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Pharmaceutical industry headwinds in remission: ICRA

Mumbai, India: ICRA expects the revenues of the sample set of 25 Indian pharmaceutical companies (which account for ~60% of the overall Indian pharmaceutical industry) to grow by 7-9% in FY2024, post a YoY growth of 10% in FY2023. The same will be primarily supported by 8-10% expansion in the domestic market and 6-8% growth in the US market, while revenues from the European market and Emerging Markets are expected to rise by 3-5% and 8-10%, respectively. The operating profit margin (OPM) for the sample set is expected to be steady at 20.5-21.5% in FY2024.

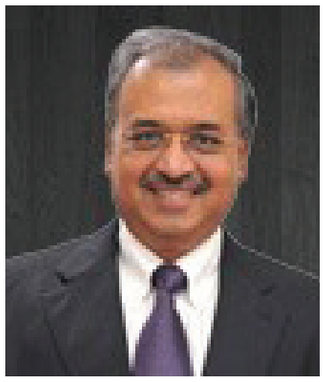
While high raw material and freight prices were a drag on margins in H1 FY2023, these input costs have stabilised now. Coupled with a continued focus on complex generics/specialty launches in the US market, this is expected to support industry margins in FY2024. The overall credit profile of Indian pharmaceutical companies is expected to remain healthy, supported by their stable earnings profile, comfortable leverage and coverage metrics, and strong liquidity position.

Commenting on the growth drivers for ICRA's sample set, Mythri Macherla, Assistant Vice President & Sector Head, ICRA, said: "8-10% growth in the domestic market in FY2024 will be supported by a WPI-linked price hike of 12.1% allowed for products under the National List of Essential Medicines (NLEM), new product introductions and, annual price hikes for non-NLEM products. While new product launches and sizeable revenues from generic Lenalidomide (launched during the end of Q4 FY2022) are expected to continue in FY2024, growth in the US market is expected to moderate to 6-8% in FY2024, given the large base and continued mid-high single digit price erosion for base products."

Patent expirations in the US are expected to be nearly US$ 115-125 billion between CY2023 and CY2026. Of this, biosimilars will comprise around US$ 35-40 billion. This is expected to boost the growth for Indian pharma companies over the next few years. Moreover, increasing per capita wallet share of specialty drugs and industry players' focus on the same is expected to augur well going forward. Indian pharma companies have also made some acquisitions in recent times to strengthen their specialty molecule portfolio in this market. The key focus areas include biosimilars, inhalation, ophthalmology, dermatology, CNS, oncology, anti-diabetes, osteoarthritis and pulmonary.

With the pick-up in inspections by the United States Food & Drug Administration (USFDA), Indian pharmaceutical companies have received multiple official action indicated (OAI) observations, warning letters, and import alerts in the recent past. Commenting on the same, Macherla said: "While some facilities of key pharmaceutical companies have received warning letters and/ or placed under import alerts, there has been no material impact on their revenues from the US market until now. However, delayed resolution of the same could impact the new launches and revenue growth momentum in the US market over the medium term. Accordingly, companies are increasingly focusing on remediating the observations at the earliest and are also filing ANDAs from dual locations to mitigate the adverse impact of such observations on a particular facility. That said, the regulatory risk remains one of the key monitorable for the industry."

Sun Pharma Q1 Gross sales up 10.7%



Dilip Shanghvi, Managing Director, Sun Pharmaceutical Industries

Mumbai, India: Sun Pharmaceutical Industries Limited reported financials for the first quarter ending June 30th, 2023. The company reported net profit for Q1FY24 was ₹ 20,225 million compared to net profit ₹ 20,609 mn for Q1 last year. The company's gross sales stood at ₹ 117,852 million, growth of 10.7%, while EBITDA at ₹ 33,318 million, up 15.5% as against Q1 last year. The company's India formulation sales stood at ₹ 35,604 million, up 5.1%, while US formulation sales was at US$ 471 million.

Dilip Shanghvi, Managing Director of the Company said, "All our business continued to have growth this quarter and we are well positioned to meet our growth guidance for FY24. US has led the revenue growth in Q1 and Global Specialty has continued to increase as a share of our revenues. I am excited about the progress in our specialty pipeline and the potential for offering new treatments for patients in need."

"We have a comprehensive product offering in the US market consisting of approved ANDAs for 518 products while filings for 98 ANDAs await US FDA approval, including 32 tentative approvals.For the quarter, 2 ANDAs were filed. Additionally, the portfolio includes 54 approved NDAs while 13 NDAs await US FDA approval, the company stated.

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Dr. Reddy's Laboratories Q1 net profit stood at ₹ 14,025 mn

G V Prasad, Co-Chairman & MD, Dr. Reddy's Laboratories

Hyderabad, India: Dr. Reddy's Laboratories Ltd. announced its consolidated financial results for the quarter ended June 30, 2023. The company's revenue stood at ₹ 67,384 mn, while Profit after Tax stood at ₹ 14,025 mn. The company's EBITDA stood at ₹ 21,372 mn.

Commenting on the results, Co-Chairman & MD, G V Prasad said: 'We delivered strong sales growth and witnessed robust margin expansion in Q1FY24 driven by market share gains & new product momentum in our US generics business and superior performance in Russia. We are on track in executing our strategy, delivering growth while continuing to invest in future growth drivers and innovation to create sustainable value." The company's global Generics business for FY24 revenue stood at ₹ 60.1 billion, YoY growth of 36% and QoQ growth of 11 %, while Q1 FY24 revenue from emerging markets stood at ₹ 11.6 billion.

Biocon Q1 net profit stood at ₹ 101 crore

Bengaluru, India: Biocon posted consolidated financial results for the fiscal first quarter ended June 30, 2023. The company's revenue stood at ₹ 3516 crore, while net profit stood at ₹ 101 crore.The company's EBITDA stood at Rs 808 Crore."We have had a strong start to the year. At a consolidated level, revenues rose 59% YoY to Rs 3,516 crore driven primarily by the 106% jump in Biosimilars revenue. Research Services revenue rose 25%, and Generics reported 15% growth. Our Core EBITDA for the quarter was up 42% at Rs 936 crore, reflecting a margin of 28%. R&D investments at Rs 315 crore increased by Rs 117 crore this quarter, reflecting our advancing pipeline, which will support future growth. Our key biosimilars are gaining traction in both U.S. and Europe with Fulphila® becoming the leading biosimilar Pegfilgrastim in the U.S. and biosimilar Glargine's market share crossing the 12% mark. A higher new prescription share reflects the prescriber confidence in our portfolio and the overall improvement in the adoption of biosimilars, stated Kiran Mazumdar-Shaw, Executive Chairperson, Biocon and Biocon Biologics.

"The Generics business delivered a healthy 15% year-on-year revenue growth, driven by growth in our formulations business in the U.S. and new product launches in a few key MoW markets. We also saw a volume increase in immunosuppressant APIs.Our product pipeline continues to advance with an approval for Vigabatrin tablets and a tentative approval for Lenalidomide capsules in the U.S., and for Mycophenolic acid tablets in Europe. The positive outcome of the two U.S. FDA inspections at our Hyderabad API and Bengaluru OSD sites will help in accelerating new product approvals. "We continue to make investments for future growth, with work having commenced on the expansion of our peptide and fermentation capacities in Bengaluru, with a timeline for completion in the second half of FY25, stated Siddharth Mittal, CEO & Managing Director, Biocon Limited.

Strides Pharma Science Q1 revenue stood at ₹ 9,320 mn

Arun Kumar, Founder, Managing Director, Strides Pharma Science

Bangalore, India: Strides Pharma Science Ltd announced its consolidated financial results for the quarter (Q1FY24).The company's revenue stood at ₹ 9,320 mn, while EBITDA was at 1,686 mn. The company's Q1FY24 gross margins stood at 58.7%.

Arun Kumar, Founder, Managing Director, and Executive Chairperson, commented on the performance and said, "We are pleased to report a strong start to FY24, with Q1FY24 EBITDA reaching historical highs. Our focus on profitability and efficiency is clearly witnessed in the results as we expanded EBITDA margins by 200 bps QoQ and generated strong operating cash flows. We are on track to achieve the targets we setout for FY24 at the beginning of this year on all financial parameters. The Regulated markets grew by 25% YoY with US growing by 32% YoY and Other Regulated markets growing by 15% YoY. The growth is driven by disciplined approach on product launches and sustainable market share on existing products. The emerging markets performance had a slow start and expected to gain traction during the year. We are confident of sustaining the momentum

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WHO includes Cadila Pharmaceuticals Polycap combination in essential medicine list

Dr. Rajiv Modi, CMD, Cadila Pharmaceuticals

Ahmedabad, India: Cadila Pharmaceuticals, one of the oldest and largest privately held pharmaceutical companies in the country, has welcomed the inclusion of "Polypills" for the primary and secondary prevention of cardiovascular diseases in the Essential Medicine List 2023 by the World Health Organization (WHO).

The Cadila polypill formulation (polycap) which was approved in 2009 by DGCI for secondary prevention of coronary heart disease/stroke in patients with multiple risk factors, is included in the Essential Medicine List. This latest development is a huge milestone and an achievement for Cadila Pharmaceuticals. This reaffirms that Polypills are safe, effective, and affordable medicines that cater to the priority health needs of the population, particularly for the prevention of cardiovascular (specifically atherosclerotic) diseases. The recognition underscores the clinical and economic advantages of Polypills, and bolsters Cadila Pharmaceuticals' commitment to consistently provide innovative healthcare solutions for the domestic and global markets.

Dr. Rajiv Modi, Chairman and Managing Director of Cadila Pharmaceuticals, said, "This validation by the World Health Organization is a recognition of our efforts for improving global health. Polycap will help contain the burden of cardiovascular diseases and save millions of lives globally."

The Polypill formulation (Polycap) is a combination of medications to modify the risk factors like hypercholesterolemia and high blood pressure in patients with atherosclerotic cardiovascular diseases. Extensive research is done on more than 7000 patients in TIPS 1, TIPS 2 and TIPS 3 studies proved that Polycap reduces the risk of cardiovascular problems by almost 60%. Cadila Pharmaceuticals has made these huge benefits available to the community and the importance of the same is now strongly endorsed by WHO by including Polypills into the Essential Medicine list.

A WHO release quoted Director-General Dr. Tedros Adhanom Ghebreyesus, as saying that "These treatments could have a very large public health impact globally, without jeopardising the health budgets of low- and middle-income countries."Updated every two years, the Essential Medicine List is a register of medications that WHO recommends to every health care system as a minimum mandatory requirement. This list is recognised as a guide for countries' health systems to prioritise medications that are both effective and affordable. Each addition is considered essential to address key public health needs, as per WHO. The inclusion of Polypills further bolsters the list, which now stands at 502 medications for adults and 361 for children.

Syngene Q1 revenue up 26% to ₹ 832 crores

Jonathan Hunt, MD & CEO, Syngene International Limited

Mumbai, India: Syngene International Limited announced its first quarter results. The company's quarterly revenue was up 26% year-on-year to ₹ 832 crores, while profit after tax for the quarter increased 26% year-on-year to Rs 93 crores. During the quarter, the Company marked three events: the previously announced acquisition of a biologics manufacturing facility in Bangalore from Stelis Biopharma Ltd.; the receipt of regulatory approval for the commercial manufacturing plant in Mangalore from the US Food and Drug Administration; and the acquisition of additional land in Hyderabad to support further growth.

Commenting on the first quarter, Jonathan Hunt, Managing Director and Chief Executive Officer, Syngene International Limited, said, "First quarter performance was strong, led by Development and Manufacturing Services and well supported by our research divisions: Discovery Services and the Dedicated Centers.

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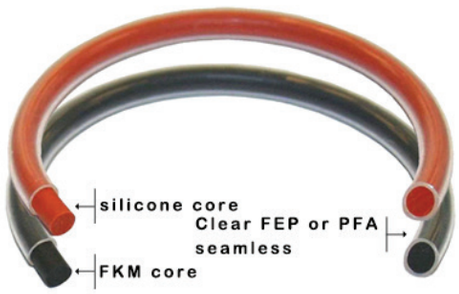

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Earlier this month we announced our intention to acquire a site offering additional biologics manufacturing capacity close to our existing Bangalore campus. With 20,000 liters of installed biologics capacity - and scope for further expansion – the site strengthens our position as a leading biologics contract development and manufacturing service provider.Also during the quarter, we were pleased to receive US FDA approval for our API facility in Mangalore. This approval reflects the robust quality standards applied in all our operations and represents an important building block for our small molecule commercial manufacturing strategy. Finally, we completed the acquisition of development land in Hyderabad to support the long-term growth ambitions of our Research Services division.

Together, these actions show meaningful progress on our strategy to become a global leader in both research services (CRO) and manufacturing services (CDMO) and give us the capacity we need for the next stage of growth."

Sibaji Biswas, Chief Financial Officer, Syngene International Limited added, "We are pleased to report a solid start to the year.The financial performance is in line with the revenue growth guidance for the year on a constant currency basis. At 25%, EBITDA growth reflects better operating leverage as we gain scale in development and manufacturing services.We made investments in growing our portfolios in biologics manufacturing and discovery services. Despite these investments, the Company will continue to maintain a strong balance sheet and a low debt profile."

JB Pharma records revenue growth of 14% to ₹ 896 crores in Q1 FY24

Mumbai, India: JB Chemicals & Pharmaceuticals ltd, one of the fastest growing pharmaceutical companies in India, announced its financial results for the quarter ended 30th June, 2023.

For the first quarter of FY24 ended 30th June 2023, JB Pharma recorded revenue of ₹ 896 crores growing 14% from ₹ 785 crores in the corresponding quarter. Operating EBITDA* (Earnings before Interest Depreciation and Taxes) improved 28% to ₹ 243 crores, while Profit after Taxes registered a strong growth of 35% to ₹ 142 crores. The company's domestic business revenue for the quarter was ₹ 489 crores, recording growth of 17%, while International Business recorded 11% growth to ₹ 407 crores

Nikhil Chopra, CEO and Wholetime Director, JB Pharma mentioned, "JB Pharma delivered a good quarter driven by focused execution. Our domestic business continued its growth trajectory through strong momentum in our chronic portfolio and acquired assets. Our big brands, especially in chronic segment, continue to outpace the market and have reached new milestones. CDMO business scaled further during the quarter and the healthy momentum continues for this segment too. EBITDA margins improved during the quarter on account of better business mix, increased efficiencies in sourcing, and higher volumes. The first quarter has been a robust performance both in terms of topline and operating profit, and we remain positive about delivering on our business objectives. We will maintain our distinctive focus on India and the CDMO business, while maintaining our efforts to control costs & increase efficiencies across the organisation."

Lupin launches Luforbec 100/6 for Adult Asthma and COPD treatment in Germany

Frankfurt, Mumbai: Hormosan Pharma GmbH, Lupin's wholly-owned subsidiary in Germany, announced the launch of Luforbec 100/6 (beclometasone 100 µg / formoterol 6 µg), a fix combination in a pressurized metered dose inhaler (pMDI) for the treatment of adult asthma and chronic obstructive pulmonary disease (COPD) in Germany.

Luforbec 100µg/6µg pMDI is indicated for adult asthma and COPD treatment, where the use of an inhaled corticosteroid and long-acting beta2-agonist (ICS/LABA) is suitable. With the same active ingredients as Foster® 100/6 pMDI and an extra fine formulation, Luforbec offers the same licensed indications and similar device characteristics. Luforbec® pMDI provide significant cost savings, priced at - 47% below the fixed reference price on the pharmacy selling price. With a significant portion of the population (5% of adults and 10% of children) currently undergoing asthma treatment, Luforbec 100/6 pMDI aims to provide comprehensive support to patients and healthcare professionals. This launch reflects Lupin's unwavering commitment to addressing the critical needs of asthma management in Germany. Luforbec 100µg/6µg is indicated in the regular treatment of asthma where the use of a combination product (inhaled corticosteroid and long-acting beta2-agonist (ICS/LABA) is appropriate. This includes patients not adequately controlled with ICS and 'as needed' inhaled short-acting beta2-agonist or patients already adequately controlled on both ICS and LABA.

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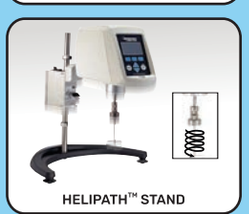
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Aurobindo Pharma's arm APL Healthcare receives USFDA approval for Sevelamer Hydrochloride Tablets 400 mg and 800 mg

Mumbai, India: Aurobindo Pharma Limited announce that it's wholly owned subsidiary company, APL Healthcare Limited, has received a final approval from the US Food & Drug Administration (USFDA) to manufacture and market Sevelamer Hydrochloride Tablets 400 mg and 800 mg, Sevelamer Hydrochloride Tablets 400 mg and 800 mg, to be bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Renagel Tablets, 400 mg and 800 mg, of Genzyme Corporation.The approved product has an estimated market size of around US$ 37 million for the twelve months ending May 2023, according to IQVIA. This is the 57th ANDA approved out of APL Healthcare Unit IV formulation facility, used for manufacturing oral products. Aurobindo now has a total of 463 ANDA approvals (437 Final approvals and 26 tentative approvals) from USFDA. Sevelamer Hydrochloride Tablets 400 mg and 800 mg is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis.

Glenmark Pharma ties up with OMRON Healthcare India

Mumbai, India: Glenmark Pharmaceuticals Limited, a leading, integrated, research-led, global pharmaceutical company has joined hands with OMRON Healthcare India, the Indian arm of the Japanese global leader in home blood pressure monitoring and solutions for cardiovascular disease management, to raise awareness on measuring blood pressure at home from the age of 18. The lack of specific guidelines on the right age to begin blood pressure screening has led to neglect in initiating checks, leaving many individuals vulnerable to hypertension and its complications. In response to this critical issue, Glenmark initiated discussions with 94 cardiologists across India, leading to a unanimous consensus that 18 is the ideal age to commence blood pressure screening. This expert consensus statement was published in the Journal of the Association of Physicians of India (JAPI) in 2020i.

Glenmark and OMRON Healthcare India's collaboration, named as "Take Charge @18" initiative, comprises of generating effective communication to enhance awareness around the cause via incorporating an inlay card into every OMRON Blood Pressure monitor sold in India. The message conveys the importance of initiating blood pressure screening at the right age which is 18 years. The objective is to encourage patients and care givers who come across this inlay card to sensitize at least four family members of or above the age of 18 to start monitoring their blood pressure and make it a part of their health regime. This message will also be seamlessly integrated into the OMRON Connect app, ensuring it reaches all its subscribers and also on OMRON social media and websites. Speaking about this collaboration, Alok Malik, Executive Vice President & Head of India Formulations, Glenmark Pharmaceuticals Ltd., said, "As leaders in hypertension therapy, we are dedicated to making a positive impact on public health. Our collaboration with OMRON Healthcare India is a testament to our commitment to raise awareness about hypertension and early blood pressure screening. There has been a concerning rise in the incidence of hypertension among young adults in India, with about 10-30%ii of young adults (<40 years of age) suffering from high blood pressure in the countryii. Together, we aim to empower individuals to proactively safeguard their health from a young age."

Tetsuya Yamada, Managing Director, OMRON Healthcare India said, "Partnering with Glenmark Pharmaceuticals for the 'Take Charge @18' campaign aligns perfectly with our vision of 'Going for Zero' promoting home blood pressure monitoring as one of the key preventive healthcare practices to significantly reduce hypertension-led diseases such as stroke and heart failure. Our internal studies indicate that the penetration rate of blood pressure monitors usage amongst hypertensive patients in India remains low at around 2% only. By integrating the campaign's message into our products and services we aim to inspire millions to lead healthier lives."

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Supriya Lifescience Ltd and Plasma Nutrition, Inc announce collaboration in Protein Technology

Dr Saloni Wagh, Executive Director, Supriya Lifescience Ltd

Mumbai, India: Supriya Lifescience Ltd, a prominent Mumbai-based company specializing in active pharmaceutical ingredients (API), proudly announces its recent collaboration with Plasma Nutrition, Inc, a renowned United States-based company known for innovative consumer products located at Delaware. The strategic partnership involves an exclusive technology licensing agreement, granting Supriya Lifescience Ltd the sole rights for manufacturing and marketing Ingredient Optimized Protein (ioProtein) in India. The primary purpose of this collaboration is to bring the optimized protein into the Indian market. ioProtein is a patented process (patent pending in the US) This revolutionary protein powder is designed for use as protein supplements and boasts a significant advantage, and it is highly bioavailable. This means that higher amounts of proteins are absorbed quickly by the body, providing consumers with a more effective and efficient protein supplement.

During the term of the agreement, Supriya Lifescience Ltd will lead the manufacturing and marketing of ioProtein in India. This marks the introduction of a new category of protein powders in the Indian market, and it is relatively healthier compared to other popular protein powders available through various Gyms, general stores, and digital marketing channels.

"We are thrilled to be the exclusive partner of Plasma Nutrition, Inc in introducing the innovative ioProtein to the Indian market," said Dr Saloni Wagh, Executive Director at Supriya Lifescience Ltd. "This strategic partnership represents our commitment to providing high-nutrition solutions to consumers in India. With ioProtein's high bioavailability and its unmatched advantage, we are confident that the 'IO' technology will revolutionize the nutrition industry and become the preferred choice for health-conscious individuals."

"We are excited to collaborate with Supriya Lifescience Ltd and bring our patented ioProtein technology to India," said Chris Flynn-Rozanski, co-founder & CEO at Plasma Nutrition, Inc. "India's rapidly growing demand for protein supplements presents an excellent opportunity for us to introduce this highly bioavailable protein powder, which has already been well-received in other markets. We believe this partnership will create a new standard for protein supplementation in India."

GCV Life Pvt Ltd, led by Shailesh Gadre, played a pivotal role as an exclusive advisor in facilitating this landmark transaction. GCV Life Pvt Ltd, renowned for its expertise in investment banking & innovation licensing, will also spearhead the marketing of the 'Ingredient Optimized' products as per the arrangement among the three companies.

Indoco Q1 revenues up 5 %

Aditi Panandikar, Managing Director, Indoco Remedies

Mumbai, India: During the first quarter of FY 2023-24, revenues of Indoco Remedies grew by 5 % at ₹ 413.2 crores, as against ₹ 394.9 crores, same quarter last year. EBIDTA to net sales for the quarter is 15.2 % at ₹ 62.9 crores, compared to 18.1 % at ₹ 71.3 crores, same quarter last year. Profit After Tax is at ₹ 25.7 crores, compared to ₹ 37.5 crores, same quarter last year. Commenting on the results, Aditi Panandikar, Managing Director, Indoco Remedies Ltd. said, "Our first quarter results demonstrate good growth in API business, complemented by steady performance in the Domestic Formulation business. We remain optimistic for the rest of the year and are committed to building and further strengthening our position in the market". Indoco is a fully integrated, research-oriented pharmaceutical company with presence in 55 countries. The Company's turnover is US$ 200 million with a human capital of 6000 employees, including over 300 skilled scientists and Field Staff who are the strength of the organization.

AstraZeneca's Dapagliflozin gets additional indication approval

New Delhi, India: AstraZeneca Pharma India Ltd, a science-led biopharmaceutical company, announced it has received extended indication approval from the Drugs Controller General of India (DCGI) for its drug, Dapagliflozin in the treatment of heart failure (HF) in adults.

The approval is based on the detailed results from the DELIVER Phase III trial—the largest and broadest HF trial to date in patients with LVEF (left ventricular ejection fraction) >40%. AstraZeneca's original research product dapagliflozin significantly reduced the composite of cardiovascular (CV) death or worsening heart failure in patients with HF with mildly reduced or preserved ejection fraction (EF), compared to placebo. The results were consistent across pre-defined subgroups. Dapagliflozin is already approved for HF with reduced ejection fraction. The additional indication will expand the indication for all types of HF irrespective of ejection fraction. Dapagliflozin is the only SGLT-2i which has shown mortality benefits in the pooled analysis of heart failure across LVEF.

Heart failure is a chronic, progressive disease impacting nearly 64 million people globally and about 10 million in India, which comprises of both heart failure with preserved ejection fraction and reduced ejection fraction. The available data from Indian HF registries show that HF patients in India are younger by 10-years, and the majority of the burden lies below 65 years of age, as compared to the patients from high-income countries.

Dr. Bagirath Raghuraman, Sr. consultant Interventional & Transplant cardiologist, Narayana Health, Bangalore, said, "Heart Failure is a condition which has high mortality rates irrespective of ejection fraction. Despite this, it is not well recognised or diagnosed. All people with breathlessness should be evaluated with a simple blood test and echocardiogram to rule out heart failure. This approval is significant for heart failure patients specifically for patients with preserved ejection fraction who have limited treatment options."

Dr. Anil Kukreja, Vice-President, Medical Affairs and Regulatory, AstraZeneca India, added: "We are committed to push the boundaries of science and bring the best-in-class life changing original research medicines for patients across the world including in India. Our ground-breaking results from the DELIVER study indicates Dapagliflozin's positive and significant impact on patients with heart failure even when their ejection fraction is above 40%. This approval reinforces our commitment to reducing the burden of this life-threatening disease and help patients across the HF spectrum live longer and healthier lives."

Venus Remedies launches its flagship R&D drug Elores in Oman

Mumbai, India: In a landmark achievement, Venus Remedies Ltd, a leading research-driven pharmaceutical company, has launched its flagship R&D drug, Elores, in the $1.4-billion pharmaceutical market in Oman.

Clinically proven to be one of the best drugs against ICU infections caused by multidrug-resistant extended spectrum beta lactamase (ESBL) and metallo beta lactamase (MBL)-producing gram negative bacteria, Elores is effective against bacterial strains resistant to the last-resort carbapenem class of antibiotics. An outcome of more than 15 years of in-house R&D, Elores is Venus Remedies' answer to the global health threat posed by antimicrobial resistance. Its clinical trial study, completed to very high standards, was the first antibiotic study from India to get listed on the US clinical trial web portal.

"We expect this product, which has been patented in 46 countries, including the largest pharmaceutical markets of the US and Japan and many European countries, to generate a revenue of around $0.5 million by 2025. With Elores launched in Oman, we are now targeting the $237-million antibiotic market in the GCC region, out of which 54 per cent accounts for ESBL and MBL resistance segment. We are aiming to secure a 0.1 per cent share in this segment, which amounts to $0.23 million," said Aditi K Chaudhary, President, International Business, Venus Remedies.

The antibacterial market in Oman is worth US $7.5 million, and Elores is looking to capture 0.5 per cent of this segment ($0.375 million) by year 2025. Oman has alarmingly high rates of ESBL and MBL-producing gram negative infections, as high as 54 per cent. About 63.4 per cent of K. pneumoniae isolates from Oman are multi-drug resistant and produce ESBL against which Elores exhibits remarkable efficacy.

Laurus Labs Q1 PAT stood at ₹ 25 crore

Hyderabad, India: Laurus Labs Ltd, a leading research and development driven pharmaceutical and biotech company in India announces its Q1 FY24 results. The company's revenue stood at ₹ 1,182 crore, while PAT was at ₹ 25 crore. The company's FDF business generated revenue of ₹ 285 crsore during Q1FY24, while API business reported revenues of ₹ 597 crore.

Commenting on the highlights, Founder and Chief Executive Officer Dr. Satyanarayana Chava stated, "While our operating results this quarter were primarily impacted by lower sales, operational deleverage and elevated expenses, the underlying demand for key growth portfolio within Non-ARVs generics and CDMO progress remains strong and healthy. ARV business have incrementally stabilised on overall basis and therefore we remain optimistic in our H2 growth prospects as indicated earlier. During the quarter, Laurus continued to advance its R&D driven commercial strategy by successful signing its first multi-year commercial partnership in Crop science and further deepening commitment into emerging CGT technology platform. Our CDMO growth projects are on track with Animal health manufacturing block commissioned recently and dedicated R&D centre coming online in late FY24. We remain committed to ensuring greater business resilience and long term performance, with growing scientific capabilities remaining the source of our company's energy and value creation."

Commenting on the results, V V Ravi Kumar, Executive Director & Chief Financial Officer said; "We delivered subdued financial performance for Q1FY24. We achieved ₹ 1,182 crs in revenues, representing 23% decline, and ₹ 168 crs EBITDA, resulting to 14.2% margin. Performance mainly affected by operational deleverage, material drop in the CDMO business, price fall in ARV portfolio over last year. We are anticipating rebound from H2, with recovering revenue trend, positives from cost improvement programs and raw material price stabilisation. Our future capex projects towards strengthening CDMO and Bio division is advancing as per schedule and Debt leverage position remains comfortable".

US FDA conducts inspection of IPCA Laboratories'

Mumbai: IPCA Laboratories stated that US FDA conducted the inspection of the Company's formulations manufacturing facility situated at SEZ Indore, Pithampur (Madhya Pradesh) from 15th June,2023 to 23rd June, 2023. At the conclusion of the inspection, US FDA has issued a Form 483 with 8 (eight) observations. The Company will submit its comprehensive response on these observations to the US FDA within the stipulated time and shall work closely with the agency to resolve these issues at the earliest.The Company takes the quality and compliance issues with utmost importance and remains committed to maintain the highest standards of quality and compliance across all its manufacturing facilities.

Mankind Pharma Q1 PAT rises 66%

Rajeev Juneja, Vice Chairman & Managing Director, Mankind Pharma

New Delhi, India: Mankind Pharma, India's fourth largest pharmaceutical Company announced its financial results for the first quarter of FY24. The company's revenue from Operations stood at ₹ 2,579 crore, up by 18% YoY, while PAT was at ₹ 494 crore, up by 66% YoY with margin of 19.2%. The company's domestic Business achieved a robust 14% YoY* growth in Q1FY24, while Exports business witnessed a growth of 214% YoY in Q1FY24 aided by certain one-off opportunities in the US.

Rajeev Juneja – Vice Chairman & Managing Director, "We have started the year on a healthy note, with strong double digit growth in sales and profitability. The Pharma segment outperformed the IPM by 1.5X led by volume led growth and highest ever chronic share. Our consumer healthcare segment maintained dominant brand leadership in respective categories. We have also seen positive results of our prior initiatives to improve profitability, with EBITDA growing 43% YoY. Our market disruptive "DMF Quality Products" campaign has seen an outstanding response and we are rapidly expanding our product offerings in this important initiative. Our strategic initiatives across the businesses are delivering positive results and we are hopeful that we will continue to outperform industry growth, going ahead".

Akums gets DCGI approval for triple combination diabetes treatment

Delhi, India: Akums Drugs and Pharmaceuticals Limited, India's leading CDMO, has secured approval for its groundbreaking triple combination diabetes treatment. Sitagliptin 100, Pioglitazone 15 and Metformin 1000/500 comes as a more advanced treatment for diabetes, with much more efficacy and precision than monotherapy drugs that are currently in the market. Sitagliptin 100, Pioglitazone 15 and Metformin 1000/500 is specifically formulated for the treatment of diabetes and offers a number of pharmacological advantages. The combination contains three distinctly active formulations such as Metformin, a glucose-lowering agent often prescribed as a first-line therapy for Type-2 diabetes (T2D).

Pioglitazone, on the other hand, is an outstanding component as it is considered effective against T2D because of its ability to improve insulin sensitivity, lower HbA1c levels, and promote lipid metabolism and insulin secretion. The third component in the combination is Sitagliptin, which has been observed to significantly reduce HbA(1c) levels when used as an add-on therapy after the administration of insulin, sulfonylureas, or thiazolidinediones, or alone with or without metformin. "We have carefully studied the pharmacological properties of these formulations and with Sitagliptin 100, Pioglitazone 15 and Metamorfin 1000/500, we found the right blend for our triple-active combination. This is going to better serve anti-diabetic patients who require better treatment without necessarily swallowing multiple drugs. The approval is a boost because it shows that we followed all laid down procedures, and the drug is fit for use by patients who need relief from the impacts of not just Type-2 diabetes, Patient convenience and dosage compliance " said Mr. Sanjeev Jain, Jt. Managing Director, Akums Drugs & Pharmaceuticals. The bi-layered combination was formulated following well-researched processes and operations, as well as adherence to pharmacological guidelines. Speaking on the approval, Mr. Sandeep Jain, Jt. Managing Director, Akums Drugs & Pharmaceuticals, noted that the renoprotective effects of drugs like metformin coupled with the functional and corrective influence of pioglitazone on beta-cell and metabolic syndrome, and the stability of Sitagliptin, make an effective solution for diabetes. "As a brand, we will continue to introduce new combinations to help patients around the world get better," he added.

Indegene get SEBI nod to float IPO

Mumbai, India: Indegene Limited has received markets regulator Securities and Exchange Board of India (Sebi) clearance to raise funds through Initial Public Offerings (IPOs). Indegene filed their preliminary IPO papers with Sebi in December 2022. The IPO of Indegene consists of a fresh issue of equity shares worth up to Rs 950 crore and OFS of up to 3.63 crore equity shares by existing investors, according to the Draft Red Herring Prospectus (DRHP).

The OFS consists of up to 27 lakh equity shares to be sold by individual selling shareholders -- Manish Gupta, Rajesh Bhaskaran Nair, and Anita Nair -- and up to 3.36 crore equity shares by existing investors, including Carlyle, Brighton Park Capital and the Nadathur Family Office.

The funds raised through the fresh issue would be used to pay debt, fund capital expenditure requirements, payment of deferred consideration for one of its past acquisitions, fund inorganic growth and general corporate purposes. Founded in 1998, Indegene offers solutions that help enable biopharmaceutical, emerging biotech and medical devices companies to develop products, launch them in the market, and drive sales throughout their life cycle.

The company reported revenue from operations of Rs 1,665 crore in FY2021-22, growing at a 61 per cent CAGR from FY2019-20 to FY2021-22 and posted a profit after tax of Rs 163 crore in FY2021-22, increasing at an 81 per cent CAGR from FY2019-20 to FY2021-22. Kotak Mahindra Capital, Citigroup Global Markets India, J P Morgan India, Nomura Financial Advisory and Securities (India) are the book running lead managers to the issue.

ENTOD Pharmaceuticals unveils clinical experience launch of Vasuki NT and Eyecirque Pro

Mumbai, India: ENTOD Pharmaceuticals, a leading pharmaceutical company in India, announced the successful clinical experience launch of its groundbreaking products, Vasuki NT and Eyecirque Pro. The company's dermatological venture, Entod Beauty London, has introduced "Vasuki NT," a revolutionary Facial Gel Serum developed by Entod Research Cell UK Ltd., and "Eyecirque Pro," an innovative nanotechnology-based Under Eye Gel Serum. Both products have been meticulously formulated with scientifically proven

ingredients for optimal results.

"Witnessing the successful clinical experience launch of Vasuki NT and Eyecirque Pro fills me with immense pride. These two products represent a culmination of our relentless pursuit of innovative and safe skincare solutions. Vasuki NT's revolutionary use of synthetic tripeptide snake venom neurotoxin has proven to be a game-changer in the skincare industry, delivering anti-ageing benefits with remarkable efficacy. On the other hand, Eyecirque Pro's nanotechnology-based formula addresses the unique needs of the delicate skin around the eyes, offering nourishment and revitalization. I believe these products will have a profound impact on our consumers, empowering them to embrace a healthier and more radiant skin and eye care regimen," remarked Mr. Nikkhil K Masurkar, CEO of ENTOD Pharmaceuticals.

Vasuki NT and Eyecirque Pro, the revolutionary products unveiled by ENTOD Pharmaceuticals, mark a significant leap forward in the world of skincare and eye care. Vasuki NT, a Facial Gel Serum, stands as a testament to cutting-edge innovation with its clinically proven synthetic tripeptide snake venom neurotoxin developed by Entod Research Cell UK Ltd. This nanotechnology-based serum offers remarkable anti-ageing benefits, providing a painless and affordable alternative to invasive procedures like lasers and Injectable neurotoxins. On the other hand, Eyecirque Pro, a nanotechnology-based Under Eye Gel Serum, showcases ENTOD Pharmaceuticals' commitment to safety and effectiveness with its carefully curated plant-based natural ingredients. With soothing, non-sticky, and non-irritant properties, this unique gel serum effortlessly nourishes the delicate skin around the eyes, delivering highly prominent results.

"As the Clinical Director of ENTOD Pharmaceuticals, I am elated to witness the remarkable clinical experience launch of Vasuki NT and Eyecirque Pro. Vasuki NT's groundbreaking synthetic tripeptide snake venom neurotoxin and Eyecirque Pro's nanotechnology-based formula demonstrate our pursuit of cutting-edge solutions. These products hold the promise of transforming the way individuals approach skincare and eye care, empowering them to rediscover their beauty with confidence. At ENTOD, we take pride in our holistic approach, combining science, nature, and expertise to create products that inspire a renewed sense of well-being and self-assurance in our valued consumers." said Mrs. Anjula Masurkar, Clinical Director, Entod Pharmaceuticals.

The clinical experience launch of Vasuki NT and Eyecirque Pro showcases ENTOD Pharmaceuticals' steadfast dedication to delivering cutting-edge skincare solutions that are underpinned by rigorous scientific research and expert collaborations.

Alembic Pharma Q1 net sales rises 18%

Mumbai, India: Alembic Pharmaceuticals Limited reported its consolidated financial results for the first quarter ended 30th June, 2023.The company's net sales grew 18% to ₹ 1486 crores for the quarter, while company's Net Profit for the quarter at ₹ 121 crores.Pranav Amin, Managing Director, Alembic Pharmaceuticals Limited said "The company grew in all the business segments with India outperforming the market with 9% growth, Ex US generics grew 46%, API grew 31% and the US generics business grew 6%. We have also started commercializing products from our Oncology and Injectable Facilities". The company's India Branded Business was up by 9% to ₹ 524 crore in the quarter, while Specialty therapies recorded growth of 12% as against industry growth of 7%*.Acute therapies recorded growth of 16%* vis a vis Industry growth of 10%*. In Anti Infective, Industry has shown growth of 10%* where as Alembic recorded 19%* growth. The company's US Generics up 6% to ₹ 390 crores in the quarter, while Ex-US International Formulations grew 46% to ₹ 266 Crores in the quarter.The company received 5 ANDA approvals received during the quarter; with 184 Cumulative ANDA approvals.The company's API business grew 31% at ₹ 305 crores in the quarter.

Ajanta Pharma Q1 revenue from operations up 7%

Mumbai, India: Ajanta Pharma Ltd. a specialty pharmaceutical formulation company reported its performance for the 1st quarter ended 30th June 2023. The company's revenue from operations at ₹ 1,021 crore as against ₹ 951 cr.; up 7%, while EBITDA was at ₹ 271 crore against ₹ 222 crore.; up 22%; EBITDA at 26%.The company's Profit after tax stood at ₹ 208 crore. As against ₹ 175 crore.; up 19%; PAT at 20%. The company's board of Directors have approved 1st interim dividend of ₹ 315 cr. for the year FY 2024. It translated into ₹ 25 per share (1250%) for each ₹ 2 face value share.

Granules India's arm completes USFDA's post-marketing inspection

Hyderabad, India: Granules India Limited, announced that Granules Pharmaceuticals, Inc. (GPI), a wholly owned foreign subsidiary of the company, located in Chantilly, Virginia, USA has completed the United States Food and Drug Administration (USFDA) Post-marketing Adverse Drug Experience (PADE) Inspection for all its entities in the United States, including Granules India Limited. The inspection was closed with zero observations. The inspection was conducted at Granules Pharmaceuticals Inc. (GPI) from July 31, 2023 to August 03, 2023. This inspection covered the Granules' PADE surveillance, receipts, evaluations, processing and reporting system for the marketed drug products worldwide. This is Granules India's fourth FDA audit since March with zero observations - a testament to Granules India's unwavering commitment to ensuring the highest level of patient safety and product quality.

Torrent Pharma Q1 net profit stood at ₹ 378 crore

Mumbai, India: Torrent Pharma posted results for the first quarter ended 30 June, 2023.The company's net profit stood at ₹ 378 crores, while Revenue was at ₹ 2,591 crores up by 10%. The operating EBITDA was at ₹ 791 crores up by 11%, while Adjusted for one off income in both periods, it is up by 16. The company's India revenue was at Rs 1,426 crores grew by 14.5%, while Germany revenue was at Rs 258 crores was up by 21%. While US revenue was at Rs 293 crores, was down by 2%. As per AIOCD secondary data, Torrent's growth for the quarter was 9% as against IPM growth of 4%. Torrent Pharma, with annual revenue of more than Rs 9,600 crores, is the flagship Company of the Torrent Group, with group revenue of ~₹ 37,000 crores.

Gland Pharma Q1 revenue from operation rises 41%

Hyderabad, India: Gland Pharma Limited, a generic injectable focused pharmaceutical company, announced its financial results for the first quarter ended June 30, 2023. During the first quarter of financial year 2024, Revenue from operation grew by 41% as compared to corresponding quarter of the previous year of which 37% contributed from the acquisition of Cenexi and 4% from the base business. The Company has improved Gross Margin both on yearly and sequential basis due to improved margin from the base business US portfolio and Cenexi's margin profile. The company's total capex incurred during the quarter ended June 30, 2023 was ₹ 687 million

Commenting on the results, Srinivas Sadu, MD & CEO of Gland Pharma said "I am pleased to share that the efforts made for business recovery, after a challenging previous year, are yielding fruitful results. The operating revenue for the quarter stood at ₹ 12,087 Mn, a y-o-y growth of 41% with an EBITDA of ₹ 2,982 Mn. The outcomes of the recently conducted US FDA inspections at three of our sterile facilities demonstrate our commitment to being a quality-focused and regulatory-compliant company. Maintaining an unwavering focus on quality and regulatory compliance establishes trust with our partners and will keep us in good stead in further strengthening our customer base." The total R&D expense for Q1FY24 was ₹ 457 million which is 5% of revenue from operation (excluding Cenexi). During the quarter we have filed 5 ANDAs and received approval for 9 ANDAs.As of Jun 30, 2023, we along with our partners had 337 ANDA filings in the United States, of which 270 were approved and 67 pending approvals.

Eris Lifesciences Q1 PAT stood at ₹ 936mn

Mumbai, India: Eris Lifesciences Limited, a leading Indian branded formulations manufacturing company, announced its earnings for the first quarter of FY24. The company's PAT for Q1 FY 24 is ₹ 936 mn with 20.1% PAT margin, while consolidated Revenue for Q1 FY 24 grew by 17.1% YoY to ₹ 4,666 mn. The company's consolidated EBITDA for Q1 FY 24 grew by 31.4% YoY to ₹ 1,697 mn. Branded Formulations segment revenue grew by 21% yoy. Eris Lifesciences Ltd. is a publicly listed Indian pharma company with a pure-play domestic branded formulations business model. Established in 2007, Eris ranks 21st in the Indian Pharmaceutical Market ('IPM') and is by far the youngest company in the IPM Top-25. Commenting on the results, Amit Bakshi, Chairman & Managing Director of Eris Lifesciences Ltd., said, "All strategic investments we made in FY23 have started delivering tangible and measurable results right from Q1 of this year. Our strategic priority for FY24 is to accelerate our organic growth trajectory and expand our covered market." Krishnakumar V, Executive Director & Chief Operating Officer of Eris Lifesciences Ltd., added, "We continue to be among the Top 10 fastest growing companies in the market on a MAT basis. In FY24, we target to cross ₹ 2000 crore in revenue with an EBIDTA growth of 30%."

Hester Biosciences Limited Q1 net profit rises 88%

Rajiv Gandhi, MD & CEO, Hester Biosciences

Ahmedabad, India: Hester Biosciences Limited, one of India's leading animal health company, manufacturing vaccines and health products has reported consolidated net profit of ₹ 6.71 crore in Q1FY24 ended June 2023 as against net profit of ₹ 3.56 crore in Q1FY23, growth of 88%. The company reported revenue from operations of ₹ 87.85 crore for the Q1FY24, growth of 73% Y-o-Y as compared to revenue of ₹ 50.70 crore in Q1FY23. Operating profit during Q1FY24 ended June 2023 was reported at ₹ 14.36 crore, 93% growth Y-o-Y from ₹ 7.43 crore in Q1FY23. EPS for Q1FY24 was reported at ₹ 7.89 per share. The consolidated results include operations of subsidiaries from Nepal and Tanzania. Hester Nepal had a turnover of ₹ 6.54 Crore primarily from exports of vaccines with overall Net Profit of ₹ 3.67 Crore during Q1 FY24. Hester Africa has registered export sales of ₹ 1.76 Crore.

The company's Petcare division which was launched last year, has registered promising sales of ₹ 0.80 Crore in Q1 FY24. Petcare products have been well received in the market as reflected by a steady upward trend in month-on-month sales. During the period, the Company has exported other pharmaceutical products aggregating to ₹ 26.79 Crore.

IOL Chemicals and Pharmaceuticals Q1 net profit grows 32% YoY

New Delhi, India: IOL Chemicals and Pharmaceuticals Ltd, a leading manufacturer of pharmaceutical APIs and speciality chemicals, announced its financial results for the first quarter ended June 30, 2023. The company's Net profit for Q1 FY24 at ₹ 46 crore as compared to ₹ 35 crore YoY, while total income for Q1 FY24 stood at ₹ 570 crore at the same level of ₹ 570 crore YoY. EBITDA for Q1 FY24 at ₹ 80 crore as compared to ₹ 61 crore YoY.

Commenting on the performance, Vikas Gupta, Joint Managing Director, said "We are pleased to report sustainable performance during the 1st quarter of FY24, tackling present challenges while positioning ourselves for forthcoming opportunities. We are hopeful for increased presence in regulatory market as the Company got CEP for paracetamol. Additionally, with the commencement of Acetic Anhydride plant, focus on improved efficiencies, product mix and timely execution we are hopeful to generate strong cash flow". ■

Complete Pharma Solution – Testo Saveris Pharma

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Complete Pharma Solution – testo Saveris Pharma

A sector like pharmaceuticals which is, governed by strict norms and regulations must operate with utmost efficiency. Testo provides the best-in-class solution for comprehensive data monitoring & management for equipment as well as environmental parameters in pharma industry called as the **testo Saveris Pharma.** It is an automated system that is integrated in the facility & constitutes of wireless or Ethernet probes installed at different locations that are connected to one base station to document and monitor all measurement data of its own. The monitoring process is uninterrupted, and the system provides number of alarm options in case the measurement values violate the defined limit values.

Some advantages of testo Saveris Pharma for environment and equipment monitoring system include:

- Holistic system comprising sensors, software, and services
- In accordance with 21 CFR Part 11 and GAMP compliance
- Provides seamless recording, automated tamper proof documentation
- Secure triple layer storage of the measurement data of all audit-relevant parameters
- The data is stored in the probes, so even if software connectivity is lost the data is safe and can be downloaded once the software is logged in
- Real time alarm facility to highlight unexpected results

Testo Saveris Pharma system consists of testo Saveris base V 3.0 which is the core component of the system. It manages & evaluates data from all over the facility from 3000 channels. The four testo 150 data logger modules can be flexibly combined with the three communication modules (WLAN, LAN, testo UltraRange) making it very convenient and user-friendly system along with the web-based, intuitive cockpit to detect alarms, initiate corrective measures and to acknowledge them whenever necessary.

Application areas

Manufacturing/ Production area | Research & QC labs | Cleanrooms and data centers | Warehouses and packaging | Deep freezers, refrigerators, cold rooms | Incubators, Stability test and walk-in chambers | Blood and tissue banks | Autoclaves and nitrogen tanks | Sterilizers and many more

Our specially trained service team supports you throughout the process in a very systematic way – from planning, documentation, system qualification and software validation through to service and support. Testo also has a NABL accredited service & calibration LAB that takes care of the after sales support locally from Pune. ■

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GUEST COLUMN

Indian Pharmaceutical Industry following the Good Manufacturing Process (GMP)- Entod Pharmaceuticals

Nikkhil K Masurkar
CEO
Entod Pharmaceuticals

Nikkhil K Masurkar spoke about how Current Good Manufacturing Practice and Good Manufacturing Practice is important in ensuring the quality, safety, and efficacy of pharmaceutical products for the Indian Pharmaceutical Industry.

The Indian pharmaceutical industry, often recognized as the "pharmacy of the world," faced a significant spotlight last year due to the alleged deaths of children in Gambia caused by an Indian syrup. Despite this unfortunate incident, India remains at the forefront of vaccine production and is the largest supplier of generic drugs worldwide, offering affordable pharmaceutical products without compromising on quality, performance, and safety. With India already contributing over 20 percent of the global supply of generic drugs, the country's pharmaceutical sector is poised for further growth as exports continue to soar. However, this expanding industry also brings inherent risks, including the potential for tainted and counterfeit medicines, thereby putting India's regulatory bodies to the test. To ensure the integrity of the Indian pharmaceutical market, adherence to stringent Good Manufacturing Practices (GMP) becomes crucial. GMP serves as the foundation for maintaining product quality, safety, and efficacy, safeguarding not only the reputation of Indian pharmaceutical companies but also the well-being of patients worldwide.

Good Manufacturing Process (GMP) – What is it?

GMP, or Good Manufacturing Practice, is a comprehensive manufacturing system that ensures the production and control of various products, including medical devices and pharmaceuticals, in accordance with specific quality standards. These practices encompass every stage of the manufacturing process, aiming to minimize and ideally prevent risks such as cross-contamination, mislabeling, failures, and other

potentially catastrophic issues. Several key areas are integral to the GMP guidelines, including sanitation and hygiene, building, facilities, and equipment, raw materials, quality management, personnel, complaints, documentation and recordkeeping, validation and qualification, as well as inspections and GMP audits.

By emphasizing on these areas, manufacturers strive to achieve GMP compliance. Adherence to Good Manufacturing Practices requires that products are consistently of high quality, designed for their intended use, and capable of meeting the requirements outlined in marketing authorization and/or clinical trial authorization. It is through the meticulous implementation of GMP that manufacturers can assure the integrity, safety, and efficacy of their products, promoting consumer trust and upholding regulatory standards.

The enforcement of Good Manufacturing Practice (GMP) regulations is carried out by individual states and regulatory bodies across the globe. In the United States, the responsibility lies with the US Food and Drug Administration (USFDA). Similarly, in the European Union, National Regulatory Agencies such as the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK oversee GMP compliance. In India, the Central Drugs Standard Control Organization (CDSCO) under the Ministry of Health and Family Welfare is responsible for ensuring GMP compliance within the pharmaceutical industry.

One of the primary regulatory standards for maintaining pharmaceutical quality is the Current Good Manufacturing Practice (CGMP) regulation specifically designed for human pharmaceuticals. This standard is essential in meeting consumer expectations, as individuals rely on the assurance that each batch of medicine they consume adheres to quality standards to ensure their safety and effectiveness. By upholding CGMP regulations, regulatory authorities and manufacturers work together to safeguard public health and maintain the trust of consumers in the pharmaceutical products they rely on.

Why GMP and CGMP is Important for the Indian Pharmaceutical Industry

GMP (Good Manufacturing Practice) and CGMP (Current Good Manufacturing Practice) play a crucial role in ensuring the quality, safety, and efficacy of pharmaceutical products within the Indian pharma industry. Here are some reasons why GMP and CGMP are important:

Product Quality: GMP and CGMP standards set stringent guidelines for manufacturing processes, ensuring that pharmaceutical products are consistently produced to high-quality standards. Compliance with these standards helps prevent manufacturing errors, contamination, and deviations that could compromise the quality of medicines.

Patient Safety: GMP and CGMP regulations prioritize patient safety by minimizing the risks associated with substandard or counterfeit drugs. By implementing robust quality control measures, including proper documentation, testing, and traceability, the industry can mitigate the chances of distributing unsafe or ineffective medications to patients.

Regulatory Compliance: Adhering to GMP and CGMP regulations is essential for compliance with the regulatory authorities in India, such as the Central Drugs Standard Control Organization (CDSCO). Compliance not only ensures smooth operations within the industry but also helps maintain India's reputation as a trusted global pharmaceutical supplier.

International Acceptance: Indian pharma companies heavily rely on exports to global markets. Compliance with GMP and CGMP standards is a prerequisite for international market access, as many countries require proof of adherence to these regulations. Meeting these standards enhances the reputation and competitiveness of the Indian pharma industry in the global market.

Quality Management Systems: GMP and CGMP guidelines promote the establishment of comprehensive

quality management systems within pharmaceutical companies. These systems encompass various aspects of manufacturing, including documentation, training, risk management, and quality assurance. Implementing such systems ensures continuous improvement, consistency, and reliability in the production of medicines.

Patient Confidence and Trust: GMP and CGMP compliance instills confidence and trust in patients and healthcare professionals regarding the safety and efficacy of pharmaceutical products. When patients have faith in the quality of medicines they receive, it strengthens their trust in the Indian pharma industry as a whole.

GMP Non-Complaince – How to tackle it?

There is often a debate surrounding how a manufacturing facility approved by a local regulatory agency may still have gaps in compliance with current Good Manufacturing Practices (cGMP) identified by foreign regulatory agencies. The World Health Organization (WHO) has revised its guidelines multiple times since the 1992 version, with supplementary guidance documents issued in 2002, 2006, 2008, 2014, and more. Additionally, the Pharmaceutical Inspection Co-operation Scheme (PIC/s) updates its GMP guidelines annually. In India, Schedule M of GMP was incorporated in 1988 and revised in 2001 to align with WHO Technical Report Series (TRS) recommendations.

To address these compliance issues and bridge the gaps, it is essential for every pharmaceutical industry to prioritize employee training. Training is typically scheduled in two ways: in response to identified deficiencies in performance or qualification, and according to a predetermined calendar.

Deficiency-based training includes activities such as new employee orientation, business process redesign, standard operating procedure (SOP) revision, and technical training. In these cases, training aims to equip trainees with the necessary skills, knowledge, and motivation to address identified gaps.

Continuing education programs play a vital role in ensuring ongoing learning and professional development. It is important to consider continued education as an opportunity and an asset to one's profession. Conducting a competency assessment can help identify areas that require improvement or specific attention.

Regulations from the US Food and Drug Administration (FDA) emphasize the need for continuing cGMP training. For finished pharmaceutical products, the FDA explicitly states that training in current good manufacturing practice should be conducted by qualified individuals continuously to ensure employees remain familiar with applicable cGMP requirements. The European Union (EU) similarly emphasizes the importance of continuing training in GMPs, stating that newly recruited personnel should receive appropriate training based on their assigned duties, and continuing training should be provided.

Conclusion

In conclusion, adherence to Good Manufacturing Practice (GMP) and Current Good Manufacturing Practice (CGMP) is of utmost importance for the Indian pharmaceutical industry. By implementing these rigorous standards, manufacturers can ensure the consistent production of high-quality medicines while prioritizing patient safety. Compliance with GMP and CGMP regulations not only ensures regulatory compliance but also enhances the industry's reputation globally. Furthermore, addressing compliance gaps and investing in employee training are crucial steps in bridging deficiencies and upholding the integrity of the pharmaceutical sector. By embracing GMP and CGMP principles, the Indian pharmaceutical industry can continue to thrive as the "pharmacy of the world" while safeguarding the well-being of patients worldwide. ■

"Strategic growth initiatives, product and geographical expansion, and operational efficiency are likely to contribute to growth going forward"

Mahendra Patel
Managing Director
Lincoln Pharmaceuticals Ltd

Mahendra Patel talks about the overview of the pharma industry and plans for export market. He also spoke about company's future roadmap and strategy, capacity expansion plan, product launches and growth target for next year.

Please share your thoughts about the overview on the pharma industry.

The Indian pharmaceutical industry is a prominent global player, known for its significant production of generic drugs and affordable medicines. It ranks among the largest producers of generic pharmaceuticals worldwide, catering to both domestic and international markets. India's expertise in API manufacturing and its robust export business contribute to its "Pharmacy of the World" reputation. Despite challenges, such as increasing competition, stringent regulations, and the need for continuous innovation, the sector continues to grow, supported by government initiatives and investments in research and development, strengthening India's position in the global pharmaceutical market.

What is the company's roadmap and strategy going forward?

Strategic growth initiatives, product and geographical expansion, and operational efficiency are likely to contribute to growth going forward.

Over the last 5 years, the company has delivered a robust 15% plus CAGR in profits and higher single-digit growth in sales. The company has been reporting strong operational and financial performance and has managed to grow its profit margins from around 9% in FY18 to over 14% in FY23.

Going forward, the company looks to maintain the strong growth in the domestic and exports market.

Commercial operations of Cephalosporin Plant and Export to EU & Australia will fuel growth. Company aims to maintain healthy growth in Sales, EBITDA and Net profit margins while maintaining 'Net Debt Free' status '.

The company is planning deeper penetration in the domestic market in the focused therapeutic areas and continue to build a strong portfolio in lifestyle and chronic segment especially women healthcare, dermatology to complement its strong presence in the acute segment.

Please tell us about the Mehsana capacity expansion plan.

In September 2021, the company acquired a plant in Mehsana, Gujarat to launch Cephalosporin products. The company has invested Rs. 30 crore in the cephalosporin plant – including acquisition and subsequent capacity expansion using an internal source of funds. Company has completed the capex for Cephalosporin products.

During FY23, company got an approval from WHO-GMP for Tablet Capsule, dry-powder Suspension products at Cephalosporin plant. The production from this plant is expected to start soon. The acquired facility in Mehsana has been designed as per the PIC's and European Region. Company has started product registration for the domestic and exports market.

Cephalosporin is a bactericidal, broad-spectrum, and □-lactam antibiotic originally derived from fungus Acremonium, which is used to treat bacterial infections such as pneumonia, skin infections, ear infection, strep throat, staph infections, tonsillitis, bronchitis and others. The global cephalosporin market size was valued at $13.69 billion in 2019, and is estimated to reach $16.87 Billion by 2027, growing at a CAGR of 2.6% from 2019 to 2027. The plant is expected to contribute sales of around Rs. 150 crore in the next 3 years. The company has received approval from WHO-GMP for Tablet Capsule, dry-powder Suspension products.

What are your plans for European Union market?

The company has received TGA – Australia and European Union (EU) GMP certification from Germany FDA for its manufacturing facility located at Khatraj in Gujarat. The certification allows the company to market its products in all the 27 member countries of EU and also give access to European Economic Area (EEA) countries. Company has started product registration and likely to commence the operation soon.

The company plans to enter EU markets with its dermatology, gastro and pain management products and gradually expand product portfolio. TGA - Australia and EU GMP approvals will strengthen the company's presence and expand its network to 90 plus countries.

Comment on your R&D front.

The company invests sizable amount for the R&D, innovation and new product development. And key strength is embedded in its cutting-edge research and development capabilities. The company has a strong R&D team including 30 plus scientists. It has filled 25 plus patent applications and is awarded seven patents. R&D facility of the company is recognised by the Department of Scientific and Technology, Government of India and furnished with state-of-the-art devices and equipment for internal physical, chemical and microbiological analysis of all products.

What are your plans for export markets?

Our export business has shown strong growth over the years. It currently exports to 60 plus countries including East & West Africa, Central & Latin America and Southeast Asia. Export sales is over 55-60% of the total revenues of the company.

The company is reporting excellent growth in the domestic and export operations and expected to grow at a healthy double digit in the years to come. Domestic Sales for FY23 was Rs. 220 crore while export segment reported sales of Rs. 290 crore. TGA - Australia and EU GMP approvals will strengthen the company's presence and expand its network to 90 plus countries.

Brief us about the new product launches in lifestyle and chronic segment.

The company has over 1700 registered products and another 700 in pipeline. During FY23, company launched 18 products in the domestic market and filled 130 dossiers in the export market. The company will continue to build a strong portfolio in lifestyle and chronic segment especially women healthcare, dermatology to complement its strong presence in the acute segment.

The company has developed 600 plus formulations in 15 therapeutic areas and has a strong product/ brand portfolio in anti-infective, respiratory system, gynaecology, cardio & CNS, anti-bacterial, ant-diabetic, anti-malaria among others. Company has filed 25 plus patent applications and is awarded with seven patents.

Please share the insights about your financials.

The company has reported a standalone net profit of Rs. 19.01 crore for the Q1 FY 2023-24 ended June 2023 as against net profit of Rs. 15.01 crore in Q1 FY2022-23, growth of 26.66% Y-o-Y. The company's total income for the quarter ended June 2023 was reported at Rs. 143.31 crore, higher by 10.27% Y-o-Y over total income of Rs. 129.97 crore in Q1 FY2022-23.

The company's EBITDA for Q1FY24 was reported at Rs. 28.41 crore as compared to EBITDA of Rs. 23.41 crores in Q1FY2022-23, growth of 21.36% Y-o-Y. EPS for Q1FY24 was at Rs. 9.49 per share. During FY23, company launched 18 products in the domestic market and filled 130 plus dossiers in the export market. In FY24, the company will continue to build a strong portfolio in lifestyle and chronic segment especially women healthcare, dermatology to complement its strong presence in the acute segment. The company has over 1,700 registered products and another 700 in pipeline.

What is your growth target for next year?

The company is growing from strength-to-strength over the years and expects to maintain the growth in years to come. The company has set a target of achieving Rs. 750 crore revenue by FY26 while maintaining or improving its margins.

For FY23, company has reported its results in a financial year with highest - Revenue, EBITDA and Net Profit. The company achieved milestone of Rs. 500 crore plus revenue and Rs. 100 crore plus profit before tax for the first time in a financial year. ■

GUEST COLUMN

Emerging cybersecurity challenges in the digitization era for the Pharma Industry

Sanjay Kaushik
Managing Director
Netrika Consulting

Sanjay Kaushik talks about the cybersecurity challenges for the pharmaceutical industry and pharmaceuticals are witnessing a surge in cyberattacks. He also spoke about how pharmaceutical industry plays a catalytic role in providing essential medications and healthcare solutions to the nation's population.

Thanks to technological advancements, today's ever-evolving business landscape is witnessing robust growth. Among various industries, the pharmaceutical sector emerged as a prominent player that has embraced modern advancements. With modern advancements, the industry has undergone a digital transformation to enhance customer experiences more effectively and efficiently. With its diverse and promising nature, the pharma industry has leveraged myriad solutions to cater to the diverse needs of patients. While digitalization has significantly benefited the sector, it has also brought several challenges, with cybersecurity attacks being the most prominent.

Today, all subsets of the healthcare sector, particularly pharmaceuticals, are witnessing a surge in cyberattacks. According to CheckPoint Research, the healthcare sector has witnessed a significant rise, with a 22% increase in cyberattacks compared to the first quarter of 2022. Thus, adopting strategic approaches such as robust cybersecurity measures, strict regulatory compliance, and continuous efforts to combat misinformation and counterfeit drugs has become an urgent and essential requirement for the pharmaceutical industry. But before that, one needs to understand the details of why solid cybersecurity is the need of the hour for the industry.

Pharmaceutical Industry: catalysts for economic growth

The pharmaceutical industry plays a catalytic role in providing essential medications and healthcare solutions to the nation's population. In addition, the sector is also a significant contributor to building the country's economy by generating substantial revenue and employment opportunities. The Market size of the Indian pharmaceutical industry is expected to reach US$ 65 billion by 2024 and ~US$ 130 billion by 2030. According to government data, the Indian

pharmaceutical industry is worth approximately US$ 50 billion.

There are some emerging cybersecurity obstacles hampering the growth of the pharmaceutical sector.

Data Breaches: Cyberattacks can cause much more damage than we can imagine. In this context, one significant threat that comes to light is data breaches, where all sensitive medical and research data can be compromised. This attack can lead to privacy issues, potential misuse of critical information, and monetary losses. As per IBM, the country has reported a 28% increase in data breaches since 2020, with an average cost of 17.9 crores.

Ransomware: Another challenge is ransomware attacks, where a cybercriminal encrypts the data and holds it hostage, as a condition of receiving payment. As access to the data is restricted, it impacts the information's confidentiality, integrity, and availability. According to the Ransomware Report 2022 by CERT-In, India has seen a 53% increase in ransomware attacks. The growing reliance on connected devices and networks has exposed pharmaceutical companies to ransomware threats.

Phishing Attacks: Given the increased use of online devices and software, Cybercriminals exploit vulnerabilities through deceptive emails, websites, or messages to steal sensitive information, compromise research data, and gain unauthorized access to critical systems. Along with the surge in phishing attacks, smishing and deep-fake attacks will also increase. Furthermore, with the rise of new-age technologies, there will likely be great opportunities for data leaks of sensitive and confidential information.

Robust Cybersecurity: Need of the Hour

The advent of digitalization has streamlined various aspects of the pharma industry. However, it has also exposed them to several difficulties, the most serious of which are cybersecurity threats, such as ransomware, phishing, and data breaches. Pharmaceutical companies are cash rich. In addition, the data for this industry is vital to them, but also affects other industries, such as the healthcare sector. As India doesn't have a data protection/privacy act thus, it is even more critical for the pharmaceutical industry to prioritize cybersecurity measures, regularly evaluate risks, use strong data encryption, train staff members on best cybersecurity practices, and work with specialists in the field to preventatively combat emerging threats. It is, therefore, safe to say that in a bid to strive in today's digital era, robust cybersecurity for the pharmaceutical industry is the need of the hour. ■

INTERVIEW

"Our focus in India is to deliver innovations to address the need gaps in therapies for non-communicable diseases and women's health."

Manoj Saxena
Managing Director
Bayer Zydus Pharma

Manoj Saxena spoke about the expansion plans, key focus areas and growth drivers going forward. He also talked about the innovations, product launches and to bring new therapies to help address unmet medical needs.

What are the emerging challenges & factors impacting your business?

India's population, while growing rapidly, also accounts for an increasingly aging population, susceptible to Non-Communicable Diseases (NCDs). The burden of NCDs such as cardiovascular disease, diabetes, chronic kidney disease, and cancer is very high in the country. In India, there are between 8-10 million people with heart failure. The average age of Indian HF patients is 50-60 years, a decade younger than their Western counterparts. India also now has the second largest population (100 mn) of people with diabetes with almost >30 Mn patients suffering from CKD & T2D. The rise in chronic health conditions, lifestyle and environment-related health issues has also had a noteworthy influence on the activity of the women's healthcare sector.

Though life expectancy has increased, quality of life may not increase in tandem due to the high burden of such NCDs. This is especially true for people living in peri-urban and rural areas, who need sustained access to robust healthcare systems designed to manage, treat and diagnose diseases on time. These factors make India a potential market to introduce innovative therapies to address these growing unmet health needs.

The Government has taken cognizance of the rising NCD burden in recognizing it as a national priority. However, to tackle these diseases holistically, innovation and R&D are key. This includes innovation across drug development, diagnostics, access mechanisms and even regulatory pathways.

Collaborations between industry stakeholders along with those in policy, academia, and patient support groups, are critical to understanding the challenges and can also aid long-term pharmaceutical innovation in the country. It is equally imperative to leverage emerging digital technologies to enhance patient centricity, enabling individualized, effective, and efficient care, thereby improving health outcomes at large.

This provides an opportunity for Bayer to support the sector's efforts in providing patients access to drugs and innovative healthcare solutions, thereby reducing the prevalence of unmet needs in India. Bayer is actively using technology and digitalization, which enables integrating rural communities into larger health networks, enhancing health literacy about key diseases. As India emerges to be a favourable destination for clinical trials and Bayer is harnessing this opportunity to advance clinical trials across a range of potential therapeutic modalities and indications, with a focus on oncology, cardiovascular, diabetes, ophthalmology and women's health.

While India provides a favorable environment for innovation and growth, there is a need to streamline the regulatory framework, in line with international standards so that investments in innovation are uninterrupted. A stable IP policy environment and a well-defined pricing regime taken into consideration the cost of research and development. The value offered to patients in terms of improved treatment outcomes can resolve the bottlenecks in the IP ecosystem.

We aim to harness this mindset to encourage investment in research and development and help introduce innovations to the Indian market rapidly. Bayer's focus is to accelerate the expansion of our portfolio of innovative medicines and bring new therapies to help address unmet medical needs.

Brief us about the expansion plans.

The Union Budget 2023 gave a boost to the pharmaceutical industry by increasing the fund allocation by more than 12 times from Rs 100 crore to Rs 1,250 crore for the fiscal year for drugs and medical devices. In line with this, Bayer continues to strengthen its research and development pipeline in the country. We believe the government's push towards bolstering research in the country is a positive step towards

pharmaceutical innovation at large. We are actively looking at opportunities to leverage technology and data to strengthen the drug discovery process, especially for diseases that pose an urgent unmet need in the country.

Bayer has been building up its cell and gene therapy capabilities, globally, through a combination of strategic partnerships and acquisitions. Our goal is to develop new treatments for disease and therapy areas where current options are very limited or don't exist. We believe that cell and gene therapy holds tremendous promise for the future of medicine, and we're excited to be at the forefront of this field. Our Centre of Excellence for Pharmaceuticals in Hyderabad supports global drug discovery and manufacturing initiatives. The center plays a huge role for Bayer Pharma in producing clinical trial deliverables to the highest standards. Additionally, it enables us to create meaningful job opportunities in the country owing to the growing talent pool in data and analytics. Bayer has also collaborated with several technology partners, like TCS, Accenture, Wipro, etc. to support our R&D efforts in the area of pharmacovigilance, clinical trials and drug development.

Could you brief us about the growth drivers for future?

India is a strategic market for Bayer Pharma and we have been introducing new drugs in the country at the same time as in the western countries and sooner than in other parts of the world. Bayer Pharma's current business focus in India is to deliver innovations to address the need gaps in therapies for non-communicable diseases and women's health. In the last two years, we have launched innovative drugs like Kerendia (for diabetes and chronic kidney disease (CKD), Nubeqa (for prostate cancer), and Verquvo (for worsening heart failure).

At Bayer, we are driven by our purpose of 'Science for a better life' to help people living with these particular NCDs. We are committed to investing in cutting-edge technologies to enhance research, innovation, and advancements in these areas. We are also bringing innovative products into the women's health segment and are also driving advocacy efforts for several issues related to women's reproductive health such as unwanted hysterectomies and endometriosis.

Apart from introducing innovative products, Bayer's sustainability and health initiatives are a step towards reducing disease disparities among underserved communities in the country. Bayer and the National Cancer Institute of India-All India Institute of Medical Sciences (NCI-AIIMS) have partnered to improve cancer care in the country.

Our continued partnership with the Federation of Obstetric and Gynaecological Societies of India (FOGSI) enabled us to collaboratively work on initiatives in the area of family planning and safe contraception. We plan to meet the contraceptive needs of 100 million women by 2030 in low to middle-income countries, our work in India will be crucial. In collaboration with the Family Planning Association of India (FPAI) and United Nations Population Fund (UNFPA), Bayer is driving both access and awareness to resources that will contribute to family planning and reproductive health outcomes.

What are the innovations and new products in the pipeline?

With a vision of 'health for all', our goal in India is to launch new assets while working towards expanding the accessibility and affordability of our already-launched drugs. We also plan to bring late-stage pipeline assets to the market sooner. Our sustainability initiatives include improving access to medicines to enhance the quality of life of Indian patients.

We work with an agile, innovative and research-focused model that enables bringing treatments and solutions faster with country-specific pricing ensuring affordability, so more patients can have access to our products & solutions. In India, a large number of people suffer from Diabetes and are at a high risk to develop complications, like chronic kidney disease.

There are no treatment options for end stage kidney disease except for dialysis or transplant. Our product, Kerendia, was launched to prevent the progression of chronic kidney disease due to diabetes into end stage kidney disease.

We are planning to launch an oral hormonal treatment for Heavy Menstrual bleeding in India soon. Globally, Bayer has a candidate for the treatment of vasomotor symptoms during menopause, which is one of our key late-stage projects and a priority in our pipeline. Going forward, we will focus on new launches in the women's health segment, while realizing the full potential of our projected candidates Nubeqa, Kerendia, as well as late-stage pipeline assets asundexian and elinzanetant. ■

How can Pharma SMEs transform swiftly and economically

Ashutosh Parasnis spoke about the significance of merging pharma manufacturing with digital technology. He also spoke about that there is need to focus on quality and compliance.

(Image by usertrmk on Freepik)

Preamble

Quality Control is of prime importance, which can certainly be tackled with process improvements. What is changing though is the rapid transitioning of Healthcare to a new world of personalisation, with a laser-like focus on outcomes and value. For that, healthcare systems need to understand additional data of exogenous factors such as environmental influences, behaviour, genetics, treatment outcome etc. to create and deliver value.

The Problem

What this means is that the pharmaceutical industry shall face increasing pressures. Stepping up the focus on quality and compliance is indeed the immediate need. The companies have to achieve it in a highly dynamic environment where speed, collaboration, and personalisation are becoming the norm.

Most pharma companies have sophisticated automated equipment installed on the shopfloor. Let us look at the top macro drivers which tell us why that is so.

- Skilled worker shortage and pressure to keep current leaders and workforce skilled to become more flexible and competitive.
- As raw material prices continue to rise, reducing production costs and keeping plant capacity utilisation high have become a priority for business owners.
- Quality and Compliances are being tightened.

Customers and Regulators are demanding increasing transparency.

- Need for personalisation will mean flexible manufacturing and lower volumes.

At the commercial level, in a report published by Bioplan Associates, it has been noticed that the top 3 reasons for batch failures are Operator Errors, Equipment Failure and Contamination – in that order.

As any business would know, the impact of batch failure can be significant ranging from absolute financial loss to shutting down the operations.

From the above, one can deduce that businesses need to focus on Embracing technology and leadership and workforce development.

The Concerns

Does it Apply to My Business?

While there may be in-principle agreement, in reality, no one wants to trigger changes when the outcome is not exactly known, especially SMEs.

The long-term perspective is the one which can give companies an assured ROI, provided they commit to the roadmap.

Our decade-long consulting experience in business growth and digital Transformation has established one fact- for any change to be successful in the shortest possible time, one has to focus on 4 key elements- An integrated Strategy, newly skilled leadership and workforce, creating a conducive work environment and reviewing processes.

While there is an intense focus on the implementation of technology, it must be remembered that success is dependent on how the correct choice and use of technology. Lack of skills or resistance to change can scuttle any well-designed strategy.

Compared to large pharma companies, SMEs face additional challenges such as access to capital, lack of technological expertise and infrastructure constraints being the major ones. We have worked with SMEs with great potential who are unable to gather momentum.

Does that mean that SMEs should stay behind? Well, there is a way out.

The Recommendation: "SME-Lite" Transformation.

After years of working with manufacturing companies that are large and small, family-owned and corporates, we recommend that SMEs should take a time-bound two-phase approach.

1. Fortify your Current Business: The objective is to streamline and free up financial, process and human resources to fully focus on the growth drivers of your business.
2. Become Future Ready: Understand how Smart and Connected business enables revenue and cost savings without large investments.

As far as Digital technologies are concerned, there is no reason to get overwhelmed. To be in control of transformation, you need to understand four basic technologies- Sensors, automation, networking and data analytics. Once you get a grip of these things, you will realise which technologies are best suited for you.

Actually, this approach works for companies of any size. It has proven to yield results that have helped our clients to adapt faster, move faster and grow faster even in disruptive conditions.

Business Benefits: The real benefits can be achieved in almost any area of business. A good practice is to demonstrate success through the simpler ones. It motivates the leadership and the workforce to sustain the momentum of change.

And to help you get started on the right track, 3 strong business use cases have been identified earlier.

As an example, to reduce Operator errors, one can start with a digital document control system where data is

digitised, stored and managed centrally. Later on this same data can be used for advanced analytics once a certain level of maturity is reached.

In Conclusion

Every pharma company is now part of a value chain that is increasingly getting integrated. The integration of digital technology into pharmaceutical manufacturing

processes offers a promising solution to achieve manufacturing with expected or superior standards.

Going Digital also opens up benefits on multiple fronts - to create new revenue channels, increase productivity, quality, compliance and speed, while lowering your costs and risks. Invest in people, to profit from technology.

So what should Pharma companies Do?

While Quality has shown improvement, in a changing scenario, without a comprehensive capabilities development strategy, companies will continue to face challenges. ■

Author

Ashutosh Parasnis
Founder, NewBox Consulting

GUEST COLUMN

Impact of Internet of Medical Things (IoMT) in Pharma

Mayank Kumar
Analyst, Technology Research
and Advisory
Aranca

Mayank Kumar spoke about Internet of Medical Things (IoMT) in Pharma and Supply chain. He also talked about how pharmaceutical companies must prioritize robust cybersecurity measures.

The pharmaceutical industry has long been at the forefront of innovation, inventing and developing life-changing medications for patients worldwide. With the advent of the Internet of Medical Things (IoMT), this industry is experiencing a transformative shift that has the potential to revolutionize drug discovery, streamline supply chain operations, and strengthen cybersecurity measures. IoMT devices, such as wearable health monitors, sensors, and smart pills, are opening up new possibilities for data-driven decision-making and patient-centric strategies. Some of the main application areas of IoMT are:

Drug Discovery and Development

Monitoring Patient Response - In the realm of drug discovery and clinical research, IoMT devices are proving to be invaluable tools for improving the efficiency and effectiveness of pharmaceutical processes. Real-time patient data collection is now possible, due to wearable health monitors, patches, and smart pills such as Abilify MyCite, Proteus Discover, and ID-Cap System. These devices continuously monitor vital signs, glucose levels, heart rate, and other essential health metrics, enabling healthcare providers and researchers to observe patient responses to medications in real time.

Measuring Drug Efficacy - The data collected is crucial in identifying early signs of adverse effects, tracking improvements in patients' conditions while on specific drugs, and assessing the efficacy of different medications for specific conditions. By leveraging machine learning algorithms for data analysis, including feature extraction, regression analysis, ensemble methods, and classification, researchers can uncover patterns and correlations that aid targeted drug development efforts.

Recruiting Patients for Clinical Trials - IoMT devices also play a pivotal role in patient recruitment for clinical trials. Leveraging data analysis and machine learning algorithms, researchers can identify eligible participants

who match specific inclusion criteria, streamlining the recruitment process and ensuring a diverse and well-matched pool of trial subjects. This approach leads to more reliable and generalizable results from clinical trials, ultimately accelerating the drug development timeline.

Bioinformatics for IoMT- The integration of bioinformatics with IoMT in the pharmaceutical industry is paramount for data processing and drug discovery. Various open-source software platforms like KNIME, RapidMiner, and Orange, alongside proprietary solutions such as Cognite Data Fusion, IBM Watson Health, Oracle Health Sciences Data Cloud, and SAP Cloud for Healthcare, facilitate data analysis, data mining, and predictive modeling. These platforms enable researchers to analyze vast amounts of data generated by IoMT devices, extracting valuable insights and driving evidence-based decision-making throughout the drug discovery and development process.

Supply Chain

IoMT's impact extends beyond drug discovery and development, significantly influencing the pharmaceutical supply chain. The implementation of IoMT devices and platforms empowers pharmaceutical companies to gather real-time data on various processes, including manufacturing, distribution, and patient usage.

Data-Driven Insights - By analyzing this real-time data, pharmaceutical companies can gain invaluable insights into inefficiencies and bottlenecks within the supply chain. Armed with this knowledge, companies can implement targeted improvements, streamline processes, and optimize resource allocation, ultimately leading to lean and more cost-effective operations.

Patient-Centric Strategies - The IoMT also enables pharma companies to develop patient-centric strategies, enhancing the overall patient experience. With the help of IoMT devices, patients can actively engage with their medication packaging, receive personalized information, and contribute to their treatment plans. This heightened level of engagement fosters better medication adherence and improved health outcomes for patients.

Risk Minimization through Agility and Visibility - The adoption of IoMT and data analytics provides pharmaceutical companies with great visibility into their supply chain. This heightened visibility enables proactive risk mitigation and effective responses to disruptions, ensuring a more agile and resilient supply chain.

Compliance and Regulation - While IoMT and data analytics offer significant benefits to the pharmaceutical industry, companies must prioritize robust security measures to protect against cyber threats and adhere

to data protection and privacy regulations. Ensuring the responsible and secure handling of patient data is crucial to maintaining trust and compliance with regulatory requirements.

Cybersecurity

Pharmaceutical companies must prioritize robust cybersecurity measures when utilizing IoMT devices to safeguard sensitive patient data and ensure the integrity of their operations. Key security measures include:

Robust Authentication and Access Controls - To enhance the security of IoMT devices, it is essential to establish strong authentication mechanisms and access controls. This involves implementing password policies, multi-factor authentication, and other appropriate methods to ensure that only authorized personnel can access the devices.

Regular Firmware Updates - To safeguard IoMT devices from known vulnerabilities, it is imperative to schedule and apply regular firmware updates. Keeping the devices updated with the latest software releases helps bolster their defenses against potential threats.

Network Segmentation - To mitigate potential risks, IoMT devices should be segregated from the corporate network. By adopting network segmentation, these devices are isolated from other systems and networks, reducing the attack surface and enhancing overall security.

Data Encryption - To safeguard sensitive data transmitted or stored on IoMT devices, it is crucial to implement robust encryption protocols. Encrypting data ensures that even if unauthorized individuals gain access to the information, it remains unreadable and protected.

Vulnerability Scanning - Conducting periodic vulnerability scans is vital to identify potential security flaws in IoMT devices. By proactively scanning and promptly addressing any vulnerabilities discovered, organizations can maintain a high level of security and reduce the risk of exploitation.

Biopharma Processing

The utilization of IoMT devices in biopharma processing has brought about significant advancements in various aspects of pharmaceutical manufacturing.

Real-time Monitoring - IoMT devices play a pivotal role in monitoring critical parameters, such as temperature, pH, dissolved oxygen, and nutrient levels, throughout the cell culture and upstream processing phases. The real-time data collection capabilities facilitate immediate adjustments and interventions, ensuring optimal conditions for cell growth and product yield.

Remote Sensing - Incorporating IoMT sensors and devices at different stages of the biopharma processing chain enables seamless remote monitoring of manufacturing facilities. This empowers experts and quality control personnel to assess processes and address issues without the need for physical presence on-site.

Data Analytics - The extensive data generated by IoMT systems can be leveraged for advanced analytics and machine learning algorithms. By analyzing this data, patterns can be identified, process parameters optimized, and potential deviations or failures predicted. Consequently, this drives enhanced process efficiency and reduces the likelihood of production errors.

Pharmacokinetics and Pharmodynamics - IoMT has proven to be invaluable in studying drug interactions, drug response, and characterizing drug responses. Notable studies on drugs such as gefitinib, rosuvastatin, and ipilimumab have extensively utilized IoMT technology to further our understanding in this area. IoMT is transforming the pharmaceutical industry by enhancing drug discovery, optimizing supply chain operations, and bolstering cybersecurity measures. IoMT will also contribute to personalized medicine plans for patients. With more sophisticated data analytics tools, patient care will evolve further. One significant trajectory will be amalgamation of real-time data analytics and machine learning algorithms, culminating in predictive models that can anticipate market demands and optimize production processes. This predictive intelligence could potentially revolutionize inventory management and minimize wastage, fostering a more sustainable and cost-effective industry. The emergence of IoMT within the pharmaceutical industry is not merely a trend but a completely new dimension that will design the future. ■

Prescription for a Greener Future

Sanjeev Jain, Jt. Managing Director, Akums Drugs & Pharmaceuticals talks about how pharmaceutical industry has been actively working to reduce its carbon footprint through various initiatives. He also talked about how pharmaceutical industry is investing in research and development to discover innovative green solutions.

In recent years, the call for environmental sustainability has grown louder across various industries. One sector that has been actively addressing this concern is the pharmaceutical industry. With its significant impact on global health, the pharmaceutical sector has recognized the need to align its practices with environmental conservation. Through innovative measures and a commitment to sustainable development, the industry is playing a vital role in paving the way for a greener future. This article explores how the pharmaceutical industry is driving environmental sustainability and the positive outcomes it brings.

Reducing Carbon Footprint

The pharmaceutical industry has been actively working to reduce its carbon footprint through various initiatives. From manufacturing processes to transportation and packaging, pharmaceutical companies are adopting cleaner technologies and sustainable practices. Many companies have implemented energy-efficient measures in their production facilities, reducing greenhouse gas emissions and energy consumption. Furthermore, the sector is exploring renewable energy sources such as solar and wind power to meet its energy needs, thereby reducing reliance on fossil fuels.

Waste Management and Recycling

Proper waste management and recycling are critical for minimizing the environmental impact of pharmaceutical operations. The industry is increasingly investing in advanced waste treatment technologies to ensure the safe disposal of pharmaceutical waste, including expired or unused medications. Moreover, pharmaceutical companies are implementing robust recycling programs to repurpose packaging materials and reduce plastic waste. These efforts not only

contribute to environmental sustainability but also help prevent contamination of water sources and ecosystems.

Sustainable Supply Chains

The pharmaceutical industry recognizes the importance of sustainable supply chains to achieve environmental goals. Companies are working closely with suppliers to ensure responsible sourcing of raw materials. This includes selecting suppliers that adhere to ethical and sustainable practices, such as sustainable farming and harvesting methods. Additionally, efforts are being made to reduce the carbon footprint associated with transportation and logistics by optimizing routes and exploring greener alternatives like electric vehicles.

Clean Water Management, Water Recycling, and Discharge

Through the adoption of water recycling, discharge initiatives, and clean water management practices, the pharmaceutical industry is actively working towards a more sustainable future. Companies are executing water recycling systems to treat and reuse water within their manufacturing processes. This reduces the reliance on freshwater sources and minimizes the overall water footprint. Technologies like advanced filtration, ultrafiltration, and reverse osmosis are used to remove contaminants, allowing the treated water to be reused for non-critical applications such as cleaning or irrigation.

These days, Zero Liquid Discharge (ZLD) systems are witnessing huge demand in the pharmaceutical industry as they enable companies to minimize wastewater discharge. These systems employ advanced treatment processes, such as evaporation and crystallization, to recover and concentrate dissolved solids, while the purified water is recycled back into the manufacturing process. This way, the pharmaceutical companies can reduce the environmental impact associated with wastewater disposal.

Research and Development for Green Solutions

The pharmaceutical industry is investing in research and development to discover innovative green solutions. This involves exploring alternative manufacturing processes that require fewer resources and produce less waste. Companies are also investing in the development of environmentally friendly drug formulations, such as water-soluble medications that minimize the release of harmful substances into the environment. By embracing sustainable practices at the R&D stage, the industry is ensuring a greener future throughout the lifecycle of pharmaceutical products.

Collaborative Partnerships and Advocacy

To drive environmental sustainability, the pharmaceutical industry is actively engaging in collaborative partnerships and advocating for sustainable practices. Many companies are joining industry alliances and working closely with environmental organizations to share knowledge and best practices. Furthermore, pharmaceutical companies are engaging with policymakers and regulatory bodies to encourage the adoption of environmentally friendly regulations and standards.

By leveraging their influence, the industry is fostering a collective effort to create a greener future. As the industry continues to prioritize environmental conservation, it sets an inspiring example for other sectors and reinforces the notion that environmental sustainability is not just an option but a necessity for the well-being of our planet. ■

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