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**Pharmaceutical Industry Practices on Genotoxic Impurities** Heewon Lee, 2014-08-29 A great deal of confusion and uncertainty over genotoxic impurity GTI identification assessment and control exists in the pharmaceutical industry today Pharmaceutical Industry Practices on Genotoxic Impurities strives to facilitate scientific and systematic consensus on GTI management by presenting rationales strategies methods interpretati

**Drug Delivery Trends** Ranjita Shegokar, 2020-03-01 Drug Delivery Trends examines a drift in the pharmaceutical field across the wide range of dosage forms drug delivery systems micro and nanoparticulate at the regulatory front and on new types of therapies in the market This volume additionally covers the challenges on drug delivery systems in terms of preclinical and current ways of determining quality and the options to solve the challenges associated with this Most small medium scale industries and academics struggle with initial regulatory challenges so a detailed discussion on regulatory trend covers the necessary basic understanding of regulatory procedures and provides the required guidance The series Expectations and Realities of Multifunctional Drug Delivery Systems examines the fabrication optimization biological aspects regulatory and clinical success of wide range of drug delivery carriers This series reviews multifunctionality and applications of drug delivery systems industrial trends regulatory challenges and in vivo success stories Throughout the volumes discussions on diverse aspects of drug delivery carriers such as clinical engineering and regulatory facilitate insight sharing across expertise area and form a link for collaborations between industry academic scientists and clinical researchers Expectations and Realities of Multifunctional Drug Delivery Systems connects formulation scientists regulatory experts engineers clinical experts and regulatory stake holders The wide scope of the book ensures it as a valuable reference resource for researchers in both academia and the pharmaceutical industry who want to learn more about drug delivery systems Encompasses trends in drug delivery systems and selected dosage forms Illustrates regulatory preclinical and quality principles Contains in depth investigation of upcoming types of drug delivery systems

**Measuring Heavy Metal Contaminants in Cannabis and Hemp** Robert J. Thomas, 2020-09-30 The surge of interest in cannabis based medicinal products has put an extremely high demand on testing capabilities particularly for contaminants such as heavy metals which are naturally taken up through the

roots of the plants from the soil growing medium and fertilizers but can also be negatively impacted by the grinding equipment and extraction distillation process Unfortunately many state regulators do not have the necessary experience and background to fully understand all the safety and toxicological issues regarding the cultivation and production of cannabis and hemp products on the market today Measuring Heavy Metal Contaminants in Cannabis and Hemp offers a comprehensive guide to the entire cannabis industry for measuring elemental contaminants in cannabis and hemp For testing labs it describes fundamental principles and practical capabilities of ICP MS and other AS techniques for measuring heavy metals in cannabis For state regulators it compares maximum contaminant limits of heavy metals with those for federally regulated pharmaceutical materials For cultivators and processors it helps them to better understand the many sources of heavy metals in cannabis And for consumers of medical cannabis it highlights the importance of choosing cannabis products that are safe to use Other key topics include The role of other analytical techniques for the comprehensive testing of cannabis products Tips to optimize analytical procedures to ensure the highest quality data Guidance on how to characterize elemental contaminants in vaping liquids and aerosols Suggestions on how to reduce errors using plasma spectrochemistry The role of certified reference materials to validate standard methods Easy to read sections on instrumental hardware components calibration and measurement protocols typical interferences routine maintenance and troubleshooting procedures Written with the cannabis testing community in mind this book is also an invaluable resource for growers cultivators processors testers regulators and even consumers who are interested in learning more about the potential dangers of heavy metal contaminants in cannabis and hemp

Vaccine Analysis: Strategies, Principles, and Control Brian K. Nunnally, Vincent E. Turula, Robert D. Sitrin, 2014-11-27 This book is an indispensable tool for anyone involved in the research development or manufacture of new or existing vaccines It describes a wide array of analytical and quality control technologies for the diverse vaccine modalities Topics covered include the application of both classical and modern bio analytical tools procedures to assure safety and control of cross contamination consistent biological transition of vaccines from the research laboratory to manufacturing scale whole infectious attenuated organisms such as live attenuated and inactivated whole cell bacterial vaccines and antiviral vaccines using attenuated or inactivated viruses principles of viral inactivation and the application of these principles to vaccine development recombinant DNA approaches to produce modern prophylactic vaccines bacterial subunit polysaccharide and glycoconjugate vaccines combination vaccines that contain multiple antigens as well as regulatory requirements and the hurdles of licensure

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