2026
【藥物開發及臨床試驗從業人員培訓班】
筆試解答

是非題：

1. (是) The primary objective of a single-blind clinical trial is to reduce potential bias caused by subjects' expectations toward the investigational treatment.

2. (是) A pharmaceutical dosage form consists of an active pharmaceutical ingredient (API) and excipients, where excipients are pharmacologically inactive but may influence drug stability, absorption, or patient acceptability.

3. (否) All critical information required for the development of a generic drug, including formulation composition and manufacturing processes, can be completely obtained from the innovator product's patent documents.

選擇題：

4. 藥品上市後安全監視中，藥商的責任包括哪些？（複選）
   A. 依規定期限通報 ADR
   B. 取消例行批次品質檢驗
   C. 建立藥品安全監視系統
   D. 主動蒐集與評估不良反應

5. In pharmaceutical regulatory submissions, CMC refers to:
   A. Critical Material Certification
   B. Clinical Manufacturing Compliance
   C. Compound Molecular Characterization
   D. Chemistry, Manufacturing and Controls

6. According to ICH-GCP, who holds the ultimate responsibility for the ethical and scientific conduct of a clinical trial at a trial site?
   A. Principal Investigator
   B. Clinical Research Coordinator
   C. Sponsor
   D. IRB/IEC

7. The Common Technical Document (CTD) format consists of how many modules?
   A. 3
   B. 4
   C. 5
   D. 6

8. Which of the following components are typically required for submission of a New Drug Application (NDA)? (Multiple answers)
   A. Clinical study reports from Phase I–III
   B. Nonclinical pharmacology and toxicology data
   C. Post-marketing surveillance results
   D. Chemistry, Manufacturing and Controls (CMC)

9. 下列關於臨床試驗之敘述，何者錯誤？
   A. 試驗執行前需經 TFDA 與 IRB 審查
   B. 試驗設計須保障受試者權益
   C. 所有臨床試驗皆僅在健康志願者中進行
   D. 數據須準確記錄並可查核

10. Most typical antipsychotic drugs exert their primary pharmacological effect by modulating:
   A. Dopaminergic pathways
   B. Cholinergic transmission
   C. GABAergic inhibition
   D. Glutamatergic signaling

11. In a double-blind clinical trial design:
   A. Treatment allocation is disclosed after database lock
   B. Both subjects and investigators remain unaware of treatment assignments
   C. Subjects are blinded but investigators are not
   D. Only the sponsor is blinded to treatment allocation

12. Key objectives of ICH-GCP include which of the following? (Multiple answers)
   A. Assurance of data credibility and integrity
   B. Optimization of trial cost efficiency
   C. Compliance with ethical and scientific standards
   D. Protection of human subjects

13. 關於臨床試驗知情同意，下列何者錯誤？
A. 簽署後不得中途退出
B. 應以受試者可理解語言說明
C. 應完整揭露風險與效益
D. 受試者可隨時退出試驗

14. A core principle of Good Manufacturing Practice (GMP) is:
A. Prioritizing output speed over quality
B. Reducing production cost through minimal testing
C. Delegating quality responsibility to suppliers
D. Ensuring consistent product quality and compliance

15. In a randomized controlled clinical trial, randomization is primarily implemented to:
A. Reduce confounding factors between treatment groups
B. Ensure faster regulatory approval
C. Increase statistical power by enlarging sample size
D. Improve patient compliance

16. Which study is NOT considered part of toxicological evaluation?
A. Single-dose toxicity study
B. Carcinogenicity study
C. Genotoxicity study
D. Pharmacokinetic study

17. 依 GDP 規範，藥品運輸須符合哪些要求？（複選）
A. 建立完整追溯與紀錄系統
B. 外包裝完整即可，不需管控環境
C. 運輸設備定期清潔與維護
D. 維持適當溫濕度條件

18. The fundamental objective of a bioequivalence (BE) study is to demonstrate:
A. Similar rate and extent of drug absorption
B. Equivalent safety profiles under long-term use
C. Comparable clinical efficacy between two drugs
D. Therapeutic equivalence based on clinical outcomes

19. Which of the following is NOT classified as a protein-based therapeutic?
A. Vaccines
B. Insulin
C. Paracetamol
D. Clotting factors

20. Which of the following would be classified as a serious adverse drug reaction (sADR)?
A. An event resulting in hospitalization or death
B. Transient nausea resolved without treatment
C. Self-limiting dizziness
D. Mild injection site pain