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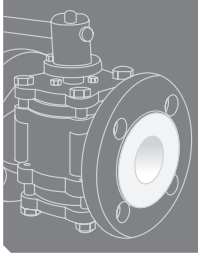

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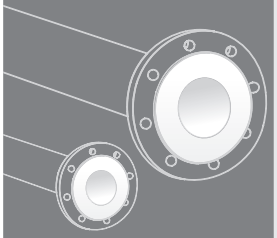

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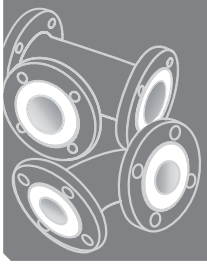

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CONTENTS

INTERVIEW

Suresh Garg
Managing Director
Zeon Lifesciences Ltd

FEATURES

Prabir Das
Head - Pkgg Tech Services,
OSD (India) Mylan Laboratories Ltd

Andreas Reitberger
Sales Manager
GFH GmbH

Garima Gupta
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AD INDEX

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IPCA Lab's Q3FY22 Result Update

Mumbai, India: IPCA Lab's (IPCA) Q3 performance was largely in line and we expect margin recovery from FY23 onwards. Domestic business (45% of total sales) continued to remain strong and should continue to outperform IPM. Strong API capabilities and diversified model benefit IPCA in the current environment. Our FY23E and FY24E earnings broadly remain unchanged. We recommend 'Buy' rating on the stock with target price of Rs 1,225 based on 23x FY24E earnings. Remain our preferred pick in mid cap space.

In line revenues aided by domestic segment: IPCA's sales grew 1.5% YoY at Rs 14.3bn vs our est of Rs 13.8bn. The domestic business grew 22% YoY aided by higher growth in acute segment and on good seasonality while export formulation was weak with 19% YoY decline. Institutional business declined 57% YoY, impacted by delay in shipments. Branded business grew by 41% YoY (on low base) while generics declined by 17% YoY. Export API declined by 22% QoQ due to lower sales from Sartans. Domestic API grew by 17% YoY. Revenue from subsidiaries in Q3 came in at Rs 1bn.

Steady GM; higher other expenses: EBITDA margins came at 20.8%, down 160bps QoQ impacted by negative operating leverage. Gross margins were at 65.1% in Q3, up 30bps QoQ and 170bps YoY mainly on better product mix. There was forex gain of Rs100m.Adj for forex, overheads grew 22% YoY led by higher freight cost. PAT declined by 26% YoY and 21% QoQ to Rs 2bn.

Key Concall takeaways: (1) Sartans constitute 30% of export API business, company has resolved the issue of Azido impurity however business stabilization will be gradual and should normalized from Q1FY23 (2) Guided for 67% GM however other expenses will continue to remain elevated in near term (3) Dewas commercialization of entire plant in H1FY23 however it has partially commercialized to fulfill certain shortages on KSM. (4) Delay in shipments impacted institutional business and guided for Rs3.5bn of revenues in FY22. (5) UK business likely to remain muted in FY23 and has shifted to own distribution model given delay in payments from third party distributors. (6) Domestic business – 25% of portfolio under NLEM and company will take benefit of entire price hike available. Overall will outperform IPM by 150-200bps. Pain segment contributing 48% of sales grew 22% YoY (ex-HCQS). Among other segments- Anti-bacteria, Cough & cold, Derma and Anti-malaria grew by 20%, 51%, 32% and 34% respectively for Q3FY22 (6) Company guided for 20% revenue growth in Q4 on standalone nos.

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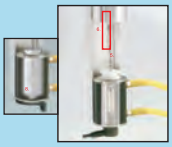
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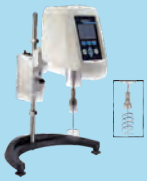
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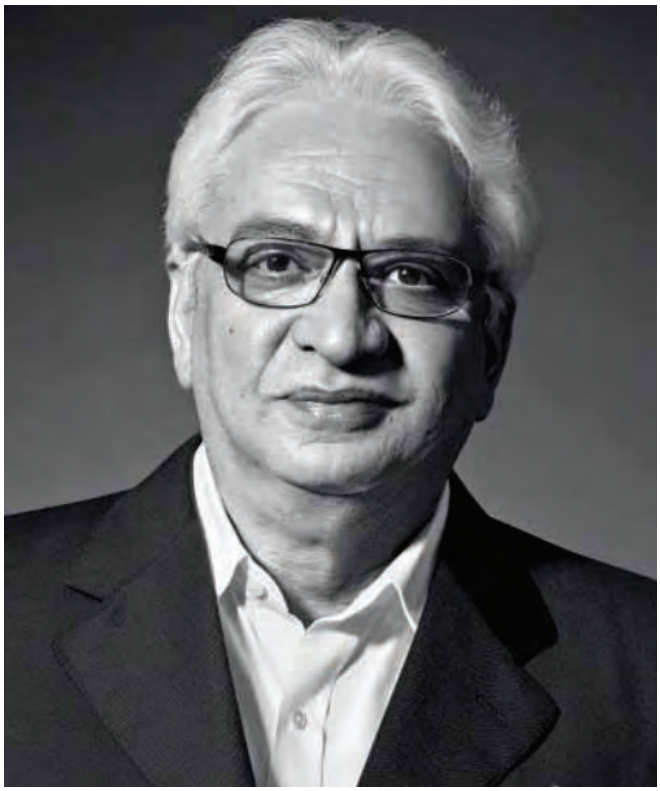
RHEOLOGY VISCOSITY TEXTURE IN-LINE POWDER MOISTURE GAS

Hikal Limited Reports PAT of Rs.45 Crores with a Resilient Quarterly Performance



Jai Hiremath, Chairman & Managing Director, Hikal Ltd

Mumbai, India: Q3FY22 Highlights are declared an interim dividend of 60%, Revenue of Rs. 515 crore; YoY growth of 11%, EBITDA of Rs. 93 crore; EBITDA Margin of 18.1%, PAT of Rs. 45 crores; YoY growth of 12%, Hikal's long term credit rating upgraded to A+ by ICRA.

Key Highlights are Change in product mix and increase demand of key products, Strong performance in Pharma own products and Crop Protection CDMO segments, Positive impact of higher sales curbed by unfavorable product mix and increased utilities, YoY PAT growth of 12% driven by increased EBITDA, reduced interest cost and change in tax regime, Lowered interest rates due to a combination of factors – improvement in Credit Rating and successful renegotiations, The Company declared an interim dividend of 60% i.e., Rs. 1.20/share, Pinnacle, our Business transformation initiative, is on track to create a roadmap across business vertical to drive growth as well as improve profitability, by giving new strategic direction and enabling to chart our progress in a sustainable manner.

Segmental Performance for the quarter ended 31st December 2021

Pharmaceutical sales remained flat at Rs. 268 crore as compared to Rs. 269 crore in Q3 FY21, Stable sales corresponding with change in product mix, Product mix change coupled with increased raw material and energy price, Higher fixed cost in combination with flat revenues resulted in lower EBIT, Several new customers acquired in different geographies, Anti-diabetic portfolio of APIs for future is receiving healthy traction from customers, Process development has started for several active ingredients for the multi-year Animal health project with a global innovator.

Commenting on the results, Jai Hiremath, Chairman & Managing Director, Hikal Ltd. said,

"Hikal has recorded a resilient performance in Q3 as we continued the growth trajectory that the company has established over the past few quarters. Despite the hurdles presented by global supply chain challenges combined with increasing raw material as well as utility prices, we have been able to grow our revenues as well as bottom line in the past quarter."

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- Instrumentation & Process Control
- Industry Automation (Process & Factory)
- Systems Integration & ERP Solutions Providers
- Water & Waste Water Treatment Consultants
- Environment Solutions Providers
- Waste Management Consultants
- Financial Institutions
- Fire & Safety Solutions Providers
- Material Handling Solutions
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- Quality Health & Environment Solutions
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- Packaging Materials, Machinery & Systems
- Business Consultants

FACTS & FIGURES - CHEMTECH WORLD EXPO 2019

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Scope for Specialty Chemicals World Expo 2022

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- Adhesives & Sealants
- Agrochemicals & Crop Protection
- Bulk Drugs & Intermediates
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- Cosmetics & Personal Care Ingredients
- Hygiene & Cleaning Chemicals
- Laboratory Chemicals
- Surfactants
- Water Treatment Chemicals
- Catalysts
- Electronic Chemicals
- Flavours & Fragrances
- Contract Manufacturers

Scope for Biopharma World Expo 2022

- Materials Processing
- Pharma Machinery
- Pharma Ingredients
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Elanpro launches its First Experience Center in Hyderabad

Sanjay Jain, Director, Elanpro

Gurugram, India: Underlining its commitment to offer quality products with best-in-class technology and efficient customer service, Elanpro, one of India's leading commercial refrigeration companies, announced the launch of its First Experience Centre in Hyderabad, Telangana. Spread across 500 sq. ft., the experience center is located at a prime location of the city – Madhapur, and seamlessly combines quality and technology under one roof, offering a unique, engaging, and immersive experience to our end users.

Establishing its footprint in Southern India, Elanpro is expanding its business and growing its presence across India. The newly launched experience center will give its customers access to various ranges under Retail, Hospitality, HoReCa, Bio-Medical, Food & Beverage sector. Additionally, qualified experts/representatives at the store will give users product demos.

Consisting of advanced technology, energy efficiency, and good quality, Elanpro's finest Commercial Refrigerators are designed ergonomically, giving its product an aesthetic look. The retail range offers variations in their dimensions & integration, whereas HoReCa products are equipped with quality and technology. Elanpro's wide range of Bar products and Bakery/confectionery is the perfect combination of unique style and display. The bio-medical range are equipped with best-in-class technology maintaining the temperature and efficacy of all medical products. In addition to this, Elanpro is proud to show off its temperature monitoring device, 'Thingif(y)', which is put in all of its products and keeps the temperature of all units' constant.

Mr. Sanjay Jain, Director, Elanpro said, "Elanpro has been at the forefront in developing quality and tech-enabled products in the commercial refrigerator segment. Expanding our product portfolio to a growing footprint across India, we enhance our brand approach and increase our visibility. South India is one of the growing markets which possesses several opportunities across industries, and entering Hyderabad is one of our biggest steps. With the launch of our new experience center, we will give our products experience to our end-users before purchasing. Moreover, we also expect to see significant outreach in our existing clients and expanding our clientele"

Dr. Reddy's Laboratories to Acquire German Medical Cannabis Firm Nimbus Health Gmbh

Hyderabad, India: Dr. Reddy's Laboratories Ltd, along with its subsidiaries together referred to as "Dr. Reddy's") announced that it has entered into a definitive agreement to acquire Nimbus Health GmbH ("Nimbus Health"). Nimbus Health is a privately owned, licensed pharmaceutical wholesaler from Germany focusing on medical cannabis in Germany. Dr. Reddy's will acquire Nimbus Health for an upfront payment plus performance and milestone-based earn-outs over the next four years. Founded in 2018, Nimbus Health is one of the pioneer companies for medical cannabis in Germany. The acquisition will allow Dr. Reddy's to build on Nimbus Health's strengths and introduce medical cannabis-based medicines as a promising treatment option for patients. The company will be operating under the brand Nimbus Health and as a wholly-owned subsidiary of Dr. Reddy's. The demand for medical cannabis has increased over the past years with the legalization of medical cannabis by the German Parliament (Bundestag) in 2017. The medical cannabis market in Germany is already valued at ~122 Mio. € with growth of ~25% in 2021 compared to 2020 and a CAGR of ~55 % since 2017, making Germany one of the largest markets in Europe. Around 150,000 German patients benefit from medical cannabis for their unmet health needs1 .

The closing of the transaction is subject to customary closing conditions. Patrick Aghanian, Head of European Generics, Dr. Reddy's, commented: "Medical cannabis is increasingly used to address and treat high unmet medical needs, especially in pain management and CNS. Further, with numerous studies being conducted to leverage and introduce medical cannabis, we believe this is a must-be field for future healthcare delivery. Nimbus Health has established itself as a fast-growing, highly reputable, pioneering platform with an excellent network of trade partners and know-how access, where the German sick-funds fully reimburse medical cannabis. As more European countries adopt the usage of medical cannabis, the ability to leverage and access newer geographies will be key. We are very excited that with Nimbus joining Dr. Reddy's family, together with Linus and Alessandro, we embark on a new, exciting journey of medical cannabis, which supports

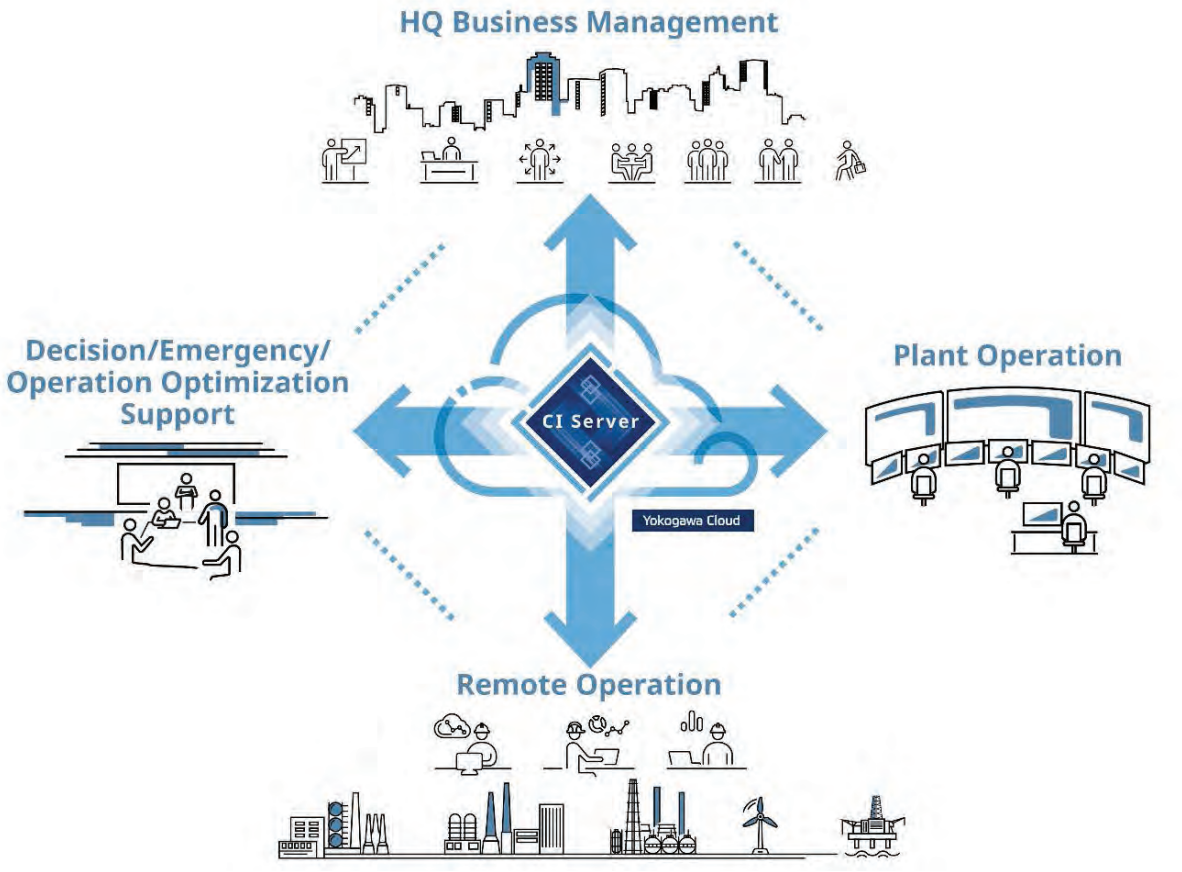
Dr. Reddy's mission of meeting unmet patient needs." "We were really excited when Dr. Reddy's approached us and recognized Nimbus's highly efficient importing, registering, and launching platform for various medical cannabis brands in Germany. The close alignment between the values of Dr. Reddy's and Nimbus gave us the confidence that we can stay focused on the existing business and grow future endeavors together.

Yokogawa Launches OpreX Managed Service Cloud edition

Tokyo, Japan: Yokogawa Electric Corporation announces that it will release Collaborative Information Server (CI Server) R1.02 in March 2022. This new version of CI Server, a product in the OpreX™ Control and Safety System family, will have the ability to be delivered on Yokogawa Cloud*1, the company's cloud platform.

Since its release in January 2021, CI Server has been adopted for use in plants all over the world. By integrating the handling of all kinds of data from plant equipment and systems, this solution facilitates the optimized management of production activities across an entire enterprise, while also providing a remote operation environment to ensure efficient plant operations from any location.

In order to help customers drastically reduce their system infrastructure design, maintenance, and management workload, this release of CI Server has been enhanced to enable cloud-based operation, in addition to conventional system configuration in an on-



premise environment. Customers will be able to use CI Server in a platform as a service*2 (PaaS) format that combines Yokogawa Cloud, a software license, and maintenance. The use of CI Server together with Yokogawa Cloud will ensure a high-security environment.

Key Benefits

- Lower cost project implementation and swift project launch

  Running CI Server in a cloud environment enables a reduction in the number of PCs and other such hardware in plants. This eliminates the need for design and configuration work necessary for hardware setup, and speeds up project development. Furthermore, given that projects can be launched without having to purchase additional hardware, initial implementation costs are lower.

- Safe and efficient operation

  With the reduction in hardware, maintenance workload is reduced. And as server capacity can be scaled up for cloud-based operations, it is possible with this version of CI Server to swiftly respond to changes in the operating environment.

The combination of CI Server with Yokogawa Cloud can also reduce the need for cloud environment-related maintenance. In addition, the provision of operating system updates, anti-virus software management, and security monitoring services help customers improve the safety and efficiency of their operations.

Yokogawa Cloud is an industrial transformation and IoT platform that accelerates the development and deployment of industrial cloud applications. It supports the ingestion, processing, and curation of data from various sources, provides industry-specific algorithms and models, and integrates across applications to support insightful decision-making and higher levels of automation.

The provision of a platform consisting of hardware, an operating system, and other components that runs software applications in the cloud. A PaaS includes the installation of all the hardware resources necessary for the deployment of CI Server in the cloud.

Major Target Markets

Oil and gas upstream, midstream gas and liquid pipelines, petrochemicals, chemicals, renewable energy, power, pulp and paper, pharmaceuticals, food, mining, iron and steel, water distribution, and wastewater treatment

Applications

Plant monitoring, operation, and control; data collection and storage; etc. ■

Market Dynamics of the Flourishing Pharma & Nutraceuticals Industry

Suresh Garg
Managing Director
Zeon Lifesciences Ltd

Awareness about preventive healthcare has increased tremendously after the pandemic. What is your observation & how does Zeon Lifesciences plan to leverage this opportunity in India & other global markets?

In 2019, preventive healthcare accounted for ~11% of India's overall healthcare expenditure. The preventive healthcare market in India was valued at INR 3.71 Tn in 2019 and is expected to reach INR 14.58 by 2025, expanding at a compound annual growth rate (CAGR) of ~27.30% during the 2020-2025 period. There's no doubt that the COVID-19 pandemic has put a spotlight on preventive healthcare. As a result, the nutraceuticals industry is experiencing tremendous growth. The outbreak has forced people to focus on aspects of immunity, wellness, and nutrition. That being said, with preventive healthcare being the most important line of defense in the fight against Covid-19

and its variants, the nutraceuticals sector is set for positive growth.

The global preventive healthcare technologies and services market size is expected to reach USD 432.4 billion by 2024, according to a new report by Grand View Research, Inc. The adoption of advanced technology and the development of preventive measures, such as vaccines, screening and monitoring devices, and smart devices to reduce medical errors, are credited with the market's growth. Factors such as lower birth rates are fueling market growth, resulting in an increase in the geriatric population, which is more susceptible to chronic diseases.

Zeon Lifesciences plans to export herbal and Ayurvedic products manufactured in its state-of-the-art manufacturing unit in Paonta Sahib (Himachal Pradesh), India, to ten more international markets. Its expansion is strategically targeted in these growing markets because of the rising popularity of herbal products ranging from traditional concoctions to new variations tailored to local tastes.

What is your company's share of nutraceuticals in the product basket? Pharmaceuticals vs Nutraceuticals, how are you expanding your market reach and bridging the gap between the two industries?

Both pharmaceutical and nutraceuticals have their respective importance.

Zeon Lifesciences' product portfolio majorly comprises the manufacturing of nutraceutical products (about 90%). We are into various segments of male nutrition, female nutrition, kids nutrition, immunity, sports nutrition, weight management, medical nutrition and many more.

Through medical nutrition and a combination of other segments, we are bridging the gap between the two industries. Nutraceutical products for cardiac care, Nutraceutical products for diabetes, Nutraceutical products for Ortho care, Nutraceutical products for Neuro care, Nutraceutical products for Derma car, Nutraceutical products Gut Health, Nutraceutical products for General Health & Wellness, Nutraceutical products for Male Infertility, Nutraceutical products for Female Wellness, Nutraceutical products for Eye Health, Nutraceutical products for Healthy Hair and skin, Nutraceutical products for Pulmonary care, etc.

The market for nutraceuticals stood at approx. USD 40.1 million in 2021. How are the market dynamics expected to

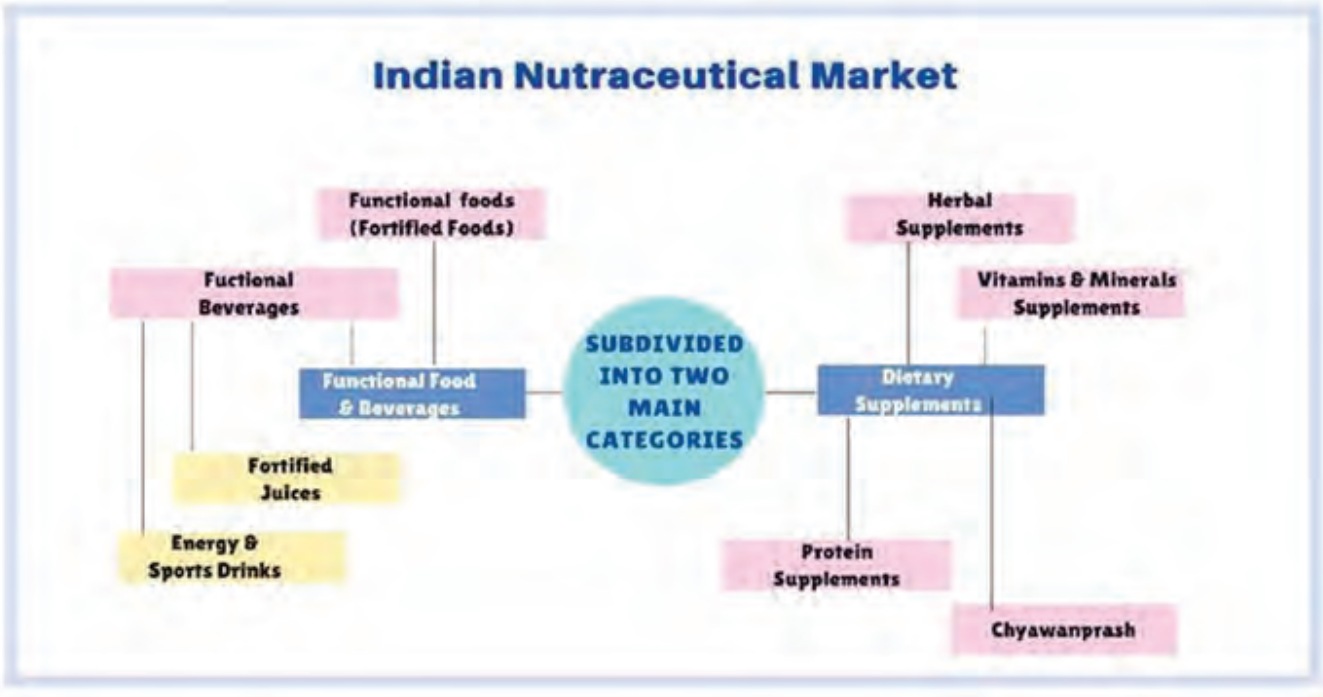
change over the horizon of the next 5 years in India as many major pharma players are also entering the space of offering wellness solutions? How do you plan to stay competitive?

India's nutraceutical market is stood at approx. USD 40.1 million. Experts and reports suggested that it will grow to approximately USD 18 billion by 2025.

There are various ways by which we will stay competitive in the market- In the Emerging Nutraceutical Niches, We are planning to launch a nutraceutical product line that will consider focusing on one of the top target markets for the following:

Joint health- especially seniors, struggle with joint pain, Gut remedies- Health-conscious people are looking for ways to improve digestion and metabolism, Skeletal strength- As we age, bone density and resiliency diminish, Anti-diabetic segment- India has an estimated 77 million people with diabetes, which makes it the second most affected in the world, after China, Building Your Nutraceutical Brand Image and regularly launching new products according to consumer needs and keeping in regulatory compliance.

According to a report by Research & Markets, the global nutraceuticals market is a highly competitive space & expected to reach USD 722.49 billion by 2027. What kind of opportunities will be available for Indian pharma manufacturers?



The rising prevalence of diabetes, obesity, thyroid issues, cardiovascular disease (CVD), and other lifestyle conditions has led to a surge in nutraceutical and dietary supplement consumption across India.

The most prominent consumers of nutraceuticals would be adults, as they easily outnumber the infants and children segment of this industry. This is usually attributed to rising awareness about one's well-being, and increasing incidents of lifestyle diseases like diabetes, hypertension, Anaemia, other immunological deficiencies, etc.

The senior population comes second, as there's been substantial emphasis put on regular consumption of supplements by seniors, owing to the increase in cases of osteoporosis, arthritis, and other bone and joint health issues.

The nutraceuticals products demanded by adults are more than older ones than scope is also more there.

After covid19, the nutraceutical product growth rate is very high due to preventive measures taken by the individuals for their safety. ■

Packaging Compliance through Automation and Digitalization

Prabir Das
Head - Pkgg Tech Services,
OSD (India) Mylan Laboratories Ltd

We learnt how people in every community across the world now realized the importance of health and fitness. We also learnt how a disciplined healthy lifestyle helps us to survive and sustain during a crisis like pandemic. We learnt how entire Healthcare sector across the globe extended support to the people during this crisis. Pharmaceutical Industry, being one of the important members of the Healthcare sector, is doing their best with supply of all the essential medicines and allied products. In Pharmaceutical Industry Compliance to Quality, Regulatory and Statutory norms are fundamental requirements to ensure the safety and security of overall community health.

Quality is the attribute that adds positive value to goods and services right from Design & Development to Distribution & Delivery to the intended customers. All the quality & statutory norms and regulatory guidelines are created keeping the customer benefit & patient safety in mind. Compliance is nothing but transmitting this kind of quality through goods and services to the intended customers which eventually benefits them. That is how we are accomplishing Process, Quality, Statutory and Regulatory compliance in the pharmaceutical industry to achieve Patient Safety & Patient Compliance.

Just like any other product, pharmaceutical products (medicines) are also delivered to people (patient) along with its packaging. Packaging and labelling are integral part of the product. The packaging-labeling effectiveness is largely responsible to establish the product-people connectivity with its communicative features. The process of safe & secure delivery of a product to a customer along with its packaging, is not so simple. It is an end-

to-end process right from raw materials, packaging materials, conversions, handling, storage, transportation and distribution. There are many internal and external challenges encountered to make it happen. Packaging takes a critical role right from design & development stage of the product to its distribution & delivery. However, in each stage of this end-to-end process, compliance is a must. Selection on input materials, its compatibility with the product, design of the primary, secondary and tertiary packaging and their evaluation is mandatory. Each input material needs to comply the specifications, each unit process to comply the operational parameters, every intermediate process needs to comply in-process checks and finally each single unit need to comply the specifications of the finished goods. The equipment involved in various operations and instruments involved in testing & evaluation also need specific design, qualification and calibration to ensure the consistent result and intended quality. This is how product quality is assured, delivered quantity is ensured, product safety is secured and human health is insured through good manufacturing & laboratory practices in this industry.

Over the years industry has experienced many difficult situations and responded with stronger designs and features to sustain and survive in the competition. Now, in this fenceless global business, when multiple technologies are available for easing the process of globalization, industry has responded well to compete in the global market. Quantity, quality and strict regulatory compliance are the need of the hour. Evolution in industrial automation and digitalization are strongly supported with revolution in communication systems too. Most of the advanced features in product-packaging-labeling became feasible because of this automation-digitalization-communication systems. This is how they are analogous and inseparable from each other.

The product-people connectivity is very important in trust-building process and success of a brand is largely dependent on this trust building. While some of the features on packaging and labeling are visible and readable, there are features that are invisible and requires different tools to make it visible or readable to know the desired information. The purpose of including these features in packaging-labelling is either to promote the brand or to protect the brand or both. The basic packaging and its in-built design prevent product spillage, leakage, breakage and spoilage. Adverse external environmental conditions and external threats like theft, diversion, cloning are very common. Apart from internal operational controls, there are many external logistics controls too, to protect the product from these threats and challenges. Similarly, labelling helps to comply various regulatory guidelines through instructions for identification, storage, handling, dispensing and disposal. There are elements for branding too through text, color and graphics.

A combination of packaging-labelling design and features take care of all these requirements to support the brand promotion and brand protection.

Automation-Digitalization-Communication has influenced and improved every stage of operations in the industry and it has been well adapted to our changing lifestyle as well.

Evolution to Revolution - Local to Global - Large wholesale pack to small consumer pack.

Scaling up operations - Quantity with Quality - Consistency and Reproducibility.

Manufacturing and Packaging - Testing and Releasing - Data management and Documentation.

Promotion and Protection - Prevention of Cloning and Counterfeiting - Prevention of Theft and Diversion.

Storage, Handling and Transport - Logistics and Distribution - Safety, Security and Traceability.

Digitalization is a great support to Automation and Communication systems through Data and Information Capture, Data Transform, Storage, Processing, Transfer, Exchange, Retrieval, Integrity, Transparency and Compliance.

These help to optimize cycle time, space utilization and convenience. It enhances speed to all the business processes.

Quality and Compliance are well ensured with Transparency and Integrity. It also strengthens the Communication system.

There are many basic tools to support this Automation-Digitalization-Communication relationship. Over the period these tools have been fine-tuned for their practical applicability. Such tools help to build different custom-made programs, which directly or indirectly facilitates the operations, conversions, controls and communications. Often multiple tools and technologies are blended to get a customized hybrid model, which are more powerful than a single technology.

Packaging Compliance covers Basic Design Compliance, Labelling Compliance, Quality Compliance, Statutory Compliance, Regulatory Compliance, Operational Compliance, Excise & Customs Compliance and finally Patient Compliance. We need to address all these areas for overall compliance from design & development to distribution & delivery of the product. Across the world packaging professionals always try to find a customized solution to support brand protection and brand promotion with their knowledge in material science, conversion technologies, application feasibility and flexibility. Basic packaging materials vary from simple paper to complex composites, inclusive of metals, glass, plastics, and many more options. Accordingly, their conversion technologies also vary to finalize the design and process options. While doing so it is always ensured basic

safety and security of the product pack is maintained.

There are logistics challenges as well which cover multiple options like roadways, railways, airways and water routes. Each of these has its own challenges. Similarly, there are many external mandates like compliance to regulatory guidelines, benchmarking with competitors, obsoletion of technology, change in consumer behaviors, etc. Hence a good balance is required while designing and developing a product pack that can sustain and survive longer in competition. Even though technology is evolving regularly, our practices with basic qualities like discipline, dedication and determination can easily help to overcome all forthcoming challenges. There are few opportunity areas to explore in the coming days:

Research & Skill Development – Often the needs are considered as challenges due to lack of knowledge & skill in the new technologies. Continuous research & skill development can convert these challenges into opportunities. Product development sometimes necessitates new packaging materials, processes or dispensing requirements which can be made possible only if a parallel study is done. New requirements always emerge due to safeguarding stability, quality, branding and supply chain. Similarly, there is a need for training and skill development of the people for robust development and smooth execution of the new system.

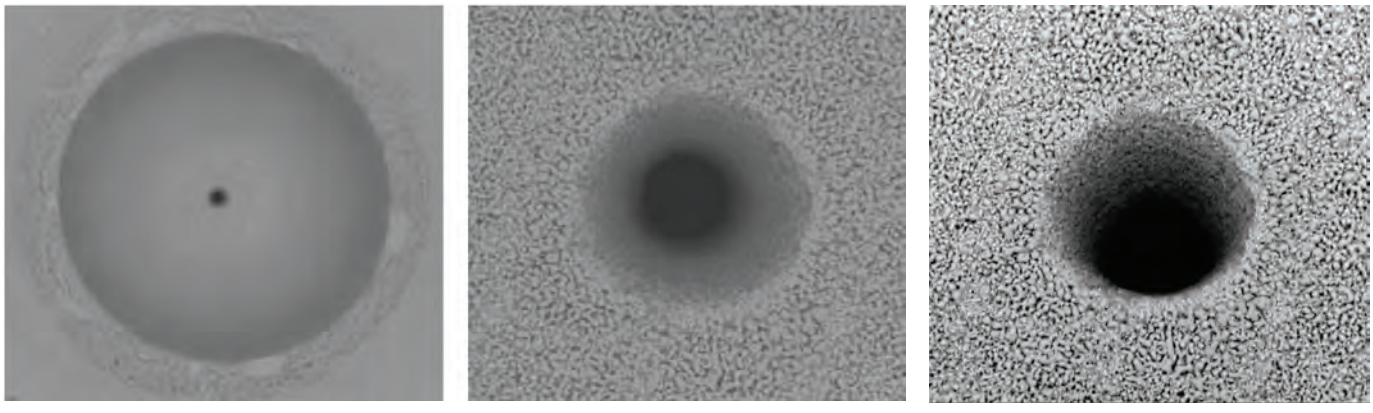
Technology Integration – This is the most complex challenge currently prevailing in the industry. Packaging and Labelling is now integrated with various other technologies to sustain competitive compliance in the industry. There are continuous cross-functional upgrades happening in Packaging, Printing, IT & Communication systems. But these upgrades are not always in synchronization to have an overnight solution. Depending on the nature of the need, some projects are driven by Packaging, some are by IT, some are by Supply Chain and some are by Engineering or Project. These functions need to integrate internally. The more seamless this integration is, the more will be the success.

Harmonized Regulations – The other challenges are diverse practices across the World and the unavailability of a unified and harmonized regulation for Global Trade. There is a need for a unified and harmonized regulation that can be adopted for a fenceless global business through stronger product-people connectivity. Similarly, the medical treatment and reimbursement practices are different in different countries which haves resulted in diverse purchase and usage patterns. If these practices are imagined unified, many of the challenges would have looked like opportunities. ■

Quality Assurance in Health Technology

Andreas Reitberger
Sales Manager
GFH GmbH

Innovative solutions are needed to quickly and cost-effectively check the required hygiene and quality standards in order to ensure access to high-quality, safe medical and pharmaceutical equipment in the future. Various essential quality and stability tests are already carried out during the manufacturing and processing process of products such as syringe cylinders, vaccine vials or infusion and transfusion bags. Thereby, the control mechanisms used have to reliably detect even the smallest variation and damage in the material, to exclude contamination in the context of the application. Therefore, GFH GmbH offers manufacturers of medical and pharmaceutical products a laser-based solution. A cost- and time-saving opportunity is offered to validate this quality test, which works particularly flexibly and gently on materials by drilling high-precision leak holes of just 5 µm to



Scanning electron microscope images of the leakage hole

Leakage drilling in glas

50 µm diameter into individual specimens of a production line. While the hole sizes can be kept very accurately, no cracks or pressures will arise around the drilling site.

As a result of the ongoing pandemic the demand especially for so-called 'leakage drilling' in Syringe cylinders increases rapidly. During manufacturing, these deliberately selected samples are intended to exclude defects in the material of the vials and cylinders for example to prevent subsequent contamination of the transfusion or leakage during usage. Increasing demand for such control procedures is due not least to global vaccination campaigns and the associated increased demand for flawless medical and pharmaceutical products. Manufacturers therefore need reliable methods that can carry out random quality check with high precision in a time- and cost-saving way. For this purpose, laser technology is a predestined method due to its very precise and non-contact processing beam, which is why some well-known manufacturers have already approached GFH GmbH regarding the generation of leakage drills.

The Bavarian laser experts have developed a process, which allows the drilling of high-precision leak holes validating the control mechanisms used in production without much effort. The resulting (defective) products with micro drill holes are then integrated into the manufacturing process of the medical device manufacturers. These ´prepared´ products then form the control group for the quality- and leak test. "The ultrafast laser serves as an excellent tool to equip the glass vials with leakage holes which are very small and precise, but still do not damage the material around the drill hole", explains Andreas Reitberger, Sales Manager at GFH GmbH. "There are numerous reasons for this: on the one hand, the ultrafast laser pulses that hit the material prevent tensions and cracks in it by means of so-called "cold ablation". On the other hand, there are no limits to the variety of materials used in laser processing. This enables even hard-to-machine materials such as glass or special medical plastics to be processed with high precision." ■

Achieving compatibility of Packaging in Pharmaceutical industry with Regulatory Framework

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India's pharmaceutical industry is growing at a fast pace and was estimated to be USD 42 billion in 2020 with the potential to reach the level of USD 65 billion by 2021 and to around USD 120 billion by 2030.

The robust growth of the pharmaceutical industry is also resulting in growth and the increased importance of the ancillary pharmaceuticals packaging industry. As per a recent study, Indian pharmaceutical packaging market is expected to reach - USD 3.02 billion by 2030. Pharmaceutical packaging is the enclosing of the pharmaceutical products for their distribution, storage, sale and usage and it refers to three levels of packaging of the drugs as a product – primary, secondary and tertiary. Primary packaging is the first envelope of the drug product and has a direct effect on shelf life and prevention of contamination of product as this packaging is in direct contact with the drug. Secondary packaging groups the primary packaged products together while the tertiary packaging is designed in a manner to handle products in bulk and to facilitate transportation. Each type of packaging of pharmaceutical products has its own importance and together performs the function of product stability, safety,

patient compliance, medical practitioner's education and xxx marketing.

Considering the importance and functionality of packaging, a recent trend has emerged whereby pharmaceutical packaging companies come up with innovative ways to package the products.

While both drug manufacturing companies and pharmaceutical packaging are working towards improved ways of packaging the drug product for ease of use and safety of drug..., it is important to keep in mind that the packaging of the drug product is regulated. Pharmaceutical and its packaging industry need to be aware of regulatory compliances of packing and labelling of the drug product to ensure that the drug package is regulatory compliant.

Drug Controller General of India (DCGI) is the nodal agency that regulates India's drug market. DGCI through Central Drug Standard Control Organisation (CDSCO) formulates policies governing the industry. Drug and Cosmetics Act 1945 and Drug and Cosmetics Rules 1945 regulate the packaging and labelling of drug along with other drug manufacturing aspects. Drug and Cosmetics Rules 1945 is directory in nature whereas the Drug and Cosmetics Act 1945 is penalising in nature. The Drug and Cosmetics Act 1945 prohibits the manufacture and sale of certain categories of drugs and cosmetics including those which are misbranded. As per Section 17 and 17C respectively of the Act, a drug /cosmetics are deemed to be misbranded if it is not labelled in the prescribed manner; or if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim about the drug or which is false or misleading in any particular. A drug label should be compliant with regulatory requirements for sale of a drug which are defined in Rule 96 and 97 of the Drug and Cosmetics Rules 1945. The said Rule 96 and 97 defines all necessary information which should be displayed on the label of the drug to ensure patient awareness and compliance. There are different rules for different categories of drug and cosmetics which are mentioned under various rules. Schedule M of Drug and Cosmetics Act defines the good manufacturing practices for manufacturing of drug which includes specific requirements for maintenance of batch packaging records and provides instruction of packaging for each product, pack size and type of packaging etc. Further, Schedule P1 defines pack sizes of drug and Schedule S defines standards for cosmetics. Requirements, as defined in pharmacopeia and standards by Bureau of Indian Standards, must also be considered for packaging of the drugs.

Though the domestic sale of drugs / cosmetics and other products governed

by the Drug and Cosmetics Act 1945 are governed by stringent rules and regulations, the packaging and labelling requirements for exports of such products are relaxed and flexible. Rule 94/105 mentions that the labelling and pack size of drug for export shall be adapted to meet the specific requirement of the law of the country to which they are being exported. With exports of pharmaceutical products from India rising rapidly, as indicated by India ranking 3rd in terms of pharmaceutical production by volume and 14th in terms of value of trade, a sincere effort is being made by Directorate General of Foreign Trade to prevent counterfeit of these products. DGFT has recently notified that all export pharmaceutical consignments should be marked and barcoded. This puts in place a traceability system to address counterfeit and ineffective product recall challenges which effects various players in supply chain. To prevent counterfeiting of drug within domestic sale, a recent amendment has been made under Rule 71 of? which requires the applicant intending to market the drug under a brand/trade name, to furnish an undertaking in Form 51 to the licensing authority to the effect that to the best of his knowledge based on search in trademarks registry, central data base for brand/trade name of drugs maintained by CDSCO and literature and reference books on details of drug formulations in India, and internet, such or similar brand name or trade name is not already in existence with respect to any drug in the country.

Along with the Drugs and Cosmetics Act and Rules 1945, the Legal Metrology Rules 2011also define the declaration to be made on the packaging of the drugs such as the declaration of name and address of manufacturer, packer and importer separately. Violation of these rules can lead to prosecution to be launched shall be against the manufacturer in the first place. If the brand owner name also appears on the package as a marketer then such 'marketer 'is also responsible for violation of these rules. These Rules also prevent the affixing of individual stickers on the package altering or making a declaration under these Rules, with the exception that for reducing MRP, a sticker with revised MRP (inclusive if taxes) may be affixed without covering the other declaration by the manufacturer or the packer.

The aforementioned various regulations in packaging and labeling are often seen as a barrier to innovation and creative packaging due to operational hurdles and delays. Manufacturers often sell the same product under different names in different markets, but considering the regulations, they can manufacture the product on a single process line but the task of printing, labeling and packaging becomes complicated to carry out separately. On the

other hand, such regulations are important from the point of view of creating a healthy environment for various players to operate on an equal platform and to ensure patient safety and compliance through disclosure of relevant information about drug and methods of administration. This also contributes towards the prevention of counterfeiting of drug.

Evaluating the regulations governing the packaging and labeling of the pharmaceutical products requires that there is a need to harmonize Indian regulations with global trends keeping artwork and labeling space practicality in mind to achieve all benefits of good packaging and also there is a need to develop creative solutions for pharma packaging which are compatible for regulatory framework. For this, all three players i.e Pharma manufacturers, Packaging Experts and Legal expert/ Expert on Regulatory Matters need to act together to ensure regulatory compliances at all levels. ■

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