



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

Hi %BASIC:FIRST_NAME%,

We greatly value your continued association with us. Please find the newsletter for this month. Hope you find the content interesting and useful.

Latest updates on Lotus Labs:

We are glad to inform that Lotus Labs has been successfully inspected by USFDA in the month of June, 2014 thus taking the number of inspection faced from USFDA to 15 with no observations since last three audits.

Apart from the latest USFDA inspection, Lotus Labs has been inspected by authorities like EMA, MHRA, ANSM, AGES, WHO, ANVISA, MCC (South Africa & Zimbabwe) and MoH Turkey.

Lotus Labs has so far successfully completed 61 Regulatory Inspections and is also approved for submission of studies to MoH Israel, NPCB Malaysia, Sudan and Tanzania.

Lotus Labs has completed 1700 studies till date. Studies conducted at Lotus Labs have been submitted and approved by more than 60 countries. Nearly 200 submitted studies have been approved by USFDA and another approximately 180 studies have been approved by European regulatory authorities.

In order to augment our bio-analytical capability Lotus Labs has added a new LCMS/MS instrument in June 2014, taking our total tally of high end LCMS/MS machines to 16.

Lotus Labs been constantly working to develop an exhaustive list of validated analytical method and has around 320 + methods in its assay bank. Details of assays available with Lotus Labs are shared in our website along with the information on assays under development.

Lotus Labs also conducts cosmetology and personal care studies as per the client requirements and is equipped with adequate instrumentation to support such studies.

Lotus Labs has successfully completed the process of self identification in May 2014 for all its sites to comply with USFDA requirements.

Lotus Labs operates from 4 clinical facilities with a combined bed strength of 340 beds. Lotus Central Lab, located at Bangalore, is CAP

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and NABL accredited Laboratory catering to the diagnostic needs for bioequivalence studies and clinical trials of Indian and international sponsors.

We welcome you to visit our website for more detailed information on Lotus Labs and its capabilities

Indian pharma cos appreciate US FDA guidance on stability testing data recommendations for ANDAs

The Indian pharma, which has been receiving clearances for its Abbreviated New Drug Applications (ANDAs) from the US FDA, now views the recently issued norms of the US regulator on ANDA stability data recommendations in a question and answer format as a convenient reference information during their submissions.

Source: <http://pharmabiz.com/ArticleDetails.aspx?aid=82003&sid=1>

Lucrative Biosimilars Space to Erode Biologics Market from 2019, says Global Data

The increasing prevalence of biosimilars will have a noticeably negative impact on the biologics market beyond 2019, despite an initial projected CAGR of 8.3%, taking the overall biologics market value from \$162 billion in 2013 to more than \$262 billion by 2019.

Source: <http://www.drugdeliverytech.com/Main/Back-Issues/Lucrative-Biosimilars-Space-to-Erode-Biologics-Mar-713.aspx>



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

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