

SELF-PACED COURSE · STUDY HANDBOOK

Good Manufacturing Practice (GMP)

Make it safe, make it right, prove it — every batch, every time.

WHO GMP main principles (TRS 986, Annex 2) — the same 17 sections our auditors inspect against. Applies to pharmaceuticals, food, cosmetics (ISO 22716) and packaging.

6 h study time **6** modules Level: **Foundation** Pass mark: **70%**

AuditCert International

ABOUT THIS COURSE

How to use this handbook

Who it is for: Production and warehouse staff, QA/QC officers, supervisors, managers preparing for a GMP inspection.

You will be able to

- Explain what GMP is, why it exists and how it differs from QA and QC
- Apply the personal hygiene, gowning and training rules expected of every person on site
- Keep premises and equipment fit for use: layout, cleaning, calibration and status labels
- Control materials and production: quarantine, line clearance, in-process checks and batch records
- Write and correct records the GMP way (ALCOA+) and support independent QC
- Handle complaints, recalls and self-inspections, and get ready for a GMP inspection

How you pass

- Study each module and pass its knowledge check (3 of 4 correct).
- Complete the GMP audit self-check on your own workplace.
- Score 70% or more on the 20-question final exam.
- Submit the practical assignment (graded by your trainer, pass 60/100).

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MODULE 1 OF 6 · 45 MIN

GMP foundations: why it exists

What GMP means, the 5 Ps, and how quality assurance, GMP and quality control fit together.

Auditor checks: `WHO 1 - 2`

What is GMP?

Good Manufacturing Practice (GMP) is the part of quality assurance that makes sure products are **consistently produced and controlled** to the quality standards right for their intended use. Testing alone cannot prove a batch is good — a sample only tells you about the sample. GMP builds quality **into every step**, so the finished product is right because the process was right.

> **Remember:** *Quality cannot be tested into a product. It has to be built in.*

Why GMP matters

- **Patients and consumers** — contaminated, mixed-up or wrongly labelled products can injure or kill.
- **The business** — recalls, rejected batches, lost buyers and licence suspension cost far more than prevention.
- **Regulators and buyers** — DGDA (medicines), BSTI and BFSA (food) in Bangladesh, and export buyers, expect GMP evidence.

Most GMP failures in history came from a handful of causes: **contamination, cross-contamination, mix-ups and errors**. Every GMP rule you will learn controls one of these four.

The 5 Ps of GMP

P	What it covers	Example control
People	Competence, hygiene, behaviour	Training records, gowning procedure
Premises	Buildings, equipment, utilities	Logical flow, calibrated balances
Processes	How work is done	Validated process, in-process checks
Products	Materials in and goods out	Quarantine, approved suppliers
Procedures (Paperwork)	Instructions and records	SOPs, batch manufacturing records

QA, GMP and QC — how they fit

- **Quality Assurance (QA)** is the whole system that makes sure products are fit for use. It *includes* GMP.
- **GMP** is the set of practices in production and control that keep quality consistent.
- **Quality Control (QC)** is the sampling, specifications and testing part of GMP.

A key principle: the **quality unit must be independent of production**. The person who makes a batch must not be the person who decides it can be sold. Release is done by an **authorized person** after reviewing the batch record and QC results.

Quality risk management

GMP is not "do everything to the maximum". Effort goes where the **risk to the product and the patient** is highest. A sterile injectable needs stricter controls than outer cartons. Risk thinking is used when you decide how often to clean, what to validate and how to deal with deviations.

> **Tip for the shop floor:** When you are unsure, ask: *Could this harm the product, cause a mix-up, or leave us without proof?* If yes, stop and tell your supervisor.

Key points

- Quality is built in, not tested in
- GMP controls contamination, cross-contamination, mix-ups and errors
- The 5 Ps: People, Premises, Processes, Products, Procedures
- QC is part of GMP; GMP is part of QA
- Quality unit independent; release by an authorized person

Knowledge check

1. Why can testing alone not guarantee that a batch is good?

A. Tests are too expensive
B. Regulators do not accept test results
C. Testing is done after the product is sold
D. A sample only tells you about the sample, not every unit

2. Which group of risks do GMP rules mainly control?

A. Marketing, pricing, sales and delivery
B. Holidays, overtime, wages and leave
C. Contamination, cross-contamination, mix-ups and errors
D. Energy, water, waste and emissions

3. Who should decide that a finished batch can be released for sale?

A. The sales manager
B. The production supervisor who made it
C. An authorized person from the independent quality unit
D. The warehouse in-charge

4. How do QA, GMP and QC relate?

A. QA includes GMP, and QC is part of GMP
B. They are three names for the same thing
C. They are unrelated systems
D. QC includes GMP, which includes QA

Answers are in the answer key at the back.

MODULE 2 OF 6 · 50 MIN

People: training, health and personal hygiene

The people side of GMP: competence, training records, health, gowning and behaviour in production areas.

Auditor checks: `WHO 9 - 10` `WHO 11`

People are the biggest source of contamination

A person sheds thousands of skin particles every minute, carries microbes on hands and hair, and can bring in dust, jewellery or illness. People also make most errors. That is why GMP begins with **people**.

Competence and training

- There must be **enough qualified people**, each with a **written job description** and clear responsibilities.
- Everyone working in production, storage or QC gets **initial GMP training** before they start, and **continuing training** (at least yearly and when procedures change).
- Training is **recorded** and its **effectiveness is checked** — a signed attendance sheet is not enough; observe the person or test them.
- Visitors and untrained staff do not enter production areas without guidance and supervision.

> **Auditor question (WHO 9-10):** *Are there enough qualified personnel with job descriptions and initial and continuing GMP training?* Auditors pick a name from the shift roster and ask to see that person's training file.

Health

- Medical examination at recruitment, and repeat checks as required for the product type.
- **Report illness immediately**: diarrhoea, vomiting, fever, infected wounds, skin lesions or eye infections. People who may contaminate product are moved to other work.
- Cuts are covered with a **coloured, detectable dressing** (blue in food).

Personal hygiene rules

1. **Wash and dry hands** on entering production, after the toilet, after breaks, and after touching anything dirty.
2. **Wear the protective clothing** for the area — cap or hairnet covering all hair, beard cover, gown, shoes or shoe covers, gloves and mask where required.
3. **No jewellery, watches, nail polish or false nails.**
4. **No eating, drinking, chewing, smoking or storing food or medicine** in production and storage areas.
5. **Do not touch product, open containers or product-contact surfaces with bare hands.**

Gowning — order matters

A typical sequence: remove outdoor shoes → step over the bench into area shoes → hairnet/cap → wash hands → gown, buttoned fully → mask → sanitize hands → gloves. Each site displays its own gowning procedure with photos at the changing room.

> **Real-world example:** In a tablet plant in Gazipur, recurring black-particle complaints were traced to a worn rubber band on a worker's hairnet. Fixing the gowning standard and checking it at shift start stopped the complaints.

Key points

- Enough qualified staff with job descriptions
- Initial + continuing training, recorded and checked for effectiveness
- Report illness; cover wounds with detectable dressings
- Hands, hair, clothing, no jewellery, no food in production
- Follow the displayed gowning sequence

Knowledge check

1. A worker has diarrhoea but feels able to work. What should happen?

A. Wear two pairs of gloves
B. Take medicine and say nothing
C. Work as usual and wash hands more
D. Report it to the supervisor so they can be moved away from product contact

2. Which is the best evidence that GMP training was effective?

A. A training certificate on the wall
B. Observation or a test showing the person applies what was taught
C. The trainer's slides
D. A signed attendance sheet

3. Which item is NOT allowed in a production area?

A. A hairnet
B. A buttoned gown
C. Area shoes
D. A wristwatch

4. How often should continuing GMP training happen at a minimum?

A. Only before an audit
B. Every five years
C. Only at recruitment
D. Regularly — at least yearly and whenever procedures change

Answers are in the answer key at the back.

MODULE 3 OF 6 · 55 MIN

Premises, equipment and sanitation

Designing and keeping buildings and equipment so they prevent errors and contamination.

Auditor checks: `WHO 12` `WHO 13` `WHO 3`

Premises that prevent mistakes

Buildings must be **located, designed, built and maintained** to suit the operations. Good design makes it hard to do the wrong thing.

- **Logical flow:** materials move in one direction — receiving → quarantine → dispensing → production → packing → finished goods — with no back-tracking that could mix clean and dirty.
- **Separate areas** for receiving, sampling, quarantine, rejected materials, production, packaging, QC labs, toilets and canteens (toilets never open directly into production).
- **Surfaces** smooth, free from cracks, easy to clean; no exposed wooden pallets in clean areas.
- **Lighting, temperature, humidity and ventilation** suitable for the product, with air filtration where needed and pressure differences monitored.
- **Pest control:** sealed openings, insectocutors away from open product, bait stations mapped and checked, a contracted service with reports.

Equipment fit for purpose

Equipment must be **designed, located and maintained** for its use, easy to clean, and must not add anything to the product (no rust, flaking paint, or leaking lubricant — use food-grade lubricant where contact is possible).

Qualification proves equipment is right before use:

Stage	Question it answers
DQ — Design qualification	Is the design right for our needs?
IQ — Installation qualification	Is it installed correctly?
OQ — Operational qualification	Does it work across its operating range?
PQ — Performance qualification	Does it consistently make good product in real use?

Calibration: balances, thermometers, pressure gauges and other measuring devices are calibrated at set intervals against traceable standards, with a **calibration label** (date done, due date). Out of calibration = do not use.

Equipment logs record use, cleaning, maintenance and breakdowns for major equipment.

Status labelling

Every piece of equipment and every room shows its status: **"Cleaned"**, **"To be cleaned"**, **"Under maintenance"**, or the **product and batch in process**. Unlabelled equipment is treated as dirty.

Sanitation and hygiene programme

Written **cleaning procedures** state what, how, with what agent and concentration, how often, who, and how it is checked. Records are signed when the cleaning is done. Cleaning of product-contact equipment between products is **validated** to show no carry-over.

> **Auditor question (WHO 13):** *Is equipment suitable, qualified, cleaned, maintained and calibrated, with logs?* The auditor will read the calibration label on a balance and then ask for its certificate.

Key points

- One-way logical flow; separate areas for quarantine and rejects
- Cleanable surfaces, controlled environment, documented pest control
- DQ → IQ → OQ → PQ
- Calibrated instruments with labels; out of calibration = do not use
- Status labels on every room and machine

Knowledge check

1. Why should materials move through the factory in one direction?

A. It looks tidy
B. It reduces electricity
C. To prevent mix-ups and contamination between clean and dirty or different products
D. It is required for fire safety only

2. Which qualification stage proves equipment consistently makes good product in real use?

A. DQ
B. IQ
C. OQ
D. PQ

3. A balance's calibration label shows the due date passed last week. What do you do?

A. Use it and note the date
B. Recalibrate it yourself with any weight
C. Do not use it; label it and inform the supervisor/QA
D. Use it carefully

4. A mixer has no status label. How should it be treated?

A. As clean and ready
B. As under maintenance
C. As belonging to the last product
D. As dirty until cleaned and labelled

Answers are in the answer key at the back.

MODULE 4 OF 6 · 60 MIN

Materials and production control

From approved suppliers to batch records: controlling what goes in and how it is made.

Auditor checks: `WHO 14` `WHO 4` `WHO 16`

Materials: only approved, only identified

- Buy starting and packaging materials only from **approved suppliers** against an approved **specification**.
- On receipt: check delivery against the order, container integrity, labels and seals; clean the outside; give a **receipt number**.
- Every container carries a **status label**:

Status	Colour (common)	Meaning
Quarantine	Yellow	Waiting for sampling and QC decision — do not use
Released / Approved	Green	Tested and approved for use
Rejected	Red	Failed — store in a locked reject area for return or destruction

- Store under the right **conditions** (temperature, humidity, light), off the floor, and issue by **FEFO** (first expiry, first out) or FIFO.
- **Printed packaging** (labels, cartons, leaflets) is high risk for mix-ups: store securely, count on issue and reconcile after use.

Validation

Critical processes (for example mixing time, sterilization, drying) and cleaning procedures are **validated**: documented evidence that the process consistently gives the expected result. Any **change** to materials, equipment or process goes through **change control** and may need re-validation.

Production: follow the instructions, prove it

1. **Line clearance before starting:** remove all materials, documents and labels from the previous batch; QA or the supervisor checks and signs.
2. **Dispensing:** weigh with calibrated balances; a second person verifies; label each dispensed material with name, batch and quantity.
3. **Follow the approved master instructions** exactly. No shortcuts and no "I always do it this way".
4. **In-process controls** (weight, pH, temperature, fill volume, seal check) at the stated frequency, recorded immediately.
5. **Prevent mix-ups:** one product per room or line at a time, labelled rooms and equipment, closed containers.
6. **Yield reconciliation:** compare actual vs expected yield; investigate significant differences.

7. **Deviations:** anything that differs from the instructions is reported immediately, investigated and approved by QA — never hidden.

The batch manufacturing record (BMR)

The BMR is the **history of the batch**: materials and quantities used, equipment, times, in-process results, deviations, signatures of who did and who checked each step. If it is not in the BMR, the auditor assumes it did not happen.

> **Auditor question (WHO 16):** *Are production operations following approved instructions with in-process controls, line clearance, prevention of mix-ups and batch records?*

Key points

- Approved suppliers, specifications and receipt checks
- Quarantine (yellow) → Released (green) / Rejected (red)
- FEFO, secure printed packaging and reconciliation
- Validated processes and cleaning; change control
- Line clearance, double-checked dispensing, in-process controls, BMR

Knowledge check

1. A pallet of raw material has a yellow 'Quarantine' label. Can you use it today?

A. Yes, if the supplier is approved
B. Yes, with the supervisor's verbal permission
C. Yes, if production is urgent
D. No — wait until QC releases it

2. What is the purpose of line clearance?

A. To remove everything from the previous batch so nothing gets mixed into the new one
B. To check staff attendance
C. To speed up the changeover
D. To clean the floor

3. During compression you notice tablet weight drifting outside the limit. What is correct?

A. Ignore it if the average is fine
B. Record it, adjust per the instruction, and report a deviation
C. Remove the record page
D. Adjust silently and continue

4. Why are printed labels and cartons counted and reconciled?

A. It is not needed
B. To control cost only
C. Because surplus or missing labels can cause mix-ups and mislabelled product
D. To satisfy the printer

Answers are in the answer key at the back.

MODULE 5 OF 6 · 55 MIN

Documentation and quality control

Good documentation practice (ALCOA+), document control and the independent QC laboratory.

Auditor checks: `WHO 15` `WHO 17`

"If it is not written down, it did not happen"

Documents give instructions; records give **proof**. Both must be controlled.

Document types

- **Specifications** — what materials and products must meet.
- **Master formula and instructions** — how to make and pack.
- **SOPs** — how to do routine tasks (cleaning, sampling, calibration).
- **Records** — BMRs, logs, test results, training files.

Document control

Documents are **approved, dated and version-numbered**; only the current version is at the workplace; obsolete copies are withdrawn; a **master list** shows what is current; records are kept for the defined retention period (often at least one year after product expiry).

ALCOA+ — the rules for good records

Letter	Meaning	In practice
Attributable	Who did it and when	Sign and date every entry
Legible	Readable for ever	Indelible ink, no pencil
Contemporaneous	At the time of the action	Never "fill in later"
Original	First record	No rough notes copied later
Accurate	True and correct	Real values, not "as expected"
+	Complete, Consistent, Enduring, Available	No blank fields, consistent dates, kept safe

Correcting a mistake

Draw **a single line** through the wrong entry so it can still be read, write the correct value, **initial, date and give a reason**. Never use correction fluid, overwrite, or tear out pages. Empty fields are crossed or marked "N/A".

Quality control

- QC is **independent of production** and has its own qualified head.
- **Sampling** follows a written plan by trained people, using clean tools, with sampled containers labelled.

- Testing follows **approved methods** against **specifications**; instruments are qualified and calibrated.
- **Retained samples** of each batch (and of starting materials) are kept for the defined period.
- **Out-of-specification (OOS)** results are never simply re-tested until they pass: they are investigated (lab error first, then production) and documented.
- **Stability** programmes confirm shelf life.

> **Auditor question (WHO 15):** *Are documents approved, controlled and records completed at the time of each action?* Auditors compare clock times in the BMR with machine printouts — "back-filling" is easily found.

Key points

- Documents instruct; records prove
- Approved, versioned, only current copies in use
- ALCOA+: Attributable, Legible, Contemporaneous, Original, Accurate
- Single-line correction with initial, date and reason
- QC independent; OOS results investigated, not re-tested away

Knowledge check

1. You wrote 25.4 kg but the correct value is 24.5 kg. How do you correct it?

A. Tear out the page and rewrite it
B. Use correction fluid and rewrite
C. Single line through, write 24.5, initial, date and reason
D. Overwrite the numbers

2. What does 'Contemporaneous' mean in ALCOA+?

A. Recorded in modern format
B. Recorded at the time the activity is done
C. Recorded in two copies
D. Recorded by the supervisor

3. A QC result is out of specification. What should happen first?

A. Re-test until it passes
B. Average it with earlier results
C. Start a documented OOS investigation
D. Release the batch anyway

4. Why must obsolete versions of an SOP be removed from the workplace?

A. To save paper
B. So nobody follows outdated instructions
C. Because auditors dislike paper
D. They do not need to be removed

Answers are in the answer key at the back.

MODULE 6 OF 6 · 55 MIN

Complaints, recalls, self-inspection and audit readiness

Closing the loop: complaints, recalls, contracts, self-inspection, CAPA, and what a GMP inspection looks like.

Auditor checks: `WHO 5 - 6` `WHO 7 - 8`

Complaints

Every complaint about quality is **recorded, assessed and investigated** by a responsible person. Look for trends (same defect, same batch, same line). If a defect is found, consider whether **other batches** are affected and whether a **recall** is needed.

Recalls

A written **recall procedure** allows any batch to be **quickly and effectively** removed from the market. Distribution records must show who received which batch. The procedure is **tested by mock recall** — trace one batch forward to all customers and backward to all raw material lots, and time how long it takes.

Contract manufacture and testing

When any work is outsourced (contract manufacturing, testing, pest control, calibration), there is a **written agreement** that says who is responsible for what. The contract giver remains responsible for the product and must evaluate the contractor's competence.

Self-inspection

The company inspects itself at planned intervals against a checklist covering all GMP areas, with **independent** team members. Findings are reported to management and **corrective actions** are tracked to closure.

Deviations and CAPA

- **Correction** fixes the immediate problem (re-label the carton).
- **Corrective action** removes the root cause so it does not happen again (change the label layout).
- **Preventive action** stops a potential problem elsewhere (apply the new layout to all similar products). Use tools like **5 Why** to reach the root cause, and **check effectiveness** afterwards.

What happens in a GMP inspection

Our GMP audit follows the inspection approach in the ERP:

1. **Opening meeting** — scope, plan, people.
2. **Site tour** — following the material flow; auditors watch people work.
3. **Document and record review** — training files, BMRs, calibration, cleaning, complaints, recall.

4. **Findings graded** as **Critical** (significant risk of harmful product), **Major** (significant departure from GMP), **Minor** (limited departure) or **Observation**.
5. **Closing meeting** and **inspection report** with result: *Satisfactory*, *Conditionally satisfactory (corrective actions required)* or *Unsatisfactory*.

> **Be ready:** answer honestly, show the record instead of describing it, and say "I will check" rather than guessing. Use the **GMP self-check** in this course — it uses the same questions our auditors ask.

Key points

- Record, investigate and trend complaints
- Written recall procedure, tested by mock recall
- Written agreements for all outsourced work
- Planned, independent self-inspections
- Correction ≠ corrective action; check effectiveness
- Findings: Critical, Major, Minor, Observation

Knowledge check

1. What is a mock recall?

A. A test of the recall procedure by tracing a batch forward and backward
B. A recall of fake products
C. A recall ordered by the regulator
D. A training video

2. Re-labelling a wrongly labelled carton is an example of…

A. Corrective action
B. Correction
C. Validation
D. Preventive action

3. A GMP finding that poses a significant risk of producing harmful product is graded…

A. Critical
B. Observation
C. Major
D. Minor

4. Who stays responsible for product quality when testing is outsourced?

A. The regulator
B. Nobody
C. Only the contract laboratory
D. The contract giver (the manufacturer)

Answers are in the answer key at the back.

APPLY IT

GMP audit self-check

General GMP checklist based on the WHO GMP main principles (TRS 986, Annex 2); use the sector code that applies (food, cosmetics ISO 22716, pharmaceuticals, packaging). These are the same questions our inspectors use. Rate each one: **Compliant · Observation · Minor · Major · Critical · N/A**.

Indicative result: any Critical → Unsatisfactory; any Major or Minor → Conditionally satisfactory (corrective actions required); otherwise Satisfactory.

Ref	Question	Rating	Evidence / note
Quality and personnel			
WHO 1 - 2	Is there a quality assurance system with GMP responsibilities, a quality unit independent of production, and product release by an authorized person? Evidence: Quality manual, organization chart, release records		
WHO 9 - 10	Are there enough qualified personnel with job descriptions and initial and continuing GMP training? Evidence: Job descriptions, training records		
WHO 11	Are personal hygiene rules applied: health checks, protective clothing, hand washing, no eating or smoking in production? Evidence: Health records, hygiene rules, observation		
Premises and equipment			
WHO 12	Are premises designed, constructed and maintained to minimize errors and contamination, with logical flow, adequate lighting, ventilation and pest control? Evidence: Layout, site inspection, pest control records		
WHO 13	Is equipment suitable, qualified, cleaned, maintained and calibrated, with logs? Evidence: Equipment logs, calibration and cleaning records		
WHO 3	Are sanitation and hygiene programs documented and followed?		

	Evidence: Cleaning procedures and records
Materials and production	
WHO 14	Are starting and packaging materials sampled, tested and released, stored under proper conditions and identified (quarantine, released, rejected)? Evidence: Material specifications, status labels, warehouse inspection
WHO 4	Are critical processes and cleaning qualified or validated? Evidence: Validation protocols and reports
WHO 16	Are production operations following approved instructions with in-process controls, line clearance, prevention of mix-ups and batch records? Evidence: Batch manufacturing records, line clearance records
WHO 17	Is quality control independent, with specifications, sampling, testing, retained samples and out-of-specification investigations? Evidence: QC test records, OOS investigations, retained samples
Documentation and control	
WHO 15	Are documents (specifications, procedures, records) approved, controlled and records completed at the time of each action? Evidence: Document control, sample records

WHO 5 - 6	Are complaints investigated and is there an effective, tested recall procedure? Evidence: Complaint files, recall procedure and mock recall	
WHO 7 - 8	Are contract manufacturing and testing controlled by written agreements, and are self-inspections carried out? Evidence: Contracts, self-inspection reports	

PRACTISE

Practical assignment: GMP walk-through and improvement plan

Walk through one production or storage area at your workplace using the GMP self-check in this course. Rate each question, take photos of two good practices and three gaps, and write a short improvement plan.

What to submit

1. Completed GMP self-check (download from the course)
2. 5 photos with one-line captions (2 good practices, 3 gaps)
3. Improvement plan: for each gap — root cause (5 Why), correction, corrective action, owner and target date
4. One paragraph: which gap carries the highest risk to the product and why

Marking criterion	Marks
Accurate use of the self-check	25
Quality of gap evidence and photos	20
Root cause and corrective actions	35
Risk reasoning	20
Total (pass 60)	**100**

Glossary

ALCOA+	Attributable, Legible, Contemporaneous, Original, Accurate — plus Complete, Consistent, Enduring, Available.
BMR	Batch manufacturing record: the full history of a batch.
CAPA	Corrective and preventive action.
Deviation	Any departure from an approved instruction or standard.
FEFO	First expiry, first out.
IQ / OQ / PQ	Installation, operational and performance qualification.
Line clearance	Removing everything from the previous batch before starting the next.
OOS	Out of specification: a result outside the approved limits.
Quarantine	Status of materials held until a QC decision.
Validation	Documented evidence that a process consistently gives the expected result.

Answer key: knowledge checks

Module 1: 1–D, 2–C, 3–C, 4–A

Module 2: 1–D, 2–B, 3–D, 4–D

Module 3: 1–C, 2–D, 3–C, 4–D

Module 4: 1–D, 2–A, 3–B, 4–C

Module 5: 1–C, 2–B, 3–C, 4–B

Module 6: 1–A, 2–B, 3–A, 4–D