VOL 19 | ISSUE 12 | JULY 2021 | MUMBAI

www.jasubhaimedia.com

PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

HI-TECH™
APPLICATOR
a Global Trusted Brand
www.ptfeindia.com

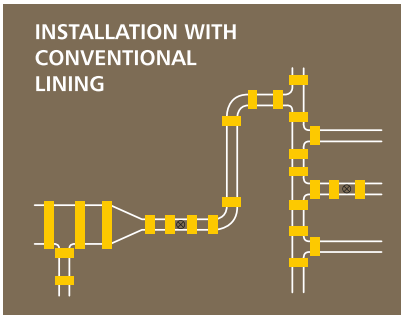
INTRODUCING FIRST TIME IN INDIA

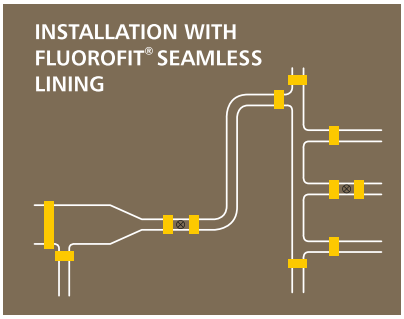
CORROSION RESISTANT SEAMLESS LINING IN COMPLEX SHAPES AND LARGE DIAMETER EQUIPMENTS

FLUOROFIT®
COMPLEX SHAPE SEAMLESS LINING

FLUOROFIT® ADVANTAGE

- Seamless Lining in Complex Shapes
- Full Vacuum Resistance Even in Bigger Sizes
- No Welding Seams or Adhesives
- Reduction of Flange Joints & Leakage Points
- Reduction of Costs & Weight
- Conductive Lining Option Available
- Reduced Residual Tension
- FDA Complaint





Teflon® fluoropolymer

Teflon® Diamond logo and Teflon® are registered trademark of The Chemours Company FC, LLC used under licence by HI-TECH APPLICATOR

PTFE LINED SYSTEMS™
VALVES | PIPES | FITTINGS | COATINGS

| PTFE | PFA | FEP
| ETFE | PVDF | ECTFE
| PP | HDPE | PEEK | PA11/12

HI-TECH APPLICATOR
1102-B, Phase-3, G.I.D.C. Ind. Estate, Vatva, Ahmedabad - 382 445, Gujarat, India.
P : +91-079 2583 3040 | 2589 1740 | F : +91-079 2583 3461 | E : hitech@ptfeindia.com

MS-TS Analytical Balance

Trusted Results at your fingertips

MS-TS analytical balance which offers advanced connectivity, publishing and reporting features for improved data management and process control. With Ethernet and Wi-Fi options, connection to peripheral devices or LAN/WLAN networks is easier and more flexible. Data transfer from the balance to other devices is faster and easier. Save, print or export weighing results in a variety of formats, to different places simultaneously. Web browser access to the balance terminal offers convenient viewing of results remotely.

Easy and Comfortable Use

The 7-inch extra-large color TFT touchscreen display can be operated through cotton, silicone and rubber gloves. An intuitive user interface and 18 millimeter high digits bring comfort to your daily tasks.

Advanced Data Management

LAN, USB Host, USB Device, RS232 and optional WLAN/Bluetooth interfaces enable simple and comprehensive data handling. Transfer data to a PC, FTP server, USB memory stick or a printer, including comprehensive PDF reports or XML files.

Effortless Cleaning

The QuickLock draft shield dismantles in seconds without any tools and all parts are dishwasher-safe. Surfaces are smooth and rounded to make cleaning easy.

Write to us
at sales.sales@mt.com or
Call Toll Free at 1800 22 8884 / 1800 10 28460
or visit us at www.mt.com

METTLER TOLEDO

www.mt.com/ms-analytical

CONTENTS

GUEST COLUMN

INTERVIEW

FEATURES

IMPACT FEATURES

HRS process systems

MOST EFFICIENT HEAT TRANSFER EQUIPMENT FOR PHARMA INDUSTRY.

Our association with the pharmaceutical industry is built on the solid premise of technological competence. Our heat transfer innovations like **ECOFLUX*** corrugated tube heat exchangers, **HRS FUNKE** Plate Heat Exchangers & compact skid based HE systems continue to be the trusted choice of major leading pharma companies in key applications.

ECOFLUX*
Corrugated Tube Heat Exchanger

HRS Heat Exchanger
Based Systems

HRS FUNKE
Plate Heat Exchanger

HRS Process Systems Ltd.
201/202 Karan Selene, 851, Bhandarkar Institute Road,
Pune 411 004, Maharashtra - India
Ph. : +91-20-2566 3581/6604 7894 & 95 | Fax :+91-20-2566 3583
info@hrsasia.co.in | www.hrsasia.co.in

TÜV NORD ISO 9001

ASME 'U' Stamp Certified Company

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
Sunil Kulkarni

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

AD INDEX

PharmaBio World
INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

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**

XPlanar®: Levitating, contactless, intelligent!

Free 2D product movement with up to 6 degrees of freedom

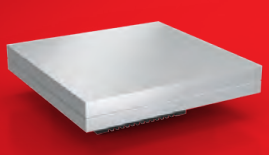
www.beckhoff.com/xplanar

XPlanar enables new degrees of freedom in product handling: Levitating planar movers float over individually arranged planar tiles on freely programmable tracks.

- Individual 2D transport at up to 2 m/s
- Processing with up to 6 degrees of freedom
- Transport and processing in one system
- Wear-free, hygienic and easy to clean
- Free arrangement of planar tiles enabling customized machine layout
- Multi-mover control allowing parallel and individual product handling
- Fully integrated into the powerful PC-based Beckhoff control system (TwinCAT, PLC IEC 61131, Motion, Measurement, Machine Learning, Vision, Communication, HMI)
- For use across all industries: assembly, food, pharma, laboratory, entertainment, …

Beckhoff Automation Pvt. Ltd.
Pune – 411 001, India
Phone: +91 (20) 6706 4800
info@beckhoff.co.in

BECKHOFF ENABLING
MADE BY
INDIA



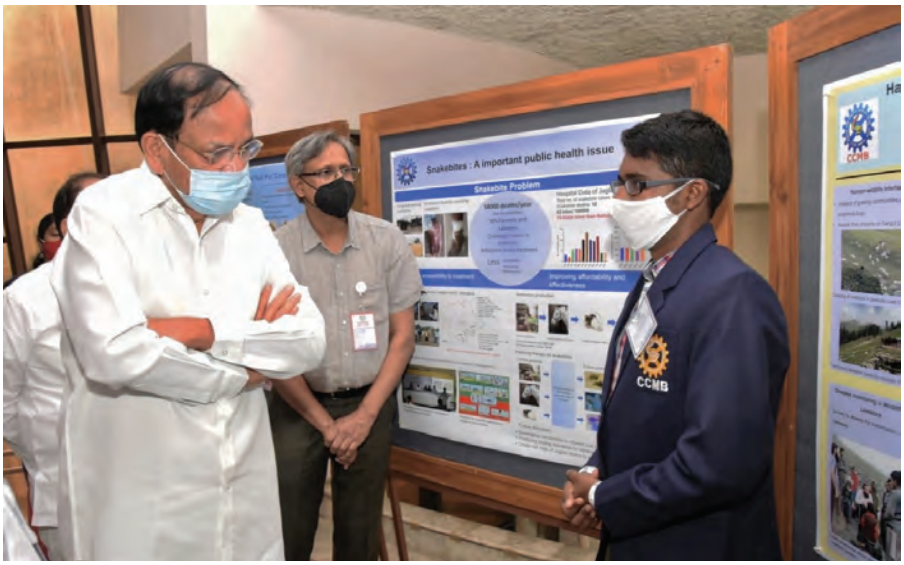
Fully integrated, compact XPlanar drive tile

Scalable payload (in kg) with different mover sizes

XPlanar tiles form a modular base on which the XPlanar movers can move freely about

New Automation Technology **BECKHOFF**

Vice President Calls for Fast-Tracking Genome Sequencing of New COVID-19 Variants



New Delhi, India: The Vice President of India, Shri M Venkaiah Naidu , urges international partnership to study developing a universal vaccine for various variants. VP visits CCMB's LaCONES (Laboratory for the Conservation of Endangered Species), Compliments CCMB for its role in COVID-19 mitigation, Lauds LaCONES for developing several biotechnology tools for wildlife conservation

VP refers to the impact of climate change and stresses the importance of protecting and preserving our ecosystems and called for fast-tracking of genome sequencing of new COVID-19 variants to speed up finding suitable vaccines and drugs.

The Vice President visited CCMB's LaCONES (Laboratory for the Conservation of Endangered Species) facility soon after his arrival in Hyderabad. He witnessed a presentation by Scientist-in-charge of LaCONES, Dr. Karthikeyan Vasudevan and visited National Wildlife Genetic Resource Bank, Assisted Reproduction Lab and animal cages at the facility.

Addressing scientists and research scholars, Shri Naidu observed that sequencing, as an adjunctive tool, plays a critical role in identifying the emergence of new viral mutations and thus helps combat the spread of Covid-19. It would also help in timely interventions, he added.

Stating that the need for genome sequencing of new variants becomes crucial in the light of reports of big cats contracting COVID-19 in a few zoos in the country, Shri Naidu pointed out species jump of a virus—from humans to animals or vice versa—could lead to new variants and pose fresh challenges in the ongoing fight against the pandemic.

The Vice President also stressed the need for strengthening international collaborations by research institutions to study the feasibility of developing a universal vaccine that could neutralize various SARS-CoV-2 variants.

Appealing to the people to shed vaccine hesitancy, Shri Naidu reiterated that vaccines made in India are safe and effective and everyone should get vaccinated and encourage others to do so too. He called for cultural and sporting icons to become active partners in the drive and motivate people to go for vaccination. "Vaccination drive should

Plastic AODD Pumps

The most versatile pump on the market

tapflo®

Polyethylene Pump

PTFE Pump

- Suitable for most chemicals and abrasive liquids
- Suitable for the most aggresive chemicals

Tapflo Fluid Handling India Private Limited
Office No 207, Amar Neptune
Baner, Pune 411045, INDIA

Tel: +91 7767014104
E-mail: ac@tapflo.in

www.tapflo.in

become a national movement", he stressed.

Complimenting CCMB for its contribution to the cause of COVID-19 mitigation, Shri Naidu referred to the need for strong collaborative arrangements between institutions and added that LaCONES-CCMB, was rightly positioned to make linkages at both national and international levels, to understand the emergence of infectious diseases and prevent such pandemics in the future.

Referring to the activities of LaCONES and the formation of a consortium involving five zoos to promote bio-banking of endangered species, he termed it "a timely initiative". Touching upon the impact of climate change on all life forms, Shri Naidu pointed out that India has some of the most bio-diverse regions and is home to a wide range of ecosystems.

In order to mitigate climate change, the Vice President said that a massive afforestation programme is the need of the hour and that everyone should actively participate in planting trees in their communities and localities.

"We not only need to protect and preserve our ecosystems but also make every effort for conservation of endangered species for the well-being of animals, plants and humans", he added and expressed confidence that the modern bio-technological tools will help in mitigating the adverse effects on wildlife and ecosystems.

During the visit, the Vice President released a book 'An Introduction to Genetic Resource Banks for Wildlife Conservation'. He also interacted with research scholars and inquired about their work.

Shri Mahmood Ali, Telangana Home Minister, Dr. Vinay Nandicoori, Director, CCMB, Dr. Karthikeyan Vasudevan, Scientist-in-Charge CCMB-LaCONES, R. Shobha, Chief Wildlife Warden Telangana, scientists and research scholars were present during the event.

Minister of Ayush Shri Kiren Rijiju Launches Five Important Portals on Ayush Sector

It was an historic and momentous day for the Ayush sector as five portals of importance were launched and four publications were released by the Union Minister of Ayush (IC) Shri Kiran Rijiju in an online event. The Minister also reminded that Ayush is going to play a big role in the National Digital Health Mission to provide health security to Indian people.

At a virtual event, the Minister launched CTRI portal pertinent to Ayurveda Dataset along with AMAR, RMIS, SAHI and e-Medha portals. He also released four publications related to the Traditional Indian Medicine System of India and lauded the collaborative efforts of

praj | HiPurity Systems

Delivery of fill finish injectable line suitable for COVID vaccine in 6 weeks*

Aware and Prepared!!
Delivery in **6 weeks***

We at Praj HiPurity Systems are committed to deliver process skids for COVID vaccine formulations in a quick time.

With its vast experience in the pharmaceutical and biotech industry,
Praj Hipurity Systems Limited blends its vision with values to respond to this pandemic.

What we offer

1. **Manufacturing and filtration skid capacity ranging from 70L to 600L up to 2 manufacturing lines**
2. **Suitable CIP/SIP systems**
3. **PLC based fully automatic system with 21 CFR Part 11 compliance**
4. **Modularized solution to serve as a plug and play system**
5. **SIP validator cycle (Thermal Mapping Study) by KAYE validator during FAT (on demand)**

Connect. Collaborate. Conquer

*For more details connect with our subject matter experts.

www.prajhipurity.net

ICMR and Archaeological Survey of India for these initiatives.

After the inclusion of dataset pertinent to Ayurveda in CTRI portal, the Ayurveda Clinical Trials would have worldwide visibility and will further the cause of strengthening Ayurvedic Research. Similarly, SHAHI portal incorporates authentic resources and will be of immense help in showcasing historical veracity of Ayurveda. With the help of e- Medha portal anyone can have online access to more than 12 thousand books. These books are related to Indian Medical Heritage and can be accessed through NIC's e- granthalaya platform. AMAR portal, which was also launched today, is a repository for Ayurveda, Yoga, Unani, Siddha and Sowa- Rigpa Manuscripts and catalogues. Another Portal CCRAS- Research Management Information System or RMIS in short, is a research guidance platform.

While lauding the efforts of Ayush team in developing the portals, the Minister said that Indian Digital Health Mission is going to be the biggest programme in the Indian health sector and every effort is done to maximize the role of Ayush in it. The Minister termed development of portals as revolutionary, robust and momentous and said that as Indians, we all should take pride in our national heritage, customs and traditions. There is a mindset to look down on traditional Knowledge systems, referring to them as a thing of the past, or of no modern significance and unscientific. "We need to counter this and we need to celebrate our success in rediscovering our past, our national heritage and our traditional medicine system," He said.

Hetero Announces Interim Clinical Results from Phase III Clinical Trials of Molnupiravir

Hyderabad, India: Phase 3 Trial Demonstrates Statistically Significant fewer hospital admissions, Faster Time to Clinical Improvement and early negative SARS CoV-2 RT PCR with Molnupiravir Treatment in Mild COVID 19 Patients Compared to Standard of Care alone~ ~ Hetero has approached the Drug Controller General of India (DCGI) to seek Emergency Use Authorization for Molnupiravir in India ~ India, Hyderabad, 9th July 2021: Hetero, a globally renowned vertically integrated pharmaceutical organization, today announced the interim clinical results from Phase III Clinical trials of Molnupiravir in mild Covid-19 patients conducted across multiple COVID-19 dedicated hospital sites across India.

In April this year, Hetero had entered into a non-exclusive licensing agreement with MSD (tradename of Merck & Co., Inc., Kenilworth, N.J., USA (NYSE: MRK), to manufacture and supply Molnupiravir in India and over 100 low and middle-income countries (LMICs). Molnupiravir is an investigational, orally administered form of a potent ribonucleoside analog, being developed globally by MSD, that inhibits the replication of multiple RNA viruses including SARS-CoV-2, the causative agent of COVID-19 with demonstrated activity against SARSCoV-2 in human airway epithelial cell cultures and potential to completely eliminate SARS CoV-2 from the body within 5 days. Hetero had commenced a phase-III, comparative, randomized, multicenter clinical trial on mild Covid-19 patients (N=1218).

15 Years of Service in India

Be sure. testo

Because only safe vaccines can save lives.

Transport data loggers
testo 184

Wi-Fi data loggers
testo Saveris 2

Testo measurement technology for transportation and safe storage of medicines

Transport Data Loggers

- testo 184 with 21 CFR Part 11 compliance for uninterrupted monitoring of climatic conditions during transit with immediate creation of a PDF report directly after connection to a computer
- Use & throw models testo 184 T1/T2 loggers for long transits
- testo 184 T4 for extreme temperatures down to -80 °C

Wi-Fi Data Loggers

- testo Saveris 2 refrigerator kit for monitoring storage temperatures in refrigerators and deep-freezers down to -30 °C
- testo Saveris 2 with alarm function for limit value violations for additional security and data access from anywhere anytime 80 °C

Enquire now

Testo India Pvt Ltd

+91 20 2592 0000 | info@testo.in

MADE IN GERMANY

www.testo.com

These clinical trials were aimed at evaluating the efficacy and safety of Molnupiravir plus standard of care (test arm) versus standard of care alone (control arm), in mild Covid-19 patients with a positive SARS CoV-2 RT PCR test for COVID-19 and randomized within 5 days of onset of symptoms. Patients in the clinical trial were randomized to receive either Hetero's Molnupiravir capsules 800 mg (4 x 200 mg) every 12 hours (twice daily) for 5 days along with standard of care as per the Indian Council of Medical Research (ICMR) guidelines or, in the control arm, to receive standard of care alone. The interim results from mild COVID-19 patients (N=741) revealed the following encouraging outcomes: ▪ Earlier clinical improvement (2-point decrease in WHO Clinical Progression Scale) observed in Molnupiravir group compared to standard of care.

Shri Mansukh Mandaviya Visits Vaccine Manufacturing Plant in Ahmedabad

Ahmedabad, India: Minister of State for Chemical & Fertilizers and Ports, Shipping & Waterways (I/C) Shri Mansukh Mandaviya today visited Zydus Biotech Park at Ahmedabad.

Shri Mandaviya also visited Hester Biosciences Limited today. He informed via Twitter that Hester has inked an MoU with Bharat Biotech for production of Covaxin.

The Minister commended their efforts and assured them of all Government assistance for ramping up vaccine production to ensure free vaccination for all.

IIT Madras Researchers Develop AI-based Algorithm to identify Cancer-causing Alterations

Chennai, India: Indian Institute of Technology Madras Researchers have developed an Artificial Intelligence-based Mathematical Model to identify cancer-causing alterations in cells. The algorithm uses a relatively unexplored technique of leveraging DNA composition to pinpoint genetic alterations responsible for cancer progression.

Cancer is caused due to the uncontrolled growth of cells driven mainly by genetic alterations. In recent years, high-throughput DNA Sequencing has revolutionized the area of cancer research by enabling the measurement of these alterations. However, due to the complexity and size of these sequencing datasets, pinpointing the exact changes from the genomes of cancer patients is notoriously difficult.

This research was led by Prof. B. Ravindran, Head, RBCDSAI, and Mindtree Faculty Fellow IIT Madras and Dr. Karthik Raman, Faculty

MAKE IN INDIA

UFLEX

'A part of your daily life'

"Protect your Brand with Effective Anti-Counterfeiting Solutions"

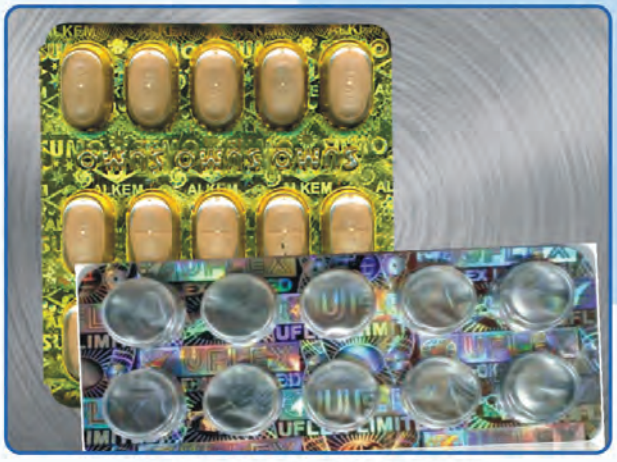
FOR PHARMA INDUSTRY

CAN YOU GUESS WHICH ONE OF THESE MEDICINES ARE FAKE

COUNTERFEIT FALSEHUNG FACTICE नकली
FALSIFICATION Поддельный تزوير BANDIA

HOLOGRAPHIC LIDDING FOILS

CARTON



HOLOGRAPHIC PVC

HOLOGRAMS / LABELS

UFLEX LTD. (HOLOGRAPHY BUSINESS)
A1, Sector 60, Noida-201 301 (U.P.) India
Phone: +91-0120-4002121, +91-0120-6100000, Mail: holography@uflexltd.com
www.uflexltd.com / holography.php

Member, Robert Bosch Centre for Data Science and AI (RBCDSAI), IIT Madras, and also the Coordinator, Centre for Integrative Biology and Systems Medicine (IBSE), IIT Madras. Mr. Shayantan Banerjee, a Master's Student at IIT Madras, performed the experiments and analysed the data.

The results have been recently published in the reputed peer-reviewed International Journal Cancers.

Explaining the rationale behind this study, Prof. B. Ravindran, Head, Robert Bosch Centre for Data Science and AI (RBCDSAI), IIT Madras, said, "One of the major challenges faced by cancer researchers involves the differentiation between the relatively small number of 'driver' mutations that enable the cancer cells to grow and the large number of 'passenger' mutations that do not have any effect on the progression of the disease."

Natural Capsules Board Approves Capacity Expansion Plan

Over the next two years, the Natural Capsules Board of Directors has authorized a capacity development plan that will boost manufacturing capacity to 22.08 billion capsules.

The project will cost Rs 39.90 crore to complete. Internal accruals as well as fund raising will be used to fund the project.

The completion of capacity expansion was also recorded by the Board of Directors.

DBT-NIBMG Creates World's First Database of Genomic Variants of Oral Cancer

NIBMG

Kalyani , India: DBT-National Institute of Biomedical Genomics (NIBMG), Kalyani an Autonomous Institute funded by the Department of Biotechnology, Government of India has created a database of genomic variations in oral cancer; the first of its kind in the world. NIBMG has made this database publicly-accessible.

dbGENVOC is a browsable online database of GENomic Variants of Oral Cancer and is a free resource. First release of dbGENVOC contains (i) ~24 million somatic and germline variants derived from whole exome sequences of 100 Indian oral cancer patients and whole genome sequences of 5 oral cancer patients from India, (ii) somatic variation data from 220 patient samples drawn from the USA and analyzed by TCGA-HNSCC project and (iii) manually curated variation data of 118 patients from recently published peer-reviewed publications. Variants were identified by the community approved best practice protocol and annotated using multiple analytic pipeline.

The repository, which will be updated annually with variation data from new oral cancer patients from different regions of India and

Virosil PHARMA™

ECO-FRIENDLY

AERIAL DISINFECTION

Pfizer · Piramal Healthcare · SUN PHARMA · Johnson & Johnson · Dabur · SERUM INSTITUTE OF INDIA Cyrus Poonawalla Group · Cipla

TRUSTED BY BRANDS

VIROSIL PHARMA

Virosil Pharma is a revolutionary, eco-friendly, non-toxic disinfectant & fumigant used in Pharma Companies, Life Science Institutes, Research Labs and Hospitals, for elimination of airborne bacteria, fungi including the coronavirus family.

Used by India's leading

Corporate Offices, IT Parks, Banks, Hotels, Transportation, Armed Forces and Heavy Industry Units.

info@virosil.com
+91 9820233200
www.virosil.com

southeast Asia, has the potential to support advances in oral cancer research and will be a major step in moving forward from simply cataloguing variants to gain insight into their significance.

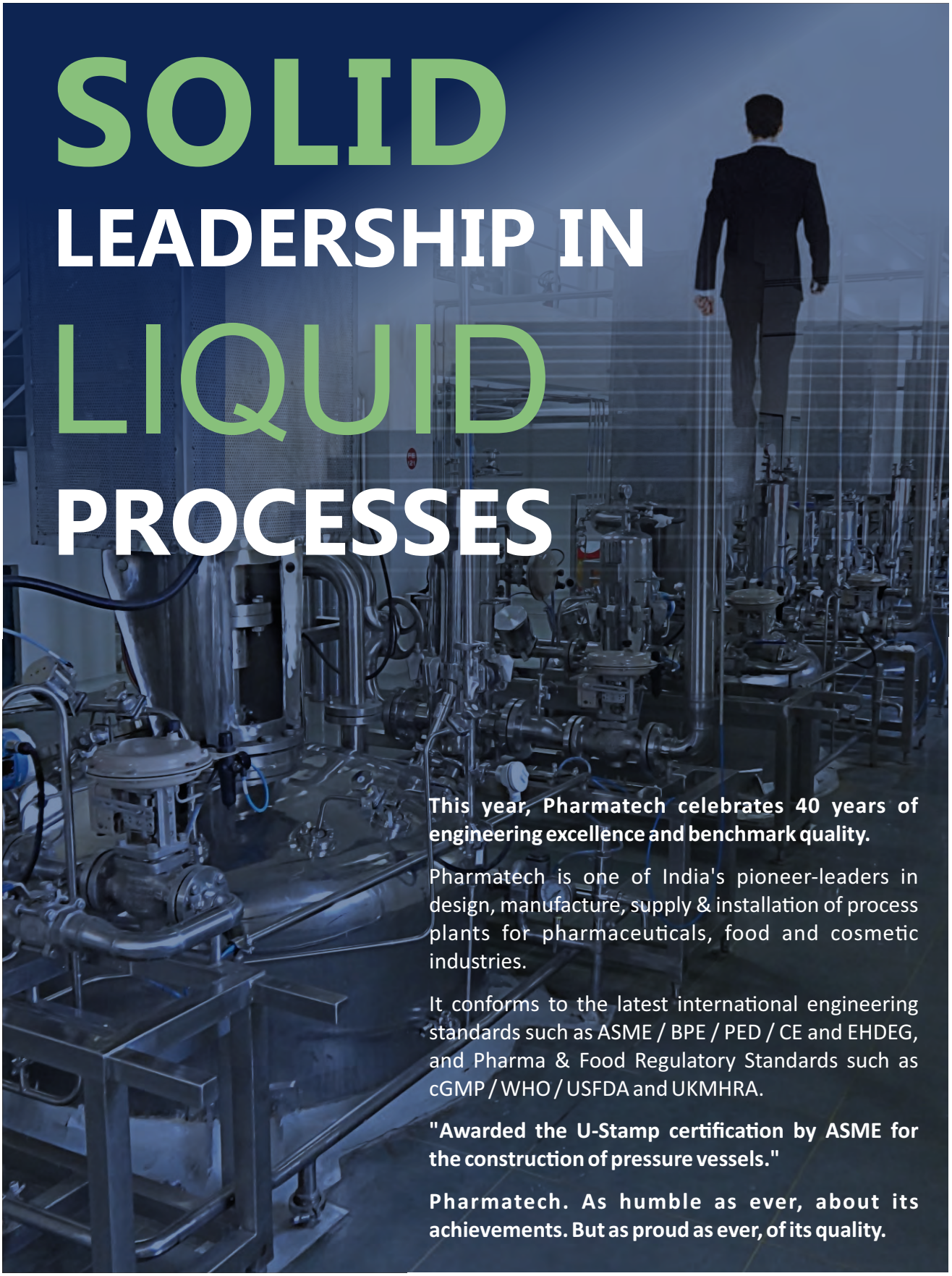
Oral cancer is the most prevalent form of cancer among men in India, largely fuelled by tobacco-chewing. Tobacco-chewing causes changes in the genetic material of cells in the oral cavity. These changes (mutations) precipitate oral cancer. Research to identify those genetic mutations that drive oral cancer are ongoing. Such driver mutations may be variable across populations

Leading Indian Pharma Company ENTOD Pharmaceuticals Celebrates 44th Foundation Day

Nikkhil K Masurkar, ENTOD, Executive Director

Mumbai, India: ENTOD Pharmaceuticals, an Indian international research-based pharmaceutical company with over four decades of pharmaceutical expertise in Ophthalmology, ENT and Dermatology medicine, celebrated its 44th Foundation Day. The company was founded in 1977 by G. V. Masurkar, a pharmacist and a visionary. With more than 1000 employees, it is one of the fastest-growing super-specialty pharma companies, which has its footprints across more than 55 countries around the world. With over 150-crore revenue in FY21, the company has seen a growth of 30-40% from last year even during the COVID pandemic. Not only that, but as many businesses were forced to reduce their employees' salaries during the lockdown, ENTOD offered hope and support with no salary cuts at all. Furthermore, the pharma giant has plans of adding 100 employees to their workforce each month until September 2021.

While ENTOD has a victorious history of revolutionizing the pharmaceutical industry in India and more than 55 countries, their collaborations and plans are even more promising. The company has ventured into the market of medical cosmetics through a joint-venture with NuSkin London. NuSkin London is a research initiative of ENTOD Research Cell UK Ltd, to improve skin formulation research and create innovative dermatological solutions. The joint-venture is expected to help commercialise NuSkin London's skincare & medical cosmetic innovations across the Indian sub-continent and international markets like Malaysia, Philippines, Hong Kong, Singapore and others. In addition to that, they also have projects in motion to expand in the ophthalmic surgical segment by launching their HyTek Division, which will deal with surgical products. Their expansion in the ophthalmic surgical segment will be supported by their state-of-the-art DSIR approved laboratory and FDA-approved international R&D centres, along with their



SOLID LEADERSHIP IN LIQUID PROCESSES

This year, Pharmatech celebrates 40 years of engineering excellence and benchmark quality.

Pharmatech is one of India's pioneer-leaders in design, manufacture, supply & installation of process plants for pharmaceuticals, food and cosmetic industries.

It conforms to the latest international engineering standards such as ASME / BPE / PED / CE and EHDEG, and Pharma & Food Regulatory Standards such as cGMP / WHO / USFDA and UKMHRA.

"Awarded the U-Stamp certification by ASME for the construction of pressure vessels."

Pharmatech. As humble as ever, about its achievements. But as proud as ever, of its quality.

Pharmatech
Innovative Processing solutions

E-mail: ppe@pharmatechprocess.com

www.pharmatechprocess.com

affiliation to 50+ ophthalmic societies (including many international societies like WSPOS, WGA, ISMSICS, etc.).

Speaking about the latest development and expansion plans, Executive Director of ENTOD, Mr. Nikkhil K Masurkar said "We have strong ties with a variety of research institutes and centres, research centres, and other pharmaceutical firms, giving us access to cutting-edge technology and research results, as well as allowing us to work collaboratively. We effectively operate a global network of highly specialized Formulation R&D centres and labs, which we offer to numerous pharmaceutical firms across the globe. We've also worked on developing new and safer speciality preservatives and excipients for the ophthalmic pharmaceutical sector. Over the next 2-3 years, we are also planning to venture into the surgical products sector that would further enable us to establish our presence across the domestic and international markets."

Nouryon to Expand its Kromasil Facility to Meet Global Pharma and Biotech Demand

Amsterdam, Netherlands: Nouryon, a global specialty chemicals leader, plans to invest in its Kromasil manufacturing facility in Bohus, Sweden, to meet the increasing global demand from the pharmaceutical and biotechnology industries for high-performing solutions. The investment is expected to double the facility's existing production capacity, which will strengthen Nouryon's global leadership position in high-performance silica.

"This investment reflects Nouryon's commitment to be a trusted partner to the pharma and biotech industries, which increasingly rely on us to provide solutions that contribute to the production of safe pharmaceuticals," said Johan Landfors, Executive Vice President and President, Technology Solutions and Europe at Nouryon.

Kromasil products are used by the pharmaceutical, food and beverage, clinical, and environmental industries for applications ranging from laboratory analysis to industrial-scale purification. Kromasil contributes to improved treatment of diabetes as a vital part of the purification of insulin. Other uses include complex bio-pharma applications.

"Bio-pharmaceuticals, such as peptides, proteins and hormones, are a growing market and we see an increase in demand worldwide, particularly from our customers in India, China and Southeast Asia," said Patrick Wilhelm, Vice President of Inorganic Specialties at Nouryon. "This facility expansion will reinforce our leadership position in the global high-performance silica market targeted to the pharma and biotech industries, and it will allow us to meet the growing demand for our

VALVE SOLUTIONS
FOR CORROSIVE APPLICATIONS

UNPPolyvalves

Manufacturer of PFA/FEP/PTFE Lined & Plastic Valves, Pipes & Pipe Fittings

LINED VALVES

CASTING OPTIONS AVAILABLE
ASTM A216 GR. WCB
ASTM A351 GR. CF8/CF8M
ASTM A494 GR. 4A (CD3MN)
HESTALLOY C - 276

LINING OPTIONS AVAILABLE
PFA, FEP
PVDF
ETFE (TEFZEL)
ANTISTATIC PFA (CONDUCTIVE)

SIZE RANGE : MANUAL VALVES : ½" to 24" I ACTUATED VALVES : ½" to 24"

VADODARA - OFFICE & FACTORY

5 to 12 PR Industrial Estate, Por GIDC - Kashipura Road,
Moje : Kashipura - 391 243, Dist. Vadodara. INDIA
Phone: +91 70434 30467/77, 70430 20707
Email : sales.baroda@polyvalve.com

MUMBAI - THANE

207, Orion Business Park, Next to Cine Max, Kapurbawdi,
Ghodbunder Road, Thane (W) - 400 607. INDIA.
Phone: +91 22 2589 6422, 2589 6524 /25
Email : sales.thane@polyvalve.com

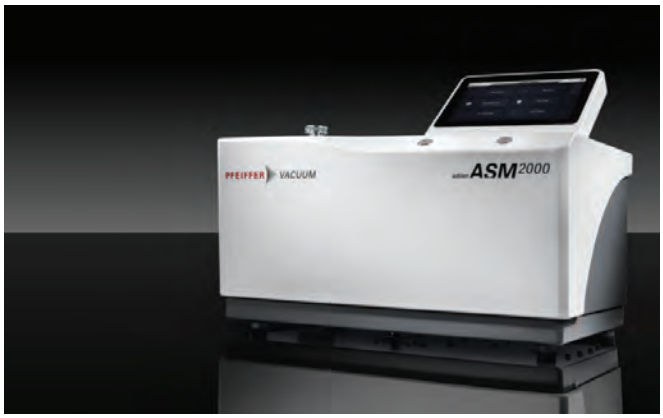
www.polyvalve.in
www.polyvalve.com

in house

Kromasil products." The cnstruction of the Nouryon facility expansion is scheduled to begin in 2022.

Nouryon is a leading producer of high-performance silica worldwide and has more than 30 years of expertise in spherical silica for analytical to process-scale liquid chromatography under the brand Kromasil. Kromasil chromatography resins offer superior separation performance leading to increased efficiency and decreased costs.

Pfeiffer Vacuum's Virtual Showroom: Leak Testing & CCIT Solutions for the Pharmaceutical Industry



Asslar, Germany: In its virtual showroom, Pfeiffer Vacuum presents a variety of different leak testing methods for pharmaceutical packaging (container closure integrity testing or CCIT). Visitors to the site will find information about the challenges of leak testing IV bags, syringes, blister packs, plastic bottles, vials and other nonporous containers. At the virtual trade show booth, visitors will learn about Pfeiffer Vacuum's unique portfolio of leak detectors. Informative videos explain the different technologies used – helium mass spectrometry, optical emission spectroscopy and mass extraction. A tight and reliable seal is essential in primary packaging for drugs. Contamination such as humidity, oxygen or microbiological ingress can considerably impact drug quality throughout the product life cycle.

To prevent risks such as the stability failure of highly moisture-sensitive drugs (such as dry powder for inhalation) or biological ingress into parenteral drugs, integrity tests with a high sensitivity are required. As well as presenting the different leak testing methods for pharmaceutical packaging, the showroom also provides more information on individual feasibility studies. The experts from Pfeiffer Vacuum use studies like these to visualize the particular packaging and test the possible use of CCIT.

Pfeiffer Vacuum uses the three CCIT technologies to obtain a realizable detection limit and cycle time for the packaging.

Avantor Aids Indian Red Cross COVID-19 Relief Work With Needed Supplies

New Delhi, India: Avantor, Inc, a leading global provider of mission-critical products and services to customers in the life sciences, advanced technologies and applied materials industries, is donating 30,000 N95 masks, 600 infrared thermometers and 600 pulse oximeters, valued at approximately US$30,000 to the Indian Red Cross Society state branches in Maharashtra and Uttarakhand to support COVID-19 relief work. This is in addition to the Avantor Foundation US$30K

maxima

Non IBR Boilers

Thermic Fluid Heaters

Steam Boilers

Fluidized Bed Combustion Boilers

Small Industrial Boilers

Since 1986, Maxima Boilers has been supplying heating solutions to various industries across the world.

Ideal for batch or continuous processes, our products are used in a wide range of applications.

Our product range includes steam boilers, hot water & steam generators, thermic fluid heaters, waste heat recovery boilers, boiler accessories, & turnkey projects.

With our customer-centric approach, we work with you to develop efficient products designed to meet your applications & operating conditions.

When you need a safe & economical heating solution, choose Maxima Boilers.

MAXIMA BOILERS PVT LTD
G 14, Meghal Industrial Estate
Devidayal Road, Mulund West
Mumbai 4000080
E: sales@maximaboiler.com
P: 9870772325 / 77188066165

www.maximaboiler.com

Mr. Pankaj Thapliyal, Dehradun Plant Head, Avantor and Inderjit Saini, Plant HR Manager, Avantor

donation to Project HOPE to aid COVID-19 relief work in India.

"Avantor India takes pride in supporting the critical humanitarian efforts of providing relief for vulnerable people and communities in these challenging times. We believe that our donation of much needed supplies and funding support will contribute to the Indian Red Cross Society and Project HOPE to aid vital on-ground COVID-19 relief efforts in the country", said Amit Sehgal, Country Head at Avantor India.

The Avantor Foundation donation to Project HOPE will focus on three program areas including distribution of medical equipment and supplies, COVID-19 training for front-line healthcare workers and vaccine public awareness campaigns in India.

While ensuring Avantor associate safety and well-being during the pandemic, the Company introduced several initiatives and impactful programs for its associates and immediate families in the country during this unprecedented situation. Enumerating the details on the Avantor associate well-being program in India, Sehgal said, "Throughout the pandemic, we have had an unwavering focus on helping keep our associates safe and leveraging guidance from creditable health agencies to establish safety protocols. We have developed a vaccination program including on-site vaccination drives at major locations, providing an alternative to the government vaccination program."

In India, Avantor has engaged trained medical practitioners to run virtual education sessions for associates and family members pertaining to the management of COVID-19-related scenarios. The Company has also launched an Employee Well-being & Assistance Program (EWAP) that offers support and helps to address any personal or work-related challenges that may affect the associate's well-being and work performance. Avantor's regional HR team continues to explore other ways to support associates and immediate families as the situation evolves.

SPT Labtech Announces Leadership Transformation

David Newble has been appointed CEO, SPT Labtech, stepping up from his previous position as Managing Director. In his new capacity he takes responsibility for all SPT Labtech businesses including the recently acquired organisations. David

SHANBHAG & ASSOCIATES

Total Pumping Solutions

Authorised Distributor for India

ECCENTRIC SCREW DRUM PUMPS

SOLID BLOCK AODD PUMPS

DELLMECO
AODD DIAPHRAGM PUMPS

- PE, PTFE, SS, Alu Material
- Low Maintenance costs
- Hygienic Construction Available

DRUM & CONTAINER PUMPS

PERISTALTIC PUMPS LAB & INDL. DUTY

boyser®

- Accurate Chemical Dosing
- Ideal for abrasive slurries, Viscous Liquids

DRUM EMPTYING SYSTEM WITH FOLLOWER PLATE

MAGNETIC DRIVE PUMPS

CM MAG M

CL MAG M

CENTRIFUGAL IMMERSION PUMPS

B50 - FOR IBC

B6 - FOR CIRCULATION TANKS

SANITARY LOBE PUMPS

OMAC

TWIN SCREW PUMPS-HYGIENIC

HYGHSPIN

- Pump for CIP & Viscous Liquids
- Ideal for food, beverages, creams, ointments, dairy, personal care applns

SHANBHAG AND ASSOCIATES

B-50 Nandbhuvan, Mahakali Caves Road, Andheri (E), Mumbai 400 093,
Tel: +91-40365700/711, E-mail: info@shanbhags.com

www.shanbhags.com

David Newble, CEO, SPT Labtech

brings a wealth of industry expertise and experience and has been instrumental in SPT Labtech's transformation and growth since its acquisition by Battery Ventures in 2018. Patrick Bennett, the former Group CEO, will assume the role of Chairman of the Board and continue to work with David and the wider SPT Labtech team in executing the company's ambitious commercial strategy.

Paul Ventura will lead global sales of SPT Labtech in the newly created role of Vice President of Sales. Drawing on his track record as Director of Sales - SPT Labtech, he will oversee and unify commercial operations across all the group's brands and sales teams worldwide.

Joby Jenkins will take on overall responsibility for business development of all the SPT Labtech product brands. His role as Vice President of Business Development, also a newly created position, encompasses responsibility for product management and marketing.

Patrick Bennett, Chairman at SPT Labtech, said, "From a strong foundation of organic achievement, and with several significant strategic acquisitions under our belt, we are extremely well placed to create and deliver even more innovative solutions that enable our customers to do better research. These leadership appointments will enable us to further capitalize on our current position and advance our mission to transform laboratory workflows. I am confident that under David, Paul, and Joby's direction our exceptionally talented global teams will continue to go from strength to strength."

Rossari to Acquire Tristar Intermediates

Mumbai, India: Rossari Biotech Limited (Rossari, Company), a Speciality Chemicals manufacturer providing intelligent and sustainable solutions for customers across industries, today announced that its Board of Directors has approved the acquisition of Tristar Intermediates Pvt. Ltd. (Tristar Intermediates, company). As per the agreement and subject to customary closing conditions, Rossari will be acquiring 100% of the equity share capital of Tristar Intermediates. 76% of the equity share capital will be acquired upon closure of the transaction, and the balance 24% over the next 3 years. The total enterprise value of the transaction is Rs. 120 crores. Rossari plans to fund the investment through cash on balance sheet and doesn't intend to raise any debt for this acquisition.

The transaction brings together two high-potential companies within the speciality

BROOKFIELD AMETEK U.S.A.
www.brookfield.com

Material Characterization At its Best ...

Laboratory Range of Viscometers


Dial Reading Viscometer


DV-E™ Viscometer


DV-I™ Viscometer


DV-2T™ Viscometer

New

DVNext Rheometer

New

CTX Texture Analyzer

New

Gel Timer Instrument

New

RSO® Oscillatory Rheometer

New

Wells Cone & Plate DV Next CP Viscometer


PFT™ Powder Flow Tester

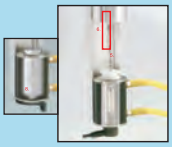

PVS Rheometers


RST-CPS Touch™ Rheometers

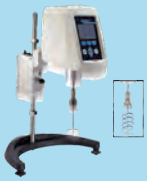

RST-SST Touch™ Rheometer


RST-CC Touch™ Rheometer


Viscosity Standards


Small Sample™ Adapter


Enhanced UL Adapter™


Helipath™ Stand


Thermosel® System


Circulating Temp. Bath

Process Viscometers (To measure in-line Viscosity)


FMXTS
FAST101/MXTS
Viscosity Sensor/Transmitter


FAST-102
Compliant to 3A sanitary standards


TT-100
For in-line system applications requiring pipeline mounting


Viscosel VTE-250
For systems open to the atmosphere


AST-330SY™
Single Station Viscosity Controller

We are official Distributors for INDIA duly Authorised by **BROOKFIELD AMETEK,** U.S.A.

KOMAL Scientific Co.

AN ISO 9001 : 2015 CERTIFIED COMPANY

SHOWROOM : 633, LAXMI PLAZA, LAXMI INDUSTRIAL ESTATE, NEW LINK ROAD, ANDHERI (W), MUMBAI- 400 053. (INDIA)

(+91-22) 2633 5560 - 61 - 62 bachhawatprasan@gmail.com

prasan@komalscientific.com info@komalscientific.com

komalscientific.com

CRISIL Rating : SME 1 'Highest'

JAS-ANZ M5000712ID

RHEOLOGY VISCOSITY TEXTURE IN-LINE POWDER MOISTURE GAS

chemical space. The blend of capabilities will add scale, provide cross-selling opportunities, and accelerate growth for Rossari, while significantly enhancing value creation in the longer term. The synergistic acquisition provides Rossari with enhanced portfolio of products, stronger presence in new & untapped international markets and access to newer technologies. Through the transaction, the Company also welcomes on-board Tristar Intermediate's four experienced promoters with proven entrepreneurial expertise across technical & marketing functions, who will continue driving this business for atleast next three years. Rossari and Tristar Intermediate's complementary cultures and business models will together strengthen and consolidate Rossari's market position as a preferred solutions provider in the Speciality Chemicals space in India.

Tristar Intermediates established in the year 1998, is one of the prominent companies in India in the field of Preservatives, Aroma Chemicals, and Home & Personal Care Additives with high-tech distillation facilities. Headquartered in Thane, Maharashtra, Tristar Intermediates is a preferred supplier to various reputed companies and MNCs across India, Europe, USA and Far East countries. With a superior presence in Personal Care and Home Care segments, the company's expansive product range also has applications across diverse industries such as Pharmaceuticals, Textiles, Paints, Automotive, Agro-chemicals and others. Tristar Intermediates has manufacturing facilities at Sarigam (Vapi), Gujarat, India with a total capacity of 15,000 MTPA.

Commenting on the business update, in a joint statement, Mr. Edward Menezes, Promoter & Executive Chairman, and Mr. Sunil Chari, Promoter & Managing Director, said, "We are pleased to announce the acquisition of Tristar Intermediates, which is a strategic and important milestone for us. The combined capabilities will provide a strong growth momentum and will enable us to expand further into the high-potential product categories of personal care and home care, among others. The addition of new international markets, cross-selling opportunities, talent, and technology know-how will also drive business efficiencies.

The acquisition meets all operational & financial criteria laid down by our Board. The complementary heritage of Rossari and Tristar Intermediates will allow for a smooth integration to the benefit of our stakeholders, customers and employees, in the coming months."

BDR Pharmaceuticals announces license agreement with DRDO for manufacturing Covid-19 Drug 2-DG in India

Mumbai, India: BDR Pharma, one of India's leading generic pharmaceutical companies, has received an approval and signed a license agreement with the Defence Research and Development Establishment (DRDE) and the Institute of Nuclear Medicine and Allied Sciences (INMAS) of the Defence Research and Development Organisation (DRDO) for the manufacturing, distribution, and marketing of 2- Deoxy-D-Glucose (2-DG) in India. Last month, the Drugs Controller General of India (DCGI) approved the oral medication for

Solvent Recovery Systems

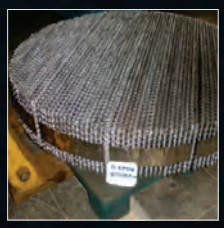
High performance solvent recovery systems to reuse solvents and reduce cost.

DISTILLATION | EXTRACTION | ABSORPTION | EDIBLE OIL REFINING
BIODIESEL | USED OIL RE-REFINING | OIL & GAS | ENVIRONMENTAL

FENIX offers complete solvent recovery systems on Turn-key basis. Depending on customer and process requirements, various distillation systems for the separation and purification of solvents these systems can be designed for either continuous or batch operations for single solvent system or multipurpose solvent handling. Fenix distillation systems are the preferred choice by customers in the chemical, pharmaceutical, and other specialty industries around the world for recovery, recycle, and reuse of solvents for applications ranging from solvent mixtures to solvent contaminated wastewater. The solvent recycling systems are efficient, safe, versatile, and comply with regulatory guidelines and standards. We are having decades of industrial experience in the field of Process Design, Equipment Design, Process equipment Manufacturing, System Integration, Plant Design, Plant Modifications, Automation, Project Management and Process Consultancy.

PROCESS ENGINEERING - EQUIPMENTS - TURNKEY SYSTEMS



TURNKEY SOLVENT RECOVERY SYSTEMS

For more information visit:

www.fenix.in

FENIX

Fenix Process Technologies Pvt. Ltd.
K- 6/1, Malini, Erandwane Co-op. Housing Society
Nr. Deenanath Mangeshkar Hospital, Pune - 411 004. India
Tel. No.: +91-8237008770 / 72 / 73 Email: info@fenix.in Url: www.fenix.in

emergency usage as adjuvant therapy in mild to severe Covid-19 patients.

The Defence Research and Development Establishment (DRDE) in Gwalior had produced 2-DG. The clinical trials were carried out in collaboration with Dr. Reddy's Laboratories by the Institute of Nuclear Medicine and Allied Sciences (INMAS), a DRDO lab. After receiving positive responses in Phase-II and Phase-IIb trials, DCGI permitted 2DG phase-III trials in November 2020. The Phase-II trial, which lasted from December 2020 to March 2021, enrolled 220 patients. The medicine was discovered to speed up the recovery of COVID-19 patients in hospitals and to lessen the need for supplementary oxygen in COVID-19 patients.

Commenting on the development Mr. Dharmesh Shah, CMD, BDR Pharmaceuticals, expressed, "We are pleased to secure a license from the DRDO and add 2-Deoxy-D-Glucose to our Covid product offering. This arrangement aims to ensure that this drug reaches as many eligible Indian patients as possible who are suffering from the devastating pandemic. Our aim is to ramp up the availability of successful treatment and coordinate manufacturing so that there is no scarcity of drugs to give to people fighting the disease. We expect that by widening and deepening the identification and development of COVID-19 therapy options, this collaboration can address more unmet medical needs."

This collaboration will improve local treatment options and positively impact the lives of COVID-19 patients in India. Clinical trial data supplied by the government based on the emergency approval demonstrated that the chemical aids in the speedier recovery of Covid-19 patients and minimizes their reliance on supplementary oxygen. In addition, the medication builds up in virus-infected cells and stops viral manufacturing and energy production, preventing the virus from spreading.

The product will be priced competitively and will be available in powder form in a sachet that can be consumed orally after being dissolved in water.

BDR has applied to the Drug Controller General of India (DCGI) for restricted emergency use authorization to manufacture Drug 2-DG to treat COVID-19 patients in India. For the development of 2-DG drugs, the DRDO has recently signed agreements with four major Indian generic medicine producers. ■

A Swiss Eco-Friendly Solution for Aerial Disinfection: Virosil Pharma

Some of its Key Features are Being a clear, colorless, odorless, liquid disinfectant that is non-carcinogenic, non-mutagenic, non-toxic and can be used where other chlorine based disinfectants are ineffective, Does not have a foul odor, No irritation to the eyes, Requires no de-fumigation, Very easy to handle, No fears of overdosing and no residual effects and thoroughly tested in Western Europe, Australia, the Middle East and India.

The Active Constituents include Hydrogen Peroxide (10%) and Silver Nitrate Solution (0.01%)

Some of its major applications are

- For use in Pharmaceutical companies, Life Science Institutes, Research Labs and Hospital Operation Theatres
- Ideal choice of the users for replacing Formalin Formaldehyde Fumigation.
- Concentration of 20% solution to be fogged with an ULV fogger - i.e. 200 ml of Virosil Pharma in 800 ml of water.

Virosil Pharma, a revolutionary disinfectant and fumigant for use in Pharmaceutical companies, Life Science Institutes, Research Labs and Hospital Operation Theatres. Our tried and tested patented formulation includes a complex compound which kills all forms of bacteria, viruses and spores rendering spaces perfectly safe and sterile.

Some major Specifications-	
Colour	Clear as water
pH – Value	Approx. pH 1.5
Odour	Odourless
Sensitivity	Sensitivity to light, to be stored in dark
Foaming characteristics	Does not foam
Coat Formation	No coat
Corrosive Property	At the prescribed concentrations and at a temperature below 50 degree C no corrosion should occur

- Virosil Pharma when used with a recommended ULV fogger which generates a very fine mist that allows our product to the suspended in the atmosphere for a longer period of time ensuring elimination of all types of Airborne bacteria and viruses.
- It can be successfully used for disinfection of Air Handling Units (AHU), Ducts, Air Shafts, Humidifiers and Filters which harbor loads of bacteria & bio-films.
- Surface / Instrument Disinfection: Apply 10% solution of Virosil Pharma on floors, walls, tables and linen. Dip the instruments in a 10% solution.
- CIP/Loop System Disinfection: When used in recommended dosages it completely eliminates Biofilms.
- Resin and Filter Disinfection; Dip in a 1% to 3% solution to control foul odor & contamination
- Storage Tank Disinfection; Spray the surfaces of the tank with 5% solution

Contact :

www.sanosilbiotech.com

The Indian Scenario of Drug Safety

Dr. R.B. Smarta
CMD-Interlink, Vice President (HADSA)

Drug safety and monitoring is a continuous scientific process which is consist of detection, assessment, perception and prevention of Adverse Drug Reaction (ADR). The process is essential to understand the potential benefits of the medicines along with the risks associated with it. We call it a 'continuous process' as it starts with drug development and continues till the launched drug/product is available in the market in patient care.

This process has to be prolonged till the life of particular medicine, as many times the side-effects come into the picture in the post-marketing scenario and after the prolonged use of the drug in the population.

Evolving over the decades, drug safety systems (or pharmacovigilance) are making significant progress. However, the challenges are still there which are inevitable and require new thought every time. Some of those common roadblocks are related to patient engagement, informatics, business and lack of globalized approach toward pharmacovigilance. Discussed below are some social, technical and business-related aspects of drug safety issues in India.

Social barriers for drug safety

In my opinion, social barriers which are depressing the drug safety systems are occasionally hard to identify and challenging to nullify. Public belonging to different levels in the society have different pitch of understanding and awareness about drug safety which makes it difficult

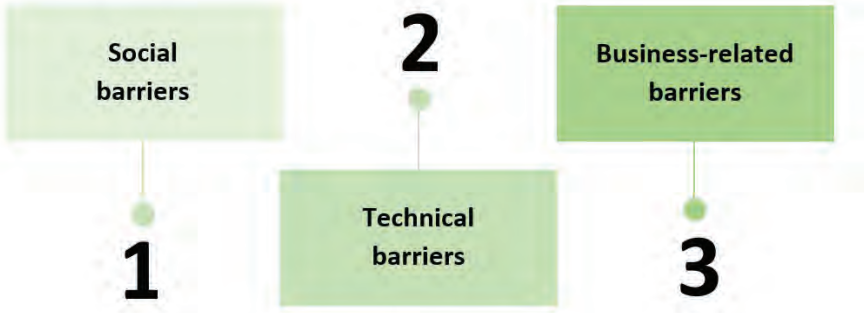


Fig.1- Barriers to drug safety in India

Source- Interlink Knowledge Cell

for organizations and government to resolve the issues. Following are some of those major obstacles.

Ignorance toward minor side effects- This particular issue is very common and serious at the same time. Because of this, pharmacovigilance systems are not getting prioritized in the society despite of tremendous efforts of government. One of the major reasons behind this is lack of knowledge about the severity of adverse drug reactions and varying mentalities of people. Frequent use of antibiotics and injections is an issue of concern in recent times. Nations are struggling to put light on these issues and find the ways out.

Medical professionals seemingly lacking experience, up-to-date knowledge and drug information- This is another major issue in the society. This can be complementary to the previous issue as medical professional play crucial role in shaping the reliable healthcare. Inadequate treatment guidelines are passed on through such medical professional. Poor prescribing practices can also be seen.

Prevalence of counterfeit products and use of traditional medicines (without any knowledge)- This issue is gaining much attention in today's scenario. Cheap, substandard and spurious drugs in the market used to put the drug safety systems in questionable circumstances. Although, as the research and development is advancing, various government initiatives through regulatory actions are making a big difference between today's and a decade ago scenario in pharmacovigilance.

Another issue is use of traditional medicines without any fundamental background knowledge. As many alternatives are available in the market at cheaper prices, the public is seemed to be inclined toward them through the word-of-mouth information.

Technical barriers for drug safety

The gaps between guidelines and law for drug safety is one of the matters of concern for nation like India. Lack of harmonization of guidelines due to presence of different ministries for drug regulation make it hard to coordinate and maintain transparency in the process. Discussed ahead are some of these regulatory issues which require serious

attention-

Ambiguity in licencing mechanisms- In India, there is a thing called as dual licencing mechanism which has emerged as a roadblock for effective implementation of regulatory processes in India. Moreover, transparency in licensing procedures need to be further improved. Lack of better clarity on patentability of pharmaceuticals for which any organisation applies for compulsory licences leads to legal dispute between MNCs and local firms.

Interpretation issue of GMP guidelines- Inadequate and not correct interpretation of rules and guidelines of drug development in India generate multiple barriers for effective implementation of drug safety programmes. Experts who have very less knowledge about strict legal terminologies in documents such as Schedule M, Drugs and Cosmetics Act, 1940 and, Drugs and Cosmetics Rules, 1945, can't interpret the things efficiently which result in difference in the assumptions of regulatory officials and drug developer.

Compliance in clinical trials Noncompliance of ethically documented clinical trial practices result in unethical practices in clinical trials of drugs in India. This is a product of corruption, poor compliance, low-cost trials and the conniving acts of drug developing company and medical professionals. Such cases are on the rise in the current scenario. Moreover, unavailability of basic facilities and sophisticated instruments lead to unethical clinical practices by producers.

Issues of pharmaco-negligence- This is one of the factors behind proliferation of substandard and spurious drugs. In India, huge number of patients having malaria and tuberculosis died because of such counterfeit drugs and products. Lack of coordination between centre and state regulatory bodies has resulted into very tough time for pharmacovigilance in India in earlier times.

Inadequate recall mechanism- In India, it takes about three to four months for laboratory to process through the fraudulent product. During this large timespan, the huge percentage of batch gets consumed in the market. The recall mechanism is unclear and the information of the product recalled are not available in public domain. This makes the situation even more complicated and tough to deal with.

Business-related barriers for drug safety

Many times, processes at drug producers level/company level are also responsible for the failure of pharmacovigilance programmes in India. Following are some of those issues which need legal consideration.

Organizational insufficiencies and malpractices- Unavailability of required funds, inadequate and unprofessional staff, etc result in weak organizational

functioning. Frustration resulting from extra-working hours and the ignorance arising through it is responsible for poor quality end product.

Many drug producers, manufacturing poor quality products, invade the supply chain of slow-moving products (products which usually have slow turnover rate and likely to be stored into the warehouse for longer timespan) to avoid the detection procedures.

Unclear third-party agreements- This involves entitling a manufacturer to do the manufacturing on behalf of other party. This entire process is a big question mark owing to the unclear legal liabilities associated with quality of the product rolling in the market through third-party manufacturing.

Unawareness about handling new technologies- Most of the stakeholders are not technically competent and some of the reasons behind it are affordability and lack of knowledge. Indian stakeholders, many a times, avoid costly and complicated technologies like 'track and trace technology' which make their growth less sustainable and such situations result in adoption of cheaper ways of making money, E.g., Counterfliet products.

Change is essential

Social conflicts associated with drug safety require considerable attention in the form of public campaigns for pharmacovigilance and awareness-enhancing initiatives in rural areas. The adverse drug reactions can be minimized to the great extent through such social approaches. Communication is the key to knowledge, government and regulatory bodies should design these initiatives in much comprehensive manner. Such approaches are essential for health professionals as well for the better healthcare outcomes.

Technical issues, particularly regulatory system related issues, are need to be tackled with thorough understanding about the current scenario of pharmacovigilance in the nation. Uniformity in the regulations as well as in the interpretation of the same is mandatory for 'up to the mark product.' Various technologies used abroad can be utilized in India to achieve efficient licensing mechanism, ethical clinical trials and accelerated recall processes.

Such approaches require active participation of the stakeholders with the dedicated and honest efforts in producing the high-quality pharmaceutical product. Drug safety programmes can be successful only if the data provided by the stakeholders to the regulatory bodies is accurate in all the aspects in order to device the essential policies.

Global approach is mandatory to develop a science-based, patient centric healthcare through high quality products. To strengthen the pharmacovigilance system in the world, regulatory harmonization is the key. ■

'Leveraging Automation and Digitalization to Gain Competitive Edge'

Dr. Ashok Kumar FRSC *the President of Centre for Research & Development accelerated IPCA's R&D initiatives that spearheaded IPCA to grow from a 350-crore company to one clocking an annual turnover of over 2,500 crore. He shares his views about the Indian pharma industry evolving substantially and Ipca's journey.*

Dr. Ashok Kumar FRSC
President – Centre for Research & Development

Changing market dynamics

The Pharma market has been impacted by ongoing SARS-COV2 Pandemic and it varied according to the business segments and the model. While Vaccine segment registered multifold growth, the small molecule generic manufacturers faced hiccups in raw material, key starting material or intermediate availability due to global lockdown. However, the pharma market is likely to spring/bounce back and expand as the impact of the virus subsides. In the post Pandemic era, the market is expected to evolve at a rapid pace via adoption of new technologies and business strategies. Portfolio diversification and shift in Business approach is expected, along with upward trend of collaborations/partnerships.

Critical challenges & addressing them to drive the growth of the organization

The pandemic has affected the Raw material trade a lot. Ipca believes that reduced dependence on other nations for APIs, or more importantly drug intermediates, is vital to long term sustenance. Mr. Premchand Godha, Chairman and MD, Ipca Laboratories, during a webinar emphasized on reducing the dependency on other nations for drug intermediates; which are required in much larger proportion than APIs. Ipca is of opinion that to grow whilst remaining competitive in the global Pharma market in longer run, the in-house capability to produce Raw material/Key starting material and intermediates, atleast for high value APIs, is must. Since its inception, Ipca has been working towards strengthening backward integrations to have sustainable future and reduced dependency on imports from other countries.

Growth drivers for your organization

- Portfolio optimization, strategies to identify needs/gaps to build, enter, maintain and exit approach.
- Utilizing Clinical research as a tool to launch innovative combination formulations / NDDS.
- Geographical expansion by global acquisitions.
- Introduction of new products, mainly complex or difficult to make
- Registered Formulations to be backed by in-house API
- Increased focus in emerging markets like LATAM, CIS & China
- In licensing/ out licensing to build business in the promoted therapy.
- Tapping the full potential of contract development and manufacturing capabilities
- Production of APIs or drug intermediates using fermentation technology

Vertical acquisitions have been notable growth drivers for Ipca. Ipca acquired Ramdev Chemical which produces fine chemicals, drug intermediates and APIs, British pharmaceutical chemistry firm Onyx Scientific, New Jersey based Bayshore Pharmaceuticals LLC, North Carolina API maker Pisgah Labs to name a few. Recently Ipca picked additional stake in Trophic Wellness Pvt Ltd, thus bringing Nutraceuticals too under its ambit. Ipca's vertical acquisitions based growth strategy is propelled by gap filling of the existing

portfolio and fortification of growth drivers. Further, Ipca continuously explores strategic business relationships with smaller API manufacturers for increasing product basket and also partnering growth with its vendors and suppliers.

Leveraging digitalization to gain competitive edge

It's digital era, and though considerable working capital is required for continuous tech up- gradation, Ipca firmly believes in leveraging automation and digitalization to gain competitive edge, better returns and long term sustainability. Ipca is of the opinion that cutting edge technology is must for high throughput output and cost-effective viability in near future and hence made significant investments in adopting newer advanced technologies viz.

- Investments in manufacturing/ analytical/quality/PAT
- Robotics and automation, being routinely used in Ipca R&D
- Implementation of ELN, a step forward towards digitalization of data and records

Future plans (in terms of new products & innovations, investments, capacity expansions & increasing the market footprint etc.

Ipca's research and development activities are diversified into development of small molecules through chemistry and biotechnology and large molecules, proteins, mainly biosimilar mAbs. Two of its in-house developed mAbs are in manufacturing stage for clinical evaluation. To reduce dependence on cheap raw materials/intermediates from China, Ipca is making a designed approach in continuous process developments and research activities are being further extended to develop high value secondary metabolites with the help of Synthetic

Biology and Metabolic Engineering of Eukaryotes. On discovery front, efforts are also in place to repurpose drugs with clear cut objective to either improve their efficacy or finding new therapies. One of such small molecule is in advanced stage of development in collaboration with MMV. ■

Infusion of Strategies, Innovations and Business Dynamics in the Indian Pharma Sector

Praful R Naik, Bachelors, Masters & Ph.D. in Pharmaceutics *from the Indian Institute of Technology, Banaras Hindu University has steered creations of inventions resulting in over 40 granted patents and over 200 patent applications globally. Dr. Naik gives a gist of the roadmap of the Indian pharma industry with an overview of change adapted amid the pandemic.*

Praful R Naik, Ph.D.
Director & CEO, Prashak Techno Enterprises Pvt. ltd.

Changing market dynamics

Novel Corona virus (SARS-CoV-2) has brought about an incessant transformative change universally, not only to the business dynamics, but to the consumer behavior and psyche as well. This change can also be termed novel as it itself looks continual. Governments, Businesses, Markets and People - All have had to adapt and adopt evolving changes to align and defy the dynamic lethality of the virus which has been on the continuous mutation path. In Healthcare, the impact on both the supply and demand sides has led to more focus on futuristic prophylaxis apart from therapeutic management. The buzz word is Wellness management and enhancing Immunity which has rightfully driven the focus towards natural products and their potential to enable holistic health and well-being management.

Consumers at large have become more health conscious and also aware of the need to have a better management of their wellness and augment their intrinsic immunity. This has resulted in the Healthcare sector's renewed interest in the abilities of Natural products to address the consumer's new aspiration.

Critical challenges & addressing them to drive the growth of the organization

Speaking in generic terms the impact has been quite catastrophic on the MSME across diverse sectors and business verticals mainly due to the weak financial strength and reserves. For MSME in the manufacturing sector including Healthcare, continuity of operations and overhead costs have become the main challenge due to inadequate cash flows. Apart from providing strategic business and Innovation consulting services to the large and MSME entities in the healthcare domain which includes Pharma, Nutraceuticals & Natural products based organizations, my entity is also into an entirely different manufacturing sector of low carbon footprint construction and sanitation technologies. This diversity enabled me to visualize the universalization of adverse impact of the pandemic across business sectors. Focus on products and ideation strategies related to Wellness and Immunity including new novel alternatives for Covid and other health impacting microbial contaminants as well as for those ailments which impact Well being and Wellness directly or indirectly have become the nucleus for driving growth and sustainability.

Being a staunch proponent of Innovations and Intellectual property, have remained steadfastly aligned to them and have been striving to use them as the key to drive both the services and manufacturing initiatives at both my organizational and individual levels. Having been involved in steering creations of inventions in diverse industrial segments spanning across medical devices, medical diagnostics, pharmaceuticals, natural products, nutraceuticals, specialty polymer/metal materials, product degradation evaluation technologies, Nano materials-based security technologies, construction & sanitation technologies and air purification systems resulting in over 40 granted patents and over 200 patent applications globally, the pandemic has only strengthened my belief that Innovations can become the focal point for business growth as well as sustainability. In the Healthcare domain, the pandemic has also been instrumental in reinforcing the potential of Nature's offerings and there seems to be a renewed interest by both the Global and MSME Enterprises not only in our Country but across the globe, in evidence-based natural products and Nutraceuticals.

Leveraging digitalization to gain competitive edge

"Virtual" has become the "Reality"with

all major activities during the pandemic being managed through various forms and modes of digitalization. "Online" has replaced "Physical" in majority of the routine activities except for the manufacturing sector which is striving to catch up with mechanization, Robotics and integration of a wide range of AI based digitalized controls and operations. Balancing the judicious blend of Digitalization with Manually managed activities will become the new norm and the way forward for gaining competitive edge.

Future plans (in terms of new products & innovations, investments, capacity expansions & increasing the market footprint etc.

In the Services segment, business strategies alignment to Wellness and Immunity will be the core proposition to the Healthcare associated organizations. This will be augmented by new ideations leading to Innovative end use products complimenting the realigned business strategy. As infusion of investments will be hard to accomplish in the current situation, out licensing existing and newly created Innovations for business expansion and sustainability will be the focus. Partnering with complimenting organizations will be the way forward for enhancing market footprint. ■

Pharmacovigilance as an Indispensable Ingredient for India's Pharma Growth Formula

Dr J Vijay Venkatraman
Managing Director & CEO
Oviya MedSafe Pvt Ltd

India has always been an essential element in the global pharmaceutical milieu over the past several decades. This is not only because India is one of the largest producers and exporters of pharmaceuticals and vaccines but also because India is a huge market for all global pharma players given our status as the second most populous country in the world. Be it the global supply of Hydroxychloroquine in 2020 or Covishield in 2021, the COVID-19 pandemic has convinced the world about the inevitability of India in this context much more than ever before. While the future for Indian pharma industry is undeniably bright, India's current leadership position in the global Pharmacovigilance domain is a key strength that could and should be leveraged for our country to scale much greater heights during the period between 2022 and 2030.

Pharmacovigilance is defined by the World Health Organization as the science and activities relating to the

detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. Properly performed pharmacovigilance activities help in augmenting the benefits while minimising the risks associated with medicines. Although the pharma industry has been known to exist for centuries, it would not be an exaggeration to state that the emergence of Pharmacovigilance as a Science and consequently as a Regulation particularly in the past 60 years has made medicinal products much safer and more effective for the patients, thereby enhancing public confidence on the accountability of the industry. Hence, it has become increasingly important for pharma companies to focus on pharmacovigilance.

Pharmacovigilance became a buzzword in India about 15 years ago when it surprisingly turned out to be a promising unique vertical for Business Process Outsourcing companies and resulted in the hiring of Life Science professionals in large numbers. These companies were contracted by foreign multinational pharma giants for processing their voluminous drug safety data and then went on to quickly gain their confidence to the extent that end-to-end global pharmacovigilance operations of these clients started happening in India. Contract Research Organizations and exclusive Pharmacovigilance Service Providers also followed suit to join the bandwagon with even more specialised services. Some pharma majors, in addition to outsourcing to companies with teams based in India, also set up their own captive units in the country for carrying out their global pharmacovigilance activities. Motivated by these developments, Indian multinational companies, which had erstwhile outsourced their pharmacovigilance activities (for regulated markets) to service providers abroad, decided to either establish their global pharmacovigilance systems in-house or seek support from newer India-based service providers. On top of excelling in providing functional support in pharmacovigilance, India's time-tested proficiency in Information Technology was harnessed subsequently and that led to India becoming home to several multinational IT companies working on pharmacovigilance software databases initially and on cutting edge intuitive technological tools for pharmacovigilance later.

There was a time when pharmacovigilance was considered needed only for that part of the pharma industry which exported its products and in fact marketed them in developed countries (consequentially known as "regulated markets"). Over the past decade, regulatory reforms have happened throughout the world and we are now aware that not only the regulated markets have become more stringent in implementing their pharmacovigilance

regulations but the semi-regulated markets too have formulated regulations on the lines of the developed countries. Thanks to certain countries demanding a defined level of pharmacovigilance standard to be followed by the pharma company worldwide, it has become almost impossible for any ambitious pharma company to ignore pharmacovigilance even in unregulated markets. On a related note, the term 'unregulated markets' is becoming a misnomer, as almost every country in the world has some regulation for drug safety. Furthermore, even companies that wish to cater just to the domestic market are not exempt from pharmacovigilance, as India has begun demanding the implementation of pharmacovigilance requirements as in the local regulations since quite a few years. In fact, a specific Pharmacovigilance Guidance Document for Marketing Authorisation Holders of Pharmaceutical Products in India was notified and made effective since January 2018.

Another key driver that could be said to create peer pressure for pharmacovigilance in India is the active evangelization of the subject by several interested stakeholders. The fact that the Pharmacovigilance Programme of India (PvPI) has grown to cover a wide range of ADR Monitoring Centres throughout the length and breadth of the country, along with the proactive steps taken by the Indian Pharmacopoeia Commission (the National Coordination Centre of PvPI), speaks a lot about the commendable role of the governmental agencies. Although the Central Drugs Standard Control Organisation (CDSCO) is the national regulatory authority in India, PvPI also has a role in engaging with the industry and monitoring compliance with their pharmacovigilance obligations. In addition to these, professional associations with specific interest in pharmacovigilance such as the Pharmacovigilance Council of the Indian Society for Clinical Research (ISCR), Pharmacovigilance Standing Committee of the Indian Medical Association (IMA) Headquarters, International Society of Pharmacovigilance (ISoP), Drug Information Association (DIA), among others, keep emphasising the significance of pharmacovigilance through their awareness and advocacy initiatives. Last but not the least, the COVID-19 pandemic, especially the debates surrounding vaccine-associated adverse events, has heightened the awareness of pharmacovigilance among the public to levels never seen before. From a largely binary approach of "safe" versus "unsafe" drugs, the narrative has changed towards accepting that even good drugs may have adverse effects and that continuous monitoring of the benefit-risk balance is essential throughout the life cycle of any therapeutic product. All

these developments may not result in an overnight increase in ADR reporting rate but it is certain that the mindset change has begun and is here to stay and grow.

From the above, it is clear that pharmacovigilance as a 'need to have' compliance element is for real and not complying with it will directly impact the reputation and consequently the growth of the said pharma company. Not only that, prescribers and many consumers too have begun thinking seriously on whether the safety and effectiveness of the medicinal products they use are backed by solid evidence. Healthcare professionals outside the regulatory pharmacovigilance environment too have now understood that randomised clinical trials alone do not define the safety profile of a drug and the true safety profile of a drug will be known only when it is used in the population at large, which can obviously happen only in the post approval phase. This realisation could impart a sense of apprehension to pharma companies which still believe in the traditional thinking that pharmacovigilance is just a cost centre but it has been proven time and again that pharmacovigilance is a life-saving term insurance policy instead.

Moreover, the good news is that India has already cultivated enormous knowledge and versatile capability in pharmacovigilance which means that it is not difficult to adopt globally acceptable pharmacovigilance standards even in a comparatively smaller pharma company in the country. With the Indian innovation in play, numerous business models both in the outsourced pharmacovigilance services space and in the technology front have come into existence, thereby creating an environment that is conducive to compliance in a cost-effective manner. Many new age pharma companies have accepted this reality and have started building pharmacovigilance as integral components of the foundations of their organizations.

Looking at the future, it is evident that the foreseeable phenomenal growth of Indian pharma industry will in all probabilities involve more and more focus on product safety and effectiveness, as is the case throughout the world. Thousands of pharmacovigilance professionals based in India are the primary reason for our country to rightly and rightfully claim the title of the Mecca of outsourced global pharmacovigilance operations today. India achieved this distinction several years ago and this unparalleled capacity is waiting to be leveraged for the purpose of taking the already tall Indian pharma industry to much greater altitudes. ■

AGILE Practice: Can it really drive future Business Growth?

Many pharmaceuticals, health services, and medical device companies have recognized that the rapid transitioning of Healthcare to a new world of personalization, with a laser-like focus on outcomes and value calls for a change in their operations models. The search is for new ways to increase speed to market, lower development costs, and increase overall operational efficiency.

Ashutosh Parasnis
Founder, NewBox Consulting

Many businesses succeed in small AGILE projects, but only few succeed in bringing about the transformation.

Mindset Shift Influences Management Shifts

The pharma industry is known for sequential drug-development, strict processes and quality requirements, creating rigid silos. Without a direct relationship with patients, the industry also struggles to understand their desires and expectations beyond what clinical data reveals.

Today, Agile ways of working are proving that they can help pharma companies get past those constraints to achieve speed

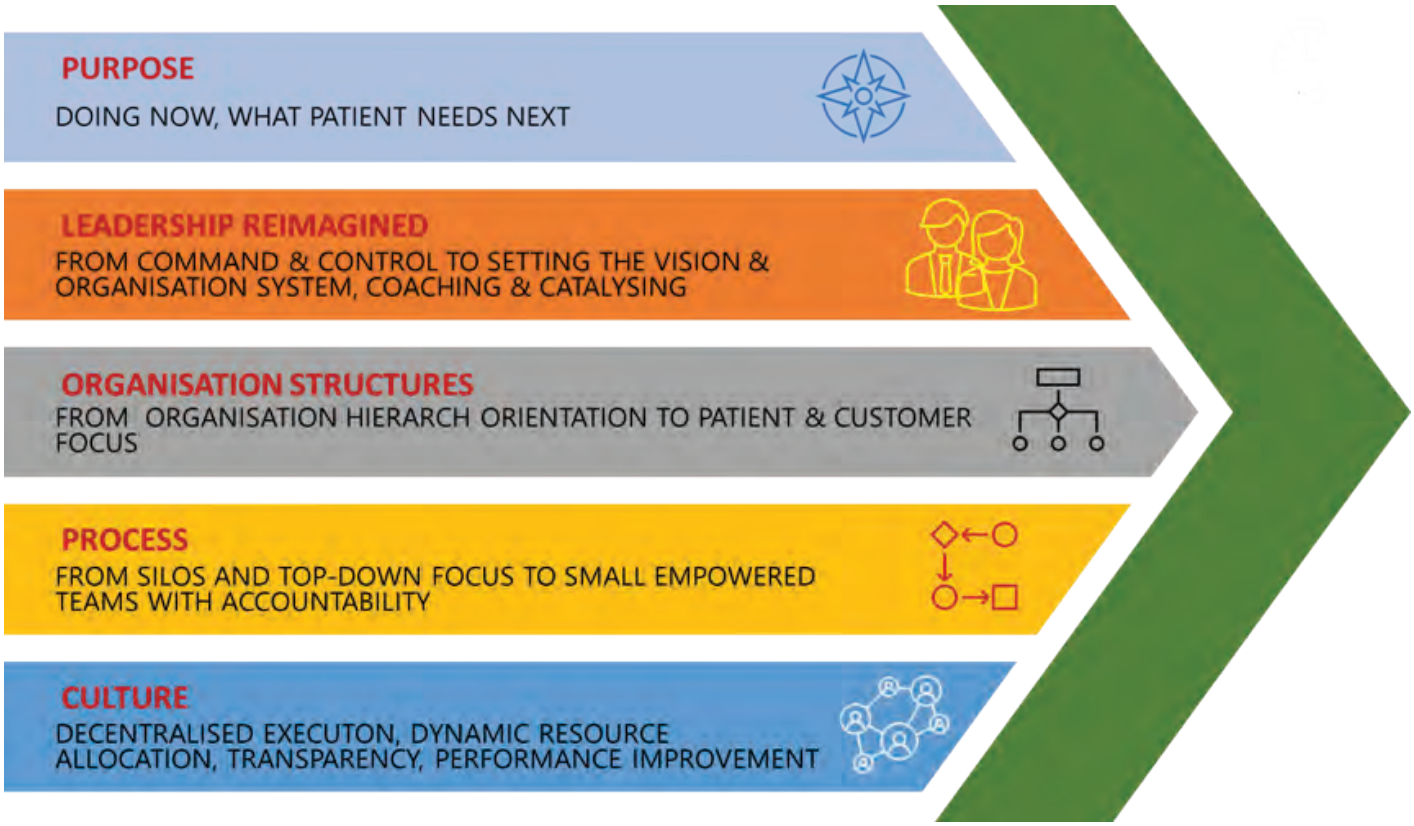


Fig 1: Agile Transformation at ROCHE

to market, experimentation, digitization, customer focus, and the power of cross-functional teams.

ROCHE introduced AGILE practice (Fig 1) in 2016-17. The first step was taken when the Executive Committee focused on Agile to initiate flexibility and dynamism. It soon realized benefits in new product launches and business performance. Its share price too has witnessed handsome returns 2018 onwards.

The Spread of Agile:

Before you think that Agile is Software/ IT industry specific practice, here is an interesting fact. Agile framework has its roots in Toyota Production System (TPS) and Lean Manufacturing. This means the software industry learnt, evolved from manufacturing sector. So now we are seeing the spread of Agile from the software industry to financial services, consumer packaged goods, the public sector, and now pharma. It is the flexibility in delivering value in multiple contexts. While Agile was created to replace the waterfall method of software development, we find that all industries have siloed sequential processes that slow down decision making and innovation.

KANBAN	SCRUM
Aims to eliminate waste activities and improve	Aims to address complex problems while delivering high value products
Roles are not prescribed	Prescribed roles: Product Owner, Scrum Master and Scrum Team
KANBAN does not prescribe time limits. It ensures flow of work.	Scrum is timeboxed. Work must be completed in specified time (called A SPRINT)

Fig 2: Differences between SCRUM & KANBAN

So, What is Agile?

Before we move forward, it is important to understand what AGILE does. Agile enables organizations to master continuous change and flourish in a world that is dynamic. An Agile team is a cross-functional group of people that each have roles and responsibilities in a team environment to achieve a common goal.

Agile is an umbrella framework that uses methodologies such as Scrum, Kanban and eXtreme Programming (XP). While XP is used in software development, Kanban and Scrum are being increasingly accepted in multiple sectors. Both practices are similar to the extent that they empower teams to complete tasks in a prescribed manner.

But there are differences as well. Detailing these practices is beyond the scope of this article, however, a high-level comparison between SCRUM and KANBAN is depicted in Fig 2

It is thus necessary to understand which practice is suitable to create business value. As an example, SCRUM would be more useful in new product development, whereas KANBAN would be useful in ensuring a smooth quality control process.

Benefits to an Agile Company Include:

- Deliver value to the customer, faster. (₹₹₹)
- Build trusted and accountable teams. (Process, Productivity, Engagement)
- Transparency through visualization of all work, saving time. (Process, Productivity)

Fig 3: S.T.E.P challenges determine roadmap to change

- Reduce waste, eliminating work that is not valued by the customer. (₹₹₹, Productivity)
- Improve the quality of the work. (₹₹₹)
- Empowering Leadership, Empowered Teams (Competitive Strategy, Engaged Employees)

Overcoming Challenges, Getting Ready to be Agile:

Inducting a new organizational practice means a significant change. So, there are bound to be challenges in effecting it. A few major ones are depicted in Fig 3.

It must be remembered that whenever a new capability needs to be developed within the organization, 4 key dimensions need to come together.

- First is having a Strategy. A meaningful, well-articulated and often communicated strategy emerges only if there is conviction about the need to change. (WHY ARE WE DOING IT?)
- Second is Talent. It is People who execute strategies. Having the right talent is the key to strategy & success, especially in today's world where new skills are in high demand. (WHO WILL EXECUTE?)
- Third is the Environment of Work– internal and external- that determines the engagement of staff to execute the change. Leadership, culture, infrastructure, work practices would form a part of this. (HOW WILL WE ENABLE?)
- Last but not the least is Business Processes that have to be reviewed and reimagined. (WHAT WILL WE DO AND HOW?)

Only if you believe you have answers to these four S.T.E.P. dimensions and willing to make the shift, you can lay the foundation for an AGILE organization.

Agile at Scale

3 Levers – Business Value | Digital Adoption | Innovation

Once the Agile concept is piloted successfully, it is time to take it across the organization. Agile at scale is the ability to implement Agile at the team level, while applying the same sustainable principles, practices, and outcomes at other layers of the organization. So, the same S.T.E.P. should be used to determine the roadmap for scale-up.

Given that the complexity increases in scaling, additional methods are needed, beyond SCRUM and KANBAN. Given that LEAN has established itself in many organizations, hybrid approach of LEAN-AGILE has now emerged for scaling up.

Today, Agile at Scale is more visible in digitally driven organizations. On the Indian front companies such as TCS, Asian Paints, Hindustan Unilever, ICICI Bank (to name a few) have embraced Agile in response to changing needs of the market trends. Their growth strategies aim to drive value for the customer by embracing digital technologies and commitment to innovate.

Even investors value companies who not only deliver superior financial performance today but are also focused on their readiness for tomorrow. Readiness for tomorrow is not just about solving

Fig 4: Prepared for better future , Image courtesy: Moneycontrol.com

today's problem more efficiently, but also developing the capability to identify the most important problem that will emerge in the near future and then solving it efficiently. That establishes the need to enable your staff to understand the purpose and equip them with higher order thinking skills.

In Conclusion

Highly regulated businesses, like Healthcare, will not release products to market like software industry. But they can surely benefit in creating new agile processes that are faster, while eliminating "waste" in the form of hierarchical structures, legacy processes or products that do not meet customer needs.

5 Tips to Define a Successful Roadmap

1. Management Shift: Focus on changing organizational mindset and creating a supporting culture. The entire organization must have the conviction to change and commitment to act.
2. Value Creation: Consider shifting to Agile only after carefully assessing what creates business value. Avoid bias towards traditional practices.
3. People & Culture: Only the right leaders and talent will drive successful transformation. Shifting to this new way of working needs to be handled carefully. Enable the workforce with new capabilities and provide confidence to adopt new processes and organizational structures.
4. Collaboration: Ensure cross-functional collaboration becomes a habit internally. Externally, ecosystem players need to come together through well-defined policies. Indian government has already initiated steps in that direction, which is a welcome move.
5. Digital Innovation: Agile cannot be seen in isolation. It needs the companionship of digitalization and innovation. For manufacturing companies Agile and Industry 4.0 complement each other perfectly. Agile can drive innovative uses of digitalization, whereas Industry 4.0 principles can spur agile innovation.

References:

1. *https://www.roche.com/dam/jcr:5c4d8deb-381c-4d3f-9aed- 990980b52441/en/irp20200914-pharma-strategy.pdf*
2. *https://www.globaldata.com/indias-proposed-new-agile-pharma-regulations-will- benefit-innovator-companies-says-globaldata/*
3. *http://newbox-consulting.com/resources/Competencies%20Matter%20v2.1.pdf.* ■

Drug Safety in the New Millennium for Novel Small Molecule Drugs

Uday Saxena
COO, Reagene Biosciences Private Limited

Co-authored by :
Subharamanyam Vangala, CEO of ReaGene Biosciences
and **Satish Chandran,** CEO of ProdIgY Bio

The safety of a new drug is of paramount importance – even if a drug is highly efficacious but not found to be safe it will not be approved by the regulatory bodies. The safety standards that the new drugs have to meet have dramatically increased over the years. It is said that if aspirin, a decades old drug, were to be launched today, it may not have gotten approved given the range of unwanted pharmacological activities it possesses. Regulatory bodies such as USFDA and Indian DCGI place very high bar on proving the safety of a drug prior to its approval. In this short review we can examine the various types of pivotal safety studies needed for a new drug as well propose what could be done in the future.

Typical safety studies requirement currently needed is shown below

Preclinical Tox studies needed

The earliest studies that are needed are preclinical safety studies. These include both in vitro and in vivo studies. All safety studies have to be conducted under GLP compliant conditions – basically the studies are done in highly controlled and rigorous conditions with through documentation of every step.

The in vitro studies include HERG channel assays, mutagenicity and genotoxicity test for the compound. These are mandatory and a positive signal in any of these tests could be a matter of concern to the regulator.

The preclinical animal studies form the bulk of the drug safety study requirements by the regulators. These studies have to be done in at least two animal species, one usually a rodent such as mice or rat and another a higher species such as dog. In special cases depending on the expected safety liability, the regulator may ask for studies to be done in non-human primates as well. The preclinical safety and efficacy data package is submitted to the regulator in the form of an Investigational New Drug application (IND) to the regulator to get permission to initiate clinical trials.

Clinical studies

The most expensive part of drug development are the clinical trials. Clinical trials form the basis of approval of any drug. There are two aspects to clinical trials, demonstration of safety of the drug and efficacy of the drug. Phase I clinical trials are performed in healthy human volunteers and are mainly designed to explore the safety of the drug. The studies are usually done in a step wise fashion starting with single ascending dose (SAD) escalation and then multiple ascending dose (MAD) studies.

If these are successful, then the drug moves into Phase II clinical trials. This is the first time that the drug is explored in patients. Here the objectives are two-fold, to explore the safety of the drug as well as demonstrate the efficacy of the drug

at various doses chosen from Phase I studies.

The final stage of drug development are the Phase III clinical trials. This is largely an expansion of Phase II trials with the number of patients being increased as well a comparator drug is also added to the trial. The main objectives are to show the safety, efficacy and comparative activity of the drug relative to the current standard of care drug. However efficacious the drug may be if there are safety concerns then this raises a red flag and the whole drug profile is thoroughly scrutinized. Occasionally extended studies may be requested by the regulator. Successful drug development end in the submission of and New Drug Application (NDA) and its approval by the regulator.

Future of drug safety evaluations – The use of "human like" models

Despite such well organized and rigorous studies laid out by the regulators, the drug attrition rates are very high for approval of new drugs. For every single drug that enters the market, there are few hundred/ thousand preclinical compounds that do not make the cut. The biggest drop is seen when drugs transition from preclinical into clinical studies. Why is that?

One reason could be that bulk of safety and efficacy work done preclinically is done in animal models, which may or may not capture what happens in human biology. The biggest "black box" is there fore the transition from preclinical to clinical studies. Regulators globally are now thinking about newer approaches to predicting drug safety rather than solely relying on animal studies.

One approach is the use of humanized in vitro and animal models. The in vitro human like models are designed used actual healthy or patient derived human cells and are used to generate human organs or systems using organoid or the more advance 3D bioprinted tools. The idea is to capture human like biology rather than use animals which do not accurately reflect human disease.
In certain cases, the animal model themselves may not be readily available such as in the case of rare diseases or even COVID 19 when the pandemic initially struck. We designed a human vascular lung model to mimic COVID 19 damage to the lungs and searched for repurposed drugs to treat this disease. We made some startling observations using the model which later on were confirmed by others independently in clinical studies. Thus, this type of use of human like tools may well become the future of drug safety and efficacy measurements rather than just rely on animal models. The way forward will be to reduce the use of animals and create improved human like tools to better predict drug safety. Many regulators around the world are moving in this direction. ■

Floating Planar Mover Simplifies Transportation of Sensitive Workpieces

BECKHOFF
New Automation Technology

Floating Planar Mover Simplifies Transportation of Sensitive Workpieces

No need to move the plasma jet: A floating planar mover carries the workpiece exactly into position for surface treatment. Picture: © Plasmatreat, Jan Düfelsiek

Plasmatreat GmbH, a Steinhagen, Germany, based manufacturer of plasma systems for high-efficiency surface treatment and environment-friendly production processes, unveiled a new plasma treatment unit at the K 2019 trade show. A key innovation with this treatment unit is that it uses XPlanar, a planar motor system from Beckhoff, to transport workpieces with precision and flexibility. XPlanar replaces prior systems used to move often sensitive workpieces such as PCBs and eliminates the need to install complex 6-axis robots and linear motors.

The plasma treatment unit can surface-treat a variety of material samples in a two-stage process, as Jochen Stichling, Head of Design at Plasmatreat, explains: "During the first stage, the substrate is moved under a nozzle for cleaning and activation. During the second, a separate nozzle applies a functional coating." This, he explains, is where the company focused its innovation efforts: "We wanted a fast, fully programmable, wear-free system to transport the workpieces. And when it

came to custom-programming tracks and travel there was no real alternative to XPlanar."

Planar motor system with floating movers

The XPlanar system consists of planar tiles that can be arranged in any pattern, combined with contactless movers that float over them and can be positioned exceptionally fast, flexibly and precisely. The movers operate jerk-free and are capable of traveling at speeds of up to 2 m/s; they can also accelerate at 1 g, and be positioned with a repeatability of 50 µm – silently, and without wear or abrasion. The system not only supports movement within the x-y space, it provides additional functions to allow movers to be positioned with up to six degrees of freedom when necessary:

- Raising and lowering by up to 4 mm (unloaded),
- Tilting by up to 5° when transporting and handling liquids,
- Rotation by up to 360°.

The XPlanar system in the Plasmatreat machine consists of six 240 x 240 mm planar tiles and a single planar mover.

The new plasma treatment unit is highly compact as it no longer requires a 6-axis robot or additional linear axes. Picture: © Plasmatreat, Jan Düfelsiek

Greater flexibility, lower mechanical complexity

A major advantage with XPlanar is that the plasma jets used to treat surfaces no longer need to be moved and, as a result, can now be installed in fixed mountings. The jets are complex, both mechanically and electrically, and the ability to move the workpieces rather than the plasma jets themselves reduces wear to the feed lines. For Jochen Stichling, there are additional

benefits from the increased flexibility too: "We can attach a variety of material samples to the mover for treatment using just simple adapters. We can easily add processing stations alongside the plasma jets – markers for good parts, for instance, or optical sensing heads to conduct full part inspections – and carry workpieces to them flexibly as needed. And XPlanar's rapid acceleration also lets us move material samples at high speeds; with thin samples, for instance, this helps minimize treatment time with the fixed jet."

According to Stichling, XPlanar's functional benefits are proving valuable in a range of applications: "Conventional setups use a 6-axis robot or linear motors to move a plasma jet around a stationary workpiece. From a cost perspective, XPlanar comes in somewhere between linear-axis and robotic systems. With flat parts that don't require much vertical travel on the z-axis, where robotic systems are usually ideal, XPlanar offers an excellent alternative to gantry-type systems. XPlanar's advantages in terms of lack of wear, easy cleaning, and clean-room compatibility also play out here."

For Stichling, XPlanar has the potential to optimize plasma surface treatment in two key areas, going forward: direct integration of in-line testing for full inspections during the treatment process, and custom-programmable mover travel routes for end customers.

Another advantage for Plasmatreat was that it took less than two months to integrate the XPlanar system into its machine – not least because Beckhoff was quick to supply the 3D data and the electrical connection information that enabled the company to rapidly incorporate the XPlanar starter kit into its machine design. XPlanar, according to Jochen Stichling, has proved to be both robust and reliable. And another advantage, he points out, is that the entire plasma treatment cell has now been fully automated using PC-based control,

For more information

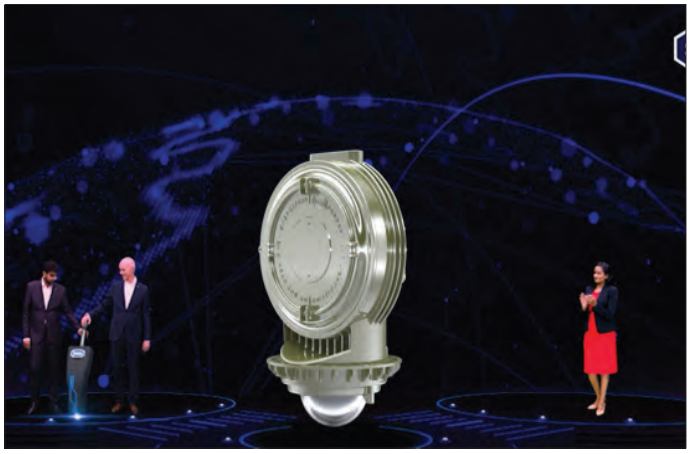
Email: info@beckhoff.co.in
Website: www.plasmatreat.com
www.beckhoff.com/xplanar

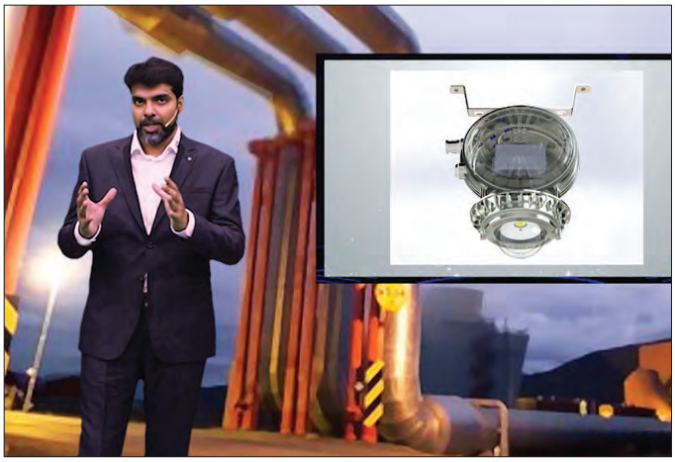
R. STAHL launches the all-new LED Pendant light fitting series 6057 / 6457 for hazardous areas

R. STAHL, the leading manufacturer, supplier and solution provider of explosion protection electrical equipment and automation systems, launches LED pendant light fitting series 6057 / 6457 - an innovative lighting solution with global standards to meet the changing needs of industries, worldwide. Born out of the 'spark of innovation', this LED Series is a world-class, lighting solution with a revolutionary design. Every component that goes into making of this energy efficient light is tested for quality and durability. Accredited with international and national certifications of **IECEx & PESO,** the Ex db certified 6057 and Ex db ec certified 6457 LED pendant lights are ideal for application in **Zone 1, 2, 21 & 22** of diverse industries. This uniquely engineered lighting solution is a versatile performer with rich features designed for focused and brighter illumination covering wider areas with better lumen per watt. This LED series is made of high-

The revolutionary LED pendant light fitting from R. STAHL can withstand extreme operating and environmental conditions

grade copper free aluminium alloy with powder coating for ultimate durability & corrosion resistance. It is tested as per IEC standards, and comes with an assured service life of 50,000 hours and efficacy of 113 lm/W. With an exclusive design of





Glimpses from the "one-of-a-kind" product launch event held virtually on July 15th, 2021. The event saw great participation from customers & partners across Asia Pacific, Middle East & Africa. Click here to watch the video recording https://youtu.be/hemOxZwqDP8

2 separate compartments; one for driver and terminal components and the other for the LED unit, it ensures uncompromised safety & ultimate protection. Designed for the harshest environments, it can withstand ambient temperatures from **-20° C to +60° C** and comes with an ingress protection of **IP 66 & IP 67.** Combined with its easy installation, cost effective maintenance, enduring durability and long life, the pendant light fitting LED series 6057 / 6457 is the most reliable and energy saving lighting solution for oil & gas, pharmaceutical, chemicals, marine and shipbuilding, machine building and food & beverages industries worldwide. ■

Contact Details

Email: sales.india@r-stahl.com
Website: www.r-stahl.com/in/6057

In the Battle Ground of Pandemic

praj | HiPurity Systems

Sankhajeet Kole , Head Engineering
Praj HiPurity Systems

Praj HiPurity Systems Limited provides "End to End Solution" to Pharma / Life science clients. We offer solutions for a variety of applications in Vaccines, Biopharma & Sterile Formulations. Praj HiPurity has contributed to healthcare fraternity in 50+ Biotech facilities, 70+ USFDA Sites, 40+ Different applications of Pharma / Biotech, 70+ Greenfield sites, 150+ sterile facilities and approximately 70 overseas references.

The key to this efficiency and performance is excellence in design, engineering, manufacturing and field construction followed by meticulous planning and execution.

"Quality by Design" requires high-quality material, precise engineering, cleanability/ sterility built-in design and par excellence manufacturing processes. Praj HiPurity boasts of one of the best & most comprehensive facilities for building water & process systems in-house with little or no dependence on external agencies. In-house vessel manufacturing to orbital welding to system integration and testing enables Praj HiPurity to help customers achieve faster time to market targets in this ever-challenging & dynamic business environment.

Modularization of process and pre-building small and Mega skids remains the centrepiece of our growth story in the last few years. Pre-built, pre-tested skids have and will remain the focal point of our effort.

Since COVID-19 outbreak, mankind's vulnerability to be able to respond to the need of the hour has once again been exposed. This is inspite of decades of learnings and advancements in our understanding of vaccine technology, our ability to respond with speed to find a suitable solution has once again come under the scanner. Not only has been the cure elusive, but to be able to scale up

the possible solution to cover a global pandemic like COVID-19 it may take a completely different approach. We have all witnessed advent of Covishield, Covaxin & Sputnik to save us from this pandemic.

The need of the hour is:

'A Joint effort' of vaccine manufacturers and OEMs to trim CAPEX and improve productivity.

To have a 'Right Balance' for assessing risk & reward with a close watch on expenditure, one needs a robust framework & subject matter expertise.

Look at all aspects in 'One Frame' to ensure that the lens for assessment is wider including various aspects of plant design together & not in isolation.

'Right Start' is 'Good Start' - To prevent time loss and shorten time to market, it is crucial to fix all technical and regulatory requirements during the design phase itself.

Praj HiPurity has been a foundation of our client's success, through an array of specializations like:

Praj HiPurity has been a foundation of our client's success, through an array of specializations like:

- Clean utilities & Sterile equipments designed and manufactured under one umbrella.
- Sharing practical cumulative expertise as producers of recombinant biotherapeutics and vaccines.
- In-depth understanding of Continuous Manufacturing (CM) for Continuous fermentation, continuous bio-kill system, continuous CIP refill / supply & Continuous sterilizer.
- Streamlining manufacturing processes and accelerating technology transfer by leveraging our Praj Matrix R&D Centre.
- Capability to manufacture in parts and assemble at client's site for faster & customised delivery
- Manufacturing excellence from 2 L to 200,000 L equipment through 3 of our own manufacturing units.
- Validation & regulations (ASME BPE, U Stamp, DOSH, PED)
- Modular designing for faster manufacturing & assembly.
- Modular programming for flexibility & user-friendliness.
- Dedicated testing facility.
- Value added services (VAS) to attend all maintenance needs.

To fast-track projects of Covid vaccine, we have endeavoured to maintain semi-

finished inventory of equipments, which can be easily assembled, tested, installed and validated for serving the cause to humanity.

All in all, Praj endeavours to fulfil customer requirements and provide proven technologies.

We look forward to your support and faith in our capabilities and expertise.

We are open to suggestions, ideas and discussion for your requirements. Feel free to contact us at info@prajhipurity.net

'Now & Beyond'

While the current pandemic has exposed the limited manufacturing base for vaccines, many companies have taken upon themselves to diversify in this difficult segment of VACCINES and focus on capacity building. Praj HiPurity is ready to support the industry for future capacity build-up by deeper support in Process Engineering for a future ready design with modularized approach. ■

Contact Details

Email: info@prajhipurity.net
Website: www.prajhipurity.net

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

Powder Transfer Pumps

Application

In many API Plants there are requirements to transfer non-hygroscopic powders of low bulk density from storage sacks / bags to vessels and reactor tanks at a height of 2-3 mts.

Available options

Powders can be transferred either manually or by the blower based powder transfer system (PTS). The manual system is labour-intensive, wastes materials during transfer & poses high operator & plant risk in transfer of flammable powders due to static build-up during transfer. We present the DELLMECO air or Nitrogen gas operated double diaphragm pump to transfer free-flowing non-hygroscopic powders till 0.8 bulk density to heights of 3-5 mts.

Solution

To avoid manual process or use of a capital intensive powder transfer system we can use the **DELLMECO** powder pump. The pump is Atex certified, safe to use with flammable powders, labour-saving & saves material wastage during transfer. Dellmeco Pumps can be used to transfer dry powders more quickly, cleanly and at a fraction of the cost than other systems. The pumps can be operated by air or Nitrogen gas. With different pump sizes from 1" to 3", powders can be transferred at rates to 15 kg/min

Advantages

- The powder transfer pumps are ATEX certified, allowing use in explosive or hazardous zones.
- Portable can moved from site to site.

- Economical and Simple compared to PTS (Powder Transfer System).
- BSP, Flanged and Tri-Clamp pump end-connections.
- Reduces airborne contamination, transfers powders directly and in a closed system ensuring minimal wastage.

Customers

We have supplied the DELLMECO powder pumps in many API plants now successfully. Many Indian API pharma companies have been successfully using our Dellmeco powder transfer aodd pumps for transfer applications at their plants. With successful installations, good commissioning support, post–sale services & trouble-free usage we have now received repeat orders from many plants as well. ■

For more information

Email: info@shanbhags.com
Website: www.shanbhags.com

HRS Heat Exchangers acquired by Exchanger Industries Limited

V Gokul Das, CMD, HRS PSL, India

V Gokul Das, CMD of HRS PSL, India, mentioned that over the years, HRS has built a formidable position in the Indian and ASEAN markets for its range of innovative and energy efficient heat exchangers and systems for various sectors like the chemical, agrochem, pharmaceutical, petrochemical, nutraceuticals, edible oil, fertilizer, cement, steel, fruit and vegetable processing, fruit based beverage processing, carbonated fruit beverage, dairy products, health drinks, dairy creamer and many others. This acquisition will enable us venture into the high value Oil & Gas and Petrochemical sector in India, with better technology and engineering to manufacture heat exchanger and systems from Exchanger Industries Ltd.

HRS is a specialist global supplier of heat exchangers and custom process systems across the environmental, food, beverage, chemical and pharmaceutical sectors. The acquisition by EIL creates new opportunities by combining HRS's capabilities and market sectors with EIL's accelerating expansion into power generation, Liquified Natural Gas (LNG), renewable energy, power storage and biofuels applications. The combined business is positioned to create market growth by providing its customers with environmentally sustainable heat exchange solutions. The seasoned HRS management team will be retained by EIL and will play a critical role in executing plans for robust international expansion afforded by the strategic combination of two distinct, yet complementary industry leaders.

Mark el Baroudi, CEO of EIL, stated: "For decades, we've worked hard on behalf of our customers in Canada, the U.S. and

25 countries worldwide, consistently providing them with mission-critical, innovative solutions in some of the most demanding environments," stated Mark el Baroudi, EIL's CEO. "The HRS acquisition will provide numerous benefits to our customers including a broader capability to provide heat transfer solutions to environmentally sustainable projects in the biogas and wastewater treatment sectors, in addition to EIL's existing projects in clean power generation, Liquified Natural Gas (LNG), emissions-free power storage and biofuels applications."

To deliver these projects competitively, the acquisition provides EIL immediate access to a cost- effective global footprint with scalable hubs in both India and Spain, and a combined portfolio of anti- fouling technologies that enhances differentiation and acts as a unique platform to create value for customers.

Additionally, Mark el Baroudi stated that the acquisition of HRS Heat Exchangers provides EIL an extraordinary opportunity to expand their exposure to an impressive international customer base across rapidly growing geographic market positions in the U.S., U.K., Spain, Mexico, India, the Middle East, Malaysia, Australia and New Zealand. As evidence of this opportunity, HRS was ranked number 161 in U.K.'s prestigious Sunday Times HSBC international top league table that tracks the international growth of U.K. based companies.

Steven Pither, founder and CEO of HRS, said: "We're thrilled to join the EIL family and continue our journey to building a highly respected global supplier of heat transfer products. Leveraging EIL's expertise in designing innovative heat transfer systems, and their established track record in creating streamlined, highly efficient business processes will allow us to enhance our product offering and effectively scale our Spanish and Indian manufacturing operations; delivering timely, cost effective solutions to our customer base around the world. We are confident that this will drive growth to the next level."

"Our combined manufacturing capability and leading-edge product technologies will strengthen our value proposition and increase market penetration internationally," continued el Baroudi. "In short, this acquisition combines the capabilities of both parties to enhance an already differentiated market position. It creates better outcomes for everyone we serve."

"Global Technologies, Indigenised Solution" has been our motto says Gokul Das. This acquisition brings in an exciting range of offering to the energy solutions sector. We plan to invest in building up our infrastructure and facilities to cater to the growing demand locally and globally, which will give boost to our Make in India initiative too. ■

Ensuring Pharma Compliance with Testo Data Monitoring Solutions

Testo Saveris Pharma for automated quality management.

Due to the crucial necessity and its direct impact on human health and welfare, Pharma is probably the most important and critical sector among others. As a consequence of which, it becomes essential to store pharmaceuticals, vaccines, laboratory samples or units of blood at the right temperatures to ensure that they remain effective and that quality is maintained. Another reason for the Pharma division to ensure safety measures & controlled environment is stringent regulations and inspection of the facilities. This elementary need for climate control can only be ensured with right data monitoring systems. Testo being a market leader in testing & measurement sector provides the best in class data loggers and data monitoring systems for the Pharma division.

Ensuring end to end climate monitoring – Testo Data Loggers

Pharma goods must be stored well in every situation as any deviation in the ambient temperature or humidity values may lead to deteriorated quality of the product. Testo data loggers can be used to test the optimum conditions for specific products or surroundings. In particular, temperature & humidity data loggers are often used in Pharma industries to monitor the conditions in which drugs, medicines, vaccines are kept. Not only storage, but during the transit of goods, testo transport data loggers are useful to measure the transport conditions. The range of data loggers is very extensive. A temperature & humidity loggers such as 174 T guarantees continuous monitoring in a storage or warehouse. Also, data loggers with multi channels for connecting external sensors & thermocouples, like testo 176

WiFi Data Logger

Transport Data Logger

are available for ensuring secured work process in labs.

These data loggers are also critical for production quality assurance where the temperature has to be frequently checked at various points in production processes. Using thermocouple probes, data loggers can also record data in the kinds of extreme temperature ranges. The probe's fast response also contributes in the validation processes and quality standard optimization in QA units & clean room applications. These instruments are the most convenient and pocket friendly solution for all Pharma application areas.

The **testo Saveris 2 WiFi data logger** system is the simple, flexible and reliable solution to humidity and temperature monitoring in cold storage area like blood banks. This innovative monitoring system is ideal for high product quality & eliminates manual work of reading out or documenting measurement data. With a secure online storage of all readings in Testo Cloud the data can be managed and analyzed online by the user via smart phone, tablet or PC anywhere and anytime. In case of crises and deviations, it is provided with an alarm by e-mail, or optionally by SMS.

Another important and crucial application of a Pharma industry involves validation of sterilization and freeze-drying processes. Not only that, validating cleaning and disinfecting equipment is equally necessary. In order to allow a seamless operating procedure, the validation process and the documentation work must be as efficient and smooth as possible which could be easily achieved with **testo 190 data logger** solution that has innovative data loggers for temperature & humidity, smart software and accessories.

Testo data logger for Clean room & Lab

Testo 190 autoclaving application

Complete Pharma solution – Testo Saveris system

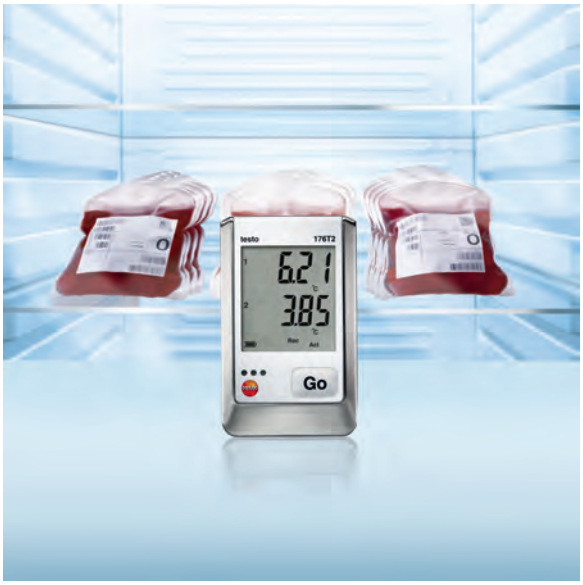
A sector like pharmaceuticals which is, governed by strict norms and regulations must operate with full efficiency. Testo provides the best in class solution for comprehensive quality management in pharma industry called as the testo Saveris. It is an automated system that is integrated in the facility & constitutes of wireless or Ethernet probes installed at different locations that are connected to one base station which documents and monitors all measurement data of its own. The monitoring process is uninterrupted and the system provides number of alarm options in case the measurement values increase or decrease the standards. Some advantages of testo Saveris- Data Monitoring System include:

- Mixed system with both wireless & wired probes connected to the base station
- Data from multiple locations can be monitored centrally at one location
- 21 CFR Part 11 compliant system for pharma industry.
- Provides automated documentation, reduces human efforts & non-compliance
- The data is stored in the probes, so even if software connectivity is lost the data is safe and can be downloaded once the software is logged in.

Data compliance for audits and inspections

Testo offerings are majorly related to the data security along with comprehensive analysis & evaluation of all the recorded measurement data. Testo data loggers ensure continuous monitoring of temperature and relative humidity of pharmaceutical products during production, storage or transit of goods. Real time data monitoring is important

Testo 176 T3 data logger



Testo 176 T2 data logger

for the quality of Pharma goods and also enables the supplier to improve the life of the goods. Transportation trucks, warehouses, cold rooms etc. can now be remotely monitored via Testo data loggers & data monitoring systems. Our data loggers are EN 12830 and 21 CFR Part 11 compliant which ensure complete documentation of parameters, be it humidity, temperature or absolute pressure. They come with professional software where the data recorded cannot be modified and the audits can be easily complied with.

Service & Calibration made easy

Testo also has an established state-of-the-art NABL accredited service & calibration LAB in accordance with the standard ISO/IEC 17025:2017, that takes care of the after sales support locally from Pune.

Testo service & calibration facility is highly cost effective as it delivers international standards very conveniently within a week's time. Instruments of any brand/ make can be calibrated and serviced locally maintaining necessary standards.

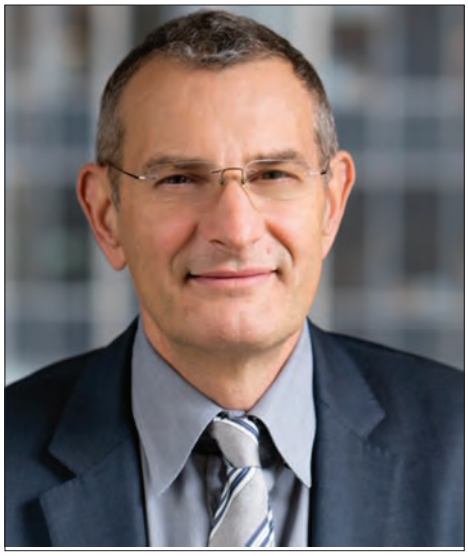
The accredited parameters include Humidity, Pressure, Absolute Pressure, Contact Type Temperature, Non-Contact Type Temperature (Infra Red Thermometer, Thermal Imager). In fact, ours is the First and Only Lab in India to get NABL Accreditation for Dew Point Temperature as well. ■

Contact Details

Email: info@testo.in
Website: www.testo.com

Balancing the Act of 'Flight to the East'

For Aceto, the past year has been a tale of two industries. The industrial specialties & pharma businesses saw a sharp contrast in growth during the pandemic. With the recent acquisition of Finar in India, Aceto is consolidating its position in Indian domestic market and the fast-growing Asian region. In an exclusive interview ***Gilles Cottier, CEO of Aceto,*** *delves into the growth plans of the company.*



Gilles Cottier
CEO, Aceto

What has been the greatest learning from the pandemic and how have these impacted Aceto's business units?

After COVID hit us last year, Aceto adapted by working remotely using the tools such as Microsoft teams, Zoom, etc., and our people swiftly adapted to this new and fast-changing environment. We grew our business, recruited some outstanding talent, and acquired five companies largely by communicating through a screen. I know that Aceto isn't alone in saying that this will change the way that we will work forever; and we will be more efficient and nimbler as a result.

We experienced two very different markets last year. Our industrial markets, coatings for the automotive industry as an example,

suffered due to shutdowns and market uncertainty; this impacted our business negatively.

On the flip side, our pharma and life science markets saw significant growth, driven by the acceleration of customers' programs directly or indirectly related to COVID.

It is the supply chain that has been the most consistent challenge for us through the pandemic. We manage over 10,000 international shipments per year, and we pride ourselves on world-class logistics to keep our customers lives stress free. The dynamics over the past year have put stress on our systems, as they have for virtually every company in every industry. But I'm really pleased with the way our teams have been able to innovate and actually improve our already strong on-time delivery rates. We're coming out of this even stronger based on what we've learned and been able to endure.

Apart from the supply chain challenges how do you see the market dynamics changing, the demand for the products supplied by Aceto?

As many in the industry know, Aceto built a legacy of robust sourcing, fit for purpose quality, and strong logistics. Over the past 15 months we've made five acquisitions, all with manufacturing assets. We are transforming Aceto from a value-added distributor to a global supplier of critical raw materials with a robust manufacturing footprint.

As a distributor, one relies on suppliers, which we have been doing successfully for many years. Now with an expanded manufacturing, R&D and portfolio offering, we can quickly and more efficiently innovate new solutions, upgrade the quality of some products, and/or customize them for our customers. This doesn't mean that we will abandon our robust sourcing business. Customers appreciate the choice in supply chain that we now have to offer.

Talking about market dynamics, in the decade of 2000-2010, our industry saw companies from the US & Europe 'Fly to the East'; setting up their manufacturing and drug development facilities to capture Asian demand and drive cost effectiveness. From 2010 – 2020 one could see companies returning to the West which has been reemphasized with the spread of COVID. For example, if you look at some of the recent headlines, Governments are talking about manufacturing significantly more in the US and in Europe to manage supply chain for any given situation. We're seeing several of our customers follow-suit and push selectively for materials to be produced domestically, but a significant portion of the materials and different components will continue to be manufactured in China, India and other countries.

In my view, it is a balancing act for the industry and for organizations like ours with manufacturing facilities spread across North America, Europe & Asia. Aceto has

a strong position to cater to our customers' needs across various global markets.

Which are the strategic focus areas for Aceto, challenges in the foreseeable future & how do you plan to stay competitive?

We have disproportionately focused our attention on the broad life science market and have placed an emphasis on investments that allow us to be more in control of our destiny. First, as already discussed, we have made many inorganic moves. Secondly, we are doubling down on existing strengths including sourcing, regulatory support, sales excellence, and supply chain to ensure that we continue to deliver world class solutions. We will supplement these moves with new initiatives around targeted new product introduction, a process excellence focus, and digitalization.

Supply chain security and quality are the biggest challenges and have always been our topmost priorities. We continue to focus on offering customized innovative solutions compliant with the highest standards of regulatory norms to our customers not only for life sciences markets, but also to industrial, cosmetic, and nutritional marketplaces.

Before the acquisition of Finar, Aceto had a significant operational presence in Asia with sourcing offices in India and China. But our commercial presence was modest – one sales office in Singapore. The acquisition of Finar was a strategic move to strengthen our position in the Asia market commercially, as well as in manufacturing and R&D. The acquisition is proving to be a nice marriage; Finar gives Aceto a full suite of capabilities within the Asia market, while Aceto is able to help grow the Finar business in the West, and other Asia markets as well.

You have very strong growth plans lined up for India and Asia, especially in this BioPharma space.

The life sciences market is as strong as it has every been for obvious reasons, but we like the five- year outlook as well: The small molecule market is still going to grow in single digit, where our large molecule market is going into mid to high single digits.

With our acquisitions and our growth strategy overall, we are focused on helping our customers in the Life Science space. Aceto aims to be a significant supplier for custom and critical materials to help our customers develop and manufacture drugs and vaccines to support current and future material demands.

What products will Aceto offer to the Indian Pharma market?

Aceto has a wide array of products and customized solutions to offer to the Indian pharmaceutical industry including advanced intermediates, process solutions, excipients and high-Value GMP API's for Innovative drugs. ■

Risk and Remedies Associated with Analytical Vials

Dr. Ajit Datar
Application Advisor, Borosil Limited

"Look Closely, the beautiful may be small" --- by Immanuel Kant

An Analytical vial is a small container usually made of glass or plastic. It may be shaped like a tube or bottle and have a flat bottom, unlike common blood collection tubes. Vials are available with various caps to meet specific storage or handling requirements. Analytical vials are those which are used with Analytical Instruments for Chemical Analysis of samples to be screened for qualitative or quantitative analysis. The vials are so small that these are not even listed as a component of any Analytical Instrument. However, they are most significant part.

There are several analytical instruments which require vials for storing the sample in an Autosampler of the instrument from where the sample gets introduced in to the analytical system. Some of these instruments are listed below.

- Gas Chromatography (GC)
- Head space GC
- High Performance Liquid

Chromatography (HPLC)

- Ion Chromatography (IC)
- Atomic Absorption Spectroscopy (AAS)
- Inductively Coupled Plasma (ICP) Atomic Emission Spectroscopy (AES)
- GC-Mass Spectrometry (MS)
- HPLC-MS
- ICP-MS
- Total Organic Carbon (TOC) Analyser.

Depending on the analytical requirement the size, material of construction and specificity of the vial changes significantly.

Since there are so many types of vials available, choosing the right one for your lab or work can feel like a challenge. It's worth choosing quality vials to protect your samples and products, and guarantee the quality of your product. Once you understand the different materials, benefits and applications, it'll be easier to make that choice.

Most vials are made of glass or plastic, and the material you choose must be compatible with your samples and storage methods.

The glass continues to be the ideal material for general laboratory applications. Glass keeps chemicals safe from environmental factors like light and moisture and allows a long shelf life. You'll find glass containing some of the world's most valuable liquids, from venom to insulin.

The Glass Vials

Different types of glass vials are available, and it's critical to select the right kind. Vials may be made of soda-lime glass, the most common and least expensive type of glass. The United States Pharmacopeia (USP) groups glass containers into three categories. According to the USP, BOROSILicate glass is classified as a Type 1 glass, meaning it is appropriate for most products meant for injection and non-injection purposes. In general, Type 1 cate glass is considered a high-quality vial material. Amongst Type I there are three varieties on the basis of Linear expansion coefficient from 70-type basic glass to 51-type, up to 33-type. The 33-type expansion glass is the best BOROSILicate glass used for vials as it has the least linear expansion coefficient.

BOROSILicate glass contains at least 5% boric oxide which increases the vial's hydrolytic and thermic resistance. This type of glass is also valued for its extremely low coefficient of thermal expansion. For this reason, BOROSILicate glass is widely used in chemical and pharmaceutical industries as laboratory ware.

For Analytical applications, Type I vials are most preferred There are many benefits of glass vials as given below:

Clarity: A glass vial features a smooth, clear surface, which allows you to inspect the contents for contamination or degradation.

Inertness: BOROSILicate glass will not generally react with other substances. Therefore, you can also expect a long shelf life.

Heat resistance: BOROSILicate glass has a low coefficient of thermal expansion and is less vulnerable to thermal shock than other materials. Due to this, BOROSILicate glass is ideal for chromatography.

Nonporous surface: Glass is nonporous and won't impart the smell or taste of products stored. It reduces the risk of evaporation or contamination from materials that would otherwise be trapped in a container's pores.

Recyclable and sustainable material: Glass is recyclable and sustainable You can feel good choosing glass vials and knowing you are contributing to the health of the environment.

Autosampler Vials

Autosamplers automatically and accurately load samples for analysis. It's critical to choose the appropriate vial for autosampler use. The incorrect vial could lead to problems such as sample degradation or damage to the autosampler.

Regarding autosampler vial material, you can usually choose BOROSILicate glass or plastic. Use amber BOROSILicate glass for UV light protection. You might select polypropylene or polyethylene vials for substances that are sensitive to glass or stick to glass.

Vial Caps and Septa

The vial caps play a crucial role in guarding the sample from spills, contamination and evaporation. The caps should form an airtight seal and be inert. The caps are either screw caps or Crimp caps and both come with septa.

Screw caps: Screw caps are excellent at forming a tight seal. When you turn a screw cap, you apply pressure that holds the septum between the vial rim and the cap, and it won't move when it's pierced. Screw caps may have an opening to use with an autosampler.

Crimp cap: it consists of an aluminium cap and PTFE/silicone septum. This type of cap tightly squeezes the septum between the vial and the cap, forming a superior seal and reducing evaporation. Crimp caps require the use of manual or automatic crimping tools.

The Caps come with a silicone or polytetrafluoroethylene (PTFE) septum, which creates a tight seal. Needles can pierce the septum because the elasticity of the material allows it to reclose. There are several benefits of silicone septa. It can withstand extremely high and low temperatures and maintain flexibility. It is also chemically inert. Lastly, silicone is resistant to UV radiation and is suitable for various sterilization methods.

PTFE/silicone: A PTFE/silicone septum consists of pure silicone laminated with PTFE. This creates a high inertness and exceptional resealing abilities, even after multiple punctures. This is a preferred choice for chromatography applications.

PTFE: PTFE septa provide excellent resistance to solvents and are easy to penetrate. However, PTFE septa are not resealable and are recommended only for short-term storage and single-injection use.

Pre-slit PTFE/silicone: Pre-slit septa feature a slit in the centre, allowing easier penetration and sample removal. This type of septum is similar to a silicone septum without a slit because it also has excellent resealing capabilities. Pre-slit septum, however, is slightly less tolerant of aggressive solvents.

PTFE/red rubber: PTFE/red rubber septa are a popular and affordable option for standard gas chromatography uses. These septa provide moderate resealing capabilities and high chemical inertness. It's not recommended for multiple injections.

Automatic manufacturing process: the best quality glass tubes, fully automatic manufacturing process and computerised camera control quality check of dimensions and packing in clean environment are the key factors for making quality vials.

Understanding the Risk associated with Vials:

Even if the best quality vials are used, the risk is involved while analysing the samples using these vials. because of several causes related to interaction of the sample with vial surface. Some of these are listed below:

- Evaporation Loss, Increase in peak area counts
- Decrease in area counts (Related to absorption on glass surface)
- Extra peak or Ghost peak observed in chromatogram (Degradation of sample on the surface of the vial)
- Cap and Septa related problems
- RSD variation of area counts

Evaporation Loss: Due to evaporation

of the solvent and its escape from the vial through the cap and septa, the concentration of the sample in vial increases and hence area counts of the sample with time. The method can be developed by using the vial and standard (Caffeine) with known concentration run at different time intervals using HPLC to prove if there is an evaporation loss.

Decrease in area counts: This can happen due to interaction of analyte with the surface of the vial. There are cases reported in the literature and mainly has relation with the structure of the analyte, its pH or hydrophobicity/hydrophilicity of the analyte. There are methods available to reduce the surface activity of the vial.

Cap and Septa related problems:
The septa are polymeric material. There is a possibility that septa could have extractable organic impurities of monomers, solvents etc. Thermal Desorption GC-MS method is generally used for the analysis.

RSD variation of area counts: Any one above can be responsible for it. Many a times it can happen due to some other part of chromatography system as well.

Ghost peak observed in a chromatogram:
One of the potential risks in Chromatography is the presence of unexpected or ghost peaks resulting from the vials. Such peaks may be due to contaminants from the vial, septa, or the unpredictable degradation of the analytes caused by impurities present in the glass. Degradant peaks can get induced by the alkaline impurities from the glass vials. To demonstrate the absence of free alkaline impurities as well as organic impurities from the glass vials, the study by using GC-MS, LC-MS & ICP-OES techniques can be conducted.

The above quality issues can be challenged by experiments using most sensitive analytical tools, and one can establish the quality of the vials. The user is thus assured that he can rely on the SMALL but an important component of his analytical instrument. ■

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