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

Hi %BASIC:FIRST_NAME%,

Commerce ministry may step up MAI sops to exporters to cope with burden of GDUFA

In a move that could bring huge relief to the Indian exporters to the US, the commerce ministry may soon provide some incentives to support the exporters to cope up with the increasing burden of huge user fee that the US FDA has been levying from them under its Generic Drug User Fee Act (GDUFA). The ministry is said to be seriously considering the possibility of increasing the reimbursement fees from the current Rs.50 lakh per annum for all the companies interested in registering their products in the US under the MAI scheme.

Source:
http://pharmabiz.com/ArticleDetails.aspx?aid=74400&sid=1

US FDA norms on Non-clinical Safety Studies may be a relief to Indian CROs

US Food and Drug Administration (FDA) has now issued a guidance to the clinical research organisations (CROs) titled M3(R2) Non-clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals. The guidelines are seen to come in as a big relief to Indian CROs which are now looking to ensure that all human studies and the related protocols for approvals are transparent and documented with adequate data.

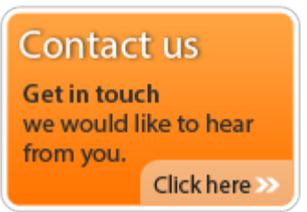
Source:
http://pharmabiz.com/NewsDetails.aspx?aid=74327&sid=1

MHRA not to open Indian office but prefers sending expert inspectors: Gerard Heddell

The UK based Medicines and Healthcare products Regulatory Agency (MHRA) has not considered setting up an Indian office on similar lines of US FDA which has an India centre at New Delhi. Instead, it has decided to interact with the Indian pharma industry who are seeking MHRA approvals through seminars and discussions, said Gerald Heddell, director of Inspection, Enforcement and Standards, MHRA.

Source :

http://www.pharmabiz.com/PrintArticle.aspx?aid=74806&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