The Veeda Newsletter

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CPhI worldwide

5-7 Nov 2019

Meet our representative
At Frankfurt, Germany

Mr. Rajkumar Agarwal -
Manager Business Development

To schedule a meeting write to us at Rajkumar.Agarwal@veedacr.com

INDIAN PHARMA

Indian pharma aims to corner 7% of global market by 2030

REGULATORY

Updated: Interchangeable biosimilars: FDA finalizes guidance

CLINICAL RESEARCH

Changing Paradigms in Clinical Trials, 2019-2050

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The global clinical trials market size is expected to reach USD 68.9 billion by 2026

M & A

Pfizer, 'never say never' with big M&A, inks $11.4B Array cancer deal

ARTICLE

Current regulatory landscape for drug approvals and clinical trials in India

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REGULATORY

Updated: Interchangeable biosimilars: FDA finalizes guidance

The FDA on Friday finalized a long-awaited guidance spelling out how biosimilars can achieve an interchangeable status, which means they may be substituted for the reference biologic without a prescriber intervening.
Read more: https://endpts.com/fda-finalizes-guidance-on-interchangeable-biosimilars/

FDA approved vs. FDA cleared: Why you need to know the difference

The Food and Drug Administration is responsible for telling us which foods, drugs and medical devices are safe for us to use. And while we assume that anything that's been cleared or approved by the FDA has been rigorously tested, that's not always true.
Read more : https://www.cnet.com/news/fda-approved-vs-fda-cleared-whats-the-difference/

USDA ANNOUNCES PROPOSED RULE UPDATING BIOTECHNOLOGY REGULATIONS

The USDA's Animal and Plant Health Inspection Service released a rule proposal that's designed to update its biotechnology regulations.
Read more : https://www.newsdakota.com/2019/06/07/usda-announces-proposed-rule-updating-biotechnology-regulations

FDA Releases New Data to Help Generic Drug Competitors

Generic drug applicants will now have more information from the US Food and Drug Administration (FDA) when deciding whether to file a generic drug application, which could potentially increase the odds of earlier approvals, the agency said on Tuesday.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/6/fda-releases-new-data-to-help-generic-drug-competi

FDA Updates List of Off-Patent, Off-Exclusivity Drugs Without Generic Competition

Since 2017, the US Food and Drug Administration (FDA) has been striving to help generic companies understand which brand name drug products are no longer protected by patents or exclusivities and currently have no generic competitors
Read more : https://www.raps.org/news-and-articles/news-articles/2019/6/fda-updates-list-of-off-patent-off-exclusivity-dr

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FINANCIALS

Indian injectables maker KriGen to build $7M plant in North Carolina

KriGen Pharmaceuticals, an India-based injectables maker, unveiled plans to build a $7 million facility in Lillington, North Carolina.
Read more : https://www.fiercepharma.com/manufacturing/indian-injectables-maker-krigen-to-build-7m-plant-north-carolina

Branded Generics Market to register high revenue growth at 7.3% CAGR during 2016-2026

Differential and innovative product strategies that are adopted by various multinational pharma companies have been fuelling the growth of branded generics market at a global scale.
Read more : https://www.wikitimes.co.uk/2019/06/05/branded-generics-market-to-register-high-revenue-growth-at-7-3-cagr-during-2016-2026/

25.8 billion earmarked for AI-driven drug discovery

The Korean government said it would spend 25.8 billion won ($21.7 million) on supporting the discovery and development of innovative medicines using artificial intelligence (AI) in the next three years.
Read more : http://www.koreabiomed.com/news/articleView.html?idxno=5924

CNH Partners LLC Takes $10.73 Million Position in ANDINA ACQUISIT/SH SH (NASDAQ:ANDA)

CNH Partners LLC acquired a new stake in ANDINA ACQUISIT/SH SH (NASDAQ:ANDA) during the 1st quarter, according to the company in its most recent filing with the SEC.
Read more : https://techknowbits.com/2019/06/16/cnh-partners-llc-takes-10-73-million-position-in-andina-acquisit-sh-sh-nasdaqanda.html

Indian Pharma industry aspiring to grow to $120-130 billion by 2030: IPA

NEW DELHI: The Indian pharmaceutical industry is aspiring to touch USD 120-130 billion by 2030 from the current USD 38 billion, industry body Indian Pharmaceutical Alliance (IPA) said on Wednesday.
Read more : https://economictimes.indiatimes.com/articleshow/69861213.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst

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CLINICAL RESEARCH

Enhancing Clinical Trial Participation

Having worked as a research nurse, I have heard an abundance of reasons for low attrition from both providers and patients. Physicians in busy office practices have time constraints limiting their availability to explain the nature of trials. A lack of research personnel in the ambulatory setting is also a barrier.

Read more : : https://www.oncnursingnews.com/contributor/debi-boyle/2019/06/enhancing-clinical-trial-participation

The top 10 drug launches of 2019

As part of CEO Ludwig Hantson's plan for Alexion to pivot away from ultrarare diseases and reach more patients, the biotech has priced Ultomiris at a 10% discount to Soliris and is aiming to convert70% of Soliris patients to the improved therapy. Paroxysmal nocturnal hemoglobinuria (PNH), the current condition Ultomiris is approved in, is a rare disease that involves the immune system.

Read more : https://www.fiercepharma.com/special-report/top-10-drug-launches-2019

Accelerating drug development at a lower cost: How adopting AI can transform the pharma industry

To combat the complex drug discovery process, medical industry is organising steps to adapt the futuristic technologies like AI to step in to generate new ideas, hypotheses, design experiments and accelerate the scientific process, informs Dr Neeraj Mahindroo, Dean, School of Health Sciences, UPES

Read more : http://www.expressbpd.com/pharma/latest-updates/accelerating-drug-development-at-a-lower-cost-how-adopting-ai-can-transform-the-pharma-industry/409768/

Five Tips for Evaluating Clinical Studies

Evaluating the results of clinical studies can be daunting, but some simple tools can make it a fun experience. I consider drug literature evaluation to be a journey down a somewhat winding road that ultimately leads to a better understanding of a clinical study.

Read more : https://www.drugtopics.com/latest/five-tips-evaluating-clinical-studies

Changing Paradigms in Clinical Trials, 2019-2050

The process of developing novel and effective healthcare products is both cost and time intensive. Studies suggest that each prescription drug requires around 10 years and over USD 2.5 billion in working capital before it reaches the market. Further, it is estimated that, in the US, 40% of the pharma industry's R&D budget is spent solely on conducting clinical trials.

Read more : https://finance.yahoo.com/news/changing-paradigms-clinical-trials-2019-200100390.html

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MERGER AND AQUISITION

PharmaCielo to acquire Creso Pharma for $122m.

Canadian listed company PharmaCielo has launched a takeover bid for Creso Pharma (ASX: CPH), which Creso's board endorses and values the company at A$122 million.
Read more : https://smallcaps.com.au/pharmacielo-acquisition-creso-pharma-122m/

Pfizer, 'never say never' with big M&A, inks $11.4B Array cancer deal

In the first big M&A deal under new CEO Albert Bourla, Pfizer has agreed to buy oncology specialist Array BioPharma for a total value of about $11.4 billion, the two companies unveiled Monday. The $48-per-share offer represents a premium of about 62% to Array stock's closing price on Friday.
Read more : https://www.fiercepharma.com/pharma/pfizer-never-say-never-m-a-buys-oncology-innovator-array-for-11-4b

Gryphon-Backed Water's Edge Dermatology Acquires Coast Dermatology

Water's Edge Dermatology ("Water's Edge" or "the Company"), a leading provider of comprehensive dermatology services through 37 Florida locations, announced today that it has acquired a controlling interest in Coast Dermatology ("Coast"), a medical/cosmetic dermatology practice in Venice, Florida. Terms of the transaction were not disclosed.
Read more : https://finance.yahoo.com/news/gryphon-backed-waters-edge-dermatology-110000318.html

Mundipharma inks biosimilars deal with Egis Pharma

Mundipharma has entered into an exclusive distribution agreement with Egis Pharmaceuticals for Pelmeg, a pegfilgrastim biosimilar treatment. The agreement covers Hungary, Romania, Latvia and Lithuania, where Mundipharma does not have a direct commercial presence.
Read more : https://www.thepharmaletter.com/article/mundipharma-inks-biosimilars-deal-with-egis-pharma

Genesis Drug Discovery & Development Expands Preclinical Contract Research Portfolio by Acquiring NexusPharma

HAMILTON, N.J., June 18, 2019 /PRNewswire/ -- Genesis Drug Discovery & Development (GD3), the contract research organization (CRO) of Genesis Biotechnology Group® (GBG), announced that it has expanded its drug development services through the acquisition of a majority interest in NexusPharma
Read more : https://www.prnewswire.com/news-releases/genesis-drug-discovery--development-expands-preclinical-contract-research-portfolio-by-acquiring-nexuspharma-300869712.html

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INDIAN PHARMA

Indian e-pharma market poised to touch US$2.7 billion by 2023: EY

According to a new EY report 'e-pharma: delivering healthier outcomes', e-pharma players are expected to attain a combined market size of US$2.7 billion by 2023 from about US$360 million currently in the next four years.
Read more : https://www.equitybulls.com/admin/news2006/news_det.asp?id=251784

GSP withdrawal by US may have marginal impact on Indian pharma exporters

The withdrawal of the Generalized System of Preferences (GSP) benefits by the US could have an impact of 4-5 percent on margins of Indian pharmaceutical companies exporting drugs to the country.
Read more : : https://www.moneycontrol.com/news/business/companies/gsp-withdrawal-by-us-may-have-marginal-impact-on-indian-pharma-exporters-4059841.html

Pharmaceutical intermediates market to see growth

This is according to a new report by Future Market Insights which states that the global sales of pharmaceutical intermediates closed in on US$26 billion 2018.
Read more : https://www.europeanpharmaceuticalreview.com/news/89498/pharmaceutical-intermediates-market-growth/

Indian pharma aims to corner 7% of global market by 2030

The Indian pharmaceutical industry aspires to have a 7 percent share in the global drug market by 2030, a joint report by the Indian Pharmaceutical Alliance (IPA) and McKinsey said.
Read more : https://www.moneycontrol.com/news/business/companies/indian-pharma-aims-to-corner-7-of-global-market-by-2030-report-4120651.html

Govt may make barcoding compulsory for all medicines sold in country: Report

The Central Drugs Standards Control Organization (CDSCO) is considering making barcoding mandatory on all medicines sold within India to curb sale of counterfeit medicines, according to a Mint report.
Read more : https://www.moneycontrol.com/news/economy/policy/govt-may-make-barcoding-compulsory-for-all-medicines-sold-in-country-report-4081341.html

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