WHO vs FDA vs EU GMP Requirements

A practical comparison for pharma learners and professionals

WHO

Global GMP guidance

vs

FDA

21 CFR Parts 210 & 211

vs

EU GMP

EudraLex Volume 4

AGENDA AT A GLANCE

01 Framework

02 Core requirements

03 Validation & sterile GMP

04 Records, release & inspections

How to Use This Guide

A practical GMP comparison deck for learners and professionals

① Learn the map

- ✓ Understand what each framework covers
- ✓ Know when regional rules matter
- ✓ Avoid mixing guidance with law

② Compare the controls

- ✓ Quality systems
- ✓ People, premises, process
- ✓ Records, deviations and CAPA

③ Apply it at work

- ✓ Read SOPs more critically
- ✓ Prepare for audits
- ✓ Build GMP career language

Best approach: first learn the common GMP backbone, then study the regional details.

Why Compare WHO, FDA and EU GMP?

Different frameworks, one patient-safety objective

WHO

- ✓ Global reference for many regulators
- ✓ Training and inspection baseline
- ✓ Useful for international GMP language

FDA

- ✓ U.S. cGMP regulations
- ✓ Enforceable under federal law
- ✓ Strong focus on quality unit authority

EU GMP

- ✓ EudraLex Volume 4
- ✓ Chapters plus product-specific annexes
- ✓ QP batch certification culture

THE PRACTICAL QUESTION

How should a learner or GMP professional understand the similarities and differences without memorising every clause?

Sources: WHO GMP main principles; eCFR 21 CFR Parts 210 & 211; European Commission EudraLex Volume 4.

Framework and Scope

How the three GMP systems are structured

WHO

- Main principles + supplementary GMP guidelines
- Used globally by many NRAs and procurement programs
- Broad baseline for finished products, APIs, and sterile products

FDA

- 21 CFR Parts 210 & 211
- Legally enforceable U.S. cGMP requirements
- Additional rules/guidances may apply by product type

EU GMP

- EudraLex Volume 4, Parts I–IV + Annexes
- Covers medicinal products and API GMP
- Key annexes: 1, 11, 15, 16

All three aim to ensure quality, safety, and consistent manufacture.

Who Uses Which GMP Framework?

The same company may need more than one standard

WHO lens

- National regulatory authorities may use WHO GMP as a baseline
- Procurement and international programs may expect WHO-aligned quality systems
- Useful where many markets are involved

US FDA lens

- Manufacturers supplying the U.S. must meet applicable cGMP rules
- Inspections often focus on quality unit, records and investigations
- Warning letters often reference Part 211 expectations

EU EU lens

- Manufacturers supplying EU/EEA markets follow EU GMP expectations
- Annexes add product and process detail
- Qualified Person certification is a distinctive concept

For global companies, GMP is rarely a single-document exercise. The market, product type, site activity and regulatory commitments decide what applies.

Guidance, Regulation and Inspection Reality

Know the status before you quote the requirement

G WHO

- International GMP guidance
- Often used by NRAs, inspectors and procurement bodies
- Important baseline for harmonised understanding

R FDA

- 21 CFR Parts 210 & 211 are regulations
- Failure to comply may make a drug adulterated
- FDA guidances may add current thinking

E EU GMP

- Guidelines in EudraLex Volume 4
- Used with EU pharmaceutical legislation
- Annexes create detailed expectations

Practical rule: quote the exact applicable document in SOPs, audit reports and training materials.

Sources: eCFR 21 CFR Part 210 §210.1; European Commission EudraLex Volume 4; WHO TRS 986 Annex 2.

Core GMP Requirements

What all three frameworks expect from manufacturers

	WHO	FDA	EU GMP
Quality system	Quality management focus	Quality control unit authority	Pharmaceutical Quality System
Personnel & training	Trained, hygienic personnel	Personnel qualifications and responsibilities	Personnel and defined responsibilities
Premises & equipment	Suitable facilities, sanitation, maintenance	Buildings, facilities, equipment controls	Premises/equipment and self-inspection
Documentation	Documented procedures and records	Written procedures, batch and lab records	Structured documentation requirements

Common GMP backbone: people, process, premises, and paperwork.

Quality System / PQS Comparison

All three expect management control, not only laboratory testing

Q WHO focus

- ✓ Quality management system
- ✓ QA, QC and production responsibilities
- ✓ Risk reduction through organized controls

U FDA focus

- ✓ Quality control unit authority
- ✓ Approve or reject materials and drug products
- ✓ Review records and investigations

P EU GMP focus

- ✓ Pharmaceutical Quality System
- ✓ Quality risk management and lifecycle control
- ✓ Management accountability

Key insight: GMP systems should prevent errors, detect problems early, and prove control through evidence.

Personnel, Training and Hygiene

GMP compliance depends on trained behaviour

Common expectation

- ✓ Defined responsibilities
- ✓ Training before independent work
- ✓ Hygiene and contamination awareness

FDA emphasis

- ✓ Personnel qualifications
- ✓ Training records
- ✓ Consultant qualifications where used

EU GMP emphasis

- ✓ Written job responsibilities
- ✓ Continuous training
- ✓ Specific expectations for key personnel

AUDIT QUESTION

Can the site show that each person was trained, qualified and supervised for the actual task performed?

Premises, Equipment and Utilities

Facilities must support controlled manufacturing

Facilities

- Adequate space to prevent mix-ups
- Cleanable and maintainable design
- Logical material and personnel flow

Equipment

- Appropriate design and location
- Cleaning and maintenance controls
- Calibration and qualification evidence

Utilities

- HVAC, water and compressed gases
- Monitoring based on risk
- Change control for critical systems

Good facility design only works when cleaning, maintenance and documentation are disciplined every day.

Documentation and Data Integrity

If it is not recorded correctly, it is hard to prove

D Documents

- ✓ SOPs and work instructions
- ✓ Master production records
- ✓ Approved specifications

R Records

- ✓ Batch records
- ✓ Laboratory records
- ✓ Equipment logs

A Data

- ✓ Complete and attributable
- ✓ Legible and contemporaneous
- ✓ Original, accurate and traceable

Common mistake: treating documentation as paperwork after the process instead of evidence created during the process.

Production and Process Controls

The process must be defined, followed and documented

FDA example

Written production and process control procedures must be followed and documented at the time of performance.

Practical lesson

Batch quality is built during manufacturing. Final testing alone cannot rescue an uncontrolled process.

Source: eCFR 21 CFR Part 211, Subpart F, §211.100.

Quality Control Laboratory Expectations

Testing confirms quality, but the lab system must also be controlled

People

- ✓ Qualified analysts
- ✓ Method training
- ✓ Supervisor review

Methods

- ✓ Validated or verified methods
- ✓ Approved specifications
- ✓ Controlled reagents and standards

Records

- ✓ Raw data traceability
- ✓ OOS/OOT investigations
- ✓ Certificate and report review

Audit focus: can the lab explain how results were generated, checked, investigated and approved?

Materials and Supplier Controls

GMP begins before production starts

M Starting materials

- ✓ Approved suppliers
- ✓ Quarantine and release
- ✓ Identity and quality checks

P Packaging materials

- ✓ Label control
- ✓ Artwork and version control
- ✓ Reconciliation where needed

S Excipients and APIs

- ✓ Risk-based qualification
- ✓ Specifications and COA review
- ✓ Change notification expectations

GMP risk: the wrong or uncontrolled material can affect every batch that uses it.

Validation Landscape

Validation links process knowledge, qualification and routine control

W WHO

- ✓ Validation is part of GMP principles
- ✓ Qualification and validation guidance exists in the WHO GMP family
- ✓ Sterile guidance adds process and contamination controls

F FDA

- ✓ Process validation is supported by FDA guidance
- ✓ Part 211 requires written controls and investigation of deviations
- ✓ Control strategy is built through lifecycle evidence

E EU GMP

- ✓ Annex 15 gives detailed qualification and validation expectations
- ✓ Annex 1 adds sterile manufacturing controls
- ✓ Annex 11 covers computerized systems

Learner shortcut: learn IQ/OQ/PQ, process validation, cleaning validation and computerized system validation as connected topics.

Qualification vs Validation vs Verification

Use the right word for the right evidence

Q Qualification

- Equipment, utilities or facilities are fit for intended use
- Often includes DQ, IQ, OQ and PQ
- Example: HVAC qualification

V Validation

- A process consistently produces expected results
- Uses defined acceptance criteria
- Example: process or cleaning validation

✓ Verification

- Checks that a requirement was met
- May support ongoing control
- Example: daily balance check

Why it matters: inaccurate terminology can make a validation plan unclear during review or inspection.

Computerized Systems and Electronic Records

Regional expectations overlap, but terminology differs

WHO

- Data integrity is expected in GMP documentation
- Computerized systems must be controlled according to risk
- Procedures and access controls matter

FDA

- 21 CFR Part 11 applies to certain electronic records/signatures
- Part 211 records still need GMP control
- Audit trails and access control are common focus areas

EU GMP

- Annex 11 covers computerized systems
- Validation and lifecycle control are emphasized
- Supplier and service provider control may apply

Practical reminder: system validation, access control and data review must match the system risk.

Production, Validation & Sterile GMP

Where the comparison becomes more practical

WHO

- General GMP main principles
- Separate sterile GMP guideline
- 2022 sterile revision harmonised with EU/PIC/S

VS

FDA

- Written procedures and documented deviations
- In-process controls and yield checks
- Control of microbiological contamination

VS

EU GMP

- Annex 15: qualification and validation
- Annex 1: contamination control strategy
- Strong expectations for environmental monitoring and aseptic control

EU GMP is often seen as the most annex-driven, especially for sterile manufacturing.

PRODUCTION → VALIDATION → STERILE GMP

Contamination Control Strategy

The sterile GMP topic that connects people, process and environment

Sources of risk

- People and gowning
- Airflow and pressure cascades
- Equipment, utilities and materials
- Cleaning and disinfection

Control layers

- Facility design
- Validated sterilisation/depyrogenation
- Aseptic process simulation
- Environmental monitoring

Evidence

- Trend review
- Deviation investigation
- CAPA effectiveness
- Periodic strategy review

EU GMP Annex 1 makes contamination control strategy a central concept for sterile manufacturing.

Source: European Commission EudraLex Volume 4, Annex 1.

Environmental Monitoring and Aseptic Control

Monitoring is not just data collection

1 Plan

Define locations, methods, limits and responsibilities

2 Sample

Collect viable and non-viable data at risk-based points

3 Trend

Review results over time, not only single excursions

4 Act

Investigate, justify, correct and prevent recurrence

Inspection question: does the site understand what the monitoring data means for process control?

Records, Deviations, CAPA & Batch Release

Operational controls that matter every day

WHO

- Documented investigations
- Complaints and recall controls
- QA/QC oversight of quality events

vs

FDA

- Master and batch records
- Production record review
- Complaint files and quality unit approval/ rejection

vs

EU GMP

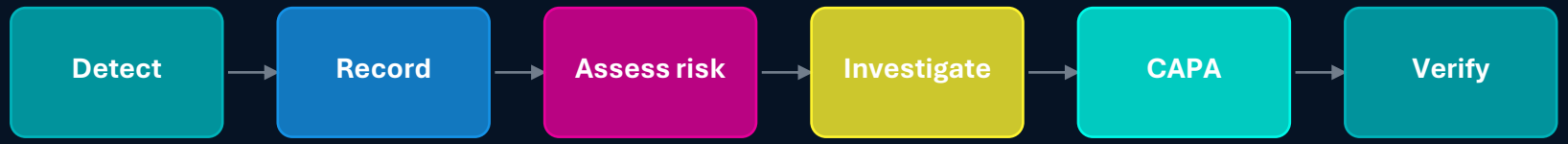
- Documentation chapter + complaint/recall chapter
- Annex 11 for computerized systems
- Annex 16 for Qualified Person batch certification and release

ACROSS ALL THREE

Data integrity | Change control | Investigation | CAPA | Traceability

Deviation and CAPA Workflow

A practical flow used across GMP systems



Good investigation

Defines the problem, protects the batch, finds root cause and documents evidence.

Good CAPA

Corrects the issue, prevents recurrence and includes an effectiveness check.

Complaints and Recalls

Post-market signals must connect back to the quality system

1 Complaint intake

- ✓ Capture product, batch and event details
- ✓ Assess seriousness and product risk
- ✓ Link to pharmacovigilance when needed

2 Investigation

- ✓ Review batch and distribution data
- ✓ Check retain samples and trends
- ✓ Escalate when risk changes

3 Recall control

- ✓ Define decision authority
- ✓ Trace distribution quickly
- ✓ Document communication and effectiveness

Practical link: complaints, deviations, CAPA and change control should not live in separate silos.

Batch Release: Different Regional Language

The release decision is built from evidence

US FDA

- Quality control unit approves or rejects drug products
- Production records are reviewed
- Errors must be investigated

QP EU GMP

- Qualified Person certifies batch release
- Annex 16 provides specific expectations
- Supply chain and importation status matter

WHO WHO

- QA/QC oversight of batch quality
- Records and test results support release
- Inspections evaluate quality system control

Learner note: do not translate “Quality Unit” and “Qualified Person” as the same role.

Sources: eCFR 21 CFR Part 211 §211.22 and §211.192; EudraLex Volume 4 Annex 16.

How Inspectors Look at GMP Systems

Inspectors test whether the system works in real operations

S System

- ✓ Is there a controlled process?
- ✓ Are responsibilities clear?
- ✓ Are procedures current?

E Evidence

- ✓ Are records complete?
- ✓ Can data be traced?
- ✓ Were deviations investigated?

F Effectiveness

- ✓ Did CAPA prevent recurrence?
- ✓ Are trends reviewed?
- ✓ Does management act on risk?

Inspection readiness is not a binder. It is the daily ability to explain and prove control.

GMP Inspection Readiness Checklist

A simple pre-audit view for teams

Before the inspection

- Current SOPs and controlled forms
- Training records linked to tasks
- Batch records complete and reviewed
- Deviation investigations closed or justified

During the inspection

- CAPA effectiveness checks available
- Validation status known
- Equipment logs and calibration current
- Management review and trend data ready

Tip: every checklist item should point to real evidence, not only a statement.

Common Gaps Seen Across GMP Audits

Most findings are system weaknesses, not isolated mistakes

1. **Procedures do not match real practice**
2. **Training records exist but competence is unclear**
3. **Deviations close without root cause depth**
4. **CAPA actions do not prevent recurrence**
5. **Data review misses trends and recurring signals**
6. **Change control does not assess regulatory impact**

Use these gaps as review prompts when updating training, SOPs and internal audits.

Which Standard Should You Study First?

Choose based on your market, role and product type

W Start with WHO if...

- ✓ You need a global GMP baseline
- ✓ You are new to pharmaceutical manufacturing
- ✓ You work across emerging markets

F Start with FDA if...

- ✓ Your site supplies the U.S.
- ✓ You work with U.S. records or inspections
- ✓ You need 21 CFR Part 211 language

E Start with EU GMP if...

- ✓ Your site supplies EU/EEA
- ✓ You work in sterile manufacturing
- ✓ You need annex-driven detail

Best path: common GMP principles → regional framework → product-specific annexes and guidances.

Career Map: Who Needs This Comparison?

Different roles use the same standards differently

Q QA

Deviation, CAPA, audits, batch release

Q QC

Testing, lab records, OOS investigations

P Production

SOPs, cleaning, in-process controls

V Validation

Qualification, validation, lifecycle evidence

R RA

Regulatory impact and commitments

S Students

Career language and interview confidence

One standard does not make a career. Strong GMP thinking across standards does.

Mini Case Study: Process Change

A site changes a mixing time from 20 to 30 minutes

? GMP questions

- ✓ Was change control opened?
- ✓ Was risk assessed?
- ✓ Were validation and stability impacts reviewed?

R Regional lens

- ✓ FDA: process control and records
- ✓ EU: validation status and QP impact
- ✓ WHO: documented QA oversight

E Expected evidence

- ✓ Approved change rationale
- ✓ Updated SOP/batch record
- ✓ Impact assessment and training

Lesson: a small process change can become a regulatory, validation and batch-release question.

Mini Case Study: Sterile Filling Line

A recurring environmental monitoring excursion appears in Grade B

1 Immediate action

- ✓ Assess product and process risk
- ✓ Protect batch and environment
- ✓ Escalate according to SOP

2 Investigation

- ✓ Review trends and locations
- ✓ Check gowning, cleaning and HVAC data
- ✓ Review intervention history

3 CAPA

- ✓ Correct the root cause
- ✓ Verify effectiveness
- ✓ Update contamination control strategy if needed

Sterile GMP is a system: people, airflow, equipment, cleaning, monitoring and documentation must align.

90-Day Learning Plan

A practical route for GMP learners

30 Days 1–30

- ✓ Learn GMP fundamentals
- ✓ Study quality systems and documentation
- ✓ Read one SOP deeply

60 Days 31–60

- ✓ Compare WHO, FDA and EU structures
- ✓ Map key chapters to job tasks
- ✓ Practice deviation/CAPA examples

90 Days 61–90

- ✓ Study validation and sterile topics
- ✓ Prepare interview examples
- ✓ Build a personal GMP checklist

Outcome: you can discuss GMP with role-specific examples, not memorised definitions.

Quick Glossary

Terms that appear across the three frameworks

cGMP	Current good manufacturing practice; often used in the U.S. context	**PQS**	Pharmaceutical Quality System; common in EU GMP language
QCU	Quality Control Unit; key FDA Part 211 concept	**QP**	Qualified Person; central to EU batch certification
CAPA	Corrective and preventive action	**CCS**	Contamination Control Strategy in sterile GMP

Key Takeaways

What should learners and professionals remember?

WHO

- Best viewed as a global GMP benchmark
- Useful baseline for international understanding

VS

FDA

- Detailed, legally enforceable U.S. cGMP
- Strong quality-unit and record-control emphasis

VS

EU GMP

- Highly structured with Parts and Annexes
- Distinctive QP batch release and Annex 1/15 focus

COMMON GROUND

Trained people | Controlled facilities | Validated processes | Clear documentation | Investigations and CAPA

Learn the common GMP backbone first, then master regional differences.

Sources and Next Steps

Use primary references when updating SOPs or training

S Primary sources

- ✓ WHO GMP main principles, TRS 986 Annex 2
- ✓ WHO sterile GMP, TRS 1044 Annex 2
- ✓ eCFR 21 CFR Parts 210 and 211
- ✓ European Commission EudraLex Volume 4

U Use this deck to

- ✓ Train new GMP learners
- ✓ Prepare article downloadable content
- ✓ Support QA, QC, RA and validation discussions
- ✓ Create short social media summaries

N Next steps

- ✓ Add Pharmuni course CTA
- ✓ Convert key slides into infographics
- ✓ Link the deck from the article
- ✓ Track downloads with UTM parameters

Reference URLs: who.int/publications/m/item/trs986-annex2 • who.int/publications/m/item/trs1044-annex2 • ecfr.gov/current/title-21/part-210 • ecfr.gov/current/title-21/part-211 • health.ec.europa.eu/medicinal-products/eudralex/eudralex-volume-4_en

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