Unit 2 - Week 0

Assignment 0

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

Due on 2020-01-27, 23:59 IST.

Note : This assignment is only for practice purpose and it will not be counted towards the Final score

Background: Medical devices and *in vitro* diagnostics forms an important component of healthcare today. These products are not drugs but play an important role in either individually or in conjunction with drugs in patient care.

Clinical Development Service Agency (CDSA) is being involved in organising and conducting GCP (Good Clinical Practice) and regulatory workshops all over the country since 2012 to educate the stake holders and apprise them about recent drugs & cosmetics Rule amendment.

This online course "Regulatory requirements for medical devices including in vitro diagnostic in India" is designed for manufacturers, applicants for manufacturing and import license of devices, pharmacists and other healthcare professionals involved in design, development, manufacture of medical devices, IVDs, etc. These lectures are designed in such a way that it can give an insight into the topic for even lay people. Lectures in this course are delivered by current and former Central Drugs Standard Control Organisation (CDSCO) (Regulators) Senior Officers to explore the scientific, regulatory and ethical aspects of medical devices. The series of lectures deals and describes in easy language different aspects related to manufacturing requirements, standards, classification, licensing, technical and other manpower related aspects. In brief, this course attempts to give an overview of all the regulatory requirements in the area of medical devices and IVDs in India.

1) Are there differences between medical devices and drugs? ***1 point***

- Yes
- No

No, the answer is incorrect.
Score: 0

Accepted Answers:
Yes

2) Medical device manufacturing does not require any special skill and anybody can manufacture them. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False

3) Medical devices are clinically evaluated rather than undergoing routine clinical trials. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

4) In India, medical devices are regulated by specific regulations under "The Drugs & Cosmetics Act" ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

5) Products like knee caps and screws used to fix orthopaedic plates are medical devices. ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
True

6) Blood testing reagents are not covered under any law and are not devices ***1 point***

- True
- False

No, the answer is incorrect.
Score: 0

Accepted Answers:
False