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US FDA issues draft guideline on expanded access to IND for treatment; expects industry views before July 1

The US Food and Drug Administration (FDA) has now issued a draft guideline on expanded access to investigational new drugs (IND) for treatment use in a 21 questions and answers format. The regulatory authority is now seeking the responses on this by July 1, 2013. To begin with it has explained the meaning of expanded access for treatment use, when a company should make an access protocol and IND submission apart from the kind of information that needs to be included in an access submission among others.

Source:

<http://www.pharmabiz.com/NewsDetails.aspx?aid=75428&sid=1>

Fall in clinical trials & poor pipeline of blockbuster drugs impact access to newer medicines to treat tobacco related cancers: Experts

The fall in the number of clinical trials in India together with blockbuster pipeline drying up from the global pharma majors are seen to seriously impact the access to newer drugs to treat tobacco related cancers. The fewer number of novel drugs is posing to be a huge challenge for oncologists to treat the growing number of cases, according to hospitals.

Source:

<http://pharmabiz.com/ArticleDetails.aspx?aid=75666&sid=1>

WHO issues draft guidance on good pharmacopoeial practices, seeks industry views

The World Health Organisation (WHO) has come out with the draft guidelines on Good Pharmacopoeial Practices (GPhP). It is now seeking comments from the industry before July 12, 2013. The primary objective of the GPhP guidance is to harmonize approaches and policies in establishing pharmacopoeial standards, which support regulatory authorities in controlling the quality of pharmaceutical ingredients and their finished products.

Source:

<http://pharmabiz.com/ArticleDetails.aspx?aid=75628&sid=1>

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