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extractables and leachables learn to address the safety aspects of packaged drug products and medical devices pharmaceutical drug products and medical devices are expected to be effective and safe to use this includes minimizing patient user or product exposure to impurities leached from these items when the drug product is administered or when the medical device is used clearly patient or user exposure to leachables must not adversely impact their health and safety furthermore these impurities must not adversely affect key quality attributes of the drug product or medical device including its manufacturability stability efficacy appearance shelf life and conformance to standards extractables and leachables are derived from the drug product s packaging manufacturing systems and or delivery systems or from the medical device s materials of construction it is imperative to understand and quantify the release of extractables from these items the accumulation of

leachables in drug products and the release of leachables from medical devices once extractables and leachables have been discovered identified and quantified their effect on the key product or device quality attributes including safety must be systematically and scientifically established according to recognized rigorous and relevant regulatory and compendial standards and industry driven best practices in extractables and leachables the chemical compatibility including safe use of drugs and their containers delivery devices and manufacturing systems and medical devices is examined at length focusing particularly on how trace level extractables and leachables affect the quality and safety of a medical product and how to assess the magnitude of the effect this is accomplished by addressing the two critical activities required to develop register and commercialize safe effective and affordable clinical therapies measuring extractables and leachables chemical characterization and assessing their impact for example toxicological safety risk assessment each of these activities is addressed in depth based on the existing and developing international regulations and guidelines current published literature and the author s extensive personal experience written by a key contributor to standards guidelines recommended practices and the scientific literature the book provides insider insights beyond those gained by merely reading the relevant texts given that the rapidly evolving extractables and leachables landscape this book provides the most current and crucial information on new and forthcoming regulations and best practices extractables and leachables readers will also find a thorough summary of regulatory and compendial guidelines and the steps required to meet them a detailed and in depth review of essential scientific principles and recommended best practices for the design implementation interpretation and reporting of chemical characterization studies a practical resource for optimizing the development registration and commercialization of safe and effective medical products a helpful tool to maximize product development and successful regulatory outcomes extractables and leachables is the essential reference for pharmaceutical scientists analytical chemists regulatory affairs professionals engineers and toxicologists in areas such as product research and development product registration and approval regulatory affairs analytical science quality control and manufacturing

with an appendix containing a full analysis of the debts of the united states the several states municipalities etc also statements of street railway and traction companies industrial corporations etc statement omitted on later vols

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