Medical Devices Essential Principles Checklist

Manufacturers must demonstrate their medical device complies with the Essential Principles. Manufacturers must generate, collate, assess, and maintain scientific and clinical evidence that shows that their devices comply with the Essential Principles. The evidence must be relevant to the device's intended purpose and must be objective, sufficient, and robust.

- The Essential Principles Checklist is a template that may help you:
  - identify the safety and performance requirements that apply to your device
  - document a rationale for any of the safety and performance requirements that aren't relevant
  - summarise the evidence you hold in support of each of the relevant safety and performance requirements
- Completing the checklist could help you:
  - apply for an Australian conformity assessment certificate
  - comply with regulations as part of a post-market review or investigation
  - to determine if you have considered and addressed all the requirements with supporting evidence

Instructions

- Complete this checklist for each new medical device conformity assessment application
- Provide an updated checklist if applicable, for change applications relating to your medical device.
- The checklist must be applicable to the subject medical devices or may be completed for a family or group of devices.
- Complete the checklist as outlined in the table instructions below

Table instructions

Reference to Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 1, Part number and title		Applicable	Not applicable — Justification must be provided below	Medical Devices / IVD standard or other procedure applied	Evidence of compliance — Include direct reference to documents within the manufacturer's quality system
EP No.#	*Title of the Essential Principle*				
EP.s No.#	The Essential Principle requirement is contained here.	☐ Tick this box if the Essential Principle requirement is applicable to the device / family of devices. Complete the two columns on the right.	☐ Tick this box if the Essential Principle requirement is not applicable to your device / family of devices. Then provide justification.	List here the standards / procedures applied with justification (include number / title / version). These include (but are not limited to): • EN ISO international, local standards • company procedures • TGA Medical Device Standard Order • TGA Conformity Assessment Standard Order • TGA Guidance document	This column is to contain direct reference to documents within the manufacturer's quality system such as: • study results • test reports • design outputs identified by number / title / version

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Instructions for compilation of a product dossier – IMDRF ToC. Prequalification of in vitro diagnostics World Health Organization,2024-01-22 This World Health Organization WHO publication provides comprehensive guidelines for manufacturers on compiling a product dossier for in vitro diagnostic IVD medical devices The document supersedes the previous 2014 version and aligns with the International Medical Device Regulators Forum IMDRF standards It outlines the necessary information and documents required for WHO assessment ensuring safety efficacy and performance of IVD products The publication emphasizes flexibility in submission approaches allowing alternatives if scientifically justified and highlights the importance of clarity and completeness in dossiers It is intended for manufacturers seeking WHO evaluation and includes references to additional WHO technical documents **Medical Device Regulations** Aakash Deep,2022-01-13 Medical Device Regulations A Complete Guide describes a brief review of various regulatory bodies of major developed and developing countries around the world The book covers the registration procedures of medical devices for pharmaceutical regulatory organizations Sections provide guidance on dealing with the ethical considerations of medical device development compliance with patient confidentiality using information from medical devices the interoperability between and among devices outside of healthcare and the dynamics of implementation of new devices to ensure patient safety The author brings forth relevant issues challenges and demonstrates how management can foster increased clinical and non clinical relations to enhance patient outcomes and the bottom line by demystifying the regulatory impact on operational requirements Provides clear information on regulatory pathways for the design and commercialization of Medical Devices in different countries Explains the difference between standards and mandatory regulations for each region along with discussions of regulations from USFDA USA CDSCO India EMEA European Union SFDA China and PMDA Japan Compiles regulations for medical devices and pharmaceuticals worldwide helping readers create globally compliant products **Handbook of Medical Device Regulatory Affairs in Asia** Jack Wong,Raymond Tong,2018-03-28 Medical device regulation in Asia has gained more importance than ever Governments and regulatory bodies across the region have put in place new regulatory systems or refined the existing ones A registered product requires a lot of technical documentation to prove its efficacy safety and quality A smooth and successful registration process demands soft skills for dealing with various key stakeholders in the government testing centers and hospitals and among doctors This handbook covers medical device regulatory systems in different countries ISO standards for medical devices clinical trial and regulatory requirements and documentation for application It is the first to cover the medical device regulatory affairs in Asia Each chapter provides substantial background materials relevant to the particular area to have a better understanding of regulatory affairs **The Combination Products Handbook** Susan Neadle,2023-05-16 Combination products are therapeutic and diagnostic products that combine drugs devices and or biological products According to the US Food and Drug Administration FDA a combination product is

one composed of any combination of a drug and a device a biological product and a device a drug and a biological product or a drug device and a biological product Examples include prefilled syringes pen injectors autoinjectors inhalers transdermal delivery systems drug eluting stents and kits containing drug administration devices co packaged with drugs and or biological products This handbook provides the most up to date information on the development of combination products from the technology involved to successful delivery to market The authors present important and up to the minute pre and post market reviews of international combination product regulations guidance considerations and best practices This handbook Brings clarity of understanding for global combination products guidance and regulations Reviews the current state of the art considerations and best practices spanning the combination product lifecycle pre market through post market Reviews medical product classification and assignment issues faced by global regulatory authorities and industry The editor is a recognized international Combination Products and Medical Device expert with over 35 years of industry experience and has an outstanding team of contributors Endorsed by AAMI Association for the Advancement of Medical Instrumentation

Medical Regulatory Affairs Jack Wong,Raymond Tong,2025-04-16 This handbook covers medical device regulatory systems in different countries ISO standards for medical devices clinical trial and regulatory requirements and documentation for application It is the first to cover the medical device regulatory affairs in Asia Experts from influential international regulatory bodies including the US Food and Drug Administration FDA UK Medicines and Healthcare Products Regulatory Agency Japan Pharmaceuticals and Medical Devices Agency Saudi Food and Drug Authority Korea Testing Laboratory Taiwan FDA World Health Organization Asian Harmonization Working Party Regulatory Affairs Professionals Society and British Standards Institution have contributed to the book Government bodies the medical device industry academics students and general readers will find the book immensely useful for understanding the global regulatory environment and in their research and development projects The updated fourth edition includes specific contributions that address the needs of startups **Encyclopedia of Medical Devices and Instrumentation** John G. Webster,1988-03-24 This objective referenced collection of over 300 articles will cover every aspect of medical devices and instrumentation in four volumes totalling about 3 000 pages The Encyclopedia will define the discipline by bringing together the core of knowledge from all the fields encompassed by the application of engineering physics and computers to problems in medicine Some of the many areas covered will include anaesthesiology burns cardiology clinical chemistry and engineering critical care medicine dermatology dentistry endocrinology genetics gynecology microbiology oncology pharmacology psychiatry radiology surgery and urology Cross references and index included **Techniques and Principles for the Operating Room** Matthew Porteous,Susanne Bäuerle,2010-06-16 Lavishly illustrated succinct coverage of the latest advances in operative fracture care Reflecting the recent dramatic advances in orthopedic trauma care and orthopedic implants this highly practical surgical guide provides step by step descriptions of new state of the art techniques as well as in depth

information on classic time tested methods Packed with hundreds of the high quality full color illustrations for which AO books are known the expert authors of this must have text discuss operating room principles for different aspects of OR management for ORP orthotic rehabilitation products and AO principles of fracture management and give advice on how to perform common procedures with an emphasis on the use of surgical instruments Features Comprehensive discussion of relative stability biological fixation minimally invasive techniques the correct use of locking head screws and the locking compression plate and more Concise chapters designed to aid ORP and junior residents as they assist during surgery Full color illustrations complement thorough descriptions of each step of the procedures AO Techniques and Principles for the Operating Room is an invaluable tool for operating room staff and all residents starting their careers in orthopedic trauma care **Biocompatiblity** Julian H. Braybrook,1997-08-04 This book presents both an overview and forward assessment of medical device materials and test methods Highlighting the complex problem of host responses and related issues which may restrict the accuracy and reliability of existing test methodology the book provides an unbiased appraisal of the requirements for biocompatibility and the approaches that have been developed to evaluate it *The Practice and Principles of Surgical Assisting* Rebecca Hall,2025-01-24 This definitive guide provides the insights surgical assistants need to excel in their field and the information students need to ace the CSFA Created by the Association of Surgical Assistants The Practice and Principles of Surgical Assisting is based on feedback from educational program directors and on the approved core curriculum Packed with 400 photos and illustrations it delivers the information and insights you need as you work your way through the surgical assisting programs and study for the Certified Surgical First Assistant CSFA This authoritative guide covers all the topics you need to know including legal moral and ethical considerations perioperative infection control and patient management pharmacology and anesthesia principles preoperative patient preparation tissue handling wound closure modalities and techniques and surgical specialties including but not limited to obstetric gynecologic genitourinary ophthalmic and cardiothoracic surgeries ASQC ... Annual Quality Congress Proceedings ,1997 Medical Device Regulations Michael Cheng,World Health Organization,2003-09-16 The term medical devices covers a wide range of equipment essential for patient care at every level of the health service whether at the bedside at a health clinic or in a large specialised hospital Yet many countries lack access to high quality devices particularly in developing countries where health technology assessments are rare and there is a lack of regulatory controls to prevent the use of substandard devices This publication provides a guidance framework for countries wishing to create or modify their own regulatory systems for medical devices based on best practice experience in other countries Issues highlighted include the need for harmonised regulations and the adoption where appropriate of device approvals of advanced regulatory systems to avoid an unnecessary drain on scarce resources These approaches allow emphasis to be placed on locally assessed needs including vendor and device registration training and surveillance and information exchange systems **Journal of Medical Systems** ,1977

The Publishers Weekly ,1973-04   Software Engineering Merlin Dorfman,Richard H. Thayer,1997 Software Engineering describes the current state of the art practice of software engineering beginning with an overview of current issues and focusing on the engineering of large complex systems The text illustrates the phases of the software development life cycle requirements design implementation testing and maintenance   Medical Device Safety G.R Higson,2001-10-29 Medical Device Safety The Regulation of Medical Devices for Public Health and Safety examines the prospects for achieving global harmonization in medical device regulation and describes a possible future global system Unresolved difficulties are discussed while solutions are proposed An essential book for all those involved in health physics en   *Government reports annual index* ,199?   Journal of AOAC International ,1995   Medical Devices ,2016   *The United States Catalog* Mary Burnham,Carol Hurd,1928   **American Jurisprudence Proof of Facts, 3d Series** ,1988 Provides text and sample testimony to assist in preparing for and proving facts that may be in issue in judicial and administrative proceedings Kept up to date by packet supplements Library has second and third series

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