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Patient safety and optimal performance - CADTH.ca

Patient safety and optimal performance: a holistic framework for medical devices Michael Cheng Independent Patient Safety Advocate cheng12@sympatico.ca Canadian Agency for Drugs and Technologies in Health Symposium 2014 . WHO publication (Ref. 1) available on the Internet . Key points focus: regulated products; users –professionals, patients and public differences between medical devices and

Dregs Couverture der - who.int

This guide was prepared under the principal authorship of Dr Michael Cheng. It is based on a similar publication issued by the Pan American Health Organization (PAHO) in 1999 that reviewed the Canadian Medical Devices Regulatory System. The comments and suggestions made by members of the Global Harmonization Task Force and those of many other reviewers are gratefully acknowledged. The

An overview of medical device policy and regulation ...

An overview of medical device policy and regulation (English) Abstract. Medical devices, ranging from a simple disposable syringe to a high end PET/CT scanner, pose significant regulatory, planning and management challenges for client countries.

Medical Device Regulations - Google Books

Medical devices and equipment are a vital component of patient care. From a simple tongue depressor to a sophisticated haemodialysis machine medical devices are needed at every level of the health service. Yet many health services continue to lack information and financial resources to acquire the devices they really need i.e. those that will

Overview of Device Regulation - Food and Drug Administration

Device Advice. Overview of regulations for medical devices: premarket notifications (510(k)), establishment registration, device listing, quality systems, labeling and reporting requirements.

Medical Device Regulations from the Medical Device Control ...

Documents relating to medical device regulations published by the Medical Device Control Office (MDCO) in Hong Kong.

FDA Regulation of Medical Devices - las.org

Medical device regulation is complex, in part, because of the wide variety of items that are categorized as medical devices; examples range from a simple tongue depressor to a life-sustaining heart valve. The regulation of medical

devices can affect their cost, quality, and availability in the health care system. In order to be legally marketed in the United States, many medical devices must

Guide to the regulation of medical devices - swissmedic.ch

It summarises the regulation of medical devices in a practical manner, and references important documents and sources of information. Swissmedic recommends this guide to assist in the initial and further education of all persons having regulatory affairs duties and who are responsible for the design, development and quality control of medical devices. This document does not claim to be

MDR Gap Assessment Tool Introduction

The MDR Gap-Analysis Tool supports medical device companies to implement the new medical device Regulation EU2017/745 in a easy way. The MDR Tool can be downloaded in English or German language. Furthermore also a Gap-Analysis of the new IVDR EU2017/746 is available and we are also offer Webinars and Consulting.

Introductory Guide to new medical device regulations ...

The interactive guide will help new and experienced manufacturers navigate their obligations under new EU regulations on medical devices. Introductory Guide to new medical device regulations

Medical Device Registration in Saudi Arabia

Interested in selling your medical device in Saudi Arabia? If so, there are a lot of things to know about Saudi Arabia's regulatory process before you get started. The Saudi Food and Drug Authority (SFDA) relies on reference market approval, but it is not a "rubber stamp" registration.

Regulatory News - StarFish Medical

Stay Updated. Monthly news, tips, and resources for medical device design, development and manufacture from StarFish Medical.

Device Regulation in China | Inside Medical Devices

By Inside Medical Devices on January 6, 2014 Posted in Device Regulation in China The China FDA (CFDA) released a Notice on Matters Related to Medical Device Re-registration on December 9, 2013. The Notice reduces burdensome requirements in the application process for domestic and foreign manufacturers when renewing or making changes to an existing medical device license in China.

6 Things You Need to Do to Prepare for the New EU Medical ...

When the EU s new Medical Devices Regulation (MDR) entered into force last month, it set in motion a three-year countdown to the new rules full application in 2020. For companies marketing devices in the EU that wish to continue to do so, there is a lot to do in that relatively short time, so

BSI expert talks about the transition to the EU Medical Device Regulations

Understanding and planning your transition to the new regulations is key to ensuring compliance for your medical devices. Kevin Madden, BSI Medical Device Product Specialist, shares his expertise