Example: How do you check in material coming into the plant site?

An open-ended question is usually followed by a probing question to clarify or amplify information.

Interview: Dialogue or conversation that occurs during the normal course of an audit.

Opening meeting: A meeting held between the auditee and auditors before the audit officially starts.

Pre-PAI audits/Mock-PAI: An audit performed by QA to determine if a site is prepared for a regulatory Pre Approval Inspection (PAI). This audit usually takes place prior to the submission of a regulatory filing.

Probing Question: A question used to clarify answers or discover more in-depth information. It is usually specific, focused and used after a general question has been asked.

Example: You mentioned that you documented the arrival of raw materials, what do you record on that documentation?

Supplier: An umbrella term that covers both Vendors and Contractors supplying API, intermediates, raw materials, packaging components, excipients, formulated products, packaged products and/or providing services, e.g. calibration, validation, laboratory testing etc. to the sponsoring firm.

Vendor: Provider of API, raw material, excipients and packaging components to sponsoring firm. A vendor supplies articles of commerce (i.e. available for purchase by other companies).

Warning Letter: A letter sent by the Food and Drug Administration (FDA) to management of a company indicating that GMP violations were found in a recent inspection and what the violations were. The expectation is that the company will respond within a designated time period with an acceptable corrective action plan.

Explanation of Topic

Introduction
This unit will outline the steps to follow and important factors involved in performing a quality assurance audit. This unit will not only focus on the actual audit process but also the techniques and skills the auditor should have to conduct a GMP audit and key elements of auditing an audit function.

Auditing essentials can be categorized into the following broad topics:

> ➢ The who, what, where, when and why of a compliance audit
> ➢ The Auditor's Role
> ➢ The Audit Process

The following sections will provide more detailed information on these categories.

Auditing Principles for a GMP Audit

Interviewing/questioning

Discussions with site personnel are excellent ways to determine potential problems. These may occur during the site's response to your questions, during the walk through or during documentation reviews. Your interviewing technique is very important. Be polite and do not use a tone that may be perceived as accusatory or confrontational. The following interview techniques can help make your audit more successful.

Interviewing/Questioning

- ➢ Introduce yourself to the interviewee.
- ➢ Be polite, patient, professional, ALWAYS.
- ➢ Do not exhibit a confrontational attitude.
- ➢ Don't become emotional and remain objective.
- ➢ When asking for information, phrase your question to assure that you are NOT providing the answer.
- ➢ Don't ask yes/no questions.
- ➢ Start with overview questions and open-ended questions.
- ➢ If you receive answers that fully explain or provide the information you need, stop there.
- ➢ If you do not receive the information needed, start using probing questions. If probing questions are used, be attentive and encourage further explanation by interjecting response phrases like "I see" from time to time. When appropriate ask to see examples of information provided.
- ➢ Use your body language to encourage further discussion.
- ➢ Ask direct questions and if a general answer is given, then request an example or documentation to support the response.
- ➢ Determine the employee's function; ask for the pertinent procedures, forms, and data relevant to the task. Confirm your understanding of the task by asking questions.
- ➢ If you do not believe that you are receiving accurate information, ask confirmatory questions by asking the same question to a different interviewee or ask a different or re-phased question on the same subject to the same interviewee.
- ➢ Do not criticize an individual's performance even if you believe that it is not satisfactory. Determine if their performance is a result of their training and/ or procedures they use, or lack of management involvement.
- ➢ At the completion of the interview always thank the person for their time.

Listening technique

Another key skill that you need is a good listening technique. Unfortunately most people plan what they are going to say instead of listen to what the other person is saying. You can miss many pieces of information during an audit if you are not prepared to listen and give the auditee their time to talk.

In the following section of the text are some techniques to help increase your listening skills.

Since you will be receiving information verbally, it is important that you confirm the information collected during your interviews with documentation or field verification (observations).

- ➢ Listen—often people will be happy to provide more information than you originally requested—you just have to give them a chance!
- ➢ Give the interviewee time to respond. Keep silent. Many times people will attempt to fill awkward silence with more details.
- ➢ Practice "active listening". Ask questions at appropriate times or indicate that you are listening by interjecting, at appropriate times, small comments like " I see".
- ➢ Do not let your opinions or expectations influence what you hear!

- o Interview analysts and operators as appropriate.
- o Hold daily briefing meetings with both auditor and auditee, if appropriate.
- o Hold daily audit team meetings, if audit team approach is used.
- o Review auditee's documentation.
- o Conduct closing meeting.
- ➢ Follow-up Audit Activities
  - o Document observations in a formal report.
  - o Evaluate responses received from the firm/site ensuring responses include effective follow up actions.
  - o Ensure these actions are closed or effective closure plans are in place.
  - o Close the audit.

Audit Preparation
Determine who will conduct the audit
An audit can be conducted by a single auditor or an audit team. If you will be conducting the audit by yourself, you will need to

- ➢ Be prepared.
- ➢ Dress appropriately.
- ➢ Respond to auditee escort requirements.

If you are part of an audit team, you will need to:

- ➢ Attend a preparation meeting to discuss roles, responsibilities, strategies and logistics to be used during the audit.
- ➢ Meet with your team members at the end of each day to discuss the audit and any issues that may have appeared.
- ➢ Provide your observations, in written form, to the lead auditor.

The lead auditor will be responsible for ensuring the audit is managed effectively and efficiently. The lead auditor typically organizes the audit team, plans the audit, communicates with the auditee, prepares the agenda, conducts the audit opening and closing meetings, and coordinates and writes the audit reports. The lead auditor also reviews the auditee's response and formally closes the audit process.

Pre-audit Information Request Form
A pre-audit information request form is sent to the area managers of the site being audited.

Pre-audit Supplier Questionnaire
A supplier questionnaire is often sent to suppliers prior to the audit. The questionnaire should be evaluated before the agenda is finalized.

Develop an audit agenda
To conduct an efficient and effective audit, you should have an agenda. This will help to keep the audit flowing smoothly and will make good use of both your and the auditee's time.

The audit agenda may include:

1) Identification of the auditee contact person(s)
2) Information on when the auditee was contacted.
3) Identification of audit team members (if appropriate).
4) The purpose and scope of the audit. Internal audits and for cause audits may be limited in scope.
5) The standards that the auditee's is expected to meet.

practices are. You should also review records for accuracy and completeness.

The reasons for conducting a walk through are to:

➢ Identify both deficiencies and good compliance practices.
➢ Confirm documentation deficiencies.
➢ Verify corrective actions to previous audit findings or deviations.
➢ Verify information obtained during interviews.

As you perform the audit refer to your preparatory audit notes to assure complete audit coverage. Please refer to specific training modules for items to be reviewed/observed during the field verifications. Auditors should inform the auditee staff of observations at the time that they are observed. Auditee staff may provide information that will explain the observation or assign site resources to correct the observations or non-conformances. Immediate communication may prevent misunderstandings.

If critical issues or deviations are observed they should be **immediately** communicated to site's management and the auditor's manager or director. This assures that appropriate personnel are notified and appropriate corrective actions are implemented.

Daily briefing meetings with auditee
At the daily briefing meeting, observations and findings should be reviewed with the auditee as well as areas of concern to ensure that there are **no surprises or misunderstandings at the closing meeting.** Potential observations should be communicated to maintain openness and give the auditee an opportunity to provide additional information. If there are deficiencies that are discovered, they should also be communicated to the auditee and their staff, including members of QA.
The audit agenda should be updated if changes are required based on observations or resources.

Daily briefing meetings for audit team
These meetings are held to keep the team focused on the audit objective and the audit on course. This is when discussions should be held to update team members on the status of the audit and clarify any observations. The following should be considered when scheduling these meetings:

➢ They are generally held at the end of the day, as necessary, while everyone still is focused on the observations for that day without the auditee being present.
➢ They should be used to make schedule and/or team assignment changes.
➢ Any observations and findings should be reviewed to gain team consensus.
➢ Complex issues can be discussed and examined by all of the team.

Review Documentation
Your review may include SOPs, manufacturing and testing documentation, associated raw data, validation and qualification protocols and reports and investigations. It is important to spend time reviewing procedures for deviations, complaints and out-of-specification testing results since this may also help you to determine the company's commitment to quality.

Closing meeting
The closing meeting is the forum used to present the audit results verbally to the auditee management. It is essential that all key parties who participated in the audit and the auditee management attend the closing meeting.

The following are some guidelines for the closing meeting.