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Authority of Ethiopia (FMHACA)
Guidelines for Registration of
Biotherapeutic Protein Products
Prepared by Recombinant DNA
Technology February 2018 Addis Ababa,
Ethiopia . 2 This guideline is adapted
from Guidelines on the quality, safety
and efficacy of biotherapeutic

Food, Medicine and Healthcare Administration and Control ...

Guidelines for WHO Pre-qualified
Medicines through Collaborative
Registration Procedure. medicine-
directives: Guideline for Registration of
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medicine-guidelines

Publications - EFDA

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Guideline for Registration of Medical devices 2014. The Food, Medicine and Health Care Administration and Control Authority (FMHACA) of Ethiopia was established to safeguard the health and safety of patients, users, and other persons by ensuring that manufacturers of medical devices follow specified procedures during the design, manufacture, and marketing as described in Proclamation No. 661/2009 for the regulation of medicines and....

Medical Device Guidelines - EFDA

The document is adapted from Guidance Document Harmonized Requirements for the Licensing of Vaccines and Guidelines for the Preparation of an Application, Health Canada, 2016 and is based on the requirements of the International Conference on Harmonization (ICH) Common Technical Document (CTD) and the Technical Report Series of the World Health Organization.

Food, Medicine and Healthcare

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Standard Treatment Guidelines Fmhaca Home Among the strategies devised to improve the situation, Medicine, Food and Healthcare Administration and Control Authority (FMHACA) of Ethiopia, was involved in the preparation and distribution of Standard Treatment Guidelines (STGs) for the different levels of health institutions in the country.

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FMHACA is responsible to ensure the quality, safety and/or efficacy of medicines, food, cosmetics and medical devices. It sets standards for health and health related institutions, healthcare practice, competence and ethics of health professionals. The publications page has latest resources on policies, legislations, regulations, guidelines and other relevant documents.

Food, Medicine and Health Care Administration and Control ...

This Guideline succeeds and supersedes the 2008 Guideline, which was in use for drug approval and registration. It is prepared with the same purpose: to inform manufacturers of what documentation should be submitted with requests for approval and registration of pharmaceutical products. The Guideline provide recommendations on the quality, safety and efficacy information for both active pharmaceutical ingredients (API) and finished pharmaceutical products (FPP) that

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should be submitted to ...

Guideline for Registration of Medicines 2014 - EFDA

The Ethiopian Food and Drug Administration (EFDA) is mandated, in the proclamation 661/2009, to ensure the safety, quality and efficacy of medicines. To achieve this, the authority has been working on different regulatory activities. The medicine market authorization system is one of the top priority areas that have been implemented.

EFDA - Ethiopian Food and Drug Administration

Welcome to Electronic Regulatory Information System (eRIS) of EFDA iRegister iRegister is an online application which allows importers to apply for and receive medicine registration certificate to import medicines online and FMHACA staff to manage these applications online.

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eRIS - Electronic Regulatory Information System

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GUIDELINE FOR REGISTRATION OF MEDICAL DEVICES

Guidelines: Guideline for Registration of Medical Devices (Sept. 2014)

<http://www.fmhaca.gov.et/documents/Guideline%20for%20Registration%20of%20Medical%20devices%202014.pdf>

Guidelines on the Requirements for the Registration of Medical Devices Part II

http://www.fmhaca.gov.et/documents/GUIDMedicalDevice_PartII.pdf. National Regulatory Authority

Ethiopia - WHO

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