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

Hi %BASIC:FIRST_NAME%,

US FDA seeks industry's comments on new draft norms on ANDA submissions

The US FDA has sought the pharma industry's comments on its draft guidelines on ANDA (abbreviated new drug application) submissions — Refuse-to-Receive Standards. Now in the case of India, ending June 2013, Indian pharma received 87 final approvals and 25 tentative ANDA approvals.

Source:http://www.pharmabiz.com/PrintArticle.aspx?aid=78117&sid=1

US FDA issued norms on bioanalytical method, industry to comment before December end.

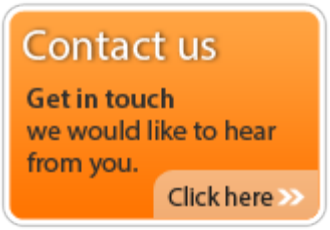
US FDA has issued a draft guidance on the Bioanalytical Method Validation. The rules provide assistance to sponsors of investigational new drug applications (INDs), new drug applications (NDAs), abbreviated new drug applications (ANDAs), biologic license applications (BLAs), and supplements.

Source:http://www.pharmabiz.com/NewsDetails.aspx?aid=78671&sid=1

European Medicines Regulatory Network issues norms for e:submission for human and vet drugs

European Medicines Regulatory Network has now issued a draft guidelines on the electronic Submission Roadmap for medicinal products for human and veterinary use across the Europe Union.

Source:http://www.pharmabiz.com/NewsDetails.aspx?aid=78205&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