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Courses » Regulatory requirements for medical devices and IVDs in India

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## Unit 2 - Week 0

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### Course outline

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#### Week 0

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## Assignment 0

The due date for submitting this assignment has passed.

As per our records you have not submitted this **Due on 2019-02-25, 23:59 IST.**  
assignment.

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 and IVDs 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 former and current Central Drugs Standard Control Organisation (CDSCO) (Regulators) 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**

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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*

End

