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Disciplina	610.28
Soggetti	Biomedical engineering Regenerative medicine Tissue engineering Medicine Pharmaceutical technology Biotechnology Biomedical Engineering/Biotechnology Regenerative Medicine/Tissue Engineering Medicine/Public Health, general Biomedical Engineering and Bioengineering Pharmaceutical Sciences/Technology
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Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	1. An Introduction to Biomedical Product Development -- 2. Basic Essentials and Applications of Quality Management System (QMS) in Biomedical Sciences -- 3. Principles of Good Laboratory Practice (GLP) -- 4. Design of Experimental Studies in Biomedical Sciences -- 5. Preclinical Studies for Development of Biomedical Products -- 6. Principles of Good Manufacturing Practice (GMP) -- 7.The importance of Cleanroom facility in manufacturing of biomedical products -- 8. Safety concerns and requirement of cell based products for clinical application -- 9. Standards and regulatory frameworks (for cell and tissue based products) -- 10. Principles of Good clinical Practice (GCP) -- 11. Design, performance and monitoring of clinical trials -- 12. Good Clinical Practice: Guidelines and Requirement -- 13. Ethical

Considerations of Biomedical Products Development.

Sommario/riassunto

This textbook covers all the steps in manufacturing a biomedical product from bench to bedside. It specifically focuses on quality assurance and management and explains the different good practice principles in the various phases of product development as well as how to fulfill them: Good laboratory practice, good manufacturing practice and good clinical practice. It provides readers with the know-how to design biomedical experiments to ensure quality and integrity, to plan and conduct standard preclinical studies and to assure the quality of the final manufactured biomedical products. Importantly, it also addresses ethical concerns and considerations. The book discusses the guidelines and ethical considerations for preclinical and clinical studies, to allow readers to identify safety concerns regarding biomedical products and to improve pre-clinical studies for the development of better products. This textbook is a valuable guide for biomedical students (B.Sc., M.S., and Ph.D. students) in the field of molecular medicine, medical biotechnology, stem cell research and related areas, as well as for professionals such as quality control staff, tissue bankers, policy-makers and health professionals.