ISO 14155:2011, Clinical Investigation Of Medical Devices For Human Subjects - Good Clinical Practice


INTERNATIONAL STANDARD

ISO 14155

Clinical investigation of medical devices for human subjects — Good clinical practice

Synopsis

ISO 14155:2011 addresses good clinical practice for the design, conduct, recording and reporting of clinical investigations carried out in human subjects to assess the safety or performance of medical devices for regulatory purposes. The principles set forth in ISO 14155:2011 also apply to all other clinical investigations and should be followed as far as possible, depending on the nature of the clinical investigation and the requirements of national regulations.ISO 14155:2011 specifies general requirements intended to protect the rights, safety and well-being of human subjects, ensure the scientific conduct of the clinical investigation and the credibility of the results, define the responsibilities of the sponsor and principal investigator, and assist sponsors, investigators, ethics committees, regulatory authorities and other bodies involved in the conformity assessment of medical devices.ISO 14155:2011 does not apply to in vitro diagnostic medical devices.

Book Information

Paperback: 68 pages

Publisher: Multiple. Distributed through American National Standards Institute (ANSI) (January 21, 2011)

Language: English

ASIN: B008S7MZF0

Product Dimensions: 8.2 x 0.2 x 10.5 inches

Shipping Weight: 7.7 ounces (View shipping rates and policies)

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