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1. What is the primary purpose of a Vendor Qualification Audit in the Pharmaceutical industry?

a. Marketing

b. Regulatory Compliance

c. Cost Reduction

d. Product Promotion

2. Which of the following is a key element to consider when selecting pharmaceutical vendors?

a. Price only

b. Regulatory compliance only

c. Reputation only

d. Price, regulatory compliance, and reputation

3. Who typically conducts Vendor Qualification Audits?

a. Marketing team

b. Quality Assurance team

c. Sales team

d. Human Resources team

4. What is the purpose of assessing a vendor's regulatory compliance during an audit?

a. To increase costs

b. To ensure product quality and safety

c. To speed up production

d. To promote the vendor's products

5. What document is often reviewed during a Vendor Qualification Audit to assess a vendor's quality management system?

a. Product Brochure

b. Employee Handbook

c. Standard Operating Procedures (SOPs)

d. Sales Report

6. Why is it essential for pharmaceutical companies to perform ongoing monitoring of their vendors?

a. It's a regulatory requirement

b. It's a marketing strategy

c. It's a cost-saving measure

d. It's not necessary

7. Which of the following is a potential risk associated with inadequate vendor qualification?

a. Increased product quality

b. Regulatory non-compliance

c. Enhanced reputation

d. Faster production timelines

8. During a Vendor Qualification Audit, what is the significance of reviewing a vendor's production facilities and equipment?

a. To admire their facilities

b. To ensure they have the latest technology

c. To assess their capability to meet quality standards

d. To compare with the company's facilities

9. What is the role of a Corrective and Preventive Action (CAPA) plan in the context of vendor qualification?

a. To punish vendors for non-compliance

b. To identify areas for improvement and prevent future issues

c. To speed up production

d. To market the vendor's products

10. Which regulatory agencies are commonly referenced in the context of pharmaceutical vendor qualification?

a. Food and Drug Administration (FDA)

b. International Organization for Standardization (ISO)

c. European Medicines Agency (EMA)

d. All of the above

Answers:

b. Regulatory Compliance

d. Price, regulatory compliance, and reputation

b. Quality Assurance team

b. To ensure product quality and safety

c. Standard Operating Procedures (SOPs)

a. It's a regulatory requirement

b. Regulatory non-compliance

c. To assess their capability to meet quality standards

b. To identify areas for improvement and prevent future issues

d. All of the above