



# **Pharma Track Pro**

**By Automation Brain Pvt Ltd.**

**Pharmaceutical Serialization in Pakistan**  
(GS1 Data Matrix & DRAP Regulations)

**Applications of GS1 2D Barcodes, Serialization &  
Track-and-Trace**

**Automation Brain Pvt Ltd**

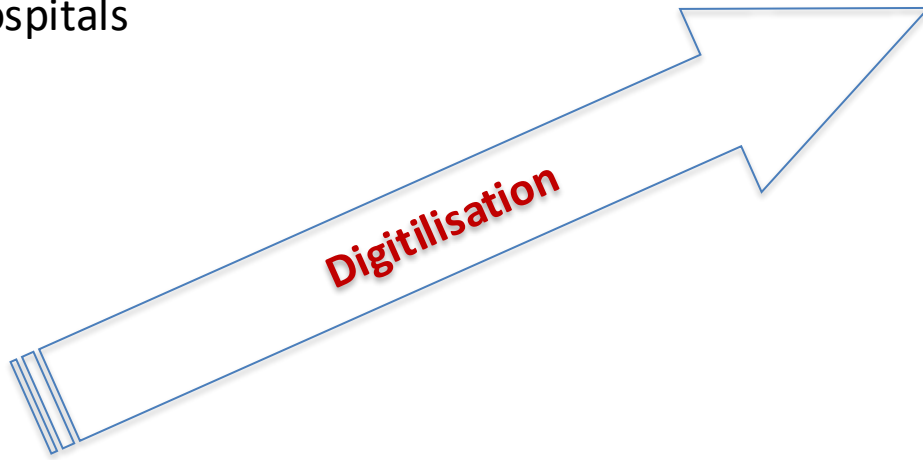
# Key Benefits of Pharma Serialization for the Pharmaceutical Industry

- Protects your brand from **counterfeiting and illegal product diversion**
- Ensures **patient safety** with unit-level product authentication
- Provides **full supply chain visibility** from manufacturing to dispensing
- Enhances **product integrity and trust** with GS1 DataMatrix verification
- Enables **quick and targeted product recalls**, reducing business risk
- Strengthens **export potential** by meeting global serialization standards (US, EU, GCC, ASEAN)
- Improves operational efficiency with **digitalized batch and expiry tracking**



# Why Pharma Companies Should Welcome Serialization

- Reduces **manual data printing errors** through automated coding & verification
- Ensures **consistent printing quality** across all packaging lines
- Streamlines **batch, GTIN, and expiry management** with centralized control
- Seamlessly integrates with **ERP, MES, and L3/L4 systems**
- Supports **future regulatory requirements** (aggregation, DRAP future phases, traceability)
- Enhances **operational transparency** for audits and regulatory inspections
- Adds a **competitive advantage** by proving product authenticity to distributors & hospitals



## Basics of Pharmaceutical Serialization?

- Prevents counterfeit medicines and protects patient safety.
- Enables traceability of every saleable unit across the supply chain.
- Required by global regulators and increasingly by DRAP in Pakistan.

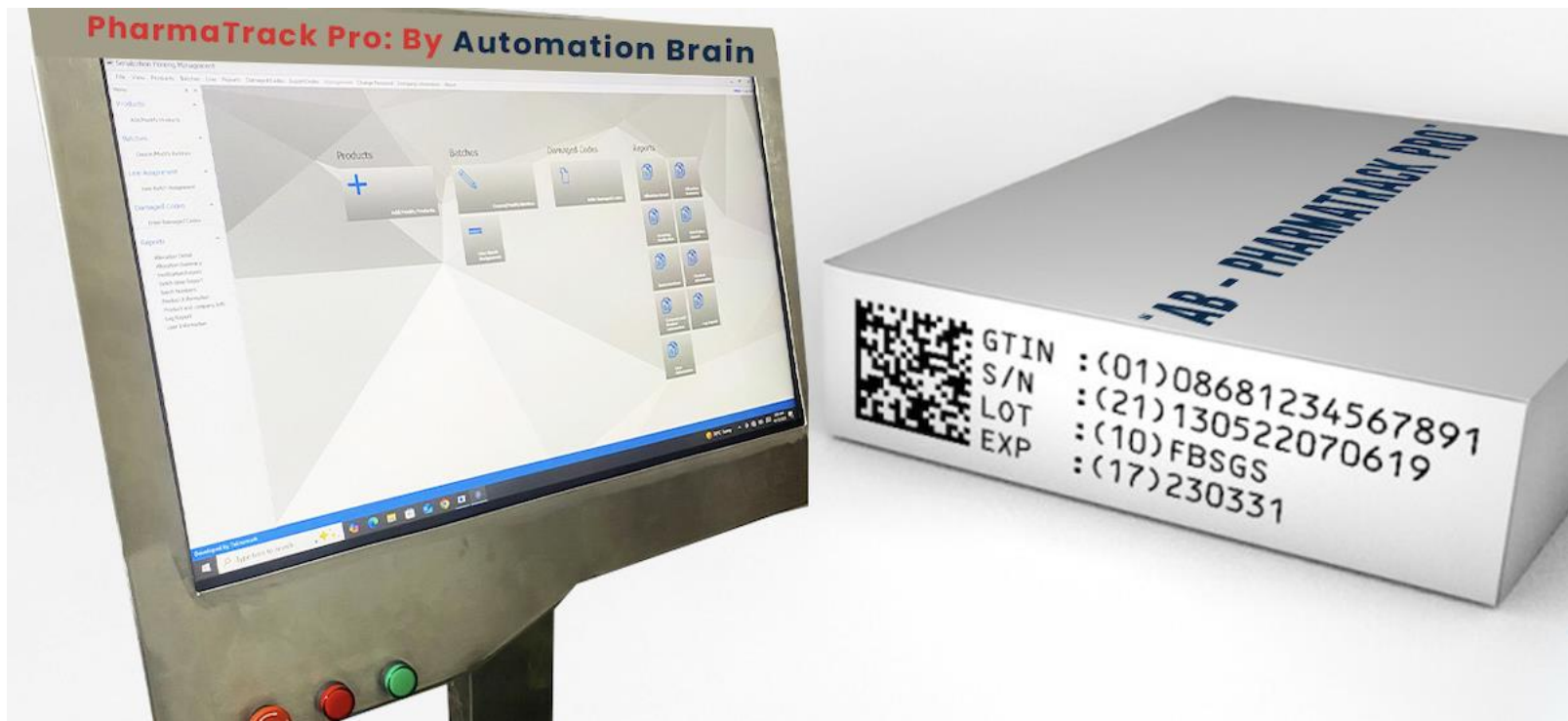


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# What is GS1 DataMatrix (2D Barcode)?

- An ISO/IEC-compliant 2D barcode (Data Matrix) carrying GTIN + variable data.
- Can encode GTIN, batch/lot, expiry date, serial number in machine-readable form.
- Suitable for printing on secondary packaging (and primary where applicable).



# **DRAP Regulations — Key Points**

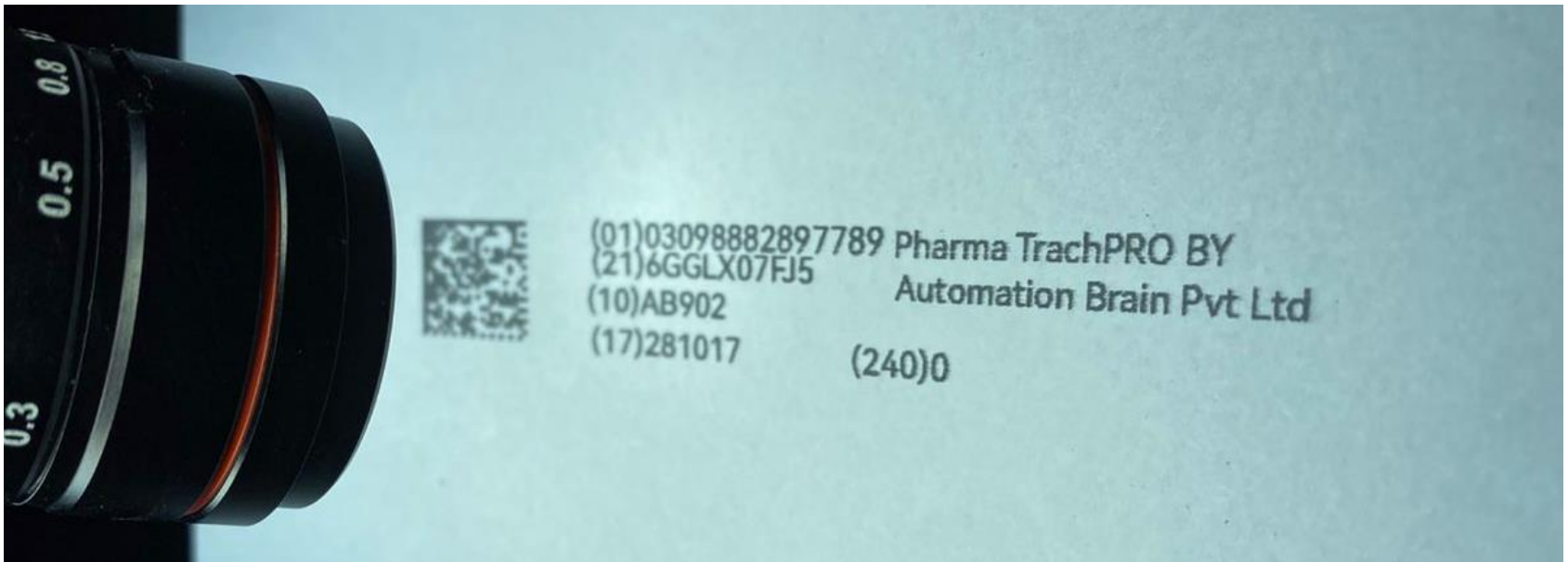
## **(SROs & Notices)**

- S.R.O. 1587(I)/2025: DRAP adopted PIC/S guidelines and advanced pharma regulation updates. (DRAP notices Aug 2025).
- DRAP mandates GS1 DataMatrix on secondary packaging with specified data elements (Form-A).
- Serialization using random serial numbers must be embedded in the GS1 DataMatrix.
- Imported drugs not conforming at import may be arranged for local printing with prior approval.
- SSCC on tertiary packs deferred (not mandatory until six years after commencement).



# Mandatory Data Elements to embed in GS1 DataMatrix (Form-A)

- GTIN (AI (01)) — Global Trade Item Number (14 digits).
- Expiry Date (AI (17)) — Format YYMMDD.
- Batch/Lot Number (AI (10)).
- Serial Number (AI (21)) — randomized serial for each saleable unit.



# Packaging Level Requirements (Per DRAP guidance)

- Secondary packaging: GS1 DataMatrix with GTIN + expiry + batch + serial.
- Tertiary packaging: GS1-128 (SSCC) for logistics (SSCC deferred for 6 years).
- Primary packaging: If sold without secondary packaging, barcode on primary is mandatory.



# Implementation Roadmap for Manufacturers

- 1. Register with GS1 for GTIN allocation and obtain company prefix.
- 2. Update artwork and packaging to reserve space and quiet zone for DataMatrix.
- 3. Select printing technology (TIJ, CIJ, thermal transfer, laser) — Sojet TIJ recommended for high-res 2D codes on many substrates.
- 4. Pilot: Print, validate scannability, integrate serialization management system (EPCIS/central database).
- 5. Scale-up: Rollout across SKUs, train staff, set up consumables supply chain.

# Validation & Scannability

- Barcodes must be printed legibly with required quiet zone so scanners can read reliably.
- Perform grade/verification testing (ISO/IEC barcode grade) during pilot.
- DRAP expects submission of product details (Form-A) to DRAP database as per notice.



# IT Systems & Traceability

- Serialization requires software to generate random serials and manage GTIN-serial mapping.
- Consider EPCIS/serialization backend for supply chain visibility and regulatory reporting.
- Integration with ERP, MES, and packaging lines for automated data capture.



# Challenges & Mitigations — Pakistan Context

- Challenge: Substrate variability and small packs — Mitigation: Choose suitable ink/printhead (TIJ options).
- Challenge: Consumables supply & maintenance — Mitigation: Local stocking and service agreements with Automation Brain.
- Challenge: Data management & compliance — Mitigation: Implement serialization software and staff training.



# Business Benefits & ROI

- Reduces counterfeit risk and supports patient safety.
- Improves recall efficiency and supply chain transparency.
- Enables compliance with DRAP and international trading partners.
- Enhances brand trust and export readiness.



# Pilot Proposal

- Select 2–3 high-volume SKUs for pilot printing of GS1 DataMatrix on secondary packs.
- Measure scannability, changeover time, and any rejects — adjust print settings/ink.
- Train operators and document SOPs for serialization printing and verification.
- Automation Brain Pvt.Ltd. Offer flexible terms for Pharma serialisation, there are various models and various type of printers suit serialisation needs in Pakistan.

The Company offers Leibinger GmbH CIJ Printers, Sojet Shanghai Thermal Inkjet Printers, Dikai Laser marking systems , all of our technologies can be used with Serialisation system made by Automatiion Brain



# Why Automation Brain Pvt Ltd

- Local integrator with experience in coding, marking and serialization projects.
- Can supply Sojet and Leibinger TIJ printers, consumables, integration and after-sales support.
- On-site commissioning, operator training, and regular maintenance plans.





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**Thanks for your time**

