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NEW QUESTION: 1
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. Information deemed appropriate by the regulatory authority
C. The process information and analytical result of Company Y API
D. The process information and the comparative analytical result of APIs from both companies
Answer: D (LEAVE A REPLY)

NEW QUESTION: 2
According to the ICH guideline on GMP for API, to which of the following is the MOST stringent requirement applied?
A. Production of Intermediate(s)
B. Physical processing and packaging
C. Introduction of the API starting material
D. Isolation and purification
Answer: B (LEAVE A REPLY)

NEW QUESTION: 3
Which of the following is the MOST desirable timing and approach for a regulatory affairs professional who wants to provide feedback on proposed new regulations?
A. After the enactment of the regulation, through a product-specific meeting
B. After the enactment of the regulation, through the industry representative
C. Before the enactment of the regulation, through formal comments gathering process

D. Before the enactment of the regulation, through the industry representative
Answer: (SHOW ANSWER)

NEW QUESTION: 4
Which of the following claims would classify an apple as a drug?
A. "It will satisfy hunger."
B. "It will make you look younger."
C. "It will whiten teeth."
D. "It will prevent colds."
Answer: D (LEAVE A REPLY)

NEW QUESTION: 5
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. Until the product has been discontinued from marketing in all ICH regions
C. Three years after the last clinical study site was supplied with investigational drugs
D. For a minimum of 10 years after completion of the clinical study
Answer: (SHOW ANSWER)

NEW QUESTION: 6
Under which of the following circumstances would a regulatory authority require a more detailed premarket submission, a more rigorous audit, and/or the provision of more performance evaluation data than would normally apply to an IVD device of that risk class?
A. The device incorporates well-established technology that is already present in the market.
B. The device is an updated version of a compliant device from the same manufacturer and contains no substantive change.
C. Internationally recognized standards are available to cover the main aspects of the device and have been used by the manufacturer.
D. The manufacturer's experience level with the type of IVD medical device is limited.
Answer: D (LEAVE A REPLY)

NEW QUESTION: 7
A regulatory affairs professional is asked to review and update regulatory affairs SOPs. Which aspect of the SOP Is MOST important to consider?
A. Scope and level of detail
B. Revision history
C. Expiration date
D. Relevance to regulations

Answer: (SHOW ANSWER)

NEW QUESTION: 8
Which of the following BEST describes the process of post-marketing surveillance for healthcare products?
A. Systematic procedure to review experiences with the products in use
B. Systematic procedure to review published scientific journals
C. Vigilance procedure to ensure the full traceability of the products
D. Vigilance procedure to notify the regulatory authorities about serious incidents
Answer: C (LEAVE A REPLY)

NEW QUESTION: 9
A company establishes a new medical device indication for its consumer disposable products. The regulatory affairs professional is asked to give a 30-minute training session on these products to sales representatives. Which of the following subjects is the MOST important to discuss?
A. Labeling
B. Regulatory application summary
C. Risk management process
D. Safety-related reporting
Answer: A (LEAVE A REPLY)

NEW QUESTION: 10
A company is considering the development of a medical device similar to those already available. Which of the following should be evaluated FIRST when developing a clinical evaluation document?
A. Adverse event reports
B. Literature search
C. Clinical experience
D. Clinical investigations
Answer: D (LEAVE A REPLY)

NEW QUESTION: 11
As part of the regulatory strategy for companies intending to manufacture a psychotropic product, which of the following approvals should be received FIRST?
A. Product license
B. Site license
C. Export license
D. Import license
Answer: B (LEAVE A REPLY)

NEW QUESTION: 12
According to WHO, what are the temperature and humidity conditions for a Zone IVb long-term stability study?
A. 30 C and 35% RH
B. 25: C and 60% RH
C. 30c C and 65% RH
D. 30: C and 75% RH
Answer: (SHOW ANSWER)

NEW QUESTION: 13
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. Complete a gap analysis to identify options.
B. Qualify another supplier and execute a supplier agreement.
C. Reformulate the products with a replacement material.
D. Review the company's existing Quality Management System
Answer: (SHOW ANSWER)

NEW QUESTION: 14
A company is developing a line of products for which no ISO standard of performance is available. As a result, the company wishes to propose developing such a standard. Whom should the company contact in order to start the development of the new standard?
A. The ISO technical committee in charge of the area
B. The ISO Secretariat
C. The country's regulatory authority
D. The ISO national member body
Answer: D (LEAVE A REPLY)

NEW QUESTION: 15
What are the MOST important elements that global regulatory agencies want to know before approving a new product for sale in their countries?
A. Quality and failure risk
B. Safety and failure risk
C. Quality and effectiveness
D. Safety and effectiveness
Answer: (SHOW ANSWER)

NEW QUESTION: 16

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. Regulatory agency

B. Quality assurance

C. Quality improvement

D. Clinical affairs

Answer: B (LEAVE A REPLY)

NEW QUESTION: 17

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

A. Safety assurance

B. Quality verification

C. Inventory control

D. Efficacy confirmation

Answer: (SHOW ANSWER)

NEW QUESTION: 18

Following the introduction of a new regulation, an evaluation of the company's products by the regulatory affairs professional indicates that 60 percent do not comply with the regulation.

What should the regulatory affairs professional do FIRST to meet the new requirement?

A. Contact the trade association for advice.

B. Prepare documents for the files.

C. Communicate with the relevant internal departments.

D. Request a permanent waiver from the new regulation.

Answer: (SHOW ANSWER)

NEW QUESTION: 19

Which of the following BEST describes the purpose of the ICH?

A. To discuss and establish common guidelines for safe, effective, and high-quality medicines for the ICH regions

B. To provide scientific evaluation of applications for international marketing authorization for safe, effective, and high-quality medicines for the ICH regions
C. To lobby for improved industry standards for the development of new safe, effective, and high-quality medicines for the ICH regions
D. To protect and promote public health through the evaluation and supervision of safe, effective, and high-quality medicines for the ICH regions
Answer: A (LEAVE A REPLY)

NEW QUESTION: 20
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 requirements
C. Product formulation
D. Product registration
Answer: (SHOW ANSWER)

NEW QUESTION: 21
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. Verify the procedure in the regulation for the corrections.
D. Contact the legal department and ask them how to proceed.
Answer: (SHOW ANSWER)

NEW QUESTION: 22
According to the GHTF, which of the following is NOT an exemption rule when evaluating the decision to report an adverse event?
A. Deficiency of a device found by the user prior to patient use
B. Malfunction occurring before the end of service life of the medical device
C. Adverse event caused by patient conditions
D. Malfunction protection operated correctly
Answer: C (LEAVE A REPLY)

NEW QUESTION: 23
SOPs for preventive and corrective actions MUST include the procedure to eliminate which of the following?
A. Inadequate training
B. Causes of non-conformities
C. Adverse environmental impacts

D. Late and/or incorrect deliverables
Answer: B (LEAVE A REPLY)

NEW QUESTION: 24
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. Request an inspection from a regulatory authority.
B. Document and perform audits.
C. Request documentation from the sub-contractor.
D. Ask the vendor to take responsibility.
Answer: (SHOW ANSWER)

NEW QUESTION: 25
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. Promote off-label use to a carefully selected patient population.
B. Delay product launch until required studies are completed.
C. Label the product for use in appropriate populations.
D. Educate patients and healthcare providers on how to use the product
Answer: A (LEAVE A REPLY)

NEW QUESTION: 26
According to the GHTF IVD guidance, which of the following is the CORRECT classification for a blood glucose self-testing kit?
A. Class D
B. Class C
C. Class A
D. Class B
Answer: (SHOW ANSWER)

NEW QUESTION: 27
A drug product presents degradation during the manufacturing process. In addition to the amount, what information should be provided FIRST in order to use API overage?
A. Formulation
B. Property
C. Justification
D. Specification
Answer: C (LEAVE A REPLY)

NEW QUESTION: 28
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. 500 patients for three months
B. 3.000 total patient exposures
C. 100 patients for 12 months
D. 200 patients for nine months
Answer: C (LEAVE A REPLY)

NEW QUESTION: 29
During a regulatory authority inspection of a manufacturing site, the inspector observes that one of the medicinal products manufactured at the site is not GMP compliant. The product
Is distributed globally.
Which of the following is the most appropriate action to take FIRST?
A. Withdraw the affected product from the markets.
B. Notify the global regulatory authorities.
C. Send a "Dear Dr." letter to customers.
D. Assess the potential safety risk.
Answer: B (LEAVE A REPLY)

NEW QUESTION: 30
GHTF recommends that the medical device manufacturer define the scope of the clinical evaluation based on which of the following?
A. Instructions for use
B. Essential principles
C. Risk analysis
D. Product literature
Answer: C (LEAVE A REPLY)

NEW QUESTION: 31
Which of the following is an example of an acceptable statement for an advertisement of an approved arthritis medication?
A. "Product X is effective for the treatment of arthritis."
B. "Product X is a guaranteed cure for arthritis."
C. "Product X is effective in all patients with arthritis."

D. "Product X is safe for arthritis and without side effects."
Answer: A (LEAVE A REPLY)

NEW QUESTION: 32
According to ICH, what is the MAXIMUM amount of time in calendar days that an organization has from the initial receipt of information to report serious and unexpected ADR of a marketed product to regulatory authorities?
A. 5
B. 10
C. 15
D. 3
Answer: A (LEAVE A REPLY)

NEW QUESTION: 33
In which section of the ICH Common Technical Document will the overview of clinical data appear?
A. Module 4
B. Module 3
C. Module 1
D. Module 2
Answer: (SHOW ANSWER)

NEW QUESTION: 34
Which of the following criteria is MOST appropriate to define the animal species needed for the pre-clinical toxicity testing of a biotechnology product?
A. Proposed product route and frequency of administration
B. Proposed dose and volume of administration
C. Biological activity with species and/or tissue specificity
D. Immunochemical and functional tests
Answer: C (LEAVE A REPLY)

NEW QUESTION: 35

Which of the following statements regarding the off-label use of drugs is CORRECT?
A. The peer-reviewed literature can ensure high-quality off-label promotion of medications, thereby increasing access to much needed drugs and devices.
B. Although the regulatory authority reviews and approves drugs for specific indications, the approval does not limit the use of those drugs in clinical practice.
C. Sponsors are allowed to distribute publications about unapproved uses of approved drugs and devices as long as the marketing application is under review by the regulatory authority.
D. The regulatory authority does not restrict physician prescribing for off-label indications or regulate the manufacturer's promotion for such use.
Answer: B (LEAVE A REPLY)