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Health Ministry revises Schedule M guidelines for pharma manufacturing units

New Delhi, India: The Ministry of Health and Family Welfare (MoHFW) notified the revised rules under Schedule M of the Drugs and Cosmetics Rules, 1945, in the Gazette of India.

Schedule M prescribes the good manufacturing practices (GMP) for pharmaceutical products. The revised Schedule M includes the introduction of a pharma quality system (PQS), quality risk management (QRM), product quality review (PQR), and specific guidelines for the qualification and validation of equipment.

Schedule M part of Drugs and Cosmetics Act 1940 deals with Good Manufacturing Practices for pharmaceuticals that should be followed by pharmaceutical manufacturing units in India. GMP requires that medicines which are of consistent high quality; are appropriate for their intended use; meet the requirements of the marketing authorisation or clinical trial authorisation.

Dr Mansukh Mandaviya inaugurates CDSCO Sub Zonal Office and Central Drug Testing Laboratory in Indore, MP

Dr. Mansukh Mandaviya, Union Minister of Health and Family Welfare

New Delhi, India: Dr. Mansukh Mandaviya, Union Minister of Health and Family Welfare inaugurated the Central Drugs Standard Control Organization (CDSCO) Sub Zonal office and Central Drug Testing Laboratory (CDTL) in Indore, Madhya Pradesh. He also laid the foundation stone for various facilities in AIIMS Bhopal and inaugurated a slew of other facilities in Madhya Pradesh which includes 190 Pharmaceutical Industries, 55 WHO-GMP Complied Manufacturing Units, 163 Blood Centres, 12 Manufacturing Units having Written Confirmation, 12 Large Volume Parenteral Units, 9 Private Drugs Testing Laboratory, 1 Vaccine Manufacturing Unit and a Special Economic Zone (SEZ) Facility in Pithampur. Prior to this, Dr Mandaviya also addressed the 75th Foundation Day ceremony of Mahatma Gandhi Memorial Medical College in Indore.

Shri Rajendra Shukla, Deputy Chief Minister, Madhya Pradesh; Kailash Vijayvargiya, State Cabinet Minister, Madhya Pradesh; Tulsiram Silavat, Water Resources Minister, Madhya Pradesh and Shankar Lalwani, Member of Parliament from Indore were present on the occasion.

Dr Mandaviya said that "monitoring the quality of medicines through CDSCO Sub-Zonal office will ensure access to high quality medicines to the citizens and provide ease of doing business for the stakeholders of pharmaceutical industries of Madhya Pradesh through the regulatory functions of CDSCO". He further said that "CDTL and Sub-Zonal Office at CDSCO Bhawan, Indore will be entrusted with various responsibilities of regulation of drugs, cosmetics and medical devices. This will ensure proper implementation of the provisions of the Drugs and Cosmetics Acts and Rules made to ensure the safety and welfare of patients and for better coordination with State Drug Controller Organizations."

The Central Drug Testing Laboratory has high quality laboratory services available for testing drugs, which will ensure essential and high-quality medicines to improve the health of the citizens of the country and Madhya Pradesh. It consists of 12 HPLCs, 1 GLC, 1 UV Spectrophotometer and other instruments. The medicine samples will be tested and analysed in the laboratory following standard testing procedures.

UP Government to build a 1472-acre pharmaceutical park in Lalitpur, Bundelkhand

UP, India: The Uttar Pradesh government, under the visionary leadership of Chief Minister Yogi Adityanath, is establishing a Pharma Park in Lalitpur, Bundelkhand, covering 1472 acres across five villages. The identified villages for the survey include Saidpur (426 acres), Gadolikala (249 acres), Largan (239 acres), Karounda (116 acres), and Rampur (441 acres). The plan, guided by Uttar Pradesh State Industrial Development Authority (UPSIDA), will unfold in two phases, with an initial focus on immediate development efforts covering 300 acres of land.

"Under the able guidance of honourable Chief Minister, the UPSIDA has come up with a comprehensive plan to conduct survey, and for this a invitation for hiring suitable

surveyor is in process. We have invited applications for the selection of a survey agency through e-tender under fixed bids process. The selected agency will complete processes soil testing, contour mapping and topographical investigation," said Mayur Maheshwari, CEO, UPSIDA.

Modern surveying techniques, such as digital total stations, DGPS, and drones, will be used to ensure precision in the survey process. The resulting map, created on a scale of 1:4000, will be based on benchmarks established by the Great Trigonometric Survey of India. In addition to mapping, the agency will conduct soil testing using established procedures, including borehole drilling, sample collection, and comprehensive testing. This approach aims to evaluate the availability and quality of resources within the designated area for the operationalization of pharmaceutical units.

UPSIDA is also taking steps to expedite development projects at Site-1 and Site-2 in Orai, along with the Plastic City project in Dibiyapur. The Plastic Park, spread across 274.4 acres, encompasses industrial units, residential areas, and basic infrastructure. UPSIDA is actively seeking agencies to provide layout guide maps, sectoral maps, and gantry signage boards.

"The establishment of the Pharma Park and the acceleration of associated projects mark a strategic move by the Uttar Pradesh government towards fostering industrial growth and economic development. The utilization of modern surveying techniques underscores a commitment to precision and efficiency in the planning and execution of these initiatives. As the survey progresses and development efforts gain momentum, the Pharma Park in Lalitpur is poised to become a key contributor to the pharmaceutical sector, offering economic opportunities and reinforcing Uttar Pradesh's position on the industrial landscape," he added.

Strong performance in the US market to support growth of the Indian pharma industry in FY2024: ICRA

Mumbai India: ICRA expects the revenues of a sample set of 25 Indian pharmaceutical companies (which account for ~60% of the overall revenues of the Indian pharmaceutical industry) to expand by 9-11% in FY2024, post a YoY growth of 10% in FY2023. The OPM for the sample set is projected to improve to 22-23% in FY2024, against 20.7% in FY2023, supported by new product launches backed by increased focus on complex generics/specialty molecules, easing of pricing pressure, and some benefits of volume expansion and better pricing due to product shortages in the US market.

ICRA expects the overall credit profile of the Indian pharmaceutical companies to remain healthy, supported by their stable earnings profile, comfortable leverage and coverage metrics, and strong liquidity position, in spite of the credit risk arising from any adverse regulatory actions.

The projected revenue growth in FY2024 will be primarily supported by 11-13% expansion in the US market and 7-9% growth in the domestic market, while revenues from the European market and emerging markets are expected to rise by 11-13% and 13-15%, respectively.

The US has always been a key market for most leading Indian pharmaceutical companies, accounting for a sizeable share of their revenues. However, the share of revenues from the US market for ICRA's sample set of companies declined to ~35% in FY2022 vis-à-vis 40% in FY2020 owing to consistent pricing pressure, lack of major blockbuster products going off-patent and increased regulatory scrutiny in the recent years. Nonetheless, with easing of pricing pressure, significant new launches and shortages of some products, the same increased to 37% in FY2023 and 38% in H1 FY2024.

Commenting on the product shortages and increasing regulatory risks in the US market, Mr. Deepak Jotwani, Assistant Vice President & Sector Head, ICRA, said: "Apart from some key drugs going off-patent, product shortages in select therapeutic segments (oncology, pain/anesthesia, cardiovascular among others) in the recent quarters have also been a growth driver for generic companies in the US market to some extent. These shortages in the US market have been partly caused by lower production/ discontinuation of operations by some pharmaceutical companies (including local ones) owing to persistent pricing pressure, supply chain challenges and increased regulatory scrutiny by the United States Food and Drug Administration (USFDA).

The incidences of warning letters and import alerts issued to manufacturing facilities of the Indian pharmaceutical companies have increased over the past year and remain a key credit risk. These have led to delays in product launches for some companies, translating into failure to supply penalties and entailing significant cost burden towards remedial measures including hiring consultants and consuming additional

management bandwidth, in turn impacting the profit margins."

ICRA expects the revenue growth of its sample set of companies in the domestic market to be 7-9% in FY2024, supported by price increases and new product launches. In H1 FY2024, ICRA's sample set of companies witnessed a 7.2% YoY growth, negatively impacted by the price reductions required to be undertaken because of price caps by the National List of Essential Medicines (NLEM) on various products besides an uneven monsoon, which affected acute therapy sales.

Glenmark launches anti-diabetic drug, Liraglutide in India

Alok Malik, President and Business Head - India Formulations, Glenmark Pharmaceuticals Ltd.

Mumbai, India: Glenmark Pharmaceuticals Ltd, a research-led, global pharmaceutical company, has launched a biosimilar of the popular anti-diabetic drug, Liraglutide, for the first time in India. The drug is being marketed under the brand name Lirafit following the approval from the Drug Controller General of India (DCGI). Priced at around ₹ 100 for a standard dose of 1.2 mg (per day), this will lower the cost of therapy by approximately 70%, and will be available only under prescription.

Liraglutide belongs to the class of glucagon-like peptide 1 receptor agonist (GLP-1 RA) drugs, which increase glucose-dependent insulin secretion and decrease in appropriate glucagon secretion. It has been approved globally for the management of type 2 diabetes mellitus in adult patients in the United States and the European Union.

"Glenmark is proud to introduce Lirafit, a novel and affordable biosimilar of the drug liraglutide, for the first time in India. Clinical trials have shown that it helps improve glycemic control in adult type 2 diabetes mellitus patients along with atherosclerotic cardiovascular diseases (ASCVD) and obesity. Liraglutide has also proven to have a positive impact on cardiac and renal safety outcomes among patients in clinical trials, making it an effective choice of treatment for patients with type 2 diabetes mellitus. With this launch, we have now ventured into the injectable anti-diabetic market taking another significant stride in the diabetes therapy space," remarked Alok Malik, President and Business Head - India Formulations, Glenmark Pharmaceuticals Ltd.

Lupin receives approval from US FDA for Loteprednol Etabonate Ophthalmic Suspension

Nilesh D Gupta, MD, Lupin

Mumbai, India: Global pharma major Lupin Limited announced that it has received approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Loteprednol Etabonate Ophthalmic Suspension, 0.2%, to market a generic equivalent to the reference listed drug (RLD) Alrex Ophthalmic Suspension, 0.2%, of Bausch & Lomb Inc. The product will be manufactured at Lupin's Pithampur facility in India.

Loteprednol Etabonate Ophthalmic Suspension, 0.2%, is indicated for the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis. Loteprednol Etabonate Ophthalmic Suspension, 0.2% (RLD Alrex), had estimated annual sales of USD 29.1 million in the U.S. (IQVIA MAT October 2023).

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the U.S., India, South Africa, and across the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions.

Biocon Biologics partners with Sandoz

Bengaluru, India: Biocon Biologics Ltd (BBL), a fully integrated global biosimilars company and subsidiary of Biocon Ltd, signed a Distribution Agreement with Sandoz, granting the Company the exclusive rights to promote, sell and distribute "Adalimumab BS for subcutaneous injection [FKB]" in Japan.

Based on this Agreement, Viatris has completed marketing and promotion of the product as of December 15, 2023, but will continue to provide transition support

until Sandoz will gradually assume responsibilities for the product starting in February 2024.

Biocon Biologics has acquired the global biosimilars portfolio of Viatris including Adalimumab. Fujifilm Kyowa Kirin Biologics Co. Ltd., the developer of the drug, has concluded an exclusive global marketing license agreement with Biocon Biologics Ltd affiliate.

Adalimumab BS for subcutaneous injection [FKB] is a biosimilar of Humira (generic name: adalimumab genetical recombination) and is indicated for immune-related diseases such as rheumatoid arthritis, psoriasis vulgaris, ankylosing spondylitis, Crohn's disease, and ulcerative colitis. Sandoz is committed to further strengthening its product pipeline to drive sustainable business growth. The transfer of the distribution rights of this product is part of this strategy, and its addition to the product portfolio will strengthen Sandoz's immunology and biosimilar portfolio.

Biocon Biologics recently announced the successful completion of its integration of the acquired Viatris' biosimilars business in 120 countries ahead of schedule, marking a significant milestone in the Company's journey as a fully integrated, global biosimilars enterprise. At a global level, Biocon Biologics has a robust pipeline of 20 assets for diabetology, oncology, immunology, and ophthalmology. Serving over 5.7M patients annually, the Company is committed to providing access to high-quality therapies and solutions to patients, healthcare systems and governments across the globe.

Sun Pharma to acquire 16.7% stake in Lyndra Therapeutics for USD 30 million

Mumbai, India: Sun Pharmaceutical announced that it has entered into an agreement to acquire 16.7 per cent stake in the US-based Lyndra Therapeutics, , a company based in Massachusetts, engaged in the business of developing novel delivery technology for long-acting oral (LAO) therapies. for US$ 30 million. Lyndra Therapeutics, Inc., a company based in Massachusetts, having its registered office at Watertown, MA. The Company is in the business of developing novel delivery technology for long-acting oral (LAO) therapies. The object of the acquisition is to support development of innovative pharmaceutical delivery technologies and get access to the technology for certain molecules and territories.

Aurobindo Pharma's arm Eugia Pharma receives USFDA approval for Posaconazole Injection

K. Nityananda Reddy
Vice Chairman & MD,
Aurobindo Pharma

Hyderabad, India: Aurobindo Pharma Limited announced that its wholly owned subsidiary company, Eugia Pharma Specialties Limited, has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Posaconazole Injection, 300 mg/16.7 mL (18 mg/mL), Single-Dose Vial, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Noxafil Injection, 300 mg/16.7 mL (18 mg/mL), of Merck Sharp & Dohme LLC (Merck).

The product is expected to be launched in December 2023. The approved product has an estimated market size of US$ 25.4 million for the twelve months ending October 2023, according to IQVIA. This is the 173rd ANDA approval (including 8 tentative approvals received) out of Eugia Pharma SpecialitiesGroup (EPSG) facilities, manufacturing both oral and sterile specialty products.

Posaconazole Injection, 300 mg/16.7 mL (18 mg/mL), Single-Dose Vial is indicated forthe prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised, such as hematopoietic stem cell transplant (HSCT) recipients with graft-versushost disease (GVHD) or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

Dr. Reddy's Laboratories acquires 6.46% stake in Edity Therapeutics

Hyderabad, India: Dr. Reddy's Laboratories, Inc., wholly-owned step-down subsidiary of the Company, has acquired 1,014,442 Preferred A-1 shares of Edity Therapeutics Limited, a biotechnology company, equivalent to 6.46% of the shareholding of Edity on fully diluted basis.

Edity is an Israel based development stage biotechnology company focusing on a breakthrough platform

technology for intracellular delivery of therapeutic proteins utilizing immune cells. Therapeutics based on the Edity technology could be useful in multiple therapeutic areas including gene editing, rare genetic disorders, oncology and inflammation.

The funds invested by Dr. Reddy's would be utilized by Edity to further develop its technology platform. This includes performing pre-clinical studies for safety and efficacy evaluation, securing intellectual property through patent filings, and exploring licensing opportunities, collaborations, and market entry strategies to optimize the commercial viability of Edity's technology platform.

Edity is an Israel based development stage biotechnology company focusing on a breakthrough platform technology for intracellular delivery of therapeutic proteins utilizing immune cells. Therapeutics based on the Edity technology could be useful in multiple therapeutic areas including gene editing, rare genetic disorders, oncology and inflammation. Edity was incorporated in Israel on in the year 2019.

Alembic Pharmaceuticals receives 8 USFDA approvals in Q3FY24

Chirayu Amin, Chairman & CEO, Alembic Pharma

Mumbai, India: Alembic Pharmaceuticals Limited announced that it has received US Food & Drug Administration (USFDA) approvals on eight of its Abbreviated New Drug Application (ANDA) in Q3FY24.

The company has received five final approvals that includes Selexipag Tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1,400 mcg and 1,600 mcg, (Brand Name Uptravi tablets Actelion Pharmaceuticals US, Inc.) of Dapsone gel, 7.5%, Fluorouracil Injection USP 5g/100mL (50 mg/mL), Pharmacy Bulk Package (Vial), Carmustine for Injection USP 100 mg/vial (Single-dose Vial) and Acyclovir Cream, 5%. The Company has also received three tentative approvals that includes Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 mg, Dapsone gel, 7.5%, Bromfenac Ophthalmic Solution, 0.07%., and Osimertinib Tablets, 40 mg and 80 mg.

Rivaroxaban Tablets USP, 2.5 mg, 10 mg, 15 mg, and 20 mg with brand name of Xarelto Tablets of Janssen Pharmaceuticals, Inc. Rivaroxaban tablets are indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. It is also used for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), for the reduction in the risk of recurrence of DVT and/or PE in patients at continued risk for recurrent DVT and/or PE after completion of initial treatment lasting at least 6 months.

These tablets also used for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery and for the prophylaxis of venous thromboembolism (VTE) and VTE related death during hospitalization and post hospital discharge in adult patients admitted for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE and not at high risk of bleeding.

These tablets also used in combination with aspirin, is indicated to reduce the risk of major cardiovascular events (cardiovascular (CV) death, myocardial infarction (MI) and stroke) in patients with chronic coronary artery disease (CAD) or peripheral artery disease (PAD).

Akums aims to empower Doxylamine + Pyridoxine ER tablets for severe morning sickness

Sanjeev Jain, Joint MD, Akums Drugs & Pharmaceuticals Ltd

New Delhi, India: Akums Drugs and Pharmaceuticals Ltd., a Contract Development and Manufacturing Organization (CDMO), has announced the launch of Doxylamine + Pyridoxine extended-release tablets, a therapy approved by the CSDCO (Central Drugs Standard Control Organization), India and the United States Food and Drug Administration (USFDA). This marks a milestone as a therapy in India, with a [patent application in process]. Akums' inventive solution aims to tackle the issues by integrating Doxylamine and Pyridoxine into extended-release tablets.

Doxylamine, a competitive histamine H1 receptor inhibitor with sedative and anticholinergic effects, is paired with Pyridoxine Hydrochloride (Vitamin B6), known for its anti-emetic properties and its role

in haemoglobin production and neurotransmitter metabolism. This combination aims to offer an effective tool to manage symptoms of nausea and vomiting during pregnancy, ensuring better outcomes for both mothers and infants.

Sanjeev Jain, Joint Managing Director, Akums Drugs & Pharmaceuticals Ltd., said "During the initial trimester of pregnancy, many women grapple with the challenges of nausea and vomiting, commonly known as morning sickness. Despite its misleading name, morning sickness is not confined to a specific time and can occur day or night. While it may be unpleasant, it is generally considered a normal facet of a healthy pregnancy. In more severe instances, referred to medically as hyperemesis gravidarum, the intensity of nausea and vomiting reaches a point where a pregnant woman experiences frequent daily episodes, weight loss, and faces dehydration or is at risk of dehydration."

Sandeep Jain, Joint Managing Director, Akums Drugs & Pharmaceuticals Ltd., noted, "This is yet another innovative product developed by our R&D team. With Akums' pioneering Doxylamine and Pyridoxine tablets, women experiencing severe morning sickness now have the opportunity to ease their symptoms and prevent further discomfort. "

In contrast, Akums introduces a more advanced solution with its Doxylamine 20 mg + Pyridoxine 20mg extended-release tablet. This formulation incorporates an immediate-release layer, allowing for a swift onset of action following ingestion. Simultaneously, the extended-release feature ensures prolonged and consistent relief from symptoms, catering to the specific demands of the disease condition. This innovative approach optimises both immediacy and sustainability, offering a more effective and comprehensive solution for managing nausea and vomiting in pregnancy.

BioPulse Solutions marks its inaugural year with a ₹360 million valuation

Hyderabad, India: BioPulse Solutions Pvt Ltd., announces significant milestones and achievements at the start of 2024 as it continues to bring in innovations in bioprocessing technologies that would significantly benefit the biopharma industry. BioPulse Solutions set out with the initial goals of introducing innovative solutions in Single-Use Bioprocessing Technology, redefining customization for the industry.

Having inaugurated the state-of-the-art certified Class 7 & 8 cleanroom facilities at Hyderabad, in October 2023, the company looks to build end-to-end single-use bioprocessing solutions for the pharmaceutical and biopharmaceutical customers. BioPulse Solutions also has a stainless steel bioprocessing customisation and engineering facility at Nashik.

BioPulse Solutions' vision revolves around 'Enabling Solutions for a better tomorrow' that transform their pain areas into performance centers. The company prides itself on being India's first open architecture single-use bioprocessing integrator, offering unique hybrid solutions that seamlessly integrate conventional stainless-steel process systems with the latest single-use technologies. This approach provides unparalleled flexibility and choice for customers.

Piyush Jain, CEO BioPulse Solutions had this to say about the achievement." We are thrilled to announce that BioPulse Solutions Pvt Ltd. has reached an astounding valuation of ₹360 million in our latest investment round. This achievement is a testament to our dedication, innovation and the incredible team that makes it all possible. As India's First Open Architecture Single-Use Bioprocessing Integrator, we have consistently disrupted industry norms and set new benchmarks. This financial achievement not only validates our unique approach but propels us toward a future of even greater impact and innovation in the Bio-Pharma and bioprocess industry. We extend our heartfelt gratitude to our investors, partners, and the entire BioPulse community for their unwavering support as we continue to shape the future of bioprocessing technologies.

Menarini India enters into partnership agreement with Pierre Fabre Laboratories

Mumbai, India: Menarini India Private Limited, a leading Italian pharmaceutical company strengthens its presence in dermatology, and has solidified its strategic position by entering into an exclusive partnership with esteemed French pharmaceutical giant - Pierre Fabre Laboratories. Pierre Fabre Laboratories stands as a global leader in dermo-cosmetics, renowned for its French expertise and research-backed products.

Under this strategic collaboration, Menarini India has obtained exclusive rights to market and distribute the dermo-cosmetic brands, EAU THERMALE AVÈNE and DUCRAY in India. The riveting partnership forms a perfect synergy between the two pharma giants to deliver world-class, innovative solutions for the Indian market, promising a better future in the dermatology and cosmetics landscape in the country.

Menarini India is moving ahead with a focused approach to carve a niche for itself with an ultimate goal of leading in the dermatology and cosmetics space. The company's synergy with Pierre Fabre Laboratories further bolster its purpose to offer the best skin and hair care solutions from across the world to Indian consumers. The entire range of EAU THERMALE AVÈNE and DUCRAY (Pierre Fabre dermo-cosmetics products) has been meticulously researched and developed to ensure optimal solutions to today's multiple skin needs.

Speaking on the momentous partnership, Girisan K, Managing Director – Menarini India, enthusiastically expressed, "The strategic partnership with Pierre Fabre Laboratories is a testament to our commitment to offering the best in dermo-cosmetics solutions to Indian consumers. Pierre Fabre's French expertise and research-backed products combined with Menarini's dermatological proficiency are poised to deliver world-class innovative products to the discerning Indian consumer. We are determined to bring the confidence of healthy skin and innovative healthcare solutions to every Indian."

Caplin Group announces Strategic Investment of ₹ 700 Crores in Tamil Nadu

Chennai, India: Caplin Group of Companies announce the signing of a Memorandum of Understanding (MoU) with the Tamil Nadu Government during the Tamil Nadu Global Investors Meet, 2024. This MoU outlines Caplin Group's commitment to invest ₹ 700 Crores over a period of 5 years in diverse projects. This investment will be made by Caplin Point Laboratories Ltd and its subsidiaries - Caplin Steriles Ltd and Caplin One Labs Ltd.

The MoU specifies that the government will provide necessary infrastructure and regulatory assistance as per applicable laws. This will also enable the availing of standard incentives, subject to eligibility. The investments, spanning Oncology, Active Pharmaceutical Ingredients and R&D facilities, are projected to generate 1,500 employment opportunities (1,000 direct and 500 indirect).

Commenting on the achievement, C.C. Paarthipan, Chairman said, "We are pleased to announce the signing of an MoU with the Government of Tamil Nadu. Aligned with the state's goals, our company's strategic investment emphasizes expanding manufacturing capabilities and driving research and development. This proactive approach not only empowers economic growth but also highlights our strong commitment to positive societal impact and social development. We appreciate the government's crucial role in ensuring the success of these key projects."

Honeywell Automation bags contract from Reliance Life Sciences

New Delhi, India: Honeywell Automation India Limited announced that its Honeywell Building Solutions business has secured a contract from Reliance Life Sciences (RLS) for building management and safety technology.

Honeywell will assist Reliance Life Sciences with supply, installation, testing and commissioning of integrated building management command and control and environment monitoring systems. It will also integrate its current fire detection and voice evacuation systems with Honeywell Connected Life Safety Services (CLSS), for its multiple plants at Nashik, Maharashtra, India. Honeywell's contract with Reliance Life Sciences encompasses a seven-year annual maintenance support commitment, providing sustained operational excellence.

"Honeywell is proud to partner with Reliance Life Sciences in its automation journey. Under the project, we will integrate and deploy Honeywell's Enterprise Buildings Integrator (EBI) Command Control Suite and CLSS making it a significant win in the pharmaceutical vertical. Our superior building management and safety technology will enhance the overall safety, efficiency and sustainability across RLS" said Ashish Modi, President, Honeywell India.

Honeywell's CLSS cloud platform integrates data for secure, compliant, and efficient fire system management, offering connectivity, intelligence, and remote monitoring.

AstraZeneca to acquire Gracell

Mumbai, India: AstraZeneca has entered into a definitive agreement to acquire Gracell Biotechnologies Inc, a global clinical-stage biopharmaceutical company developing innovative cell therapies for the treatment of cancer and autoimmune diseases, furthering the AstraZeneca cell therapy ambition.

The proposed acquisition will enrich AstraZeneca's growing pipeline of cell therapies with GC012F, a novel, clinical-stage FasTCAR-enabled BCMA and CD19 dual-targeting autologous chimeric antigen receptor T-cell (CAR-T) therapy, a potential new treatment for multiple myeloma, as well as other haematologic malignancies and autoimmune diseases including systemic lupus erythematosus (SLE).

Autologous CAR-T is a type of cell therapy created by reprogramming a patient's immune T cells to target disease-causing cells, and the manufacturing process for this type of treatment is complex and time-consuming. The Gracell FasTCAR platform significantly shortens manufacturing time, enhances T cell fitness, and will potentially improve the effectiveness of autologous CAR-T treatment in patients. Future applications of this technology may also include rare diseases.

Susan Galbraith, Executive Vice President, Oncology R&D, AstraZeneca, said: "The proposed acquisition of Gracell will complement AstraZeneca's existing capabilities and previous investments in cell therapy, where we have established our presence in CAR-T and T-cell receptor therapies (TCR-Ts) in solid tumours. GC012F will accelerate our cell therapy strategy in haematology, with the opportunity to bring a potential best-in-class treatment to patients living with blood cancers using a differentiated manufacturing process, as well as exploring the potential for cell therapy to reset the immune response in autoimmune diseases."

Snowman Logistics expands its operational capacity in North East, India

Mumbai, India: Snowman Logistics Limited, a leading cold chain and integrated temperature-controlled logistics service provider in India, has initiated operations at a newly leased multi-temperature-controlled warehouse in Guwahati, Assam. The total capacity of the warehouse is 5,152 pallets and this facility features eight chambers and four loading bays, equipped with the latest infrastructure. Specifically designed to accommodate products from ambient temperatures to minus 25 degrees Celsius, the warehouse will primarily focus on providing storage, handling and transportation services for ice cream, poultry, ready-to-eat food, dairy products, confectionery, bakery products, seafood, fruits and vegetables. Other products include pharmaceuticals, specialised chemicals and various commodities.

Sunil Nair, CEO, Snowman Logistics said "The inauguration of our latest facility in Guwahati signifies a momentous achievement for Snowman Logistics. This establishment marks our initial venture into a fully leased cold storage facility, aligning with our strategic move towards becoming asset-light. With this expansion, our overall pallet capacity has soared to an impressive 1,41,000+ pallets, strategically distributed across 20 cities, thereby expanding our foothold in Northeast India.

Snowman Logistics has garnered extensive expertise in the storage, handling, and transportation of diverse products, spanning the food, healthcare, pharmaceuticals, and specialized chemicals sectors. Our commitment to innovation is evident through the incorporation of technology-enabled facilities and platforms. This, coupled with our unwavering dedication, allows us to consistently provide tailor-made solutions that cater to the dynamic needs of the industries we serve.

As an organization, we take pride in setting industry operating benchmarks. Our ability to seamlessly adapt to the rapidly evolving requirements of our customers is a testament to our agility and commitment to excellence. With the inauguration of the Guwahati facility, Snowman Logistics reinforces its position as a leader in the logistics industry, poised to continue its journey of growth and innovation."

Creative Graphics Solutions bets big on pharmaceutical packaging business

Mumbai, India: Creative Graphics Solutions, India's leading organised and integrated packaging ecosystem player, aims to double its revenue from the pharmaceutical packaging business by March 2026. The company plans to capitalise on the adoption of sustainable packaging materials and the implementation of enhanced branding technologies in the pharma industry. Its fully-owned subsidiary, Wahren India, dedicated to offering high-quality and innovative packaging solutions for the pharmaceutical industry, has signed reputed clients in the sector, including

Skymap Pharmaceuticals, Theon Pharmaceuticals, Tirupati Lifesciences, United Biotech and Akums India.

In a strategic move to expand its business beyond the core of manufacturing flexographic printing plates, the Noida-headquartered company acquired 'Wahren India' in September 2023. Wahren India specialises in manufacturing laminated aluminium foil for pharmaceutical packaging, and its product basket includes Alu-Alu Foil, Aluminium Blister Foil, Pharmaceutical Sachet and CR Foils.Creative Graphics Solutions plans to raise funds through an IPO and invest ₹ 35 crore in Wahren India, to meet its working capital requirements in fulfilling growing demand in the pharmaceutical packaging business.

Deepanshu Goel, Founder & Managing Director, Creative Graphics Solutions India Ltd, said, "We ensure the safety and effectiveness of our clients' medicines by providing reliable packaging solutions that meet the highest regulatory standards. With the pharmaceutical industry witnessing phenomenal growth across the globe, the demand for quality packaging is set to swell further in the coming years. In order to meet the growing demand for eco-friendly packaging in the pharmaceutical industry, we are planning to invest in our packaging subsidiary – Wahren India, by raising capital through an IPO. Therefore, we are pushing fora double revenue in the pharmaceutical packaging business by March 2026."

Wahren India operates a state-of-the-art production facility in Noida with an installed capacity of 8,000 Tons per annum of printed and silver Alu-Alu foil, where it has deployed cutting-edge lamination, printing and slitter machines. The facility is certified in accordance with national and international standards, including DMF Canada, DMF USA, ISO 15378:2018, ISO 45001:2018, ISO 9001:2015 and ISO 14001:2015, demonstrating its commitment to excellence and quality.

Established in 2001 by first-generation entrepreneur Deepanshu Goel, Creative Graphics Solutions has a diversified business model – encompassing the integrated packaging ecosystem – comprising flexo plates (used to ensure sustainable printing on flexible materials), end-to-end pre-media services (through 100% subsidiary CG Premedia Pvt Ltd) and an innovative packaging solutions portfolio for pharmaceuticals companies (through another 100% subsidiary - Wahren India Pvt Ltd.). Creative Graphics caters to marquee FMCG players, including Tata Chemicals, Johnson & Johnson, Himalaya, Dabur, ITC, Amul, Mother Dairy, MARS, LG, and Patanjali.

Torque Pharma reinvents Healthcare Dynamics with 'Better Together'

New Delhi, India: Torque Pharma, a leading pharmaceutical company, has unveiled a transformative brand identity under the theme 'Better Together.' This strategic rebranding, initiated in 2024 with a fresh team and forward vision, signifies Torque Pharma's commitment to fostering collaboration, synergy, and unity in delivering innovative healthcare solutions.

This rebrand aligns seamlessly with Torque's evolution, emphasizing crucial elements such as partnerships, expert collaborations, and the cultivation of an efficient work environment, reflecting the company's growth trajectory. The overarching goal is to emphasize unity and a shared purpose among stakeholders, marking Torque Pharma's collective progress within the dynamic healthcare landscape. Key initiatives include partnerships with global research facilities, collaboration with expert scientists, and the cultivation of an efficient work environment, collectively contributing to Torque Pharma's commitment to bettering the health and well-being of its people, communities, and the planet.

A.I.S Bedi, Managing Director of Torque Pharmaceuticals, said, "In 1985, Mr. PS Chhatwal and I founded Torque Pharma with a vision to make quality medicine accessible to all. Today, Torque Pharma stands tall, embodying four decades of remarkable growth and positive impact in healthcare. Beyond a pharmaceutical entity, Torque has been a force for positive change, committed to high ethical standards and excellence. Our journey, marked by perseverance and passion, has evolved into a mission for holistic wellness, making us integral to the communities we serve. Torque, with a dedicated team of over 2000, is not just a company but a commitment to building a healthier and more accessible world. Our heartfelt thanks to everyone for being part of this transformative journey, contributing to Torque's success and vision for a better, more inclusive future."

Mandeep Singh, Executive Director of Torque Pharmaceuticals, said, "Torque Pharma, marks a new era in its journey by unveiling a new dynamic logo in 2024. Beyond pharmaceuticals, our global expansion includes ventures into Ayurveda, wellness, and Jal Mineral Water. The 'Better Together' theme symbolizes collaboration, unity, and innovation in healthcare. This strategic rebranding mirrors Torque Pharma's evolution, emphasising unity and shared purpose. The logo

represents our dedication to quality and transparency, while 'Better Together' signifies continuous improvement in medicines, sustainability, and community outreach. Torque Pharma's transformative journey is a testament to achievements made when we are truly Better Together — with the world, for the world."

Supriya Lifescience attains GMP certification from ANVISA Brazil

Mumbai, India: Supriya Lifescience Limited, a global leader in the manufacturing of Active Pharmaceutical Ingredients (APIs), announces a significant milestone in its global operations with the successful attainment of the Good Manufacturing Practice (GMP) certification from Brazil's Regulatory Authority, ANVISA, for its manufacturing facility located in Lote Parshuram, Ratnagiri District, Maharashtra, India.

The recent clearance obtained from this comprehensive audit showcases Supriya's commitment to excellence but also signifies the successful registration of 8 Active Pharmaceutical Ingredients (APIs) with CADIFA. This milestone is poised to expedite and streamline the registration process for the company's remaining APIs, facilitating a smoother pathway for their introduction into the Brazilian market.

Under the astute leadership of Chairman and Managing Director, Dr. Satish Wagh, Supriya Lifescience Limited's Lote Factory underwent a rigorous inspection by ANVISA, emerging with an exemplary record of "Zero" Observations in compliance. This accomplishment underscores the company's unwavering commitment to upholding the highest quality standards and employing advanced production and manufacturing techniques.

Dr. Satish Wagh, Chairman and Managing Director, Supriya Lifescience Ltd stated, "It is a privilege for us to have obtained the GMP accreditation from ANVISA, which clearly demonstrates our strength of manufacturing capabilities from the state-of-the-art world class facility at Lote Parshuram, Ratnagiri District, in Maharashtra. This achievement truly speaks to our team's unwavering determination in adhering to rigorous standards for quality assurance, production processes, and overall adherence."

The success of Supriya Lifescience Ltd. in achieving Brazil's strict GMP standards positions the company for significant growth and has a potential of approximately ₹ 200 crore in Brazilian market.

Natco Pharma invests around US$ 2 million in Cellogen Therapeutics

Hyderabad, India: Cellogen Therapeutics Private Limited, a Delhi based biotech startup promoted by Dr. Gaurav Kharya, Director, Centre for Bone Marrow Transplant & Cellular Therapy, Indraprastha Apollo Hospital, Delhi has raised around US$ 2 million from NATCO Pharma Limited. Cellogen is primarily involved in two R&D programs involving cell and gene therapy solutions.

Chimeric Antigen Receptor T (CAR T) cell therapy program is at an advanced stage for Cellogen Therapeutics where the T cells of the patients are genetically engineered to identify and kill the cancer cells. Cellogen Therapeutics has developed bi-specific CARs and also added another co- stimulatory domain to increase the efficacy and persistence of the CAR in human body as compared to currently available CAR constructs that are mono-specific with one co-stimulatory domain. Both these innovations are aimed at reducing the risk of relapse post CAR T cell therapy which remains a major challenge with existing CAR constructs. Current available products in market cost around US$ 500,000 – 700,000 which Cellogen aims to bring down to US$ 60,000 – 70,000.

Another program on which Cellogen Therapeutics is working is gene therapy program for transfusion dependent thalassemia and sickle cell disease. It is noteworthy that these two diseases form the largest burden of red cell disorders across the globe. As per rough estimates, 40,000 kids are born each year with these disorders in India (10,000 with thalassemia and 30,000 with sickle cell disease).

"Cellogen has been working on its next generation CAR T programme for around 2.5 years and has been able to zero on one particular CAR construct amongst around 40 such constructs. After successful pre-clinical data using the selected CAR, Cellogen intends to start phase 1 clinical trial in the first half of 2024. Just like the CAR T cell therapy, Cellogen Therapeutics also intends to bring gene therapy solutions at affordable cost to our patients in need," said Dr. Gaurav Kharya, Founder & Director of Cellogen Therapeutics.

Sri Rajeev Nannapaneni, Director & CEO, NATCO Pharma Limited states, "Cellogen's area of research work involving innovative and cost-effective cell and gene therapies for addressing various oncological, hematological and metabolic diseases is in line with our core value of providing advanced healthcare with affordability and is basis of our investment thesis. We are excited about these therapies and pleased to partner with Cellogen Therapeutics." ■

INTERVIEW

"AI will play a big role in diagnostic testing and solutions as well"

A Ganesan
Vice Chairman
Neuberg Diagnostics

A Ganesan emphasizes about the recent trends in diagnostic testing and challenges faced by diagnostic industry. He also spoke about how Artificial Intelligence plays a crucial role in diagnostic testing.

What are recent trends in diagnostic testing?

The Healthcare sector including Diagnostic Industry is going through constant technology changes and the industry must be conscious of these changes and continuously update themselves to remain competitive. Some of the changes sweeping through the Healthcare sector, particularly the diagnostic sector.

- **Home Healthcare**: The home collection of body samples is catching up very fast and patients are now very comfortable getting themselves tested at home. Most players offer blood collection @home at no extra cost, and this has become a boon as far as patients are concerned. In recent years tests such as ECG and Ultrasound are made available at home, and this will only increase in the near future.
- **Teleradiology/Telepatholgy:** The supply of Experienced Radiologists and Pathologists are in short supply in India and Teleradiology and Telepatholgy plays a big role in interpretation of images as well as body specimens. Teleradiology and Telepathology also plays a big role in getting a second opinion, which will help Clinicians in better management of diseases.

How Artificial Intelligence plays role in diagnostic testing?

Like any other sector AI will play a big role in diagnostic testing and solutions as well. AI systems can help healthcare practitioner diagnose diseases based medical images. It has been reported recently that meta-analysis has proven that diagnostic performance of deep learning AI tool was equivalent to that of highly trained healthcare professional. In future AI is expected to play a much bigger role in diagnostic testing and reporting.

What are the new technologies being developed for diagnostic testing?

- **Point Of Care Testing:** New technologies being developed allow testing near the patients, including their homes and offices. This helps in travel time and increased comfort to the patients. These new technologies include handheld testing equipment, handheld Kiosks and digital transmission of data, which avils on the spot diagnosis and solution. This also makes digitization and storage of patient data easy and available to the clinicians and patients at the touch of a button.

- **Predictive Analysis:** Genetic testing using body samples like blood, skin, hair etc will play a big role in preventive medicine in the years to come. Genome testing will be able to identify future risk of serious diseases including Cardiac diseases, cancer etc. The potential is enormous as tests can identify mutations that increase the risk of genetic disorders, and most times will be a lifesaving solution for the customers.

- **Lab Optimisation Solutions:** Labs and clinicians are constantly seeking to reduce the number of tests that are required so that the patient gets enhanced value at lesser / optimum cost. This analytical tool can analyse vast amount of test results and help lab managers to identify unnecessary tests, but at the same time do not compromise on patient wellbeing.

- **Real Time Diagnosis:** There is an explosion of wearable devices in the market from watches, rings, patches, bandages, spectacles, clothing etc These wearables are able to collect real time health data such as Pulse rate, Blood pressure , sugar fluctuation , respiratory condition etc and give alerts to the patients and clinicians in real time. These devices capture much more data as compared to traditional testing and will be very useful to clinicians in decision making.

What are the challenges faced by diagnostic industry?

Diagnostic industry is mostly unregulated. There is no entry barrier in terms of approvals accreditation, funding etc. As a result, the organized market is not even 25 percent of the total market. This has resulted in the proliferation of smaller labs with no regulations as regards quality control and other standards. Industry expects central and state governments to prescribe certain minimum quality standards and accreditation requirements for establishing and running Diagnostic centers. Such regulatory requirements can be implemented in phased manner so as to not impact the lives of many of the small lab business.

Healthcare services are not subjected to GST, though almost all input costs have to bare it. Perhaps government perceives this as an additional burden to the consumer. On the contrary, I beleive levy of GST on healthcare services will benefit the consumers as this will bring down the cost of operations, which can inturn benefit the consumers.

In case Government is not inclined to levy GST on Healthcare services, certain specific input materials / services specifically used by healthcare can be exempted from GST or rates canbe brought down to the lowest slab.

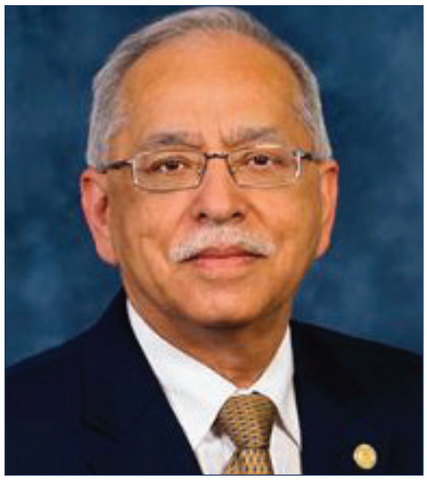
Despite significant technological advancements in curative as well as preventive diagnostics, our vast rural population is still not able to access such technologies for two reasons: lack of infrastructure and cost of such tests. Government support in extending such facilities to our rural population, whether through its own PHC s are through large chain of labs through PPP model will immensely benefit rural population.

Tamil Nadu and few other states have implemented free healthcare services to poor people and those schemes only cover hospitalisation for decease management. The scheme may also cover wellness programmes/ basic screening (at least once in two - three years) , so that deceases can be identified and treated well in advance . This might bring down the cost of healthcare support as treatment in initial stages will be less expensive.

Government gives certain Income tax benefits for wellness checks, but the amount eligible for such exemption is very meagre at ₹ 5000. The limit may be increased to ₹ 15,000 to encourage people to go for annual medical checks once in a year. Such exemption may be extended to only people above 40 years as those are the age groups who are prone to diseases.. ■

INTERVIEW

“Pharmazz plans to develop new laboratories for research and development”



Dr Anil Gulati
CEO
Pharmazz

Dr Anil Gulati emphasizes about the overview of the Pharma Industry. He also spoke about the prospects and challenges for the pharma industry, emerging trends and focus area going ahead.

Brief us about your overview of the pharmaceutical industry?

The Indian pharmaceutical industry is a global cornerstone, providing millions worldwide with affordable generic drugs and vaccines. Simultaneously, India’s innovation and entrepreneurship ecosystem is rapidly growing by integrating technology and improving manufacturing processes. As per government data, the Indian pharmaceutical industry is presently valued at approximately USD 50 billion, with around USD 25 billion stemming from international sales. Projections envision its growth to USD 65 billion by 2024 and a staggering USD 130 billion by 2030. The merger and acquisition of foreign companies by Indian pharmaceutical companies has increased to expedite the launch of innovative or branded products beyond India and enhance revenue generation from abroad.

What are the prospects and challenges you see for the Pharma industry?

The biggest challenge is to improve the quality of manufacturing processes, so that the quality of drugs and vaccines is at par with countries with established procedures.

The need for a skilled workforce is another challenge; although the government is establishing many educational institutions towards R&D it has has a long way to go.

Financial investment needs a significant boost to improve the research and development of new chemical entities.

Systematic generation of clinical data is a big challenge and is much needed for the industry’s long-term growth. The health of the country depends on the data and its reliability.

Other concerns are improved patent protection, implementation, data breaches, and cybersecurity threats.

What are your greatest observations and lessons learnt from the last year?

We need to improve the quality of the production of medicines and improve our image of not only generating drugs for the world but also making sure that quality standards are well maintained . In particular, smaller pharmaceutical companies have to emphasize the quality aspect of production and manufacturing. Assistance from the government will significantly help smaller pharmaceutical companies generate better-quality medicines and gain market share in India and abroad.

What are the emerging trends and focus areas going ahead?

The focus area has been oncology for many years; however, central nervous system diseases will likely take the centre stage for years to come. It has been possible that for decades, drugs could be developed for the treatment of diseases such as Alzheimer's disease and Cerebral Stroke. However, in the past few years, the successes in such diseases have generated significant interest and activity in CNS (central nervous system) diseases.

In addition, precision medicine is getting much attention. Targeting DNA and RNA to generate new drugs has been a trend that tends to cntinue even today.

Brief us about your product launches?

Pharmazz has been engaged in the development of drugs for critically ill patients and has been able to successfully obtain marketing authorization for two drugs in India, one of which is to treat cerebral stroke patients, and the other is a resuscitative agent.

Sovateltide is a first-in-class innovative drug that has, in clinical trials, demonstrated practice-changing results with a statistically scaling and clinically meaningful improvement in neurological outcomes in acute cerebral ischemic stroke patients. The currently approved treatment for stroke has to be carried out within 4.5 hours of stroke onset, and a significant number of patients become ineligible. On the other hand, Sovateltide is efficacious even when used within 24 hours from the onset of stroke symptoms and is, therefore, more accessible to stroke patients.

India market approval was granted to Pharmazz in 2023, and after extensive due diligence, a sales and marketing agreement was signed between Sun Pharmaceuticals and Pharmazz, and then the product was launched by Sun Pharma in 2023, under its brand name of Tyvalzi. The FDA approved the US IND for a Phase 3 trial in acute cerebral ischemic stroke, and an agreement was reached with the US FDA for Special Protocol Assessment of Sovateltide to treat cerebral ischemic stroke patients.

Centhaquine (Lyfaquin) is a novel, premium resuscitative agent for treating hypovolemic shock. It is an effective resuscitative agent free of arterial constriction and increases blood pressure by increasing cardiac output. Almost 70 percent of blood is pooled on the venous side of circulation and is not engaged in supplying oxygen and nutrition to the tissues. Centhaquine diverts the venous blood towards arterial circulation to increase cardiac output and improve tissue perfusion. Centhaquine reduces mortality as a resuscitative agent and improves cardiac output and blood pressure without arterial constriction in hypovolemic shock patients. The product was launched in November 2020 under the brand name Lyfaquin.

What are your R&D plans?

In the coming years, Pharmazz plans to develop new laboratories for research and development and replace the existing ones with more advanced equipment. The investment will be carried out to make the laboratories so advanced that they can assist in manufacturing sovateltide and centhaquine for a worldwide supply.

Brief us about your agreement with Sun Pharma for Sovateltide in India?

Sun Pharmaceutical Industries Limited has entered into a license agreement with Pharmazz to introduce the innovative drug Tyvalzi (Sovateltide) to the Indian market. Tyvalzi is designed to treat cerebral ischemic stroke and is a first-in-class drug developed by Pharmazz for potential global use. Under the agreement, Sun Pharma gains exclusive marketing rights for Sovateltide in India, and Pharmazz will receive upfront and milestone payments and ongoing royalties as part of this collaboration. ■

The Hybrid Trials Revolution

India's robust healthcare infrastructure – and highly trained professionals – make it a cost-effective haven for international clinical trials. Sponsors can expect significant savings in the conduct of clinical trials through process and technology-driven efficiency that drives faster trial completion thanks to India's efficient recruitment capabilities. **Sanjay Vyas** emphasizes about landscape of clinical trials is undergoing rapid transformation with remote and Patient-Guided approaches.

Boasting a diverse population of over 1.4 billion people representing a wide range of demographics and disease profiles, India simplifies patient recruitment and offers a wealth of data for research. This combination of factors has propelled India to the forefront of global clinical trials, making it the ideal partner for international sponsors seeking high-quality research with exceptional value.

Decentralized Clinical Trials changing the course of CT in India

Although the concept of decentralized clinical trials (DCTs) has been under exploration in the industry the COVID-19 pandemic has significantly accelerated the adoption of such trials with an elevated sense of urgency.

Traditionally, participants in clinical trials have been required to visit a physical site for various activities such as study visits, assessments, and data collection. However, with evolving times and the advent of decentralized clinical trials, the participants are empowered to engage in the trial comfortably from their homes or local healthcare settings. DCTs harness digital technologies and remote processes to enhance patient convenience, streamline data collection, and improve the overall efficiency of the trial.

Countries like India emerge as ideal locations for the effective implementation of DCTs due to their promotion of integrity and inclusivity in healthcare treatment. India also presents advantages for establishing DCTs, including a diverse patient pool and a growing talent base in clinical research.

DCTs have gained strategic importance in the field of clinical research as patient-guided approaches continue to be a key focus. DCTs have the potential to remove geographical barriers for clinical trial participants, making them an appealing option for a nation like India. However, to fully unlock the potential of DCTs in India, navigating the evolving regulatory landscape is crucial.

Evolving Regulatory Landscape for Decentralized Clinical Trials (DCTs) in India

During COVID-19, unanticipated deviations to clinical research protocols became unavoidable, as subjects were unable to attend study visits due to travel restrictions, clinic closures, and quarantine requirements. Regulatory bodies around the world were forced to quickly revise their regulations or guidance to minimize disruptions to clinical research.

Many of these clinical research companies turned to Direct to and from Patients (DTP/DFP) distribution to

enable continuation of drug delivery to their patients. Another successful implementation of DTP/DFP was in India, where home delivery of clinical trial medications was not previously available before the outbreak of COVID-19. However, given the critical need to keep patients in their clinical trials, the Indian government permitted DTP services.

In May, the FDA released draft guidance for implementing DCTs, sparking a wave of excitement and anticipation within the field of clinical trials. The much-awaited guidance marks a significant milestone in the evolution of clinical trial methodologies, signalling clear support for the global shift toward expanded trial models. By releasing the guidance, the FDA reaffirms its commitment to promoting innovation in clinical trial design and emphasizes the need for careful consideration, training, oversight, and risk management for the successful implementation of DCTs.

Bridging the gap between centralized and decentralized CT - The Rise of Hybrid Trial Designs

A hybrid clinical trial is a type of medical research study that incorporates both traditional face-to-face elements and virtual or remote components, such as those delivered over the internet or via a mobile device. This approach allows for greater flexibility in conducting clinical research and can have benefits such as reduced costs and easier recruitment of participants. However, it also presents challenges related to data security, patient privacy, and oversight. Hybrid trials can offer greater efficiency, engagement, and the generation of stronger evidence for clinical trial sponsors. They are particularly effective for studies with difficult-to-recruit patient populations. The integration of digital health technologies, in-home clinical visits, and agile monitoring are key components of decentralized and hybrid clinical trial designs.

The use of hybrid clinical trials has become more prominent due to the rising cost and time to bring new drugs to market, as well as the impact of the pandemic outbreak. These alternative trial models are being leveraged to address challenges and improve the efficiency of the drug development process.

Deployment of Digital Tools to Leverage Hybrid Clinical Trials

Given the advancements in digital tools and technology, several segments in the field of clinical research have growth potential. These breakthroughs addressed challenges encountered during the

pandemic and had a significant impact on clinical research. Digital tools are increasingly being used to leverage hybrid clinical trials, allowing for more convenient, accurate, and efficient data collection. Some of the key digital tools used in hybrid clinical trials include eConsent, ePRO (electronic patient-reported outcomes), telemedicine, wearable devices, and remote patient monitoring.

The use of digital technology in clinical trials benefits patient recruitment and retention, data collection, and ultimately, the speed at which new therapeutics can be brought to market. Digital tools, such as wearable devices, remote monitoring, and electronic data capture systems, have the potential to change the way clinical trials are conducted. These digital tools increase patient engagement, allow for real-time data collection, improve data accuracy, and alleviate logistical challenges. Integrating digital solutions into clinical trials can help increase recruitment, improve patient compliance, and simplify data management processes.

The future of clinical trials will be defined by the adoption and implementation of powerful artificial intelligence technologies to handle the growing volume of data in standard and non-standard formats. Predictive analytics can help with disease detection, pattern recognition in medical images, genomic data analysis, and faster data analysis and inferences.

Hybrid Clinical Trials and Global Capability Centers

India has become an attractive choice for pharmaceutical and biotechnology firms conducting clinical trials due to its extensive and varied patient population, cost-effectiveness, and proficient medical workforce. The digitalization of clinical trials is poised to boost market expansion by optimizing processes like data collection, regulatory compliance, logistics, and supply management. The integration of digital therapies has further streamlined the collection of real-time safety and toxicity data, enabling swift adjustments to trial designs and fostering market growth.

The establishment of Global Capability Centers (GCCs) in India plays a crucial role in facilitating these hybrid trial models. Equipped with advanced technology infrastructure and a skilled workforce, GCCs enhance the efficiency of clinical trial operations. They are well-positioned to support the intricate requirements of hybrid trials by offering specialized services in data analytics, regulatory affairs, and quality assurance. This integration of GCCs not only reinforces India's status as a hub for clinical trials, but also provides global pharmaceutical and biotechnology companies with the technological expertise and adaptability needed to conduct research and development activities efficiently in the evolving landscape of hybrid clinical trials.

As India embraces the future of hybrid clinical trials, propelled by its robust infrastructure, diverse population, and digital prowess, it stands poised to revolutionize medical research. The hybrid approaches, coupled with the expertise of GCCs, promise faster drug development, wider patient access, and ultimately, healthier lives for all. ■

Author

Sanjay Vyas
Executive Vice President and Managing Director, Parexel India

Navigating the Transformative Landscape of Stem Cell Technology in Medicine and Biotechnology

Stem cell technology is an advancing field that holds immense promise for effective disease treatment through the unique characteristics of involved progenitor cells. Stem cells, distinguished by their unlimited yet controllable proliferative potential and multipotency, exhibit the capacity to undergo prolonged self-renewal through cell division and can, under specific conditions, differentiate into specialized cells such as cardiac muscle cells or pancreatic insulin-producing cells. **Subhadra Dravida and Praveen Parkali** talks about the transformative landscape of Stem Cell Technology and key trends and applications of Stem cell technology.

To fully harness the potential of stem cell technology, decoding mechanisms underlying stem cell proliferation, differentiation into tissue-specific cells, role in repair and regeneration, identifying the combination of signals directed towards the functions is fundamental biology.

Key trends and applications of Stem cell technology

Stem cells in treatment and disease management: Stem cell-based therapeutic modalities represent a paradigmatic advancement in the treatment and management of various chronic diseases. This approach harnesses various types of viable human stem cells, including embryonic stem cells (ESCs), induced pluripotent stem cells (iPSCs), and adult stem cells (ASCs), for both autologous and allogeneic therapies. These cells exhibit the capacity to generate therapeutic proteins or facilitate the restoration of tissue function. Conditions such as macular degeneration, strokes, osteoarthritis, neurodegenerative diseases, and diabetes are particularly managed by stem cell-based therapies. Notably, ESCs and ASCs are produced from natural sources for the repair of diseased tissue or organs under both physiological and pathophysiological conditions. The multifaceted potential of stem cell-based therapies positions them as significant contributors to the advancement of medical treatments.

Stem cells in safety and efficacy testing

Drug discovery and development is a protracted, expensive, and high-risk process, spanning 10-15 years with an average cost exceeding USD 1-2 billion per approved drug to reach the markets. Approximately 40-50 percent of clinical failures are due to insufficient clinical efficacy data and adverse

safety related concerns, prompting substantial efforts to change the strategy of assessing safety or efficacy concerns during preclinical and clinical investigations. In vitro methodologies offer high-throughput, in-depth screening, surpassing the capabilities of animal models. Commercially available human-derived cell lines, including those for astrocytes, neurons, microglia, and oligodendrocytes, permit the study of specific cell types, overcoming limitations associated with animal models . A paradigm shift towards human surrogate cell and tissue-based microphysiological models particularly human induced pluripotent stem cells (hiPSCs), is evident in being adopted with the latest FDA modernization act 2.0 coming into force. Replacing hiPSCs obtained from patient-derived fibroblasts with human MicroPhysiological Systems (hMPS) composed of primary and progenitor cells harvested from human biological discards provide a scalable and flexible approach, allowing for large-scale, in vitro studies that can be repeated any number of times for meaningful insights. The hMPS models ensure relevance without the need for extrapolation to the human species, offering closer mimicry of human physiology .

Vaccines and biotherapeutics, derived from biological sources, undergo rigorous testing at various stages of development including routine testing during manufacturing stages to ensure batch consistency, safety and potency owing to their labile components. The World Health Organization's guidelines play a pivotal role in setting international standards and influences global regulatory practices especially in assessing Critical Quality Attributes (CQAs). While historically, quality control relied on animal tests; recent advancements including non-animal technologies (NATs), new approach methodologies (NAMs) have reduced animal-based testings in in-process controls, and testing CQAs. Despite the viability of these technologies, awareness remains a key barrier to the widespread adoption of 3R's (Replacement, Reduction, Refinement) approaches, with organizations like the National Centre for the Replacement, Refinement, and Reduction of Animals in Research (NC3R's) actively addressing this gap through engagement with the scientific community.

Stem cells in artificial organs

3D bioprinting stands as a promising edge in artificial organ fabrication and advancements in regenerative medicine, Throughout the evolution of tissue engineering, diverse cell types have been utilized, with traditional methodologies involving either in vitro seeding of scaffolds with cells and biomaterials or direct cell therapy through stem cell injection into the native tissue or organ. The criticality of selecting an appropriate cell type cannot be overstated, as it profoundly influences the functionality and design of the tissue-engineered model. Stem cells, with their self-renewal and potent properties, emerged as a widely employed cell source for 3D bioprinting and regenerative medicine, offering an expansive reservoir for cellular materialization. Stem cells, sourced from embryonic or mesenchymal origins, exhibit differentiation potential, with demonstrated versatility in generating blood or nerve cells, and differentiating into diverse cell lineages such as bone or cartilage cells. Stem cells, particularly mesenchymal stem cells, are pivotal for clinical applications, contributing to the regeneration of diseased tissues through tissue-engineered implants composed of stem cells and biodegradable scaffolds. Moreover, mesenchymal stem cells, amenable to genetic modification, present promising prospects for somatic gene therapies targeting systemic or local diseases.

Stem cells in Cellular Agriculture

Cultured meat (CM) involves the invitro production of meat from animal cells cultivated outside of the living organism. This innovative process occurs in a bioreactor, where animal cells undergo two distinct phases: proliferation, aimed at achieving the maximum cell yield, and differentiation and maturation, wherein cells are seeded onto scaffolds and guided to mature into skeletal muscle cells for optimal protein production. Stem cells, specifically adult and pluripotent stem cells, emerge as prime candidates for initiating the cultured meat production process due to their ability to self-renew and differentiate into mature cell types essential for meat composition. The ideal cells for invitro meat manufacturing should exhibit robust self-renewal capabilities and the capacity for continuous division .

Despite embryonic stem cells possessing pluripotent features ideal for culturing meat, practical challenges and consumer controversies surround their use. Nevertheless, undifferentiated progenitor cells such as mesenchymal stem/stromal cells (MSCs) and fibro/adipogenic progenitors (FAPs) present in organs and tissues are good contributors to meat components, underscoring the significance of stem cells in the production of cultured meat. Ensuring the palatability, nutritional value, texture, and safety of cultured meat necessitates the utilization of cell lines derived from species familiar to consumers, such as chicken, turkey, duck, geese, cattle, or pigs .

Integration of artificial Intelligence in stem cell technology

Artificial Intelligence (AI), leveraging Machine Learning (ML), deep learning, and other methodologies, represents a powerful approach to addressing complex data analysis. Notably, AI has demonstrated exceptional proficiency in image recognition, marking its initial foray into the field of biology. This has been particularly evident in providing advanced tools for the description and classification of cellular morphology. Given the inherent high-dimensionality of data generated through computational image analysis, the integration of artificial intelligence, employing machine learning algorithms, has seen a surge in the development of methods for cell image classification. Machine learning algorithms, capable of learning from extensive datasets and making predictions based on novel inputs, have surpassed human performance in the classification of specific cancer types, invitro data analysis, and quality control assessments. Varied machine learning methods have emerged, showcasing superiority in classifying skin cancer, predicting outcomes for colorectal cancer through deep learning-based tissue analysis, machine learning approaches linking genomic data to disease phenotypes, in vitro assays utilizing stem cell technology and AI/ML digital workers for bio/pharmaceutical safety and efficacy evaluations. Furthermore, AI has proven instrumental in ensuring accurate and automated characterization and quality control analyses in stem cell bioprocessing, illustrating its diverse applications in biotechnology and medicine.

Conclusion

Stem cell technology stands as a transformative force with groundbreaking impacts in medicine and biotechnology. It has potential and proven applications in disease treatment, in safety and efficacy testings, artificial organ creation, cellular agriculture, and integration with artificial intelligence. From addressing neuro degenerative diseases to accelerating drug/vaccine development, sourcing cells for bioprinting and shaping the future of cultured meat production, stem cells technology has got midas touch in translating the applications for real time use. ■

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Meeting sustainable health commitments through ESG

In the pharmaceutical industry, a sector fundamental to safeguarding global health, there is a growing commitment towards innovation and improvement, as being realised through the adoption of Environmental, Social and Governance (ESG) principles. **Saransh Chaudhary** talks about shift towards impactful actions that intertwine with global health and sustainability. The Adoption of Environmental, Social and Governance (ESG) principles in pharma industry marks a journey of constant innovation and improvement

The Imperative of ESG in Pharma

The pharmaceutical sector is undergoing a transformative shift towards ESG, driven by public consciousness and evolving regulatory frameworks. This change is fostering a revaluation of manufacturing practices, prioritising resource efficiency and embracing circular economy models. Furthermore, the industry is adopting a more transparent and ethical approach, underscoring the significance of these elements in its core values.

Proactive ESG Implementation

In response to these emerging demands, pharmaceutical companies are intensifying their efforts towards environmental stewardship, such as optimizing energy use and minimising carbon footprint. Socially, the focus is shifting towards ensuring more equitable access to medicines and upholding ethical standards in clinical trials. In terms of governance, there is an increased commitment to maintaining high standards of business ethics, compliance and risk management.

Aligning ESG with UNSDGs

The convergence of ESG principles with the United Nations Sustainable Development Goals (UNSDGs) is particularly pronounced in the pharmaceutical industry. ESG initiatives correspond with several UNSDGs, including those focusing on health, clean water, and responsible consumption and production. A prime illustration of this alignment is the industry's approach to antibiotic resistance. This effort not only supports various UNSDGs but also showcases a deep obligation towards global health and responsible antibiotic usage.

Antibiotic Sustainability: A Focal Issue

Central to this discussion is the sustainability of antibiotics, a key element in combating the escalating challenge of antibiotic resistance (AMR). Efforts to address AMR resonate with UNSDG 3, which aims to diminish infections and deaths caused by communicable diseases.

The Broad Impact of Addressing AMR

Under UNSDG 3, which signifies health, the focus on effective management of resistant infections can significantly enhance global health outcomes. Likewise, combating AMR can contribute to the protection of water sources from contamination, thus meeting the objective of UNSDG 6 concerning water sources. The responsible use of antibiotics is also in line with sustainable consumption and production patterns, which are associated with sustainable practices (UNSDG 12). Similarly, we can meet UNSDG 17 relating to global partnerships through cooperative initiatives in

AMR research by fostering international collaborations and developing collective responses.

Sustainable Antibiotic Research

The issues concerning ESG are so intertwined that working towards one priority area of UNSDGs can enable progress across multiple related fields, including antibiotic research where the end results should be directed towards ensuring equitable access and sustainable use through policy interventions and coordinated efforts of all stakeholders led by the government.

Challenges and the Way Forward

Integrating ESG principles into core business strategies remains a complex task that necessitates a paradigm shift at every level of the organisation. The industry is also tasked with the challenge of maintaining consistent, transparent ESG reporting to provide substantial insights. Moving forward, the establishment of robust ESG governance structures and the use of technology for ESG data analysis will be pivotal.

Toward a Healthier, More Sustainable World

The pharmaceutical industry is on a journey to cultivate a culture of sustainability, educating its workforce about the importance of ESG principles and their role in ongoing sustainability efforts. While significant strides have been made in ESG initiatives, the journey towards a healthier and more sustainable world is ongoing. It demands continuous effort and a focused approach on identified areas. ■

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Innovations in Drug Delivery Systems

An oral solid dosage (OSD) form, comprising tablets, capsules, and powders, is considered the most attractive drug delivery mechanism due to its convenience and cost-effectiveness. Within these, capsules have gained prominence owing to their simplicity, ease of manufacturing, and patient acceptance. **Kinjal Shah** emphasizes about the drug delivery mechanism to enhance the therapeutic efficacy of the drugs.

Capsules were traditionally being manufactured from animal-based gelatin, also known as empty hard gelatin capsules (EHGC). However, lately, the industry has started manufacturing hydroxypropyl methylcellulose (HPMC) capsules, which are made from wood pulp and thus vegetarian in nature. The demand for HPMC has increased in export markets such as the US and Europe as well as in the domestic market owing to changes in consumer dietary and religious preferences. The oral solid dosage forms have also evolved over time with respect to the release of the active ingredients – from immediate release to extended release or sustained release and even controlled release.

The global pharmaceutical generics industry has been lately witnessing significant challenges, such as intense pricing pressures, especially in the US market, increasing competition, rising costs of raw materials and manufacturing, regulatory uncertainties and supply chain disruptions. The pricing pressures in the US generics market, which started in 2014/15, have been more pronounced lately for the oral solid dosage form due to its high competitive intensity. Thus, in recent years, the pharmaceutical industry has seen a surge in innovation in drug delivery systems. The industry is constantly endeavouring to improve the drug delivery systems to enhance the therapeutic efficacy of the drugs, reduce side effects and improve patient compliance.

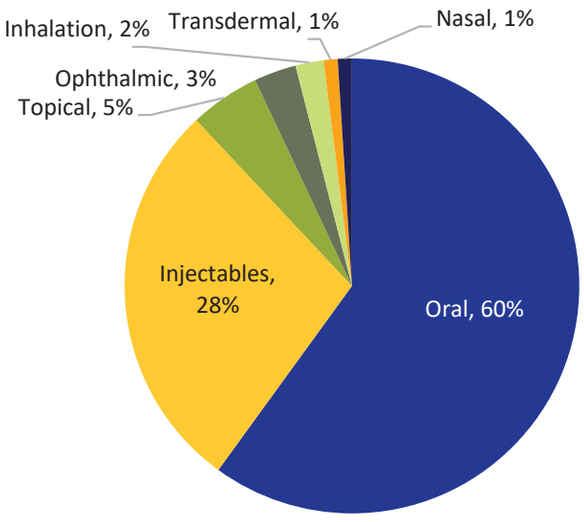
As the therapeutic landscape has evolved from small-molecule drugs to a new generation of therapeutics and even live cells, drug delivery technologies have also evolved to meet their unique delivery needs. Driven by increased investment in research and development (R&D) and consistent regulatory support, the pharmaceutical industry is constantly advancing the processes and technologies from the earlier conventional processes.

The industry currently has developed various other dosage forms or delivery systems, such as injectables, transdermal patches and inhalers. Each of these delivery systems has its own benefits and challenges depending on the drug and targeted outcome. Thus, the delivery system is selected taking into account factors such as drug solubility, stability, and bioavailability. Combination drug delivery is also a growing trend. This strategy of

combining different drugs with different delivery mechanisms is expected to lead to a synergistic effect with better treatment outcomes. It enables the constituent drugs to function together, offering an overall enhancement to the therapeutic effect.

Exhibit: ANDA approvals by USFDA for the global pharmaceutical market in CY2022

According to ICRA Research, of the total 742 abbreviated new drug approvals (ANDAs) approved by the United States Food and Drug Administration (USFDA) in CY2022, oral dosage forms accounted for 445 or 60%, followed by injectables at 28% and others at 12%. Within the oral dosage form, ~16% were extended-release/

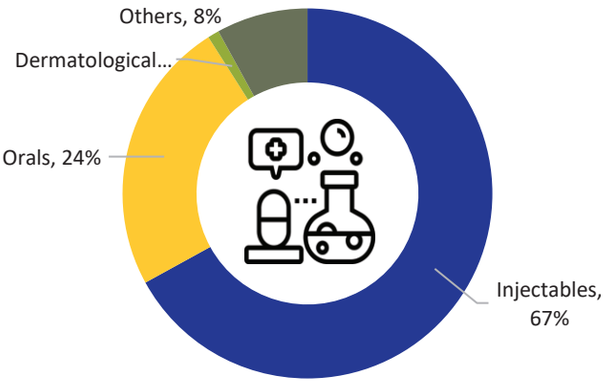


Source: ICRA Research

delayed-release formulations. For India, of the 355 ANDA approvals received in CY2022, 69% were for oral formulations, and a little less than 20% were for injectables.

Exhibit: Product shortages in the US – Drug Administration type

More recently, the US pharmaceutical market has been witnessing product shortages across therapy areas, including pain/ anesthesia, cardiovascular, infectious diseases, central nervous system, and oncology. Considerable pricing pressure, discontinuation of operations by some local pharmaceutical companies, and tightening USFDA scrutiny have continued to result



Source: IQVIA, ICRA Research

in product shortages in the US pharmaceutical market. Injectables accounted for 67% of the drug shortages, with oral solids accounting for 24%.

ICRA believes that as the current therapeutic landscape shifts from small molecules to biologics, drug delivery systems will continue to evolve. ■

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Internet of Things (IoT): The New Prescription for Pharmaceuticals Manufacturing and Supply Chain

The application of Internet of Things (IoT) in the pharmaceutical industry will be the next phase of growth for pharma companies. IoT refers to the networking of physical objects through the use of embedded sensors, actuators, and other devices that can collect or transmit information about the objects. Advances in wireless networking technology have made it possible to collect data from these sensors almost anywhere at any time.

Imagine running a pharmaceuticals manufacturing company. You are not only managing the complexities of the batch manufacturing process, but also looking at plugging all gaps in your logistics chain, and ensuring complete quality to your customer. Although industrial automation and control technologies are well established in life sciences manufacturing facilities, integral information on real-time status of equipment is still not readily available to the management to take timely decisions. Moreover, stringent CGMP (Current Good Manufacturing Practice) regulations expect top quality compliance across all your equipment.

A rising number of biologics drugs (temperature-sensitive, short shelf-life drugs) in the market would mean that you have to ensure temperature consistency and loss-free shipping from the source to the point where the drug is administered. Operating costs run high due to expensive cold chain logistics, and also because of losses due to bad handling.

The challenge is accentuated in the manufacturing and distribution of generic drugs, which constitute up to 80 percent of today's pharma market. To handle the stiff competition in the market for generics, you also need highly developed logistics capabilities with the highest efficiencies at the lowest cost.

Warehousing, a vital component in the manufacture of pharmaceuticals, is costly, and its efficiency and quality are crucial for the company's survival. Many companies choose to manage the processes internally, given the sensitive nature of the products. A McKinsey study says that warehousing accounts for 95 per cent of all pharma logistics costs.

Today, pharmaceutical companies have a compelling opportunity to adopt and profit from the game-changing technological advancement called the Internet of Things (IoT) that promises to fix all the aforementioned gaps. In an IoT environment, every 'thing' is equipped with a sensor that allows it to intelligently communicate and interact with other objects and systems within the IoT ecosystem. The IoT environment helps pharmaceutical companies to automate and revitalise their manufacturing and supply chain management operations.

IoT extends visibility into every area of the business from development through manufacturing, transport, distribution, dispensing, and consumption. On the shop floor, real-time data from sensors will allow visibility across all areas of work, and result in improved productivity, efficiency, reduced cycle time and manufacturing costs.

Smart warehouse management systems enabled by IoT integration will bring in increased visibility, provide

real-time data to track and report inconsistencies (for example, storage temperature), and ensure that the right data is available at the right time to enable the right people to act when it truly matters. In logistics, tracking drug inventory movements in real time can save billions of dollars. Smart pharma packaging can help ensure that shipments and medications are accurately tracked, and the supply chain remains fluid, efficient, and cost-effective.

According to IDC, there were 9.1 billion IoT units installed in 2013, which is predicted to increase to 28.1 billion in 2020. In such a fast-changing world, connected equipment, men and material tracking, sample lifecycle management, smart packaging, and cold-chain monitoring are among the top IoT applications suited for the pharmaceuticals industry. Investing in these transformational technologies comes with its challenges. Below are some recommendations and best practices for pharmaceutical companies to fully benefit from their IoT integration.

- Invest in supportive IoT infrastructure and be future-ready.
- Invest in IoT-based security solutions because security is paramount and workarounds are costly.
- Focus on robust change management to make sure people, processes, and responsibilities adapt seamlessly and make the transition successful.
- Think big, start small, fail fast, and scale quickly.
- Make sure that key decision-makers are on board and success criteria in project lifecycle are defined early.
- Perform pilots, establish business benefits through proofs-of-concept (POCs), employ Agile methodologies, choose suitable partners, and leverage expert teams to effect this digital transformation.

Looking ahead, the advances in digital technologies, ubiquity of mobile computing, dominance of social media, and a growing portfolio of smart products are sure to bring real-time actionable intelligence. Enterprises must constantly use emerging technologies to innovate, stay relevant, constantly hone competitiveness and make profits. The risks of doing nothing must be evaluated. The time for pharmaceutical companies to accelerate implementation and use of IoT platforms and solutions is now. ■

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Navigating challenges : CRAMS Industry holds long-term growth potential

The Contract Research & Manufacturing Services (CRAMS) contribute approximately 15% to 20% of the Indian Pharmaceutical Industry, which has a total value of around USD 48 billion in FY23. Over the period of FY18 to FY22, the CRAMS segment experienced a robust growth rate of about 17%. However, due to geopolitical developments and recessionary trends in regulated markets, the growth rate of the segment decelerated to approximately 4% in FY23. This slowdown in growth has also impacted the operating profitability margins, causing a decline of about 350 basis points during the same fiscal year, based on industry aggregates representing over 70% of the CRAMS segment.

CareEdge Ratings anticipates that this contraction in the CRAMS segment is temporary and expects a recovery starting from Q3FY24. The palpable reason for this recovery lies in the resumption of research activities by innovator and biotech companies, gradually returning to normalcy. The following section highlights the factors that contributed to the slowdown and contraction in the CRAMS segment and outlines the expected evolution of the segment going forward.

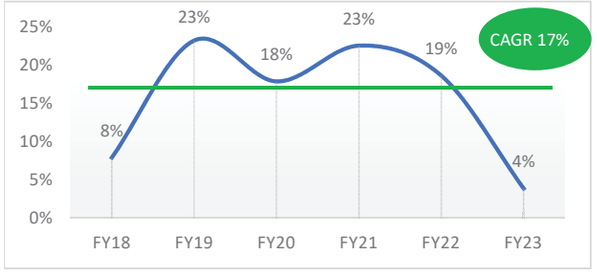
Factors for Higher Growth Rate during FY18 to FY22:

Discovery and development of a new drug is a quite lengthy and complex process, generally involving 10-15 years of time with investments running in billions (more than USD 5 billion). More than ever, the innovator companies are looking for partners across the pharmaceutical value chain to encourage innovation, optimise costs, enhance efficiency, flexibility and productivity through the various stages of drug discovery to development.

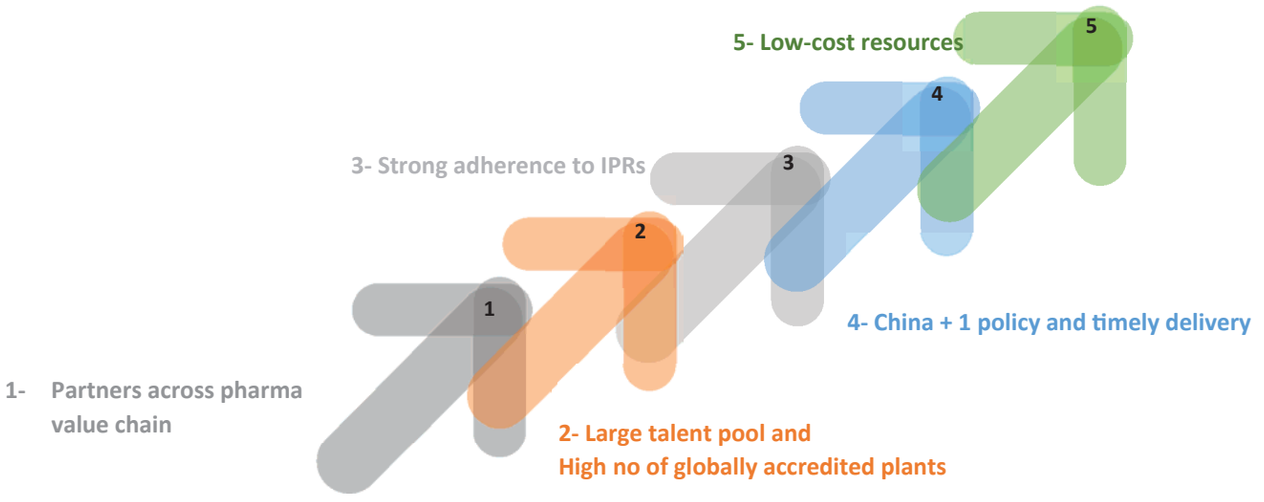
Indian CRAMS players offer a complete end to end solution viz. right from the drug discovery and preclinical studies to drug development and manufacturing. The segment has grown over time from simple molecule research and manufacturing to manufacturing of complex molecules requiring high end research. The presence of large talent pool, large globally accredited plants, strong adherence to Intellectual Property rights (IPR), efficient and reliable delivery timelines, China plus one policy, low cost and deep research acumen has made India as the preferred destination for global pharma innovators. The analysis of data of industry aggregates that represent over 70% of the CRAMS segment shows over a period of 7 years viz. FY18-FY28, the industry has registered a CAGR growth. of about 17%.

Factors Denting Growth Rate and Profitability Margins in CRAMS Segment during FY23:

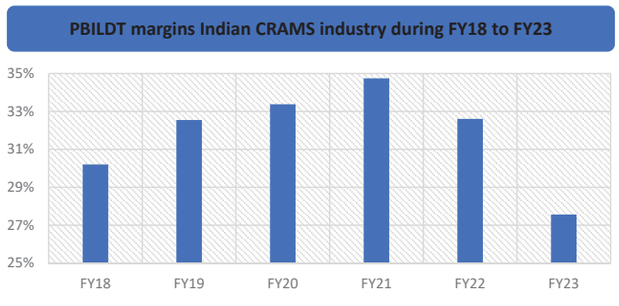
Revenue growth rate of CRAMS **industry during FY18 to FY23**



Despite the promising long-term growth potential of the Indian CRAMS market, the industry is currently grappling with several challenges that have affected the performance of key players in FY23. The slowdown can be attributed to the impact of rising inflation and recessionary pressures in the US and European markets. Leading innovator and biotechnology companies have reduced their investment in research and development for drug discovery and development, which has directly impacted the Indian CRAMS segment, predominantly reliant on exports.



Specifically in the European market, energy prices have surged by over 30%, logistics costs have increased by over 100%, and there has been a more than 50% rise in the input cost of raw materials due to geopolitical tensions. These factors have resulted in significant cost inflation. Notably, CRAMS players with manufacturing units overseas have been more severely affected, experiencing deeper margin reductions compared to those with manufacturing units in India. Furthermore, leading CRAMS players in India have witnessed an overall increase



in raw material and freight costs, amounting to approximately 20%, thereby denting their margins by around 350 basis points during FY23.

Way Forward

The credit quality of Indian CRAMS players has demonstrated stability and is expected to continue in the future. This is primarily due to their low-leveraged balance sheets and moderate capital expenditure plans. According to CareEdge Ratings, the CRAMS segment is projected to experience robust growth of around 10% in the medium to long term. This growth will be driven by the increasing trend of outsourcing by innovator.

CareEdge Ratings anticipates that innovator and biotechnology companies will regain momentum in their research and development spending during the current fiscal year, gradually returning to normal levels by Q3FY24. This is crucial for them as each stage of the drug discovery process is time-bound and critical. Looking ahead, CareEdge Ratings expects the PBILDT (Profit Before Interest, Taxes, Depreciation, and Amortization) margin of CRAMS players to improve and remain within the range of 29-30%, aligning with the normalization of revenue growth.'■

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The Pharma Revolution: How Artificial Intelligence is Reshaping the Landscape

The quest for improved health and longevity has reached a pivotal point. Artificial intelligence (AI) is not just a futuristic buzzword anymore; it is actively transforming the pharmaceutical industry. In recent years, the integration of AI in pharmaceuticals has paved the way for groundbreaking advancements, offering new avenues for drug discovery, personalized medicine, and enhanced patient care. **Dr. Romel Bhattacharjee** explores the merging of AI and pharma, discussing its use cases, innovative prospects, and limitations associated with this technological revolution.

From clinical trials to supply chain management, AI has the potential to accelerate innovation, improve quality, and reduce costs across the pharmaceutical value chain. However, careful management of both opportunities and challenges is required to realize this potential.

Beyond the Lab: AI in Action

- **Drug Discovery and Development:** One of the most significant applications of AI in pharmaceuticals is in drug discovery and development. Traditional drug discovery is a time-consuming and costly process. AI, however, can significantly expedite this process by analyzing vast datasets, predicting drug-target interactions, designing novel molecular structures, synthesizing potential drug candidates, and predicting their efficacy. Atomwise, for instance, uses AI to analyze molecular structures and predict potential drug compounds, speeding up the discovery phase. Exscientia also uses AI to automate almost the entire drug discovery process. In 2021, it identified an Alzheimer's candidate that moved to Phase 1 trials in just 12 months versus the industry average of 4–5 years. AI drug design can also improve success rates in clinical trials.

- **Personalized Medicine:** AI allows to create personalized treatment plans based on individual patient characteristics. By analyzing genetic, clinical, and lifestyle data, AI algorithms can identify the most effective treatments for specific patients. For example, IBM Watson for Oncology employs AI to assist oncologists in recommending personalized cancer treatment options by analyzing vast amounts of medical literature and patient records.

- **Clinical Trials Optimization:** AI streamlines the clinical trial process by identifying suitable candidates, optimizing patient recruitment, and predicting potential challenges. AI can also help to optimize trial design, monitor safety, ensure protocol adherence via sensors and apps, to analyze complex trial data. Trials are expensive and time consuming, so AI efficiencies provide a major competitive advantage. Startup Mendel.ai uses AI and big data analytics to reduce trial costs by 10–50 percent. Tempus, a technology company, employs AI to enhance clinical trial design and execution, leading to more efficient trials and faster time-to-market for new drugs.

- **Drug Repurposing:** AI techniques like deep learning and machine vision can analyze vast sums of biomedical data to help in identifying existing drugs that can be repurposed for new therapeutic purposes. BenevolentAI, a technology company, utilizes AI to analyze biomedical literature and databases to find a potential target for treating COVID that led to a clinical trial in just months. AI can also model target interactions to validate and prioritize the most promising targets.

- **Healthcare Delivery:** AI chatbots, virtual nurses, and clinical decision support systems can provide guidance to doctors at the point of care. In time, they may help democratize cutting-edge treatment expertise across geographies and levels of care. Chatbots and virtual assistants can also personalize patient communication and medication adherence. In the near future, AI would presumably be used to analyze medical records to predict adverse drug reactions before they occur, ensuring patient safety.

- **Supply Chain Management:** AI improves supply chain efficiency by predicting demand, optimizing inventory, and minimizing disruptions. AI is also being applied across manufacturing for improving yields, monitoring quality, and predicting equipment maintenance needs before failures occur. Pharmaceutical companies can use AI to track medicines across complex global supply chains to enhance forecasting accuracy, ensuring a steady supply of medications and reducing the risk of shortages or overstock.

Opportunities Galore

- **Cost Reduction and Efficiency:** AI applications in pharmaceuticals can significantly reduce costs and boost efficiency. By automating processes, optimizing workflows, and accelerating drug development, pharmaceutical companies can streamline operations and allocate resources more effectively.

- **Enhanced Diagnosis and Treatment:** AI-powered diagnostic tools contribute to more accurate and timely disease diagnosis. This, in turn, facilitates the development of targeted and effective treatment plans, improving patient outcomes and decreasing healthcare costs associated with misdiagnosis or delayed treatment.

- **Predictive Analytics for Disease Prevention:** AI can analyze patient data to identify patterns and predict disease outbreaks, enabling proactive measures for disease prevention. By leveraging predictive analytics, pharmaceutical companies and healthcare providers can implement preventive strategies and allocate resources strategically.

- **Patient-Centric Healthcare:** AI facilitates the development of patient-centric healthcare solutions by tailoring treatments to individual patient profiles. This shift toward personalized medicine ensures that patients receive treatments that are not only effective but also minimize adverse reactions, ultimately improving overall healthcare outcomes.

Challenges

The incorporation of AI in pharmaceuticals largely depends on the scrutiny of extensive volumes of sensitive patient data. A pivotal concern revolves around the assurance of privacy and security for this data, given that unauthorized access or data breaches could yield severe consequences. Such incidents have the potential to weaken patient trust and impede the widespread adoption of AI technologies within the pharmaceutical domain.

Another significant challenge stems from the highly regulated environment in which the pharmaceutical industry operates. The integration of AI into various facets such as drug development and patient care necessitates strict adherence to regulatory standards. Navigating these regulatory hurdles is often time-consuming, posing a potential impediment to the swift adoption of AI technologies in the industry. It becomes imperative for regulatory frameworks to evolve and adapt to accommodate the nuances of AI-powered drug development and clinical trials.

Furthermore, the increasing sophistication of AI systems introduces ethical considerations, particularly in the healthcare sector. The transparency of AI processes becomes crucial, especially when dealing with black-box algorithms that raise concerns regarding trust and accountability. Addressing questions about potential biases in AI algorithms is paramount to ensure fair and equitable access to healthcare resources.

AI could increase barriers to market access and competition. The handful of large companies with vast data and AI talent can increase dominance over smaller players struggling to keep pace with the technical complexity. Policymakers should address these issues early to ensure developments benefit patients equitably while managing risks.

As AI continues to advance, a thoughtful approach to ethical considerations is essential to navigate the evolving landscape of healthcare technology responsibly.

Limitations

- **Lack of Human Intuition**: AI systems, while powerful, lack the human touch and intuition that is often crucial in healthcare decision-making. The reliance on algorithms may lead to a disconnect between technology and the nuanced, individualized care required in certain medical scenarios.
- **Limited Generalization:** AI models are trained on specific datasets, and their performance may be limited to the conditions present in those datasets. Generalizing AI models to diverse populations or unforeseen scenarios may result in discriminatory outcomes with reduced accuracy and reliability.
- **Overreliance on AI**: Overreliance on AI systems without proper human oversight can be risky. Healthcare professionals must remain actively involved in decision-making processes, utilizing AI as a supportive tool rather than a replacement for human expertise.

Outlook

AI adoption in pharma is still in early stages but advancing rapidly thanks to accelerating technical capabilities, lowered computational costs, and fierce market competition. Navigating AI's duality of opportunities and challenges will determine winners and losers. Stakeholders across the pharmaceutical and AI sectors must engage in open dialogue to address ethical concerns, foster collaboration, and build robust regulatory frameworks. Continuous R&D is crucial to unlock the full potential of AI while mitigating its risks. Companies focused closely on patient benefit as the guiding light while responsibly and proactively addressing AI risks have the best prospects to lead this next wave of biopharmaceutical innovation. ■

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