Lotus Labs; why India's No 1 CRO??

Hi %BASIC:FIRST_NAME%,

US FDA norms for clinical investigators, sponsors & to ascertain need for human studies for IND

In a major development on the regulatory landscape for clinical trials, the US Food and Drug Administration (FDA) has now issued a guidance which is intended to assist clinical investigators, sponsors, sponsor-investigators and institutional review boards (IRBs). The norms are to determine whether research studies involving human subjects need to be conducted under an investigational new drug application (IND).

Source:http://pharmabiz.com/ArticleDetails.aspx?aid=77835&sid=1

US FDA issues guidance on oversight of clinical investigations & calls for stringent trial monitoring

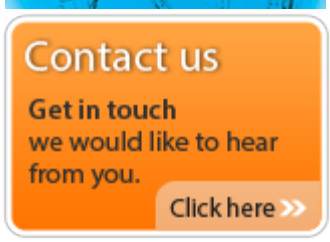
The US FDA has released a guidance titled 'Oversight of Clinical Investigations A Risk-Based Approach to Monitoring' to the clinical research organizations. The guidance assists sponsors of clinical investigations in developing risk-based monitoring strategies and plans for investigational studies of medical products, including human drug and biological products, medical devices, and combinations thereof.

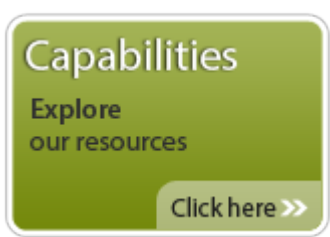
Source:http://www.pharmabiz.com/NewsDetails.aspx?aid=77738&sid=1

Need for sustainable FDI policy in pharma: Experts

Even as the Department of Industrial Policy and Promotion (DIPP), the nodal body for FDI policy, has circulated a draft Cabinet note that seeks to bring down FDI limit in Brownfield pharma and calls for putting foreign investment in drug facilities defined as "critical" on the approval route, industry experts advocate the need to clear ambiguities in the current FDI policy to give the much required boost to the Indian pharma industry.

Source:http://www.pharmabiz.com/NewsDetails.aspx?aid=77698&sid=1





About us: : Lotus Labs is a Clinical Research Organization working towards widening the frontiers of Medicine through services of the highest Quality that conform to International Standards, combining speed, accuracy and reliability and aims to be the most admired Clinical Research Organization from India