



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

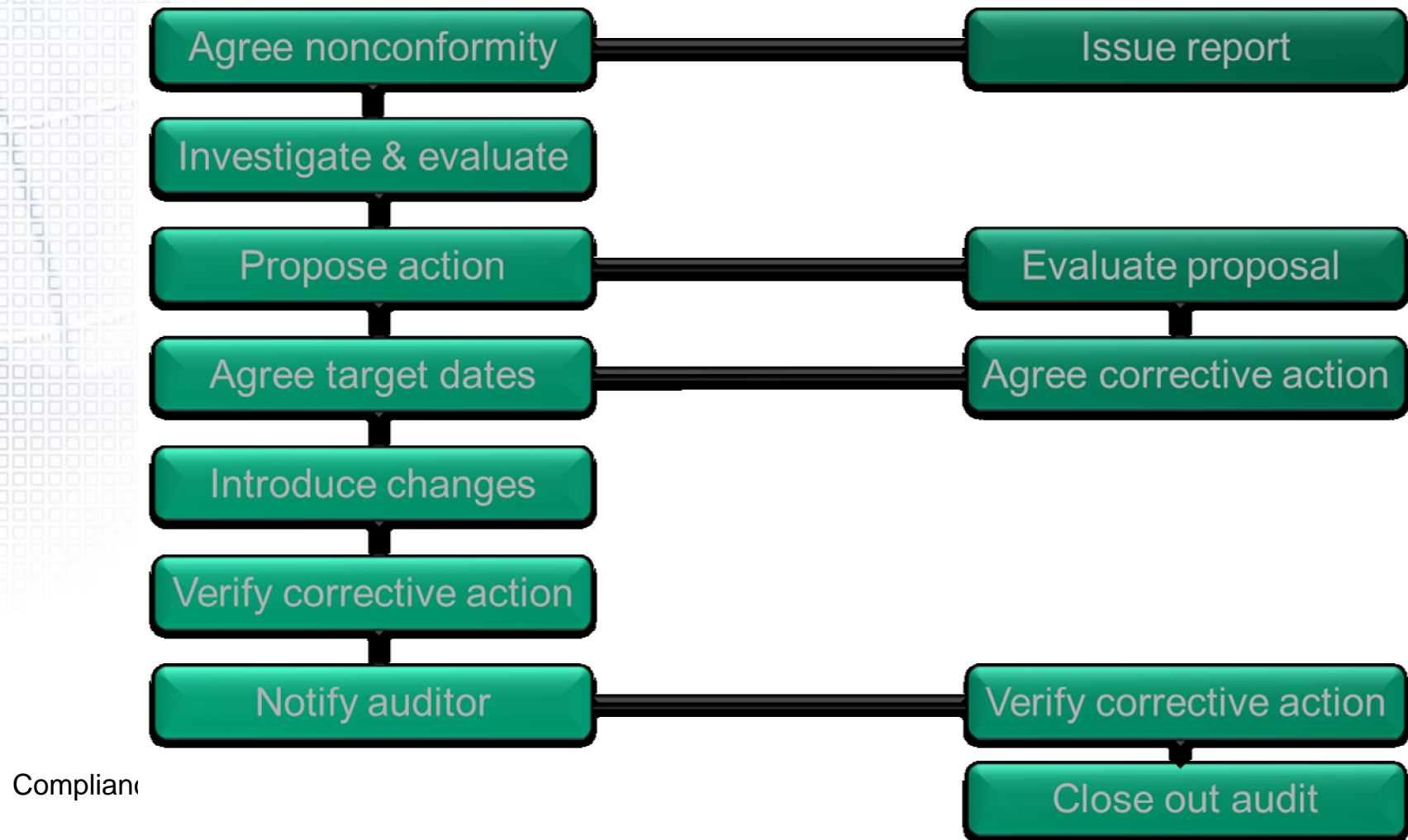
- Note attendees
- Thanks for cooperation
- Objectives, criteria & scope
- Summarise audit findings (positives & negatives)
- Present findings
- Agreement on corrective action
- Conclusion
- Follow up



Agreeing Corrective Actions

Auditee

Auditor





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 filing.
- 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**

- Trial of strength

- Insincerity

- Pity

- Absentees

- Amnesia

- **Remedies**

- Be firm; know your facts

- Ignore it

- Sympathize; carry on

- Call for deputy

- 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

Edwin Lindsay
Principal Consultant

Compliance Solutions (Life Sciences) Ltd,

Tel: + 44 (0) 7917134922

E-Mail: edwin@cslifesciences.com