Unit 3 - Week 1

Assignment 1

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

Due on 2020-02-12, 23:59 IST.

Dear Participants,
This entire four-week course is split into 12 lectures (3 lectures every week.)

This week we have covered 3 lectures. They were:

Lecture 1: Medical device and in vitro diagnostic: Introduction & types of devices including combination devices
Lecture 2: Medical Device Rules, 2017: Implications on medical devices
Lecture 3A: Classification of medical devices
Lecture 3B: Labelling of medical devices and diagnostics

Lecture 1: Medical device and in vitro diagnostic: Introduction & types of devices including combination devices
In this lecture, we covered what is a medical device, its WHO definition, difference between a drug and a device, the medical device regulatory framework in India. We also came to know how medical devices are regulated in India, their historical perspectives, list of medical devices notified, users of medical device, and definition of medical device as per the D & C Act 1940. We also discussed very briefly the Medical Devices Rules, 2017. Lecture 1 also covered the definition of in vitro diagnostics (IVD), their classification. In types of devices including combination devices, 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 2: Medical Device Rules, 2017: Implications on medical devices
In this lecture, we discussed about the medical devices sector and their present challenges. This lecture mainly addressed the medical devices rules 2017, its scope in the regulation, risk-based classification in very brief. It also gave a very brief idea about the medical device regulatory framework addressing the activities controlled by the Central and State Licensing Authorities. This lecture also covered information related to registration of notified bodies, scope of these notified bodies. All the forms related to medical devices were also covered in this lecture. This lecture gave an overview of the online portal.

Lecture 3A: Classification of medical devices

Lecture 3B: Labelling of medical devices and diagnostics
In this lecture, we discussed why the classification of medical devices are required. It also covered the basic principles of classification of medical devices. This lecture was focused on risk-based classification. This lecture also gave us a brief understanding on the responsibilities of regulatory authorities in India when it comes to import, manufacture, permission to conduct clinical investigation, sale and QMS verification of medical devices (class wise). This lecture addressedhow classification is done globally. The general parameters for classification were discussed. This lecture also addressed the labelling requirements of medical devices and IVDs in great detail.

Best of luck for completing the assignment 1

1) Fill in the blanks. **2 points**

IVDs are substances that are intended for the use in _____ of _____in human being or animals

- Analytes, Reagent kits
- Diagnosis, Disease/Disorders
- Treatment, Disease/Disorders
- Diagnosis, Treatment

No, the answer is incorrect.
Score: 0
Accepted Answers:
Diagnosis, Disease/Disorders

2) Scope of notified bodies only include class _____ and class _____ in medical devices. **2 points**

- A; B
- B; A
- A; C
- B; C

No, the answer is incorrect.
Score: 0
Accepted Answers:
A; B

3) Import of all classes of medical devices are controlled by **1 point**

- State Licensing Authorities
- Central Licensing Authority
- Both of the above
- None of the above

No, the answer is incorrect.
Score: 0
Accepted Answers:
Central Licensing Authority

4) Match the following : **4 points**

A. Low risk	**1. Class A**
B. High risk	**2. Class B**
C. Moderate high risk	**3. Class C**
D. Low moderate risk	**4. Class D**

- A-1; B-4; C-3; D-2
- A-1; B-2; C-3; D-4
- A-4; B-3; C-2; D-1
- A-1; B-2; C-2; D-4

No, the answer is incorrect.
Score: 0
Accepted Answers:
A-1; B-4; C-3; D-2

5) Medical Devices Rules, 2017 has _____ Rules, _____ Chapters, _____ Schedules and _____ Forms **4 points**

- 08;12:40;96
- 96:40;12:08
- 96;12;08;40
- 96:08:12:40

No, the answer is incorrect.
Score: 0
Accepted Answers:
96;12;08;40

6) G.S.R. _____ dated the 31st January 2017 to have specific requirements for import, manufacture, sale and distribution of medical devices and in vitro diagnostics in the country. **1 point**

- 74(E)
- 75(D)
- 78(C)
- 78(E)

No, the answer is incorrect.
Score: 0
Accepted Answers:
78(E)

7) What GMP is to a drug _____ is to a device. **1 point**

- LQMS
- QMS
- ISO
- NABL

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

8) All notified bodies for medical devices should be registered with _____. **1 point**

- IDMA
- SLA
- AIMeD
- CDSCO

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

9) Medical device is any instrument, apparatus, appliance, software, material, or other article whether used *alone* or in *combination* , including the software to be used for _____ and/or _____ purposes in human. **2 points**

- Analytes, Reagent kits
- Diagnosis, Disease/Disorders
- Treatment, Disease/Disorders
- Diagnostic, Therapeutic purposes

No, the answer is incorrect.
Score: 0
Accepted Answers:
Diagnostic, Therapeutic purposes

10) Manufacture of class A and B are controlled by _____ while class C and D are controlled by _____ **1 point**

- State Licensing Authorities and Central Licensing Authority
- Central Licensing Authority and State Licensing Authorities
- Central Licensing Authority in both cases
- State Licensing Authorities in both cases

No, the answer is incorrect.
Score: 0
Accepted Answers:
State Licensing Authorities and Central Licensing Authority

11) Basic principle of classification of medical device is _____ based. **1 point**

- Classification
- Risk
- Value
- Price

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