
PART III

The Medical Product Life Cycle

OUTLINE

Introduction: Biomaterials in Medical Devices

Total Product Lifecycle for Biomaterial- Based Medical Devices

Safety and Risk Considerations in Medical Device Development

Sterilization and Disinfection of Biomaterials for Medical Devices

Verification and Validation: From Bench to Human Studies

Commercial Considerations in Medical Device Development

Regulatory Constraints for Medical Products Using Biomaterials

Role of Standards for Testing and Performance Requirements of Biomaterials

Medical Device Failure—Implant Retrieval, Evaluation, and Failure Analysis

Legal Concepts for Biomaterials Engineers

Moral and Ethical Issues in the Development of Biomaterials and Medical Products