Name:

Company:

Title:

Email:

Phone:

Please answer the following questions by checking the appropriate box or by filling in the blank. This exam is open book, open notes, a copy of both 21 CFR 820.198 and 21 CFR 803. A passing score is 7 out of 10 questions correct. Completed exams should be emailed to [rob@13485cert.com](mailto:rob@13485cert.com).

1. In which clause of ISO 13485 are the requirements for complaint handling and vigilance found?
2. Which of the following is a potential source of complaints?
3. Customer email to sales representative
4. Mention of a device malfunction in a medical journal
5. Hospital buyer venting to customer service about mismarked packaging labels
6. Service department receives request for replacement part while in warranty
7. All of the above
8. In which section of the QSR can you find the requirement for complaint handling?
   1. 21 CFR 820.40
   2. 21 CFR 820.50
   3. 21 CFR 820.100
   4. 21 CFR 820.198
   5. 21 CFR 820.200
9. If a customer does not return a device that allegedly malfunctioned, then the issue is not reportable and the complaint record should be closed?
10. True
11. False
12. Which of the following pieces of information is required for a complaint record (check all that apply)?
    1. Date complaint was received
    2. Lot number of the device
    3. Investigation results
    4. Reference to CAPA(s)
    5. Letter to the person that complained
13. If a reason for a device malfunction is obvious, no investigation is required?
    1. True
    2. False
14. For a product that is distributed to the USA, Canada and Europe there are reporting deadlines for which of the following time periods (check all that apply)?
15. Immediately
16. 2 Days
17. 5 Days
18. 10 Days
19. 15 Days
20. 30 Days
21. The EU vigilance guidance document is?
    1. MEDDEV 2.4/1
    2. MEDDEV 2.7/1
    3. MEDDEV 2.7/3
    4. MEDDEV 2.12/1
22. eMDRs are      . Currently eMDRs are optional, but they will become required for manufacturers on      .
23. If it is obvious why reporting a complaint is not required, then documenting the rationale is not required?
    1. True
    2. False