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Concluding RemarksReferences; 9: Medical Devices; 9.1 General Use Devices; 9.1.1 Medical Gloves; 9.1.2 Syringes; 9.2 Extracorporeal Circuits; 9.3 Devices for Administration of Aerosolized Drugs; 9.4 Reprocessed Medical Devices; 9.5 Tissue Substitutes; 9.5.1 Skin Substitutes and Surgical Dressings; 9.5.2 Hard Tissue Substitutes; 9.5.3 Soft Tissue Substitutes; Concluding Remarks; References; PART II: Physical Contamination; 10: Particulate Matter; Concluding Remarks; References; PART III: Microbiological Contamination; 11: Microbiological and Endotoxin Contamination; 11.1 Water
11.2 Raw Materials11.3 Sterile Products; 11.3.1 Single- and Multiple-Dose Products; 11.3.2 Parenteral Nutrition (PN); 11.3.3 Propofol; 11.3.4 Ophthalmic Products; 11.4 Medicinal Gases; 11.5 Medical Devices; 11.5.1 Syringes; 11.5.2 Endoscopes; 11.5.3 Other Devices; 11.6 Biofilms; 11.7 Dialysis Circuits; 11.8 Nosocomial Infections; Concluding Remarks; References; PART IV: Miscellaneous; 12: Contamination from Sterilization Procedures; 12.1 Residuals from Radiation Sterilization; 12.1.1 Radiolysis of Water; 12.1.2 Effect of Ionizing Radiation on Drug Products; 12.1.3 Polymers in Drug Delivery
12.1.4 Radiolysis of Selected Nondrug Components12.1.5 Effect of Ionizing Radiation on Materials Used in Packaging and in Medical Devices; 12.2 Heat Sterilization; 12.3 Residuals from Chemical Disinfection and Sterilization Agents; 12.3.1 Ethylene Oxide (EtO); 12.3.2 Peracetic Acid and Hydrogen Peroxide; 12.3.3 Formaldehyde; Concluding Remarks; References; 13: Biotechnological Products; 13.1 DNA and HCP Residuals; 13.2 Viruses and Mycoplasma; 13.3 Endotoxin; 13.4 Protein Degradation; 13.5 Protein Aggregation; Concluding Remarks; References
Appendix Polymeric Materials: Components, Additives, Extractables, and Degradation Products

Sommario/riassunto

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, i