Research and Markets: Biocompatibility and Performance of Medical Devices

The Associated Press

DUBLIN--(BUSINESS WIRE)--Nov 6, 2012--Research and Markets (http://www.researchandmarkets.com/research/84zr7c/biocompatibility) has announced the addition of Woodhead Publishing Ltd's new book "Biocompatibility and performance of medical devices" to their offering.

Implant and device manufacturers are increasingly facing the challenge of proving that their products are safe, biocompatible, and perform as expected. Biocompatibility and Performance of Medical Devices provides an essential guide to the performance analysis of these vital devices.

Part one introduces key concepts and challenges faced in relation to biocompatibility in medical devices. Part two goes on to discuss the evaluation and characterisation of biocompatibility in medical devices, including material and chemical characterization, allowable limits for toxic leachables, in vivo and in vitro testing, and blood compatibility assessment. Testing and interpreting medical device performance is the focus of part three, with preclinical performance studies for bone, dental and soft tissue implants, and mechanical testing for soft and hard tissues implants discussed. Part four provides information on the international regulation of medical devices in the European Union, Japan and China, before concluding in part five with a review of histopathology principles for biocompatibility and performance studies.

Key Topics Covered: Part 1 Introduction to biocompatibility in medical devices: Concepts in biocompatibility - Challenges in biocompatibility and failure of biomaterials - Biological safety evaluation planning of biomaterials - Biomechanical and biochemical compatibility in innovative biomaterials.

Part 2 Evaluation and characterisation of biocompatibility in medical devices: Material and chemical characterization for the biological evaluation of medical device biocompatibility - Allowable limits for toxic leachables: Practical Use of ISO 10993-17 Standard - In vivo and in vitro testing for the biological safety evaluation of biomaterials and medical devices - Blood compatibility assessment in medical devices: Considerations and standards - Evaluating biocompatibility in biomaterials - an industry perspective - Case study - overcoming negative tests results during manufacture - Methods for the characterisation and evaluation of drug-device combination products.

Part 3 Testing and interpreting the performance of medical devices: Methods and interpretation of preclinical performance studies for bone implants - Methods and interpretation of preclinical performance studies for dental implants - Methods and interpretation of preclinical performance studies for soft tissues implants -

Mechanical testing for soft and hard tissues implants.

Part 4 International regulation of medical devices: Biological evaluation and regulation of medical devices in the European Union - Biological evaluation and regulation of medical devices in Japan - Medical device regulations in China.

Part 5 Histopathology principles for biocompatibility and performance studies: Microscopic and ultrastructural pathology in medical devices.

Author Jean-Pierre Boutrand is General Manager and Scientific Director for Biomatech, the European division of NAMSA. Dr. Boutrand has been involved in more than 60 public presentations or publications on topics related to medical device evaluation and is registered as an expert on the biological safety of medical devices for the AFSSAPS.

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