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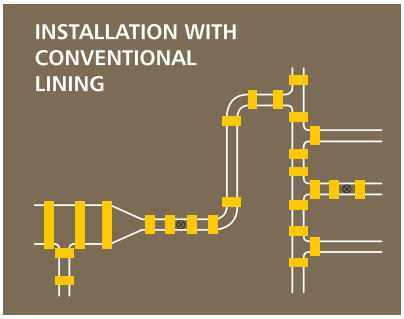

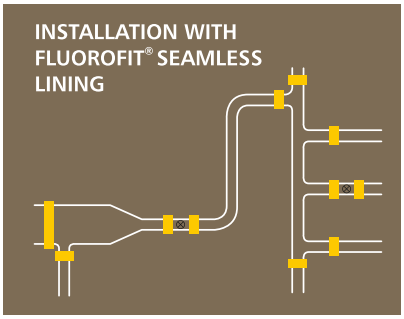

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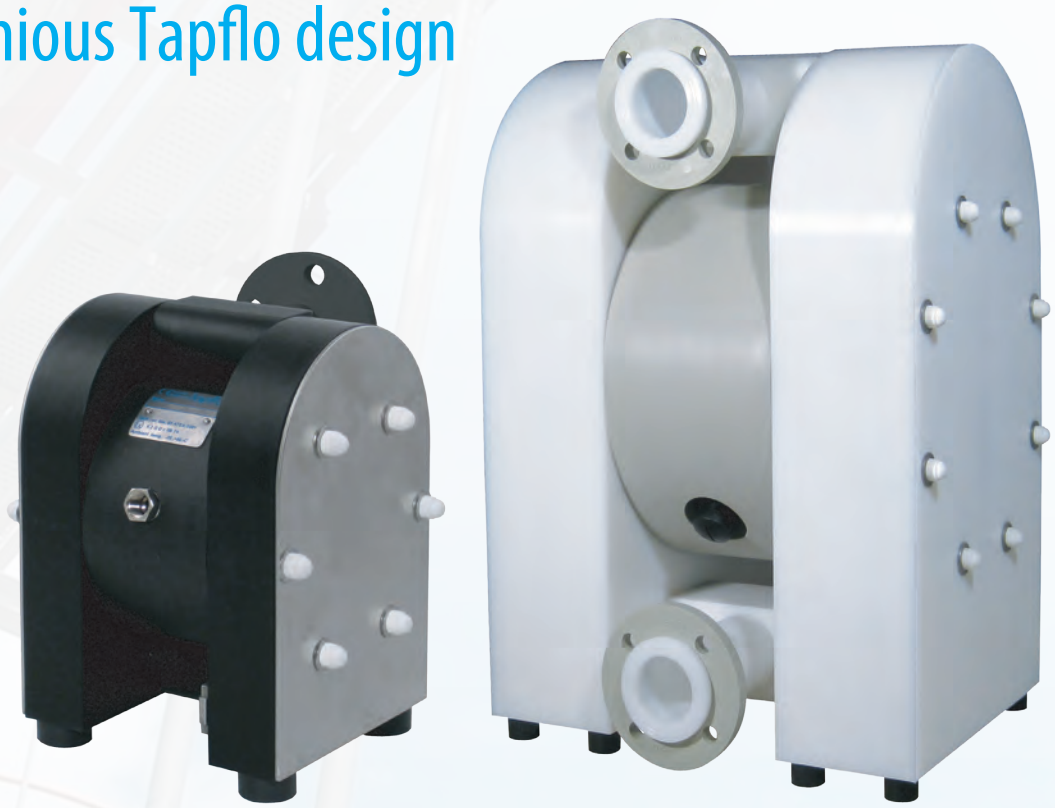

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Biocon Biologics' First-Ever Interchangeable Biosimilar Insulin Glargine

Dr Arun Chandavarkar, Managing Director, Biocon Biologics

Bengaluru, India: Biocon Biologics Limited (BBL), a subsidiary of Biocon Ltd. announced that Express Scripts, a leading pharmacy benefit management organization in the US, will list Biocon Biologics interchangeable biosimilar Insulin Glargine (Semglee*), which will be commercialized by Viatris, as a preferred glargine brand on its National Preferred Formulary® (NPF), which includes more than 28 million lives.

Broad coverage of Semglee by Express Scripts will help ensure that the many patients on its network who need Insulin Glargine may receive the full benefits of and access to treatment with lower or maintained out-of-pocket costs. Biocon Biologics co-developed Semglee with Viatris and together they are committed to improving patients' access to sustainable, high-quality and affordable biosimilars. As part of this commitment, Viatris will soon commercialize two versions of our landmark Insulin Glargine injection, the first-ever interchangeable biosimilar approved by the U.S. Food and Drug Administration (FDA): Semglee® (insulin glargine-yfgn) injection, a branded interchangeable product, and Insulin Glargine (insulin glargine-yfgn) injection, an authorized interchangeable biosimilar.

Both products will be available in pen and vial presentations and are interchangeable for the reference brand, Lantus Semglee will also be included in Express Scripts' Patient Assurance Program. This dual product approach is intended to ensure that this historic interchangeable biosimilar insulin glargine can reach as many patients as possible regardless of financial circumstances, insurance or channel.

Commenting on this marquee development, Dr Arun Chandavarkar, Managing Director, Biocon Biologics said, "The inclusion of our interchangeable biosimilar insulin glargine in Express Scripts' National Preferred Formulary® (NPF) in the U.S. is a major milestone for Biocon Biologics. It furthers our mission of enabling affordable access to quality insulins to a large number of patients. We expect our partner to commercialize the product in the U.S. by end of the year and formulary coverage to begin in Jan 2022, making it an important growth driver for Biocon Biologics."

"We believe adoption of biosimilars through PBMs like Express Scripts, will drive down the high cost of biologics therapy for chronic diseases like diabetes. Our biosimilar Insulin Glargine has the potential to bring significant

West's award-winning NovaGuard® SA Pro safety system is now available for ISO 0.5mL standard and 1mL long glass staked needle syringes

The COVID-19 has impacted lives, healthcare systems, the pharmaceutical industry, and pharmaceutical packaging organizations, world-wide. The resultant treatments, therapies, and vaccines that are administered by injection bring to mind a long-term safety concern – needle-stick injuries. A way to address this concern is with safety systems.

Driven by innovation and committed to safety, West has developed and expanded our solution to help prevent needle stick injuries: the NovaGuard® SA Pro safety system – a single-use accessory for pre-filled ISO standard 0.5mL standard and 1mL long stakedneedle syringes. The system can be deployed using a single-handed technique and was designed to prevent pre-activation during handling.

Key Benefits of the NovaGuard® SA Pro safety system include:

- Compatible with ISO 0.5mL standard and 1mL long glass staked needle syringes
- Comprehensive technical document provided
- Tamper resistant function to help prevent needle recapping
- Ease of use assembly on low and high-speed filling lines
- Transparent for drug inspection and labelling
- Compatible with standard or custom plunger rods
- Functionality studies in temperatures ranging from -40°C to 60°C
- Minimal impact for their use on pre-filled syringe assembly lines
- Low activation force for end-user comfort in the delivery of drug product
- Designed to not pre-activate during handling

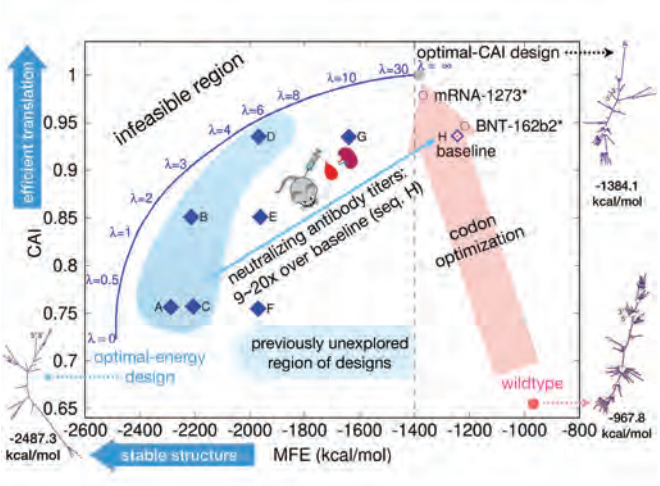
West's NovaGuard® SA Pro safety system was awarded at the 2019 India Packaging Awards for Excellence in Design and User Experience.

The NovaGuard SA Pro product line is now even more comprehensive. It is available in 0.5mL device and 1mL long device, suitable for most drugs that use pre-filled syringes deliver doses between 0.1mL and 1.0mL fill volumes.

Learn more about the NovaGuard® SA Pro safety system by visiting **https://www.westpharma.com/products/prefillable-systems/safety-systems/novaguard-sa-pro** or contact **Kriti Kotian (Kriti.Kotian@westpharma.com)** for more information.

cost savings for patients, employers and PBMs," he added. In July 2021, the U.S. Food and Drug Administration (FDA) had approved our biosimilar Insulin Glargine-yfgn injection (Semglee®) as the first interchangeable biosimilar product under the 351(k) regulatory pathway, endorsing our scientific excellence and robust quality comparability data. Semglee* (insulin glargine-yfgn) Injection and Insulin Glargine-yfgn Injection will be available in pharmacies before the end of the year, and further details related to our partner Viatris' access programs, which aim to ensure that as many patients as possible will benefit from the product, will be available at that time.

Baidu and Stemirna Therapeutics' Preclinical Studies Demonstrate Linear



Shanghai, China: Baidu, a leading AI company with strong Internet foundation, and Stemirna Therapeutics, a leading mRNA biotechnology company, announced the completion of pre-clinical studies that characterized the mRNA vaccine sequences for COVID-19 designed using Baidu's proprietary algorithm LinearDesign. These studies indicated that the LinearDesign-based mRNA sequences significantly outperform the benchmark sequences designed by traditional algorithms in terms of stability, protein expression and immunogenicity, which are critical attributes of mRNA vaccines. The results, published on the preprint server arXiv, validate the effectiveness of LinearDesign along with its promising value in the field of biopharmaceuticals. mRNA vaccine has emerged as a ground-breaking vaccine platform for controlling and preventing infectious diseases, including COVID-19.

However, despite its several beneficial features, such as rapid production and non-infectious properties, mRNA instability remains a major limitation that affects the storage, distribution, and efficiency of mRNA vaccines. Since 2018, Baidu has been advancing computational biology research underlying LinearDesign, with a major effort devoted to the RNA secondary structure study. LinearDesign, first published on arXiv in April 2020 has proved to be an efficient algorithm for optimized mRNA sequence design. Computer simulations have indicated that it takes just 11 minutes to use this novel algorithm to design an optimal mRNA sequence that can theoretically improve the stability and protein expression of an mRNA vaccine candidate.

To further validate the effectiveness of LinearDesign, Baidu teamed up with Stemirna Therapeutics, the first innovative company in China focused on the R&D of mRNA vaccines and drugs, to test seven mRNA COVID-19 vaccine sequences designed using LinearDesign. An mRNA sequence (benchmark) designed using the

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widely-used codon optimization method was tested side-by-side for comparison. An illustration of seven mRNA COVID-19 vaccine sequences designed using LinearDesign Results show that the LinearDesign-based mRNA vaccine sequences for SARS-CoV-2 Spike protein outperform the benchmark sequences in stability, protein expression, and immunogenicity.

Jagsonpal Pharmaceuticals Announces Q2 Fy22 Results

R.P.S. Kochhar, Chairman & Managing Director Jagsonpal Pharmaceuticals

New Delhi, India: Jagsonpal Pharmaceuticals Ltd., a leading pharmaceutical company from Delhi, announced their Q2FY22 results. Commenting on the performance, Mr. R.P.S. Kochhar, Chairman & Managing Director, Jagsonpal Pharmaceuticals said, "We have delivered another steady quarter of revenues while our EBITDA margins continue to show consistency. As mentioned last quarter, our efforts on product rationalization, focus on high margin products, cost control initiatives, and improvement in operational matrix with better supply chain management have started yielding results. I would like to highlight that the Company has recorded an EBITDA of INR 207 mn in the first half of this fiscal against INR 235 mn reported for the whole year in fiscal 21 and INR 87 mn in H1FY21. We expect the momentum to continue in the H2 FY22 barring unforeseen circumstances.

The board has recommended a special interim dividend @80% per Equity shares of value of Rs 5/-, which translates to Rs. 4 per share. The decision was taken by the board keeping in mind the excess cash in the balance sheet with no immediate capex plans in the horizon. The board will continue to assess the cash situation and reward shareholders after meeting all the needs of the Company.

In keeping with its strategy for growth, the Company has engaged Accenture to review and chalk out a business transformation plan with a focus on revenue growth, cost optimization and building organization enablers." Total income of ₹598 mn, registering a growth of 5.3% YoY, EBITDA of ₹ 106 mn, up 101.3% YoY translating to an EBITDA Margin of 17.7%. This was an increase in margin of 844 bps.

EBITDA margin improved due to- Increase in sale of high margin products, Improvement in the ratio of manufacturing cost overheads as percentage of sale, Better financial control and monitoring of other administrative expenses, Profit after Tax of ₹ 73 mn, registering a growth

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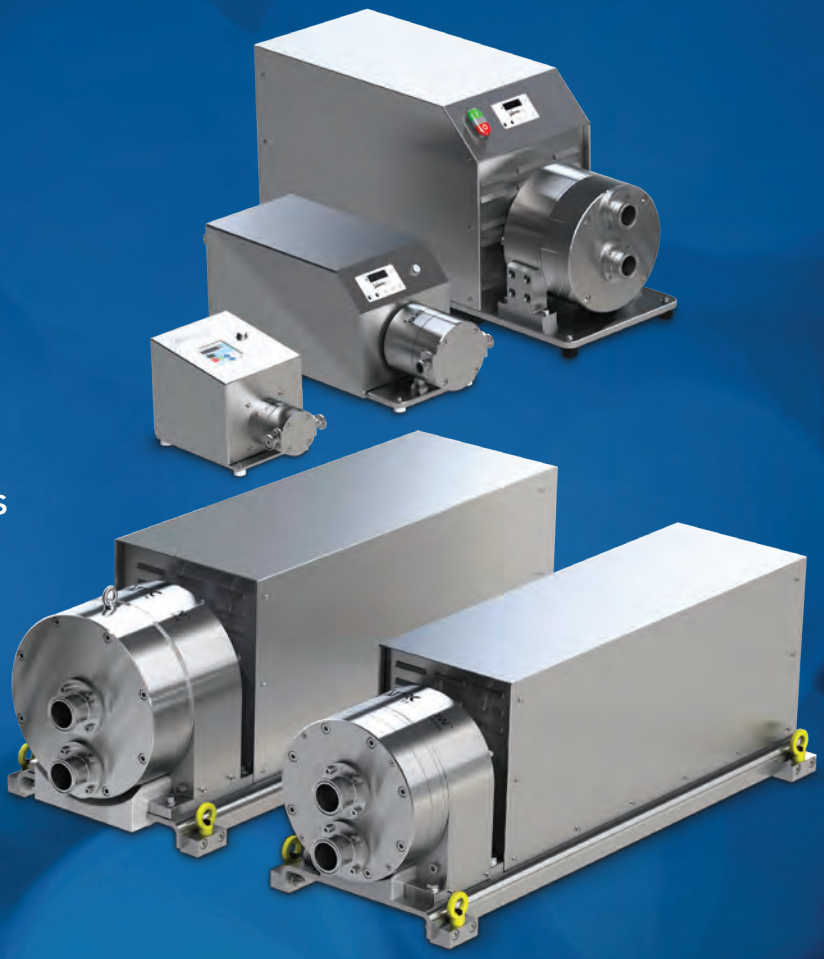

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of 82.3% YoY and EPS was ₹2.79 as compared to ₹ 1.53; a growth of 82.3%.

The company has launched two Dydrogesterone formulations under the brand names Divatrone and Proretro in the mid of August and witness sale of ~ Rs 3 Crore in just 45 days of Product launch. This is the first Indian Micronized brand featured in Iqvia ORG MAT in first month of launch. More than 2000 doctors has already started prescribing our brand Divatrone and Pro-retro. Through Divatrone & Pro-Retro company has entered new horizon by capitalizing customer's potential in terms of increased yield per prescription especially among our existing gynecologists.

The Company's performance was consistent during the 2nd quarter with both the existing brands as well as the momentum due to the new brand launches including Divatrone & Pro-retro. As per IQVIA data, the current market size of Dydrogesterone is roughly about Rs. 480 crores.

Focused campaigns like Physician, Ortho & Gynae Premier Leagues and Specialist Clubs were created and implemented, which motivated the field staff to generate higher prescriptions as well as prescriber base. The campaigns were focused on select high potential customers in targeted HQs which resulted in desired outcomes. The campaigns have created a strategic intervention to yield short term results as well as facilitating long term customer retention.

Lincoln Pharmaceuticals Ltd Receives Approval from Australian Regulator, TGA

Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Limited

Ahmedabad, India: Lincoln Pharmaceuticals Limited, one of India's leading healthcare companies has received approval from Australia's medicines and medical devices regulator - Therapeutic Goods Administration (TGA). Company's manufacturing facility in Khatraj, Gujarat received the GMP clearance from TGA for all three departments Tablet, Capsule and Cream & Ointment, which will cover a wide range of Pharmaceutical Formulation manufactured by the Company. Company looks to enter the Australian markets soon with its dermatology, gastro and pain management products and gradually expand its product portfolio. The certification will be valid till June 2023.

TGA and EU GMP approval will strengthen the company's presence in the regulated markets. In May 2020, company had received European

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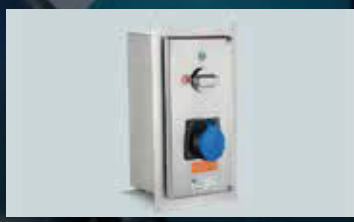

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Union (EU) GMP certification from Germany FDA for its manufacturing facility which allows the company to market its products in all the 27 member countries of EU and also give access to European Economic Area (EEA) countries.

The company manufactures wide-range of drugs at its Khatraj facility and includes anti-infective, respiratory system, gynaecology, dermatology, gastro, pain management, cardio & CNS, anti-bacterial, anti-diabetic, anti-malaria among others.

Mr. Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Limited, said, "TGA and EU GMP approval are important stepping stones in the journey of the company and will help to expand its presence in more regulated markets. TGA and EU GMP approvals are the result of stringent quality and compliance norms followed at Lincoln Pharma across all departments, especially the R&D and compliance. Over the years, the company has seen good traction in the export business, which is expected to get further boost once TGA & EU operations commence. The certification will allow us to address the growing needs of patients in the regulated markets and provide affordable and innovative medicines."

Lincoln Pharma has a state-of-the-art manufacturing facility unit at Khatraj in Ahmedabad, Gujarat, complying with stringent international quality and compliance norms and certified by EUGMP, WHO-GMP and ISO-9001: 2015. Company has developed 600 plus formulations in 15 therapeutic areas and has a strong product/brand portfolio in anti-infective, respiratory system, gynaecology, cardio & CNS, anti-bacterial, ant-diabetic, anti-malaria among others. Company has filed 25 plus patent applications and is awarded with seven patents. Company has a strong presence in the domestic market nationally with a dedicated field force of over 600 personnel who cater to more than 30,000 doctors, chemists across the country.

Overcoming Challenges in Effervescent Dosage Manufacturing

Mannheim, Germany: Easy to use and with improved technical properties, BENEO's galenIQ™ 721 filler-binder optimizes the production of fizzy tablets and powders. To improve the taste and stability of effervescent tablets and powders, BENEO presents galenIQ™ 721. This filler-binder enables pharmaceutical and nutraceutical manufacturers to target consumers that have difficulty swallowing standard tablets. As a non-hygroscopic, water-soluble and directly compressible excipient, galenIQ™ 721 also provides high content uniformity

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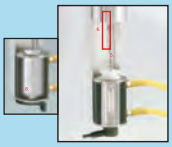
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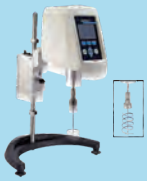
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and production efficiency for effervescent applications.

Effervescent dosage forms offer distinct advantages compared with traditional tablets. For instance, many patients have problems swallowing tablets. Effervescent powders and tablets offer a more convenient way to deliver medicines or dietary supplements. They dissolve upon contact with water to release carbon dioxide and create a drink. In addition, they can be used to formulate pharmaceuticals that are difficult to digest, that cause stomach or esophageal irritation or that rely on a rapid onset of action, such as analgesics. However, manufacturing effervescent dosage forms is often challenging. To produce highly stable tablets, a non-hygroscopic, direct compression filler-binder such as galenIQ™ 721 is needed. It ensures high content uniformity and facilitates production. BENEO's excipient has a sugar-like taste profile, a pleasant mouthfeel and can enhance the palatability of effervescent formulations. Furthermore it is non-cariogenic and therefore is both sweet and tooth-friendly.

Dr Maj-Britt Cepok, Head of Business Development, Pharma, BENEO, comments: "Fizzy tablets are ideally suited to administer a wide range of light-, oxygen- and other sensitive active ingredients and those that require a large dose. In addition, effervescent preparations are more appealing to consumers than traditional dosage forms. galenIQ™ 721 helps manufacturers to tap into this market and enhance their development programs."

IISER Bhopal Scientist Proposes the Biochemical Link between COVID-19

Bhopal, India: Indian Institute of Science Education and Research (IISER) Bhopal Scientists have recently published a review of the biomolecular relationships among COVID-19, aging, and diabetes.

Dr Amjad Husain, Principal Scientist, and Chief Executive Officer, Innovation and Incubation Center for Entrepreneurship (IICE), IISER Bhopal, along with researchers from The University of Arizona, USA, have presented that existing drugs used to treat diabetes, obesity and ageing can potentially be used to treat COVID-19. In addition, there are similar naturally existing biomolecules that can be also explored in combination for the COVID treatment. Their review, co-authored by Dr. Udeep Chawla, Dr. Manoj Kumar Kashyap and Dr. Amjad Husain, has recently been published in the journal Molecular and Cellular Biochemistry and offers insight into future directions in COVID-19 therapeutics.

Highlighting the research, Dr. Amjad Husain, Chief Executive Officer, Innovation and Incubation Center for Entrepreneurship (IICE), IISER Bhopal said, "With the nearly-two-year-long COVID-19 pandemic continuing to ravage the world, we are beginning to slowly understand the virus and its functioning." It is now known that the effects of the viral infection is severe on aging population and people with existing diabetic conditions. There are studies being conducted worldwide on the effects of aging and diabetes on the short- and long-term outcomes of the COVID-19 infection.

The published review shows that at the molecular level, there are intersecting pathways that are common to diabetes, aging, and COVID-19. All three conditions are associated with oxidative stress and lowering of the immune response and complications arising from them lead to the onset of numerous other diseases such as cardiovascular disorders, eye diseases, neuropathy (nerve diseases), and nephropathy (kidney problems).

The researchers believe that an ideal therapeutic candidate for COVID-19 should be able to target the pathways that are common to diabetes, ageing and the SARS-CoV-2 infection. There are classes of compounds such as polyphenols found in plant-based food – curcumin (found in turmeric), and resveratrol (found in grapes), have been shown to not only slow down the ageing process, but also possess anti-viral properties," said Dr. Husain. Some other polyphenols that the researchers have identified as being useful for both COVID-19 treatment and comorbidity conditions such as diabetes and ageing may include catechins (present in green tea, cocoa and berries), procyanidins (found in apples, cinnamon and grape skin), and theaflavin (found in black tea).

The researchers also present evidence of some existing potential anti-aging drugs such as Rapamycin that can be explored for the COVID-19 treatment because of the common biochemical pathways associated with these diseases. Another such example is a drug Metformin , which is usually used to control blood sugar. ■

PSG Global & India Evincing as a Biotech Applications Specialist

Michael Franco
Director, Global Biopharma Sales

How has PSG QF performing year 2021 so far?

2021 has been a challenging year in so many aspects, most of them related to the COVID-19 pandemic but I am pleased to say that our Dover's PSG Biopharma team has worked very hard, meeting every challenge with great resolve and determination, and as a result, Quattroflow has done very well this year been able to meet the needs of our customers.

QF being pump for Biopharma, how it has supported vaccine demand globally?

Quattroflow is a brand of PSG Dover that specializes in biotech applications, and our team works exclusively with those companies that are in research, product development and commercial manufacturing of many kinds of vaccines, including the vaccine for the Corona virus COVID19. So, Dover PSG proudly supports the global demand for vaccines by bringing providing products that have enabled the Research & Development and manufacturing of the vaccines when they were ready for production into market. Quattroflow pumps that have been specifically designed to attend the extremely delicate nature of biotech applications. For example, the Quattroflow is a positive-displacement quaternary diaphragm pump that

mimics the human heart, and as such, it can generate an optimized flow path for different types of shear-sensitive biologics with minimum pulsation and minimum particle generation, ensuring optimal process conditions.

What is the view on single use pump demand?

The demand for single-use pumps has grown steadily for the last few years, and 2021 was no exception, as Quattroflow has seen a larger share of orders for our single-use pumps, with a considerable number of those going to companies working on COVID-19-related projects. Even though we believe that multiple-use systems will never go away completely, our projection is that the market share for single-use systems will continue its expansion.

How our pumps supported COVID vaccines globally?

Shortly after the USA Government created the Operation Warp Speed agency, Dover PSG was informed that Quattroflow pumps had been qualified by several companies as critical components for their work on finding a vaccine against the COVID-19 virus, and to better support those companies, PSG Dover PSG established a special task force team at our facility in Duisburg, Germany, where the Quattroflow pumps are manufactured, to exclusively oversee all COVID-19 projects and prioritize them. The work of the special task force team allowed Dover PSG to ship Quattroflow pumps and parts on a timely basis supporting the global effort to end the pandemic.

Tell us about the adjacent product you have added in your biopharma value chain?

Early last year, Dover PSG acquired em-tec®, a German-based company, with its headquarters located in Finning, that specializes in non-contact flow measurement, using ultrasonic technology, for critical applications in the medical and the biopharmaceutical industries. The association between Quattroflow and em-tec has been a very successful one, as Dover PSG is now able to provide a complete solution to all customers who are looking for a reliable integration between a high-performance pump and an accurate flow sensor, a concept that has expanded with the launching of the QCON series, a platform of Quattroflow pumps with an integrated pump controller.

Mr. Ravi Prasad

PSG India (MMD) – GM

Tell us about your PSG India presence in India

Our state-of-the-art India facility at Chennai is around 30,000 sq. ft. and we produce our Global brands pumps Wilden, Blackmer (including Gas Compressors), Ebsray, Neptune, Quattroflow and Hydro to serve India and International Markets. To enhance our customer responsiveness, PSG India has strategically located our Sales & after-sales footprints in all major like Mumbai, Delhi, Bangalore, Chennai, Coimbatore, Hyderabad and Vadodara. Our long-standing & well-trained Channel Business partners of PSG India are positioned in various Industrial-centric cities & hubs in India to any immediate demand & services.

Can you explain about biopharma market dynamics in India and how you are positioning QF products in India?

Indian Biopharma industry was valued at $40 bn in 2020 and this industry is growing at 16% CAGR. The impact of COVID 19 and the Government of India vaccination campaign has contributed to exponential growth in this industry. This industry is backed by vaccination demand, which is created by the growing population, economic growth, and new diseases. To cater to this industry, we are positioning our Quattroflow pumps, (which are also called quaternary diaphragm pumps) for critical applications of the biopharma industry where it allows the gentle transfer of shear sensitive biological products and aqueous solutions such as blood proteins, blood by-products of vaccines, etc. Moreover, these pumps are seal-less pumps and have CIP and SIP capabilities. Our Quattroflow pumps are used in the process for manufacturing various

vaccines and now of COVID19 vaccines in India. We are pleased to highlight here that we have supplied to various leading vaccine manufacturers in India for Covid19 for critical and supercritical applications.

Aftermarket support is important for critical products like QF, how you ensure customer delight?

Quattroflow being used for critical applications of biopharma we are extremely sensitive to aftermarket support. Our objective is 'Availability+' as we emphasize ourselves to connect with our customers continuously for periodic and predictive health check of the products which will help to them to extend the product life and reduce overall product life-cycle cost. We always attune our customers by providing end-to-end know-how of Quattroflow pumps by providing both classroom and field training which makes them comfortable to operate their overall system. ■

Novel Drug Delivery System for Nutraceuticals

Dr. R.B. Smarta
CMD-Interlink
Vice President (HADSA)

The Indian Nutraceutical market is a thriving sector with a promising future for growth and development. In the past few years, the industry has gained momentum due to an increase in preference for a healthy lifestyle. The sedentary and strenuous way of living has resulted in an increase in diseases such as diabetes, obesity and hypertension. Therefore, in order to combat such issues, researchers are opting to manufacture nutraceutical products such as antioxidants, fatty acids, prebiotics and probiotics using novel drug delivery systems. Drug delivery is a strategy to introduce the drug inside the body and result in maximum safety and efficacy. Similarly, novel drug delivery systems are the ones that are more specific in nature leading to an increase in efficiency and decrease in toxicity.

The novel drug delivery systems such as nanotechnology and liposomal technology are gradually finding their

application in the field of Nutraceuticals as well. This is because the novel technologies overcome various barriers in manufacturing nutraceutical products. Various products are challenging to manufacture due to constraints such as poor solubility, permeability, short half-life, unwanted interaction of the ingredient with food or other excipients to name a few. For instance, compounds such as Epigallocatechin Gallate (EGCG – found in green tea) which is an antioxidant poses manufacturing challenges because of its poor solubility and rapid degradation in the gut environment. Hence, adopting newer delivery strategies enhances the applicability of such nutraceuticals.

Let us have a look at some of the novel drug delivery systems that are utilized in manufacturing nutraceutical formulations:

Nanotechnology is majorly used in encapsulating nutraceutical ingredients. Encapsulation is the process of extensively coating or covering the ingredient in a shell using appropriate coating materials. This technology which is also termed Nano-encapsulation offers various advantages such as improved bioavailability and solubility. It has a targeted approach that reduces the toxic and unwanted effects. The Nano-encapsulated formulations protect the ingredient from various external factors. For instance, the ingredient is safe from the changes in pH or from acid and enzymes of the digestive tract. It also increases the shelf life of the product as well.

The nanoparticles are also used to fortify various minerals and nutrients in food, thereby increasing the nutritional content of the food. Various carriers in nanotechnology include Nanoparticles, Nano-emulsions, Nanogels, etc.

Let us have a look at some of the carriers in detail-

Nanoparticles

Nanoparticles are a prominent drug delivery mechanism that has a particle size of up to 100 nanometers. The nanoparticles show an improved absorption and enhanced efficiency as compared to the conventional dosage form. The coating materials comprise food-grade polymers, lipids and proteins.

Various nutraceutical products are marketed using nanoparticles, out of which iron supplements combined with Folic acid are prominent. These oral supplements increase the hemoglobin content of the body and have negligible side effects. Soft gel Omega-3 fatty acids capsules are also encapsulated in the form of nanoparticles.

Nano-emulsions

In order to increase the effectiveness of the formulation, good delivery of nutraceuticals is crucial. The Nano-emulsion can be essential to achieve the necessary efficacy. Various formulations are utilizing this technology out of which curcumin is the most prominent nutraceutical ingredient. Nano-curcumin or self-emulsifying Nano-capsules or Nano-tablets of turmeric are available in the market providing various health benefits such as antioxidant and anti-inflammatory activities. Additionally, various vitamin supplements are also available. Soy proteins, Hesperidin, beta-carotene, and Resveratrol are some of the nutraceutical ingredients under research that are encapsulated using this nanotechnology.

Liposomes are a prominent drug delivery system used in various pharmaceutical products. Furthermore, its applications are being found in nutraceuticals and various products are available in the market as well. They are found in the form of vitamin D3, vitamin K2 and vitamin C formulations using carriers such as phosphatidyl choline. GABA with L-theanine formulation are also available using liposomal technology.

Broadly speaking, a liposome is a lipid bilayer with an aqueous cavity in the center. It is an excellent carrier for a spectrum of hydrophilic and hydrophobic ingredients. Moreover, they are non-toxic as well as biologically compatible. Currently, various formulations involving nutraceutical ingredients such as flavonoids, polyphenols including Oleuropein and retinoic acid have not only shown promising results in research findings but also indicate scope in the future market application as well.

Liposomal technology, however, has a lot of scope for improvement. The bilayer can be rigid that leads to inefficient drug delivery. Hence, various changes in composition and manufacturing techniques should be applied to increase the penetration efficiency of the molecule.

Various patents have been filed that involve novel drug delivery systems in nutraceuticals. They involve various manufacturing technologies that incorporate nutraceutical ingredients into delivery strategies for an increase in the efficiency of the formulation.

For instance, Curcumin is microencapsulated in the form of nanoparticles with the help of phospholipid carriers to treat H. pylori infections. Similarly, Selenium nanoparticles embedded in the honey matrix are used as anti-fungal agents and other skin infections. Anti-aging preparations such as collagen are formulated in liposomal dosage forms.

Liposomal vitamin B12, vitamin E and Oenothera oil (extracted from the primrose) can be formulated as ointments or skin patches to treat eczema. Abscisic acid (a plant hormone), a novel formulation for the treatment of diabetes and prostate enlargement is formulated using micro-emulsions and liposomes.

These examples of patents indicate the amount of research happening around the novel drug delivery systems for nutraceutical ingredients. Moreover, it can be stated that this novel approach has a lot of scope for market growth and development.

The novel drug delivery systems can be used as an excellent marketing strategy to increase the sales of the products since these products provide an advantage as compared to the traditional dosage forms. Furthermore, it offers a plethora of opportunities for nutraceutical manufacturers as they help them overcome various manufacturing barriers. However, in order to avail the maximum benefit of such trends, it should be important to note that standardized regulatory guidelines are essential that are lacking in the Nutraceutical market. ■

Meeting the Pharma Expectations by Ensuing 'Time, Quality & Innovation'

Mihir Mehta is the BU Head & Vice President at PRAJ HiPurity Systems Ltd, *Mumbai and heads global business and operations of HiPurity systems. In Talks with PharmaBioWorld, Mr Mihir shares the latest updates of his firm and leading the team to deliver solutions to more than 10 Pharma companies producing COVID related medications amid the pandemic.*

Mihir Mehta
Vice President & BU Head, Praj HiPurity Systems

How has Praj HiPurity Systems performed in the previous quarter and what has been its turnover?

Praj Hipurity has been at the forefront of critical solutions for pharma and lifesciences segment for more than 3 decades now. Years of insights, dedicated team and concerted efforts have ensured Praj Hipurity provide solutions to many organizations across the globe. In the last quarter riding on increased focus on the Pharma segment and years of efforts, we recorded a stellar growth in order inflow as well as revenue realization both Q on Q

and Half year completed on 30th Sep 2021.

How has the pandemic shaped Praj HiPurity Systems' stance in the growing pharmaceutical and biotech industry?

Praj Hipurity chose to remain in the most critical segment of a Pharma facility i.e water systems, process skids and Process Skids for Complex Injectables, Fermenters and Bioreactors for the Biotech Industry. With leadership in Fermentation Technology of its parent group (Praj Industries) coupled with its unique positioning, Praj Hipurity has become the obvious choice for many reputed & experienced pharma companies. These companies understand the significance of having subject matter experts on board in these critical areas of operations. With clients looking to rapidly setting up a facility to directly or indirectly support COVID related medications, Praj Hipurity contributed actively to more than 10 such projects. That speaks volume on the trust placed by the Industry in Team Praj Hipurity when the stakes are high.

What has been your company's latest value-added services that were launched and have fared well adjusting to the new normal and current demand of the industry?

One of the core industry issue is availability of skilled resources as the industry is growing at rapid pace. Praj Hipurity understood this critical aspect of client need in 2 critical areas – Operations management of Water Plants – During the lockdown, Praj Hipurity through its Value Added services (VAS) offerings recorded 100% uninterrupted service to not only operate but maintain client's water plants for many high profile plants. This success has led to 100% client retention and the good work is spreading. With acute shortage of resources, we believe more and more clients would rely on such services offered by Praj Hipurity through their well- and & programmed O&M offerings.

Another critical need of the industry is Process Engineered solutions for Customized complex molecules. It has been seen that for customized sterile facilities, the key to success for Pharmaceutical clients have been pushing the products to market. The 'First to Serve' (FTS) expectations for certain products leads to tremendous pressure on the overall project completion timelines. Praj Hipurity have now created a benchmark of sorts in providing 'First time Right' (FTR) process design for customized applications/ facilities involving Complex Injectables and Fermentation based solutions through its Process Engineering

Package. The advantage for clients to handhold during the critical Early design Phase has made them proceed with speed without compromising on quality.

What have been your recent top technology and R&D Breakthroughs that have geared your workforce?

Praj Hipurity has successfully indigenized a Swedish technology (from AQUANOVA) to provide a 'COMBI' system for all sterile facilities which can produce WFI & Pure Steam simultaneously. This has since become a system and design of choice for many successful companies in India and abroad. This has helped not only reduce the footprint by 30% but also assisted in reducing validation efforts by more than 40% and spares cost by 20-30% which helps reduce the total cost of ownership the plant significantly.

Praj Hipurity have successfully helped run manufacturing trial runs for highest number of Complex Injectables facilities in India. This has been achieved by integrating key know-how in terms of Process design, Product handling, 3D modelling and Visualization of the plant and 100% correct deliverance of the system's functionalities. These successes have created and opened up various opportunities for Team Praj Hipurity in the recent times.

As we witness more and more research efforts in the Biopharma Industry, the need for Lab scale and Pilot scale Fermenters are constantly on the rise. Each researcher & scientist's expectations are unique, hence a standardized solution for lab scale fermenters will not satisfy their needs. The industry has many solution providers for standard catalogued fermenters. Team Praj Hipurity hence is trying to find a way to provide partially customized solution through its SMART BIOREACTOR even in this 'One Size Fits All' segment. In the coming time, this will be the space to watch out for as we see more and more efforts in the Biopharma space in India.

How has your company responded to challenges in the industry and what had been your motto to adapt and grow throughout the decade years of experience working in the specific sector?

Though we are in general categorized as a Capital Goods company, in the Pharma space we are more of service provider. The foundation of this lays in the fact that the most critical expectations of Industry could only be based on Time, Quality & Innovation. We have focused on 'On time Performance' as a critical measure of our delivery. The systems and processes have

been aligned to be able to engage smartly with clients before and after a contract to ensure on time delivery. A rich team of experts with the right blend of industry specific experience and youthful energy have enabled us to clock industry leading OTP. With solid exposure to International markets and design agencies in the west, Praj Hipurity have adapted some of the leading standards to deliver top quality with speed. We at the core believe right Quality is not a mere outcome of the high cost input but outcome of meticulous planning and an eye to detailing. Praj Hipurity's Fully Integrated manufacturing facility is one of its kind focusing on these detailing which have helped us stand out amongst a list of other age old suppliers. Praj Hipurity have equipped itself to serve specific COVID related sterile facilities in the shortest possible time frame (in some cases with deliveries in 6 weeks). Praj Hipurity is amongst the few organized companies in the segment which has a fully developed Services support structure to serve clients during the operational life of a plant. As the Indian Pharma industry grows in reputation of being the Pharmacy of the World, there is a need to reach a different strata of the industry to strengthen the industry at its core. This has led us to believe that through our recently launched Franchise Partner program, this need can be served with focus on reach and speed making our top class products and services available to a larger client base.

What is your company's way ahead and milestones?

One of the guiding lights have essentially been our parent setup and its core expertise which focuses on providing end to end solutions along with technology platforms for Fermentation Based solutions in the field of Biofuels, Breweries, etc. Praj Hipurity will diligently focus on providing effective and efficient solutions in the Water space reducing the water footprint inline with a larger objective of making our products eco-friendly and also simultaneously addressing the 2 POE's (POINT OF ENTRY & POINT OF EXIT i.e Zero Liquid Discharge Water systems) for the Industry. The Focus will also be on providing solutions in the High Capacity Fermentation Space for the ever growing Biopharma Industry. In the Complex Injectables Space, Praj Hipurity continues to focus on being the leader with RFT (Right First Time) and Efficient Plants with highest level of Process Engineering support and guidance. ■

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Lipids & Liposomal Based Drug Delivery Systems Managing Cardiovascular Disease

Arun Kedia
Managing Director, VAV Life Sciences

It is a known fact that worldwide cardiovascular disease (CVD) is one of the major causes of mortality, especially in developing countries. While there are many reasons for CVD, atherosclerosis, and hypertension are two of the major ones. In addition to this, increasing age and an unhealthy lifestyle can lead to many physiological changes which ultimately increase the chances of a cardiac ailment in the later years of life. It is estimated that by 2030, the number of deaths associated with cardiovascular diseases will reach 23.3 million globally.

Post-Covid 19, there was a sudden surge in deaths reported due to cardiovascular complications like heart failure, myocarditis, arrhythmias, and myocardial injuries. The SARS COV 2 virus has been shown to invade the cardiovascular cells or tissues via the angiotensin-converting enzyme, leading to endothelial dysfunction, inflammation, diminished supply of oxygen to the heart causing muscle damage and thereby leading to myocardial infarction. It has been studied and proven that lipids and lipoproteins, namely, low-density lipoproteins (LDL) and high-density lipoproteins (HDL), lipid triglycerides, and fatty acids are the most crucial contributors to cardiovascular disease such as atherosclerosis and inflammation of cardiac cells and tissues.

While cholesterol is required for normal cell function, hypercholesterolemia contributes to the development of cardiovascular disease (CVD). Though statins form the first line of defence in blocking cholesterol synthesis, additional lipid-lowering drugs may also be required. More recent developments suggest possible therapeutic

benefits of phospholipids, specifically phosphatidylcholine (PC) and its component choline in the treatment of cardiovascular disease.

Phosphatidylcholine (PC) is involved in the mechanism of scavenging free cholesterol & eliminating it through the liver which is very crucial to reduce the high cholesterol levels in the blood. It works by a reverse cholesterol transport mechanism caused by effecting an enzyme made in the liver. This enzyme catalyzes the uptake of free cholesterol from the plasma into the lipoprotein particle.

The enzyme converts the smaller HDLs to mature, large round HDL particles. These particles get bigger as cholesterol is brought into its core. PC allows the enzyme to put more cholesterol into the HDL particles. Doing this clears more non-HDL cholesterol from the circulation, reducing levels in the blood.

Purified forms of phosphatidylcholine and lecithin have been shown to work both orally and intravenously to improve cholesterol numbers. Intravenous injections of PC are found to be equally effective in reducing symptoms of angina pectoris.

Data and studies indicate that phospholipids play a very crucial role in the treatment and reduction of atherosclerosis. One of the most critical phospholipids is phosphatidylcholine (PC) derived from different plants, animal or synthetic origin. At the time of birth, our cell membranes contain 90% of phosphatidylcholine, but as we age, we lose most of it. This leads to loss of cell membrane fluidity, enzyme function, and ultimately cell damage with an increase in LDL levels, formations of plaques, and increased risk of CVD. Study indicates atherosclerosis further enhances the decrease in phospholipids with age, specially, choline–containing phospholipids.

With the growth and increased research on nanotechnology, there is an enhanced therapy that has been made possible for the treatment of cardiovascular diseases. Liposomal nanotechnology has important applications in the delivery of drugs that are poorly soluble or have a danger of increased toxicity to the healthy cells. These nanoparticles have offered hope for increased bioavailability of drugs as well as many diagnostic agents. They also offer tremendous potential in the treatment of atherosclerosis. They play a dual role not only as an effective carrier for therapeutic agents but are also used in imaging diagnostic systems to monitor the efficiency of the treatment

Liposome-based drug delivery mechanisms are non-toxic, biodegradable, stable, biocompatible, and sustainable as they avoid being detected by the host defence mechanism. This increases the

stability of the drug and offers active site targeting. They can therefore be administered across a variety of routes like oral, intravenous, or semi-solid forms.

Liposomes are known to increase the therapeutic index of certain drugs. In more recent times, the possible use of improved or long-circulating liposomes is also gaining importance in the treatment of cardiovascular disease. This comprises of coating the liposomes with a biocompatible molecule which helps in preventing recognition and destruction of the liposome drug carrier and helps to sustain the same for a longer time in the system for better effects.

Lipids and lipid nanocarrier-based technologies offer tremendous hope for future applications in managing cardiovascular disease both from therapeutic and diagnostic areas. Future applications of the technology may include combining molecular imaging for detection of inflammation, apoptosis, and angiogenesis with drug delivery of a therapeutic agent. With sufficient advancements, the technology may also evolve to new nanocarriers that may be used in the non-invasive treatment of patients with cardiovascular diseases to reduce the morbidity and mortality rates.■

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