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QUESTION 1

A materials supplier informs a company that it intends to stop supplying a material critical to the manufacture of the company\\'s products. What action should the company take FIRST?

A. Review the company\\'s existing Quality ManagementSystem

B. Reformulate the products with a replacement material.

C. Qualify another supplier and execute a supplier agreement.

D. Complete a gap analysis to identify options.

Correct Answer: CD

QUESTION 2

Which of the following is MOST appropriate for the purpose of lot release of biologics?

A. Inventory control

B. Safety assurance

C. Efficacy confirmation

D. Quality verification

Correct Answer: D

QUESTION 3

A manufacturer is involved in a recall event process for a plasma-derived product. From which stage should the manufacturer be able to trace back the product?

A. Plasma fractionation

B. Product distribution

C. Individual plasma donation

D. Plasma pooling

Correct Answer: B

QUESTION 4

Which of the following BEST describes the process of post-marketing surveillance for healthcare products?

A. Systematic procedure to review published scientific journals

B. Systematic procedure to review experiences with the products in use

C. Vigilance procedure to ensure the full traceability of the products

D. Vigilance procedure to notify the regulatory authorities about serious incidents

Correct Answer: CD

QUESTION 5

After numerous failed attempts to decrease an identified risk in a medical device to an acceptable level, the medical device continues to have unacceptable risks. However, the development team wants to continue development. Which is the BEST recommendation to make in this situation?

A. Add a warning in the IFU.

B. Discontinue the project.

C. Perform another risk-benefit analysis.

D. Redesign the device.

Correct Answer: D

QUESTION 6

Which of the following double-blind clinical trial designs would be MOST appropriate for a Phase III study with a new product intended to treat an acute life-threatening disease with less than optimal available therapy?

A. Active-controlled

B. Cross-over

C. Dose-ranging

D. Placebo-controlled

Correct Answer: B

QUESTION 7

According to the ICH guideline on GMP for API,to which of the following is the MOST stringent requirement applied?

A. Physical processing and packaging

B. Isolation and purification

C. Production of Intermediate(s)

D. Introduction of the API starting material

Correct Answer: A

QUESTION 8

What is the BEST approach to ensure that raw materials, services, and sub-contractors at the level of the vendors comply with GMP requirements?

A. Ask the vendor to take responsibility.

B. Document and perform audits.

C. Request an inspection from a regulatory authority.

D. Request documentation from the sub-contractor.

Correct Answer: B

QUESTION 9

According to WHO,what are the temperature and humidity conditions for a Zone IVb long- term stability study?

A. 25: C and 60% RH

B. 30?C and 35% RH

C. 30c C and 65% RH

D. 30: C and 75% RH

Correct Answer: D

QUESTION 10

A superiority advertising claim for a product versus its competitor\\'s product can only be made under which of the following circumstances?

A. In vitro studies show the product to be superior.

B. Government survey data indicate the product is superior.

C. Results of a three-year, post-market patient survey indicate the product is superior.

D. Results of adequate, well-controlled comparative clinical trial show the product is superior.

Correct Answer: D

QUESTION 11

At the last internal audit, a regulatory affairs professional identified a need for a corrective action for the manufacturing process. Which of the following stakeholders should be notified FIRST?

A. Quality improvement

B. Quality assurance

C. Clinical affairs

D. Regulatory agency

Correct Answer: B

QUESTION 12

After submission to the regulatory authority, a substantial error was found in the application. In order to resolve this issue, what should be done FIRST?

A. Resubmit the entire package.

B. Inform upper management immediately.

C. Contact the legal department and ask them how to proceed.

D. Verify the procedure in the regulation for the corrections.

Correct Answer: D

QUESTION 13

A company is developing a new medical device using innovative technology. Which of the following is MOST critical in working with regulatory authorities?

A. Documented agreement

B. Frequent communication

C. Early collaboration

D. Follow-up meeting after submission

Correct Answer: B

QUESTION 14

The safety database for an anti-hypertensive drug consists of the following: 461 patients exposed for three months 343 patients exposed for six months 112 patients exposed for nine months 74 patients exposed for 12 months Overall exposure is 2.000 patients. Which long-term ICH data requirement has NOT been met?

A. 100 patients for 12 months

B. 200 patients for nine months

C. 500 patients for three months

D. 3.000 total patient exposures

Correct Answer: A

QUESTION 15

The manufacturer of an API was changed from Company X to Company Y during the late stage of a new drug development. Despite differences in the manufacturing processes of the companies, both APIs meet the current specifications. Which is the MOST appropriate information to include in the final submission documents?

A. The process information and analytical result of Company X API

B. The process information and analytical result of Company Y API

C. The process information and the comparative analytical result of APIs from both companies

D. Information deemed appropriate by the regulatory authority

Correct Answer: C