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QUESTION 1

The intermediate manufacturing process was changed during development of a pharmaceutical. The change may impact the API specification. Which functional area is responsible for the final approval of the change?

A. Production

B. Analytical

C. Quality

D. Regulatory

Correct Answer: CD

QUESTION 2

A global company is developing a sophisticated implantable medical device that is coated with antibiotics and biologics to enhance its efficacy. The product is marketed in Country X. where it is regulated as a medical device. The same product, without theantibiotics and biologics, is marketed as a medical device in Country Y. The company is proposing to start marketing the coated device in Country Y. Which regulatory approach should the company propose?

A. Submit the product for review as a pharmaceutical product in Country Y.

B. Submit the product as a medical device in Country Y as the product is already marketed in Country X as a medical device.

C. Apply for review of the additional part of the product as a pharmaceutical product in Country

D. Examine decisions made about similar products in Country Y to propose the classification ofthe product.

Correct Answer: CD

QUESTION 3

Which of the following is the PRIMARY purpose of an audit report?

A. To carry out a complete review of product applications

B. To define how to prepare new product submissions

C. Todocument compliance history

D. To train sales representatives

Correct Answer: C

QUESTION 4

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

QUESTION 5

Which of the following claims would classify an apple as a drug?

A. "It will make you look younger."

B. "It will satisfy hunger."

C. "It will whiten teeth."

D. "It will prevent colds."

Correct Answer: D

QUESTION 6

Which term does NOT describe the same concept as the others?

A. Biosimilars

B. Follow-on protein products

C. Monoclonal antibody

D. Subsequent entry biologics

Correct Answer: C

QUESTION 7

A company\\'s product was approved by a regulatory authority with the condition that further studies must be completed prior to full approval of the product. To minimize product-associated risk to patients during the period of conditional approval, what is the LEAST effective way to achieve this goal?

A. Label the product for use in appropriate populations.

B. Educate patients and healthcare providers on how to use the product

C. Delay product launch until required studies are completed.

D. Promote off-label use to a carefully selected patient population.

Correct Answer: D

QUESTION 8

A clinical study of a drug is completed to support a marketing approval application. According to ICH,how long should a sponsor retain the clinical study essential documents?

A. For at least two years after the last approval of an application in an ICH region

B. Fora minimum of 10 years after completion of the clinical study

C. Three years after the last clinical study site was supplied with investigational drugs

D. Until the product has been discontinued from marketing in all ICH regions

Correct Answer: AD

QUESTION 9

Which of the following BEST describes the content of the "Physical, Chemical, and Pharmaceutical Properties and Formulation" section of an IB?

A. A review of available data to support the determination of the chemical structure and physical attributes of the drug substance plus batch analysis and stability data for the finished formulation

B. A detailed summary of the physical and chemical properties of the drug product with a signed expert statement addressing the suitability and stability of the formulation for its intended use

C. A description and flow chart illustrating the synthetic route for the active ingredient and the preparation method of the finished product

D. A brief summary of relevant physical, chemical, and pharmaceutical properties: instructions for storage and handling of the dosage form: and a description of the formulation

Correct Answer: D

QUESTION 10

In a distribution contract for high-risk medical devices, which of the following regulatory requirements is the MOST important for the distributor?

A. Local reimbursement requirements

B. Service operation procedures

C. Training program for sales people

D. Written procedure for product traceability

Correct Answer: C

QUESTION 11

The regulatory authority in Country X issued a request for a mandatory product recall in Country X due to serious injuries to patients. This product also is distributed in Country Y.

What should the regulatory affairs professional of the product\\'s manufacturer FIRST do in Country Y?

A. Draft a formal letter to customers in Country Y about this recall.

B. Initiate a mandatory recall of the product in Country Y.

C. Review alt distribution records and complaints reported in Country Y.

D. Prepare the legal team in Country Y for possible litigations.

Correct Answer: C

QUESTION 12

Which of the following is NOT considered a serious adverse event in a cardiovascular clinical trial?

A. Subject is hospitalized due to complications of the product administration.

B. Subject is hospitalized for the purpose of product administration.

C. Subject\\'s hospitalization is due to an unscheduled hip operation.

D. Subject\\'s hospitalization is prolonged during the clinical trial.

Correct Answer: BC

QUESTION 13

In order to develop a global drug product, what is the MOST important environmental characteristic to consider in the country of intended use?

A. Product stability

B. Product registration

C. Product formulation

D. Product requirements

Correct Answer: A

QUESTION 14

During an audit of a contract manufacturing facility by a potential client, the auditor requested to be left alone in the records room. The records room contains information on all products produced by the contract manufacturer.

Which action is MOST appropriate for the regulatory affairs professional to take?

A. Allow the auditor access to the room and records due to the current audit.

B. Allow the auditor accompanied access to the room to retrieve the records.

C. Deny the auditor access to the room and retrieve only the requested records.

D. Deny the auditor access to the room and records due to confidentiality concerns.

Correct Answer: B

QUESTION 15

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