Unit 5 - Week 3

Assignment 3

The due date for submitting this assignment has passed.
As per our records you have not submitted this assignment.

Due on 2020-02-19, 23:59 IST.

Dear Participants,

This week we have covered 3 lectures. They were:

Lecture 7: Quality assurance and quality management system
Lecture 8: How to obtain a licence to manufacture a medical device?
Lecture 9: ISO 14971 (Medical devices: Application of risk management to medical devices)

Lecture 7: Quality assurance and quality management system
In this lecture, we explained the difference between the quality assurance and quality control. We also covered ISO 13485 guidelines used in the medical device. The quality management system (QMS) derived from the ISO 13485 were also covered adequately. A brief discussion on Schedule M III were covered along with paragraphs of fifth schedule and paragraphs related to Good Manufacturing Practice /9/GMP).

Lecture 8: How to obtain a licence to manufacture a medical device?
In this lecture, we learned about the sequence of procedures involved in the grant of device licence. We also covered the basic requirements of device manufacturing licence. We covered in details about how to obtain a licence to manufacture a medical device. All the documents for the grant of device manufacturing licence were discussed along with the forms etc.

Lecture 9: ISO 14971 (Medical devices: Application of risk management to medical devices)
In this lecture, we learned what is risk management? The risk management (RM) process was discussed in detail. The standards for RM along with its general requirements were discussed. The key terms and their definitions were discussed.

Best of luck for completing the assignment 3!

1) **State true or false.** ***2 points***

ISO 14971 provides manufacturers with a framework to manage the risks associated with the use of medical devices.

- True
- False

No, the answer is incorrect.
Score: 0
Accepted Answers:
True

2) _____ is the update version of Quality Risk Management. ***2 points***

- ISO 14971: 2015
- ISO 14971: 2017
- ISO 14971: 2019
- None of the above

No, the answer is incorrect.
Score: 0
Accepted Answers:
ISO 14971: 2019

3) _____ is physical injury or damage to the health of people, or damage to property or the environment. ***2 points***

- Harm
- Hazard
- Hazardous situation
- None of the above

No, the answer is incorrect.
Score: 0
Accepted Answers:
Harm

4) The manufacturer shall compile documentation on known and foreseeable hazards associated with the medical device in _____ conditions. ***2 points***

- Normal
- Fault
- Both of the above
- None of the above

No, the answer is incorrect.
Score: 0
Accepted Answers:
Both of the above

5) In case of investigational medical device or new IVD, the applicant shall obtain prior permission in Form MD-27 or Form MD-29 from the Central Licensing Authority and no licence to manufacture any class of such medical device shall be granted without such permission. ***2 points***

- True
- False

No, the answer is incorrect.
Score: 0
Accepted Answers:
True

6) The State Licensing Authority (SLA) shall, in cases where licence has been granted for manufacturing Class A and Class B medical devices, cause an inspection of the manufacturing site to be carried out by a medical device officer on a random basis and such inspection shall not be less than _____ of the total audits carried out by the notified bodies. ***2 points***

- 01%
- 02%
- 05%
- 10%

No, the answer is incorrect.
Score: 0
Accepted Answers:
02%

7) A small quantity of Class A/B/C/D of medical devices may be manufactures for the purpose of clinical investigations. ***2 points***

- True
- False

No, the answer is incorrect.
Score: 0
Accepted Answers:
True

8) The fees for medical devices and IVDs of Class A & B is _____ for each site and _____ for each distinct medical device. ***2 points***

- INR 5000 & INR 50,000
- INR 50,000 & INR 5000
- INR 5000 & INR 5000
- INR 5000 & INR 500

No, the answer is incorrect.
Score: 0
Accepted Answers:
INR 5000 & INR 500

9) ISO 13485 is not the only document required in QMS of medical devices. ***2 points***

- True
- False

No, the answer is incorrect.
Score: 0
Accepted Answers:
True

10) The Quality Management System in medical devices and IVDs is complementary in nature to the technical requirements for product and do not replace them. ***2 points***

- True
- False

No, the answer is incorrect.
Score: 0
Accepted Answers:
True