VOL 19 | ISSUE 8 | MARCH 2021 | MUMBAI

www.jasubhaimedia.com

PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

Bio Pharmaceuticals: The Next Big Opportunity for India

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

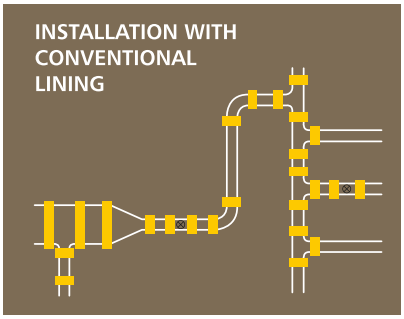
INTRODUCING FIRST TIME IN INDIA

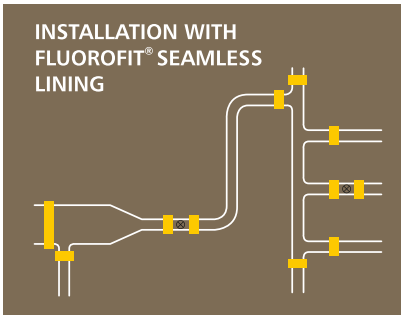
CORROSION RESISTANT SEAMLESS LINING IN COMPLEX SHAPES AND LARGE DIAMETER EQUIPMENTS

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

Easy KFV

Easy Pro

EasyPlus™ Titrator for Your Sample Simple and Affordable

Affordable Swiss technology
Swiss engineering, the highest quality parts and materials, make the compact and accurate titrator a perfect addition to any quality laboratory.

Quick start with iTitrate™ operation
Operation is simple with the App based user interface and intuitive system menu navigation; save training time and make daily tasks simpler and quicker.

Ready for your sample with iTitrate™ intelligence
The built-in intelligence requires only a few parameters to be set before the instrument is ready for titration.

To know more call us Toll Free
1800 22 8884 / 1800 10 28460
or email
sales.sales@mt.com

METTLER TOLEDO

www.mt.com/easyplustitration

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
Harshad Gaikwad

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

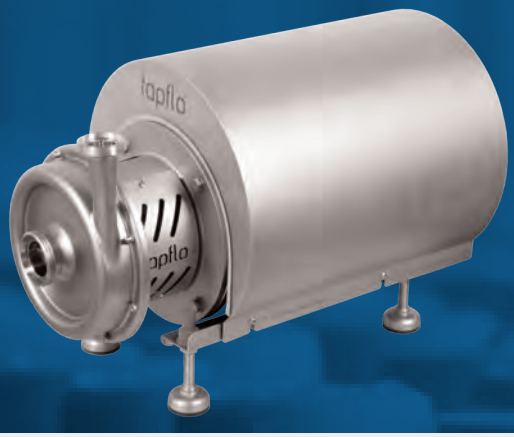
Bry-Air (Asia) Pvt. Ltd.....15
Hitech Applicator.....1
Komal Scientific Co.....19
Mettler-Toledo India Pvt. Ltd.....3
Mettler-Toledo India Pvt. Ltd.....7
Mettler-Toledo India Pvt. Ltd.....13
Roots Multiclean Ltd.....11
Tapflo Fluid Handling India Pvt Ltd.....5
UFLEX Ltd.....17
West Pharmaceutical Packaging India Pvt. Ltd.....9

Hygienic Pumps

Keeping your process clean

tapflo®

High performance centrifugal pumps hygienic execution



- Designed for the applications requiring high efficiency
- The Impeller can be adjusted (trimmed) to work with specific parameters
- Robust construction and easy maintenance thus less downtime

Electrically operated sanitary diaphragm pumps

- Self-priming from dry suction pipe
  More options of installation
- Run dry without damage
  Easy to use, no need of guarding device
- Clean & easy maintenance - No hydraulic fluid required, no danger of leakage

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

CONTENTS

FEATURES

Why Pharmaceutical Manufacturers Should Embrace Machine Learning – Now 20

Sunil Patil
Solution Consulting Director
Aspen Technology

COLUMN - LEGAL

The Evolution of Law & Ethics in Pharma Sector: Role of the Executive & Judiciary in India – I 42

R. S. Raveendhren
Advocate, High Court of Madras & Legal Expert in the Institutional Ethics Committee of SRM Medical College Hospital & Research Centre.

IMPACT FEATURES

Calibration of Weighing Instruments 46

Staying Compliant and Profitable 49

AccelTRA® Component Case Study: 54

AD INDEX 04

NEWS 10

COVER STORY

Bio- Pharmaceuticals: The Next Big Opportunity for India 30

Emerging Biotherapeutics Landscape 31

Dr. Dinesh Dua
Executive Director , Nectar Lifesciences Limited, Chairman BioPharma World . IE 2021

Indian Regulatory Landscape 32

Arun Kumar Ramteke
Ex- Joint Drugs Controller General of India

India's growing Biopharmaceutical companies 33

Dr. Mahesh Bhalgat
COO, Syngene International Ltd, Vice Chair, BioPharma World . IE 2021

Leveraging Stem Cell Technology 34

Dr. Subadra Dravida
Founder & CEO, Transcell Biologics

Connect, Collaborate and Accelerate 35

Dr. Girish Joshi
Business Development at Kemwell BioScience

Winners of ChemTECH BioPharma World.IE 2021 Awards 36

XPR Analytical Balances

Valid Results First Time. Every Time.

METTLER TOLEDO's new XPR analytical balances are the answer to most challenging analytical weighing workflows.

- Intelligent quality assurance functions
- Comprehensive static detection and elimination capability
- Convenient and consistent workflows
- Ensured data integrity

www.mt.com/xpr-analytical

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

FORM IV

Statement about ownership and other particulars about newspaper **PHARMA BIO WORLD** to be published in the first issue every year after the last day of February

1.	Place of Publication	Mumbai
2.	Periodicity of its Publication	MONTHLY
3.	Printer's Name	NA – ONLINE PUBLICATION
	Nationality	
	[1][(a) Whether a citizen of India?	
	(b)If a foreigner, the country of origin]	
	Address	
4.	Publisher's Name	HEMANT K SHETTY
	Nationality	INDIAN
	[1][(a) Whether a citizen of India?	YES
	(b)If a foreigner, the country of origin]	NOT APPLICABLE
	Address	406-D, Karachi Citizens CHS, Juhu-Versova Link Road, Andheri (West), Mumbai – 400 053.
5.	Editor's Name	MITTRAVINDA RANJAN
	Nationality	INDIAN
	[1][(a) Whether a citizen of India?	YES
	(b)If a foreigner, the country of origin]	NOT APPLICABLE
	Address	3rd Floor, Taj Bldg., D N Road, Fort, Mumbai 400 001
6.	Names and Addresses of individuals who own the newspaper and partners or shareholders holding more than one per cent of the total capital	JASUBHAI MEDIA PVT LTD., 26, Maker Chambers Vi, Nariman Point, Mumbai 400 021 Maulik Jasubhai Shah (1100, Shanudeep, 10, Altamount Road, Mumbai 400 026), Maulik Business Services Pvt. Ltd & Jasubhai Business Services P Ltd., (26, Maker Chamber VI, Nariman Point, Mumbai 400 021

I Hemant K Shetty, hereby declare that the particulars given above are true to the best of my knowledge and belief.

Date: 29th January 2021

Signature of Publisher

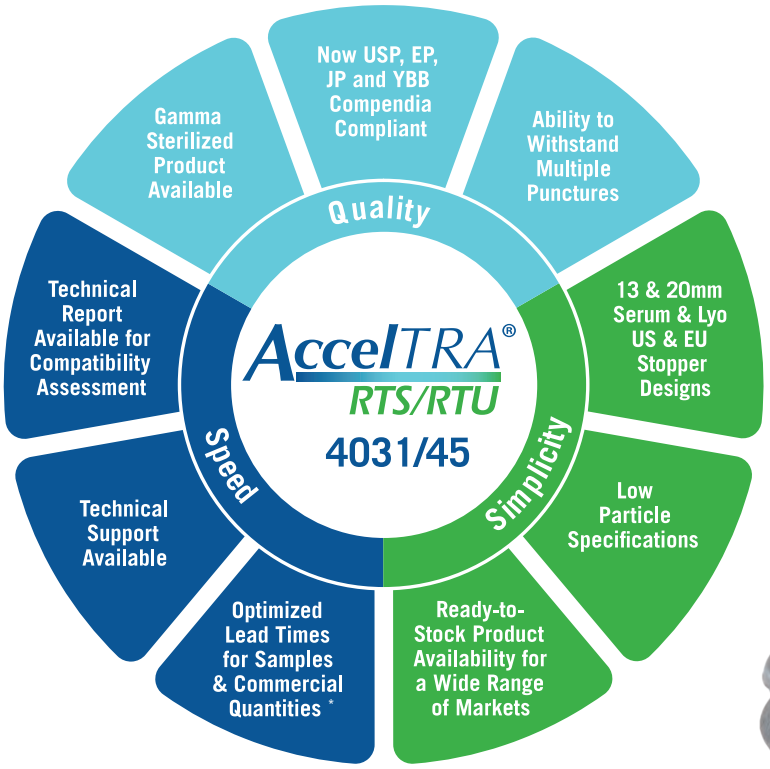
West

By your side
for a healthier world™

Are you a generic drug manufacturer wanting to standardize on a high-performing elastomer formula to reduce your inventory costs and operate more efficiently?

West is pleased to introduce its AccelTRA® program - designed to meet the needs of the generics injectable market.

Delivering packaging quality, speed and simplicity for generics customers,the AccelTRA® Component Program offers market leading delivery times and a single next generation formulation for stoppers and plungers that help customers stay competitive.



Rely on West's more than 95-year industry-leading technological expertise and quality – Choose AccelTRA® components.

For more information, contact us today at **westpharma.com/AccelTRA** or contact Kriti Kotian (Kriti.KotianEXTERNAL@westpharma.com) for more information.

Approval accorded under PLI Scheme for Promotion of Domestic Manufacturing of critical KSMs, Drug Intermediates & APIs

New Delhi, India: The Indian pharmaceutical industry is the 3rd largest in the world by volume. It has high market presence in several advanced economies such as the US and EU. The industry is well known for its production of affordable medicines, particularly in the generics space. However the country is significantly dependent on the import of basic raw materials, viz., Bulk Drugs that are used to produce medicines. In some specific bulk drugs, the import dependence is 80 to 100%.

With an objective to attain self-reliance and reduce import dependence in these critical Bulk Drugs - Key Starting Materials (KSMs)/ Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country, the Department of Pharmaceuticals had launched a Production Linked Incentive (PLI) Scheme for promotion of their domestic manufacturing by setting up Greenfield plants with minimum domestic value addition in four different Target Segments (In Two Fermentation based - at least 90% and in the Two Chemical Synthesis based – at least 70%) with a total outlay of Rs. 6,940 cr. for the period 2020-21 to 2029-30.

In total, 215 applications have been received for the 36 products spread across the 4 Target Segments. The guidelines prescribed that the applications would be processed and decided within a period of 90 days, i.e., up to 28th February, 2021. Nineteen applications with a committed investment of Rs.4623.01 crore have already been approved under Target Segment I, II and III.

174 applications were received for 23 Eligible Products under Target Segment IV - Other Chemical Synthesis Based KSMs/ Drug Intermediates/APIs. Out of 174 applications, 79 applications received for 11 eligible products were considered as per the decided evaluation and selection criteria by the Empowered Committee in its meeting held on 27th February, 2021. The setting up of these plants will lead to total committed investment of Rs.459.47 crore and employment generation of about 3,715 by the companies. The commercial production of these plants is projected to commence from 1st April, 2023 onward. With this approval, a total of 33 applications with committed investment of Rs.5082.65 crore have been approved by the Government under the PLI Scheme for Active Pharmaceutical Ingredients (APIs). Setting of these plants will make the country self-reliant to a large extent in respect of these Bulk drugs. The disbursal of production linked incentive by the Government over the six years period would be up to a maximum of Rs.5,440 crore.

National Pharmaceutical Pricing Authority (NPPA) brings 80 plus medicines under Price Regulation

New Delhi, India: National Pharmaceutical Pricing Authority (NPPA) NPPA fixes the price of 81 medicines including off-patent anti-diabetic drugs allowing due benefits of patent expiry to the patients. NPPA has fixed the Retail Price of 'Insulin Human Injection, 200IU/ml' and '70% Isophane Insulin Human Suspension + 30% Insulin Human Injection

ROOTS
ADDING VALUE

Roots Multiclean Ltd

Air Operated Vacuum Cleaners

ROOTS MULTICLEAN LTD 25 YEARS SINCE 1992

- » **Certified to use in ATEX zones 1, 2, 21, 22.**
- » **Complete stainless steel construction.**
- » **Compressed air operated through venturi unit.**
- » **Earth grounding as a standard.**

ATEX Certified
Industrial Vacuum Cleaners
for Explosion Zones

Our Complete Range of Solutions : Sweepers | Scrubber Driers | Single Disc Scrubbers | Mini Floor Washers | Commercial Vacuum Cleaners | Industrial Vacuum Cleaners| High Pressure Jet Cleaners | City Sweepers | Bins | Mops & Trolleys | Floor Pads | Detergents.

- Roots Multiclean products are Made In India for the World -36 Countries / 6 Continents
- India's Largest Mechanized Cleaning Equipment Manufacturer.
- Assured Service Quality : Pan India Service Network ; 15 Branches.

ROOTS MULTICLEAN LTD.
R.K.G. Industrial Estate, Ganapathy, Coimbatore - 641 006. India.
Tel : +91 422 4330 330, Email : rmclsales@rootsemail.com
Website : www.rootsmulticlean.com
Toll Free: 1800-419-9779

200IU/ml' for M/s Wockhardt Ltd at Rs. 106.65 per ml each (excluding GST) and 'Prasugrel Hydrochloride 10 mg (as film coated) + Aspirin 75 mg (as enteric coated) Capsule' for M/s Torrent Pharmaceuticals Ltd. at Rs. 20.16 per Capsule (excluding GST) with effect from 17.03.2021. Both the medicines were being sold at MRP of Rs. 132.50 per ml and at MRP of Rs. 27.26 per capsule respectively. With this price regulation, NPPA has re-assured availability of medicines at fair prices to public at large.

NPPA had granted price exemption for above mentioned formulations to the respective companies under Para 32 of the 'Drug Prices Control Order (DPCO), 2013 for a period of five years due to new drug delivery system developed through indigenous Research and Development. Price regulation was not applicable during the exemption period. NPPA in its meeting on 10.03.2021 decided to regulate the price of these formulations as per provisions of DPCO, 2013 as the exemption period has been over. This has resulted in reduction of the prices of Insulin Human Injection, 200IU/ml' and '70% Isophane Insulin Human Suspension + 30% Insulin Human Injection 200IU/ml', causing sizeable reduction over the existing prices. Now, these medicines have become more affordable to the public.

NPPA also fixed retail price of 76 new drugs in the meeting dated 10th March 2021 to be launched by existing manufacturers including off-patent Anti-diabetic drugs allowing due benefit of patent expiry to the patients. In addition, NPPA fixed ceiling price of 2 scheduled formulation namely Povidone Iodine 7.5% Scrub an anti-infective formulation and Levo-Thyroxine 37.5mg tablet used for treatment of Thyroid related diseases, causing considerable reduction to their present prices. Revision in existing ceiling prices of scheduled formulations based on the Wholesale Price Index (WPI) was also approved by the Authority. The revised prices will be effective from April, 2021.

Need for integration of various regulatory agencies with a single-window system: DoP Secretary

S. Aparna, Secretary, DoP, MoC&F

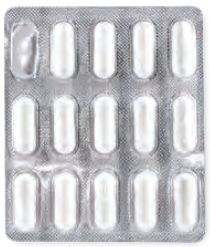
New Delhi, India: Growing at an accelerated pace in pandemic times and projected to become US$ 65 billion industry by 2024, the medical devices sector offers a big opportunity for domestic players, especially engineering MSMEs to make deep inroads into global markets. Ms. S. Aparna, Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers emphasized that innovation, adoption and adaptation of new technologies would be key to tap the huge opportunities in both domestic and export markets.

4 Ways to Assure Product Quality

X-Ray Inspection in Pharma Production

Contamination detection

Component checks



Identifying missing or broken items

Checking fill levels

X-ray inspection in the pharmaceutical industry is set to rise as manufacturers see the benefits the technology brings to improving product quality and compliance, and enabling high levels of traceability and validation. X-ray systems detect physical contaminants, as well as conducting completeness and package integrity checks for blister packs, missing guidance leaflets and medical diagnostic kit inspection.

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/xray-pharma

She noted that the medical devices industry which is growing at a CAGR of close to 15% holds the highest growth potential among all the constituents of the healthcare sector ranging from pharma, hospital services etc. "It is important to remember that this is an interdisciplinary sector with a huge range of products covering reagents, diagnostic kits, high-end imaging equipment and therefore it is a sector that requires a very nuanced approach," said Ms. Aparna.

Other than incentives for domestic production of medical devices, the Secretary also highlighted the critical need for integration of various regulatory agencies with a single-window system and putting in place a transparent, stable, predictable and easy-to- navigate interface between investors, manufactures, exporters and the regulatory eco-system. As India added sizable production capacity for various critical care items like PPE kits, surgical gloves, sanitizers and N95 masks it has emerged as an important destination for manufacturing healthcare engineering products and services.

"The medical device industry in India consists of large MNCs as well as small and medium enterprises (SMEs) growing at an unprecedented scale. It is poised for significant growth in the next five years," said EEPC India Chairman Mahesh Desai. Indian medical device market is the fourth largest in Asia after Japan, China and South Korea. It has, however, potential to overtake some of its peers in size and scale given the government support it has been receiving over the last few years.

The government initiatives to boost the sector include 100% FDI, setting up of Medtech Parks and Production Linked Incentive (PLI) scheme. The recent Medical Devices Amendment Rule 2020 is aimed at making the sector more regularized. "Covid 19 pandemic has pushed us further on the track of strengthening our medical devices industry and India has appropriately risen up to the cause," said Arun Kumar Garodia, Vice Chairman of EEPC India. The Indian healthcare sector has been growing at a brisk pace due to its strengthening coverage, services and increasing expenditure by public as well as private players. It remains very cost-competitive compared to its peers in Asia and Western countries.

Yokogawa Establishes Yokogawa Bio Frontier Inc. to Advance Biomass Materials Business

Tokyo, Japan: Yokogawa Electric Corporation (TOKYO: 6841) announces the launch of Yokogawa Bio Frontier Inc. to develop businesses related to the production and sales of innovative plant-derived biomass materials, as well as associated licensing and consulting activities. Yokogawa Bio Frontier will focus on developing and commercializing high value-added plant-based biomass materials, such as nanocellulose and lignin monomer, which can be used to substitute chemicals and materials currently derived from fossil resources,

PAWA GROUP
Innovation is life

Control Moisture

during manufacture, storage and packaging of

Diagnostic Kits

Dehumidifiers

lower humidity level to below 15% RH

to protect diagnostic kits from degradation

Protect your product... and your reputation

Components of diagnostic kits are highly hygroscopic. They react with moisture and get degraded rapidly, unless they are made and packaged in a dry environment.

Bry-Air is the trusted choice of Pharma industry worldwide to control moisture effectively and economically.

ECODRY™
Desiccant Wheel
At the heart of it all

Contact today

BRY-AIR (ASIA) PVT. LTD.
21C, Sector-18, Gurugram 122015, Haryana, India
Phone: +91-124-4091111 • E-mail: bryairmarketing@pahwa.com
www.bryair.com

RB/BA/2012FCA2

Leaders in Dehumidification . . . Worldwide

thereby enabling a sustainable carbon cycle. The company will apply

Yokogawa's long experience in industrial automation to develop highly efficient extraction and production processes and facilities, and will market biomass materials to a wide range of customers in the chemical, food & beverage, pharmaceutical, and other industries.

The bio-economy is considered to be an important pillar for building a sustainable society, and is one of the focus areas defined in Yokogawa's long-term business framework. The rapidly expanding biomass materials market has been identified as a field in which Yokogawa can leverage its core technologies and global sales and service network. To obtain technologies and expertise in this field, Yokogawa has already taken steps such as investing in and partnering with AlgaEnergy, a Spanish company that is a technology leader in the production and application of microalgae, and Bloom Biorenewables SA, a Swiss startup focusing on the utilization of biomass with its highly efficient lignin extraction technology. Yokogawa Bio Frontier will work with these and other strategic partners to contribute to the development of a circular economy.

Veeda Clinical Research acquires stake in preclinical CRO, Bioneeds

Mumbai, India: Veeda Clinical Research, a leading independent clinical research organisation (CRO) in India, has acquired a significant minority stake in Bioneeds, a preclinical CRO based in Bangalore. Veeda will seek to further increase its stake in Bioneeds in the near term. Veeda's investment in Bioneeds comes shortly after its launch of Ingenuity BioSciences Pvt. Ltd, an innovation-centric bioanalytical laboratory for biosimilars, in joint venture with Somru BioScience, a leading Canadian biotechnology company.

Ajay Tandon MD, Veeda Clinical Research

Speaking on the occasion, Ajay Tandon, Managing Director of Veeda said,"Veeda aspires to be the research partner of choice for innovative (bio)pharmaceutical companies worldwide by supporting their critical product development programs with a comprehensive portfolio of services spanning pre-clinical, clinical and bio analytical research. We are delighted to see our partnership with Bioneeds come to fruition and look forward to collaborating with Dr. Vinaya Babu and his team of highly qualified professionals to serve our global clientele. We believe that the combined platform will leverage the significant adjacencies and synergies in our capabilities to seamlessly deliver integrated programs under a common umbrella."

UFLEX
'A part of your daily life'

FlexiTubes
Endless **Possibilities**

anti Counterfiet solutions for
PHARMA TUBES

HOLOGRAPHIC & METALLIC EFFECTS

360° PRINTING VISUAL APPEAL

HIGH GRAPHICS TRUE TO LIFE PICTURES

MULTI-LAYER STRUCTURED HIGH BARRIER

GLOSS/MATTE SURFACE

PREVENTS DUPLICATION SECURING BRANDS

AN ARRAY OF ANTI COUNTERFEIT FEATURES

- Different holography patterns
- Customised hologrphy solutions
- Security strip on the side seam
- Multiple lens
- Single lens / fresnel lens
- Security strip with costomised holography

TUBE DIA & TYPE OF **CAPS** Specifications

STANDUP		19ø	22ø	25ø	28ø	30ø	35ø	40ø
CONICAL		19ø	22ø	25ø	28ø	30ø	35ø	

FOR FURTER DETAILS, PLEASE CONTACT:
A-1, SECTOR 60, NOIDA-201301, UTTAR PRADESH, INDIA
PH: +91 120 400 1914 EMAIL: ENQUIRY@UFLEXLTD.COM | WWW.UFLEXLTD.COM

Dr. Vinaya Babu, founder and Managing Director of Bioneeds said "Partnering with Veeda is a logical forward integration of the discovery and regulatory capability and hence the combined platform makes one stop solution for to pharma, biopharma, medical device and chemical industries from discovery to market".

Glenmark Pharmaceuticals receives ANDA approval

Mumbai, India: Glenmark Pharmaceuticals Limited (Glenmark) has received final approval by the United States Food & Drug Administration (U.S. FDA) for Diltiazem Hydrochloride Extended-Release Capsules USP, 60 mg, 90 mg, and 120 mg, the generic version of Cardizem®1 SR Extended-Release Capsules, 60 mg, 90 mg, and 120 mg, of Biovail Laboratories Inc.

Glenmark has been granted a competitive generic therapy (CGT) designation for Diltiazem Hydrochloride Extended-Release Capsules USP, 60 mg, 90 mg, and 120 mg, therefore, with this approval, Glenmark is the first approved applicant for such competitive generic therapy and is eligible for 180 days of CGT exclusivity upon commercial marketing. According to IQVIATM sales data for the 12 month period ending January 2021, the Cardizem® SR Extended-Release Capsules, 60 mg, 90 mg, and 120 mg market2 achieved annual sales of approximately $56.7 million*. Glenmark's current portfolio consists of 170 products authorized for distribution in the U.S. marketplace and 42 ANDA's pending approval with the U.S. FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

IISER Bhopal and University of Nebraska Medical Centre Researchers identify drug that can be repurposed to treat COVID-19

Bhopal, India: Indian Institute of Science Education and Research (IISER) Bhopal and University of Nebraska Medical Centre, Nebraska, (UNMC), U.S.A. Researchers have identified 'Rapamycin' as a drug that can be repurposed to treat COVID-19. Currently being used for patients having undergone organ transplantation and certain cancer patients, Rapamycin and its analogues are commonly available in India and abroad.

Research was conducted by Dr. Amjad Husain, Principal Scientist, and Chief Executive Officer, Innovation and Incubation Center for Entrepreneurship (IICE), IISER Bhopal, and Dr. Siddappa N. Byrareddy, Associate Professor, Pharmacology, and Vice-Chair, Research at UNMC, U.S.A

In a peer-reviewed paper published recently in the reputed International Elsevier journal, Chemico Biological Interactions, the researchers showed that the biochemical working of this drug molecule points to its promise in the treatment of COVID-19. The paper elaborates on the rationale of repurposing this drug for treating COVID-19 patients. Since the repurposed drug has gone through the clinical development process for the treatment of other diseases and has already been tested for toxicity, many steps in

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

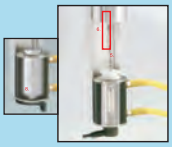

PVS Rheometers


RST-CPS Touch™ Rheometers

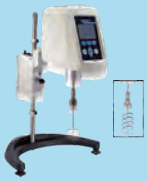

RST-SST Touch™ Rheometer


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

Why Pharmaceutical Manufacturers Should Embrace Machine Learning – Now

Author

Sunil Patil
Solution Consulting Director
Aspen Technology

The manufacture of pharmaceuticals is a highly regulated and complex process. Patented products are licensed for a finite amount of time before they become generic, equating to a constant sense of 'the race is on' to be able to meet demand.

Now, possibly more than ever before, these businesses globally have an intense focus on reducing supply chain disruption, increasing capacity of batch production and reducing batch losses. Reducing lifecycle maintenance costs and CAPEX remain high on the agenda too.

Notwithstanding compliance and safety, manufacturing equipment availability is therefore a top priority. Without exception, pharma manufacturers tell us that they want to be able to predict asset degradation and failure well in advance of an impending breakdown or disruption to be able to make decisions that can minimize cost and disruption.

Figure 1: Pharmaceutical companies have an unprecedented need for operational excellence.

Simplicity – high accuracy, fewer false positives

Today's machine learning solutions allow pharma manufacturers to achieve fast results without needing to write a single line of code. The data science is hidden and allows 'normal' workers to manage them. Current staff, already employed, can be easily taught and trained to manage the platform. The number of "qualified" users is therefore very high, enabling engineers to solve their own engineering problems!

In many industries data is unpredictable. It has anomalies, there is a danger that you can be sent unwillingly down the wrong path.

Pharma, however, has very little, if any 'crazy data.' Why? Because by its very nature, the process of manufacturing drugs is hyper-controlled. The adoption of machine learning can bring rapid results and value to pharma companies within weeks.

Scalability – failure signatures transferable across assets

The pharma industry also has pools of similar equipment, such as the same pumps used in multiple services, or several of the same packaging lines. This is where transfer learning comes in to its own. By sharing the normal and failure behaviours of assets that we find on one machine with the other members of the pool, we can rapidly increase the scale, safety and prevent breakdown of all equipment of the same type and configuration. This ability to rapidly scale an enterprise can create millions of dollars in value.

Speed – faster results as no asset model required

One example that demonstrates such results can be found at a large-scale pharmaceutical plant, where several large chillers and compressors are critical equipment infrastructure. Despite all six sigma efforts, failures were still causing

Figure 2: Now is the time for pharmaceutical manufacturers to accelerate their approach to digital transformation and machine learning solutions.

enormous losses. Aging equipment, increasing energy usage, higher maintenance and inadequate equipment health status reporting contributed to the problem. Aspen Mtell's industrialized machine-learning reversed the situation. Autonomous agents turned corrective and preventive maintenance into prescriptive maintenance. These agents now advise when equipment should be maintained with early warning of impending failures. This gives sufficient notice for orderly, rapid problem correction at the lowest cost. Overall production has improved dramatically.

In another application, AspenTech's Aspen Mtell solution was used to determine the early signs of seal failure through learning of similar patterns from live equipment. It was also focused on continuously learning new events (normal and abnormal) together with additional late stage indicators, providing a confidence increase in seal change decisions. The result was a decrease in the frequency of the need to make mechanical seal replacements, leading to a lessening of supply chain disruption; a reduction in lifecycle maintenance costs of 60%, and a reduction in CAPEX and associated lifecycle costs of 50%.

Across the pharmaceuticals industry today, the latest asset performance management (APM) solutions are enabling pharmaceuticals companies to protect their supply chain, increase asset utilization and avoid unplanned downtime by accurately predicting when equipment anomalies will occur, understanding why they do, and prescribing what to do to avoid a potential failure. Given today's volatile and challenging marketplace, it is exactly the right time for pharmaceutical manufacturers to act to accelerate their approach to digital transformation and machine learning solutions. ■

Dr. Amjad Husain, Chief Executive Office, Innovation and Incubation Center for Entrepreneurship (IICE), IISER Bhopal

Dr. Siddappa N. Byrareddy, Associate Professor, University of Nebraska Medical Center, U.S.A.

preclinical and early clinical development can be avoided and the drug can be directly tested on COVID-19 subjects in phase-II trials.

Elaborating on the importance of this finding, Dr. Amjad Husain, Principal Scientist, and Chief Executive Officer, Innovation and Incubation Center for Entrepreneurship (IICE), IISER Bhopal, said, "The development of a new drug is time-consuming and cannot be relied on as a solution in combating the immediate pandemic. Drug repurposing is an attractive solution, wherein, an existing drug used to treat another related or unrelated ailment may be tested against COVID-19." An example of such a repurposed drug is Remdesivir. It was originally developed to treat Hepatitis C infection. The drug has shown limited success in treating COVID-19 patients. Identification of more such drugs is important given the scale of the pandemic. Rapamycin works differently from Remdesivir. While the latter targets the virus itself, this Rapamycin targets the host proteins and may resist the infection.

"Using repurposed drug such as Rapamycin that targets mTOR, a central molecule affecting multiple signalling pathways, may yield a significant clinical benefit for the treatment of COVID-19" added Dr. Husain. One of the main challenges in developing antiviral drugs for COVID-19 has been the extensive mutations that the virus undergoes, which makes one antiviral drug ineffective against another mutant, and the development of drug-resistant strains. Treatment with drugs such as Rapamycin will not face that problem because it acts on host proteins and not on the virus. Rapamycin inhibits protein synthesis and can also arrest virus replication, irrespective of the type of mutant.

At a biochemical level, apart from inhibiting protein synthesis, Rapamycin has been known to inhibit pro-inflammatory cytokines. It is known that severe COVID-19 infection results in an increase in inflammatory cytokines in a process known as the 'cytokine storm.' The inhibitory action of Rapamycin towards cytokines also makes it a promising treatment for COVID-19.

In addition, Rapamycin is known to reduce obesity through various pathways and this can help in mitigating the severity of COVID-19 effects in obese people. Furthermore, Rapamycin is known to induce autophagy, a cellular recycling process that helps in eliminating the damaged proteins and delaying ageing. Given the connection between age and COVID mortality, i.e. more fatalities with older people, the anti-ageing properties of Rapamycin can have protective effects against COVID-10-induced morbidities.

There is a worldwide scramble to find drugs for the ongoing COVID-19 pandemic. While the commencement of vaccination brings lots of hope and promises for the successful vaccination drive, the need for drugs to treat COVID-19 patients continues to be of paramount importance, not only for now but also for the future. Worldwide, there are already well-known research groups that are pushing for the Rapamycin trials. Recently another study got published in the prestigious journal The Lancet-Healthy Longevity that proposed the potential of Rapamycin analogues (rapalogs) to enhance resilience against SARS-CoV-2 infection and reduce the severity of COVID-19.

Cole-Parmer is now Antylia Scientific

Formerly Cole-Parmer Instrument Company, Antylia Scientific (An-til-e-a) will continue to build on the platform of unique products and expert customer support

Antylia Scientific, a global leader in peristaltic and single use bioprocessing solutions, and a diverse portfolio of life sciences and diagnostic products for the pharma, biopharma, healthcare, and environmental markets, has been launched.

Formerly Cole-Parmer Instrument Company, Antylia Scientific (An-til-e-a) will continue to build on the platform of unique products and expert customer support by expanding the company's organic product research and development capabilities and acquiring complementary products and companies.

"The evolution as a provider of mission critical products to the customers in their quest to discover and manufacture new therapeutics, vaccines, and diagnostic tests has led to creating Antylia Scientific," said Bernd Brust, Chairman & CEO, Antylia Scientific.

Antylia Scientific is creating two operating divisions, bioprocessing and life sciences. Bioprocessing portfolio includes the industry

leading Masterflex® I/P®, L/S®, B/T®, Ismatec® and Reglo range of peristaltic pumps, the MasterflexLive® connected products, pump and transfer tubing, flow meters and single-use components and assemblies. Masterflex addresses the entire fluid path from research to production with a solution set developed for the specific needs of the bioprocessing, pharma and food and beverage customers.

"Masterflex has become the industry standard. We are the customer's first choice in peristaltic pumps that support their need for providing consistent, repeatable, reliable and pure end products in cGMP environments across the globe," added Brian Barnett, SVP, Bioprocessing.

The life sciences portfolio includes well-recognised brands such as the environmental sampling and testing innovator, Environmental Express®; real-time monitoring and cold storage expertise at Traceable®; the standards and external diagnostic control specialists, SPEX® and ZeptoMetrix®; and lab essentials and consumables brand Cole-Parmer®.

"Innovation is in the DNA. Bringing together this portfolio of exceptional businesses, products and talent allows us to continue to deliver trailblazing products that improve the quality, accuracy, efficiency and repeatability of the customers' critical processes," said Jon Salkin, President, Antylia Scientific. "Antylia Scientific will serve as a catalyst for further organic investment and acquisitions in the burgeoning life sciences and environmental markets."

"With great respect for the company's venerable history," added Brust, "we are confident that Antylia Scientific is now well positioned to serve the customers in their quests to accelerate scientific discovery and improve the quality of life."

Aptamer Group and Mologic enter commercial partnership to develop aptamer-based SARS-CoV-2 rapid antigen test

York and Bedfordshire, UK (March 17, 2021) – Aptamer Group, the developer of diagnostic and therapeutic Optimer™ reagents, today announced a commercial partnership with Mologic, a leading developer and manufacturer of lateral flow and rapid diagnostic tests. The partnership will work towards CE marking of Aptamer Group's AptaDx SARS-CoV-2 lateral flow rapid antigen test for professional use, to detect the SARS-CoV-2 spike protein antigen in anterior nasal swabs. Initial test analysis with laboratory samples has demonstrated excellent sensitivity being able to detect as little as 1000 virus particles per mL, with further clinical validation to support the CE marking to be performed at the Integrated COVID Hub North East in Newcastle, UK.

Testing of the Optimer reagents has shown that they recognise the original viral strain and the dominant emerging variants. These variants are the 'Kent' variant, B.1.1.7, the Danish variant, D614G, and the South African variant, B1.351 (also known as 501Y.V2).\

Working with Mologic will help to accelerate the development of Aptamer Group's test to market and provide Aptamer Group with manufacturing capacity through Mologic, in addition to other partners, for the final

commercialized test. Aptamer Group is involved in ongoing discussions with other global manufacturers to access additional capacity for the delivery of several million tests per month.

Aptamer Group's SARS-CoV-2 rapid antigen test will be the first aptamer-based diagnostic test to be commercialised. Aptamers are synthetic nucleic acid-based affinity reagents, produced by solid phase synthesis offering simple, scalable, and highly cost-effective affinity solutions. The production of aptamers compared to standard protein-based affinity reagents offer significant cost advantages, allowing large scale development and delivery of tests globally, including to low- and middle-income countries.

Further updates will be provided following the completion of the clinical evaluation of the test performance.

Dr Arron Tolley, CEO of Aptamer Group, commented: "'Following our initial collaboration with Mologic to develop the AptaDx SARS-CoV-2 rapid antigen test over recent months, I am delighted to have now extended our partnership to progress the CE marking of Aptamer Group's test. We have seen encouraging laboratory performance of the rapid antigen test and have demonstrated the detection of the current main SARS-CoV-2 variants. We are now keen to take the test through clinical evaluation with Newcastle's Integrated COVID Hub to support the CE marking with Mologic. I look forward to updating the market on clinical and commercial progress in due course."

Mark Davis, Chief Executive Officer of Mologic, said: "The agreement with Aptamer Group further demonstrates our commitment to efforts tackling the COVID-19 pandemic, globally. In doing so, Mologic and our partners are able to offer an accelerated route to market, with increased manufacturing capacities, to crucially support expanded access to these rapid test technologies."

Godrej & Boyce aims to strengthen Vaccine Cold Chain till the last mile, for India and the World

Godrej Vaccine Refrigerators being manufactured at its Shirwal plant

Mumbai, India: Godrej & Boyce, the flagship company of the Godrej Group, has been contributing to making India self-reliant since its inception. Taking a step further

Godrej Ultra Low Temperature Freezer

towards building the nation's healthcare infrastructure, Godrej & Boyce through its business unit Godrej Appliances, has been partnering the ongoing Covid vaccination drive in India through its advanced, made in India, medical refrigeration solutions which safeguard the sensitive vaccines at just the right temperature. It has added state of art ultra-low temperature freezers to its portfolio, strengthening the vaccine cold chain further. These advanced medical freezers can preserve life-saving medical supplies including critical vaccines below -80°C and are aimed at boosting both Indian and global medical cold chain.

Godrej Appliances is currently deploying vaccine refrigerators which maintain a precise temperature of 2 to 8°C to store the highly temperature sensitive Covaxin and CoviShield vaccines being administered in India, as part of the national tender it received in October 2020. Medical Freezers which maintain -20°C are also being deployed for diluents and ice packs needed for the last mile delivery in the Covid vaccination drive. The vaccines run the risk of damage if they are subjected to fluctuations beyond the specified temperature band, leading to both health and economic implications.

The ultra-low temperature freezers are a new addition to this portfolio and are particularly suited to mRNA based vaccines which are being deployed in other countries currently. The mRNA-based Covid 19 vaccines are extremely temperature-sensitive as well and must be stored at very cold temperatures. mRNA is constantly at risk of being destroyed by other molecules in the environment. Although manufacturers of the vaccines have made chemical changes to the synthetic mRNA and wrapped it in a protective layer, they need to be stored at temperatures as low as below -80°C, to prevent wastage of vaccines, which has a direct implication on human health. Hence, any wastage or inefficiency in the vaccination process due to logistical issues related to cold chain must be avoided.

The operating principle for the Godrej Ultra Low Temperature freezer is a cascading system having a PHE (Plate heat exchanger) as a heat exchanger between the primary and the secondary system. This lowers

the standing pressure of the secondary system leading to lowering of temperature. Additionally, Godrej Ultra Low Temperature Freezers have inbuilt safety systems with alarms to protect secondary compressor in case of unlikely pressure build up. Features like (a) 2 step sealing & Internal separate doors to help avoid temperature ingress and (b) Oil recovery for secondary system for long running, boost the overall efficiency of the unit during operation. Furthermore, back-up systems like Liquid CO2 or Liquid NO2 ensure safety of stock stored, by maintaining a stable temperature for over 48 hours, in case of a power outage or an unlikely system failure. The current capacity for Ultra Low Temperature Freezers is 12,000 units per annum, which Godrej Appliances is working towards quickly ramping up to 30,000 units per annum, to meet the growing global demand.

Commenting on the recent developments, **Mr. Jamshyd Godrej, Chairman and Managing Director, Godrej & Boyce Manufacturing Company Ltd.** said, "Depth of coverage and sustenance of Covid-19 vaccination drive will be key to ward off further spread of the pandemic. Today, nations across the globe are facing challenges in running effective covid-19 vaccination programs. Inadequate cold chain equipment is one of the key challenges, which can lead to inefficacy of the vaccines and cost human health. With Godrej's decades of expertise in refrigeration technology, the brand offers a range of advanced cold storage solutions for vaccines and life-saving supplies that can help governments across the world in their fight against the covid-19. This pandemic has underscored the need to be future ready when it comes to vaccine cold chain infrastructure. As a group we are constantly transforming to get newer technologies and partner to make the nation self-reliant. Our latest offering of Ultra Low Temperature Freezers will help make India more ready for vaccines of the future as well. This endeavor also brings alive our ethos of Made in India for the World."

Commenting on these developments, Mr. Kamal Nandi, Business Head and Executive Vice President, Godrej Appliances said, "We are glad that we have been able to apply our refrigeration expertise in developing a strong vaccine cold chain in India at a critical time. Our medical refrigerators and medical freezers deliver the precise cooling temperature of 2°C - 8°C and -20°C respectively, needed for the vaccines being administered by India currently. Now, with our newly launched range of advanced ultra-low temperature freezers, which can provide a temperature of below -80°C, India will also have the storage solutions readily available, for other Covid-19 vaccines being deployed across the world. We are partnering with various stakeholders in strengthening the healthcare cold chain and aiming to assist in other potential vaccine roll out challenges - like through mobile clinics for last mile vaccine deployment in remote areas, for the next phase of Covid-19 vaccine inoculation."

ICPA Health Products Ltd launches ICPAMOX – CV 625 for Odontogenic Infections

Abha Damani, Director, IPCA Health Products

Mumbai, India: ICPA Health Products Ltd (ICPA), a leading pharmaceutical company and pioneers in the oral-health segment has launched ICPAMOX – CV 625 meant to treat odontogenic infections. The product is an antibiotic with a broad-spectrum activity against the commonly occurring bacterial pathogens in the oral cavity and other parts of the body. An antibiotic indicated in multiple conditions, ICPAMOX – CV 625 is recommended for use along with dental treatments like root canal, tooth extractions and various oral surgeries to reduce post-operative infection. The product composition is Amoxycillin 500mg + Clavulanic acid 125mg and is approved by the DCGI. "The launch of ICPAMOX – CV 625 is a testament to our focus in the oral health care segment. ICPAMOX – CV 625 marks our foray into antibiotics and we plan to introduce more products in the segment. The product is extremely effective for treating odontogenic infections in patients undergoing various types of dental treatments," says Ms Abha Damani, Director, ICPA.

ICPA are the manufacturers of trusted brands like Thermoseal and Hexidine in the oral health-care segment and are also present in the dermatology, haemorrhoids and ENT segments. It also has products in the FMCG segment with brands in perfumes, sanitizers, hand-washes, disinfectants and soaps, among others. A box of ICPAMOX – CV 625 is available at an MRP of Rs.189/- and contains 10 tablets. ■

Bio- Pharmaceuticals:
The Next Big Opportunity for India

Chemtech organised BioPharma World. IE 2021, focused online tradeshow & 2 day conference for Bio-pharma industry during ChemTECH World . IE 2021 from February 23- 26, 2021. With participation from over 300 participants, the conference had a packed agenda with 21 speakers sharing their depth insights on various Nuances of Bio-Pharmaceuticals ranging from R&D, Supply Chain, Digitization, Operational Excellence , Clinical Research and Policy making for the conducive growth of the India's BioPharma sector.

On the 2nd day of BioPharma conference, Chemtech felicitated Bio Innovation Start-ups during award presentation ceremony held virtually on 26th February 2021. Kris Goplakrishnan, Chairman, Axilor Ventures Co- Founder, Infosys presented the awards as the Guest of Honour.

Speakers deliberated on the emerging trends in biopharmaceuticals industries and the allied sectors of technology & services on the 1st day of conference in thematic sessions on 'The Next Big Opportunity for India.' Vishal Gandhi, Founder & CEO, BIORx Ventures Advisors Pvt Ltd. moderated the panel discussion Nuances of Bio-Pharmaceuticals – Acceleration Impact Initiatives from bench to Bedside in India.

Sponsors and partners for BioPharma World . IE 2021 were Aspentech , DHL Express, Syngene International, SKS Law Associates, BIORx Venture Advisors Pvt. Ltd., BDMA, FABA, BioSpectrum, Life force.

Chemtech also presented BioPharma World. IE 2021 Bio Start up Awards

1. Oncosimis Biotech : Emerging Bio-Pharma Start-up
2. Transcell Oncologics : IP-managed Stem Cell Start-up
3. Reagene Biosciences Pvt. Ltd : Emerging Bio-Pharma Start-up
4. Fibroheal Woundcare Pvt. Ltd : IP-Managed Med-Tech Start-Up
5. Kanpur Flowercycling Pvt. Ltd : Special Recognition for Sustainable Bio-Innovation
6. Robosurg Med-Tech Pvt. Ltd (SSI Group Company) : Emerging Med-Tech Start-up

The awards were sponsored by Chemtech Foundation, Syngene International Ltd. & SKS Law Associates with BIORx Venture Advisors as the Process Partners for the awards.

Emerging Biotherapeutics Landscape

Video Link: https://youtu.be/pSy9paumcCA

Dr. Dinesh Dua

Executive Director , Nectar Lifesciences Limited, Chairman BioPharma World . IE 2021

The global emerging bio therapeutics landscape has been facing many changes globally and the pharmaceutical industry going through a massive shift from chemical based drugs to biologics and biosimilar. Recombinant proteins and antibodies have dominated the biologist clinical indication list. India is likely to achieve USD 12 billion market size for biosimilar vaccines by 2025 with progressive innovation in technology and economies of scale. Robust growth in India's biotech industry is estimated to increase to $100 billion by 2025.

For the first time in history, there are 4 generations of employees in the workplace ranging from Baby Boomers to Generation Z. The EPC industry is being buffeted by a rapidly changing market dynamic, coupled with significant disruptors in the delivery ecosystem. An appropriate balance between operating environment is needed for an organization to thrive in today's dynamic business environment. The big question of how can the XYZ generation and their preferences is co-opted into driving the future of the EPC industry saw coming forward optimized solutions in terms of Alighting, Enabling, Motivating and Outpacing.

Indian Regulatory Landscape

Video Link: https://youtu.be/PCQOj-Arqig

Arun Kumar Ramteke
Ex- Joint Drugs Controller General of India

Talking about Demystifying the Indian Regulatory Landscape for Biopharmaceutical, the objective of new rules issued by the DCGI Controller General India relating to clinical trial and biomedical health research was discussed. Guidelines on Similar Biologics, Regulatory Requirement for Marketing Authorization in India 2016 , Proposed rules for Clinical Study Design, New drug applications as per Trial Rules 2019 was extensively described.

India's growing Biopharmaceutical companies

https://youtu.be/bYfOOFhZVPs

Dr. Mahesh Bhalgat
COO, Syngene International Ltd, Vice Chair, BioPharma World . IE 2021

India being a pioneer in the developed space of Biopharmaceutical Company enables us to handle supply chain, efficiency, and cost pressure. Another pillar that has really moved in the right direction is regulation. A lot of positive trending understanding the need to evolve has been a cornerstone of how we can leverage in the biopharmaceutical company.

Leveraging Stem Cell Technology

Video Link: https://youtu.be/HZWYd8NNC_c

Dr. Subadra Dravida
Founder & CEO, Transcell Biologics

Dr. Dravida spoke about Leveraging Stem Cell Technology for BioPharma in Vitro Testing, alternatives to Animal Testing. She talked about CDC's research on the historical safety of vaccines and its neurological and neuropsychiatric complication of Covid-19 in patients. The global biologics safety testing market is projected to reach USD 4.9 billion by 2022 at a CAGR of 12.2%.

The value proposition and impact of Neurovirulence was keenly highlighted of being Cruelty Free safety tested vaccine and meant for global immunization. Affordable & High value workstation product as in vitro testing solution has been delivered to the global BioPharma industry. The end goal is to protect global healthy population from debilitating Neurovirulence caused by vaccines.

Connect, Collaborate and Accelerate

https://youtu.be/jev4t8nG7Fs

Dr. Girish Joshi

Business Development at Kemwell BioScience

The projected biosimilar market size of China will reach 8.1 billion by 2025. India on the other hand is growing at a rate of 20 to 30%. In an overview of the global bio manufacturing capacity which lists top companies like F.Hoffmann, Samsung Biologics and Johnson & Johnson, India is yet to enter the charts of gaining global recognition.

In terms of Top Indian Biopharma companies, more than 30 companies have over 100 biosimilar approved. Most of them develop and manufacture biosimilar in-house. For efficiency and pipeline acceleration, it is recommended to partner with well-established Indian CDMO like Kemwell. This strategy will significantly reduce Capex & Opex cost that allow focus on core competencies.

BioPharma & CDMO Partnership has key points like Customer's Supply Network, Commitment to Customer Products, predicting the right need for manufacturing, and experienced partners heightening Customer's Supply Network.

Indian CDMOs need assurance of businesses from BIRAC-funded start up to ensure CDMOs grow by adding newer technologies and offer competitive advantage to Indian and global companies. Kemwell is pure-play CDMO, wanting to play critical role in addressing Market Demand by increasing capacities, expertise and offer flexible manufacturing scale.

Winners of ChemTECH BioPharma World.IE 2021 Awards

Winners of ChemTECH BioPharma World.IE 2021 Awards

Chemtech FOUNDATION
Inspiring Intelligence > Igniting Innovation

45 CHEMTECH FOUNDATION 1975-2020
Inspiring Intelligence...
..Igniting Innovation

Bio Pharma World.IE

BIO-STARTUP AWARDS 2020

CERTIFICATE OF ACHIEVEMENT

Presented to

KANPUR FLOWERCYCLING PVT. LTD

Special Recognition
Sustainable Bio-Innovation

Maulik Jasubhai
Chairman & Chief Executive
Jasubhai Group &
Chemtech Foundation

Winners of ChemTECH BioPharma World.IE 2021 Awards

Winners of ChemTECH BioPharma World.IE 2021 Awards

Winners of ChemTECH BioPharma World.IE 2021 Awards

Chemtech FOUNDATION
Inspiring Intelligence › Igniting Innovation

45 CHEMTECH FOUNDATION 1975-2020
Inspiring Intelligence...
..Igniting Innovation

Bio Pharma World.IE

BIO-STARTUP AWARDS 2020

CERTIFICATE OF ACHIEVEMENT

Presented to

ROBOSURG MEDTECH PVT LTD
(SSI GROUP COMPANY)

Emerging Med-Tech Start-up

Maulik Jasubhai
Chairman & Chief Executive
Jasubhai Group &
Chemtech Foundation

Winners of ChemTECH BioPharma World.IE 2021 Awards

The Evolution of Law & Ethics in Pharma Sector: Role of the Executive & Judiciary in India – I

The author has so far delved into the legislative framework that gave a phenomenal boost to the country's pharmaceutical sector. From this issue, he will examine the role of the Executive and the Judiciary in helping to cement its place in the world economy.

R. S. Raveendhren
Advocate, High Court of Madras & Legal Expert in the Institutional Ethics Committee of SRM Medical College Hospital & Research Centre.

The reasons that prompted the Executive to step in

On one hand, the Indian pharma industry was growing to become a diversified and vertically-integrated industry. And yet, there were areas where it needed to re-orient itself to serve the local health needs of the people.

The problems that plagued the industry

- The pattern of production fell short of matching the healthcare needed in the country.
- There was a rapid increase of formulations without any adequate therapeutic rationale
- The smaller players had proper facilities and a great record of quality control and good manufacturing practices. The same could not be said about larger manufacturing units.
- There was a deeply-felt need for institutional and statutory enforcement of quality control for registration of new formulations, for monitoring of adverse reactions, and for the dissemination of information with regard to safety.

I. The Hathi Committee:

The Government of India in February 1974 constituted a committee consisting of 15 members under the chairmanship of Jaisukhlal Hathi. Its scope was to examine licensing, price control, and quality control of imports besides analysing industry practices. It dealt in detail with all the restrictions imposed on the pharmaceutical multinationals on the soil. The committee's report that it submitted in 1975 is considered to be an important milestone in the onward march of the Indian pharma industry.

II. The Drug Consultative Committee 1980

Section 7 of the Drugs and Cosmetics Act of 1940 conferred power on the central government to constitute a drugs consultative committee to advise the union government, state governments, and the advisory board for the uniform application of the Act throughout the country. In exercise of such powers, the Drugs Consultative Committee was formed in 1980 to screen the formulations of drugs in the Indian market and to ban harmful combinations of drugs. The committee recommended banning several drugs in its report that was accepted by the Ministry of Health in 1981. Sadly, none of its recommendations were enforced.

III. Amendment to the 1940 Act

An amendment was made in 1982 to the Drugs and Cosmetics Act of 1940 by which

sections 10A and 26A were added. The newly added sections empowered the union government to prohibit the import of any drugs and/or cosmetics that it thought was against the public interest.

IV. The National Health Policy 1983

Another significant step in the improvement of public health was the formulation of the National Health Policy in 1983. It laid the path for India's commitment to "Health for all by the year 2000 A.D." through comprehensive primary health care services.

- It urgently required the development of inputs to the health care system including life-saving drugs and efficacious vaccines.
- It categorically reiterated that drugs alone were not sufficient for providing health care. A comprehensive approach was the need of the hour.

This was the combination of the Hathi Committee report, the Drugs Consultative Committee Report and the National Drug Policy that signalled impending reforms in the industry. The necessity to strengthen the existing framework was for the first time strongly felt in the history of the sector.

The real meaning of law is what judges decide during the course of giving judgements

In a civilised society, decisions of courts have a long-lasting impact on policies, laws, and legislative and executive actions. In India, the Supreme Court has played a pivotal role in assuming the role of the protector of rights under the Constitution of India.

Article 21 of our Constitution states 'no person shall be deprived of his life or personal liberty except according to procedures established by law.' Article 21 directly corresponds to the Magna Carta of 1215, the Fifth Amendment to the American Constitution, Article 40(4) of the Constitution of Eire 1937, and Article XXXI of the Constitution of Japan, 1946.

The Supreme Court over the years and through its judicially creative interpretation of Article 21 has expanded its scope in order to ensure that the life and liberty of people are never put to peril by the vicissitudes of the drug trials.

The Starting Point of Judicial Intervention

It was the year 1987 when Vincent Panikurlangara approached the Supreme Court with a Public Interest Litigation

seeking a ban on the manufacture, sale, and import of certain drugs recommended by the Drugs Consultative Committee. The case was not decided on merits since it involved several questions relating to policymaking but the Supreme Court found merit in the contentions raised by the petitioner and issued directions to the Union government to examine and address the issues raised by the litigant. The Hon'ble Court had invoked Article 21 of the Constitution of India along with Article 47 which provides for the prohibition of drugs that are injurious to public health.

The Evolution of Principles Relating to Life & Health

1. As early as 1963, the Supreme Court held in the case of Kharak Singh v. State of Uttar Pradesh (AIR 1963 SC1295), that the term 'life' means "something more than mere animal existence". The inhibition against its deprivation extends to all those limbs and faculties by which life is enjoyed.
2. In Parmananda Katara v. Union of India (AIR 1989 SC 2039) the Supreme Court specifically clarified that preservation of life is of paramount importance.
3. In the State of Punjab v. M.S. Chawla AIR (1997) SC 1225 it has been held that the right to life guaranteed under Article 21 includes within its ambit the right to health and medical care.
4. The Supreme Court in Vincent v. Union of India emphasized that a healthy body is the very foundation of all human activities. Article 47, one of the Directive Principle of State Policy in this regard lays stress on the improvement of public health and on the prohibition of all drugs that are injurious to health as one of the primary duties of the state.

It can be unhesitatingly said that the expanding horizon of Article 21 has laid a firm basis for several positive future developments that influenced policymaking in this sector. ■

Calibration of Weighing Instruments Weighing in the Safe Weighing Range

Calibration is one of the key activities that must be performed periodically when instruments are used for quality relevant measurements. Internationally, there are many standards which stipulate this requirement, e.g. ISO9001, GMP regulations or standards concerned with safety. Unfortunately, there is no common understanding on the definition, the implementation and the specific activities that comprise calibration.

The "International Vocabulary of Metrology" (VIM) provides the official definition of calibration:

"Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication."

It is evident that the relation between the known and the measured values can only be established if the associated measurement uncertainties are derived. Basically, measurement uncertainty describes how far away from the true value a measurement result reasonably might be. Besides calibrating, an instrument can also be adjusted. Adjustment is defined in the "International Vocabulary of Metrology" (VIM) as follows:

"Set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured."

In other words, when adjusting an instrument, its indications are modified in a way so that they correspond – as far as possible – to the quantity values of the measurement standards applied. Unfortunately, many users apply the words calibration and adjustment interchangeably, incorrectly or even randomly. Quite often, they talk about calibrating a weighing instrument, however they mean adjusting it. The VIM also emphasizes this by stating:

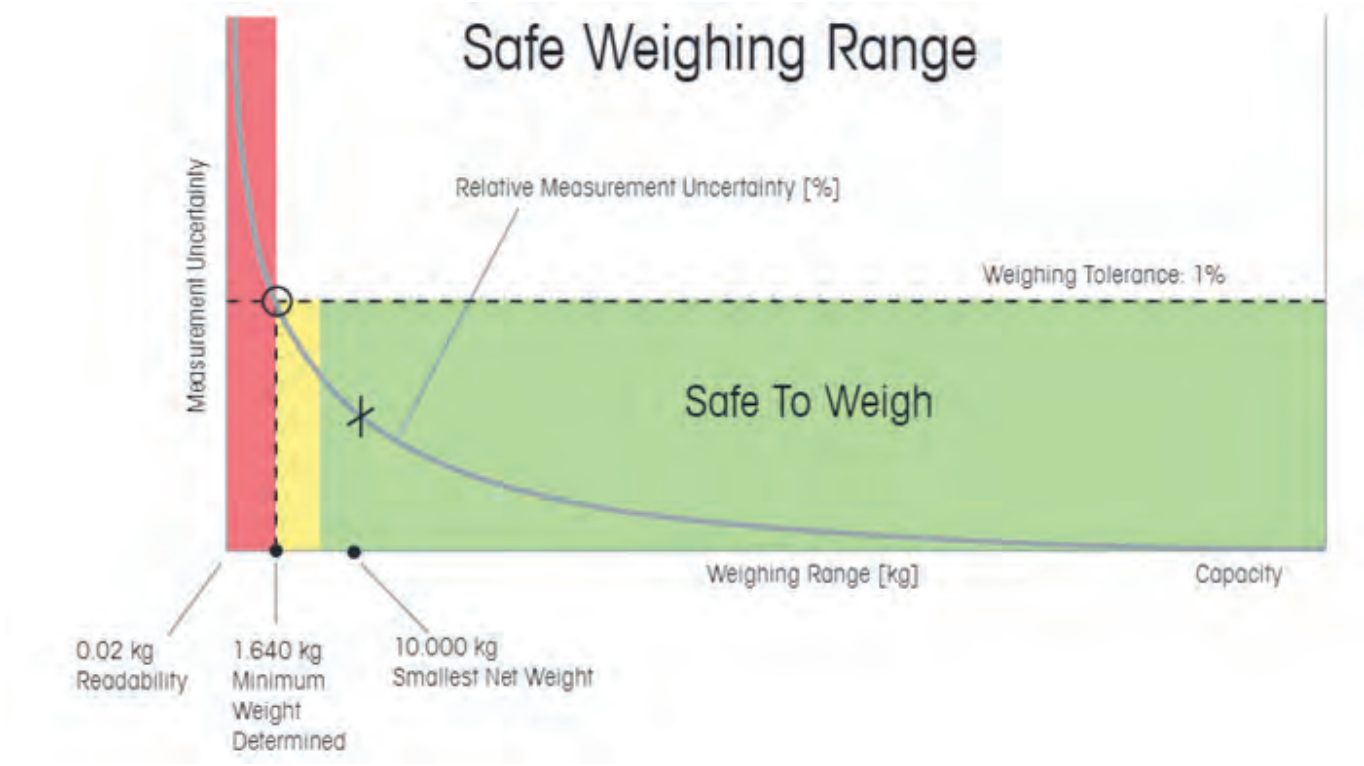
"Adjustment of a measuring system should

not be confused with calibration, which is a prerequisite for adjustment. After an adjustment of a measuring system, the measuring system must usually be recalibrated."

The tough reality is that a balance calibration without measurement uncertainty is meaningless. Measurement uncertainty is an integral part of any calibration; it is the quantified doubt about the result of a measurement. If not reported in the certificate, the calibration is incomplete.

Besides of calibration, measuring instruments can also be verified. Usually, instruments need to fulfill predefined requirements, quite frequently expressed as tolerances. The "International Vocabulary of Metrology" (VIM) defines verification as follows:

While calibration only establishes the relationship between measurement standards and indications ("how well performs the instrument"), verification assesses the instrument on whether or not it meets specific requirements ("does the instrument perform well enough"). Usually, the outcome of verification is a "pass" or a "fail". In respect to weighing instruments, the requirements can come from the manufacturer who specifies tolerances for each balance or scale model, international or national testing recommendations and



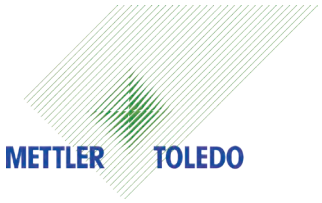
handbooks for weighing instruments used for applications involving commercial transactions as well as industry specific regulations. However, even more importantly, the user needs to specify weighing tolerances that assure that the instrument performs well enough to fulfill his specific process requirements. In view of the application of the weighing instruments, these tolerances are the most important ones as they have a direct impact on the quality of the final product.

METTLER TOLEDO Accuracy Calibration Certificate (ACC) provides calculation of Measurement Uncertainty at site and Good Weighing Practice Verification (GWPv) provides Safe Weighing Range by comparing relative measurement uncertainty with required weighing tolerance for given application. GWPv also provides Routine Test Plan based on selected weighing tolerance and Risk assessment at site. ACC and GWPv ensure that the weighing equipment is fit for its intended purpose throughout the life cycle of the equipment. ■

Contact Details

Email us at: sales.sales@mt.com
Call us toll-free at – 1800 22 8884 &
1800 1028 460
Website: www.mt.com

Staying Compliant and Profitable in the Pharmaceutical Packaging Process with Checkweighing



High demand in the pharmaceutical industry is a constant. Manufacturers both large and small must look to optimize their production lines in order to ensure production quotas are met in a timely, profitable and above all safe manner. Larger producers running single product batches seek outstanding reliability and accuracy in checkweighing, whilst smaller contract packagers – who are likely servicing multiple clients – need the flexibility to effect quick changeovers in order to keep throughput to a maximum.

As manufacturers need to remain certified in order to produce pharmaceutical products, compliance is also critical. Products entering the supply chain that do not meet the required standard threaten patient safety, retailer confidence and in the worst case scenario a company's ability to continue production. All are damaging to profit margins to varying degrees and the risks can be mitigated with a well executed product inspection programme.

Automation is a given in these environments and it is universally recognized that checkweighers play an instrumental role in day to day production. A checkweigher's main function in a pharmaceutical environment is to check the package for missing components such as the leaflet or complete blisters. This is a vital part of the package, as a box of tablets for example will not be considered safe or compliant without it. End of line applications are also commonplace, where systems are used to check the completeness of secondary and tertiary packaging, ensuring that what is sent into the supply chain is exactly what is expected.

Checkweighers automatically inspect 100% of products on the line - which is highly recommended compared with random off-line sampling, as the latter gives a sample size that is now considered to be of little statistical significance.

Checkweighing solutions can help pharmaceutical manufacturers to maximize productivity

Downtime is the enemy of any manufacturer, therefore identifying areas that affect this directly is important when looking at Overall Equipment Effectiveness (OEE). System setup is one such area that can be optimized, and checkweighing features such as digital position control help to verify this is carried out correctly - otherwise the batch cannot be run at all. Running a batch with incorrect inputs can be very costly to correct due to the wastage involved. Also, should these products enter the supply chain it could have significant consequences, both in terms of consumer safety and brand reputation.

Another feature that increases OEE is In-Process-Testing. The test procedure, to be followed step by step, is normally written down on a separate instruction document and the results are manually entered on separate documents. Such testing procedures are very labour intensive, cause operational downtime and rely heavily on the operator consistently testing for reliable results.

In-Process Tests significantly reduce the risk of errors during test procedures and are highly flexible - so are able to adapt to customers' specific requirements. They are easy to operate, generate automatic reports for each test scenario, and – most importantly of all – require no shutdown of production. In-Process Tests are carried out with the help of special screen prompts, which guide the operator through the complete procedure and automatically record the results, which can then be saved and printed. Clear guidance during testing reduces labour time and possible operator errors and manufacturers benefit from more consistent, reliable results and higher operational uptime. In-Process Tests enable several configurable test scenarios.

In addition, there is an easy to operate, intuitive Graphical User Interface (GUI), that helps the user to make changes easily. Mettler-Toledo also offers ProdX, a product inspection data management software application, which can significantly increase OEE as it enables nearly all processes on the line to be monitored from a central point.

Compliance with Good Manufacturing Practice (GMP) guidelines

Pharmaceutical checkweighers in

particular are designed to meet the regulatory requirements of the pharmaceutical industry. First of all, GMP offers a broad guidance, although GMP regulations are not prescriptive instructions but consist of guidelines based on general principles. These include, for example, the validation of processes, record keeping, operator training or prevention of cross-contamination. It is always up to the manufacturer to design the production process and quality programs in accordance with GMP principles, to interpret the guidelines and asseses process risks accurately. Mettler-Toledo, in order to maintain process safety, offers equipment qualification, which is a huge benefit to users as it reduces the qualification and validation time in order to comply with FDA or CGMP (Current Good Manufacturing Practice) requirements. Equipment qualification comprises all aspects of design, installation, operational and performance qualification.

Minimizing changeover downtime with checkweighing technology

Minimizing changeover downtime is critical. Advanced checkweighing systems offer useful features such as digital positioning control. Due to a plausibility check the system does not allow users to enter false parameters. Users are immediatley alerted if settings are entered incorrectly and the system will not start if the parameters are wrong - another factor that influences the usability of the GUI also helps users to save time and therefore minimize changeover times - key factors when looking to increase productivity.

Statistical Process Control (SPC), in addition, is possible via software functions that can be utilised to predict issues on the line. SPC measures and refers to industry standard values of process capability CP and CPK. Standalone or integrated systems allow users access to the statistical data needed to understand, document and control profitability and production efficiency. This way, early detection of problems can be achieved ahead of any major issues that may have a significant impact on uptime. The ability to monitor performance is directly linked to OEE, and the net effect of reduced machine downtime is that higher production levels can be achieved using the same amount of resources. This leads to a faster return on investment with regard to capital purchases such as checkweighers.

Tracebility of Process Changes

Individual boxes, for blister packs of pills for example, are lightweight, therefore the load cell of a checkweigher has to be very precise. The checkweigher helps to check for product completeness, to reject falsely produced products and ensure the safety of the processes comply with FDA requirements. Another demand is the legal compliance with CFR 21 Part 11, which describes the way access to information is managed and changes made to the checkweigher. Everything has to be traceable and logged. This is integrated into the audit trail feature that the pharmaceutical checkweigher offers and a local audit trail operates completely automatically in the background and usually requires no user intervention.

Another useful feature is the domain login server, which enables the manufacturer to use accounts, passwords and rules issued and administered by the company's IT department for the checkweighers. Operators, maintenance personnel, supervisors and quality managers can use their normal network log-in name and password for tasks at the checkweigher just as they would with a network PC. This is not an FDA requirement but is a very valuable addition to the system.

Regulations: looking to the future

A challenge for pharmaceutical manufacturers will be the European Falsified Medicine Directive (EUFMD), that is expected to be implemented by the first half of 2018. Two years may sound like a long time, but depending on how many products the manufacturer has, how they are produced and whether they are produced using internally owned facilities or with external partners, it really isn't a great deal of time at all. Manufacturers generally deal with multiple facilities, that will all have to be enhanced with hardened serialization software to comply with these regulations.

Overall serialization is the key to success here and the EUFDM will require a unique serialization number on every salable unit of drug product intended for dispensation to a patient. So, for instance, a batch of 60 boxes of blister pack pills will have 60 different identifiers, not just one at the lot level. During production every aggregation level will have to be integrated into the serialization process and can be

supported by checkweighing technology. Added value can be generated either by checkweighers with integrated serialization functionality, tamper evident sealing or aggregation solutions for the secondary and tertiary packaging at the end of the line.

If a pharmaceutical manufacturer works together with contract packagers, which is quite common in Europe, it should keep in mind that those contractors may not be ready for serialization when it needs them to be.

In addition to upcoming regulatory requirements, the US Drug Supply Chain Security Act (DSCSA) is in development for the pharmaceutical industry, which is to be applied in three phases for the US market up until 2023. First is to ensure lot traceability, followed by unique serialization and last, but not least, a combination of the two. Like the EUFMD this act will involve an increase in work, and systems such as checkweighers will be instrumental in helping manufacturers to remain both compliant and profitable as the regulatory landscape continues to evolve.

About METTLER TOLEDO

METTLER TOLEDO is a leading global manufacturer of precision instruments. The Company is the world's largest manufacturer and marketer of weighing instruments for use in laboratory, industrial and food retailing applications. The Company also holds top-three market positions for several related analytical instruments and is a leading provider of automated chemistry systems used in drug and chemical compound discovery and development. In addition, the Company is the world's largest manufacturer and marketer of metal detection systems used in production and packaging. ■

Contact Details

Email us at: sales.sales@mt.com
Call us toll-free at – 1800 22 8884 &
1800 1028 460
Website: www.mt.com

AccelTRA® Component Case Study: Reducing lead time and optimising cost

The Situation: Because of competitive pressures, generic manufacturers are under considerable influence to get their products to market quickly. With significantly higher quality expectations from regulators, and the need to ensure the quality and safety of medical products for patients, fast commercialization of a new generic drug product can be a challenge. To meet these increasing quality standards and ensure a quick move to market, emerging generics injectable manufacturers needed flexibility and simplicity when dealing with drug containment and delivery.

The Challenge: Seeking to reduce lead time and optimize costs, a generic drug manufacturer reached out to West Pharmaceutical Services Inc. (West) to learn more about its AccelTRA® component platform. West hoped to reduce the number of its elastomer SKUs and was interested in learning about the AccelTRA platform's applicability to, and suitability with, its current drug product offerings and upcoming product lines. In addition, the company was open to exploring how a commitment to purchase a greater volume of a single formulation could reduce costs by enabling the reduction of the company's on-hand inventory.

The Solution From the beginning, the company was skeptical yet hopeful of the value they could realize by selecting AccelTRA components. Upon learning that the AccelTRA component program provided robust extractables data and optimized lead times for both samples and commercial quantities, the company realized not only a six-week time savings associated with component testing, but also a significant reduction in elastomer SKUs. West Technical Services experts analyzed the company's molecular entities to understand which drug products would work best with AccelTRA components. Detailed analysis found a 95% match with the company's existing product lines. Because of this analysis, as well as the continued technical support provided by West experts and the potential cost

savings, the company went ahead with its use of the AccelTRA component 4031 formula elastomers for the original drug product line's containment needs, and is now considering expanding its use of AccelTRA components for other product lines. Use of the AccelTRA component platform – including components, extractables data and collaboration with West's technical experts – helped the customer realize significant savings, reduced elastomer SKU complexity, and increased speed to market.

If you are facing the same challenge to get pharmaceutical drug product to the market quickly, choose West's AccelTRA Component Program.

Launched in March 2017, the AccelTRA component program's high-quality 4031/45 elastomer formulation enables optimised lead times, extremely low particulate levels and can withstand multiple punctures. These features help to reduce patient risk and ensure the drug and its packaging meet strict standards for quality set by regulatory agencies. Through the AccelTRA component program, West can provide generic drug manufacturers with sample components for injectable drug packaging in as little as one week and commercial quantities in six weeks.

Available globally, the high-quality components are offered either Ready to Sterilise (RTS) or Ready to Use (RTU), have an industry-leading extractables profile and meet United States Pharmacopeia (USP) and European Pharmacopoeia (EP) compliance requirements.

AccelTRA products are currently stocked in India to deliver speed to the local generic drug manufacturers. ■

Contact Details

Email us at: Kriti.KotianEXTERNAL@westpharma.
Website: www.westpharma.com/AccelTRA

R.N.I. No.: MAHENG/2002/08502

Process Industry's Gateway to Indian Market

Chemtech FOUNDATION
Inspiring Intelligence > Igniting Innovation

ChemTECH WORLD EXPO 2022

SPECIALTY ChemICAL WORLD EXPO 2022

Bio Pharma World Expo 2022

30th International Exhibition and Conferences

22-25 February 2022

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

Concurrent Events

EPC 2022 Engineering Procurement Construction | Refining & Petro CHEMICALS 2022 | LAB ANALYTIX World Expo 2022 | Industry AUTOMATION & Control 2022 | PVF Pumps, Valves & Fittings WORLD EXPO 2022 | WaterEX WORLD EXPO 2022 | Paint & Surface Coating World Expo 2022 | BOILERO World Expo 2022

Scope for CHEMTECH + Biopharma World Expo 2022

- Refining & Petrochemical products
- Biotechnologies
- Chemical & Pharma Processing Equipment
- EPC Services
- Automation Technologies
- Environment Solutions
- Water & Wastewater Treatment Technologies
- Pumps & Valves
- Pipes & Fittings
- Packaging Solutions
- Material Handling Systems
- Analytical & Laboratory Technologies
- Consulting Services
- Equipment Fabricators

Scope for Specialty Chemicals World Expo 2022

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

FACTS & FIGURES - CHEMTECH WORLD EXPO 2019

612	18962	18	85	923	2150
EXHIBITORS	VISITORS	COUNTRIES	SPEAKERS	DELEGATES	STUDENTS

Benefits for Exhibitors

- ✓ **Business Interactions:** Meet over 800 exhibitors from across the entire value chain of the chemical process industry
- ✓ **Strategic alliances:** Interact with the entire supply network across the Chemical, Pharma & Biotechnology sectors from a single location
- ✓ **Market analysis:** Evaluate the Indian consumption market and get feedback with over 25,000 visitors walk-ins over 4 days

Jasubhai MEDIA

Organised by:

Jasubhai Media Pvt Ltd

Taj Building, 3rd Floor, 210, Dr. D N Road, Fort, Mumbai – 400 001, INDIA.
Tel: +91-22-4037 3636 | **Fax:** +91-22-4037 3635 | **Email:** sales@jasubhai.com
www.chemtech-online.com

Supported by

45 CHEMTECH FOUNDATION 1975-2020 Inspiring Intelligence... ...Igniting Innovation

Ahmedabad - 09662513062 | Bangalore - 09892644177 | Chennai / Coimbatore - 09176963737
Delhi - 09818148551 | Hyderabad / Pune - 09822209183, 09823410712 | Vadodara - 09820544904