Unit 4 - Week 2

Assignment 2

The due date for submitting this assignment has passed. **Due on 2020-02-12, 23:59 IST.**
As per our records you have not submitted this assignment.

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 4: Standards of medical device, quality assurance, and testing
Lecture 5: Regulatory requirements of biocompatibility of medical devices and ISO 10993
Lecture 6: Clinical investigation of medical devices: regulation of investigational medical devices

Lecture 4: Standards of medical device, quality assurance, and testing
In this lecture, we discussed all the standards agencies across the world. We also discussed the standards situation in India. The lecture covered the preparation of standards process in India as well as the process followed by developed economies in case of standard. We briefly covered quality assurance, testing methodology in development and release as well as usual tests carried out by the manufacturer or notified bodies for medical devices evaluation.

Lecture 5: Regulatory requirements of biocompatibility of medical devices and ISO 10993

In this lecture, we learned what is biocompatibility? We also understood the biological evaluation procedures within the risk management process. The lecture also covered the characterization of medical devices and test selection. Standards of biocompatibility tests - ISO 10993 was discussed in brief. All the general principles being applied to the biological evaluation of medical devices were covered in this lecture.

Lecture 6: Clinical investigation of medical devices: regulation of investigational medical devices

In this lecture, we learned that clinical trials of medical devices is not the same as that of new drugs (phytopharmaceuticals, vaccines, etc.). There is no Phase I, II and III studies in medical devices. We also studied various requirements for clinical investigation as per the Medical Devices Rules, 2017 in this lecture.

Best of luck for completing the assignment 2!

1) Which is NOT an example of biomaterials application in medical devices. **2 points**

- Bone plates
- Bone cements
- Bone joints
- Artificial ligaments and tendons

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

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

_____ is the ability of a device material to perform with an appropriate host response in a specific situation or a measurement of how compatible a device is with a biological system.

- Bioavailability
- Bioequivalence
- Biological evaluation
- Biocompatibility

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

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

_____ is a device or a device component that includes all manufacturing processes including packaging and sterilization.

- Final Finished Form
- Finished Form
- Final Form
- None of the above

No, the answer is incorrect.
Score: 0
Accepted Answers:
Final Finished Form

4) Biocompatibility standards that can be used to facilitate information submission to the regulator is/are: **2 points**

- ISO 10993-1 and related 10993 series of standards
- ASTM, ICH, OECD, and Pharmacopoeial biocompatibility standards
- Both of the above
- None of the above

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

5) _____ is a device, first time and first of its kind, approved for manufacture for sale or for import by the Central Licensing Authority and has the similar intended use, material of construction, and design characteristics as the device which is proposed for licence in India. **2 points**

- Investigational medical device
- Investigational IVD
- Modified device
- Predicate device

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

6) Amount of fees (Indian Rupees) to be paid for seeking permission to conduct pilot clinical investigation is _____ and to conduct pivotal clinical investigation is _____. **2 points**

- 50, 000; 1,00,000
- 50,000; 75,000
- 75;000; 75,000
- 1,00,000; 1,00,000

No, the answer is incorrect.
Score: 0
Accepted Answers:
1,00,000; 1,00,000

7) A small number of medical devices for personal use can be imported and the application by the patient needs to be made in _____ along with the prescription from a registered medical practitioner. **2 points**

- MD-18
- MD-19
- MD-20
- MD-21

No, the answer is incorrect.
Score: 0
Accepted Answers:
MD-20

8) What is the document(s) necessary for seeking a grant of permission to conduct a clinical investigation? **2 points**

- Investigator's undertaking
- Ethics Committee approval
- Regulatory Status in other countries
- All of the above

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

9) **Which of the option is correct.** **2 points**

Statement 1: Medical device testing should not be compared with the testing of drugs,
Statement 2: Drugs are tested destructively. This means that the drugs actually tested cannot be used.

- Statement 1
- Statement 2
- Both Statement 1 and 2 are incorrect
- Both Statement 1 and 2 are correct

No, the answer is incorrect.
Score: 0
Accepted Answers:
Both Statement 1 and 2 are correct

10) Standard testing procedures may not be applied for the medical device testing due to large number of _____ and _____. **2 points**

- Variables; Models
- Complexities; Procedures
- Patients; Institutions
- None of the above

No, the answer is incorrect.
Score: 0
Accepted Answers:
Variables; Models