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Unit 5 - Week 3

Register for Certification exam

Course outline

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Assignment 3

The due date for submitting this assignment has passed.
As per our records you have not submitted this assignment. **Due on 2019-03-20, 23:59 IST.**

Dear Participants,

I hope you enjoyed the 2 lectures covered last week. They were:

Lecture 7: Quality assurance and quality management system
Lecture 8: How to obtain a licence to manufacture a medical device?

Lecture 7: Quality assurance and quality management system
In this lecture, we understood the details about the quality assurance and quality management system with respect to medical devices. We studied what is ISO 13485 in detail. All the paragraphs of Fifth Schedule were covered in this lecture along with a brief overview of Schedule M III. This lecture also apprised us about the paragraphs related to GMP.

Lecture 8: How to obtain a licence to manufacture a medical device?
In this lecture, the focus was to understand the step by step procedures for obtaining a license to manufacture a medical device. This lecture briefly covered the rules that apply for the grant of manufacturing licence including all basic requirements of device manufacturing licence. It also covered various other information such as fees and form numbers (including the appendix forms) applicable for manufacturing and/or loan licence for various class of medical devices.

Best of luck for completing the assignment 3.

1) Quality control and quality assurance are same. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Government of India
Ministry of Human Resource De

- Infructuous
- Better
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Infructuous

3) ***4 points***

Match the following.

A. ISO/TR 14969:2004	1. Biological evaluation of medical devices (Evaluation and testing within a risk management process)
B. ISO 10993-1:2009	2. Application of risk management to medical devices
C. ISO 14971:2007	3. Medical devices (Application of usability engineering to medical devices)
D. ISO 62366-1:2015	4. Medical devices (Quality management systems — Guidance on the application of ISO 13485:2003)

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

No, the answer is incorrect.
Score: 0

Accepted Answers:
4,1,2,3

4) The Fifth Schedule has _____paragraphs describing each and every aspect of the quality management system that a firm needs to follow.

No, the answer is incorrect.
Score: 0

Accepted Answers:
(Type: String) Eight
(Type: String) 8
(Type: String) VIII

1 point

5) Para 3 of the Fifth Schedule deals with the Quality Management System ***1 point***

- Ture
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

6) ***3 points***

Match the following.

The licensing authorities with respect to the type of medical devices and in vitro diagnostics they regulate in India

A. CDSCO	1. QMS verification of Class B devices
B. SLA	2. Manufacture of Class C devices
C. Notified bodies	3. Sale of Class D devices

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

No, the answer is incorrect.
Score: 0

Accepted Answers:
3,1,2

7) Para 6.4 of work environment mentions that all personnel shall bear clean body covering appropriate to their duties. Smoking, eating, drinking, chewing or keeping food and drink shall not be permitted in production, laboratory and storage areas. ***1 point***

- Ture
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
Ture

8) ISO 13485:2016 deals with the medical devices quality management system – requirements for regulatory purposes. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

9) The manufacturer shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. ***1 point***

The above sentence addresses _____.

- Corrective action
- Preventive action
- Corrective and preventive action
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Preventive action

10) The basic requirements for applying a manufacturing license for medical devices includes that the premises should be as per the requirements laid down by the Medical Device Rules 2017. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

11) The fees for medical devices or in vitro diagnostics Class _____& Class _____ ***4 points***
for site is INR 5000 and INR 500 for each distinct medical device.

- A & B
- B & C
- C & D
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
A & B

12) ***1 point***

Match the following.

A. Rule 24	1. Inspection for grant of licence or loan licence for Class C or Class D medical device
B. Rule 21	2. Grant of licence or loan licence to manufacture for sale or for distribution
C. Rule 25	3. Application for manufacturing Class C or Class D devices
D. Rule 23	4. Inspection report

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

No, the answer is incorrect.
Score: 0

Accepted Answers:
4,3,2,1

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