



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

Hi %BASIC:FIRST_NAME%,

[US FDA issues draft norms on reference product exclusivity for biologicals to determine date of first licensure](#)

The US Food and Drug Administration (FDA) has issued a guidance for industry on the reference product exclusivity for biologicals filed under Section 351(a) of the Public Health Service (PHS) Act.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=83362&sid=1>

[DCGI sets up Independent Expert Committee for examination of reports of SAEs occurred during trials](#)

The drugs controller general of India (DCGI) has constituted an Independent Expert Committee (General) for examination of reports of serious adverse events (SAEs) of deaths occurred during clinical trials in the country.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=83364&sid=1>

[US FDA issues draft norms on regulatory submissions in electronic format, industry lauds move](#)

The US Food and Drug Administration (FDA) has issued a draft guidance for the pharma and biotechnology industry to provide regulatory submissions in electronic format. This would be related to certain human pharmaceutical product applications.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=83289&sid=1>

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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

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