



Ebook Directory
the best source of ebook

The book was found

ISO 14155:2011, 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)

Average Customer Review: Be the first to review this item

Best Sellers Rank: #2,762,877 in Books (See Top 100 in Books) #26 in Books > Engineering & Transportation > Engineering > Reference > American National Standards Institute (ANSI)

Publications #474943 in Books > Textbooks

[Download to continue reading...](#)

ISO 14155:2011, Clinical investigation of medical devices for human subjects - Good clinical practice ISO 14971:2007, Medical devices - Application of risk management to medical devices ISO 14971:2000, Medical devices -- Application of risk management to medical devices Praxis II Elementary Education Multiple Subjects 5001 Study Guide: Test Prep & Practice Test Questions for the Praxis 2 Elementary Education Multiple Subjects 5001 Exam ISO/IEC 27002:2005, Information technology - Security techniques - Code of practice for information security management (Redesignation of ISO/IEC 17799:2005) ISO 13485:2016, Third Edition: Medical devices - Quality management systems - Requirements for regulatory purposes ISO 13485:2003, Medical devices -

Quality management systems - Requirements for regulatory purposes ISO 11135:2014, Second Edition: Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices Medical Terminology: Medical Terminology Easy Guide for Beginners (Medical Terminology, Anatomy and Physiology, Nursing School, Medical Books, Medical School, Physiology, Physiology) Medical Terminology: Medical Terminology Made Easy: Breakdown the Language of Medicine and Quickly Build Your Medical Vocabulary (Medical Terminology, Nursing School, Medical Books) Prostheses: Design, Types, and Complications (Biomedical Devices and Their Applications; Medical Devices and Equipment) ISO/TS 20022-3:2004, Financial services - UNlversal Financial Industry message scheme - Part 3: ISO 20022 modelling guidelines ISO 20022-1:2004, Financial services - UNlversal Financial Industry message scheme - Part 1: Overall methodology and format specifications for inputs to and outputs from the ISO 20022 Repository ISO/TS 20022-5:2004, Financial services - UNlversal Financial Industry message scheme - Part 5: ISO 20022 reverse engineering ISO/TS 20022-4:2004, Financial services - UNlversal Financial Industry message scheme - Part 4: ISO 20022 XML design rules ISO/TS 22004:2005, Food safety management systems - Guidance on the application of ISO 22000:2005 Sully's Challenge: "Miracle on the Hudson" â “ Official Investigation & Full Report of the Federal Agency: True Event so Incredible It Incited Full Investigation ... after Both Engine Stopped by Canada Geese Casualty investigation code: code of international standards and recommended practices for a safety investigation into a marine casualty or marine incident Spitz and Fisher's Medicolegal Investigation of Death: Guidelines for the Application of Pathology to Crime Investigation ISO 22716:2007, Cosmetics - Good Manufacturing Practices (GMP) - Guidelines on Good Manufacturing Practices

[Contact Us](#)

[DMCA](#)

[Privacy](#)

[FAQ & Help](#)