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## Medical devices Essential Principles checklist

Manufacturer name

Product name

ID

### Notes on what to include in each column

**Applicable/Not applicable** – respond with 'A' or 'NA' for the device. If not applicable (NA) include justification.

**Medical Device Standards applied by manufacturer** - only include standards published by the TGA as Medical Device Standard Orders or Conformity Assessment Standard Order.

**Other standards or procedures applied by manufacturer** – include: EN, ISO, international or local standards or company procedures identified by number or title.

**Evidence of compliance or reason for non-applicability** – include direct reference to documents such as: study results, test reports, design outputs identified by number or title within the Quality System.

**Note:** [Therapeutic Goods Act 1989](#) (the Act) and [Therapeutic Goods \(Medical Devices\) Regulations 2002](#) (the Regulations).

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**TGA** Health Safety  
Regulator

Schedule 2	Essential Principle from the Regulations	Applicable/Not applicable	Medical Device Standards applied by manufacturer	Other standards or procedures applied by manufacturer	Evidence of compliance or reason for non-applicability
Part 1.	General principles				
1.	<b>Use of medical devices not to compromise health and safety</b> A medical device is to be designed and produced in a way that ensures that: (a) the device will not compromise the clinical condition or safety of a patient, or the safety and health of the user or any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training; and (b) any risks associated with the use of the device are: (i) acceptable risks when weighed against the intended benefit to the patient; and (ii) compatible with a high level of protection of health and safety.				
2.	<b>Design and construction of medical devices to conform with safety principles</b> (1) The solutions adopted by the manufacturer for the design and construction of a medical device must conform with safety principles, having regard to the generally acknowledged state of the art. (2) Without limiting subclause (1), in selecting appropriate solutions for the design and construction of a medical device so as to minimise any risks associated with the use of the device, the manufacturer must: (a) first, identify hazards and associated risks arising from the use of the device for its intended purpose, and foreseeable misuse of the device; and (b) second, eliminate, or reduce, these risks as far as possible by adopting a policy of inherently safe design and construction; and (c) third, if appropriate, ensure that adequate protection measures are taken, including alarms if necessary, in relation to any risks that cannot be eliminated; and (d) fourth, inform users of any residual risks that may arise due to any shortcomings of the protection measures adopted. (3) In paragraph (2) (d): <b>residual risk</b> , for a medical device, means the risk remaining after the measures described in paragraphs (2) (a), (b) and (c) have been applied.				

# Medical Devices Essential Principles Checklist

**Val Theisz**



## **Medical Devices Essential Principles Checklist:**

**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 A Guidance Document for Medical Devices Dr. Priyanka Gupta Manglik, 2024-08-15

This document offers clear guidance on the development assessment and regulation of medical devices focusing on safety efficacy and compliance Useful for manufacturers regulators and biomedical engineers **Instructions for compilation of a product dossier - IMDRF ToC. Prequalification of in vitro diagnostics** World Health Organization, 2024-01-22

Medical Devices Seeram Ramakrishna, Lingling Tian, Charlene Wang, Susan Liao, Wee Eong Teo, 2015-08-18 Medical Devices and Regulations Standards and Practices will shed light on the importance of regulations and standards among all stakeholders bioengineering designers biomaterial scientists and researchers to enable development of future medical devices Based on the authors practical experience this book provides a concise practical guide on key issues and processes in developing new medical devices to meet international regulatory requirements and standards Provides readers with a global perspective on medical device regulations Concise and comprehensive information on how to design medical devices to ensure they meet regulations and standards Includes a useful case study demonstrating the design and approval process

**Handbook of Medical Device Regulatory Affairs in Asia** Jack Wong, Raymond Tong Kaiyu, 2013-03-27 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 Handbook of Medical Device Regulatory Affairs in Asia covers medical device regulatory systems in different countries ISO standards for medical devices clinical trial and regulatory requirements and documentation for application Government bodies the medical device industry and

academics and students will find this book immensely useful in understanding the global regulatory environment and in their research and development projects      **Manual of Commercial Methods in Clinical Microbiology** ,2016-03-28 The Manual of Commercial Methods in Clinical Microbiology 2nd Edition International Edition reviews in detail the current state of the art in each of the disciplines of clinical microbiology and reviews the sensitivities specificities and predictive values and subsequently the effectiveness of commercially available methods both manual and automated This text allows the user to easily summarize the available methods in any particular field or for a specific pathogen for example what to use for an Influenza test a Legionella test or what instrument to use for identification or for an antibiotic susceptibility test The Manual of Commercial Methods in Clinical Microbiology 2nd Edition International Edition presents a wealth of relevant information to clinical pathologists directors and supervisors of clinical microbiology infectious disease physicians point of care laboratories professionals using industrial applications of diagnostic microbiology and other healthcare providers The content will allow professionals to analyze all commercially available methods to determine which works best in their particular laboratory hospital clinic or setting Updated to appeal to an international audience The Manual of Commercial Methods in Clinical Microbiology 2nd Edition International Edition is an invaluable reference to those in the health science and medical fields      Medical Regulatory Affairs Jack Wong,Raymond Tong,2022-01-26 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      **Point-of-Care Technology for Portable Testing Devices** Tharmaraj Vairaperumal,Devi Selvaraj,Ping-Yen Liu,2025-06-02 Point of Care Technology for Portable Testing Devices Nanomaterials Based Optical Biosensors for Cardiovascular Disease Biomarkers presents the latest advances in nanomaterials based optical biosensor enabled point of care testing PoCT devices for the rapid and accurate detection of cardiovascular disease CVD biomarkers This book begins with the introduction of novel cardiovascular biomarkers and advances in point of care diagnostics Subsequent chapters focus on the selection of bioreceptors and the overview of optical nanomaterials for nanobiosensors applications A major focus is targeted on colorimetric detection fluorescence chemiluminescence Localized Surface Plasmon Resonance and Surface Enhanced Raman Scattering based optical nanobiosensor signaling readout techniques which enable the detection of CVD biomarkers Furthermore this book explores

emerging healthcare technologies for next generation portable PoCT devices and recent advances in nanobiosensor techniques for the rapid detection of CVD biomarkers One dedicated chapter explores the role of artificial intelligence in enhancing point of care diagnostics for CVDs while another addresses critical regulatory challenges and safety considerations in translating nanomaterial based biosensors into clinical practice Provides a comprehensive overview of novel CVD biomarkers and advances in point of care diagnostic platforms Detailed exploration of bioreceptor selection and optical nanomaterials for enhancing the selectivity and sensitivity of nanobiosensors for point of care diagnostics Explores the design and advantages of colorimetric detection fluorescence chemiluminescence LSPR and SERS based nanobiosensors techniques which enable rapid and portable point of care testing of CVD biomarkers Integration of artificial intelligence to improve the precision and efficiency of CVD diagnosis at the point of care Addresses key regulatory safety and clinical translation challenges that bridge the gap between laboratory innovations and real world healthcare applications

The Combination Products Handbook Susan Needle, 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

*International Pharmaceutical Product Registration* Anthony C. Cartwright, Brian R. Matthews, 2016-04-19 Discover the latest ICH news from international experts in the pharmaceutical industry academia and regulatory bodies The recent International Conference on Harmonisation ICH revisions of regulatory requirements for quality nonclinical and clinical pharmaceutical product registration are the focus of this timely update This cutting edge resou

*International Labeling Requirements for Medical Devices, Medical Equipment and Diagnostic Products* Charles Sidebottom, 2003-06-27 Completely revised this second edition provides the practical hands on labeling information needed to secure rapid regulatory approval gain marketplace acceptance and assure user comprehension A complete guide to all aspects of advertising labeling and

packaging it explains the relevant laws regulations and requirements in major markets w

**Medical Devices and IVDs** Wolfgang Ecker,2022-03-25 With this book you get a really complete seminar for the new Regulations on medical devices and IVDs in the EU ready at hand at any time These EU regulations create new rules for medical technology and laboratory diagnostics in Europe Concise regulatory know how is now required to keep or reposition medical devices and in vitro diagnostics on the European market from syringes contact lenses medical device apps pregnancy tests nuclear magnetic resonance tomography to cancer tests genetic diagnostics HIV tests hip implants heart catheters artificial spinal discs stents and pacemakers Concise regulatory training and further education of employees in companies and health care facilities is the order of the day This also applies to biomedical and medical technology students at universities of applied sciences and biomedical universities start ups and spin offs who must make use of this know how from the initial product idea through the further stages of product development to market access The book provides a thorough compact course on the new regulations starting with perfect overview and easy navigation and going into depth where you need it this book will make you fit and confident for the new European challenges 344 pages 47 col figures 26 tables

**Technical specifications for pre-market assessment of blood pressure measuring device with cuff, automated and semi-automated** World Health Organization,2023-09-21 To provide technical specifications to blood pressure measuring device with cuff automated and semi automated for manufacturers who intend to seek their WHO prequalification PQ Manufacturers should consider the technical specifications outlined as minimum requirements for participating in the PQ programme in order to ensure that the blood pressure measurement device has been designed evaluated and validated in conformity with these requirements and is therefore safe and effective

**Medical Device** Rommel Garcia,2017-06-06 This book is meant to be a guide to all who want to learn about a highly regulated industry My approach is to give you the reader an example of a fictitious device and we will take it from a conceptual idea all the way to launch and beyond My intention is to incorporate the best experiences that I and other contributors have had into this book and convert them into laymans terms for those who are in need These experiences can and will be indispensable to beginners and professionals alike who are trying their hand in the medical device industry and to those who have not been out of their silo to help see how each of the systems relate to each as a whole However it should be noted that the contents of this book should be taken only as information and is not intended to demonstrate how companies can be in compliance In some instances there are multiple ways to go through the maze of regulations that are documented and made by agencies because the regulations are pretty much made and designed to be flexible and high level so that companies can adopt their systems which are solely designed for their purposes Therefore this book will try to avoid complicated words and complex technical details of engineering and statistics This book will strive to be an embodiment of the honest to goodness everyday experiences and issues that folks experience while working in the medical device industry

**Plastics in Medical Devices** Vinny R. Sastri,2021-11-24 Plastics in Medical Devices Properties Requirements and

Applications Third Edition provides a comprehensive overview on the main types of plastics used in medical device applications The book focuses on the applications and properties that are most important in medical device design such as chemical resistance sterilization capability and biocompatibility The roles of additives stabilizers and fillers as well as the synthesis and production of polymers are covered and backed up with a wealth of data tables The book also covers other key aspects in detail including regulations compliance purchasing controls and supplier controls and process validation This updated edition has been thoroughly revised with regard to new plastic materials applications and requirements This is a valuable resource for engineers scientists and managers involved in the design and manufacture of medical devices Presents detailed coverage of commercially available plastics used in medical device applications organized by polymer type and supported by data Includes up to date regulatory requirements and practical information on purchasing and supplier controls process validation and risk management Supports the development marketing and commercialization of medical devices and materials for use in medical devices

**Medical Device Regulatory Practices** Val Theisz,2015-08-03 This book is intended to serve as a reference for professionals in the medical device industry particularly those seeking to learn from practical examples and case studies Medical devices like pharmaceuticals are highly regulated and the bar is raised constantly as patients and consumers expect the best quality healthcare and safe and effective

*Human-Robot Interaction* Paolo Barattini,Federico Vicentini,Gurvinder Singh Virk,Tamas Haidegger,2019-04-12 Human Robot Interaction Safety Standardization and Benchmarking provides a comprehensive introduction to the new scenarios emerging where humans and robots interact in various environments and applications on a daily basis The focus is on the current status and foreseeable implications of robot safety approaching these issues from the standardization and benchmarking perspectives Featuring contributions from leading experts the book presents state of the art research and includes real world applications and use cases It explores the key leading sectors robotics service robotics and medical robotics and elaborates on the safety approaches that are being developed for effective human robot interaction including physical robot human contacts collaboration in task execution workspace sharing human aware motion planning and exploring the landscape of relevant standards and guidelines Features Presenting a comprehensive introduction to human robot interaction in a number of domains including industrial robotics medical robotics and service robotics Focusing on robot safety standards and benchmarking Providing insight into current developments in international standards Featuring contributions from leading experts actively pursuing new robot development

**Health technology assessment of medical devices** World Health Organization,2025-05-30 HTA is a multidisciplinary process used to evaluate the clinical economic ethical implications and social impact of new health technologies This document describes the critical role of HTA in supporting decision making by informing policy makers about the adoption and or reimbursement of medical technologies by healthcare systems HTA links the three distinct but complementary functions of health technology decision making the first being regulatory approval of

health technologies for market access followed by HTA for the adoption of technologies into health systems and lastly health technology management across the lifetime of a technology

**Planning, Writing and Reviewing Medical Device Clinical and Performance Evaluation Reports (CERs/PERs)** Joy Frestedt, 2024-09-19 A Practical Guide to Planning Writing and Reviewing Medical Device Clinical Evaluation Reports guides readers through clinical data evaluation of medical devices in compliance with the EU MDR requirements and other similar regulatory requirements throughout the world This book brings together knowledge learned as the author constructed hundreds of CERs and taught thousands of learners on how to conduct clinical data evaluations This book will support training for clinical engineers clinical evaluation scientists and experts reviewing medical device CERs and will help individual writers teams and companies to develop stronger more robust CERs Identifies and explains data analysis for clinical evaluation of medical devices Teaches readers how to understand and evaluate medical device performance and safety in the context of new regulations Provides analysis of new clinical evaluation criteria in the context of medical device design as well as in hospital deployment and servicing

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



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