BP804T · B.Pharm Semester VIII · Theory Notes

Pharmaceutical Management

Unit V — Operations & Supply Chain Management (6 hours)

Unit V (6 hours)

Pills & Python Notes

From-zero teaching standard: every technical term is defined before use.

Syllabus coverage: Unit V (6 hours).

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CHAPTER 6: Operations and Supply Chain Management

BP804T — Pharmaceutical Management, Unit V

Learning Objectives

After studying this chapter, the student will be able to:

1 Explain **operations management** and its objectives in a pharmaceutical plant.

2 Describe **production planning and control (PPC)**, its four steps — **routing, scheduling, dispatching, follow-up** — and prepare a simple schedule.

3 Explain **inventory management**, compute the **Economic Order Quantity (EOQ)** from simple data, and describe **ABC analysis**, **reorder level**, and **safety stock**.

4 Explain **lean manufacturing** (waste/MUDA, 5S) and **Six Sigma** (DMAIC) and their benefits in pharma.

5 Describe **supply chain management**, its components, and the pharma supply-chain flow from manufacturer to patient.

6 Explain **logistics** and the roles of members in **drug distribution channels in India**.

7 Explain **cold chain management** — why it matters, its elements, and the role of technology.

8 Describe **e-commerce in pharma distribution** — its models, advantages, and challenges.

9 Explain **supply-chain risk management** (types of risks, the risk matrix) and **sustainability** practices in pharma operations.

Definitions

- **Operations management** — the management of the processes that convert inputs (raw materials, labour, machines) into outputs (finished medicines). In simple words: managing *how the factory actually makes things*.
- **Production planning and control (PPC)** — planning *what* to produce, *when*, *where*, and *how*, and then controlling the work so the plan is actually followed.
- **Routing** — deciding the path a product will take through the factory: which machines, in which order.
- **Scheduling** — fixing the timetable: when each job starts and finishes on each machine.
- **Dispatching** — releasing the work orders — giving the "go" signal to start production.
- **Follow-up (expediting)** — checking progress during production and removing delays so the schedule is met.

- **Inventory** — the stock of materials a company holds: raw materials, work-in-progress (partly made goods), and finished goods.
- **Inventory management** — deciding *how much* stock to keep, *when* to order more, and *how much* to order each time, so that production never stops and money is not locked up unnecessarily.
- **Economic Order Quantity (EOQ)** — the order size that gives the lowest total cost (ordering cost + holding cost) per year.
- **Ordering cost** — the cost of placing one order (paperwork, transport arrangement, inspection of incoming material).
- **Holding (carrying) cost** — the cost of keeping one unit in stock for one year (warehouse rent, interest on locked money, insurance, risk of expiry).
- **Reorder level** — the stock level at which a new order must be placed so that fresh material arrives before the old stock runs out.
- **Safety stock** — extra stock kept as a buffer against unexpected delays or sudden demand.
- **Lead time** — the time gap between placing an order and receiving the material.
- **ABC analysis** — a method of classifying inventory items into A (few items, high value — tight control), B (medium), and C (many items, low value — simple control).
- **Lean manufacturing** — a production philosophy that aims to create maximum value for the customer with minimum waste.
- **MUDA** — the Japanese word for *waste*: any activity that consumes resources but adds no value for the customer.
- **5S** — a five-step workplace-organisation method: Sort, Set in order, Shine, Standardize, Sustain.
- **Six Sigma** — a quality-improvement approach that aims for nearly defect-free processes by finding and removing the causes of variation (mistakes).
- **DMAIC** — the five Six Sigma problem-solving steps: Define, Measure, Analyze, Improve, Control.
- **Supply chain** — the complete network of organisations, people, and activities that moves a product from raw-material supplier to the final patient.
- **Supply chain management (SCM)** — planning and managing all activities involved in sourcing, production, and delivery so that the right product reaches the right place at the right time at the lowest reasonable cost.
- **Logistics** — the part of the supply chain that physically moves and stores goods: transport, warehousing, and order handling.
- **Cold chain** — a temperature-controlled supply chain (typically refrigerated) that keeps temperature-sensitive products like vaccines, insulin, and biologics safe from factory to patient.
- **Data logger** — a small electronic device placed with the goods that continuously records temperature during transport and storage.
- **E-commerce (in pharma)** — buying and selling medicines through digital/online platforms.
- **Risk management** — identifying possible future problems, judging how likely and how serious they are, and preparing plans to prevent or handle them.

- **Sustainability** — running the business in a way that meets today's needs without harming the ability of future generations to meet theirs — in practice: less waste, less pollution, less energy.

Key Terminology

Term	Simple meaning
Work-in-progress (WIP)	Material that has started production but is not yet a finished product (e.g., granules waiting to be compressed into tablets).
Stock-out	Running out of stock — production stops or a customer order cannot be fulfilled.
Overstocking	Keeping far more stock than needed — money locked up, risk of expiry.
Gantt chart	A simple bar chart showing which job runs on which machine and when — the visual form of a schedule.
Value-added activity	An activity the customer is willing to pay for (e.g., actually making the tablet). Its opposite is waste (MUDA).
Kaizen	Japanese for "continuous improvement" — small improvements by everyone, every day; the spirit behind lean.
Defect	Any output that does not meet specifications and must be rejected or reworked.
Distributor / stockist	A middleman who buys medicines in bulk from the manufacturer and supplies them to retailers in a territory.
C&F agent (Carrying & Forwarding agent)	An agent who receives goods from the manufacturer, stores them, and forwards them to distributors on the company's behalf.
Last-mile delivery	The final step of delivery — from the retailer or warehouse to the patient's hands.
Temperature excursion	Any time a cold-chain product goes outside its required temperature range — a serious quality risk.
B2B / B2C	Business-to-Business (company selling to another company) / Business-to-Consumer (company selling directly to the patient/customer).
Risk matrix	A simple grid that rates each risk by *likelihood* (how probable) × *impact* (how serious) to decide which risks need action first.
Green packaging	Packaging designed to harm the environment less — recyclable, biodegradable, or reduced material.
Carbon footprint	The total greenhouse-gas emission caused by an activity or product; companies try to shrink it.

Detailed Explanation

1. Operations management: meaning and objectives

Technical concept: Operations management is the design, planning, and control of the *transformation process* — the system that converts inputs (materials, labour, machines, energy, information) into outputs

(finished medicines and services).

Simple explanation: If management is "running the company," operations management is "running the *making* part of the company." The purchase department buys the API, but operations decides how the API becomes a tablet: which machines, in what sequence, with what quality checks, and at what speed.

Objectives of operations management in a pharma plant:

1 **Right quality** — every batch must meet specifications; patient safety comes first.

2 **Right quantity** — produce enough to meet demand, without wasteful overproduction.

3 **Right time** — deliver on schedule; a delayed life-saving drug is a failed operation.

4 **Right cost** — produce efficiently so medicines stay affordable.

5 **Flexibility** — be able to switch products or batch sizes when demand changes.

6 **Compliance** — follow GMP and all regulations in every operation.

7 **Safety** — protect workers, the plant, and the environment.

Key takeaway: Operations management = managing the making. Its objectives: quality, quantity, time, cost, flexibility, compliance, safety.

2. Production planning and control (PPC)

Technical concept: PPC has two halves. *Production planning* decides what to produce, how much, when, where, and how. *Production control* ensures the plan is actually carried out — it tracks progress and corrects deviations.

Simple explanation: Planning is drawing the route map; control is driving the car and staying on the route. A plan without control is a wish; control without a plan is confusion.

The four steps of PPC:

1 **Routing** — fixing the *route*: the sequence of machines and operations. Example: for a tablet — dispensing → sifting → granulation → drying → blending → compression → coating → packing. Routing answers: *which machines, in which order?*

2 **Scheduling** — fixing the *timetable*: start and finish times for each job on each machine. Example: "Batch A on the tablet press from 8 am to 12 noon; Batch B from 1 pm to 5 pm." Scheduling answers: *when does each job run?*

3 **Dispatching** — *releasing* the work: issuing the batch manufacturing record, materials, and the formal "start" order to the shop floor. Dispatching answers: *go!*

4 **Follow-up (expediting)** — *tracking* progress: comparing actual progress with the schedule, finding delays (machine breakdown, material shortage), and taking corrective action. Follow-up answers: *are we on track, and if not, what do we fix?*

Simple scheduling example: One tablet press, three batches waiting, one 8-hour shift (8 am–4 pm):

- Batch C: 2 hours → schedule 8 am–10 am
- Batch A: 3 hours → schedule 10 am–1 pm

- Batch B: 3 hours → schedule 1 pm–4 pm

(Ordered shortest-first so the quick batch finishes early and the customer waiting for it is served sooner — a basic priority rule. A Gantt-style bar view of this timetable is shown in the Worked Examples section.)

Key takeaway: PPC = plan the work, then work the plan. Route (path) → Schedule (time) → Dispatch (start) → Follow-up (stay on track).

3. Inventory management and optimization

Technical concept: Inventory management balances two opposite costs: keeping *too little* stock causes stock-outs (production stops, sales lost), while keeping *too much* locks up money and risks expiry. Optimization means finding the stock policy with the lowest *total* cost.

Simple explanation: Inventory is like the rice stock in a hostel kitchen. Too little rice → students go hungry (stock-out). Too much rice → money locked in sacks, rats and spoilage (overstocking). The warden must decide *when to order* and *how much* — that is inventory management.

Why inventory matters (especially in pharma):

1. **Continuity** — production must never stop for want of material; a stock-out can delay essential medicines.
2. **Bulk savings** — buying in economic quantities reduces ordering and transport cost per unit.
3. **Demand fluctuations** — stock absorbs sudden rises in demand (e.g., seasonal cough syrup).
4. **Lead-time protection** — material ordered today arrives after the lead time; stock covers the gap.
5. **But** — excess stock locks working capital, needs warehouse space, and risks *expiry* (a uniquely pharma pain: expired API must be destroyed).

The EOQ concept: Every time you order, you pay an **ordering cost** (fixed per order). Every unit you keep in stock costs a **holding cost** per year. Big, rare orders → low ordering cost but high holding cost. Small, frequent orders → high ordering cost but low holding cost. The **Economic Order Quantity (EOQ)** is the order size where the *sum* of the two costs is minimum — the sweet spot.

Formula: **EOQ = √(2DS / H)**, where D = annual demand (units/year), S = ordering cost per order (₹), H = holding cost per unit per year (₹).

A full worked numerical with every step is given in the Worked Examples section.

ABC analysis (selective control): Not all items deserve equal attention. Classify by annual consumption value:

- **A items** — roughly 10–15% of items but ~70–75% of value (e.g., costly APIs). *Tight control:* frequent review, accurate records, low safety stock.
- **B items** — roughly 20–25% of items, ~15–20% of value. *Moderate control.*
- **C items** — roughly 60–70% of items but only ~5–10% of value (e.g., labels, cartons). *Simple control:* larger orders, less frequent review.

This follows the Pareto idea: a small number of items account for most of the money.

Reorder level and safety stock:

- **Reorder level = (Average daily usage × Lead time in days) + Safety stock.**
- Example: a plant uses 100 kg of an excipient per day; lead time is 10 days; safety stock is 200 kg. Reorder level = (100 × 10) + 200 = **1,200 kg**. When stock falls to 1,200 kg, place the next order — the 1,000 kg will be consumed during the 10-day wait, and the 200 kg buffer protects against surprises.
- **Safety stock** is sized from demand variability and lead-time variability: more unpredictable → more safety stock. But safety stock costs money, so it must be justified.

Key takeaway: Keep stock lean but never zero. EOQ finds the cheapest order size; ABC focuses control where the money is; reorder level (+ safety stock) tells *when* to order.

4. Lean manufacturing and Six Sigma in pharma

Technical concept: *Lean manufacturing* is a production philosophy focused on maximizing customer value while minimizing waste. *Six Sigma* is a data-driven quality methodology that reduces process variation so defects become extremely rare. In pharma, both serve the same master: safe, effective, affordable medicines made efficiently.

Simple explanation: Lean asks, "Where are we wasting time, material, or effort — and how do we stop it?" Six Sigma asks, "Why do defects happen — and how do we prevent them systematically?" Lean makes the process *fast and lean*; Six Sigma makes it *stable and defect-free*.

4a. Lean: MUDA (waste) and 5S

MUDA is the Japanese word for *waste* — anything that uses resources but adds no value for the customer. The classic **seven wastes**, with pharma examples:

1. **Overproduction** — making more than needed (extra batches that expire in the warehouse).
2. **Waiting** — idle time (operators waiting for QC release of raw material).
3. **Transport** — unnecessary movement of materials (poorly laid-out stores far from production).
4. **Over-processing** — doing more than required (re-testing what is already proven, excessive documentation steps that add no safety).
5. **Inventory** — excess stock (API bought in bulk "just in case," then expiring).
6. **Motion** — unnecessary movement of people (analyst walking across the plant for every printout).
7. **Defects** — rework and rejection (a failed batch that must be reprocessed or destroyed).

5S — a five-step method to organise the workplace so waste becomes visible and work flows smoothly:

1. **Sort (Seiri)** — remove what is not needed. (Clear expired labels and broken tools from the packing hall.)
2. **Set in order (Seiton)** — a place for everything, everything in its place. (Shadow boards for tools; labelled locations for each raw material.)

3 **Shine (Seiso)** — clean the workplace and equipment regularly. (In pharma, cleaning is also a GMP and contamination-control requirement.)

4 **Standardize (Seiketsu)** — make the first three S's a routine with checklists and schedules.

5 **Sustain (Shitsuke)** — keep it going through audits, discipline, and habit.

4b. Six Sigma: the DMAIC idea

Six Sigma aims for processes so stable that defects are nearly zero. Its problem-solving cycle is **DMAIC**:

1 **Define** — state the problem clearly. (Example: "Tablet weight variation is causing 4% rejection.")

2 **Measure** — collect data on the current process. (Weigh 200 tablets; record the variation.)

3 **Analyze** — find the root cause. (Analysis shows the granule flow into the die is uneven because of poor blending.)

4 **Improve** — fix the cause and test. (Optimise blending time; trial batches show rejection falling.)

5 **Control** — lock in the improvement with SOPs, monitoring, and control charts so the problem does not return.

Benefits of lean and Six Sigma in pharma:

1 Lower manufacturing cost → more affordable medicines.

2 Fewer defects and rejections → better quality and patient safety.

3 Shorter lead times → faster availability of medicines.

4 Less waste → lower environmental impact.

5 A culture of continuous improvement (Kaizen) among employees.

Key takeaway: Lean removes *waste* (MUDA) using tools like 5S; Six Sigma removes *defects* using DMAIC (Define → Measure → Analyze → Improve → Control).

5. Supply chain management (SCM)

Technical concept: A **supply chain** is the end-to-end network — suppliers, manufacturer, distributors, retailers — that moves a product from raw material to the final customer. **SCM** is the planning and management of sourcing, production, inventory, logistics, and information across this network so that the right product reaches the right place, at the right time, in the right condition, at the lowest reasonable cost.

Simple explanation: Think of a relay race: the API supplier passes the baton to the manufacturer, who passes it to the distributor, then the stockist, then the retailer, and finally the patient. If any runner drops the baton (delay, damage, stock-out), the patient suffers. SCM is the coaching that keeps every runner coordinated.

Components of SCM:

1 **Plan** — demand forecasting and production planning (what, how much, when).

2 **Source** — selecting suppliers and purchasing raw/packing materials.

3 **Make** — manufacturing under GMP with quality control.

4 **Deliver** — warehousing, transport, and distribution to customers.

5 **Return** — handling returns: expired stock, recalls, damaged goods.

6 **Enable** — the information systems and coordination that connect all the above.

Pharma supply-chain flow (text flowchart):

```
API / excipient SUPPLIERS
        │
        ▼
MANUFACTURER (pharma plant: production + QC + packing)
        │
        ▼
C&F AGENT (company's warehouse in each state/region)
        │
        ▼
DISTRIBUTOR / STOCKIST (bulk buyer serving a territory)
        │
        ▼
RETAILER (community pharmacy / hospital pharmacy)
        │
        ▼
PATIENT (final consumer)
```

Information and money flow in the *reverse* direction (orders and payments move upward), while the physical product flows downward. In India, the C&F → distributor → stockist → retailer chain is the traditional backbone of drug distribution.

Key takeaway: SCM coordinates plan → source → make → deliver → return. In pharma, the product flows manufacturer → C&F → distributor → stockist → retailer → patient.

6. Logistics and drug distribution channels in India

Technical concept: Logistics is the operational arm of SCM: the physical movement and storage of goods — transport, warehousing, inventory handling, and order fulfilment. **Distribution channels** are the chain of intermediaries through which the product passes to reach the patient.

Channel members and their roles (India):

1 **Manufacturer** — produces medicines under drug-manufacturing licence and GMP; packs, labels, and releases batches through QC.

2 **C&F (Carrying & Forwarding) agent** — the company's regional warehouse keeper; receives stock from the factory, stores it properly, and dispatches to distributors as instructed. One C&F typically serves one state or region.

3 **Distributor / stockist** — buys in bulk from the C&F, holds territory-level stock, and supplies retailers; often extends credit to retailers.

4 **Retailer (community pharmacist)** — the licensed chemist shop that dispenses medicines to patients against prescriptions (or OTC, where allowed), counsels patients, and is the last quality checkpoint.

5 **Hospital pharmacy** — dispenses within hospitals; often buys directly from distributors or through institutional supply.

6 **Government supply chain** — parallel channel: central/state medical stores supplying government hospitals and health centres, often through tender-based procurement.

Key takeaway: Logistics = moving and storing. India's drug channel: manufacturer → C&F agent → distributor/stockist → retailer (or hospital/government channel) → patient.

7. Cold chain management

Technical concept: The **cold chain** is a temperature-controlled supply chain that maintains products within their required temperature range (commonly 2–8 °C for refrigerated products, sometimes frozen or deep-frozen ranges) at every stage — manufacturing, storage, transport, and last-mile delivery — so they remain safe and effective.

Simple explanation: Some medicines are like milk — leave them in the heat and they spoil. Vaccines, insulin, and biologics lose potency (or become unsafe) if they get too warm *or* freeze. The cold chain is an unbroken "chain of refrigerators" from the factory to the patient's arm. One broken link — one hot truck, one failed fridge — can silently destroy the medicine's power.

Why it matters: Vaccines, insulin, many biologics/biosimilars, blood products, and some eye drops and suppositories are temperature-sensitive. A **temperature excursion** (going outside the required range) can reduce potency without any visible change — the patient gets a useless or unsafe injection that *looks* normal.

Elements of a cold chain:

1 **Cold rooms / walk-in coolers** — refrigerated storage at manufacturing plants, C&F warehouses, and large distributors.

2 **Refrigerated transport** — reefer vans/trucks and insulated boxes with coolant packs for movement between points.

3 **Last-mile equipment** — vaccine carriers and ice-boxes used by health workers for the final leg.

4 **Temperature monitoring** — thermometers, alarms, and continuous recording at every stage.

5 **Trained people and SOPs** — staff who know what to do when an alarm sounds or a fridge fails, including backup power arrangements.

Role of technology in cold chain and SCM:

1 **Data loggers** — small devices packed with the shipment that record temperature continuously; the data is downloaded at arrival to prove the cold chain was never broken.

2 **GPS tracking** — live location of refrigerated vehicles, so delays (which risk temperature rise) are spotted immediately.

3 **IoT sensors and alerts** — wireless sensors in cold rooms and trucks that send instant SMS/app alerts if temperature drifts out of range.

4 **Barcoding/serialization** — tracking each pack through the chain, which also fights counterfeit medicines.

Key takeaway: Cold chain = unbroken refrigeration (commonly 2–8 °C) from factory to patient for vaccines, insulin, and biologics. Technology (data loggers, GPS, IoT alerts) proves and protects the chain.

8. E-commerce in pharma distribution

Technical concept: E-commerce in pharma means buying and selling medicines through online/digital platforms — websites and mobile apps — instead of (or alongside) physical pharmacy counters.

Models:

1. **B2C e-pharmacy (inventory-led)** — the online pharmacy owns the stock in its own warehouses and delivers to the patient's home against an uploaded prescription.
2. **B2C e-pharmacy (marketplace)** — the platform connects patients with licensed partner pharmacies that fulfil the orders.
3. **B2B platforms** — digital ordering portals where retailers order from distributors/C&F agents online, replacing phone-based ordering.

Advantages:

1. **Convenience** — home delivery, especially valuable for elderly, chronic-disease, and rural patients.
2. **Wider reach** — patients in small towns can access medicines not stocked locally.
3. **Price transparency and discounts** — easy comparison; often lower prices.
4. **Digital records** — prescription uploads, refill reminders, and order history improve adherence.

Challenges:

1. **Prescription verification** — ensuring every prescription-only medicine is genuinely prescribed by a registered doctor.
2. **Regulatory compliance** — online sellers must hold valid drug licences and follow the same rules as physical pharmacies.
3. **Cold chain and handling** — delivering temperature-sensitive products safely to homes is difficult.
4. **Counterfeit risk** — weak verification can let fake medicines enter the online channel.
5. **Pharmacist counselling gap** — the face-to-face advice a community pharmacist gives is hard to replicate online.

Key takeaway: E-pharmacy (B2C inventory or marketplace models; B2B ordering portals) brings convenience and reach, but must solve prescription verification, licensing, cold-chain delivery, and counselling.

9. Risk management and sustainability

Technical concept: Risk management in the supply chain means systematically identifying what could go wrong, assessing each risk, and preparing responses. **Sustainability** means operating so that today's medicine needs are met without compromising the environment or future generations.

Types of supply-chain risks (with pharma examples):

1 **Supply risks** — sole-source API supplier fails; raw-material price spike; import disruption.

2 **Operational risks** — machine breakdown, batch failure, fire, power outage.

3 **Quality/regulatory risks** — GMP non-compliance, product recall, licence suspension.

4 **Logistics risks** — transport strike, cold-chain failure, warehouse flood.

5 **Demand risks** — sudden demand surge (epidemic) or collapse (product ban).

6 **Financial risks** — currency fluctuation affecting imported API costs; customer payment defaults.

7 **Cyber/information risks** — ransomware halting plant systems; data-integrity breaches.

The simple risk matrix: Rate each risk on two scales — **Likelihood** (Low/Medium/High) and **Impact** (Low/Medium/High) — and place it in a 3×3 grid. Priority order: **High likelihood × High impact** (act first — e.g., cold-chain failure for a vaccine distributor) → High×Medium / Medium×High → the rest (monitor). For each priority risk, prepare a response: *avoid, reduce, transfer* (e.g., insurance), or *accept with a contingency plan*.

Sustainability practices in pharma operations:

1 **Green packaging** — recyclable cartons, reduced plastic, biodegradable materials where possible.

2 **Waste reduction** — solvent recovery, lower rejection rates (lean thinking), proper segregation and treatment of pharma waste.

3 **Energy saving** — efficient HVAC (a huge energy user in pharma plants), LED lighting, waste-heat recovery, solar panels where feasible.

4 **Water stewardship** — recycling purified-water reject streams for non-critical uses; effluent treatment plants (ETP) before discharge.

5 **Responsible sourcing** — preferring suppliers with sound environmental practices.

Key takeaway: List risks → rate likelihood × impact on a matrix → act on high-high risks first. Sustainability = green packaging, less waste, less energy, cleaner water.

Classifications

Classification 1: Steps of production planning and control

1 **Routing** — the path (which machines, in which order).

2 **Scheduling** — the timetable (when each job runs).

3 **Dispatching** — the release ("go" signal with documents and materials).

4 **Follow-up** — the tracking (compare progress, fix delays).

Classification 2: Types of inventory

1 **Raw materials** — inputs waiting to be used (API, excipients, packing material).

2 **Work-in-progress (WIP)** — partly processed material (granules, uncoated tablets).

3 **Finished goods** — packed products ready for sale.

Classification 3: ABC analysis of inventory

1 **A items** — few items (~10–15%), high value (~70–75%): tight control.

2 **B items** — moderate items (~20–25%), moderate value (~15–20%): moderate control.

3 **C items** — many items (~60–70%), low value (~5–10%): simple control.

Classification 4: The seven wastes (MUDA)

1 Overproduction 2. Waiting 3. Transport 4. Over-processing 5. Inventory 6. Motion 7. Defects.

Classification 5: The 5S steps

1 **Sort** 2. **Set in order** 3. **Shine** 4. **Standardize** 5. **Sustain**.

Classification 6: DMAIC phases

1 **Define** 2. **Measure** 3. **Analyze** 4. **Improve** 5. **Control**.

Classification 7: Components of SCM

1 **Plan** 2. **Source** 3. **Make** 4. **Deliver** 5. **Return** 6. **Enable**.

Classification 8: E-commerce models in pharma

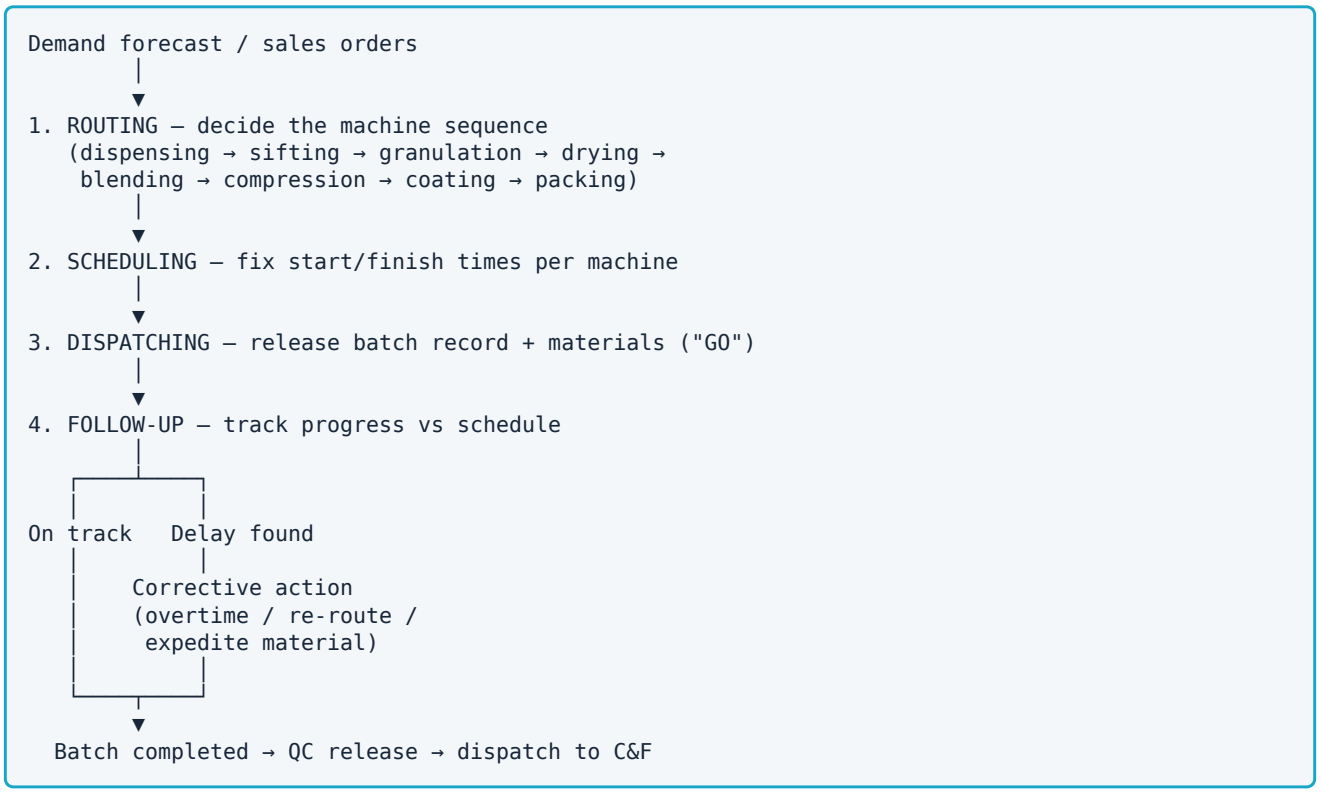
1 **B2C inventory-led e-pharmacy** 2. **B2C marketplace e-pharmacy** 3. **B2B ordering portals**.

Classification 9: Supply-chain risk types

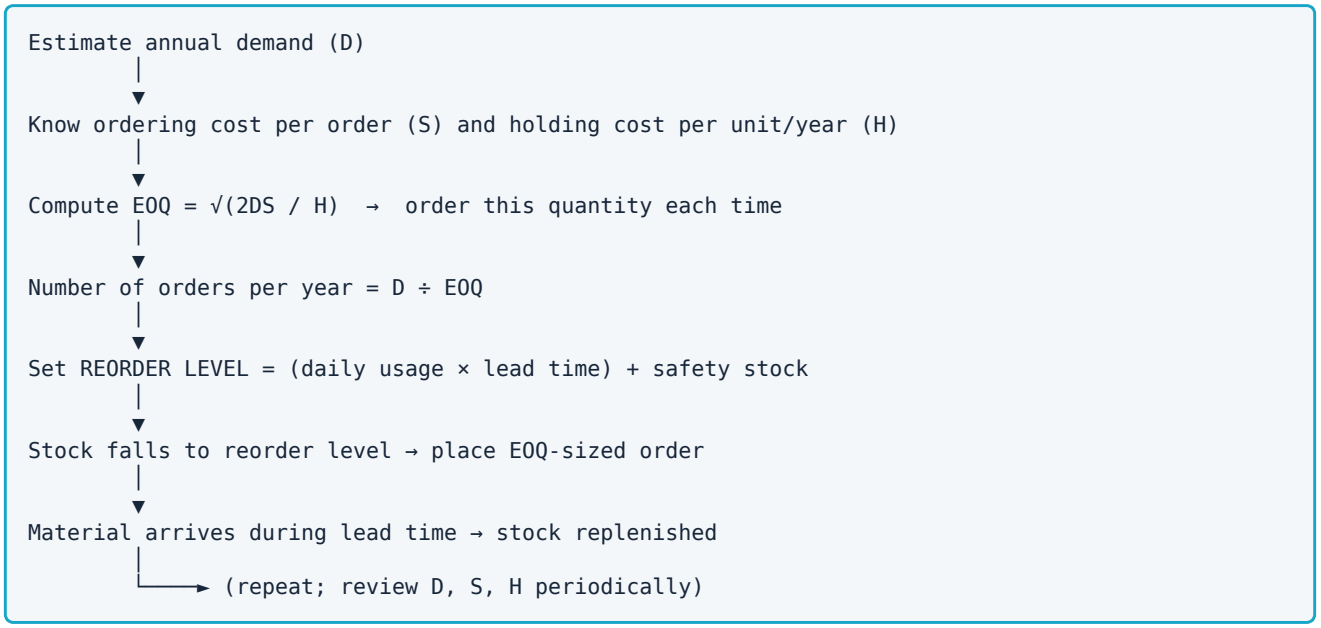
1 Supply 2. Operational 3. Quality/regulatory 4. Logistics 5. Demand 6. Financial 7. Cyber/information.

Processes/Flows

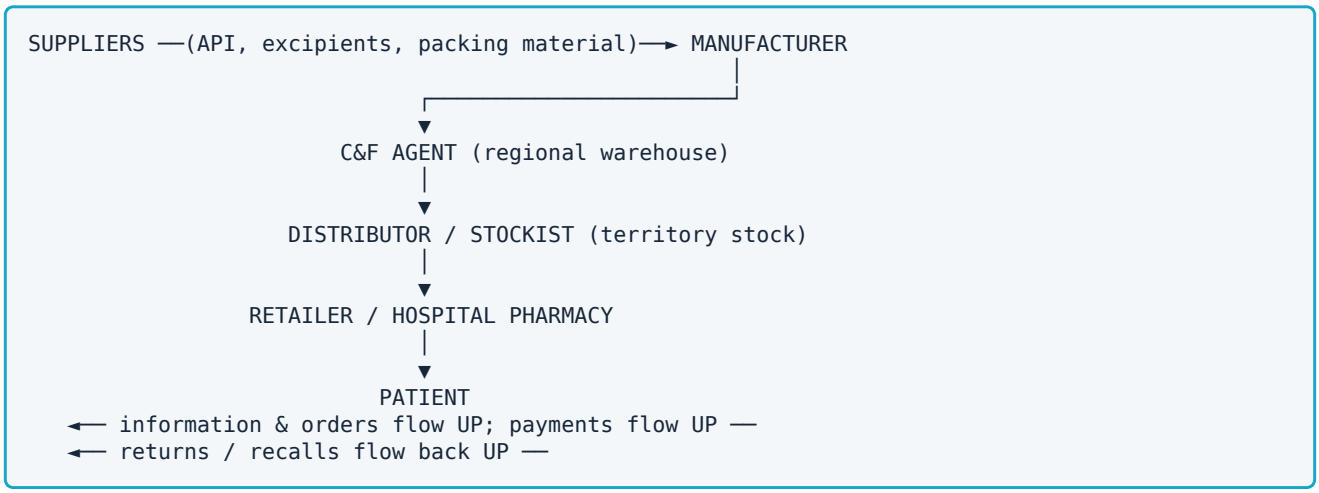
Flow 1: The PPC cycle



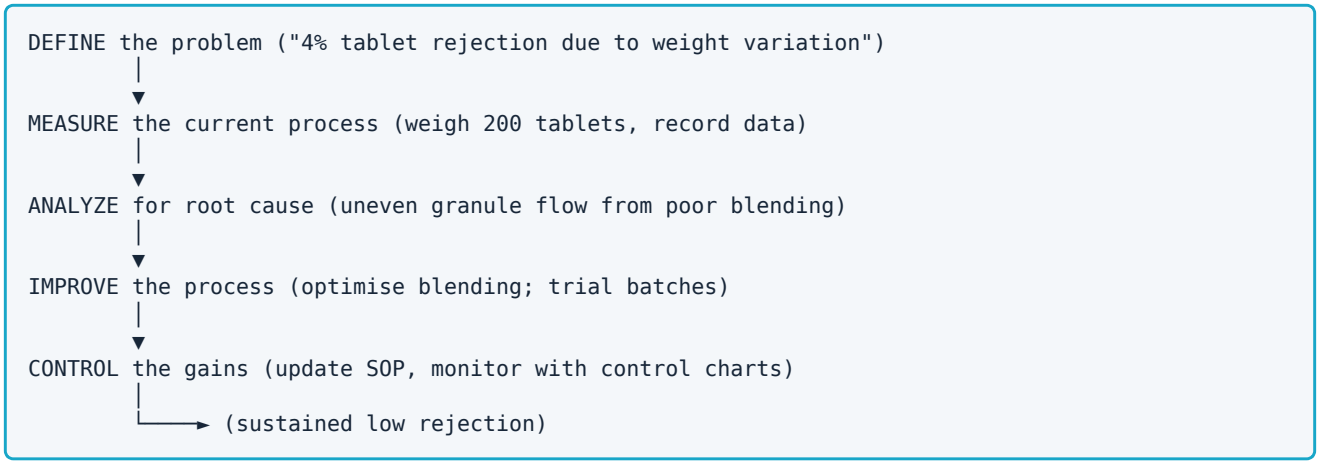
Flow 2: The inventory decision loop (EOQ logic)



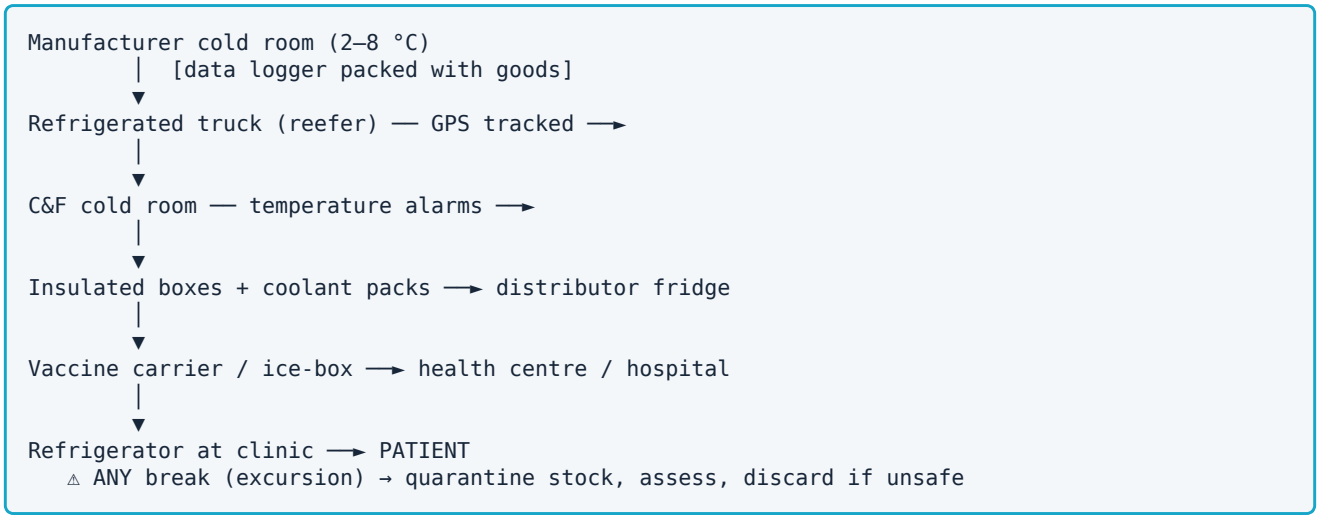
Flow 3: Pharma supply-chain product flow (with reverse flows)



Flow 4: DMAIC problem-solving cycle



Flow 5: Cold chain — the unbroken chain



Flow 6: Risk management process

```
IDENTIFY risks (brainstorm across supply, operations, logistics…)
        │
        ▼
ASSESS each risk: Likelihood (L/M/H) × Impact (L/M/H) → risk matrix
        │
        ▼
PRIORITISE: High×High first
        │
        ▼
RESPOND: Avoid / Reduce / Transfer (insurance) / Accept + contingency plan
        │
        ▼
MONITOR: review the risk register regularly; update after incidents
```

Infographic Concepts

Infographic 1 — "The Pharma Supply Chain Relay" (one page): A relay-race track with six runners passing a medicine-box baton: **Supplier → Manufacturer → C&F Agent → Distributor/Stockist → Retailer → Patient**. Above the track: the five SCM components as flags (Plan, Source, Make, Deliver, Return). Below: two thin arrows flowing backward labelled "Orders & information ↑" and "Payments ↑". Caption: *"If one runner drops the baton, the patient waits."*

Infographic 2 — "EOQ: The Sweet Spot" (one page): A U-shaped total-cost curve. The falling curve labelled "Ordering cost" (fewer orders = less ordering cost), the rising curve labelled "Holding cost" (bigger orders = more stock cost). Where they cross, a star marks **EOQ = √(2DS/H)** — "the cheapest order size." Side panel: a mini worked example (D = 12,000, S = ₹500, H = ₹10 → EOQ ≈ 1,095 units).

Infographic 3 — "5S Your Workplace" (one page): Five panels in a row, each with an icon: **Sort** (bin with a cross — "remove junk"), **Set in order** (labelled shelves — "a place for everything"), **Shine** (sparkle — "clean daily"), **Standardize** (checklist — "make it routine"), **Sustain** (circular arrow — "keep it alive"). Footer: *"In pharma, 5S is also GMP: a clean, ordered plant is a compliant plant."*

Infographic 4 — "Cold Chain: Never Break the Chain" (one page): A chain of five refrigerator icons linked together: **Factory cold room → Reefer truck (GPS) → C&F cold room → Insulated box → Clinic fridge → Patient**, with a data-logger tag on the box. One broken link shown in red with a warning: *"One hot hour can silently kill a vaccine's power."* Bottom strip: "2–8 °C • Monitor • Alarm • Backup power."

Tables

Table 1: PPC steps — at a glance

Step	Question it answers	Example (tablet batch)
Routing	Which machines, in which order?	Dispensing → granulation → drying → compression → coating → packing
Scheduling	When does each job run?	Batch C 8–10 am, Batch A 10 am–1 pm on the tablet press
Dispatching	Go — with what papers/material?	Issue batch record + weighed materials to the floor

Step	Question it answers	Example (tablet batch)
Follow-up	Are we on track?	Track progress; expedite if the dryer breaks down

Table 2: EOQ inputs and what raises/lowers the order size

Input	Symbol	If it increases, EOQ...	Reason
Annual demand	D	Increases	More usage → bigger economic lots
Ordering cost per order	S	Increases	Costly orders → order rarely, in bulk
Holding cost per unit/year	H	Decreases	Costly storage → order often, in small lots

Table 3: ABC analysis — control policy

Class	Share of items	Share of value	Control policy
A	~10–15%	~70–75%	Tight: frequent review, accurate records, low safety stock
B	~20–25%	~15–20%	Moderate: periodic review
C	~60–70%	~5–10%	Simple: large EOQ, infrequent review

Table 4: Lean vs Six Sigma

Point	Lean manufacturing	Six Sigma
Main enemy	Waste (MUDA)	Variation / defects
Core question	"Where is the waste?"	"Why do defects happen?"
Key tools	5S, Kaizen, waste elimination	DMAIC, data analysis, control charts
Result	Faster, cheaper flow	Stable, near-defect-free quality
Pharma example	Cutting waiting time for QC release	Reducing tablet weight variation

Table 5: Drug distribution channel members (India)

Member	Role
Manufacturer	Produces under licence + GMP; QC-releases batches
C&F agent	Regional warehouse; stores and forwards as instructed
Distributor / stockist	Territory-level bulk stock; supplies retailers, extends credit
Retailer (chemist)	Dispenses to patients; last quality checkpoint + counselling
Hospital pharmacy	In-hospital dispensing; institutional supply
Government supply chain	Tender-based supply to government hospitals/health centres

Table 6: Simple 3×3 risk matrix (likelihood × impact)

	Impact: Low	Impact: Medium	Impact: High
Likelihood: High	Monitor (e.g., minor packing damage)	Plan action (e.g., seasonal demand surge)	**ACT FIRST** (e.g., cold-chain failure for vaccines)
Likelihood: Medium	Monitor (e.g., small courier delay)	Plan action (e.g., single-supplier API delay)	Plan action (e.g., transport strike during peak season)
Likelihood: Low	Accept (e.g., rare paperwork error)	Monitor (e.g., mild currency fluctuation)	Contingency plan (e.g., plant fire, major recall)

Worked Examples

Worked Example 1 — EOQ (step-by-step)

Situation: A pharma plant uses **12,000 kg per year** of an excipient (D = 12,000). Each order costs **₹500** to place (S = 500 — paperwork, transport arrangement, incoming inspection). Keeping 1 kg in stock for a year costs **₹10** (H = 10 — warehouse, interest, insurance, expiry risk).

Question A: What is the Economic Order Quantity?

- **Step 1:** Write the formula: EOQ = √(2DS / H).
- **Step 2:** Substitute: EOQ = √(2 × 12,000 × 500 / 10).
- **Step 3:** Compute the numerator: 2 × 12,000 × 500 = 12,000,000.
- **Step 4:** Divide by H: 12,000,000 ÷ 10 = 1,200,000.
- **Step 5:** Take the square root: √1,200,000 ≈ **1,095.45 kg**.
- **Answer:** Order ≈ **1,095 kg** each time.

Question B: How many orders per year, and how often?

- **Step 1:** Orders per year = D ÷ EOQ = 12,000 ÷ 1,095 ≈ **10.96** ≈ **11 orders**.
- **Step 2:** Time between orders = 365 ÷ 11 ≈ **33 days**.
- **Answer:** About **11 orders a year**, roughly **one order every 33 days**.

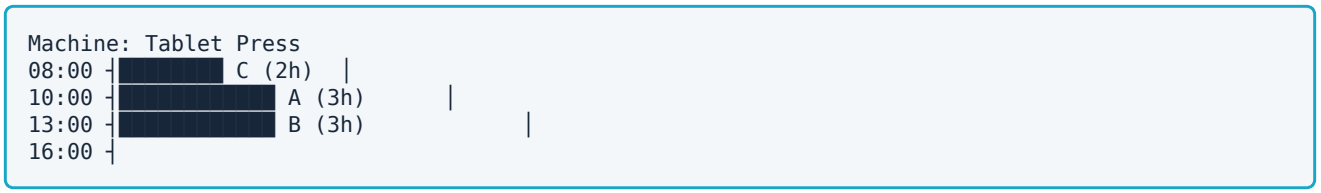
Question C: Verify that this is the cheapest (ordering cost ≈ holding cost at EOQ).

- **Step 1:** Annual ordering cost = orders × S = 11 × 500 = **₹5,500**.
- **Step 2:** Annual holding cost = (EOQ ÷ 2) × H = (1,095 ÷ 2) × 10 = 547.5 × 10 = **₹5,475**.
- **Step 3:** Total = 5,500 + 5,475 = **₹10,975**. The two costs are nearly equal — that balance point is exactly what makes EOQ the minimum. (Check: ordering 6,000 kg twice a year would give holding cost 30,000 — far worse; ordering 500 kg 24 times would give ordering cost 12,000 — also worse.)

Worked Example 2 — Simple scheduling (Gantt-style)

Situation: One tablet press, one 8-hour shift (8 am–4 pm), three batches: C = 2 h, A = 3 h, B = 3 h. Priority rule: shortest processing time first.

- **Step 1:** Order by duration: C (2 h) → A (3 h) → B (3 h).
- **Step 2:** Slot them: C: 8–10 am; A: 10 am–1 pm; B: 1–4 pm.
- **Step 3:** Draw the Gantt view:



- **Result:** All three batches finish within the shift; the shortest job (C) completes first at 10 am, so its waiting customer is served earliest.
- **Lesson:** Scheduling = jobs + machines + time on one visual plan; follow-up then tracks whether reality matches it.

Worked Example 3 — ABC classification (scenario)

Situation: A store lists 200 inventory items with annual consumption values. The top 24 items (12%) account for ₹72 lakh of ₹100 lakh total value; the next 46 items (23%) account for ₹18 lakh; the remaining 130 items (65%) account for ₹10 lakh.

- **Step 1:** Class A = top 24 items (12% of items, 72% of value) — e.g., costly APIs. Policy: tight control — weekly review, exact records, minimal safety stock.
- **Step 2:** Class B = next 46 items (23% of items, 18% of value) — e.g., common excipients. Policy: moderate control — monthly review.
- **Step 3:** Class C = remaining 130 items (65% of items, 10% of value) — e.g., labels, cartons, caps. Policy: simple control — order in bulk twice a year, minimal paperwork.
- **Lesson:** Management attention follows the money: 12% of items deserve most of the control effort.

Worked Example 4 — Risk matrix in action (scenario)

Situation: A vaccine distributor lists three risks: (R1) refrigerator power failure in summer; (R2) minor packing-carton damage in transit; (R3) a transport strike during the immunisation drive.

- **Step 1 — Rate each:** R1: likelihood High (frequent summer cuts) × impact High (vaccines spoil) → **High–High**. R2: likelihood Medium × impact Low → **Medium–Low**. R3: likelihood Medium × impact High → **Medium–High**.
- **Step 2 — Prioritise:** R1 first, then R3, then R2.
- **Step 3 — Respond:** R1 → *reduce*: install generator + temperature alarms with SMS alerts. R3 → *contingency*: tie up with two transporters in different unions. R2 → *monitor*: track damage rates monthly.
- **Lesson:** The matrix turns a vague worry-list into a prioritised action plan.

Worked Example 5 — Reorder level (step-by-step)

Situation: Daily usage of starch excipient = **100 kg/day**; lead time = **10 days**; safety stock = **200 kg**.

- **Step 1:** Demand during lead time = 100 × 10 = 1,000 kg.
- **Step 2:** Reorder level = 1,000 + 200 (safety stock) = **1,200 kg**.
- **Step 3:** Meaning — when the stock display shows 1,200 kg, place the next EOQ order immediately; 1,000 kg will be used while waiting, and 200 kg covers surprises.
- **Answer:** Reorder level = **1,200 kg**.

Analogies

1. **Operations management = running a kitchen.** Inputs (vegetables, spices, cooks, stoves) go in; meals come out. The head cook plans the menu, sequences the cooking, times each dish, and checks taste — exactly what operations does in a pharma plant.
2. **PPC = planning a wedding.** Routing = deciding the order of functions; scheduling = fixing dates and times; dispatching = sending the invitations ("go"); follow-up = checking on the day that the caterer actually arrived.
3. **EOQ = buying rice for a hostel.** Buy a year's rice at once → storeroom full, money locked, rats happy (high holding cost). Buy daily → the buyer spends all day travelling (high ordering cost). Buy a month's stock → the sweet spot (EOQ).
4. **Safety stock = a spare tyre.** You hope never to use it, it costs money and boot space to carry — but one puncture (one supply delay) proves its worth.
5. **ABC analysis = a teacher's attention.** The teacher spends most energy on the few students who decide the class result (A items), moderate time on the average group (B), and routine checks on the rest (C).
6. **Cold chain = a relay of ice boxes.** Like runners passing a chilled baton, every handler must keep it cold; one runner who leaves it in the sun ruins the race for everyone after.
7. **Data logger = a CCTV camera for temperature.** It silently records everything during the journey; at arrival, you replay the footage to check nothing went wrong.
8. **Risk matrix = a doctor's triage.** In an emergency ward, the most critical patients are treated first. The risk matrix triages risks the same way: high likelihood × high impact gets treated first.

Pharmacy Relevance

- **Operations is where pharmacists work.** Production, QC, QA, warehousing, and PPC departments are staffed largely by pharmacy graduates — this chapter describes your future workplace.
- **Inventory decisions need pharma knowledge.** Only a pharmacist understands why an API needs tighter control than cartons (ABC), why safety stock of a life-saving drug matters, and why expired stock must be destroyed, not discounted.
- **Cold chain is a pharmacist's responsibility.** From the C&F cold room to the clinic refrigerator, pharmacists verify data loggers, handle excursions, and quarantine suspect stock.

- **Lean/Six Sigma need shop-floor pharmacists.** Continuous improvement works only when the people running the process — production and QA pharmacists — lead it.
- **Distribution is a career path.** C&F operations, depot management, and supply-chain roles are major employers of B.Pharm graduates in India.

India Context

- India's pharma distribution network is one of the world's largest and most fragmented — lakhs of retailers served through C&F agents and distributors, making SCM a genuine national challenge.
- The **government supply chain** (central and state medical stores, tender-based procurement) runs parallel to the private channel and supplies public hospitals and health centres.
- India's **universal immunisation programme** depends on a vast cold chain reaching remote villages — cold boxes, ice-lined refrigerators, and trained health workers carry vaccines the last mile.
- Indian pharma's cost advantage in global generics comes directly from operational excellence — lean plants, smart inventory, and efficient logistics keep "the pharmacy of the world" affordable.
- The growth of **e-pharmacies** in India is reshaping last-mile delivery, pushing even traditional distributors toward B2B digital ordering.

Key Points

1 **Operations management** = managing the making (inputs → transformation → outputs); objectives: quality, quantity, time, cost, flexibility, compliance, safety.

2 **PPC** = route (path) → schedule (timetable) → dispatch (go) → follow-up (stay on track).

3 **Inventory** = raw materials + WIP + finished goods; keep it lean but never zero.

4 **EOQ = √(2DS/H)** — the order size where ordering cost and holding cost balance at the minimum total.

5 **ABC analysis**: A = few items, most value, tight control; C = many items, little value, simple control.

6 **Reorder level = (daily usage × lead time) + safety stock** — tells *when* to order.

7 **Lean** fights waste (**MUDA**: the 7 wastes) with tools like **5S** (Sort, Set in order, Shine, Standardize, Sustain).

8 **Six Sigma** fights defects with **DMAIC** (Define, Measure, Analyze, Improve, Control).

9 **SCM** = plan → source → make → deliver → return (+ enable); product flows manufacturer → C&F → distributor/stockist → retailer → patient.

10 **Logistics** = transport + warehousing + order handling; India's channel members each have a defined role.

11 **Cold chain** = unbroken temperature control (commonly 2–8 °C) for vaccines, insulin, biologics; data loggers, GPS, and IoT sensors protect and prove it.

12 **E-commerce models**: B2C inventory-led, B2C marketplace, B2B portals; advantages (convenience, reach) vs challenges (prescription checks, licensing, cold chain, counselling).

13 **Risk matrix** = likelihood × impact; act on High×High first (avoid/reduce/transfer/accept + contingency).

14 **Sustainability** = green packaging, waste reduction, energy saving, water stewardship, responsible sourcing.

Common Confusions

1 **Scheduling vs dispatching.** *Scheduling* fixes the timetable on paper; *dispatching* actually releases the work to the floor. A schedule without dispatching never starts.

2 **Ordering cost vs holding cost.** *Ordering cost* is paid per order (paperwork, transport setup) — it falls when you order rarely. *Holding cost* is paid per unit stored — it falls when you order often. EOQ balances the two.

3 **Reorder level vs EOQ.** *EOQ* answers **how much** to order; *reorder level* answers **when** to order. Students often swap these.

4 **ABC analysis vs grades of students.** ABC classifies *items by consumption value*, not by quality — a "C item" is not a bad item, just a low-value one needing simple control.

5 **Lean vs Six Sigma.** Lean removes *waste* (speed, flow); Six Sigma removes *variation/defects* (stability, quality). They are partners, not rivals.

6 **Logistics vs supply chain management.** *Logistics* is the physical part (moving and storing); *SCM* is the whole coordination (plan, source, make, deliver, return). Logistics sits inside SCM.

7 **Cold chain vs refrigerator.** A refrigerator is one *link*; the *cold chain* is the entire unbroken series of links from factory to patient, including transport and monitoring.

8 **Safety stock vs reorder level.** *Safety stock* is the buffer quantity; *reorder level* is the trigger point that already *includes* the safety stock.

Common Mistakes

1 **Treating EOQ as a one-time calculation.** Demand (D), ordering cost (S), and holding cost (H) change — review EOQ periodically.

2 **Setting safety stock by guesswork.** Base it on demand and lead-time variability; unjustified safety stock is just expensive overstocking.

3 **Applying tight control to C items.** Inspecting every carton label delivery weekly wastes the very management time ABC analysis is meant to save.

4 **Starting improvement with tools instead of problems.** Doing 5S for show, without targeting a real waste, produces tidy shelves and zero savings.

5 **Skipping the Control phase of DMAIC.** Improvements slide back within months if new SOPs and monitoring are not locked in.

6 **Breaking the cold chain at handover points.** Most excursions happen during loading/unloading and last-mile transfer — monitor the *links*, not just the rooms.

7 **Ignoring reverse logistics.** Expired stock and recalls need a planned return flow; without it, expired medicines risk re-entering the market.

8 **Rating risks by gut feeling only.** Use the likelihood × impact matrix so the loudest worry does not crowd out the most dangerous risk.

Mnemonics

1 **PPC steps — "RSD F": *R**outing, **S**cheduling, **D**ispatching, **F**ollow-up* — "**R**oute the **S**hip, **D**ispatch it, **F**ollow it."

2 **EOQ formula — "2DS over H, root it": *E**OQ = √(2**D**S/**H**)* — "**E**very **O**rder **Q**uantity balances **D**emand, **S**etup cost and **H**olding cost."

3 **ABC — "A is Attention": *A** items get most **A**ttention (money), **C** items get **C**asual control.*

4 **7 wastes — "TOW T DIM" (say "tow-tee-dim"): *T**ransport, **O**verproduction, **W**aiting, **T**ransport…* — better: "**W**e **O**rder **T**oo **M**uch, **I**dle, **M**ove, **D**ouble-work, **D**efects" → **W-O-T-M-I-M-D-D**: **W**aiting, **O**verproduction, **T**ransport, **M**otion, **I**nventory, **M**… let students use: "**D**efects **O**verproduction **W**aiting **Non-utilised… " — simplest exam-safe version: *T-O-W-T-I-M-D** = "**T**im **O**ver-**W**orks, **T**hen **I** **M**ake **D**efects" (Transport, Overproduction, Waiting, over-processing ["over-Works"], Inventory, Motion, Defects).

5 **5S — "SSSSS": *S**ort, **S**et in order, **S**hine, **S**tandardize, **S**ustain* — "**S**weep, **S**ettle, **S**parkle, **S**ystem, **S**tick-to-it."

6 **DMAIC — "Doctors Make Accurate Informed Cures": *D**efine, **M**easure, **A**nalyze, **I**mprove, **C**ontrol.*

7 **SCM components — "PSM DRE": *P**lan, **S**ource, **M**ake, **D**eliver, **R**eturn, **E**nable* — "**P**harma **S**upply **M**anagers **D**eliver **R**ight, **E**very time."

8 **Supply-chain flow — "MCDSRP": *M**anufacturer → **C**&F → **D**istributor → **S**tockist → **R**etailer → **P**atient* — "**M**edicines **C**ome **D**own **S**afely to **R**each **P**atients."

Exam Summary

- **Operations management:** meaning (managing the transformation of inputs into medicines); 7 objectives — quality, quantity, time, cost, flexibility, compliance, safety.
- **PPC:** meaning (plan the work, control its execution); 4 steps — routing (path), scheduling (timetable; shortest-first example with Gantt view), dispatching (release), follow-up (track and correct).
- **Inventory management:** meaning (how much, when, how much per order); why it matters (continuity, bulk savings, demand swings, lead-time cover — vs locked capital and expiry); EOQ

concept and formula with full worked numerical (EOQ ≈ 1,095 kg; ~11 orders/year; ~33-day cycle; ordering ≈ holding cost at optimum); ABC analysis (A/B/C policy); reorder level = (daily usage × lead time) + safety stock (worked: 1,200 kg).

- **Lean & Six Sigma:** lean = kill waste; MUDA = 7 wastes with pharma examples; 5S steps; Six Sigma = kill defects via DMAIC (Define → Measure → Analyze → Improve → Control); benefits (cost, quality, speed, environment, culture).
- **SCM:** meaning; 6 components (plan, source, make, deliver, return, enable); product flow manufacturer → C&F → distributor/stockist → retailer → patient, with information/payments/returns flowing back.
- **Logistics & channels (India):** logistics = movement + storage; roles of manufacturer, C&F agent, distributor/stockist, retailer, hospital pharmacy, government supply chain.
- **Cold chain:** meaning (unbroken temperature control, commonly 2–8 °C); why (vaccines, insulin, biologics — excursions silently destroy potency); elements (cold rooms, reefer transport, last-mile carriers, monitoring, trained people + SOPs); technology (data loggers, GPS, IoT alerts, barcoding).
- **E-commerce:** meaning; models (B2C inventory-led, B2C marketplace, B2B portals); advantages (convenience, reach, transparency, digital records); challenges (prescription verification, licensing, cold-chain delivery, counterfeit risk, counselling gap).
- **Risk & sustainability:** 7 risk types; risk matrix (likelihood × impact; High×High first; avoid/reduce/transfer/accept); sustainability (green packaging, waste reduction, energy saving, water stewardship, responsible sourcing).

One-Minute Revision

Operations = managing the making: quality, quantity, time, cost, flexibility, compliance, safety. **PPC**: **R**oute (path) → **S**chedule (time) → **D**ispatch (go) → **F**ollow-up (track). **Inventory**: how much, when, how much per order. **EOQ = √(2DS/H)** — cheapest order size (worked: ≈1,095 kg, ~11 orders/year). **ABC**: A = few items, most money, tight control. **Reorder level** = (daily use × lead time) + safety stock. **Lean** kills **MUDA** (7 wastes) with **5S**; **Six Sigma** kills defects with **DMAIC**. **SCM**: plan → source → make → deliver → return. Flow: **M**anufacturer → **C**&F → **D**istributor → **S**tockist → **R**etailer → **P**atient. **Logistics** = moving + storing. **Cold chain** = unbroken 2–8 °C for vaccines/insulin/biologics; guard it with data loggers, GPS, alarms. **E-pharmacy**: B2C (inventory/marketplace) + B2B; convenient but needs prescription checks and licensing. **Risks**: rate likelihood × impact, fix High×High first. **Sustainability**: green packaging, less waste, less energy, clean water.

MCQs

1. Operations management is primarily concerned with: (a) Advertising the product (b) Managing the transformation of inputs into outputs (c) Fixing employee salaries (d) Filing tax returns

2. In PPC, deciding the sequence of machines a batch will pass through is called: (a) Scheduling (b) Dispatching (c) Routing (d) Follow-up

3. EOQ = √(2DS/H). Here "S" stands for: (a) Safety stock (b) Ordering cost per order (c) Selling price (d) Storage space

4. D = 12,000 units/year, S = ₹500, H = ₹10. The EOQ is approximately: (a) 775 units (b) 1,095 units (c) 1,200 units (d) 2,190 units

5. In ABC analysis, "A" items are characterised by: (a) Many items, low value (b) Few items, high value (c) Few items, low value (d) Many items, high value

6. Reorder level 1,200 kg, daily usage 100 kg, lead time 10 days. The safety stock is: (a) 100 kg (b) 200 kg (c) 1,000 kg (d) 1,200 kg

7. Which of the following is NOT one of the seven wastes (MUDA)? (a) Overproduction (b) Waiting (c) Preventive maintenance (d) Defects

8. In 5S, "Seiton" (Set in order) means: (a) Throwing away unneeded items (b) A place for everything and everything in its place (c) Cleaning daily (d) Writing SOPs

9. The correct order of DMAIC phases is: (a) Define → Measure → Analyze → Improve → Control (b) Define → Analyze → Measure → Control → Improve (c) Measure → Define → Improve → Analyze → Control (d) Define → Improve → Measure → Analyze → Control

10. In the Indian pharma distribution channel, the C&F agent's main role is: (a) Manufacturing the drug (b) Dispensing to patients (c) Regional warehousing — receiving, storing and forwarding stock (d) Fixing the ceiling price

11. A temperature excursion in the cold chain means: (a) The truck took a longer route (b) The product went outside its required temperature range (c) The data logger battery died (d) The delivery was early

12. Which of these is a B2B e-commerce model in pharma? (a) Patient ordering from an e-pharmacy app (b) Retailer ordering stock from a distributor through an online portal (c) Doctor consulting online (d) Patient reading medicine reviews

13. In a risk matrix, the risk needing FIRST action is: (a) Low likelihood × Low impact (b) High likelihood × High impact (c) Low likelihood × High impact (d) Medium likelihood × Low impact

14. Which of the following is a sustainability practice in pharma operations? (a) Increasing batch rejections (b) Green packaging and solvent recovery (c) Ordering excess API stock (d) Skipping preventive maintenance

Answer Key:

1 **(b)** — Operations manages the input-to-output transformation process.

2 **(c)** — Routing fixes the path/sequence; scheduling fixes the timetable.

3 **(b)** — S = ordering (setup) cost per order.

4 **(b)** — √(2 × 12,000 × 500 / 10) = √1,200,000 ≈ 1,095.

5 **(b)** — A items: few in number (~10–15%) but most of the value (~70–75%).

6 **(b)** — Reorder level = (100 × 10) + safety stock → 1,200 = 1,000 + safety stock → 200 kg.

7 **(c)** — Preventive maintenance prevents waste; the seven wastes are overproduction, waiting, transport, over-processing, inventory, motion, defects.

8 **(b)** — Set in order = organised placement with labels and designated locations.

9 **(a)** — Define → Measure → Analyze → Improve → Control.

10 **(c)** — The C&F agent is the company's regional warehouse keeper.

11 **(b)** — An excursion is any breach of the required temperature range.

12 **(b)** — B2B = business-to-business; a retailer ordering from a distributor online is B2B.

13 **(b)** — High likelihood × High impact risks get first priority.

14 **(b)** — Green packaging and solvent recovery reduce environmental harm; the others increase waste or risk.

Viva/Application Questions

1. Why can't a pharma plant simply keep huge stocks "to be safe"? *Model answer:* Huge stocks lock working capital, need warehouse space, and risk expiry — expired API must be destroyed. The safe approach is right-sized stock: EOQ for order size, reorder level plus justified safety stock for timing.

2. Your excipient order size was fixed five years ago. Demand has doubled since. What should you do? *Model answer:* Recalculate EOQ with the new annual demand — EOQ rises with the square root of demand — and update the reorder level, since daily usage has also doubled.

3. Give one example each of MUDA from a tablet packing hall. *Model answer:* Waiting — operators idle while QC releases the packing material. Motion — the supervisor walking to another floor for every printout. Defects — strips rejected for poor sealing that must be reworked.

4. A distributor's reefer truck breaks down for 6 hours in summer with vaccines inside. Walk through your response. *Model answer:* Quarantine the stock on arrival — do not use or sell it; download the data logger to check for a temperature excursion; follow the SOP (inform QA, assess stability data); destroy the stock if safety cannot be assured; arrange backup transport for future trips.

5. How does ABC analysis save a store manager's time? *Model answer:* It focuses tight control on the ~10–15% of items holding ~70–75% of the value (A items) and allows simple bulk handling of the many low-value C items — effort follows the money.

6. "Six Sigma and lean are the same thing." Do you agree? *Model answer:* No. Lean attacks waste (speed and flow); Six Sigma attacks variation and defects (stability and quality). They complement each other in a pharma plant.

7. An online pharmacy delivers a prescription medicine without asking for a prescription. What is wrong? *Model answer:* It violates drug-sale rules — prescription-only medicines need a valid prescription from a registered doctor, whether sold offline or online; it also risks patient safety and invites counterfeit supply.

8. Name two high-likelihood × high-impact risks for an insulin distributor and one mitigation for each. *Model answer:* (1) Cold-chain/power failure — mitigation: generator plus temperature alarms with SMS alerts. (2) Stock-out during demand surge — mitigation: higher safety stock and two transporters under contract.

References

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2 Pandey, I. M. *Financial Management*. Vikas Publishing House. (Inventory cost concepts supporting EOQ.)

3 Joseph, A. S. *Pharmaceutical Management and Marketing*. CBS Publishers & Distributors. (Pharma distribution channels and Indian context.)

4 Drucker, P. F. *Principles of Management*. Harper Business. (Management process foundations.)

5 Students should consult current GMP guidelines, drug-distribution rules, and e-pharmacy regulations for the latest legal position. (No figures, notification numbers, or dates reproduced here.)