Sources of Contamination in Medicinal Products and Medical Devices

Denise Bohrer

DESCRIPTION

The first one-volume guide to sources of contamination in pharmaceuticals and medical devices

Most books dealing with contaminants in medicinal products often focus on analytical methods for detecting nonspecific impurities. Key to the work of the pharmaceutical chemist, this unique reference helps identify the sources of contamination in medicinal and pharmaceutical products and medical devices. Divided into three parts, Sources of Contamination in Medicinal Products and Medical Devices covers chemical, microbiological, and physical (particulate matter) contamination, including those originating from sterilization procedures.

As compelling as a medical documentary, the book sheds light on how impurities and contaminants can enter the human body transported via a specific product or treatment. Focusing on only those medicinal products and medical devices that may lead to exposure to contaminants harmful to human health, the book offers a comprehensive, systematic look at the entire universe of medical contamination:

- Chemical contaminants including residual solvents, catalyst residuals, and genotoxic impurities in active pharmaceutical ingredients (APIs)

- Diagnostic imaging agents (i.e., radiopharmaceuticals and contrast agents)

- Microbiological and endotoxin contamination involving single and multiple dose products, medical devices, and biofilms
• Contamination from sterilization procedures, residuals from radiation sterilization, ionizing radiation on packaging materials and medical devices

• Medicinal gases and volatile anesthetics

• Biopharmaceuticals including recombinant DNA technology products

• Extractables and leachables from containers made of glass, plastics, and metal

Each section of the book contains information on what contaminants could be expected in a particular product, and how they were generated and reached that product. With up-to-date regulatory guidelines for determining contamination, as well as methods for assessing, quantifying, avoiding and removing contaminants, Sources of Contamination in Medicinal Products and Medical Devices is essential to fully understanding the specific threats that undermine the safety of medicines and medical devices.

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ABOUT THE AUTHOR

DENISE BOHRER, PhD, is Professor of Analytical Chemistry at the Federal University of Santa Maria, Brazil. Her research has focused on sources of contamination in pharmaceutical products, specifically, infusion solutions for patients with kidney disease and preterm infants. She has published sixty-eight papers and two book chapters on pharmaceutical manufacturing.

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