

Hi %BASIC:FIRST_NAME%,

US FDA issues norms on delaying a drug inspection, awaits industry comments

The US FDA has issued guidance to the pharma industry on circumstances that constitute delaying, denying, limiting, or refusing a drug inspection. The regulatory major is seeking industry comments to this effect by September 30, 2013. In the wake of the new regulations and the possibilities for the production of spurious and not of standard quality drugs, the US FDA is now keen to address four issues through its draft guidelines.

Source: <http://pharmabiz.com/ArticleDetails.aspx?aid=77416&sid=1>

CDSCO initiates steps to synergise regulatory activities with state drug regulatory bodies

With a view to synergise and strengthen the role of the state drug regulatory bodies in ensuring best regulatory practices, which are at par with the international standards, the Central Drugs Standard Control Organisation (CDSCO) for the first time has decided to send a state drug controller to an international drug regulatory programme to be organised in Korea.

Source: <http://pharmabiz.com/ArticleDetails.aspx?aid=77375&sid=1>

WHO getting ready to unveil norms on prequalification of finished pharmaceuticals

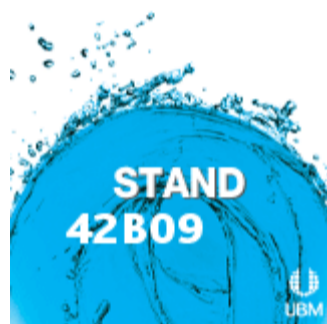
The World Health Organisation (WHO) is reviewing the draft guidelines for the scientific evaluation of finished pharmaceutical products (FPPs) by regulatory authorities which apply similarly stringent standards for quality, safety and efficacy as those recommended by it. It is now gearing up to release the final guidance by September this year. The draft guideline which was issued for comments from the industry in May this year calls for a stringent regulatory authority (SRA) which is a member of the International Conference on Harmonization (ICH) to agree sharing information on an FPP with WHO.

Source: <http://pharmabiz.com/ArticleDetails.aspx?aid=77137&sid=1>

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