The Veeda Newsletter

AUG 2018
ISSUE 08

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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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Abu Dhabi pharmacies told to dispense generic medicines in new regulation

Pharmacies in Abu Dhabi have been told to dispense generic medicines to all patients and people who prefer a specific brand will have to pay the difference in price, according to a new decision by the health industry regulator.

Read More: https://gulfnews.com/news/uae/health/abu-dhabi-pharmacies-told-to-dispense-generic-medicines-in-new-regulation-1.2260407

FDA finalizes guidance on integrating EHRs into clinical trials

The FDA recently finalized an eagerly awaited guidance on the incorporation of electronic health records and real-world data into clinical trials and product submissions, including the use of patient medical histories, pharmacy records, radiology scans and lab test results from routine care, including from foreign clinical sites.

Read More: https://www.fiercebiotech.com/medtech/fda-finalizes-guidance-integrating-ehrs-into-clinical-trials

FDA Unveils FY 2019 GDUFA, BsUFA and MDUFA Fees

With the new five-year user fee programs now in their second year, generic drug and medical device companies are seeing increases in user fees while biosimilar companies are seeing decreases.

Read More: https://www.raps.org/news-and-articles/news-articles/2018/7/fda-unveils-fy-2019-gdufa-bsufa-and-mdufa-fees

United States: USFDA Advances On Patient-Focused Drug Development And Regulatory Decision-Making

USFDA released the draft guidance on 'Patient-Focused Drug Development: Collecting Comprehensive and Representative Input30' for Industry, Food and Drug Administration Staff, and Other Stakeholders.

ReadMore:http://www.mondaq.com/unitedstates/x/719828/food+drugs+law/USFDA+Advances+On+PatientFocused+Drug+Development+And+Regulatory+DecisionMaking

FDA Drafts 26 New Product Specific Guidances for Generic Drugmakers

The batch of new and revised US Food and Drug Administration (FDA) guidance features 43 product-specific guidances, including 26 new guidances and 17 revised guidances that, when finalized, will describe FDA’s expectations on how to develop generic drugs that are therapeutically equivalent to their respective reference-listed drugs.

Read More: https://www.raps.org/news-and-articles/news-articles/2018/7/fda-drafts-26-new-product-specific-guidances-for-g

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INDIAN PHARMA

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India keen to cooperate with local enterprises of Azerbaijan

India is interested in cooperation with the Agency for Development of Small and Medium-Sized Enterprises and the Azerbaijan Export and Investment Promotion Foundation (AZPROMO).
Read More: https://www.azernews.az/business/135713.html

Fixed Dose Combination drugs face another ban

Around 6,000 medicine brands belonging to different companies and with a combined market size of Rs 2,000-2500 crore may soon vanish from the Indian drug market, as a sub-committee of the Drugs Technical Advisory Board (DTAB) is likely to recommend the health ministry soon to ban or restrict these drugs, said sources.
Read More: https://www.businesstoday.in/current/corporate/fixed-dose-combination-drugs-face-another-ban/story/280747.html

India may look again at domestic serialization proposals

An Economic Times article says that the Central Drugs Standard Control Organisation will ask the group to "critically appraise" the plans, which envisage print a unique serial number on medicine packages so that consumers may authenticate the product via an SMS- or call-enabled check.
Read More: https://www.securingindustry.com/pharmaceuticals/india-may-look-again-at-domestic-serialization-proposals/s40/a8138/#.W1v6ntIzbIU

Indian drug companies eye opportunities in China

"The Chinese government has waived import tariffs for 28 drugs, primarily anti-cancer drugs and antibiotics, from 5-6 pc to zero," Udaya Bhaskar, Director, Pharmaceutical Exports Promotion Council (Pharmexcil), told BusinessLine on Friday.
Read More: https://www.thehindubusinessline.com/news/indian-drug-companies-eye-opportunities-in-china/article24534515.ece

R&D based Indian pharma players secure 125 final ANDA approvals from US FDA during first half of 2018

Indian Pharmaceutical companies and their subsidiaries have received 125 final ANDA approvals from US FDA during the first half ended June 2018 out of total 323 Abbreviated New Drug Applications (ANDA) approvals.
Read More: http://www.pharmabiz.com/NewsDetails.aspx?aid=110122&sid=1

Indian Pharma Industry's Revenues Estimated To Have Surged 7.4% In 2017

The Indian pharmaceuticals market witnessed growth at a compound annual growth rate (CAGR) of 5.64%, during 2011 to 2016, with the market increasing from US$ 20.95 billion in 2011 to US$ 27.57 billion in 2016.
Read More: https://www.business-standard.com/article/news-cm/indian-pharma-industry-s-revenues-estimated-to-have-surged-7-4-in-2017-118071300830_1.html

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CLINICAL RESEARCH

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First-of-its-Kind Clinical Trial Will Try and Cure Parkinson's Disease Using 'Reprogrammed' Stem Cells

Japanese scientists have just been given permission from the government to begin clinical trials for "reprogrammed" stem cells as a means of curing Parkinson's disease.

Read More: https://www.goodnewsnetwork.org/first-of-its-kind-clinical-trial-will-try-and-cure-parkinsons-disease-using-reprogrammed-stem-cells/

New research in mice shows triggering positivity could one day treat cancer

Scientists working on ways to combat dangerous cancers are exploring a treatment path that may wind up being as simple as feeling happy thoughts.

Read More: https://qz.com/1342588/new-research-in-mice-shows-triggering-positivity-could-one-day-treat-cancer/

Exploring the Use of Placebo in Cancer Clinical Trials

The use of placebos dates back to at least the end of the 18th century.3 After World War II, randomized controlled trials gained in popularity, making the inclusion of placebos more common.

Read More: https://www.oncnursingnews.com/publications/oncology-nurse/2018/august-2018/exploring-the-use-of-placebo-in-cancer-clinical-trials

Scientists are developing Organs-on-chips for new drug discovery

The approach of organs-on-chip is to recreate the natural physiological microenvironment of human cells inside particular tissues and organs

Read More: https://www.techexplorist.com/scientists-developing-organs-on-chips-new-drug-discovery/15773/

New drug discovery system can target 'undruggable' enzymes, say scientists

The research, which has been published in Cell, has demonstrated the capabilities of a new system to identify a molecule that could successfully target a phosphatase to reduce the accumulation of Huntington's disease-associated proteins in the brains of mice.

Read More: https://www.epmmagazine.com/news/new-drug-discovery-system-can-target-undruggable-enzymes/

For the first time in 15 years, a new drug promises to slow Alzheimer's

The drug could be available for use by patients within five years.

Experts said that the new treatment was the first significant step forward in the fight against the disease in 15 years.

Read More: https://www.express.co.uk/news/uk/994916/alzheimers-new-drug-spectacular-results-british-scientists-clinical-trial

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FINANCIAL NEWS

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Biocon targets $200 mn revenue from biosimilars on the back of EMs growth

Biotechnology major Biocon is aiming to register a 66 per cent growth in its biologics business this fiscal, which the company hopes will help it clock a revenue of $200 million on the back of emerging markets growth.

Read More: https://www.business-standard.com/article/companies/biocon-targets-200-mn-revenue-from-biosimilars-on-the-back-of-ems-growth-118073101511_1.html

US Savings From Generics Totaled $265.1 Billion in 2017, Says AAM

The report, which represents data derived from IQVIA, discovered that in 2017, 9 out of every 10 prescriptions in the United States were dispensed using generic drugs.

Read More: https://www.centerforbiosimilars.com/news/us-savings-from-generics-totaled-2651-billion-in-2017-says-aam

Local pharma market set to hit $5.11b by 2023

Bangladesh's pharmaceuticals sector will grow 15 percent year-on-year to reach $5.11 billion by 2023, propelled by high investments by local companies as they seek to grab a bigger share of the global market, said a new study yesterday.

Read More: https://www.thedailystar.net/business/local-pharma-market-set-hit-511b-2023-1614133

NHS saved £324million by switching from pricey drugs to cheaper generics

Patients with rheumatoid arthritis and some cancers and inflammatory bowel conditions received the cut-price pills.NHS Improvement said the NHS spent £17.4billion on medicine in 2016/17 – around 15 per cent of all NHS spending.

Read More: https://www.thesun.co.uk/news/6902276/nhs-saved-money-switching-to-cheap-pills/

Dr Reddy's Q1 net profit sees six-fold growth to Rs 4.76 billion

Dr Reddy's Laboratories Limited has reported more than a six-fold increase in consolidated net profit at Rs 4.56 billion for the quarter ended June 30, 2018, over an exceptionally lower base of Rs 0.6 billion in the corresponding quarter previous year

Read More: https://www.business-standard.com/article/companies/dr-reddy-s-q1-net-profit-sees-six-fold-growth-to-rs-4-76-billion-118072601520_1.html

Liquidia plans to use $50M from IPO to fund drug development

In the media world, print products appear to be going extinct. But the PRINT technology platform developed by Morrisville-based drug development company Liquidia Technologies is drawing eyeballs and investment in a very public way.

Read More: https://www.wraltechwire.com/2018/07/27/liquidia-plans-to-use-50m-from-ipo-to-fund-drug-development/

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MERGER & AQUISITION

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PSC Biotech Corporation and PSC Software Announce Acquisition of Three of the Four Largest Pharmaceutical Companies as Customers of Adaptive Compliance Engine™ aka ACE

PSC Biotech Corporation and PSC Software, a wholly owned division of PSC Biotech Corporation, is pleased to announce that its cloud-based enterprise quality management software is now used by three of the four largest health care companies in the world.

Read More: https://www.prnewswire.com/news-releases/psc-biotech-corporation-and-psc-software-announce-acquisition-of-three-of-the-four-largest-pharmaceutical-companies-as-customers-of-adaptive-compliance-engine-aka-ace-300690979.html

Aurobindo's Apotex deal marks 'Enter Europe' plan of Indian pharma companies

Hyderabad's has signed a definitive agreement to acquire Canadian pharmaceuticals company International Inc's commercial operations and certain supporting infrastructure in five European countries for €74 million (Rs 5.93 bn) in an all-cash deal.

Read More: https://hollandreview.com/aurobindo-acquires-apotex-incs-business-in-5-european-countries-for-e74-mn/7726/

AMPAC Fine Chemicals To Be Acquired By SK Holdings

AMPAC Fine Chemicals ("AFC"), a leading US-based Contract Development and Manufacturing Organization ("CDMO"), today announced its sale to SK Holdings ("SK"), an investment holding company of SK Group (South Korea).

Read More : http://markets.businessinsider.com/news/stocks/ampac-fine-chemicals-to-be-acquired-by-sk-holdings-1027367879

Cipla to acquire South African drug firm for $33M

India's drugmaker firm Cipla Ltd has agreed to acquire South Africa's Mirren (Pty) Ltd to strengthen its foothold in the African nation.Mirren, set up in 1983, makes over-the-counter (OTC) pharmaceutical products.

Read More: https://www.biospectrumasia.com/news/49/11270/cipla-to-acquire-south-african-drug-firm-for-33m.html

Aurobindo closing in on acquisition of Mallinckrodt's specialty generics ops: Report

Aurobindo Pharma is closing in on the acquisition of Mallinckrodt's specialty generics business in the US, including its portfolio of opioid-based painkillers, for $850-900 million, The Economic Times reported.

Read More: https://www.moneycontrol.com/news/business/aurobindo-closing-in-on-acquisition-of-mallinckrodts-specialty-generics-ops-report-2691411.html

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ARTICLE

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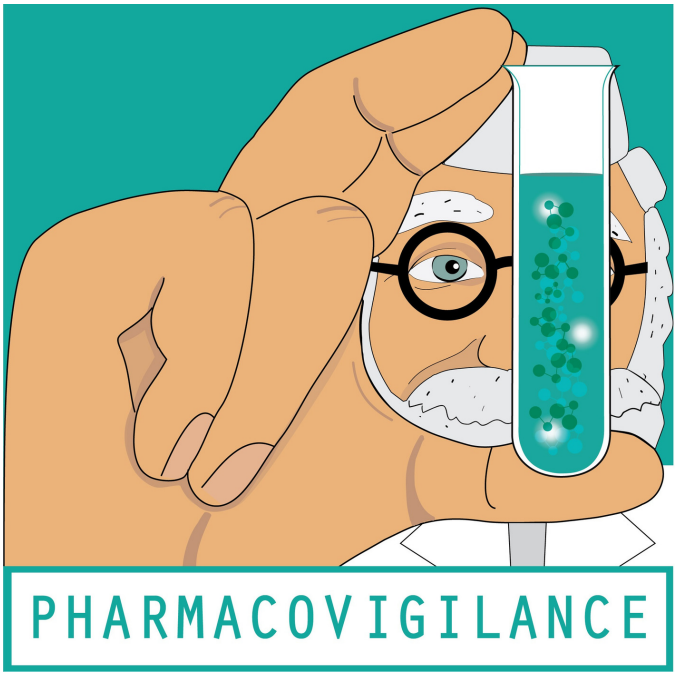
Positive signs for the Pharmacovigilance Market

Pharmacovigilance has a firm foothold in the medical sector as a consequence of mandatory drug safety monitoring. The Pharmacovigilance Market is gaining remarkable momentum due to a strict regulatory framework pertaining to drug testing and approval. Leading pharmacovigilance service providers often collaborate with CROs and their compeers to maximize their service portfolio and offer customized, foolproof services.

Key players accumulating a major share of the pharmacovigilance industry include Accenture, Cognizant Technology Solutions Corporation, Quintiles, Boehringer Ingelheim, Synowlwedge, Bristol-Myers Squibb, ICON, United BioSource, PAREXEL, and Covance. Mergers & acquisitions is a prime growth tactic adopted by these giants to sustain the market and counter their rivals.

Unique services ranging from drug testing, drug approval and drug commercialization provided by these companies will contribute to the expansion of the pharmacovigilance industry in the years to come. A report by Global Market Insights states that the pharmacovigilance market is expected to surpass a valuation of USD 8 billion by 2024, in comparison to USD 3 billion in 2015.



Credits: https://www.pharma-iq.com/business-development/articles/positive-signs-for-the-pharmacovigilance-market

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UPCOMING CONFERENCE

1. Bio Pharm America

Sep 5-6, 2018

Boston, MA, USA.

BIOPHARM AMERICA

2. CPhI Worldwide 2018

Oct 9-11, 2018

Madrid , Spain.

CPhI worldwide

3. BIO-Europe

Nov 5-7, 2018

Copenhagen, Denmark

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