



Biomaterials, Medical Devices, and Combination Products: Biocompatibility Testing and Safety Assessment

Shayne Cox Gad, Samantha Gad-McDonald

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Biomaterials, Medical Devices, and Combination Products is a single-volume guide for those responsible for—or concerned with—developing and ensuring patient safety in the use and manufacture of medical devices.

The book provides a clear presentation of the global regulatory requirements and challenges in evaluating the biocompatibility and clinical safety of the materials used in producing medical devices as well as the devices themselves.

Starting with material characterization and selection, considerations of concerns arising from packaging and contact with production machinery, and extensive coverage of combination products, the book also provides the latest approaches to isolating, quantitating, identifying and assessing the risk arising from chemical entities released from market-ready devices.

Also incorporated are new case examples and citations with the means of access to Internet-based regulatory and scientific sites, reflecting the universal adoption of this technology into our world.

The book takes into consideration the fact that device markets are global, the continual advancement of technology, and the increasing global harmonization of safety regulations. Each aspect of device safety evaluation is reviewed in terms of the International Organization for Standardization (ISO), US Food and Drug Administration (FDA), European Union (EU), and Japanese Ministry of Health, Labour, and Welfare (MHLW) perspectives.

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