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Riley,K. Lien Nguyen,2024-09-22 Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals There have been several recent developments in the ICH Guidelines which were not captured in previous editions notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines and the specification guidelines This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products Presents critical assessment potential impact and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non ICH regions Addresses comprehensive treatment of the development and validation of analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins nRNA based drugs vaccines and gene therapy This book will also address drug device combinationproducts such as digital drug delivery systems transdermal systems and inhalation products Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data **WHO Expert Committee on**

Specifications for Pharmaceutical Preparations World Health Organization,2024-04-26 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools The Expert Committee develops standards through worldwide consultation and an international consensus building process The following new guidance texts were adopted and recommended for use WHO good manufacturing practices for excipients used in pharmaceutical products revision IAEA WHO good manufacturing practices for in house cold kits for radiopharmaceutical preparations new WHO good practices for pharmaceutical quality control laboratories revision WHO UNFPA female condom generic specification new WHO Biowaiver List proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release updated solid oral dosage forms WHO guideline on Biopharmaceutics Classification System based

biowaivers revision and Multisource generic pharmaceutical products guidelines on registration requirements to establish interchangeability republished All of the above are included in this report and recommended for implementation *Quality assurance of pharmaceuticals: a compendium of guidelines and related materials, tenth edition. Volume 1. Good practices and related regulatory guidance* World Health Organization, 2024-10-24 This publication represents a significant achievement in our ongoing effort to ensure that everyone can reach the highest possible level of health Over the last three decades we have seen the transformation of the pharmaceutical industry and the increasing intricacy of the product life cycle The challenges we face today are very different from those we faced when the first edition of this Compendium was published in 1997 However our mission remains the same to promote health keep the world safe and serve the vulnerable The new edition reflects the collective knowledge and expertise of countless professionals who have worked diligently to develop revise and implement WHO guidelines for pharmaceuticals This includes experts from WHO Member States our Expert Advisory Panels and Expert Committees on Specifications for Pharmaceutical Preparations and other organizations and has undergone extensive consultation with stakeholders worldwide This Compendium covers development through manufacturing and quality control to post marketing surveillance It provides a comprehensive framework for quality assurance that is both strong and flexible capable of meeting the requirements of a rapidly changing global health landscape The 10th edition is a collection of knowledge and tools for empowerment enabling all stakeholders in the pharmaceutical industry to make informed decisions that prioritize patient safety and well being **Drugs in America** David F. Musto, 2002-07-28 Beer was brought to America on the Mayflower hemp was once a major approved cash crop and cocaine heroin and opium had several waves of popularity in the 19th and 20th centuries Drugs and alcohol have been with America from the start

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Farid, 2025-05-09 This book comprehensively explores the intersection between traditional herbal medicine and cutting edge nanotechnology The chapters introduce modern techniques used in herbal extraction and analysis The principles of drug discovery from plants are discussed with a focus on the identification and development of bioactive compounds that have therapeutic potential It discusses the pharmacological properties biotechnological approaches in drug development and challenges in the formulation and standardization of herbal medicines Emerging trends and applications of nanotechnology in herbal pharmacotherapy such as nanoparticle synthesis enhanced bioavailability using nanocarriers safety assessments novel and targeted delivery systems and regulatory considerations are thoroughly discussed Additionally it includes a comparative analysis of traditional and nano formulated approaches and their implementation in clinical settings Towards the end the book reviews the regulatory considerations for herbal products and future perspectives in herbal pharmacopeia This book is intended for researchers clinicians and professionals in herbal medicine pharmacology and nanotechnology

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