

Hi %BASIC:FIRST_NAME%,

Nearly 500 ethics committees registered after CDSCO made it mandatory in Feb, 2013

Evoking a very good response to the steps by the regulatory authorities to streamline the clinical trials sector, nearly 500 ethics committees of hospitals and clinical trial organisations have secured registration within just five months after it was made mandatory. The Government had issued the notification on February 8 this year to make it mandatory the registration of ECs and so far, the Drugs Controller General of India (DCGI) has given registration to 493 panels during this brief period, it is learnt.

Source:

<http://www.pharmabiz.com/NewsDetails.aspx?aid=76480&sid=1>

Govt to further modify rule on timeline, compensation for injury during clinical trials

The Centre is planning to further modify the newly added clause 122 DAB of the Drugs and Cosmetic (D&C) Rules, 1945 to further relax the norms on compensation in the case of injury or death during the clinical trials. The timeline for reporting the serious adverse events will also be modified in line with the international practices.

Source:

<http://pharmabiz.com/ArticleDetails.aspx?aid=76420&sid=1>

US FDA issues guidance to API sector specific to Bulk Density and Tapped Density of Powders

US Food and Drug Administration (FDA) has issued norms on the Q4B evaluation and recommendation of pharmacopoeial texts for use in the ICH regions specifically with reference to Bulk Density and Tapped Density of Powders.

Source:

<http://pharmabiz.com/ArticleDetails.aspx?aid=76418&sid=1>

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