115 年度
【醫療器材產業從業人員培訓班】
筆試解答

一、是非題

1. （X）所有第一等級醫療器材皆以登錄方式即可完成上市程序並領取許可證，不須辦理查驗登記。
2. （O）醫療器材優良運銷(GDP)許可有效期為 3 年，因此到期前需提早提出展延申請。

二、選擇題

1. Which of the following **best** describes the difference between Class II and Class III medical devices in Taiwan?
   A. Class III devices are more expensive than Class II devices.
   B. Class III devices are more complex than Class II devices.
   C. Class III devices are used for more serious medical conditions than Class II devices.
   D. Class III devices require a more rigorous regulatory review process than Class II devices.

2. A medical device _____is a structured system of procedures and processes covering all aspects of design, manufacturing, supplier management, risk management, complaint handling, clinical data, storage, distribution, product labeling, and more.
   A. ISO 14971
   B. ISO 10993
   C. ISO 17025
   D. Quality management system (QMS)

3. The term "medical device clinical trials" shall refer to the systematic studies on the _____of medical devices carried out in human.
   A. Duration of validity
   B. Diagnosis and treatment
   C. Medical advertisements
   D. Safety or effectiveness

4. Which of the following is **not** a key element of a QMS?

A. Quality policy and objectives
B. Sales strategy
C. Organizational structure and responsibilities
D. Document control

5. What is the purpose of chemical testing for medical devices?
A. To determine the device's biocompatibility
B. To evaluate the device's performance
C. To identify potential chemical hazards associated with the device
D. To assess the device's durability

6. Which of the following is **not** a medical device?
A. COVID-19 rapid test kit
B. Surgical scalpel
C. Dental floss
D. Hyaluronic acid

7. Which of the following circumstances would **not** be considered as defective medical devices?
A. The duration of validity or storage life has expired.
B. Some materials that affect product quality are mixed or packed.
C. Toxic or hazardous substances are contained, resulting in harm to the health of human body.
D. The performance or specification is consistent with the content that has been approved in registration, listed, or announced.

8. 為保障國人使用醫療器材之安全、效能及品質、增進國民健康及強化醫療器材管理，因此管理醫療器材的主管機關，有：
A. 衛生福利部
B. 直轄市政府
C. 縣（市）政府
D. 以上皆是

9. 製造業者製造以下何種醫療器材，應建立醫療器材品質管理系統，並符合「醫療器材品質管理系統準則(QMS)」？
A. 第二級和第三等級醫療器材，如血糖機、人工水晶體
B. 第一等級醫療器材，如醫療口罩
C. 經公告免取得醫療器材製造許可之第一等級醫療器材，如咬合紙

D. 以上皆是

10. 公司生產製造一次性使用的醫療器材，為避免重複使用造成交叉感染，以下何者是最好的風險管制措施：

A. 設計使用後即可自行破壞使產品不再具備該項功能

B. 產品標示為一次性使用

C. 警告標示勿重複使用及重複使用的後果

D. 要求醫療院所簽署不重複使用的切結書

11. 近年衛生主管機關推動 UDI（Unique Device Identification）的「主要目的」為何？

A. 為了提升產品的市場售價

B. 為了取代醫療器材許可證字號

C. 為了產品辨識與流向管理

D. 方便消費者辨識產品品牌

12. 某醫療器材產品在使用後發生不良事件，經調查發現是因為使用者未遵循產品內附之使用限制與警告事項。請問該資訊原則上應記載於哪一文件中？

A. 授權書

B. 仿單

C. 品質手冊

D. 技術文件

13. 下列何種軟體最符合 Software as a Medical Device (SaMD) 的定義？

A. 記錄每日運動步數的健康 App

B. 提供飲食建議的 AI 營養助手

C. 分析心電圖並提供心律異常判讀的 App

D. 醫院的預約掛號系統

14. Which of the following medical devices is **not** classified as an IVD?

A. Blood glucose meter

B. Cardiac stent

C. HIV test kit

D. Pregnancy test kit

15. What does GDP mean in medical device?

A. Good dispensing Practices

B. Good devices practice

C. Gross domestic product

D. Good distribution practice

16. What is the purpose of the Medical Device Regulation (MDR) in the European Union?

A. To regulate the export of medical devices outside of the EU

B. To regulate and harmonize the approval process for medical devices across EU member states

C. To provide guidelines for the use of medical devices in home settings

D. To regulate the use of medical devices in clinical trials

17. What is ISO 14971?

A. A standard for medical device sterilization

B. A standard for medical device clinical evaluation

C. A standard for medical device risk management

D. A standard for medical device design control

18. Medical device manufacturers shall not commission other manufacturers to manufacture or accept the commissioning to manufacture medical devices in Taiwan, unless otherwise _____.

A. certified by WHO

B. authorized by the commercial agreement

C. accredited by the international foundation

D. approved by the central competent authority