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QUESTION 1

In preparation for the development of a new line of products, a regulatory affairs professional is asked to prepare a short presentation for senior management. Which of the following topics is MOST important to cover?

A. Potential clinical sites for the Phase III clinical trial

B. Regulatory requirements for labeling and packaging

C. Capacity of the manufacturing facilities to fully produce the new product

D. Previous actions taken by regulatory authorities on similar products

Correct Answer: D

QUESTION 2

As part of the regulatory strategy for companies intending to manufacture a psychotropic product, which of the following approvals should be received FIRST?

A. Site license

B. Product license

C. Import license

D. Export license

Correct Answer: A

QUESTION 3

A global company has obtained a patent in a specific country for a newly marketed product. What would be the BEST advice In order to protect the patent in other countries?

A. Use the Madrid system.

B. Use the community patent system.

C. File patents of interest in target countries.

D. File design patents in target countries.

Correct Answer: C

QUESTION 4

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 5

What are the MOST important elements that global regulatory agencies want to know before approving a new product for sale in their countries?

A. Safety and failure risk

B. Safety and effectiveness

C. Quality and failure risk

D. Quality and effectiveness

Correct Answer: B