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Unit 6 - Week 4

Assignment 4

The due date for submitting this assignment has passed.
As per our records you have not submitted this assignment. **Due on 2019-03-27, 23:59 IST.**

Dear Participants,

I hope you enjoyed the last two lectures of this course. We have completed the course.

Lecture 9: Inspection of medical device and IVD establishments
Lecture 10: Import and export of medical devices and IVDs

Lecture 9: Inspection of medical device and IVD establishments
In this lecture, we studied the definition of inspection, understood the reason behind the conduct of inspections. We also studied various types of inspections. We learnt the steps in inspection

Lecture 10: Import and export of medical devices and IVDs
In this lecture, the focus was to understand import and export formalities of medical devices and in vitro diagnostics in India. The lecture covered the provisions for import of medical devices in brief. It stated the requirements for import licence for test, evaluation and demonstration. This lecture covered the timelines of all import related steps. This lecture also briefly covered the export related information of medical devices.

Best of luck for the exam.

1) Inspection of establishments licensed/to be licensed under the Drugs & Cosmetics Act are carried out to evaluate if the they have been set up according to the norms, as stated in the regulations. ***1 point***

- True
- False

No, the answer is incorrect

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- Non-regulatory
- Can be either regulatory or non-regulatory
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Non-regulatory

3) _____ inspections are carried out to investigate complaints or inconsistencies of the firms products or in its working. ***1 point***

- Investigational
- Investigation
- Investigative
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Investigative

4) Investigative inspections can be announced or non-announced and surprise, depending on the nature of the _____. ***1 point***

- Investigation
- Inspection
- Complaint
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Complaint

5) Self-inspections are done by the regulators. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

6) _____ have the power under the regulations to carry out inspections of medical device manufacturing establishments. ***1 point***

- Inspectors
- Auditors
- Medical device officers
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Medical device officers

7) Import of medical device is covered under Chapter VI. **1 point**

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

8) As per Rule 35, the applicant for import has to deposit an inspection fee specified in the second schedule of the regulation. **1 point**

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

9) Results of inspection can have the following outcomes: **1 point**

- Grant of licence,
- Grant of licence subject to re-inspection after removal of shortcomings
- Rejection of application for grant of license
- All of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
All of the above

10) "Medical Device Officer" means an officer appointed or designated by the Central Government or the State Government, as the case may be, under sub-rule (2) of rule 22. **1 point**

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

11) A plant master file is prepared by the licensee and submitted to get a birds eye view of the manufacturing site **1 point**

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

12) _____ ensures the safety and effectiveness of a device. **1 point**

- Inspection
- Compliance

- Audit
- None of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
Compliance

13) Validity of licence is covered under Rule 36 **1 point**

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

14) The licensee shall inform the licensing authority, within a period of _____ days **1 point** of any administrative action taken on account of any adverse reaction, such as market withdrawal, regulatory restrictions, cancellation of authorisation or declaration of the medical device as not of standards quality by the regulatory authority of the country of origin or by any regulatory authority of any other country, where the medical device is marketed, sold or distributed.

- Ten
- Fifteen
- Thirty
- Sixty

No, the answer is incorrect.
Score: 0

Accepted Answers:
Fifteen

15) As per Rule 42, a Government hospital or a statutory medical institution is allowed to import an investigational medical device subject to the following: **1 point**

- Only small quantity of such devices shall be imported
- The devices shall be approved in the country of origin may be allowed for treatment of patient suffering from life threating diseases, diseases causing permanent disability or disease requiring therapy for unmet medical need.
- The application in form MD-18 has to be made by a medical officer through the medical superintendent of the Hospital along with fee as specified in second schedule.
- A license in Form 19 shall be issued once the central license authority is satisfied about the information and documents submitted by the medical officer.
- All of the above

No, the answer is incorrect.
Score: 0

Accepted Answers:
All of the above

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