
Industry Outlook
HEALTHCARE REGULATORY &
CLINICAL TRIALS SERVICE PROVIDERS
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CLINICAL RESEARCH
SHAPING A VIBRANT FUTURE TO DRIVE INNOVATIONS IN HEALTHCARE
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EDITOR'S NOTE

Transforming Healthcare

In the vast expanse of India, the realms of healthcare regulation and clinical experimentation witness a burgeoning ascent, propelled by a myriad of factors distinct to the Indian milieu. The metamorphosis of India's healthcare sector unfolds swiftly, spurred forth by demographic shifts, burgeoning maladies, escalating healthcare expenditures, and governmental endeavors to widen the reach of superior healthcare provisions. Within the domain of healthcare regulation, India bears witness to a surge in regulatory restructuring, aimed at streamlining approval protocols, augmenting transparency, and harmonizing with global benchmarks. Endeavors like the enactment of fresh regulations for drugs and clinical experiments, simplifying regulatory pathways for drug endorsements and clinical tests, have nurtured a more hospitable atmosphere for pharmaceutical and biotechnological enterprises to pursue research and developmental ventures within India.

Likewise, the sphere of clinical experimentation in India undergoes a robust expansion, fueled by the nation's vast and varied patient populace, cost efficiencies, and growing acclaim as a favored locale for clinical inquiries. The evolution of India as a nucleus for clinical tests is ascribed to its reservoir of adept healthcare practitioners, well-entrenched healthcare infrastructure, and a conducive regulatory backdrop. Moreover, the adoption of pioneering trial methodologies, such as adaptive trials and digital healthcare technologies, further embellishes India's allure as a clinical test hub. Despite the plethora of growth prospects, obstacles like regulatory adherence, ethical deliberations, and infrastructural lacunae persist within India's healthcare regulatory and clinical trial landscapes. Overcoming these hurdles mandates collaborative endeavors among industry cohorts, regulatory bodies, and policymakers to nurture a sturdy ecosystem that fosters innovation, ensures patient well-being, and expedites the development and accessibility of life-preserving healthcare remedies across India.

In this issue, we acquaint you with the top companies in these fields. After studying the industry landscapes in-depth, Industry Outlook has zeroed in on the topcompaniesthat have excelled with their meticulous approach. Having proven their dedication in order to meet the customer's expectations in an end-to-end manner, these leaders have stood out from the crowd.

We look forward to receiving your feedback and suggestions.

Sudhakar Singh
Managing Editor
editor@theindustryoutlook.com

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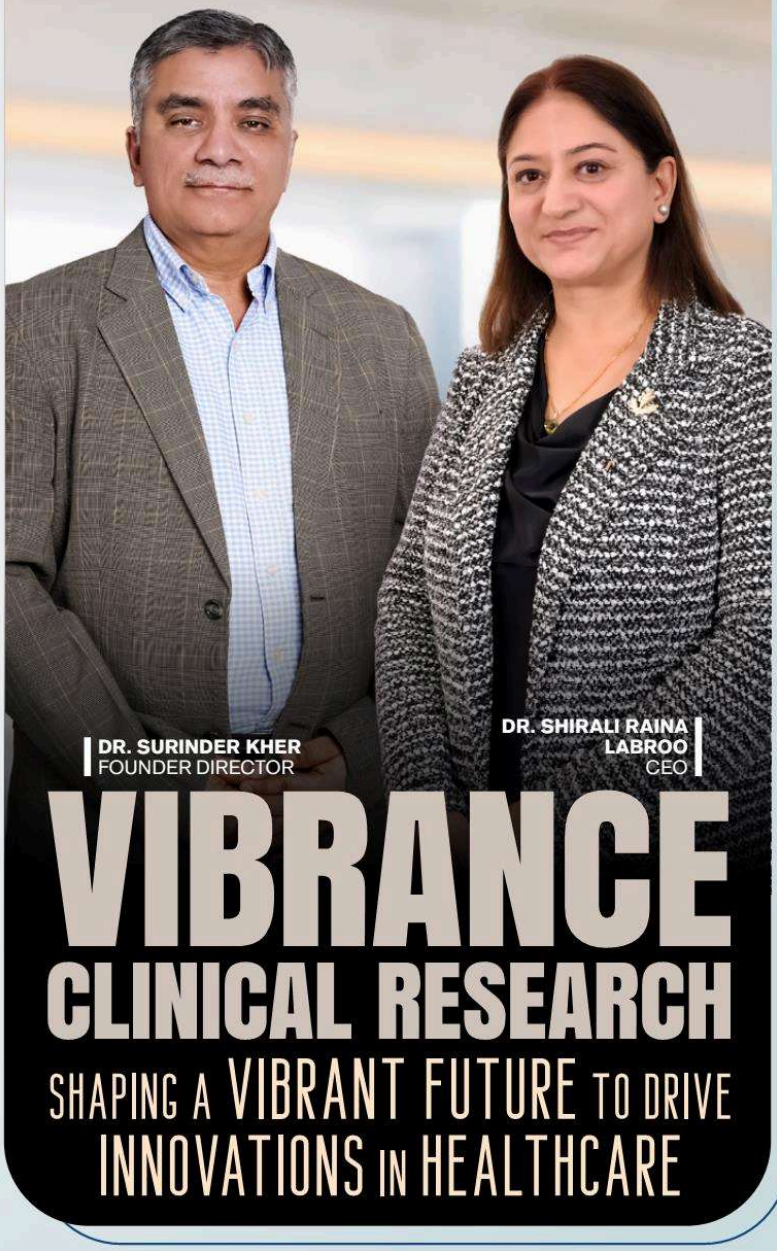


UNILEVER SPLITS ITS ICE CREAM DIVISION AS PART OF COST CUTTING OPERATIONS

Under the leadership of CEO Hein Schumacher, Unilever is embarking on a significant restructuring effort aimed at accelerating growth. As part of this initiative, the company announced job reductions, integral to its Growth Action Plan, to achieve €800 million in cost savings over the next three years.

One of the key decisions made by the Unilever Board is to streamline the company's portfolio by focusing on unmissably superior brands in highly attractive categories with complementary operating models. In line with this strategy, the Board has decided to separate its Ice Cream business to optimize future growth opportunities for both the Ice Cream division and Unilever as a whole.

The company stated that various options will be explored for the separation, with a demerger leading to creating a new publicly listed company being the most likely choice. Unilever's CEO indicated they are "open to options" regarding where the ice cream unit will be listed.

Unilever's Ice Cream business, which includes renowned brands such as Magnum and Ben & Jerry's, generated sales of €7.9 billion ($8.6 billion) in 2023. After separating the Ice Cream business and implementing its productivity program, Unilever anticipates achieving a "structurally higher" margin. Post-separation, the company forecasts mid-single-digit underlying sales growth and modest margin improvement.

The separation of the Ice Cream business is expected to enable Unilever's management to accelerate the implementation of its Growth Action Plan, which focuses on doing fewer things but better, driving consistent and stronger topline growth, enhancing productivity and simplicity, and fostering a performance-driven culture.

Moreover, Unilever highlighted that it has identified further opportunities for efficiency enhancement as part of its GAP initiative, which can now be expedited to drive greater operational effectiveness and growth.

REC ARM & BHEL JOIN HANDS FOR RENEWABLE ENERGY PROJECTS

REC Power Development and Consultancy and BHEL have reached an initial agreement to establish a special purpose vehicle (SPV) to build utility-scale renewable energy projects. Utility-scale renewable energy projects are those that have a capacity of 10 megawatts or more.

REC Power Development and Consultancy Limited (RECPDCL) is a completely owned subsidiary of the state-owned company REC. According to the announcement, the SPV will benefit from BHEL's core engineering knowledge as well as REC's infrastructure investment expertise. It will focus on meeting the energy needs of the commercial and industrial (C&I) segment, with an initial capacity of 1 GW that would be scaled further.

"This collaboration brings together our extensive experience in the renewable energy sector with BHEL's proven expertise in manufacturing and engineering. This SPV will play a crucial role in achieving India's ambitious renewable energy targets and contribute to a cleaner and greener future," REC Chairman and Managing Director Vivek Kumar Dewangan said.

BHEL Chairman and MD Koppu Sadashiv Murthy stated that there are numerous potential in the RE market for both enterprises to leverage their combined expertise to meet the government's green targets.

RECPDCL provides expert and value-added advisory services to power utilities across the country, including 41 Power Distribution Companies (Discoms) and four cooperative societies in 27 Indian states.

DBS BANK ALLOTS RS.2,000 CRORES FOR NEW AGE STARTUPS

DBS Bank India has set aside $250 million (approximately ₹2,000 crore) to extend lending support to new-age startups, recognizing their resilience and potential amid a challenging funding environment. The bank's focus on profitability and efficiency in the startup sector reflects a broader shift in perspective, with startups increasingly prioritizing sustainable growth.

Rajat Verma, head of institutional banking at DBS Bank India, highlighted the opportunity to provide financial assistance to startups that have weathered the storm and are now looking to scale up. The bank is particularly interested in startups operating in healthcare, technology, AI-driven financial services, transportation, logistics, retail, waste management, and supply chain logistics.

Utilizing its extensive corporate banking network, DBS Bank aims to offer a range of tailored financial products and digital solutions to startups, including escrow services, foreign exchange, cash management, trade financing, and regulatory reporting. The bank plans to leverage its expertise in risk management to ensure prudent lending practices while supporting the unique needs of startups in the digital economy.

Verma emphasized that DBS Bank would adopt a flexible approach to credit assessment and risk management, acknowledging the unconventional nature of startup financing. While the bank will not provide equity funding, it remains committed to providing innovative banking solutions to support the growth aspirations of startups across various sectors.

NTPC ISSUES TENDER FOR SUPPLYING POWER TO HYBRID PROJECTS

NTPC, India's largest power utility, has issued a tender inviting bids for power supply from 1 GW of wind-solar hybrid power projects across India. These projects will be developed on a build-own-operate (BOO) basis and connected to the Interstate Transmission System (ISTS) grid. The last date for bid submission is April 16, 2024, with bids to be opened on the same day. Successful bidders will be selected through an online reverse auction conducted by NTPC at a later stage.

Combining renewable sources like wind and solar, hybrid projects offer improved grid stability, particularly when sunlight or wind availability fluctuates. This tender marks the sixth tranche of NTPC's initiative to procure hybrid renewable power through international competitive bidding.

Bidders are required to furnish an earnest money deposit of ₹1.16 million ($14,000) per MW and can purchase the Request for Selection (RfS) document for ₹22,500 ($271). The RfS document can be downloaded from NTPC's e-tender portal between March 21 and April 3, 2024. Bidder evaluation will be based on their technical and financial capabilities, as specified in the RfS document.

Furthermore, bidders from countries sharing a land border with India must be registered with the competent authority to participate. However, this registration requirement is waived for countries with which India has extended lines of credit or is engaged in development projects.

In addition to this tender, NTPC Renewable Energy, a subsidiary of NTPC, has recently invited bids for a 150 MW grid-connected solar photovoltaic power project in Bhadla, Rajasthan. NTPC has also called for bids to retrofit a solar inverter for its 5 MW solar photovoltaic power project at the Dadri thermal power plant in Uttar Pradesh. These initiatives underscore NTPC's commitment to expanding its renewable energy portfolio and contributing to India's clean energy transition.

PANORAMA

HOW DECENTRALIZED CLINICAL TRIALS ARE REVOLUTIONIZING THE PHARMACEUTICAL INDUSTRY

Clinical trials are critical in the development and testing of novel pharmaceutical medicines. Traditionally, these studies have been carried out in controlled clinical settings, with volunteers required to attend certain places and follow stringent protocols. However, as technology advances and the demand for more efficient and patient-centred procedures grows, decentralized clinical trials (DCTs) have emerged as a game-changing answer. DCTs use remote technology, patient involvement, and data analytics to revolutionize clinical research, transforming the pharmaceutical sector.

Decentralized clinical trial success is altering the pharmaceutical industry. Decentralized clinical trials are conducted remotely, which saves money on travel, lodging, and other standard clinical trial costs. Furthermore, decentralized clinical trials make use of cutting-edge technology like artificial intelligence and data analytics to speed up the procedure and deliver findings.

Furthermore, the utilization of decentralized clinical trials has given pharmaceutical firms access to a bigger pool of people, which has increased the accuracy of the results. While employing decentralized clinical trials has benefits, it also has drawbacks. One disadvantage is that these studies are sometimes more expensive than standard trials. Furthermore, because these studies are being done online, there is a danger that the data collected will be less credible than that collected in person.

Decentralized clinical trials are those in which participants are recruited and enrolled online, and the experiment is conducted online. These studies have grown in popularity in recent years because they provide several advantages over traditional trials, such as more flexibility and reduced expenses. Decentralized clinical trials, for example, have been used to collect data on the efficacy of drugs for illnesses like chronic pain or depression, which can be difficult to assess in a standard clinical trial environment. Let us now look at how decentralized clinical trials are transforming the pharmaceutical sector.

Enhanced Patient Access & Engagement

One of the key benefits of decentralized clinical trials is better patient access and involvement. DCTs provide a bigger and more diversified participant pool by reducing the geographical limits and travel difficulties associated with traditional trials. Patients who previously could not participate in clinical trials owing to distance, mobility challenges, or other obligations can now do so from the comfort of their own homes.

DCTs enable real-time interactions between patients and healthcare providers through the use of telemedicine and remote monitoring technology. This improves patient involvement by allowing for regular conversation, resolving problems, and offering immediate assistance. Furthermore, these technologies enable patients to actively participate in their own treatment, resulting in a more patient-centric approach.

Additionally, DCTs provide flexible scheduling, minimizing interruption to patients' everyday life. This enhances the possibility of study participants finishing, boosting overall data quality, and lowering dropout rates. Decentralized clinical trials are altering the patient experience and promoting a better feeling of cooperation between patients and researchers by putting patients at the centre of the trial process.

Improved Data Quality & Real-Time Insights

Decentralized clinical trials make use of cutting-edge data collecting and analytics technology, resulting in higher data quality and real-time insights. Researchers may acquire a large quantity of objective data remotely by using wearables, smartphone applications, and linked gadgets. This information includes physiological parameters, medication adherence, and patient-reported outcomes, among other things. The capacity to record this data in real time improves the trial's precision and dependability.

Furthermore, the adoption of electronic health records (EHRs) and digital platforms enables the seamless integration and aggregation of data from disparate sources. This integration allows for in-depth research and insights into patient groups, treatment responses, and safety profiles. Researchers may find trends, correlations, and prediction models using artificial intelligence and machine learning algorithms, delivering crucial insights for customized medicine.

The capacity to gather data remotely minimizes the likelihood of missing data points and improves data completeness. This results in more strong and trustworthy conclusions, which eventually speeds up the medication development process. In decentralized clinical trials, the combination of high-quality data and real-time insights has the potential to transform evidence creation, allowing speedier decision-making and improved patient outcomes.

Enhanced Cost & Time Efficiency

When compared to typical trials, decentralized clinical trials provide considerable cost and time savings. DCTs reduce operating expenses by eliminating the requirement for physical infrastructure such as specific research locations and in-person visits. Eliminating participant travel fees minimizes the financial burden on patients, making studies more accessible and inclusive.

Furthermore, dispersed trials simplify the recruiting and enrolment processes. Researchers can speed up patient recruitment and consequently decrease trial timeframes with a bigger and more varied participant pool. The use of digital platforms and targeted advertising facilitates the identification and recruitment of qualified participants. This not only saves time but also lowers the overall expenses of patient recruitment and retention.

Decentralized clinical trials also allow for real-time monitoring and remote data collecting, which eliminates the need for site visits and manual data entry. This automation decreases human mistakes and administrative effort, allowing researchers to devote more time to data analysis and interpretation.

In the pharmaceutical sector, decentralized clinical trials are ushering in a new era of patient-centricity, data-driven insights, and cost reductions. DCTs are transforming clinical research by boosting patient access and participation, improving data quality and real-time insights, and increasing cost and time efficiency. As the industry continues to adopt decentralized methodologies, we may anticipate even more dramatic advances in drug development, which will eventually benefit patients globally.


HEALTHCARE REGULATORY &
CLINICAL TRIALS SERVICE PROVIDERS

Innovating Health for a Better Future

Healthcare regulatory services play a pivotal role in ensuring the safety, quality, and efficacy of healthcare delivery systems. These services encompass a range of activities aimed at monitoring, enforcing, and improving compliance with healthcare regulations and standards. One key aspect involves overseeing healthcare facilities to ensure they adhere to licensing requirements, maintain appropriate standards of care, and meet safety protocols. Additionally, healthcare regulatory services monitor healthcare practitioners to ensure they uphold professional standards and ethics, thereby safeguarding patient well-being. This includes licensing and credentialing healthcare professionals, investigating complaints or malpractice allegations, and imposing disciplinary actions when necessary. Moreover, regulatory bodies play a crucial role in overseeing the approval and monitoring of healthcare products and services, including pharmaceuticals, medical devices, and treatment protocols. This involves evaluating clinical trial data, assessing risks and benefits, and monitoring post-market safety and effectiveness. Overall, healthcare regulatory services serve to protect public health and safety by establishing and enforcing standards for healthcare delivery, promoting transparency and accountability within the healthcare industry, and facilitating continuous improvement in quality of care. Through robust regulation, these services contribute to building trust and confidence in healthcare systems, ultimately benefiting patients and communities.

Clinical trials service providers play a pivotal role in advancing medical research and drug development. These entities facilitate the entire process, from protocol design to data management, ensuring adherence to regulatory standards and ethical guidelines. Their expertise spans various phases of clinical trials, from Phase I (safety) to Phase IV (post-market surveillance). One crucial function of these providers is patient recruitment and retention, ensuring diverse and representative participant pools. They employ innovative strategies, including digital marketing and patient advocacy, to enhance recruitment rates and trial efficiency. Moreover, clinical trials service providers offer comprehensive data management solutions, employing state-of-the-art technologies for secure data collection, storage, and analysis. This ensures accuracy, integrity, and compliance with regulatory requirements. Furthermore, these entities streamline communication between stakeholders, including researchers, sponsors, regulatory authorities, and trial participants. Effective communication fosters collaboration, transparency, and timely decision-making throughout the trial process. In conclusion, clinical trials service providers play a vital role in advancing medical science by facilitating efficient, ethical, and compliant clinical research. Their contributions are essential for the development of safe and effective treatments, ultimately benefiting patients worldwide.

Industry Outlook in this issue presents a list of **Healthcare Regulatory & Clinical Trials Service Providers – 2024'** who have leveraged their extensive industry expertise and experience in offering high quality services in the industry. The following list has been prepared after being closely scrutinized by a distinguished panel of judges including CXOs, analysts, and our editorial board. We recognize their valuable contribution to the ever expanding and competitive market and their ability to sustain themselves and emerge as top contestants through their reliable products.

> **Driving Innovation in Clinical Research, Where Science Meets Compassion**

COVER STORY

Industry Outlook TOP 10
HEALTHCARE REGULATORY SERVICE PROVIDERS 2024

VIBRANCE CLINICAL RESEARCH

SHAPING A VIBRANT FUTURE TO DRIVE INNOVATIONS IN HEALTHCARE

BY SAMRAT PRADHAN

The healthcare regulatory services market, vital for licensing and drug/device development, is evolving significantly today. Here, the healthcare sector's dynamic nature greatly emphasizes the integration of regulatory considerations early in the product development lifecycle to prevent delays and deviations, particularly as startups increasingly seek regulatory guidance during program conceptualization. This is where Vibrance Clinical Research employs a distinctive and comprehensive approach in crafting clinical development and regulatory strategy plans for life sciences and healthcare organizations. The company's commitment lies in being more than just a service provider, wherein it functions as an extension of its clients' teams who work collaboratively as partners. Vibrance Clinical Research's consultative approach is rooted in clinical and scientific expertise which guides clients not merely through the execution of requested services but also delves into the rationale behind their objectives.

> "VIBRANCE CLINICAL'S CONSULTATIVE APPROACH IS ROOTED IN CLINICAL & SCIENTIFIC EXPERTISE WHICH GUIDES CLIENTS NOT MERELY THROUGH THE EXECUTION OF REQUESTED SERVICES BUT ALSO DELVES INTO THE RATIONALE BEHIND THEIR OBJECTIVES


DR. SURINDER KHER
FOUNDER DIRECTOR
DR. SHIRALI RAINA LABROO
CEO

"We actively engage in the design and development phase, questioning and advising on the most effective paths to achieve desired endpoints. This goes beyond a transactional service model, wherein we seek to ensure that the services provided align with the overarching goals of the client's program. As a team of medical and scientific professionals, we integrate medical and scientific considerations into our regulatory science approach," states Dr. Surinder Kher, Founder Director at Vibrance Clinical.

DR. SHIRALI RAINA LABROO
CEO

"We adopt a design thinking mindset, focusing on understanding the end product's objectives, market needs, and the problems it aims to solve. This approach sets us apart in the industry as it emphasizes strategic planning and developmental insights. While we do facilitate licensing and approvals, our primary emphasis is on strategy and clinical developmental planning. We guide clients on how to approach the market, addressing the fundamental questions surrounding their program's purpose and its impact on the healthcare landscape. This differentiation underscores our commitment to delivering strategic value beyond routine regulatory procedures," he adds.

Meeting Diverse Requirements with Optimal Due Diligence

Vibrance Clinical Research ensures a streamlined and ethical Institutional Review Board (IRB) process for clients who are engaged in clinical trials. As a competent service provider and developmental partner, the company perfectly understands the critical role of IRBs and ethics committees in the clinical trial lifecycle. Its approach involves meticulous planning to align with the specific requirements of each IRB or Ethics Committee associated with the institutions where trials are conducted. Furthermore, Vibrance Clinical Research leverages its extensive experience working with diverse hospitals and centers to anticipate and address specific compliance needs at different locations. And when it comes to preventing potential challenges or delays, the company prioritizes thorough documentation and understanding of each committee's expectations. This includes proactively addressing anticipated questions and concerns, saving valuable time during the review process.

"Our team, which includes professionals with in-depth expertise on IRBs, is well-versed in tailoring strategies to meet the distinct requirements of various clients. And when it comes to handling challenges or deviations, we employ a strategic approach by tracking essential elements for each IRB and anticipating potential differences in their processes. This involves having contingency plans in place, such as data backup strategies, to mitigate any obstacles that may arise. Furthermore, our SOPs are designed to accommodate variations in requirements, ensuring flexibility without compromising compliance. Ultimately, our commitment is to navigate the complexities of the IRB processes efficiently, maintaining ethical standards, and addressing challenges with strategic foresight and adaptability," highlights Dr. Shirali Raina Labroo, CEO at Vibrance Clinical.

Expediting Regulatory Approvals & Ensuring Utmost Compliance

Vibrance Clinical Research employs strategic approaches to expedite regulatory approvals and ensure compliance, thereby ensuring successful product development. The company's methodologies are always aligned with the regulatory landscape, focusing on efficiency, and anticipating challenges. By closely monitoring subject expert committee meetings and events, it determines optimal submission timings and anticipates potential requirements. Additionally, the company analyzes past interactions which aids in predicting and addressing queries during the approval process. Furthermore, adopting a consultative and strategic planning approach from the protocol design stage, Vibrance Clinical Research provides in-depth insights to clients which prevents extensive need for modifications later.

Adding to aforementioned aspects, Vibrance Clinical Research maintains a needed flexibility with buffer periods for complex protocols, thereby accommodating additional meetings without compromising timelines. Internationally, the company is well-informed about specific regulatory requirements, particularly in the Asia Pacific region, thereby ensuring a tailored approach for diverse client's needs. Moreover, the company has always been abreast of changing market trends and technological advancements. All of this is ingrained in their operating procedures, enabling them to seamlessly adapt to the ever-evolving regulatory landscapes.

Hence, this comprehensive and anticipatory approach positions Vibrance Clinical Research to navigate regulatory challenges efficiently, accelerating approvals and contributing to successful product development.

Staying Ahead of the Regulatory Curve

Vibrance Clinical Research proactively stays ahead of regulatory changes, ensuring alignment with the evolving landscape through a multi-faceted strategy. Internally, diligent monitoring by audit and quality assurance teams tracks alterations in guidance documents and regulatory frameworks. This systematic approach ensures compliance with the latest standards, especially in technology and MedTech-related guidelines.

Moreover, key team members actively engage with industry organizations like FICCI on pharma and clinical research to foster dialogue with regulatory bodies and gain firsthand insights. The company also participates in government initiatives and collaborates with other pharma and research associations to enhance understanding which enables proactive adjustments to services. Adding to it, individual efforts, such as involvement in industry committees and expert roles with funding agencies, complement institutionalized processes. Further to note, the company's established protocols incorporate newly published guidelines from regulatory agencies, the DBT, and ICMR into standard operating procedures. This ensures consistent alignment with current regulatory requirements. Moreover, the company believes in carrying out regular updates and modifications in its approaches to consider changes in biosimilar guidelines, medical device laws, or any regulatory amendments. Vibrance Clinical Research is also committed to institutionalizing a culture of continuous monitoring and adaptation, providing clients with compliant services that anticipate and address emerging challenges in the dynamic regulatory environment.

Going Above & Beyond

Vibrance Clinical Research specializes in supporting clients in the life sciences and healthcare product development, particularly in drugs and devices. Also, import licenses and related processes are seamlessly integrated into the overall application and regulatory strategy, forming an intrinsic part of the entire development program. In strategic partnerships, Vibrance becomes intimately involved in the development program, understanding when and how to apply for test licenses, import licenses, and other relevant licenses tied to regulatory requirements. The process is dynamic, evolving alongside the product's development stages. Import-export licensing is not pursued as a standalone service but is an integral aspect of Vibrance's holistic approach to clinical development and regulatory compliance. The focus remains on the strategic and regulatory aspects, ensuring

seamless addressing of licensing requirements within the larger framework. In cases requiring expertise for import-export procedures in other countries, Vibrance Clinical collaborates with local partners. While leveraging local resources for tasks like customs clearance, the overall design and understanding of required licenses at different stages remain a core competency. In summary, Vibrance's approach is to comprehensively address licensing requirements as an embedded component of broader regulatory and developmental processes, ensuring a smooth, compliant flow of products across international borders within the overall program.

A Robust Roadmap Ahead

Vibrance Clinical Research envisions a strategic roadmap aligned with its unique consultative and developmental approach. The primary focus in the immediate future is on leveraging the extensive database of consultants, partners and clients cultivated over the years of its existence, particularly within the healthcare and health tech sectors in India. With the dynamic growth of the Indian economy and the thriving startup environment, the company sees opportunities for its unique service model. Heading forward towards the next two to three years, the company's focus would be to explore expansion into larger markets, with a specific emphasis on the United States, recognizing the global significance of the pharmaceutical and medical technology industry in these regions. The company will also be focusing on catering to the European market. The three to five-year plan of the company involves continued growth and differentiation within the Indian market, capitalizing on the burgeoning startup ecosystem. Simultaneously, the company aims to strategically position itself on the global stage and offer consultative and developmental expertise to a broader clientele in the pharmaceutical and medical technology sectors.

Industry Outlook TOP 10
HEALTHCARE REGULATORY SERVICE PROVIDERS 2024

01

Aariya Regulatory Services
Delhi
aariya.net

Pallab Roy
Co-Founder & Director

The firm provide sustainable outsourcing of all regulatory affairs services, specialize in regulatory filings across all major markets around the globe for all types of products drugs, biologics, and more

02

Alceon
Vadodara
alceon.in

Atonu Dutta
CEO

The company providing genuine consulting support to medical device manufacturers who want to tap the world market, catering services regulatory affairs, QA, training, design & development and more services

03

Arogya legal
Mumbai
arogyalegal.com

Anay Shukla
Founding Partner

The firm offers a broad range of services in various areas of laws that apply to health-focused businesses such as pharma, medical device, food and cosmetics which operate in a highly regulated environment

04

Camomile Healthcare
Chennai
camomilehealthcare.com

Raghava Rao
Co-Founder & CEO

A global healthcare consultancy and transformation services organization that leverages deep industry expertise includes compliance & regulation consulting, hospital planning, operational, digital health and many more

05

NKG Advisory Business & Consulting Services
Delhi
nkgabc.com

Gulshan Bindra
Founder

A cumulative experience of more than 50 years in regulatory consulting in categories such as medical devices, ivd, drugs, cosmetics, legal metrology, narcotics, food, veterinary and more services

06

Nuvo Consultancy
Mumbai
nuvoconsultancy.com

Pooja Telavane
President

Provides reliable regulatory and quality support, specializing in meeting international standards also experienced in life cycle management, GMP audits, dossier management and many more regulatory services

07

RN Pharma Consulting
Pune
rnpconsulting.com

Dr. Ravindra Purohit
Promoter

The pharmaceutical consultancy firm specializes in the development of formulations, processes, and plant designs for inhalation technologies, injectables, ophthalmic products, and solid oral products

08

Silmed Scientific
Bangalore
silmedscientific.com

Lini Subin
CEO & Senior Regulatory Affairs Consultant

Bring 20 years of excellence in global regulatory affairs and promoting global access of medicine through scientific support to Pharmaceutical development, manufacturing compliance, packaging, and commercialization of medicines

09

Tacit MedTek
Noida
tacitmedtek.com

Vivek Singh
Founder & CEO

The consulting firm provides regulatory advice and compliance solutions to healthcare to various manufacturers in the healthcare industry, including system integration, training, licensing, regulatory approvals and more services

10

Vibrance Clinical Research
Bangalore
vibranceclinical.com

Dr. Surinder Kher
Founder Director,
Dr. Shirali Raina Labroo
CEO

The organization specializes in clinical development and regulatory sciences consulting, offering tailored solutions to life sciences and healthcare companies to meet their clinical, medical, and regulatory requirements

ALCEON

EMPOWERING MEDICAL DEVICE MANUFACTURERS TO ACHIEVE REGULATORY COMPLIANCE

Atonu Dutta
CEO

India is Asia's fourth-largest medical device market and one of the world's top 20. The overall market is expected to be worth $50 billionby 2025. Owing to this, the country's regulatory environment for medical and IVD devices has been gradually reinforced, requiring manufacturers to invest more in regulatory affairs. However, there aren't enough experienced regulatory experts who can assist the medical device manufacturers with the regulatory formalities. As per a recent report published by the Regulatory Professionals Society (RAPS), there are only about 15 percent of professionals who have experience of 5 years and above of working in the medical device industry. This is where Alceon comes in.

"Our key strength lies in our people. All of them come from the healthcare background, are highly trained and regularly updated with the latest requirements. They are highly committed in going out of the way and providing solutions to customers. We also gain from the larger ecosystem of our parent company Eupraxia which provides us the talent and experience in aspects of data analysis and biostatistics," says Atonu Dutta, CEO, Alceon.

A division of Eupraxia Centre for Clinical Excellence

Alceon's team consists of medical device industry veterans who have worked on a variety of devices including cardiac, orthopaedic, wound care, and general clinical usage. Their staff is led by a former Notified Body Lead Assessor, and the documents are examined independently by senior external consultants who have previously worked for regulatory bodies and medical device businesses. In addition, the company organizes training sessions at regular intervals to keep their employees updated with all the trends. According to Atonu Dutta, "We keep our employees trained through internal or external training and this is a continuous process. In fact, we have weekly two-hour training and experience exchange sessions to keep everyone updated on the requirements."

One-stop solution

Health care regulation is a complicated process; hence there is a growing need among businesses to hire regulatory professionals who can provide them with multiple benefits. For example, a manufacturer might need advice on which tests to perform, which labs to select, how to set up the site infrastructure and also the routine services of dossier preparation. Also, clients look not just for regulatory solutions, but also technical solutions. Alceon has been able to prove its efficiency in this segment as well. The company maintains a team of both internal resources and external experts who can provide the required advisory to the customers. They maintain contact with Notified Bodies (for CE marking) as well as different labs, giving them an insight on the expectations of these entities while preparing the dossier or even applying for a quotation.

> Our key strength lies in our people. All of them come from the healthcare background, are highly trained and regularly updated with the latest requirements

At present, Alceon provides regulatory services to both medical devices and in vitro diagnostic devices. Its services are provided both to mature, older companies as well as to start-ups operating out of an incubator environment. In the future, the company wants to explore new technology areas like SaMD, Additive Manufacturing and newer areas of IVD devices.

INDIAN MANUFACTURING INDUSTRY'S PATH TOWARDS GREEN FUTURE

● **By Ravichandran Purushothaman,** *President, Danfoss India*

Ravichandran Purushothaman
President

Ravi is a member of Danfoss Global management team, Board member & Global mentor since 2013, who is working actively in energy, water, food & agri technology space supporting & mentoring several early stage startups.

Energy efficiency, value chain mobilization, and sustainable alternatives can help achieve Net Zero Emissions. The world economy is battling inflation accentuated by the energy crisis. There was a period of oil shocks and soaring inflation in the 1970s and early 1990s when the world was in this situation before. But this is a rude shock to the globe as it was just overcoming the nightmares of the pandemic. Should this be a wake-up call for India? India can use this situation as a blueprint and set the foundation for a cleaner, cheaper, more resilient, and self-sufficient energy infrastructure.

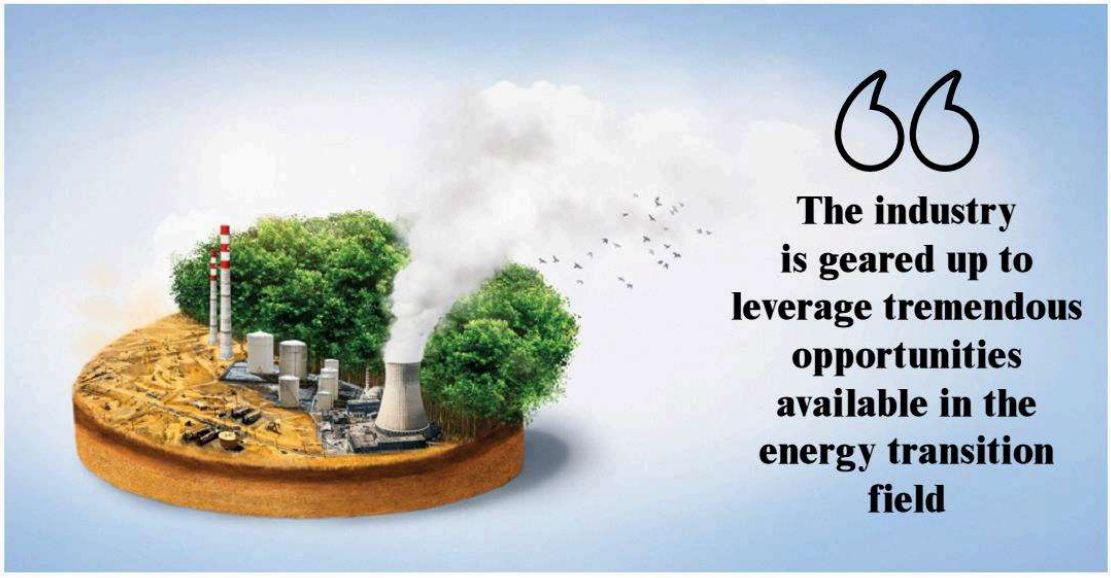
Fortunately for India, the government began advocating the goal of 'Net Zero' emissions well before the energy crisis, not as a reaction to it but for the sake of the greater good of humanity. India pledged to cut greenhouse gas emissions by 45 percent from 2010 by 2030 to achieve net-zero emissions by 2070. At the COP26 conference in Glasgow, Prime Minister Narendra Modi unveiled the 'Panchamrit' five-pronged strategy to combat climate change. The pledge to meet 50 percent of its energy needs from renewable sources by 2030 is one of this policy draft's standout elements.

India's path towards 'Net Zero' would be challenging as India's GHG (Greenhouse Gas) emissions would be peaking by 2040s. Further Mitigation required to become Net Zero by 2070 will be exponentially higher than historic performance on this count. Despite several efforts by the government and industry players, India faces several pressing near-term challenges.

Interventions for accelerating Decarbonization for the Indian Manufacturing Industry:

1. **Energy Efficiency:** Energy Efficiency will play a major role by contributing 44 percent in BAU (Business as Usual) and 32 percent in Deep Decarbonization Scenario for the Indian Industry. To achieve the nation's goal of improvement in energy intensity per unit of GDP, the industry will have to invest in technologies, processes, and end-mesh. This will require a rate of progress more than double what it has been in the past. For example, standards and labeling by the Bureau of Energy Efficiency (BEE), Energy Conservation Building Codes (ECBC) by the Ministry of Power, and the Promotion of Electric vehicle - National Electric Mobility Mission Plan (NEMMP), among others, all contribute to achieving energy efficiency goals.

2. Use of the Renewables & Clean Technologies: The emphasis laid by the government on green energy has opened the floodgates. The industry is geared up to leverage tremendous opportunities available in the energy transition



field. Advancement in technologies is enabling corporates to procure round-the-clock green power. RE deployment is expected to double (or even triple), and more than 30 percent of industrial emission mitigation depends on EE measures. Renewable electricity is growing fast in India, with new capacity additions doubling by 2026. The share of solar and wind in India's energy mix have grown phenomenally.

3. Circular Economy or Value Chain Mobilization: Circularity is about the five Rs: Reduce, Repair, Resell, Refurbish and Recycle. Value chain emissions constitute more than a company's total carbon footprint. The transition can be based on the redesign of the supply chain. Innovations in logistics is a key enabler to drive circularity when it comes to optimizing production volumes, enhancing the life cycles of the products, and devising end-of-life recycling.

4. Biomass, Hydrogen & Other Zero Carbon Fuels: Many futuristic technologies like Hydrogen, CCUS, Fuel Cells, and many are still nascent and have high-cost implications. India is one of the world's largest producers of modern bioenergy. Hydrogen has the potential to decarbonize transportation, heating systems, and industrial operations, which are currently challenging to decarbonize through renewable energy. On the one hand, these technologies require a huge push on the policy front, but industry leaders also need to come forward and demonstrate their commitment to adopting the same.

5. Carbon Capture Utilization & Storage (CCUS): With CCUS, carbon can be captured from large point sources and energy facilities that burn fossil fuels or biomass. According to the IEA, the role of CCUS in achieving net zero emissions is crucial, since without it, options for tackling heavy industry emissions would be limited or nonexistent.

Way Ahead

International Energy Agency (IEA), in its report on achieving Net Zero for Heavy Industry Sectors recommends:

- **Foster Innovation & Green Finance in Heavy Industry: Near-**zero emission technologies should be funded with grants and low-interest loans. These funds would benefit industrial plants, logistics, storage, and related areas.
- **Promote Demand for Near-zero Technologies:** By encouraging the use of materials with near-zero emissions, the government can help boost demand. Long-term public-sector procurement is an example of government support.
- **Uniform Industry Standards & Tools:** Measurements are being developed to assess carbon emissions across industries and nations. As a result, governments can agree on a common reporting framework.
- **Clarity in the Taxonomy:** Existing efforts undertaken by the industry and the governments; IEA suggests can be termed as 'low emission production'. This way, it can be differentiated from net zero emissions.

A shift to green energy is a huge economic opportunity. As a large developing economy with over 1.3 billion people, India's energy ambitions are not just transformational for India but the entire planet.

AROGYA LEGAL

INNOVATIVE HEALTHCARE REGULATORY SOLUTIONS WITH QUICKTURNAROUND TIME


Anay Shukla
Founding Partner

Laws that regulate healthfocused businesses such as pharma, medical devices, cosmetics, food and beverages and others are becoming more and more stringent with every passing day. Getting a license to operate these health-focused businesses in a timely and seamless manner is not an easy task. Although the government has streamlined regulatory document submission process, it remains extremely scientific, detailed, and factual. There is little room for error, and the consequences of non-compliance are borne by businesses in terms of not only penalties but also wasted time and, more importantly, lost opportunities. These circumstances create the need for a competent and efficient healthcare regulatory service provider who can understand the nuances of any health business, provide quality support, and get the necessary license and registration for the business in the most time effective and efficient manner. This is where Arogya Legal comes in.

According to Anay Shukla, Founding Partner, Arogya Legal, "At Arogya Legal, we exclusively offer our services to businesses in health and well-being space because it is our mission to enable more business to touch the lives of people, and thus make a difference to the health and well-being of the people. We take great pride in creating value for our clients by finding solutions to complex problems, which is possible only because of our deep domain knowledge, expertise and experience of the industry. As a firm comprising of lawyers, our legal training in interpreting and applying the laws is deeply appreciated by our clients".

"Arogya Legal emphasizes the quality, strategic approach and quick turn-around times. We take satisfaction in the fact that we are able to provide all of our clients with the essential regulatory strategy and compliance assurance, allowing them to focus on their business," mentions Anil Upadhyay, Senior Partner, Arogya Legal.

Solving the complexity with experience

Clients of health regulatory service providers nowadays expect them to be experts in applicable laws and regulations while having a thorough awareness of their industry. This is because, in addition to assisting with the acquisition of a license or registration, clients today want external service providers to assist them in navigating the intricate web of rules and regulations in order to remain compliant and profitable. Customers respect the quality of the work output as well as the turnaround time, which is a direct result of the service provider's experience.

Arogya legal has positioned itself to meet with the same. It is because of the deeply ingrained domain expertise, experience, emphasis on quality, strategic approach of the firm that it advances with simple, innovative, and workable solutions to meet with every possible complexity related to health care legal issues that are faced by its clients. With a competent understanding of the delicate requirement that the health care regulatory field demands, Arogya Legal has made itself efficient enough to aid its clients with a quick turnaround time.

> At Arogya Legal, we exclusively offer our services to businesses in health and well-being space because it is our mission to enable more business to touch the lives of people

Presently, Arogya legal assists its clients with a variety of situations ranging in various dimensions like litigation and regulatory, data protection and privacy, ethics and anti-bribery, environmental laws, and a lot more. The firm follows a diverse, unique methodology to meet any challenge that its clients assign them with. It is due to its problem-solving proficiency that Arogya legal caters to the needs of different firms across India. Most of its clients are firms that have a footprint in the International market. Right now the firm is operational in Mumbai and Delhi. However, the firm is optimistic to serve to expand into other cities in India and outside India as well.

INDUSTRY INSIGHTS

FAST-TRACKING THE GROWTH OF INDIAN VACCINE INDUSTRY

By **Dr. Kapil Maithal,** *President-Vaccines & Diagnostics, Zydus Lifesciences*

Dr. Kapil Maithal, President – Vaccines & Diagnostics, Zydus Lifesciences, in an exclusive interview with Indranil Chakraborty, Assistant Editor, Industry Outlook, shares his insights on the Indian vaccine industry, scaling up vaccine manufacturing, the road ahead for vaccine development and more.

Dr. Kapil Maithal
President-Vaccines & Diagnostics

The global vaccines market is projected to reach $125.49 billion by 2028. How is the vaccine industry developing in India? What are factors affecting the growth?

India is one of the major vaccine manufacturing hubs in the world as we cater to almost 60 percent of the global vaccine demand. The major drivers of this has been the world class manufacturing infrastructure, available talent pool, and highly efficient cost of manufacturing which are prerequisites for providing high quality and low cost vaccines especially to low and middle income countries (LMIC) where the disease burden of vaccine preventable diseases is the highest.

After the onset of COVID-19 pandemic, we shed our image of just being a manufacturing power to now also an innovation driven industry. The major drivers of this inflection has been the significant push-and-pull funding by the government and support from regulatory agencies, which helped in fast-tracking research, development and subsequent commercialization of these vaccines which in turn has helped the vaccine industry to grow. Moving forward, this momentum in growth can be further accelerated by continued risk sharing by the government in terms of providing funding and incentives to the industry and encouraging more investment in new vaccines where the risk of failure is high. Another important area to be prioritized is in setting up national centers for specialized testing and for providing curated, well-characterized bacterial and viral seeds for vaccine manufacturing.

Inconsistencies in the supply chain often imposts a great threat to the visibility and data centralization of the entire supply chain network. How can end-to-end supply visibility be attained?

Vaccine supply chain has greatly evolved over the years. One of the primary reasons behind this has been the continued emphasis on it by various regulatory and procurement agencies. In fact, UNICEF, one of the major vaccine procurement agency spends significant amount of resources in procurement of affordable and efficient cold chain equipment (CCE) for

storage, handling, stock management and delivery of vaccines to the remotest locations. Similarly, GAVI, the major funding agency for vaccine supplies to LMIC across the world also helps in distribution, installation, commissioning, as well as on-site training on cold chain equipments to the countries under its Cold Chain Equipment Optimization Platform (CCEOP).

As vaccines are usually supplied in very large volumes, the packaging configuration for vaccines meant for most institutional supplies is usually defined. Over the years, there have also been myriad of technological advancements when it comes to vaccine supply chain including track and trace systems for real-time on-route dynamic logistics planning and monitoring and management of any In-Transit Cold Chain excursions. In most of the institutional supplies, vaccine vial monitors (VVM) are used, which will change color if there is any temperature excursion. That said, there is a need for consistent improvement in this segment as about 20 million children still remain at risk from vaccine preventable diseases in the world due to under or no vaccination.

Manufacturing process complexity arises from the need for rapid production and the prompt resolution of technical issues. Whilst traditional manufacturing processes are well established, these require time to scale-up. How can vaccine manufacturing be scaled-up?

Rapid scaling-up of vaccine production can be a challenge. This can be primarily attributed to the fact that vaccines can be developed using different platforms like whole virion vaccines, subunit vaccines or viral vectored vaccines and now we even have nucleic acid based vaccines, which may require very different type of manufacturing units.

The major factors, which need to be considered for scalingup are process and utility optimization as well as the availability of raw material and consumables besides numerous factors related to facility design, man-material movement and other resources. When it comes to process optimization, one would need to continue improving in the area of biochemical engineering and process quality controls, which can be integrated with computational sciences to develop mathematical models and predictive tools to identify critical process parameters or indicators, which can help to have a better design of experiments. Such an approach drastically narrows down the options as long as the critical process equipments are scaled up linearly to avoid more variables. In fact, many leading industries are already using these methodologies very successfully for traditional platforms and as more data related to newer vaccine platforms emerges, these tools will become even more powerful for scaling up these platforms.

Today, there is an increased need to ensure patient safety. How do you see the industry working to attain the same?

Vaccination is one of the most successful tools in reducing the burden of diseases and mortality in the world and WHO estimates that vaccination prevents around 3.5 to 5 million deaths every year. However, as vaccines are usually given to a healthy population, safety is definitely of paramount importance. In order to ensure safety, the vaccine developers

undertake rigorous pre-clinical testing in both in vitro and in vivo models for vaccine potency and safety using sophisticated analytical tools before moving into toxicology study in animals. If the vaccine is found suitable in this stage, then it moves into different phases of clinical trials before being approved.

Vaccine introduction for public supplies is also examined by National Technical Advisory Group on Immunization (NTAGI) and based on risk to benefit ratio, which depends on disease burden, mortality, morbidity along with vaccine safety, efficacy and ease of delivery, appropriate recommendations are made. Additionally, there are strong pharmacovigilance system in place, which helps in detection, assessment, understanding, prevention and communication of adverse events following immunization (AEFI) on periodic basis to regulatory agencies even after vaccine introduction and in case there are any alerts in safety signal the vaccine registration can be withheld or withdrawn completely.

> **The major factors, which need to be considered for scalingup are process and utility optimization as well as the availability of raw material and consumables besides numerous factors related to facility design, man-material movement and other resources**

With increased demand for vaccines, it is now imperative to reduce the time to market. How do you see the industry working to attain the same?

As vaccines are usually given to healthy individuals so its safety and efficacy especially of the new ones, need to be evaluated carefully before licensure and public use and this may take some time, which is essential for complete evaluation. Usually the time from initiation to commercialization of a vaccine ranges from 06 to 12 years depending on the complexity of the disease, disease burden, market demand and availability of clinical assays and correlate of protection and more. One of the major breakthroughs which happened during COVID pandemic is licensure of DNA and mRNA based vaccines which are plug and play technologies and would help in expediting the delivery of vaccines in case of new wave of COVID or emergence of new pandemic.

Besides this, there are lessons learnt from COVID vaccine development and all critical stakeholders need to play a strong role in expediting the vaccine development. In this regard, there needs to be a greater emphasis on the 'One Health' concept as majority of diseases are of zoonotic origin. We also need to further strengthen disease surveillance and epidemiological centers for disease reporting and identification of related pathogen as new diseases emerge. At the same time we also need to set up specialized testing facilities for non-human primate and 'Controlled human infection model' challenge studies to identify possible correlates of protection, which may reduce clinical trial timelines and help in our preparedness for next pandemic.

Besides this, there needs to be focus on various public private partnership programs to improve and develop next generation viral vectored vaccines and nucleic acid based vaccines.

How do you see the vaccine industry evolving in the future?

The vaccine industry has evolved a lot in the last three to four decades with many new vaccines being licensed. Further, we have learned a lot in the last two years because vaccines garnered global attention, which was a major turning point for the vaccine industry. Going forward, I believe that there will be major advancements in all aspects of vaccine research, development, manufacturing and delivery.

The next generation of vaccines would be universal vaccines targeting most of the strains and genotypes of a pathogen. We would also have therapeutic vaccines including those for non-communicable diseases. Newer vaccines are expected to be more thermostable and having better safety profile and providing longer duration of protection which can be done by advancements in protein engineering, our understanding of pathogen evolution and development of new class of adjuvants.

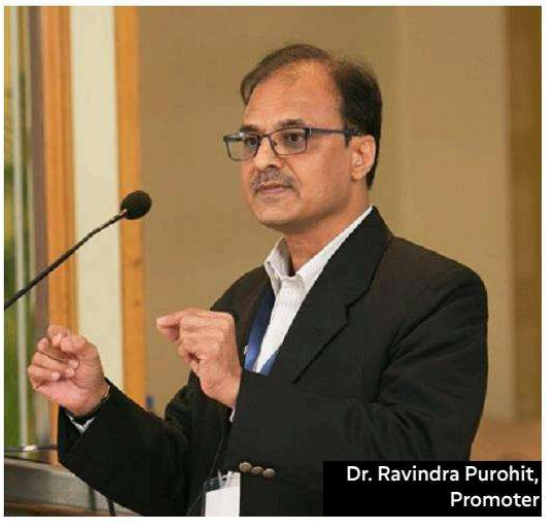
One would also expect better in vitro and in vivo disease models for potency and safety evaluation including challenge studies. There would be superior clinical trial designs with improved monitoring of disease prevalence, which will help in better cohort selection, establishment of safety biomarkers for quick evaluation of adverse events of special interests and high throughput assays to evaluate innate, humoral and cellular immune responses. At the same time, vaccine delivery is expected to improve with use of needle free injection system, micro patches, implants and also non-invasive routes of delivery like oral and intranasal. Already lot of work is going on these areas both in our country and globally and there are some reports emerging which suggest that in the next decade, we may have many such innovations and discoveries, which will revolutionize the field and vaccine industry, as we know today.

RN PHARMA CONSULTING

A LEADING INDIAN PHARMA CONSULTANT SETTING NEW BENCHMARKS FOR THE REST TO FOLLOW

The Indian Pharma industry is known for its positive approach to changes which helps the industry to come out stronger from any challenges they face. The recent changes happening in the regulatory front would help the Indian pharma industry to move closer to the regulatory norms of advanced markets. Hence, the projected growth of the market is at CAGR of 8.4 percent. RN Pharma Consulting is one such pioneering consultancy firm that has been able to develop into one of the most reputed and well-established brands in the market owing to the quality and innovativeness of its services.

RN Pharma always works by knowing the upcoming plans of the sponsor company, preferably 5-10 years projections. They suggest strategies for manufacturing plant or product development projects that will satisfy the company's need over the projected horizon of 5-10 years, thereby cutting costs and timelines involved in restructuring, alterations, or multiple times product development efforts. The company's USP is their expertise in the niche segment of Inhalation and Injectable formulations and manufacturing that largely satisfies the need of Indian and Overseas markets. Owing to this expertise, RN Pharma does many projects in Inhalation and Injectables, providing "end-to-end" consultancy to their sponsor companies. The company has an impressive track record when it comes to repeat clientele which showcases their quality.



Dr. Ravindra Purohit, Promoter

> Dr. Ravindra Purohit has 30 years plus experience in pMDIs, DPIs & Nasal Sprays Formulation and Medical Device & Device Material Development. With his excellent skills and knowledge in pMDIs, DPIs & Nasal Sprays Process Development and Projects for Commercial Manufacturing, Dr. Ravindra Purohit has developed a plethora of products for OINDP markets in domestic, regulated and semi regulated

While talking about what makes RN Pharma different from the rest of the competitors in the industry, Dr. Ravindra Purohit, Promoter, RN Pharma says, "We believe in competing with ourselves, so our efforts are always directed towards improving our services. This approach ensures that we end up being self-competitors. Our tagline is "We are the missing piece of your jigsaw puzzle". We strive to live up to this expectation, so we do not restrict our services merely to the "You ask, I tell" approach. We proactively suggest to our sponsors about all possibilities in a project and actively strive to practice the accepted suggestions to benefit our sponsors in achieving the crucial timelines in optimum budgets. For us, the sponsor company's

needs and the possible resource allocation to the projects are critical. Our primary motto is to provide "pro-active" consultancy that necessitates taking ownership of the

project. We are also always happy to take ownership of the projects allocated to us. And we ensure adequate training to our sponsor company's technical team in all aspects of product manufacturing and development. In a few niche areas such as Inhalation technology, we are amongst the very few in the country, so we need to ensure that we remain updated and pass on our expertise to the sponsors effectively".

Elucidating more on their future plans, Dr. Ravindra Purohit, states that, "We have our firm work ethics, and in the long run, we would like to be known for our reliability, ethics, and integrity. We take pride in the fact that we do not compromise on our work ethics. After all, if we are "the missing piece of a jig-saw puzzle" of our clients, then we would want to be that piece of the puzzle that holds the entire picture together and make it meaningful. Over a period of the next 5 years, we envisage becoming a globally known consultancy firm. We also want to expand our services in Quality Assurance and Compliance areas, more specifically for the niche formulation areas such as Inhalation and Injectables. We would be striving to break the mould of generic product development and strive to work on newer technologies, new products, and repurposed drugs. We are already working on one New product and would like to take up some more challenges of this type shortly.

INDUSTRY INSIGHTS

EVOLUTION OF MARKETING STRATEGIES IN ANIMAL NUTRITION & HEALTH FOOD MANUFACTURING

● **By Dr. Chandani Parihar,** *Marketing Director, Nutreco South Asia*

Chandani Parihar holding an MBA in Agribusiness Management from National Institute of Agriculture Extension Management (MANAGE), Hyderabad, has been associated with Nutreco for six years now. Prior to this she has held key marketing roles in the industry. In a recent conversation with Thiruamuthan, Correspondent, Industry Outlook, Chandani shared her insights on emerging trends in marketing strategies and their impact on the animal nutrition and health food sectors.

Dr. Chandani Parihar
Marketing Director

How are the evolving market dynamics reshaping marketing strategies for animal nutrition and health food products currently?

Use of technological advancements and data are the two major factors that are shaping-up the marketing strategies for animal nutrition and health food products. At the same time, a fast-evolving consumer base, changing consumer behaviour, uncertainties of livestock business – all have an impact on how the marketing strategies are formulated. Being dynamic is key. A basic practice of marketing when we talk about customer segmentation is targeting them according to their requirements. However, the ways in which you view data now, store it, generate insights, and understand the buying patterns of the customers have taken a better shape today. Also, the extensive usage of technology tools such as AI, e-Commerce applications and Whatsapp is another key factor that impact how we choose to reach our customers.

What is the impact of prevalent industry trends on marketing strategies within the animal nutrition and health food sector?

As I mentioned earlier that livestock business is seasonal and has many uncertainties, while at the same time consumer base is evolving with more information available readily.

One particular trend that is reshaping the dynamics is presence of D2C platforms and increase in use of processed items. Keeping the end consumer in mind is becoming more important, branding of end products (chicken, egg, milk) is a requirement rather than option. Information about feed-to-food safety, anti-microbial awareness, mycotoxins and consumer awareness are all bringing changes in marketing strategies. These factors play a prominent in organizations' long-term marketing and business strategies.

> **When it comes to brand loyalty, the only strategy that works is to be close to your customers and keep an eye on what their needs are at all times**

Suggest a few ways in which organization can adopt their marketing strategies when exploring new markets or segments.

This has much more to do with how an organization wants to view themselves in the long run – vertical or horizontal expansion, organic or inorganic growths. For any business, it is critical to first analyse the feasibility of the project – Capex, Opex and expected revenue generation. However, when exploring new markets and segments, first and foremost is to identify your potential customers, the pain points that you're going to solve for them, what your products are, and do your products meet their purchasing power. Therefore, it is important to conduct a thorough market research of the region you are wanting to foray into, launch a pilot project, gather feedback, and tweak your offering as per that feedback prior to deploying full-scale product/solution.

Tell us about the role of marketing in an organization's innovation and research efforts pertaining to animal nutrition products.

In marketing, one of the most important aspect is to have a clear understanding of your customer's requirements, perform gap-need analysis. Post identifying that, they are able to assess areas of innovation and collaborate cross functionally to achieve desired outcomes. On a function basis, I strongly feel that innovation is also related to some of your day-to-day activities. Following the cycle of implementation, assessment and adoption of changes is necessary for any activity or process in order to bring efficiencies.

Briefly explain a few ways organizations can engage customers and foster brand loyalty within the animal nutrition industry.

It is often said that brand loyalty is a myth. When it comes to brand loyalty, the only strategy that works is to be close to your customers and keep an eye on what their needs are at all times. If you miss-out on it, you are just creating an opportunity for your competitors to come-in and take advantage. Especially is animal health & nutrition segment, this requires a very close coordination between marketing, sales and technical teams (the demand teams) and support each other in every way possible.

Industry Outlook TOP 10 CLINICAL TRIALS SERVICE PROVIDERS - 2024

01

Ardent Clinical Research Services
Pune
ardent-cro.com

Chandu Devanpally
Founder & Managing Director

Offer comprehensive clinical research services to a diverse clientele, including biopharmaceutical, herbal, neutraceutical, device companies, and the generic drug industry

02

Croissance Clinical Research
Hyderabad
croissancecr.com

Satish Marukurthi
Founder & CEO

A full-service CRO firm offering services like project management, capacity building, medical writing, safety oversight, quality assurance, regulatory support, clinical data management and biostatistics

03

Ethicare Clinical Trial Services
Ahmedabad
ethicare-cro.com

Milan Satia
CEO

Highly synergistic company offers a seamless comprehensive array of clinical trial services from protocol development to clinical summary, expertise in clinical development services across multiple therapeutics specialties

04

Ethicscare Clinical Research Services
Chandigarh
ecrsindia.com

Shashank Gour
Founder & Director

The firm providing solutions for clinical trials, health economics & outcomes research, post-marketing trials and market access in a wide range of therapeutic areas and GCP trained investigators and CRCs to healthcare industry

05

Icbio Clinical Research
Bangalore
icbiocro.com

Dr. Harish S
Founder & CEO

Provides comprehensive end-to-end clinical research solutions in India and around the world, catering to varied sectors includes pharmaceutical, biopharmaceutical, herbal/ nutraceuticals medical devices and more

06

Innovitae Clinical Research Services
Bangalore
innovitae.in

Prathap Vasu C
Founder & CEO

The company offers a comprehensive range of clinical research services to clients, including site management, site monitoring, clinical research training, regulatory services, and additional services

07

Insignia Clinical Services
Delhi
insigniacs.com

Amardeep Singh Hunjra
Director

The firm offers customized, timely managed and goal oriented solutions for requirements related to regulatory affairs, clinical trials, non-clinical studies, medical writing & pharmacovigilance

08

Safevig Solutions
Hyderabad
safevigsolutions.com

Dr. Krishna C. Vallabhaneni
Co-Founder,
Sridivya Palacharla
Director - Operations

A clinical research organization that provides end-to-end services will meet all your needs, through all phases of clinical trials, expertise in clinical trials involving drugs, vaccines, biosimilars, and medical devices

09

Xplora Clinical Research Services
Bangalore
xplorahealth.com

Hasan Ahmed
Director

A fastest growing clinical research organization specializing in the stipulation of management and conduction of clinical trials with its various aspects, also offering a fully integrated package and service for its clients globally

10

Zenovel
Ahmedabad
zenovel.com

Rakesh Sutariya
CEO & Managing Director

With 17+ years of experience is committed to providing a comprehensive solution to the pharmaceutical industry, also specialize in clinical research, GMP, and regulatory affairs to ensure safe and medicine introduction

Industry Outlook TOP 10
CLINICAL TRIALS
SERVICE PROVIDERS - 2024

SAFEVIG SOLUTIONS

ELEVATING CLINICAL RESEARCH WITH EXPERT BIO-PHARMACEUTICAL SERVICES

The clinical trials market, a cornerstone of medical advancement, is experiencing unprecedented growth. According to Fortune Business Insights, the market size, valued at $54.24 billion in 2022, is projected to reach $92.45 billion by 2030. As active contributors to this landscape, SAFEVIG Solutions, a clinical research organization has observed key factors propelling this expansion and have strategically positioned them to lead the charge.

Sridivya Palacharla, Director of Operations

Dr. Krishna C. Vallabhaneni Co-Founder

Factors Fueling Growth

The surge in clinical trials is attributed to several key factors. Technological advancements in medical research, coupled with innovative trial designs and digital health solutions, have streamlined processes and attracted substantial investments. Chronic diseases have heightened the demand for new therapeutic interventions, further boosting the need for clinical trial services. Regulatory bodies globally are expediting drug development efforts, leading to increased investments from various sectors.

Enhanced connectivity and globalization of trials have broadened patient access, fostering more inclusive clinical trials. Post-COVID collaborations among pharmaceutical companies, CROs, and academia spur innovation and investments in clinical trials.

Strategic Positioning of SAFEVIG Solutions

SAFEVIG Solutions holds a strategic position and revolves around innovation and excellence, offering a comprehensive spectrum of services from clinical operations to technology solutions. This integrated approach addresses both safety and efficacy concerns for drugs progressing through various phases.

"Our adaptability ensures compliance and expedites trial timelines. Focusing mainly on pharmacovigilance in all trial phases is particularly advantageous for small to midsize pharmaceutical companies", shares Dr. Krishna C. Vallabhaneni, Co-Founder.

State-of-the-Art Technologies

SAFEVIG Solutions strategically integrates cutting-edge technologies, including automation, artificial intelligence, and machine learning, in clinical trials, notably in pharmacovigilance. These advancements enhance event monitoring, ensuring precision, while collaboration tools improve communication among cross-functional teams. Automated systems ensure regulatory compliance, upholding the highest standards in quality, efficiency, and patient-centricity in clinical research services.

Quality Assurance

SAFEVIG ensures efficiency and quality under Director Sridivya Palacharla's oversight. Regulatory affairs prioritize compliance through meticulous submissions and engagement with health authorities. Clinical data management emphasizes real-time access for trial accuracy. Biostatistics procedures ensure robust statistical analysis, and advanced technologies which enhance adverse event monitoring. Quality assurance is upheld through regular audits and ongoing training, ensuring compliance with evolving standards.

Regulatory Compliance

SAFEVIG tailors strategies to meet region-specific requirements, navigating complex regulatory frameworks. Adhering to the European Medicines Agency's (EMA) guidelines in the EU and aligning with the FDA's requirements in the U.S., the company internally establishes timelines with buffer periods, minimizing the risk of missing regulatory deadlines. Ethical practices are integral, fostering transparency, honesty, and respect in participant recruitment, informed consent procedures, and drug safety monitoring.

Future Plans for Expansion

SAFEVIG is proactively incorporating AI tools into its pharmacovigilance initiatives, positioning itself for expansion across multiple sectors including clinical data management, biostatistics, regulatory affairs, medical affairs, and pharmacovigilance technology. Additionally, the company is introducing innovative solutions while actively pursuing opportunities in previously unexplored geographical regions. With a dedicated focus on leveraging the capabilities of artificial intelligence and blockchain technology, SAFEVIG invites readers to join its journey in advancing healthcare through clinical research. Dr. Krishna emphasizes, "Together, let's shape a healthier and more promising future for patients worldwide".

INDUSTRY INSIGHTS

MANUFACTURING INNOVATIONS ACROSS INDUSTRIES: INSIGHTS FROM PHARMACEUTICAL EXPERTISE

● **By Andiappan Murugan,** *Vice President - R&D API, Troikaa Pharmaceuticals*

Andiappan achieved his Post Doctorate in Chemistry at UT Southwestern Medical Center in 2006. With 18 years of research experience in the pharmaceutical sector, he specializes in synthetic chemistry, showcasing exceptional scientific and leadership skills. His ability to blend classical wisdom with modern innovations equips him to address intricate challenges effectively.

Andiappan Murugan
Vice President - R&D API

What are some significant changes in manufacturing related to technology that has enhanced in terms of efficiency, quality etc. affecting pharma and broader industries?

In recent times, manufacturing has witnessed remarkable technological advancements that have greatly enhanced efficiency and quality, impacting not only the pharmaceutical sector but also various other industries. One notable transformation has been the extensive automation integrated into manufacturing processes. High levels of automation and continuous manufacturing have become prevalent, supported by the utilization of online tools for real-time process monitoring. Additionally, in the realm of research and development (R&D), there is a significant emphasis on Quality by Design (QbD) and enhanced process comprehension. Improved chemical understanding and the integration of advanced instrumentation for material analysis have ushered in a new era of manufacturing precision.

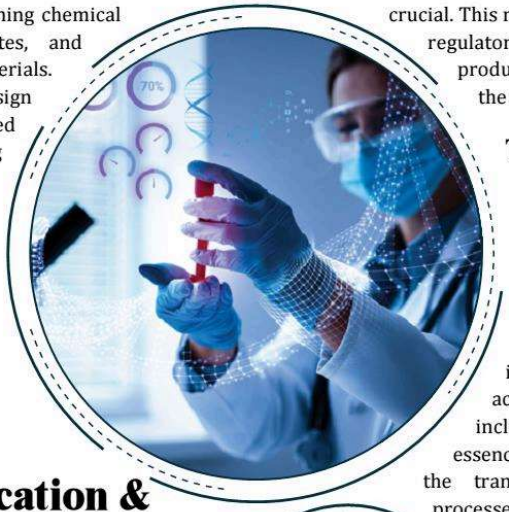
Furthermore, the industry has seen the emergence of cutting-edge software solutions, particularly in simulation, which has revolutionized the assessment of product quality, manufacturing efficiency, and output consistency. This has, in turn, reduced the reliance on manual labor and increased productivity. From an R&D perspective, a shift toward a science-based and risk-based approach for material quality attributes has marked a significant advancement.

Moreover, the integration of artificial intelligence and machine learning software has gained momentum, influencing technologies like 3D printing, which have the potential to revolutionize final product manufacturing. These innovations collectively represent the substantial progress witnessed in the manufacturing sector.

How have Route Design, Process Design, and Quality by Design improved safety and effectiveness in pharmaceuticals and beyond?

The enhancement of safety and effectiveness in the pharmaceutical and industrial sectors through improved design processes and quality by design principles is a critical aspect. The focus here is on the optimization of manufacturing pathways, especially in the pharmaceutical

industry. This involves streamlining chemical steps, minimizing intermediates, and selecting high-quality raw materials. By employing quality by design principles, the process is refined to identify optimal operating methods. Metrics like process mapping and mass intensity are used to measure efficiency. The goal is to achieve consistent quality, yield, and minimal waste in the development and production process.



Open communication & seamless collaboration are indispensable tools for ensuring efficient technology transfer, enabling manufacturing sites to adapt suitable equipment & absorb the new technology seamlessly

What are the challenges and opportunities in developing and manufacturing complex generics, and how your experience has contributed to overcoming these challenges?

The increasing significance of complex genomics in today's market presents both challenges and opportunities in the development and manufacturing of such genetics. Complex genetic products differ from typical ones, as their characteristics are less defined due to structural nuances and being shaped by the production process itself. Achieving equivalency standards in complex genomics is less straightforward. However, recent advancements in analytical techniques allow for better product characterization, understanding of nuances, and precise micro-level analysis. Effective communication with regulatory authorities is key to establishing product standards. Additionally, collaboration with experienced professionals in the field is crucial. This multi-faceted approach, involving regulators and domain experts, ensures productive product development in the complex genomics domain.

Tell us how can seamless technology transfer enhances product quality in both pharmaceuticals and other industries.

Seamless technology transfer plays a pivotal role in enhancing product quality across various industries, including pharmaceuticals. The essence of technology transfer involves the transmission of knowledge and processes to a manufacturing site, be it for a single component or an entire product line. To ensure its success, a robust process development is essential, encompassing a comprehensive grasp of critical process parameters. This entails a deep understanding of factors like heat transfer, mass transfer, reaction kinetics, and hydrodynamics within reactors.

Effective technology transfer necessitates advanced collaboration between research and development teams and manufacturing units. This collaboration facilitates a profound comprehension of the process intricacies and product specifics. Moreover, it aids in establishing a robust process, driven by data-based relationships between critical process parameters and key quality attributes. Statistical analysis, response surface methodologies, optimal query analysis, and enhanced process understanding further contribute to a successful technology transfer.

Open communication and seamless collaboration are indispensable tools for ensuring efficient technology transfer, enabling manufacturing

sites to adapt suitable equipment and absorb the new technology seamlessly.

> This multi-faceted approach, involving regulators and domain experts, ensures productive product development in the complex genomics domain

Navigating evolving regulations is crucial. How do you align CMC strategies with dynamic requirements?

Navigating evolving regulations is crucial when aligning CMC strategies with dynamic requirements. Implementing regulatory requirements into the product lifecycle presents significant challenges. During development, the CMC strategy, which dictates control activation, is primarily guided by ICS and product-specific guidelines established at the product's inception. However, unexpected regulatory changes can pose roadblocks to manufacturing, as seen recently in the pharmaceutical industry.

To address these challenges, a deep technical understanding of the chemical process and the use of in silico software are essential. Not all products contain the same complexities, and regulators may accept variations based on sound chemistry understanding. When facing challenges, it's crucial to comprehend the reasons behind regulatory changes, their impact on your products, and how they align with regulatory pathways. By gaining clarity on these aspects, many regulatory issues can be effectively managed.

What trends do you foresee shaping the future of pharmaceutical manufacturing? How can the industry stay ahead of these trends to maintain high standards of quality for consumers?

When considering the future of pharmaceutical manufacturing over the next five to ten years and the imperative to align with evolving trends while upholding high-quality standards, several noteworthy developments come to the forefront. Firstly, the automation of manufacturing processes has been gaining traction, although not universally adopted. In the coming decade, it is foreseeable that a substantial majority, potentially 80-90 percent of manufacturers, will have embraced automation extensively. This transformation will be further facilitated by the integration of AI and machine learning, simplifying automation implementation.

Continuous manufacturing is another pivotal trend. It has been gradually gaining prominence and is poised to revolutionize the production of pharmaceuticals. With its innovative potential, continuous manufacturing promises to enhance both product quality and productivity, making it a vital element in meeting industry targets.

Moreover, the adoption of online monitoring tools and 3D printing will significantly impact quality control and production efficiency. These technological advancements are poised to play a vital role in achieving industry objectives, potentially extending to the point where AI-controlled processes yield products directly from 3D printers. Overall, these trends represent an exciting trajectory for pharmaceutical manufacturing, promising increased efficiency, quality, and innovation to meet the needs of patients and consumers.

INDUSTRY INSIGHTS

INDIAN AGRICULTURAL COMMODITY PROCESSING

● **By Rahul Kamath,** *Director, Bolas Agro*

Rahul Kamath, an experienced professional with expertise in the processing of agricultural commodities in India, is well-versed in the dynamic nature of the industry. His proficiency lies in effectively addressing the intricate trends and challenges faced by food manufacturers in the country. In a recent conversation with Thiruamuthan (Correspondent, Industry Outlook) Rahul delved into industry-specific quality control measures and certifications. Additionally, he highlighted essential sustainability practices, technological innovations within the cashew manufacturing sector, initiatives supporting local farmers, and endeavours promoting sustainable agricultural practices in India and many other African countries. Below are the excerpts from the exclusive interview –

Rahul Kamath
Director

What industry-specific quality control measures and certifications are crucial for ensuring the safety of agricultural commodities like cashews, coffee beans, edible oil, almonds, and dry fruits?

Ensuring the safety and quality of agricultural commodities like cashews, coffee beans, edible oil, almonds, and dry fruits involves industry-specific quality control measures and certifications. In cashew processing, adherence to ISO 22000 and HACCP standards is crucial for maintaining hygiene and ensuring the final product meets accepted safety standards, especially in larger facilities. The coffee bean industry, while requiring hygiene standards, may focus on certifications such as UTZ or Rainforest Alliance to address sustainability and social responsibility concerns. Edible oil production, being directly consumed, demands stringent measures, with certifications like ISO 22000, and HACCP playing a vital role in ensuring safety throughout processing and packaging. For almonds, certifications like Global G.A.P. and HACCP are important for safe agricultural practices, while ISO 22000 and HACCP are relevant for maintaining food safety standards in dry fruit processing.

Could you outline key sustainability practices that are becoming prevalent within the agricultural commodity processing and export sector in India?

In the agricultural commodity processing and export sector in India, key sustainability practices are emerging to address challenges such as post-harvest damage and underutilization of by-products. To tackle post-harvest losses, there is a growing emphasis on adopting efficient treatment plans, particularly in crops like cashews, where exploration of mechanical or artificial drying processes is underway to salvage yields during challenging weather conditions. Additionally, initiatives focusing on the underutilization of by-products, such as cashew apples, are gaining traction. Efforts to maximize the use of cashew apples, rich in vitamin C and fiber, not only contribute to reducing waste but also aim to boost farmer income sustainably. Furthermore, in the broader context of Indian agriculture, there is a push for improved infrastructure, including cold storage facilities, to mitigate market rate uncertainty and ensure the preservation of agricultural products.

What technological innovations are currently influencing the efficiency and sustainability of food manufacturing processes in this industry?

Over the past 15 years, the cashew processing industry has shifted from manual to highly mechanized methods, with specialized machines for tasks like shelling and blanching. This technological transformation has significantly enhanced

Initiatives like artificial drying methods support local farmers, enhancing the sustainability of India's cashew manufacturing industry

efficiency, scalability, and overall product quality, minimizing breakage and contamination. Technological evolution in cashew processing has boosted labor efficiency, reduced man-days, and shifted the process to be predominantly mechanical, minimizing human involvement. These advancements not only enhance efficiency but also contribute to sustainability by allowing flexible production adjustments based on demand. Unlike the past, where manpower constraints limited production adjustments, the current mechanized approach allows for more responsive and adaptable changes, fostering a more sustainable and efficient cashew processing industry.

In the context of the cashew manufacturing industry, what initiatives are supporting local farmers and promoting sustainable agricultural practices in India?

The key approach to supporting local farmers and promoting sustainable agriculture in India's cashew manufacturing industry entails adopting artificial and mechanical drying methods, as specified in the proposal. The strategy aims to improve cashew quality and ensure a stable market for growers, especially crucial during the concentrated harvest season in April, May, and June. Recognizing the unique annual crop cycle, efficient post-harvest processing is emphasized. To counter post-harvest price drops due to bulk cashew availability, the proposal suggests an on-farm drying concept. This supports farmers by enabling prompt processing and storage until September and October, aligning with higher demand and prices during festivals.

From an industry perspective, what are the prominent trends and challenges impacting food manufacturers of agricultural commodities in India today?

Food manufacturers in India face challenges in maintaining consistent high-quality products, particularly in the agricultural sector, where seasonal variations affect raw material quality. Adhering to global standards and addressing the inherent variability in agricultural commodities is essential for establishing and sustaining a brand that meets consumer expectations for consistent quality and satisfaction. Food manufacturers in India also confront supply chain challenges, requiring efficient storage and transportation infrastructure to manage the impact of seasonal fluctuations. Staying informed about trends in sustainable and ethical sourcing, as well as meeting the demands of a growing health-conscious consumer base, adds complexity to the industry.

How can dry fruit and cashew manufacturers boost their market presence and attract health-conscious consumers?

In response to the heightened health consciousness observed during the COVID-19 pandemic, dry fruit, and cashew manufacturers enhance their market presence by strategically promoting the nutritional benefits of their products. They prioritize clear communication of immune-boosting properties and overall health advantages, particularly in areas such as heart health, diabetes, and reproductive health, through informative packaging and online platforms. Targeted advertising and promotions focused on the health benefits, leveraging social media and health-related publications, effectively reach and resonate with the health-conscious consumer base. Diversifying product offerings, introducing innovative variants, and incorporating health-friendly features such as low-sugar or organic options attract a broader audience. To enhance credibility and visibility, dry fruit and cashew manufacturers should prioritize transparent sourcing and collaborate with health influencers. Aligning marketing strategies with health-conscious trends and ongoing innovation establishes them as prominent players in the health-focused consumer market.

AFTERWORD

FIVE MAJOR STEPS TO EASILY AUTOMATE YOUR PROCUREMENT PROCESS

By Arun Krishnamoorthy, CMO, Techpanion

Arun Krishnamoorthy
CMO

Arun is an Experienced Techno-Commercial Professional, with a demonstrated history of working in IT sector. Skilled in Marketing, Solution Selling, Business Modelling, Customer Relationship Management, Strategy and Business Process Reengineering.

Procurement is a crucial aspect of businesses. It plays a vital role in expansion and optimization of industries therefore it involves obtaining goods and services including sourcing, negotiating terms, making purchases, tracking when supplies are received and maintaining records. When all the parts are done efficiently, it leads to increased business profitability and archived targets. It's important to monitor and recheck the procurement process to ensure best results.

1. Digitize Supplier On-Boarding

This is the process of gathering information and data needed to set up an organization as an approved vendor or supplier. This step enables any company to efficiently conduct business, purchase goods and services, and make payments to said supplier. Supplier on boarding also requires checking the prospective supplier and making sure it is in compliance with laws, regulations and corporate standards of the organization.

2. Automated Contract Management

Automated contract management involves the use of software to enable legal and non-legal teams to self-serve on routine legal documents, and replace the lawyer work with automation software. It can be understood as the process of generating, managing, and storing contracts digitally to create a more efficient contract workflow. It is used to strengthen admin tasks and reduce businesses overheads. This helps businesses by providing a simple contract lifecycle by transforming analog manual processes into a digital automated workflow.

3. Quick Supplier Resolution via Multi-channel Communication

Quick supplier resolution via multi-channel communication means fasten the shareholder resolution process of approving vendors by the Vendor of the Shares, the Comtek Business and the Assets to the Purchaser. Multichannel communication refers to a company's way of communicating with customers over several different platforms, including, social media email, SMS, webinar, personal meet and more helping improve the customer experience.

4. Easy Integration with ERP & Other Portals

The easy integration for procurement with Enterprise Resource is an important role to ease the process. It involves a planning business software that simplifies the way businesses track, manage and work with data for managing inter-departmental department management seamlessly. A business might use an ERP to keep track of inventory levels for each of its products and orders.

> **Voice bots are gaining mainstream use in every corporate industry and transforming human-machine interaction**

5. Track Master Data & Actionable Insights

Track master data and actionable insights absolutely essential for procurement and running operations within a business enterprise or unit. Tracking master data is the coding system which specifies the item level. It helps list each product and service with its own standardized, generic description accurately and uniformly by expert analysts.