Gmp Asean Guideline Ministry Of Public Health

This report is structured in five parts: national framework for traditional and complementary medicine (T&CM); product regulation; practices and practitioners; the challenges faced by countries; and, finally, the country profiles. Apart from the section on practices and practitioners, the report is consistent with the format of the report of the first global survey in order to provide a useful comparison. The section on practices and practitioners, which covers providers, education and health insurance, is a new section incorporated to reflect the emerging trends in T&CM and to gather new information regarding these topics at a national level. All new information received has been incorporated into individual country profiles and data graphs. The report captures the three phases of progress made by Member States; that is, before and after the first WHO Traditional Medicine Strategy (1999-2005), from the first global survey to the second global survey (2005-2012) and from the second survey to the most recent timeline (2012-2018).

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Seventeen in a series of annual reports comparing business regulation in 190 economies, Doing Business 2020 measures aspects of regulation affecting 10 areas of everyday business activity.

The conceptualization and formulation of skin care products intended for topical use is a multifaceted and evolving area of science. Formulators must account for myriad skin types, emerging opportunities for product development as well as a very temperamental retail market. Originally published as "Apply Topically" in 2013 (now out of print), this reissued detailed and comprehensive handbook offers a practical approach to the formulation chemist's day-to-day endeavors by: Addressing the innumerable challenges facing the chemist both in design and at the bench, such as formulating with/for specific properties; formulation, processing and production techniques; sensory and elegancy; stability and preservation; color cosmetics; sunscreens; Offering valuable guidance to troubleshooting issues regarding ingredient selection and interaction, regulatory concerns that must be addressed early in development, and the extrapolation of preservative systems, fragrances, stability and texture aids; Exploring the advantages and limitations of raw materials; Addressing scale-up and pilot production process and concerns; Testing and Measurements Methods. The 22 chapters written by industry experts such as Roger L. McMullen, Paul Thau, Hemi Nae, Ada Polla, Howard Epstein, Joseph Albanese, Mark Chandler, Steve Herman, Gary Kelm, Patricia Aikens, and Sam Shefer, along with many others, give the reader and user the ultimate handbook on topical product development.

Regionalism Support and Norm Diffusion between the EU and ASEAN

Validation Compliance Biannual 1996-1997
Who Global Report on Traditional and Complementary Medicine 2019
Supporting Economic Growth and Serving the Public Interest
Doing Business 2020

The adulteration and fraudulent manufacture of medicines is an old problem, vastly aggravated by modern manufacturing and trade. In the last decade, impotent antimicrobial drugs have compromised the treatment of many deadly diseases in poor countries. More recently, negligent production at a Massachusetts compounding pharmacy sickened hundreds of Americans. While the national drugs regulatory authority (hereafter, the regulatory authority) is responsible for the safety of a country's drug supply, no single country can entirely guarantee this today. The once common use of the term counterfeit to describe any drug that is not what it claims to be is at the heart of the argument. In a narrow, legal sense a counterfeit drug is one that infringes on a registered trademark. The lay meaning is much broader, including any drug made with intentional deceit. Some generic drug companies and civil society groups object to calling bad medicines counterfeit, seeing it as the deliberate conflation of public health and intellectual property concerns. Countering the Problem of Falsified and Substandard Drugs accepts the narrow meaning of counterfeit, and, because the nuances of trademark infringement must be dealt with by courts, case by case, the report does not discuss the problem of counterfeit medicines.
This comprehensive review of Myanmar's policies regarding inward direct investment covers such issues as trends in investment in Myanmar, responsible business conduct, regulation and protection of investment, investment promotion and facilitation, taxes, the financial sector, and infrastructure.
A very high portion of the seafood we eat comes from abroad, mainly from China and Southeast Asia, and most of the active ingredients in medicines we take originate in other countries. Many low- and middle-income countries have lower labor costs and fewer and less stringent environmental regulations than the United States, making them attractive places to produce food and chemical ingredients for export. Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad explains that the diversity and scale of imports makes it impractical for U.S. Food and Drug Administration (FDA) border inspections to be sufficient to ensure product purity and safety, and incidents such as American deaths due to adulterated heparin imported from China propelled the problem into public awareness. The Institute of Medicine Committee on Strengthening Core Elements of Regulatory Systems in Developing Countries took up the vital task of helping the FDA to cope with the reality that so much of the food, drugs, biologics, and medical products consumed in the United States originate in countries with less-robust regulatory systems. Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad describes the ways the United States can help

strengthen regulatory systems in low and middle income countries and promote cross-border partnerships - including government, industry, and academia - to foster regulatory science and build a core of regulatory professionals. This report also emphasizes an array of practical approaches to ensure sound regulatory practices in today's interconnected world.

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.

fifty-fifth report

Regulatory Policy and Governance Supporting Economic Growth and Serving the Public Interest

Pharmaceutical Manufacturing Handbook

Guidelines for Good Manufacturing Practice of Cosmetic Products (GMPC)

In the Context of the International Treaties

Pharmaceutical Policy in Countries with Developing Healthcare Systems

Using a framework of norm diffusion to determine the EU's international actorness in the context of its relations with ASEAN, this book provides a timely and in-depth analysis of EU-ASEAN relations. By investigating three aspects of regionalism support by the EU it presents a comprehensive account of norm diffusion between the EU and ASEAN.

This report encourages governments to “think big” about the relevance of regulatory policy and assesses the recent efforts of OECD countries to develop and deepen regulatory policy and governance.

These guidelines, aimed at governments, and in particular cosmetics manufacturers, in order to improve public health safety, offer organisational and practical advice on the management of the human, technical and administrative factors affecting product quality. They describe the manufacturing conditions and management activities involved in the different stages of production, from the purchase of the raw materials to the dispatch of the packaged end-products.

Quality assurance of pharmaceutical products is a continuing concern of WHO. Despite efforts made around the world to ensure a supply of quality and effective medicines, substandard, spurious and counterfeit products still compromise health care delivery in many countries. To

respond to the global need for adequate quality assurance of pharmaceuticals, WHO's Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel. Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices (GMP). Important texts on inspection are also included. Most of the material has been published separately in the Expert Committee's reports. This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy, in medicines regulation and control and in the pharmaceutical industry. This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series.

Thailand: Doing Business and Investing in Thailand Guide Volume 1 Strategic, Practical Information and Contacts

WHO Expert Committee on Specifications for Pharmaceutical Preparations

Guide to ASEAN Practices and Protocol

Safe Food for the Association of Southeast Asian Nations (ASEAN) – Engaging in Codex Standards setting.

Evaluation of Health Services

A Special Publication for the Promotion of Sustainable Fisheries for Food Security in the ASEAN Region

Thailand: Doing Business and Investing in ... Guide Volume 1 Strategic, Practical Information, Regulations, Contacts

Drawing on anthropology, historical sociology and social-epidemiology, this multidisciplinary book investigates how pharmaceuticals are produced, distributed, prescribed, (and) consumed, and regulated in order to construct a comprehensive understanding of the issues that drive (medicine) pharmaceutical markets in the Global South today. Based on primary research conducted in Benin and Ghana, and additional data collected in Cambodia and the Ivory Coast, this volume uses artemisinin-based combination therapies (ACTs) against malaria as a central case study. It highlights the influence of the countries colonial and post-colonial history on their models for state regulation, production, and distribution, explores the determining role transnational actors as well as industries from the North but also and increasingly from the South play in influencing local pharmaceutical markets and looks at the behaviour of health care professionals and individuals. Stepping back, the authors then unpick the pharmaceuticalization process and the multiple

regulations at stake by looking at the workings of, and linkages between, (biomedical health) pharmaceutical systems, (representatives of companies) industries, actors in private distribution, and consumer practices. Providing a thorough comparative analysis of the advantages and disadvantages of different pharmaceutical systems, it is an important contribution to the literature on pharmaceutalization and the governance of medication. It is of interest to students, researchers and policy-makers interested in medical anthropology, the sociology of health and illness, global health, healthcare management and pharmacy.

Medicinal plant materials are supplied through collection from wild populations and cultivation. Under the overall context of quality assurance and control of herbal medicines WHO developed the Guidelines on good agricultural and collection practices (GACP) for medicinal plants providing general technical guidance on obtaining medicinal plant materials of good quality for the sustainable production of herbal products classified as medicines. These guidelines are also related to WHO's work on the protection of medicinal plants aiming promotion of sustainable use and cultivation of medicinal plants. The main objectives of these guidelines are to: (1) contribute to the quality assurance of medicinal plant materials used as the source for herbal medicines to improve the quality safety and efficacy of finished herbal products; (2) guide the formulation of national and/or regional GACP guidelines and GACP monographs for medicinal plants and related standard operating procedures; and (3) encourage and support the sustainable cultivation and collection of medicinal plants of good quality in ways that respect and support the conservation of medicinal plants and the environment in general. These guidelines concern the cultivation and collection of medicinal plants and include certain post-harvest operations. Good agricultural and collection practices for medicinal plants are the first step in quality assurance on which the safety and efficacy of herbal medicinal products directly depend. These practices also play an important role in protection natural resources of medicinal plants for sustainable use.

This document has been created with the aim of highlighting the significant advances by the Association of Southeast Asian Nations (ASEAN) in engagement and support to its ten member countries in implementing their national Codex activities. The authors consolidated inputs provided by the national focal points together with FAO country offices. This report supersedes the previous version entitled “Status of National Codex Activities” published in 2012. It also provides information for food safety competent authorities in the government sector outside of the ASEAN region. In addition, the intention is that the document will help to indirectly strengthen collaboration within the region through the discussion and benchmarking of good practices. This document will also serve as the new baseline for the success of further projects and improvements made by the countries and FAO in strengthening capacities for enhancing Codex Alimentarius activities in ASEAN.

Promoting Access to Medical Technologies and Innovation - Intersections between Public Health, Intellectual Property and Trade

The EU, ASEAN and Interregionalism

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017

Countering the Problem of Falsified and Substandard Drugs

Assam as India's Gateway to ASEAN
Fish for the People

This book offers practical applications addressing the specifics of contamination, including particle origination, characterization, identification, and elimination, with a special focus on quality considerations. Written by an industry expert, this material offers a clear and concise understanding of particle populations and their control in stability, efficacy, and predictability in the manufacture of healthcare products. Complete with a full-color insert of micrographs illustrating commonly encountered particulate matter and over eighty figures, tables, and charts. Features
OECD Investment Policy Reviews: Myanmar 2014OECD Publishing
Commonly known as the Orange Guide, this book remains an essential reference for all manufacturers and distributors of medicines in Europe. It provides a single authoritative source of European and UK guidance, information and legislation relating to the manufacture and distribution of human medicines.
Provides practical guidance on pharmaceutical analysis, written by leading experts with extensive industry experience Analytical Testing for the Pharmaceutical GMP Laboratory presents a thorough overview of the pharmaceutical regulations, working processes, and drug development best practices used to maintain the quality and integrity of medicines. With a focus on smaller molecular weight drug substances and products, the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices (GMP) regulations. Concise yet comprehensive chapters contain up-to-date coverage of drug regulations, pharmaceutical analysis methodologies, control strategies, testing development and validation, method transfer, electronic data documentation, and more. Each chapter includes a table of contents, definitions of acronyms, a reference list, and ample tables and figures. Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products, this authoritative resource: Describes the structure, roles, core guidelines, and GMP regulations of the FDA and ICH. Covers the common analytical technologies used in pharmaceutical laboratories, including examples of analytical techniques used for the release and stability testing of drugs. Examines control strategies established from quality systems supported by real-world case studies. Explains the use of dissolution testing for products such as extended-release capsules, aerosols, and inhalers. Discusses good documentation and data reporting practices, stability programs, and the Laboratory Information Management System (LIMS) to maintain compliance. Includes calculations, application examples, and illustrations to assist readers in day-to-day laboratory operations. Contains practical information and templates to structure internal processes or common Standard Operating Procedures (SOPs). Analytical Testing for the Pharmaceutical GMP Laboratory is a must-have reference for both early-career and experienced pharmaceutical scientists, analytical chemists, pharmacists, and quality control professionals. It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs.
Emerging Trends
Handbook of Formulating Dermal Applications
OECD Investment Policy Reviews: Myanmar 2014
Thailand Investment and Business Guide Volume 1 Strategic and Practical Information
Analytical Testing for the Pharmaceutical GMP Laboratory
Doing Business and Investing in Thailand Guide Volume 1 Strategic and Practical

Information

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

On 28 July 2008, the ASEAN Studies Centre and the Regional Economic Studies Programme, both of the Institute of Southeast Asian Studies, and the Konrad Adenauer Stiftung organized a roundtable on The ASEAN Economic Community Blueprint. The brainstorming session gathered Southeast Asian experts from the region to discuss the AEC Blueprint, which ASEANs leaders had adopted at their summit meeting in November 2007, and the prospects of any obstacles to its implementation by the target year, 2015. The roundtable started with a progress report on the AEC Blueprint given by S. Pushpanathan, Principal Director of Economic Integration and Finance, ASEAN Secretariat, Jakarta. Thereafter, the sessions examined the various aspects of the Blueprint tackling the non-tariff barriers, designing a comprehensive ASEAN Investment Agreement, a regional framework for competition policy, the role of infrastructure development in economic integration, the importance of international production networks in economic integration, etc.

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. Standards are developed by the Expert Committee through worldwide consultation and an international consensus-building process. The following new guidance texts were adopted and recommended for use: Guidelines and guidance texts adopted by the Expert Committee on Specifications for Pharmaceutical Preparations; Points to consider when including Health Based Exposure Limits (HBELs) in cleaning validation; Good manufacturing practices: water for pharmaceutical use; Guideline on data integrity; WHO/United Nations Population Fund recommendations for condom storage and shipping temperatures; WHO/United Nations Population Fund guidance on testing of male latex condoms; WHO/United Nations Population Fund guidance on conducting post-market surveillance of condoms; WHO "Biowaiver List": proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; WHO Certification Scheme on the quality of pharmaceutical products moving in international commerce; Good reliance practices in the regulation of medical products: high-level principles and considerations; and Good regulatory

practices in the regulations of medical products. All of the above are included in this report and recommended for implementation.
Seven independent variables were used including the five financing instruments, the firm's ordinary debt, and the firm's operating risk.
ASEAN Economic Community Blueprint
Understanding Drugs Markets
WHO Guidelines on Good Agricultural and Collection Practices [GACP] for Medicinal Plants
Social Enterprise in Asia
Production and Processes
Packaging and Storage of Fruits and Vegetables

2011 Updated Reprint. Updated Annually. Doing Business and Investing in Thailand Guide

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.

As the costs and resources of delivering health services have increased over the years, the importance of evaluating health services and interventions has become essential. An evaluation provides a systematic process of assessing the efficacy and efficiency of health services, including an assessment of their impact on beneficiaries, whether it be individuals or communities. Evaluation in the health sector includes the evaluation of burden disease where human and economic costs resulting from poor health are measured.In this book, various evaluation studies are detailed, providing an excellent resource for both evaluation practitioners and academics alike. The geographical range and variety of case studies showcase how evaluation has become integral for health service planning and assessment and to assist public health policy makers decide how to use limited resources to minimize burden and inequity. This book will act as a ready resource for both workers experienced in health service evaluation and those intending to learn about burden of disease of evaluation.

This biannual offers detailed coverage of the regulations, requirements, and techniques for the validation of processes and systems used in regulated international industries. It addresses significant requirements for pharmaceutical, medical device, and biologic companies as well as environmental laboratories. It examines Good Manufacturing Principles (GMPs), Good Clinical Practices (GCPs), Good Laboratory Practices (GLPs), Good Automated Library Practices (GALPs), and others, and elucidates up-to-the-minute industry changes and international concerns.

A Definitive Practical Guide
Food, Drug, Cosmetic Law Journal
Regulatory Affairs in the Pharmaceutical Industry

Handbook of Stability Testing in Pharmaceutical Development
Annual Report on the Activities of the International Trade Centre UNCTAD/WTO
Guidelines for the Control of Narcotic and Psychotropic Substances

Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry. Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs, the content covers new drugs, generic drugs and their development, regulatory filings in different countries, different phases of clinical trials, and the submission of regulatory documents like IND (Investigational New Drug), NDA (New Drug Application) and ANDA (Abbreviated New Drug Application). Chapters cover documentation in the pharmaceutical industry, generic drug development, code of Federal Regulation (CFR), the ANDA regulatory approval process, the process and documentation for US registration of foreign drugs, the regulation of combination products and medical devices, the CTD and ECTD formats, and much more. Updated reference on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the fundamentals of manufacturing controls and their regulatory importance

In the absence of a widely accepted and common definition of social enterprise (SE), a large research project, the "International Comparative Social Enterprise Models" (ICSEM) Project, was carried out over a five-year period; it involved more than 200 researchers from 55 countries and relied on bottom-up approaches to capture the SE phenomenon. This strategy made it possible to take into account and give legitimacy to locally embedded approaches, thus resulting in an analysis encompassing a wide diversity of social enterprises, while simultaneously allowing for the identification of major SE models to delineate the field on common grounds at the international level. These SE models reveal or confirm an overall trend towards new ways of sharing the responsibility for the common good in today's economies and societies. We tend to consider as good news the fact that social enterprises actually stem from all parts of the economy. Indeed, societies are facing many complex challenges at all levels, from the local to the global level. The diversity and internal variety of SE models are a sign of a broadly shared willingness to develop appropriate—although sometimes embryonic—responses to these challenges, on the basis of innovative economic/business models driven by a social mission. In spite of their weaknesses, social enterprises may be seen as advocates for and vehicles of the general interest across the whole economy. Of course, the debate about privatisation, deregulation and globalised market

competition—all factors that may hinder efforts in the search for the common good–has to be addressed as well. The first of a series of four ICSEM books, Social Enterprise in Asia will serve as a key reference and resource for teachers, researchers, students, experts, policy makers, journalists and other categories of people who want to acquire a broad understanding of the phenomena of social enterprise and social entrepreneurship as they emerge and develop across the world.

This publication builds on a vision for Assam, the largest state in northeast India, to follow an outward-looking growth strategy and become a $75 billion economy by 2025. It outlines the potential and key features of Assam as a geostrategic location for multimodal connectivity, regional and cross-border trade, and economic corridors between India and the Association of Southeast Asian Nations (ASEAN) as well as Bangladesh, Bhutan, and Nepal. The vision for Assam as India's gateway to ASEAN is also geared toward ensuring that both the state and the country remain committed toward achieving the Sustainable Development Goals.

A comprehensive and granular insight into the challenges of promoting rational medicine, this book serves as an essential resource for health policy makers and researchers interested in national medicines policies. Country-specific chapters have a common format, beginning with an overview of the health system and regulatory and policy environments, before discussing the difficulties in maintaining a medicines supply system, challenges in ensuring access to affordable medicines and issues impacting on rational medicine use. Numerous case studies are also used to highlight key issues and each chapter concludes with country-specific solutions to the issues raised. Written by highly regarded academics, the book includes countries in Africa, Asia, Europe, the Middle East and South America.

Regulations for Agricultural Products Derived from Biotechnology

Regulations, Methodologies, and Best Practices

A Multicountry Study

Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad

A Compendium of Guidelines and Related Materials. Good manufacturing practices and inspection

Theory, Models and Practice

This new volume shares a plethora of valuable information on the recent advances in packaging and storage technologies used for quality preservation of fresh fruits and vegetables. This book, with chapters from eminent researchers in the field, covers several essential aspects of packaging and storage methods and techniques generally used in fruit and vegetables. Important considerations on selection and characteristics of packaging materials, new packaging methods, storage hygiene and sanitation issues along with recent trends in storage

technology are discussed in this volume. Key features: Provides an inclusive overview of fruit and vegetable requirements and available packaging materials and storage systems Imparts an understanding of the fundamentals of the impact of packaging on the evolution of quality and safety of fruits and vegetables Includes examples of mathematical modeling and mechanical and engineering properties of packaging materials Provides an in-depth discussion of innovative packaging and storage technologies, such as MA/CA packaging, active packaging, intelligent packaging, eco-friendly materials, etc., applied to fruit and vegetables Packaging and Storage of Fruits and Vegetables: Emerging Trends will be useful for graduate and postgraduate students and teaching professionals of horticultural science, food science and technology, packaging technology etc. It will also provide valuable scientific information to the academic scientific research community as well as to the packaging and storage industries for preservation of quality characteristics of fruits and vegetables. The professional community involved in handling processing and commercialization of horticultural crops will benefit as well.

Quality Assurance of Pharmaceuticals

Regulations and Quality

An Analysis of Medicines, Regulations and Pharmaceutical Systems in the Global South

Effective Drug Regulation

Control of Particulate Matter Contamination in Healthcare Manufacturing

ASEAN Newsletter