VOL 21 | ISSUE 9 | MARCH 2023

www.jasubhaimedia.com

PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

Clean Rooms

PTFE LINED SYSTEMS
VALVES | PIPES | FITTINGS | COATINGS

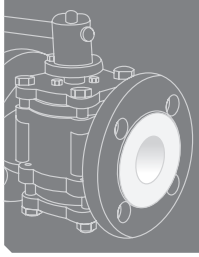
| PTFE | PFA | FEP | ETFE
| PVDF | ECTFE | PP | HDPE

www.ptfeindia.com

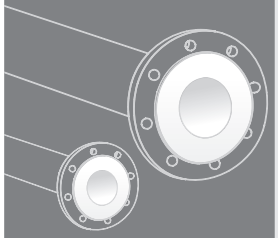
HI-TECH®
APPLICATOR
a Global Trusted Brand

YOUR SUSTAINABLE BUSINESS PARTNER
IN FLUOROPOLYMER LINED PRODUCTS SINCE 1994

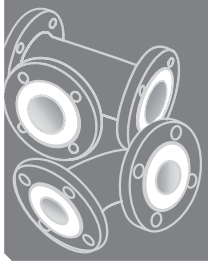
LINED VALVES



LINED PIPES



LINED FITTINGS



FLUORO-POLYMER HEAT EXCHANGER

Material options available on customer request from world renowned fluoropolymer suppliers

Chemours™ | dyneon 3M | AGC Fluon | SOLVAY asking more from chemistry® | DAIKIN | GFL™

HI-TECH APPLICATOR
1102-B, Phase-3, G.I.D.C. Ind. Estate, Vatva, Ahmedabad - 382 445, Gujarat - India.
+91 79 4030 7621 / 2583 3040 / 2589 1740 | +91 97370 46491 | hitech@ptfeindia.com

ISOQAR REGISTERED | UKAS MANAGEMENT SYSTEMS | CE | ASTM F-1545 | D&B

HORIZON POLYMER

www.horizonpolymer.com

India's Largest Processor of **FLUOROPOLYMERS**

Valves qualified ISO 15848-Part 1.

Pipework qualified ASTM F 1545

Chemours Co FC LLC - Delaware appoints Horizon Polymer as TEFLON® Licensing Partner for India Under Trademark license agreement to promote and sell PTFE/PFA/FEP Lined Piping products using TEFLON® PTFE/PFA/FEP Fluoropolymer.

TEFLON and Teflon diamond brand logo are registered trademarks of The Chemours Company FC, LLC used under license by Horizon Polymer Engineering Pvt. Ltd.

Horizon Polymer Eng Pvt. Ltd.:
204, Sumer Kendra, Pandurang Bhudhkar Marg, Worli, Mumbai - 400018. India
Contact: +91 22 24965031-36 I **Fax:** +91 22 24961073
Email: **vp@horizonpolymers.com**

PHARMA BIO WORLD
R.N.I. No.: MAHENG/2002/08502

CHAIRMAN
Maulik Jasubhai Shah

PUBLISHER & CEO
Hemant K. Shetty

EDITOR
Mittravinda Ranjan

CREATIVES
Arun Parab

GENERAL MANAGER SALES
Amit Bhalerao
Prashant Koshti

BRAND MANAGER
Sudhanshu Nagar

SALES
Godfrey Lobo
Priyaranjan Singh
Chandrahas M Amin
Yonack Pradeep

JASUBHAI MEDIA PVT. LTD.

Registered Office: 26, Maker Chambers VI, 2nd Floor, Nariman Point, Mumbai 400 021, INDIA.
Tel.: 022-4037 3737 Fax: 022-2287 0502
E-mail: sales@jasubhai.com

PUBLISHED BY:

Jasubhai MEDIA

THE NEW MODULAR PLATFORM WITH EASYCONNECT CLICK-FIT SYSTEM

THE STRONGEST LINK.

STAHL

GLOBALLY CERTIFIED MODULAR SOLUTION

The R. STAHL ORCA HMIs are prepared for the future and have the features and capabilities to improve your work environment's safety, efficiency, and flexibility. With its intelligent and modular design and worldwide certifications, our HMIs have been designed to meet all your needs. Some key features include the EasyConnect click-fit system, which makes installation a breeze, and the Future-proof investment, which ensures that you are getting a product that will be relevant for years to come. The modular operator stations and panel-mount devices are the perfect solution for Zones 1, 2, 21 and 22 as well as for Class I & II, Division 2 and Class III.

Discover more at: **r-stahl.com/in** or **sales.india@r-stahl.com**

Follow us: R. STAHL Group R. STAHL Group @rstahlgroup

CONTENTS

FEATURES

AD INDEX

PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

Quantum Leap your Business

via

Dynamic

'Pharma Bionetwork' platform

Directly Reach the Inboxes of **40,000+**Affluent Leaders & Business Influencers' from the **Pharma Industry** each month with the PharmaBio World Digital Edition

sales@jasubhai.com

www.jasubhaimedia.com

Dr Mansukh Mandaviya emphasises upon accelerating research & innovation in pharma

Dr Mandaviya along with members of Governing Council at NIPER

New Delhi, India: "Research and innovation are necessary for the sustained growth of pharmaceuticals sector. Our focus must shift from self-sustenance model to profit model through expanding research base, creating industry connect and ramping up infrastructure. The expertise of our human resources must be utilized along with implementation of best practices from other institutions. Only then we will be able to make National Institutes of Pharmaceutical Education and Research (NIPERs) as the centre for high quality research and create a fundamental base for pharmaceutical innovation in the country." Union Minister for Chemicals & Fertilizers, Dr. Mansukh Mandaviya stated this as he chaired the first Governing council meeting of National Institute of Pharmaceutical Education and Research (NIPERs) along with Ramesh Bidhuri, Member of Lok Sabha, Dr. Maddila Gurumoorthy, Member of Lok Sabha, Dr. Radha Mohan Das Agarwal, Member of Rajya Sabha at National Institute of Health & Family Welfare (NIHFW), here yesterday. He invited suggestions from everyone on efficient implementation of guidelines and structures so that all stakeholders come up with quality ideas which can be speedily put into operation. In a tweet posted by Union Minister, Dr. Mandaviya reiterated the government's commitment towards strengthening the holistic research ecosystem in the pharma sector and the brand NIPER.

Government updates monitoring mechanisms

New Delhi, India: Central Drugs Standard Control Organisation (CDSCO) in coordination with various State Licensing Authorities (SLAs) conducts inspections of pharmaceutical manufacturing units in order to assess the status of compliance, to the requirements of Good Manufacturing Practices (GMP) under the Drug Rules 1945, as per risk-based approach. There are laid down guidance and checklist for conduct of inspections to assess the compliance of manufacturing facilities with the specified GMP and Good Laboratory Practice requirements.

CDSCO and Ministry of Health and Family Welfare have taken regulatory measures to ensure the quality of medicines in the country as: The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable; States/UTs have set up special Courts for trial of offences under the Drugs

and Cosmetics Act for speedy disposal; The number of sanctioned posts in CDSCO has been significantly increased in last 10 years; To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs; The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government; The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.

Indian API industry to grow at 7-8% CAGR

Mumbai, India: ICRA expects the Indian active pharmaceutical industry (API) industry, which has an estimated size of Rs. 1,000-1,100 billion in CY2022, to grow at a CAGR of ~7-8% over the next three-four years. This will be driven by steady growth in the formulations industry, which in turn will be aided by the increasing geriatric population, growing prevalence of chronic diseases, and increasing demand for contract manufacturing with global customers looking to diversify their supply chain dependence from China to alternative destinations. Further, the Central Government's legislative support and the production linked incentive (PLI) scheme under its broader Atmanirbhar Bharat mission will boost the API industry's growth significantly, helping to reduce the dependence on Chinese imports.

"The Indian API industry has faced various headwinds such as rising input costs (raw materials, freight, and energy), forex volatility and supply chain disruptions due to the ongoing geopolitical disruptions, resulting in a sharp contraction of ~550-600 bps in the operating profit margins (OPM) of ICRA's sample set to ~13.0% in FY2023E over ~18.7% in FY2021. However, with the easing of supply chain disruptions and freight costs, and the expected stabilisation of raw material prices over the next few quarters, the OPM is likely to improve by 80-100 bps in FY2024. Moreover, the industry is expected to benefit from the Government's increasing focus on reducing import dependence on China by incentivising local production through the introduction of schemes like the PLI and the bulk drugs parks scheme. The successful implementation of these schemes will reduce the dependence on China by ~25-30% in 4-5 years,"said Deepak Jotwani, Assistant Vice President & Sector Head – Corporate Ratings, ICRA Limited.

Promising patient focused drug development

Massachusetts, USA: New evidence-based reports offer timely analysis and actionable guidance to drug developers bringing critical new therapies to market. Parexel, one of the world's largest clinical research organizations (CROs) providing the full range of Phase I to IV clinical development services, today announced the launch of a new expert series, New Medicines, Novel Insights. The series will feature fresh insights from the company's global, cross-functional experts

Chemtech FOUNDATION
Inspiring Intelligence › Igniting Innovation

Supported by

सत्यमेव जयते
Ministry of Chemicals & Fertilizers
Department of Chemicals and Petrochemicals, Government of India

DECHEMA Society for Chemical Engineering and Biotechnology e. V.

VDMA Process Plant and Equipment

World Meet of the CHEMICALS, PETROCHEMICALS, BIOPHARMA & PROCESS Industry in India

ChemTECH WORLD EXPO 2024

31st International Exhibition & Conferences

4-7 March 2024

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

50 CHEMTECH FOUNDATION 1974-2024
Inspiring Intelligence... ..Igniting Innovation

Join us for 50th Years Celebration

LEADERSHIP FOR CHEMTECH 2024

Patron & Brand Ambassador
ChemTECH World Expo 2024
Shri Suresh Prabhu
Former Member of Parliament
Government of India

Jury ChairmanChemtech Leadership & Excellence Awards 2024
Dr. R A Mashelkar
Scientist, Former Director General, Council of Scientific and Industrial Research (CSIR)

Chairman
Specialty Chemicals World Expo 2024
Mr. Nadir Godrej
Managing Director, Godrej Industries Ltd

Chairman, EPC World Expo 2024
Mr. B Narayan
Group President Projects & Procurement, Reliance Industries Ltd

Co-Chairman, EPC World Expo 2024
Mr. Subramanian Sarma
Whole time Director & Sr. EVP Energy
Larsen & Toubro Limited

Chairperson, Refining & Petrochemicals World Expo 2024
Ms. Sukla Mistry
Director (Refineries), Indian Oil Corporation Ltd

Co-Chairman
Refining & Petrochemicals World Expo 2024
Mr. Sanjay Khanna
Director (Refineries)
Bharat Petroleum Corporation Ltd

Chairman, WaterEX World Expo 2024
Mr. P Raghavendra Rao, IAS
Chairman, Haryana State Pollution Control Board, Ex Secretary (Chemicals & Petrochemicals)

Convener, Specialty Chemicals World Expo 2024
Dr. Raman Ramachandran
Head of Management Development Programmes K J Somaiya Institute of Management

Key Board Member
Specialty Chemicals World Expo 2024
Mr. Rajendra Gogri
Chairman & Managing Director
Aarti Industries Ltd

EXHIBITOR GROUPS

- Chemical & Pharma Processing
- Process Plants & Equipment
- Thermal & Mechanical Processing
- Engineering Procurement & Construction
- Technology Licensors
- Project Management Consultants
- Refining
- Chemicals & Petrochemicals
- Specialty Chemicals
- Chloroalkali
- Fertilizers
- Water & Waste Management
- Environment Technologies & Services
- Digital Services
- Industrial Automation
- Instrumentation & Process Automation
- Electrical Equipment
- Research & Development
- Biotechnology
- Green Chemistry
- Banking Finance & Insurance
- Lab & Analytical Instruments

PHARMA & BIOPHARMA

- Ingredients
- Bulk drugs
- R&D
- Warehousing
- Cold chain
- Packaging
- Contract Research & Manufacturing

CLEAN ENERGY

- Hydrogen
- Biofuels
- Methanol
- Carbon Capture Utilization & Storage
- Renewables – Solar Wind & Hydro

LOGISTICS

- Logistics Services
- Containers
- Supply Chain Management
- Packaging
- Material Handling
- Storage & Warehousing
- Cold Chain Management

CORROSION CONTROL

- Industrial Coatings
- Corrosion Control Technologies & Services
- Surface Engineering Solutions
- New metallurgies
- Inspection & Monitoring Technologies

Concurrent Events

EPC 2024 Engineering Procurement Construction · Specialty ChemICAL World Expo 2024 · Refining & Petro CHEMICALS 2024 · Bio Pharma World Expo 2024 · Industry AUTOMATION & Control 2024 · PVF Pumps, Valves & Fittings WORLD EXPO 2024

WaterEX WORLD EXPO 2024 · BOILER World Expo 2024 · SURFACE ENGINEERING & Corrosion Control World Expo 2024 · Student Outreach Program 2024 Develop Future Leaders

ChemTECH World Expo 2022

300+	19350	6	150	650+	200	27
EXHIBITORS & PARTNERS	VISITORS	CONFERENCES	SPEAKERS	DELEGATES	STUDENTS	COUNTRIES

Organised by:

Jasubhai MEDIA

Jasubhai Media Pvt Ltd

Taj Building, 3rd Floor, 210, Dr. D N Road, Fort, Mumbai – 400 001, INDIA.
Tel: +91-22-4037 3636, **Email:** sales@jasubhai.com

Ahmedabad - 09833104834 | Bangalore - 09892644177 | Chennai - 09176963737 | Delhi - 09818148551
Hyderabad / Pune - 09822209183 | Vadodara - 09820544904

analysing trends impacting drug development and offering evidence-based guidance to the biopharmaceutical industry. The inaugural report — Advancing Rare Disease Drug Development — explores the unique regulatory, scientific and market access challenges surrounding rare disease drug development and shares best practices to address them.

"Cutting-edge medicines are becoming more personalized and precise across the therapeutic landscape, while the process to develop those therapies is reaching new heights of complexity," said Amy McKee, MD, Chief Medical Officer and Head of Oncology Centre of Excellence. "Parexel's New Medicines, Novel Insights research series offers expert-led guidance to deliver on the promise of patient-focused drug development and bring impactful treatments to patients more rapidly."

Glenmark receives acceptance from USFDA for first-in-human clinical study

Mumbai, India: Glenmark Specialty SA, the subsidiary of Glenmark Pharmaceuticals Ltd., an innovation-driven, global pharmaceuticals company received acceptance from the U.S. Food and Drug Administration (FDA) on its Investigational New Drug (IND) application for GRC 54276 to proceed with a Phase 1/2, first-in-human, clinical study of GRC 54276 for the treatment of patients with advanced solid tumours and lymphomas.

GRC 54276 is an orally available, small molecule hematopoietic progenitor kinase 1 (HPK1) inhibitor developed by Glenmark. HPK1-regulated functions are involved in nearly every step of the cancer immunity cycle making it an attractive target for immuno-oncology. By inhibiting HPK1, GRC 54276 is designed to potentially enhance the patient's own immune system to fight cancers.

A Phase 1/2 multicentre, open-label study to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumour activity of GRC 54276 is currently underway in India. GRC 54276 is being studied as monotherapy or in combination with Anti PD-1 or Anti PDL-1 therapy in adults with advanced solid tumours and lymphomas. To date, 16 patients with various type of advanced cancers have been enrolled in this ongoing study in India, and company plans to expand the study at ex-India research sites in the subsequent months.

Sanofi receives marketing authorization for Soliqua

Mumbai, India: Sanofi (India) has announced that they have received marketing authorization for its diabetes drug Soliqua

(in pre-filled pen) from the Central Drugs Standard Control Organization (CDSCO). Soliqua is indicated as treatment to improve glycaemic control as an adjunct to diet and exercise, in adults with obesity and type 2 diabetes who are insufficiently controlled on oral or injectable therapies. It comes in once daily dosing of pre-filled pens in fixed-ratio combination of 10-40 and 30-60 of insulin glargine and lixisenatide.

"With approximately 74 million Indians between the ages of 20-79 years living with diabetes, healthcare professionals need more treatment options to customize diabetes care for them. Soliqua is the latest addition to our comprehensive diabetes portfolio (OADs and insulins) indicated for people with obesity who are living with insufficiently controlled diabetes," said Cyrus Aibara, head, Diabetes Business Unit, Sanofi (India).

Indian Immunologicals receives DCGI approval for measles-rubella vaccine

Mumbai, India: Indian Immunologicals Limited (IIL), a leading vaccine manufacturer has announced receipt of approval from Drugs Controller General of India and State Drug Control Administration for manufacturing of measles-rubella (MR) vaccine.

This is the outcome of the Indo-Vietnam partnership, where IIL partnered with the Centre for Research and Production of Vaccines and Biologicals, also called Polyvac, Vietnam.

Measles causes severe, sometimes permanent, complications including pneumonia, seizures, brain damage, and even death. Measles is caused by a virus that lives in the nose and throat mucus of an infected person and spreads easily through breathing, coughing, and sneezing. There is no specific antiviral drug available to treat measles. The best way is to prevent measles through vaccination. The measles, mumps, rubella (MMR) vaccine is a safe and effective way to protect people from measles. Measles kills nearly 50,000 children every year in India. As there is not enough evidence to suggest that mumps is a disease of public health importance, MR vaccine is being used instead of MMR vaccine in India for routine immunization.

Indian pharma firm Granules opens packaging facility in US' Virginia

Hyderabad, India: Granules has opened a packaging facility in the Virginia State of the US to expand the packaging capacity of essential drugs in the state, thus strengthening the biopharma supply chain. The facility was inaugurated by India's Ambassador to the US Taranjit Singh Sandhu.

Granules, which was one of the first Indian pharmaceutical companies that received FDA authorization to export to the United States, has invested more than USD 100 million in the country, said Dr Krishna Prasad Chigurupati, the founder, chairman and managing director of the firm.

"We have nearly 200 employees in Virginia with a large majority of them first-generation Indians," he said, adding the company also has a team of 30 scientists for research and development.

Schott launches amber pharma glass production line

(L to R) : Pawan Schuklar, MD, Schott Glass India, Dr. Patrick Markschläger, VP Schott Tubing, Peter Scherer, VP Sales & Marketing Schott Tubing, Parag Parikh, AVP and Sundeep Prabhu, Sr. VP Sales Schott Tubing India

In a strategic move, Schott inaugurated the amber pharmaceutical glass tubing facility in Jambusar, Gujarat to meet the growing demand of glass containment solutions by pharma industry. As a global leader in pharmaceutical glass manufacturing, Schott offers a wide range of products and services to help store injectable medications safely. To meet the increasing demand in Asia, Schott has invested INR 660 crore over the last three years to double the capacity in the region amber glass tubing is first of its kind in Asia to meet the growing demand amber pharmaceutical glass tubing for containment of vials, ampules, and syringes for storing light-sensitive drugs like antibiotics and chemotherapeutic agents. With this move, an additional 150 jobs will be created in the Schott facility in Gujarat.

Schott holds a major part of global market share in tubing solutions and the growth rate for these solutions is far higher in Asia as compared to Europe. Dr Patrick Markschlaeger, Executive VP tubing business, Schott shared, “India is one of the largest and strategically important markets for Schott which enables us to me strategically close to our customers by enabling their growth plans and ensuring a sufficient regional supply of high-quality pharmaceutical glass tubing.” The facility will reduce the imports of FIOLAX amber glass for critical applications thus improving the availability, planning reliability, cost efficiency & optimizing supply chain for pharmaceutical converters. “We are going ahead with another Brownfield expansion for additional capacity for clear tubing which we target to commission by 2024”, he adds.

Current demand of amber glass tubing stands at around in India and is growing at 3-4 % per annum. There was a surge in demand of amber glass solutions during Covid for containment of vaccines and Schott was responsible for almost 95% of COVID-19 vaccine packaging in India. These solutions will continue to maintain positive momentum driven by the growth of Indian pharma and healthcare sector. This is company's fifth global manufacturing facility for amber glass tubing which will enable the group to provide complete portfolio borosilicate glass variations, a high-quality material that is converted to pharmaceutical containers in India and global markets.

"We combined Indian and European state-of-the-art technologies with local skills to manufacture premium quality borosilicate glass tubing. This unique mix allows us to offer specifications that meet the high standards of the international pharma industry", states Pawan Shukla, Managing Director, Schott Glass India Pvt Ltd.

The Jambusar facility has capacity for clear glass tubing and for amber tubing. Schott uses automation, big data, and smart manufacturing technologies such for quality assurance & quality control along with 100 % traceability of all products. The manufacturer maintains uniform specs & highest standards of compliance globally to facilitate interchangeable transfers to respond to the demand variations. Globally, the group uses perfeXion®, inspection system developed by in house R&D team to detect even the tiniest of deviations in specs. During the visit to factory Schott Glass India Pvt Ltd informed, the group does meticulous planning to carry out planned furnace maintenance shutdowns every three and a half years. So far, Schott was importing the FIOLAX amber glass from Germany to meet the local Indian demand. With the current expansion the group will enable the group to further consolidate the position as market leader. The group targets meeting the overall demand in India and other Asian countries through this new tank. ■

Dry Compressed Air – Enhancing the Medicine Life Cycle

Deepak Pahwa

Dry Compressed Air – Enhancing the Medicine Life Cycle

Pharmaceutical forms an intricate part of healthcare services. Though it always played a pivotal role, the importance was starkly felt during the pandemic. Responsible for curing and enhancing human health, pharmaceutical products are sought worldwide and this mandates the industry to be strictly regulated. Considering that India secures 3rd position in pharmaceutical production globally, the need to comply with the highest industry standards becomes a prerequisite more than ever.

The country emerges as the prominent supplier in the global pharmaceutical market, where India fulfills the demand for 50% of various vaccines globally along with meeting 40% of generic demand in the US and 25% of all medicine requirements in the UK. As a result, a great responsibility is vested on the manufacturers to deploy dry compressed air throughout the manufacturing till the packaging to produce quality drugs and medicine suitable for the international as well as domestic market. This becomes necessary as even the Food and Drug Administration (FDA) issues directions to the pharma companies to adopt uncontaminated compressed air for rendering high-quality end products.

Therefore, to maintain the supreme quality of pharmaceutical products, quality compressed air finds irreplaceable application in the entire processing, manufacturing, and packaging of

pharmaceutical products. All the intricate operations involving pneumatic processes like tablets and capsule manufacturing; giving the required texture, color, and flavor to the tablet; maintaining the right balance of the ingredients; protecting the products from contamination, etc. require compressed air at every step to produce high-quality end products meeting the highest industry standards. Quality compressed air confers the necessary framework to the pharmaceutical industry. It is widely used in automatic packaging machinery for sealing, Capsule Filling Machine, Powder Filling Machine, Blister Pack Machine, Tablet Press Machine, Drying Container, Vacuum cleaning system. In case untreated compressed air is supplied for any of the processes then there are high chances of the presence of moisture in the airline. As moisture inherently comes with various destructive characteristics, it can potentially threaten the production efficiency and quality of the end products.

Moisture is invariably present in the air and can enter the manufacturing facility through the ceilings, walls, and floors. It is a great deterrent for the pharmaceutical industry as it gives rise to problems ranging from the disintegration of tablets to lumping, caking, uneven coating on tablets, decomposition of formulations, agglomeration of chemical compounds, and inability to compress tablets which cumulatively lead to shorter shelf life of products. Considering that pharmaceutical products are hygroscopic in nature, they undergo physical, microbiological, enzymatic, and biochemical deterioration even when moisture is present in a negligible amount. Moisture not only changes the color coating of the tablet but even causes blisters in them that lead to breakage of the tablets.

The detrimental effect of moisture can be clearly seen in tablet compression. In this, the powdered materials are bounded into a capsule or tablet in its dry state under the presence of high pressure. Here, humidity is not just responsible for falling of the tablets apart but it initiates decomposition of the drugs which ultimately reduces their medicinal value. Even during tablet coating, if the cooling and drying are not done at the desired rate with the proper quality of compressed air, then it leads to the rough, translucent coating which is unsatisfactory in appearance. Furthermore, excessive moisture can initiate injurious activities of micro-organisms. It is responsible for increased microbial activity in the organic material that indirectly contributes to the destruction of the material. The mold, mildew, and fungi are already present in the air and germinate when met with a conducive combination of temperature and humidity. The microbial growth causes the decomposition of the material which

in turn leads to the mechanical weakening of the product. Here, it is important to note that the menace of moisture is not just limited to the manufacturing of medicines and other pharmaceutical products but it can contaminate the product even during the packaging. Hence, it is important to address the issue at every level of the product cycle and one must not relax just at the production stage. Therefore, it is clear that untreated compressed air is heavily loaded with potentially harmful or dangerous contaminants. It is mandatory to remove the moisture from the air for the protection of the consumers by providing them with safe and cost-effective drugs. Manufacturers must ensure the compressed air is free from any form of contaminants like water/ moisture, dust particles, oil, and solid contaminants.

The moisture menace is not just limited to the deterioration of drugs and medicine but has a damaging effect on the pneumatic tools and machines as well. High levels of humidity cause corrosion in the pipelines, cylinders, and other components that lead to the malfunctioning of the equipment. It is responsible for the sluggish and inconsistent performance of the pneumatic valve and cylinder. The problem is further compounded by the freezing of moisture during cold weather. All the factors together are responsible for the increased downtime of the machines which invariably incurs heavy liability in the form of maintenance costs for the company.

Looking at the various repercussions of moisture, the pharmaceutical industry must install compressed air dryers to eliminate even the slightest presence of moisture in the air. It helps in the treatment of compressed air powering various pneumatic processes. The advanced dryers come with a wide range of refrigeration and desiccant/ adsorption dryers. Though both of them work on different principles but are well equipped to achieve the same desired result of removing moisture from the compressed air. Hence, it can be said that dry compressed air is the fourth utility of the pharmaceutical industry. It gives a structural framework to the industry which ensures the highest quality end product. Along with this, intervening with the malfunctioning effects of moisture on the pneumatic machines, substantially reduces the downtime of the equipment. This plays a major role in invariably adding value to the revenue of the company as they can avoid any unnecessary maintenance costs and even curb the instances of production glitches that could result from damaged machines. ■

PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

Quantum Leap your Business

via

Dynamic

'Pharma Bionetwork' platform

Directly Reach the Inboxes of **40,000+**Affluent Leaders & Business Influencers' from the **Pharma Industry** each month with the PharmaBio World Digital Edition

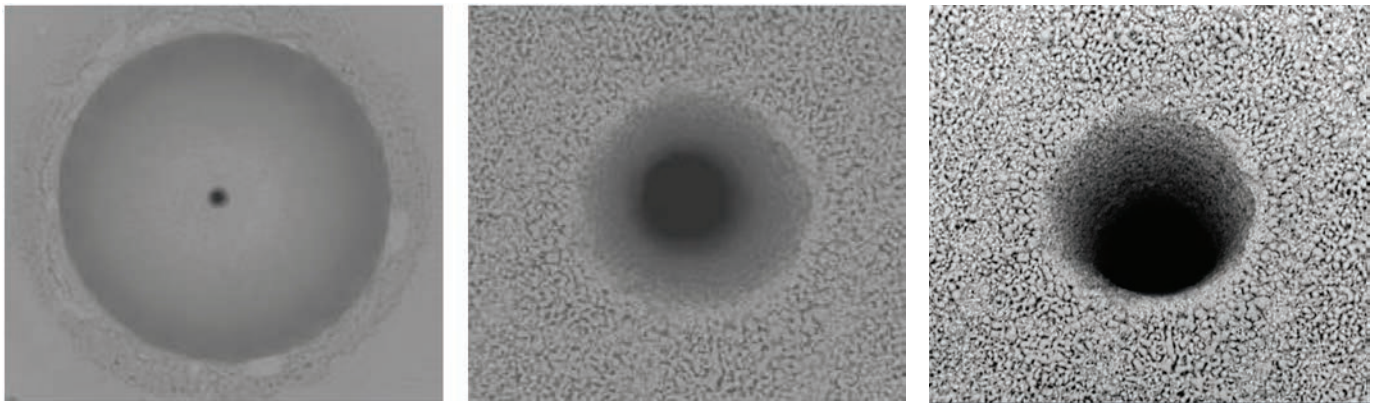
sales@jasubhai.com

www.jasubhaimedia.com

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." ■

The Cold Chain of the Future

Nick Gilmore
Global Head of Sales and Marketing
Tower Cold Chain

In today's continuously volatile market, with customers demanding greater efficiencies at increasingly lower costs, logistics providers are constantly searching for new technologies and processes that will not only improve operations but help give their business a competitive edge. With the cold chain logistics market for the pharmaceutical industry set to grow by USD 9.37 billion from 2020 to 2025, according to Technavio, specialist freight providers must be forward thinking to stay ahead and make its processes as efficient as possible.

Product images

Adapting to meet new demands through product innovation

Putting the triumph of the COVID-19 vaccine rollout to one side, the demand for

effective temperature sensitive solutions in the pharmaceutical supply chain has increased hugely in recent years. With a growing prominence for personalised medicines, we are now beginning to see the advancements of precision therapies in the pharmaceutical cold chain industry. There is no longer a "one-size-fits-all" approach to medical practice. Instead, we're seeing a shift towards bio-specific treatments, tailored to a particular

individual's needs based on their genetic material. And, with manufacturing adjusting to smaller batch, precision medicines, the vendors and outsourcing partners must adapt too as the need for transparent, closely controlled global chains demands rise.

Thus, it is vital for pharmaceutical manufacturers to have a cold chain partner that is committed to continually expanding and evolving to keep pace with the complexities of transporting pharmaceuticals. Cold chain shipping providers should have the technology, resources, and network in place for handling lower volumes of products with tight manufacturing-to-patient timeframes. Delivering a consistent customer outcome, is a need not a want. Put simply, manufacturers will choose partners who can assure products will arrive on time, undamaged, and with no temperature excursions.

Tower's critical and mission-defining objective is to improve the quality and consistency of pharmaceutical deliveries across a global market. An example of how this has been achieved is the recent development of the KTEvolution – a robust, lightweight, handleable solution that provides the same reliable thermal protection and reusable durability as Tower's existing range. With the growing trend in smaller shipments such as direct-to-patient, sample shipment, clinical trials and last-mile deliveries, combined with customer feedback, it became clear that there was a gap in the cold chain shipping market for a passive solution, ideal for manual handling.

Hence, the KTEvolution was born, striking the optimum balance between high performance, durability and optimised weight. And, like all our range of passive containers, any pharmaceutical products stored in a Tower solution, require zero in-transit manual intervention, or electricity. Passive solutions have contingency built in, providing 120+ hours of product protection, whether the requirement is for frozen, chilled, or ambient temperatures. Our robust containers are intended to perform in all supply chains regardless of transport type or environment, delivered to patients reliably when, and where they need them.

The network approach to planning and beyond

With the amount of sensitive biopharmaceutical and biologic products expanding, coupled with the demand for advanced pharmaceuticals in middle to low-income countries, cold chains will continue to be pushed to globalise in the coming years. Pharmaceutical organisations are increasingly relying on their external suppliers to operate lean supply chains, with extended distances to ship products quickly and efficiently. Logistic providers must ensure these needs are met, offering a global network for localised deliveries – all whilst complying with each country's regulations and maintaining the strictest requirements.

For Tower, our international hub network is expanding month on month and is set to double in 2022 alone. With new hubs and service centres opening in Europe, throughout the APAC and Americas regions, this is set to further improve the proximity and availability of Tower containers, whilst being the securest way to reduce the risk of disruption. An optimised global network for localised shipments, enables Tower to react even more quickly to customer requests, and provide assurance of supply, anywhere in the world.

Knowledge is power

The unpredictability of the market, combined with today's increasingly connected, world, means pharmaceutical businesses are depending on their third-party cold storage partners to deploy end-to-end tracking processes and capabilities to ensure product integrity and maintain profits. Data is no longer a bonus feature, but a vital part of cold chain operations and smart packaging which delivers traceability is becoming a cornerstone of supply chain fulfilment.

A key aspect provided by Tower are dataloggers, designed to monitor external and internal temperatures throughout each individual container's journey. These advanced features, integrated into the external body of the container, inform customers of the solutions' pre-conditioned temperature, prior to the loading process, thus guaranteeing product integrity from the very beginning of the cold chain. Using Bluetooth Low Energy Technology, each logger communicates wirelessly, sending accurate data to the cloud. Users can get a text or email notifications of temperature excursions, as well as automatic data downloads throughout the transit when it's in range of an InTemp Gateway device. This data communication allows for accurate compliance checks and on-delivery sign-off, providing complete visibility and transparency to customers.

And yet, as with everything we do at Tower, we are constantly innovating and improving our offering to ensure all cold chain pharmaceutical products make it to their destination safely and securely, ensuring critical medicines are delivered intact and always within the manufacturer's temperature stability requirements. To stay ahead of the curve, we're actively looking into the sphere of cellular GPS tracking geared specifically towards pharmaceutical shipments and compatible with airline regulations. Ultimately, strength is already there but technology is helping us to take that process to the next level to maintain a robust, reliable, reusable supply chain.

The example of the last few years underlines how turbulent and fast changing the pharmaceutical supply chain can be. With demand set to increase further, this complexity isn't going to go away and that's why it's vital to anchor cold chain decisions in the essential elements that won't change. For Tower, our customers continue to require robust, reliable, reusable cold storage solutions, to provide effective temperature sensitive control to protect the integrity of pharmaceutical products – and, at our core, is what we will continue to do, whilst providing peace of mind that, whatever happens in the world, your pharmaceuticals products will arrive safely and on time. ■

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. ■

R.N.I. No.: MAHENG/2002/08502. Date of Publication: 26th of every month.

PharmaBio World
INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

www.jasubhaimedia.com

Each month PBW Digital reaches
>40,000 INBOXES

Share DYNAMIC CONTENT with your customers
Get SINGLE CLICK Connectivity &

Embed Product Video

Choose the embedded features: insert all embedded features Contact: sales@jasubhai.com

Jasubhai MEDIA