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Hazardous Chemicals in Medical DevicesBiomarkers, Diagnostics and Precision Medicine in the Drug Industry Prakash Srinivasan Timiri Shanmugam Abdel Halim

Hazardous Chemicals in Medical Devices Biomarkers, Diagnostics and Precision Medicine in the Drug Industry *Prakash Srinivasan Timiri Shanmugam Abdel Halim*

hazardous chemicals in medical devices safety risk analysis and regulations provides a comprehensive overview of the hazardous chemicals used in medical device manufacturing the book discusses the basics of these chemicals their presence in various components and the regulations that govern their use it also delves into the processes involved in manufacturing and the added chemicals during these stages with a focus on risk assessment and analysis the book emphasizes the importance of safety in medical devices and outlines the types of hazards associated with these substances the book further explains the regulatory classification of hazardous chemicals and the labeling and safety data sheet requirements it includes a list of notified bodies that discuss hazardous substance data aiding in risk assessment and toxicological profiling additionally it underscores the critical understanding of toxicological profiles of materials used in medical devices ensuring that readers are well informed about the safety measures and regulations in place to protect both manufacturers and users describes how hazardous chemicals are added in the manufacturing and process discusses the hazardous chemicals and composition present in the materials and the significance of material procurement to ensure the safety of medical devices lists the regulatory requirements guidelines and organizations involved in monitoring hazardous substances

the high failure rate in the pharmaceutical industry has positioned biomarkers and personalized medicine in the frontline as possible solutions if executed right biomarkers and companion diagnostics cdx can potentially help the drug industry enhance the probability of success accelerate the time to market and

more importantly benefit patients by supporting accurate diagnosis and selection of the most effective and least toxic therapies this book aims to examine the challenges and limitations in biomarkers and laboratory tests it also offers advice on best practices to ensure proper application of biomarkers and bridges the gap between diagnostic business development claims and real life deliverables the book covers biomarkers for different purposes provides examples from different technologies which includes standard of care approved assays as well as for investigational use and for research use only assays it also includes new data for biomarkers in different therapeutic indications and offers case studies and practical examples this book serves as a reference to drug developers ivd providers clinical labs healthcare givers academicians and researchers for best practices to help increase the probability of success in drug development and improve patient management provides the unique insight of an expert with extensive experience in diagnostics and clinical laboratory on one side and drug discovery and development on the other side addresses the challenges of drug development and precision medicine and suggests how to eliminate or mitigate these challenges through better utilization of biomarkers and diagnostics in drug development and patient management features case studies and real life examples from different classes of biomarkers on different platforms for different therapeutic areas and includes more than 200 illustrations

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