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W3C Integrated Safety and Risk Assessment for Medical Devices and
Combination Products The Combination Products Handbook
The Ruby Way

Integrated Safety and Risk Assessment for Medical Devices and Combination Products

2020-02-24 while the safety assessment biocompatibility of medical devices has been focused on issues of local tissue tolerance irritation sensitization cytotoxicity and selected quantal effects genotoxicity and acute lethality since first being regulated in the late 1950s this has changed as devices assumed a much more important role in healthcare and became more complex in both composition and in their design and operation add to this that devices now frequently serve as delivery systems for drugs and that drugs may be combined with devices to improve device performance and the problems of ensuring patient safety with devices has become significantly more complex a part of this requirements for ensuring safety once based on use of previously acceptable materials largely polymers and metals have come to requiring determining which chemical entities are potentially released from a device into patients and how much is released then an appropriate and relevant yet also conservative risk assessment must be performed for each identified chemical structure the challenges inherent in meeting the current requirements are multifold and this text seeks to identify understand and solve all of them identify and verify the most appropriate available data as in most cases such data is for a different route of exposure transform it for use in assessing exposure by the route of interest as the duration and rate of exposure to moieties released from a device are most frequently different longer than what available data speaks to transformation across tissue is required as innate and adaptive immune responses are a central part of device patient interaction assessing potential risks on this basis are required incorporating assessments for special populations such as neonates use of q sar quantitative structure activity relationships modeling in assessments performance and presentation of integrative assessments covering all potential biologic risks appendices will contain summarized available biocompatibility data for commonly used device materials polymers and metals and safety assessments on the frequently seen moieties in extractions from devices

The Combination Products Handbook 2023-05-16 combination products are therapeutic and diagnostic products that combine drugs devices and or biological products according to the us food and drug administration fda a combination product is one composed of any combination of a drug and a device a biological product and a device a drug and a biological product or a drug device and a biological product examples include prefilled syringes pen injectors autoinjectors inhalers transdermal delivery systems drug eluting stents and kits containing drug administration devices co packaged with drugs and or biological products this handbook provides the most up to date information on the development of combination products from the technology involved to successful delivery to market the authors present important and up to the minute pre and post market reviews of international combination product regulations guidance considerations and best practices this handbook brings clarity of understanding for global combination products guidance and regulations reviews the current state of the art considerations and best practices spanning the combination product lifecycle pre market through post market reviews medical product classification and assignment issues faced by global regulatory authorities and industry the editor is a recognized international combination products and medical device expert with over 35 years of industry experience and has an outstanding team of contributors endorsed by aami association for the advancement of medical instrumentation

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