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.

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