Ph Eur Monographs And Biosimilars Edqm

This report presents the recommendations of an international group of experts convened by the World Health Organization, to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Issues discussed include: the latest volume of the International Pharmacopoeia and quality specifications for pharmaceutical substances and dosage forms, as well as quality control of reference materials, good manufacturing practices (GMP), inspection, distribution and trade and other aspects of quality assurance of pharmaceuticals, and regulatory issues.
This book contains the summaries of the "Innovation in Pharmacy: Advances and Perspectives" that took place in Salamanca (Spain) in September 2018. The early science of chemistry and microbiology were the source of most drugs until the revolution of genetic engineering in the mid 1970s. Then biotechnology made available novel protein agents such as interferons, blood factors and monoclonal antibodies that have changed the modern pharmacy. Over the past year, a new pharmacy of oligonucleotides has emerged from the science of gene expression such as RNA splicing and RNA interference. The ability to design therapeutic agents from genomic sequences will transform treatment for many diseases. The science that created this advance and its future promise will be discussed. Phillip Allen Sharp is an American geneticist and molecular biologist who co-discovered RNA splicing. He shared the 1993 Nobel Prize in Physiology or Medicine with Richard J. Roberts for " the discovery that genes in eukaryotes are not contiguous strings but contain introns, and that the splicing of messenger RNA to delete those introns can occur in different ways, yielding different proteins from the same DNA sequence. He works in Institute Professor Koch Institute for Integrative Cancer Research, Massachusetts Institute of Technology (MIT), Cambridge, MA, US. Este libro recoge los res ú menes de la « Innovation in Pharmacy: Advances and Perspectives » que tuvo lugar en Salamanca (Espa ñ a) en septiembre de 2018. La ciencia primitiva de la qu í mica y la microbiolog í a fue la fuente de la mayor í a de las drogas hasta la revoluci ó n de la ingenier í a gen é tica a mediados de la d é cada de 1970. Luego, la biotecnolog í a puso a disposici ó n agentes prote í nicos novedosos como interferones, factores sangu í neos y anticuerpos monoclonales que han cambiado la farmacia moderna. Durante el a ñ o pasado, surgi ó una nueva farmacia de oligonucle ó tidos a partir de la ciencia de la expresi ó n g é nica, como el empalme de ARN y la interferencia de ARN. La capacidad de dise ñ ar agentes terap é uticos a partir de secuencias gen ó micas transformar á el tratamiento de muchas enfermedades. La ciencia que cre ó este avance y su promesa futura ser á discutida. Phillip Allen Sharp es un genetista y bi ó logo molecular estadounidense que co-descubri ó el empalme de ARN. Compartí ó el Premio Nobel de 1993 en Fisiolog í a o Medicina con Richard J. Roberts por "el descubrimiento de que los genes en eucariotas no son cadenas contiguas, sino que contienen intrones, y que el empalme del ARN mensajero para eliminar esos intrones puede ocurrir de diferentes maneras, produciendo diferentes prote í nas de la misma secuencia de ADN. Trabaja en el Instituto Profesor Koch Institute for Integrative Cancer Research, Instituto Tecnol ó gico de Massachusetts (MIT), Cambridge, MA, EE. UU.
This study has emerged from an ongoing program of trilateral cooperation between WHO, WTO and WIPO. It responds to an increasing demand, particularly in developing countries, for strengthened capacity for informed policy-making in areas of intersection between health, trade and IP, focusing on access to and innovation of medicines and other medical technologies.
The editors have engaged leading scientists in the field to participate in the development of this book, which is envisioned as a " one of a kind " contribution to the field. The book is a comprehensive text that puts fundamental bioanalytical science in context with current practice, its challenges and ongoing developments. It expands on existing texts on the subject by covering regulated bioanalysis of both small and large molecule therapeutics from both a scientific and regulatory viewpoint. The content will be useful to a wide spectrum of readers: from those new to bioanalysis; to those developing their experience in the laboratory, or working in one of the many critical supporting roles; to seasoned practitioners looking for a solid source of information on this exciting and important discipline.
This report presents the recommendations of the WHO Expert Committee responsible for updating the WHO Model List of Essential Medicines. The first part contains a progress report on the new procedures for updating the Model List and the development of the WHO Essential Medicines Library. It continues with a section on changes made in revising the Model List followed by a review of some sections such as hypertensive medicines and fast track procedures for deleting items. Annexes include the 13th version of the Model List and items on the list sorted according to their 5-level Anatomical Therapeutic Chemical classification codes.
Absorption, Distribution, Metabolism and Excretion (ADME) processes and their relationship with the design of dosage forms and the success of pharmacotherapy form the basis of this upper level undergraduate/graduate textbook. As an introduction oriented to pharmacy students, it is also written for scientist from different fields outside of pharmaceutics. (e.g. material scientist, material engineers, medicinal chemists) who might be working in a positions in pharmaceutical companies or whose work might benefit from basic training in the ADME concepts and some biological background. Pedagogical features such as objectives, keywords, discussion questions, summaries and case studies add valuable teaching tools. This book will provide not only general knowledge on ADME processes but also an updated insight on some hot topics such as drug transporters, multi-drug resistance related to pharmacokinetic phenomena, last generation pharmaceutical carriers (nanopharmaceuticals), in vitro and in vivo bioequivalence studies, biopharmaceuticals, pharmacogenomics, drug-drug and food-drug interactions, and in silico and in vitro prediction of ADME properties. In comparison with other similar textbooks, around half of the volume would be focused on the relationship between expanding scientific fields and ADME process. Each of these burgeoning fields has a separate chapter in the second part of the volume, and was written with leading experts on the correspondent topic, including scientists and academics from USA and UK (Duquesne University School of Pharmacy, Indiana University School of Medicine, University of Utah College of Pharmacy, University of Maryland, University of Bath). Additionally, each of the initial chapters dealing with the generalities of drug absorption, distribution, metabolism and excretion would include relevant, classic examples related to each topic with appropriate illustrations (e.g. importance of active absorption of levodopa, implications in levodopa administration, drug drug interactions and food drug interactions emerging from the active uptake; intoxication with paracetamol as a result of glutathione depletion, CYP induction and its relationship with acute liver failure caused by paracetamol, etc). ADME Processes and Pharmaceutical Sciences is written as a core textbook for ADME processes, pharmacy, pharmacokinetics, drug delivery, biopharmaceutics, drug disposition, drug design and medicinal chemistry courses.
WHO's international guidelines, written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States, international organizations, United Nations agencies, regional and interregional harmonization efforts, and underpin important initiatives, including the prequalification of medicines, the Roll Back Malaria Programme, Stop TB, essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The International Pharmacopoeia,/1>.
The specifications under development are internationally applicable test methodologies for anti-infective, antimalarial, antituberculosis, contraceptives and antiretroviral medicines, as well as medicines for children. In addition, the following four written standards were adopted in the area of quality assurance and are now available for implementation : * Release procedure for International Chemical Reference Substances (update); * WHO guideline on quality risk management (new) * WHO guideline on variations to a prequalified product (update) * Collaborative procedure between the WHO Prequalification of Medicines Programme and national medicines regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products (new).
Providing guidance for chemists and other scientists entering pharmaceutical discovery and development, this up-to-the-minute reference presents contributions from an international group of nearly 50 renowned researchers—offering a solid grounding in synthetic and physical organic chemistry, and clarifying the roles of various specialties in the development of new drugs. Featuring over 1000 references, tables, and illustrations, Process Chemistry in the Pharmaceutical Industry is sure to find its way to the bookshelves of organic, physical, analytical, process, and medicinal chemists and biochemists; pharmacists; and upper-level undergraduate and graduate students in these disciplines.
The rules governing medicinal products for human use in the European Union
The Science and the Regulatory Landscape
Open Scientific Data
Dosage, Design, and Pharmacotherapy Success
The Rules Governing Medicinal Products in the European Union
Forty-eighth Report
Process Chemistry in the Pharmaceutical Industry
The Challenge of CMC Regulatory Compliance for Biopharmaceuticals
The Selection and Use of Essential Medicines
Pharmaceutical Manufacturing Handbook
Who Expert Committee on Specifications for Pharmaceutical Preparations
Evidence-Based Pharmacy

This book provides a comprehensive overview of the biosimilar regulatory framework, the development process and clinical aspects for development of biosimilars. The development path of a biosimilar is just as unique as a development path of a new drug, tailored by the mechanism of action, the quality of the molecule, published information on the reference product, the current competitive environment, the target market and regulatory guidance, and most importantly, the emerging totality of evidence for the proposed biosimilar during development. For the ease of readers, the book comprises of six sections as follows: Section I: Business, Health Economics and Intellectual Property Landscape for Biosimilars Section II: Regulatory Aspects of Development and Approval for Biosimilars Section III: Biopharmaceutical Development and Manufacturing of Biosimilars Section IV: Analytical Similarity Considerations for Biosimilars Section V: Clinical aspects of Biosimilar Development Section VI: Biosimilars- Global Development and Clinical Experience Chapters have been written by one or more experts from academia, industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development. The authors and editors have an expertise in commercialization and pricing of biosimilars, intellectual property considerations for biosimilars, chemistry manufacturing controls (CMC) and analytical development for biosimilars, regulatory and clinical aspects of biosimilar development. Besides the industry practitioners, the book includes several contributions from regulators across the globe.
Authoritative guide to the principles, characteristics, engineering aspects, economics, and applications of disposables in the manufacture of biopharmaceuticals The revised and updated second edition of Single-Use Technology in Biopharmaceutical Manufacture offers a comprehensive examination of the most-commonly used disposables in the manufacture of biopharmaceuticals. The authors-noted experts on the topic-provide the essential information on the principles, characteristics, engineering aspects, economics, and applications. This authoritative guide contains the basic knowledge and information about disposable equipment. The author also discusses biopharmaceuticals' applications through the lens of case studies that clearly illustrate the role of manufacturing, quality assurance, and environmental influences. This updated second edition revises existing information with recent developments that have taken place since the first edition was published. The book also presents the latest advances in the field of single-use technology and explores topics including applying single-use devices for microorganisms, human mesenchymal stem cells, and T-cells. This important book: • Contains an updated and end-to-end view of the development and manufacturing of single-use biologics • Helps in the identification of appropriate disposables and relevant vendors • Offers illustrative case studies that examine manufacturing, quality assurance, and environmental influences • Includes updated coverage on cross-functional/transversal dependencies, significant improvements made by suppliers, and the successful application of the single-use technologies Written for biopharmaceutical manufacturers, process developers, and biological and chemical engineers, Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition provides the information needed for professionals to come to an easier decision for or against disposable alternatives and to choose the appropriate system.
"The WHO Expert Committee on Biological Standardization met in Geneva from 8 to 12 October 2007"--Introduction.
"The greater our knowledge increases, the more our ignorance unfolds. " U. S. President John F. Kennedy, speech, Rice University, September 12, 1962 My primary purpose for writing this book was much more than to provide another information source on Chemistry, Manufacturing & Controls (CMC) that would rapidly become out of date. My primary purpose was to provide insight and practical suggestions into a common sense business approach to manage the CMC regulatory compliance requirements for biopharmaceuticals. Such a common sense business approach would need (1) to be applicable for all types of biopharmaceutical products both present and future, (2) to address the needs of a biopharmaceutical manufacturer from the beginning to the end of the clinical development stages and including post market approval, and (3) to be adaptable to the constantly changing CMC regulatory compliance requirements and guidance. Trying to accomplish this task was a humbling experience for this author! In Chapter 1, the CMC regulatory process is explained, the breadth of products included under the umbrella ofbiopharmaceuticals are identified, and the track record for the pharmaceutical and biopharmaceutical industry in meeting CMC regulatory compliance is discussed. In Chapter 2, while there are many CMC commonalities between biopharmaceuticals and chemically-synthesized pharmaceuticals, the significant differences in the way the regulatory agencies handle them are examined and the reasons for why such differences are necessary is discussed. Also, the importance of CMC FDA is stressed.
The seventh edition of the Indian Pharmacopoeia (IP 2014) is published by the Indian Pharmacopoeia Commission (IPC) on behalf of the Government of India, Ministry of Health & Family Welfare. The Indian Pharmacopoeia (IP) is published in fulfilment of the requirements of the Drugs and Cosmetics Act, 1940 and Rules thereunder. It prescribes the standards for drugs produced and/or marketed in India and thus contributes in the control and assurance of the quality of the medicines. The standards of this pharmacopoeia are authoritative and legally enforceable. It intends to help in the licensing of manufacturing, inspection and distribution of medicines. IP is published in continuing pursuit of the mission of IPC to improve the health of the people through ensuring the quality, safety and efficacy of medicines. The Commission has been receiving significant inputs from regulatory, industrial houses, academic institutions, national laboratories, individual scientists and others. Publication of IP at regular and shorter intervals is one of the main mandates of the Commission. The seventh edition of Indian Pharmacopoeia is published in accordance with the principles and designed plan decided by the Scientific Body of the IPC. To establish transparency in setting standards for this edition the contents of new monographs, revised appendices and other informations have been publicized on the website of the IPC, besides following conventional approach of obtaining comments. The feedback and inputs were reviewed by the relevant Expert Committee to ensure the feasibility and practicability of the standards and methods revised. The principle of "openness, justice and fairness" is kept in mind during compiling and editing the contents of this edition. The Indian Pharmacopoeia 2014 is presented in four volumes. The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, veterinary vaccines
Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products. These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the CMC strategy and regulatory compliance requirements for these challenging products. Companies clearly plan out the strategy for their clinical study plans, but frequently, the development of a strategy for CMC is an afterthought. Coupled with the complexity of the biopharmaceutical manufacturing processes and products, and this can be a recipe for disaster. The third edition of this book provides insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for all biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and genetically engineered human cells) from early clinical stage development through market approval. The third edition of this book provides added coverage for the biosimilars, antibody drug conjugates (ADCs), bispecific antibodies, genetically engineered viruses, and genetically engineered cells. This third edition of the book also addresses the heightened pressure on CMC regulatory compliance timelines due to the introduction of expedited clinical pathways moving the clinical development closer to a seamless phase process (e.g., FDA Breakthrough Therapy designation, CBER Regenerative Medicine Advanced Therapy (RMAT) designation, EMA Priority Medicines (PRIME) designation). The Challenge of CMC Regulatory Compliance for Biopharmaceuticals is essential, practical information for all pharmaceutical development scientists, Manufacturing and Quality Unit staff, Regulatory Affairs personnel, and senior management involved in the manufacture of biopharmaceuticals.
The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use, in addition to 20 monographs and general texts for inclusion in The International Pharmacopoeia and 11 new International Chemical Reference Substances. The International Pharmacopoeia – updating mechanism for the section on radiopharmaceuticals; WHO good manufacturing practices for pharmaceutical products: main principles; Model quality assurance system for procurement agencies; Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection; Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities; and Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part.
This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biologicals and the establishment of international biological reference materials. The report starts with a discussion of general issues brought to the attention of the Committee and provides information on the status and development of reference materials for various antibodies, antigens, blood products and related substances, cytokines, growth factors, endocrinological substances and in vitro diagnostic devices. The second part of the report, of particular relevance to manufacturers and national regulatory authorities, contains revised WHO recommendations for production and control of live attenuated influenza vaccines and for production and control of pneumococcal conjugate vaccines. New WHO guidelines on the regulatory evaluation of similar biotherapeutic medicines are also provided. Also included are a list of recommendations, guidelines and other documents for biological substances used in medicine, and of international standards and reference reagent for biological substances.
Fifty-Third Report
Guide to the Quality and Safety of Tissues and Cells for Human Application
Current Challenges in Pharmacovigilance
Peptide Therapeutics
Health at a Glance: Europe 2018 State of Health in the EU Cycle
Pragmatic Approaches
Sixty-eighth Report
Sixtieth Report
Sixty-Third Report
Dictionary of Pharmaceutical Medicine
WHO Expert Committee on Specifications for Pharmaceutical Preparations
Thirty-eighth Report

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: - WHO guidelines on good herbal processing practices for herbal medicines; - Guidelines on good manufacturing practices for the manufacture of herbal medicines; - Considerations for requesting analysis of medicine samples; - WHO model certificate of analysis; - WHO guidance on testing of "suspect" falsified medicines; - Good pharmacopoeial practices - Chapter on monographs for compounded preparations; - Good pharmacopoeial practices - Chapter on monographs on herbal medicines; - Guidelines on heating, ventilation and air-conditioning systems for non-sterile pharmaceutical products; - Guidance on good practices for desk assessment of compliance with good manufacturing practices, good laboratory practices and good clinical practices for medical products regulatory decisions; - Stability testing of active pharmaceutical ingredients and finished pharmaceutical products; and - Collaborative procedure in the assessment and accelerated national registration of pharmaceutical products and vaccines approved by stringent regulatory authorities.
Updated annually, the British Pharmacopoeia (BP) is the only comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products. It includes approximately 4,000 monographswhich are legally enforced by the Human Medicines Regulations 2012. Where a BP monograph exists, medicinal products or active pharmaceutical ingredients sold or supplied in the UK must comply with the relevant monograph.All monographs and requirements of the European Pharmacopoeia (Ph. Eur.) are reproduced in the BP, making the BP a convenient and fully comprehensive set of standards that can be used across Europe and beyond.
The definitive textbook on the chemical analysis of pharmaceutical drugs – fully revised and updated Introduction to Pharmaceutical Analytical Chemistry enables students to gain fundamental knowledge of the vital concepts, techniques and applications of the chemical analysis of pharmaceutical ingredients, final pharmaceutical products and drug substances in biological fluids. A unique emphasis on pharmaceutical laboratory practices, such as sample preparation and separation techniques, provides an efficient and practical educational framework for undergraduate studies in areas such as pharmaceutical sciences, analytical chemistry and forensic analysis. Suitable for foundational courses, this essential undergraduate text introduces the common analytical methods used in quantitative and qualitative chemical analysis of pharmaceuticals. This extensively revised second edition includes a new chapter on chemical analysis of biopharmaceuticals, which includes discussions on identification, purity testing and assay of peptide and protein-based formulations. Also new to this edition are improved colour illustrations and tables, a streamlined chapter structure and text revised for increased clarity and comprehension. Introduces the fundamental concepts of pharmaceutical analytical chemistry and statistics Presents a systematic investigation of pharmaceutical applications absent from other textbooks on the subject Examines various analytical techniques commonly used in pharmaceutical laboratories Provides practice problems, up-to-date practical examples and detailed illustrations Includes updated content aligned with the current European and United States Pharmacopeia regulations and guidelines Covering the analytical techniques and concepts necessary for pharmaceutical analytical chemistry, Introduction to Pharmaceutical Analytical Chemistry is ideally suited for students of chemical and pharmaceutical sciences as well as analytical chemists transitioning into the field of pharmaceutical analytical chemistry.
Health at a Glance: Europe 2018 presents comparative analyses of the health status of EU citizens and the performance of the health systems of the 28 EU Member States, 5 candidate countries and 3 EFTA countries.
The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating, ventilation and air-conditioning systems (HVAC) illustrative part; Guidance on GMP for Validation, including the general main text, analytical procedure validation, validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.
This dictionary is aimed primarily at the beginners entering the new discipline of Pharmaceutical Medicine, an area comprising aspects of toxicology, pharmacology, pharmaceutics, epidemiology, statistics, drug regulatory and legal affairs, medicine and marketing. But also more experienced colleagues in departments engaged in clinical development as well as researchers and marketing experts in the pharmaceutical industry will find concise and up-to-date information. The book is completed by a list of a about 1000 abbreviations encountered in pharmaceutical medicine and a compilation of important addresses of national and international health authorities.
The Australian Health Ministers' Advisory Council (AHMAC) Blood and Blood Products Committee Report of the Working Party on the Supply and Use of Factor VIII and Factor IX in Australia was published in April 2003. This report made several recommendations about the extended use of recombinant factors VIII and IX. These recommendations were endorsed in the Report of the Expert Advisory Group on Hepatitis C and Plasma in 1990 (Barraclough Report) tabled in the Senate in May 2003 and later in The Senate Community Affairs References Committee report Hepatitis C and the blood supply in Australia in June 2004.
Recoge:1. Introduction - 2. Why a new definition? - 3. Applying the new SME definition - 4. Conclusion.

British Pharmacopoeia 2017 [online Edition - Single User Licence]
Chemistry and Biology of Heparin and Heparan Sulfate
Volume One, Compressed Solid Products
Regulatory, Clinical, and Biopharmaceutical Development
Regulated Bioanalysis: Fundamentals and Practice
Forty-seventh Report
Single-Use Technology in Biopharmaceutical Manufacture
ADME Processes in Pharmaceutical Sciences
Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade
Biosimilars
WHO Expert Committee on Biological Standardization

This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biologicals, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development of revised WHO Recommendations and Guidelines for a number of vaccines, blood products and related substances. Specific discussion areas included the development of WHO guidance on the quality, safety and efficacy of poliomyelitis vaccines (oral, live, attenuated); recombinant malaria vaccines; diphtheria vaccines (adsorbed); tetanus vaccines (adsorbed); combined vaccines based on diphtheria and tetanus vaccines; and Japanese encephalitis vaccines (live, attenuated). Subsequent sections of the report then provide information on the current status and proposed development of international reference materials in the areas of vaccines and related substances; blood products and related substances; in vitro diagnostic device reagents; biotherapeutics other than blood products; and antibiotics. A series of annexes are then presented which include an updated list of WHO Recommendations, Guidelines and other documents on biological substances used in medicine (Annex 1), followed by a series of WHO Recommendations and Guidelines adopted on the advice of the Committee (Annexes 2-7). All additions made during the meeting to the list of International Standards and Reference Reagents for biological substances maintained by WHO are then summarized in Annex 8.
This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples.
The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume One, Compressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this first volume of a six-volume set, compiles data from FDA new drug applications, patent applications, and other sources of generic and proprietary formulations to cover the broad spectrum of GMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent.
Peptide therapy has become a key strategy in innovative drug development, however, one of the potential barriers for the development of novel peptide drugs in the clinic is their deficiencies in clearly defined chemistry, manufacturing and controls (CMC) strategy from clinical development to commercialization. CMC can often become a rate-limiting step due to lack of knowledge and lack of a formal policy or guidelines on CMC for peptide-based drugs. Regulators use a risk-based approach, reviewing applications on a case-by-case basis. Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls covers efficient manufacturing of peptide drug substances, a review of the process for submitting applications to the regulatory authority for drug approval, a holistic approach for quality attributes and quality control from a regulatory perspective, emerging analytical tools for the characterisation of impurities, and the assessment of stability. This book is an essential reference work for students and researchers, in both academia and industry, with an interest in learning about CMC, and facilitating development and manufacture of peptide-based drugs.
This report presents the recommendations of a WHO Expert Committee commissioned to coordinate activities leading to the adoption of international recommendations for the production and control of vaccines and other biological substances, and the establishment of international biological reference materials. Following a brief introduction, the report summarizes a number of general issues brought to the attention of the Committee. The next part of the report, of particular relevance to manufacturers and national regulatory authorities, outlines the discussions held on the development and adoption of new and revised WHO Recommendations, Guidelines, and guidance documents. Following these discussions, WHO Guidelines on the quality, safety and efficacy of Ebola vaccines, and WHO Guidelines on procedures and data requirements for changes to approved biotherapeutic products were adopted on the recommendation of the Committee. In addition, the following two WHO guidance documents on the WHO prequalification of in vitro diagnostic medical devices were also adopted: (a) Technical Specifications Series (TSS) for WHO Prequalification - Diagnostic Assessment: Human immunodeficiency virus (HIV) rapid diagnostic tests for professional use and/or self-testing; and (b) Technical Guidance Series (TGS) for WHO Prequalification - Diagnostic Assessment: Establishing stability of in vitro diagnostic medical devices. Subsequent sections of the report provide information on the current status, proposed development and establishment of international reference materials in the areas of: antibiotics, biotherapeutics other than blood products; blood products and related substances; in vitro diagnostics; and vaccines and related substances. A series of annexes are then presented which include an updated list of all WHO Recommendations, Guidelines, and other documents on biological substances used in medicine (Annex 1). The above four WHO documents adopted on the advice of the Committee are then published as part of this report (Annexes 2-5). Finally, all additions and discontinuations made during the 2017 meeting to the list of International Standards, Reference Reagents and Reference Panels for biological substances maintained by WHO are summarized in Annex 6. The updated full catalog of WHO International Reference Preparations is available at: http://www.who.int/bloodproducts/catalogue/en/.
Introduction to Pharmaceutical Analytical ChemistryWiley
An introductory guide to cleanrooms in the life science sector.
The effective delivery of primary care now requires a much higher calibre of staff than was previously considered acceptable. Selection, assessment and management are skills that need to be properly understood to ensure that the best possible service is being provided; and inappropriate actions can lead employers into a legal minefield with unwelcome consequences. This manual provides concise but comprehensive information on the situation as applied to general practice, illustrated by numerous case studies.
State of Health in the EU Cycle
Fifty-eighth Report
Alternatives to Animal Testing
British Pharmacopoeia
Evidence-based Clinical Practice Guidelines for the Use of Recombinant and Plasma-derived FVIII and FIX Products
Fifty-second Report
An International Guideline for the Preparation, Care and Use of Medicinal Products
Production and Processes
Practical Pharmaceutics
Introduction to Pharmaceutical Analytical Chemistry
Guide to Cleanrooms
Handbook of Pharmaceutical Manufacturing Formulations, Third Edition

The rise of bio- and nano-technology in the last decades has led to the emergence of a new and unique type of medicine known as non-biological complex drugs (NBCDs). This book illustrates the challenges associated with NBCD development, as well as the complexity of assessing the effects of manufacturing changes on innovator and follow-on batches of NBCDs. It also touches upon proven marketing authorization requirements for biosimilars that could be effective in evaluating follow-on NBCDs, including a demonstration of control over the manufacturing process and a need for detailed physico-chemical characterization and (pre)clinical tests. This book is meant to be used for years to come as a standard reference work for the development of NBCDs. Moreover, this book aims to stimulate discussions and further our thinking to ensure that decisions regarding the approval of complex drugs are made with relevant scientific data on the table.
The British Pharmacopoeia (BP) 2017 supersedes the BP 2016 and becomes legally effective on 1 January 2017. This edition incorporates new BP and European Pharmacopoeia monographs and a significant number of revised monographs. Also included is new information for unlicensed medicines and DNA barcoding. Updated annually, the BP is the only comprehensive collection of authoritative official standards for UK pharmaceutical substances and medicinal products. The BP 2017 includes almost 4,000 monographs which are legally enforced by the Human Medicines Regulations 2012. Where a pharmacopoeial monograph exists, medicinal products sold or supplied in the UK must comply with the relevant monograph. All monographs and requirements of the European Pharmacopoeia are also reproduced in the BP.
In spite of recent progress in the harmonization of terminology and processes affecting work on the clinical safety of medicines consensus is needed on standards for many difficult aspects of day-to-day pharmacovigilance that continue to pose problems for both the pharmaceutical industry and drug regulators. The CIOMS V Working Group has generated proposals for pragmatic approaches to dealing with such issues as: classification and handling of individual safety case reports from a variety of sources (spontaneous consumer reports solicited reports literature the Internet observational studies and secondary data bases disease and other registries regulatory ADR databases and licensor-licensee interactions); new approaches to case management and regulatory reporting practices (proper clinical evaluation of cases incidental vs other events patient and reporter identifiability seriousness criteria expectedness criteria case follow-up criteria and the role and structure of case narratives); improvements and efficiencies in the format content and reporting of periodic safety update reports (PSURs) (including results of an industry survey on PSUR workloads and practices; proposals for high case volume and long time-period reports simplification of certain PSURs summary bridging reports addendum reports license renewal reports for EU and Japan dealing with old products and other technical details); determination and use of population exposure (denominator) data (sources of data and a guide to analytical approaches for a variety of circumstances).The Group has also taken stock of the current state of expedited and periodic clinical safety reporting requirements around the world with summary data on regulations from more than 60 countries. Recommendations are made for enhancing the harmonization steps already taken as a result of previous CIOMS publications and the ICH process. In addition to dealing with unfinished and unresolved issues from previous CIOMS initiatives the report covers many emerging topics such as those involving new technologies. Its 20 Appendices provide a wealth of detailed explanations and reference information. It is the most comprehensive and recent treatment of difficult pharmacovigilance issues affecting the working practices and systems of drug safety and other pharmaceutical professionals.
This book shows how the vision for open access to scientific data can be more readily achieved through a staged model that research funders, policy makers, scientists, and research organizations can adopt in their practice. Drawing on her own experiences with data processing, on early findings with open scientific data at CERN (the European Organization for Nuclear Research), and from case studies of shared clinical trial data, the author updates our understanding of research data - what it is; how it dynamically evolves across different scientific disciplines and across various stages of research practice; and how it can, and indeed should, be shared at any of those stages. The result is a flexible and pragmatic path for implementing open scientific data.
This guide provides state-of-the-art information in order to maximise the quality and minimise the risks during donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells. As with all transplanted material of human origin, tissues and cells carry risks of disease transmission, which must be controlled by the application of scrupulous donor selection criteria (including testing) and comprehensive quality systems. The idea behind this guide is to help professionals on a practical level by providing generic guidance that will help improve the rate of successful clinical application of tissues and cells. The guide makes reference to EU mandatory requirements where appropriate and describes generally-accepted good practice. It has been divided into two parts. Part A contains general requirements applicable to all establishments involved in the donation, procurement, testing, processing, preservation, storage and distribution of tissues and cells. Part B contains specific guidelines and requirements for the different tissue and/or cell types
This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.
This open access book presents recent advances in the pure sciences that are of significance in the quest for alternatives to the use of animals in research and describes a variety of practical applications of the three key guiding principles for the more ethical use of animals in experiments – replacement, reduction, and refinement, collectively known as the 3Rs. Important examples from across the world of implementation of the 3Rs in the testing of cosmetics, chemicals, pesticides, and biologics, including vaccines, are described, with additional information on relevant regulations. The coverage also encompasses emerging approaches to alternative tests and the 3Rs. The book is based on the most informative contributions delivered at the Asian Congress 2016 on Alternatives and Animal Use in the Life Sciences. It will be of value for those working in R&D, for graduate students, and for educators in various fields, including the pharmaceutical and cosmetic sciences, pharmacology, toxicology, and animal welfare. The free, open access distribution of Alternatives to Animal Testing is enabled by the Creative Commons Attribution license in International version 4: CC BY 4.0.
The chemistry, biochemistry and pharmacology of heparin and heparan sulfate have been and continue to be a major scientific undertaking - heparin and its derivative remain important drugs in clinical practice. Chemistry and Biology of Heparin and Heparan Sulfate provides readers with an insight into the chemistry, biology and clinical applications of heparin and heparan sulfate and examines their function in various physiological and pathological conditions. Providing a wealth of useful information, no other tome covers the diversity of topics in the field. Students, doctors, chemists, biochemists, and research scientists will find this book an invaluable source for updating their current knowledge of developments in this area. Comprehensively reviews all aspects of heparin and heparan sulfate research Uniquely describes the chemistry, biology and clinical application of heparins and heparan sulfates in one work Provides an invaluable source of knowledge of current developments for chemists, biochemists, medical doctors, researchers, students and practitioners