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Nota di contenuto	Research and Development of Vaccines and Pharmaceuticals from Biotechnology; Preface; Table of Contents; Biotechnology in Pharmaceutical Research; Biotechnology in the 1990's; Research Structures; Basic or Applied Research or Where Do You Want To Get To?; The Aim of a Project; Defining the Aim; Creative Market Research and Other Valuable Background Information; Project Planning; The Backwards Approach to Establish a Plan; Linking Project Tasks; Objectives and Milestones; Time and Task Dependencies; Project Team Approval and Refinement of the Plan; Allocation of Resources and Budget Planning

Changes to the PlanImplementing a Project Plan; Project Management Computer Software; Product Development; Product Development Follows Different Rules; Commercial Chances and Risks of Pharmaceutical Development; Product Profile and Market Assessment of Development Products; Planning and Managing Product Development; Risk Oriented Planning; Product Development Phases; Decision Making; The Project Manager; Organizational Structures; Technical Aspects of Product Development; Process Development and Manufacturing; Analytical Development and Quality Assurance; Patents for Biomedicinal Products
The Purpose of a PatentAlternatives to Patents; Basic Requirements for a Patentable Invention; Novelty; Non-obviousness; Utility or Industrial Applicability; Inventions, Discoveries and Products of Nature; Patentable Inventions and Exclusions; Product, Process and Use Patents; Dependent Patents; The Patent Application; The Patent Description; Deposition of Microorganisms; Patent Claims; Filing a Patent Application; Priority of Patents and Continuation-in-Part; Duration of Patent Protection; Extension of Patent Terms for Pharmaceuticals; Oppositions against Patents; Patent Costs
Patent InformationCheck List for Prospective Patent Applicants; Selling an Invention, Licences and Royalties; Registration Requirements; Three Basic Elements; Quality; Safety; Efficacy; Registration Applications and Procedures; Approval for Clinical Trials; Applications for Market Approval; Registration in the EEC; Registration in the USA; Registration in Japan; Requirements for the Preclinical Pharmacology and Safety Assessment; Exceptions and Variations for Biological Products; New Vaccine Adjuvants and Other Excipients; Pharmacokinetics; Pharmacodynamics; Bioequivalence and Bioavailability
Single Dose Toxicity (Acute Toxicity)Repeated Dose Toxicity (Subacute, Chronic Toxicity); Reproduction Toxicity; Mutagenicity; Tumorigenicity (Carcinogenicity); Immunotoxicity; Local Tolerance; Additional Preclinical Studies for Veterinary Products; User Safety; Tolerance in the Target Species; Ecotoxicity; Safety of Residues; Annex A; Outline of Major Registration Requirements; Major Registration Requirements for Human; Medicinal Products, Tables 11-15; Major Registration Requirements for Veterinary; Medicinal Products, Tables 16-21; Annex B
References and Information Sources on Regulatory Matters

Sommario/riassunto

Unique in approach, exhaustive in coverage: this book provides information usually not available to scientists.It explains the basic scientific and technical requirements which apply to the patenting and registration of human or veterinary vaccines and therapeutic biomedicinal products. Pragmatic and practice-oriented, it helps users select and manage successfully the most attractive research and development projects. An impressive number of topics is covered, including: * planning and managing product development* product development phases* requirements for a