The Veeda Newsletter

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VEEDA NEWS

Veeda Clinical Research reaffirms Quality credentials by successfully clearing USFDA inspections at the Shivalik, Vedant and Insignia facilities.

Veeda Clinical Research is pleased to share the successful completion of the USFDA Inspections at its Shivalik and Vedant clinical facilities as well as a simultaneous USFDA inspection at its Insignia bioanalytical facility in August 2019 without any 483 issuances. While the inspections at the clinical facilities were routine inspections under USFDA's BioResearch Monitoring Program (BIMO), the inspection at the bioanalytical facility by the USFDA Office of Study Integrity and Surveillance, CDER was unannounced.

The inspection covered a comprehensive evaluation of the Clinical and Bioanalytical systems along with the respective study data. The methodology included a comprehensive review of Protocol and SOP compliance as well as the entire workflow of the clinical and bioanalytical study plans. In the clinical facilities, the inspection covered activities starting from recruitment to study conduction and data generation whereas in the bioanalytical facility, the inspection covered bioanalytical method validation, sample management and project sample analysis related activities including batch acceptance, repeat analysis and incurred sample reanalysis. The inspection also included electronic data review of chromatographic system and audit trails.

The inspection outcomes reaffirmed Veeda's commitment to the highest Quality standards and compliance with the defined SOPs and regulatory guidelines. The outcomes also validated Veeda's successful progression towards 'anytime audit readinesses. With an enhanced focus on 'Right First Time' and sustaining a strong Quality Culture that underscores its Quality Policy and robust Quality Management System, Veeda continues to steadfastly pursue its mission – "To Strive for Excellence in Quality and endeavor to become the partner of choice for our Sponsors and our Stakeholders".

About Veeda CR

Veeda is the leading independent CRO in India. Veeda offers a diverse range of clinical studies including bioequivalence as well as PK, PD and Clinical End point studies for Generics, NCE and Biopharmaceuticals. Veeda is a partner of choice for many global pharmaceutical companies and is reputed for its best-in-class scientific knowledge, quality and ethics. Veeda has an exemplary regulatory track record of successfully completing 33 USFDA, 7 ANVISA, 5 WHO, 3 MHRA, 1 AGES, 1 ANSM, 1 MCC, 13 DCGI and 4 NPRA audits till date.

www.veedacr.com info@veedacr.com Contact Us

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INDIAN PHARMA

India wants to become a very significant player in the global supply chain of pharmaceuticals

Today, India is at a very interesting stage. We say very proudly that we are the pharmacy of the world and we want to become a global supply hub, not only for the advanced markets but for the emerging nations and the rest of the world.
Read more : https://health.economictimes.indiatimes.com/news/pharma/india-wants-to-become-a-very-significant-player-in-the-global-supply-chain-of-pharmaceuticals-dr-sanjit-singh-lamba/70458521

Indian government begins fresh exercise to revise the NLEM

The National List of Essential Medicines (NLEM) in India, which determines the basis of drug price regulation, is set to add new medicines for the treatment of cardiac diseases and cancer along with certain antibiotics to its list.
Read more : : https://www.thepharmaletter.com/article/indian-government-begins-fresh-exercise-to-revise-the-nlem

Indian pharma industry may achieve double-digit growth by 2030

Indian pharmaceutical industry can achieve a target of double-digit growth by 2030 through a host of measures including regulatory support from government like increase in budgetary allocations for healthcare and promotion of innovation, a pharmaceutical industry body said.
Read more : https://health.economictimes.indiatimes.com/news/pharma/indian-pharma-industry-may-achieve-double-digit-growth-by-2030/70665164

Government Role in Indian Pharmaceutical Industry to Achieve Vision 2030

'The Indian pharmaceutical industry – the way forward' was published by an Indian Pharmaceutical Alliance (IPA) representing research based pharmaceutical companies in collaboration with McKinsey & Co and stakeholders. The report lists the growth ambitions that Indian pharmaceutical industry ('Industry') needs to follow to achieve its targets for year 2030 (Vision 2030)
Read more : http://www.mondaq.com/india/x/833810/Healthcare/Government+Role+In+Indian+Pharmaceutical+Industry+To+Achieve+Vision+2030

China's pharmaceutical market reforms could benefit Indian drug-makers: Jefferies India

The USD $160 billion Chinese pharmaceutical market, which is on a significant reforms overhaul, is expected to benefit Indian and global generics players, according to Jefferies India.
Read more : http://www.newindianexpress.com/business/2019/aug/10/chinas-pharmaceutical-market-reforms-could-benefit-indian-drug-makers-jefferies-india-2016904.html

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REGULATORY

China's new drug law may open door for Indian generic medicines

China's revised drug law, which removes drugs that are legal in foreign countries but not approved in China from the category of fake medicines, may allow entry of Indian generic medicines in the country, media reports said on Tuesday.
Read more: https://www.business-standard.com/article/pti-stories/china-s-new-drug-law-may-open-door-for-indian-generic-medicines-report-119082701417_1.html

FDA Releases Guidance On REMS Modifications And Revisions

The U.S. Food and Drug Administration (FDA) released a final guidance on changes to approved Risk Evaluation and Mitigation Strategies (REMS). For certain drugs, the FDA may require a REMS as an additional risk management plan to ensure that the benefits of the drug outweigh the risks.
Read more : http://www.mondaq.com/unitedstates/x/836510/Healthcare/FDA+Releases+Guidance+On+REMS+Modifications+And+Revisions

United States: HHS And FDA Release Drug Importation Action Plan

On July 31, 2019, the U.S. Department of Health and Human Services (HHS), in conjunction with the Food and Drug Administration (FDA), released an action plan for the importation of certain drugs originally intended for foreign markets, deviating from the FDA's long history of opposing drug importation.
Read more : http://www.mondaq.com/unitedstates/x/832534/Healthcare/HHS+And+FDA+Release+Drug+Importation+Action+Plan

IGBA's Trade Principles Address Regulatory Convergence and Intellectual Property Concerns

The International Generic and Biosimilars Medicines Association (IGBA), which represents generic and biosimilar medicines associations worldwide, recently released its report on how trade agreements can foster generic and biosimilar medicines and improve patient access to care.
Read more : https://www.centerforbiosimilars.com/news/igbas-trade-principles-address-regulatory-convergence-and-intellectual-property-concerns

Experts Seek Tweaks to FDA Draft Guidance on Clinical Trial Diversity

Recent US Food and Drug Administration (FDA) draft guidance on enhancing clinical trial populations' diversity should discuss the role of real-world data/evidence (RWD/RWE), comments to FDA say.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/8/experts-seek-tweaks-to-fda-draft-guidance-on-clini

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CLINICAL RESEARCH

5 Tactics To Overcome Technology & Innovation Adoption Challenges In Clinical Research

Our global digital population — people around the world that are active internet users — has grown to 4.3 billion as of July 2019, representing roughly 56 percent of the global population. Of this global digital population, almost 4 billion are accessing the internet using mobile devices, with non-tablet mobile devices contributing nearly half of web page views worldwide.2

Read more : : https://www.clinicalleader.com/doc/tactics-to-overcome-technology-innovation-adoption-challenges-in-clinical-research-0001

Ebola is now largely curable, new clinical trials suggest

In August 2018, an Ebola outbreak struck a conflict zone in the Democratic Republic of Congo's North Kivu province. It soon spread elsewhere throughout the nation of 81.3 million people, many of whom are embroiled in battles over DRC's valuable minerals.

Read more : https://bigthink.com/surprising-science/ebola-cured?rebelltitem=1#rebelltitem1

Virtual Clinical Trials: A New Model for Patient Engagement

Nearly 70 percent of potential clinical trial participants live more than two hours away from a study center, limiting their opportunities to benefit from possibly life-changing therapies. For many, getting to the site for one or multiple visits is not an option.

Read more : http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=822019

A New Framework Addresses Ethical Concerns With the Use of Biopsies in Clinical Trials

In acknowledgment of under-regulation for research biopsies in clinical trials, a group of researchers has developed an ethical framework that will require physicians to define how the information obtained from a tissue sample will be beneficial for the trial research and the patient.

Read more : https://www.targetedonc.com/news/a-new-framework-addresses-ethical-concerns-with-the-use-of-biopsies-in-clinical-trials

Smartphone-controlled device could deliver drugs into the brain

An international research team has designed a wireless, smartphone-controlled device that is able to deliver drugs straight into the brain. It can also stimulate brain cells using light. So far, the scientists have tested this device in mice.

Read more : https://www.medicalnewstoday.com/articles/325972.php

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FINANCIALS

Everest Clinical Research Receives $100,000 Investment from Canadian Minister of Small Business and Export Promotion

The Honourable Mary Ng, Canadian Minister of Small Business and Export Promotion, announced in August an investment of up to $100,000 in Everest Clinical Research ("Everest") through the Women Entrepreneurship Fund.

Read more : https://www.businesswire.com/news/home/20190830005445/en/Everest-Clinical-Research-Receives-100000-Investment-Canadian

India to rethink RCEP engagement if China denies market access

India will rethink its engagement with the 16-nation Regional Comprehensive Economic Partnership (RCEP) grouping and may even be forced to pull out of the mega trade deal if negotiations are sought to be concluded hurriedly without addressing its concerns on its massive trade imbalance with other members, especially China, sources told FE.

Read more : https://www.financialexpress.com/industry/rcep-india-to-rethink-if-china-denies-key-market-access/1666129/

Opportunities for Indian pharma companies in China as market set to be worth $209bn

INDIAN pharmaceutical companies are finding lucrative opportunities for growth in the Chinese pharma market, which is set to rise from nearly $132 billion in 2018 to over $209bn by 2022, GlobalData, a data and analytics company said.

Read more : https://www.easterneye.biz/opportunities-for-indian-pharma-companies-in-china-as-market-set-to-be-worth-209bn/

Chinese socialism needs Indian medicines

Every major advanced country in the world is importing generic medicines from India. In 2018, the US imported from India medicines worth $5.02 billion, UK $550 million, Canada $248 million, Australia $248 million, Germany $215 million, France $190 million, Belgium $180 million and the Netherlands $129 million.

Read more : https://www.theweek.in/news/biz-tech/2019/08/22/opinion-chinese-socialism-needs-indian-medicines.html

FSD Pharma launches private placement to raise up to US$5 million

The company will offer its class B subordinate voting shares at a price of C$0.10 per share without any warrant coverage. It expects to close the placement by September 30. To date, C$1.3 million in proceeds have been committed and received, FSD Pharma said in a statement.

Read more : https://www.proactiveinvestors.com/companies/news/901802/fsd-pharma-launches-private-placement-to-raise-up-to-us5-million-901802.html

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MERGER AND AQUISITION

Australian CRO buys US-based Ph I clinical trials organization

Australia-based Nucleus Network has acquired an early-phase clinical research organization in the US, which has a broad range of access to specialist patient populations, says CEO.
Read more : https://www.outsourcing-pharma.com/Article/2019/08/29/Australian-CRO-buys-US-based-Ph-I-clinical-trials-organization

Jazz Pharmaceuticals Announces Acquisition of Cavion, Inc.

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced the acquisition of Cavion, Inc. through a merger with a Jazz subsidiary.
Read more : https://www.prnewswire.com/news-releases/jazz-pharmaceuticals-announces-acquisition-of-cavion-inc-300900270.html

Lupin to sell Japanese injectable biz to Neopharma group

Indian Pharma major Lupin Limited (including its subsidiaries together referred to as Lupin) announced that it has entered into a definitive agreement through its Japanese subsidiary Kyowa (Kyowa Pharmaceutical Industry Co., Ltd.) for the sale of its Japanese Injectables business and related assets in Japan to neo ALA Co. Ltd, a wholly owned subsidiary of Neopharma group, the UAE's largest pharmaceutical manufacturer headquartered in Abu Dhabi.
Read more : https://www.biospectrumasia.com/news/25/14306/lupin-to-sell-japanese-injectable-biz-to-neopharma-group.html

Virtual clinical research company Thread acquired by two private equity firms

Yesterday private equity firms Water Street Health Partners and JLL Partners announced that they had acquired virtual clinical research company Thread for an undisclosed amount. The new owners say they plan on investing in Thread in order to further expand its customer base and offer the platform on a global scale.
Read more : https://www.mobihealthnews.com/news/north-america/virtual-clinical-research-company-thread-acquired-two-private-equity-firms

Ajinomoto Bio-Pharma buys Indian API plant from JV partner

Ajinomoto Bio-Pharma Services is taking full control of an API manufacturing facility in India as the CDMO continues to bulk up in a market that favors companies that can do it all.
Read more : https://www.fiercepharma.com/manufacturing/ajinomoto-bio-pharma-buys-indian-api-plant-from-jv-partner

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VEEDA CLINICAL RESEARCH® PVT. LTD.

Corporate Office

Veeda House, Beside YMCA club S.G.,
Highway, Vejalpur, Ahmedabad- 380015
Gujarat, India

Registered Office

Shivalik Plaza-A, Near IIM Ambawadi,
Ahmedabad- 380015, Gujarat, India.
CIN No. U73100GJ2004PTC044023

Other Office

Insignia, Besides Auda Garden, Opp. Zenobia
Residency, Sindhu Bhavan Road, Off. S. G. Highway,
Bodakdev, Ahmedabad- 380059, Gujarat, India

For more Information and Business Inquiry contact us at

+91 79 3001 3000 info@veedacr.com

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