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India Ratings and Research maintains neutral outlook for pharmaceuticals sector in FY25

Mumbai, India: India Ratings and Research has maintained a neutral outlook for the pharmaceuticals sector in FY25. Sector companies will continue to benefit from growth in the domestic as well as export markets, while maintaining healthy EBITDA margins led by a moderation in the price erosion in the US generics business, softening of input costs, and high-value product launches in the US generic market.

The rating agency expects the Indian pharmaceuticals market (IPM) to grow 8%-9% year on year in FY25 (FY24: 6%-7% year on year; FY23: 9.3% yoy). It further expects its US-focused pharma issuers to remain stable or report mid-to single-digit revenue growth in FY25 on account of lack of revenue from one-off products. Hence, the overall proportion of sales from the US is likely to remain stable.

The agency expects the active pharmaceuticals ingredients (API) business of India Ratings selected companies to report high single-digit growth in FY25 due to a demand uptick. The overall revenue growth for them is also expected at around 9% year on year while maintaining healthy EBITDA margin performance (around 22%) in FY25. There has recently been a wave of M&A activity in the domestic formulations space, which is likely to continue.

India Ratings has maintained a Stable rating outlook of its rated pharma companies for FY25, driven by a low leverage ratio and adequate liquidity, expecting limited rating movements in the sector. Like in FY24, the agency expects the rating actions in FY25 to be driven by company-specific factors (United States Federal Drug Administration (USFDA) action, operating profitability and business visibility). The agency expects a significant increase in USFDA inspections in FY25. Ind-Ra continues to monitor its rated portfolio and any material deviation in the credit metrics from its expectations could result in a rating downgrade.

Most large pharma companies rated by India Ratings belong to high investment-grade categories. Large players are adequately capitalised to make big investments in FY25 to adjust for the ongoing fundamental shift in market opportunities.

The agency expects sales to the US to be stable or there will be mid-single-digit revenue growth in FY25 on account of lack of revenue from one-off products. Hence, the overall proportion of sales from the US is likely to remain stable. Ind-Ra expects IPM to grow 8%-9% year on year in size during FY25, on account of an increase in drug prices (4%-5%), incremental sales from added field force last year, higher growth in chronic therapies and anticipation of favourable seasonality. The agency expects the cash flow-sticky chronic segment to continue to grow at a higher rate than the acute segment.

"India Rating's rated large pharma corporates continue to deliver healthy sales growth while maintaining strong operating margin. We expect a pick-up in USFDA inspections during FY24 and FY25; however, the impact on some facilities and entities will be less disruptive for the sector compared to the situation during 2015-2016," says Vivek Jain, Director, Corporate Ratings at India Ratings and Research.

Health Ministry: Reports claiming significant hike in prices of medicines are false and misleading

New Delhi, India: The Ministry of Health and Family Welfare clarified that significant hike in prices of medicines are false and misleading. Some media reports have highlighted that medicine prices will witness a significant hike by up to 12% from April, 2024.

These reports further claim that more than 500 medicines will be affected by this increase in price. Such reports are false, misleading and malicious.

As per the provisions of Drug Price Control Orders (DPCO) 2013, drugs are categorized as scheduled and non-scheduled formulations. The formulations which are listed in Schedule-I of DPCO 2013 are scheduled formulations and the formulations that are not specified in Schedule-I of DPCO 2013 are non-schedule formulations.

National Pharmaceutical Pricing Authority (NPPA) under the Department of Pharmaceuticals annually revises the ceiling prices of scheduled medicines on the basis of Wholesale Price Index (WPI). The scheduled medicines included in the Schedule-I of the DPCO, 2013 are essential medicines. During the calendar year 2023 over the corresponding period in 2022, the annual change in WPI with base year 2011-12 was (+) 0.00551% as per data published by Department for Promotion of Industry and Internal Trade (DPIIT). Accordingly, the Authority in its meeting held on in March, 2024 has


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approved the WPI increase at the rate (+) 0.00551% for the scheduled medicines.

The ceiling prices on 923 medicines are effective as on date. Based on the above mentioned WPI factor of (+) 0.00551%, there will be no change in the prevailing ceiling prices for 782 medicines and the existing ceiling prices will continue to prevail up to 31st March, 2025. Fifty-Four (54) medicines with ceiling price ranging from ₹. 90 to ₹. 261 will have miniscule increase of ₹. 0.01(one paisa). As the permissible price increase is miniscule, the companies may or may not avail this increase. Thus, in the year FY 2024-25, there will be almost no change in the ceiling price of medicines based on WPI.

The WPI increase is the maximum increase permissible as per the DPCO, 2013 and the manufacturers may or may not avail this increase, keeping in view the market dynamics. The companies adjust their Maximum Retail Price (MRP) depending upon the ceiling price of their medicines, as MRP (excluding GST) can be any price which is less than the ceiling price. The revised prices will be applicable from 1st April 2024 and the detail of revised prices is available on NPPA's website www.nppaindia.nic.in.

In case of non-scheduled formulation, a manufacturer is at liberty to fix the price. However, no manufacturer of non-scheduled formulation can increase the MRP by more than 10% during preceding 12 months under Para 20 of DPCO, 2013.

Sanofi & Cipla announce distribution partnership to expand reach of CNS portfolio in India

Achin Gupta, CEO-One India Business, Cipla Limited

Mumbai, India: Sanofi India Limited and Sanofi Healthcare India Private Limited and Cipla Limited announced an partnership for distribution and promotion of Sanofi India's Central Nervous System (CNS) product range in India. As a part of this partnership, Cipla will be responsible for the distribution of Sanofi India's six CNS brands including Frisium, a leading brand in the anti-epileptic medication category.

While Sanofi India will continue to own, import, and manufacture its complete range of CNS products across plants in India and internationally, Cipla will leverage its capabilities and robust India-wide network of strong marketing and sales professionals, distributors, institutions, and market outreach programs to expand access to these treatments for patients who need them.

Rodolfo Hrosz, Managing Director, Sanofi India Limited says, "Sanofi India's CNS products are leaders in their respective categories. These well-established brands already improve lives of many patients across urban centres in the country. Cipla's wide presence will enable us to expand the reach of this portfolio to healthcare professionals and patients across all India."

Achin Gupta, Chief Executive Officer – One India Business, Cipla Limited says, "Enhancing access to high quality treatments is central to our purpose of 'Caring for Life.' We are pleased to collaborate with Sanofi India to enhance accessibility to highly efficacious and quality therapeutic solutions in CNS and bring value to patients across the country. Central Nervous System is one of the most challenging areas in medicine, and we believe this partnership is a significant step forward to address unmet needs of patients."

SPARC announces results of interim analysis from PROSEEK study of Vodobatinib

Anil Raghavan, CEO, SPARC

Mumbai, India: Sun Pharma Advanced Research Company Ltd. (SPARC) announced results of interim analysis from the PROSEEK study, a global, randomised, double blind, placebo-controlled Phase 2 study in patients with Early Parkinson's Disease. PROSEEK compared two doses of Vodobatinib with placebo and enrolled a total of 513 patients from US, Europe and India.

The interim analysis was based on data from 442 patients who completed 40 weeks treatment in Part I of the study. The study failed to demonstrate superiority of Vodobatinib in the prespecified primary endpoint of change in MDS-UPDRS Part III total score as compared to placebo.

SPARC has reviewed the data and determined that the study has not shown evidence of treatment benefit

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in patients receiving Vodobatinib, and consequently decided to close the study. SPARC plans to complete the full analysis of clinical outcomes and correlative biomarker data in the coming months.

Anil Raghavan, CEO of SPARC commented, "While the interim analysis results were not what we aspired for our patients, the findings from this study will significantly contribute towards expanding the understanding of the role of c-Abl kinase in alpha synucleinopathies. Our gratitude extends to all those who played a role in the PROSEEK study, particularly the patients and their caregivers, researchers, and our dedicated team that worked relentlessly on the study."

Bharat Biotech and Bilthoven Biologicals B.V. announce Collaboration to produce and supply Oral Polio Vaccines

Dr. Krishna Ella, Executive Chairman, Bharat Biotech

Hyderabad, India: Bharat Biotech, a global leader in vaccine and biotherapeutic innovation, also the largest manufacturer of oral polio vaccines, and Bilthoven Biologicals B.V., (BBio), a wholly owned subsidiary of Serum Institute of India Private Limited, based in Netherlands, announced a collaboration, to further strengthen the production and supply security of Oral Polio Vaccines (OPV).

A requisite agreement has been signed between BBIL and BBio wherein BBIL will procure drug substances for the production of oral polio vaccines to be supplied within India and globally.

Through this collaboration, BBIL and BBio will jointly obtain the regulatory approvals and licenses required to commercially manufacture OPVs in India for global supplies from drug substances manufactured in the Netherlands at Bilthoven Biologicals.

Adar Poonawalla, CEO of Serum Institute of India, said, "We are delighted to join forces with Bharat Biotech to reinforce the global supply of polio vaccines. Our vision is to eradicate Polio worldwide, taking a crucial step towards reducing the impact of this deadly disease on vulnerable populations."

Dr. Krishna Ella, Executive Chairman of Bharat Biotech, said, "Oral polio vaccines have been an integral part of the Govt of India's Universal Immunisation Program (UIP) for several decades, with Bharat Biotech being one of the largest suppliers to immunisation programs across the world. This collaboration between BBIL and BBio exemplifies cooperation between vaccine companies, ensuring a secure supply of oral polio vaccines and fortifies the nation's mission to eradicate polio."

As we approach the critical phase of global polio eradication, this collaboration will support the effort to create a polio-free world.

Lupin receives tentative approval from US FDA for Migalastat Capsules

Nilesh Gupta, MD, Lupin Ltd

Mumbai, India: Global pharma major Lupin Limited announced that it has received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Migalastat Capsules, 123 mg, to market a generic equivalent of Galafold Capsules, 123mg of Amicus Therapeutics US LLC. This product will be manufactured at Lupin's Goa facility in India.

Migalastat Capsules are indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data. Migalastat Capsules (RLD Galafold) had global net sales of USD 388 million in the U.S. for the year ending December 2023.

The company has received approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application (ANDA) for Eslicarbazepine Acetate Tablets, 200 mg, 400 mg, 600 mg, and 800 mg, to market a generic equivalent of Aptiom Tablets, 200 mg, 400 mg, 600 mg, and 800 mg, of Sumitomo Pharma America, Inc. Lupin is one of the first ANDA applicants and may be eligible for 180 days of shared generic exclusivity. The product will be manufactured at Lupin's Pithampur facility in India.

Dr. Reddy's launches drug-free migraine management device Nerivio in Europe

M.V. Ramana, CEO Branded Markets (India and Emerging Markets), Dr. Reddy's

Hyderabad, India: Dr. Reddy's Laboratories Ltd., a global pharmaceutical company, announced the launch of the drug-free non-invasive migraine management wearable device Nerivio in Germany through its step-down subsidiary betapharm. The launch marks the company's entry into digital therapeutics in Europe. Nerivio is approved by the United States Food and Drug Administration (USFDA), and is CE-mark certified in Europe.

Nerivio was presented in 2023 by Dr. Reddy's at the DGN Kongress organised by the German Association of Neurology in Berlin, and the 17th European Headache Congress held in Barcelona, Spain.Dr. Reddy's will present and launch Nerivio during the Neurological Association of South Africa annual congress on April 17, 2024, in the presence of Dr. Stewart Tepper, Professor of Neurology at the Geisel School of Medicine – Dartmouth, and Vice President, New England Institute for Neurology and Headache.

In May 2024, Nerivio will also be presented at International Headache Society 2024 iHEAD meeting in Berlin, Germany. In subsequent months, Dr. Reddy's will launch Nerivio in Spain and the UK.

M.V. Ramana, Chief Executive Officer, Branded Markets (India and Emerging Markets), Dr. Reddy's said, "At a time when conversations on migraine focus on migraine5 as a women's health issue, relief from migraine through the use of technology and drug-free solutions, challenges associated with managing migraine during the child-bearing age, and distinguishing migraine from headache, we are happy to take our clinically-proven first digital therapeutics product, Nerivio®, to patients in our identified markets. Nerivio has had an encouraging start in India, with recommendation from neurologists in India and bringing relief to patients living with migraine. We believe this product meets a genuine unmet clinical need among migraine patients, and has the potential to reduce pill burden in migraine. We look forward to receiving patient and HCP feedback from these markets.

Suven announces merger of Cohance Lifesciences

Annaswamy Vaidheesh, Executive Chairman, Suven

Mumbai, India: Suven Pharmaceuticals Limited and Cohance Lifesciences Limited, announced a proposed scheme of amalgamation for the merger of Cohance with Suven. This marks a pivotal moment in Suven's journey, underscoring commitment to scaling, ensuring consistent earnings, fortifying our financial standing, and advancing towards forging leadership in the integrated CDMO space.

Cohance is a leading CDMO and Merchant API platform with global leadership in select low-mid volume molecules as well as unique capabilities in the form of its antibody drug conjugates (ADC) platform. Their CDMO segment has grown at healthy CAGR of 30%+ over FY20-23 and contributes~44% to its Gross Profits for 9mFY24.

On the proposed merger, Annaswamy Vaidheesh, Executive Chairman, Suven said, "This is a transformative step in Suven's journey of growth and building a respected integrated CDMO player. We are extremely excited about the benefits of combined scale, capabilities, complementary customer base and best practices that will further help enhance our leadership position in India and globally".

Commenting on the proposed merger, Dr V Prasada Raju, Managing Director, Suven, said, "Our entire management team, spanning Suven and Cohance, is enthusiastic about shaping the future of the Pharmaceutical & Specialty Chemical landscape. The combination helps us drive multiple synergies both on revenue and cost front."

Zydus receives tentative approval from USFDA for Letermovir tablets


Dr. Sharvil Patel, MD, Zydus Lifesciences Ltd

Mumbai, India: Zydus Lifesciences Limited has received tentative approval from the United States Food and Drug Administration (USFDA) to market Letermovir tablets, 240 mg and 480 mg, (Prevymis tablets).

Letermovir tablets are used to prevent disease caused by a virus called cytomegalovirus (CMV) in people who have received a bone marrow transplant or kidney transplant. The drug will be manufactured at the group's formulation manufacturing facility at Ahmedabad SEZ, India. Letermovir tablets, 240 mg and 480 mg had annual sales of USD 289.5 mn in the United States (IQVIA MAT Jan-24).

The group now has 393 approvals and has so far filed over 460 ANDAs since the commencement of the filing process in FY 2003-04.

Aurobindo Pharma completes US FDA Inspection at new injectable facility of Eugia Steriles

Hyderabad, India: Aurobindo Pharma stated that it has Completed US FDA Inspection at the new injectable facility of Eugia Steriles Private Limited, a 100% stepdown subsidiary of the Company. The new injectable facility of Eugia Steriles Private Limited (a 100% subsidiary of Eugia Pharma Specialities Limited and a stepdown subsidiary of the Company), situated at Parawada Mandal, Anakapalli District, Andhra Pradesh, has recently started the commercial operations.

The United States Food and Drug Administration (US FDA) inspected the above-mentioned facility from March 28, 2024 to April 05, 2024. The inspection closed with 3 observations.

The observations are procedural in nature and will be responded to within the stipulated time, the company said.

Takeda partners with Biological E


Sri Anumula Revanth Reddy, CM, Telangana

Mumbai, India: Takeda announced a strategic partnership with Biological E. Limited, a leading vaccines and biologics company in India, to manufacture Takeda's dengue vaccine, TAK-003. The partnership marks a crucial step in the fight against the global public health threat of dengue fever, aligning with the disease-specific target set by the World Health Organization (WHO) to achieve zero case-fatality rate due to dengue by 2030.

The partnership will substantially enhance manufacturing capabilities to ensure a sustainable global supply of the vaccine. Biological E will scale up its production capacity to potentially reach 50 million doses annually, accelerating Takeda's efforts to manufacture 100 million doses annually within the decade.

Announcing the partnership at BioAsia 2024, a regional life sciences and healthcare forum organized by the Government of Telangana, Sri Anumula Revanth Reddy, the Chief Minister of Telangana said, "We are delighted that Hyderabad in Telangana will host the facility where the dengue vaccine, a result of the partnership between Takeda and Biological E., will be manufactured. The state of Telangana offers a conducive R&D and manufacturing environment with a focus on life sciences, particularly vaccines and biologics, and I am delighted that the dengue vaccine production in Hyderabad is aimed at accelerating its access in India and other endemic countries".

"Leveraging Takeda's technological expertise and Biological E's manufacturing capabilities will support greater accessibility and affordability of dengue vaccines, contributing to the nation's healthcare resilience and future preparedness. We are happy to support this partnership among science, government and industry to drive and scale innovations for universal health coverage," added Sri Duddilla Sridhar Babu, Hon'ble Minister of Industry & Commerce of Telangana.

"This strategic partnership reaffirms our commitment to supplying vaccines to protect the health of people around the world and our efforts to strengthen

partnerships in Asia. With vaccine approvals in Thailand, Indonesia, and recently in Malaysia, we are excited for a future where integrated protection against dengue can potentially improve the lives of countless people in India, Southeast Asia and beyond", said Dion Warren, Head of India and Southeast Asia Multi-country Organisation, at Takeda.

Bain & Company and HealthQuad releases 'Healthcare Innovation in India' report

New Delhi, India: India's healthcare innovation landscape is poised for a significant leap, with its market potential expected to double to approximately USD60 billion by FY 2028. Pharma services and healthtech are anticipated to drive about 80% of this growth, maintaining their positions as the largest segments in the market, according to the findings of 'Healthcare Innovation in India' report by Bain & Company and HealthQuad. This growth will be driven by rising consumerization of health, reconfigurations to the global healthcare value chain, a deepening of Indian scientific and technological expertise, and regulatory tailwinds.

The report outlines the opportunity in healthcare innovation where companies increasingly leverage emerging technologies to add innovation vectors—including new business models, software-led solutions, and products—that extend beyond more longstanding value engineering considerations.

The overall Indian healthcare market, valued at about USD180 billion in FY 2023, is projected to grow at approximately 10–12% CAGR to reach USD320 billion by FY 2028. Healthcare innovation is a rapidly growing segment currently valued at USD30 billion and accounts for 15% of the overall market. It has almost doubled over the last three years, with 55% of the market size led by exports. This segment is dominated by pharma services (CDMO, CRO, pharma IT) and healthtech with vaccines and biotech, and medtech emerging as green shoots.

"From cutting-edge pharma services to disruptive healthtech and medtech advancements, India's healthcare innovation landscape is experiencing a remarkable transformation. With its focus on innovation, quality, and cost-effectiveness, India's healthcare innovation market is addressing domestic needs and making its mark on the global stage. This USD30 billion sector is fuelled by rising investments, supportive government policies, a deepening scientific talent pool and is brimming with potential in nascent fields such as Biotech and MedTech" said Aarthi Rao, Partner at Bain & Company.

The Indian pharma services account for approximately 50% of the healthcare innovation market, valued at USD16 billion in FY 2023, with 85%–90% of revenue driven by exports. The CDMO segment saw the highest growth, driven by global supply chains shifting away from China and improvement in capacity, capability, and quality by Indian players. Pharma IT also showed robust growth, led by growing global price pressures and demand for omnichannel transformation.

Alembic Pharma gets USFDA approval for Ribociclib Tablets

Mumbai, India: Alembic Pharmaceuticals Ltd stated that it has received US Food & Drug administration (USFDA) Product Approval (Tentative) for Ribociclib Tablets, 200 mg.

Ribociclib tablet is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy.

Alembic has a cumulative total of 197 ANDA approvals (170 final approvals and 27 tentative approvals) from USFDA.

Caplin Group completes new Oncology (anti-cancer) facility

Chennai, India: Caplin One Labs Limited, a wholly owned subsidiary of Caplin Point Laboratories Limited, announce the completion of its state-of-the-art Oncology facility at Kakkalur, near Chennai, and immediate commencement of operations. The total investment commitment for this facility is ₹. 150 Crore, funded entirely from internal accruals. To start with, the unit will focus on manufacturing a range of Oral Solid Dosage Oncology products, with the Injectable division to commence operations in the next few months. The company plans to expand the portfolio to over 50 oncology products progressively.

The facility will manufacture tablets (both coated & uncoated), capsules, and injections, catering to the

growing demand for high-quality pharmaceuticals in the oncology segment. Initially, these oncology products will be targeted at Latin American countries, leveraging Caplin Group's established presence in these markets. In the medium term, Caplin One Labs Limited aims to launch these oncology products in regulated markets such as the US, EU, Mexico, and others.

The facility's compliance with US FDA standards from the outset is expected to streamline the approval process, ensuring swift market entry and availability of these critical treatments to patients worldwide. Caplin Group remains dedicated to advancing healthcare solutions, improving patient outcomes, and making a positive impact on communities globally.

Venus Remedies awarded its first incentive of ₹.7.50 cr. under PLI scheme

Saransh Chaudhary, CEO, Venus Medicine Research Centre

Mumbai, India: Venus Remedies Ltd, one of India's leading manufacturers of generic drugs, has been awarded its first disbursement of ₹ 7.5 crore under the Central government's Production Linked Incentive (PLI) scheme for the financial year 2022-23, which covers 75% of the total incentive due to the company for the year.

The company has met the government's rigorous investment and sales criteria to qualify for the scheme. Venus Remedies belongs to the Category C of non-MSME pharmaceutical companies chosen under the PLI scheme. The disbursement will bolster the company's manufacturing capabilities and foster product diversification, including manufacturing of complex generics, in line with the vision of Atmanirbhar Bharat.

Saransh Chaudhary, CEO, Venus Medicine Research Centre, said, "We are thrilled to receive the first disbursement under the PLI scheme, which emphasises our commitment to driving innovation, creating employment opportunities and contributing to the country's economic development. This milestone not only validates our efforts but also propels us to enhance our manufacturing capabilities further and contribute to India's self-reliance goals."

Strides receives USFDA approval for Fluoxetine tabs 10 mg and 20 mg

Arun Kumar, Executive Chairperson & MD, Strides Pharma

Bangalore, India: Strides Pharma Science Limited announced that its step-down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has received approval for Fluoxetine Tabs 10 mg and 20 mg, from the United States Food & Drug Administration (USFDA). The product is bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD) Prozac Tablets of Eli Lilly.

Fluoxetine tablets has a market size of ~USD 23.9 Mn as per IMS. This approval further strengthens the Company's presence in the Fluoxetine portfolio, complementing the existing approval of Fluoxetine capsules, which has a market size of USD106 Mn. The Fluoxetine tablets will be manufactured at the company's facility in Puducherry.

The company has 260 cumulative ANDA filings (including the recently acquired portfolio from Endo at Chestnut Ridge) with USFDA, of which 245 ANDAs have been approved. The company has set a target to launch ~ 60 new products over three years in the US.

Roche Diagnostics launches India's heart failure test for screening diabetes patients

Mumbai, India: Roche Diagnostics India announced the launch of its point-of-care NT-proBNP test for screening diabetes patients who are at risk of cardiovascular diseases (CVD) such as heart failure (HF). This innovation is designed to bring testing closer to clinics and revolutionise patient care. The claim extension of the NT-proBNP biomarker, available exclusively on the cobas h 232 system, aims to provide faster, more efficient diagnosis and management of HF in patients with type 2 diabetes (T2D).

Although diabetes is a global health concern, its burden is more evident in developing countries like India. India is considered the diabetes capital of the world, with over 101 million people living with disease, as per recently

published the Indian Council of Medical Research–India Diabetes (ICMR-INDIAB)national cross-sectional study.

Diabetes is associated with significant morbidity and mortality. Patients living with diabetes are at a higher risk of developing CVD: up to 46% of diabetic patients will develop CVD in their lifetime which is responsible for about 50% of mortality in T2D patients. 2 Moreover, statistics indicate a staggering 30% of diabetic patients develop HF during their lifetime. Individuals with T2D and HF face up to an 8x increased risk of death compared to those without HF. Despite the number, approximately 80% of HF cases are only diagnosed following acute hospitalisation, despite patients experiencing symptoms up to ve years prior.

The challenge lies in the non-speci c symptoms of HF, which often remain undetected until advanced stages. Recognising this critical gap, Roche Diagnostics India's NT-proBNP test on the cobas h 232 system facilitates early detection (screening) and intervention, enabling clinicians to identify high-risk T2D patients and initiate timely treatment discussions.

Mankind Pharma bridges Digital Divide with 'Digital Smart Class' initiative

Sheetal Arora, CEO, Mankind Pharma

Mumbai, India: Mankind Pharma, one of India's leading pharmaceutical companies, is making strides in enhancing the quality of education in remote areas through its ongoing 'Digital Smart Class' initiative. Under their CSR arm, this comprehensive program has established 220 smart classrooms equipped with cutting-edge technology across government schools in Uttar Pradesh, Uttarakhand, and Himachal Pradesh.

The Digital Smart Class initiative is a strategic effort by Mankind Pharma to bridge the digital divide in education and provide underprivileged students with access to modern learning resources. The smart classrooms are equipped with integrated teaching devices, the Kyan system, which can convert any surface to an interactive board and multimedia playing surface, enabling a more engaging and immersive learning experience.

Sheetal Arora, CEO of Mankind Pharma, expressed his vision for the initiative, stating, "At Mankind Pharma, we are committed to contributing to the overall development of society. Education is a fundamental right, and we believe that every child, regardless of their geographical location, deserves access to quality education. The Digital Smart Class initiative is our endeavour to empower rural communities by providing them with the necessary tools and resources to thrive in the digital age."

The initiative spans across 170 schools in 23 clusters, benefiting thousands of students in remote areas. Mankind Pharma has collaborated closely with local authorities and educational institutions to ensure the successful implementation and sustainability of the smart classrooms.

Natco Pharma receives warning letter from USFDA for its Kothur unit

Hyderabad, India: Natco Pharma Ltd stated that it has received a Warning Leter dated 8th April, 2024 from the United States Food and Drug Administration (USFDA). The Company does not believe that the Warning Letter will have an impact on disruption of supplies or existing revenues from this facility. It may cause delay/ withholding of pending product approvals from this site.

The Company will respond to the Warning Letter within the stipulated timelines and work closely with the USFDA to address the concerns in a holistic and timely manner to ensure sustained compliance. The Company also remains commited to being cGMP compliant and in supplying high-quality products to its customers and patents globally.

Indegene acquires Trilogy Writing & Consulting GmbH

Mumbai, India: Indegene, a digital-first, life sciences Commercialization Company, announced the acquisition of Trilogy Writing & Consulting GmbH, a global provider of specialty medical writing capabilities across clinical, regulatory, safety and medical content to life sciences companies. The acquisition by Indegene Ireland, a subsidiary of Indegene Limited, augments Indegene's depth of clinical and regulatory writing expertise for market authorization applications globally.

Trilogy Writing & Consulting is a Germany, UK, and US-based, medical writing consultancy with know-how in the development and delivery of clinical, regulatory, safety, and medical content. It applies its expertise and unique approaches to deliver quality medical writing output.

Trilogy has a proven track record of more than 22 years of providing medical writing services to the biopharmaceutical and medical devices industry with strength in expertise across oncology, immunology, neurosciences, urology, anti-infectives, endocrinology, respiratory diseases, and many other therapeutic areas. Trilogy's dedication to strategic medical writing ensures client success in regulatory submissions across a breadth of health authorities including the US FDA, EU EMA, Health Canada, UK MHRA, China NMPA, Japan PMDA, and many others.

According to Grand View Research, the medical writing market was $4.2 billion in 2023 and is forecasted to grow at 10.46% CAGR to $8.4 billion by 2030. However, biopharma companies are increasingly challenged by a lack of internal expertise (especially in complex therapeutic areas), continuous pressure on margins, and stringent expectations from regulatory authorities. By combining Trilogy's expertise in medical writing with Indegene's scalability and technology, especially Generative AI, life sciences companies stand to benefit by way of higher productivity, lower cost, and greater flexibility even as they set up themselves to be future-ready, ultimately leading to faster regulatory approval for their products.

"Trilogy has years of demonstrated knowledge in medical writing, clearly evident from its team that has won the trust of life sciences leaders over the years," said Manish Gupta, CEO of Indegene. "Combining Trilogy's expertise with Indegene's capabilities, life sciences companies benefit from partnering with a single service provider to deliver effective medical writing expertise at scale across thevalue chain. Our investments in content automation, especially leveraging Generative AI, will further improve outcomes for our clients in clinical and regulatory writing and even beyond. We welcome the Trilogy team to the Indegene family and are excited for our journey together."

Merck India appoints Dhananjay Singh as MD of Merck Life Science

Mumbai, India: Merck, a leading science and technology company, announced the appointment of Dhananjay Singh as the Managing Director of Merck Life Science in India, in addition to his current position as Head of Science & Lab Solutions Commercial, India. Effective April 1, 2024, Dhananjay Singh has taken over from Sreenath NS, who is retiring after 36 years of illustrious service with Merck in India.

"As an expert with 26 years with Merck, Dhananjay has been instrumental in shaping the Science and Lab Solutions Commercial business in India and is exemplary in his commitment to advancing scientific progress

Dhananjay Singh, MD, Merck Life Science

in partnership with our customers. Dhananjay's expertise in market dynamics and multi-stakeholder relationship management will further strengthen Merck Life Science's position in the Indian market. Together with the India country leadership team, I look forward to his continued leadership to spearhead initiatives aimed at shaping India's narrative towards people-centric performance and progress." said Pratima Reddy, Country Speaker, Merck India.

In his role as the Managing Director, Dhananjay Singh will be responsible for driving the Life Science strategy in India, ensuring governance and compliance alongside other leaders from Merck's businesses in India. Dhananjay Singh joined Sigma-Aldrich in 1997. Over the years he took on several leadership roles in Commercial Organisation before his appointment as Head of Science & Lab Solutions Commercial for India, a position he held since 2022.

"Merck Life Science is committed to meeting our customers' demands through our strategic focus on "India for India and India for the Globe", aligned with our country strategy, our strong partnerships with valued customers and our dedicated team. I am enthusiastic to drive our collective efforts toward achieving unparalleled success. Together, we will be able to navigate the intricate landscape of the life sciences industry in India, steadfastly supporting government initiatives like "Make in India" to foster growth and innovation," said Dhananjay Singh, Managing Director of Merck Life Science, India.

Gland Pharma receives approval for Eribulin Mesylate Injection

Hyderabad, India: Gland Pharma Limited (Gland or Company), a generic injectable-focused pharmaceutical company, has received approval from the United States Food and Drug Administration (USFDA) for Eribulin Mesylate Injection, 0.5 mg/mL Single Dose Vial (Product). The Product is expected to be the first generic approval on the market, and the Company expects to launch this product in the near term through its marketing partner.

The Product has US sales of approximately USD 92 million for twelve months ending in February 2024, according to IQVIA. The Company is co-developing several complex injectables, including this product, with Orbicular Pharmaceutical Technologies Pvt Ltd.

AstraZeneca and Daiichi Sankyo's drug gets USFDA approval for HER2-positive solid tumours

Cambridge, UK: AstraZeneca and Daiichi Sankyo's Enhertu (trastuzumab deruxtecan) has been approved in the US for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumours who have received prior systemic treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on objective response rate (ORR) and duration of response (DoR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

Enhertu is a specifically engineered HER2-directed antibody drug conjugate (ADC) discovered by Daiichi Sankyo and being jointly developed and commercialised by AstraZeneca and Daiichi Sankyo. The first tumour-agnostic approval of a HER2-directed therapy and ADC by the Food and Drug Administration (FDA) was based on results from the subgroup of patients with HER2-positive IHC 3+ tumours in each of the DESTINY-PanTumor02, DESTINY-Lung01 and DESTINY-CRC02 Phase II trials.

Funda Meric-Bernstam, MD, Chair of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center, US, said: "Until the approval of trastuzumab deruxtecan, patients with metastatic HER2-positive solid tumours have had limited treatment options. Based on the clinically meaningful response rates seen across clinical trials, this tumour-agnostic approval means that patients may now be treated with a HER2-directed medicine."

Dave Fredrickson, Executive Vice President, Oncology Business Unit, AstraZeneca, said: "As the first antibody drug conjugate to be granted a tumour-agnostic indication, Enhertu is truly delivering on its potential across metastatic HER2-targetable tumours. This approval also elevates the importance of testing for biomarkers, including HER2, across a broad range of tumours to ensure these patients with advanced cancer who have few options know whether a targeted medicine might be right for them."

Ken Keller, Global Head of Oncology Business, and President and CEO, Daiichi Sankyo, Inc., said: "This fifth indication in the US is a significant milestone as eligible patients with previously treated metastatic HER2-positive solid tumours may now be treated with Enhertu. The accelerated approval by the FDA for this tumour-agnostic indication is based on the clinically meaningful efficacy seen with Enhertu across numerous types of metastatic cancers."

Parexel Named "Best Contract Research Organization" at 17th Annual Vaccine Industry Excellence (ViE) awards

Mumbai, India: Parexel, one of the world's largest clinical research organizations (CROs) providing the full range of Phase I to IV clinical development services, announced it has been named "Best Contract Research Organization" at the 17th Annual Vaccine Industry Excellence (ViE) Awards. Winners were named across 13 categories, including Best Contract Research Organization, which recognizes the role of CROs in supporting the development of safe and effective vaccines.

"We are honored to be recognized with this year's ViE Award for Best Contract Research Organization," said Amy McKee, MD, Chief Medical Officer & Head of Oncology Center of Excellence. "This accomplishment reflects the depth of experience and commitment of our cross-functional infectious disease and vaccine experts and global delivery team to develop leading preventive and therapeutic vaccines that advance global health. We look forward to our continued collaboration with our biopharmaceutical customers in this important area to improve patient outcomes."

Parexel was named from among eight CRO finalists. A distinguished industry advisory board selected the company based on its ability to: provide a range of services in niche and core therapeutic areas; demonstrate methods of performance improvement and introduction of new services; ensure attention to and quality of relationships with clients; reach milestones and final outcomes; and build and maintain existing and long-term partnerships.

Over the last five years Parexel has conducted more than 225 clinical projects in the infectious disease and vaccine therapeutic area involving more than 9,150 global sites. Parexel's Infectious Disease and Franchise core team is led by Anne Kasmar, MD, MSc, Senior Vice President and Global Therapeutic Head of Infectious Disease and Vaccines, and is comprised of dedicated physicians and cross-functional colleagues.

The annual ViE Awards, organized by Terrapin, celebrate the industry's most outstanding achievements and showcase excellence in the global vaccine industry. Parexel was recognized at the ViE Awards ceremony during the World Vaccine Congress on April 2 in Washington, D.C. ■

GUEST COLUMN

Enabling Global Health: India's Rise in Biologics Accessibility

Dr. Mahesh Bhalgat
Group CEO
Veeda Clinical Research

Dr. Mahesh Bhalgat emphasizes about the India's role in enabling access of biologics to the world. He also spoke about the Research and Development (R&D) Initiatives and Investments in next-generation Biologics.

Biologics, a class of medical products derived from living organisms, has revolutionized the healthcare industry by providing innovative treatments for a wide range of diseases, including cancer, autoimmune disorders, and rare genetic conditions. However, despite their efficacy, biologics often come with exorbitant price tags, limiting access for many patients globally. In this context, India has emerged as a crucial player in democratizing access to biologics worldwide. Through its robust pharmaceutical industry, regulatory framework, and commitment to affordable healthcare, India has significantly contributed to making biologics more accessible to patients worldwide. Biologics represent a diverse array of therapeutic agents, including vaccines, monoclonal antibodies, recombinant proteins, and gene therapies. Unlike traditional small molecule drugs, biologics are complex molecules produced using living organisms such as bacteria, yeast, or mammalian cells. Their complexity often translates into higher manufacturing costs, making them expensive for patients and healthcare systems.

India's pharmaceutical industry is renowned globally for its expertise in manufacturing generic drugs and biosimilars, which are biologic products that are highly similar to already approved biologics.

The country's biopharmaceutical sector benefits from skilled workforce, cost-effective manufacturing processes, excellent demographic dividend coming from a young population, access to a large trial

Some examples, which are non-exhaustive include biosimilar versions of

- Insulin including insulin glargine and insuline aspart developed by Biocon.
- Trastuzumab, a monoclonal antibody used in the treatment of breast cancer and gastric cancer, developed by Dr. Reddy's Laboratories.
- Adalimumab, a tumor necrosis factor (TNF) inhibitor used in the treatment of autoimmune diseases such as rheumatoid arthritis and psoriasis, developed by Zydus Cadila.
- Pegfilgrastim, a granulocyte colony-stimulating factor (G-CSF) used to stimulate the production of white blood cells in cancer patients undergoing chemotherapy, developed by Intas Pharmaceuticals.
- Etanercept, a TNF inhibitor used in the treatment of autoimmune diseases such as rheumatoid arthritis and psoriasis, developed by Sun Pharmaceuticals

population and an evolving conducive regulatory environment. These factors have positioned India as a leading supplier of affordable medicines to both domestic and international markets. India launched the National Biopharma Mission in 2017 as part of its larger 'Make in India' initiative. This mission focuses on developing biopharmaceuticals, including vaccines, biosimilars, and biologics, to address healthcare challenges and enhance India's competitiveness in the global biotech market. Commendations from Dr. Kiran Mazumdar-Shaw and Dr. Cyrus S Poonawalla highlight constant CAGR of >50% for the last 5 years for the Biopharma sector and >24 WHO-approved vaccines for global supply. Association of Biotechnology Led Enterprises (ABLE) in India estimates the size of the broader economic impact for biologics to grow at a compounded annual growth rate (CAGR) of 22% to become USD 12bn by 2025. Contract research services in early discovery and clinical development for biologics and biosimilars in India are estimated to be USD 200Mn and growing at a CAGR of at upwards of 20% (source: Association of Biotechnology Led Enterprises: ABLE)

India is a major supplier of generics worldwide, meeting 50% of Africa's drug needs, 40% of the USA's, and approximately 25% of the UK's. While this "Pharmacy of the World" reputation comes from small molecule generics, there is a noticeable shift in India towards high-value drugs, beginning with value-added generics and now expanding into innovative medicines. India is also advancing in biologics, evident in its production of Covid vaccines, and biosimilars, recently highlighted through the approval of Ogivri (a Trastuzumab biosimilar) in multiple countries. Indian CDMOs enjoy higher operating margins (35% compared to 20% in the West), which encourages investment in biologics technologies. The biosimilars market is expected to grow six-fold in the next 6 years, with India having around 200 biosimilars in development. Biosimilar development in India takes 3-5 years on average, compared to 7 years in the West, at a cost that may be sometimes 10-times lower. Like the growth in generics, India's expertise in biologics is likely to fuel the expansion of CRO and CDMO services. Consequently, India is poised to lead in biologics growth globally in the next 5 years, with a burgeoning bio CDMO sector, similar to what is seen in the APAC region.

R&D Initiatives and Investments in Next-Generation Biologics

India's biopharmaceutical sector is characterized by a vibrant ecosystem of academic institutions, research organizations, and biotechnology companies engaged in innovative R&D activities. These efforts encompass a wide range of areas, including bioprocess optimization, cell line development, structure-function characterization, and novel drug delivery systems aimed at enhancing the efficiency, safety, and affordability of biologic therapies. Government support through initiatives such as the Department of Biotechnology's Biotechnology Industry Research Assistance Council (BIRAC) and various grant schemes encourages innovation and entrepreneurship in biotechnology.

These initiatives provide funding, infrastructure, and mentorship to researchers and startups, facilitating the translation of innovative ideas into commercially viable biologic products. The focus is on the development of next-generation biologics, including cell and gene therapies, RNA-based therapeutics, and therapeutic precision monoclonal antibodies targeting emerging diseases.

Emerging Biotechnology Hubs and Collaborations with Global Partners

India's biotechnology hubs, such as Hyderabad, Bengaluru, Ahmedabad, and Pune, serve as focal points for biopharmaceutical innovation and manufacturing. These regions host excellent research institutions, bio-parks, and industrial clusters, attracting domestic and international investments in biotechnology. The presence of state-of-the-art facilities for bioprocessing, analytics, and clinical research further accelerates the development and commercialization of biologics. Furthermore, India's participation in international consortia and research networks facilitates knowledge exchange and capacity building in biopharmaceutical innovation. Collaborations with organizations such as the Bill & Melinda Gates Foundation, the Wellcome Trust, and the Global Alliance for Vaccines and Immunization (IAVI/GAVI) contribute to addressing global health challenges and expanding access to biologic interventions in resource-limited settings.

India has taken several initiatives to make biologics more accessible and affordable globally, primarily through its robust generic pharmaceutical industry and policies favoring the production and distribution of affordable medicines. Some specific initiatives include:

Introduction of Biosimilar Guidelines: India's central drug regulatory authority CDSCO introduced guidelines for the development and approval of biosimilar products, allowing Indian pharmaceutical companies to produce cheaper versions of biologics after patent expiration.

Compulsory Licensing: India has provisions for issuing compulsory licenses, allowing domestic companies to produce generic versions of patented biologic drugs in the interest of public health. This has been utilized in cases where patented drugs are priced prohibitively high, enabling the production of more affordable alternatives.

Encouraging Export of Generic Medicines: India has actively encouraged the export of generic medicines, including biologics, to developing countries and regions facing health crises. This not only promotes accessibility but also strengthens India's position as the "pharmacy of the world."

Partnerships and Collaborations: Indian pharmaceutical companies often collaborate with international organizations, governments, and NGOs to expand access to biologics in low- and middle-income countries. These partnerships may involve technology transfer, capacity building, or joint ventures to manufacture and distribute affordable biologics.

Role of Chemistry, Manufacturing, and Controls (CMC)

CMC plays a crucial role in enabling access to biologics worldwide, and India's CMC capabilities contribute significantly to this process. Indian biotech companies and research institutions conduct research to engineer and optimize cell lines to produce biologic drugs. Efficient cell line development ensures high productivity, scalability, and consistency in biologics production. Indian biopharmaceutical companies focus on process development to optimize bioproduction processes and improve manufacturing efficiency. Process development involves optimizing cell culture conditions, fermentation parameters, downstream purification techniques, and formulation strategies to maximize yield, quality, and cost-effectiveness. India's expertise in process development enables the production of high-quality biologics at competitive costs, enhancing accessibility for patients worldwide.

Structural and functional characterization is essential for ensuring the safety, efficacy, and quality of biologic drugs. Indian researchers and analytical laboratories specialize in conducting comprehensive analytical studies to characterize the structure, post-translational modifications, and biological activity of biologic molecules. Advanced analytical techniques, such as mass spectrometry, chromatography, spectroscopy, and bioassays, are employed to assess the critical

quality attributes of biologics, ensuring consistency and comparability throughout the manufacturing process. Leveraging the talent base in India and looking at the growth of the biologics sector in India, companies such as Veeda, a traditional clinical research organization have also diversified into specialized analytical and process development CRO service providers. Such diversification, which is built on the foundation of strong biologics and analytical skills, has further strengthened the ecosystem in India.

Influence on Pricing, Challenges and Opportunities

The entry of Indian biosimilars into the global market has exerted downward pressure on the prices of biologic therapies. Competition from Indian manufacturers has compelled originator companies to reconsider their pricing strategies, leading to more competitive pricing and improved affordability for patients. Despite its significant contributions, India faces several challenges in its quest to enhance global access to biologics. Intellectual property rights issues, regulatory complexities, and the need for continuous innovation pose hurdles to the growth of India's biopharmaceutical sector. However, these challenges also present opportunities for collaboration, innovation, and policy reform to overcome barriers and further expand access to biologic therapies worldwide. The entry of smaller specialized biologics CMC service providers such as Veeda, maintains affordability, due to their smaller size and agility.

Clinical Research and Trials

India has a large and diverse patient population, offering access to a wide range of genetic backgrounds and disease profiles. This diversity is crucial for conducting clinical trials to assess the safety, efficacy, and pharmacokinetics of biologic drugs across different populations, thereby enhancing the generalizability of study results. Conducting clinical trials in India is more cost-effective compared to many Western countries due to lower operational costs, site expenses, and regulatory fees. Recruitment of patients across multiple therapeutic areas can be much faster as compared to many developed countries, especially through the use of real-world data based approaches. This cost advantage and the speed of recruitment attracts multinational pharmaceutical companies and contract research organizations (CROs) to conduct clinical trials in India, leading to increased access to biologics for patients worldwide. India has a pool of experienced investigators, clinicians, and research professionals who are proficient in conducting clinical trials according to international standards and guidelines.

Additionally, India has research infrastructure, including hospitals, clinics, and research centres, equipped to conduct various phases of clinical trials for biologics. India's improving regulatory approval process and efficient patient recruitment often result in shorter trial timelines compared to other countries. Accelerated trial timelines enable faster drug development and regulatory approval, expediting

the availability of biologics to patients worldwide. With an overall population of 1.4 billion, India offers access to patient populations with untreated or under-treated medical conditions, providing opportunities to evaluate the efficacy of biologic drugs in disease areas with significant unmet medical needs.

With the growing emphasis on decentralized clinical trials and inclusion of diverse populations, India is well equipped to contribute valuable data to support regulatory submissions and market approvals for biologics globally. Indian CROs and academic institutions collaborate with international partners to conduct multicenter clinical trials and share data. In some cases, Indian CROs, such as Veeda, have globalized their footprint not only through collaborations, but also by acquiring facilities in the West. This provides speed and consistency in global trial execution through a single reputed and established CRO. In addition, this facilitates the generation of robust clinical evidence, strengthens regulatory submissions, and accelerates the global acceptance and adoption of biologics. India specifically gains by getting access to biologic drugs earlier, which is a boon to patients, and doctors who now have more approaches for disease management. An additional factor that impacts access is, India's expertise in biosimilar development which allows manufacturing of high quality biologics at affordable prices. Clinical trials conducted in India play a crucial role in demonstrating the similarity, safety, and efficacy of biosimilars, expanding access to essential biologic therapies for patients worldwide.

Regulatory Framework

India's regulatory framework plays a pivotal role in enabling the development and commercialization of biosimilars, an important mechanism for improving access to biologics drugs. The Central Drugs Standard Control Organization (CDSCO) oversee the approval and regulation of biologic products, ensuring adherence to stringent quality and safety standards. The regulatory pathway for biosimilars in India follows established guidelines set forth by international regulatory bodies such as the World Health Organization (WHO) and the U.S. Food and Drug Administration (FDA), facilitating acceptance of Indian-manufactured biosimilars in global markets.

New Drugs and Clinical Trials Rules, 2019 and The Drugs and Cosmetics Act, 1940, along with its associated rules and regulations, provides the legal framework for regulating drugs, including biologics, in India. The Act governs various aspects of drug manufacturing, import, distribution, and sale, ensuring compliance with quality standards and safety requirements. Biopharmaceutical companies are required to obtain

approval from the CDSCO's Drug Controller General of India (DCGI) before initiating clinical trials in India. The approval process involves the submission of detailed clinical trial protocols, investigational product information, and documentation demonstrating compliance with ethical and regulatory standards. Before the global biologics are allowed to be tested on Indian clinical trial participants, the Indian regulatory authorities ensure that they meet the desired standards of safety, efficacy, and quality. The regulatory requirements for global biologics are well aligned with international standards, although there may be specific Indian regulatory considerations and requirements that companies need to address. Additionally, India is increasingly playing a role in the global regulatory landscape for biologics, particularly in biosimilars. Indian biopharmaceutical companies are developing biosimilar versions of global biologic drugs and seeking regulatory approval not only in India but also in other countries and regions around the world. This involves navigating the regulatory requirements of multiple jurisdictions to ensure compliance and market access for their biosimilar products.

Conclusion

India's role in enabling access to biologics for patients worldwide is undeniably critical. Through its thriving pharmaceutical industry, trained workforce, regulatory framework, and commitment to affordability, India has emerged as a key player in democratizing access to life-saving biologic therapies. By producing high-quality biosimilars, nurturing biologics CMC service providers, fostering global partnerships, and advocating for equitable healthcare, India continues to make significant strides in ensuring that patients worldwide can benefit from the transformative potential of biologic medicines India's expertise in biologics is poised to have a significant impact on the global biotech market over the next five years in several ways:

- Increased Access to Affordable Biologics
- Market Expansion in Emerging Economies (Asia, Africa and Latin America)
- Competition and Price Reductions
- Research and Innovation Collaboration
- Regulatory Harmonization and Standards Alignment

With access to a very large population, India is well suited to participate in global clinical trials, therefore opening the Indian market for manufacturers early. As the global demand for biologics continues to rise, India's contributions will remain indispensable in shaping a more accessible and inclusive healthcare landscape for all.

As the world continues to grapple with complex healthcare challenges, India's expertise, infrastructure, and commitment to equitable healthcare will remain instrumental in shaping a more inclusive and sustainable future for biologic medicines. India has made rapid progress in fostering innovation and promoting collaboration. The country is poised to make valuable contributions towards the advancement of biotechnology and the improvement of global health outcomes. ■

Typbar TCV®, Two Decades of Innovation and Product Development

Dr. Krishna Ella
Founder & Executive Chairman
Bharat Biotech International Limited

Typhoid fever, caused by Salmonella Typhi, poses a significant global threat, especially impacting children. India shoulders over half of the burden, necessitating urgent interventions. Antibiotic resistance complicates treatment, prompting the development of vaccines like Typbar-TCV® by Bharat Biotech. This conjugate vaccine offers enhanced efficacy, validated through extensive trials and WHO pre-qualification. A comprehensive strategy integrating vaccination with Water, Sanitation, and Hygiene (WASH) practices is crucial for combating enteric diseases and improving public health outcomes worldwide.

Typhoid fever afflicts 11 million people globally and causes more than 100,000 deaths. Salmonella Typhi, a bacterium, causes it. History's most famous carrier of this bacteria, a 37-year-old American cook Mary Mallon (a.k.a Typhoid Mary), taught us of its transmission through contaminated food and water and that you can be asymptomatic while transmitting the disease to thousands of people.

The typhoid epidemic is particularly concerning because of its disproportionate burden on children, who bear a higher risk compared to other age groups. Notably, India shoulders more than half the global incidence, underlining the urgency for effective interventions. Furthermore, the emergence of typhoid cases among travellers in non-endemic regions underscores the need for comprehensive strategies beyond the borders. Being vaccine manufacturers, we had to recognise the urgency of the situation. In an era of challenges that differed from those today, our commitment to finding solutions to control disease remained unwavering.

The emergence of antimicrobial resistance (AMR) in the late 1980s/1990s posed a formidable challenge in the fight against typhoid. Historically, antibiotics such as chloramphenicol, ampicillin, and fluoroquinolones were mainstays in treating this infectious disease. However, the rise of a typhoid superbug, resistant to five classes of antibiotics, underscores the gravity of the situation. Alarmingly, approximately 60% of the typhoid cases were resistant to drugs.

The substantial burden of typhoid, soaring treatment costs, AMR, and inadequate diagnostic methods were significant problems that required a proactive approach. Vaccination emerged as the cornerstone solution, offering a cost-effective preventive measure against persistent threats. By prioritising immunisation efforts, we could potentially mitigate the toll of typhoid and safeguard public health.

In the 1990s, the typhoid vaccine landscape witnessed notable achievements, primarily revolving around two main types of vaccines: live-attenuated vaccines and Vi-capsular polysaccharide (Vi-PS) vaccines. The live-attenuated vaccine, Ty21a, was among the pioneering options, offered oral administration, and demonstrated efficacy in typhoid incidence. This vaccine utilised weakened strains of Salmonella typhi, stimulating an immune response without causing illness. Conversely, Vi-PS vaccines, consisting of purified Vi polysaccharides, were administered via injection. The challenges in terms of vaccine access persisted, particularly in resource-limited settings. Despite these strides, the quest for improved vaccines continued, aiming for increased efficacy, durability, and accessibility. The 1990s laid the foundation for ongoing research and development efforts, driving innovation in typhoid vaccination strategies to address the evolving landscape of global health challenges.

Despite their advancements, existing typhoid vaccines exhibited notable limitations:

1. They proved ineffective in protecting children below two years of age, leaving a vulnerable demographic at risk.
2. Conflicting evidence arose from low socio-economic regions in Kolkata, India and Karachi, Pakistan, casting doubts on their efficacy.
3. Both vaccines necessitated re-vaccination to maintain effectiveness, posing logistical and economic challenges.
4. They failed to induce a T-cell-mediated response to establish long-term memory, potentially limiting their efficacy and durability in providing sustained protection against typhoid fever.

Bharat Biotech's journey to combat the limitations of existing typhoid vaccines commenced during the late 1990s, culminating in the development of Typbar (Vi-PS vaccine) in 2003, marking a significant milestone in the fight against typhoid fever. However, we quickly recognised the shortcomings of a vaccine that had similar limitations to the existing typhoid vaccines at the time.

Recognising the need for a more effective solution, our team embarked on a comprehensive research and development endeavour, starting with R&D for a conjugate typhoid vaccine. A conjugate bacterial vaccine is made by chemically linking a protein molecule with the polysaccharide (that makes up the bacterial cell wall) to improve the immune response. This resulted in a vaccine that enhanced T-cell memory, long-lived antibody production, and improved immune response in children.

Collaborating with the National Institute for Biological Standards and Control (NIBSC), United Kingdom,

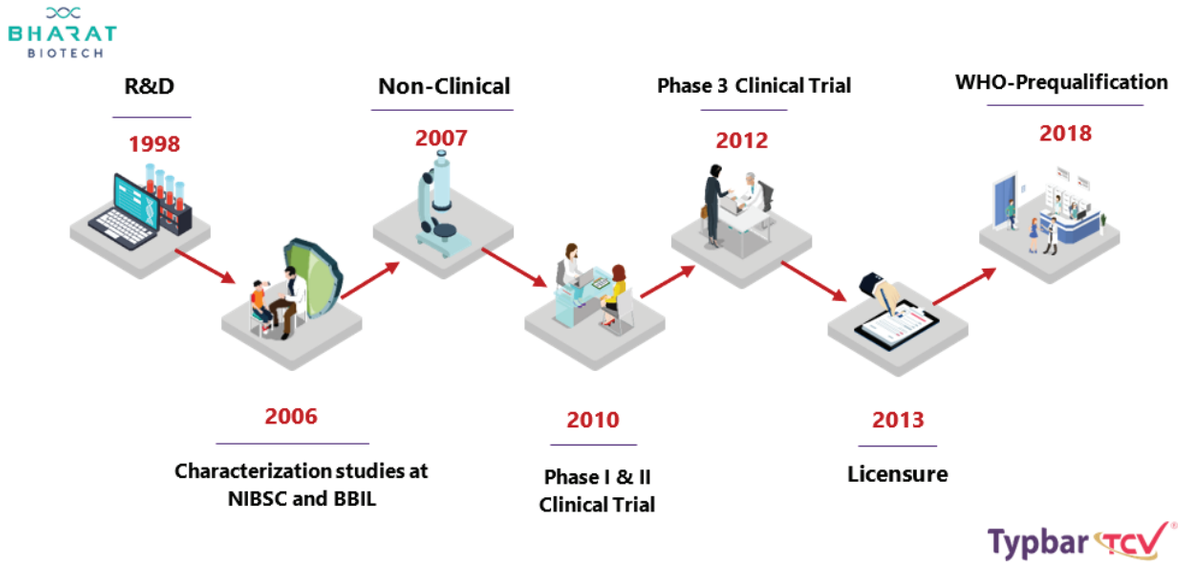

Figure 1. The journey of Bharat Biotech's Typbar-TCV®

in 2006, we conducted pre-clinical trials for the conjugate vaccine. It underwent rigorous analytical characterisation via mouse immunogenicity studies and non-clinical toxicity testing as part of these tests.

Subsequently, our team at Bharat conducted human clinical trials spanning phases I, II, and III between 2010 and 2012, culminating in the licensure of Typbar-TCV® in 2013. The vaccine's efficacy was further evaluated through a human challenge studies at Oxford.

Bharat Biotech is an innovator of vaccines. The product development of Typbar TCV® started before licensure in India but didn't stop post-licensure with a series of studies globally. This highlights our overall approach to product life cycle management, where product development efforts don't end with licensure and continue until we obtain data evaluating multiple aspects of the vaccine.

Further validation came from our study in collaboration with Aga Khan University in Pakistan, which assessed Typbar-TCV®'s effectiveness against extensively drug-resistant (XDR) strains of Salmonella Typhi. Achieving

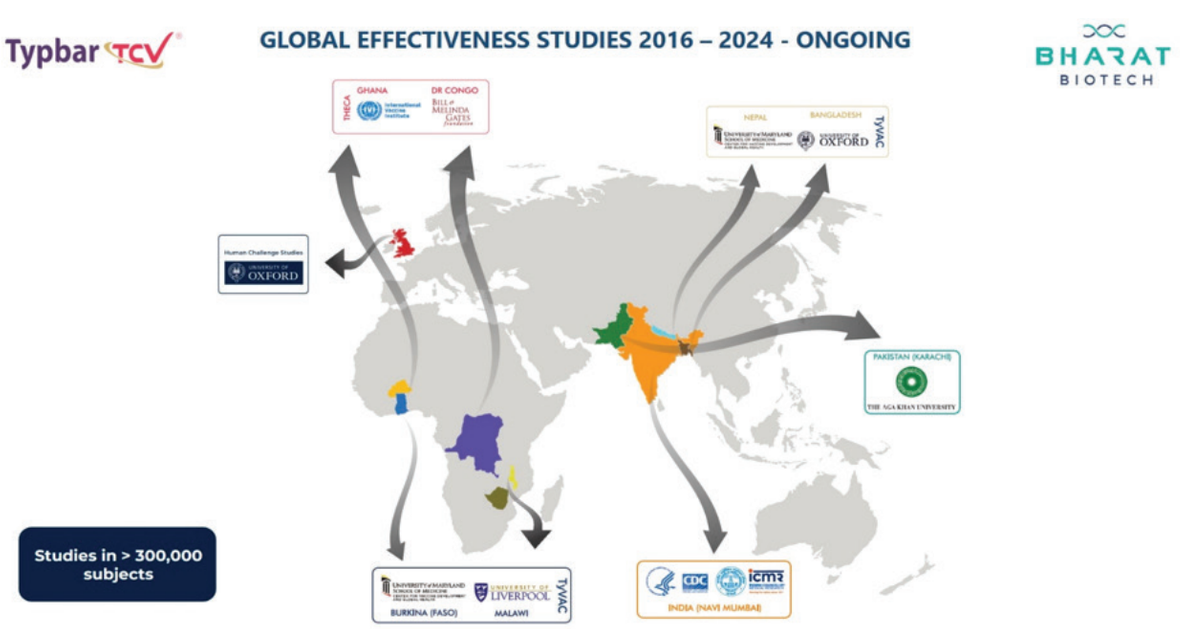

Figure 2. Global Safety and Effectiveness Studies conducted in seven countries, in collaboration with several organizations

WHO pre-qualification in 2018 underscored our vaccine's adherence to stringent global standards.

Efficacy studies across diverse geographical regions, including the UK, Malawi, Nepal, and India, provided crucial insights into Typbar-TCV®'s performance in varied populations. Global effectiveness studies conducted in seven countries — India, Zimbabwe, Burkina Faso, Pakistan, Bangladesh, and Ghana — further demonstrated the vaccine's ability to confer protection against typhoid fever across different endemic settings.

TCVs have substantially reduced typhoid disease burden concerning disability-adjusted life-years or DALYs. By preventing both morbidity and mortality related to typhoid infections, TCVs help avert years of healthy life lost due to disability or premature death.

Through a meticulous and collaborative approach spanning pre-clinical research, extensive clinical trials, and real-world effectiveness studies, our Typbar-TCV® emerged as a game-changer in typhoid prevention. Its licensure, coupled with WHO pre-qualification and global effectiveness data, cemented Typbar-TCV® 's position as a cornerstone in the battle against typhoid fever, offering hope for enhanced protection and reduced disease burden worldwide.

Conclusion

Water, Sanitation, and Hygiene (WASH) techniques are just as important as vaccinations in preventing enteric diseases like typhoid towards comprehensive disease elimination. WASH practices encompass access to clean water, adequate sanitation facilities, and proper hygiene behaviours, all essential in breaking the transmission cycle of enteric pathogens. Therefore, a comprehensive approach addressing vaccination and WASH is vital to achieving sustainable and equitable elimination of enteric diseases.

Typbar-TCV® is a successful global vaccine resulting from a long-term vision and product development. We're constantly critical of our vaccines and didn't stop development after licensure in 2003. Today, we supply this vaccine regularly to more than 20 countries, transcending variable socio-economics and geopolitics. This vaccine is a fine example of our commitment to public health in two decades and battling forthcoming challenges.' ■

Why GMP Is Important In The Pharmaceutical Industry?

Good Manufacturing Practices (GMP) constitute a comprehensive framework of guidelines to safeguard the safety, quality, and efficacy of pharmaceutical products. These regulations cast a wide net, enveloping every facet of drug manufacturing, from the sourcing of raw materials to the maintenance of facilities, and the training of personnel. ***Nikkhil K Masurkar, CEO, Entod Pharmaceuticals*** *spoke about the importance of Good Manufacturing Practices (GMP) in pharmaceutical industry. He also emphasizes about the Key Principles of GMP governing the manufacturing, packaging, labeling, and testing processes of healthcare products.*

Within the pharmaceutical realm, strict adherence to GMP standards emerges as a non-negotiable imperative, serving as the cornerstone for upholding the integrity and effectiveness of medicinal offerings. By adhering rigorously to these standards, companies ensure that their products not only meet regulatory requirements but also inspire confidence among healthcare professionals and patients alike. The rigorous implementation of GMP not only enhances product quality but also minimizes the risk of contamination, ensuring that pharmaceuticals consistently deliver the intended therapeutic benefits. As such, understanding and embracing GMP principles are paramount for fostering a culture of safety, reliability, and innovation within the pharmaceutical landscape.

The Key Principles of Good Manufacturing Practices (GMP)

Good Manufacturing Practices (GMP) encompass a series of guidelines and principles governing the manufacturing, packaging, labeling, and testing processes of healthcare products. These standards ensure the consistent production and control of products in accordance with established quality benchmarks. The overarching aim of GMP is to mitigate risks related to product contamination, errors, and deviations, thereby safeguarding patient safety and maintaining product integrity. Compliance with GMP protocols is essential for upholding the highest standards of quality assurance within the pharmaceutical and healthcare industries. Here are the key principles that underpin Good Manufacturing Practices (GMP):

Quality Management Systems (QMS): Manufacturers must institute and sustain a robust framework for quality management that encompasses all stages of manufacturing, quality control, and documentation. This involves the development of standardized operating procedures (SOPs), quality policies, and a thorough quality assurance program. By doing so, manufacturers can ensure consistency and reliability throughout their production processes.

Personnel: Ensuring the adequate training, qualification, and continual education of individuals engaged in manufacturing processes is paramount. GMP underscores the importance of having competent and knowledgeable staff who diligently follow prescribed procedures and adhere to ethical practices. This focus on personnel ensures the integrity and reliability of the manufacturing operation.

Facilities and Equipment: Within the realm of GMP, manufacturers are mandated to maintain appropriate facilities and equipment that are meticulously designed, constructed, and upheld to uphold product quality, safety, and integrity. This encompasses providing suitable storage conditions, controlled environments, and ensuring the regular calibration of equipment. Such adherence ensures the reliability and consistency of the manufacturing process.

Materials Management: GMP underscores the critical significance of exercising proper control and traceability over raw materials, components, and packaging materials utilized in the manufacturing process. This entails meticulous documentation, adherence to proper storage conditions, and the rigorous qualification of suppliers. Such practices ensure the integrity and safety of the final product, maintaining compliance with regulatory standards and bolstering consumer confidence.

Documentation and Record-Keeping: In adherence to GMP, the importance of maintaining accurate and comprehensive documentation throughout the manufacturing process cannot be overstated. This encompasses the meticulous recording of batch records, manufacturing instructions, standard operating

procedures, and quality control records. Thorough documentation of all activities is essential to ensure traceability and facilitate effective quality control measures, thereby upholding the integrity and safety of the manufactured products.

Quality Control and Testing: Under the mandate of GMP, it is imperative to implement stringent quality control measures, encompassing sampling plans, testing methods, and specifications for raw materials, finished goods, and intermediate products. Analytical testing and validation play a pivotal role in ensuring product quality and compliance with established standards. These rigorous measures are essential safeguards to maintain the integrity and efficacy of pharmaceutical products, safeguarding public health and instilling confidence in consumers.

The Significance of GMP in the Pharmaceutical Sector

Adherence to GMP guidelines is paramount in ensuring the integrity, safety, and efficacy of pharmaceutical products. Here are some key points illustrating the significance of GMP in the pharmaceutical industry:

Ensuring Patient Safety: Patient safety stands as a paramount concern within the healthcare industry, and Good Manufacturing Practices (GMP) play a pivotal role in upholding this imperative. GMP guidelines serve as a robust framework, ensuring that healthcare products are manufactured under stringent quality standards to mitigate the risk of harm to patients. By adhering to GMP protocols, manufacturers can significantly reduce the likelihood of contamination, errors, and deviations that may compromise the safety and efficacy of medical products. Moreover, strict adherence to GMP principles enables the identification and mitigation of risks associated with manufacturing processes, guaranteeing that only safe and effective products reach patients, thereby safeguarding their well-being.

Product Quality Assurance: Product quality assurance is vital in the healthcare industry, and adherence to Good Manufacturing Practices (GMP) is key to achieving this goal. By following GMP guidelines, manufacturers can establish robust quality control systems and procedures throughout the manufacturing process. This includes rigorous testing of raw materials, implementation of in-process controls, and meticulous documentation of batch records to guarantee that products meet predetermined specifications and quality standards. GMP ensures that healthcare products are dependable, effective, and devoid of defects, thereby fostering trust among healthcare professionals and patients alike.

Promoting Regulatory Compliance: In the healthcare industry, stringent regulatory oversight is essential to protect public health. Good Manufacturing Practices (GMP) serve as a vital framework for regulatory compliance by establishing minimum standards for manufacturing, quality control, and documentation of healthcare products. Regulatory agencies worldwide enforce GMP regulations and conduct inspections to verify manufacturers' adherence to these standards. Compliance with GMP guidelines not only guarantees the safety and quality of products but also minimizes the risk of regulatory non-compliance and associated penalties or sanctions.

Fostering Public Trust: In the healthcare industry, maintaining public trust and confidence in the safety and efficacy of healthcare products is paramount. Adhering to Good Manufacturing Practice (GMP) standards plays a crucial role in preserving this trust by ensuring that products are manufactured under rigorous quality control measures. GMP demonstrates a steadfast commitment to product quality, safety, and regulatory compliance. It also facilitates transparency through proper documentation, traceability, and accountability in the manufacturing process. By upholding GMP principles, manufacturers can cultivate and sustain public trust, which is indispensable for the success and reputation of the healthcare industry as a whole.

Conclusion

As GMP guidelines continue to evolve in tandem with advancements in technology and the pharmaceutical landscape, their adaptability remains crucial in ensuring the ongoing safety and efficacy of healthcare products. With the constant development of new drugs and manufacturing techniques, the evolution of GMP guidelines becomes imperative to uphold the highest standards of quality assurance. Looking ahead, we anticipate GMP guidelines will persistently evolve, reflecting the dynamic nature of the pharmaceutical industry and reaffirming their pivotal role in safeguarding public health and instilling confidence in healthcare products. ■

Author

Nikkhil K Masurkar
CEO, Entod Pharmaceuticals

Growing Focus on Domestic Manufacturing in the Pharmaceutical Sector in India

Over the past decade, the pharmaceutical industry in India has witnessed increasing investments flows for research and development, innovation as well as a keen interest from foreign manufacturers in setting up manufacturing units in the country. The trend is supported by the adoption of favourable policies and initiatives in the sector after undertaking stakeholder discussions to enable partnership with the industry. ***Dr. Milind Antani and Tanya Kukade*** *discussed the overview of the Indian pharmaceutical sector and growing focus on increasing domestic innovation and manufacturing.*

The developments outlined such as the release of the draft National Pharmaceutical Policy, 2023 and revision of the Good Manufacturing Practices are meant to bring domestically manufactured pharmaceutical products at par with the global standards. These developments in the sector are supplemented by the focus of the government on the Make in India initiative which seeks to encourage domestic manufacturing and projecting India as the global manufacturing hub. The objectives of the government under the initiative adopted in 2014, and subsequently refurbished in 2018 are being further supplemented by internal policy changes to mould the industry standards and harmonizes them with international standards while also to encourage foreign investment in the country. This coupled with the government allowing 100% foreign direct investment in the pharmaceutical sector is a development with potential for tremendous growth of the sector.

Given that manufacturing forms the backbone of development for every sector, there is strong focus on increasing domestic innovation and manufacturing in each sector in the country. The Government introduced various production linked incentive (PLI) schemes such as the PLI Scheme for Promotion of Domestic Manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates and Active Pharmaceutical Ingredients (APIs) to cater to the increasing focus on the sector by incentivising local production and development. The PLI schemes coupled with the Make in India initiative aid the objective of strengthening the pharmaceuticals industry in the country.

In an effort to increase the scale of manufacturing in India and to promote the country's ability as well as to make the country self-sufficient, the Make in India initiative is primarily implemented by the Department for Promotion of Industry and Internal Trade (DPIIT). The DPIIT overlooks the public procurement process and has released the Public Procurement (Preference to Make in India) Order, 2017 or the General Order which prescribes the requirements for suppliers to be eligible to participate in the public procurement process basis the value added to the product in India. The nodal ministry of each industry is empowered to prescribe the requirements and qualifications for suppliers to be eligible to participate in the tendering process for the government requirements basis the local manufacturing capacity for the products and the extent of local competition.

The nodal ministry for the pharmaceutical industry is the Department of Pharmaceuticals (DoP) under the Ministry of Chemicals and Fertilizers. The DoP has notified higher local content requirements for pharmaceutical products under the Public Procurement (Preference to Make in India) Order, 2017 - Goods and Services in Pharmaceutical Formulations. The public procurement orders place heavy reliance on local value addition which may take the form of manufacturing, research and development, assembly, etc.

The steady growth of the industry as well as the adoption of the policies by the Government give a flavour of the intended approach and objective to encourage domestic manufacturing in the country and to cater to the growing global demand for goods and services. The Indian market has fair demand as well as capacity to cater to domestic as well as global markets. India has also witnessed a keen interest on behalf of global pharmaceutical companies, seeking to either establish operations in India for research and development, manufacturing or distribution or to enter into collaborations to meet the unique eligibility requirements under the procurement orders adopted by each nodal ministry.

India's low-cost research and development abilities help companies optimize costs in a shrinking economy. For a trans-national entity seeking a presence in India, whether directly or through contractual arrangement, structuring of the investment arrangement from a tax and regulatory perspective is very critical. This is especially true because the Indian pharmaceutical market has become the hotbed of manufacturing activity.

The impact of the Make in India initiative is expected to yield positive results for the pharmaceutical industry in the coming years. The initiatives and policies of the government to encourage domestic manufacturing in the pharmaceutical sector are likely to reduce the reliance of the industry on imports of drugs and APIs, making the sector self-sufficient.

The industry requires policy interventions to support the adoption of new pharmaceutical technologies through onboarding of stakeholders in the sector on the Ayushman Bharat Digital Mission ecosystem to provide a platform for collaboration and exchange of knowledge and innovations. There is a need for collaborative efforts to be undertaken by the industry players to meet the broader initiatives of universal healthcare access, innovation-driven economic growth, and sustainable development. Continued stakeholder discussions and recognition of innovative developments in the sector are likely to steer the growth of the pharmaceutical industry in a positive direction. ■

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Injectable Implants-Pioneering a New Era in Sustained Drug Release

In the ever-evolving landscape of medicine, the search for innovative drug delivery systems has led to the emergence of injectable implants as a ground-breaking approach. These implants, designed for sustained drug release, hold tremendous promise in various therapeutic areas.

***Srivardhan Khemka, Director, Sanjivani Parenteral** spoke about how injectable implants have changed over time, the market landscape, their possible effects, the challenges they face, and their future potential.*

Evolution of Injectable Implants

The development of long-acting injectables (LAI) for anti-psychotic drugs marked the beginning of the journey that led to the creation of injectable implants in the year 1966. The difficulties that are associated with oral medications, in particular in conditions such as schizophrenia and psychosis, were the impetus for the development of these medications. It was common for patients to have difficulty adhering to their daily dosing regimens, and even missing a single dose could result in an aggravation of their symptoms. Injectable implants offered a solution by providing sustained drug release over an extended period of time, which ensured that the therapeutic treatment would remain consistent.

Mechanisms and Benefits

Injectable implants function by delivering medication gradually into the body through concealed administration. Upon injection, the implant forms a gel-like depot under the skin, from which the drug is released slowly over weeks or months. This mechanism removes the need for frequent dosing, addressing issues of patient adherence and compliance—a critical aspect of overall health treatment. Additionally, the use of organic oils as carriers for lipophilic compounds ensures controlled release, optimizing therapeutic outcomes.The benefits of injectable implants extend beyond improved adherence. By skipping the gastrointestinal tract, these implants offer enhanced bioavailability, ensuring that a higher proportion of the drug reaches its target site. This characteristic is particularly advantageous in our health treatment, where precise dosing and consistent drug levels are essential for symptom management and relapse prevention.

Market Landscape and Growth Potential

The global market for injectable implants has witnessed exponential growth, driven by increasing demand for effective drug delivery systems and the rising prevalence of mental and physical health disorders. As of 2024, the market is estimated to be valued at USD 14.9 billion, with projections indicating a significant rise to USD 24.4 billion by 2031.

Driving Factors and Challenges

Several factors contribute to the growing demand for injectable implants in health treatment. Firstly, these implants offer drug delivery efficiency compared to traditional dosage forms, ensuring optimal therapeutic outcomes. Moreover, the convenience of less frequent administration appeals to patients, addressing concerns about medication adherence and simplifying treatment regimens. However, challenges persist, hindering the widespread adoption of injectable implants. Patient acceptance of injectable delivery methods remains a significant barrier, with some individuals expressing reluctance towards injections or discomfort with hidden administration. Additionally, healthcare providers may require specialized training to administer injectable implants effectively, highlighting the importance of education and skill development in this area.

Impact on Mental Health Treatment

Injectable implants hold significant promise in revolutionizing mental health treatment, particularly for severe psychiatric disorders like schizophrenia and psychosis. Statistics reveal that mental health conditions

often require long-term management, with 50% of these conditions beginning by age 14 and 75% developing by age 24. Moreover, India faces significant mental health challenges, with close to 60 to 70 million people suffering from common and severe mental disorders. The country has been labelled the world's suicide capital, with over 2.6 lakh cases of suicide reported annually and an average suicide rate of 10.9 for every lakh people.

In this context, the introduction of injectable implants represents a significant advancement. As mentioned, for individuals with conditions like schizophrenia and psychosis, maintaining consistent medication levels is paramount for symptom management and relapse prevention. Injectable implants ensure sustained drug release, reducing the risk of relapse and improving long-term stability. This is crucial given that persistent negative thoughts, difficulty concentrating, and severe paranoia are common symptoms associated with these disorders.

Moreover, injectable implants offer a practical solution for individuals who struggle with adherence to oral medications. Studies show that approximately 50% of patients with chronic illnesses do not take their medications as prescribed, often due to forgetfulness, lack of understanding, or adverse side effects. Injectable implants eliminate the need for daily dosing, providing a convenient and reliable alternative. This not only enhances medication adherence but also empowers individuals to take control of their mental health.

Furthermore, injectable implants facilitate personalized treatment plans tailored to each patient's needs and preferences. With only 43 state-run mental health institutions in the country and a shortage of mental health professionals, personalized care is essential for optimizing treatment outcomes. By offering a range of options, including different formulations and dosing schedules, injectable implants enable healthcare providers to customize therapy regimens for optimal efficacy and patient comfort.

Overall, the advent of injectable implants represents a significant step forward in mental health treatment. By addressing compliance challenges, ensuring sustained drug release, and facilitating personalized care, these implants have the potential to improve the lives of millions of individuals affected by mental illness in India and beyond.

Advancements in Long-Acting Injectable Antipsychotics (LAI APs)

The utilization of long-acting injectable (LAI) antipsychotics (APs) has emerged as a critical intervention for managing serious cases of psychosis and schizophrenia. Despite initial suspicions and negative perceptions of LAI APs, these medications have proven to be extremely effective in balancing blood levels and lowering the risk of relapse in people with severe psychotic disorders. Stable blood levels are critical for maintaining therapeutic efficacy and preventing symptom flare-ups, ultimately improving patients' long-term outcomes. Moreover, the introduction of newer, second-generation LAI APs has expanded therapeutic opportunities by offering improved dosing regimens, enhanced tolerability, and greater compatibility with integrated rehabilitation programs. These advancements highlight the evolving landscape of mental health treatment, highlighting the importance of adopting innovative approaches to address the complex needs of individuals with schizophrenia and psychosis.

Conclusion

Injectable implants represent a transformative approach to drug delivery, offering sustained release technology that holds a promise for revolutionizing mental health care. As research and development efforts continue to advance, injectable implants are poised to address unmet needs and enhance patient well-being in the field of mental health treatment. Embracing this innovative approach underlines the commitment to advancing therapeutic outcomes and improving the lives of individuals affected by mental health disorders worldwide.' ■

Author

Srivardhan Khemka
Director, Sanjivani Parenteral

The Crucial Role of Research and Development in Driving Innovation: A Comprehensive Exploration

Innovation is the lifeblood of progress, propelling humanity forward through the power of creativity and ingenuity. At the heart of this transformative force lies Research and Development (R&D), a dynamic process that fuels breakthroughs, fosters growth, and shapes the future. ***Dr. Preeti Nigam Joshi, Founder, FastSense Innovations Private Limited*** *explores the multifaceted role of R&D in driving innovation across various sectors, from science and technology to healthcare, sustainability, entrepreneurship and beyond.*

The Fundamentals of Research and Development

Research and Development (R&D) embodies a diverse array of endeavors aimed at progressing knowledge, resolving challenges, and innovating new products, procedures, and services. It entails methodical exploration, experimentation, and cooperation, often traversing various fields and industries.

While R&D are often grouped together, they represent distinct yet interrelated processes within the innovation continuum. Research primarily focuses on scientific inquiry, aiming to expand knowledge and understanding within a particular domain. It involves conducting experiments, gathering data, and generating new insights into fundamental principles and phenomena. Research is inherently scienceoriented, driven by a quest for discovery and exploration. Basic research delves into fundamental scientific principles and comprehension, while applied research endeavors to convert scientific insights into pragmatic solutions.

On the other hand, development serves as the bridge between scientific findings and practical applications in the real world. It entails translating the outcomes of research into tangible products, services, or processes that address specific needs or problems. Development encompasses activities such as design, prototyping, testing, and refinement, with the ultimate goal of creating commercially viable solutions. Unlike research, which is driven by curiosity and exploration, development is focused on achieving tangible outcomes and delivering value to end-users.

The primary objectives of R&D encompass the enhancement of both existing and emerging core competencies, the advancement of current and novel products, and the evolution of established and innovative business processes through inventive approaches. The R&D process serves as the driving force behind the differentiation of products and processes, propelling innovation within organizations. Innovation, in its essence, encompasses ideas, products, services, or processes that are recognized as novel and distinctive, having been implemented or even brought to commercial fruition.

Importance of Research and Development in Innovation

Research and Development (R&D) stands as the catalyst for innovation, igniting progress across varied spheres. The role of Research and Development (R&D) in innovation is pivotal, serving as the backbone for progress and transformation across various domains. Cultivating a spirit of inquiry and fostering

experimentation, R&D fuels the birth of fresh concepts. It empowers organizations to anticipate shifts in market dynamics, embrace emerging trends, and seize newfound opportunities. R&D fosters a culture of exploration and curiosity, driving the generation of novel ideas and breakthrough discoveries. It provides the necessary framework for translating scientific knowledge into practical solutions, bridging the gap between theory and application. For example, Intel's adherence to Moore's Law, shifting from CPU clock rates to multi-core architectures, illustrates this iterative path of innovation and role of R&D.

Research and Development (R&D) serves as the cornerstone of innovation, propelling progress and shaping the landscape of various industries. One prominent example lies within the pharmaceutical realm, where R&D efforts are instrumental in discovering and developing life-saving drugs and therapies.

For instance, the arduous process of researching and testing vaccines against diseases like polio, measles, and most notably, the recent COVID-19 pandemic, underscores the critical role of R&D in safeguarding public health and combating global health threats.

Moreover, the technology sector provides a rich tapestry of R&D-driven innovation. Companies like Apple exemplify this notion by consistently investing in R&D to conceive and bring to fruition groundbreaking products that redefine consumer experiences. The iPhone, iPad, and MacBook series are stellar examples of how relentless R&D endeavors yield transformative advancements, pushing the boundaries of what's possible in the realm of consumer electronics.

These illustrations underscore the indispensable role of R&D in fostering innovation. Through meticulous research, experimentation, and collaboration, R&D endeavors pave the way for groundbreaking discoveries and advancements that have a profound impact on society. As companies and industries continue to invest in R&D, they not only drive innovation but also contribute to the collective progress and betterment of humanity.

Ultimately, investment in Research and Development (R&D) reaps benefits in the form of rewards, revenues, and profits. Despite potential limitations in technology performance, further advancements in R&D and fundamental science, coupled with customer demand, reignite the innovation process.

Research and Development in Entrepreneurship

Research and Development (R&D) stands in the realm of entrepreneurship, embodies the spirit of innovation and progress. It serves as the engine driving transformative ideas, fueling the journey from conceptualization to commercialization. In the dynamic landscape of entrepreneurship, where creativity meets commerce, R&D assumes a pivotal role in shaping the trajectory of ventures.

At its core, R&D embodies the ethos of exploration and experimentation, guiding entrepreneurs through the maze of uncertainty toward novel solutions and breakthroughs. It represents the relentless pursuit of knowledge, the quest for answers to pressing questions, and the quest for solutions to complex problems. Whether it's uncovering the next disruptive technology or refining existing processes, R&D empowers entrepreneurs to push the boundaries of what's possible.

In the entrepreneurial journey, R&D serves as a compass, guiding ventures toward uncharted territories and untapped markets. It enables entrepreneurs to differentiate their offerings, carve out unique value propositions, and stay ahead of the competition. By investing in R&D, entrepreneurs can unlock new opportunities, drive innovation, and create sustainable competitive advantages.Moreover, R&D fosters a culture of resilience and adaptability, equipping entrepreneurs with the tools to navigate through challenges and capitalize on emerging trends. It instills a mindset of continuous learning and improvement, enabling ventures to evolve and thrive in dynamic environments. From refining product prototypes to optimizing business models, R&D empowers entrepreneurs to iterate, innovate, and iterate again.

In the ever-evolving landscape of entrepreneurship, success hinges on the ability to innovate and adapt to changing market dynamics. R&D provides entrepreneurs with a strategic advantage, enabling them to anticipate trends, identify opportunities, and capitalize on emerging technologies. By fostering a culture of experimentation and creativity, R&D fuels the entrepreneurial spirit,

driving ventures toward sustainable growth and long-term success.

Challenges & Risk Factors

Embarking on research and development (R&D) initiatives and innovative endeavors entails confronting a multitude of challenges and inherent risks. These hurdles, while daunting, serve as crucial drivers for growth, innovation, and competitive advantage. Some of the key challenges and risk factors associated with R&D and innovation:

Financial Constraints pose significant challenges for R&D projects. Securing adequate funding for research activities, sustaining long-term investments, and managing budgetary constraints require careful financial planning and strategic allocation of resources.

Rapid advancements in technology introduce complexities and the uncertainties can impede R&D efforts. Specialized expertise is needed in navigating complex technologies to stayahead and overcome technical hurdles.

Fluctuations in market conditions, changing consumer preferences, and competitive pressures present challenges for R&D initiatives. Anticipating market dynamics, identifying emerging trends, and aligning R&D activities with market demands require market intelligence and strategic foresight.

Protecting intellectual property rights, safeguarding proprietary technologies, and mitigating the risk of infringement are paramount in R&D activities.

Recruiting and retaining skilled talent is critical for R&D success but can be challenging. Competing for top talent, addressing skill shortages, and fostering a culture of innovation and collaboration require effective talent management strategies.

R&D inherently involves risks and uncertainties, with outcomes often unpredictable. Managing risk, embracing experimentation, and fostering a culture that tolerates failure are essential for promoting innovation and resilience.

Successfully bringing R&D innovations to market and achieving commercial success pose significant challenges. Developing scalable solutions, securing market adoption, and navigating product launch and commercialization require comprehensive market strategies and business acumen.

Navigating these challenges and risk factors requires resilience, strategic planning, and a willingness to embrace uncertainty. By addressing these hurdles proactively and leveraging opportunities for growth and innovation, organizations can drive meaningful progress and achieve sustainable competitive advantage in today's dynamic business landscape.

Conclusion

In summary, our dialogue shed light on the profound significance of research and development (R&D) in propelling innovation across diverse realms. From its foundational role in advancing understanding and resolving intricate dilemmas to its pivotal function in nurturing economic expansion, fostering technological strides, and confronting societal imperatives, R&D emerges as a catalyst for advancement and prosperity. Despite the myriad hurdles and inherent uncertainties accompanying R&D and innovation, entities that prioritize strategic investment, collaboration, and adaptability stand poised to unlock fresh prospects, instigate transformative shifts, and craft a brighter future for succeeding generations. ■

Author

Dr. Preeti Nigam Joshi
Founder
FastSense Innovations Private Limited

High Efficiency Mist Cooling System - A Superior Alternative to Conventional Cooling Tower

Water cooling is essential for process industries and power plants, but conventional cooling towers face efficiency challenges, especially in humid conditions. Introducing mist creation technology as an alternative offers consistent cold water temperatures year-round. With a compact design and minimal maintenance requirements, this system surpasses traditional cooling towers in performance and cost-effectiveness. ***Makarand A. Chitale, Director (Technical), Mist Ressonance Engineering Pvt Ltd.,*** *explores its superiority in this article.*

In Process / Chemical Plants, product vapour generated in the process is condensed in a Heat exchanger and is recovered back.

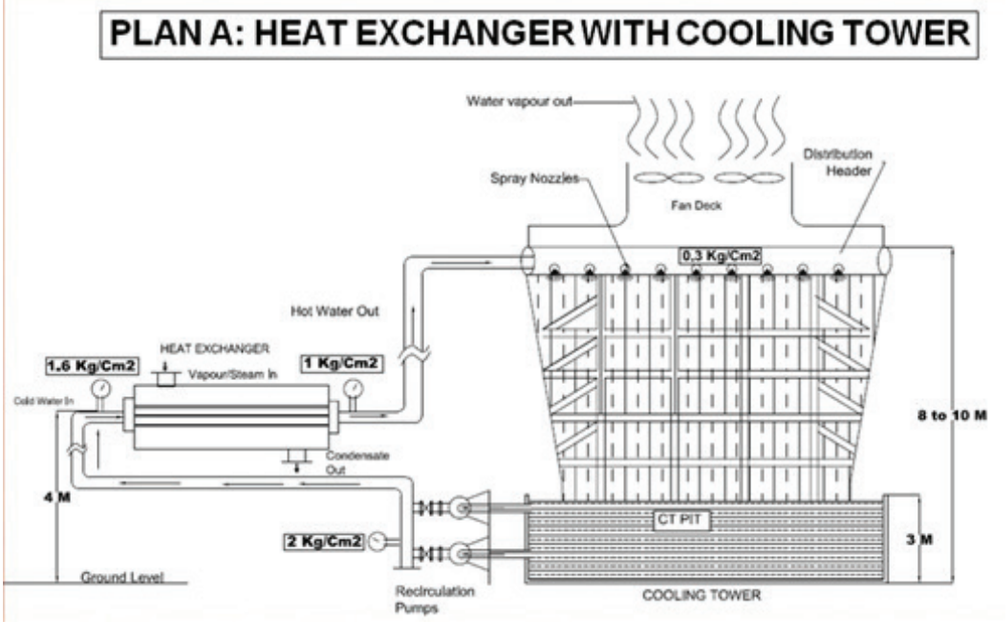
The condensation of steam / Vapour requires a cooling medium. In early days this was achieved by using water from a river, a basin or seawater. The cold water is pumped through a heat exchanger and the warm water is discharged back to the water source. This is called Once Through cooling system.

A once through system is an open loop system. The necessity to reduce the huge amount of water gave birth to the idea of closed loop system. Thus the Wet Cooling system came into effect.

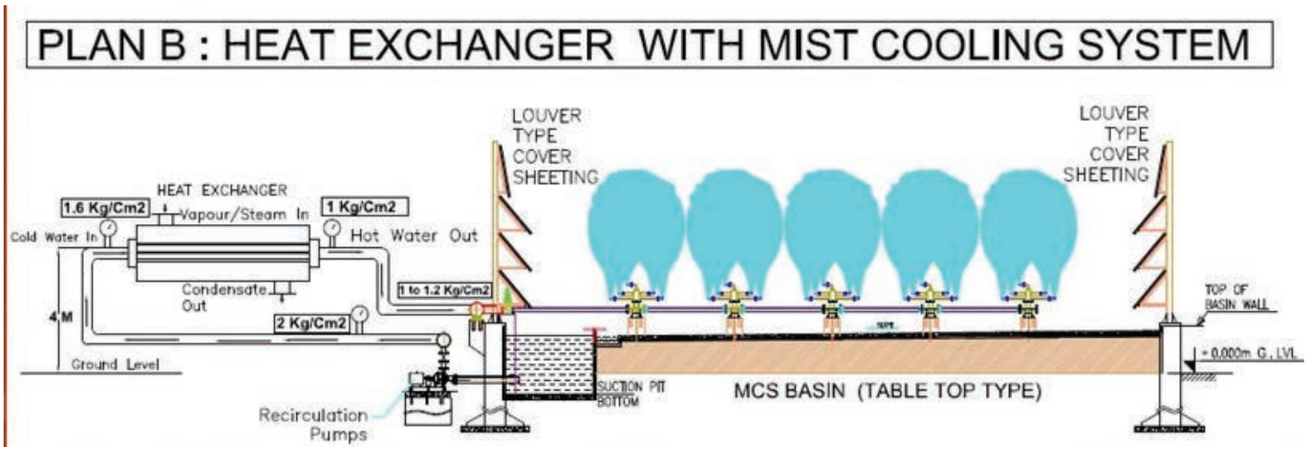
In a wet cooling system, water is circulated to condense the steam in the same type of heat exchanger that is used in the once through cooling. The warm water, instead of being returned to the water source, is cooled in a cooling tower using air as the cooling medium. Only the water carried away due to evaporation, drift and blow-down needs to be replenished by make-up water. Thus requirement of water quantity is vastly reduced.

Wet Cooling Systems

- Wet Cooling Tower System



Circulation Water Cycle in Cooling Tower Plan A:



Circulation Water Cycle in MCS Plan B :

We will first consider the Wet Cooling Tower System. The wet cooling tower system is based on the principle of evaporation. The heated water coming out of the surface condenser is cooled as it flows through a cooling tower, where air is forced through the tower by either mechanical or natural draft. Now a days, mostly, all wet cooling towers are mechanical draft cooling towers, where the air flow is accomplished by fans.

The Principle cooling device used in an Induced / forced draft cooling tower are Fans which run at the top of Cooling Tower (CT). Air enters through side louvers and escapes from the top. Water enters at the top and trickles down while getting cooled by air draft.

A correctly designed induced draft CT can give an approach of 4 to 6°C to wet bulb temperature with a temperature drop of 10°C. Even a very highly efficient CT can not give an approach less than 4°C to WBT. Moreover, if ambient temperature or humidity levels rise, efficiency of CT reduces.

Let's consider the same with an Example:

For a Chemical Plant, an induced draft cooling tower is designed to maintain Cold water temperature of 32°C at a WBT of 28°C with an approach of 4°C. Cooling Tower performs as desired during winter, early summer months. But during peak summer / Monsoon, efficiency of cooling tower reduces as humidity rises & its approach to WBT reaches beyond 6°C from design 4°C. Thus due to this rise in Cold Water temperature, these industries always experience loss in production by at least 5 to 7%. These losses do not occur in winter months. This means that the plant will operate at a reduced efficiency for almost 5 to 6 months as per Graphs A & B.

Also due to use of Fans, CT consumes a lot of power. It is observed that the efficiency of CT reduces over a period of time due to ware and tear of moving parts, Fills, Fins etc. which invites heavy maintenance.

Hence there is an urgent demand from the industry for a water-cooling system, which will operate with high efficiency even in adverse climatic conditions and maintain cold water temperature in closed vicinity to WBT.

Mist Cooling System

MREPL has come out with a solution by designing MIST COOLING SYSTEM which is a high efficiency system, which ensures an approach of 1°C to prevailing wet bulb temperature with a temperature drop of 12 to 15°C even in adverse climatic conditions.

In tropical conditions, worst wet bulb temperature even at coastal applications is maximum 30.5°C. Hence MCS will always maintain Cold Water of around 31°C+1°C throughout the year. No other cooling system can operate with such efficiency and it makes cooling tower/spray pond systems obsolete.

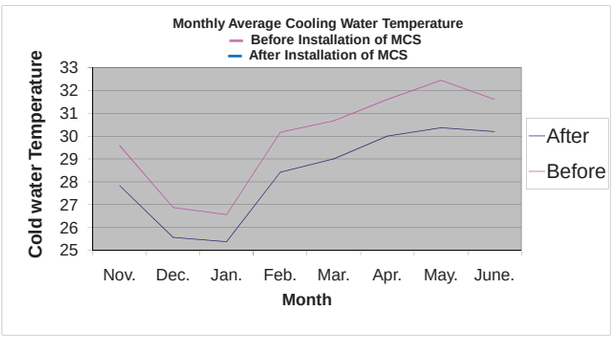
Graph A & B:

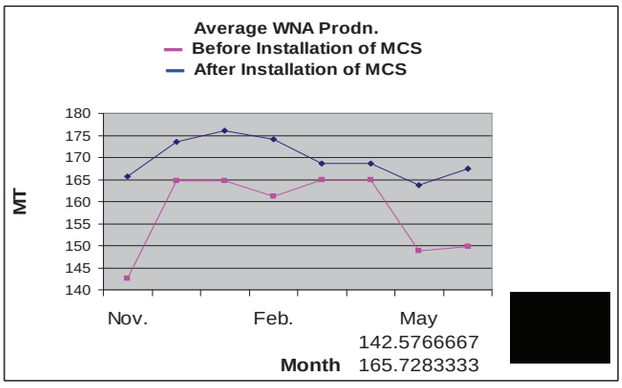
Results from a chemical unit in Andhra Pradesh.

COMPARISON TABLE BETWEEN
INDUCED DRAFT COOLING TOWER / FAN LESS COOLING TOWER &
LOUVER TYPE MIST COOLING SYSTEM

Sr. No.	Feature	Induced Draft Cooling Tower (IDCT)	Fan less / Jet Cooling Tower	Louver Type Mist Cooling System
1	Approach to WBT	**4 to 5 degrees.**	**6 to 8 degrees.**	**1 to 2 Degrees.**
2	Temperature Drop	**8 to 10 Degrees**	**6 to 8 Degrees**	**Regular: 12 Degrees. Advanced Model guarantees up to 40 Degree C in a single stroke**
3	**POWER CONSUMED** (Comparison for a 1000 m3/hr circulation flow assuming IDCT's Total Power as 100%) (Please refer PLAN-A & PLAN-B)	100 HP : 100% (70 HP : 100% on Pumping & 30 HP : Fan)	100 HP : 100% (100 HP : 140% on Pumping & 00 HP : Fan)	70 HP : 70% (70 HP : 100 % on Pumping & 00 HP : Fan)
4	**Nozzles**	Ordinary type which choke frequently	Ordinary Jet type which choke frequently	Special whirling type, choke-less design incorporating non-moving parts with 25 mm bore opening.
5	**Water droplet size**	5 mm	2 to 3 mm	Atomized to 5 to 50 Microns
6	**Travel time**	Less due to Downward fall only.	Less due to Downward fall only.	Two time travel due to upward & downward travel leads to Double air retention time
7	**Fills/ fins**	Various types used - prone to scaling, need Periodical changing	Various types used - prone to scaling, need Periodical changing	ABSOLUTELY NO FILLS / NO FINS REQUIRED.
8	**Drift Loss**	Same	Same	Same
9	**Make Up Water**	same	same	Same due to similar hold up.
10	**Flexibility**	Limited	Limited	Individual Line Isolation offers max. flexibility to use capacity as per requirement.
11	**Standby**	Required	Not Required.	Not Required.
12	**Erection/delivery**	Substantially high	Low	Fairly less
13	**Maintenance**	Very high due to replacement of fills/ fins/ fan blades etc. Also due to deposition of dust on fills, efficiency reduces with time.	Very high due to replacement of fills/ fins etc. Also due to deposition of dust on fills, efficiency reduces with time.	Negligible maintenance due to choke less operation and non-moving parts.
14	**Aesthetics**	Bulky, Generally most neglected part in a Plant	Untidy	Appears Fresh and Dynamic resembling active water like fountain
15	**Civil Construction**	Heavy due to static and dynamic load	Less	Simple due to table top construction with static load
16	**Total Footprint**	Less	Higher than CT	* More by 2 to 4 times to IDCT

* Note: As capacity (Flow, M3/Hr) through MCS increases, ratio of area required between MCS and CT reduces.





Salient Features Of Mist Cooling System

Cold Water Temperature

Mist Cooling System ensures an approach of 1°C to WBT with a temperature drop of 12°C to 15°C.

▪ **Energy Savings (Refer Diagrams Plan A & B) :**

Due to increase in DT, water quantity required at the process side is much less. MCS requires water pressure equivalent to the height of cooling tower as shown in the following diagrams. Hence, considerable amount of energy is saved on circulation water pumping. Also, MCS does not require any fans for cooling. Thus, a huge amount of energy is saved on circulation and cooling.

▪ **Process Benefits :** Mist Cooling System will supply cold water at a temperature very close to WBT (Approach of 1°C) as against an approach of 4 to 5°C in cooling tower. This will reduce the product vapour losses in shell & tube heat exchangers. This will ensure that your plant operates at an enhanced yield in summer and monsoon, also giving stable throughout throughout the year.

▪ **MAINTENANCE:** MCS has no moving parts. It does not use any Fills and Fins for cooling. Also material

used in the MCS is special grade saran polymer, a highly non-corrosive material having a life of more than 10-15 years.

▪ **Chokeless Design of Nozzles:** MCS operates with a chokeless design. Size of smallest opening in MCS is more than one inch (25 MM) in diameter. Hence chances of particles choking the system are remote. This make MCS absolutely maintenance free.

▪ **Various Designs of MCS to Suit Site Conditions:** Open Type MCS: Here, MCS ensures an approach of 1°C to WBT with a ΔT of 12 to 15°C. Water loss due to drift is 0.1 to 0.25% depending on wind load.

▪ **Louver Type MCS:** Here MCS basin is closed from all sides, up to a height of 6 mtrs. by louver type cover sheeting. MCS ensures an approach of 2°C to WBT with a ΔT of 12 to 15°C. Drift loss can be limited up to 0.002% and also space requirement reduces considerably.

▪ **Table Top Design to Prevent Algae Formation:** Latest table top design does not allow formation of water level inside the basin and all water passes to

suction pit which is covered from top thus minimizing chances of algae formation.

▪ **MCS Design for Working in Dusty Environment:** Unique suction pit design does not allow dust to pass to the inlet of circulation pumps. Dust is drained from drain valve, while only clear water passes to circulation water pumps.

▪ **System Flexibility (Capacity Turn down Ratio):** MCS is offered with individual line isolation valve. MCS is the only system, which gives such a high flexibility in operation.

▪ **Hydro- Balance Valve: Hydro-Balance Valve (HBV)** is provided to take care of sub-cooling, which may happen in winter & also is helpful to release excess pressure which may develop on system at times.

▪ **Chemical Treatment:** Chemical dosing requirements are similar to that of cooling tower as same hold up of water is maintained in suction pit of table top MCS.

▪ **Make-Up Water Requirement:** Due to latest "Louver Type" design, drift loss through MCS can be limited to less than 0.002%. Hence, Overall make-up water quantity required is approximately same as compared to cooling towers.

▪ **Pay Back Period:** The Pay Back period of the MCS in most of the cases, will be obtained in less than ONE year only.

Mcs Matches The Design As Per Need:

MCS can be put to use in Open Type or Louver Type MCS designs to suit the need. Open Type design ensures an approach of 1°C to WBT while louver type MCS design ensures an approach of 2.5°C to WBT. Space requirement of Louver Type Design is only 65 to 70% of open Type Design. Also, there is an option of Advance MCS best suitable for plants where there is space limitations.

Terrace Top MCS Design:

Considering the need for high efficiency system required by the various industries, MCS surely meets the demand at an extremely affordable price. ■

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