

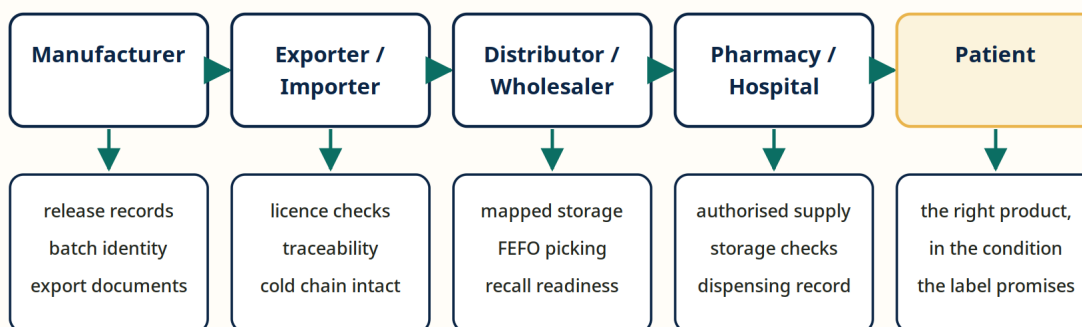
### Unit 4: Good Distribution Practices

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#### 4.1 Why distribution needs its own practice

A medicine can leave a perfect factory and arrive at the patient ruined or replaced. Between release and dispensing it passes through exporters, importers, distributors, wholesalers, transporters, warehouses and pharmacies, across climates and borders, in the hands of people the manufacturer does not employ. **Good Distribution Practice (GDP)** is the quality system for that journey: the set of requirements that keeps the product's quality and integrity intact through storage and transport, keeps its movement traceable, and keeps falsified products out of the legitimate chain. Its founding anxiety differs from GMP's. GMP fears the factory's own errors; GDP fears the world's: heat in a container on a dock, a broken cold chain, theft and re-entry of expired stock, a falsified consignment wearing a genuine product's name. Regulators elevated GDP from guidance to law after repeated falsified medicine incidents showed the distribution chain, not the factory, as the soft target.

#### The Distribution Chain Under GDP



At every hand over: conditions proven, documents complete, batch traceable in both directions.

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Figure: From manufacturer to patient: every hand over in the chain is a GDP control point for storage conditions, documentation and traceability.

#### 4.2 Legal GDP requirements worldwide

The syllabus asks for the legal position across the world, and the honest summary is a patchwork with one design. In the **European Union**, GDP became a binding guideline in 2013 (the Guidelines on Good Distribution Practice of medicinal products for human use, 2013/C 343/01), given force through the amended Directive 2001/83/EC and the Falsified Medicines Directive 2011/62/EU: wholesale distribution requires authorisation, a **responsible person**, a quality system, and safety features (unique identifiers and anti tampering devices) on packs. **WHO** publishes GDP for pharmaceutical products (in its Technical Report Series, notably TRS 957, Annex 5, within the wider WHO good distribution and trade practices), which member states adopt or adapt; it is the reference text for most of the world. In the **United States**, distribution is governed state by state through wholesaler licensing under the Prescription Drug Marketing Act tradition, overlaid federally by the **Drug Supply Chain Security Act (DSCSA)** of 2013, which builds unit level traceability across the supply chain. **India** regulates distribution through the Drugs and Cosmetics

Act licensing system for sale and distribution, CDSCO guidance and, for exports, the traceability and barcoding requirements imposed on exported medicines. The legal forms differ; the requirements converge on authorisation, responsible persons, premises and transport control, records, and recall capability.

### 4.3 Principles of GDP

GDP can be reduced to principles that any of the legal systems above would recognise. **Quality is managed, not inspected, in distribution too:** the distributor operates a quality system with defined responsibilities, risk management and change control proportionate to its activities. **The product's identity and history are never lost:** every movement is recorded, stock is traceable batch by batch, and the chain of custody can be walked in both directions, which is what makes recalls and falsified product investigations possible. **Conditions are controlled and proven:** storage and transport keep the labelled conditions, with monitoring records to prove it, not merely intentions. **Only legitimate product moves:** suppliers and customers are qualified and verified as authorised, suspicious offers and incidents are reported, and falsified products are quarantined and reported, never quietly returned to stock. **Problems are handled in the open:** complaints, returns, recalls and deviations are recorded, investigated and closed under procedure. Examiners reward the observation that GDP is GMP's philosophy (system, records, named responsibility, independent checking) re-expressed for warehouses and trucks.

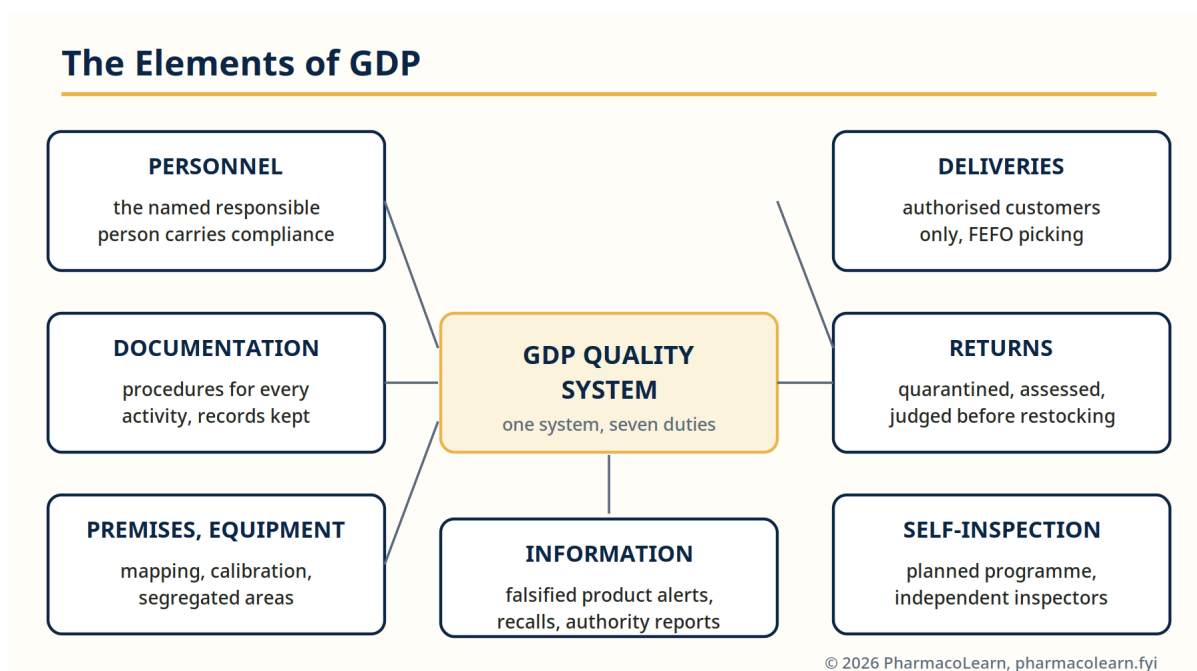


Figure: The GDP elements named in the syllabus: personnel, documentation, premises and equipment, deliveries, returns, self-inspection and information.

### 4.4 Personnel: the responsible person

GDP names its accountable human just as GLP names the study director. The **responsible person** (in EU terminology) is the named individual, suitably qualified and experienced, who carries personal responsibility for the distributor's GDP compliance: for the quality system, for the accuracy of records, for training, for the handling of recalls, complaints and returns, for approving suppliers and customers, and for ensuring self-inspections happen. Around this office the ordinary personnel requirements stand: an organisational structure with defined duties, enough staff for the volume of work, documented training in GDP and in each person's tasks, and hygiene and conduct rules for warehouse work. The regulatory point of a named responsible person is the same as in Unit 2: when something fails in a warehouse at midnight, the system must already know whose decision it was and whose it now is.

## 4.5 Documentation, premises and equipment

GDP **documentation** mirrors GMP's: written procedures for every activity that can affect quality (receipt, storage, order processing, transport, returns, recalls), records made at the time of each operation and kept for defined periods (in the EU scheme, at least five years, or one year beyond the product's expiry, whichever is longer), and delivery documentation that lets every consignment be traced. **Premises** must be designed or adapted to protect stock: clean, dry, within acceptable temperature limits, segregated areas for quarantined, rejected, returned and recalled goods under lock or electronic separation, security against unauthorised entry, and pest control. **Equipment** includes the monitoring estate itself: calibrated thermometers and data loggers, **temperature mapping** of storage areas in summer and winter to find hot and cold spots, alarms for excursions, and **qualification of vehicles and shipping containers**, including validated cold boxes for cold chain products, so that the labelled conditions are maintained in a truck as provably as in a warehouse. The recurring examination theme is proof: GDP does not ask whether the warehouse felt cool, it asks for the mapping study, the calibration certificates and the monitoring record.

## 4.6 Deliveries to customers, returns, self-inspection, and provision of information

The operational heart of the unit is four procedures. **Deliveries to customers**: orders are supplied only to authorised recipients (licensed pharmacies, hospitals, wholesalers), stock is picked by **FEFO** (first expiry, first out) so the earliest expiring batch moves first, transport conditions and packaging are matched to the product, and the transaction is recorded completely enough to execute a recall of that batch to that customer. **Returns**: goods returned from customers are not stock until judged; they are quarantined, assessed against defined criteria (unopened, in original packaging, within expiry, demonstrably stored correctly, returned within an agreed short period), and the decision to restock, destroy or return to the supplier is recorded with reasons, because the returned goods stream is a known door for falsified products. **Self-inspection**: the distributor audits itself against GDP at planned intervals under a written programme, by staff independent of the area inspected, recording findings and closing corrective actions, the GDP form of the self inspection principle met in Unit 1's European articles. **Provision of information**: the duty to tell regulators and partners what they need to know: notifying authorities of suspected falsified products, informing customers and authorities in a recall, and supplying the documentation that lets the next link in the chain meet its own duties.

## 4.7 Stability testing principles in distribution

GDP borrows one laboratory discipline and bends it: **stability**. A product's shelf life is earned in stability studies (the ICH stability framework of Unit 5's guidelines, run in climatic zones), and its labelled storage condition is a promise made on that data. Distribution is where the promise is kept or broken. The governing principles: **excursions are data, not gossip**: a recorded temperature excursion is assessed against the product's stability data and budget (the total time out of condition the data can support) by a competent person, and the decision is documented; **mean kinetic temperature** and excursion allowances exist precisely because perfect chains are impossible and assessed chains are acceptable. **Cold chain products** (typically 2 to 8 degrees Celsius) receive the strictest handling, with continuous monitoring and validated shippers, because freezing can damage a vaccine or biologic as surely as heat. And **stability testing principles** flow back upstream: distribution experience (recurrent excursions on a route, seasonal extremes) feeds the manufacturer's stability and packaging decisions, which is why GDP sits inside the quality system and not outside the factory gate.

## 4.8 WHO GDP, USP GDP and supply chain integrity; CDSCO guidance and ISO standards

Two reference texts close the syllabus's list. **WHO GDP** (the WHO good distribution practices for pharmaceutical products, with the companion WHO guidance on good trade and distribution practices) is the model most national systems copy: it covers the quality system, personnel, premises and equipment, shipment containers and labelling, dispatch, transportation, documentation, repackaging and relabelling, complaints, recalls, returned products, counterfeit products, importation, contract activities and self-inspection, a table of contents that doubles as a GDP syllabus in itself. The **USP** treatment appears in its general chapter on good distribution practices for drug products (USP <1079> and its family), which frames distribution as **supply chain integrity**: the discipline of keeping a product within its quality system from manufacturer to patient, managing the risks of adulteration, diversion, theft, temperature abuse and falsification as one connected problem rather than as separate accidents. In India, **CDSCO guidance** and the Drugs and Cosmetics Act licensing regime govern distributors, the Indian Pharmacopoeia Commission and industry bodies publish aligned guidance, and export consignments carry government mandated barcoding and traceability. The **ISO standards** that support GDP are the generalists: **ISO 9001** for the quality management system itself (Unit 5), and supply chain security standards of the ISO 28000 family where a distributor formalises its integrity controls. The student should leave the unit able to say, for any GDP question, which text governs in which territory and what all of them agree on.

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