The Veeda Newsletter

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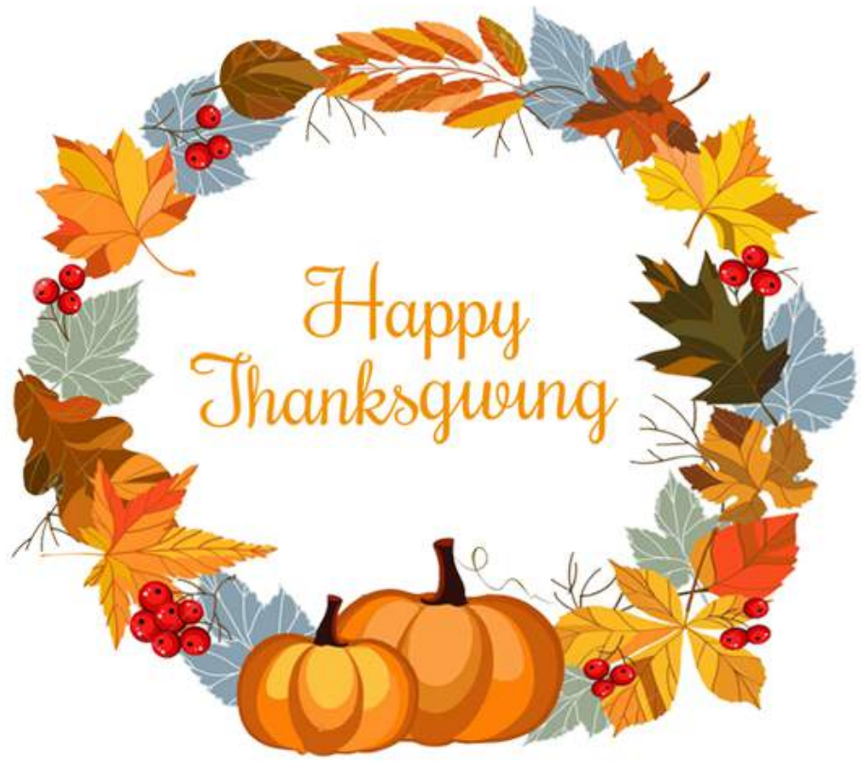

**May the good things of life be yours in abundance,
not only at Thanksgiving but throughout the coming year.**

INDIAN PHARMA

World's first male birth control method close to approval in India

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Drug Importation Is a High-Profile Addition to USFDA's Regulatory Agenda

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Article

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INDIAN PHARMA

Union Health Minister of India announces scale-up of Triple Drug Therapy

Union Health & Family Welfare Minister, Dr. Harsh Vardhan, announced an aggressive strategy to address and eliminate Lymphatic Filariasis by 2021. Inaugurating the national symposium on 'United to Eliminate Lymphatic Filariasis' organized by the National Vector Borne Disease Control Programme (NVBDCP) in New Delhi today, he stressed upon the importance of building a mass movement or 'Jan Andolan' to address this preventable vector borne disease which affects is still endemic in 160 districts across India.
Read more : http://www.newspatrolling.com/union-health-minister-of-india-announces-scale-up-of-triple-drug-therapy/

Indian drug market will soon rule the world: Dr VG Somani

Stating that the pharmacy industry had grown manifold in the country, Dr VG Somani, Drug Controller General of India (DCGI), said India's drugs market share in the world is 40 per cent including in the US, Europe, Japan and Africa.
Read more : : https://telanganatoday.com/indian-drug-market-will-soon-rule-the-world-dr-vg-somani

India's top-10 selling drugs dominated by diabetes products

Of the top 10 drug brands by sales, seven belong to multinationals, with the top selling brand being Danish diabetes major Novo Nordisk (NOV: N) for its insulin drug called Mixtard. The drug had sales in India of $75 million to September on a moving annual turnover (MAT) basis.
Read more : https://www.thepharmaletter.com/article/india-s-top-10-selling-drugs-dominated-by-diabetes-products

World's first male birth control method close to approval in India

The primary compound constituting the reversible inhibition of sperm under guidance (RISUG) is Styrene Maleic Anhydride. RS Sharma, a senior scientist with ICMR, claims that the contraceptive is effective for a span of 13 years, after which it loses potency. The non-surgical process will simply involve injecting the contraception under local anaesthesia into the sperm-containing tube near the testicles (vas deferens).
Read more : https://www.ibtimes.co.uk/worlds-first-male-birth-control-method-close-approval-india-1672032

India to Track API Packs

Utilizing the 2D barcode technology, the system makes it harder for counterfeit drugs to enter the pharmaceutical supply chain. The authenticity of each pack is checked by entering its unique identifier number into a repository system at the time of manufacture. The unique identifier can be verified against its entry in the storage system at one or more points in the supply chain. As this simple technology makes the distribution system more transparent, it becomes easier for authorities to locate at exactly which point fake drugs infiltrated the distribution system.
Read more : https://www.contractpharma.com/issues/2019-11-01/view_india-report/india-to-track-api-packs/

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REGULATORY

FDA Releases Draft Guidance on Insulin Biosimilars, Interchangeable Insulins

The FDA released draft guidance for industry on clinical immunogenicity considerations for biosimilar insulins and interchangeable insulins. The guidance document provides recommendations as to whether—and when—comparative clinical immunogenicity studies will be needed to support an application to the FDA for insulin products under the biosimilar approval pathway.
Read more: https://www.centerforbiosimilars.com/news/fda-releases-draft-guidance-on-insulin-biosimilars-interchangeable-insulins

DCGI directs manufacturers to furnish undertaking for not marketing drugs having similar brand names

The Drugs Controller General of India (DCGI) has directed all manufacturers to furnish an undertaking in Form 51 to the licensing authority that respective company is not marketing similar brand names of any drug in the country so that the proposed brand name or trade name of the respective company could not lead to any confusion in the market.
Read more : http://www.pharmabiz.com/NewsDetails.aspx?aid=119266&sid=1

EC Offers Further Clarity on Clinical Trial Regulation

The European Commission (EC) recently updated guidance on the incoming clinical trials regulation, with new questions and answers (Q&As) on requests for information (RFIs), how assessment reports will be made public and the sponsor's responsibilities regarding changes to a clinical trial that are not substantial modifications but are relevant for supervising the trial.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/11/ec-offers-further-clarity-on-clinical-trial-regula

France to Maintain Fast Track Schemes for Clinical Trials

As the new EU clinical trial regulation is expected to take effect next spring, France's drug regulator, Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), said it will maintain two fast tracks to speed clinical trials for new and already known medicinal products.
Read more : https://www.raps.org/news-and-articles/news-articles/2019/11/france-to-maintain-fast-track-schemes-for-clinical

Drug Importation Is a High-Profile Addition to US FDA's Regulatory Agenda

Agency is targeting January 2020 for release of controversial proposed rule to allow importation of certain types of prescription drugs from Canada; although most Rx drug-related proposed and final rules on the Fall 2019 regulatory agenda are making repeat appearances, a final rule on electronic distribution of prescribing information has fallen off the list.
Read more : https://pink.pharmaintelligence.informa.com/PS141235/Drug-Importation-Is-A-HighProfile-Addition-To-US-FDAs-Regulatory-Agenda

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CLINICAL RESEARCH

Improving Integrated Clinical Trial Management Systems through Blockchain

Clinical trials are an expensive stage in a pharmaceutical product's development. According to a recent study,1 it costs more than $2.6 billion to bring a drug to market. R&D costs play a significant role, as the industry spends more than $150 billion per year, and clinical development is nearly 70% of that cost.

Read more : : https://www.genengnews.com/insights/improving-integrated-clinical-trial-management-systems-through-blockchain/

Research Letter Suggests That Off-label Use May Be Boosting Eculizumab Sales

Since its initial approval by the FDA in 2007, eculizumab (Soliris) has gathered a total of 4 indications, and it brought in sales of $3.5 billion in 2018. One of the most expensive drugs in the world, the C5 complement inhibitor targeted by multiple biosimilar development projects has long raised concerns about cost.

Read more : https://www.centerforbiosimilars.com/news/research-letter-suggests-that-offlabel-use-may-be-boosting-eculizumab-sales

Digital endpoints library can aid clinical trials for new medicines

At nearly every major industry conference — from HLTH to CNS Summit, Exponential Medicine, and Rock Health Summit — speakers are talking about the benefits of decentralized clinical trials and digital endpoints. We are quite excited about the latter.

Read more : https://www.statnews.com/2019/11/06/digital-endpoints-library-clinical-trials-drug-development/

Basic Research Spurs new wave of Clinical Trials of Therapies for T-Cell Lymphoma

By banding together to study the basic biology and vulnerabilities of T-cell lymphoma, scientists at several major cancer research centers have sparked a surge of clinical trials of promising treatments for the disease.

Read more : https://blog.dana-farber.org/insight/2019/11/basic-research-spurs-new-wave-of-clinical-trials-of-therapies-for-t-cell-lymphoma/

IP Protections Are Key to Drug Innovation

The FDA approved Trikafta, a breakthrough therapy for the disease, which causes a life-threatening buildup of mucus in the lungs and digestive tract. Before Trikafta, most patients didn't have any treatment options.

Read more : https://townhall.com/columnists/peterpitts/2019/11/24/ip-protections-are-key-to-drug-innovation-n2556939

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FINANCIALS

Post-monsoon Indian pharma market growth slips to 5.1% in October

After having one of the best quarters in about a year, domestic pharma market growth slipped to mid-single digits in October as the monsoon extended this year.

Read more : https://www.business-standard.com/article/companies/post-monsoon-indian-pharma-market-growth-slips-to-5-1-in-october-119111000779_1.html

Pharma pulse improves in Q2, but challenges remain heading into Q3

Indian pharmaceutical companies reported improved numbers for the second quarter, but much of the sector is not out of the woods yet. Revenue growth in the September quarter was helped by improvements in the domestic pharma market. This recovery reflected in the Nifty Pharma index, which gained about 6% in the last month compared to a 2.5% increase in the Nifty 500.

Read more : https://www.livemint.com/market/mark-to-market/pharma-pulse-improves-in-q2-but-challenges-remain-heading-into-q3-11574407035746.html

The global AI in the drug discovery market is projected to reach USD 1,434 million by 2024 from USD 259 million in 2019, at a CAGR of 40.8%

Growing number of cross-industry collaborations and partnerships and the need to control drug discovery & development costs and reduce the overall time taken in this process are the key factors driving the AI in the drug discovery market.

Read more : https://www.prnewswire.com/news-releases/the-global-ai-in-the-drug-discovery-market-is-projected-to-reach-usd-1-434-million-by-2024-from-usd-259-million-in-2019--at-a-cagr-of-40-8-300964473.html

Temasek leads $220m round for Indian online pharmacy startup PharmEasy

Mumbai-based online pharmacy startup PharmEasy has raised $220 million in a fresh round of financing led by Singapore state investment firm Temasek Holdings Pte.

Read more : https://www.dealstreetasia.com/stories/temasek-pharmeasy-164465/

Sun Pharma posts Rs 1,064 crore net profit in September quarter, India sales up 35%

Pharma major Sun Pharmaceutical Industries on Thursday reported a consolidated net profit of Rs 1,064.09 crore for the second quarter ended September 30, 2019.

Read more : https://www.businesstoday.in/current/corporate/sun-pharma-swings-back-into-profit-posts-q2-net-profit-at-rs-1064-crore/story/389049.html

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MERGER AND AQUISITION

Zealand Pharma Completes Cross-Border Acquisition Of Encycle Therapeutics

Copenhagen-based Zealand Pharma A/S ("Zealand") (NASDAQ: ZEAL) (CVR-no. 20 04 50 78) announced its cross-border acquisition of Toronto-based Encycle Therapeutics, Inc. ("Encycle")

Read more : http://www.mondaq.com/canada/x/860662/Corporate+Commercial+Law/Zealand+Pharma+Completes+CrossBorder+Acquisition+Of+Encycle+Therapeutics

WCG Acquires Clinical Trial Management Consultancy Waife & Associates, Inc.

WIRB-Copernicus Group®'s (WCG™) Clinical Services Division today announced the acquisition of Waife & Associates, Inc. (W&A), which has been providing management consulting services for biopharmaceutical clinical research clients for 26 years.

Read more : https://www.prnewswire.com/news-releases/wcg-acquires-clinical-trial-management-consultancy-waife--associates-inc-300954853.html

BASi to Buy Pre-Clinical Research Services

West Lafayette-based Bioanalytical Systems Inc. (Nasdaq: BASI) is purchasing the assets of Colorado-based Pre-Clinical Research Services Inc., a provider of surgical and medical device contract research services. Officials say the two companies are merging to expand the development and research opportunities.

Read more : http://www.insideindianabusiness.com/story/41302472/basi-to-buy-pre-clinical-research-services

Novartis agrees Aspen generics acquisition for €400m

The deal, which will expand Novartis' presence in the world's third-largest drug market, will include a €300m upfront payment, with a deferred amount not higher than €100m to follow on completion of various conditions.

Read more : https://www.cityam.com/novartis-agrees-aspen-generics-acquisition-for-e400m/

Aurobindo to buy R&D assets of U.S. vaccine firm

Aurobindo Pharma, through a step-down subsidiary in the U.S., is acquiring certain R&D (research and development) assets of U.S. clinical-stage vaccine development firm Profectus BioSciences Inc.

Read more : https://www.thehindu.com/business/Industry/aurobindo-to-buy-rd-assets-of-us-vaccine-firm/article30109772.ece

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ARTICLE

Why 97% of Oncology Clinical Trials Fail To Receive FDA Approval

As more drug targets are discovered in the fight to treat diseases such as cancer, producing the right drugs for these targets is key to providing the best treatment and prolonging health in cancer patients.

Read more : https://www.technologynetworks.com/drug-discovery/articles/why-97-of-oncology-clinical-trials-fail-to-receive-fda-approval-327724

How to Address the Challenges of Biologics Discovery and Development

The biologics industry is growing at an incredible rate. While its global market value was estimated at $236B in 2017, it is expected to rise to $310B by 2023. As key market players enter the field, competition is increasing.

Read more : : https://www.labiotech.eu/sponsored/challenges-biologics-development/

What 9 Biopharma Trendsetters Expect For 2020 – And Beyond

Meteorologists accurately predict a five-day weather forecast about 90 percent of the time. I imagine we'd be pretty pleased if we had a similar rate of success regarding the predictions made from our biopharma industry thought leaders in this annual CEO outlook article. Of course, there is a big difference between predicting the weather five days out and predicting what will take place in the biopharma industry in 2020 and beyond.

Read more : https://www.lifescienceleader.com/doc/what-biopharma-trendsetters-expect-for-and-beyond-0001

fishbat Shares Tips for Monitoring Patient Activity During Clinical Trial Recruitment Periods

There is considerable work that goes into clinical trials before they are even set into motion: ranging from drug approval to patient screening to the steps that lead to the trials themselves. The pre-planning phase and monitoring of patient activity pre-clinical trial represents a critical aspect of a clinical trial that can dramatically impact its success.

Read more : https://www.prnewswire.com/news-releases/fishbat-shares-tips-for-monitoring-patient-activity-during-clinical-trial-recruitment-periods-300953824.html

How an AI solution can design new tuberculosis drug regimens

With a shortage of new tuberculosis drugs in the pipeline, a software tool from the University of Michigan can predict how current drugs -- including unlikely candidates -- can be combined in new ways to create more effective treatments.

Read more : https://www.sciencedaily.com/releases/2019/11/191121183925.htm

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