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

Hi,

US FDA issues draft guidance on formal meetings for applicants of PDUFA products

The US FDA has issued draft guidance on the formal meetings between the FDA and sponsors or applicants of PDUFA products. The industry needs to revert to the global regulator by June end.

Source: http://www.pharmabiz.com/NewsDetails.aspx?aid=87182&sid=1

FDA issues guidelines for reusable medical devices

The U.S. Food and Drug Administration today announced new actions to enhance the safety of reusable medical devices and address the possible spread of infectious agents between uses.

Source:
http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm437804.htm

US FDA expects Indian pharma to seek third party audits to resolve data integrity issues

The US FDA has re-emphasized the serious deviations it observed during inspection made in Indian pharma companies. The regulator has been noticing that especially with Indian companies, it did not rely on their capability to resolve the data integrity problems without external support.

Source: http://www.pharmabiz.com/NewsDetails.aspx?aid=87318&sid=1

Barcoding on secondary packaging including mono cartons comes into effect from April 1, 2015

The track and trace system for export of pharmaceuticals and drug consignments on secondary level packaging including mono cartons has come into effect in the country from April 1, 2015.

Source: http://www.pharmabiz.com/NewsDetails.aspx?aid=87591&sid=1

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