Quality Audit Training Workshop (BSQR)

Session Three

Audit Planning & Preparation

Purpose of Session

To review audit planning activities including:

- Audit programmes
- Audit planning & preparation
- Setting objectives, criteria & scope
- Audit preparation & checklists

Definition: An Audit

'systematic, independent and documented processes for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled'

ISO 19011 Section 3.1

Types of Audit

TYPE OF AUDIT	DESCRIPTION	CONDUCTED BY
Internal	First Party	By Organisation on Itself
External	Second Party	By Organisation on Supplier
Independent (and external)	Third Party	Notified Body - MHRA

Internal Audit Objectives

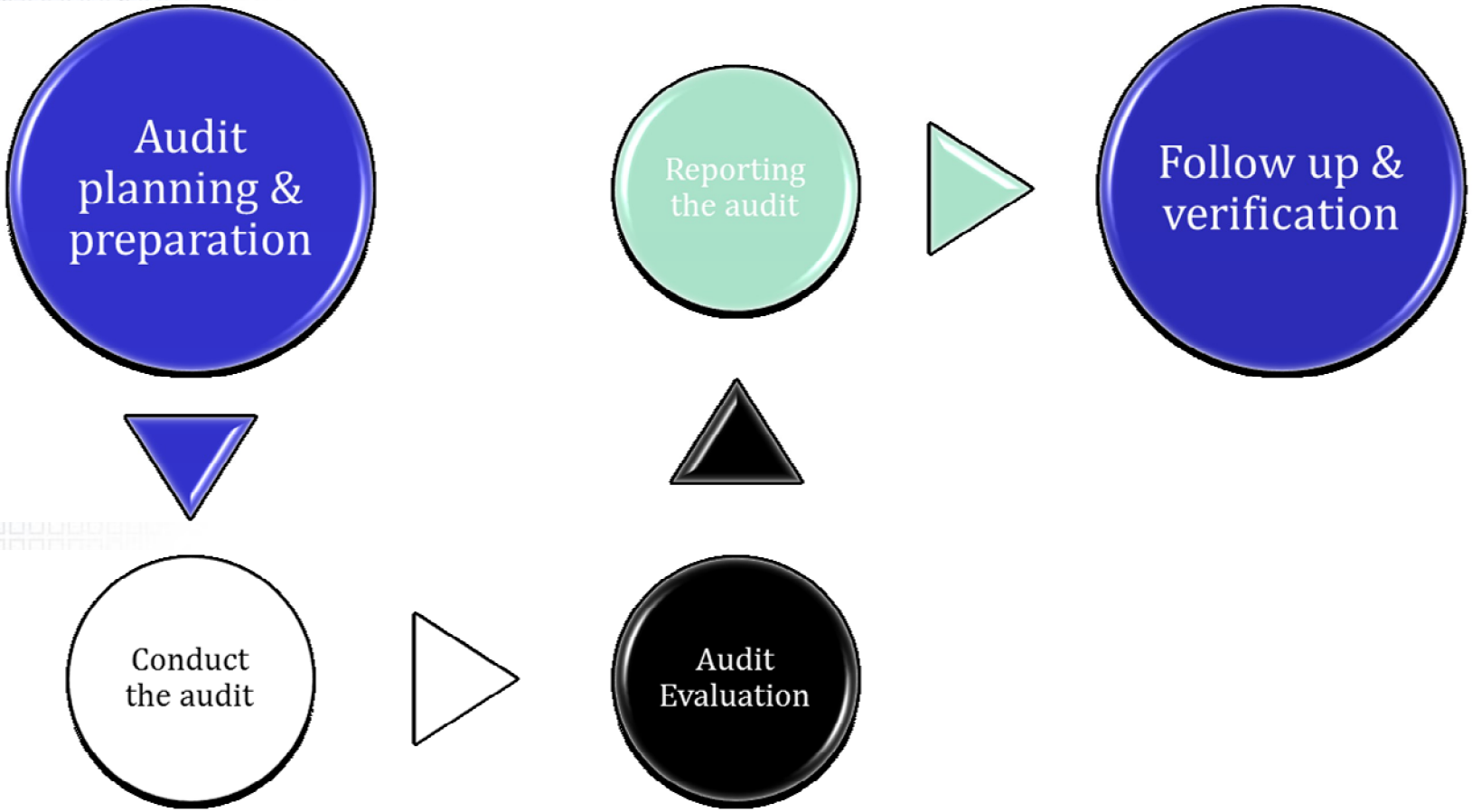
- Management priorities and objectives
- System requirements
- Regulatory requirements
- Compliance to BSQR
- Improvement Audits

Audit Programmes

Audit Programme: *Set of one or more audits planned for a specific time frame, directed towards a specific purpose*

ISO 19011

Audit Life Cycle



Audit Planning

- Defining the scope of the audit
- Defining the audit criteria
- Defining the overall audit objectives
- Contacting the area to be audited
- Review documentation
- Determine if expert help is required
- Produce audit plan (agenda)
- Prepare audit checklist

Audit Scope

‘Extent & boundaries of an audit’

Includes

- Physical location
- Organisation unit
- Activities
- Processes
- Documentation
- Time scale

Audit Criteria

'Set of policies, procedures or requirements used as reference'

- BSQR
- 'Orange Guide' & 'Red Guide'
- ICH 9,10
- Procedures (documented or otherwise)
- Specifications/standards
- Regulatory requirements

And many more…

Internal Auditor Responsibilities

- Plan the audit
- Contact the auditee & ensure availability
- Agree audit plan(agenda), scope and criteria
- Documentation review
- Checklist preparation

Checklist Contents

- Specific questions to criteria (BSQR)
- Documentation available
- Activities to observe
- Concerns/points to raise
- Records to verify
- Other considerations…
  - Previous audits
  - Changes
  - Know issues
  - Experience & knowledge

Process Checklist

BSQR	Checkpoint	Notes
5.1	Is the SOP in date? Is there a review date?	
5.1	Is the SOP clear and unambiguous?	
5.1	Is there an author, reviewer and authoriser?	
4.1	Is there a complete materials list?	
5.3 these	Are there any amendments or alterations to the SOP? Are dated and signed? Is there a reason given for the alterations?	
2.3	Are there training records available for the procedure?	
2.3/5.3	Have all staff been trained in the procedure?	

Examples of Questions....

Position	Sample Question	Guidance to Reply
All	**How was you trained and/or qualified to perform your job?**	**Mention how do you train**
All	**Are there training records that give evidence to this?**	**Answer Yes/No**
All	**Where are training records located?**	**Shop floor-HR-…etc**
All	**What forms and/or records do you use while performing your job?**	**According to your procedure you are following**
All	**How to store forms you are using?**	**Records are identified by address date, indexed and maintained according to control of records procedure**
All	**How long are they to be kept?**	**According to your procedure you are following**
All	**Who has the access of that records?**	**Your dept., members… any one who can access the record**

Examples of Questions....

Position	Sample Question	Guidance to Reply
BMS	Do you ever have problems come up? How do you handle them?	*According to the type of problems
BMS	When you find nonconforming part, what do you do?	Inform the Forman who follows the controlling of non conformity procedure
BMS	If you are responsible to perform Inspection? how do you record your results?	In Inspection Forms according to given from "XYZ" procedures
BMS	If your documentation says you should do something a specific way and someone else tells you to do it differently, what do you do?	Ask him to issue a change note
BMS	What do you do if your machine breakdown?	Make a Break down report according to procedure 123

Session Four

Conducting the Audit

Purpose of Session

At the end of the session you should have an understanding of:

- Use of checklists
- Process-based auditing
- Sampling and interviewing techniques
- Obtaining and recording objective evidence
- Effective audit practice

Use of Checklists

- Defines the scope and sample of the audit
- Use as an aide memoir
- Used to record audit evidence for:
  - You
  - The audit system
  - Objective evidence that you have done the audit

Process Audits

- Assess process risks
- Implementation of process controls
- Monitoring and measurement of the process
- Effectiveness of the process
- Continual improvement of effectiveness and efficiency

Always ask:

- Is the process implemented and maintained?
- Is the process effective?

Fact Finding not Fault Finding

Collect Objective evidence to:

- Compare
- Evaluate
- Inform

<u>Does the system conform to the criteria!</u>

Opening Meeting

May be formal or informal but will aim to:

- Confirm the audit plan
- Summarise how the audit will be conducted
- Confirm communication & reporting
- Provide opportunity for the auditee to ask questions

The Auditors 6 friends….

WHAT?

WHY?

WHEN?

HOW?

WHERE?

WHO?

The auditors 7th friend: SHOW ME!

Good Practices

- Speak clearly & simply
- Look at the person
- Body language
- Rephrase question
- Ask the right person
- Be relaxed, confident
- Impartial
- Apologise for interrupting
- Don’t look for issues
- Give positive feedback when deserved

Bad Practices

- Asking too many questions at once
- Saying you understand when you don’t
- Answering your own question
- Not giving enough time to answer
- Getting into an argument
- Relying on your memory
- Subjective opinions
- Taking sides
- Criticising individuals

Objective Evidence

- What was observed, examined or stated, where and when
- Details of requirement (standard, procedure, work instruction, specification etc.)
- Who made what statement(s)

Objective Evidence

- Evidence which exists
- Uninfluenced by emotions or prejudice
- Can be traced
- Does not need further clarifications
- Within the scope of the document

Observation

- People
- Product and service
- Processes
- Information systems

Taking Samples

When planning samples, consider:

- The major process of the department
- The other duties it undertakes
- What it does when things go wrong

Taking Samples

- Released products
- Raw materials
- In-process materials
- Inspector or sampler
- Number of samples and sample size
- Authorization

Look out for ...

- Employees understanding of the procedures that affect their work
- Managers understanding of their quality objectives and progress towards meeting these objectives
- What happens to the system when responsible person for a job is absent from work
- System integrity under an emergency

Session Five

Audit Evaluation

Purpose of Session

- Evaluating audit evidence against agreed criteria
- Writing clear nonconformity reports

Evaluating Objective Evidence

- Determine system components in full compliance and those which show best practice
- Identify nonconformities and rate them according to importance
- Identify areas of weakness where an opportunity for improvement should be raised to prevent future nonconformity or promote best practice.

Definition: Nonconformity

‘Non-fulfillment of a requirement’

ISO 9000:2005

Reporting Categories

Critical: **Has produced** a product harmful to a person, leads to a significant risk of harming a person.

Major: Has produced or may produce a product which does not comply with GMP, indicates a major deviation from GMP.

Other: A combination of several 'other' deficiencies none of which may be major but which may together represent a major deficiency and should be explained and reported as such. A departure from GMP.

Opportunity for Improvement: Minor weakness or potential improvement (optional)

Establish the facts

- Get help from the auditee
- Discuss concerns
- Verify the findings
- Record all the evidence:
  - Exact observation
  - Establish why a nonconformity or otherwise confirm
- State who (if relevant) – preferably by job title

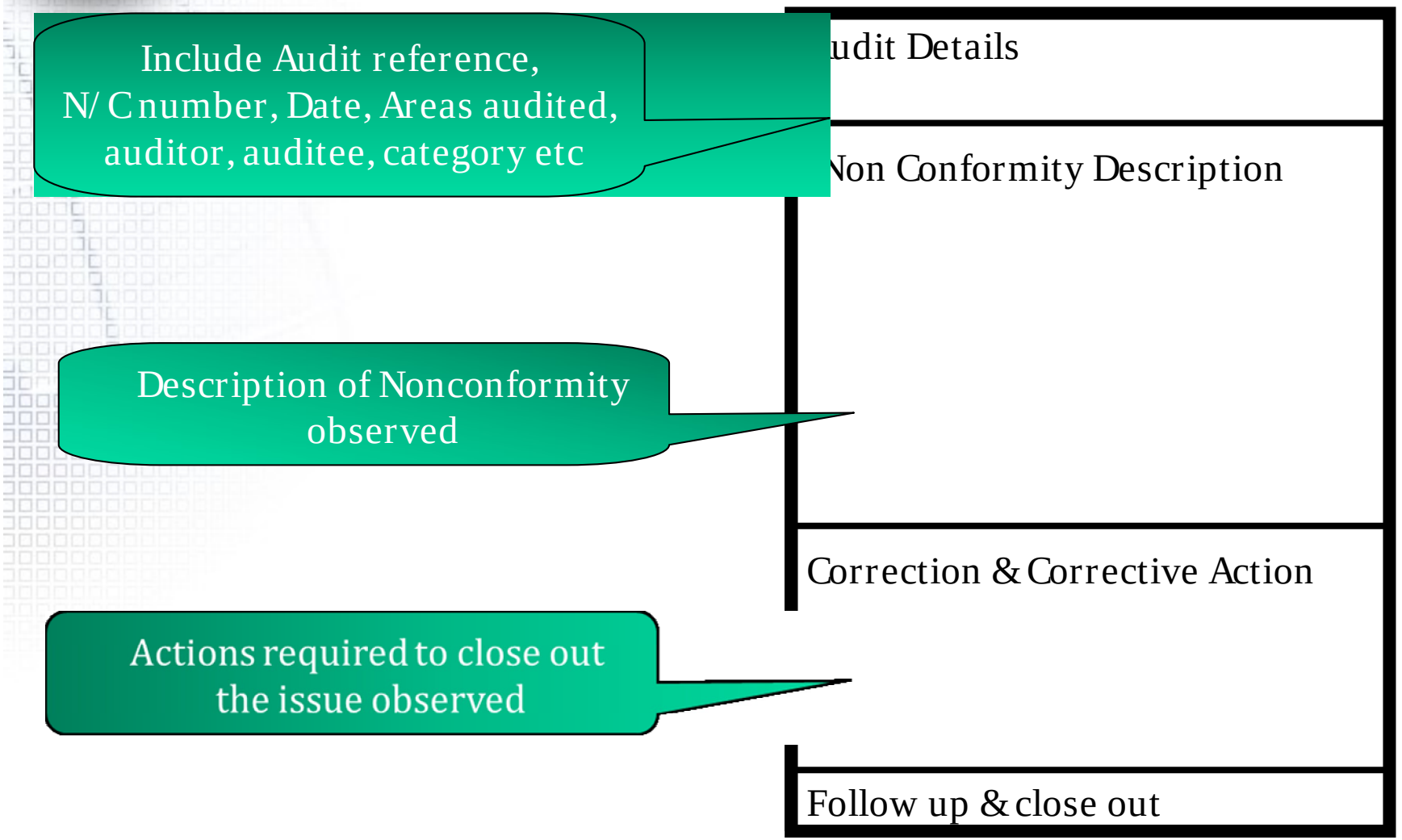
Consider the seriousness

Two questions to be answered:

1. What could go wrong if the nonconformity remains uncorrected?

2. What is the likelihood of such a thing going wrong?

Nonconformity report



Nonconformity Description

Anyone reading the nonconformity should know:

- What is the issue (location, details of issue)
- So What is wrong (stick to the facts)
- Why is it an issue (i.e. what criterion not met)

<u>Without having to ask the auditor!</u>

Writing a Nonconformity

State what you saw…

During an audit of the quality management audit system, corrective actions had not been established for nonconformities raised for audits performed in 2008 (i.e. Audits 01/08 to 06/08).

Writing a Nonconformity

State Why this is an issue

BSQR Section 10.2 states that action shall be taken to eliminate the cause of nonconformities without undue delay.

Session Six

Audit Reporting

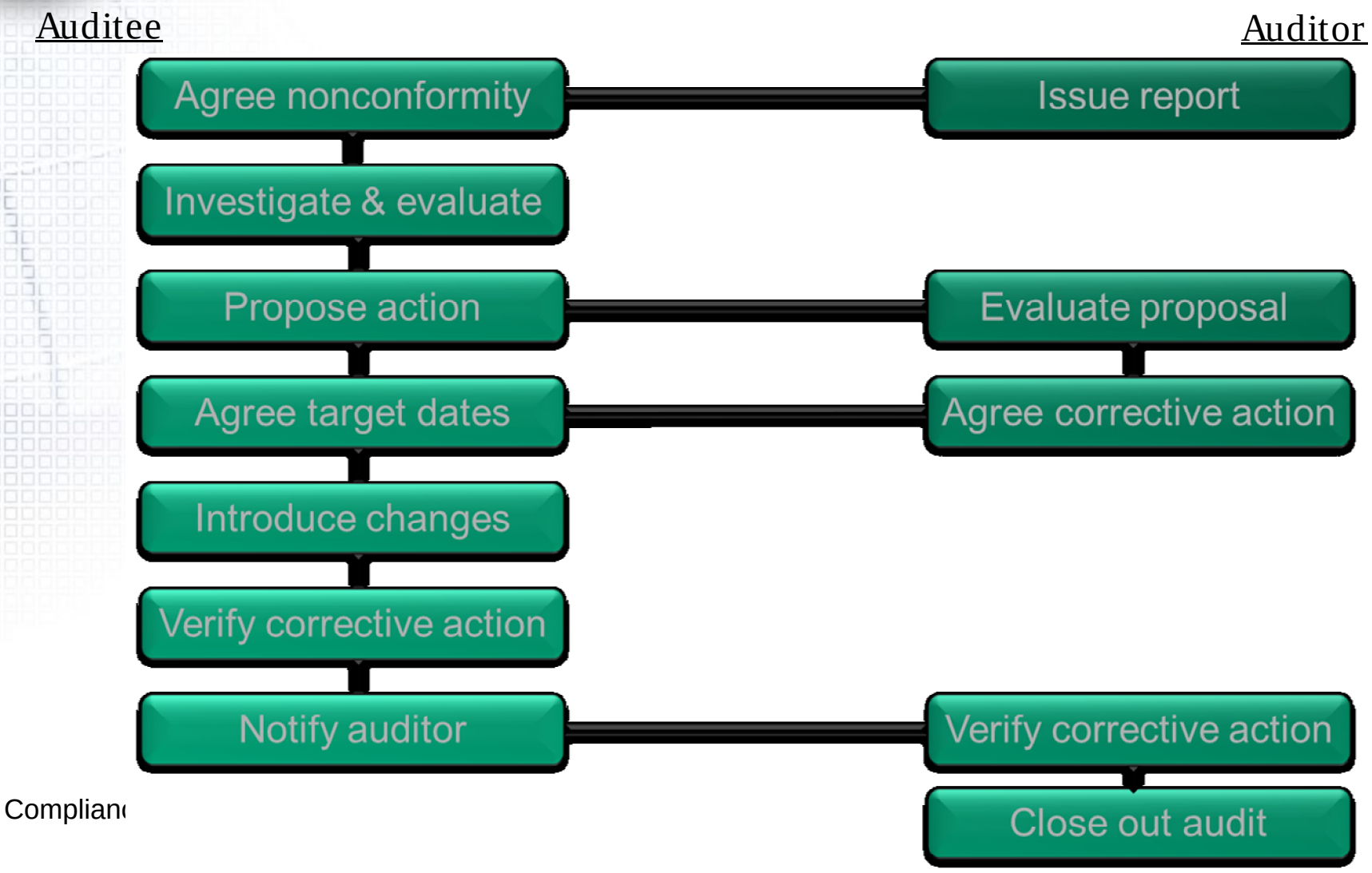
Purpose of Session

- Presenting findings at the closing meeting
- Writing an audit summary report
- Proposals for corrective actions

Closing Meeting Agenda

- Note attendees
- Thanks for cooperation
- Objectives, criteria & scope
- Summarise audit findings (positives & negatives)
- Present findings
- Agreement on corrective action
- Conclusion
- Follow up

Agreeing Corrective Actions



Correction vs. Corrective Action

Correction: Ensure an action plan is in place for all nonconformities raised during audits 01/08 to 06/08 (3 Days)

Corrective Action: Update audit procedure & train auditors (1 month)

Content of Audit Report

- Report reference
- Date of audit
- Areas visited
- Personnel involved
- Objectives, criteria & scope
- Standards and procedure
- Findings
- Agreed actions
- Corrective action follow up
- Report distribution

Audit Reporting Principles

- Never loose sight of the basic aim of an audit, namely to get management commitment to act on the findings
- It should be fair and balanced
- Never point the finger!
- Keep it simple and concise
- Keep the audit outcome confidential
- Publish in a timely manner

Audit Report.....

- A summary or record of the outcome of an audit, in line with the agreed audit objectives, scope and criteria

- Complete all findings of noncompliance and compliance on the audit report forms.

Style of Report

- Use past tense
- Keep it simple and based on fact
- Include a summary

- Be sure to sign the reports and check them for correct completion.

Avoid including…

- Insignificant details
- Confidential information
- Any points not discussed
- Ambiguous statements
- Your personal opinions

Session Seven

Audit Follow Up & Verification

Purpose of Session

At the end of this session you will have an understanding of:

- Evaluating corrective actions for effectiveness
- Closing out corrective actions

Follow Up Objectives

- Ensure corrective action has been taken
- Evaluate effectiveness
- Close out each action
- Limit to original findings
- Record/report verification of corrective actions

Follow up.....

- Follow-up activities are scheduled according to the established time frames in the corrective action.
- Follow-ups must be done and the auditor must feel that the finding has been corrected to close out the nonconformity report.
- Minor non-conformances and observations can be followed up for effective corrective action at the next scheduled internal audit.

Follow up.....

- Evaluation of submitted corrective actions
- Evaluation by continuing assessment
- Partial re-audit
- Full re-audit

Follow up action.....

- Auditee receives nonconformity report
- Corrective action plan prepared
- Submit plan (where appropriate) to auditor
- Auditor evaluates response
- Auditee implements plan
- Auditee evaluates effectiveness
- Auditee revises plan if necessary
- Auditee documents the changes
- Auditor verifies implementation and effectiveness
- Records made of all actions taken (by auditor and auditee)

Close out.....

- Once all of the follow-up is complete and the auditor is satisfied with the corrective action, he or she may close out the audit and submit it to the Quality Manager for filling.

- Copies should go to: the auditor and the auditee.

Final Session

Summary of the Course

What to Audit ?

- Understanding of corporate policies and objectives
- Compliance to procedure and standards
- Effective control on documentation & standards
- Record preparation & filing
- Competence and training of staff to perform job effectively
- Commitment of managers and workers towards continuous improvement

Scope of Internal Auditing....

- Written instructions

- Covering all aspects of GMP:
  - personnel
  - premises including personnel facilities
  - maintenance of buildings and equipment
  - storage of starting materials and finished products
  - equipment
  - production and in-process controls
  - quality control

Scope of Internal Auditing....

- documentation
- sanitation and hygiene
- validation and revalidation programmes
- calibration of instruments or measurement systems
- recall procedures
- complaints management
- labels control
- results of previous self-inspections and any corrective steps taken

Principles.....

- Ensures that a organisations operations remain compliant with GMP
- Assists in ensuring continuous quality improvement
- Should
  - cover all aspects of the organisation
  - be designed to detect shortcomings in the implementation of GMP
- Must
  - recommend corrective action if shortcomings are observed
  - set a timetable for corrective action to be completed

Principles.....

- Special occasions may demand additional internal audits.

For example

- Recalls
- Repeated incidents
- Major change

Principles.....

- Team consist of personnel who can evaluate the situation objectively
- No conflict of interest
- No revenge in mind

Points to look out for .....

- **Tricks**
- Time-wasting
- Side-tracking
- Provocation
- Samples provided
- Special case looking
- Circular argument

- **Remedies**
- Threaten to extend inspection
- Stick to programme
- Remain calm
- Select your own sample
- Take notes and keep looking
- Recognize and stop

Points to look out for .....

Tricks	**Remedies**
Trial of strength	Be firm; know your facts
Insincerity	Ignore it
Pity	Sympathize; carry on
Absentees	Call for deputy
Amnesia	Go back and get it yourself

Communication Skills

- Verbal
- Body language
- Style and tone of speech
- Facial
- Range of literacy

Listening.....

- Stop talking!
- Help the speaker to feel free to talk
- Be approachable
- Show the speaker that you are interested
- Remove distractions
- Try to understand the speaker’s point of view
- Be patient
- Hold your temper
- Try not to criticize
- Ask questions
- Stop, look and listen

Listening.....

- Listen to what is being said and look for your answers as well as the next question.

What will happen if.....

- If an auditor finds a problem :

  They will let the auditee knows immediately

- If the auditor leaves the area and says nothing about a possible problem, you can be sure no problem (s) were found.

- Auditors do NOT report findings to management without discussing it with the auditee **FIRST**.

- There are no tricks. Nothing is ‘hidden’ until later.

Thank you

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