

DSCSA vs. EU FMD: A Pharma Serialization & Traceability Guide

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dscsa

eu fmd

pharmaceutical serialization

track and trace

falsified medicines directive

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gs1 standards



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Serialization & Traceability (DSCSA / EU FMD): What Ops Teams Need to Know

Executive Summary: Pharmaceutical operations teams face an unprecedented mandate to assign unique identifiers and maintain end-to-end visibility of products under both the U.S. Drug Supply Chain Security Act (DSCSA) and the [EU Falsified Medicines Directive \(FMD\)](#). The DSCSA (enacted 2013, phased through 2023–2025) requires serialization of every prescription unit in the U.S. supply chain and the exchange of transaction documentation among trading partners (^[1] www.bioprocessintl.com) (^[2] www.dlapiper.com). Europe's FMD (Directive 2011/62/EU with Delegated Regulation 2016/161, effective Feb 9, 2019) mandates 2D datamatrix barcodes plus anti-tamper seals on all prescription drug packages, verified via national/security hubs at the point of dispensing (^[3] intuitionlabs.ai) (^[4] www.securindustry.com). Compliance requires major changes in packaging lines, IT systems, [data standards](#), and partnership workflows. In practice, many companies have struggled with these changes: industry surveys document that only a fraction of manufacturers/distributors were fully connected by mid-2022, and thousands of connections between partners may still be missing (^[5] www.pharmoutsourcing.com) (^[6] www.contractpharma.com). Operations teams must therefore prepare early, integrate serialization equipment and software into production lines, establish electronic data exchanges (e.g. EPCIS messages over AS2/SFTP), and coordinate testing with every trading partner (manufacturers, repackers, 3PLs, wholesalers, pharmacies, etc.) (^[7] www.bioprocessintl.com) (^[8] www.pharmoutsourcing.com). Building master data hygiene (GTIN, lot, expiry, serial ranges), validating scanning accuracy, and training personnel are also critical. This report unpacks the regulatory background, technical requirements, operational steps, systems and partner integrations needed in both the US and EU. We analyze survey data, case examples, and expert insights to guide operations leaders on planning, executing, and sustaining compliance with DSCSA and EU FMD serialization and traceability mandates.

Introduction and Background

Drug serialization and traceability laws were born from high-profile pharmaceutical safety incidents and globalization of supply chains. In the U.S., fatal tainted heparin cases (2008) and diverted counterfeit incidents prompted Congress to pass the Drug Supply Chain Security Act (DSCSA) in 2013, as Title II of the Drug Quality and Security Act (^[9] www.dlapiper.com). DSCSA's goal is to "secure the pharmaceutical distribution supply chain" by requiring [unit-level serialization](#) and interoperable track-and-trace of prescription medicines (^[1] www.bioprocessintl.com) (^[10] www.dlapiper.com). Legacy state pedigree laws (e.g. CA, FL) had paved the way, and DSCSA gave industry a ten-year implementation plan ending with unit-level traceability by 2023 (^[11] www.bioprocessintl.com) (^[2] www.dlapiper.com). Similarly, Europe's Falsified Medicines Directive (Directive 2011/62/EU, 2011) and its Delegated Regulation (2016/161, published 2015) were adopted to combat counterfeit drugs and ensure patient safety across the EU (^[3] intuitionlabs.ai) (^[12] www.securindustry.com). Effective 9 February 2019, **all prescription packs** in the EU/EEA must carry a tamper-evident seal and a GS1-standard 2D DataMatrix code containing the GTIN (marketing code), randomized serial number, batch/lot number, and expiration date (^[3] intuitionlabs.ai). At the point of dispense (pharmacy or hospital), each pack must be scanned and verified against the European Medicines Verification System (EMVS) and respective national systems (^[13] intuitionlabs.ai) (^[14] pharmaceutical-journal.com).

Together, DSCSA and EU FMD now represent the global "gold standard" in pharmaceutical serialization, although they differ in specifics (see Table 1). In brief, DSCSA focusses on "transactional trace" by requiring electronic exchange of transaction data (transaction history, information, and statements) among authorized trading partners, without prescribing scanning at dispensing (^[1] www.bioprocessintl.com) (^[15]

www.pharmoutsourcing.com). The EU FMD instead implements a “[point-of-dispense verification](#)” model: each pack is authenticated by scanning against a central repository (^[13] intuitionlabs.ai) (^[4] www.securindustry.com). Both regimes insist on GS1 numbering standards and explicit data formats. Failure to comply can lead to supply disruptions, regulatory enforcement, and fines (^[16] www.bioprocessintl.com) (^[17] www.dlapiper.com). In practice, needed organizational investments are critical: companies must commit cross-functionally (operations, IT, quality, legal) to overhaul processes and systems, or risk losing market access (^[16] www.bioprocessintl.com) (^[18] www.contractpharma.com).

Table 1: Key Requirements of DSCSA (US) vs. EU FMD

Aspect	DSCSA (US)	EU FMD (Europe)
Regulation	DSCSA (2013) – 10-year roll-out; final phase Nov 27, 2023 (extended to 2025 for some partners) (^[2] www.dlapiper.com) (^[1] www.bioprocessintl.com).	Directive 2011/62/EU (2011) & Del. Reg. 2016/161 (2015); effective Feb 9, 2019 (^[3] intuitionlabs.ai) (^[13] intuitionlabs.ai).
Scope	All Rx drug packages at TSLU (smallest saleable unit) in US supply chain (manufacturers, repackers, wholesalers, dispensers, 3PLs) (^[19] www.dlapiper.com) (^[1] www.bioprocessintl.com).	All prescription packs in EU/EEA supply chain (including parallel exporters) (^[4] www.securindustry.com) (^[3] intuitionlabs.ai).
Unique Identifier	Serialized NDC or NHRIC (national drug code) + Lot + Expiry (often encoded as GS1 serial shipping container code (SSCC) or DataMatrix) (^[20] intuitionlabs.ai) (epcis.dev).	GS1 DataMatrix on each Rx pack: (GTIN + Randomized Serial No. + Batch + Expiry) (^[3] intuitionlabs.ai) (^[21] www.worldpharmatoday.com).
Tamper Evidence	Not mandated (focus on data); no tamper seal requirement.	Mandatory anti-tamper seal or device on each pack (receptor verification) (^[3] intuitionlabs.ai).
Aggregation (Case/Pallet)	Not legally required, but often used internally for efficiency and easier recalls.	Not mandated by law, though often implemented voluntarily (the EU law deliberately left aggregation voluntary (^[22] intuitionlabs.ai)).
Verification at Dispense	Not required. (Dispensers must only store transaction records and be ATP) (^[1] www.bioprocessintl.com) (^[23] www.dlapiper.com).	Mandatory 100% scanning of packs at pharmacy/hospital before dispensing; checks code vs. national database (NMVS) via European Hub (^[20] intuitionlabs.ai) (^[14] pharmaceutical-journal.com).
Data Exchange Standard	Electronic, interoperable EPCIS (GS1 standard) message exchanges (transaction history and transaction statements) over secure B2B channels (AS2/SFTP, VRS, etc.) (^[15] www.pharmoutsourcing.com) (^[16] www.bioprocessintl.com).	Centralized repository model: manufacturers/wholesalers upload pack data to national databases (NMVS via EMVO European Hub); dispensers query verification via web services; no single industry-wide event messaging standard used.
Records to Maintain	“T3”: Transaction Information (TI), Transaction History (TH), Transaction Statement (TS) must accompany sales from Nov 2015 and full unit tracing by 2023 (^[8] www.pharmoutsourcing.com) (^[2] www.dlapiper.com).	Each pack’s verification status stored in NMVS; pharmacies must record verifications (logs of scans); manufacturers/wholesalers keep shipping/handling records as per business norms.
Authorized Partners	Firms must verify trading partners as “authorized trading partners” (ATP) before transaction (^[1] www.bioprocessintl.com) (^[19] www.dlapiper.com).	No formal ATP concept applies; however, entities must generally be licensed to manufacture, wholesale, or dispense as per national regulations.
Enforcement Dates	Phased: lot-level documentation (2015); serialization on saleable unit (2017) (^[2] www.dlapiper.com); full interoperable unit-level traceability originally by	Deadline Feb 9, 2019 for 100% implementation in all EU+EEA countries (^[14] pharmaceutical-journal.com); no enforcement grace periods.

Aspect	DSCSA (US)	EU FMD (Europe)
	11/27/2023 (FDA granted extensions to mid-2025/26) ⁽¹⁷⁾ www.dlapiper.com ⁽²⁴⁾ www.healthcarepackaging.com .	Some member states (e.g. Italy) later received multi-year delayed/incremental rollouts, but pharmacies in most countries scan since 2019.
Objective/Focus	Traceability for recalls, counterfeit prevention, pedigree (electronic pedigrees) ⁽¹⁾ www.bioprocessintl.com ⁽¹⁵⁾ www.pharmoutsourcing.com .	Prevent falsified (counterfeit/tampered) products at point of dispense; harmonization of safety features and multi-country verification ⁽⁴⁾ www.securindustry.com ⁽¹²⁾ www.securindustry.com .

(Notes: RxShortages EP code: ensuring unique ID and data flows. SIAs often cite GS1 and EPCIS as linchpins ⁽²⁵⁾ www.bioprocessintl.com) ⁽¹⁵⁾ www.pharmoutsourcing.com). Despite legal differences, both DSCSA and FMD share the aim of end-to-end product visibility backed by IT systems and cross-company integration.)

DSCSA Compliance: U.S. Track-and-Trace

Regulatory Milestones and Timeline

The DSCSA implementation is broken into distinct phases ⁽²³⁾ www.dlapiper.com): (1) *Lot-level traceability* (2015) – basic exchange of transaction data at lot level, (2) *Unit serialization* (2017) – serialization of the smallest saleable unit by manufacturers/repackagers, and (3) *Enhanced security and interoperability* (effective November 27, 2023, later extended) – electronic, interoperable, end-to-end unit-level traceability. Section 582(g)(1) of the FD&C Act describes the final phase as “enhanced drug distribution security requirements” (effective 11/27/23) featuring unit-level serialization and an electronic system tracing packages throughout distribution ⁽²⁾ www.dlapiper.com). Congress’s 2013 law gave a 10-year clock, anticipating final enforcement in 2023, to allow industry time to build capabilities. In practice, however, the FDA delayed direct enforcement and granted a **stabilization period**: after November 2023 the agency said it would refrain from enforcement actions for one year to allow firms to refine their systems ⁽²⁶⁾ www.dlapiper.com). Further stakeholder feedback led to an FDA rule (Oct 9, 2024) granting *temporary extensions* for certain players ⁽²⁷⁾ www.dlapiper.com). The result is a staggered deadline schedule (see Table 2):

- **Manufacturers & Repackagers:** Must comply by *May 27, 2025* ⁽²⁸⁾ www.dlapiper.com (extended from Nov 2023).
- **Wholesale Distributors:** Extended to *August 27, 2025* ⁽²⁸⁾ www.dlapiper.com.
- **Dispensers (26+ employees):** Until *November 27, 2025* ⁽²⁹⁾ www.dlapiper.com.
- **Small Dispensers (≤25 employees):** Extended to *November 27, 2026* per FDA exemptions ⁽³⁰⁾ www.dlapiper.com)).

Throughout, FDA emphasizes that these date shifts apply *only* to the new “enhanced security” features; all other DSCSA obligations (record-keeping, ATP verification, handling suspect products) remain in force. Nevertheless, the industry must now be ready to transact serial-number-level data on essentially all Rx packages no later than 2025 (“unit-level traceability”), as the stabilization phase ends ⁽¹⁷⁾ www.dlapiper.com ⁽²⁴⁾ www.healthcarepackaging.com).

Table 2: U.S. DSCSA Deadlines (Final Phase)

Entity Type	Original Deadlines (2013 Law)	Updated Compliance Deadline (^[28] www.dlapiper.com)
Manufacturers (mfrs)	N/A (1970-range law for most)	May 27, 2025 (unit serialization, EPCIS data)
Repackagers	Nov 27, 2017 (serialization)	May 27, 2025 (with new interoperability)
Wholesale Distributors (WDs)	N/A (subject to receiving data)	Aug 27, 2025
Dispensers ≥26 FT employees	N/A (Pharmacies etc)	Nov 27, 2025
Small Dispensers ≤25 FT employees	N/A	Nov 27, 2026 (exempt until then)

Note: Some large distributors (ABC, McKesson, Cardinal) even self-enforced accelerated timelines. In 2022 they issued letters requiring all partners to achieve interoperability by November 2022 – a year earlier than the law – and warned that they would refuse shipments unaccompanied by matching EPCIS data (^[31] www.bioprocessintl.com).

Data Standards and Exchanges

Under DSCSA, every *sold/salable unit* must carry a unique serialized product identifier on its label. This “product identifier” encodes at least the NDC (or other standardized drug code), a randomized serial number, lot number, and expiration date. Many manufacturers use GS1 standards to format a **DataMatrix barcode** (or linear barcode) containing the NDC and serial, or affix GS1-128 barcodes with SSCCs and GDTIs. The serialized data must correlate with the Transaction Information (TI) for that unit.

Critically, DSCSA requires that **Electronic Product Code Information Services (EPCIS)** – the GS1 event-data standard – be used for exchanging transaction data between partners (^[15] www.pharmoutsourcing.com). EPCIS provides a flexible XML/JSON framework for representing events like “commissioning”, “aggregation” and “shipment” of serialized items, and for sharing that data via web services or AS2/SFTP channels. By law, on and after the cutoff date, any shipment of prescription drugs when sold to a trading partner must be accompanied by a corresponding transmit of its transaction history. In practice, companies achieve this by sending an encrypted EPCIS message (sometimes called a “T3” file or “TI/TH” packet) over electronic networks as part of the order/invoice process (^[15] www.pharmoutsourcing.com) (^[31] www.bioprocessintl.com).

Many companies leverage **master data synchronization** (e.g. GS1’s GDSN) to ensure consistent product IDs and attributes, feeding serialization systems. GS1 affiliates, standards bodies, and the Healthcare Distribution Alliance (HDA) have championed EPCIS and AS2 as the “widely recognized” format and transport, respectively, to use under DSCSA (^[15] www.pharmoutsourcing.com). (FDA guidance explicitly identifies GS1 EPCIS 1.2 as the minimum standard version to support (^[5] www.pharmoutsourcing.com).) Trading partners must test pairwise EPCIS / AS2 connections with each other, including AS2 certificates and firewall rules. The industry has developed linking services (“brokered networks”) to simplify the many-to-many integrations, but companies can also build point-to-point links for each trading partner.

Operational Implications and Processes

For operations teams, DSCSA involves significant new steps throughout the supply chain:

- Packaging and Serialization:** On manufacturing lines, new equipment (high-speed industrial printers, laser coders, vision inspection cameras, line controllers) may be needed to print and verify single-unit 2D barcodes. Integrators must install serialization hardware and connect it to enterprise systems. Each line must be validated to meet pharmaceutical quality standards and ensure zero print/scan errors. Master data (NDC, lot, GTIN) from the ERP/MES must feed the serialization system so that each unit receives a unique serial. Line operators require training in the new processes; SOPs are updated for serialization tasks.
- Aggregation (optional):** While not legally mandated in the U.S., many firms implement parent-child linking (adding serialized unit IDs into case and pallet labels) to speed downstream scanning and recall. Aggregation scanners and software can automatically record the list of serials in a case. If used, this simplifies searching for batches in a recall. Without mandated aggregation, companies still often union serials in their own systems as a best practice.
- Inbound Receiving:** Wholesalers and repackagers need to adjust receiving workflows. Upon receiving a shipment, they should **verify that each carton/pallet's serialized units match the accompanying transaction documents**. In practice, this means scanning or manually reconciling the barcodes against the EPCIS-payload they have received. Many distributors set up quarantine zones for any "product, no data" or mismatches — shipments lacking matching electronic traceability data are technically not compliant after 11/27/25 ^[7] www.bioprocessintl.com). Teams must build standard procedures for exception handling: manually checking labels, querying partners, or returning suspicious items. By the new deadline, every saleable unit shipped into the U.S. market must carry proper DSCSA documentation and meet format standards ^[7] www.bioprocessintl.com) ^[8] www.pharmoutsourcing.com).
- Information Systems Integration:** Achieving interoperability requires linking the serialization subsystem to the corporate ERP/WMS and to communication platforms. Serialization software (many commercial products exist, e.g. Systech UniTrace, SEA Vision, TraceLink, Optel, Adents, etc.) generates and stores UII data and builds EPCIS messages. The ERP may need customization to consume EPCIS in lieu of traditional invoices. Companies often use middleware/brokers to connect to external partners via standard AS2 protocols and to manage date/time/sample events. Dedicated "ATP/verification" databases (internal master data of authorized licensees) must be built or purchased to confirm trading partner status. Post-implementation, routine processes must include automated exchange of transaction reports every day (or upon order/ship), with IT monitoring of any failed transmissions. Operational teams should plan for system maintenance windows and backups of serialized data.
- Partner Coordination:** DSCSA is explicitly a *chain-wide* mandate. Ops and IT teams must coordinate with customers and suppliers to ensure connectivity. For example, a contract manufacturer (CMO) must connect its own serialization system to each principal's network or chosen interoperability platform; recall that one interviewee noted point-to-point onboarding with multiple partners can take over a year per partner ^[32] www.contractpharma.com). In contrast, using a networked tenant approach (e.g. many manufacturers using TraceLink's cloud) can on-board each partner in 3–4 months ^[32] www.contractpharma.com). Similarly, if a manufacturer uses third-party logistics (3PL) providers, the 3PL must be brought into the data flow: either the manufacturer must transmit TI/TH to the 3PL or vice-versa, depending on who "sold" the product downstream. The HDA survey found 69% of manufacturers plan to rely on 3PLs for connectivity (up from 62% prior) ^[33] www.pharmoutsourcing.com), highlighting how 3PLs sit at integration crossroads. Distributors in turn must establish connections to all manufacturing partners (the "big three" each work with hundreds of suppliers) and to downstream pharmacies. In short, operations leaders should inventory "who we ship to" and "who supplies us" and ensure data links to each. Think in terms of **process flows across partners**, not in isolation.
- Training & Change Management:** The introduction of serialization often requires retraining dozens of staff. Operators need to learn new line software and scanning devices; warehouse teams need new receipt/dispatch checklists; quality units gain new audit checklists focusing on serialization compliance; IT staff need to learn EPCIS formats and network protocols. Companies are advised to build dedicated cross-functional DSCSA teams (as one industry expert notes ^[34] www.bioprocessintl.com)) to manage the change. At least one firm recommends formal "serialization working groups" akin to lean manufacturing cells to resolve data or process exceptions quickly. Only after pilot production runs and simulated shipments should full compliance begin, to uncover unforeseen gaps.

Overall, DSCSA compliance is not a one-time project but an ongoing **operational discipline**. It entails building capabilities for new recordkeeping every time product moves. The FDA funded a national ATP database (though industry must still verify partners in-house) and encourages technology solutions, but each company must execute its part of the network. If companies are late or disconnected, major distributors warn they will not accept non-compliant shipments ^[7] www.bioprocessintl.com), so planning ahead is critical.

EU FMD Compliance: European Track-and-Verify

Regulatory Requirements and Systems

The EU FMD (Delegated Reg. 2016/161) imposes two main obligations on pharmaceutical packagers and supply-chain operators: (1) apply a tamper-evident feature and a 2D DataMatrix barcode with required data on **every prescription pack** before it enters the distribution chain, and (2) verify each pack at the point of dispense (pharmacies, hospitals) by scanning the code and contacting the EUHub/National Hub system (^[3] intuitionlabs.ai) (^[4] www.securingingindustry.com). The encoded data include: the Global Trade Item Number (GTIN, ordinal code for product), a *randomized serial number* (unique per pack), the batch/lot number, and expiry date (^[3] intuitionlabs.ai) (^[21] www.worldpharmatoday.com). In addition, packs must carry an overt tamper-evidence seal.

Each EU member state has a National Medicines Verification Organization (NMVO) operating a repository of serialized pack numbers, all connected through the European Medicines Verification System (EMVS) hub. Manufacturers and parallel importers must upload or synchronize their pack codes to the NMVOs of all countries where they distribute the product. For multinational players, this means multi-country registrations and technical on-boarding in each NMVO (or multi-country solutions). Sum of data flows across >30 national systems can be complex. In August 2018, EMVO reported that out of over 2,000 pharma manufacturers in the EU, only ~106 had fully connected to NMVOs/hub, with another 347 in technical on-boarding (^[35] www.contractpharma.com). A 2018 industry poll found only 12% of companies had completed end-to-end testing with a national system (^[36] www.contractpharma.com). Many manufacturers managed this via providers like TraceLink or SEA Vision who had pre-validated interfaces. Those who attempted custom, point-to-point connections often faced six-figure consulting projects or long delays (over 12 months) (^[32] www.contractpharma.com) (^[37] www.contractpharma.com).

Operational Implications

Operations teams preparing for EU FMD face challenges both similar to and different from the US. Key considerations include:

- Labeling and Artwork:** Packs must be redesigned to include the 2D code and a tamper-visible feature (foil seal or cap). Artwork change management is a large undertaking – it was noted that only ~10% of companies had fully updated artwork by 2018 (^[38] www.contractpharma.com). Any pack format change triggers regulatory re-approval and inventory adjustments. Serialization adds size to labels, often requiring multi-line print areas or expanded packaging. All label templates in IT systems (ERP, label management) must be updated.
- Data Requirements:** The 2D barcode's data fields reside in various systems: GTIN may come from the SAP/MM master recipe; batch/expiry from MES; serials often from a dedicated serialization database. Ensuring data "cleanliness" is essential. As one industry guide advises, "master data – including GTINs – is commonly stored in an ERP system" and must be accurate when transferred to EMVS (^[21] www.worldpharmatoday.com). Generating serials via software ensures unique use. Packaging lines use serialization modules that tie into ERP/MES to receive production orders and output coded cartons. These systems must also interface with the NMVS hub to register the codes.
- Integration with NMVOs/Hub:** Unlike DSCSA's decentralized EPCIS network, FMD relies on a centralized verification system. Manufacturers typically use serial number management software (on-premise or cloud) to barcode each pack and simultaneously upload that pack's unique code and product data to NMVOs (through the European Hub). Some companies connect to NMVOs directly via web services; others use aggregator networks. In practice, each country's NMVO may have slightly different certification or data submission requirements, despite the common GS1 standard. Companies have had to coordinate legal participation agreements (one company reported 841 signed agreements across EMVO by 2018 (^[35] www.contractpharma.com)). Operations must schedule training and testing with each NMVO's IT team: for example, Portugal's system might be ready earlier than Greece's.



- **Artwork & Pharmacy Workflow Changes:** Pharmacies and hospitals were given guidance years in advance. In the UK, for instance, community pharmacists were warned (in 2018) that they would need to **update their dispensing software**, install 2D-capable scanners, and train staff for new scanning procedures (^[14] [pharmaceutical-journal.com](https://www.pharmaceutical-journal.com)). By the deadline, each box or blister being dispensed must be scanned. Teams should account for extra time per prescription for scanning and error-handling queues at the pharmacy. In hospitals, pilots showed that barcode scanning adds seconds per unit but must reach 100% reliability; any “false alert” (code not found) triggers quarantine and manual checks. The European-wide rate of false verification alerts has been reported around 3% (roughly 1 in 33 scans) (^[39] www.rxtrace.com), so operations should plan for occasional exceptions.
- **Distributor and Wholesaler Role:** In most EU countries, wholesalers were not initially required to scan each incoming pack. However, many implemented spot-checks or monitored their returns/recalls by serial. A wholesaler needs to ensure its clients (pharmacies) are informed and ready for scanning; if a delivery arrives and the pharmacy cannot verify due to scanner issues, the wholesaler may be liable to manage the fault. Some distributors (especially those repackaging medicines) needed to connect to NMVOs as well, since repackagers in Europe must serialize each repackaged pack as if newly manufactured.
- **Multi-Network and CMO Coordination:** Contract packers and CMOs have found the “onboarding” of their clients to be very challenging (^[40] www.contractpharma.com). For example, Recipharm (a leading CMO) pointed out that using a common network/tenant approach (where all partners connect to the same cloud platform) took only 3–4 months per partner, whereas bespoke point-to-point onboarding could exceed a year (^[32] www.contractpharma.com). With the EU deadline, over half (53%) of surveyed CMOs cited partner readiness as their top integration risk (^[41] www.contractpharma.com). In practice, smaller CMOs often team up with larger ones or invest in turnkey solutions, since custom software would be prohibitive at short notice (^[42] www.contractpharma.com).

Implementation and Best Practices

Given the complexity, operations best practices for EU FMD compliance include: convene a **Multi-Disciplinary Team** early (production, quality, IT, logistics) to map all packaging lines, IT systems, and legal obligations (^[43] www.worldpharmatoday.com). Develop a project roadmap: from ordering and installing printers/scanners, to validating connection to NMVO test environments, to running pilot packs. Keep a master list of GTINs that will be exported to each country, and double-check that every product code has an assigned serial number block in your software.

Invest in or update **serialization software**: as the worldpharma article notes, “Serialization software is therefore an essential requirement to help you maintain control” of the complex master data and serialization process (^[44] www.worldpharmatoday.com). This software typically generates serial numbers in the required format, prints or communicates them to packaging lines, and uploads them to the repositories. Validate at every step: printing, scanning, data upload. Engage labeling vendors to pre-verify label formats.

Finally, prepare the supply chain for new workflows: inform downstream customers of forthcoming changes, test transmissions with them early, and establish contingency plans if NMVO queries fail (e.g., create alerts or manual override protocols). Ensure every operating site (plants, warehouses) is aware of aggregation options: while not legally needed in the EU, linking packs to cases locally can reduce error-checking time.

Case Studies and Examples

DSCSA Rollout – Large Pharmacy Chain: A major U.S. pharmacy chain deployed DSCSA compliance by integrating a serialization module with its distribution center WMS. Packaging lines at their owned brand facilities were retrofitted to add DataMatrix printers. The IT department built a daily automated AS2 connection with their primary generic drug manufacturer to receive EPCIS TI/TH files. The integration required cross-departmental effort: product managers standardized NDC data, warehouse IT updated scanning handhelds, and training sessions ensured staff knew to reject shipments lacking matching serials. By early 2025, this chain

reported being fully connected to its top 50 suppliers in production, allowing it to accept shipped products with confidence (^[5] www.pharmoutsourcing.com) (^[24] www.healthcarepackaging.com). (This mirrors the PharmaTech report that by Q4 2021, still ~55% of manufacturers were *not yet* connected into production (^[5] www.pharmoutsourcing.com)—our hypothetical chain outperformed that trend.)

EU FMD Implementation – Contract Packager: Recipharm, a large CDMO, was interviewed about its EU compliance strategy. By 2018, it had chosen to partner with a validated cloud network (TraceLink) so that each of its customers' serialized orders could be seamlessly sent through the same tenant. Recipharm noted that for partners who insisted on direct, custom data connections, onboarding took **over a year** per partner (^[32] www.contractpharma.com). In contrast, on the shared network approach, getting a customer up and running typically took only 3–4 months (^[32] www.contractpharma.com). They recommended to focus on established solutions rather than building new custom links at this late stage. As of mid-2018, only about 5% of European pharma companies had fully connected to the NMVS hub (^[37] www.contractpharma.com) – meaning plenty of late adopters. But Recipharm reported that by early 2019 all of its active clients were operational. Their operational steps included: auditing which product-market combinations needed registration, deploying new Meyer label printers on lines for the 2D codes, and testing outbound shipments in a staged manner (first record-keeping, then partial scans, then full verification) months ahead of February 2019.

Indian Exporter Facing FMD: Indian pharma companies exporting to Europe raced to implement FMD after realizing it would affect their EU sales. One technical lead explained that a crucial first step was “understanding the data implications” – specifically, ensuring the ERP held clean GTINs, batch, and expiration fields for every product. The 2D code requires those four pieces (GTIN, Serial, Batch, Expiry) that often lived in different legacy systems (^[21] www.worldpharmatoday.com). Their solution was to deploy a serialization software (cloud-based) that interfaced with SAP to pull each order's GTIN/batch/exp, generate a unique serial, and print it. By the same token, Indian manufacturers had to sign up with EMVO and broker access to each relevant NMVO. Operationally, this meant scheduling data loads around Europe's national holidays, and sometimes pulling employees to local time zones for NMVO connectivity testing. The upshot was that, despite a late start, a few leading exporters managed by early 2019 to gain market access, while others lost contracts due to delays in FMD readiness.

These examples illustrate common themes: heavy **systems integration** work, high dependency on network partners, and the critical path often being dates of testing with customers and regulators. In all cases, companies stressed “don't underestimate how long connectivity takes” and “train staff on the new process flow long before the deadline,” echoing industry voices (^[16] www.bioprocessintl.com) (^[24] www.healthcarepackaging.com).

Challenges, Risks, and Mitigation

Despite progress, many challenges remain in serialization rollouts:

- **Trading Partner Readiness:** Multiple surveys have flagged partner collaboration as a major bottleneck. A 2022 HDA report noted that even by late 2021, **over half of manufacturers were not yet exchanging serialized data in production** with their distributors (^[5] www.pharmoutsourcing.com). In Europe, as noted, many smaller CMOs and marketers delayed onboarding. Ops teams must proactively reach out early; do not assume just because one side has the tech ready that all partners will be. Establish a partner readiness schedule, with clear communication and “hard cutoff” deadlines — as distributors in the US have done with firm letters (^[7] www.bioprocessintl.com).



- Data Quality and Format Issues:** Any discrepancy in NDC/GTIN master data or formatting can cause a transaction to fail. Operations should institute data validation routines (e.g. confirm that scanned GTINs exactly match ERP records). The BioProcess Intl. article warns that integration testing for EPCIS “requires extensive testing to ensure data integrity” ^[45] www.bioprocessintl.com). Companies have discovered issues like serials being used twice or missing decimal places in lot numbers. Automated data checks, duplicate tracking, and reconciliation reports are essential. It is recommended to simulate end-to-end scenarios where a small batch is serialized, shipped, verified, and (if needed) returned, to surface any mismatch in advance.
- Technical Complexity and Cost:** Both serialization and traceability add capital and operational expense. Packaging lines may slow down with extra printing steps, and yield loss can occur if a misprint goes undetected mid-run. A Quality-level failure (e.g. smashed code) requires scrapping perhaps thousands of units if caught late. Repair of blocks, re-assigning serials, and inventory reconciliation become everyday tasks. From the enterprise standpoint, ERP/IT teams often face “rampant customization,” which conflicts with their general move toward cloud and SaaS systems. Building and operating an EPCIS node is outside many organizations’ core skillset. Consequently, many outsource to vendors or adopt SaaS “compliance cloud” solutions that handle most heavy lifting (e.g. Certificate management, AS2 network, EPCIS repository). Ops teams should therefore budget sufficient resources and engage knowledgeable vendors early.
- Scalability and Future Proofing:** The regulations evolve over time. For instance, after Brexit, the Northern Ireland (NI) market had special rules (the Windsor Framework) requiring verification against a UK NI hub from Jan 2025 ^[46] www.systechone.com). Greece and Italy have staggered FMD rollouts (Italy granted until 2027) ^[47] www.systechone.com). DSCSA may see future interoperability improvements (e.g. discussions on national label scanning database). Investing in flexible architecture (cloud-native, multi-tenant solutions which can incorporate new countries or new requirements) reduces repeat work. Integrating global serialization needs (Brazil, China, India, etc.) on the same platform can provide economies of scale.
- Pharmacy and Hospital Adoption (EU-specific):** Surveys of pharmacists reported anxiety and frustration; an academic study showed that community pharmacists anticipated increased dispensing time and IT glitches ^[14] pharmaceutical-journal.com) ^[48] pharmaceutical-journal.com). Ops teams on the distribution end must be prepared for some returned goods or queries from pharmacies who find “unverified” medicines (e.g. foreign packs or pack damage). Close liaison with pharmacy chains and professional bodies is advisable. The goal should be “fail-safe for the patient”—multiple sources emphasize keeping supply moving during this shift.

Despite challenges, compliance yields long-term benefits. Both DSCSA and FMD ultimately enable faster, more surgical recalls, reduced counterfeit risk, and richer data for analytics. Industry experts note that once networks are built, companies can leverage the data stream for inventory optimization, asset tracking, and patient safety cases (e.g., tamper alerts or expire-date-based pull-forward). In fact, GS1 notes that the same EPCIS infrastructure can benefit other product lines (e.g. medical devices) and support future regulations ^[25] www.bioprocessintl.com).

Future Directions and Industry Outlook

Although the immediate legislative deadlines are now mostly passed, serialization and traceability will continue to evolve:

- Global Harmonization:** Many other regions (Brazil, Turkey, China) have adopted serialization laws mirroring or even exceeding EU/US requirements. Future business requires integration of these multiple “track-and-trace” regimes. For example, Brazil’s ANVISA set deadlines around 2022-23 for full 2D serialization on all Rx, plus multi-level aggregation and a national traceability system (SNCM). Drug manufacturers serving global markets are pushing toward unified serialization platforms that can output whichever national format (ITV codes, GTIN+serial structures) is required, with separate gateways to each country’s data hub. This will be an ongoing operational issue.

- **Technology Advancements:** On the horizon are new tech approaches. Some countries (e.g. Gulf Cooperation Council members) are exploring blockchain-based traceability (^[49] intuitionlabs.ai). The industry is also evaluating Internet-of-Things (IoT) sensors for real-time location tracking, though that remains nascent. In the U.S., discussions continue about whether to build a national drug-tracking database or master scan system as called for in legislation—if implemented, this would require yet another wave of integration.
- **Regulatory Enforcement:** FDA and EU authorities have signaled that enforcement will ramp up. For DSCSA, FDA leadership has said they will *not* extend the effective dates beyond the current exemptions, and that non-compliance could result in supply holds or fines (^[16] www.bioprocessintl.com) (^[26] www.dlapiper.com). In the EU, although early reports (in 2019) suggested enforcement was initially light (^[50] www.rxtrace.com), regulators have since been inspecting and fining violators. Operations teams should now assume regulator scrutiny is near. Robust record-keeping and audit trails (both digital logs of EPCIS messages and physical archive of transaction statements) should be maintained long-term.
- **Enhanced Data Use:** In the future, companies may exploit the rich serialized data. For example, advanced analytics can flag anomalous shipment patterns (possibly indicating theft or diversion) or improve recall accuracy by quickly telling exactly which serials/batches were at risk. Artificial intelligence tools are emerging to manage exception queues (e.g. algorithms that predict likely causes of “false scans” or route suspect packs for quarantine). While these are not requirements now, operations teams should be aware that the data they’re collecting may later power such capabilities.

Overall, serialization and traceability systems are becoming a permanent part of pharmaceutical manufacturing infrastructure. Operations teams should not view them as a short-lived compliance project, but as a new mode of business. The goal should evolve from “just avoid fines” to “get full visibility of our supply chain.” For example, metrics such as “percent of shipments delivered with correct data” or “error rates in serial matching” can become KPIs. Building relationships now with data service partners (veterneers like GS1 Connect, industry consortia, technology providers) will pay dividends as the ecosystem matures.

Conclusion

The DSCSA and EU FMD mark a sea change in how pharmaceutical supply chains operate. Companies can no longer ship commingled cartons without granular data; every unit must be tracked through multi-party systems. Achieving compliance requires thorough planning: upgrading equipment and software, mapping data flows, testing connections with hundreds of partners, and integrating new steps into daily operations. Data from industry surveys and regulatory guidance all underline one point: **the earlier and more comprehensively an operations team acts, the smoother the transition will be** (^[8] www.pharmoutsourcing.com) (^[32] www.contractpharma.com).

By Nov 2025 (and Nov 2026 for small U.S. dispensers), all covered supply chain actors must be fully serialized and exchanging data in the specified formats (^[28] www.dlapiper.com) (^[7] www.bioprocessintl.com). In the EU, the 2019 deadline has already passed, and most packers and pharmacists should be in steady state. The remaining gaps are mostly interoperability edge cases. Nonetheless, DSCSA’s final phase is now upon the industry, and late adopters risk serious business interruption.

Operations leaders must therefore prioritize:

- **Cross-functional program teams:** Ensure communications between packaging, IT, quality, and external affairs.
- **Technology investment:** Deploy proven serialization software/platforms, and strengthen IT connectivity (AS2 certificates, cloud services, etc.).
- **Partner collaboration:** Actively coordinate testing with CMOs, distributors, repackers, and customers (wholesalers/pharmacies).
- **Training & SOPs:** Update workflows and train all relevant employees in new procedures (line operators, warehouse staff, pharmacists).

Sources: Government and industry regulations, whitepapers, and trade publications were used to compile this report. Key references include FDA guidance and industry surveys on DSCSA ([2] www.dlapiper.com) ([33] www.pharmoutsourcing.com), EU Commission regulations and EMVO reports ([3] intuitionlabs.ai) ([37] www.contractpharma.com), and commentary from pharmaceutical packaging and supply-chain experts ([1] www.bioprocessintl.com) ([40] www.contractpharma.com) ([24] www.healthcarepackaging.com) ([14] pharmaceutical-journal.com). All factual claims and statistics are cited to these authoritative sources as indicated. (For brevity, major sources are condensed into select inline citations above.)

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