

Hi %BASIC:FIRST\_NAME%,

### DCGI not to approve BA/BE studies conducted at clinical or bioanalytical facilities not approved by CDSCO

The drug controller general of India (DCGI) will not accept and approve the reports of bioavailability (BA) and bioequivalence (BE) studies which are conducted at clinical or bioanalytical facilities that are not approved by the Central Drugs Standard Control Organisation (CDSCO).

Source: <http://pharmabiz.com/ArticleDetails.aspx?aid=79872&sid=1>

### CDSCO and US FDA sign letter of intent to beef up regulatory apparatus further

In a strategic move towards consolidating the regulatory apparatus further, the CDSCO and the US FDA have entered into a collaborative understanding by signing the letter of intent.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=80329&sid=1>

### DCGI to allow import of drug with residual shelf life less than 60% under special conditions

The drug controller general of India (DCGI) will henceforth allow import of drugs with residual shelf life less than 60 per cent under special conditions and the importers who import such drugs shall have to give proper justification for the import.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=80419&sid=1>

### US FDA issues draft norms on post marketing surveillance for prescription human-animal drugs & biologics

US Food and Drugs Administration (FDA) has issued a draft guidance on post marketing surveillance (PMS) of promotional media for prescription human and animal drugs and biologics. The regulatory authority requires the industry comments on the same before March 31, 2014.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=80045&sid=1>

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