2025

Good Distribution Practice (GDP)

WHAT IS GDP?

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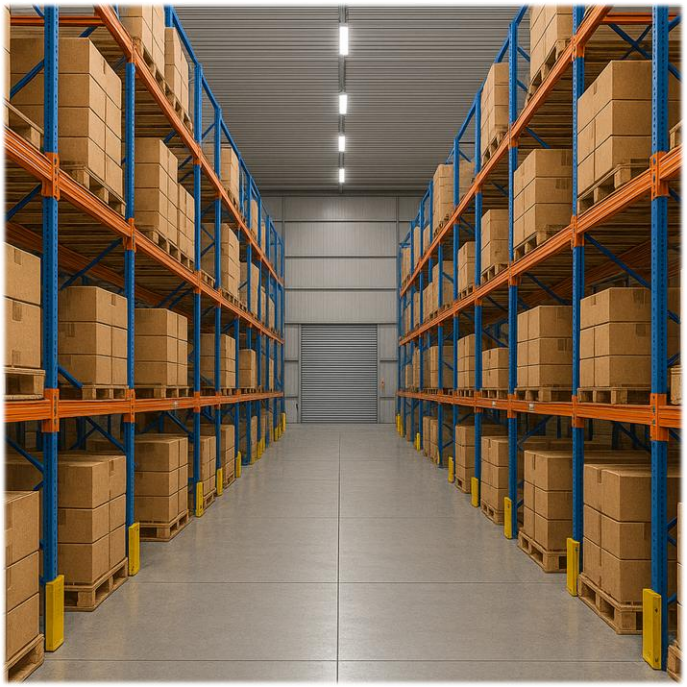
KYLE WINN / ADAM WALKER

Good Distribution Practice (GDP) – Safeguarding Medicines beyond the factory

Chapter 1: GDP in Context – Why the Journey Matters

Medicinal products do not earn their value the moment they leave the filling line; they earn it when a patient finally a receives safe, effective medicine. Good Distribution Practice (GDP) bridges that critical gap. It is the internationally recognised standards framework that keeps medicines within their qualified temperature range, protected from tampering, and fully traceable from manufacturer to patient.

GDP sits alongside GMP and GCP in the GxP family, but its focus is unique: logistics rather than manufacture. By codifying how wholesalers, third party logistics (3PLs) and distributors handle product, GDP makes sure that manufacturing effort is not undone by a careless excursion, a lost pallet, or an incomplete audit trail.



Chapter 2: Whose Responsibility Is GDP?

Conventional wisdom says GDP belongs to licensed wholesalers, yet the reality of modern supply chains is far broader. Any organisation that stores, transports, repackages, or even temporarily stages medicinal goods inherits GDP duties, whether it holds a Wholesale Distribution Authorisation (WDA) or operates under a service contract, simply by extension of the distributors regulatory responsibilities.

That scope covers international and local distributors, regional pharmacy procurement units, specialist couriers, and airport freight handlers alike. If your facility accepts product into physical custody, even for a single night you must control temperature, security, documentation, and traceability to the same standard as a WDA(H) holder.

Chapter 3: Pillars of a GDP Quality System

A compliant GDP quality system mirrors GMP in structure, but with logistics-specific emphasis:

- Product Integrity & Security:
    - Warehouses and vehicles are controlled, alarmed, and subject to route risk assessments to prevent theft or diversion.

- Traceability:
    - Every inward receipt, pick, dispatch, and return is captured in a validated system that links product, lot/batch, expiry, source and destination.
- Environmental Control:
    - Temperature-mapped storage zones, qualified shipping solutions, data-logger monitoring, and real-time alerts for excursions.
- Deviation & CAPA Management:
    - Excursions are not simply recorded; they are risk-assessed against stability data and patient impact, then closed by

documented CAPAs (often with the support of the manufacturer).

- Governance:
    - Oversight by a named Responsible Person (RP) who maintains continuous knowledge of operations, resolves and escalates issues to senior leadership.

Chapter 4: The Responsible Person – Beyond the Signature

Regulations require each WDA licence holder to nominate an RP, but effective compliance demands more than a name on a certificate. The RP must be empowered to halt shipments, quarantine stock, mandate recalls, and approve customers and suppliers. Their authority extends across every lane, road, air, sea and into every contracted 3PL.

Successful RPs embed themselves in deviation triage, temperature trend reviews, and change-control boards. They champion a culture where drivers understand the 'why', warehouse teams escalate issues without fear, and senior management allocates the resources needed to close CAPAs on time.

Chapter 5: Storage Excellence – Designing Facilities That Protect Product

GDP-compliant warehouses do more than sit between 15 °C and 25 °C. They are temperature-mapped to identify hot and cold spots, equipped with calibrated probes linked to 24/7 monitoring systems with alarms, and supplied by validated HVAC systems. Refrigerated and frozen chambers undergo design, installation, operational, and performance qualification (DQ/IQ/OQ/PQ) according to Annex 15, ensuring that worst-case loading patterns still meet specification and seasonal variation in ambient conditions does not impact the controlled environmental conditions. Routine review of min-max data and bi-annual re-mapping detect seasonal drift or rack configurations that might compromise control.

Chapter 6: Cold Chain Logistics – Validation in Motion

Once product rolls onto a lorry or boards an aircraft, static validation gives way to lane qualification. Passive shippers, refrigerated vehicles, or active containers must be stress-tested in environmental chambers that simulate summer tarmac and winter runway extremes.

Validated route risk assessments pair these data with actual transit durations, layover times, and contingency airports. Drivers and ground crews receive SOP-driven instructions on pre-conditioning, loading sequence, and immediate escalation if data loggers alarm mid-journey.

Chapter 7: Common Pitfalls and How to Prevent Them

Unqualified Storage: Renting short-term overflow space without temperature mapping invites excursions. Always execute a rapid mapping study before the first pallet arrives, and then repeat a full mapping to account for seasonal variation.

Training Gaps: Couriers often see GDP as "just another parcel." Embedding bite-size GDP modules and driver sign-offs turns external partners into informed guardians of product quality.

Paper-Heavy Processes: Reliance on manual logs, delivery records, deviation discovery. Transitioning to validated digital systems shortens feedback loops and supports real-time release decisions.

Chapter 8: Preparing for an MHRA GDP Inspection (Always Inspection-Ready)

- Inspection narrative on demand:
    - Map one representative batch from goods-in to dispatch; cross-reference each step to live SOPs, forms, warehouse and transport monitoring records and temperature files.
- Data integrity & trend visibility:
    - Keep temperature and deviation data trended (metrics may include mean temperature, range, excursion rate/1 000 shipments, deviation investigation status, number of deviations open); The RP uses the dashboard to maintain awareness, drive change-control and focus training. Ensure longer term data retention is compliant with current regulatory expectations.
- Validation always current:
    - Storage areas re-mapped after any layout/HVAC change; lane and shipper reconfiguration or qualifications refreshed for seasonal extremes; calibration certificates traceable and in date.
- Full control of outsourcing:
    - For every courier / 3PL ensure you have: GDP audit report, signed contract, technical agreement with escalation times + CAPA ownership, KPI review meeting minutes.
- Empowered Responsible Person:
    - CPD log, training records, deviation triage attendance, authority examples (shipments held, suppliers blocked); RP dashboard reviewed at exec meetings.

- People readiness:
    - Mock interviews prove staff know where the SOP is, how to escalate an alarm and what must appear on a POD; refresher training triggered by any weak answer. Make sure your staff know how to respond to questions from an inspector.
- Space to host an inspection:
    - Live system access (read-only), printer, PPE; refreshments and sufficient space available.
    - Separate 'war-room' where personnel can assemble requested documentation and review them before they are sent to the inspection room.
- Daily traceability drill:
    - Choose one shipment each day on the run up to an inspection. Retrieve an order, locate the relevant picking ticket, logger file, container or vehicle seal records and POD within 15 minutes; file in an "Always Ready" folder.
- Rolling audits & self-inspections:
    - Examples include: Ten-minute spot checks every week against a single GDP clause; findings logged as deviations and closed with CAPA + effectiveness review.
    - Tracing materials from receipt to delivery
    - Simulated (or real) recalls including reports
    - Quality and Operational Dashboard reviews, evidenced by meeting minutes
- Continuous-improvement evidence:

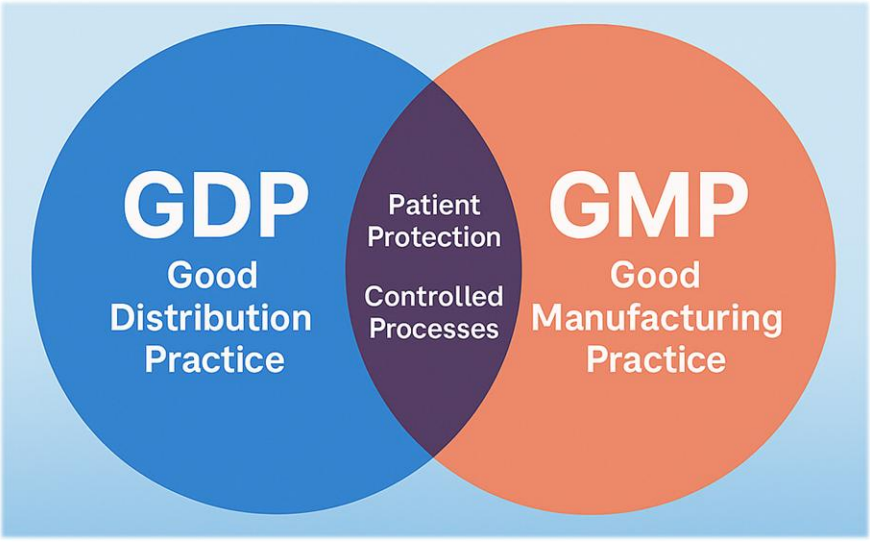
- CAPAs closed on time, internal-audit schedule current, management-review minutes link quality metrics to resource decisions, and lessons shared via GDP flash notices.

- A system that works like this every day shows the MHRA a living, self-correcting quality culture rather than a display prepared for inspection week.

Chapter 9: GDP vs GMP – Complementary, Not Competitive

GMP manufactures a medicine fit for release; GDP ensures it arrives unchanged. Both rely on documented processes, validated equipment, trained personnel, and rigorous deviation management. Where GMP can focus on aseptic integrity, GDP focusses on tamper-proof seal integrity, but the underlying philosophy, patient protection through controlled, documented practice is identical.

Teams that view GDP as an extension of GMP, rather than an administrative burden, develop seamless handoffs where batch records close with distribution data already attached, simplifying recalls and reinforcing supply-chain resilience



Chapter 10: Key Takeaways – Embedding GDP in Everyday Operations

- Treat every transfer as a critical step:
    - Products are vulnerable when moving or waiting.
- Invest in people:
    - Trained staff and a competent, respected RP are the best risk controls.
- Validate with data not assumptions:
    - Map, monitor, trend, and adjust.
- Document with purpose:
    - Documentation should drive action, not dust collection.
- Continuously improve:
    - Audit internally, learn from excursions, and share lessons across the supply chain.

By mastering GDP, your organisation safeguards therapeutic value, protects patients, and upholds public trust in the pharmaceutical supply chain.

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