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The Veeda Newsletter

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CONFERENCE

Bio Pharm America
Sep 5-6, 2018
Boston, MA, USA.

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REGULATORY NEWS

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Drug shortages again on the rise after 5 years of improvements, FDA says.

After 5 years of declines in the number of new drug shortages in the U.S., they jumped to 39 last year from 26 in the two preceding years.
Read More: https://www.fiercepharma.com/manufacturing/fda-says-drug-shortages-again-rise-after-5-years-improvements

DTAB approves DCGI's proposal for introducing unique code to drug packs to curtail spurious drugs in domestic market.

The Drugs Technical Advisory Board (DTAB), the highest decision making body under the Union health ministry on technical matters, has approved Drug Controller General India (DCGI)'s proposal for introducing a unique code on drug packs whether it is bottle, strip or vial to ensure authenticity of the medicine
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=109029&sid=1

To spot fake drugs, DCGI may introduce trace and track mechanism for top 300 drug brands.

The Drug Controller General of India (DCGI) has called a meeting with all major pharmaceutical companies on June 25 to discuss the proposal regarding introduction of trace and track mechanism for top 300 drug brands that are sold in India.
Read More: https://indianexpress.com/article/business/business-others/to-spot-fake-drugs-dcgi-may-introduce-trace-and-track-mechanism-for-top-300-drug-brands-5222963/

Trade associations seek demarcation of generics to comply with DCGI direction on separate shelf for generics

Joydeep Sarkar, general secretary of the All India Chemists and Distributors Federation (AICDF) said keeping a separate shelf for generic drugs is not an issue for chemists but there is no demarcation of generics on drug pack. The domestic market is dominated by branded generics
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=109528&sid=1

FDA Finalizes Guidance on Biosimilar User Fees Under BsUFA II

The US Food and Drug Administration (FDA) on Thursday finalized guidance explaining changes to its user fee program for biosimilar products and the fees it charges industry under the Biosimilar User Fee Amendments of 2017 (BsUFA II).
Read More: https://www.raps.org/news-and-articles/news-articles/2018/6/fda-finalizes-guidance-on-biosimilar-user-fees-und

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INDIAN PHARMA

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India to oppose planned patents rule

An effort by the World Intellectual Property Organization (WIPO) to bring in a new rule that would allow countries to delegate the functions of their patents office to another country or international organization has set alarm bells ringing among many developing countries and activists working on access to medicines

Read more: https://timesofindia.indiatimes.com/india/india-to-oppose-planned-patents-rule/articleshow/64608781.cms

India has a huge role to play in global pharma opportunity, says Biocon

"Economies are grappling with healthcare costs and India has a huge role to play in containing those costs," she said.Therefore, pharma companies in India have huge opportunity going forward as countries and economies focus on a larger footprint of their healthcare commitments and societal obligations, she added.

Read More: https://www.cnbctv18.com/videos/healthcare/india-has-a-huge-role-to-play-in-global-pharma-opportunity-says-biocon-154111.htm

Pharma industry recovers from GST pangs, poised for double digit growth

The Indian pharmaceutical market returned to double digit growth of 10.8 percent in May for the first time in over a year indicating the pangs of transitioning to the Goods and Service Tax (GST) regime have been left behind

Read More: https://www.moneycontrol.com/news/business/companies/pharma-industry-recovers-from-gst-pangs-poised-for-double-digit-growth-2652111.html

One year of GST: Crawling, toddling, and on its feet

As the landmark tax reform — Goods and Services Tax (GST) — completes one year on June 30, the journey remained a rather challenging for both the industry and the governments.

Read More: https://timesofindia.indiatimes.com/city/ahmedabad/one-year-of-gst-crawling-toddling-and-on-its-feet/articleshow/64810400.cms

Govt aims to boost small pharma firms with 6% interest relief on loans

The Union government is ready to roll out an interest subvention scheme for small pharma companies, who wish to upgrade their infrastructure and technology.

Read More: https://www.livemint.com/Industry/RiRecBv6WZXfwP5u0lZ0qI/Govt-aims-to-boost-small-pharma-companies-with-6-interest-r.html

Pharma exports see double digit growth after a gap of three years

After a gap of three years Indian pharmaceutical exports are seeing a double digit growth in value terms starting this financial year, driven by a surge in exports across all the major destinations in the world, according to Pharmaceutical Export Promotion Council (Pharmexcil).

Read More: https://www.business-standard.com/article/companies/pharma-exports-see-double-digit-growth-after-a-gap-of-three-years-118070300440_1.html

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CLINICAL RESEARCH

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Clinical trials in a dish: A perspective on the coming revolution in drug development

A new SLAS Discovery article available now for free ahead-of-print, offers perspective from researchers at Coyne Scientific (Atlanta, GA) about Clinical Trials in a Dish (CTiD), a novel strategy that bridges preclinical testing and clinical trials.
Read More: https://www.eurekalert.org/pub_releases/2018-06/sfl-cti052618.php

Blacks underrepresented in 'Life and Death' clinical research, study finds

Doctors have been depending for years on inaccurate research to determine cardiovascular risks, which helped them to decide which treatments individual patients needed, the study published Monday in the Annals of Internal Medicine found.
Read More: https://www.theatlantavoice.com/articles/blacks-underrepresented-in-life-and-death-clinical-research-study-finds/

From Phase 1 to FDA Approval: Following a Drug through the Development Pipeline

The room full of researchers and doctors erupted in applause around Peter Chin as positive results from the phase 3 trial of ocrelizumab were announced. After over a decade of hard, uncertain work on the multiple sclerosis drug, the team celebrated their success.
Read More: http://www.mdmag.com/medical-news/from-phase-1-to-fda-approval-following-a-drug-through-the-development-pipeline

New DNA test could end 'trial and error' of antidepressant treatments

A new genetic profile test is bringing personalized medicine into the realm of psychology by determining how individual patients are predisposed to respond to more than 30 different drugs.
Read More: https://www.ctvnews.ca/health/new-dna-test-could-end-trial-and-error-of-antidepressant-treatments-1.3967165

New approaches to oncology may require new approaches to clinical trials

Precision medicine offers a lot of promise for targeting specific genetic markers in cancers and helping to ensure drugs used to treat them are effective.
Read more at: https://medcitynews.com/2018/06/new-approaches-to-oncology-may-require-new-approaches-to-clinical-trials/?rf=1

Disruptive innovation – the impact on clinical trials

Emerging disruptive innovations for clinical trials have immense potential to benefit entrepreneurs and established companies alike.
Read More: https://www.biopharmadive.com/news/disruptive-innovation-the-impact-on-clinical-trials/525940/

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FINANCIAL NEWS

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A year on, FDA expects 2017 generic approvals to generate $16 billion in savings

As part of its efforts to promote the use of generics in the US healthcare system, the Food and Drug Administration has released a document outlining what it believes are the cost-savings associated with the use of copycat drugs approved last year.

Read More: https://www.thepharmaletter.com/article/fda-expects-2017-generic-approvals-to-generate-16-billion-in-savings-this-year

Second Patent Cliff Lies Ahead for Pharma with $251 Billion in Sales at Risk by 2024

EvaluatePharma, a company that provides consensus forecasts of the pharmaceutical and biotechnology sphere, recently published the 11th edition of its World Preview.

Read More: http://www.centerforbiosimilars.com/news/second-patent-cliff-lies-ahead-for-pharma-with-251-billion-in-sales-at-risk-by-2024

India, China should set up new bilateral trade target of USD 100 billion by 2020: Xi to Modi

President Xi Jinping on Saturday suggested Prime Minister Narendra Modi that the two countries set up a new bilateral trade target of USD 100 billion by 2020 as Beijing is looking at importing non-Basmati rice as well as sugar to address the trade deficit.

Read More: https://www.moneycontrol.com/news/india/india-china-should-set-up-new-bilateral-trade-target-of-usd-100-billion-by-2020-xi-to-modi-2586685.html

US-focused pharma cos see 30% drop in FY18 earnings

Regulatory clampdowns, increased competition and channel consolidation in the US have led to a drop of 30% — one of the worst — in earnings of US-focused Indian pharma companies in FY18.

Read More: https://timesofindia.indiatimes.com/business/india-business/us-focused-pharma-cos-see-30-drop-in-fy18-earnings/articleshow/64594023.cms

Top selling drugs face patent expiration between 2018 and 2024, sales worth $251 bn at stake: Report

A looming patent cliff could potentially wipe off branded drug sales worth $251 billion of global pharma companies as patents of key drugs are expected to expire between 2018 and 2024

Read More: https://www.moneycontrol.com/news/business/companies/top-selling-drugs-face-patent-expiration-between-2018-and-2024-sales-worth-251-bn-at-stake-report-2604401.html

Amazon Will Acquire Online Pharmacy PillPack

U.S.-based PillPack is a pharmacy company that focuses on customers who take multiple-daily prescriptions. "PillPack delivers medications in pre-sorted dose packaging, coordinates refills and renewals, and makes sure shipments are sent on time," the press release states.

Read More: https://www.thestreet.com/technology/amazon-will-acquire-pillpack-14636993

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MERGER & AQUISITION

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ACON Investments and Humus Capital Acquire Biosidus

ACON Investments ("ACON") announced today that affiliates of ACON Latin America Opportunities Fund IV, L.P., in partnership with Humus Capital Partners ("HCP"), a private equity firm based in Argentina

Read More: http://www.bnamericas.com/en/news/banking/acon-investments-and-humus-capital-acquire-biosidus/

Admescope acquires Swedish contract research organisation, MetaSafe

Swedish based company, MetaSafe, is a contract research organisation working with small, midsize and large pharmaceutical companies in the area of drug biotransformation/metabolism.

Read More: https://www.epmmagazine.com/news/admescope-acquires-metasafe/

Lupin ties up with Japan-based Nichi-Iko for biosimilar launch

Indian Pharma major Lupin said it has signed an agreement with Japan-based generics maker Nichi-Iko to market its upcoming biosimilar drug, Etanercept, in the far eastern nation.

Read More: https://ultra.news/t-t/40362/lupin-ties-up-with-japan-based-nichi-iko-for-biosimilar-launch

LabConnect and Symphony Clinical Research Partner to Improve In-Home Clinical Services

LabConnect, LLC, a leading global provider of central laboratory and support services for biopharmaceutical, medical device and contract research organizations.

Read More : https://www.heraldcourier.com/news/business_ap/labconnect-and-symphony-clinical-research-partner-to-improve-in-home/article_5dd5c914-425d-59c6-8e44-8c0b655fec87.html

Syneos Health and Elligo Announce Strategic Collaboration to Advance Clinical Research for Real-World Patients

Syneos Health™ (Nasdaq:SYNH), the only fully integrated biopharmaceutical solutions organization, and Elligo Health Research, the only platform that brings clinical research direct to clinical health care.

Read More: https://www.nasdaq.com/press-release/syneos-health-and-elligo-announce-strategic-collaboration-to-advance-clinical-research-for-20180621-00266

Sanofi Agrees To Sell European Generics Unit To Advent For $2.2B

Headquartered in Prague, Zentiva provides access across Europe to a broad generics portfolio covering a variety of therapeutic areas. The company reaches more than 40 million patients in 25 European countries and focuses on three European generics market areas—pharmacy, physician, and wholesaler.

Read More: https://www.pharmpro.com/news/2018/06/sanofi-agrees-sell-european-generics-unit-advent-22b

Clinical Trials: Not Broken, But In Need Of Repair.

We all know the days of Big Pharma companies launching billion-dollar blockbuster drugs are generally behind us. Today, novel new therapies are harder to bring to market. Trials are costly, take a long time to complete, and too many of them fail. On top of that, many of the issues companies face today are the same ones they dealt with 20 years ago.

The challenges have led Janet Woodcock, director of the Center for Drug Evaluation and Research at FDA, to remark in 2017 that the clinical trial system is broken. But if that's the case, how do we uncover the underlying problems and bring all stakeholders together to fix them?

A panel at the 2018 Clinical Leader Forum came together to discuss this issue. The panel consisted of Greg Koski, founder and CEO of the Alliance for Clinical Research Excellence and Safety (ACRES); Dan Milam, VP of Global Engagement for the Society for Clinical Research Sites (SCRS); Patty Leuchten. president and CEO, of The Avoca Group; Jim Kremidas, executive director of the Association of Clinical Research Professionals (ACRP); Doug Peddicord, executive director of the Association of Clinical Research Organizations (ACRO); and Robert Hardi, president of the Academy of Physicians in Clinical Research (APCR).

Koski started the discussion by noting a recent article in Fortune that discussed the problems with clinical trials. In addition to the issues noted above, it cited regulation, enrollment problems, and patient centricity obstacles.

Read More: https://www.clinicalleader.com/doc/clinical-trials-not-broken-but-in-need-of-repair-0001

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UPCOMING CONFERENCE

1. Bio Pharm America

Sep 5-6, 2018

Boston, MA, USA.

2. CPhI Worldwide 2018

Oct 9-11, 2018

Madrid , Spain.

3. BIO-Europe

Nov 5-7, 2018

Copenhagen, Denmark

23RD ANNUAL INTERNATIONAL PARTNERING CONFERENCE

For Inquiry & Meeting Appointment please mail us at info@veedacr.com

CONTACT US:

Veeda Clinical Research Pvt. Ltd.

Veeda House, Beside YMCA Club,
SG Highway, Ahmedabad,
Gujarat 380015, India.

Fax: +91 79 30013010
Phone: +9179 30013000
Mail: Info@veedacr.com,
Web: https://veedacr.com/