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Question: 1

Serious enforcement letter issued by FDA notifying a regulated entity of violative activity; requires immediate action within 15 days.

A. True
B. False

Answer: A

Question: 2

Adverse event monitoring and reporting.

A. Common Rule
B. Phase Ii
C. Pharmacovigilance
D. Pharmacoepidemiology

Answer: C

Question: 3

A meeting needed to help an otherwise stalled product development program proceed. Scheduled within 30 days of FDA receipt of a written meeting request. Examples include:
- Dispute resolution meetings as described in 21 CFR 10.75, 312.48, and 314.103 and in the guidance for industry Formal Dispute Resolution: Appeals Above the Division Level
- Meetings to discuss clinical holds in which a response to hold issues has been submitted, but the FDA and the sponsor or applicant agree that the development is stalled and a new path forward should be discussed
- Special protocol assessment meetings that are requested by sponsors or applicants after receipt of FDA evaluation of protocols under the special protocol assessment procedures as described in the guidance for industry Special Protocol Assessment

A. Type A Meeting
B. Agreement Meeting
C. Class Ii Device
D. Clinical Hold

Answer: A

Question: 4

Health Insurance Portability and Accountability Act of 1996, also known as the Privacy Rule, established the minimum federal requirements for protecting the privacy of individually identifiable health information.

A. HIPAA
B. USP
C. FOIA
D. OBRA

Answer: A

Question: 5

Good Clinical Practice. Regulations and requirements with which clinical studies must comply. These regulations apply to manufacturers, sponsors, clinical investigators and industrial reivew boards.

A. GMP
B. CPR
C. GLP
D. GCP

Answer: D

Question: 6

Financial Disclosure by Clinical Investigators

A. 21 CFR 54
B. 21 Cfr 49
C. 21 Cfr 207
D. 21 Cfr 312

Answer: A

Question: 7

A report filed with FDA within three working days of obtaining information on any distributed drug product that has contamination, significant chemical or physical change, deterioration, batch failure or labeling causing mistaken identity.

A. Phase Ii
B. Cdrh
C. NDA Field Alert
D. Bimo

Answer: A

Question: 8

Required by certain countries to prove that an exported product can be legally marketed in the US.

A. Orphan drug
B. Primary mode Of Action (pmoa)
C. Transitional device
D. Certificate to Foreign Government (CFG)

Answer: D

Question: 9

Premarket notification procedures

A. 105 Cfr 807 Subpart E
B. 21 Cfr 812 Subpart E
C. 21 Cfr 312 Subpart E
D. 21 CFR 807 Subpart E

Answer: D

Question: 10

Documents published by the FDA to provide currently interpretation of regulations.

A. Component
B. Wisdom
C. Guidance
D. Rules

Answer: C

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