

Unit 3: Audits

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3.1 What an audit is

An **audit**, in the standard definition of ISO 19011 adopted across the quality world, is a **systematic, independent and documented process for obtaining objective evidence and evaluating it objectively, to determine the extent to which audit criteria are fulfilled**. Every word in the definition carries weight in an examination answer. Systematic: planned against a programme and a checklist, not wandering. Independent: the auditor does not audit his or her own work. Documented: the audit leaves a report and records, and is itself a piece of documentation of the kind Unit 1 teaches. Objective evidence: verifiable facts, records, statements and observations, not impressions. Audit criteria: the standard against which evidence is judged, a law, a GMP guide, a registered dossier, an SOP, a contract. The audit's product is a set of **findings**, graded by seriousness, and its purpose is improvement and assurance, not blame: an audit that produces only comfort has failed, and one that produces only fear will be fed no evidence next time.

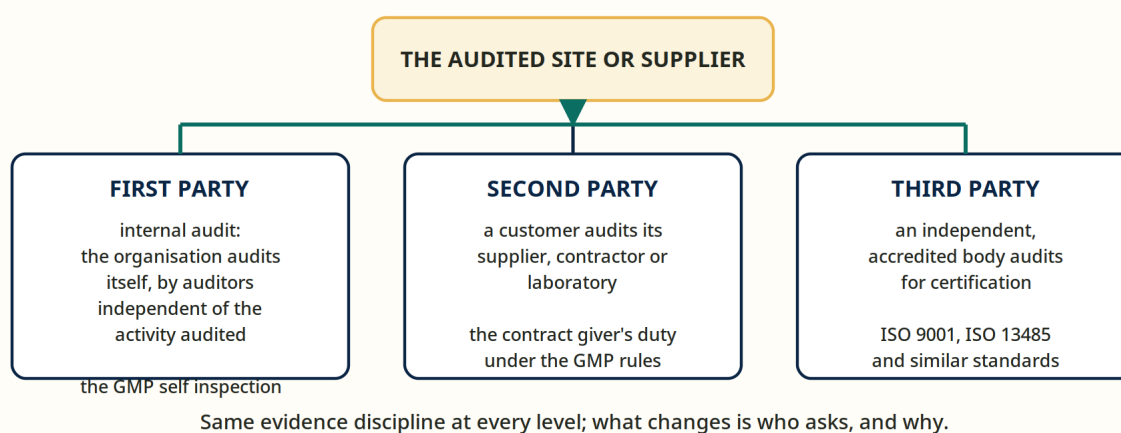
3.2 The parties of an audit: first, second and third

Audits are classified first by **who stands on each side** of the table, and the syllabus names each party in turn:

Audit party	Who audits whom	Typical use
First party (internal audit)	An organisation audits itself, by its own or contracted auditors independent of the activity	Self inspection under GMP; the audit programme of section 3.4
Second party	One organisation audits another it has a direct interest in, classically a customer auditing a supplier, or a company auditing its contract manufacturer or laboratory	Supplier qualification, contract giver audits under GMP contract rules
Third party (external)	An independent body with no commercial interest in the outcome audits for certification or regulatory purposes	Certification audits to ISO standards by accredited bodies; audits by or for authorities

The **internal audit** (first party) is the GMP self inspection of MRA101T in its formal dress: required by the GMP texts themselves, it examines all parts of the quality system on a planned cycle. **Second party audits** externalise the same instrument along the supply chain: because GMP holds the contract giver responsible for the contract acceptor's work, supplier and contractor audits are a duty, not a courtesy, and their reports are documents a regulator will ask to see. **External third party audits** carry the certificate market: an accredited certification body's audit against a standard such as ISO 9001 or ISO 13485 (section 3.8), whose certificate other parties rely on. Beside the party classification stand classifications by object, **system audits** (the whole quality system), **process audits** (one process end to end) and **product audits** (conformance of a product and its file), and by notice, announced and unannounced; the mature programme mixes all of them deliberately.

The Three Parties of an Audit



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Figure: First party audits look inward, second party audits look along the supply chain, third party audits stand outside both, independent and accredited.

3.3 The GMP compliance audit

The **GMP compliance audit** is the audit aimed specifically at the GMP criteria: does this site, system or supplier actually operate as the GMP guide and its own registered commitments require? Its scope is the GMP map of MRA101T, organisation and personnel, premises and equipment, documentation, production, quality control, validation, distribution, complaints and self inspection, checked against the applicable GMP text (Parts 210 and 211, the EU Guide, WHO GMP or Schedule M, as the audit's purpose requires).

Compliance auditing has a literature of its own, Ginsbury and Bismuth's *Compliance Auditing for Pharmaceutical Manufacturers* heads this subject's reference list, and its professional habit is worth naming: the compliance auditor tests **the system against its claims**, sampling records for the story they tell about everyday practice, because a site can be immaculate on the day and non compliant in its records, and the records, under Unit 1's rule, are the only admissible version of everyday practice.

3.4 Audit policy and the audit programme

Audits do not happen by enthusiasm; they run under an **audit policy** and a managed **audit programme**. The policy, set by senior management, states the organisation's commitment: what will be audited (all GMP areas, all sites, all critical suppliers), how often (a risk based cycle, commonly every area at least annually and critical suppliers on a defined rhythm), by whom (trained auditors independent of the audited activity), and what happens to findings (grading, response times, escalation, follow up). The programme is the policy made calendrical: the schedule of audits for the period, auditor assignments and competence records, notification rules, and the tracking of reports and closures. An inspector evaluating a company's self inspection almost always begins here, with policy and programme rather than with any single report, because a programme that quietly omits an awkward area or lets findings age unclosed condemns the system more efficiently than any individual deficiency.

3.5 Auditing strategy and the conduct of an audit

Auditing strategy is the choice of how evidence will be gathered efficiently: which areas and records to sample, in what depth, in which order, with what mix of document review, interview and direct observation, and how to follow the **audit trail**, the technique of taking one object (a batch, a complaint, a deviation) and chasing it through every system it touched. The conduct of an individual audit then follows the profession's fixed rhythm:

The rhythm of an audit (the sequence examinations expect)

Preparation: scope, criteria, checklist, document request, plan

-> Opening meeting: purpose, scope, method, timetable agreed

-> Evidence gathering: records, interviews, observation, trails

-> Findings: graded, evidenced, discussed as they arise

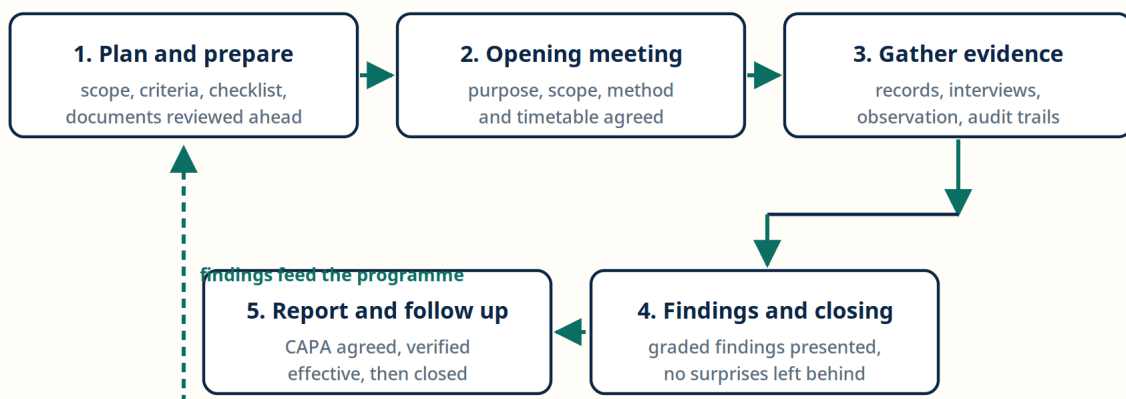
-> Closing meeting: findings presented, no surprises left

-> Report: written, distributed to defined recipients

-> Response and follow up: CAPA agreed, verified, closed

Preparation deserves its own sentence: the auditor reviews the auditee's documents in advance (the site master file of Unit 1, previous reports, the deviation and change profile) and builds a **checklist** from the criteria, so the audit day is spent on evidence rather than orientation. During evidence gathering the craft is triangulation, claim, record and observation agreeing before a point is scored compliant, and findings are graded in the vocabulary of the system under audit: in regulatory inspection language **critical, major and other** deficiencies; in internal systems often critical, major and minor. Professional conduct is part of the method: auditors observe and record, do not consult or design corrections on the spot, and do not conceal a finding for later ambush.

The Audit Cycle



An audit is a cycle inside a programme, not an event on a calendar.

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Figure: The audit cycle. Findings return to the programme as new risk information, which is why the audit programme is a cycle and not a diary.

3.6 Audit analysis, the audit report and follow up

After the closing meeting, the work of **audit analysis** converts notes into findings that can survive challenge: each finding written as criterion, evidence and conclusion (what the rule requires, what was objectively found, why the two diverge), graded, and stripped of opinion and excess. The **audit report** fixes this in the record: identification of the audit (scope, dates, auditors, criteria), the findings in full, the auditee's areas of strength where relevant, and the required response and its deadline. The report is a controlled document with defined distribution, because it may later be read by a regulator as evidence of the company's honesty with itself. **Audit follow up** closes the loop: the auditee's response with root cause and CAPA (Unit 4), the auditor's assessment of that response, verification that the promised actions were actually taken and effective (a **follow up audit** where the findings warrant), and formal **closure** recorded against each finding. The measure of an audit system is its closure discipline: findings that recur audit after audit announce that follow up, not auditing, is the broken step.

3.7 Audits and inspections of facilities by regulatory agencies, and timelines

Above the company's own audit system stands the **regulatory inspection**, which Unit 4 treats in full; this unit places it in the audit landscape and teaches its **timelines**, the calendar discipline both sides work to. The patterns worth stating are these. Inspections may be **announced or unannounced**: routine GMP surveillance inspections by many authorities are unannounced or short notice, while pre approval inspections (Unit 4) are scheduled against the application's review clock. The inspection itself occupies days, scaled to the site; its written outcomes run on defined clocks, most famously the expectation that a company **responds to a US Form FDA 483 within 15 business days** if the response is to inform the agency's decision on escalation (Unit 5), and the European practice under which a **GMP certificate is issued following a satisfactory inspection and is generally valid for three years**, with the inspection report and any deficiency letter answered within the period the inspectorate sets. Audit and inspection preparation inside companies, the mock audits and readiness programmes of industry, are built backwards from exactly these timelines: the professional skill is not knowing that an inspection will come, but knowing precisely what will be asked, and by when, at every step after it does.

3.8 GHTF Study Group 4 and ISO 13485: auditing in the device world

For medical devices, the audit framework was harmonised by **GHTF Study Group 4**, met in MRA101T for the GHTF family as a whole: SG4 wrote the guidance on **regulatory auditing of quality management systems of medical device manufacturers**, covering the audit process itself, the competence and training of regulatory auditors, and a **graded nonconformity system** that converts findings into a common scale so different auditing organisations reach comparable conclusions, work carried forward today under IMDRF and visible in the Medical Device Single Audit Program (MDSAP), in which one audit by a recognised auditing organisation serves several regulators at once. The criteria those audits test against are the device quality system of **ISO 13485**, the international standard specifying quality management system requirements for medical devices, design control, sterile manufacture, risk management linkage and regulatory reporting among them. For this subject the pairing is the point: SG4 standardised **how device QMS audits are done**, ISO 13485 states **what they are done against**, and a regulatory affairs professional meets both wherever devices enter a dossier, a supplier file or an audit programme.

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