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# **P**harma**Bio** World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

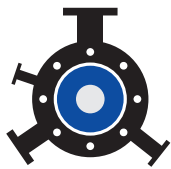
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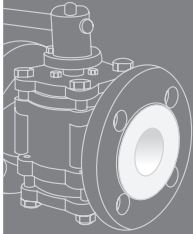


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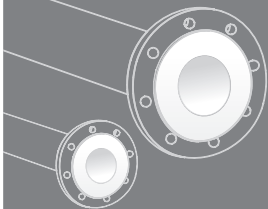
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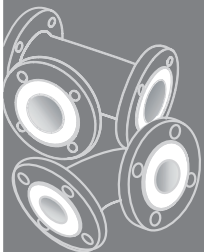
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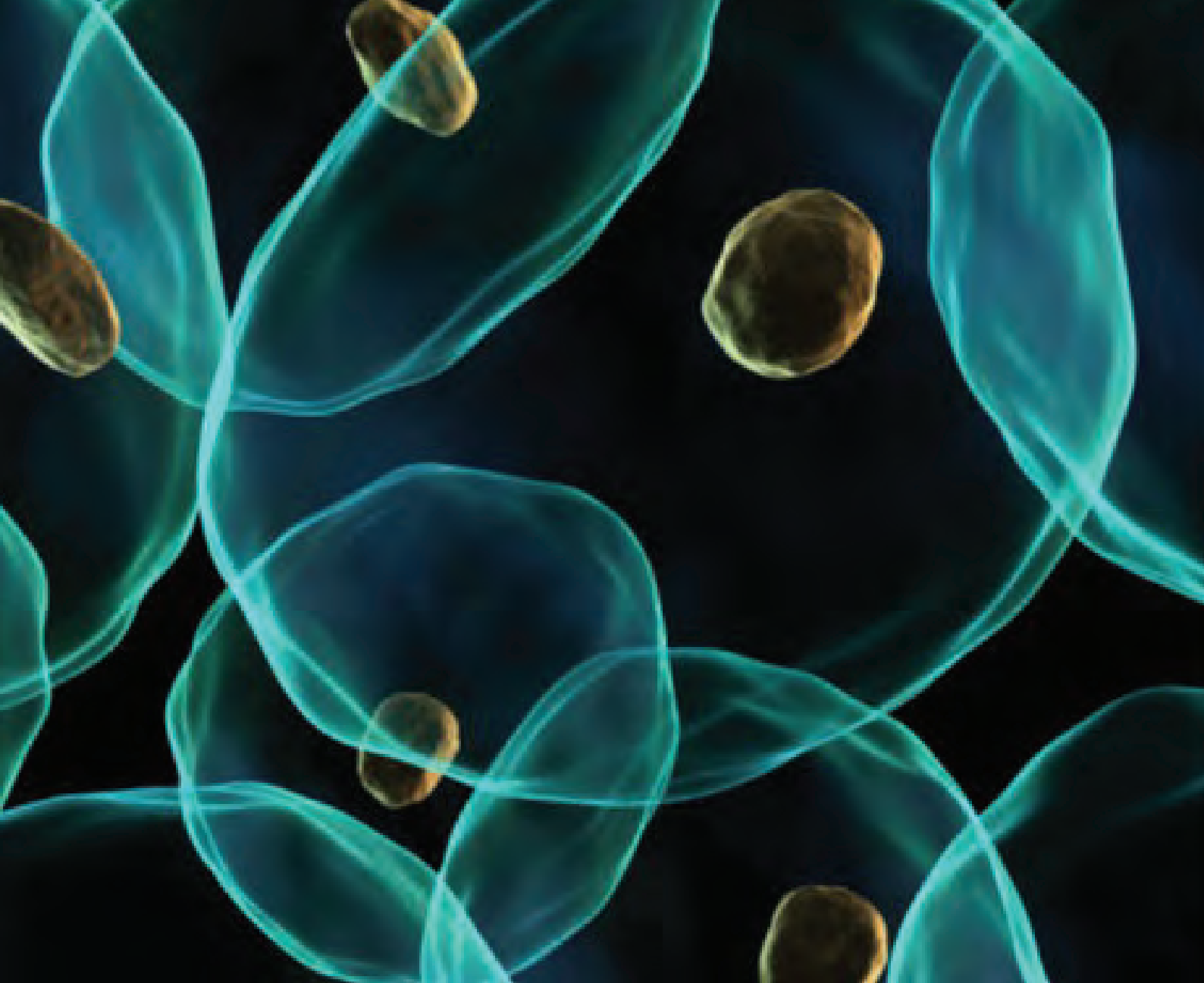
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**Rashmi Pimpale**  
CEO, Research and Innovation Circle of Hyderabad

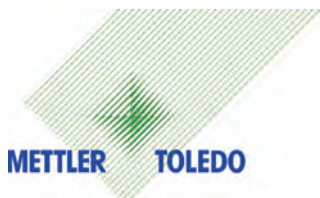
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**Jayanti Sawant**  
Pharma Packaging Consultant

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**Accurate Weighing Through GWP® - The Global Weighing Standard**

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# New Age Evaporator System for Zero Liquid Discharge

## Environment friendly solution for Liquid Waste Disposal

MREPL is recognized as pioneer of revolutionary Mist Cooling System having more than 30 years experience & over 400 installations in various industries. We now offer an innovative Mist Evaporation System for Zero discharge of effluent/RO reject.

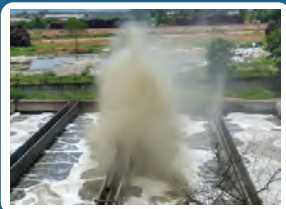


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## PM Inaugurates Biotech Startup Expo 2022



**New Delhi, India:** The Prime Minister, Narendra Modi inaugurated the Biotech Startup Expo - 2022 at Pragati Maidan. He also launched Biotech products e portal. Union Ministers Piyush Goyal, Dharmendra Pradhan, Dr Jitendra Singh, stakeholder of biotech sectors, experts, SMEs, investors were among those present on the occasion.

Speaking on the occasion, the Prime Minister said that India's bio-economy has grown 8 times in the last 8 years. "We have grown from \$10 billion to \$80 billion. India is not too far from reaching the league of top-10 countries in Biotech's global ecosystem", he said. The Prime Minister also noted the contribution of Biotechnology Industry Research Assistance Council (BIRAC) in the development of the sector in the country. The Prime Minister said that, when the country is taking new pledges during the Amrit Kaal, role of biotech industry is very significant in the development of the country.

Talking about the growing reputation of Indian professionals on the global stage, the Prime

Minister said "trust in the skill and innovation of our IT professionals in the world is at

new heights. This same trust and reputation, this decade, we are seeing happening for the Biotech sector of India and for the Bio Professionals of India."

There are, the Prime Minister said, five big reasons why India is being considered a land of opportunities in the field of biotech. First- diverse population and diverse

climatic zones, Second- India's talented human capital pool, Third- increasing efforts for ease of doing business in India. Fourth- The demand for Bio-Products is increasing continuously in India and fifth- India's Biotech Sector and its track record of success.

## Balaxi Pharmaceuticals reports continued solid growth in Q4 and FY22

**Hyderabad, India:** Balaxi Pharmaceuticals Limited (Balaxi), a branded IPR-based pharmaceutical company headquartered in Hyderabad, reported its results for the quarter and full year ended March 31, 2022. Revenue: The strong growth in revenue of 20.8% YoY in FY22 was driven by Pharmaceuticals, with share of the LATAM market increasing to 41%. The LATAM demonstrated healthy growth with Guatemala (45%) and Dominican Republic (29%), EBITDA: EBITDA of INR 55.18 Cr. was recorded in FY22, registering 23.6% growth YoY, as the Company was able to pass on cost



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escalation on account of higher freight and other supply chain disruptions. Profit After Tax: On the back of strong performance of revenue and higher margins, the company was able to report an increase in Profit After Tax by 25% YoY in FY22.

Commenting on the results, Ashish Maheshwari, Chairman and Managing Director said, "In FY22, Balaxi has demonstrated solid execution and showcased the inherent strengths of its business model. We have achieved substantial scale-up in revenues, margin expansion and profit growth to deliver value in a tough operating environment marked by continuing impact of the global pandemic, geo-political upheavals, inflationary trends and supply chain bottlenecks.

10 While the Angola business continues to be a cash cow, we are now starting to see the results of our efforts in the LATAM markets. We will continue to pursue our strategy of targeting leadership in difficult-to-enter markets and have drawn out a roadmap to grow rapidly in other high-potential countries in Latin America over the next few years.

We are also taking forward our manufacturing initiative that will allow us to create strong backward integration in our supply chain, completely reliant on outsourcing at present. Production from our planned facility will find immediate traction from established demand in existing markets. This EU GMP-compliant unit is also expected to open up new markets for our products, resulting in shorter pay-back on the investment and strong return on capital. We now look into the future with excitement and purpose, confident

in our ability to drive continuing value for stakeholders by delivering on the strategic business plan."

## Strengthening the Access to Rare Disease Treatment in India

**Mumbai, India:** In November 2021, Takeda Pharmaceutical Company Limited, a global values-based, R&D-driven biopharmaceutical leader, together with UNGCNI launched a national initiative for improving early access to treatment for Rare Disease Patients in India. The joint rare disease initiative took charge of addressing the challenges to ensure access to treatment for rare disease patients waiting on the crowdfunding portal in an integrated manner. Through the initiative, 300+ PSUs and Corporate leaders were reached, which has helped to generate a pool of insights and recommendations that will help in shaping the future of access to rare disease treatment in the country.

The 6-months intensive initiative has been able to bring together stakeholder groups (private sector, PSUs, corporate giants, etc.) that can support mobilizing and operationalizing funding for the rare disease under CSR grants and donations for strengthening the existing crowdfunding mechanism and pathways set in the India Rare Disease Policy. Furthermore, it has created the roadmap for addressing rare disease funding requirements in alignment with the Government policies and guidelines Ministry of Corporate Affairs, Department of Public Enterprises, and Ministry of Health and Family Welfare, Govt of India.

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sector organizations participated in the initiatives including MoHFW, AIIMS (New Delhi), Kerala State Legal Services Authority (KELSA), CoEs (SGPGI, Lucknow, KEM, Mumbai, SSKM, Kolkata), and 24 PSUs and Corporate Leaders (e.g., BHEL, Bharat Petroleum, ONGC etc).

Aseem Kumar, Officiating Executive Director, UNGCNI said, "Rare diseases, underpin a situation where health lies at an intersection of several Sustainable Development Goals, going well beyond only SDG 3 (Good Health and Well-being). The need to address rare diseases on priority was made a reality in 2019 when UN Member States adopted the historical Political Declaration on Universal Health Coverage. This included a commitment to strengthen efforts to address rare diseases as it was for the first-time that rare diseases were included within a UN declaration. This helped in channelizing collaborative efforts with multi-stakeholders to strengthen the national rare disease policy execution".

## Cipla adds Capacity of Captive Renewable Energy Power Plant in Maharashtra & Karnataka

**India; June 2, 2022:** Cipla Limited announced the commercial operation of additional capacity of captive renewable energy power plant in Maharashtra & Karnataka. In Jan'21, Cipla had commissioned 30 MWp solar project at Tuljapur, and now further added 16 MWp of solar capacity for supplying the renewable energy for its manufacturing units/facilities in Maharashtra. These projects have been commissioned in partnership with AMP Energy India and is one of the largest



solar open access projects in the state set up by a corporate. The project will support the Company's green energy requirements for its manufacturing units at Kurkumbh & Patalganga and R&D centre at Vikhroli in Maharashtra, replacing around 70 % of total consumption for these unit to green energy.

In Karnataka wind solar hybrid captive power plant with capacity as 9 MWp solar + 2.7 MVA of wind has been commissioned in partnership with CleanMax Enviro Energy Solutions, this project will help in migrating the 85 % of power requirement to renewable source for its manufacturing units in Karnataka.

Ms. Geena Malhotra, President and Global Head – Manufacturing Operations, Cipla, commented, "Sustainability is at the core of Cipla's DNA and this project is a big step forward in our goal to achieve carbon

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neutrality by 2025. We endeavour to continue growing the share of renewable energy across our sites with an aim to contribute to India's agenda of increasing energy generation from non-fossil fuel sources." Over last 3-year Cipla has added significant capacity of 66 MWp of equivalent solar power portfolio through various initiatives such as an on-site solar roof top & ground mounted solar projects under RESCO model, and captive solar / wind open access project in partnership with leading IPP (Independent Power Producers).

## Parexel Expands Patient Access to Clinical Trials through New Community Alliance Network

**BOSTON, and Durham, N.C:** Parexel, a leading global clinical research organization (CRO), announced the launch of its Community Alliance Network, a novel program further integrating clinical research into the community healthcare setting to better serve patients and in turn create further opportunity for increased diversity in clinical trials. CVS Health®, the leading health care solutions company, and Javara, the leading Integrated Research Organization, have joined the network as inaugural members, opening the door to community-based research sites and increasing access to new patient populations to support trial delivery for Parexel's biopharmaceutical customers. "For too long, clinical research has been siloed in small pockets of the healthcare system," said Clare Grace, PhD, Chief Patient Officer at Parexel.

"Not only has this slowed therapeutic innovation, it has limited patient access to

clinical research as a care option. Providing patients more opportunities to access and participate in clinical research — through their physician's office, in CVS MinuteClinics® within designated HealthHUB® locations, or through traditional academic sites or hospitals — is a critical and strategic decision. Parexel is leading the way in providing access to the 95 percent of patients who don't currently participate in research to design clinical trials that revolve around the patient." Over the last 10 years, Parexel has built its Site Alliance Network with more than 500 of the top clinical research institutions and 21,000 principal investigators across 20+ countries with diverse site staff and patient populations across all therapeutic areas. The company's Community Alliance Network builds on these efforts through alliances with healthcare and research organizations that have close relationships with and proximity to patients who previously had no or little ability to participate in clinical research.

"The traditional research delivery model does not effectively connect the majority of patients to clinical trial opportunities as part of a patient's routine healthcare experience, and as a result, only a small percentage are currently aware of research as a potential care option," said Jennifer Byrne, Chief Executive Officer at Javara. "Parexel's Community Alliance Network aligns perfectly with Javara's mission to advance access to clinical research as a care option by connecting with patients through the healthcare organizations and physicians they already know and trust. It is a privilege to join this program as an inaugural member to further bridge the gap between clinical research and clinical care and bring



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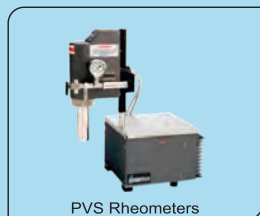
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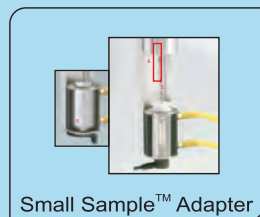
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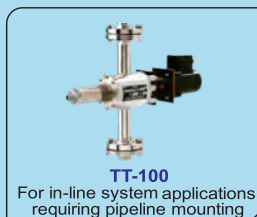
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trials to those who need them most." "By joining the Community Alliance Network, we can continue to bring healthcare solutions to consumers within the communities where they live and work," said Tony Clapsis, SVP and General Manager of CVS Health's Clinical Trial Services™. "With our community presence across the U.S., we're able to accelerate access to clinical trials, and at the same time help to address longstanding issues with recruitment and diversity."

## Dr. Reddy's Arm Inks Pact with US-Based Olema Pharmaceuticals

**Hyderabad, India:** Dr Reddy's Laboratories on Thursday said its subsidiary has inked a pact with US-based Olema Pharmaceuticals Inc to research, develop and commercialise novel small molecule inhibitors of an undisclosed oncology target. Olema and Aurigene Discovery Technologies, a wholly-owned unit of Dr Reddy's Laboratories, have inked an exclusive global licence agreement in this regard. Under the terms of the agreement, Olema will make an upfront licensing payment of USD 8 million for the rights to a pre-existing Aurigene programme.

Aurigene will also be eligible for up to USD 60 million in potential clinical development and regulatory milestones and up to USD 370 million in potential commercial milestones, as well as royalties ranging from the mid-single digits to the low double digits, based on annual net sales. During the research term, Olema will contribute funding to Aurigene to facilitate ongoing discovery efforts, Dr Reddy's said in a regulatory filing.

Olema and Aurigene will jointly direct further

preclinical work and, if successful, Olema will lead clinical development along with regulatory and commercial activities, it added. "This agreement with Olema further validates Aurigene's proven expertise in discovery and preclinical development of effective cancer therapeutics," Aurigene CEO Murali Ramachandra said. The company looks forward to the continued development of an Aurigene programme, which will now be ably supported by the extensive development capability of Olema, he added. ■

## Process Industry's Gateway to Indian Market



## 31<sup>st</sup> International Exhibition and Conferences

**4-7 March 2024**

**Venue:** Bombay Exhibition Center, Goregaon (East), Mumbai, India

### Concurrent Events



### Scope for ChemTECH World Expo 2024

- Plant Machinery & Industrial Consumables
- Engineering Consultants
- OEMs for Chemicals & Pharmaceutical Processing Equipment
- Metals & Metallurgy
- Bioprocessing Equipment
- Construction Services Providers
- Plant Maintenance Services Providers
- Logistics & Supply Chain Solutions Providers
- 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
- Certification Bodies
- Welding Solutions
- Quality Health & Environment Solutions
- Analytical & Laboratory
- Packaging Materials, Machinery & Systems
- Business Consultants

### Scope for Specialty Chemicals World Expo 2024

- Agrochemicals Intermediates
- Adhesives & Sealants
- Agrochemicals & Crop Protection
- Bulk Drugs & Intermediates
- Enzymes
- Colorants, Dyes & Pigments
- 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 2024

- Materials Processing
- Pharma Ingredients
- Plant Engineering, Process Plants & Equipment
- Laboratory & Analytical Solutions
- Process Measurement & Inspection
- Sterilization & Clean Room Solutions
- Biopharma R&D And Manufacturing
- IT Solutions
- Pharma Machinery
- Water & Waste Treatment Solutions

### FACTS & FIGURES - CHEMTECH WORLD EXPO 2022

**300+** EXHIBITORS | **19350** VISITORS | **20** COUNTRIES | **6** CONFERENCES | **150** SPEAKERS | **650+** DELEGATES | **200** STUDENTS

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# Fostering Research and Innovation across Industry Sectors



## Rashmi Pimpale

CEO, Research and Innovation Circle of Hyderabad

**M**odern India has a strong focus on science and technology research and innovation, as a key pillar of economic growth. It is, thus, no wonder that India ranks third globally as one of the most attractive investment destinations for technology transactions. Over the past decade, the Indian government has sought to boost this innovation ecosystem through pragmatic changes across sectors, such as by setting up central entities like the Biotechnology Industry Research Assistance Council (BIRAC), National Innovation Foundation, CSIR

Innovation Complexes, and Technology Business Incubators; formulating national-level missions like the Atal Innovation Mission, Mission AGNli (Accelerating Growth of New India's Innovations), and Start-up India; creating supportive policies such as the drone policies and those to boost electric vehicles; and so on. The MedTech and life sciences sectors are witnessing the benefits of this transformation. The recent successful COVID-19 vaccine production by various Indian organisations is a prime example.

All this support has successfully made India's research ecosystem more fertile. A testament to this is the fact that in 2021, India moved 35 places in six years to a rank of 46 on the Global Innovation Index. When it comes to the life sciences sector, Telangana has played a big part in this ranking by ensuring that research and industrial infrastructure is not only competitive but forms a comprehensive ecosystem designed to thrive. Telangana alone has delivered 30% of the total revenue generated by the Indian life sciences industry.

Moreover, Telangana hosts one of India's fastest-growing life sciences hubs, Hyderabad, where there are plug-and-play labs, testing facilities, access to CROs, and great scientific research infrastructure. Also dubbed as the "Pharma capital of India", Hyderabad has over 800 life sciences companies and is deemed the epicentre of the life sciences industry. This is further helped by the presence of premier research institutions like CSIR-Indian Institute of Chemical Technology (IICT), CSIR-Centre for Cellular and Molecular Biology (CCMB), and Centre for DNA Fingerprinting and Diagnostics (CDFD), among others. In fact, the city is seen as a hotspot for acquiring highly skilled talent and developing world-renowned R&D institutes across the various industries in the life sciences sector.

The establishment of Research and Innovation Circle of Hyderabad (RICH)

and the projects RICH takes up are part of national and state efforts to bolster research and innovation across industries in Telangana's life sciences sector. The overarching goal is to make Telangana the preferred location for life sciences research, innovation, and industry.

Within this goal, RICH focuses on bringing together pre-existing pockets of strength of various stakeholders, fill the gaps in the innovation-entrepreneurship-investment ecosystem, fully harness the potential of science and technology, and drive the socio-economic transformation of India.

Inequity with respect to affordability, accessibility, and availability of medicines and healthcare to marginalised communities is a systemic problem in the healthcare system in our country. The lack of access to drugs, testing kits, PPEs, medical professionals, etc., among the economically underprivileged and rural populations during the COVID-19 pandemic was merely a symptom of these systemic problems. Some pandemic-time initiatives in which RICH was involved successfully overcame these challenges. A key initiative was the National Reagents Consortium, the Hyderabad arm of which was led by CSIR-CCMB and RICH. This was a nation-wide capacity-building programme for diagnostics that identified indigenous micro, small, and medium enterprises and start-up manufacturers of test kit components and reagents, and enabled the scaling-up of processes and quality upgradation of their products.

The Consortium successfully developed affordable COVID-19 test kits that can be manufactured indigenously at scale and also conducted a large-scale data collection exercise, called the Demand Estimation Study, to estimate the nation-wide requirement of test kits to facilitate industry preparedness for COVID-19 testing. This programme played an important role in creating a research and innovation framework for a system where innovations have equitable benefits across populations.

These initiatives are important because India has a unique socio-economic landscape, and its unique problems are best solved through indigenous solutions. Fortunately, there is no paucity of innovators in India. Given the right support, facilities, and collaborations, start-ups, innovators, and researchers can find effective solutions to our nation's problems. Several projects by RICH seek to identify the best innovations in the MedTech and HealthTech spaces, and create the right environment for those innovations to become on-ground realities. For instance, the Acceleration Initiative for Diagnostics (AID) provides a select cohort of innovators an acceleration grant, one-on-one mentorship from top technical and business experts, incubation support, and connections with investors. Its follow-up project, called Project Tej, helps entrepreneurs test and validate their innovations in practical settings in hospitals. Under Project Tej as well,

RICH provides mentorships to start-ups and new innovators, and organises regular meetups and discussions among various stakeholders in the ecosystem to troubleshoot challenges and improve upon shortfalls.

RICH curates projects with an attempt to avoid a pitfall of most important initiatives in healthcare, which suffer due to the lack of data and clinical samples. Standardised patient data systems, with proper privacy controls, can help both health administrators and researchers to identify disease patterns, disease spread, and localised reasons thereof. The availability of tailored information on lifestyle and behaviour-based health risks open doors to providing patient risk classification solutions and making personalised and precision medicine more holistic.

These initiatives are important steps on the road to achieving Telangana's goal of making the state the preferred location for the life sciences sector. They are also strong foundations for future initiatives. Telangana, being a leading life sciences research and innovation hub, aims to further strengthen its position by fostering research and innovation to become Asia's go-to destination for the life sciences sector. ■



# Functions of packaging and labeling in pharmaceutical perspective



**Jayanti Sawant**

Pharma Packaging Consultant

*Packaging & labeling are vital and need to be done correctly in new product development, production, and supply chain, until the product reaches the consumer. Jayanti Sawant, Pharma Packaging Consultant explains the functions of packaging and labeling in the pharma industry.*

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**T**he pandemic has had devastating impact on almost all industry sectors and so on the global economy. The pharmaceutical and healthcare sector, however will continue to grow as the need of medication remains and cannot be ignored at any cost.

In such a crisis, the pharma and healthcare sector successfully are delivering essentials to the suddenly grown demand. There is a continuous demand of one time use packaging or disposable packaging. The scenario will surely be different for packaging materials after the world is

done dealing with Covid-19. Most of the medicines are being ordered online during lockdown and hence, cardboard packaging, plastics will be in demand. Shortage of waste paper may result in hiked prices of cartons during this phase and glass will continue to be dominating injectable sectors.

The use of masks and sanitary products has caused a sudden demand and a pressure on packaging industry. Packaging is under essential services for all kinds of industries. Labeling is a vital part of packaging, and both, packaging and

labeling need to be done correctly in new product development, production, and supply chain, until the product reaches the consumer.

Functions of packaging and labeling in pharmaceuticals.

Over the last two decades, pharmaceutical packaging has evolved . At one point it was a simple packing operation of finished goods which has now emerged as a separate, intricate process. The term ' packaging technology' is appropriate to indicate that this process is an amalgam of art, science and technology .

The development gained momentum in last decade due to availability of various kinds of materials , upgradation in printing technology , availability of professionals in this field , and even changed regulatory requirements. Globalisation resulted in complete transformation of pharma packaging and labeling .

Pharma packaging and labeling are two sides of the same coin, fused or merged to complete the definition of a package of any product. It is an integral part of product development and remains crucial until the consumption of the drug by the customer . Hence packaging and labeling have defined functions which if not identified correctly during product development , can result into serious complaints and ruin the brand image in the market .

## Packaging

For packaging operations, Once the bulk drug or the batch is ready, all the operations like washing, filling, sealing ,packing will be treated as 'packaging' .For instance, the silicon tubing for injectables or any such material in direct contact with the product during production, may call for the detailed studies of extractables and leachables with respect to regulation compliances. These are packaging compliances. Hence the word 'packaging Technology' emerged and replaced 'packing'.

There are certain regulatory requirements that have to be fulfilled, such as suitability, safety, protection, convenience, compatibility, quality control, vendors and stability. The content of the dosage forms are often very sensitive towards external elements such as light and moisture. Hence, once the product is packed it is to be completely safe from direct exposure to light and moisture. Simultaneously sealing the pack should be excellent and shouldn't allow reactive gases like oxygen, as this might lead to dangerous consequences like failing of the product in stability. Moreover, if any leakage is found in this sealing, it might raise a question on sterility and closure integrity of the container.

## Labeling

Labeling on the other hand is the factor that determines the safety and briefly

introduces integrity of the product. This operation includes both printing on the carton and pack inserts provided individually with the pharma products.

The primary purpose of labeling is to make identification of the product unambiguous.

Labeling information is important for both healthcare professionals and patients to prescribe and consume, respectively. This is crucial also because people have an obvious belief on medicines' company that they will provide right information on the product. Hence, the faith of the customer or end user is associated with the brand which is created by packaging and labeling. Thus, with evolution from packing to packaging, functions of packaging and labeling evolved.

## FUNCTIONS OF PACKAGING .

1. To carry the product: It is the first and foremost function of the pack and has been right since the time we have evolved as humans, from the zeitgeist of wrapping food in leaves to carrying it in modern day revolutionary packaging.
2. To protect a product from damage or contamination: The product must be protected from any damage during transit or storage. The product must also be protected against the climate, including high temperatures, humidity, light and gases in the air.
3. To act as a marketing tool: It

identifies and represents the brand. Packaging is the main way products are advertised and identified. To the manufacturer, the package clearly identifies the product inside and it is usually the package that the customer recognises when shopping. Thus it helps to sell the item and create a brand identity. Marketing communications and graphic design are applied to the surface of the package and often to the point of sale display. Most packaging is designed to reflect the brand's message and identity on the one hand while highlighting the respective product concept on the other hand.

4. Protection during Transport and Ease of Transport. A package should be designed to make it easy to transport, to move and lift. A regular shaped package can be stacked without too much space between each package without space being wasted. This means that more packages can be transported in a container thereby systemising logistics and supply chain.
5. Stacking and Storage: In stacking and storage, symmetric packs lead to minimum errors in the transit and in distribution.

### **The choice for a packaging material usually depends on:**

1. The level of protection required: Highly hygroscopic dosage forms like



amoxicillin and clavulanic acid tablets need high barrier packaging.

2. User friendliness: The size ,shape and weight matter. It should be easy to carry, accorded to taste of the product , and dispensed carefully.
3. Filling method of the dosage form
4. Compatibility with the dosage form
5. Sterilization method: The pack has to withstand the sterilization process.
6. Reusability of the pack: Refill packs should be sturdy as they undergo multiple use at the hands of the end user.

#### 4. Tertiary Or Transport Packaging, (TPM)

Here we consider primary, secondary and tertiary packaging which are mainly used in pharma .

The display or intermediate packaging holds secondary units , for example, a bunch of cartons, tetra packs or bottles and facilitates distribution channels , displays brand , supports consumer in bulk purchasing . It also provides strength to the main pack while in storage and during display .

**The image below is self explanatory, showing different levels of packaging .**

1) Primary packaging: it includes blisters, ampoules ,vials etc. This is the material that is in direct contact with the product and holds/envelops the product. It is, therefore, the most important and undergoes difficult selection for sensitive products .

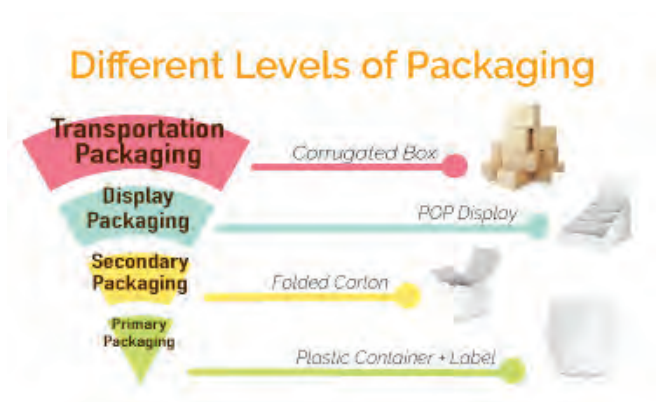
The most important function of primary packaging is to protect and preserve the product from external damage, contamination, spoiling and spillage . It also serves the purpose of keeping the product in storage, often for a long period of time .It also defines shelf life of the product and contributes to shelf life studies .

It should be able to withstand the product sterilization process , develop good barrier against microorganisms and

### Functions of packaging materials also vary for different packaging materials.

These types can be divided as:

1. Primary Packaging Material (PPM)
2. Secondary Packaging Material (SPM)
3. Display Packaging Or Intermediate Packaging (Mainly Used For Food Products )



environmental contamination .It should support the product in WVTR ,MVTR and OTR as the more the migration through PPM to product , more will be damage to product in terms of shelf life .

The objects enclosed in the package may require protection from mechanical shock, vibration, electrostatic discharge, compression, temperature, etc.

A barrier to oxygen, water vapor and dust is often required. Permeation is a critical factor in design. Some packages contain desiccants or oxygen absorbers to help extend shelf life. Modified atmospheres or controlled atmospheres are also maintained in some cold packages. Keeping the contents safe for the duration of the intended shelf life is a primary function.

2) Secondary packaging: Cartons have been used to put together single products or many primary packages. It does not come in direct contact with the product.It:

- Markets the brand by creating brand identity : Since this pack is directly seen by the end user , its design and aesthetics get registered in consumers while browsing through shelves in medical shops or pharmacies . Thus it is one of the P's of marketing since it displays the brand . .
- Protects the primary pack and provides mechanical support to the product and primary pack thereby

enhancing product protection , product appeal and safety .

- Is an intermediate block for the supply chain ,hence a low quality grade shipper can damage the entire product if it fails to withstand the transit hazards like shocks ,vibrations , multiple handlings and compression due to stacking during storage .
- Provides convenience and security to the pack at the consumer's end .This concept has given entry to small portion packs or one time use sachets like vitamin D pouches, rehydration solution pouches .

3) Tertiary packaging: Shippers are mostly used for bulk handling, warehouse storage, and transport . They are the backbone of the supply chain.

Tertiary packs are generally not seen by the customer . most of the shippers are tertiary packs which give protection to the product by safeguarding the primary and secondary packs .

Thus it protects the product from damage , moisture and environmental hazards while in transit and in storage warehouses

If the product is not delivered on time, notwithstanding the fact that it is a successful product, it will become useless to market. Hence, timely delivery of the product with the intact product is the tool for success in supply chain and hence for marketing also. Many a times , quality

of the tertiary packs is still a last minute development in many organizations . Even now, the problems include hidden or invisible damages which crop up suddenly in transit. Damages to the shippers, bulging of shippers in new product launches are a phenomena.

Hence transport packs are important for any business. We can categorically define functions of these packs:

▪ **Most important tool of transport:**

Optimum size transport pack or shipping box helps in successful transition of goods anywhere in the world and thereby makes the product available where it is needed the most .Thus , it's a building block of any supply chain .

▪ **Protects goods inside:**

It protects the primary , secondary packaging and the product . During transport ,when goods arrive from a supposed port A to port B in a damaged condition , it may have to undergo replacement of damaged goods, which then becomes an additional cost .

Apart from the extra cost , it will beget sour relationships with customers , distributors which can affect the image of the organisation .

▪ **Conveys important information:**

There can be a lot of important information that distributors need to know about your

product. Your transport packaging is the perfect place to display this information.

A lot of different things can be printed on your boxes. It could be something simple, like the order in which the packages need to go, or a declaration that the contents are fragile. You can also specify more detailed handling instructions, such as temperature range your products need to be stored at.

▪ **Makes storage and transport possible:**

Perfectly designed shipper or transport box uses optimum space on pallets .These boxes on pallets fit perfectly in containers , providing safety from damage to the goods till they reach the destination port and are further distributed .Hence, while designing shippers, following technical specifications is important .

GSM, Burst Factor , Virgin Or Recycled, Edge Crush , Compression , Bursting Strength , Type Of Flute Used . With correct use of combinations the strength of 7 ply box can also be obtained in 5 ply box

Image below shows perfectly designed shipper -optimum utilization of pallets .

▪ **Helps to sell:**

Good logistics are preferred by the retailers , distributors as they help in protecting the goods in storage and such packs are always preferred by the supply chain personnel.



The display labels carry detailed information about the product which helps in identification of the brand, thus helping in selling the product . We will see labeling in detail under the labeling section.

### Functions of labeling:

Pharmaceutical labeling is a complex and stringently done process with increasing global quality compliances , regulatory requirements.

For local markets ,it is governed by Drugs And Cosmetics act 1945 has to be updated in accordance with the updated provisions .For export , labeling is governed by the concerned regulatory body or ministry of health of the countries. The term label refers to all labels which display content of the medicines along with other important matters about the drug or its formulation .

A label may be of paper , printed packaging material like foil or laminates, sleeves , ceramic or screen printing on ampoules ,paper tags .Label matter should be approved by FDA , Hence the content of the artworks shall also be FDA approved .

The minimum legal information that needs to be on the label is :

- Brand name and generic name of the product
- Composition
- Storage
- Strength and dosage form
- Quantity or pack size
- Instructions for use
- Mfg Lic No , B.no, Mfg Date ,Expiry date ,MRP
- Name and address of Manufacturer.
- For prescription drugs : The pack should display Schedule G,H,H1 and X warnings in accordance with latest updated guidelines of Drugs and Cosmetic Act, 1945 .These guidelines are released in Gazette of india as and when updated .

### Pharma labeling:

- Provides detailed product information to the consumers , doctors , pharmacists about the product's content .



- Helps in safe usage of the product by providing detailed such informative labels .
- Secures the brand by providing anticounterfeit measures .

For instance, Betadine gargle pack has got a tamper evident cap with a holographic label, helping the brand to be secured .The shape of the bottle is unique combination of square and round which creates an intricate mold which is difficult to copy .Thus packaging and labeling are effectively used to protect and secure the brand .

- Helps in brand development and acts a marketing tool since it identifies the brand: For instance, a customer can easily choose or identify Crocin among all other paracetamol brands as the design and pack are easily distinguished by consumers for years .Hence the brand name Crocin has become a synonym for Paracetamol .
- Aids brand development: Packaging and labeling combined together create a brand identity in market . A standard pack with various label shades segregates variants of the same brand . A few images will help us understand this concept. For example, Iodex pain balm, Headfast balm, Iodex gel: Shipping boxes are crucial to supply chain since they carry significant information right since warehouse storage, till distribution.

It is labeled or printed with brand name , generic name , batch number, manufacturing date, expiry date ,storage , gross weight, net weight, shipper number, address of the manufacturer, and that of the importer and exporter .

It also displays 1d code label adhering to DGFT compliances for export and it has to be treated as per the guidelines released by the DGFT . This label has a relation with the secondary packaging, which can track the goods in transit and is considered to be one of the most powerful tools to arrest spurious drugs . That also makes it an anticounterfeit tool.

It also displays common instructions for handling it since the shipper undergoes tremendous handling, loading and unloading during the entire cycle of distribution .

Packaging and labeling together offer product security and are largely used as anticounterfeit tool. Let's look at anticounterfeit techniques.

Counterfeit products are growing day by day and are a nuisance for businesses all over the world .These are fake products that have been copied exactly like the original in every sense , resulting in huge economic losses and harm to the consumer. Pertaining to pharmaceutical products ,if the drug is spurious , it will be certainly life threatening to the consumer or end user .This need of protecting the drug and its pack from being spurious

or prevent it from being copied has led to demand of anticounterfeit packaging which can protect brands from being easily replicated.

Packaging and labeling in pharma have to protect the brand and the product, also tell apart the brand from other brands with unique anticounterfeit features included in the pack. Day by day, the demand of such packaging material is increasing, and the anti-counterfeiting labels and packaging market will continue to grow and evolve.

One of the first steps brand owners can take towards protecting their brand is learning about various anti-counterfeiting techniques so they can find suitable and cost effective solutions for them.

Most widely used Anti-Counterfeit Labels and Packaging Techniques:

There are two main types of anti-counterfeiting techniques for labels and packaging which are often used together to create a comprehensive security solution. Overt and covert features are noticeable and hidden details, especially, make it easier to detect fakes and increase traceability across the supply chain, and make it harder to counterfeit products.

**1) Track and trace:** A two-dimensional (2D) barcode looks like a square or



rectangle and contains many small, individual dots. The two most popular types are Quick Response (QR) Code and Data Matrix, but there are other options available. According to GS1, "A single 2D barcode can hold a significant amount of information and may remain legible even when printed at a small size or etched onto a product."

Track and trace works like parental child tracking methods where every secondary unit will have a unique serial number under the main or parent shipper or pallet which helps in tracking the shipment or a particular pack in transit. This is a directive from DGFT for export.

**2) Watermarks:** watermarks are images or patterns that are embedded into the design of a package or paper to authenticate products and support brand identity. Watermarks can be





generic or customized using a logo, brand name, or other symbology.

**3) Microtext:** Like watermarks, microtext is used to authenticate products. Extremely small text, codes, or symbols are tricky to replicate or copy without using advanced detection and printing equipment. Microtext can be inserted into overt images, larger text, and other design elements without being noticeable to the naked eye. Since microtext is not easily noticeable, counterfeiters would be unaware that it exists in the pack.

**4) Holograms:** A hologram is a three-dimensional image formed by the interference of light beams from a laser or other intense light source. Hologram technology is popular for anti-counterfeiting because it can incorporate various data forms and product tracking information.

It can be used as a label to close a carton, thus acting as a tamper evident seal also. It can be a part of a blister embedded in a foil.



**5) RFID Tags:** Radio frequency identification (RFID) technology uses radio waves to automatically identify people or objects.

**6) Tamper Evident Seals:** Tamper evident seals can be printed in different styles to fit your security and packaging needs. Shrink sleeve labels with a perforated seal or shrink bands are full-body labels that make products stand out with visually attractive graphics that completely wrap around a container. They are more than a pretty face – they are harder to counterfeit than pressure sensitive labels because they're more complex and need high volume products to be cost effective.

Shrink bands are film strips that are shrunk to fit around the cap and neck of a bottle or jar to show the product has not been opened. You can choose between non-perforated or perforated for easy removing, and blank or custom printed design (recommended for brand identity and anti-counterfeiting).

Tamper evident seals and anti-counterfeiting techniques offer brand owners many benefits like product security, brand identification, and product authentication.

**7) Epedigree :** The E Pedigree label tracks the origin of prescription drugs through an electronic pedigree and

provides data on the history of a particular batch of a drug. When the system is set up, this tracking is done during the reception and dispatching of batch.

Thus Anti-counterfeit packaging is mainly intended to prevent brand reproduction. It enables brand protection and enables clients distinguish between original and counterfeit.

### Conclusion:

All in all, it is difficult to imagine pharmaceutical industry sans the functions of packaging and labeling which are integral part of production activities once the new pack has been developed and commercialised. The products meant to safeguard human beings will be useless if they are not packed and labeled in accordance with the compliances. It is of utmost importance that the drug retains its original quality until consumed by the end user. Packaging and labeling, though different activities, intermingle and together lead to the creation of a quality pack.

The success and failure of any product depends on how the end user or the customer has responded, especially the healthcare sector. While the end user reacts, he /she is educated enough to check the packaging and labeling of the pack, hence packaging and labeling are crucial and important factors of the pharma domain. ■



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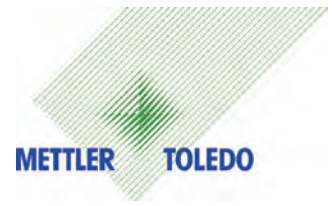
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are adequate and functioning according to their intended use.' The US Pharmacopeial Convention takes this one step further, with "USP Chapter 41" recommending the adoption of a risk management approach to scheduled calibration and routine testing of weighing equipment.

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