



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

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Table instructions

Reference to Therapeutic Goods (Medical Devices) Regulations 2002 Schedule 1, Part number and title		Applicable	Not applicable <i>Justification must be provided below</i>	Medical Devices / IVD standard or other procedure applied	Evidence of compliance <i>Include direct reference to documents within the manufacturer's quality system</i>
EP Reg.#	Title of the Essential Principle				
EP.# Reg.#	The Essential Principle requirement is contained here.	<input type="checkbox"/> Tick this box if the Essential Principle requirement is applicable to the device / family of devices. Complete the two columns on the right.	<input type="checkbox"/> 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): <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • study results • test reports • design outputs identified by number / title / version

Medical Devices Essential Principles Checklist

Jack Wong, Raymond Tong



Medical Devices Essential Principles Checklist:

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

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

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

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

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AOAC International, 1995 **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 *Government Reports Annual Index*, 1984 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 *The United States Catalog* Mary Burnham, Carol Hurd, 1928 Cumulative Index of Hospital Literature American Hospital Association Staff, 1979-02 CIS Abstracts International Occupational Safety and Health Information Centre, 1980

Reviewing **Medical Devices Essential Principles Checklist**: Unlocking the Spellbinding Force of Linguistics

In a fast-paced world fueled by information and interconnectivity, the spellbinding force of linguistics has acquired newfound prominence. Its capacity to evoke emotions, stimulate contemplation, and stimulate metamorphosis is truly astonishing. Within the pages of "**Medical Devices Essential Principles Checklist**," an enthralling opus penned by a highly acclaimed wordsmith, readers attempt an immersive expedition to unravel the intricate significance of language and its indelible imprint on our lives. Throughout this assessment, we shall delve into the book's central motifs, appraise its distinctive narrative style, and gauge its overarching influence on the minds of its readers.

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