

# ISO 19011 - Guidelines for auditing QMS / PQS

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**Pharm****Out**  
Regulatory Knowledge, Practically Applied.

# Auditing

## Principles of ISO 19011

- Clause 3 – Terms and definitions
- Clause 4 – Principles of auditing
- Clause 5 – Managing an audit programme
- Clause 6 – Performing an audit
- Clause 7 – Competence and evaluation of auditors
- Annex A – Guidance and illustrative examples of discipline-specific knowledge and skills of auditors
- Annex B – Additional guidance for auditors for planning and conducting audits

# Clause 3 - Definitions

## Audit

- Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

## Audit criteria

- Set of policies, procedures or requirements used as a reference against which audit evidence is compared.

## Audit evidence

- Records, statements of fact or other information which are relevant to the audit criteria and verifiable.

# Clause 3 - Definitions

## Audit findings

- Results of the evaluation of the collected audit evidence against audit.

## Audit conclusion

- Outcome of an audit, after consideration of the audit objectives and all audit findings.

## Management system

- System to establish policy and objectives and to achieve those objectives.

# Clause 4 - Six Principles of Auditing

The guidance given in Clauses 5 to 7 are based on the following six principles:



## 1: Integrity

- Be professional



## 2: Fair presentation

- Be truthful and accurate



## 3: Due professional care

- Use diligence and good judgement



## 4: Confidentiality

- Ensure security of information



## 5: Independence

- Be impartial and objective



## 6: Evidence-based approach

- Be rational and systematic

Clause 5

# Managing an audit programme



# Objectives: Plan

5.2 Establishing the audit programme objectives

5.3 Establishing the audit programme

- 5.3.1 Roles and responsibilities of the person managing the audit programme
- 5.3.2 Competence of the person managing the audit programme
- 5.3.3 Establishing the extent of the audit programme
- 5.3.4 Identifying and evaluating audit programme risks
- 5.3.5 Establishing procedures for the audit programme
- 5.3.6 Identifying audit programme resources

Plan

Do

Check

Act

# The benefits of planning



Good preparation allows you to start the audit smoothly in professional manner

Good preparation shows that you are taking it seriously

Involving the auditee builds positive working relation

Plan

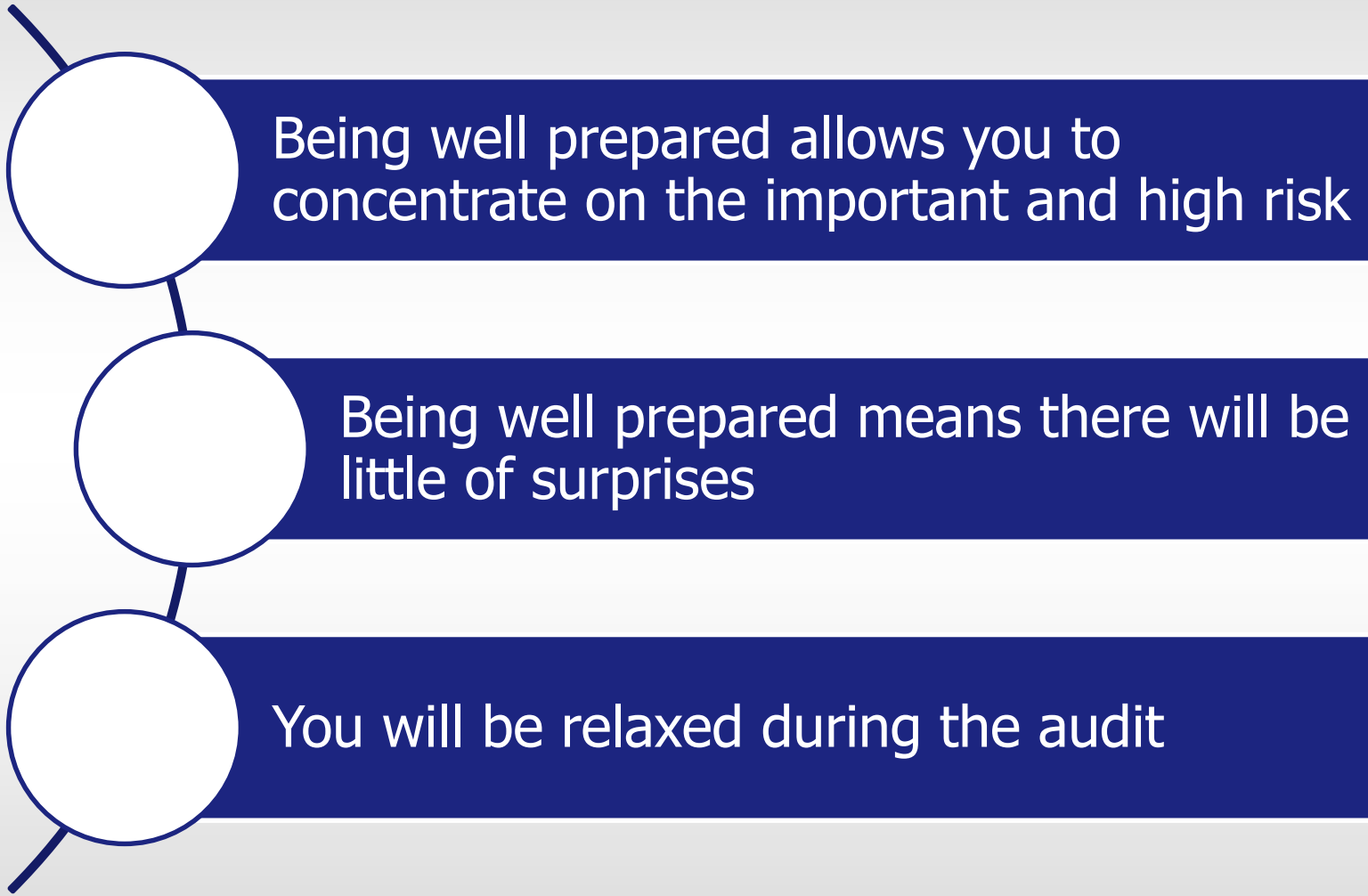
Do

Check

Act



# The benefits of planning



Plan

Do

Check

Act

# 5.3 Establishing the audit programme

## 5.3.6 Identifying audit programme resources



Plan

Do

Check

Act

# 5.4 Implementing the audit

## 5.4.2 Defining the objectives, scope and criteria for an individual audit

### Audit objectives

- Define what is to be accomplished by the individual audit

### Audit scope

- Physical location, organisational units, activities and processes to be audited

### Audit criteria

- Reference against which conformity is determined e.g. policies, standards, legal requirements

Plan

Do

Check

Act

# 5.4 Implementing the audit

## 5.4.3 Selecting the audit methods

Extent of involvement between the auditor and the auditee	Location of the auditor	
	On-site	Remote
<b>Human interaction</b>	<ul style="list-style-type: none"><li>• Conducting interviews</li><li>• Completing checklists and questionnaires with auditee participation</li><li>• Conducting document review with auditee participation</li><li>• Sampling</li></ul>	Via interactive communication means: <ul style="list-style-type: none"><li>• Conducting interviews</li><li>• Completing questionnaires and checklists</li><li>• Conducting document review with auditee participation</li></ul>
<b>No human interaction</b>	<ul style="list-style-type: none"><li>• Conducting document review (e.g. records, data analysis)</li><li>• Observation of work performed</li><li>• Conducting on-site visit</li><li>• Completing checklists</li><li>• Sampling (e.g. products)</li></ul>	<ul style="list-style-type: none"><li>• Conducting document review (e.g. records, data analysis)</li><li>• Observing work performed via surveillance means, considering social and legal requirements</li><li>• Analysing data</li></ul>

Plan

Do

Check

Act

# Objectives: Check

## 5.5 Monitoring the audit programme

- Evaluate conformity with objectives
- Evaluate audit team members' performance
- Evaluate audit teams' ability to implement audit plans
- Evaluate feedback from management
- Take note of changes that impact the audit programme, for example:
  - Changes to suppliers, standards, legal requirements, or auditee's management system

Plan

Do

Check

Act

# Objectives: Act

## 5.6 Reviewing and improving the audit programme

### Review and improve audit programme

- Monitoring results and trends
- Conformity with procedures
- Audit programme records
- New/alternative auditing methods
- Effectiveness of mitigation measures to address audit programme risks
- Confidentiality and information security issues

### Report results to management

Plan

Do

Check

Act

# Clause 6 - Performing an audit

6.2 Initiating the audit

6.3 Preparing audit activities

6.4 Conducting the audit activities

6.5 Preparing and distributing the audit report

6.6 Completing the audit

6.7 Conducting audit follow up

## 6.4 Conducting the audit

Recognise ploys that could be used to confuse or frustrate and take evasive actions:

Time  
wasting

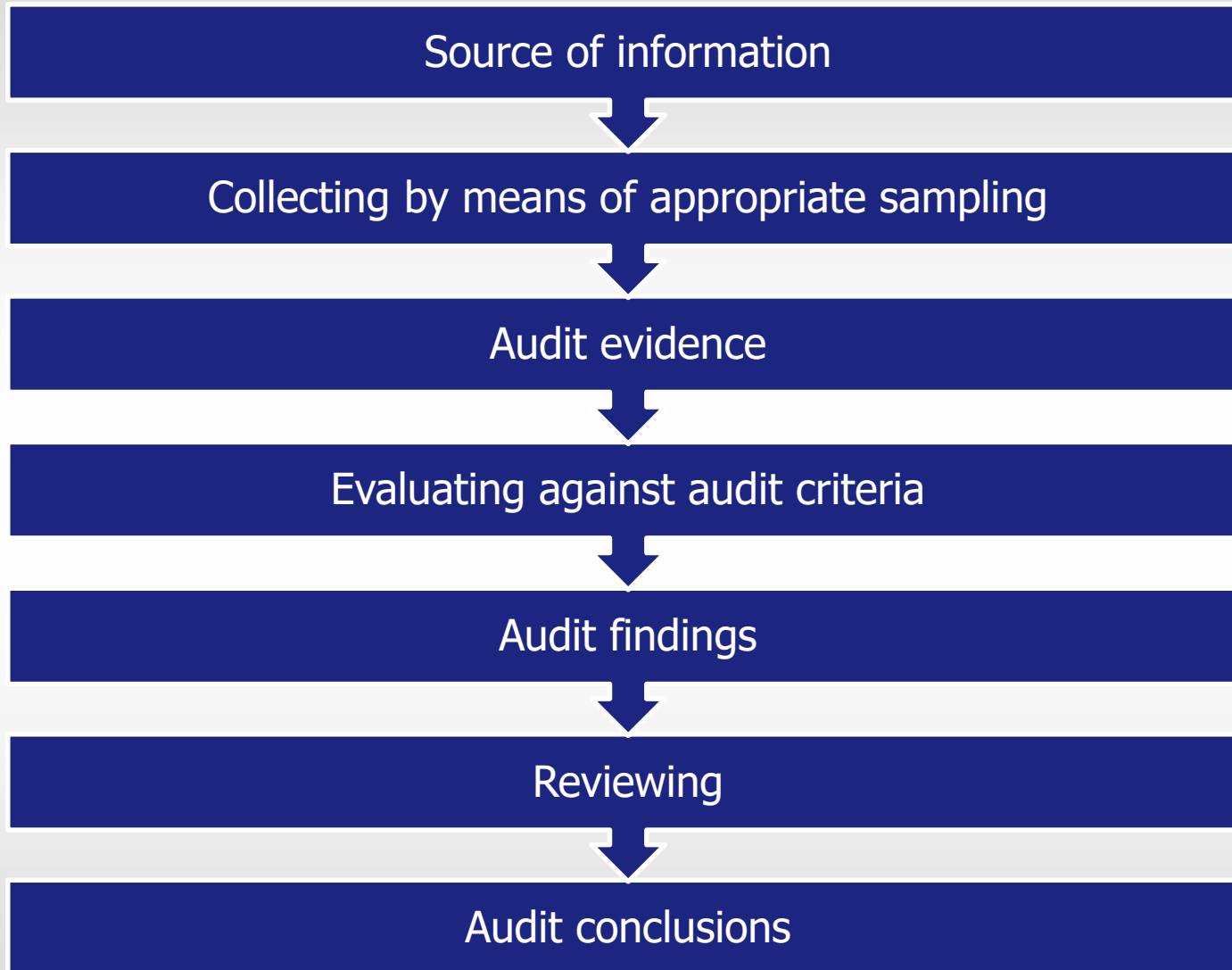
Deliberate  
attempt to  
confuse

Deliberate  
attempt to  
intimidate  
the auditor

→ Handle these situations with courtesy, but firmly



# Collect and verify information



# Note taking

It is important to take good notes on what, when and where. Notes must be accurate and legible.

- These will be used for exit interview (little preparation time) and preparation of your final report

## Some useful hints on note taking:

- Avoid long descriptive text
- Use key words
- Do not write anything down unless you understand it
- Use symbols
- Re-write at your earliest convenience



# Conducting an audit

## Daily progress meetings

- Summarise findings and try to get agreements
- List outstanding items
- Communicate any changes to audit plan
- Discuss disagreements
- Confirm plan for the next day

# Conducting an audit

## Closing meeting

- Encourage the management to invite all concerned
- Summarise your findings for each department:
  - Strengths
  - Weaknesses
  - Areas of concern

# Final audit activities

**6.5** Prepare and distribute the audit report

**6.6** Complete the audit

**6.7** Conduct audit follow-up

Clause 7

# Competence and evaluation of auditors



## 7.2 Determine Auditor Competence

### Personal behaviour

Ethical

Open-minded

Decisive

Observant

### Knowledge and skills

Education

Work experience

Auditor training

Audit experience

# Auditor Attributes

## Desirable

- Honest, unbiased
- Diplomatic
- Self-disciplined
- Communicates with clarity
- Good listener, patient
- Resilient, firm

## Undesirable

- Irrelevant qualifications
- Lack of good judgement
- Dishonest
- Impatient, argumentative
- Bad communicator



# Audit Report

- When preparing an Audit Report:
  - Think of the people who may read it
  - Be objective, Be diligent, Pay attention to detail
  - Keep deficiencies simple and clear - Use wording from a relevant clause in the Code or Standard
  - Always reference the correct clause(s)
  - Be factual - Every deficiency must be supported by evidence gathered during the audit

# Audit Close-Out

- Use formal “Audit Close Out” record for communications
- “Critical” and “Major” deficiencies should be closed on provided evidence
- “Other” deficiencies could be closed on corrective action plan and target day for completion

All audits should be reviewed upon completion.

# The Art of Auditing



**Fair**



**Firm**



**Friendly**



**Thorough**



# Fair

## Objectivity

- No personal opinions
- Stick to the regulations and standards

## Balance

- Provide positive as well as negative feedback

## Transparency

- Explain potential discrepancies at the time they are observed
- Allow reasonable time for discussion – don't jump to conclusions

# Fair

## Be constructive

- Be open to discuss options for correction

## Don't be petty

- Minor one-off slip-ups may not need to be recorded as deficiencies
- Concentrate on systematic failures

## Risk management

- Focus on activities that may significantly impact product quality
- Consider findings in terms of consequences and likelihood – not absolute worst case

# Firm



Auditors, not manufacturers, decide what is going to be done and when



If you ask for something, follow through and insist



Don't be distracted



Be firm, but don't be unfriendly!

# Friendly



- Establish a friendly atmosphere
- Auditors can set the tone of an audit
- Staff open up and involve themselves in the audit process
- Better cooperation leads to an effective audit

# Friendly



- Be courteous, respectful, calm, confident and humble
- Don't discuss religion, politics, personal matters
- Never, even if provoked, be aggressive, rude, angry or use bad language



# Thorough

A short audit can be thorough

Manage time on a risk basis

Stay focussed and keep moving

Horizontal vs vertical inspection

Be prudent in deciding when to dig deeper and how deep to dig

Critical elements should never be left out

Note in the audit report “not covered” or “briefly covered”

The next audit should cover these properly

Thank you for your time.  
Questions now or later?

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