

DCVMN - PRE-WORKSHOP TEST PAPER

1. Regarding critical suppliers (mark ONE correct answer):
 - a) It is not necessary to audit very well-known and recognized suppliers.
 - b) The criteria to select and continuously evaluate a supplier is by auditing them on site
 - c) The frequency of audits to suppliers depends on the risk and their ongoing performance
 - d) Purchasing & Material management departments should NOT participate in the evaluation of suppliers

2. Which of the following should be used to demonstrate objectivity of an auditor? (mark ONE correct answer):
 - a) Documenting more about the valuable opinion and experience of the auditor rather than the facts.
 - b) Use unbiased language
 - c) Expect from the auditee a fast and correct answer always.
 - d) Use "track forward" method when auditing a process.

3. Regarding CAPA, a Correction is (mark ONE correct answer):
 - a) An action aimed at solving the nonconformity or the direct consequences of the same
 - b) Action to eliminate the cause of the detected nonconformity
 - c) To analyze the risks associated to a nonconformity
 - d) Action to change an adverse trend that could lead to a nonconformity

4. Regarding CAPA, a Corrective Action is (mark ONE correct answer):
 - a) Action to eliminate the cause of a detected nonconformity
 - b) Prevents occurrence of a nonconformity
 - c) A typical example of Corrective Action is to repeat an invalid test.
 - d) There is no need to investigate a major nonconformity if the cause is obvious.

5. A First Party audit is: (mark ONE correct answer)
 - a) An audit done by a company to a contract manufacturer
 - b) An audit done by a certified body, e.g. ISO
 - c) An audit done by a regulatory body
 - d) An internal compliance verification within the company.

6. Regarding Preventive Actions (mark ONE correct answer):
 - a) An action aimed at solving the nonconformity or the direct consequences of the same
 - b) Quality Risk Management usually leads to preventive actions
 - c) Actions aimed at solving the cause of nonconformities
 - d) Optional actions aimed at the continuous improvement.

7. Audits is: (mark ONE correct answer)
 - a) An activity best done by the same expert persons of the department being audited.
 - b) An activity best done by QA regardless of his knowledge of the process being audited.
 - c) A systematic, independent and documented process for obtaining objective evidence
 - d) An activity which is based on the experience and seniority of the auditors.

8. Regarding Audits: (mark ONE correct answer)
 - a) A process used by QA to show compliance.
 - b) A process aimed at the process owners' improvement.
 - c) The main purpose of audits is to detect nonconformities
 - d) One of the purposes of audits is to punish behaviors linked to possible nonconformities.

9. An Horizontal audit: (mark ONE correct answer)
 - a) Is a cross-functional examination of an entire process
 - b) Is an audit done by auditors of the same knowledge level.
 - c) Is an audit done mainly in one department.
 - d) Is to create the right atmosphere and empathy to facilitate the audit process

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10. Mark the WRONG option: (mark ONE)
- a) The auditor must always be familiar with the area to be audited.
 - b) All the possible aspects of a process, area or department must be seen in each audit.
 - c) The audit should focus on key parts within the quality system.
 - d) Risk assessment may be used during the planning phase of the audit.
11. A non-compliance /non-conformance during the audit is: (mark ONE correct answer)
- a) The failure to adhere to an act or its regulations, to comply with a requirement, standard, or procedure.
 - b) When a certain practice is not the same as the one the auditor is used to.
 - c) When the auditee makes a mistake and brings the wrong documentation.
 - d) When a media fill is done late 1 month after the scheduled date.
12. Quality Audits (internal and external) are an example of Data Sources to measure the QMS performance for the Continuous Improvement Process. Mark below which is another example:
- a) SOPs
 - b) Complaints
 - c) Layout drawings
 - d) Training records
13. Regarding the Audit Report, (mark ONE correct answer)
- a) Should not include criticism in order to make a point.
 - b) Should focus primarily on each of the deviations found.
 - c) Should be given to the auditee in the closing meeting so they can start addressing the deviations as soon as possible.
 - d) Should provide correct, summarized and clear data that will be effective as a management aid in addressing important organizational issues.
14. Example of corrective action: (mark ONE correct answer)
- a) The autoclave valve was replaced after breaking for the second time in the year.
 - b) A FMEA (Failure Mode & Effects Analysis) was done for the cold chain of Polio vaccine.
 - c) The lot was destroyed after the sterility positive.
 - d) After the root causes of the positive sterility test were identified, a series of actions were implemented to lower the risk of false positives.
15. What does a “Post-audit review feedback” mean? (mark ONE correct answer)
- a) An analysis made by the auditee based on the audit observation aimed at finding other similar situations and preventive actions across the organization.
 - b) Auditors meeting to evaluate the outcome of the audit, prepare the audit report, and to debrief the QA manager.
 - c) Meeting with upper management to discuss the outcome of the audit and the next steps.
 - d) Follow up actions by the auditee associated to the deviations found during the audit.
16. The best auditor should: (mark ONE correct answer)
- a) have authority, sufficient experience, and fully trained in GMP
 - b) be aggressive enough to overcome tense audit situations
 - c) go alone to certain places to find out more about the process
 - d) always interview the managers who perfectly know the process
17. During the performance of the audit; (mark ONE correct answer)
- a) Auditors need to spend more time saying what should be done.
 - b) Auditors need to spend more time listening to the auditees.
 - c) Confrontation is acceptable in order to over impose the auditor’s view.
 - d) If the audit plan is the right one, there is no need to talk between the audit members

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18. Identify the Open question: (mark ONE correct answer)
- a) Give me an example of a sanitization procedure, please.
 - b) Were you involved in this process?
 - c) May I see the training records of this analyst?
 - d) Which is the cleaning frequency of this reactor tank?
19. Identify the biased question. (mark ONE correct answer)
- a) Please, could you show me the raw data of this test?
 - b) May I see the training records of this analyst?
 - c) Shouldn't this be in under quarantine?
 - d) Which were the personnel involved in this task?
20. Identify the wrong audit question: (mark ONE correct answer)
- a) Please, could you show me the raw data of this test?
 - b) May I speak privately with this operator?
 - c) Which were the personnel involved in this task?
 - d) Couldn't you have placed this in the right place to begin with?