Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.007

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

An assessment of the US Presidential Emergency Plan for Aids Relief

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The President's Emergency Plan for AIDS Relief, also known as PEPFAR, is American Government initiative to combat the global HIV/AIDS epidemic. Since the HIV/AIDS epidemic began in the early 1980s, and it is not new to world but it is as lethal as always. Over 60 million people have been infected, which is equivalent to approximately 20 percent of the U.S. population, and nearly 30 million people have died of HIV-related causes (Census, 2011; UNAIDS). PEPFAR works for AIDS relief around the world but has a special focus on 15 countries hardest hit by the HIV epidemic in Africa, the Caribbean and Asia. The purpose of the present study is to assess President's Emergency Plan for AIDS Relief (PEPFAR) and the success of PEPFAR through analyzing scale up of funding and Number of People on Treatment under PEPFAR FY 2004-FY 2013. Study also includes requirements of submission and the no. of products (NDA and ANDA) approved under President's emergency expedited review process for better understanding. Finally, PEPFAR alone cannot solve the immense health systems challenges that many countries face, it can set an important example for other donors and affected countries by making the strengthening of health systems through integration with treatment and development programs.

Biography

Anoop S. Pillai has completed his Bachelors in Pharmacy from Rajiv Gandhi University of Health Sciences, Bangalore at the age of 22 years and currently pursuing Masters of Pharmacy in Pharmaceutical Regulatory Affairs from JSS University, Mysore. He has published 2 papers in reputed journals, 3 poster presentation at national and international conferences and currently is a project trainee in Regulatory Affairs Department at Micro Labs Ltd.

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Regulatory approach for combination drug products as per US FDA

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A combination product in general consists of two or more regulated components namely drug/device, biologic/device, drug/biologic, drug/drug (packed together), device/device or drug/biologic/device that is physically, chemically or mixed up to form as a single entity. Combination products are regulated by the Office of Combination products (OCP), which will assign a lead Agency center among Center for Biologics Evaluation and Research (CBER), Centre for Devices and Radiological Health (CDRH), and Center for Drug Evaluation and Research (CDER) based up on the mode of action, which should be a single mode of action. OCP has a Standard Operating Procedure (SOP) for "Inter center Consultative collaborative review process" for reviewing of combination product. The product should be in compliance with cGMP of drug, device, biologic. Paradigms are to be employed, in case of scientific and technical issues like interaction of drug/biologic/device and also while representing mode of action. Stability studies and design controls must be established. Pre Market approval Application (PMA) fee is applicable as per Medical Device User Fee and Modernization Act (MDUFMA). In case of special issues like manufacturers intellectual property, confidentiality can be maintained by providing Letter of Access to FDA.

Biography

Currently I am doing my internship at Mylan Laboratories and pursuing my masters in pharmaceutical Regulatory affairs at Manipal College of Pharmaceutical Sciences, Manipal University.

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