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

Hi,

Panel for D&C Rule amendments forms 7 sub-groups on drugs, medical devices, clinical trials, biologicals, etc

The Union Health Ministry's high level committee, constituted for examining and recommending amendments in the Drugs and Cosmetics Rules, 1945, has set up seven sub-groups for different segments like drugs, medical devices, clinical trials, biologicals, blood banks and cosmetics with a nodal person from the industry and a resource person from the CDSCO.

Dr. B. R. Jagashetty, National Advisor (Drugs) will be the overall coordinator for all sub-groups.

The first meeting of this high powered committee, under the chairmanship of Joint Secretary (Regulation), Department of Health and Family Welfare, was held on January 21, 2015. Besides the committee members, the meeting was attended by representatives of industry associations. It was agreed in the meeting that 31st January, 2015 would be the last date for sending comments on the proposed amendments in the said Rules.

Earlier in December 2014, the union health ministry decided to constitute this high level committee to expeditiously revisit the Drugs and Cosmetics Rules, 1945 and make recommendations for amending the same in order to make these rules contemporary while keeping in view the requirements of quality, safety and efficacy of medical products and also the efficiency of regulatory structures and the industry and to keep pace with changing scenario of drugs, medical devices and cosmetics industry.

CDSCO introduces PSM system to discuss regulatory pathway for approval of clinical trial, new drug, medical devices, etc.

The Central Drugs Standard Control Organisation (CDSCO) has introduced a system of formal Pre-submission Meetings (PSM) of applicants with CDSCO officers and subject experts to discuss regulatory pathway in respect of specific application for approval of clinical trial, new drug, medical devices, etc.

Source: http://www.pharmabiz.com/ArticleDetails.aspx?aid=86452&sid=1

CDSCO to work with international regulators on exploring regulatory opportunities

Giving a huge thrust to boost the drug regulatory mechanism in the country and ease stakeholders concerns, the Central Drugs Standard Control Organisation (CDSCO) and top drug regulators from across the globe have agreed to cooperate on exploring regulatory opportunities.

Source: http://www.pharmabiz.com/ArticleDetails.aspx?aid=86534&sid=1

MHRA issues GMP data integrity definitions & guidance document for pharmacos

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) recently released its GMP data integrity definitions and guidance document for the pharma industry

Source: http://www.pharmabiz.com/ArticleDetails.aspx?aid=86467&sid=1

About us: Lotus Labs is a Clinical Research Organization which works towards widening the frontiers of Medicine through services of the highest Quality that conform to International Standards, combining speed, accuracy and reliability to be the most admired Clinical Research Organization from India.