Quality Assurance
TRAINING LAB

GMP AUDITING GUIDELINES

Conduct effective GMP audits and prepare for inspections

Agenda

- Introduction to GMP Audits
- Audit Planning
- Conducting the Audit
- Documentation and Reporting
- Preparing for Regulatory Inspections
- Practical Exercise
- Conclusions and Q&A

What is a GMP Audit?

Systematic, independent, and documented review to determine whether activities and results conform to planned arrangements and whether those arrangements are effectively implemented.

Auditing is NOT a hunt for errors.
It is a tool for continuous improvement.

- Identify non-conformities
- Find opportunities for improvement
- Protects quality and patient

Tipi in Audit

Part One **INTERNAL AUDIT**	**The organization audits itself to evaluate the quality system**
Second Part **SUPPLIER AUDIT**	**Qualification and monitoring of critical suppliers**
Third Part **EXTERNAL AUDIT**	**Certification bodies or regulatory authorities (FDA, EMA, AIFA)**

Today's Focus: Internal Audits and Third-Party Inspection Preparation

Regulatory Framework

ISO 19011:2018	Guidelines for management systems audits
EU GMP Chapter 9	Self Inspection
FDA 21 CFR 820.22	Quality Audit (Medical Devices)
ICH Q10	Pharmaceutical Quality System
ISO 13485:2016 §8.2.4	Internal Audit

Common principles: Independence • Risk-based • Documentation of evidence • CAPA follow-up

The Annual Audit Program

- Coverage of all GMP processes in the cycle (1-3 years)
- Frequency based on RISK (critical areas = more frequent)
- Consideration of HISTORY (areas with NC = more attention)
- Available resources (qualified auditors, time)

Best Practice: Include "surprise" audits and follow-up audits to verify CAPA effectiveness.

Single Audit Preparation

Quality Assurance TRAINING LAB

1. **SCOPE**
   Define processes, areas and documents to be covered

2. **DOCUMENTATION**
   Review SOPs, batch records, previous audits, CAPAs

3. **CHECKLIST**
   Prepare specific questions and checkpoints

4. **LOGISTICS**
   Dates, rooms, access to areas, companions

5. **AGENDA**
   Opening meeting, aree da visitare, closing meeting

Preparation is 50% of the success of an audit

The Effective Audit Checklist

- Organized by PROCESS or regulatory REQUIREMENT
- Includes REFERENCES to SOPs and regulations
- OPEN-ENDED questions (not yes/no) to stimulate discussion
- Space for HIGHLIGHTS and notes
- Flexibility to FOLLOW-UP on interesting responses

The checklist is a GUIDE, not a cage. Follow the evidence even outside the checklist!

Opening Meeting

- Presentation of the audit team and auditees
- Confirmation of scope, objectives and agenda
- Explanation of the methodology and evaluation criteria
- Confidentiality and Information Management Agreements
- Logistics: escorts, access, safety briefing

Make it clear from the outset that the goal is improvement, not punishment. A defensive environment produces less useful information.

Interview Techniques

OPEN

"Describe to me how you manage..."

To understand the process

CLOSED

"Do you have an SOP for this?"

To confirm facts

INSIGHT

"Can you show me an example?"

To check

HYPOTHETICAL

"What would you do if...?"

To test understanding

The 80/20 Rule: Listen more than you speak

Gathering Evidence

DOCUMENTARY

Procedures, records, reports, batch records

TESTIMONIALS

Staff statements during interviews

PHYSICS

Direct observation of processes, areas, equipment

"Trust but verify"

Everything they tell you must be confirmed by objective evidence.

ALWAYS write down: what, who, where, when.
"I saw document X, shown to me by Y, in room Z at W hours."

Plant Tour: What to Look For

CLEANLINESS and ORDER
General state of the areas

FLOWS
Personnel, materials, waste

IDENTIFICATION
Materials, equipment, status labels

BEHAVIORS
Dressing, hygiene, ongoing procedures

DOCUMENTATION
Logbook, batch record, instructions

Technique: Ask operators to SHOW you how they do a specific operation

Classification of Observations

CRITICISM	Deviation that has produced or may produce non-compliant product with risk to the patient
GREATER	Significant deviation from GMP requirements, indicates potential systemic deficiency
MINOR	Deviation from requirements that does not significantly impact product quality
OFI	Area for improvement, not a true non-conformity

Multiple MINOR observations in the same area may indicate a SYSTEMIC problem → MAJOR

Writing a Good Observation

1 REQUIREMENT

Which rule/SOP
was violated?

2 EVIDENCE

What did you observe
(facts, not interpretations)

3 IMPACT

Why it is important
(quality/patient risk)

CORRECT EXAMPLE

EU GMP Annex 1 §4.8 requires continuous particle monitoring. During the March 15 audit, in Area B12, the meter was off from 9:15 to 11:30 during filling (Batch ABC-2024).
Risk: Unable to demonstrate adequate conditions.

INCORRECT: "Environmental monitoring is not being performed properly." (vague, no requirement, no evidence)

Closing Meeting

- Summary of areas covered by the audit
- Presentation of observations (no surprises - already discussed)
- Opportunity for the auditee to clarify or provide evidence
- Agreement on response timelines and CAPA
- Acknowledgements and recognition of strengths

The closing meeting should NEVER contain surprises!

Preparing for Inspections

Preparation CONTINUES

- Updated document system
- CAPA closed on time
- Updated staff training
- Regular mock audit
- Management reviews performed

IMMEDIATE preparation

- Identify support teams
- Preparare "war room"
- Staff briefing
- Review previous inspections
- Check CAPA associates

"Inspection-ready" is not an event, it is a CONTINUOUS state

Inspection preparation begins long before the inspectors arrive

Behavior during the Inspection

1. Answer ONLY what is asked (don't ramble)
2. If you don't know: "I don't know, I'll check and come back with the answer."
3. NEVER lie or hide information
4. Be professional, NOT defensive
5. Take note of all requests and comments

Regola d'oro: "Be honest, be accurate, be responsive, be brief"

Quality Assurance TRAINING LAB

PRACTICAL EXERCISE

Role Play: You are the Auditor

Estimated time: 15-20 minutes

Exercise Scenario

During the packaging department audit, observe:

1. An operator is packaging Batch XYZ-2024-015. The batch record is open at the workstation, but the operator is NOT filling it in real time—he completes the records at the end of the shift.
2. In the same area, notice that the calibrator used to test the scales has a 15-day EXPIRED calibration label.
3. Ask the operator where they can find the procedure for managing deviations. They reply, "I think it's in the document management system, but I've never had to use it."

Tasks (10 min):

1. Identification of NCs
2. Classify him
3. Write 1 complete observation
4. Ask 2-3 questions

Solution: Observation 1 - Batch Record

NC MAJOR

REQUIREMENT

EU GMP Annex 15 §1.9 and Chapter 4 §4.8 require that production records are made at the time of execution of each action.

EVIDENCE

During the [date] audit, the packaging department operator (Batch XYZ-2024-015) stated that he completes batch record entries at the end of the shift rather than in real time.

IMPACT

Retrospective recording increases the risk of errors and omissions, and does not guarantee the accuracy and traceability of transactions.

Solution: Observation 2 - Calibration

NC MAJOR

REQUIREMENT

EU GMP Chapter 3 §3.41 requires that measuring instruments are calibrated at defined intervals.

EVIDENCE

Calibrator ID# CAL-0045, used for checking scales in the packaging department, had a calibration label with an expiration date [date - 15 days ago].

IMPACT

Using an instrument with expired calibration calls into question the reliability of all scale checks performed during the period.

Common Mistakes to Avoid

AUDITOR Errors

- Arriving unprepared
- Being too rigid on the checklist
- Vague observations without evidence
- Arrogant behavior

AUDITEE Errors

- Answer unasked questions
- Being defensive or making excuses
- Documentation not ready
- Lying or hiding problems

Honesty and transparency are ALWAYS the best strategy

Key Messages

Auditing is a tool for improvement, not a hunt for errors

Preparation is half the success – for auditors and auditees

Objective evidence is the basis of all observation

"Inspection-ready" is not an event, it's a continuous state

Honesty and transparency are always the best strategy

Resources for Further Study

- ISO 19011:2018 - Guidelines for auditing management systems
- EU GMP Chapter 9 - Self Inspection
- FDA Compliance Program Guidance Manual
- PIC/S PI 002-3 - Inspection of Pharmaceutical Manufacturing
- ICH Q10 - Pharmaceutical Quality System
- ISO 13485:2016 Section 8.2.4 - Internal Audit

Requests?

The best audit is the one that finds nothing because the problems have already been fixed. But the second-best audit is the one that finds the problems before the inspector finds them.

Thank you for your attention!

Thank you

Quality Assurance
TRAINING LAB

@qatraininglab

Thank you

Quality Assurance
TRAINING LAB

@qatraininglab