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Unit 4 - Week 2

Register for Certification exam

Course outline

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Assignment 2

The due date for submitting this assignment has passed.
As per our records you have not submitted this assignment. **Due on 2019-03-13, 23:59 IST.**

Dear Participants,

This week we have covered 3 lectures. They were:

Lecture 4: Types of devices including combination devices
Lecture 5: Standards of medical device, quality assurance and testing
Lecture 6: Technical personnel: Manufacture of medical devices & IVDs

Lecture 4: Types of devices including combination devices
In this lecture, we revisited the definition of medical devices to have a better understanding when it comes to describing various types of devices which includes combination device. We also covered some facts related to medical devices. This lecture addressed active devices, active implantable devices, non-invasive and combination devices. We also studied about types of combination devices citing various examples.

Lecture 5: Standards of medical device, quality assurance and testing
In this lecture, we discussed the basic characteristic differences between medical device and drugs that define testing. We studied formal standards, medical device standards, ISO etc. This lecture also addressed how do standards gets incorporated in to the regulations. The Rule 7 of product standards for medical device as per MDR (Medical Devices Rules), 2017 were briefly covered. This lecture gave an overview of quality assurance in medical device industry addressing the quality assurance processes. In the medical device testing, determining the testing requirements for novel devices were discussed. It also covered the testing requirements for regulatory submissions. The lecture covered various aspects of testing of active and non-active medical devices. It also briefly covered IEC 60601, environmental testing, ISO 10993-1 biocompatibility testing, CB scheme process, biological, physical and chemical testing, sterilisation processes for medical devices - ISO 11135, ISO 11137, ISO 17665, ISO 14644 Cleanroom environments for medical devices etc.

Lecture 6: Technical personnel: Manufacture of medical devices & IVDs
In this lecture, we understood why we require technical personnel in the manufacture of medical devices and IVDs. We referred to the regulations where there is a mention of competent technical personnel in-charge of manufacturing and testing. We covered Form MD-9 and chapter IV briefly.

Government of India
Ministry of Human Resource De

1) Active implantable medical devices are _____ devices that are inserted into a patient's body, through either a natural orifice or by surgical means, and are intended to remain in the patient's body after the procedure.

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) powered

1 point

2) _____medical device is a device that involves a medical device and/or a drug and/or a biologic

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) Combination

1 point

3) combining any two of these product categories, and sometimes even all _____.

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) three
(Type: String) 3
(Type: String) III

1 point

4) Hypodermic needles are an example of _____ device ***1 point***

- Non-invasive
- Invasive
- Both invasive as well as non-invasive
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Invasive

5) ***4 points***

Match the following.

A. Coagulation test	1. Invasive device
B. Blood gas analyser	2. Active implantable medical device
C. Defibrillators	3. Active therapeutic medical device
D. Suture needles	4. Active diagnostic medical device

- 4,3,2,1

- 3,1,2,4
- 2,4,1,3
- 1,3,4,2

No, the answer is incorrect.
Score: 0

Accepted Answers:
4,3,2,1

6) _____establishes the requirements for a quality management system for both the design and manufacture of medical devices.

Hint

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) ISO 13485

1 point

7) _____covers aspects including risk management, design control during product development, and verification and validation systems.

Hint

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) ISO 14179

1 point

8) IEC 60603 is a series of technical standards thata ensure the safety and essential performance of medical electrical equipment. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

9) _____deals with the basic safety and essential performance requirements of medical electrical equipment, and serves to ensure that no single electrical, mechanical or functional failure shall pose an unacceptable risk to patients and/or operators.

Hint

No, the answer is incorrect.

Score: 0

Accepted Answers:
(Type: String) ISO 60601-1

1 point

10) The ISO standard dealing with the biocompatibility testing of medical devices (biological evaluation of medical devices) is _____.

Hint

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) ISO 10993-1

1 point

11) Sterilisation processes for medical devices are briefly covered in ISO 11135, ISO 11137 and ISO 17665 ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

12) The control of microbial contamination in cleanrooms is expected to meet the requirements under _____ ***1 point***

- ISO 13485
- ISO 11135
- ISO 14698
- ISO 14644

No, the answer is incorrect.
Score: 0

Accepted Answers:
ISO 14698

13) The manufacturing site shall comply with the requirements of the Quality Management System as specified under which Schedule? ***1 point***

- Fifth
- Third
- Second
- First

No, the answer is incorrect.
Score: 0

Accepted Answers:
Fifth

14) The establishment's responsibility end with competent technical personnel. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

15)_____covers manufacture of medical devices for sale or for distribution.

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) Chapter IV
(Type: String) Chapter 4
(Type: String) 4th Chapter
(Type: String) 4 Chapter
(Type: String) IV

1 point

16)_____ of the manufacturer shall ensure that responsibilities and authorities are defined, documented and communicated within the manufacturing organisation. ***1 point***

- HR
- Admin
- Finance
- Top management

No, the answer is incorrect.
Score: 0

Accepted Answers:
Top management

17)Smoking, eating, drinking, chewing or keeping food and drink shall not be permitted in _____ areas. ***1 point***

- Production
- Laboratory
- Storage
- All the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
All the above

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