Quality Audits

Here we are in the Quality Auditing Section of the CQT Body of Knowledge!

First, what is an audit.

An audit can be described as formal, systematic, independent & fact-based process of collecting objective evidence to assess the extent to which the auditee is in compliance with the audit criteria (requirement or standard).

Why do we Audit

In the last chapter we discussed the ISO 9000 series of Quality Management Standards, and one of the **requirements within ISO 9001** (8.2.2 - Internal Audits) says that organizations shall conduct audits of their Quality Management System to ensure effectiveness & conformity.

To take that one step further, there's actually one ISO Standard within the ISO 9000 series that we have not discussed yet- **ISO 19011:2011** (Guidelines for Auditing Management Systems).

As the name of the standard implies, this standard lays out the guidelines (read: NOT requirements) for auditing a management system.

What's the Value in Auditing

Do we only audit because ISO says we have to, or does it actually improve our businesses?

The answer is the later, **auditing is a proven method to quality control and quality improvement.**

Auditing is, very simply, collecting data about our systems/processes/products in order to identify ongoing problems, or problems that might occur in order to make improvements.

Here's a quick list of the different "value propositions" associated with Quality Audits:

- Quality Audits can be utilized to **verify product conformance** to customer requirements
- Quality Audits can be used for **Registration to an ISO Standard** for ISO Certification
- Quality Audits **challenge suppliers** to ensure they are meeting all requirements
- Quality Audits **provide data to upper management** to help them:
    - Take corrective actions for any uncover issues
    - Take preventative actions for any potential issues uncovered
    - Make improvements or enhancements to the overall effectiveness of their systems, processes or products

Bottom line though, we audit to add value to & improve the organization being audited.

Topics Covered Below

There are 4 topic areas that I will touch on below to help you expand your understanding of Quality Auditing.

1. **Type of Audits** - ISO 9001 only requires internal auditing, however there are many of different types of audits that you as a Quality Technician may be called upon to participate in.
2. **Roles & Responsibilities -** There are 3 primary roles that are normally involved in Quality Audits. As a Quality Technician you will find yourself playing any of those roles and you must know what the Responsibilities are for each.
3. **Audit Planning & Implementation -** To ensure that your Quality Audits are effective and efficient, you must understand the best practices around Audit Planning & Execution. This section covers the tools & techniques that the best auditors use to plan effectively and then collect the best data during the audit.
4. **Audit Reporting & Follow Up** - An Audit is a documented exercise that requires a formal Audit Report, and then Follow Up to ensure that corrective actions have been taken to address any observations.

The 3 Types of Audits

There are 3 different ways to classify an audit; by the **relationship** of the parties involved, by the **scope** of the audit or by the **purpose** of the Audit.

One important thing to remember about these different types of audits is that they are not mutually exclusive of each other.

For example, you can have a 3rd Party Product Audit, or a 1st Party Compliance Audit, or a 2nd Party System Audit.

Audits by Relationship

The 1st way to classify an audit is by the relationship of the parties involved in the audit (Us or Them). From this perspective there are 3 different types of audits:

- **1st Party Audits** - These are audits performed by an organization, on itself and are referred to as Internal Audits. One key thing to remember when performing 1st Party Audits is that the auditor selected must be completely independent from the auditee. This will ensure there is no conflict of interest or bias that impact the audit results.
- **2nd Party Audits** - These are audits performed by an organization on a 2nd Party (suppliers, etc).
- **3rd Party Audits** - These are audits performed by an independent 3rd party on either your organization or a 2nd party (supplier).

Audits by Scope

The 2nd way to classify an audit is by the scope of the audit. From this perspective, there are 3 different types of audits:

- **System Audits** - These audits have a broad scope and encompass your entire Quality Management System.
- **Process Audits** - These audits are focused on a particular process within your QMS.
- **Product Audits** - These audits are focused on the result (product) of a particular process. They verify fitness for use (form, fit & function) and are one of the few customer-oriented audits.

As you know, A system is the set of connected processes that form a complex whole.

For example your System to manage quality (QMS) is the collection of all Quality Related Process (Document Control, Resource Management, Quality Planning, Product Realization, Measurement & Improvement, etc).

A **QMS Audit** is a ***System*** **Audit** that is used to confirm:

- A Quality Management System (QMS) has been develop and is in place
- The QMS sufficiently meets all requirements set for in the ISO Standard (If your organization is ISO Certified)
- The QMS is cascaded too & carried out at all levels of the organization

A **System Audit** is the largest and most extensive Audit which focuses on the entire Quality Management System of the organization.

A **Process Audit** usually concentrates on 1 or 2 specific processes within an organization.

A **Product Audit** is a final assessment of Final Product (after final inspection) to ensure conformance to all requirements and "Fitness for Use".

The **process audit** is the 2nd largest audit in terms of scope because these audits can cover all aspects of the process. These include the processes inputs, activities, outputs, process controls, training & any other aspect of the process.

The **product audit** is the 3rd and smallest audit in terms of scope. The product audit is different from final inspection. The product audit is conducted AFTER final inspection, and after the product has been "released" for sale. This ensures that the audit captures any issues associated with the entire process including final inspection & release.

These audits are performed to confirm "Fitness for Use" (Form/Fit & Function) and conformance to all customer requirements.

Audits by Purpose

The 3rd way to classify an audit is by the **purpose of the audit**. From this perspective, there are 3 unique audit types you need to be familiar with:

- **Registration Audits** - The purpose of a registration audit is to become certified to a particular standard, the most common registration is **ISO 9000 certification**. Other industry specific registration audits are conducted for industry specific standards (ISO 13485 for the Medical Device Industry or TL - 9000 for the Telecommunications industry). This type of audit is always a 3rd Party Audit.
- **Supplier Audits** - These audits are conducted on suppliers with one of the following purposes - initial *evaluation of the supplier*, the *certification of the supplier* or the *on-going management of a supplier*. This audit is generally considered a 2nd Party Audit, however there are large organizations that have internal suppliers that they audit.
- **Compliance Audits** - The purpose of these audits is to **confirm Compliance**. This compliance can be compliance to Regulatory Requirements, compliance to product specifications, compliance to internal procedures or compliance to any other requirement within your process. These can be 1st, 2nd or 3rd Party Audits.

Roles & Responsibilities in a Quality Audit

There are 3 primary parties that participate in a Quality Audit, these are the **Auditors** (Lead Auditor & Audit Team), the **Auditee** & the **Client**. Their responsibilities are outlined below, and then discussed in more detail as we walk through the typical audit planning & process below.

The Lead Auditor Responsibilities

The Lead Auditor is the most important role on the audit team, and in some situations this person represents the entire audit team.

The lead auditor has some unique responsibilities that include:

- communicating with the client prior to the audit,
- preparing the audit plan,
- selecting any other co-auditors,
- leading the audit,
- maintaining the ethical standards of the audit team,
- managing conflict
- preparing & submitting the final audit report to back to the client

One critically important responsibilities of the Lead Auditor that's worth repeating is *the selection of the remaining audit team*.

This process of selecting only qualified auditors is a key guideline in ISO 19011 which stipulates that the selection process should be based on the experience, skills, training & knowledge of all applicable industry or regulatory requirements associated with the audit.

When planning the audit, the Lead Auditor can use his knowledge of his audit teams strengths and weaknesses to assign audit responsibilities.

This selection & assignment process, more than any other activity, has the greatest impact on the effectiveness of the audit.

Auditor Team Responsibilities

If multiple auditors are utilized during an audit, the secondary auditors (non-lead auditors) are responsible for maintaining objectivity & confidentiality during the audit, remaining within the pre-defined scope of the audit, collecting and analyzing audit evidence for findings, acting ethically & being experienced in the areas associated with the scope of the audit.

They are also required to support the lead auditor in the preparation of the final audit report and verifying the effectiveness of the corrective actions that stem from the audit itself.

The Auditees Responsibilities

The Auditee is the individual or team who is being audited, and they also have some very unique responsibilities during a Quality Audit.

These responsibilities include cooperating with the auditors, appointing staff to accompany audit teams (guides), ensuring all subject matter experts are available to support the audit, providing resources needed by the audit team & then once the audit is over and the audit report has been received, **determining & implementing appropriate corrective actions.**

The Clients Responsibilities

The client is the individual or team who has requested the audit. In some cases, like 1st part audits, the client is the same person as the auditee.

In other cases, like 3rd party audits, your organization can be the client and you've requested that a 2nd party (supplier) be audited by an independent 3rd party auditor.

The responsibilities of the client include; **determining the need, scope, objective & purpose of the audit**, selecting the auditors (for 3rd party Audits) and determining the follow-up actions after the audit.

These follow up actions are different than the corrective actions (which are owned by the Auditee) and are normally associated with the requirement to the auditee for a response to the Audit Report along with any other decisions regarding follow up Audits.

Quality Audit Planning & Execution

Audit Planning

Similar to any other activity, the success or effectiveness of an endeavor is highly correlated to the amount of time spent planning and preparing for that endeavor. This preparation includes work from all three major parties associated with the audit; the auditor, the auditee and the client.

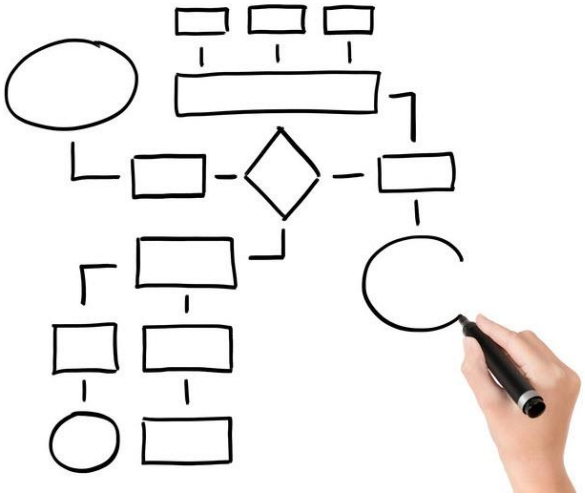
First the lead auditor must work with the client to determine the scope & purpose of the audit. With this information, the lead auditor can then prepare the Audit Plan, and then communicate that back to the client for approval and then ultimately to the auditee for awareness.

The **Audit Plan** includes the WHO, WHAT, WHEN, WHERE & WHY of the audit which include:

- The scope & purpose of the audit (WHY)
- The standards against which the audit will be conducted (WHAT)
- The auditor team conducting the audit & their areas of responsibility (WHO & WHAT)
- The time, date & location of the audit (WHEN & WHERE)
- The confidentiality requirements associated with the audit

The Audit Plan can be enhanced through the usage of two key tools; the **Flow Chart** & **Audit Checklist**.

The **Flow Chart** can be a powerful tool when preparing for a large or complex Audit. This tool can be used to summarize & delineate the audit plan and can be used to help the auditors move through the audit in a systematic method.



Similar to the Flow Chart is the **Audit Checklist**. A Checklist can also be utilized in a complex audit situation to ensure that every necessary requirement has been reviewed & verified.

This audit checklist is often a direct reflection of the audit scope & can include each unique audit criteria to be covered.

The **checklist** can also be setup to define which auditors are responsible for covering which area. This should be based on the auditors experience & qualification and can allow audit teams to work in parallel.

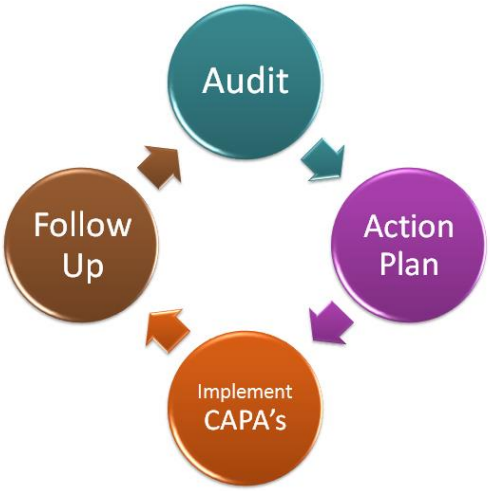
Q#	ISO 9001:2015 Clause	Audit Question	Audit Evidence
	7.1.5 Monitoring and measuring resources		
7.1.5q1	Where monitoring or measuring is used for evidence of conformity of products and services to specified requirements the organization shall determine the resources needed to ensure valid and reliable monitoring and measuring results.	How are the resources determined for ensuring valid and reliable monitoring and measuring results, where used?	
7.1.5q2	The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken; b) are maintained to ensure their continued fitness for their purpose.	How do you ensure that resources provided are suitable for the specific monitoring and measurement activities and are maintained to ensure continued fitness for purpose?	
7.1.5q3	The organization shall retain appropriate documented information as evidence of fitness for purpose of monitoring and measurement resources.	Show me the **documented information** which is evidence of fitness for purpose of monitoring and measurement resources.	
7.1.5q4	Where measurement traceability is: a statutory or regulatory requirement; a customer or relevant interested party expectation; or considered by the organization to be an essential part of providing confidence in the validity of measurement results; measuring instruments shall be: -verified or calibrated at specified intervals or prior to use against measurement standards traceable to international or national measurement standards. Where no such standards exist, the basis used for calibration or verification shall be retained as documented information; -identified in order to determine their calibration status; -safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.	Where applicable, show me how measurement instruments are: Verified or calibrated at specified intervals against national or international measurement standards; If there are no standards, show me the **documented information** which is used as the basis used for calibration or verification. Show me how measurement instruments are identified to determine their calibration status. Show me how they are safeguarded from adjustments. Show me how they are safeguarded from damage and deterioration.	

Similarly, the checklist can keep an audit member on track by including estimated audit times for each topic.

Finally, checklists are valuable in that they can be used to ensures that auditors are performing audits in a similar way.

For example, a Supplier Audit Checklist can be prepared to ensure all suppliers are rated against the same audit criteria, etc.

The Audit Checklist is also very useful in creating the final audit report as it can be used to record data, or any findings/observations.



The Audit Process

Now that audit day is here, most audits follow the linear process shown below:

1. The Opening Meeting
2. The Data Collection Phase of the Audit
3. The Closing Meeting

The Opening Meeting of a Quality Audit

The opening meeting of an audit is generally the first face-to-face meeting between the auditors and the auditees.

This opening meeting should be used as an opportunity to introduce the auditors to the auditee team & establish the lines of communication for the remainder of the audit.

The opening meeting should also include a review of the Audit Plan, to review the scope & objectives of the Audit and explain any vague information.

This opening meeting can be a simply, quick & informal event when there is familiarity between the auditees & auditors (1st Party Internal Audits), or can be a very formal process for other larger audits (3rd Party Registration Audits).

The Data Collection Phase of the Audit

Once the opening meeting is over, the audit is then underway. In this phase, it is the auditors job to collect data or evidence to either prove or disprove conformance to the requirement.

There are a handful of **techniques** that an auditor can use during this phase of the audit which include:

- **Evaluation of Physical Evidence**
- **Observations of Actual Activities**
- **Interviews with Employees & Subject Matter Experts**
- **Verifying Documents & Records**
- **Forward and Backwards tracing**

Physical Evidence can include activities like a physical inspection of process equipment or measurement tools. This can also represent a tour of the facility being audited.

This technique goes hand in hand with the **observation of actual activities**.

The best way to confirm compliance with an internal procedure is to observe that process and compare your observations against the procedure. This can go hand-in-hand with your tour of the facility (review of physical evidence).

The next major tool that an auditor can us is the **interview process**.

In this tool, an auditor will hold a discussion of the topic under audit with the employees who are affiliated with that topic and the subject matter experts in that area.

This interview process can reveal process deficiencies or deviations from the procedure. When interviewing the auditee, it is important to avoid miss-communication when possible.

Auditors should be sure to ask clarifying questions to ensure they've properly understood the auditee and allow them to clarify any important points.

Finally, auditors can perform a **verification of any physical documents or records**. As we learned in the Documentation Chapter, Records should be maintained as physical proof that a process was executed per all the applicable procedures.

These records can be reviewed for any non-conformances or trends that require additional analysis.

With all of this information, an auditor should be capable of assessing the organization degree of "compliance".

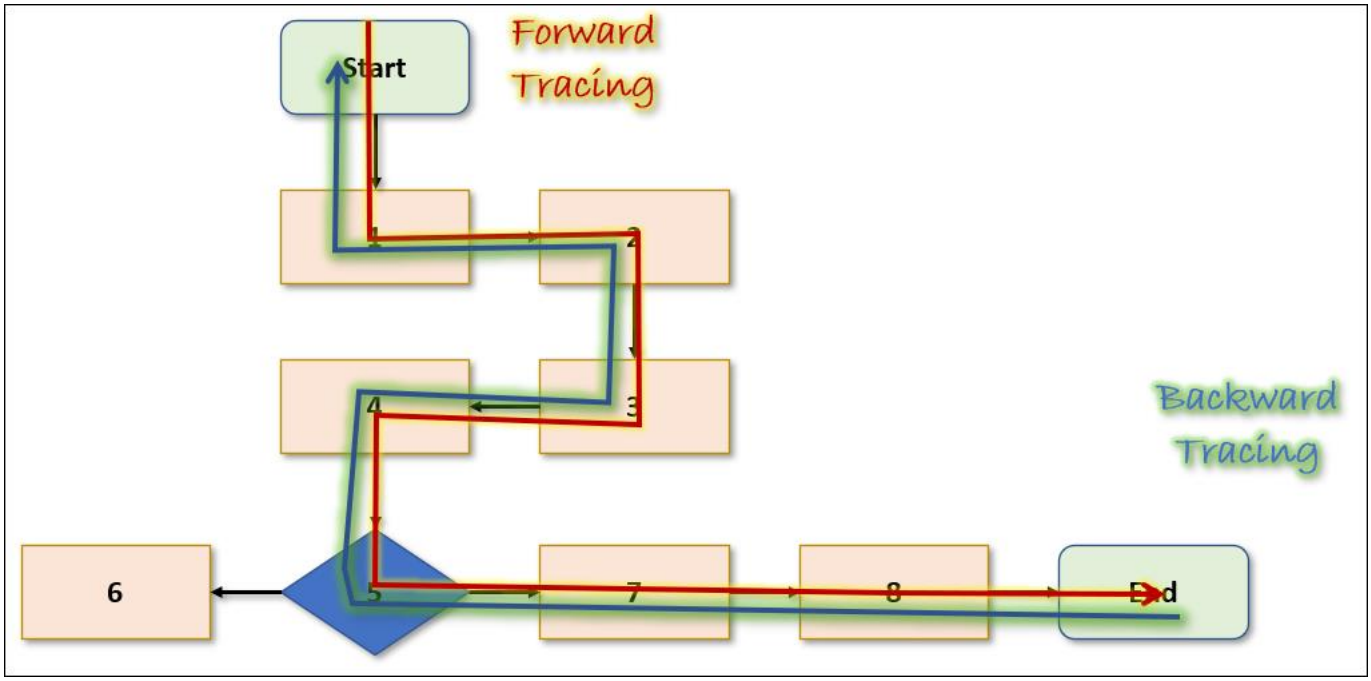
Similar to above, this compliance can be compliance to their own internal procedures, compliance to regulatory standards or compliance to the customer requirements (product specifications).

Any observations or findings made by the auditor during this period should be noted and discussed with the auditee.

The final tool in the auditing toolkit is the concept of **forward and backward tracing**.

When we're evaluating a process, the logical approach is to walk that process from start to finish, to see if the process is being followed according to the procedure. That is called **forward tracing**.

The other approach, which seems counter-intuitive, but can often be very revealing is to walk the process backwards, this is called **backward tracing**. This can often reveal inconsistencies, or issues in the process that were not observed when viewing the process from the other perspective.



Remember, while performing the audit, you can document all of your observations on your working papers, which should align with your audit checklist.

The last thing to remember in an audit, is that auditing is inherently a **sampling activity**. Meaning that we can't check every document, or review every validation, we must take a sampling from the auditee and evaluate their compliance based on that sample.

As such, there is a **risk** that the **audit evidence** may not be representative (accurate), and can lead us to the wrong conclusion in the audit results. Specifically, there are two types of error to watch out for:

- Type 1 Error – You might find "negative results" when in reality the system is satisfactory.
- Type 2 Error – You might find "positive results" when in the reality the system is broken.

Audit Findings

All Audit Findings are different, however they're all written in a similar way. **Any audit finding should include 4 things, not necessarily in the order below:**

1. The associated requirement or standard that has been violated (Audit Criteria).
2. The finding itself, which should be a direct link between the Audit Criteria & the way in which the criteria have not been fulfilled.
3. The supporting fact & data that led to the observation.
4. The classification of the finding (minor, major or critical).

The Closing Meeting of a Quality Audit

Every audit concludes with a Closing Meeting. Similar to the Opening Meeting, this event can vary in length and formality depending on the scope of the audit and the parties involved (1st party, 2nd party, etc).

This audit meeting should include a summary of any observations or findings made by the auditor to the auditee's senior management along with any positive comments or observations.

At this point the lead auditor should also commit to supplying the completed audit report within a given time period.

If requested, the auditor can also make recommendations for corrective action, however the final corrective actions are the responsibility of the auditee.

Audit Reporting & Follow Up

Once the actual audit has concluded, it is now the responsibility of the lead auditor to create the audit report.

The Audit Report contains details of the audit include findings, observations and a judgment of the extent of the auditees compliance to the criteria being audited against.

The Audit Report should be clear, concise & fact based. The Audit Report should clearly indicate areas of conformance and any observations made.

The **Audit Report** should summarize all the details surrounding the audit, including:

- The purpose & scope of the audit, similar to the audit plan
- The Standards & Requirements used in the audit
- Identification of all parties involved in the audit
- **Any findings or observations** made in the audit, potentially classified into categories (Minor, Major or Critical)
- Any positive findings that confirm the organizations compliance with key requirements, etc.
- Final Results, Conclusion & any Recommendations
- Provisions for Auditee Responses & Corrective Actions.

This audit report is then delivered to the client which signifies the completion of the audit.

The client is then responsible to work with the auditee to ensure that appropriate corrective actions are implemented to address any findings.

The client and auditor should also agree to an appropriate level of follow up to ensure that the corrective actions were implemented and effective at addressing the audit findings.

Risk-Based Thinking in Auditing

Before we wrap up, we need to discuss one new concept, that actually applies throughout the entire auditing process, and that is the idea of **Risk-Based Thinking**.

As we talked about in the Quality Standards section, the ISO 9001 standard was updated in 2015, and one of the major updates to that standard was the concept of **RISK BASED THINKING**.

As such, the ISO Standard for auditing (ISO 19011) was updated in 2018 to also incorporate Risk Based Thinking throughout the entire auditing process (Planning, Execution and Report).

The standard says - **The concept of Risk should substantively influence the planning, conducting and reporting of audits.**

Let's quickly talk about how you can apply risk-based thinking to the three phases of an audit.

Risk-Based Thinking in Audit Planning

Remember that the most important tool in audit planning is the Audit Plan, which defines the WHO, WHAT, WHEN, WHERE and WHY of an audit.

When you're creating the audit plan, you should consider RISK which might impact the scope and objective of the audit, as well as the date, time, and duration of the audit.

The updated ISO Standard also gives us guidance as to how RISK my impact our audit plan, which includes priority setting:

Priority (allocating resources and methods) should be given to **matters in a management system** with **higher inherent risk** and lower levels of performance.

Also, the use of **audit methods** (on-site, remote) should include consideration for risk.

Risk-Based Thinking in Audit Execution

Auditing is fundamentally a sampling activity. Meaning that you can't audit 100% of all activities, or all documents, you must take a sample, and then base our audit conclusions on the results of that sample.

This sampling risk can go both ways. It can cause you to conclude that your audit results are positive when in reality the audit should have a negative outcome. Similarly, it can cause you to conclude that your audit results are negative, when in reality they should be positive.

This sampling risk is something to keep in mind when collecting data during audit execution. This might mean a larger sample size when auditing criteria that have a high potential for risk. That larger sample size will increase the confidence that you have in your conclusion. Similarly, if you're auditing a criteria that has inherently lower risk, smaller sample sizes can be tolerated.

Risk-Based Thinking in Audit Reporting

Lastly, we must consider how to inject risk-based thinking into our audit reported, which can happen in multiple ways.

First, is the classification of findings (minor, major, critical) which we've already discussed. This classification is essentially a representation of **risk**.

That risk level should determine the level of audit follow up in terms of the **thoroughness and timeliness** of the corrective actions that address those findings.

Conclusion

This chapter covers the 4 areas of an audit that Quality Technicians must be familiar with.

The first of these four key areas are the different **types of audits**. As we learned, there are 3 different ways to classify an audit; by the **relationship** of the parties involved, by the **focus** of the audit or by the **purpose** of the Audit.

- **Audits by Relationship** include 1st Party Audits (Us Auditing Us), 2nd Party Audits (Us Auditing Them) & 3rd Party Audits (Them Auditing Them or Them Auditing Us).
- **Audits by Scope** include System Audits, Process Audits & Product Audits.
- **Audits by Purpose** include Compliance Audits, Registration Audits & Supplier Audits.

We also learned that these types of audits are not mutually exclusive and simply represent similar audits from different perspectives.

The second of the four key areas of a Quality Audit is the **Roles and responsibilities in audits**. This section covered the 3 primary roles in an audit & the responsibility for each:

- **The Auditors** (Lead Auditor & Audit Team) are the individuals or teams performing the audit.
- **The Auditee** is the individual or team who is being audited.
- **The Client** is the individual or team who is being audited.

The third of the four key areas of a Quality Audit is the **Audit Planning & Execution Phase**. This section covered the importance of an **audit plan**, along with the details of a typical audit plan.

Next, the section detailed the typical audit process, which normally follow the linear process shown below:

1. The Opening Meeting
2. The Data Collection Phase of the Audit
3. The Closing Meeting

Finally, this chapter discussed the fourth key area of a Quality Audit which include the **Audit Reporting and Follow Up.**

This section details the process of creating an **Audit Report**, and the appropriate level of follow up required from the Auditor, Auditee & Client to ensure that effective corrective actions are implemented to address any audit observations.