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

Pharma industry eyes global growth

REGULATORY

Drug Controller General of India says all regulatory approvals to go online for transparency

CLINICAL RESEARCH

Speeding up the drug discovery process to help patients

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CRO sees investment from Canadian government to develop clinical trials tech

M & A

Bayer completes merger of Monsanto India

V-KONNECT

"Current outlook of Biosimilar Development"

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INDIAN PHARMA

Pharma industry eyes global growth

India's pharmaceuticals industry which recorded $19.2 billion exports during 2018-19 comprising of bulk drugs, finished dosage formulations, ayush, herbals and surgical products, is looking to make deeper inroads into the US, China, Japan, Korea and Australia. India exported to 201 countries in FY19.

Read more : https://telanganatoday.com/pharma-industry-eyes-global-growth

Gujarat – A Re-emerging Pharma Destination?

Gujarat has been the flag bearer of India's pharmaceutical industry since the establishment of the country's second oldest drug company, the Alembic Chemical Works Company Limited in Vadodara in 1907.

Read more : : http://www.mondaq.com/india/x/845036/Life+Sciences+Biotechnology/Gujarat+A+Reemerging+Pharma+Destination

Chinese cheer for Indian cancer-drug manufacturers

New norms for drug imports announced by the Chinese government are expected to benefit Indian pharma companies in the oncology segment.

Read more : https://www.thehindubusinessline.com/economy/chinese-cheer-for-indian-cancer-drug-manufacturers/article29448407.ece

India: the rise of anti-infectives and price control

Heavy rains across several parts of India have provided a shot in the arm for anti-infective drugs that have been on the decline for the past several months. The category of anti-infective drugs grew at 15.3% year-on-year in August, compared to the Indian pharmaceutical market growth of 9.4%, reports The Pharma Letter's India correspondent.

Read more : https://www.thepharmaletter.com/article/india-the-rise-of-anti-infectives-and-price-control

Growing Indian pharma market needs more investment

New research from industry analyst GlobalData shows that the Indian pharmaceutical industry is set to grow from nearly $31 billion at present, to around $38 billion by 2022.

Read more : https://www.thepharmaletter.com/article/growing-indian-pharma-market-needs-more-investment

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REGULATORY

FDA to transition to new portal for NDI, structure/function submissions

Companies submitting NDIs and structure/function claims will see a different interface starting on Friday, the US Food and Drug Administration announced today.
Read more: https://www.nutraingredients-usa.com/Article/2019/09/04/FDA-to-transition-to-new-portal-for-NDI-structure-function-submissions

FDA releases updated RTA checklist

The guidance replaces the 30 October 2017 draft guidance of the same name and describes the administrative steps FDA will take to either Refuse to Accept (RTA) or file a request for an evaluation of automatic class III designation (De Novo request).
Read more : https://hoganlovells.com/en/publications/de-novo-requests-fda-releases-updated-rta-checklist

FDA Issues 53 Product-Specific Guidance to Help With Generic Drug Development

The US Food and Drug Administration (FDA) on Monday released 53 product-specific guidance documents to aid generic drug development, including 34 new guidance documents, 26 guidances for treatments that lack generic competition and 16 for complex products.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/9/fda-issues-53-product-specific-guidances-to-help-w

Drug Controller General of India says all regulatory approvals to go online for transparency

All regulatory approvals from Drug Controller General of India (DCGI) will go completely online to ensure transparency to global as well domestic players, according to V G Somani, DCGI.
Read more : https://www.thehindubusinessline.com/companies/drug-controller-general-of-india-says-all-regulatory-approvals-to-go-online-for-transparency/article29456886.ece

FDA clarifies how it will regulate digital health and artificial intelligence

The Food and Drug Administration has issued new guidelines on how it will regulate mobile health software and products that use artificial intelligence to help doctors decide how to treat patients.
Read more : https://www.statnews.com/2019/09/26/fda-artificial-intelligence-digital-health-rules/

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CLINICAL RESEARCH

Expense reimbursement model aims to 'level playing field' for clinical trial participation

Clinical trials, superficially speaking, might seem custom-made for low-income patients with cancer. Participation gives patients access to cutting-edge investigational therapies and hope for life-prolonging treatment that otherwise would be unavailable.
Read more : : https://www.healio.com/hematology-oncology/practice-management/news/print/hemonc-today/%7B7c31cd1c-05e2-42cf-99ce-77db7aa8ebaa%7D/expense-reimbursement-model-aims-to-level-playing-field-for-clinical-trial-participation

Using voice-enabled technology to 'better understand the patient'

Patients often feel more comfortable sharing their feelings with a device than with a health care provider, found researchers at Janssen, who have developed a new voice technology application for clinical trials.
Read more : https://www.outsourcing-pharma.com/Article/2019/09/11/Janssen-develops-voice-technology-application-for-clinical-trials

Speeding up the drug discovery process to help patients

An international research team has developed a new strategy that can predict the potential clinical implications of new therapeutic compounds based on simple cellular responses.
Read more : https://www.sciencedaily.com/releases/2019/09/190913120820.htm

Most cancer drugs fail in testing. This might be a big reason why.

In the quest for the next cancer cure, few researchers bother to look back at the graveyard of failed medicines to figure out what went wrong.
Read more : https://www.vox.com/2019/9/16/20864066/cancer-studies-fail

Incorporating diverse data types in clinical trials

The Internet has caused us all to be our own researchers. It seems like picking a restaurant for dinner involves more research than we put into our college thesis papers. When making almost any decision, we actively gather real world data and evidence on the Internet.
Read more : https://medcitynews.com/2019/09/incorporating-diverse-data-types-in-clinical-trials/

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FINANCIALS

Switching to 'best-value' generics and biosimilars saved the NHS £294m in 2018/2019, figures show

The uptake of 'best-value' medicines, such as generics and biosimilars, saved the NHS £294m in 2018/2019, according to figures released by NHS England.
Read more : https://www.pharmaceutical-journal.com/news-and-analysis/news-in-brief/switching-to-best-value-generics-and-biosimilars-saved-the-nhs-294m-in-2018/2019-figures-show/20207022.article?firstPass=false

CRO sees investment from Canadian government to develop clinical trials tech

The Canadian CRO Everest Clinical Research will receive up to up to $100,000 to support the development of new technology for managing data from clinical research trial sites.
Read more : https://www.outsourcing-pharma.com/Article/2019/09/05/CRO-sees-investment-from-Canadian-government-to-develop-clinical-trials-tech

UAE's health ministry reduces prices of 410 generic drugs

The Ministry of Health and Prevention will reduce the prices of 410 generic drugs with effect from September 15. The price reduction was announced by Abdul Rahman Mohammed Al Owais, Minister of Health and Prevention, through Ministerial Decree No 130 of 2019.
Read more : https://gulfnews.com/uae/health/uaes-health-ministry-reduces-prices-of-410-generic-drugs-1.66334090

Post-Market Barriers to Biosimilars Cost $2.2 Billion Since 2015, Says Biosimilars Council

The Biosimilars Council, a part of the Association for Accessible Medicines, has issued a second component of its recent white paper on barriers to biosimilars in the United States; the newly published segment highlights post-market barriers to biosimilar adoption, and says that they have taken a significant toll on the US healthcare system in terms of lost savings.
Read more : https://www.centerforbiosimilars.com/news/postmarket-barriers-to-biosimilars-cost-22-billion-since-2015-says-biosimilars-council

Peloton Therapeutics' $2.2 billion deal with Merck took root with an idea for clinical trials

Dallas-based cancer drug developer Peloton Therapeutics got on the radar of Merck when the two talked about teaming up for a clinical trial. The clinical trial didn't happen, but their talks manifested in another way: The pharmaceutical giant bought Peloton in May for up to $2.2 billion.
Read more : https://www.dallasnews.com/business/2019/09/20/peloton-therapeutics-2-2-billion-deal-with-merck-took-root-with-an-idea-for-clinical-trials/

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MERGER AND AQUISITION

PAG acquires control of biosimilars firm Hisun BioRay

Asia-focused Hong Kong-based private equity firm PAG has executed a final agreement to acquire a controlling interest in Zhejiang Hisun Pharmaceutical's (SHA: 600267) subsidiary Hisun BioRay Bio-pharmaceutical Co.

Read more : https://www.thepharmaletter.com/article/pag-acquires-control-of-biosimilars-firm-hisun-bioray

PPD nabs Bioclinica clinical research site business

As part of its ambition to become the world's largest patient access and site conduct organization, CRO PPD has snapped Bioclinica's research site biz.

Read more : https://www.fiercebiotech.com/cro/ppd-nabs-bioclinica-clinical-research-site-business

Advarra Announces Intent to Acquire Forte, Market-Leading Provider of Clinical Technology Solutions

Advarra, the premier provider of institutional review board (IRB), institutional biosafety committee (IBC), and research quality and compliance consulting services, is pleased to announce the intent to acquire Forte, the industry's leading provider of standards-based clinical research technology solutions for major academic medical centers, cancer centers, and health systems.

Read more : https://www.prnewswire.com/news-releases/advarra-announces-intent-to-acquire-forte-market-leading-provider-of-clinical-technology-solutions-300912048.html

Castle Creek Pharmaceutical Holdings to Acquire Fibrocell

Fibrocell Science, Inc. (Nasdaq: FCSC), a cell and gene therapy company focused on transformational autologous cell-based therapies for skin and connective tissue diseases, today announced it has reached an agreement to be acquired by Castle Creek Pharmaceutical Holdings, Inc. ("Castle Creek Pharmaceutical Holdings"), the parent company of Castle Creek Pharmaceuticals, LLC "Castle Creek Pharmaceuticals").

Read more : https://www.streetinsider.com/Globe+Newswire/Castle+Creek+Pharmaceutical+Holdings+to+Acquire+Fibrocell/15911563.html

Bayer completes merger of Monsanto India

German chemical and pharma major Bayer AG on Monday said it has completed the integration of biotech major Monsanto's India business with itself.

Read more : https://timesofindia.indiatimes.com/business/india-business/bayer-completes-merger-of-monsanto-india/articleshow/71154721.cms

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V-KONNECT

Veeda through its V-Konnect series interacted with Dr. Susobhan Das and discussed about "Current outlook of Biosimilar Development"

About the V- Konnect

V-Konnect interview series, is a program to get in touch with specialized industry experts to know their views on opinions on current relevant subject matters.

TRANSCRIPT

1. What are the key international developments with respect to EU and USFDA biosimilar requirements ?

A: One key development towards biosimilar acceptance has been the issuance of guidance on “interchangeability” by US-FDA in May this year. This will pave the way for the substitution of one product for the other without a prescriber’s involvement, as is the case for generic small molecule pharmaceuticals. This I believe, is a significant action and will promote competition in the biologic market in the US. Another development is the issuance of a revised guidance by FDA titled “Development of Therapeutic Protein Biosimilars: Comparative Analytical Assessment and Other Quality Considerations” also in May this year. This is the revised version of an earlier guidance titled “Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product,” published on April 30, 2015. FDA says this revision is to reflect on agency’s recommendations on the design and evaluation of comparative analytical studies intended to support a demonstration that a proposed therapeutic protein product is biosimilar to a reference product and in anticipation that this will provide additional clarity and flexibility for product developers on analytical approaches to evaluating product structure and function. For Europe, although approval rate of Biosimilars are much higher that the US, uptake of biosimilars are somewhat country specific, with the large EU5 countries still do not have interchangeability options. However, payers have significantly employing various tools which may lead to higher biosimilar uptake. For example introduction of prescribing target i.e. prescribing biosimilars to a predetermined percentage of patients. NHS of UK introduced biosimilar adoption framework with the idea that switching of patients to a biosimilar may be inserted into clinical practice with incentive offerings for staff to offset switc hing costs. This year in May, NHS has published a document titled “what is a biosimilar medicine” for clinical and nonclinical stakeholders about the role of biosimilars in the healthcare system. The document explains among many others aspects, on the overall savings from Biosimilars as well as suggest that a prescriber can switch from a reference to a biosimilar product. However, switching at the pharmacy level is still not permitted without the consent of the prescriber as of now.

Read more at: https://www.veedacr.com/2019/brochure/V-Konnect%20Dr.%20Sushobhan%20Das.pdf

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