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The Veeda Newsletter

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Bioanalytical Facility from Insignia has Successfully Relocated to the Satyamev and Vedant Facilities

Partners in Creating

a healthier tomorrow

Veeda News
Latest news about our Group CEO's attendance at SYNCHN 2024 and our webinar on Biosimilars

Regulatory
Oligonucleotides: EMA drafts new guideline on manufacturing and development

Financial
Union Budget 2024-25 allocates Rs. 89,287 crore for health sector

Clinical Research
Trial Approval for New Pacemaker Aiming to Boost Recovery in Heart Failure

Merger and Acquisition
Agilent Technologies to buy North American CDMO, Biovectra for $925 million

Indian Pharma
India focuses on new-age oncology care through new drugs and novel delivery devices

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Dr. Mahesh Bhalgat attends SYNCHN 2024, co-hosted by Biotechnology Department of Indian Government

The industry meet, SYNCHN 2024, was an ideal platform for industry leaders, start-ups, investors, funders, and academic researchers, to accelerate the development of new vaccines, diagnostics, therapeutics solutions and clinical trials.

Know More!

Our latest webinar on Advanced Strategies in Bioanalysis of Biosimilars: Achieving Similarity through Robust Assays

Watch the webinar to gain insights into the importance of robust bioanalytical assays in achieving biosimilarity, explore advanced strategies for optimizing bioanalytical methods and understand regulatory considerations and expectations in biosimilar bioanalysis.

Watch Now!

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Oligonucleotides: EMA drafts new guideline on manufacturing and development

The European Medicines Agency (EMA) on Monday issued a guideline that sets out the type of information required to develop, manufacture, and control new and existing oligonucleotide drugs.

EMA said the guideline addresses aspects of the manufacturing process, characterization, specifications and analytical control of synthetic oligonucleotides "which are not covered in the Guideline on the Chemistry of Active Substances (EMA/454576/2016) and Chemistry of Active Substances for Veterinary Medicinal Products (EMA/CVMP/QWP/707366/2017)."

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FDA makes exception for antibody drug conjugates in mass balance studies final guidance

The US Food and Drug Administration (FDA) has finalized a guidance that lays out clinical pharmacology information that sponsors of investigational drugs conducting human radiolabeled mass balance studies should include in their premarket applications. While the agency made some changes based on industry feedback, the final guidance is mostly unchanged from the draft version.

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Asia-Pacific Roundup: India health minister reviews drug, device regulations in push to raise standards

India's minister of health, J.P. Nadda, has reviewed the regulation of drugs and medical devices to establish a "world-class regulatory framework matching our scale of operations and international expectations."

Nadda has focused on raising quality since re-taking office this year, using an early meeting to set out plans to upgrade all drug and medical device manufacturing plants to "world-class standards" over the next three years.

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Biosimilars: FDA draft guidance addresses manufacturing changes

The US Food and Drug Administration (FDA) on Monday issued a draft guidance specifying how manufacturers should report postapproval manufacturing changes for licensed biosimilar and interchangeable products.

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FDA guidance addresses developing treatments for pediatric IBD

The US Food and Drug Administration (FDA) on Wednesday issued a draft guidance to spur the development of new treatments for pediatric ulcerative colitis (UC) and pediatric Crohn's disease (CD), two types of inflammatory bowel disease (IBD). The guidance addresses study population, study design, efficacy considerations, and safety assessments. The guidance does not address extraintestinal manifestations, stricturing or fistulizing disease, or treatment of long-term complications of pediatric UC or CD.

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Torrent Pharma tanks 4% post Q1FY25 results; analysts update target prices

Shares of Torrent Pharma slumped up to 4.26 per cent at Rs 646.70 per share on the BSE in Wednesday's intraday deals. This came despite the Indian drugmaker delivering a strong April-June quarter for the financial year 2024-25 (Q1FY25). However, some analysts have cut the target price of the company considering its significant run up in the last three months.

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Healthcare industry experts welcome Union Budget 2024-25

Healthcare industry experts have welcomed various initiatives announced by the Central Government in the Union Budget 2024-25, including the exemption of customs duty for three cancer drugs and the proposed changes in Basic Customs Duty (BCD) for X-ray machine components.

Dr. Ashutosh Raghuvanshi, MD & CEO, Fortis Healthcare Limited said, "We appreciate the government's decision to exempt three cancer drugs from customs duty in the FY 2024-25 budget. Cancer treatment often involves a significant financial burden for patients and their families. By exempting these drugs from customs duty, the government has taken a concrete step towards alleviating this burden, making essential medications more affordable for those in need across the country".

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Union Budget 2024-25 allocates Rs. 89,287 crore for health sector

The Union Budget 2024-25 has allocated around Rs. 89,287 crore for the healthcare sector, with a marginal increase from Rs. 88,956 crore allocated during the previous fiscal year.

The allocation for production linked incentive (PLI) scheme for pharmaceutical industry, however, has seen a growth of 78.6 per cent in budget estimate to Rs. 2,143 crore as compared to Rs. 1,200 crore budget estimate in the previous fiscal.

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US government to fund up to $500 mln for studies on oral, nasal COVID vaccines

The funding is part of Project NextGen, a $5 billion initiative led by the Biomedical Advanced Research and Development Authority (BARDA), to advance a pipeline of new, innovative vaccines and therapeutics providing broade and more durable protection against COVID-19 infection.

UK's Global AMR Innovation Fund (GAMRIF) has committed up to £5.1 million funding over 3 years to the Centre for Cellular and Molecular Platforms (C-CAMP) to foster the identification and development of AMR-focused innovative solutions. The project has a special focus on addressing challenges in low- and middle-income countries (LMICs) with local, contextual solutions.

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Syngene in Q1 reports decline in revenue by 2% to Rs. 790 crore, PAT down to 19% with dip in US funding

Syngene International in its first quarter results reported revenue from operations declined 2% year-on-year to Rs. 790 crore as against Rs. 808 crore in the corresponding quarter last year. Reported profit after tax declined 19% year-on-year to Rs. 76 crore as against Rs. 93 crore in the corresponding quarter last year.

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Trial Approval for New Pacemaker Aiming to Boost Recovery in Heart Failure

Cysoni-XT is a temporary cardiac pacemaker which aims to boost cardiac performance by resynchronisation of the heart and lungs, a natural phenomenon known as Respiratory Sinus Arrythmia (RSA).

The system has shown a remarkable ability to boost performance and induce cardiac repair mechanisms in subjects with heart failure.

Read More

'Biolyst Scientific' Announced as New Brand Name to Encompass EMS and Azer, Will Deepen Offerings to Clinical and Research Lab Customers

Biolyst Scientific today announced its new brand name, reflecting the integration of Electron Microscopy Sciences (EMS) and Azer Scientific. The combined company blends extensive industry knowledge with an uncommon passion to make a difference – creating clinical, research, economic, and relationship value every day.

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Biopharma PEG Announces Key Product Line of Monodispersed PEGs for Advanced Pharmaceutical Applications

Biopharma PEG, a leading supplier of high-quality polyethylene glycol (PEG) derivatives, is excited to highlight its important product line of monodispersed PEGs. These products are critical for applications in Antibody-Drug Conjugate (ADC) linkers, Proteolysis Targeting Chimeras (PROTAC) linkers, and PEGylated proteins and peptides, offering significant advancements in drug stability and delivery.

Biopharma PEG

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Revolutionizing Clinical Trials with Generative AI

The rapid advancements in artificial intelligence, particularly generative AI (GenAI), are enabling broader technology acceleration and driving a significant transformation in the healthcare industry. This democratization of AI capabilities opens the door to widespread innovation across clinical trials and drug development and represents a unique change in thinking compared to previous technological advancements.

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Children's Hospital Colorado Launches Research Institute For Children's Health

After more than 50 years of working together, Children's Hospital Colorado has established a formal partnership with University of Colorado Anschutz Medical Campus to launch the Colorado Child Health Research Institute. The Institute aims to unite more than 500 physician-scientists, researchers, nurse-scientists, and other investigators and enable them to develop treatments that improve the lives and health of child patients. The Institute also brings together six health professional schools at CU Anschutz Medical Campus, including School of Medicine, College of Nursing, Skaggs School of Pharmacy and Pharmaceutical Sciences, School of Dental Medicine, the Colorado School of Public Health, and the Graduate School.

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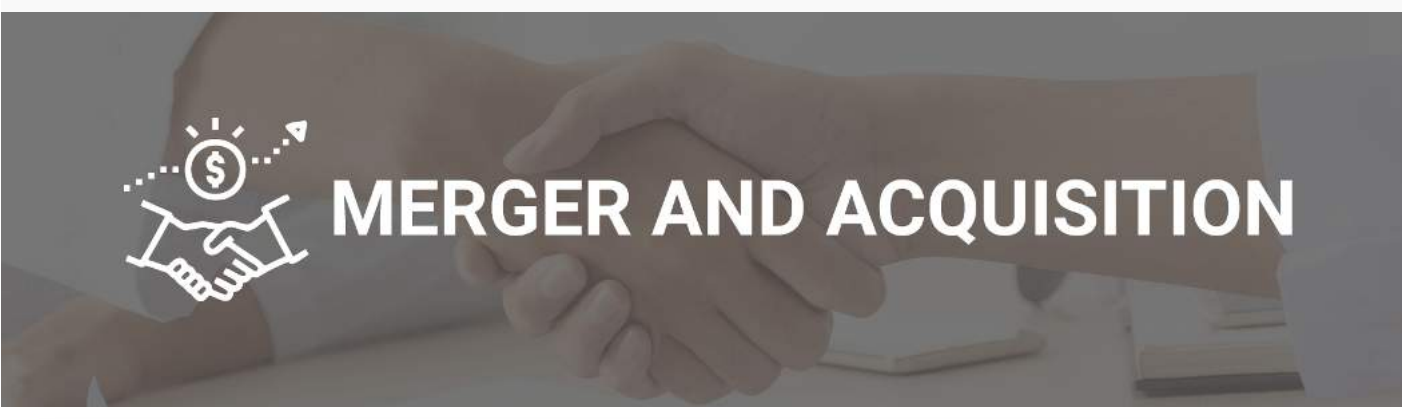

Agilent Technologies to buy North American CDMO, Biovectra for $925 million

Agilent Technologies Inc. announced it has signed a definitive agreement to acquire Biovectra, a leading specialized contract development and manufacturing organization (CDMO), for $925 million.

Based in Canada, Biovectra produces biologics, highly potent active pharmaceutical ingredients, and other molecules for targeted therapeutics.

The acquisition builds on Agilent's CDMO specialization in oligonucleotides and CRISPR therapeutics in three key areas: Expand portfolio of services, add rapidly growing modalities & Bring world-class capabilities to support gene editing.

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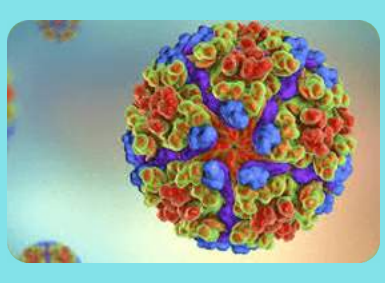
CEPI expands partnership with Valneva with $41.3 million to support broader access to world's first chikungunya vaccine

The Coalition for Epidemic Preparedness Innovations (CEPI) and Valneva SE, a specialty vaccine company, have expanded their partnership to support broader access to the world's first chikungunya vaccine, Ixchiq, in Low- and Middle-Income countries (LMICs), as well as post-marketing trials and potential label extensions in children, adolescents and pregnant women.

CEPI will provide Valneva up to US $41.3 million of additional funding over the next five years, with support from the European Union's (EU) Horizon Europe programme. The project will help generate additional data to potentially support extended Ixchiq labels in chikungunya- endemic countries and vulnerable populations at risk of being infected with this debilitating mosquito-borne disease.



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GE HealthCare to acquire clinical AI business from Intelligent Ultrasound for $51 million

GE HealthCare, a leading global medical technology, pharmaceutical diagnostics, and digital solutions innovator, announced it has entered into an agreement to acquire Intelligent Ultrasound Group PLC's (Intelligent Ultrasound) clinical artificial intelligence (AI) software business for total consideration of approximately $51 million.

Intelligent Ultrasound is a leader in integrated AI-driven image analysis tools designed to make ultrasound smarter and more efficient. GE HealthCare plans to incorporate these solutions across the ultrasound portfolio, strengthening its capabilities with technology that helps improve workflows and enhance ease-of-use for the benefit of clinicians and patients.

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Grünenthal acquires US-company Valinor Pharma for approx. $250 million

Grünenthal, a global leader in pain management and related diseases, announced the acquisition of US-based Valinor Pharma, LLC (Valinor) and its product Movantik (naloxegol), with a total deal value of approx. $250 million inclusive of all royalty obligations. Grünenthal will finance the transaction using available liquidity.

Movantik is indicated for the oral treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain. The transaction further expands Grünenthal's portfolio of established medicines and adds to the company's growing US business. Gross sales from Movantik in the United States reached over $200 million in 2023.

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MedLern opens new campus in Bengaluru in collaboration with Impelsys

MedLern, a medtech startup focused on digital learning solutions for hospitals and healthcare professionals, has inaugurated its new campus in Bengaluru. The event took place at their new location within the HPE campus in Mahadevapura and was officiated by senior executives from Impelsys, alongside key clients and partners from around the globe, including senior leadership from the American Heart Association.

The new campus marks a pivotal milestone for MedLern and its campus partner, Impelsys, a global technology company specializing in digital transformation, eLearning, and publishing platforms. This state-of-the-art facility will serve as a hub for innovation, focusing on streamlining training requirements and providing reliable, up-to-date learning resources for healthcare professionals..

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India focuses on new-age oncology care through new drugs and novel delivery devices

India's focus on new-age oncology care through new drugs and novel delivery devices underscores its role to address critical medical needs. This emphasises the need to maximise the country's pharmaceutical expertise and research capabilities.

From Aurobindo, Biocon, Sun Pharma, Zydus Cipla, Dr Reddy's Laboratories, Lupin, Glenmark to Venus Remedies, Shilpa Medicare, Odon Lifesciences, Intas and Torrent to name a few, are exploring innovative therapies and delivery methods. India aims to improve patient outcomes and contribute significantly to the fight against cancer on a global scale.

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Indian pharma to take advantage of GenAI potential to streamline drug discovery, reduce cost & time-to-market

The Indian pharmaceutical industry is working to take advantage of Generative AI potential to transform drug discovery. Functions such as establishing connections between the causative pathways and showing the genetic predispositions have the potential to enable successful interventions and revert disease progression.

There is no better time for pharmaceutical companies to seize the transformative potential of generative AI and what's more is that they wouldn't have to take this step without digital innovation support. GenAI has become a part of almost all aspects of the pharmaceutical industry, enhancing the rate of drug discovery, clinical trials, pattern recognition, and above all, reducing the costs involved, said Kapil Mehta, senior director, technology solutions, Visionet.

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Indian healthcare looks for improved public medical services with strong last-mile delivery mechanisms

The sector is of the view that this would create a positive economic impact. It would prevent expenses on health and productivity losses.

The country's diverse terrain brings in challenges for patient care and life-saving healthcare. Adequate availability of essential medical services including vaccines are vital to avert outbreaks and avoid life loss resulting from preventable diseases, said Ankita Mittal, CEO, Enhanced Innovations.

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India's lower-income groups severely impacted with financial challenges to treat cancer

India's lower-income groups face significant financial challenges when it comes to cancer treatment. High medical costs, lack of insurance coverage, and limited access to quality healthcare services exacerbate the situation. Many families are seen to opt between basic necessities and treatment, leading to increased mortality rates and a higher burden of disease.

There is a need for government and even private hospitals to come forward and provide special amenities, lower treatment cost so that the overall number of cancer cases in India can reduce, said Jyotsna Govil, Chairperson of Indian Cancer Society, Delhi Branch.

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Rezum Water Vapor Therapy offers relief to patients with benign prostate hyperplasia across India

Boston Scientific recently announced the successful completion of the 100th procedure using the company's Rezum Water Vapor Therapy to treat benign prostatic hyperplasia (BPH). Since the technology's first use in India in January 2024, the minimally invasive procedure has treated BPH in patients across states including Delhi NCR, Haryana, Punjab, Maharashtra, Gujarat, West Bengal, Kerala, Karnataka and Telangana.

BPH is a condition in which the prostate becomes enlarged and obstructs the flow of urine, causing symptoms such as difficulty urinating, inability to completely empty the bladder and a frequent or urgent need to urinate, including at night. It affects about 50% of men by age 60, and 90% of men by age 85. The 100 patients in India who have been treated with the Rezum System so far are between the ages of 46 and 91.

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