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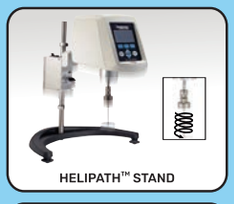
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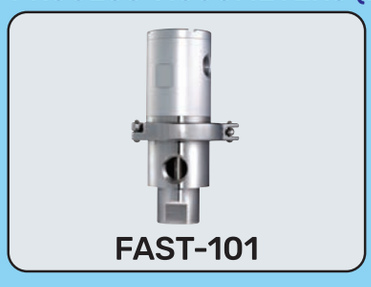
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Sun Pharma announces approval of Winlevi in Australia

Hellen de Kloet, Business Head – Western Europe, Australia and New Zealand, Sun Pharma

Mumbai, India: Sun Pharmaceutical Industries Limited announced that the Australian Therapeutic Goods Administration (TGA) has granted regulatory approval for Winlevi® (clascoterone cream 1%). Winlevi is indicated for the topical treatment of acne vulgaris in patients 12 years of age and older.

As stated by Hellen de Kloet, Business Head – Western Europe, Australia and New Zealand, Sun Pharma "Winlevi® is an exciting addition to our expanding dermatology portfolio of innovative medicines in Australia. Winlevi's novel mechanism of action will be a welcome addition to the physician's toolkit while treating acne."

Diana Harbort, President of the Dermatology Division of Cosmo, said: "We are very pleased that Winlevi will soon be available to patients in Australia. This is another achievement in the mission of Cosmo and Sun Pharma to improve the lives of patients affected by skin conditions."

Eris Lifesciences acquires the commercial rights to Biocon Biologics' India Branded Formulations business

Amit Bakshi, Chairman & Managing Director of Eris Lifesciences Ltd.

Mumbai, India: Eris Lifesciences Ltd., a leading branded formulations company, today announced the acquisition of Biocon Biologics' India branded formulation business for a consideration of ₹.1,242 crore thereby jumpstarting its entry into the Rs. 30,000+ crore injectables market in India and becoming a leading player in the Insulins segment.

The acquisition brings two major insulin brands – Basalog and Insugen – into the Eris fold. These are the largest Indian brands in their respective segments with market shares of over 10%. With this acquisition, Eris's Diabetes care franchise will soon reach ₹.1,000 crore in revenue and become the 5th largest diabetes portfolio in India. This acquisition will also mark Eris' entry into Oncology and Critical Care.

Eris has signed a 10-year supply agreement with Biocon Biologics Ltd. as part of this deal. Under this agreement, the Biocon product range will continue to be manufactured and supplied to Eris for commercialization in India. This acquisition also provides immediate synergies with the recently acquired Swiss Parenterals business. The Biocon product range can be quickly scaled up by leveraging the product portfolio of Swiss, which consists of 240+ unique molecules. The combination of the two deals also provides margin expansion opportunities through insourcing/ technology transfer of manufacturing to Swiss' facilities.

Commenting on the acquisition, Amit Bakshi, Chairman & Managing Director of Eris Lifesciences Ltd., said, "We consider it an honour and privilege to enter into this long-term collaboration with Biocon which is an organisation known for its remarkable pedigree and its pioneering efforts in the Biosimilars space in terms of innovation, product quality and interchangeability. We believe that we will be able to build on their success and take this franchise to new heights. This deal, combined with the acquisition of Swiss Parenterals that we announced last month will turbocharge our entry into the ₹.30,000+ crore India Branded Injectables market and pave the way for our next ₹.1,000 crore vertical in the next 3-4 years. Over the last 2 years we have added a number of strategic growth engines to our portfolio and now we have all the building blocks in place to be able to achieve our target of ₹.5,000 crore revenue over the next 3-4 years."

Lupin appoints Christoph Funke as Chief Technical Operations Officer

Mumbai, India: Global pharma major Lupin Limited announced the appointment of Christoph Funke to the newly-created position of Chief Technical Operations Officer. With over 30 years of global pharmaceutical manufacturing, supply chain, and technical operations experience, Christoph brings a wealth of expertise to Lupin. He will be based in Mumbai and will oversee Lupin's Technical Operations function, integrating manufacturing, supply chain, and procurement.

Amit Bakshi, Chairman & Managing Director of Eris Lifesciences Ltd.

Christoph's extensive career includes leadership roles at organizations such as Fresenius Kabi and Strides Pharma Science. In his leadership roles, Christoph has managed large-scale technical operations and manufacturing networks across 27 sites in 19 countries, overseeing production value exceeding US$ 2 billion and leading teams of over 12,500 employees. Christoph holds an engineering degree from South Westphalia University of Applied Sciences, Germany.

Commenting on the appointment, Lupin's CEO, Vinita Gupta, and MD, Nilesh Gupta said, "We are delighted to welcome Christoph to our executive leadership team. His impressive track record and extensive experience across manufacturing, supply chain, and technical operations make him a valuable addition as we continue to advance our mission of improving patient lives globally."

Akums Drugs and Pharmaceuticals Introduces Stable Oral Suspension of Hydroxyurea for treatment of Sickle Cell Disease

New Delhi, India: Akums Drugs and Pharmaceuticals, India's largest Contract Development and Manufacturing Organization (CDMO), proudly announces a significant progress in the fight against Sickle Cell Disease (SCD) with the launch of a Room Temperature Stable oral suspension of Hydroxyurea. This innovative formulation, designed to manage SCD, eliminates the need for cold storage, thereby enhancing accessibility and affordability for SCD patients nationwide.

SCD, a genetic blood disorder, profoundly impacts individuals, causing anemia, pain crises, and affecting vital organs. It is particularly prevalent in India's tribal populations, constituting 8.6% of the country's population according to the 2011 Census. Recognizing its significance, the Ministry of Health and Family Welfare has identified Sickle Cell Disease as a priority health issue, emphasizing the need for targeted interventions.

Under the visionary leadership of Honorable Health Minister Shri Mansukh Mandviya Ji and with invaluable guidance from esteemed member of Niti Aayog, Dr. V K Paul Ji, Akums has achieved this milestone. This innovative product is thoughtfully accompanied by oral syringes for precise dosage administration for pediatric, adolescent and adults.

Sanjeev Jain, Joint Managing Director of Akums Drugs and Pharmaceuticals, expressed, "Akums is passionately committed to advancing a noble cause and ensuring accessibility to affordable medication for SCD patients. In alignment with the objectives outlined in the National Sickle Cell Anemia Mission, as announced by the Honorable Prime Minister, Shri Narendra Modi Ji, Akums pledges to provide this innovative medicine at an affordable cost."

Sandeep Jain, Joint Managing Director of Akums Drugs and Pharmaceuticals, affirmed, "We are dedicated to supporting the 'Make in India' initiative by researching high-quality pharmaceuticals. We aspire to make available the Hydroxyurea Oral Suspension, manufactured at a dedicated facility, to the government at less than 1% of the cost of the global brand imported in India, ensuring equitable access to life-saving medication for all SCD patients."

This product has received regulatory approval from the Drug Controller General of India (DCGI) following rigorous review and bioequivalence studies, marking a significant milestone in Akums' commitment to Quality medicine for India and globally.

In contrast to the current import price of approximately ₹.77,000 for the global brand of Hydroxyurea solution, which necessitates storage at 2 to 8 degrees Celsius, Akums has innovated a room temperature stable oral suspension of Hydroxyurea suitable for Indian patients' requirements.

CuraTeQ Biologics announces the Phase 1 clinical study outcome of their BP11 product

Dr. Arpit Prajapati, Head of Clinical Sciences at CuraTeQ Biologics

Hyderabad, India: CuraTeQ Biologics Private Limited, a wholly owned subsidiary of Aurobindo Pharma Ltd, announced that their Omalizumab biosimilar candidate BP11 has met the Phase 1 trial end points vis-à-vis the EU and US sourced reference product Xolair. The PK/PD trial was conducted in 165 healthy volunteers in Australia and New Zealand.

"The primary objective was to prove pharmacokinetic (PK) equivalence between BP11, US and EU sourced Xolair. 165 healthy volunteers were randomized to receive either BP11 or EU or US licensed Omalizumab via subcutaneous route of administration. Results of both primary parameters, i.e. maximum serum concentration (Cmax) and area under concentration-time curve from time zero to infinity (AUC0-inf), were contained within 80-125% bioequivalence limit demonstrating PK equivalence between BP11 and both US and EU sourced Xolair. BP11 also had similar IgE levels to Xolair demonstrating comparable pharmacodynamic profile versus US and EU sourced Xolair. The safety and immunogenicity profiles were also found comparable versus the originator's product," said Dr. Arpit Prajapati, Head of Clinical Sciences at CuraTeQ Biologics.

Dr. Disha Dadke, Associate President and Head R&D, said, "We have initiated a Phase 3 study of our Omalizumab candidate BP11 for the treatment of chronic spontaneous or idiopathic urticaria, which is a presence of hives that are itchy and can last for a number of weeks with no apparent external trigger. The Phase 3 efficacy and safety study is being conducted across multiple sites in seven European countries and in 600 patients with chronic spontaneous urticaria. Additionally, a separate Phase 3 trial in asthma patients is being carried out in the Indian population. CuraTeQ intends to file the Omalizumab biosimilar product in India in 2024 and is on track to file the product in regulated markets in 2025."

Cadila Pharmaceuticals unveils Iron Injection, a revolutionary Treatment for Iron Deficiency Anaemia

Dr. Rajiv I. Modi, Chairman, and Managing Director of Cadila Pharmaceuticals

Ahmedabad, India: Cadila Pharmaceuticals, a pioneer in the pharmaceutical industry, proudly announces the launch of a novel iron injection, a next-generation solution for addressing Iron Deficiency Anaemia. The product will be available as Redshot FCM, fortified with the advanced Ferric Carboxymallose formulation, designed for administration to both adults and paediatric patients over one year of age, especially those with oral iron intolerance.

Redshot Injection stands out as an intravenous iron preparation that not only delivers effective amounts of iron but also boasts an exemplary safety profile. With superior tolerability and minimal to zero risk of anaphylaxis, Redshot accelerates the improvement of haemoglobin levels and efficiently replenishes depleted iron stores. Offering heightened tolerability, the intravenous delivery of iron in Redshot facilitates the utilization of high doses in a single administration.

Anaemia, characterized by impaired physical activities, general weakness, lethargy, and fatigue, often goes unnoticed and is inadequately managed, particularly in pregnancy, the elderly population, and cancer patients. Remarkably, Redshot addresses this gap, as anaemia is prevalent in cancer patients and has been linked to lower survival rates for those grappling with this deficiency. Anaemia in pregnancy, if not treated, can complicate childbirth and can put mothers and neonates at serious risks.

Dr. Rajiv I. Modi, Chairman, and Managing Director of Cadila Pharmaceuticals, stated, "This innovation exemplifies our commitment to pharmaceutical excellence, contribution to the safe motherhood initiative, and correction of a very common health condition of iron deficiency anaemia. It not only offers superior tolerability but also presents a transformative approach to replenishing iron stores rapidly and efficiently."

Cadila Pharmaceuticals remains committed to advancing healthcare solutions and is proud to bring Redshot Injection to the forefront, offering a

transformative approach to combating Iron Deficiency Anaemia. With its innovative formulation and enhanced safety features, Redshot marks a significant leap forward in the treatment landscape, ensuring a brighter and healthier future for patients worldwide.

AstraZeneca Pharma partners with Mankind Pharma

Bangalore, India: AstraZeneca Pharma India Limited and Mankind Pharma Ltd., entered into an agreement for exclusive distribution of AstraZeneca's budesonide and formoterol fumarate dihydrate (inhaled corticosteroid (ICS) and long-acting beta-agonist (LABA) combination) brand Symbicort in India. AstraZeneca will retain the intellectual property rights to budesonide and formoterol fumarate dihydrate and will continue to be the Marketing Authorisation Holder (MAH) and import license.

India is contributing 13% to the global asthma burden and a disproportionate 43% of the global asthma deaths. It highlights a clear scope of improving the way asthma is managed in the country1. " Our aspiration is to be pioneers in science and lead in specialist disease areas. We are focused on transforming outcomes for patients and contributing sustainably to people, society and the planet. The partnership with Mankind Pharma presents an opportunity to accelerate access and maximize the potential of our asthma drug as well as the turbuhaler which is a simple device2, efficient in consistently delivering a higher proportion of respirable particles than the other devices. As much as we are excited to bring innovative medicine to India fast, we are equally invested on improving access strategically in the country" said Dr. Sanjeev Panchal, Country President and Managing Director, AstraZeneca India.

With an expansive distribution network including close to 16,000 field force and more than 13,000 stockists across India, Mankind Pharma has positioned itself as a leader in ensuring availability and access to quality pharmaceuticals across the country, including small towns and rural areas. Commenting on the agreement with AstraZeneca India, Mr Atish Majumdar, Sr. President – Sales & Marketing, Mankind Pharma Limited said "Mankind has always been steadfast in providing access to quality treatments to the deserving patients across the nation. In this regard, we are excited to partner with AstraZeneca to make their innovative therapy flagship brand Symbicort, a global standard in treating Asthma. Symbicort's dual mechanism of action and ease of use in a single inhaler can greatly help patients manage these conditions and improve their quality of life. Through our field forces' extensive outreach, we hope to strengthen access across urban and rural markets. With our shared goal to enable better patient outcomes, I see this collaboration as strategic in more ways than one. We believe such credible partnerships that widen availability of globally established medicines in India exemplify our ethos of putting patients first while ensuring value."

Globally AstraZeneca is an established leader in respiratory care, a disruptor in immunology and will continue to transform care for some of the most debilitating and chronic respiratory and immune-mediated diseases. With an ambition to transform Respiratory & Immunology care for patients in India, moving beyond symptom control to disease modification, remission and, one day, cure, AstraZeneca India is focused to be number 1 in respiratory Biologics.

EY-CII report reveals 67% Indian healthcare companies have set up ESG board committees

Mumbai, India: Highlighting a significant stride towards environmental responsibility, the latest report from EY and CII reveals that over half of Indian healthcare firms have embraced zero liquid discharge and implemented sustainable sourcing practices as part of their environmental, social and governance (ESG) commitments. Titled 'How can sustainability and ESG be the microscope and telescope in the Indian healthcare sector', the report underscores a noteworthy surge in renewable energy adoption and sustainable sourcing practices, indicative of a heightened awareness of environmental impact.

The report further unveils compelling statistics: 18% of the energy utilized by healthcare providers now stems from renewable sources, signalling a progressive shift towards renewable energy adoption. Additionally, 61% of inputs employed by these companies are sustainably sourced, underscoring a concerted drive towards responsible procurement practices. 53% of companies have also implemented zero liquid discharge (ZLD).

Moreover, the healthcare sector demonstrates a commitment to diversity and inclusion, with 41% of the female employees and 22% female representation on company boards. Furthermore, over 67% of the companies have established ESG committees, highlighting a proactive approach towards governance and sustainability initiatives within the sector.

Reflecting on the trends, Kaivaan Movdawalla, Partner and Healthcare Leader, EY Parthenon India said, "Sustainable progress in the healthcare sector requires a multifaceted approach, particularly through the adoption of lean and green energy practices. With healthcare being a high-consumption industry, it is crucial to streamline consumption needs through leaner staffing strategies, precise HVAC (Heating, ventilation and air-conditioning) control systems, and maximizing the utilization of green energy sources for a sustainable future. Moreover, rethinking packaging designs with a focus on green packaging to align with optimal environmental outcomes is essential. Effective and efficient disposal methods are essential for long-term sustainability and mitigating environmental impact. Given the urgency of addressing climate change and healthcare's pivotal role, stakeholders must act promptly. Our report offers timely and actionable insights, guiding the sector towards a resilient future."

Venus Remedies secures regulatory approvals for three key oncology drugs in Ukraine

Mumbai, India: Venus Remedies, one of India's leading exporters of generic medicines in critical care segments, has further expanded the reach of its oncology drugs in the Asia Commonwealth of Independent States (CIS) region with marketing authorisations from Ukraine for three cancer drugs, including paclitaxel, oxaliplatin and irinotecan.

With revenues projected to grow from US $607 million in 2022 to US $650.90 million by the end of this year, the Ukrainian pharmaceutical market has been witnessing steady growth. Venus Remedies' emphasis on securing marketing approvals across the globe reflects its commitment to addressing the rising demand for high-quality healthcare solutions.

Having a presence in the Ukrainian market for more than two decades, Venus Remedies has 57 product registrations in Ukraine. Its total volume of exports to Ukraine stands at $2.20 million. By strengthening its product portfolio in Ukraine, the company aims to increase this figure by 20 per cent in the next one year.

Describing these marketing authorisations as a major stride in the company's global consolidation, Saransh Chaudhary, President, Global Critical Care, Venus Remedies, said, "These marketing approvals mark a significant milestone in our global expansion strategy. We are looking forward to introducing the entire range of our oncology products in Ukraine in due course, thereby contributing to the advancement of healthcare and making a positive impact on people's lives."

Aditi K. Chaudhary, President, International Business, Venus Remedies, said these marketing approvals from Ukraine mark a significant milestone for the company as it continues to expand its global reach. "This achievement has further strengthened our position in the international pharmaceutical market. It also exemplifies our dedication to advancing healthcare solutions for diverse populations."

Venus Remedies is awaiting approval from Ukraine on another 10 applications for marketing authorisations. With a population of 46.6 million, Ukraine is one of the largest countries in Europe, thus making it a potentially lucrative pharma market.

While Venus Remedies is the fourth largest exporter of chemotherapy drug paclitaxel from India, it is the sixth largest Indian exporter of oxaliplatin, another chemotherapy medication, and irinotecan, an antineoplastic agent. India exports paclitaxel, which is effective against advanced cancers, to 96 countries, oxaliplatin to 77 countries and irinotecan to 61 countries. The markets where Venus Remedies has been exporting these drugs include Germany, Saudi Arabia, Malaysia, Indonesia, Philippines, Colombia, Venezuela, Morocco, Thailand, Botswana, Myanmar, Guyana, Tanzania, Kenya, Zimbabwe, Pakistan, Mozambique, Senegal and Guatemala.

Aurobindo Pharma receives USFDA approval for Mometasone Furoate Monohydrate Nasal Spray

Hyderabad, India: Aurobindo Pharma Limited has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Mometasone Furoate Monohydrate Nasal Spray, 50 mcg/spray, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Nasonex Nasal Spray, 50 mcg/spray of Organon LLC. The product will be launched in Q1FY25.

The approved product has an estimated market size of US$ 44.5 million for the twelve months ending January 2024, according to IQVIA. Aurobindo now has a total of 507 ANDA approvals (488 Final approvals and 19 tentative approvals) from USFDA.

Mometasone Furoate Monohydrate Nasal Spray, 50 mcg/spray, is indicated for the treatment of the nasal symptoms of seasonal allergic and perennial allergic rhinitis, in adults and paediatric patients 2 years of age and older.

Nitesh Mehrotra, Partner, ESG & Sustainability, EY India, said, "Sustainability and climate change represent the most significant megatrends of our generation, impacting the healthcare ecosystem and its diverse

stakeholders, including investors, customers, patients, regulators, employees, and value chain partners. To achieve sustainable progress in the sector, transitioning to renewables, embracing circularity, and establishing a net-zero transition plans are imperative. This will help in reducing carbon waste and delivering truly sustainable care. Healthcare providers and systems must now focus on reducing consumption and waste in their supply chains."

The report highlights increasing allocations towards environmental and social initiatives within research & development (R&D) and capital expenditure (capex). Impressively, 21% of spending is dedicated to environmental and social activities in R&D, showcasing a commitment to innovation and sustainable practices. Equally noteworthy is the allocation of 13% of spending towards environmental and social initiatives within capex, affirming a strategic commitment to infrastructure and operational enhancements for bolstering sustainability performance.

Dr. Reddy's Laboratories launches Versavo (bevacizumab) in the UK

Hyderabad India: Dr. Reddy's Laboratories Ltd, a global pharmaceutical company announced the launch of Versavo (bevacizumab) in the United Kingdom (UK). Dr. Reddy's Versavo is a (bevacizumab) biosimilar of Avastin and indicated for the treatment of several types of cancers, including metastatic colorectal cancer, advanced non-squamous non-small cell lung cancer,recurrent glioblastoma, metastatic renal cell carcinoma, advanced cervical cancer, ovarian cancer and metastatic breast cancer.

Versavo is the first Dr. Reddy's biosimilar product to be approved and launched in the UK. It is available in strengths of 100mg and 400mg single use vials.

Dr. Reddy's launched Versavo in India in 2019. Subsequently, Versavo was introduced in other markets such as Thailand, Ukraine, Nepal, and Jamaica under the same brand name. In Colombia, the product was launched under the brand name Persivia.

Dr. Jayanth Sridhar, Global Head of Biologics at Dr. Reddy's, said: "The launch of Versavo in ahighly regulated market underscores our capability for global clinical development of high-quality biosimilar products. Versavo is a potential treatment option for patients with different types of cancers. This launch reinforces our commitment to bring more biosimilar and other critical biological products to meet the unmet needs of patients, and strengthens our focus on oncology."

Glenmark ranks #1 in dermatologist prescriptions for Protective Emollients Category and Prescribing Derma therapy

Alok Malik, President and Business Head – India Formulations, Glenmark Pharma

Mumbai, India: Glenmark Pharmaceuticals Ltd. (Glenmark), a research-led, global pharmaceutical company, has been ranked number 1 in dermatologists' prescriptions in the protective emollients category and for prescribing derma therapy. This is based on the IQVIA medical audit for MAT Dec 2023 (as per Projected Prescriptions) in India. Projected prescriptions figures are for the period from Jan 2023 to Dec 2023.

Key products in Glenmark's dermatology portfolio including Episoft, Candid Dusting Powder®, Momate, Canditral SB®, La Shield, Scalpe+, Tacroz ointment, etc. have made significant strides in providing effective solutions for multiple dermatological conditions. The Company's flagship brand Candid® Powder delivered revenue growth of 20% for Q3 FY24. La Shield® portfolio delivered YoY revenue growth of 20%, while Scalpe®+ portfolio witnessed YoY revenue growth of 12.2% in Q3 FY24.

Alok Malik, President and Business Head – India Formulations at Glenmark Pharmaceuticals Ltd, said, "We are very excited to be ranked number 1 by prescription in the dermatology therapy as per IQVIA. Our strategic focus and expertise in dermatology reflect our commitment to advancing dermatological care and addressing a broad spectrum of skin health needs of patients in India. Leveraging a robust derma portfolio that spans a wide array of treatments, Glenmark is at the forefront of addressing both common and complex skin conditions."

Glenmark continues to outperform the market in the Dermatology segment. In the market analysis ending December 2023, the dermatology sector in Indian Pharmaceutical Market (IPM) grew 6.2% on a moving annual total (MAT) basis. GPL outperformed the overall market with a dermatology value growth of 9.9%. With a market share of 7.49% in the dermatology sector as per MAT Dec 2023. ■

Biotech Boom in India Reshaping Healthcare

India's historical advantage in vaccines and drugs fueled the rise of diagnostics and new tech, which played a vital part in fighting COVID-19 both domestically and worldwide. This fast-growing ecosystem received a major boost from the Indian government's quicker approval processes, ongoing investments like Mission Covid Suraksha, and government **purchases. Harish Iyer, Deputy Director, Digital and Health Innovation, India Country Office, Bill & Melinda Gates Foundation,** believes India's broader biotech industry has a bright future for the next two decades

India is currently among the top 12 destinations for biotechnology worldwide. Biotech startups in India have grown 100 times in the last eight years, from 52 odd startups in 2014 to 6,300 plus currently. As per the India Bioeconomy Report 2023, the industry registered a 29% growth in 2022, and the biotech economy was already valued at US$137.24 billion. In fact, it is projected to reach a market size of US$300+ billion by 2030 and hit the US$3 trillion mark by 2047. The advances, investments and innovations made during Covid continue to shape the future of Indian healthcare and biomedical research. From mRNA vaccines to AI-powered diagnostics and computational modeling, here's a look at some of the platforms that startups are developing, which have the potential to help India take a transformative leap forward in the fields of medicine and biotechnology.

Revolutionizing the world of vaccines

Messenger RNA (mRNA) vaccine technology can pave the way for new vaccines that are easier to modify and develop against emerging viruses. And the pandemic proved that it was possible to swiftly design mRNA vaccines. Indian biotech companies are at the forefront of cutting-edge research on mRNA vaccines. In June 2023, Pune's Gennova Biopharmaceuticals got DCGI approval for Gemcovac-Om, India's first mRNA vaccine over about 2 years; their success was catalyzed, like many others, by funding support from Mission Covid Suraksha.

This omicron-specific booster vaccine is built on a platform similar to U.S. vaccines brought out by Pfizer-BioNTech and Moderna. Hyderabad-based PopVax is working on building a new mRNA platform for low-cost broadly-protective vaccines, to protect against the entire betacoronavirus genus. This includes current and future strains of SARS-CoV-2, the virus which causes Covid-19, the deadly MERS-CoV and SARS-CoV-1.

The success of mRNA vaccines in combating Covid-19 has spurred further research into their use for other infectious diseases as well. Chennai- and Bangalore-based Sekkei Bio, for instance, is using in-silico and mRNA technology platforms to develop vaccines and small-molecule drugs to treat diabetes, infectious diseases, and cancer.

Additionally, the search for adjuvants capable of boosting the immune response to COVID-19 vaccines has also led to the development of novel formulations and delivery systems. Covaxin, developed by Bharat Biotech International Ltd (BBIL), for instance, used an adjuvant named Algel-IMDG against SARS CoV-2. Going forward exploring adjuvants is going to be critical in tackling mutations of pathogens —several clinical trials are in progress in other countries with adjuvants such as Matrix-M, AS01 and AS02 against HIV, tuberculosis, and malaria as well.

Microfluidics platforms: Miniaturized solutions for testing and analysis

In recent years, microfluidic technology has significantly advanced biological research by efficiently processing measurements from small volumes of complex fluids—such as even a drop of blood—with remarkable speed and precision. This capability makes these platforms ideal for creating portable point-of-care (POC) medical diagnostic systems. With applications in diagnostic testing, microfluidics enables rapid and accurate screening for various viral illnesses, including dengue, malaria, typhoid, and influenza, making it a valuable POC tool in in the country's arsenal to enhance preparedness for ongoing outbreaks or even future pandemics.

Bengaluru-based Achira Diagnostics is currently developing two technology platforms rooted in microfluidic principles. One platform, utilizing a lab-on-chip concept, comprises a microfluidics chip and a reader, tailored for diagnosing disorders related to thyroid function or female infertility. The other platform involves fabric diagnostic chips, which entail coating silk yarn with reagents and weaving it into cloth. These fabric chips facilitate the detection of antigens for diseases like HIV and syphilis during standard blood banking tests, as well as for region-specific diseases in India, such as leishmania and malaria.

AI Algorithms for Image Analytics

AI-powered tools can rapidly interpret ultrasounds, eye exams, chest X-rays and CT scans, helping clinicians identify patterns indicative of infection or disease progression. In a country like India, where the patient load is high, and so is the amount of data generated in imaging and diagnostics, these algorithms can help enhance diagnostic accuracy as well as reduce the workload of radiologists.

For instance, Mumbai-based Qure.ai harnesses deep learning technology to detect clinically relevant abnormal trauma findings and provide automated reports for X-rays, CT scans and MRIs. In fact, Qure's qXR software for chest X-rays offers AI-based interpretation instantaneously and can spot up to 30 lung abnormalities. By integrating qXR within the existing healthcare framework of the National TB Programme, healthcare providers have been able to amplify the reach of TB screening using everyday chest X-rays in hospitals in Mumbai, Uttar Pradesh, and Karnataka.

Computational models for biologic design

Computational modeling has become increasingly important in drug discovery and biologic design, allowing researchers to study and predict the behavior of molecules and design novel therapeutics with enhanced efficacy and specificity. Models of how disease develops include molecular processes, cell to cell interactions, and how those changes affect tissues and organs.

At the Indian Institute of Science (IISc), a dedicated team is actively engaged in the development of an indigenous vaccine in collaboration with Mynvax, a start-up incubated at IISc. This vaccine, a recombinant sub-unit vaccine, targets the spike protein of the Novel Coronavirus, showcasing the integration of computational modeling into vaccine development efforts. PopVax, the startup I mentioned earlier, is using computationally driven antigen design to come up with a new mRNA platform. Sekkei Bio has combined forces with another start-up, Quest Compbio, which has computational biology expertise and an interest in neuropathic pain relief. These innovative approaches are just a few examples of the potential of computational modeling in revolutionizing vaccine technologies and combating infectious diseases.

These cutting-edge technology platforms, groundbreaking innovation and advancements hold immense promise for the future, as they offer smart solutions to pressing healthcare challenges. With India's prowess in innovation in the biotech and medical sectors, coupled with collaborative efforts across borders, we are poised to navigate the complexities of global healthcare in this century with greater resilience and efficacy. ■

Author

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Navigating the Future: Supply Chain Management in CRDMOs

As Contract Research and Development Manufacturing Organizations (CRDMOs), become central to the discovery, development, and manufacturing of drugs, supply chain plays a very critical role. **Sibaji Biswas, CFO of Syngene International,** underscores the importance of modernizing supply chain operations, strengthening supplier partnerships, and embracing digital solutions.

At the heart of CRDMO supply chain management lies the critical task of addressing diverse client needs and expectations. Clients demand a spectrum of attributes including speed, quality, responsiveness, and adaptability. Among these, timely access to raw materials is important, for both research and manufacturing, but significantly more important for research as material demands come in small quantities and with lesser degree of predictability and planning and in general needs are immediate.

The continuous feedback loop from clients also plays a pivotal role in shaping supply chain strategies, fostering agility, and enabling customization to meet specific requirements. This client-centric approach in Syngene ensures that we not only meet the immediate needs of our customers but also stay tuned to their evolving preferences, positioning us as responsive and adaptable partner in the dynamic field of research and development.

Localization of raw material supply has emerged as another strategic priority for CRDMOs. Incentivizing international suppliers to establish storage facilities in regions like India further enhances agility and cost-effectiveness. This need is especially pronounced in research, where the diversity of raw materials required is very high, while the volume is low, making local manufacturing economically challenging.

A robust local supply chain infrastructure with storage facilities for many thousands of input chemicals promises tangible benefits. The proximity of supply points not only reduces lead times but also enhances flexibility in response to client demands. Syngene is playing a leadership role in the industry, driving the localization strategy to build the industry's resilience around supply chain disruptions and meet client expectations with greater efficiency and adaptability.

The COVID pandemic laid bare the worldwide disruption of the supply of crucial raw materials, affecting industries across the board. Today, diversifying supply chains and reducing dependencies on a single geographical source, such as China, emerges as a deliberate imperative for CRDMOs. This strategy aims to foster partnerships with suppliers from diverse geographic regions for materials and components.

Collaborating with suppliers across different regions mitigates risks associated with geopolitical tensions and trade disruptions. This approach not only enhances the resilience of CRDMOs' supply chains but also ensures continuity of operations and minimizes the impact of external uncertainties on their business operations.

One might have noticed that near-just-in-time inventory management is gaining significant momentum within the CRDMO sector in recent times. Today, despite complexities, CRDMOs are embracing technological solutions and best practices that help optimize their inventory management processes, tackling challenges like chemistry expertise, volume forecasting, and cost competitiveness head-on.

With advanced analytics and real-time monitoring systems, CRDMOs are streamlining their inventory levels while ensuring operational efficiency and cost-effectiveness. It's interesting to see how organisations are leveraging these tools to fine-tune their supply chain operations and maintain a competitive edge in the industry.

Ecosystem creation requires collaboration across various dimensions. Partnerships with academic institutions, suppliers within the ecosystem, and the process development teams of individual companies play critical roles. Continuous learning initiatives foster a culture of innovation and improvement.

Today, industry participants are putting the building blocks in place to enhance this collaborative spirit and come together to create a strong local ecosystem in India. Syngene is at the forefront of developing this collaborative ecosystem and has rallied the industry's efforts in building a supplier group that can now locally manufacture and supply most industry-needed raw materials. However, volumes are still low, making the economics of local manufacturing challenging compared to imports from China. Proactive steering is needed to ensure local and international demands are aggregated, bringing scale to the Indian pharma supply ecosystem.

Economic competitiveness and supplier relations form the cornerstone of CRDMO sustainability. Also, the needs of a GMP value chain require strict adherence to the quality needs and appropriate documentation practices. Transparent communication and trust-based relationships with suppliers are imperative for fostering long-term collaborations and mutual success. The overarching goal for CRDMOs is to establish an integrated ecosystem, underpinned by a diverse network of suppliers capable of meeting evolving requirements.

Integrating suppliers into the organizational fabric fosters innovation, efficiency, and sustainability, emphasizing ethical practices. Governance, risk management, and compliance (GRC) serve as fundamental pillars of effective supplier relationship management (SRM), delineating clear roles, mitigating supply chain risks, and ensuring adherence to legal and ethical standards. This approach fortifies the resilience and efficacy of the entire supply chain ecosystem.

The integration of AI is revolutionising CRDMO supply chain optimization. AI tools span materials planning, demand forecasting, and resource allocation. Predictive analytics and machine learning algorithms are in place to enable CRDMOs to anticipate market trends, optimize inventory levels, and mitigate supply chain risks. AI is evolving at an unmatched speed and the adoption of AI poses some challenges such as workflow disruption and the need for specialized expertise, necessitating meticulous implementation strategies and investment in employee training and development. Additionally, addressing ethical implications like data privacy and bias requires proactive governance frameworks to ensure responsible AI deployment.

The future of supply chain management within CRDMOs hinges on innovation, collaboration, and adaptability. Embracing these principles is paramount as CRDMOs navigate the dynamic landscape, ensuring resilience and sustainability amidst challenges and opportunities. Organizations like ours, committed to sustainability targets like SBTI, see a need to integrate the supply chain with sustainable practices at every stage of the value chain. This requires governance structures, but more importantly, a strong resolve from everyone to transform existing practices for a better tomorrow.

With the relentless pursuit of excellence and the strategic leveraging of emerging technologies and collaborative partnerships, CRDMOs are poised to not just survive but thrive in an ever-evolving global marketplace. As supply chain management becomes increasingly complex, CRDMOs must remain agile and forward-thinking, consistently adapting to meet the evolving needs of clients and stakeholders alike. Through robust supply chain strategies grounded in innovation, integrity, and strategic foresight, CRDMOs can indeed navigate the future with confidence and success. ■

Author

Sibaji Biswas
CFO, Syngene International

Contract Research Organizations (CROs) are Cementing India's Life Sciences Capability

India's Contract Research Organization (CRO) market has been witnessing significant growth in recent years, driven by various factors such as a skilled workforce, cost advantages, and increasing demand for outsourcedCRO and research services. **Vishal Goel, Managing Director, RX Propellent** discusses about the growth and potential of India's CRO market.

The India CRO market has experienced substantial growth and is expected to reach US$979.8 million by 2030, growing at a CAGR of 7.5% during this period. India has emerged as a preferred destination for CRO and research collaborations, with a strong presence of pharmaceutical companies and a favourable regulatory environment. The rise of CRO has led to democratisation of research, reducing the domination of the handful of global pharma firms.

Knowledge economy strengthening base in India

Several reasons contribute to companies favouring India for preclinical trials. These include regulatory changes implemented in 2019 through New Drugs and Clinical Trials Rules (2019), reducing approval timelines by 30-40%. Besides, a high prevalence of diseases, advancements in medical infrastructure, the availability of investigators and trial sites in metro and tier-1 cities, along with the current favourable geopolitical environment have remained key considerations. The India CRO market comprises both domestic and multinational players, offering a wide range of services and have established a strong presence in the market through strategic collaborations, acquisitions, and partnerships.

The CRO market; part of India's knowledge economy, is poised to make substantial gains in market share and revenues. The knowledge economy, particularly the services industry, has left an indelible mark on the economy – India's service sector is one of the fastest-growing in the world and contributes as much as over 50% to the country's GDP. It has grown 10.8% in the first half of 2021-22 and the first advance estimates show the gross value added (GVA) in the service sector can grow by 9.1% in FY23.

India's life sciences knowledge economy is primarily driven by the two cities – Bengaluru and Hyderabad. Both the cities have seen significant growth in the Pharma and Biotech spaces with leading researchers of the world as well as domestic giants counting them as their home. According to real estate consulting firm CBRE, 57% of the space taken up by life sciences firms in these cities during 2019-22 was led by business expansions.

Presence of large clusters, top-grade office spaces, quality R&D labs, incubation centres and research institutions, Bengaluru and Hyderabad has added to growth in the life sciences sector and increase in CRO market share with respect to other global destinations such as the US, France, Canada, China and Germany.

The CRO industry in India has been immensely benefited by two world-class infrastructures – the BLR District in Bengaluru and Genome Valley in Hyderabad. The former comprises 5 districts of 5 lakh square feet each, offering an ideal platform for research, development and light manufacturing operations. The Genome Valley in Hyderabad has evolved into a hub for CROs and currently hosts over 200 companies with a workforce of over 15,000 professionals.

Key players shape the industry

Bengaluru and Hyderabad have emerged as key players in the global pharmaceutical research and development landscape due to their skilled workforces, cost advantages, and supportive regulatory environments. Syngene International, a subsidiary of Biocon Limited based in Bengaluru, has been a prominent CRO since 1993. Offering a diverse array of services encompassing drug discovery and development, Syngene's strategic location has facilitated collaborations with major pharmaceutical companies, solidifying its pivotal role in the industry.

Headquartered in Hyderabad, Aragen Bioscience, since its inception, has been providing a range of contract research, development and manufacturing services across the drug development continuum, specialises in areas like antibody discovery and analytical services and is a preferred choice for large pharma, biotech, agrochemical or animal health companies. Sai Life Sciences Limited, based in the same state, has been a reputed name for about quarter a century now in the space of drug discovery. Eurofins India, with its presence in both the cities, offers a suite of services including biopharma, food testing, genomics, among others.

The fast growing CRO market in India is also paving the way for startups and new age companies foraying into this space which are bringing innovation and agility. A stellar example of an emerging CRO is Yapan Bio that provides integrated services to develop and manufacture high-quality biologics or bio-therapeutics. Housed at Hyderabad's Genome Valley, Yapan Bio has state-of-the-art Process Development and GMP facilities for vaccines and biologics, including higher Bio-Safety levels (up to BSL-2+) and is at the forefront of serving the needs of Bio-technology industry, globally.

As we look forward to the next decade of the CRO market, it is more likely to attain the role of a knowledge economy rather than manufacturing and India is poised to make substantial gains in market share and revenues. These developments were complemented by the Indian government's proactive initiatives, such as the "Make in India" campaign and simplification of regulatory processes, alongside tax incentives for R&D activities, creating an environment conducive to CRO growth. These measures aim to attract heightened international collaborations and foster the expansion of the CRO sector within India. ■

Author

Vishal Goel
Managing Director, RX Propellent

Four Supply Chain Management Trends: Aspen Technology

Resilient and Sustainable Supply Chains

According to Professor Yossi Sheffi at MIT, supply chain resiliency is "the ability of a company to quickly respond or bounce back from a significant disruption."

Supply chain resiliency has, in fact, become a priority for some governments.

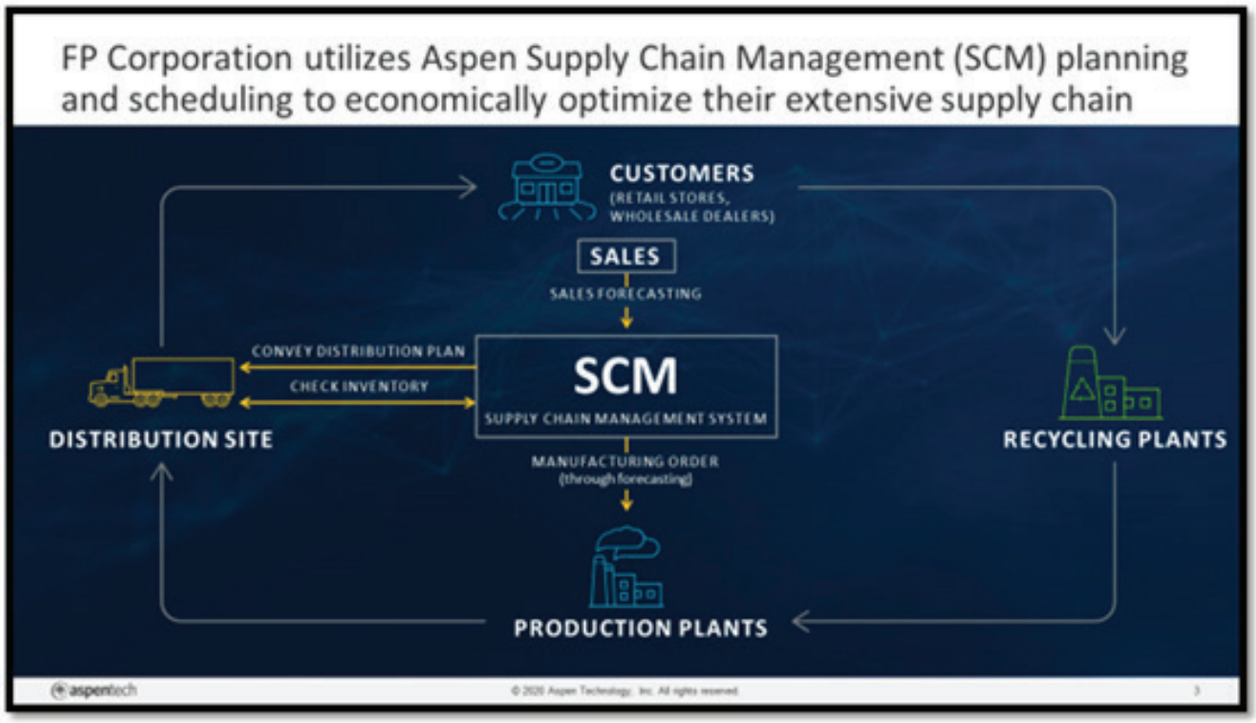
At the same time, a renewed focus on sustainability has emerged in many chemical companies as they set new targets to reduce energy use, emissions, and waste while governments include green energy policies in economic recovery packages. The lesson from the past year is that sustainability and resiliency are two sides of the same coin.

Supply chain digital twins can help manufacturers achieve their resiliency and sustainability goals. For example, AspenTech's work with FP Corporation (FPCO), along with Time Commerce (an Aspen Implementation Services Partner), was recently recognized with a 2020 Green Supply Chain Award from Supply and Demand Chain Executive. FPCO is the largest maker of plastic food containers and related packaging materials in Japan.

FPCO utilized Aspen Supply Chain Management (SCM) planning and scheduling to economically optimize its extensive supply chain on an ongoing basis and consistently supply more than 10,000 types of food containers to supermarkets across Japan, support food infrastructure, and build a recycling-oriented supply chain with the goal of a sustainable society.

Managing Change through Sales & Operations Execution (S&OE) Digital Capabilities

As every manufacturing company knows, things do not always go as planned. Supply and demand uncertainty



The Aspen Supply Chain Management (SCM) planning and scheduling system used by FPCO to optimize its extensive supply chain.

brings forth inevitable daily events and disruptions that must be managed. This can include production quality issues, logistics delays, last-minute changes to customer orders, etc. For most organizations, the pandemic amplified supply-and-demand disruptions to a whole new level.

We are seeing a trend in the market related to manufacturers wanting to become much more agile. This is driving numerous customers to implement Sales and Operations Execution (S&OE) processes and related digital solutions. S&OE is a process that allows manufacturers to align their day-to-day activities on an ongoing basis to achieve their longer-term Sales & Operations Plans (S&OP) while also improving agility.

The October 2020 Forbes article Hexion Is Blazing New Trails in Improving Profitability, authored by Steve Banker from ARC Advisory Group, focuses on how Sales & Operations Execution helps Hexion specialty chemicals improve profitability through high operating leverage and increased productivity. The article provides some insights into how "AspenTech's collaborative platform allows the demand, inventory, production planning, capacity planning, and quality teams to interact and create better production schedules based on the inevitable disruptions that are occurring.

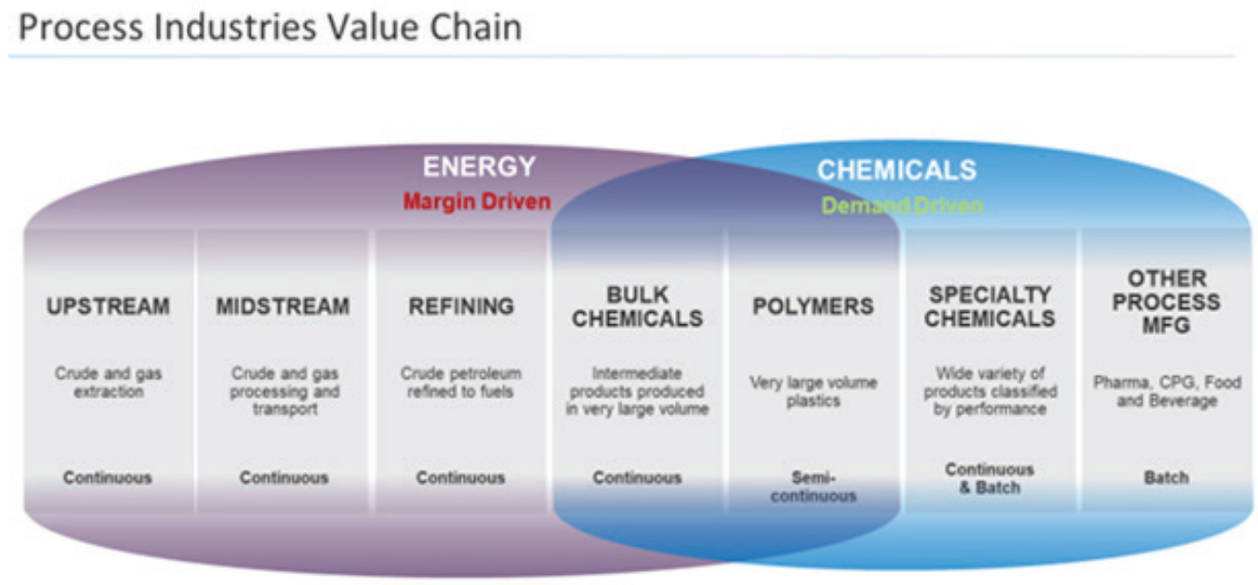
Extended Value Chain Integration and End-to-End (E2E) Optimization

Transportation fuels have historically been the biggest demand and end-use for crude oil. With the energy transition underway, demand for transportation fuels is expected to peak, driven by more efficient combustion engine technologies and the transition to electrical vehicles. As this happens, refiners will shift their attention from transportation fuels demands to chemical demands as a target area for future growth. This megatrend is referred to as crude-to-chemicals (CTC).

When looking at the CTC extended value chain, there are two key areas with integration opportunities. The first is the integration of the oil refining supply chain and the base petrochemicals supply chain. The opportunities here relate to exploiting process and molecular synergies to shift from producing fuels to chemicals.

The second is the integration of the base petrochemicals supply chain (e.g. olefins) with the downstream derivative chemicals (e.g. polyolefins) supply chain. The opportunity here is linked to being more agile and specific in the monomers and polymers value chain planning integration and optimization to best respond to changing supply/demand economic conditions

Sales and Operations Execution (S&OE) capabilities are vital because things don't always go as planned.



The intersection of Bulk Chemicals and Polymers is where the demand-driven and the margin-driven sides of the value chain meet and interact.

across the extended olefins-to-derivatives value chain.

Managing and optimizing a crude/olefins-to-polymers extended value chain is challenging, as it spans supply chains that have very different characteristics.

The upstream refining and bulk chemicals businesses are margin-driven supply chains in which the optimization opportunity consists of optimizing the operating conditions of complex continuous production processes, as well as exploiting feedstock supply and associated economics optionality.

The downstream polymers business is a demand-driven supply chain in which the optimization opportunity consists of looking at the broader business system (including changing demands for hundreds to thousands of individual finished products with unique characteristics, the distribution network and associated modes of transportation, inventories optimized according to demand patterns and production cycles of different grades, and semi-continuous/batch/continuous production units) and determining the best way to balance supply/demand while maximizing the profitability of this overall system.

Many companies are already working on or prioritizing initiatives related to extended value chain integration and end-to-end optimization. Repsol Chemicals is one of them. Repsol Chemicals recently provided an overview of its "Control Tower end-to-end supply chain optimization" project at the November 2020 European Refining Technology Conference (ERTC). The AspenTech value chain optimization solution will support Repsol Chemicals in achieving its customer service objectives and becoming more agile to respond to market and operational changes, while doing so with full visibility into the end-to-end integrated margin across the olefins-to-polymers value chain with the required accuracy and granularity.

What-if Scenarios Analysis Leveraging Mathematical Optimization at Scale

At the core of a supply chain digital twin there needs to be a representation of the manufacturing process. Multiple complexities may need to be factored into this model, such as production switching costs, utilities, minimum run sizes, and so on. Modeling becomes even more challenging when you factor in other production or tolling sites, as well as the dependencies across sites. As you extend backwards from production into suppliers, there are aspects that should be modelled here as well including different purchase minimums, costs, and lead times varying by supplier.

Finally, you have the downstream supply chain consisting of warehouses, distribution centres and customer ship-to locations. Things get complicated when you try to factor in duties and tariffs or product substitution options. As you can imagine, it can be very challenging to model these interrelated elements in a spreadsheet—rather than using a solution designed specifically for that purpose.

The other big limitation of a spreadsheet is that it wasn't designed to do mathematical optimization at scale to solve real-world problems—taking into consideration anywhere from tens of thousands to millions of variables and constraints. Using a solution designed specifically to do mathematical optimization at scale such as Aspen Supply Chain Management (SCM) is extremely valuable because:

An optimizer will find the best answer automatically, whether the goal is to maximize profit or minimize costs across the end-to-end system.

An optimizer will recommend options that a person or business wouldn't normally consider or didn't know were even possible. That's because it can easily deal with complexity in a way that a human mind cannot ■

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Supply Chain Challenges in Pharma Industry

The global pharmaceutical has witnessed significant growth in the last decade. At the end of 2020, the total global pharmaceutical market was valued at about 1.27 trillion US dollars. It has increased three-fold from 2001 when the market was valued at 390 billion US dollars

Pharma companies are now rearranging their operations and recovering from the COVID-19 impact. The market is likely to reach 1.7 trillion US dollars in 2025 at a CAGR of 8% from current levels.

Such robust growth was witnessed in India pharmaceutical Industry as well, as per IBEF India's domestic pharmaceutical market is estimated at 42 billion US dollars in 2021 and likely to reach 65 billion US dollars in 2024 and further expand to reach 120 billion USD dollars by 2030.

India's biotechnology industry comprising biopharmaceuticals, bio-services, bio-agriculture, bio-industry, and bioinformatics. The Indian biotechnology industry was valued at US$ 64 billion in 2019 and is expected to reach US$ 150 billion by 2025.

India's drugs and pharmaceuticals exports stood at US$ 17.57 billion in FY21 (From December 2020 to April 2021).

Medicine spending in India is projected to grow 12% over the next five years.

Challenges In the Pharmaceutical Supply Chain in India

Every business has challenges, but the challenges prevailing in the pharmaceutical Industry is extremely complicated. Pharma Industry is still relying on supply chain and manufacturing paradigms that have been around for many years. With various stakeholders involved and complex network design, it's extremely difficult to align everything for an efficient supply chain.

If we analyze the cost distribution of a pharma product it roughly costs about 30% for the supply chain & distribution alone. Where in R&D and primary manufacturing costs only 25%. Therefore, the current supply chain and distribution cost is extremely high compared to other costs. And it is likely to go up further northwards due to the following factors

- **Freight Cost**

Post covid outbreak, freight costs across all modes of transport have gone up skyrocketing by 3-4-folds when compared to 2019 levels. And there is no reliability or consistency in prices as well as service providers like Airlines, Shipping lines, truckers do not give long term rate contracts anymore, and literally, freight rates keep changing on weekly basis.

On one side the fuel costs are going up and on the other side, there is heavy equipment or inventory shortage which keeps destabilizing the supply chain plans and service providers are struggling to maintain the momentum.

Sea freight movements are extremely chaotic now and stressful due to various global issues like container shortage, backlogs in various ports, 2nd covid wave outbreak in key Asian ports, rerouting of shipping vessels, blank sailing, and avoidance of calling certain seaports is hitting the shipping movements terribly

The Airfreight movement is okay as most of the Airlines are surviving only on cargo revenue today as tourism post covid outbreak went for a toss. However, airfreight costs have gone up skyrocketing. For e.g., what used to cost INR 150 per kilo as airfreight cost to the USA per kilo in 2018-2019 has gone up to INR 450 per kilo now

Trucking costs have gone by 30-40% due to the increase in fuel cost. Combined with the shortage of drivers due to the covid outbreak has sent the trucking industry to an extreme difficult situation.



Overall, cost across all modes has gone up, and the situation is likely to continue for another 4-6 months period.

▪ **Technology Investments**

Pharmaceutical companies must ensure precise on-time delivery, compliance, and stability. They must ensure the cargo will turn up on time in the right condition.

Managing perishable products, degradation of the medicines as they move along the supply chain, maintaining temperature control has a heavy cost attached to it.

Many pharma companies are moving to adopt newer technologies to the fullest potential and trying to integrate various processes. Transparency and visibility are going to be a key driving factor in the ensuing years for productivity and growth. The non-visibility of inventory causes serious threats of counterfeits, loss of sale, challenges to trace products, and cannot predict the demand scenario.

Pharma companies are forced to invest in new technologies to stay afloat in their business. Managing cold storage facilities is very resource-intensive and not budget-friendly, some of the products must be stored at a very low temperature to ensure that the potency and formulation remain intact. This would need pharmaceutical supply chains equipped with specialized reefer containers for movement and the use of cold storage facilities for storage adds additional cost.

The task of bringing medicines to market is a race against time. Since the onset of the pandemic, the cold storage demand from pharma companies has increased, also flexible cold storage facilities are required now to meet the vaccine demands without any excess or wastage of vaccines. Unlike drugs, all vaccines need to be transported at cold temperatures between 2 and 8 degrees Celsius and many vaccines lose potency when exposed to higher temperatures.

Therefore, technology investment now is key to be successful and it also enables to be prepared for the future disruptions

▪ **Compliance & Regulation – Choosing the right service provider**

It requires a strategic approach to tackle the logistics issues like prioritizing, monitoring, minimizing, and controlling logistics risks, and its imperative that pharma companies shift the logistics cost to "Supply Chain as a Service (ScaaS)".

Due to increasing regulation and compliance requirements, the pharma industry is going through an enormous change and it needs a good service provider who can understand the pharma ecosystem. It requires a service provider who can respond to demand, provide multimodal options, cost-effective risk-based models, provide flexibility, visibility, and transparency.

The service provider with technical expertise, understanding of the regulation and compliance requirements is the need of the hour. Post pandemic, the traditional way of managing logistics is not going to be sufficient. Only an expert service provider can deliver the plans for the unexpected, reduces waste, cut costs, and can improve delivery times.

Good supply chain management can yield a 25-30% reduction in total supply chain costs. The traditional model is a highly fragmented model and is not going to help anymore as it will increase the cost further. Most global companies are now investing in an ecosystem internally to handle the complex requirements of pharmaceutical companies.

Pharma companies should have a holistic approach in identifying the service partner rather than comparing on a transactional basis.

An expert service provider who follows and deliver "Supply chain as a service" (ScaaS) offers companies end to end supply chain solutions & services from strategy to product delivery and in turn frees up the valuable company time to focus on customers and new product development and allows the company to focus on their core competence area.

Pharma companies that leverage the Supply chain as a service can quickly improve their commercial position by utilizing a lower and variable cost structure. Pharma companies can scale up their service that provides a competitive advantage in both the short and long term.

New software technologies, innovations, and digitization by the expert service providers help the pharma companies to meet their end-to-end operations, bridges the gap, and provides visibility and transparency with real-time information.

In the shorter run, choosing an expert service provider may cost more for the pharma companies but in the long run, it brings enormous value to the table and builds sustainability, and gives a competitive advantage for them ■

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Maximizing the Efficiency of Clinical Trial Supply Chain

For a new drug to reach the market it has to undergo a robust clinical trial process which requires considerable amount of investment and can continue in excess of 10 years. The process involves global multi-center trials and recruiting a large number of patients to achieve the trial objectives e.g. safety and efficacy. Different types of clinical trial supplies, from investigational products to ancillary supplies are required to conduct clinical trials. The clinical trial supply chain is an integral part of any clinical trial; it constitutes packaging, labeling, storage, distribution to patients located in different geographic locations, and accountability and destruction of clinical trial supplies.

Below are the examples of Clinical Trial Supplies:

- Clinical Trial Drug Supplies:

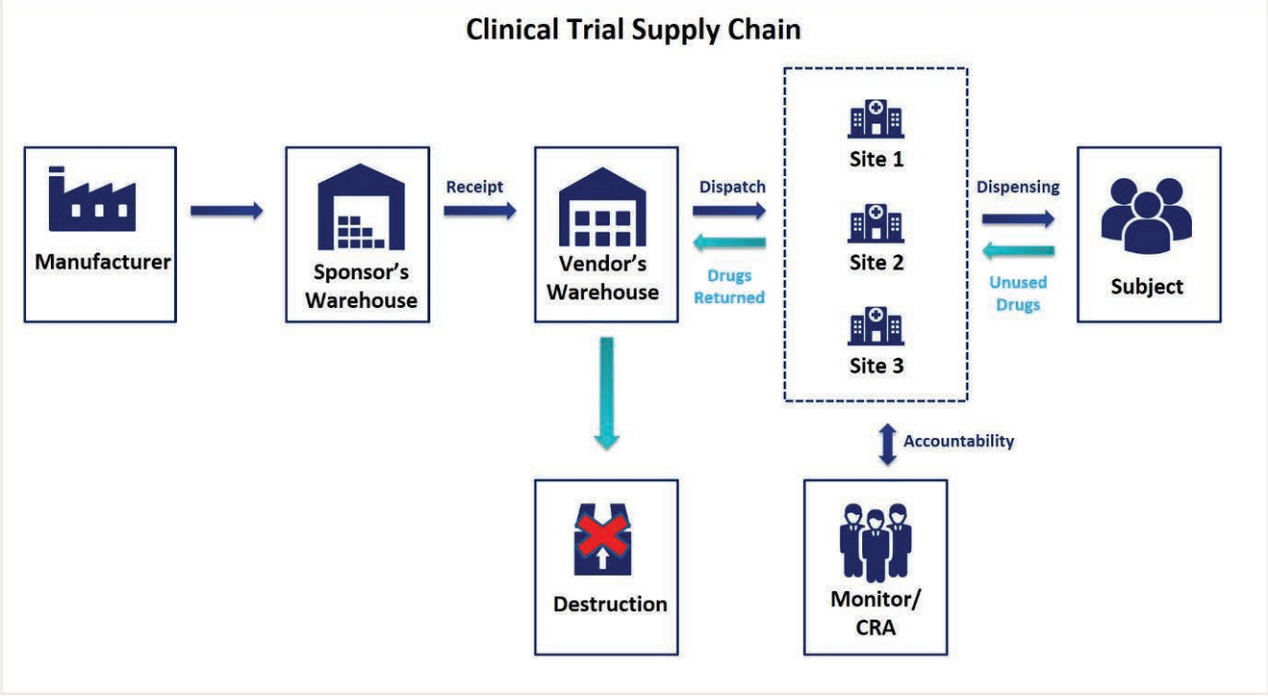
  Investigational Product & Comparators, Background / Rescue Medication
- Clinical Trial Non Drug Supplies:

  Equipment & Lab Kits, CRFs, Blinding / Randomization Envelopes
- The primary goal of clinical trial supply process is to deliver

The RIGHT SUPPLIES at the RIGHT TIME to the RIGHT INVESTIGATIONAL SITE for the RIGHT PATIENT

Although the basic principles of logistics apply to Clinical trial supply chain, it is different from Pharmaceutical commercial supply chain due to the following aspects:

- Investigational Products are still under testing hence many aspects of the investigational product are still under 'investigation' or in other words the product needs to be administered to a selective group of patients who has consented for the clinical trial. It is, therefore, extremely critical to have a controlled use of such products right from the lab where it is being produced, till the time it is consumed by the patient, while all the extra supplies are accounted for and destroyed.
- Investigational Products are exclusively manufactured and packaged depending on the



trial design so they are not available off-the-shelf.

- Some investigational products eg Oncology products are very expensive and available in limited quantity, hence any wastage could affect the fate of the clinical trial.
- Each kit used at the investigational site is accounted for down to the unit level eg tablet, capsule and it needs to be returned to the sponsor for destruction.
- The trial data is submitted to the regulatory authorities for registration hence clinical trial supply chain is prone to regulatory audits and inspections.
- The compliance level of the investigational product during the trial has a direct co-relation with the final outcome of the trial. If it is not as per the desired level, the entire trial data would be of no use. Hence, one needs to have built-in quality checks in a study design and monitor closely so that the final outcome is achieved.

Therefore, it is imperative to optimize the clinical trial supply chain process with respect to time, quality, safety & integrity, and at the same time, bring in cost efficiencies.

In order to maximize the efficiency of clinical trial supply chain, it's important to know the various challenges associated with the process and the approaches/ techniques to address them.

Geography - Multicenter/ Multinational Trials

One of the biggest challenges is the geographical location of the source and sites.

With the rapid growth in the number and spread of clinical trials, there are many multinational & multi-center trials, where multiple countries across the globe and various hospitals in those countries are involved. The clinical trial supplies need to be delivered at these sites from the source e.g. central depot. This could result in longer transit time, for example the central depot could be in USA and the sites in South East Asia.

In most of the countries, the drugs cannot be shipped to sites unless necessary approvals from Regulatory and Ethics committee are in place. Hence the clinical trial supplies cannot be sent in advance.

Global Regulatory Requirements

Regulatory requirements could differ from one country another and inadequate knowledge about it could lead to delays in customs clearance. In many countries, import license is required to import drugs and the invoice should match the import license. The labels on investigational product kits should be as per country regulatory requirements which could be country specific. For example, expiry date on the kits is not mandatory in USA but it is mandatory in India.

These situations could result in longer transit time. In case of delays in clearance, there are chances of improper handling of supplies at the custom warehouse which could ultimately compromise the cold chain and affect the quality of the product. There is also a risk of shipments being misplaced resulting in product wastage.

Product wastage can also be caused due to inaccurate forecasting, eg supplying excess investigational product to sites with low or no recruitment, or supplying products with short expiry date. Such incidences will have an adverse impact on the outcome of the clinical trial.

Poor subject compliance can occur if the investigational product is not available as the subject will not be able to adhere to the protocol specified time regime. This will adversely affect the company's reputation as it is the social and ethical obligation of the sponsor to make the investigational product available to the patients at all times during the trial period; this is also a GCP requirement.

Substandard products resulting from improper handling may jeopardize the clinical trial outcome and there could be chances of data being rejected by the regulatory authorities.

Such issues will also delay the completion of the clinical trial and, in the worst case scenario, could lead to cancellation of the trial all together. The sponsor ultimately could incur heavy losses because of all these issues.

Based on years of industry experience, here's a checklist which could help in developing the right clinical trial supply chain strategy. Use of a service provider (local depot)

The sponsor can appoint local depots in the countries which are participating in the clinical trial. As Clinical Trial Supplies Management is a niche area, many sponsors prefer to outsource it to the experienced partners rather

than managing it by themselves. These depots are GxP compliant and provide end-to-end service from receipt till destruction of the investigational product. These depots can be audited and approved by the sponsor's Quality Assurance department. This partnership has many advantages, shorter transit time to sites being the most important advantage. The local depot can receive the drugs from the central depot after DCGI approval is received for the trial & import license is in place. Once the ethics committee approval is in place, the local depot can distribute the supplies to various sites.

Shorter transit time also ensures lower courier costs. The drugs can be shipped by the central depot /sponsor to the local depot as a bulk supply instead of supplying in bits and pieces, thus there will be fewer shipments imported for a trial resulting in less frequent customs clearance.

Appointing a local depot will give an added advantage of excellent awareness of local regulatory requirements. The supplies will be always available at the depot and can be dispatched to sites on a short notice. The local depot can provide dedicated resources/ project team handling a particular client ensuring a customer-focused approach and prompt action.

Many clinical trials like Oncology trials require comparators, background or rescue medication. Local depot can also provide support in sourcing the comparators from the local market; this can ease the burden on the sponsor as the sponsor won't have to make arrangements for procuring it centrally and then distributing across the globe. Local sourcing will save time and ensure availability of supplies. By delegating this responsibility to the service provider, the sponsor can increase focus on the investigational product.

> Selection of the right courier partner

A courier agency with the right experience and expertise is essential for the Clinical Trial Supply Chain to succeed. Sponsor can directly or through the depot partner appoint a courier agency which is focused on the life sciences and has a proven track record in cold chain management. This will ensure on-time and safe delivery of supplies without any transit issues, e.g. excursions, off-loading. Such issues may result in product wastage and add to the overall cost as the product will have to be resupplied to the sites. The courier agency can be audited by Sponsor/ Depot partner. The courier agency should have processes in place for conditioning / preconditioning of gel packs, preparation of insulated shippers. They should always use validated shippers and calibrated data-loggers for the shipments.

The courier agency should track the shipment till delivery and provide the POD and data logger readings to the sponsor/ depot partner upon delivery. They should ensure that the supplies are delivered to the right person. In case of any issue, the courier agency must proactively and promptly inform the client.

> Technology and Innovation

Technology and innovation play an important role in the optimization of clinical trial supply chain. Multilingual labels or booklet labels are used for multinational clinical trials. Their main advantage is the flexibility of drug supplies. The supplies can be used in more than one country or redistributed between countries. This minimizes the drug wastage and reduces the overall medication cost. This hugely helps in trials where drugs are in short supply or expensive, e.g. Oncology trials. Booklet labels also complement the use of IXRS technology and pooled supplies.

IXRS (IWR /IVR) - Interactive Web / Voice Response System is used for forecasting, randomization, drug distribution, Inventory Management etc. This system also tracks the expiry date. As this system is linked to randomization, the drug orders are generated as per the patient recruitment and visit schedule. This minimizes product wastage and ensures the availability of supplies at sites. It also underlines the importance of using a local depot in order to manage the JIT (Just in time) delivery to the site.

Case Study

Here's a case study to help demonstrate the how a sponsor can save much of their precious time and co-ordination exercise with an experienced clinical trial supplies vendor.

In a multicentre, randomized, blinded trial number of shipments containing investigational products were sent to the sites. After using these drugs on patients at the sites, these supplies were returned to the depot on an ongoing basis by the sites. The study had a long duration of about three years. After the recruitment target and all the patient visits were over the sponsor asked the depot to provide the drug reconciliation records. As the depot had not done the reconciliation of investigational product at the time of receipt of

the returned supplies they faced lot of issues in the accountability. The depot staff spent no. of days in conducting the drug accountability and found that the documentation received from sites was not adequate, mismatch between the quantities mentioned on the returned documents and the physical returned stock received at the depot. Even after spending considerable time in this activity all the kits dispatched to the sites could not be accounted for and finally sponsor had to report them as missing with a great risk of potential audit and inspection finding. This situation could have been easily avoided if the drug accountability was done on a real time basis and all the discrepancies were promptly reported and resolved.

Conclusion:

The number of global multi-center clinical trials is increasing by day. Trial design and dosage regimes are becoming complex, and so are the challenges in clinical trial supply chain. The clinical trial supply chain has evolved over the past few years. The testing phase is over; sponsors nowadays are actively looking to reduce the cost of clinical trial supply chain without compromising the quality and integrity of the trials. The sponsors can achieve this by collaborating with the service providers who are experts in their domain and can provide a customized solution to their clinical trial supply chain requirements ■

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GUEST COLUMN

Pallets keep the pharma supply chain moving

Nitin Kalla
Founder
EXZOD India

Pallets give pharmaceutical firms the power they need to handle their products, increase storage efficiency, and protect products in the warehouse. They are used to stack, store, protect, and transport a variety of pharmaceutical materials. According to a McKinsey analysis, the pharmaceutical business has a rare opportunity thanks to a number of local producers of branded generics. The industry has had amazing expansion, going from being non-existent to having a global pharmacy.

The pandemic's ensuing supply chain problems had an influence on pallet availability. The new normal has shown, however, that pharma supply networks need to be resilient and agile, driving manufacturers and suppliers to improve their pharmaceutical product storage, shipping, and supply chain management capabilities in order to add value for consumers.

The events of the pandemic have really opened people's eyes to the relevance of the pallet industry and the role it plays in the supply chain.

Digitalisation: The supply chain can be streamlined and its agility and flexibility increased by implementing technologies like automation, blockchain, and artificial intelligence.

Fragmented logistics network: The supply chain management can become complex due to the fragmented logistics network, leading to inefficiencies.

Regulatory compliance: The sector is governed by regulations, and it can take up a lot of time to make sure that all the rules are being followed. Adhering to

regulations like Good Manufacturing Practice, Good Distribution Practice, and Good Clinical Practice can have an effect on the supply chain.

Cold chain management: Pharmaceutical products demand storage and transportation at controlled temperatures, which can pose a challenge. In India, the cold chain infrastructure does not meet the desired standards and necessitates significant investment in constructing temperature-controlled areas. The extreme temperatures in several parts of India add to the complexity of maintaining cold chains.

Transportation challenges: Pharmaceutical products require special storage and transportation conditions, particularly temperature control, which must be strictly adhered to. Any deviation from these requirements can have adverse effects on the quality and effectiveness of the products. Transportation issues like delays, damage, or loss pose a significant threat to the supply chain, causing disruptions.

Creating infra for better pharma handling: In recent years, India has made significant advancements in the handling and logistics infrastructure of the pharmaceutical industry. These improvements have contributed to India's rise as a top supplier of generic pharma products worldwide. The development of new technology and facilities, including the use of cold chain logistics, has enhanced the storage and transportation of pharma products. Although there is still scope for further improvements, these advancements have solidified India's position as a leading global manufacturer and supplier of pharmaceuticals. The National Logistics Policy has set out a clear roadmap for India to establish itself as a dominant player in the global logistics industry.

Quality control: Quality control is an essential aspect of the pharmaceutical supply chain. India, however, has encountered issues with counterfeit and substandard medications, as well as regulatory non-compliance. It is crucial to tackle these problems to uphold the supply chain's credibility.

Crucial role of technology: The transportation and storage of pharmaceutical products heavily rely on the advancements in technology and innovation. The safety of pharma shipments is at risk due to various factors, such as temperature, humidity, and light, making it necessary for shipment and storage facilities to have automated tracking systems, proper temperature-controlled storage, advanced handling equipment, and procedures. The utilisation of Artificial Intelligence, Internet of Things, and Blockchain enables real-time tracking of temperature and humidity levels, which brings transparency and enhances the entire process of pharma cargo handling and transportation.

Technology and automation: Technology and automation, like GPS tracking and real-time temperature monitoring, are effective tools for preserving the quality of time-sensitive pharmaceutical shipments. By using these tools, temperature fluctuations can be prevented, resulting in less wastage and on-time delivery of the shipments.

Minimize carbon footprint: The importance of supply chain sustainability is increasing day by day, leading to a rise in demand for reusable and recyclable pallet materials in the pharmaceutical industry. Although wood is an inherently sustainable material, the newer plastics and composites offer even higher levels of sustainability. This trend is driven by the collective desire of companies and consumers to reduce their carbon footprint.

Adoption of agile supply chain strategies: Supply chain agility is essential to ensuring that pharmaceuticals are delivered to clients quickly. To respond to shifting consumer expectations, supply chain disruptions, and regulatory changes, we created flexible supply chain methods.

Pharmaceutical companies should prioritize enhancing their supply chain efficiency to stay ahead in the industry since every life is valuable. We have taken steps to improve our supply chain and respond to evolving customer demands by developing flexible solutions that meet their requirements. Managing pharmaceutical supply chains demands expertise, and we have a team of professionals who are knowledgeable in handling shipments that require special handling conditions. Our size and variety of pallets allow us to cater to this industry effectively.' ■

Ionizable Lipids are Critical for mRNA Vaccine Development

The pharmaceutical industry has witnessed a significant transformation in vaccine development, shifting from the 1950s, with the concept of one egg yielding one vaccine dose, to adopting a streamlined and efficient manufacturing protocol. **Arun Kedia** writes about how mRNA-based vaccines with lipid nanoparticles has ushered in a highly effective and innovative vaccine platform.

Single strand messenger RNA (mRNA), a nucleic acid, triggers synthesis of specific protein chains in the living cell's cytoplasm. However, they are extremely vulnerable in the human body. In recent times, lipid nanoparticles have emerged as a cutting-edge technology, proving highly effective for the in-vivo delivery of mRNA with a protective nanocapsule of phospholipids. This is particularly relevant in the COVID-19 vaccine administration, where achieving successful and protective vaccines hinged on utilizing highly efficient mRNA delivery systems.

However, despite existing vaccines, developing more effective and easily adaptable ones that offer enhanced safety against various SARS-CoV-2 variants remains a significant challenge.

mRNA Vaccine Development: An Overview

Today, lipid nanoparticles or LNPs represent the most advanced non-viral gene delivery system in clinical practice. They are a safe and efficient means of delivering nucleic acids, effectively overcoming a critical hurdle in developing and applying genetic medicines and vaccines.

At present, LNPs are widely used in mRNA delivery vehicles. LNPs consist of four distinct lipid categories, including ionizable lipids, neutral or helper lipids, cholesterol, and sometimes lipids with polyethylene glycol (PEG) attachments. Specifically, considering ionizable lipids play a pivotal role in mRNA complexation and in vivo delivery, they assume a bigger spotlight in the discussion.

Progress in mRNA-based delivery methods has demonstrated their therapeutic potential in various biomedical uses like protein replacement treatments, vaccines, cell reprogramming, and cancer immunotherapies. To reap the best therapeutic results of mRNA delivery systems, it is essential to shield mRNA from in-vivo degradation and deliver it to specific cells for triggering protein production.

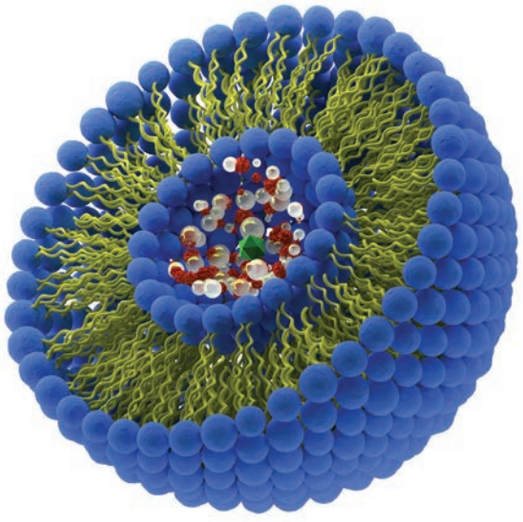
However, targetability, stability and endosomal escape remain significant challenges and hurdles in mRNA delivery systems, underlining the significance of safe and efficient mRNA delivery.

Recently, the utilization of LNPs in COVID-19 mRNA vaccines has gained popularity because of their crucial role in protecting and delivering the mRNA payload to particular cells. Currently, in clinical application, these mRNA-LNP vaccines for COVID-19 show an inventive strategy within mRNA-based treatments. The promising developments indicate a potential transformation in how we combat infectious diseases.

Ionizable Lipids and their Importance in mRNA Delivery

Promising advancements in the field involve the utilization of cationic lipids as emerging technologies for siRNA delivery. Synthetic cationic lipids, such as oxime ether lipids with hydroxylated head groups, have demonstrated superior capabilities as siRNA delivery agents. These lipid-based agents offer huge potential in breast cancer treatment through Small Interfering RNA (siRNA)-based gene silencing therapy.

By virtue of their small size, they can readily penetrate tumour cells and release the therapeutic payload within the intracellular space. This targeted delivery mechanism using lipid nanoparticles (LNPs) helps minimize side effects on surrounding healthy tissues. With their tiny size, these nanoparticles can successfully navigate various barriers encountered during treatment, enhancing bioavailability and efficacy.



In actuality, each part of the four lipid types mentioned earlier is needed to ensure the mRNA can be delivered well and the particles stay stable. However, ionizable lipids are the most essential components of LNPs. They decide how well the mRNA is delivered, how cells accept the mRNA, how it escapes from endosomes, and how safe it is. So, a well-designed LNP delivery vehicle with ionizable lipids makes it easier for cells to take in mRNA. This way, the delivery process of mRNA can be enhanced significantly.

Ionizable lipids are unique because they react to the acidity level (pH) around them, changing their charge depending on it. When the pH is low, they become positively charged. However, when the pH is normal, the ionizable lipids become neutral. This means that in a normal pH environment, they do not interact much with the cell membrane, which makes the LNPs work well with the body.

But when they get inside an endosome (a small part inside a more acidic cell), the positively charged ionizable lipids join with negatively charged lipids in the endosome, creating a unique structure that helps the LNPs work more effectively.

New Research on Applications of Ionizable Lipids in mRNA Vaccines

While research on ionizable lipids for mRNA vaccines is an ongoing endeavour, a recent effort towards designing more powerful RNA vaccines is worth mentioning. Even though the COVID-19 RNA vaccines have shown their effectiveness in lessening the disease's severity, a group of scientists at MIT is dedicated to enhancing their performance further.

Their work is a testament to the ever-evolving landscape of mRNA vaccine development and the relentless pursuit of medical innovation that showcases the potential to enhance the global response to infectious diseases.

Through alterations in the vaccine's design, the scientists aim to showcase their ability to develop mRNA vaccines in mice that stimulate a more robust immune response, all while necessitating a smaller dosage. These efforts hold promise for more efficient and accessible vaccine strategies.

As a phase in their research plan, the scientists altered the LNPs responsible for transporting the RNA vaccine. They created a library of 480 ionizable lipids with different chemistries that become positively charged when they enter acidic environments. These modified lipids assist in RNA delivery and naturally boost the immune response, making it stronger.

When tested on mice, the research team noted that the mice receiving this vaccine generated ten times more antibodies than those given the earlier COVID RNA vaccines. Also, the new vaccine induced a more vigorous response from cells crucial in combating the SARS-CoV-2 virus, highlighting its potential as a highly effective solution.

Conclusion

In recent years, there has been remarkable progress in mRNA therapeutics, largely influenced by the extensive research conducted over decades on LNPs, particularly focusing on a crucial component, ionizable lipids.

In addition to ensuring safety and effectiveness for mRNA delivery, the next-generation ionizable lipids can also incorporate extra features like specific targeting. These are extensive prospects for further enhancing and innovating ionizable lipids to facilitate the widespread adoption of mRNA therapeutics and vaccines. ■

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