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ASQ Certified Pharmaceutical GMP Professional Sample Questions (Q137-Q142):

NEW QUESTION # 137

Which aspect is specifically scrutinized in the European Product Quality Review (PQR) that might not be emphasized in the U.S. APR?

Response:

- A. Financial performance over the fiscal year
- B. Raw material supply chain sustainability
- **C. Manufacturing process deviations**
- D. Marketing strategies effectiveness

Answer: C

NEW QUESTION # 138

What is the goal of product surveillance in the pharmaceutical industry?

Response:

- A. To gather data for marketing analysis
- **B. To ensure continuous patient safety and product efficacy**
- C. To monitor competitive product launches
- D. To track the movement of pharmaceutical stocks

Answer: B

NEW QUESTION # 139

What is a significant consequence of a consent decree in the pharmaceutical industry?

Response:

- **A. Mandatory compliance with specified requirements under judicial supervision.**
- B. Automatic approval of all future product registrations.
- C. Enhanced company reputation.
- D. Increased product demand.

Answer: A

NEW QUESTION # 140

Why is it necessary to review and ensure the integrity of laboratory records, including electronic data's audit trails?

Response:

- A. To prepare for potential legal actions
- **B. To detect errors, falsification, and fraud**
- C. To create space for new records
- D. To comply with aesthetic record-keeping standards

Answer: B

NEW QUESTION # 141

ICH Q7 provides guidance specifically for:

Response:

- A. Good Distribution Practice
- **B. Good Manufacturing Practice**
- C. Good Clinical Practice
- D. Good Laboratory Practice

Answer: B

NEW QUESTION # 142

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