we're here to help"

***James Cutforth** – Global Head of Regulated Sectors*

Table of Contents

1. How Serialization Powers the Future of Pharma

Serialization was once viewed as a regulatory checkbox, a necessary cost of doing business in regulated markets. Today, it has evolved into a strategic enabler for pharmaceutical manufacturers, contract packagers, and supply chain leaders.

Beyond just printing codes and meeting deadlines, serialization is unlocking new value across operations, from the packaging line to global distribution networks.

Why Serialization Is No Longer Just a Compliance Task

- **Regulators now demand more than just codes** – they want data accuracy, event traceability, and secure, interoperable systems.
- **Global complexity is rising** with divergent requirements (DSCSA, EU FMD, ANVISA, Chestny ZNAK), but a unified serialization strategy can streamline operations.
- **Supply chain risks have escalated** – from counterfeit drugs to global disruptions, requiring greater visibility and resilience.
- **Digital transformation in Pharma 4.0** positions serialization as the backbone of traceability, data analytics, and patient–centric models.

The Strategic Value of Serialization

Quick Wins and Long-Term Impact

- **Compliance** – Global readiness for DSCSA, EU FMD, ANVISA, Chestny ZNAK, etc.
- **Patient Safety** – Greater protection from falsified or diverted medicines
- **Supply Chain Resilience** – End–to–end visibility, faster recalls, and reduced disruption
- **Waste Reduction** – Less overproduction, and better inventory accuracy
- **Innovation** – Foundation for smart packaging, digital health, and personalized logistics

Serialization isn't just about codes, it's about control, clarity, and competitive edge.
The companies that treat it as a core capability, not just a cost, will lead the next era of pharma manufacturing.

Key Benefits by Role:

For Compliance Managers:

- Reduced audit risk through accurate, real time EPCIS reporting
- Fewer errors in aggregation and commissioning
- Stronger alignment with global standards (GS1, WHO, etc.)

For Plant & Line Managers:

- Fewer line stoppages from smarter print/verify workflows
- Faster changeovers with integrated serialization setups
- Clearer root cause insights into rejects and downtime

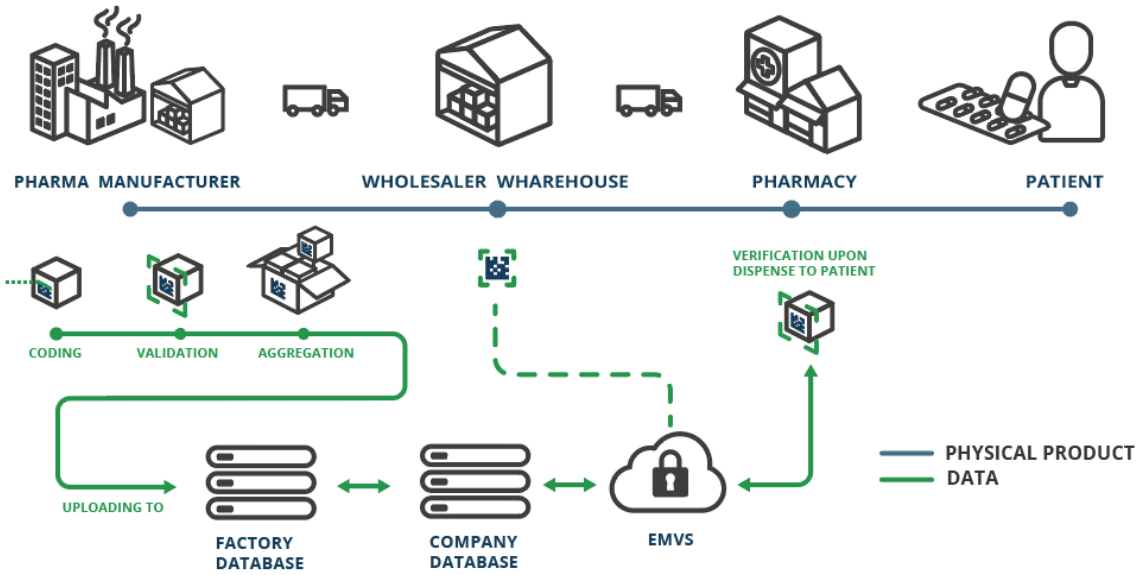
For Pharma Leaders:

- Data driven supply chain strategies
- More agile product launches into regulated markets
- Enhanced brand trust through patient safety and product integrity

2. How Does Serialization Work?

Serialization is the cornerstone of pharmaceutical traceability. It ensures that every saleable unit of medicine can be uniquely identified, tracked, and verified throughout the supply chain.

Here's how the process works from start to finish:



1. Unique Identifier Generation

Each product pack is assigned a globally unique identifier. This typically includes GTIN, Serial Number, Batch Number and Expiry Date. These elements together create a Unique Serialized Identifier (USI), meeting local and international regulatory standards.

2. Printing and Encoding

The identifier is printed directly onto the packaging, usually as a 2D Data Matrix code along with human readable text. High–resolution inkjet or laser printers are integrated into the production line to ensure speed and accuracy.

3. Verification and Inspection

Vision systems automatically verify the barcode's print quality and ensure each serial number is unique and scannable. Any faulty or duplicated packs are immediately rejected to maintain integrity.

4. Data Management

Serialization data is securely stored in multiple layers: line level and site level systems for immediate production oversight; Company wide databases for enterprise level traceability; and external repositories, such as the FDA's DSCSA systems or the EU Hub (EMVS), for regulatory compliance.

5. Aggregation (Optional but Recommended)

Serialization can include aggregation, linking units to packaging hierarchies. This enables efficient logistics, inventory control, and faster handling across the supply chain.

6. Supply Chain Tracking

As the product moves through the supply chain, each scan confirms its location and status, helping to detect diversion, theft, or counterfeiting in real time.

7. Authentication at the Point of Dispense

Before reaching the patient, the medicine is scanned one final time to:

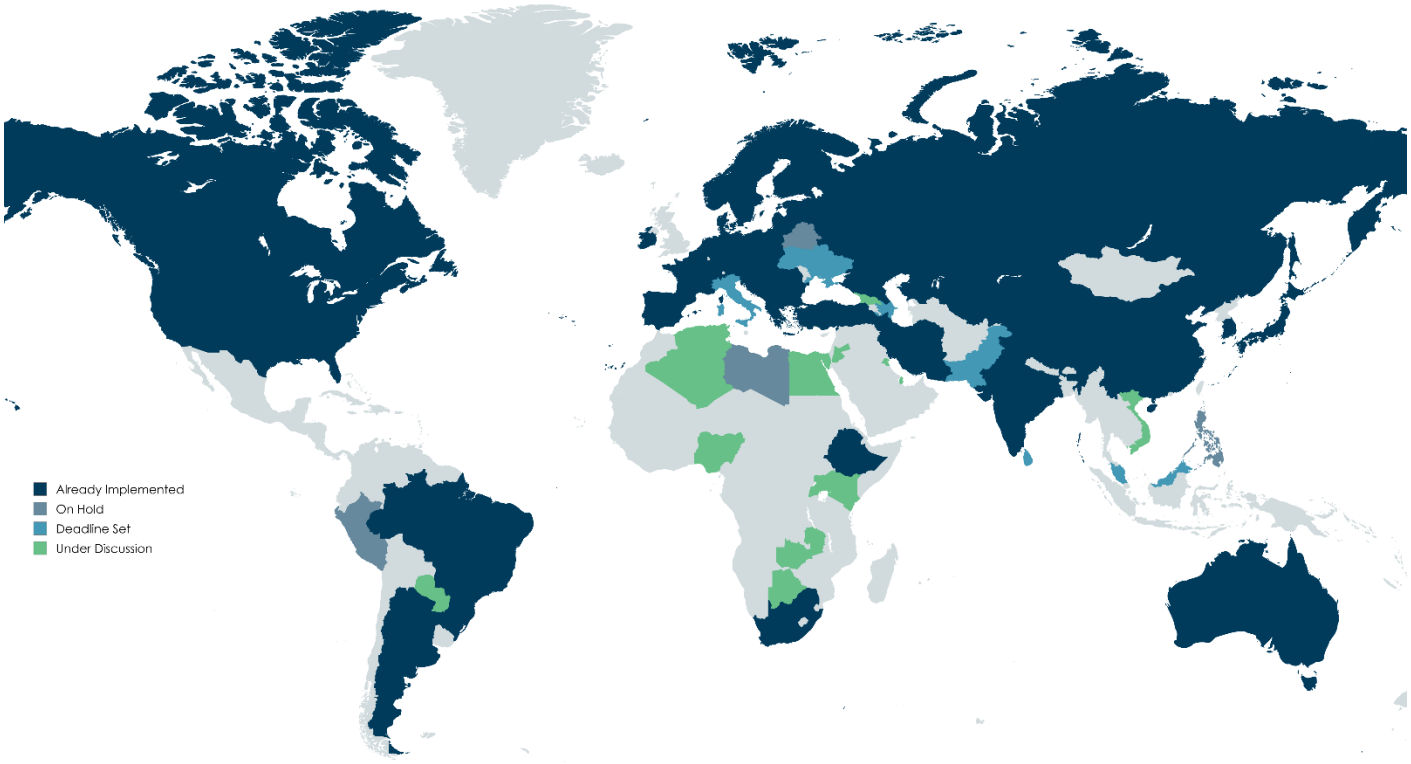
- Confirm it is valid and has not been recalled or tampered with.
- Ensure it is authorized for sale in the given country
- Comply with pharmacy or hospital protocols

Anatomy of a code

Human Readable Code (HRI) and Machine-Readable Code include:

- GTIN/NDC/China Drug Code (as applicable)
- Serial Number
- Batch/Lot Number
- Expiration Date
- Typically encoded in 2D Data Matrix, with HRI printed below/nearby

3. Global Serialization Requirements – 2026 & Beyond



Country	Serialization Required	UDI Required (Devices)	Format & Content of Human Readable Code	Aggregation Mandatory?
USA	DSCSA	FDA UDI Rule	GTIN, Serial No., Lot, Expiry (HRI + 2D Data Matrix)	Not yet, but encouraged
Canada	GS1 aligned	Phased UDI rollout	GTIN, Lot, Expiry (HRI and barcodes bilingual)	Voluntary for now
China	Drug Traceability Code	For devices	China Drug Code (QR/2D) + Product Name, Batch, Expiry	Mandatory for prescription drugs
India	Export only	Partially	Barcode with GTIN, Batch, Expiry (HRI optional)	For exports via tertiary packaging
European Union	EU FMD	EU MDR	GTIN (Product Code), Serial No., Lot, Expiry in HRI + 2D	Not mandatory EU wide
UK	MHRA FMD	UK MDR 2020	Same as EU: GTIN, Serial, Lot, Expiry (HRI + 2D)	Aggregation encouraged but not required
Switzerland	Swiss Medi Code / EMVS equivalent	Swissmedic aligned with EU MDR	GTIN, Serial, Expiry, Batch in HRI + 2D with Swiss– specific adaptations	Not yet required

Aggregation:

Aggregation refers to linking parent child relationships between unit, carton, and pallet levels.

- **Mandatory in China and India (exports)**: These require full aggregation for compliance with national track & trace systems.
- **USA & EU**: Not mandatory but highly encouraged for DSCSA compliance (USA) and logistics optimization (EU). By 2024–2025, aggregation may become the de facto standard for DSCSA.

Executive Summary

- If you're selling into China or India, your coding equipment must support serialization + aggregation + QR format.
- For US & EU, serialization + human readable info is essential, but aggregation is currently optional.
- Any labeling software must support multi format outputs, audit trails, and compliance with 21 CFR Part 11 or Annex 11 (EU).

4. What Equipment Must Be Serialization Ready?

4.1 Printers and Coders

Printers must support variable data in real time and integrate seamlessly with the line's software and inspection systems. There are several printing technologies used in pharma serialization, each suited to different packaging types, substrates, and line speeds. These include Thermal Inkjet (TIJ), Thermal Transfer Overprinting (TTO), Continuous Inkjet (CIJ), Piezo inkjet (for cartons or cases), Piezo digital printing for foil and Tyvek, and Laser coders, each with specific advantages depending on the application.

1. Thermal Inkjet (TIJ)

Thermal Inkjet is a widely adopted technology in pharmaceutical packaging, particularly for printing 2D serialization codes. It offers a combination of precision, speed, and cleanliness that makes it ideal for regulated, high throughput environments.

How TIJ Works

TIJ rapidly heats ink inside sealed cartridges, ejecting tiny droplets through nozzles without touching the surface. This non-contact method enables clean, high–resolution printing even at high line speeds.

Key Advantages for Pharmaceutical Applications

- **High print quality** – Delivers sharp, scannable 2D codes (up to 600 dpi) for reliable grading and verification.
- **Fast and clean** – Handles high speed lines without smudging, ideal for delicate or coated surfaces.
- **Low maintenance** – Cartridge based design with no moving parts; cleanroom friendly and easy to operate.
- **Compact and flexible** – Easy to integrate into existing lines and compatible with serialization systems.
- **Multi–surface capable** – Works on paperboard, labels, foils, and even plastic or glass with the right ink.

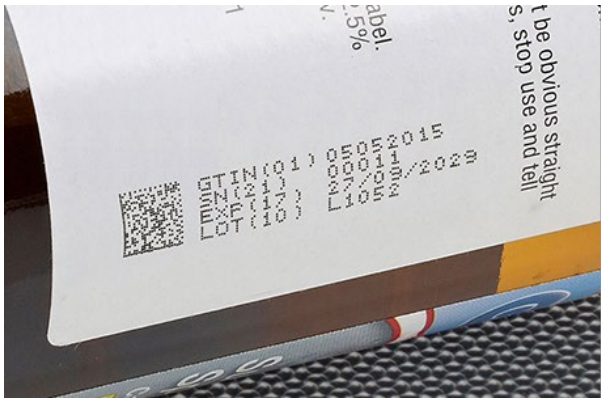
Application Surfaces

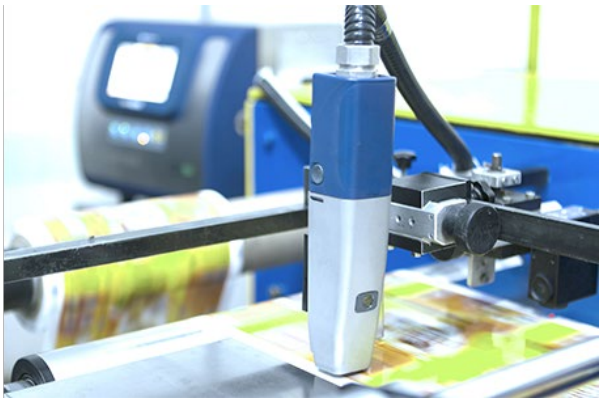
- Paperboard cartons
- Labels (paper or synthetic)
- Blister foils and films (with solvent ink)
- Plastics or glass (using specialty inks)

TIJ offers high quality, low maintenance, and adaptable printing – making it one of the most reliable and pharma ready technologies for serialization.

2. Continuous Inkjet (CIJ)

Continuous Inkjet is widely used for printing variable data on high-speed packaging lines. It is valued for its speed, flexibility, and ability to print on uneven or curved surfaces.





How It Works

CIJ works by continuously spraying charged droplets of ink through a nozzle toward the substrate. The ink is deflected by an electric field to form characters and codes as the product moves past.

Key Advantages for Pharmaceutical Applications

- **High–speed compatibility** – CIJ can print accurately at very high line speeds, making it well suited for fast moving environments.
- **Wide substrate range** – Performs well on porous and non–porous surfaces, including curved or irregular objects.
- **Non–contact and fast drying** – Ideal for coding on bottles, ampoules, or blister packs.
- **Small character capability** – Can print compact codes in tight spaces where label real estate is limited.
- **Established and flexible** – CIJ has long been used in pharma and integrates easily with existing equipment.

Application Surfaces

CIJ is commonly used on:

- Bottles (plastic or glass)

- Blister packs and lidding materials
- Vials and ampoules
- Cartons and outer cases

Final Note

CIJ offers proven performance in high–speed environments and is especially useful for curved or uneven surfaces where other technologies may struggle.

3. Laser

Laser coders are used in pharmaceutical applications where permanence, precision, and zero consumable operation are priorities. Laser marking is especially valuable for engraved, tamper evident, or high security applications.

How It Works

Laser systems use focused light beams to ablate, etch, or discolor the packaging surface. This creates a permanent, high contrast mark without using ink or ribbon.

Types of Laser Coders:

CO_2 Laser

CO_2 lasers use infrared light at a wavelength of 10.6 microns by electrically exciting a gas mixture (usually CO_2, nitrogen, and helium) to vaporize the surface layer of organic materials like paperboard, labels, and some plastics. They are ideal for high–speed coding on cartons and non–metallic substrates, offering sharp contrast without consumables.

Fiber Laser

A fiber laser generates a focused, high–intensity beam of light at a shorter wavelength (~1.06 microns) using a laser diode and a fiber optic cable doped with rare earth elements (typically ytterbium). They deliver deep, permanent engraving with excellent durability, often used on plastic caps or metal devices.

UV Laser

UV lasers (usually around 355 nm) work by photochemical reaction, “cold marking” the surface without heat damage. They are ideal for delicate or multilayer materials, like blister foil or Tyvek, where precise, low impact marking is required.

Fiber Laser, CO_2 Laser and UV Laser codes.

Key Advantages for Pharmaceutical Applications

- Permanent codes – Ideal for products that require durable, tamper proof marking.
- No consumables – Eliminates the need for ink or ribbons, reducing waste and running costs.
- Clean and contact–free – Suitable for sterile or high cleanliness environments.
- Consistent print quality – Maintains sharpness over long runs with minimal intervention.
- Supports anti–counterfeiting – Can be used for covert or high security marking features.

Application Surfaces

Laser is best suited for:

- Cartons (coated and uncoated)
- Plastic bottles or closures (with laser sensitive additives)
- Blister packs and lidding foils
- Paper labels or inserts

Final Note

Laser coding is well suited for operations that require long term code durability and minimal maintenance. It's a strategic option for premium, high security, or sustainability focused packaging lines.

4. Thermal Transfer Overprinting (TTO)

TTO is commonly used in pharmaceutical packaging where flexible films or labels are involved, offering durable, high-resolution prints well suited for serialization.

How It Works

TTO uses a heated printhead to transfer ink from a ribbon onto the substrate. The printhead applies pressure and heat in precise patterns to form characters and codes on the surface.

Key Advantages for Pharmaceutical Applications

- High quality printing – TTO delivers sharp 2D codes suitable for grading and long-term readability.
- Excellent durability – Produces smudge and abrasion resistant prints, ideal for challenging handling or storage conditions.
- Clean and consistent – Offers reliable print quality on flexible packaging like sachets, pouches, and blister foils.
- Minimal consumable waste – Ribbon advance systems are optimized to reduce material usage between prints.
- Precise placement – Particularly effective for printing in register with pre–printed packaging elements.

Application Surfaces

TTO is commonly used on:

- Flexible plastic films (e.g., PET, PE, PVC)
- Blister lidding foils
- Labels on pouches or stick packs
- Preformed sachets and wrappers

Final Note

TTO is a preferred technology for serialization when working with flexible substrates and high-volume, high-speed packaging lines, especially in solid dose, OTC, and clinical trial production.

5. Piezo Inkjet (PIJ)

Piezo inkjet printing is a drop–on–demand technology used in both high–speed and specialty pharma applications. It offers flexibility in ink types and performs well on a variety of surfaces.

How It Works

Piezoelectric crystals flex when electrically charged, forcing ink droplets through the nozzle in precise patterns. Unlike TIJ, Piezo systems do not rely on heat to eject ink.

Key Advantages for Pharmaceutical Applications

- Ink flexibility – Supports a wider range of inks (including UV, solvent, and pigmented) for different substrates and permanence requirements.
- Long printhead life – Piezo heads are durable and suitable for long production runs with minimal degradation.
- Good resolution and consistency – Suitable for printing serialization codes with acceptable grading performance.
- Adaptable to custom packaging – Performs well on unconventional shapes or materials with variable surface tension.
- Low running cost – Ink usage can be efficient in high volume environments.
- Eliminate the need for labels – Printing directly onto the box reduces waste and costs.

Application Surfaces

Piezo is used on:

- Folding cartons
- Labels and sleeves
- Blister foils
- Some rigid containers (with proper ink)

Final Note

Piezo inkjet is a flexible, scalable solution for serialization, particularly in operations that require specialty inks or print on a wide variety of substrates.

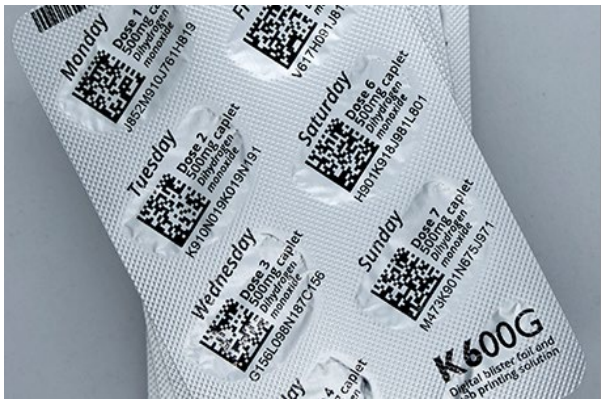
6. Piezo based on demand Hi–Res Digital Printing

Piezo digital printers designed specifically for foil and Tyvek substrates brought a revolution in pharmaceutical production, especially on blister and pouch lines. These high–resolution digital printing solutions allow pharma manufacturers to print, high quality variable data and graphics

on site, onto different substrate formats and sizes. The Domino **K600G** and **K300** exemplify this advanced category.

How It Works

These systems use piezoelectric drop–on–demand technology to eject precise ink droplets onto moving web materials (foil, Tyvek). Positioned in line with blister or form–fill–seal lines, they print unique 2D codes, batch, expiry, and graphics directly onto each pocket or sealed unit, even at high speeds.



Key Advantages for Pharmaceutical Applications

1. Dose level serialization: Designed to print unique codes on individual blister pockets or Tyvek pouches to support emerging unit level traceability requirements
2. Native 600 dpi output: Delivers sharp, ISO compliant Data Matrix codes and high–resolution variable data
3. Flexible on demand printing: Enabling variable data and unique codes to be printed in house for faster response to changes.
4. No need for pre–printed foil, web or Tyvek: Enables cost savings by eliminating the need for expensive preprinted media and maximizing throughput efficiency. It also simplifies significantly inventory, logistics, and storage.
5. Correct errors in minutes, not days: Manufacturers can update and reprint instantly, reducing delays.
6. Batch flexibility: This technology can produce batches of any size, from small runs to full scale production.
7. High–speed compatible: Capable of printing at web speeds of up to 75 m/min (**K600G**) and 250 m/min (**K300**), keeping pace with fast blister and pouch lines
8. Robust ink systems: Supports UV curable, solvent–based, or aqueous inks with pre–treatment and curing steps to ensure adhesion and durability
9. Automated reliability: Domino **K600G'**s features, such as CleanCap for automatic printhead protection, ActiFlow for ink circulation, and StitchLink for print head alignment reduce maintenance and ensure consistent quality

Application Use Cases

- Blister foil, with unit–level printed codes on each cavity
- Tyvek pouches used for device packaging or medical disposables

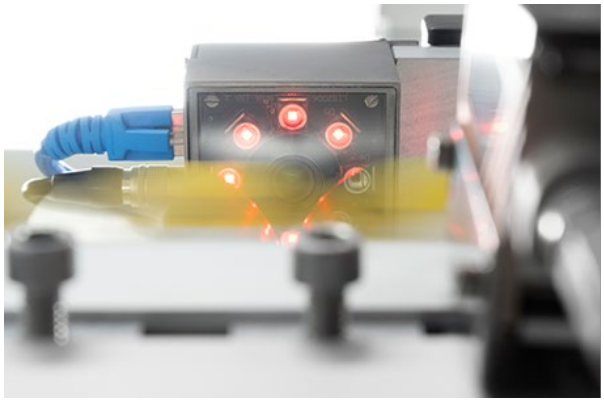
- Web–fed packaging lines for foil, films, or lamination
- Inline serialization + aggregation, with integrated vision system for verification

Final Note

Piezo digital printing on foil and Tyvek offers inline, unit level, variable data serialization, a forward-looking solution for pharmaceutical manufacturers aiming to comply with future traceability regulations and enhance patient safety through granular code placement.

4.2 Vision Systems

Vision systems are a core component of any serialization ready packaging line. They verify that every code is printed correctly, readable, and compliant, preventing incorrect or missing codes from reaching the market. Systems like Domino's **R–Series** are examples of turnkey vision solutions designed for pharmaceutical use.



How It Works

Vision systems use high–speed industrial cameras combined with intelligent software to inspect each printed code in real time. They check for presence, position, print quality, and data accuracy of 2D codes, barcodes, and human readable text. When an issue is detected, the system triggers a reject mechanism to remove the faulty item from the line.

Key Advantages for Pharmaceutical Applications

- Real time code validation – Ensures every pack carries a compliant, scannable Data Matrix or barcode, meeting global serialization standards.
- Support for OCR/OCV – Confirms that human readable elements (e.g., batch, expiry) are legible and correctly printed.
- Scalable performance – Vision systems can be configured for basic presence checks or advanced grading and character recognition, depending on regulatory and line requirements.
- Seamless integration – Easily connects with printers, reject stations, and serialization software to form a closed loop quality system.

Application Use Cases

- Inline inspection of cartons, labels, blister foils, or Tyvek packs
- Pre and post aggregation verification
- Grading of 2D codes to ISO/IEC 15415 standards
- Dual camera setups for wide web applications or multi side packaging

Final Note

Vision systems are the quality gatekeepers of a serialized line. Whether for basic code validation or advanced grading and OCR, they provide the assurance needed to meet compliance requirements, protect product integrity, and minimize risk, all at full production speed.

4.3 Serialization and Code Generation Software

Serialization software orchestrates the flow of data across packaging lines and enterprise systems. It assigns and manages serial numbers, controls print data, ensures traceability, and maintains compliance, making it far more than just a back-office tool.

How It Works

The software generates or imports unique serial numbers, assigns them to product units, and communicates code data to printers and vision systems in real time. It records those serials throughout aggregation and logistics events, and packages full traceability records (e.g., EPCIS) for regulatory reporting and downstream systems.

Key Advantages for Pharmaceutical Applications

- Regulatory readiness – Handles requirements like GS1 standards, 21 CFR Part 11, DSCSA, and EU FMD with audit trails and compliant data exchange.
- End–to–end data control – Manages serials, code payloads, batch data, and aggregation relationships from product to pallet.
- Error handling & traceability – Automatically logs exceptions, reissues serials, and supports reprint or rework processes without data loss.
- Full integration – Connects with printers, cameras, labelers, ERP/MES systems, and repositories to ensure coherent data flow.

Application Use Cases

- Item, case, and pallet level serialization workflows
- Generating compliance ready EPCIS files for external partners
- Managing rework cases (e.g., reject/recoded packs)
- Coordinating changes across printers, verifiers, and data systems

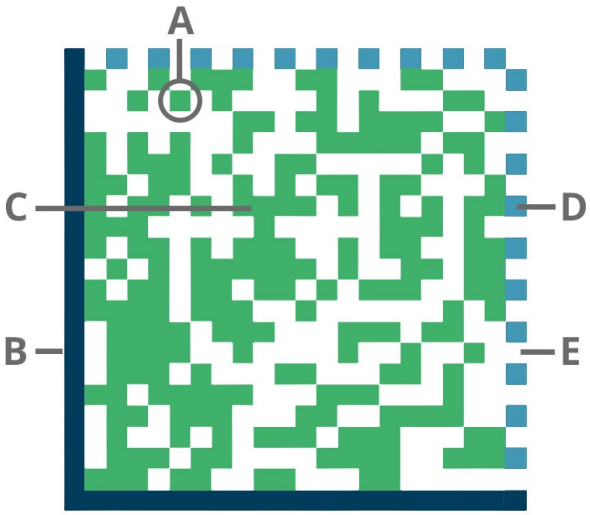
Final Note

Think of serialization software as the digital backbone of your traceability system. It ensures every printed code links accurately to a validated digital record, enabling compliance, visibility, and control across your pharma operations.

5. Serialization and Code Quality

2D codes, particularly the Data Matrix symbology, play a vital role in pharmaceutical serialization, serving as the cornerstone for global efforts to enhance drug traceability, supply chain security, and patient safety. High–quality codes are essential for machine readability, especially under high–speed production and distribution environments. Failure to meet minimum quality thresholds can result in unreadable codes, rejected batches, or compliance issues.

Its structure includes a distinctive "L"–shaped finder pattern along the left and bottom edges, and a clocking pattern along the top and right. These patterns help the scanner detect the size and alignment of the symbol and define the grid used to read the data.



A – Module
B – L–Shaped Finder Pattern
C – Data Region
D – Clocking Pattern
E – Quiet Zone

To ensure reliable scanning and decoding throughout the supply chain, code quality is typically evaluated using ISO/IEC standards:

- **ISO/IEC 15415**: Quality parameters for 2D codes (e.g., Data Matrix)
- **ISO/IEC 15416**: Applies to 1D barcodes
- **GS1 General Specifications**: Industry wide guidance that incorporates ISO standards

Symbol Grade in ISO/IEC 12415

Grade	A (4.0)	B (3.0)	C (2.0)	D (1.0)	F (0.0)
Descript	Excellent	Good	Acceptable	Poor	Fail
Typical Acceptance	Ideal	Preferred	Common Minimum	Often Rejected	Rejected

Why it Matters

- Grades below C (2.0) substantially increase the risk of read errors or scan failures, especially under sub optimal conditions
- In pharmaceutical packaging, most pharmaceutical companies, regulatory bodies and supply–chain partners typically require quality grade C or higher, often preferring grade B or A to ensure maximum reliability.

5.1 Different Code Quality Grading Standards Used by Different Legislation:

1. GS1 & ISO Standards (Globally Recognized)

GS1 General Specifications:

- Data Matrix codes on pharmaceutical packaging should meet ISO/IEC 15415 quality grading (for 2D codes) and ISO/IEC 15416 (for 1D barcodes).
- A minimum grade of 1.5 (C) is typically required, but some customers or jurisdictions may require 2.0 (B) or higher.

Purpose: Ensure consistent readability and interoperability across the supply chain.

2. EU Falsified Medicines Directive (FMD)

- Applicable in the European Union
- Requires:
  - Serialization using a 2D Data Matrix code.
  - Grading based on ISO/IEC 15415.
  - Many EU member states or stakeholders recommend a minimum grade C (1.5).
- Reference: Delegated Regulation (EU) 2016/161.

3. U.S. Drug Supply Chain Security Act (DSCSA)

- Serialization is required for prescription drugs.

- DSCSA does not mandate a grading system, but manufacturers are expected to ensure the barcode is easily readable by downstream trading partners.
- Many U.S. manufacturers voluntarily adhere to ISO/IEC grading standards (often aiming for Grade C or better).

4. WHO & International Guidance

- WHO encourages compliance with GS1 standards, including barcode quality.
- WHO's guidance indirectly supports using a minimum grade for 2D codes to ensure global interoperability.

5. Pharma Company/CMO Standards

Many pharmaceutical companies include code quality requirements in their packaging specifications:

- Data Matrix code graded at 1.5 (C) or higher.
- Graded using verified equipment.
- Rejects codes below minimum threshold.

5.2 What Parameters are Measured in the ISO/IEC 15415 Quality Grading?

1. Symbol Contrast

What it is:

Difference between the darkest and lightest module reflectance values (i.e., black vs. white).

Measurement:

Calculated as: Symbol Contrast = Rmax – Rmin, where Rmax = lightest module, Rmin = darkest module.

Grading:

- Graded A to F based on thresholds.
- Higher contrast = better grade.

FAIL	FAIL

Importance:

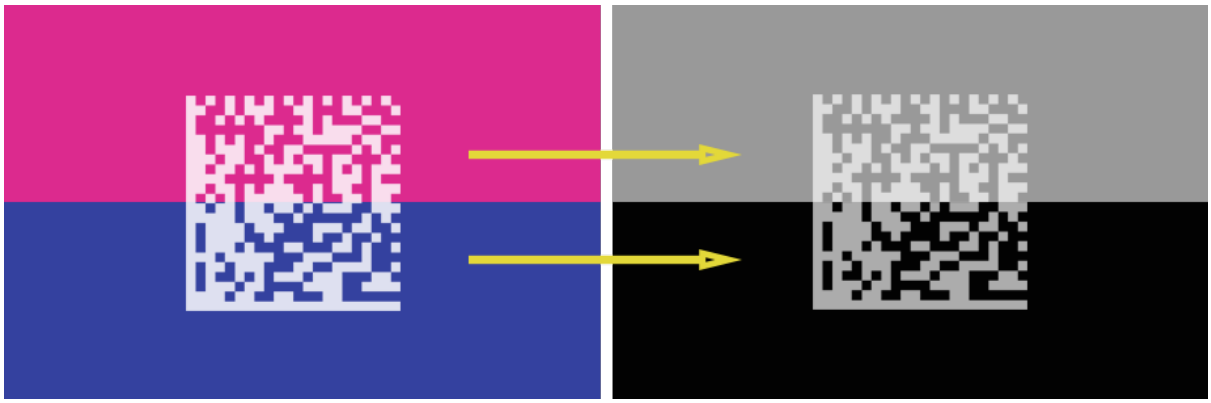
Low contrast = harder to distinguish modules = scan errors.

Possible Reason for Failure:

- Substrate material composition or color.
- Wrong ink
- Other ink issues
- Laser coding: Not enough contrast between the artwork and the base paper color

Note:

Contrast may vary depending on the substrate color and the light used, even when it may look correct to the naked eye. In the example below, the code is verified using a red light or filter (660nm)



2. Modulation

What it is:

Measures how consistently the code contrast is maintained across all modules. Based on minimum edge contrast relative to symbol contrast.

Measurement:

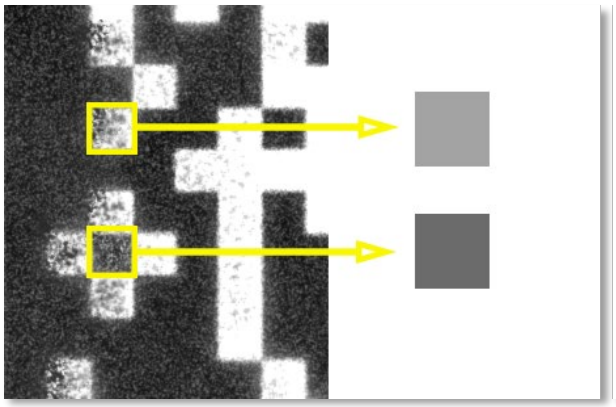
Calculated as: Modulation = Minimum Edge Contrast / Symbol Contrast.

Grading:

- A (≥70%), B (≥60%), C (≥50%), etc.

Importance:

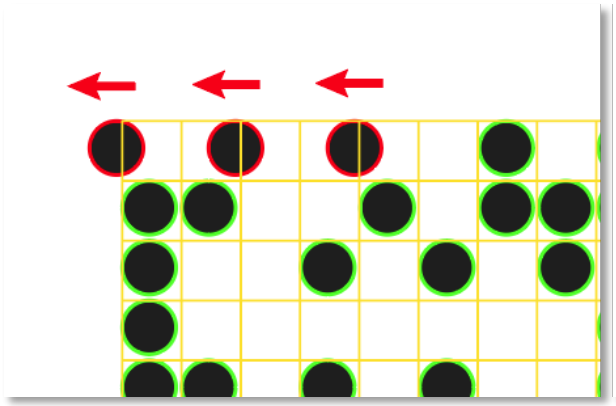
Low modulation means weak edges between light/dark areas, often due to poor printing or ink bleed.



Possible Reason for Failure:

- Product handling issues
- Machine vibrations
- Substrate material

In codes printed using a single dot for each module, the misalignment of one or more of these dots can produce a modulation error.



FAIL **FAIL**

3. Reflectance Margin

What it is:

Measures how clearly the quiet zones and finder patterns contrast with modules.

Measurement:

Calculated as: The reflectance difference between functional patterns (like timing patterns, alignment) and adjacent modules.

Grading:

Calculated for finder and quiet zones separately, worst case determines grade.

Importance:

Poor margins = confusion in code boundaries leading to decoding issues.

Possible Reason for Failure:

- Background color
- Ink density
- Poor contrast between modules and the substrate

4. Fixed Pattern Damage

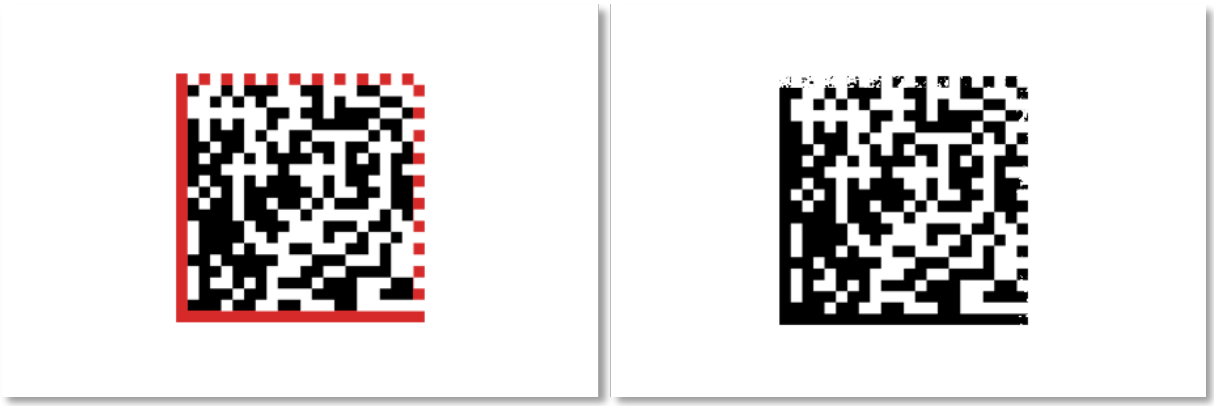
What it is: Checks for damage or distortion in required elements like finder patterns, timing lines, quiet zones.

Measurement:

- Verifier checks for missing, shifted, or damaged functional patterns.

Grading:

- Full integrity = A.
- Any visual or functional pattern damage reduces grade.



Importance: These patterns are needed to locate and decode the code accurately.

Possible Reason for Failure:

- Product handling issues

- Machine vibrations
- Substrate material

5. Grid Non–Uniformity

What it is:

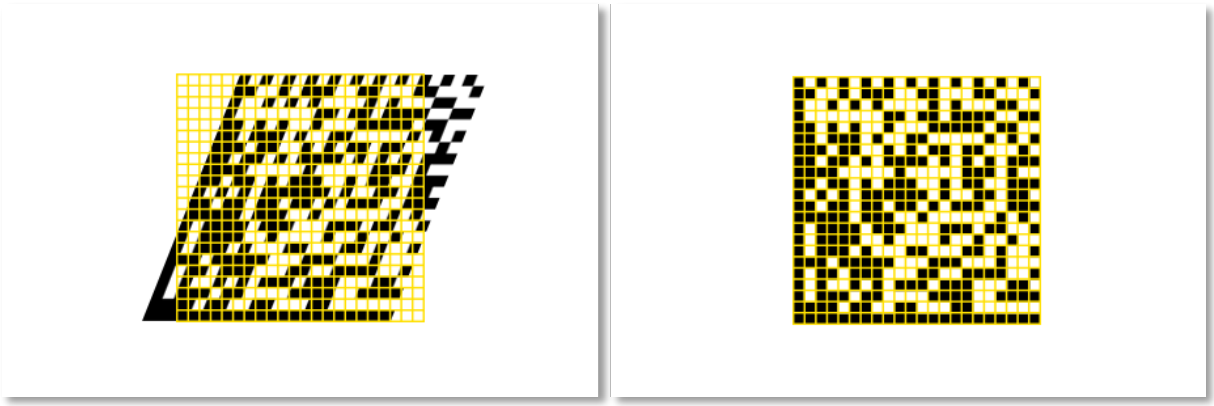
Measures how evenly spaced the grid of modules is (like warped or stretched code).

Measurement:

Calculated as: Deviations from the expected grid spacing (horizontal & vertical).

Grading:

A (≤0.15 module deviation), B (≤0.25), etc.



Importance:

Irregular spacing = trouble decoding or misreading modules.

Possible Reason for Failure:

- Product handling issues like the print head being twisted or tilted with respect to the substrate

6. Axial Non–Uniformity

What it is:

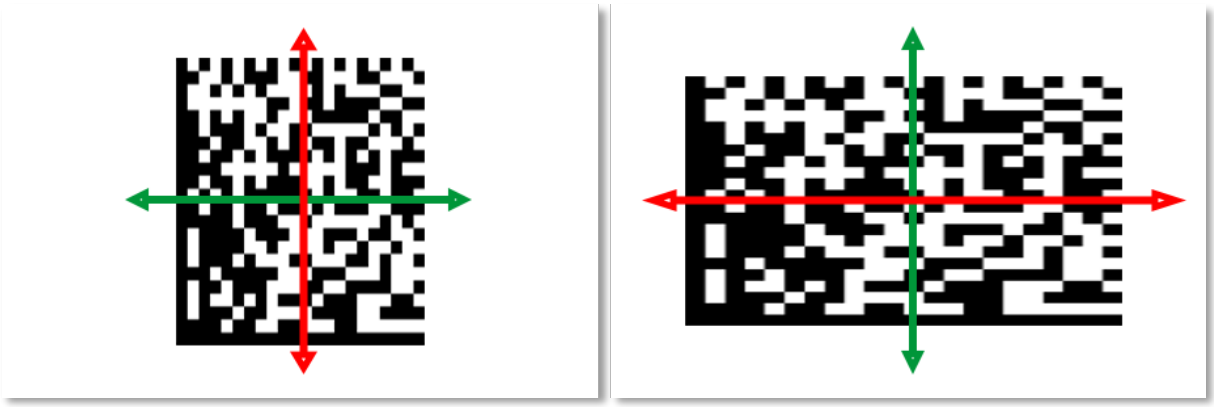
Measures skew or distortion along X and Y axes, especially when one axis is stretched or compressed.

Measurement:

- Ratio of module width to height
- Ideal ratio = 1.0 (square modules)

Grading:

- A (ratio close to 1.0), lower grades for greater deviation.



Importance:

Axial distortion can make scanners misinterpret code geometry.

Possible Reason for Failure:

- Wrong encoder settings
- Product handling issues like setting the wrong distance between the print head and the substrate

7. Unused Error Correction

What it is:

Indicates how many errors correction codewords had to be used to decode.

Measurement:

Based on the number of corrected errors vs. total available.

Grading:

- A = no correction needed
- Lower grades if correction was necessary
- F = code is undecodable, even with correction

Importance:

Even if a code can be decoded, a high need for correction implies poor print quality or damage.

Possible Reason for Failure:

- Physical Damage
- Thermal labels excessively heated during transportation

8. Print Growth

What is it:

Print Growth is not explicitly graded under ISO/IEC 15415, but some barcode verifiers report it as an informational metric. It refers to the change in size of printed modules compared to their

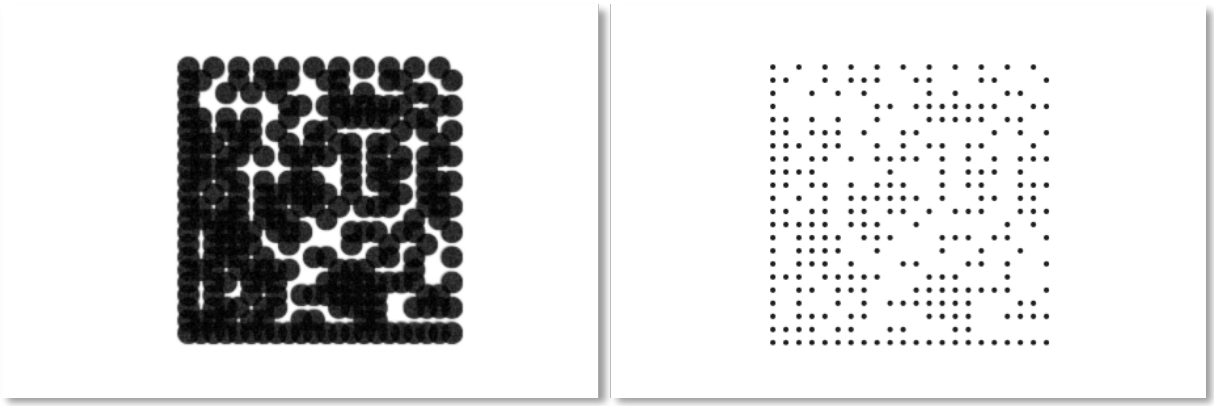
intended (nominal) size. Print Growth is one of the most common causes of poor barcode grades, especially under high–speed or thermal inkjet printing conditions.

Measurement:

Calculated by comparing the measured size (horizontally and vertically) of black and white modules against their intended size using calibrated inspection tools or verifiers.

Grading:

- Print Growth (%) = [(Actual Module Size – Nominal Module Size) / Nominal Module Size] × 100
- Internally, companies may use tolerance thresholds such as:
  - ±5% = Excellent
  - ±10% = Acceptable
  - 10% = Risk of scan failure or grade reduction
- Note: Instead of assigning it a grade (A–F), it's usually analysed in context with modulation, fixed pattern damage, and overall symbol geometry.



Possible Reasons for failure:

- Positive Print Growth (modules too large)
  - Ink spread or bleeding
    – Ink disperses beyond intended module boundaries, especially on absorbent substrates.
  - Absorbent or uncoated substrate
    – Materials like paperboard wick ink outward, enlarging modules.
  - Excessive printhead pressure or poor roller setup
    – Causes ink deformation and over–expansion of modules.
- Negative Print Growth (modules too small)
  - Under inking or drying too quickly
    – Incomplete module formation due to insufficient ink or premature curing.
  - Glossy or coated substrate
    – Poor ink adhesion can lead to thin, shrunken, or patchy modules.
  - Incorrect artwork scaling or low–resolution file
    – Barcode printed smaller than intended due to prepress or file errors.

6. Code Validation

When validating 2D codes, it's important to understand what happens during the decode process, since most grading parameters are based on how well each of these steps performs. A failure in any step, from image capture to data interpretation, can impact the overall verification score.

To ensure a Data Matrix code is both readable and reliable, the system must go through a series of steps to locate, interpret, and verify the information within the symbol. Each step is a potential failure point – which is why code quality grading is based on how likely each part of the process is to succeed or fail.

1. **Capture the Code Image**
   The camera takes a photo of the code.
2. **Clean the Image**
   The software slightly blurs the image to reduce background noise, then converts it into a clean black and white (binary) version based on light and dark areas.
3. **Find the Code's Position**
   It detects key features like the "L" shape and clock pattern that define the structure of the code.
4. **Overlay the Grid**
   A decoding grid is mapped onto the image based on the spacing of the code's pattern, this tells the software where to look for data.
5. **Read the Data Cells**
   The system checks the brightness at each point in the grid, turning it into a stream of binary values (1s and 0s), repairing any issues from non–uniform lighting, background textures etc.

6.1 Validating Code Quality: Hardware Considerations & Grading Realities

Accurate decoding and reliable grading of Data Matrix codes rely not only on the code itself but also on the **quality of the imaging setup**. While many line level cameras and verifiers are

capable of reading codes under typical production conditions, grading for compliance, especially to ISO/IEC 15415 standards, requires more stringent hardware and environmental controls.

1. Reading vs. Grading: Different Requirements

For basic readability, most camera systems can perform reliably if the image is:

- Evenly illuminated
- Consistent in contrast
- Captured at a resolution that provides approximately 4 pixels per module

This level of imaging is typically sufficient for high–speed production environments where the priority is to verify that a code is readable and correctly formatted.

However, grading a code (i.e., assigning a quality score) according to ISO 15415 requires more precision. It typically involves:

- A resolution closer to 10 pixels per module
- Red light illumination (around 660–680 nm) from four angles at 45°, simulating conditions used by retail laser scanners
- The use of a calibration target to adjust software settings for contrast, modulation, reflectance, etc.

2. Challenges of Inline Grading

Grading in a live production environment introduces additional complexity:

- Products are in constant motion, making it difficult to capture the multiple high–resolution images needed for a true average score.
- ISO 15415 recommends averaging 10 images per symbol to produce a compliant grade, a standard that is hard to achieve consistently on high–speed lines.

For this reason, many manufacturers describe their inline grading systems as operating “in accordance with ISO 15415 principles” rather than claiming full compliance.

3. Best Practice: Inline Monitoring + Offline Validation

A common approach is to:

- Use inline grading to track print quality trends and identify potential degradation over time
- Perform offline batch sampling using a calibrated desktop verifier when full compliance is required, especially for audits or QA documentation

Inline systems are generally sufficient for real–time quality control, flagging issues such as:

- Fading or inconsistent print
- Incorrect print head positioning
- Dirty or misaligned print hardware

These alerts allow operators to intervene (e.g., clean print heads, adjust throw distance, or re–align equipment) before the issue escalates.

6.2 Key Takeaway

While inline verification provides excellent day–to–day control, achieving full ISO 15415 compliance typically requires controlled offline validation. A balanced approach, combining trend-based monitoring with periodic calibrated grading, offers the best mix of production efficiency and quality assurance.

7. The Enemies of Code Readability for Serialization:

Serialization printing requires precise alignment between hardware, materials, and processes. Below are the main categories of failure, each with an explanation and list of typical root causes.

7.1 Wrong Printer Setup & Configuration

The printer's mechanical and digital setup is the foundation for reliable serialization code output. Even minor misconfigurations can lead to skewed, stretched, or unreadable codes. Ensuring the printer is properly aligned, triggered, and calibrated is essential for consistent code quality.

- Incorrect encoder or trigger timing (codes printed too early or late)
- Misaligned printhead (too far, tilted, or angled)
- Low resolution printhead unsuitable for small modules
- Excessive or uneven printhead pressure
- Poor web tension or roller setup causing print drift
- Inconsistent print positioning on moving cartons

How to Prevent it:

- Calibrate encoder and trigger timing using test prints at actual line speed.
- Set printhead alignment precisely, ensure it's square to the substrate.
- Choose a printhead resolution appropriate for 2D codes (typically ≥ 300 dpi).
- Maintain consistent web tension; avoid slack or drag between rollers.
- Perform regular printhead maintenance and validation before production.

7.2 Inadequate Ink and Print Quality

Ink performance is critical to code clarity. Issues with ink type, application, or delivery can produce blurred, faint, or incomplete codes. Regular maintenance and appropriate ink selection ensure optimal print definition and durability.

- Ink spread/bleeding causing module enlargement (print growth)
- Low ink density resulting in weak contrast or unreadable modules
- Inconsistent droplet formation from clogged or worn nozzles
- Ink drying too fast (before full transfer) or too slow (causing smudging)

- Incompatible ink for substrate surface (e.g., water-based ink on glossy material)

How to Prevent it:

- Make sure you match the ink to the substrate. At Domino we always run tests on our customers' samples before proposing any coding solution. Request samples and testing from your coding partner before choosing your solution.
- Regularly clean and test nozzles to prevent clogs and droplet drift.
- Adjust ink density settings for high–contrast output, test against ISO grades.
- Calibrate drying/curing time to avoid smudging or incomplete curing.
- Monitor ink viscosity and storage temperature (especially with thermal inks).

7.3 Incompatible Substrate Material & Coating

The packaging material directly affects how ink behaves during printing. Its absorbency, texture, and surface treatment determine how well the ink adheres, dries, and maintains edge definition.

- Highly absorbent substrates (e.g., uncoated paperboard) causing ink wicking
- Glossy or coated surfaces leading to ink beading or slipping
- Substrate color reducing symbol contrast (e.g., grey carton + black ink)
- Inconsistent coating thickness across batches
- Rough or textured surfaces distorting module edges

How to Prevent it:

- Select packaging materials tested for barcode printability.
- Avoid highly absorbent or inconsistent coatings unless fully tested with your ink.
- Use primers or surface treatments to standardize ink behaviour if needed.
- Stick to substrates with consistent color and reflectivity across batches.
- Validate each new substrate with a verification test run, as Domino does for all its customers.

7.4 Poor Product Handling

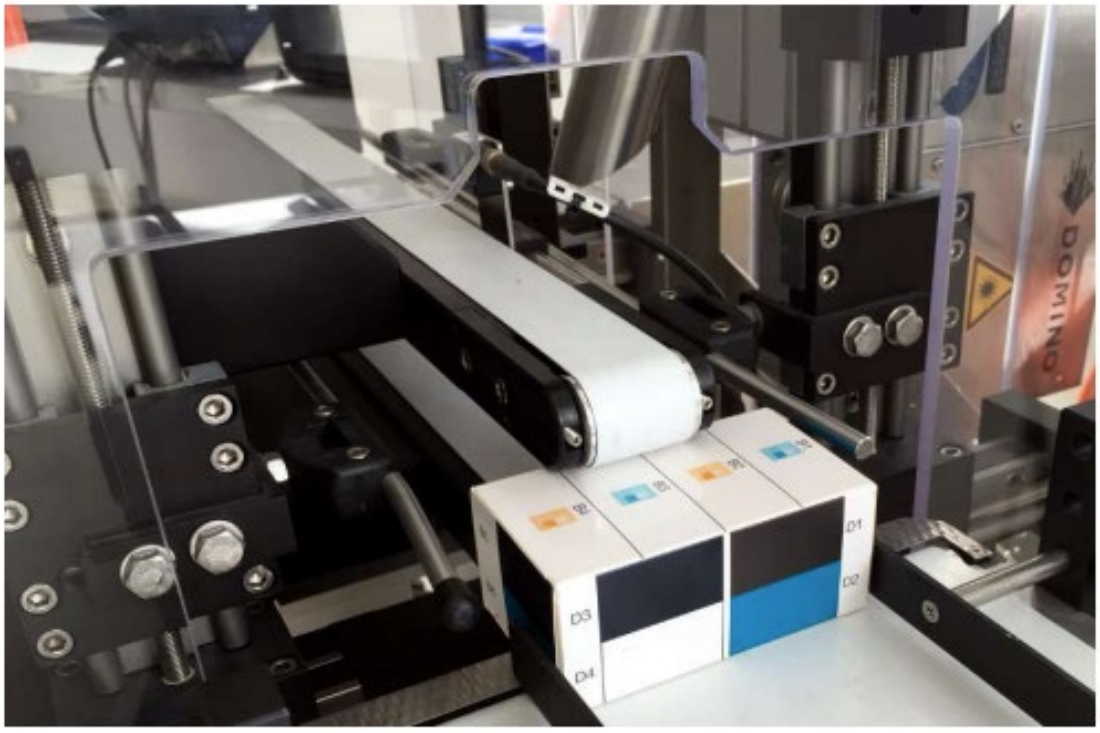
Code quality can suffer from unstable product movement during printing. If cartons or packages shift, tilt, or vibrate, the printed image will be misaligned or warped. For example:

- Products not centred or straight under the printhead
- Inconsistent product spacing or orientation
- Worn or poorly adjusted guide rails
- Product position: Small variations in the position of products may result in codes applied in the wrong area, or missing and even incomplete codes.
- Product distance from the printer: Positioning the product too close, or too far from the coding device can result in blurry or unreadable codes.
- Product angle: A slight rotation in product positioning, even if this is by just a few degrees, can result in deformed codes.

- Line speed: Even minimal speed fluctuations will affect the quality of the code leading to squeezed or stretched codes.
- Conveyor vibrations: At high speeds, minimal vibrations can affect code quality leading to low quality, blurred, or wavy codes.
- Challenging product geometry: Certain packaging types can be a challenge for a standard coding

How to Prevent it:

- Your coding and marking partner should be able to design a product handling solution that meets specific line requirements for your lines. Domino has developed several solutions that prevent vibrations and place the product at the optimal distance from the printhead.
- Install alignment rails or guides to hold cartons steady and centered
- Use encoders and sensors to synchronize printing precisely to product position
- Test conveyors for vibration, especially at print speed, adjust as needed
- Use vacuum belts or hold downs for light or unstable products
- Incorporate reject mechanisms to remove misaligned packs before coding



Domino has developed several solutions to improve product handling. This one holds the packs between two conveyor belts, one at the top and another at the bottom, working together completely synchronized.

7.5 Challenging Environmental Conditions

External factors like temperature and humidity affect ink flow, substrate behavior, and curing. Stable environmental control around the printing station ensures consistent results.

- High humidity can cause ink spread or slower drying
- Low humidity can lead to static or premature ink drying
- Temperature swings can affect ink viscosity and jetting performance
- Dust can accumulate on substrate or printhead
- Static buildup can repel ink droplets or attract debris

How to Prevent it:

- Maintain printing area temperature and humidity within the ink spec range
- Install antistatic devices if static buildup is present
- Use air filters or cleanroom protocols to minimize dust near printheads
- Store inks and substrates in climate-controlled areas to prevent pre deformation
- Avoid printing near open windows, vents, or uncontrolled airflow

7.6 Incorrect Artwork & Data Quality

Errors at the digital design stage often go unnoticed until printing. Improper file formats or encoding mistakes can distort barcode geometry or make it unreadable, even if the print itself looks fine.

- Scaling bitmap images instead of vector artwork
- Incorrect barcode dimensions in artwork (too small or too dense)
- Encoding errors in GS1 structure (invalid AI combinations)
- Low–resolution source files causing blurry or pixelated modules
- Data matrix encoded without proper quiet zone

How to prevent it:

- Always use high–resolution vector artwork (SVG, EPS) for barcode files
- Do not scale bitmap images, resize only from vector masters
- Use certified serialization software that enforces GS1 structure and quiet zones
- Test encoded data with a verifier before releasing to production
- Include pre–press approval steps to review barcode size, placement, and content

7.7 Physical & Post– Print Damage

Even after a perfect print, serialization codes can be rendered unreadable by downstream processes. Damage from equipment, packaging friction, or handling can lead to scanning failures or downgraded verification results.

- Smearing from conveyor contact, folding, or gluing
- Abrasion from mechanical parts or rough handling
- Scratching during stacking, boxing, or inspection
- Crushing or compression in downstream machinery

- Overprinting or label overlap obscuring the code

How to Prevent it:

- Add covers or guides to protect freshly printed codes from contact
- Time code drying appropriately before handling or packing
- Inspect downstream equipment for abrasion or friction points
- Use packaging designs that avoid creasing or folding printed areas
- Train operators to handle serialized units carefully and avoid stacking pressure

8. Line Level Integration Best Practices

8.1 How Plant Managers Can Reduce Print Errors & Downtime

Modern serialization begins at the packaging line, where the smallest disruptions can cascade into costly bottlenecks. Here's how to ensure line level integration is both resilient and efficient:

1. ### Calibrate Vision Systems and Printers Regularly
   Misaligned or degraded print quality is a leading cause of rejected cartons. Weekly calibration of OCR/OCV systems and printer heads is essential, especially during changeovers or after maintenance.
2. ### Automate Exception Handling
   Integrate reject verification and closed loop alarms into your line setup. This prevents manual intervention and ensures non–compliant packs are automatically removed.
3. ### Use Buffer Zones to Reduce Downtime
   Smart conveyor logic and physical buffering between print/verify and downstream processes help maintain flow during micro stoppages.
4. ### Synchronize Serial Number Provisioning
   Delays or outages in serial number requests from Level 3/4 systems can halt production. Caching a batch of serials locally reduces dependency on the network during line runtime.
5. ### Conduct Mock Recalls & Validation Routines
   Regular simulations help uncover integration flaws and give plant managers confidence in their line's traceability under real world conditions.

Pro Tip: Use root cause analysis (RCA) on every print failure, not just the major ones. Patterns emerge over time that can pre-empt major disruptions.

8.2 Data Management & EPCIS – Key Compliance Pitfalls to Avoid

Serialization compliance doesn't end with a printed code. Managing the data behind those codes, and sharing it accurately via EPCIS, is where many manufacturers stumble.

1. ### Timestamp Mismatches & Event Ordering
   Ensure that EPCIS events (commissioning, aggregation, shipping) follow logical chronology. Mismatches can lead to rejections by trading partners or authorities.
2. ### Missing Aggregation Data
   Forgetting to capture parent child relationships (e.g., bottle to carton, carton to pallet) leads to non–compliant shipments, especially under Russian and EU requirements.
3. ### Overreliance on Manual Data Corrections
   Manual edits to EPCIS files increase audit risk. Design systems to generate compliant files automatically from line level events.
4. ### Lack of Alignment with Partner Master Data
   Discrepancies in GLNs, product codes, or locations between partners can trigger EPCIS validation errors. Sync with partners regularly and test updates before deployment.
5. ### Poor Error Handling and Alerting
   Systems should flag EPCIS transmission failures in real time, not days later. Early alerts can save entire shipments from being blocked at customs.

Compliance Insight:

EU and US DSCSA authorities now place growing emphasis on the *quality* of data, not just the presence of it.

9. Serialization for Supply Chain Resilience

How Pharma Leaders Are Using Serialization to Protect and Strengthen the Supply Chain

In today's volatile global environment, supply chain resilience is no longer optional, it's a business imperative. Pharma companies are increasingly leveraging serialization not just to meet regulations, but to enhance visibility, control, and agility across the entire product lifecycle.

From factory floor to patient, serialization is helping leaders address disruption, manage risk, and respond faster to change.

End–to–End Traceability: Identifying Bottlenecks and Diversion Risks

Serialization data provides a digital footprint for every unit, enabling full visibility across manufacturing, packaging, logistics, and distribution.

- Track products from batch release through warehouses, 3PLs, and points of dispense
- Use scan data to detect unexpected detours, duplicate shipments, or delays
- Identify chokepoints in production or logistics by analysing time stamped event trails (e.g., commissioning, shipping, receiving)

Use case: A sudden spike in transit time for a specific lane reveals a customs bottleneck or regional carrier issue, triggering immediate action.

Targeted Recalls & Faster Issue Response

Without serialization, recalls are often blunt instruments. With it, they become surgical.

- Identify exactly which units, batches, or even cartons are affected, based on commissioning, aggregation, and shipment data
- Isolate problems quickly (e.g., cold chain failure, contamination risk) and avoid pulling unaffected inventory
- Demonstrate regulatory control and product accountability in audits and safety events

Result: Faster response, less waste, and stronger public trust.

Inventory Optimisation & FEFO – Serialization Data Powering Better Inventory Management

Serialization brings intelligence to inventory, especially for high value, short shelf life, or temperature sensitive products.

- Enable First Expired, First Out (FEFO) strategies with item level expiry tracking
- Reduce overstocking and obsolescence by improving demand supply alignment at a granular level
- Identify inventory that is close to expiry or stalled in the wrong market and move it proactively

Advanced benefit: Integrating expiry data from serialized packs into ERP systems enables smarter allocation and automatic reordering triggers.

Improving Security & Controlling Parallel Trade

Pharma products are vulnerable to diversion, theft, and grey market sales especially in high–demand or high-cost therapeutic areas.

- Serialization enables authentication of every unit at each handoff point, deterring counterfeiters and verifying legitimate flows
- Detect parallel trade and unauthorized exports by analysing scan locations and timing
- Geofence product flows to validate that shipments are received only in intended markets

Outcome: Stronger brand protection and pricing control, especially in fragmented regulatory regions.

Enabling Real Time Logistics Visibility – Where Serialization + IoT Shines

Combining serialization with IoT technologies unlocks true in transit visibility and risk monitoring.

- Use IoT devices (e.g., GPS, temperature, humidity sensors) linked to serialized pallets or cartons to monitor conditions in real time
- Tie the data back to serial numbers for auditable proof of compliance and faster intervention when thresholds are breached
- Provide live shipment tracking dashboards for internal teams, partners, and even regulators

Emerging capability: Serialization, integrated IoT enables real time alerts (e.g., “pallet exposed to >8°C for 2 hours”) tied directly to specific product SKUs or serials.

Resilience in Action

By building traceability into the fabric of their operations, pharma companies are transforming serialization into a strategic risk management tool.

- Prevent disruptions before they cascade

- React faster when issues arise
- Protect product integrity and patient safety

In a world of constant change, serialization is helping pharma leaders stay not just compliant, but resilient, responsive, and ready.

10. Serialization & Patient Safety

The Ultimate Mission of Serialization – Protecting Patients

While serialization delivers operational efficiency and regulatory compliance, its most important function remains clear: protecting patients from harm. Whether preventing counterfeit drugs, enabling real time product verification, or driving evidence-based care, serialization plays a central role in safeguarding public health.

As regulatory systems mature and digital health expands, serialization is becoming a foundational layer in patient safety strategy.

Blocking Counterfeit Medicines at the Source

Counterfeit and substandard medicines are a growing global threat, particularly in high–demand, high-cost therapeutic areas.

- Serialization assigns a unique, trackable identity to every pack, making it nearly impossible for fake products to blend undetected into the legitimate supply chain.
- Verification at multiple points (manufacturing, distribution, dispensing) creates a closed loop system that detects and stops unauthorized products.
- Regulatory mandates like EU FMD, DSCSA, and Russia's Chestny ZNAK enforce scan to verify protocols that serve as systemic countermeasures.

Impact: Counterfeits are no longer just a legal risk, they're a clinical one. Serialization is the frontline defence.

Product Authentication at the Point of Dispense & Administration

- In the EU, pharmacists must verify each serial number against a national system before dispensing, preventing falsified packs from reaching patients.
- Under the U.S. DSCSA, pharmacies and hospitals are preparing for interoperable systems by 2024–2025 that support serialized verification at the individual unit level.
- In hospital settings, serialization can also support administration, time checks, ensuring the right drug, batch, and expiry for each patient.

Future ready: Point of care authentication is evolving from barcode scans to smartphone enabled digital verification, even by patients themselves.

Improving Pharmacovigilance & Quality Tracking

- Serialization creates a traceable link between every dose and its production history, which is crucial for adverse event reporting.
- If a safety issue arises (e.g., contamination, cold chain breach), serialized data allows pinpointing of impacted units and patients, speeding up response and limiting exposure.
- Enables faster root cause analysis by tracing back through manufacturing and distribution events.

Regulatory bonus: This traceability strengthens MAH pharmacovigilance responsibilities under EU GVP and FDA expectations.

Serialization + Real World Data → Better Outcomes & Evidence

When combined with anonymised patient records and usage data, serialization enables post market insights that were previously impossible:

- Track product performance by batch, region, or handling conditions, identifying trends in efficacy or safety.
- Support outcomes, based contracts with healthcare funders using verified administration data.
- Enable longitudinal studies that link specific serialized products to real world health outcomes.

Example: In biologics or personalized therapies, serialization supports traceable, evidence rich care journeys, valuable for regulators and reimbursement bodies alike.

Powering Patient Engagement & Trust

Emerging Apps & Trends

- Consumer facing apps are emerging that allow patients to verify the authenticity of their medicines by scanning a serialized code (e.g., via QR or 2D Data Matrix).
- Some platforms provide additional educational content, recall alerts, expiry warnings, or refill options tied to that specific pack.
- In future models, serialization could integrate with digital wallets or health records to personalize adherence tools or enable participation in feedback programs.

Opportunity: As patients become more active participants in their care, serialization offers a trusted, data driven bridge between brand and end user.

Serialization as a Safety Platform

Serialization doesn't just stop counterfeiters, it enables a holistic safety net that spans manufacturing, distribution, clinical care, and post market use.

It supports:

- **Authentic, safe medication access**
- **Smarter dispensing and administration**
- **Higher quality data for pharmacovigilance and RWE**
- **Direct patient engagement and trust**

In the end, every scan, every serial, and every verified event is about one thing: protecting the patient.

11. Serialization & Sustainability

How Serialization Supports Pharma's Sustainability Goals

Sustainability has become a defining priority for pharmaceutical companies, not only to meet regulatory and ESG expectations, but to reduce cost, waste, and risk across complex global supply chains.

Serialization, often seen through the lens of compliance or security, is increasingly being recognized as a powerful enabler of environmental performance. With the right systems in place, it gives companies the data and control needed to operate more sustainably at every level.

Reducing Waste: Fewer Expired & Recalled Products Through Traceability

- Serialized expiry and batch data allows for granular visibility of stock across sites, regions, and partners.
- First Expired, First Out (FEFO) systems use item level data to ensure short dated inventory is used first.
- Faster, more precise recalls limit over, removal of safe product, drastically cutting waste during quality events.

Impact: Less write off, less landfill, and lower environmental impact from product destruction.

Packaging Optimization & Circular Economy Initiatives

- Aggregation data enables packaging right sizing by revealing how products are stored, shipped, and dispensed, reducing overpackaging and transportation inefficiencies.
- Returnable packaging and reusable shipper programs become viable with serialized tracking of containers and components.
- Serialization helps monitor materials recovery and recycling of serialized components, useful for clinical trials or device, based therapies.

Trend: As pharma embraces circular economy models, serialization ensures visibility and accountability at the unit level.

Serialization Data Enabling Carbon Footprint Tracking in the Supply Chain

- Aggregated serialization data (with timestamps and location events) provides the "when and where" of product movement, a key input for carbon calculations.
- When combined with shipment size, distance, and mode of transport, companies can automatically calculate CO_2 impact per SKU or batch.
- This data enables eco conscious decision making around route planning, vendor selection, and regional sourcing.

Outcome: Scope 3 emissions reporting that is traceable, auditable, and rooted in real operational data.

Supporting Cold Chain Sustainability

(IoT + Serialization = Smarter Temperature Monitoring)

- Smart packaging and IoT devices linked to serialized units allow for real– time temperature tracking, reducing the number of products discarded due to suspected excursions.
- Instead of discarding entire lots, companies can pinpoint only the affected units based on serialized tracking.
- Enables more energy efficient shipping practices by tailoring routes and packaging to actual risk profiles.

Environmental benefit: Fewer product losses, less overcompensation in packaging, and reduced need for emergency replacements.

Real World Pharma Sustainability Case Studies Enabled by Serialization

- **European biosimilar manufacturer** used serialization + FEFO logic to reduce expired product write offs by 28% across five distribution hubs.
- **Global vaccine maker** integrated serialization with carbon tracking software to report SKU level Scope 3 emissions to investors and regulators.
- **Clinical trial sponsor** used serialized reusable shippers, reducing cardboard waste by 60% and improving trial drug accountability.

Insight: When paired with the right processes and digital tools, serialization becomes a scalable sustainability asset, not just a regulatory checkbox.

The Green Payoff of Serialization

Serialization offers measurable sustainability wins by enabling:

- Less waste from expiry, misplacement, and overproduction
- Smarter packaging and returnability
- Clearer emissions data for ESG reporting
- Cold chain efficiency with fewer losses

- Foundation for a traceable, circular economy

In a world moving fast toward climate accountability, serialization helps pharma do well, by doing good.

12. Future Proofing Your Serialization Program

Trends in Aggregation – Why It's Gaining Importance

Aggregation, the process of digitally linking child units to parent containers, is no longer optional in many markets. Its relevance is expanding for several reasons:

- Regulatory Pressure is Increasing
  Markets like Russia, China, Brazil, and the U.S. (under DSCSA 2024/2025) demand robust aggregation to support traceability and verification at all packaging levels.
- Faster Warehouse and Logistics Operations
  With aggregation, entire cases or pallets can be scanned once, reducing scan time by 90% or more compared to unit level verification.
- Better Recall Management
  Aggregated data allows precise identification of affected units, reducing overkill during recalls and protecting brand trust.
- Seamless Integration with 3PLs and CMOs
  Partners increasingly demand aggregated shipments to reduce their own operational overhead and meet their customers' traceability needs.
- Foundation for Digital Supply Chain Analytics
  Aggregated serialization data fuels real time insights, from inventory tracking to demand sensing, that are key to Pharma 4.0 strategies.

Future Outlook: Aggregation in the Era of Pharma 4.0

Aggregation is quickly evolving from a compliance necessity to a strategic enabler. As technologies mature and regulatory expectations rise, here's what forward thinking Pharma manufacturers can anticipate:

AI– Assisted Aggregation at the Line

Advances in machine vision and edge AI are transforming how aggregation is done:

- Smart cameras with embedded AI will detect incorrect or duplicate serials in real time, even on complex, high speed lines, reducing reliance on operator validation.
- Real time quality scoring for every aggregated unit (e.g., carton or case) will become standard, feeding back into continuous improvement loops.
- Self-learning systems will adjust image recognition algorithms over time, improving accuracy without manual tuning.

Benefit: Fewer false rejects, faster onboarding of new SKUs, and less need for manual aggregation in rework areas.

Blockchain– Backed Chain of Custody

Blockchain is gaining traction as a trusted layer for verifying aggregation data across partners:

- Immutable aggregation records could be shared between manufacturers, 3PLs, and regulators to prove chain of custody integrity.
- This will be especially valuable for biologics, cold chain products, and high-risk SKUs, where visibility is critical and counterfeiting threats are high.

Regulatory interest: The FDA and EU regulators are already exploring pilots in blockchain, supported traceability for critical medicines.

Aggregation as a Driver of Supply Chain Intelligence

What was once just a compliance burden is becoming a data goldmine:

- Predictive logistics: Knowing how serialized products move across aggregated hierarchies enables forecasting of delays, bottlenecks, or losses.
- Automated exception handling: Aggregation data allows software to detect and act on anomalies without human intervention – e.g., a pallet showing up at the wrong site.
- Sustainability insights: Aggregated product movement data can help companies calculate carbon footprints more precisely at the unit level.

Integration with Digital Twins & AR

Leading companies are experimenting with integrating aggregation into digital twin environments:

- Every case, pallet, and shipment can be visualised in real time, enabling proactive interventions at distribution centres or customs checkpoints.
- In Augmented Reality (AR) applications, warehouse workers can use smart glasses to “see” aggregation hierarchies and scan pallets without touching a scanner.

Next gen capability: This could reduce training time and error rates in manual warehouse operations by over 50%.

Zero Touch Serialization at Remote Locations

As aggregation systems become more autonomous and error resistant:

- We'll see a rise in remote serialization hubs with little to no on-site staff, especially useful for smaller CMOs or packaging lines in developing regions.
- Cloud based validation and real time EPCIS publishing will support compliant operations even with minimal local infrastructure.

Interoperability & Global Harmonization Trends

- Regulatory bodies and industry groups (e.g., GS1, IFPMA) are increasingly pushing for harmonized data standards, enabling smoother cross border aggregation and EPCIS exchange.
- Interoperability between serialization platforms is critical for CMOs and manufacturers working across markets with diverging rules (e.g., DSCSA vs. EU FMD).

Strategic impact: Companies that design for interoperability now will avoid costly reengineering later.

IoT & Smart Packaging – Opportunities Coming to the Plant Floor

- Smart labels with embedded sensors (e.g., temperature, humidity, shock) are starting to be tied into aggregation hierarchies, enabling end–to–end condition monitoring.
- Connected packaging lines are using IoT data to adapt aggregation parameters in real time based on product type, destination, or regulatory profile.

Emerging use cases: Cold chain monitoring, anti-tamper detection, real time location tracking, all tied to the parent child structure of aggregation.

13. Final Thoughts

Within this guide, we've explored how serialization is transforming pharma operations, not just for compliance, but for control, insight, and long-term value. It can improve line level efficiency, ensures data accuracy, supports global aggregation demands, enhances supply chain resilience, reduces environmental impact, and most importantly, protects patients.

What was once seen as a regulatory burden has become an operational catalyst, and a critical piece of pharma's digital future.

Building Internal Buy– In

Why Supply Chain + Compliance + Manufacturing Must Collaborate

For serialization to deliver full value, siloed thinking must be replaced by coordinated action:

- Manufacturing teams must ensure seamless integration at the line level, reducing downtime, rejects, and rework.
- Compliance leaders ensure that evolving regulatory demands are not just met but anticipated.
- Supply chain and commercial teams unlock the downstream power of serialization data, for traceability, responsiveness, and sustainability.

Collaboration is the key. When these functions align, serialization transforms from a cost center into a value multiplier.

From Compliance Cost to Competitive Differentiator

Forward looking pharma companies are already leveraging serialization to:

- Launch into new markets faster, with confidence in local regulatory compliance
- Offer value added services (e.g., patient authentication, post market support)
- Improve ESG metrics with granular traceability and waste reduction
- Prove supply chain integrity in tenders and pricing negotiations

Insight: If positioned strategically, what begins as a compliance project can become a sales enablement tool, a data asset, and a trust builder.

Future Proofing Your Pharma Brand

The pharmaceutical industry is entering a new era of scrutiny, digital transformation, and public expectation. Brands that embrace transparency, traceability, and patient centricity will lead, not follow.

Serialization enables:

- Real time product visibility across global markets
- Safer experiences for patients and healthcare professionals

- Smarter, more sustainable operations
- Integration with future technologies, from IoT to digital health ecosystems

Serialization is not the end goal; it's the infrastructure for the next generation of pharma innovation.

A Strategic Foundation for What's Next

Done well, serialization gives companies:

- A compliant present
- An efficient operation
- And a trusted, agile future

The best time to shift your mindset around serialization was five years ago.
The second– best time? **Right now.**

14. Let's Plan Your Serialization Future – Together

As a GS1 Solutions Partner and trusted specialist in life sciences, our support extends far beyond installation. We follow a clear, transparent process that ensures your success at every stage:

Understanding Your Needs – We begin with in depth discussions and on-site assessments to understand your priorities, technical requirements, and compliance landscape.

Proposal & Planning – Our team works with yours to design the best fit solution, using real samples and clear timelines. You'll receive a transparent proposal we build and refine together.

Implementation – Each component is tested and configured in our labs. We provide full training and only sign off when the solution is running exactly as planned.

Optimization & After Care – Our Customer Success team stays with you, monitoring performance, servicing your systems, and helping you adapt to new challenges or standards.

This guide is just the beginning. Whether you're introducing serialization for the first time, expanding to meet new global regulations, or future proofing your existing systems, Domino is here to help, with proven technology, deep pharmaceutical expertise, and a commitment to partnership that lasts long after go live. Let's design your next step in serialization, together.

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Where can we help you?

An integrated approach with connected solutions across your whole production line

1. REDUCE ERRORS WITH CODE AUTOMATION

Automate processes and consolidate production data for maximum uptime and reliability .

2. CHECK AND VALIDATE EVERY SINGLE CODE

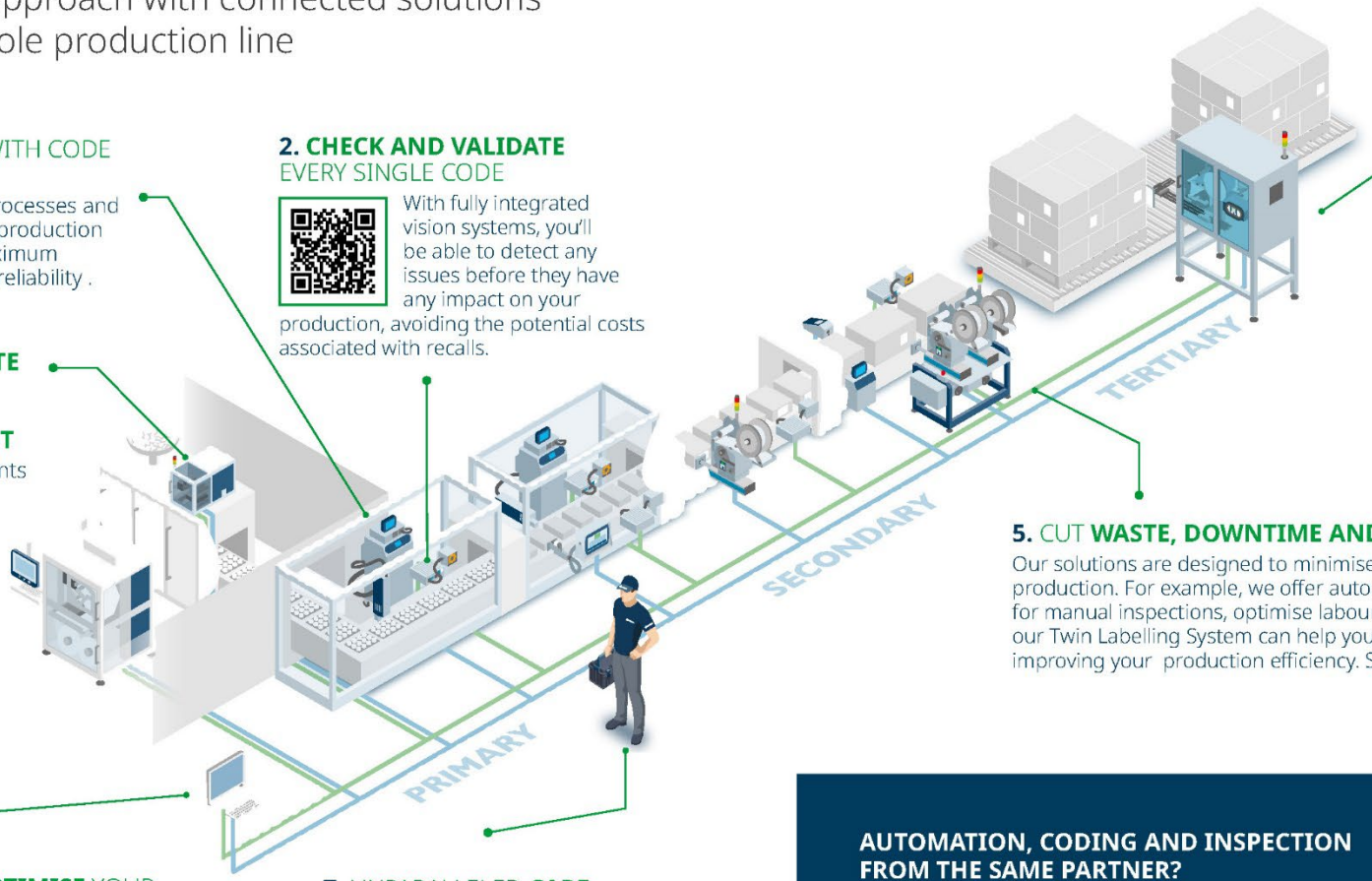
With fully integrated vision systems, you'll be able to detect any issues before they have any impact on your production, avoiding the potential costs associated with recalls.

3. ASSURED AGGREGATION AND TRACEABILITY FROM SINGLE DOSE TO PALLET

Domino offers serialisation, printing, coding and traceability solutions for all the packaging tiers, from blister to pallet.

4. EASY-TO-INTEGRATE DIGITAL PRINTING SOLUTIONS WITH **MINIMAL FOOTPRINT**

The Domino **K600G** variants have been designed to fit into the most demanding layouts and have a small overall footprint for easy integration, minimising their impact in the production line.



5. CUT **WASTE, DOWNTIME AND COSTS**

Our solutions are designed to minimise consumable usage while optimising production. For example, we offer automated vision systems to reduce the need for manual inspections, optimise labour time, and reduce waste. Or the TLS, our Twin Labelling System can help you minimise downtime due to labelling, improving your production efficiency. Simply ask and we will help.

6. MONITOR AND OPTIMISE YOUR CODING PROCESS

Your printer performance diagnostic information will be viewable anywhere or anytime, helping you to modify, optimise and adapt it to your needs.

7. UNPARALLELED **CARE AND SUPPORT**

Our cutting-edge **SafeGuard** packages provide you with the highest quality on-site assistance and the latest in augmented reality-enabled remote guidance from our expert engineers.

AUTOMATION, CODING AND INSPECTION FROM THE SAME PARTNER? THAT SOUNDS LOGICAL

- ✓ Seamless integration
- ✓ Common Domino user interface to minimise the learning curve
- ✓ Full compatibility with the host OEM equipment
- ✓ A single point of contact for the entire automation, coding & inspection system

Learn More About Us

Domino employs over 3,000 people worldwide and sells to more than 120 countries through a global network of 29 subsidiary offices and more than 200 distributors.

Domino in Life Sciences

Learn more about our solutions for the Life Sciences Sector.

Sustainability

Learn more about our sustainability commitment and how we can help you to achieve yours.

Services & Solutions

Globally consistent service, support, training and financial agreements tailored to your needs

Our Products

Discover our full range of solutions from product to pallet.

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