VOL 22 | ISSUE 7 | FEBRUARY 2024 | MUMBAI | TOTAL PAGES 44 | PRICE ₹ 150

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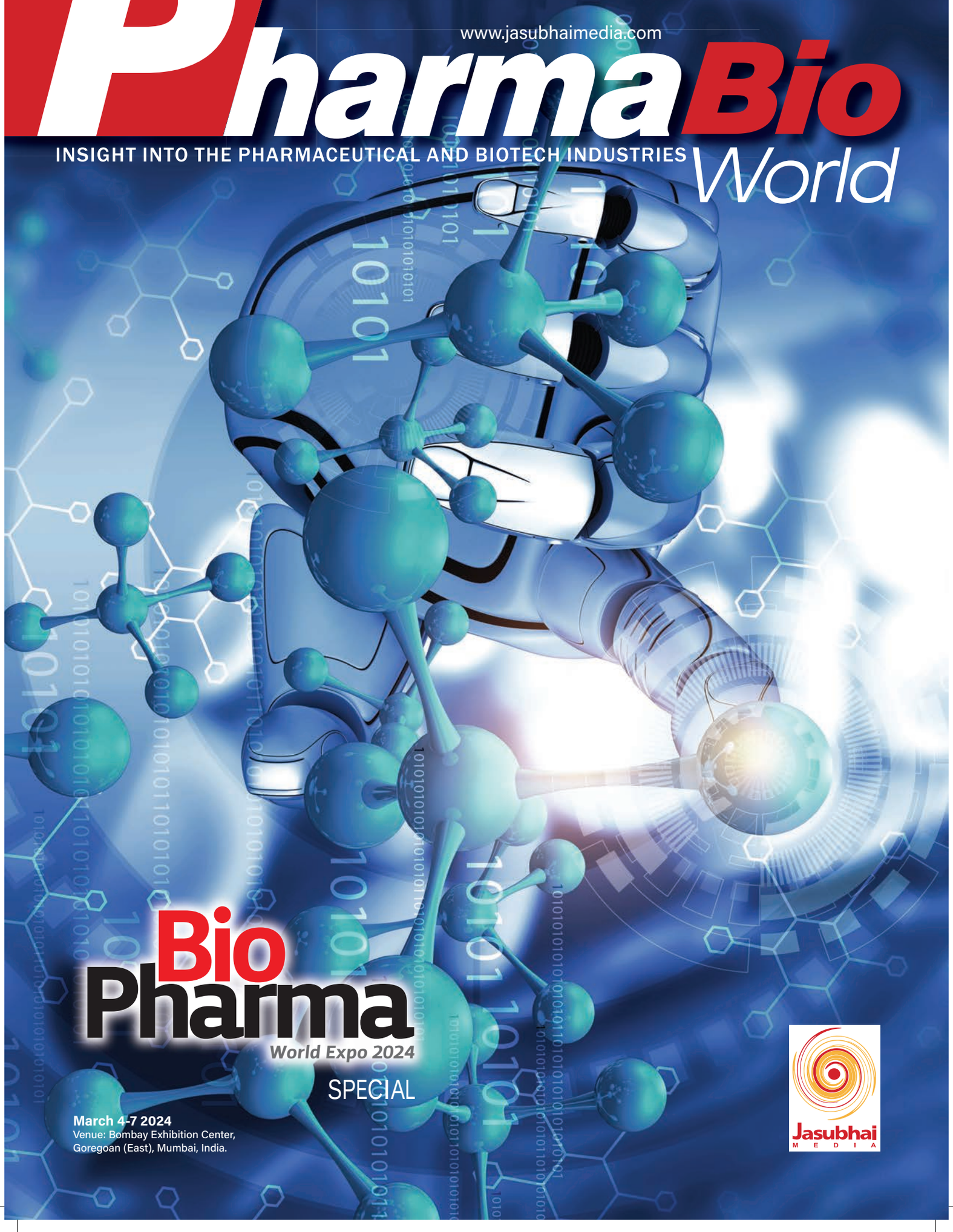
PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES



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

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Single Copy Price: ₹ 150/-
Annual Subscription: ₹ 1620/-, Foreign: USD 180

Registered Office: 26, Maker Chambers VI, 2nd Floor, Nariman Point, Mumbai 400 021, INDIA.
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PLACE OF PUBLICATION
JASUBHAI MEDIA PVT. LTD.
210, Taj Building, 3rd Floor, Dr. D. N. Road, Fort, Mumbai 400 001, Tel: +91-22-4037 3636

Printed and published by Mr Hemant K. Shetty
Address: 406-D, The Karachi Citizens Co-Op Hosg Soc Ltd., Juhu Varsova Link Road, Andheri West, Mumbai - 400053.

Printed at The Great Art Printers
25, Unique House, S A Brelvi Road, Fort, Mumbai 400 001.

Editor: Ms. Mittravinda Ranjan, 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

Published from Jasubhai Media Pvt .Ltd. 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

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AD INDEX

Akums Drugs and Pharmaceuticals Ltd 9
Dover India Pvt Ltd – PSG Chennai 5
Hitech Applicator 2
Horizon Polymer Engineering Pvt Ltd 3
Komal Scientific International Pvt. Ltd. 15
Sealmatic India Ltd 7
UNP Polyvalve 13
VEGA India Level and Pressure Measurement Pvt. Ltd 11

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Flow control Mode	Automated flow control, e.g. for cross-flow control; requires a connected flow sensor
Alarms	Free configurable alarms
PIN Codes	PIN code protection of configuration settings
USB Port	• Backup of system configuration setting • Data logging • Installation of firmware updates

CONTENTS

GUEST COLUMN

Essential Phospholipids: A Promising Candidate for Easing Inflammatory Bowel Disease 31

Arun Kedia
Managing Director, VAV Lipids

Challenges & Opportunities in Global Regulatory compliance for Biologics 37

Dr. Nirdosh Jagota
Founder & Managing Partner
GRQ Biotech Advisors LLC

FEATURES

Drug Development in the 21st century 17

Subrahmanyam Vangala
CEO and Founder
Reagene Biosciences

Uday Saxena, PhD
Co-founder & Chief Ideator
Reagene Biosciences

India has to become the Lab of the World now 20

Dr L.Ramaswamy
Managing Director-Sotax India Pvt Ltd
Secretary General – SPDS, India Ambassador – AAiPS, USA, Head , Pharma Vertical -USIIC, Affiliated to US counsalate Economic affairs, Mumbai
Convenor- AIPAC

Complete Ecosystem of Biopharma 24

Dr. Vishal G. Warke
Director
HiMedia Labs

Drugs of the Future 26

Dharmesh Kharwar
Director
NGB Laboratories Pvt Ltd

Cold WFI - A New Era for Safer, Cleaner, Smaller WFI Generation 28

N P Singh
National Sales Head, Mann+Hummel water and Membrane Solutions

Umberto Castagna
Global Product Manager ,Mann+Hummel water and Membrane Solutions

The Gap & Need for Innovative Point-of-Care Bio-Diagnostic Technology Solutions 34

Dr Praful R Naik
Director & CEP
Prashak Techno Enterprises Pvt. Ltd.

Building Cell Culture Capacities 40

Mr. Sushil Suri
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NEWS 8

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Sun Pharma sign marketing and distribution agreement with Bayer

Mumbai, India: Sun Pharmaceutical Industries Limited and Bayer announced that both companies have signed an agreement to market and distribute a second brand of Finerenone in India. Finerenone, apatented medicine is indicated to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease associated with type 2 diabetes mellitus.

Under the terms of the agreement, Bayer has granted the non-exclusive rights to Sun Pharma to market and distribute a second brand of Finerenone under the brand name Lyvelsa. Finerenone was first launched by Bayer under the brand name Kerendia TM in 2022.

Shweta Rai, Country Division Head (CDH) for Bayer's Pharmaceuticals Business in South Asia said, "With the introduction of a second brand of Finerenone in India, through our partnership with Sun Pharma, we are advancing Bayer's commitment of making healthcare accessible to as many patients as possible. India has a high incidence of diabetes and associated renal and cardiac conditions. The true value of innovations like Finerenone can only be fully realized after they reach all deserving patients."

Kirti Ganorkar, CEO - India Business, Sun Pharma said, "We are happy to collaborate with Bayer to provide patients access to a new treatment which slows down the progression of chronic kidney disease and reduces the risk of kidney failure associated with Type-2 diabetes. This partnership underscores our commitment to make innovative medicines available to patients in India."

Glenmark partners with Pfizer to launch Abrocitinib in India

Mumbai, India: Pfizer and Glenmark Pharmaceuticals Ltd have joined hands to launch abrocitinib, a first of its kind oral advanced systemic treatment for moderate-to-severe atopic dermatitis (AD), in India. Developed by Pfizer, abrocitinib has received marketing authorization from the Central Drugs Standard Control Organization (CDSCO) in India and is approved by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), and other regulatory agencies.

When launched in India, it will be co-marketed under the brand names JABRYUS and CIBINQO by Glenmark and Pfizer respectively. This collaboration combines the expertise of the companies to offer a groundbreaking treatment for moderate-to-severe AD, with improved efficacy and oral convenience to patients. Abrocitinib (CIBINQO) is available in over 35 markets globally, including the U.S., Japan, and China.

Alok Malik, President and Business Head - India Formulations, Glenmark Pharmaceuticals

Atopic dermatitis is a chronic skin disease characterized by inflammation of the skin and skin barrier defects.The persistent itching associated with moderate-to-severe AD disrupts daily life, impacting social interactions,work productivity, and overall well-being. Abrocitinib, a Janus kinase 1 (JAK1) inhibitor, providesrapid itch relief, sustained disease control, and a vastly improved quality of life for patients.

Meenakshi Nevatia, Country President and Managing Director of Pfizer India stated, "We believe in abrocitinib's transformative potential. Its approval is a milestone in bringing high-quality treatment for moderate-to-severe atopic dermatitis in India, enabling patients to manage symptoms more effectively. Our collaboration with Glenmark will help leverage the collective strengths and capabilities of our organizations to make this breakthrough therapy available to patients and physicians across our country."

Alok Malik, President and Business Head - India Formulations, Glenmark Pharmaceuticals Ltd. said, "We are excited to collaborate with Pfizer India for the launch of abrocitinib in the country. The prevalence of atopic dermatitis in India has been reported to be increasing owing to changes in environmental factors with symptoms appearing during the initial years of life in around 80% of patients.

Biocon Biologics Partners with Sandoz Australia

Bengaluru, Karnataka: Biocon Biologics Ltd (BBL), a fully integrated biosimilars company and subsidiary of Biocon Ltd announced a five-year partnership with Sandoz AG ('Sandoz') which provides Sandoz the exclusive rights to promote, sell and distribute biosimilar Trastuzumab (market value of AUD is US$35 million)

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and biosimilar Bevacizumab (market value of AUD is US$ 45 million) in Australia.

Under the agreement, Sandoz will distribute the Biocon Biologics' brands, OGIVRI (bTrastuzumab) and ABEVMY (bBevacizumab), and facilitate the sustained access of these medications that were previously distributed by another pharmaceutical company to patients in Australia. Trastuzumab is a biosimilar of Herceptin and Bevacizumab is a biosimilar of Avastin– both biosimilars are available on the PBS and utilised for the treatment of various cancers. The agreement is effective from January, 2024 and commercialisation commenced in February 2024.

Matt Erick, Chief Commercial Officer of Advanced Markets, Biocon Biologics Ltd, said: "Following the recent establishment of our strategic partnership with Sandoz in Japan, our agreement with Sandoz in Australia marks another important milestone of our global partnership and growth strategy. This relationship is also a crucial step for patients in Australia, ensuring continued access to high-quality, affordable biosimilar medicines used in oncology."

Wanbury Q3 net profit up 40%

Mumbai, India: Wanbury Ltd, one of India's fast growing pharmaceutical company having a presence in API global market and domestic branded Formulation, announced its financial results for the third quarter and nine months ended December 31, 2023. The company's net profit was up 40% at ₹ 10.3 crore in Q3FY24 as against ₹ 7.4 crore in Q2FY24.

Commenting on the performance, Mr Mohan Rayana, Director, Wanbury Ltd. said, "The results declared for Q3 & 9MFY24 marks a significant milestone in the history of the company registering its highest ever quarterly EBITDA of ₹ 22 crore and nine month EBITDA of ₹ 54 crore which is 225% and 350% higher compared to the same periods last year. This is attributed to increase in sales volume, besides yield improvement and process engineering initiatives on existing products has led to improved operating margins. As a long-term strategy, we plan to expand our API product portfolio and focus on different therapeutic areas which will propel sustainable growth. Over the years our endeavour has been to reduce debt and as a result our debt currently stands at Rs. 117 crore."

Zydus Lifesciences receives tentative approval from USFDA for Dexamethasone tablets

Ahmedabad, India: Zydus Lifesciences Ltd., has received tentative approval from the United States Food and Drug Administration (USFDA) to manufacture and market Dexamethasone Tablets USP, 1 mg. Dexamethasone is used to treat conditions such as arthritis, blood/ hormone disorders, allergic reactions, skin diseases, eye problems, breathing problems, bowel disorders, cancer, and immune system disorders. The product will be manufactured at the group's formulation manufacturing facility at Baddi, Himachal Pradesh.Dexamethasone Tablets USP, 1 mg had annual sales of USD 1.8 mn in the United States (IQVIA Dec. Nov. 2023). The group now has 387 approvals and has so far filed over 460 ANDAs since the commencement of the filing process in FY 2003-04.

Curateq Biologics receives recommendation for grant of 'Biosimilar Trastuzumab'

Hyderabad, India: CuraTeQ Biologics Pvt. Ltd., a wholly owned subsidiary of Aurobindo Pharma Ltd, received from Subject Experts Committee (SEC) operating under the aegis of CDSCO (Central Drugs Standard Control Organization) a recommendation for grant of marketing authorization of biosimilar trastuzumab.

Trastuzumab biosimilar, supplied in single dose glass vials containing 150 mg and 420 mg lyophilized powder for concentrate for solution for infusion, is a humanized monoclonal antibody for treating metastatic breast cancer and early breast cancer that is human epidermal growth factor receptor 2 positive. CuraTeQ was asked to submit Phase IV clinical trial protocol to CDSCO within three months of receiving the marketing authorization.

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Cipla Q3 PAT rises 32%

Umang Vohra, MD and Global CEO, Cipla Ltd

Mumbai, India: Cipla Limited announced its unaudited consolidated financial results for quarter ended December 31st, 2023. The company's revenue from operations stood at ₹ 6604 crore, while EBITDA recorded growth at ₹ 1748 crore. The company's PAT stood at ₹ 1056 crore, while R&D investments stands at ₹400 crore or 6.1 % of sales, higher by 10% YoY driven by product filings and developmental efforts. The company's South Africa continued its growth journey, by posting a solid 15% YoY increase in revenue in local currency terms. This performance was supported by positive traction in prescription, OTC and tender.

"I am happy to announce results for yet another quarter which further established our strengths of our core business in India, North America, and South Africa. Our topline growth for the quarter was at impressive 14% YoY with strong EBITDA margins at 26.3%. One India business grew at a healthy 12% YoY backed by strong performance across Branded Prescription, Trade Generics and Consumer Health. In North America, we continue to scale newer peaks by posting highest ever quarterly revenue yet again at us $ 230 Mn, supported by positive traction in key assets and base business. Our South Africa business further extended its momentum from last quarter by growing at 15% in local currency terms driven by strong execution across prescription, OTC and tender. Our focus continues on expansion in chronic therapies, growing big brands, global wellness as well as developing our R&D pipeline in respiratory and peptides. We will continue to focus on driving profitable growth across businesses", stated Umang Vohra, MD and Global CEO, Cipla Ltd.

Lupin Q3 gross profit stood at ₹ 33,538 mn

Nilesh Gupta, Managing Director, Lupin Limited

Mumbai, India: Pharma major Lupin Limited reported its financial performance for the quarter ending December 2023. These unaudited results were taken on record by the Board of Directors at a meeting.

The company's Gross Profit stood at ₹ 33,538 mn compared to ₹ 32,365 mn in Q2 FY2024, with gross margin of 66.0% Personnel cost was 17.5% of sales at ₹ 8,892 mn compared to ₹ 8,607 Mn in Q2 FY2024 Manufacturing and other expenses were 30.7% of sales at ₹ 15,602 mn compared to ₹ 15,519 mn in Q2 FY2024. Investment in R&D for the quarter was ₹ 3,567 mn (7.0% of sales).

Commenting on the results, Mr. Nilesh Gupta, Managing Director, Lupin Ltd. said, "We delivered our highest quarterly sales to date and crossed the ₹ 5,000 crore mark for the first time, driven by strong growth across geographies. The U.S. continues to do well driven by demand for both, in inline products and new launches, and the India business continues to grow ahead of market with strong growth across our key therapies. This positive growth momentum coupled with cost optimization measures and operating leverage has helped us deliver solid performance".

Strides Pharma Q3 net profit rises 20%

Arun Kumar, Founder, Executive Chairperson & MD, Strides Pharma

Bangalore, India: Strides Pharma Science Ltd. announced its consolidated financial results for the quarter (Q3FY24) and nine months (9MFY24) ended December, 2023.

Arun Kumar, Founder, Executive Chairperson & Managing Director, commented on the performance and said, "We are delighted to announce

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the sustained progress in our FY24 performance, highlighted by a robust Q3FY24, where we achieved a 20% Y-o-Y revenue growth and continue to grow our EBITDA over revenues. We are optimistic about delivering the upper range of our EBITDA Outlook for FY24, laying a strong foundation for the quarters ahead. Our revenues have surpassed ₹1,000 crores for two consecutive quarters with an Improved EBITDA performance predominantly driven by our US operations, which recorded its highest-ever revenue of US$ 67 million in the quarter supported by the seasonality of our product portfolio. This performance underscores our strategic approach to product launches, prioritising profitable market share sustainability. While our other regulated markets continue to exhibit strong Y-o-Y growth our access markets business remains lumpy. We remain committed to expanding our pipeline and venturing into new territories organically to ensure our growth trajectory in the quarters to come.

The company reported quarterly revenues of ₹ 10,389 million in Q3FY24, up 20% YoY, while consolidated EBITDA at ₹ 1,950mn for the quarter, up 62% YoY, led by healthy Revenue & Gross margin expansion.

RPG Life Sciences Q3 FY24 Revenue from operations grew by 18%

Mumbai, India: RPG Life Sciences, engaged in the manufacturing and marketing of pharmaceutical products, posted a jump in PBT by 38% Y-o-Y and by 2% Q-o-Q for Q3 FY24, maintaining the upward trajectory in EBITDA margins, which improved from 22.8% to 25.9% Y-o-Y and from 25.5% to 25.9% Q-o-Q. Revenue from operations at ₹ 153.70 crores registered a growth of 18% Y-oy and a flat growth Q-o-Q for Q3 FY24. For 9M FY24 too, the company posted a jump in PBT by 29% Y-o-Y and recorded EBITDA margin expansion from 22.8% to 24.8% Y-o-Y. Revenue from operations at ₹ 455.06 crores registered a growth of 15% Y-o-Y for 9M FY24.

Yugal Sikri, Managing Director, RPG Life Sciences Ltd. said, "In Q3 FY24, the overall performance of the Company continued to be strong. Revenue and PBT grew by 18% and 38% respectively Y-o-Y. EBITDA margin retained its 5-year long upward trajectory growing from 22.8% to 25.9% Y-o-Y. The Company continues to remain debt-free. We are well on course in executing all the tenets of our distinctive and smart Transformation agenda to achieve our strategic goal of consistent healthy profitable growth. Our top priority, Domestic Formulations, the biggest contributor to the Company's business, recorded robust growth both in value and volume-significantly and consistently ahead of the market basis its 5 pillar-growth strategy. The comprehensive smart lif e cycle management program is shaping some of our 'textbook' legacy brands into mega brands and our niche specialty portfolio into mega portfolio. New launches in specialty and chronic therapies are helping us to shape our specialty business. We are now working on replicating our smart and successful Rheumat ology portfolio entry strategy to enter other specialties like Gastro and Derma t o emerge as future growth drivers of Domestic Formulations business. Our MABs portfolio is continuing to post robust performance. Salesforce productivity continues to register healthy upward momentum, assisted by smart deployment of digital".

Supriya Lifescience reports 213% jump in net Profit in Q3FY24

Satish Wagh, Chairman and Managing Director
Supriya Lifescience Ltd

Mumbai, India: In the third quarter of FY24, Supriya Lifescience Ltd. witnessed remarkable growth in its revenue, reporting a 33.2% year-over-year increase, reaching ₹ 140.07 crore compared to ₹.105.14 crore in Q3 FY23. Gross Profit for Q3 FY24 stood at ₹ 85.45 crore, with a growth of 59% compared to ₹. 53.79 crore in Q3 FY23.

EBITDA for Q3 FY24 almost tripled to reach ₹41.49 crore, with an EBITDA Margin of 29.6%, as opposed to an EBITDA of ₹ 14.05 crore in Q3 FY23 with an EBITDA margin of 13.4%. This marks a growth of 195.4% YoY. The Profit After Tax (PAT) for Q3 FY24 more than tripled over the same quarter last year. PAT stood at ₹ 29.79 crore, up 213% YoY compared to ₹ 9.52 crore in Q3 FY23. The PAT Margin has gone up to 21.6% in Q3 FY24, compared to 9.1% in Q3 FY23.

The company's business in Asia picked up this quarter, contributing 42% to the net revenue, the same as from Europe. This led to a more balanced revenue distribution across regions. The Analgesic and Anesthetic segment led the revenue growth and contributed to 49% of sales in Q3 FY24, compared to 21% in the corresponding

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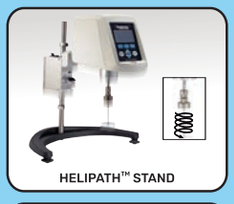
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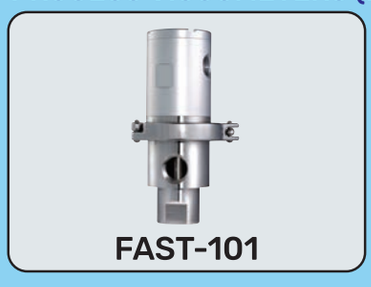
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quarter last year. The company has reported significant growth over the nine months of the current quarter. For the first nine months of FY24, the company's profit has grown 59% to ₹ 82.18 crore, as against ₹ 51.63 crore reported during the same period last year. The company has recorded a total revenue of ₹ 412.19 crore, 29% higher than last year. EBITDA margin expanded to 28.5% during the nine months in FY24 from 23.2% recorded in the corresponding period last year.

Satish Wagh, Chairman and Managing Director, Supriya Lifescience Ltd, commenting on the results, said, "With a spectacular 33.2% year-over-year rise in sales to ₹140.07 crore, as well as significant increases in Gross Profit and EBITDA, these results demonstrate our dedication to long-term success. Notably, our triple-digit increase in Profit After Tax (PAT) to ₹ 29.79 crore, along with a strong PAT Margin of 21.6%, illustrates our emphasis on operational excellence. Furthermore, our strategic expansion into Asian and European markets, together with the growth of the Analgesic and Anaesthetic category, proves our capacity to embrace opportunities and react to changing market dynamics. Looking ahead, we are committed to advancing innovation and excellence, cementing Supriya Lifescience Ltd.'s position as a trusted leader in API production across several therapeutic categories."

Aparna Group receives USFDA clearance for manufacturing unit

Mumbai, India: Aparna Pharmaceuticals Pvt Ltd., a leader in manufacturing Active Pharmaceutical Ingredients (APIs) and Advanced Drug Intermediates, states that its manufacturing facility, Aparna Organics Limited, located in Pydibhimavaram, Srikakulalam, Andhra Pradesh, India has received VAI classification from the United States Food and Drug Administration (USFDA). The USFDA audited the facility during the month of September 2023. This achievement underscores Aparna's unwavering commitment to quality and compliance with global regulatory requirement

Rakesh Reddy, Managing Director, Aparna Pharmaceuticals: "This clearance is a testament to our team's relentless pursuit of excellence. Our facility's compliance journey has been meticulous. We are thrilled to receive the USFDA's stamp of approval. We are excited to contribute to global healthcare by delivering high quality pharmaceutical APIs and intermediates."

With the successful completion of the FDA audit, Aparna Pharmaceuticals has emerged as a leading manufacturer of APIs and Advanced Drug Intermediates and attained global recognition by providing high quality products manufactured as per CGMP guidelines. Driven by innovative R&D and optimum utilization of resources, the company is strongly committed to enhancing customer satisfaction and catering to the discerning needs of renowned pharmaceutical companies.

Wockhardt 9 month revenue stood at ₹ 2,129 Crore

Mumbai, India: Wockhardt Ltd. announced its financial results for the quarter and nine months ended in December, 2023. The company's Revenue for 9 MFY24 of ₹ 2,129 crore as compared to ₹ 1,983 crore in the previous year. Consistent performance in revenue in the current quarter with marginal growth, Revenue for the quarter being ₹ 709 crore compared to ₹ 701 crore in Q3FY23. The company's India Business stood at Rs.165 crore in Q3FY24 compared to ₹ 140 crore in Q3FY23 registering a growth of 18% and contributing to 23% of the Global Revenue in Q3FY24. The company's India Business stood at ₹.459 crore in 9MFY24 contributing to 22% of the Global Revenue in 9MFY24. The company's US Business stood at ₹38 crore in Q3FY24 contributing 5% of the Global Revenue. US Business stood at ₹134 crore in 9MFY24 contributing 6% of the Global Revenue. Research and Development expenditure during the quarter was at ₹.30 crore (4.2% to sales) and including capital expenditure was at 8.5% to sales.

Eris Lifesciences Q3 revenue rises 15%

Mumbai, India: Eris Lifesciences posted results for the third quarter. The company's Revenue stood at Q3 FY 24 grew by 15% YoY to ₹ 4,863 mn and 9M FY 24 grew by 14% YoY to ₹ 14,582 mn, while EBITDA for Q3 FY 24 is INR 1,755 mn, with 36.1% EBITDA margin and 9M FY 24 is ₹ 5,263 mn with 36% EBITDA margin.

the company's PAT for Q3 FY 23 is ₹ 1,014 mn with 21% PAT margin and 9M FY 24 is ₹ 3,173 mn with 22% PAT margin, while Operating Cash flows are approximately 69% of EBITDA in Q3 and 73% of EBITDA in 9M. ■

Drug Development in the 21st century

Bringing a new drug to market is a daunting journey - 10+ years and $1.1 billion for 100 candidates, with only 6 reaching the finish line. Success rates plummet at each stage, from 32% in early tests to 58% in Phase III. This high attrition highlights the need for innovation, and researchers like **Subrahmanyam Vangala** and **Uday Saxena of Reagene Biosciences** propose 3D human systems as a potential game-changer for efficient, cost-effective drug development.

Analysis of reasons for clinical failures suggest - poor PK (10-15%), unmanageable toxicity (~30%) and lack of efficacy (40-50%) top the list. Traditionally, Phase IND-enabling trials are conducted in animal models (rodents, canines and non-human primates), before introducing into Phase I trials, yet >90% clinical trial failures questioned the validity of animal trials for safety and efficacy evaluations resulting in poor clinical outcomes. The "fail early-fail fast" high-throughput screens (HTS) deployed in Early Drug Discovery (EDD) did not improve the productivity in RDD. Failing in Phase III trials is thus a costly failure. Worldwide, exploratory research and development of Alternatives to Animal models are being developed which can be used for Safety and Efficacy (S&E) evaluations of NCEs. In specific, the focus is on developing human model systems such as 3D Micro Physiological Systems (MPS) also known as Non-Animal Models (NAMs). Organ-on-a-chip, Human-on-a-chip models with spheroids, organoids combined with tools such as microfluidics and 3D-bioprinting techniques are being developed to mimic physiological communications of various cell types and organs in humans. These are not typical HTS models used in EDD but Limited Throughput or Higher-Throughput systems. More importantly these models must be customized to enable investigative and mechanistic approaches for human relevance.

Current Approaches in First in Human (FIH) SAFE Dose Selection

The FIH dose is critically important in ensuring that the PK predicted from animal data is accurate and gives confidence to further escalate the doses to the maximum tolerated dose (MTD - derived from animal toxicology studies). Briefly, FDA guidance (download (fda.gov)) requires conversion of Animal Doses to Human Equivalent Doses (HED) for both therapeutic and toxic doses. Most sensitive species toxic MTD dose is used for these extrapolations. Allometric scaling, animal PK-PD data are used to calculate a maximum safe dose for humans and a conservative dose is used for FIH studies. Nevertheless, species differences in physiology, drug distribution & delivery, drug target pharmacology, ADME, properties of the drug candidate limit the accuracy of these extrapolations from animals to humans.

FIH dose corrections may be made using human in vitro data - target binding affinity, functional pharmacology in human derived cells, intrinsic clearance (Clint) in human liver microsomes, human plasma protein binding etc. Additionally, metabolic profile in humans is sometimes different from animals with higher exposure of metabolites in humans than animals and/or new metabolites in humans those not found in animal species. In such cases, the role of metabolites in pharmacology and toxicology of drug candidate may be underestimated and regulatory agencies require additional studies using animal models/in vitro human models.

Biomarkers of Efficacy and Toxicity in Preclinical and Clinical Development

Standard biomarkers of safety (e.g., liver enzymes) and efficacy (e.g., phenotypic expression of the disease) used

in clinical trials did not impact clinical trial outcomes. With rapidly evolving technologies (transgenic animals, LC-MS/MS, LC-NMR, Next Generation Sequencing, etc,) and availability of patient biopsies - there has been a lot of emphasis on using surrogate markers of disease diagnosis, efficacy and safety for optimal clinical trial designs. However, the progress has been very slow as the clinical validation and deployment of these emerging novel biomarkers for regulatory satisfaction is quite rigorous. To date, ery limited biomarkers have been approved for use in regulated clinical trials.

The Bottle Neck of Drug Development: Poor Translation of Animal Models

Although scientists across the globe, continuously debate, many scientists agree that Phase 0 and Phase I trials do not translate effectively to Phase II and Phase III S&E outcomes. Dissecting the reasons, the following disconnects are noticed in the strategy employed for clinical trial designs.

Animal models of disease do not reproduce human disease. The primary reason is that the genetics, biochemistry and molecular biology of disease initiation and progression are different from animals and humans. The phenotype of disease (e.g., symptoms, histopathology) may be similar between animals and humans, but the underlying molecular pathways, targets and target pharmacology are very different between animals and humans.

Healthy animals are used in safety evaluation of NCEs: Standard regulatory toxicology studies typically use healthy young animals which are kept in germ free rooms and given same food and water for the entire study period. These healthy animals do not have manifested disease and the safety outcomes reported from these studies may not be reliable for human patients with disease.

Healthy volunteers often used in Phase I trials who do not have the manifested disease pathology. For example, inflammation is a common underlying feature of many diseases. The expression of drug metabolism enzymes is often downregulated by inflammatory cytokines and thus ADME related factors are not same in patients with disease compared to the healthy volunteers. One of many reasons why Phase I trials may not translate to successful Phase II and III outcomes.

The chronic diseases in humans (average life span 70 years) may take 20-30 years to manifest. In contrast, many animal disease models are rodents with a life span of 2 years. To reproduce a 30-years of human chronic disease in rodents thus poses many challenges. Examples include: Chronic exposure at low doses of benzene, a human leukemogen, causes aplastic anaemia (pre-leukemia) in rodents but does not reproduce overt human leukemia in rodents. Chronic diabetic nephropathy takes 20-30 years to manifest in humans defined as End Stage Renal Disease. Several available rodent models (via chemical or genetic manipulation) do not reproduce ESRD similar to that in humans.

The regulatory agencies do acknowledge the poor outcomes of these flawed strategies and encouraging researchers worldwide to build alternatives to animal models to bridge the gaps in drug discovery and regulatory DD. US legislation in 2022 made a landmark decision by passing Senate Bill (BILLS-117s5002cps.pdf (congress.gov) to accept the data from alternatives such as organoids, spheroids 3D-bioprinted and other in vitro non-animal models for IND and NDA/BLA submissions .

Building in vitro Non-Animal Models using human derived tissues, cells and other recombinant models: Worldwide, there is an explosion of interest in these directions. Current major focus of the industry is to build in vitro Drug Induced Liver Injury (DILI) and Disease models those recapitulate human physiology, ADME and pathophysiology.

In vitro models of Drug Induced-Liver Injury: DILI is often a post-marketing problem. After successful safety outcomes in Phase III trials, and regulatory agency approvals, some drugs sometimes show fatal idiosyncratic DILI leading to drug withdrawals from the market. The mechanisms of these DILI are largely unknown but experts around the world believe both genetic and immune components related to the specific individual cause DILI. Troglitazone (Type 2-anti diabetic) as an example was withdrawn in 2000 due to fatal DILI, escaping preclinical and clinical trial detection. Post-marketing, at least two dozen cases of acute liver failures, deaths or requiring liver transplantation were identified. The second-generation rosiglitazone and pioglitazone were rare in inducing liver failure and patients recovered following treatment withdrawal.

Some in vitro studies using human hepatocytes could differentiate troglitazone and rosiglitazone, suggesting in vitro models can predict hepatotoxicity. Additionally, prototype human on a chip microfluidic models showed that the drug metabolism enzyme expression in human hepatocytes is several-fold higher in 3D microfluidics chips than the static single cell 2D hepatocytes. In the last two decades several companies are building organoids, spheroids of livers to mimic human liver microenvironment for DILI assessments.

Building 3D bio-printed Human Disease-In-A-Dish models (3D DIAD) for integrated ADME, Efficacy and Safety Evaluations: We, at Reagene Biosciences are developing models to mimic human diseases in vitro for a better efficacy evaluation and its modulation by ADME. More importantly, these models can be customized for PK-PD) and PBPK evaluations for effective FIH dose determinations and for safety related liabilities including DILI and Drug Induced Cardiotoxicity (DIC). To date, we developed various DIAD models as listed in Table1.

The future should employ more of in vitro 3D NAM/ MPS/DIAD models to decrease clinical failure rates from 90% down to at least 50%, saving costs, time and unnecessary use of animals and accelerate RDD process for successful drug launches into market. ■

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India has to become the Lab of the World now

India has the potential to become the laboratory of the world due to its vast pool of scientific talent, abundant natural resources, and a vibrant ecosystem of startups and research institutions. To achieve this goal, India needs to focus on investing in research and development, strengthening its intellectual property rights regime, upgrading its infrastructure and equipment, and fostering collaboration between academia, industry, and government. Additionally, India needs to promote a culture of innovation, entrepreneurship, and risk-taking to encourage the development of cutting-edge technologies and solutions that can address global challenges.

Dr. L.Ramaswamy,Managing Director-Sotax India Pvt. Ltd. stated that India has the potential to become the laboratory of the world due to its vast pool of scientific talent.

When country like India serves as a hub for innovation, research, and development across various fields. To position India as such, several key factors need to be considered and addressed:

Investment in Research and Development (R&D)

- Increase public and private investment in R&D across sectors like technology, healthcare, renewable energy, and manufacturing.
- Encourage collaboration between academia, research institutions, and industries to foster innovation.

India has implemented several measures to foster collaboration between academia, industry, and government to promote innovation and development in the country. Some of these measures include:

Setting up Innovation and Research Parks: The Indian government has established innovation and research parks across the country to provide a platform for academia, industry, and government to collaborate and work together on research projects. These parks offer state-of-the-art facilities, funding support, and access to mentorship and networking opportunities.

Creating Innovation Funds and Grants: The government has set up various funds and grants to provide financial support for research and innovation projects. These funds encourage collaboration between academia and industry by providing resources for joint research initiatives and technology development.

Promoting Public-Private Partnerships: The Indian government actively encourages public-private partnerships (PPPs) to drive innovation and development. Through PPPs, academia, industry, and government collaborate on projects, share resources, and leverage each other's expertise to develop innovative solutions and technologies.

Establishing Centres of Excellence: India has established Centres of Excellence (CoEs) in various sectors, such as information technology, biotechnology, aerospace, and renewable energy. These CoEs bring together academia, industry, and government to conduct research, develop advanced technologies, and promote innovation in their respective fields.

Encouraging Industry-Academia Collaboration: The government has introduced policies and initiatives to encourage collaboration between industry and academia. These include industry-academia joint research programs, internships and exchange programs, and industry participation in curriculum development to align education with industry needs.

Streamlining Intellectual Property Rights (IPR) Framework: India has taken steps to strengthen its intellectual property rights regime, making it easier for researchers, innovators, and companies to protect their intellectual property. This has boosted collaboration as it provides a secure environment for sharing knowledge and technology.

By implementing these measures, India aims to create a robust ecosystem that encourages collaboration between academia, industry, and government, fostering innovation, and driving sustainable development in the country.

Education and Skill Development

Education and skill development play a crucial role in helping India become the laboratory of the world. Here's how:

- Enhance the quality of education to produce a skilled and innovative workforce.
- Promote STEM (Science, Technology, Engineering, and Mathematics) education to cultivate a strong foundation for research and development.
- Enhancing Research and Innovation: A strong education system focused on research and innovation is essential for nurturing a talented workforce capable of contributing to scientific breakthroughs and technological advancements. By investing in quality education, India can cultivate a pool of skilled researchers, scientists, and innovators who can drive cutting-edge research and development.
- Fostering Entrepreneurship: Education and skill development programs can instill an entrepreneurial mindset among students and professionals. By promoting entrepreneurship, India can encourage individuals to turn their innovative ideas into successful startups and enterprises, leading to the development of disruptive technologies and solutions.
- Bridging the Industry-Academia Gap: Collaboration between academia and industry is vital for translating research outcomes into practical applications. By aligning educational curricula with industry requirements and fostering industry-academia partnerships, India can bridge the gap between theoretical knowledge and real-world applications. This collaboration can lead to the development of industry-relevant skills and the creation of a workforce that is better equipped to address global challenges.
- Promoting STEM Education: Science, technology, engineering, and mathematics (STEM) education is crucial for developing a strong foundation in scientific and technical disciplines. By emphasizing STEM education at all levels, India can nurture a skilled workforce capable of driving innovation across various sectors, including healthcare, information technology, renewable energy, and more.
- Continuous Skill Development: In addition to formal education, continuous skill development programs are essential to keep the workforce updated with the latest advancements and technologies. By providing opportunities for upskilling and reskilling, India can ensure that its workforce remains competitive and adaptable to the evolving needs of the global scientific community.
- International Collaborations: Encouraging collaborations between Indian educational institutions and renowned international universities and research organizations can facilitate knowledge exchange, research collaborations, and exposure to global best practices. Such collaborations can enrich the educational experience and promote cross-cultural learning, enabling India to leverage global expertise and become a global hub for research and innovation.

By prioritizing education and skill development, India can create a talent pool that is equipped with the

knowledge, skills, and mindset necessary to drive innovation, research, and development. This, in turn, can propel India towards becoming a leading laboratory of the world.

Infrastructure Development

Infrastructure development plays a critical role in positioning India as the laboratory of the world. Here's how:

- Advanced Research Facilities: Building state-of-the-art research facilities and laboratories is essential for attracting top researchers, scientists, and innovators from around the world. By investing in cutting-edge infrastructure, India can provide the necessary resources and equipment to support world-class research and development activities.

- Technological Connectivity: Robust technological infrastructure, including high-speed internet connectivity and advanced communication networks, is necessary for seamless collaboration and knowledge sharing. By ensuring widespread access to technology and connectivity, India can facilitate global collaborations and enable researchers to work together regardless of geographical boundaries.

- Incubation and Innovation Hubs: Establishing incubation centers and innovation hubs across the country can provide a nurturing environment for startups and entrepreneurs. These hubs can offer access to mentorship, funding opportunities, shared workspace, and networking platforms, fostering innovation and encouraging the development of disruptive technologies.

- Industrial Parks and Special Economic Zones: Developing industrial parks and special economic zones dedicated to research and innovation can attract multinational companies, research organizations, and startups. These clusters can provide a conducive ecosystem for collaboration between academia, industry, and government, leading to the creation of cutting-edge technologies and products.

- Science and Technology Parks: Science and technology parks act as a hub for research and development activities, bringing together academic institutions, research organizations, and industry players. By establishing science and technology parks, India can foster collaboration, knowledge exchange, and commercialization of research outcomes, making it an attractive destination for scientific exploration and innovation.

- Sustainable Infrastructure: Emphasizing sustainable infrastructure development can position India as a leader in clean and green technologies. By investing in renewable energy sources, efficient waste management systems, and eco-friendly infrastructure, India can showcase its commitment to sustainability while creating a conducive environment for research and innovation in the field of clean technologies.

- Connectivity and Logistics: Efficient connectivity and logistics networks are crucial for the smooth movement of goods, services, and knowledge. By developing robust transportation systems, logistics networks, and streamlined customs procedures, India can facilitate the exchange of ideas, collaboration, and seamless movement of researchers, scientists, and equipment, strengthening its position as a global laboratory.

By investing in infrastructure development, India can create an ecosystem that supports research, innovation, and collaboration. This, in turn, can attract global talent, foster partnerships, and position India as a hub for cutting-edge research and development, making it the laboratory of the world.

Government Policies and Regulations

Government policies and regulations play a crucial role in shaping the environment for India to become the laboratory of the world. Here's how they can contribute:

- Research and Development Incentives: The government can offer incentives, grants, and tax benefits to encourage research and development activities. By providing financial assistance and support to researchers, scientists, and innovators, the government can stimulate innovation and attract talent to India.

- Intellectual Property Rights (IPR) Protection: Strong and effective intellectual property rights protection is essential to incentivize innovation and protect the rights of inventors and creators. By implementing robust IPR laws and regulations, India can foster a culture of innovation, attract foreign investment, and encourage technology transfer, making it an attractive destination for research and development.

- Ease of Doing Business: Streamlining bureaucratic processes, reducing red tape, and improving the ease of doing business can attract both domestic and foreign investors. By creating a business-friendly environment, the government can encourage the establishment of research and development centres, startups, and innovation hubs, fostering a conducive ecosystem for scientific exploration and experimentation.

- Education and Skill Development Policies: The government can design policies that prioritize quality education and skill development, emphasizing STEM education and vocational training. By aligning educational curricula with industry requirements and promoting skill development programs, the government can ensure a skilled workforce capable of driving research, innovation, and technological advancements.

- Collaboration with Industry: The government can encourage collaboration between academia and industry by facilitating partnerships, joint research projects, and technology transfer. By fostering a strong industry-academia interface, the government can bridge the gap between theoretical knowledge and practical applications, promoting innovation and commercialization of research outcomes.

- Regulatory Framework for Emerging Technologies: The government can establish a clear regulatory framework for emerging technologies such as artificial intelligence, biotechnology, and nanotechnology. By ensuring responsible and ethical use of these technologies, the government can build trust, attract investment, and promote the development of cutting-edge solutions.

- Investment in Infrastructure: The government can allocate funds for the development of research facilities, laboratories, and innovation centres. By investing in infrastructure, the government can provide the necessary resources and support for researchers, scientists, and entrepreneurs to carry out their work effectively.

- International Collaboration and Partnerships: The government can foster international collaborations and partnerships with renowned research institutions and organizations around the world. By facilitating knowledge exchange, joint research projects, and mobility programs, the government can promote cross-cultural learning, attract global talent, and position India as a global hub for research and development.

By implementing favourable policies and regulations, the government can create an environment that encourages innovation, research, and development. This, in turn, can attract talent, foster collaborations, and position India as the laboratory of the world. ■

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Complete Ecosystem of Biopharma

The global biopharma market is booming: $300.5 billion in 2023 and expected to grow 8.6% annually until 2032. India aims to mirror this success, aiming for a 10x growth in its bioeconomy to reach $2.5 trillion by 2047. This ambitious goal is driven by factors like rising chronic diseases and the appeal of biopharmaceuticals' targeted treatments. Understanding the complex biopharma ecosystem, with its network of stakeholders, technologies, and processes, is crucial for keeping pace with this exciting growth.

Dr. Vishal Warke, Director, Cell Biology, PTC & Hygronics, HiMedia Laboratories Pvt. Ltd consolidates the comprehensive ecosystem of the biopharmaceutical industry in this insightful feature.

It is well established that The Biopharma Ecosystem (TBE) is a four-dimensional, dynamic state of existence. The 1st level is of ideas and innovations. The second level is of organizations addressing these ideas and innovations, 3rd level is of regulatory bodies that define the policies guiding the Biopharma industry while the 4th level is of influencers like clusters, incubators, and conglomerates. The Complete Ecosystem of Biopharma includes all the components that are involved in the complete life cycle of the Bioproduct from drug design to its sale to the patient. Research and Development in TBE includes Biomedical Research Institutions and Universities, Biotechnology and Pharmaceutical companies, that are involved in the discovery and development of new drugs, biotherapeutics, pathways, and technologies.

Regulatory dimension of TBE includes various Regulatory agencies of the World, eg. USFDA, EMA, and others that are responsible for evaluating the safety, efficacy, and quality of the biopharmaceutical product before it is commercialized, by overseeing the drug approval processes.

Clinical trials stand at a critical juncture in the TBE. They include Contract Research Organizations (CROs) and Clinical Research Sites like hospitals, research centers, etc. which conduct clinical trials, analyse the data and provide go-no-go for the drug moiety. As of now (2024), it is reported by the National Library of Medicine (NLM) that 20,465 clinical trials are currently recruiting patients in the U.S.A. Globally, a total of 65,474 trials recruiting subjects have been reported by NLM. While clinical trials are mandated by the FDA for all new treatments, including drugs, medical devices, vaccines, and gene therapies, crucial data used in making other care decisions are also produced by these studies. Treatments for cancer have the highest number of clinical trials by therapeutic area – 15.4% of all trials analyzed.

Manufacturing component in TBE includes Bioprocessing facilities producing Biopharmaceuticals using fermentation or cell culture techniques in living organisms and Contract Development and Manufacturing Organizations (CDMOs) that carry on production on a contract basis.

Innovation in manufacturing technology is helping to drive improved economics, flexibility and quality while potentially benefiting patients both directly and indirectly. Biopharmaceutical manufacturers are generally making investments in the continuous manufacturing, new process analytical tools, Single-Use Technology systems (SUT) to increase flexibility along with alternative downstream processing techniques to improve yields while lowering costs etc.

Marketing and Sales encompasses Pharmaceutical Sales representatives engaging with hospitals, pharmacies, and other stakeholders, alongside Marketing Agencies tasked with crafting strategic initiatives to raise public awareness regarding

biopharmaceutical products. Biopharma marketing is certainly evolving, but not at the speed we expected at the height of the pandemic, when sales rep visits plummeted and companies expected digital marketing to displace traditional marketing immediately. For a life-science or biopharma a marketing budget of somewhere around 5-10% of revenue is appropriate based on the size of the company. Investors and financial institutions in TBE include institutional investors, capital firms, and private equity investors who fund the biopharma companies. While financial institutions like DBT, BIRAC, NBM offer grant-in-aid and soft loans, etc. for R&D projects, facility development and commercialization of biopharma products.

A Consortium towards Atmanirbharta in India

Due to current geopolitical challenges, plus the lessons learnt in Covid, supply chain management has become very crucial for every nation. To foster a robust TBE indigenously, we have to look at concepts such as 'Friendshoring' (getting critical raw materials and equipment from supply-friendly nations) and 'Onshoring (indigenous production). TBE components such as 'biotherapeutic producing CHO Clones', Bioreactors and CDSFM (Chemically Defined Serum Free Media), should be made in India. A consortia based approach is the need of the hour where different Indian and Overseas companies can join hands. As a case in point, with this view, three Indian companies with diverse manufacturing strengths in the TBE namely, HiMedia (CDSFM), Biocognate (Custom clones of Monoclonal Antibodies) and OmniBRXTM (Single use Bioreactors and Perfusion Systems) are planning to work together to develop a complete optimized, scalable bioprocess that will provide a 'One Stop' TBE solution to Indian as well as global Biopharma.

This comprehensive framework will ensure the seamless operation of every critical step in the lifecycle of Bioproducts, guaranteeing that biopharma units receive products of the highest quality, safety, efficacy, and affordability, on time. In the manufacturing process of bioproducts HiMedia (a BIRAC-BIPP and NBM grantee) is now ready with suitable CHO growth media (CDSFM), upscaled in a cGMP facility upto 60 Tons per day. Thus indigenous companies need not only to provide solutions to technological challenges but also ensure that they are at the requisite scale.

Indian Biopharma Ecosystem: Significant features, challenges, and plans

The Indian pharmaceutical industry showcases significant features including a vast and diverse market, a robust generic drug sector, substantial investments in research and development, government support, and a strong global presence, all contributing to the production of affordable medicines. However, the industry also faces challenges such as navigating stringent regulatory approval processes, grappling with intellectual property rights issues, addressing infrastructure deficiencies and the scarcity of skilled workers and technicians, and encountering inadequate funding for research and development endeavors. Moreover, in order to complete the TBE loop, it is pertinent to indigenously produce some critical components such as chromatography resins and media components such as amino acids etc. However this would need a strong Govt policy framework to foster an ecosystem that will be parallel to that of China.

A very proactive stance by our government to facilitate multiple hubs for 'Biofoundry' and 'Bio-Manufacturing' in the near future, will surely be a big boost to achieve the target of a 2.5 Trillion USD Bioeconomy in the next 2 decades. Looking ahead, future prospects for the industry are promising, with the development of novel biopharmaceutical products such as gene and cell-based therapies, along with biologics, expansion of global biosimilar markets, improved access to affordable healthcare treatments, collaborations between Indian and international biopharmaceutical firms, advancements in data analytics, and government support through policy and regulatory reforms, all indicating an exciting and commercially prosperous outlook. ■

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Drugs of the Future

Drugs of the future for India are already a current reality in high-income markets. These are ranging from well adopted technologies like recombinant protein & mono clonal antibodies, new adoptions like mRNA, gene therapy, CAR-T, bispecific antibodies, RNAi emerging technologies like PROTAC's, TILs, Oncolytic virus, stem cells, gene editing, CAR-NK, CAR-M, TCR-T and more. **Dharmesh Kharwar, Director, NGB Laboratories** spoke about the drugs of the future for India.

Drugs of the future offer a blue ocean opportunity that had colloquially sailed with the chemical NCEs before we could board. There has been significant capex investments made in India, but only by a handful of companies. The start-ups are gasping for funding and handholding and success stories are too few and far between, at significant investments of varied resources.

Research and Development (R&D) Investment:

Allocate significant resources to research and development, focusing on cutting-edge technologies is the need of the hour. There is possible irrelevance, redundancies , overlaps and even obsolesce creeping into academic projects for the grant of degrees. I suggest that industry and scientific panels review 100% of the topics to assess strategy fit and then only students should be granted funds or else the industry can make a database of required projects to choose from.

Fostering collaborations with academic institutions and research organizations to stay at the forefront of scientific advancements comes next. While some projects will be open source platforms to licence out for free , others will be confidential based on sponsors scope. Industry level expectations need to be installed in the institution for basic infrastructure on small scale including project management, record keeping, intellectual property creation and related scope.

Maping out complete capability of personnel, processes, platforms, technologies, capacities, products, prices and timelines of all relevant stakeholders in the country and host on the common platform. The design of this workflow system will be such that it will cover complete chain of each of the technology platforms in details and also highlight gaps as necessary eg. to develop a new monoclonal antibody (MAB),

- Genration of prospective hybridomas and B cells : List these labs
- Fusion & selection : list these facilities
- Screening : List these service providers or institutions
- Characterization : List domestic and international centres
- Clinical development : based on the international regulatory and industry dialogue
- Data analytics of all of the above : Many startups are in India , need to be part of the workflow

Global Collaboration and Partnerships

Establish strategic collaborations with international pharmaceutical companies, research institutions, and startups to access new technologies, markets, and expertise is imperative. With India being evaluated for potential investments, the ecosystem needs to be holistically conducive and seamless for the entire developmental milestones, costs and timeliens including but not limited to ones below need to be presented to prospective investors .

STRATEGIC PLANNING

- Therapeutic category it belongs to
- Global disease prevalence
- Clinical study design

- Multi-country regulatory pathway
- Phases of trials

General drug development steps

- Pre-clinical development
  - Pharmacodynamics
  - Pharmacokinetics
  - Toxicology
  - Safety human dose identification
- Clinical development
  - Phase 0, Phase I, Phase II, Phase III, Phase IV studies(pivotal studies), and
  - Proof of concept trials
- Market approval
  - Country selection for marketing
  - Regulatory Process
  - Marketing

Risk anticipation and management

90% of clinical trials fail in meeting timelines and proposed budgets. It is for reasons like recruitment failures, inefficient professionals, trial initiation delays, site incapabilities, qualified investigators and facilitated sites are crucial for any successful clinical trial. Conducting clinical trial feasibility in the clinical development strategy helps find many of these answers.

Engage in joint ventures and licensing agreements to bring innovative drugs to the Indian market then global ones. Reinvent a few wheel types but not all , initially at least .

Regulatory Compliance and Intellectual Property Protection

Enlist experts on advisory and retainer basis to navigate the complex regulatory landscape by ensuring compliance with global standards, enhancing the speed of approvals, and minimizing regulatory risks.

Indians have domain strengths in evaluation of intellectual property portfolios to protect innovations and secure a competitive edge in the market. Same groups, even if superannuated, can be asked to help with the creating , filing and protection of IP.

Digital Transformation and Data Analytics

This is needless to mention that embracing digital technologies and analytics for drug discovery, development, and commercialization is already being done in India

Invest in data-driven approaches for leveraging AI and machine learning for more effective and efficient drug development processes, under relevant medical, privacy and IT policies .

Market Access and Commercialization

Develop robust market access strategies, considering factors like pricing, reimbursement, and distribution channels: This is usually the first step even before any practical work is done. Formal project report needs to be complied before a single project investment is committed.

Explore diversified commercialization models, including partnerships, licensing, and direct sales, to optimize market penetration : cost sharing or even consortium models will be needed initially for list of faster to market bio-similar products , followed by the novel products.

Talent Development and Retention

Invest in talent acquisition and development, ensuring a skilled group capable of driving innovation in phrmaceuticals : Catch then early and make creative courses that will grant degrees for live projects at sponsors location.

Implement retention strategies to keep top talent engaged in long-term projects: for post doctorates, core R &D contributors needs to be plotted in the workflow very clearly .

Patient-Centric Approach

Empanel medical doctor fraternity and focus on a patient-centric approach by aligning drug development with unmet medical needs and focusing on improving patient outcomes. ■

Author

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Cold WFI - A New Era for Safer, Cleaner, Smaller WFI Generation

The production of water for injection used in pharmaceutical and biotechnology industries, requires highly purified water to guarantee the safety and quality of the pharmaceutical products. Water for Injection (WFI) can be defined as high-purity water without significant contamination, it is the main excipient used in the production of parenteral drugs and other Life Science applications.

N P Singh and Umberto Castagna from Mann+Hummel Live Sciences stated that harmonized global regulation of Water for Injection (WFI) using membranes has created an opportunity to generate significant operational savings and sustainability advantages for pharmaceutical and biotechnology product manufacturers.

For many years, distillation has been the only choice to produce WFI. This traditional "hot" process involves a phase change of water into steam to remove bacteria and endotoxins before condensing the steam back into liquid. High operating temperatures ensure optimal water purification with low contamination risks. Though this is a highly trusted process, there are some significant downsides, such as high energy intensity, volatile fuel costs, increased carbon footprint, and large system footprints.

For decades, the USP (United States Pharmacopeia) has permitted the use of membrane-based systems, also known as "Cold WFI;" however, many still opted for distillation because the European Pharmacopeia (EP) specified distillation as the only method to produce WFI. This strong-armed many companies which produce pharmaceuticals with international distribution to only use distillation through multiple-effect or vapor compression technologies for WFI production.

In 2017 the EP revised its guidelines to allow for this alternative, effectively granting manufacturers the choice to utilize alternative methods to produce WFI. The guidelines state that water for injection can be produced using alternative technologies, as long as the quality is equivalent to distillation. Systems that can meet this requirement include membrane systems such as reverse osmosis (RO) combined with continuous electrodeionization to meet the required conductivity specification. Then instead of evaporating the water with a distillation unit, an ultrafiltration (UF) membrane-system is used to remove any biofilm growth or endotoxins. M+H can offer superior RO membrane and robust hollow fibers UF with specific molecular weight cut-off that can be heat sanitizable.

This specification change has created a new era for pharmaceutical and biotech companies, giving them a choice of the type of system to produce WFI. And companies making the switch to cold WFI are able to unlock substantial operational improvements, sustainability enhancements, and energy savings.

What is Cold WFI?

"Cold WFI" is a descriptor for a purification process to produce WFI by means other than distillation. Whilst Cold WFI operates at ambient temperatures, on the other hand, distillation, or "Hot WFI" operates at high temperatures to convert the purified water feed into steam, then condense the steam into sterile water.

Cold WFI systems have many of the same pre-treatment steps as Hot WFI processes. Both hot and Cold WFI systems often take solids free, softened, dechlorinated feedwater and treat it with reverse osmosis and electrodeionization. But, the key difference between the two types of WFI systems is that Cold WFI systems utilize a second membrane barrier, such as low-pressure

ultrafiltration (UF), to ensure microbiological quality in place of energy-intensive distillation processes.

A typical production process is as follows

Feed water is typically water from the network or well water. In this step, M+H can provide robust PVDF ultrafiltration membranes PureUltra to remove suspended solids and eventually organic matter.

The second step is the production of purified water through double pass RO, continuous Electrodeionization and eventually degassing membranes to remove CO2. M+H can provide

Turboclean RO modules: Heat-sanitizable elements deliver high purity water while also being able to withstand hot water sanitization, up to 85°C (185°F), Eliminates the need for chemical sanitizers, due to minimal bypass, TurboClean® elements allow for the most effective sanitization and energy saving

Oltremare SAL RO modules: net-wrapped elements already preconditioned that can be directly in operation

Polishing step for endotoxin removal before to be stored and distributed. M+H can provide UltraDyn FS modules: 6000 Da hollow fiber modules that can be heat sanitized up to 98°C.

All Mann+Hummel solutions can be found on our webpage Water for Injection (mann-hummel.com)

The Advantages of "Cold WFI"

Now that biopharmaceutical companies have a choice when it comes to the type of high purity water treatment process to produce safe, compliant WFI, it is important to consider both systems, the potential risks, and the lifecycle costs. Both systems are very capable of producing water for injection; however, it is important to note that the Cold WFI process can lead to measurable advantages through low-cost microbiological control interventions that mitigate any contamination risk and avoid the higher capital and operating expenses of hot WFI.

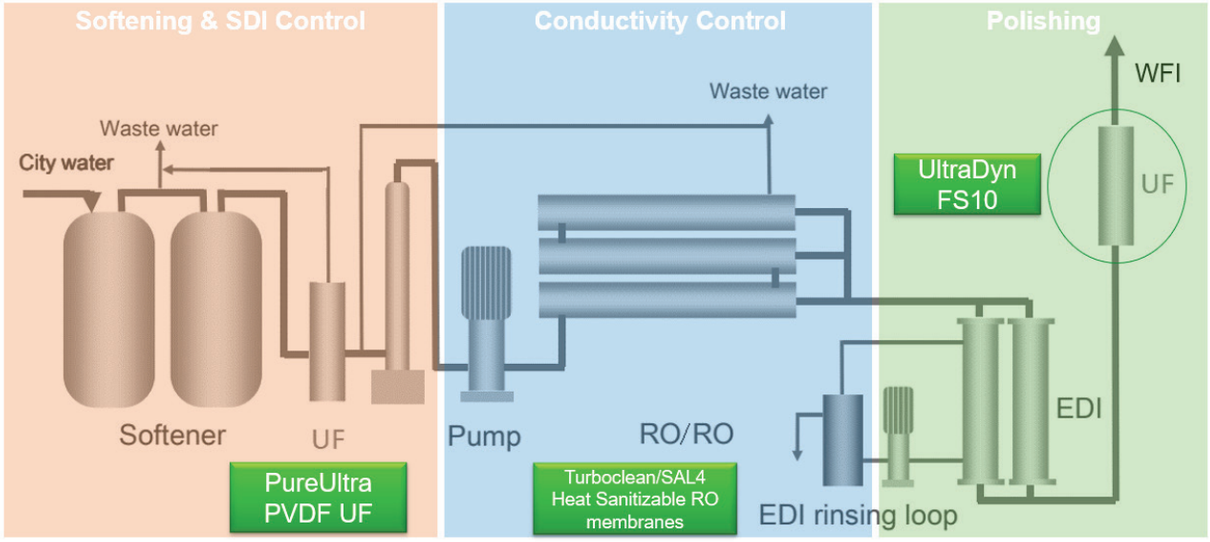
Below are some of the key advantages that Cold WFI systems can provide.

Significantly Lower OPEX Costs

One of the largest advantages Cold WFI systems have over distillation is related to operational costs. Distillation is extremely energy-intensive and requires large amounts of steam, or electricity, to facilitate the liquid to gas phase change. For many systems, a required cooling stage is also required to lower the temperature of the distilled water to the required distribution temperature. Because Cold WFI systems operate at ambient temperature, their energy requirements pale in comparison to distillation. Depending on the type of distillation process, the total OPEX savings of Cold WFI systems can reach 70% or more.

Lower CAPEX for Cold WFI Systems

Hot WFI systems require a higher level of pretreatment before the distillation step, which correlates to additional equipment and cost. Cold WFI converts any source of softened, dechlorinated drinking feed water into WFI quality thanks to a double membrane barrier integrating reverse osmosis, chemical-free



continuous electrodeionization, and ultrafiltration in a configuration that is simpler and lower in CAPEX cost. When comparing the two systems, Cold WFI systems can save manufacturers up to 40% when compared to an equivalent Hot WFI system.

Reduced Carbon Footprint and Increased Sustainability

Many corporations have aggressive sustainability initiatives that include reductions in waste, carbon, and water footprints. These initiatives are forcing engineers to creatively uncover additional opportunities to ensure all aspects of manufacturing facilities are supporting these environmental targets. Because of its outsized contribution to facility carbon emissions, Cold WFI is a key area that can help companies meet these sustainability goals. Up to 80% of the current WFI demand is generated through heat, which is produced mainly through fossil fuels.

By utilizing a Cold WFI method, the need for a constant supply of steam, or heat, to produce compendial water is removed, lowering fossil energy use and driving a more environmentally sustainable operation of clean water utilities.

Compact Footprint

Where space is limited, a membrane system may be preferred as they typically have a smaller footprint. This allows the system to be more easily integrated in a retrofit or facility upgrade when compared to distillation.

It is important to note that no system is without risk. A small risk with a Cold WFI system is the possibility of biofilm or bacterial growth. Biofilm growth may occur as a result of the inherent lower temperatures of a Cold WFI system. However, these risks can be easily managed through frequent hot water sanitization within the RO/CEDI/UF system. This sanitization step is highly effective at preventing and removing any high levels of biofilm within the system without the use of chemicals.

In cooperation with a premium clean water utilities supplier, we have made a comparison of the Total Cost of Ownership for systems to produce 3 m3/h of WFI at ambient temperature and hot temperature.

Membrane based systems (RO+CEDI+UF) are approx. 1.7 times cheaper (as annual costs) than thermal systems when producing ambient temperature WFI and approx. 1.6 times cheaper when producing hot WFI. The annual costs include: total annualized capital cost, electricity, consumable, chemicals, maintenance, water, steam and labour.

What to choose

Both cold and Hot WFI systems will produce water that meets the specified standard for WFI. Therefore clean water utility managers need to consider the operational requirements, existing equipment and systems, available space, corporate sustainability initiatives, and of course CAPEX and OPEX budget. Regardless, the ability to have options on the type of system to produce water for injection empowers pharmaceutical companies to make the best choice for their organization.. ■

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Essential Phospholipids: A Promising Candidate for Easing Inflammatory Bowel Disease

Inflammatory bowel disease (IBD) is characterized by persistent and chronic inflammation of tissues within the gastrointestinal tract. The two predominant forms of inflammatory bowel disease are ulcerative colitis and Crohn's disease. As many as 10% of cases of IBS show the symptoms of both Crohn's disease and ulcerative colitis.

While Crohn's disease affects the small and large intestines, mouth, oesophagus, stomach and anus, ulcerative colitis mainly impacts the colon and rectum, leading to superficial mucosal damage.

Arun Kedia emphasizes about the use of Phospholipids in Inflammatory Bowel Disease (IBD) Management.

Arun Kedia
Managing Director, VAV Lipids

The occurrence of IBD shows geographical variations, with higher rates observed in Europe and North America, in contrast to lower rates in Asia. In India, recent research conducted by the IBD Center of the Asian Institute of Gastroenterology (AIG) has indicated a significant increase in the prevalence of IBD, showing a surge from 0.1% in 2006 to over 5% in 2023. The study also highlights that IBD now constitutes more than 5% of individuals experiencing lower gastrointestinal symptoms, including chronic abdominal pain, alterations in bowel habits, and persistent diarrhoea.

Currently, there is no definitive cure for IBD. The approach typically involves the lifelong use of maintenance drugs. Traditional treatment methods often lack the accuracy to target specific inflammatory sites, resulting in limited effectiveness. Often, these

treatments also carry the risk of severe side effects due to the systemic redistribution of drugs.

To find an effective solution to these challenges, continuous research is underway that increasingly delves into developing targeted drug delivery systems. These cutting-edge strategies aim to transport drugs directly to inflammation sites, improving the drug's effectiveness while reducing side effects.

Use of Phospholipids in IBD Management: An Overview

During research, one approach that has shown immense potential in addressing IBD and ulcerative colitis is phospholipids. These complex lipids, consisting of phosphoric acid, a nitrogen base, alcohol, and fatty acids, have shown remarkable biocompatibility and distinctive amphiphilic properties. An amphiphile is a chemical compound with both hydrophilic (water-attracting) and lipophilic (fat-attracting) properties. These distinct characteristics are why phospholipids are so well-suited for use as essential pharmaceutical excipients.

A specific category of phospholipids that have attracted interest due to their potential to reduce inflammation is marine phospholipids. These phospholipids are filled with beneficial polyunsaturated fatty acids (PUFAs). They naturally occur in a tightly packed form, making them very stable and resistant to damage, and the body can use them efficiently.

What's more, these phospholipids play a significant role in reducing inflammation. They achieve this by influencing specific elements regulating inflammation and producing substances that contribute to calming inflammatory responses.

The distinctive structure of these phospholipids, featuring a water-repelling tail and a water-attracting head, allows them to form tiny structures known as micelles or liposomes when mixed with water. These structures, coupled with the inherent stability and resistance to damage intrinsic in marine phospholipids, offer an exciting possibility for therapeutic applications.

Recent research has also focussed on phosphatidylcholine (PC) in marine phospholipids for managing ulcerative colitis. People with ulcerative colitis exhibit a noticeable deficiency of PC in the colonic mucus. Clinical trials supplementing PC to the colonic mucus have shown reduced inflammation.

Two-pronged Benefits of Phosphatidylcholine

The notion that PC could have a role in ulcerative colitis originated while studying the mucus in the rectal wall during rectoscopy. In patients with ulcerative colitis who were in remission, the levels of PC were significantly lower compared to healthy individuals. This pattern persisted in people with active ulcerative colitis when studying mucus during colonoscopy. These findings prompted researchers to initiate clinical studies to investigate whether supplementing the deficient phosphatidylcholine in the mucus could alleviate inflammation in ulcerative colitis.

PC's protective functions include establishing a hydrophobic barrier on the mucus surface providing a shield for underlying tissues against harmful substances. Tests on samples of ulcerative colitis patients showed that they have less of this protective shield. This hydrophobic barrier acts as a frontline defence mechanism, preventing the attachment and penetration of substances that could serve as invasive agents.

Additionally, the phospholipids in the mucus become integral to the outer layer of cells in the intestines, influencing signal processes in the mucosa. PC has demonstrated the ability to reduce inflammatory responses, such as stopping the assembly of specific cell structures and preventing the activation of certain inflammatory genes.

In a nutshell, PC brings double benefits: it not only possesses anti-inflammatory properties but also reinforces the protective qualities of the mucus layer. This dual functionality makes it a promising panacea for treating inflammatory bowel diseases.

Within the digestive system, PC exists in two forms – within mucus structures and as a surface layer. It engages with mucins (proteins in the mucus) to create a protective barrier that thwarts bacterial invasion.

PC also controls cell signalling associated with inflammation, impacting receptor locations, signal activation, and production of inflammatory substances. The interaction of these actions plays a crucial role in regulating the body's inflammatory response.

Role of Supplements in Managing IBS

Given these findings, the prospect of oral supplements with marine phospholipids emerges as a feasible method to reduce inflammation in ulcerative colitis and IBS. This supplementation is a rich source of both phosphatidylcholine and Omega-3 fatty acids.

The possible advantages extend to integrating phospholipids into cell membranes, restoring phosphatidylcholine content in colonic mucus and providing the essential nutrient choline.

On a broader scale, adopting approaches centred around phospholipids can transform the treatment ecosystem for individuals dealing with inflammatory bowel diseases. As research in this domain continues, the possibilities for tailored treatments harnessing the distinctive properties of phospholipids are poised to grow.

Understanding the properties of essential phospholipids, notably phosphatidylcholine, brings forth several pathways for IBD management. With their unique properties and capacity to regulate inflammation, phospholipids have immense potential for targeted drug delivery and therapeutic supplementation.

Further research in the field will continue to show how their use in conventional treatments may offer hope and respite to people struggling with IBD.■

The Gap & Need for Innovative Point-of-Care Bio-Diagnostic Technology Solutions

The healthcare landscape is currently undergoing transformative shifts, with a primary focus on enhancing patient outcomes. However, it is marked by exigencies that necessitate a profound revaluation of conventional methodologies, particularly in the diagnostics area. While giant strides have been made in advancement of treatment and mitigation of life-threatening diseases, there still is a compelling need for ground-breaking Point-of-Care (POC) bio-diagnostic technologies, steering clear of conventional paradigms and emphasizing the imperative for innovation in advancing diagnostic capabilities.

Dr. Praful R Naik, Director & CEO Prashak Techno Enterprises Pvt. Ltd. spoke about the significance of point-of-care technologies (POCT) in delivering cost-effective solutions that effectively tackle numerous unmet healthcare needs.

Traditional bio-diagnostics while commendable in their contributions, confront formidable challenges including protracted turnaround times, logistical intricacies, and inherent financial burdens. These limitations are particularly pronounced in underserved areas, where access to advanced medical facilities is restricted. The need for rapid, decentralized, and cost-effective diagnostics has fuelled the development of POC bio-diagnostic solutions. The exigent demand for innovative POC bio-diagnostic technologies emerges as an incisive response to these limitations, propelling the scientific community towards novel avenues of exploration.

This evolution has propelled research and development on point-of-care tests which has grown steadily over the last 20 years, and the global point-of-care diagnostic market is expected to surpass US$30 billion in the year 2030. POCT signifies the utilization of technology directly at the location of patient care to elevate healthcare outcomes. Point-of-care technologies (POCT) detection in bio-diagnostics is a critical frontier in healthcare, with a profound impact on patient outcomes, when healthcare providers deliver services to patients in real-time, ensuring immediate and effective care, especially in resource-limited settings and will play pivotal role in healthcare delivery and life-saving procedures.

Key Offerings and aspects of Point of care bio-diagnostics Solutions

▪ Unleashing rapidity and precision at the point-of-care with a resolute focus on temporal dynamics, affording real-time results that are indispensable for informed clinical decision-making. It explores the precision in diagnostic methodologies with advancements aimed at unravelling the intricacies of biomolecular interactions at unprecedented levels.

- Bio-diagnostic POCT carve a niche in the proactive interception of infectious agents, critical for mitigating the dissemination of contagions and enabling effective containment.
- POCT can offer solutions to early detection of multifaceted nature of infectious diseases through a holistic analytical approach capable of deciphering intricate biomarker profiles.

- Innovations in bio-diagnostic POCT is marked by an emphasis on genomic interrogation, laying the foundation for personalized medicine and bespoke therapeutic interventions.
- Continuous and dynamic monitoring of biochemical parameters becomes the focal point, presenting a departure from static diagnostic snapshots towards a fluid understanding of physiological states.
- Bio-diagnostic POCT necessitates harmonious amalgamation of diverse scientific disciplines—engineering, biochemistry, and clinical expertise—to catalyse the inception of ground-breaking technologies. The interconnectedness of disparate scientific realms—physics, chemistry, and engineering will converge in the journey towards an evolved and refined diagnostic future.
- Veracity and reliability of the diagnostic outcomes drives continual evolution of technological innovations in bio-diagnostic POCT.

Technological Innovations In point-of-care bio-diagnostics

- Miniaturization of diagnostic processes through microfluidic systems and Lab-on-chip technologies (LOCT) resulting in integrating sample preparation, analysis, and detection on a single chip and enabling portability for on-the-spot testing.
- Polymerase Chain Reaction (PCR) and other nucleic acid amplification techniques have brought molecular diagnostics to the POCT realm, enabling rapid and accurate detection of genetic material for infectious diseases and genetic disorders. The advent of Next-generation-sequencing technologies (NGST) has further expanded bio-diagnostic POCT by allowing comprehensive genomic analysis at real-time speeds.
- Internet of Things (IoT) and wearable devices allowing seamless data transfer between diagnostic devices and healthcare system play a crucial role in continuous monitoring, providing real-time health data for improved diagnostics and personalized treatment plans.
- AI algorithms have been integrated into bio-diagnostic POCT for data analysis, interpretation, and decision-making. Machine learning enhances the accuracy of diagnostic results, particularly in complex datasets, and contributes to the evolution of intelligent diagnostic systems.
- Simple to use yet effective, bio-diagnostic POCT offer cost-effective and user-friendly solutions, particularly advantageous in resource-limited settings. For example, microfluidic paper devices enable a range of tests, from blood typing to pathogen detection. Advent of 3D printing has also facilitated the customization and rapid prototyping of bio-diagnostic devices. This technology will accelerate the development and deployment of bio-diagnostic POCT, enabling development of tailored solutions to specific healthcare challenges.
- Other noteworthy examples of POCT include the use of urine dipsticks, rapid strep tests, and blood glucose monitors. It reflects the pivotal role these technologies play in providing accessible, timely, and economically viable healthcare solutions, aligning with the broader objective of meeting diverse healthcare challenges on a worldwide scale.

Significance stems from the increasing demand for immediate results, essential for informed decision-making by healthcare professionals. Beyond addressing emergency situations, bio-diagnostic POCT can contribute significantly to preventive healthcare, enabling swift screening and early disease detection. POCT market's growth is evident in its enabled reach to remote areas, reducing healthcare disparities, and aligning with industry goals of cost-effectiveness and resource optimization. Their integration with digital health enhances connectivity, making them pivotal in shaping the future healthcare landscape.

One such innovative startup - FastSense Innovations, is at the forefront of bio-diagnostic POCT innovation, with a focus of transforming healthcare through cutting-edge technologies. FastSense vision is driven by its steadfast commitment to affordable and accessible healthcare diagnostic support at a consumer's doorstep. The ideation and development expertise at Fast Sense has been aptly recognised and supported with prestigious government grants which has propelled FastSense in its pursuit of innovation. FastSense has been able to blend interdisciplinary experts comprising seasoned

scientists, renowned doctors, and industry experts which has resulted in a holistic approach to addressing critical gaps in diagnostics, from conceptualization to the development of tangible, impactful solutions. FastSense innovations and advancements deploy molecular diagnostics, biosensor technologies, and artificial intelligence resulting in technology solutions with highest standards of diagnostic efficacy. Its flagship development comprises the Sepsis Screening solution - 'Sepsis-S', which stands as a testament to its commitment to early detection by enabling doctors with better decision making and improved patient outcomes. FastSense is also working on Cancer and liver bio-diagnostic POCT, specifically aiming to enable early detection of Hepatocellular Carcinoma (HCC) and liver ailments which has the potential to address a significant challenge in underserved populations. FastSense development pipeline includes accessible diagnostic solutions for the early identification of pancreatic cancer as well as bio-diagnostic solutions for Women-Centric Health issues.

The Epilogue

In conclusion, the imperative for novel bio-diagnostic POCT transcends the routine and beckons the scientific community towards uncharted territories. The quest for innovation in this realm is not merely an aspiration; it is a categorical mandate dictated by the exigencies of contemporary healthcare. Bio-diagnostic POCT have the potential to transform healthcare outcomes globally, more particularly in the developing and least developing regions of the world, making a meaningful difference in the lives of individuals and communities. ■

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Challenges & Opportunities in Global Regulatory compliance for Biologics

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Ensuring regulatory compliance is a critical business requirement for Biotech industry to succeed. They need to stay current with the latest regulations, guidelines, and trends in ever changing regulatory environment. FDA, EMA, WHO, PICS and ICH guidance documents provide basic framework. While each country/region has its own legal framework and enforces its own requirements, basic principles remain about the same. The basic principle is that a patient receives a medicine, which is safe, effective and has appropriate quality. Companies need to have "patient centricity" as the focus.

Dr. Nirdosh Jagota spoke about the challenges in Global Regulatory compliance for biotech industry. He also spoke about the Good manufacturing practice (GMP) and Good Distribution Practice (GDP) for development and manufacturing quality.

Aspects of Quality and Compliance

Good Laboratory Practice (GLP) and Good clinical Practice (GCP) establishes framework around safely and efficacy of the medicines. Safety is defined by non-clinical toxicology, safety pharmacology. Drug interactions, special populations, and timing of these studies. Pharmacovigilance, clinical safety data management, trial design and analysis, clinical study protocols and reports, bioequivalence, periodic safety reporting and other studies define effectiveness of the medicine.

Good manufacturing practice (GMP) and Good Distribution Practice (GDP) provide important framework for ensuring development and manufacturing quality. During development, analytics, impurities (other safely considerations), stability and specifics for biologics are important. Phase appropriate GMP is the concept during development, however data integrity requirements remain the same during

development and manufacturing. These data audits are even more critical for biologics and advance therapy products. Recent FDA compliance actions for at least two large US based companies resulted into delay of product approval because of potential data integrity issues during development. From last few years FDA has a requirement for listing development testing and manufacturing sites in the biologic license application (BLAs).

For manufacturing and life-cycle management, all aspects from raw material procurement to processing and facilities are important. Quality management system, personnel. Building and facilities, process equipment, documentation and records, material management, production, and in-process controls. Packaging and labeling, storage and distribution, lab controls, validation all are critical aspects. Controls over rejection and reuse of materials, change control. complaints and recalls, oversight of contract manufacturers, agents, brokers, traders, distributors, replacers and relabellers are equally important. Quality risk management and knowledge management are key pillars.

To ensure compliance, Biotechnology companies should

- Implement quality control systems that ensure compliance with regulatory requirements, including robust documentation practices.
- Provide comprehensive training to employees on quality and compliance requirements.
- Conduct regular audits identify potential compliance issues.
- Establish effective communication with regulatory bodies, and other stakeholders,
- Maintain data integrity throughout development, manufacturing, and distribution.
- Keep patient centricity, scientific excellence, and robust documentation as a focus.
- Seek expert advice from regulatory consultants when facing complex compliance issues.

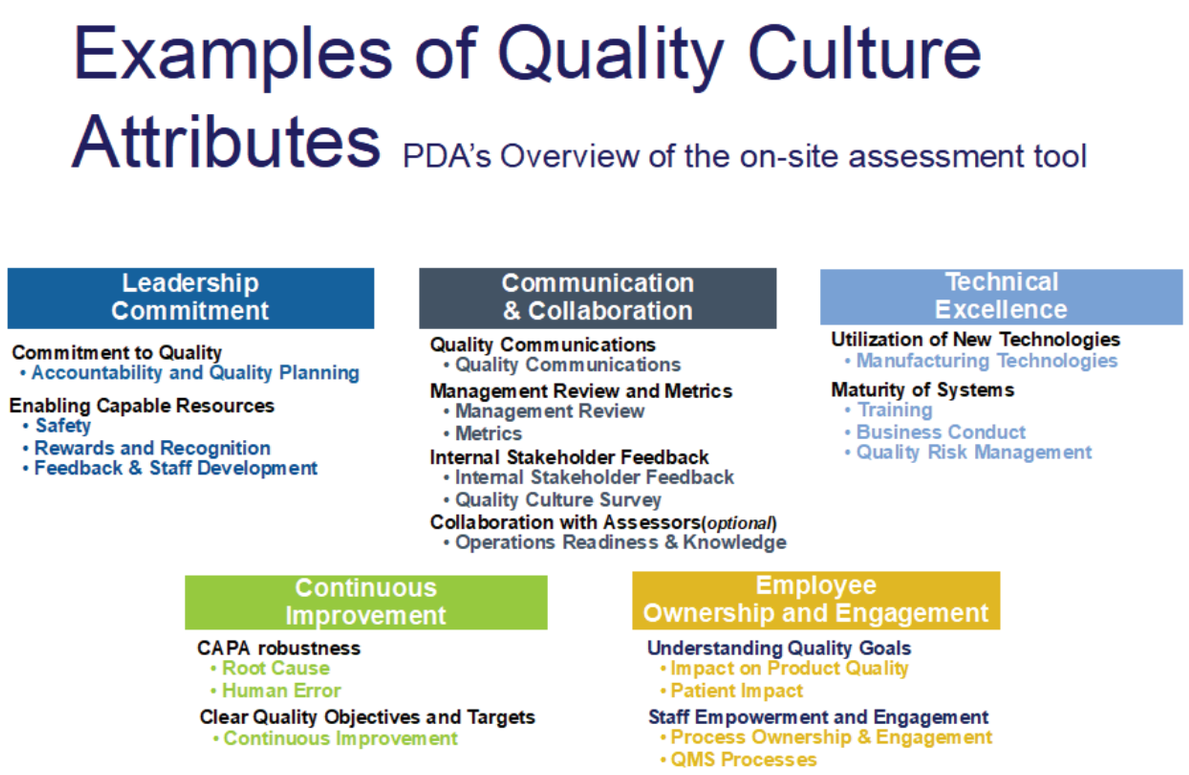
Key Regulatory Agencies

- Food and Drug Administration (FDA): FDA is US regulatory agency responsible for regulating biotechnology products such as drugs, biologics, and medical devices.
- European Medicines Agency (EMA): The EMA is the regulatory agency responsible for evaluating and approval biotechnology products in the European Union. Each country in Europe also has its own regulatory agency.
- International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH): ICH is an international organization that develops guidelines for the development, registration, and post-approval of pharmaceuticals, including biotechnology products.
- World Health Organization (WHO): The WHO guides and supports countries in developing their regulatory systems for biotech products.
- National Regulatory Bodies: Each country's regulatory body regulates biotechnology products. Examples include Drug Controller General of India (DCGI), The federal institute for drug and medical devices (BfArM), the Pharmaceuticals and Medical Devices Agency (PMDA/JAPAAM), and the National Medical Products Administration (NMPA-China).
- The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation scheme (PIC/s) are two international instruments between countries and pharmaceutical inspections authorities.

Regulatory agencies use a risk-based approach to evaluate product quality. The regulatory requirements for biotech products are complex and vary depending on the product type and the regulatory body responsible for its oversight. In addition to compliance with regulatory requirements, companies need to pay attention to reputational aspects. Reputation is critical for business success and important for patients and other stakeholders such as shareholders and investors.

Some of the key points of quality paradigm are:

- Quality must be built and will not improve by additional testing and inspection. Refer to Quality by Design (QbD) guidances from ICH
- Better utilization of modern science throughout product lifecycle is a must.
- Robust Quality System (QS) assures quality throughout product life cycle
- Quality risk management (QRM) is the critical enabler throughout product lifecycle/
- Quality culture. Attached diagram from PDA provides a good summary of Quality culture attributes.



Some hypothetical case studies

Although building and sustaining quality is the most important aspect. Sometime a situation can happen which needs relevant scientific and compliance expertise to manage.

A Company found some trace particles in an injectable drug product. Immediately risk-assessment was performed and further supply of product was placed on interim hold. Global regulatory agencies were immediately informed and teleconferences were arranged with key agencies. Internally team did a comprehensive risk-assessment based upon patient risk-benefit and safety as the key factors. Technical team worked with a speed of light and identified the particulate matter. An approach was developed which ensures the patients have the safe and effective supply. A temporary solution of "point of use filter" was proposed to the regulatory agencies with commitment to solve the problem in intermediate time frame. A data package was provided demonstrating identity of particles and filtration data from point of use approach. Most regulatory agencies agreed with the interim approach while company had to scientifically solve the issue in the long term.

Company was informed by regulatory agency about potential data integrity failure. Company decided to inform global regulatory agencies immediately and developed a risk-based approach to continue the supply of life-saving critical products which did not have any substitute or were in short supply. The approach required utilization of third party to individually review each batch record and provide certification before release of the product. Several regulatory agencies accepted the approach based on risk-benefit analyses. The approach also required simultaneous restructuring of staff and robust talent management, extensive certified third-party training and audits at the plant.

A new variant was observed in a drug product. The risk-benefit analyses indicated potential safety issue. Company immediately stopped the flow of product, and a product recall was issued. The product reintroduction took more than six months as company had to fix the process issues first.

As one can notice that each compliance issue requires careful understanding and expert input. There is no templated answer to these challenges. An understanding of global regulatory requirements, trends and deep scientific knowledge, and unbiased input from an expert consultant can help in such a situation.' ■

Building Cell Culture Capacities

In the dynamic crucible of biological and medical research, the technique of cell culture stands as an indispensable tool, providing scientists with the ability to meticulously study and manipulate cells outside their natural milieu. In the context of a rapidly evolving biotechnological landscape, the imperative to establish robust and scalable cell culture capacities has become not just a scientific pursuit but a strategic necessity.

Sushil Suri, Chairman & Managing Director, Morepen Labs spoke about the nuanced intricacies involved in building cell culture capacities, navigating through the labyrinth of facility design, equipment selection, process optimization, and the exacting realm of quality control, with a particular focus on real-world applications.

Facility Design

Cleanroom Requirements : The cleanroom, akin to a controlled biosphere, demands meticulous planning. Adherence to ISO classifications, particularly ISO 5 for critical areas, is not a mere guideline but a foundational requirement. The layout must transcend functionality; it should embody unidirectional airflow patterns, advanced gowning procedures, and a meticulous segregation of work zones. The objective is not just to prevent contamination but to create an environment where cell cultures thrive in a state of absolute purity, devoid of external interferences.

HVAC Systems: The Heating, Ventilation, and Air Conditioning (HVAC) system, often relegated to the background, is the silent conductor orchestrating the symphony of the cleanroom. Beyond the basic functions of temperature and humidity control, this system must be designed with a surgeon's precision. Regular maintenance isn't just a routine; it's a ritual. Rigorous validation protocols ensure that the air circulating within the cleanroom is not just sterile but an optimal habitat for the delicate ecosystems of cell cultures.

Facility Layout: The facility layout is not a mere blueprint; it is an architectural narrative designed for versatility. It must not only cater to an array of cell culture processes, from the delicate dance of small-scale experiments to the grand orchestration of large-scale industrial production, but also possess the elasticity to adapt to the ever-evolving needs of scientific exploration and bioproduction. The application-driven design ensures that the facility can seamlessly accommodate diverse research and production goals.

Equipment Selection

Bioreactors : The bioreactor, the crucible for cellular life, requires more than just careful selection; it demands a marriage of science and engineering. Scalability is not a feature; it is a fundamental requirement. Agitation mechanisms, whether sparging or impeller-driven, are not just components; they are the conductors of cellular symphonies. Control systems, sophisticated and nuanced, are not just interfaces; they are the guardians ensuring the optimal conditions for cellular flourishing. The application-oriented selection ensures that the chosen bioreactors align perfectly with the specific needs of the research or production at hand.

Incubators and Shakers: Incubators and shakers, often viewed as mere vessels, are the architects of a cell's environment. They are not just instruments; they are the custodians of life. Precision in controlling variables such as temperature, CO2 levels, and humidity is not a luxury; it is a mandate. The scalability of these systems isn't just an add-on feature; it's an essential characteristic ensuring seamless transitions between scales. The real-world application demands that these systems provide not just controlled conditions but an optimal setting for the specific cell culture under study or production.

Monitoring and Control Systems: Advanced monitoring and control systems are not just technological novelties; they are the vigilant sentinels safeguarding the sanctity of the cell culture environment. Automation is not a convenience; it is a necessity. These systems, overseeing parameters like pH, dissolved oxygen, and nutrient levels, are not just tools; they are the guarantors of a consistent and controlled habitat. They transcend the realm of efficiency; they are the architects of precision. In the real-world application, these systems ensure reproducibility and reliability, critical for the success of experiments or the production of consistent batches.

Process Optimization : Media and Supplements : The alchemy of cell culture media isn't a routine; it's a symphony of biochemical precision. The quest for optimization transcends the realm of formulas; it's a journey of adaptation. Serum-free or defined media options aren't just alternatives; they are the next frontier in enhancing reproducibility and scalability. Continuous refinement isn't a choice; it's an imperative in the quest for the perfect nutritional milieu. In real-world applications, media formulations are tailored to the specific needs of the cells, whether for basic research, drug development, or bioproduction, ensuring optimal growth and productivity.

Cell Line Development : Investing in cell line development isn't a transaction; it's a commitment to the very essence of cell culture. Techniques such as genetic engineering, exemplified by CRISPR/Cas9, aren't just tools; they are the architects of genetic landscapes. The focus isn't just on productivity; it's on creating cell lines that aren't just stable but exhibit consistent performance across the diverse scales of scientific exploration. Real-world applications demand cell lines with specific traits for the development of therapeutics or the study of complex cellular processes.

Scale-Up Strategies: Scaling up isn't a linear progression; it's a multidimensional puzzle. Feasibility studies and pilot trials aren't just prerequisites; they are the overtures to a grand symphony of industrial production. Transitioning seamlessly from small-scale research to large-scale production demands more than just planning; it requires the harmonious collaboration of scientific acumen and engineering finesse. It's a choreography of precision and adaptability. In real-world applications, scaling up ensures that the benefits of research findings are translated into tangible outcomes, be it the production of pharmaceuticals, vaccines, or bio-based materials.

Quality Control

Contamination Prevention: The battle against contamination isn't just a skirmish; it's an unrelenting war. Aseptic techniques aren't just protocols; they are a way of life within the cell culture facility. Personnel training isn't just an initiation; it's a continuous evolution. Stringent cleaning procedures and routine environmental monitoring aren't just tasks; they are the fortifications protecting the sanctity of cell cultures. In real-world applications, the prevention of contamination is not just a theoretical concern; it's a practical necessity to ensure the validity and reliability of research outcomes or the safety and efficacy of produced biopharmaceuticals.

Analytical Methods: The analytical journey is more than a quest for data; it's a deep dive into the health, viability, and productivity of cell cultures. Real-time monitoring isn't just observation; it's orchestration. In-process controls, whether it's cell counting, metabolite analysis, or genomic profiling, aren't just checkpoints; they are the conductors of a symphony ensuring not just consistency but a crescendo of reliable results. In real-world applications, analytical methods are the eyes and ears of the scientific process, providing insights into cellular behaviour or confirming the quality attributes of produced biological products.

Regulatory Compliance: The world of cell culture doesn't exist in isolation; it's bound by the strings of

regulatory frameworks. Meticulous documentation isn't just paperwork, it's the chronicle of excellence. Processes, procedures, and quality control measures aren't just guidelines; they are the code of ethics in the scientific narrative. Regular audits aren't just evaluations; they are the reflections on a commitment to not just compliance but excellence. In real-world applications, regulatory compliance is not just a bureaucratic hurdle; it's the assurance of safety, quality, and efficacy, essential for bringing novel therapeutics or biotechnological products to market.

Building cell culture capacities is not a task; it's an odyssey that demands more than just technical prowess. It requires meticulous planning, substantial investment, and an unwavering commitment to excellence. From the design of state-of-the-art facilities to the selection of equipment that transcends functionality to the optimization of intricate processes and the implementation of stringent quality control measures, each step is not just a process; it's a brushstroke in the masterpiece of scientific exploration. In an era of biotechnological renaissance, the ability to establish and adapt cell culture capacities is not just a strategic advantage; it's a transformative force propelling scientific research and bioproduction into uncharted realms of innovation and discovery, where every challenge is not an obstacle but an opportunity for scientific transcendence. Real-world applications are the litmus test for the success of these endeavours, where the intersection of scientific ingenuity and practical outcomes defines the true impact of building robust cell culture capacities. ■

Author

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R.N.I. No.: MAHENG/2002/08502. Date of Publication: 26th of every month. Poster Registration No: MCS/207/2023-25
Posted at Patrika Channel Sorting Office, Mumbai 400001. On 27th every month. Total Pages 44

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