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Courses » Current regulatory requirements for conducting clinical trials in India

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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: Clinical trials are a complex undertaking, but they are essential for assessing the safety and efficacy of CDSCO (Central Drugs Standard Control Organisation)-regulated new drug products in India. Since 2012-13, there has been some changes in the clinical trial rules and regulations in India.

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

This online course "Current regulatory requirements for conducting clinical trials in India" is designed for physicians, nurses, pharmacists and other healthcare professionals involved in clinical trials. Lectures in this course are delivered by former and current CDSCO officers (Regulators) as well as non-regulators from CDSA to explore the scientific, regulatory and ethical aspects of clinical trials. The course also briefly covers an overview of non-clinical, early clinical, and phase 1-3 studies, issues in the design and analysis of trials, safety and ethical considerations and CDSCO regulatory requirements related to the performance and evaluation of clinical studies.

1) Requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials is covered under _____ and it was last amended in _____ (hint: year).

Hint

No, the answer is incorrect.

Score: 0

Accepted Answers:

(Type: String) Schedule Y, 2005

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False

No, the answer is incorrect.

Score: 0

Accepted Answers:

True

3) GCP is defined as an international ethical and quality 'standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, safety and well-being of study participants are protected' **1 point**

True

False

No, the answer is incorrect.

Score: 0

Accepted Answers:

True

4) In India, drugs, new drugs, cosmetics, medical devices and clinical trials are regulated as per "Drugs & Cosmetics Act and Rules" thereunder. **1 point**

True

False

No, the answer is incorrect.

Score: 0

Accepted Answers:

True

End