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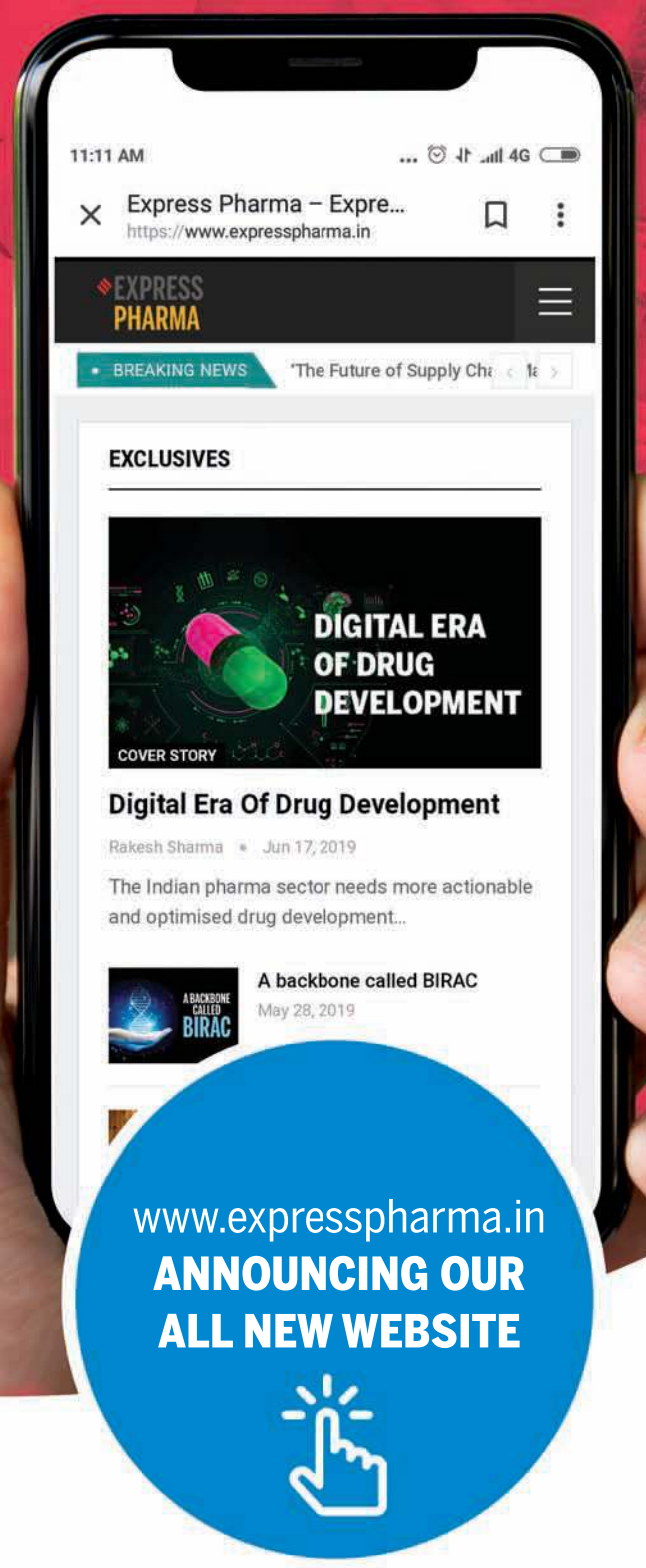

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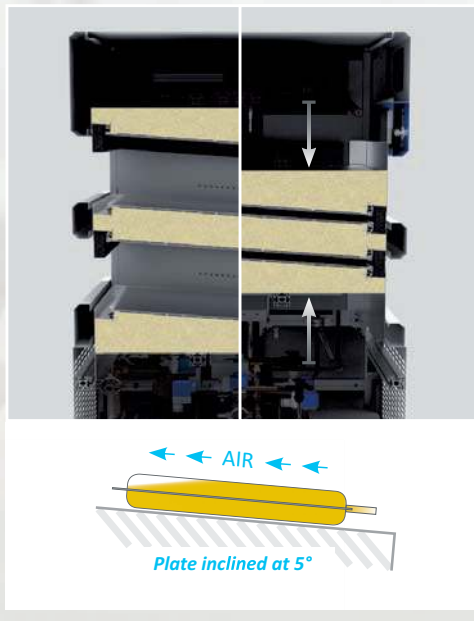

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The Covaxin-WHO EUL saga

The WHO issued the much-awaited Emergency Use Listing (EUL) to Bharat Biotech's Covaxin on 3rd November. The vaccine has not yet been approved for pregnant women, as 'available data on vaccination of pregnant women with the (Covaxin) vaccine are insufficient to assess vaccine safety or efficacy in pregnancy', as per a WHO statement. Studies in pregnant women are planned, including a pregnancy sub-study and a pregnancy registry.

Earlier on the same day, India's CDSCO extended Covaxin's shelf life from the current six to 12 months. And on 1st November, Covaxin, along with Chinese firm Sinopharm's BBIBP-CorV, was 'recognised' by Australia's vaccine regulator, the Therapeutic Goods Administration (TGA), for the purpose of establishing a traveller's vaccination status. Underlining the importance of this decision, at a time when the WHO EUL was still in the pipeline, PM Narendra Modi tweeted his thanks to his Australian counterpart H E Scott Morrison calling it "an important step forward in the post-COVID partnership" between the two countries.

These announcements will come as vindication for Bharat Biotech's management, but the process has deep learnings for all stakeholders.

Additional data requests and clarifications have marred the Hyderabad-based vaccine maker's journey from its 19th April application for an EUL to its grant on 3rd November. The latest ask, as per media reports quoting company sources, was for additional information including reportedly immunogenicity data for over 60-year-olds, as well as gender-wise split data on immunogenicity and efficacy of the vaccine. While other nations have been accepting Covaxin on a reciprocal basis, the WHO explained that asking for additional data and clarifications was part of its routine assessment guided by the recommendations of the Strategic Advisory Group of Experts on Immunization (SAGE).

A series of tweets from the WHO in mid-October explained that the timeframe for the WHO EUL procedure is dependent on how quickly a company producing the vaccine is able to provide the data required for WHO to evaluate the vaccine's quality, safety, efficacy and its suitability for low- and middle-income countries. It added that when the information provided addresses all questions raised, WHO and the Technical Advisory Group will complete the assessment and come to a final recommendation whether to grant an EUL to the vaccine.

While the WHO was "aware that many people are waiting for WHO's recommendation for Covaxin to be included in the COVID-19 Emergency Use Listing," it reiterated that they "cannot cut corners - before recommending a product for emergency use, we must evaluate it thoroughly to make sure it is safe and effective."

Manufacturers will need to cover all bases from the start, as the regulatory process will only get more stringent and competitive

The WHO has also gone on record to state that Bharat Biotech/Covaxin was not singled out. A PTI report dated 29th October quotes Dr Mariangela Simao, Assistant Director General, Access to Medicines and Health Products as saying that the agency's process was 'transparent,' that they had "daily conversations" with the company for clarifications on data required and Bharat Biotech had been submitting data on the EUL of Covaxin "regularly and very quickly" to a technical committee.

Reiterating that the WHO "trusts" the Indian industry that manufactures high-quality vaccines, Dr Simao made the point that another Indian COVID-19 vaccine (Serum Institute of India's Covishield) was approved in 30 days. Additional clarifications were also sought on the two Chinese vaccines as part of the approval process. One received an EUL a month after the first technical advisory group meeting, while the second got an EUL after six weeks.

In the 3rd November release, Dr Simao noted that this EUL expands the availability of vaccines but also cautioned that "we must keep up the pressure to meet the needs of all populations, giving priority to the at-risk groups who are still waiting for their first dose, before we can start declaring victory."

WHO's SAGE noted that Covaxin is extremely suitable for low- and middle-income countries due to easy storage requirements, an indication of the vital role of such jabs in ramping up supplies to the WHO's COVAX initiative.

However, Dr Bruce Aylward, Senior Advisor to WHO Director General Dr Tedros Adhanom Ghebreyesus, had flagged more serious concerns, saying "there were a number of inaccuracies in the way the issue was presented."

Manufacturers will need to cover all bases from the start, as the regulatory process will only get more stringent (and competitive). Today, there are reportedly as many as eight COVID-19 vaccines under WHO EUL consideration. Therefore, regulators can afford to up the ask, to keep pace with evolving understanding of this pandemic's progress. Manufacturers across the globe must, thus, be allowed time and allocated resources to keep pace with the latest global procedures and data requirements, in real time for rolling reviews.

More importantly, the vaccine sector will have to re-set its expectations. Regulators cannot make exceptions, even in the midst of a health crisis. While geo-political reasons might delay the process, hard data will stand the test of time.

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INTERVIEW

Hydroponics market is expected to grow at a CAGR of about 26 per cent by 2023

Aarthi Janakiraman, Research Director, TechVision, Frost & Sullivan, talks about the status of hydroponics market in India, its advantages and role for the pharma industry, and the scope for growth, in an exclusive interaction with **Akanki Sharma**

> In the pharma industry, hydroponics can be used to cultivate nutraceutical compounds and botanical extracts, especially for Indian traditional medicine systems. While some well-known hydroponic farms acknowledge this high-growth opportunity area, not many companies are working towards it

What is hydroponic farming, and how can it contribute to the pharma industry? Name a few companies that are active in this space and are adding value to the industry.

Hydroponics is a method of growing plants in a water-based, nutrient-rich solution. The roots are suspended in a purified water system that is enriched with nutrients. Instead of using soil, the root system is supported using an inert medium such as perlite, Rockwool, clay pellets, peat moss, or vermiculite. Hydroponics allows the plants' roots to come in direct contact with the nutrient solution while also having access to oxygen, essential for proper growth. Hydroponics caters to a host of challenges such as water and arable land shortage, global warming, overuse of harmful pesticides and fertilisers, among others. Few active players in this domain include Simply fresh in Hyderabad, GreenTokri Farms in Pune, Argos Greens in Khopoli, Madhavi farms in Bengaluru, HMAGreen Hydrofarms in Chennai, Srivardhan Biotech in Kolhapur and Nature Fit in Delhi-NCR.

What is the current market scenario of hydroponic farming in India as compared to the other parts of the world?

In 2019, the Indian Hydroponics market was estimated at 3100 Metric Tons (MT) and valued at Rs 35 crores. The market is expected to grow at a Compound Annual Growth Rate (CAGR) of about 26 per cent to reach 10,500 MT by 2023. With the increased commercial acceptance of hydroponic produce for exotic vegetables, demand is expected to pick up. However, the market is characterised by heavy competition from low-priced conventional farms supplying exotic vegetables. With the growing popularity of the technology, the competition has intensified, with over ten startups and large business groups entering the business over the last three-to-four years. The hydroponics market in India is still nascent compared to established segments in countries such as the US, western Europe, Singapore and China. However, due to the high untapped market potential, there is a fair playground available for the existing and new players.

What are the various challenges and opportunities for hydroponic companies when it comes to working for the pharma sector? How are these taken care of?

In the pharma industry, hydroponics can be used to cultivate nutraceutical compounds and botanical extracts, especially for Indian traditional medicine systems. While some well-known hydroponic farms acknowledge this high-growth opportunity area, not many companies are working towards it. Simply Fresh is a company that has the first-mover advantage in this segment.

Hydroponics as cultivation technology is well-suited for the growth of medicinal herbs. Studies have proven that the plants and herbs grown in this method have more nutritional content than traditional agricultural practices, mainly due to the controlled environment and constant monitoring. Plants such as ashwagandha, ginger, turmeric, shatavari, etc., are easy to grow in this technique.

Pharma and nutraceutical industries have more stringent guidelines and standards to maintain, which can be challenging to adhere to for small-scale farmers. There is also a need to invest in R&D to customise hydroponics techniques to cultivate medicinal plants, especially as the nutrient content and bioavailability of nutrients is of paramount importance. This can increase the burden of the already capital-intensive technology.

Joint ventures among small-scale farmers to establish cooperatives etc., can help distribute costs. However, considering the number of pre-dominant players is less than

ten and small-scale farmers are spread across the country, it's easier said than done. This can be adopted in western and southern India considering the higher number of hydroponic farms compared to other regions. Availing government subsidies, vertical integration with nutraceutical and traditional raw material suppliers can boost the use of hydroponics in pharma and nutraceutical segments.

Tell us about the technique of milking the plants for pharmaceutical applications. At present, how often and for what specific purposes is this technique being used by the industry?

Plant milking technology is traditionally based on the aeroponic cultivation of plants. It can be customised to hydroponics cultivation. The technology involves the recovery of active ingredients and botanical extracts from roots and other plant parts. A vital advantage is that the recovery is non-destructive and is sustainable and recyclable compared to traditional Active Pharmaceutical Ingredient (API) development. Currently, the technology is being used (still in emerging stages) in the cosmetics and personal care industry. Clariant is spearheading the efforts in the personal care industry. In India, companies are not actively pursuing this technique due to various factors like:

- ◆ Precedence and comfort of the traditional methods of extraction
- ◆ Nascent stage of hydroponics in India
- ◆ Focus on cultivating leafy greens and exotic vegetables gaining popularity amongst HoReCa and retail consumers, making this segment a more attractive ROI
- ◆ Need to adhere to guidelines and standards in case of using the technique (and even traditional hydroponic methods) for pharma and nutraceuticals for domestic and export markets.

How active and aware is the Indian government about hydroponic farming in India for pharmaceuticals and nutraceuticals? Are there any projects going on in the country in regard to this? If yes, kindly give details about the same.

Both central and state governments have subsidies for capital costs incurred for hydroponic farmers. The percentage of subsidies differs from state to state, ranging anywhere between 20 and 60 per cent. Hydroponic farmers can also avail credit-linked assistance from the National Horticulture Board under its hi-tech horticulture project. There is still ambiguity in governmental sops and tax credits. It is still unclear if GST is applicable for hydroponic produce and if the guidelines classify it under agricultural income. Clear guidelines from the government can help in increasing the growth of hydroponics in India.

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INTERVIEW

Bayer Consumer Health aims to reach 100 million households over the next five years in India

Sandeep Verma, Country Head, India, Bayer Consumer Health Division talks about the change in consumer preferences, emerging trends, evolving mindset due to the pandemic, as well as plans for driving business growth, in an exclusive interaction with **Lakshmipriya Nair**

What is the market size of consumer health in India?
Today, India is amongst the top 10 consumer health markets in the world and is the fastest-growing market, globally. We believe that by 2029, India will become one of the top three markets in the world. Bayer Consumer Health aims to reach 100 million households over the next five years in India. Our brands are already reaching roughly 40 million consumers. So, the plan is to more than double this reach and expand access for both the urban as well as rural consumers.

Tell us about the shifts and trends in consumer healthcare. How has the pandemic impacted growth in this space?
The pandemic has drastically reset our priorities. Consumers in India are becoming increasingly health-conscious and proactive about their health, both in terms of prompt treatment of the existing conditions and preventive treatment to boost immunity and wellness. However, to enable effective self-care, there is a need to provide reliable health information as well as innovative OTC products catering to daily health needs.

Two big needs have emerged during the pandemic amongst the consumers in India. Firstly, the level of stress has increased a lot and so have stress-induced headaches. Secondly, the need to build our immunity and energy levels and proactively protect ourselves is a lot higher now. In order to meet these evolved healthcare needs, we have recently relaunched our core brands Saridon and Supradyn.

Saridon, the headache relief solution, relaunched with 'Sar dard chhupao nahi, mitao' positioning itself as the first line of defence for relieving headaches. The genesis of the campaign lies in its category-first insight that, young adults today face frequent stress-induced headaches caused by the increase in responsibilities and associated factors like WFH-led screen time increase, financial stress, etc. However, they choose to silently suffer from the pain instead of acting on it. Leveraging its iconic five-decade-long legacy, the household staple brand's campaign appeals to the heroism drive of the resilient young Indians to make Saridon's innovative triple-action formula their secret ally in finding relief from their headache.

Further, Supradyn was relaunched with an improved formulation containing 5X zinc and 12 essential vitamins for greater energy and immunity. The brand's first-ever consumer campaign 'Sahi poshan harr din, khane ke saath supradyn', is rooted in the insight that an average Indian diet meets only up to 70 per cent of one's daily nutrition requirement, according to nine out of 10 doctors and nutritionists from urban India, as per a recent survey conducted by us.

Which are the fastest-growing categories in this sphere? What are their key drivers?
Overall, the industry growth during the pandemic has largely come about from the nutrition category, especially from the immunity segment, with the increase in demand for immunity-boosting products.

In general, the pandemic has brought a heightened focus on health and nutrition, particularly in line with ensuring adequate immunity and energy levels to tackle present-day health challenges. It has changed the way in which consumers seek care with individuals now increasingly opting for self-care solutions, so that they can take charge of their health. One challenge that the industry needs to work on more, is to also provide consumers with better quality of information which can lead to more responsible self-care.

As we are trying to leverage this higher health awareness and the greater need to find self-care solutions, we are also trying to provide consumers with the best-quality information which can lead to better choices. Both our re-launches - Saridon in June and Supradyn in September - are steps in that direction of combining the right products with the right information.

We will also continue to work on bringing innovations in digital technology that can transform self-care by empowering people to maintain and improve their health. The widespread adoption of technology gives people the information, support and convenience they need to manage their health more proactively. Digitalisation can thus be leveraged to provide individuals with high-quality health information.

How is Bayer strategising to optimise the growth potential in consumer health? Which are its focus areas and why?
At Bayer's Consumer Health division, our vision is to make self-care for a better life a reality for billions of people around the world through everyday healthcare. We touch billions of lives all over the world, helping provide them with safe, convenient and effective daily health solutions to treat minor illnesses and improve their lives.

The launch of the Consumer Health Division in India in May 2021 has received a positive response from the consumers. In India, the division currently offers ten brands, with segments focussed on pain management, nutrition, dermatology and allergy. We will be driving these four categories as our major focus areas in the coming years. We aim to drive our expansion via a digital-led approach and increased accessibility by making the product available at multiple touch points. Our goal is to leverage our portfolio in both the urban and rural markets with a focus on enhancing accessibility, crafting new products, and also raising awareness on self-care. Over the next five years, Bayer aspires to expand access to

everyday health and reach 100 million households in India with our self-care products. This is in line with Bayer's overarching vision of 'Health for all, Hunger for none,' and we are focussed on improving human lives while ensuring nobody is left behind along the way.

How has the regulatory and operating environment for Consumer Health changed in India?

Effective laws and well-defined regulations are essential for the smooth functioning of the OTC market in India so that consumers can be well-informed of the relevant health information, the right kind of responsible self-care in line with their needs. These are necessary to define preventive health options as well as those that do not require a prescription. The industry bodies have been closely working with the health authorities to put together the OTC Policy for India.

Globally, information on each product within the OTC space is available, but India still needs laws mandating defined regulations for OTC medicines. This will help circumvent challenges in the Consumer Health space while also supporting responsible consumer behaviour and providing a level-playing field for all companies operating in consumer health. Further, the OTC space in India is still at a nascent stage. The penetration across all these categories in the sector is still low. The core task we will endeavour to do is make the OTC market size bigger across the categories (pain management, nutrition, etc.) that we are present in. Our focus is to get more consumers to adopt these categories so that they can proactively manage their health and consequently also reduce the stress on our primary healthcare systems.

What are the most important steps that need to be taken by both, stakeholders and regulators, to streamline this segment and spur growth?

As previously mentioned, there is a need for effective laws and defined regulations for the smooth functioning of the OTC market in India. In India, our contributions are closely linked to national priorities and we aim to contribute towards 'Digital India' through the creation and delivery of digital technology services across crop science, pharmaceuticals and now consumer health, with a focus on increasing access to information and tailored solutions for farmers, patients and consumers. Bayer Consumer Health also plans to launch a national self-care knowledge service which will be a digitally-enabled solution, backed by scientific expertise, to empower consumers with uninterrupted access to credible self-care information.

We have announced the launch of a Self-Care Council in India. The focus of the council's discussions and work will be on identifying how the creative industry can address pressing topics including misconceptions about health, brand sustainability and to inspire and generate interest with other companies as well as to partner in addressing global challenges in consumer health. Educating our consumers remains a key global and national priority while we deliver self-care solutions. We are excited to bring this council and key insights and learnings generated from its global experiences, to India.

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INTERVIEW

India has robust manufacturing capability with sufficient skilled manpower to foster innovation

Poornachandra Tejasvi K, Senior Director - Emerging Markets, India, Pharma Intelligence, talks about shifts and trends in healthcare, growth opportunities and challenges in Indian biopharma industry, its role towards global harmonisation for biopharma regulatory guidelines and drug discovery, advancements in biologics, cell and gene therapy, vaccines and biosimilars segments, and more, in an interaction with **Lakshmipriya Nair**

Give us an overview of the major advancements, shifts and trends in healthcare and lifesciences due to the COVID-19 pandemic. How will these spur investments in the research and manufacturing of biopharmaceuticals in India?

The pandemic made the world rethink the way of doing business across industries. It's no different for the biopharma industry. One of the major disruptions seen in 2019-2020 was the immediate need to ensure that the production of raw materials critical for the development of drugs and vaccines and other essentials for maintenance of the healthcare system was not affected. However, with multiple countries around the world going into lockdown to contain the spread of the pandemic, there was a large-scale shortage and an inability to access raw materials due to international transportation restrictions and protectionist measures. This made businesses reconsider and rethink the way they sourced their raw materials from a single source/country. Experts have underscored the need to build resiliency through diversification to offset risks posed by factors such as natural disasters, political upheaval and disease outbreaks.

> On the policy front, the Indian government has set the right tone by offering incentives for areas like cell and gene therapy apart from building self-sufficiency in active pharma ingredients (APIs). Now, the industry needs to follow through with the right intent and execution

Over the past few years, lifesciences companies have faced intensifying pressure from many directions, including cumulative regulatory necessities, constant technological advances and intense pricing pressure. Moreover, the unprecedented pandemic has accelerated the need to modernise compliance and upraise the value and partnerships within syndicates as well as external stakeholders.

India is an emerging hub in the biopharma and biosimilar industry and currently tops the chart for domestically-approved biosimilars and clinical trials surpassing the US and Europe. Hyderabad is a major scientific and R&D hub with over 800 lifesciences companies and an emerging destination for biopharma, biosimilars and vaccine manufacturing in India. Given India's prevalence of cancer, diabetes, rheumatoid arthritis, respiratory and other immune-mediated diseases, there is a need to manufacture affordable biosimilars and further develop novel approaches in biologics and vaccines, and revolutionise cell- and gene-therapy manufacturing. Pockets of promise have already emerged - for instance, a startup backed by the Indian Institute of Technology and the National Cancer Institute in the US, which has been the "knowledge partner" for the research effort, hopes to deliver a cut-price CAR-T cell therapy.

There is also an unmet need to cater to India's rare and neglected diseases where our capabilities in biopharma and vaccines can be explored further.

With the lessons learnt from the coronavirus pandemic and prior biological calamities, it is important to have a further structured ecosystem for pursuing different variations in the biopharma and lifesciences space to manage future biological risk.

India has already demonstrated its strength with COVID-19 vaccine manufacturing as well as developing its own vaccines. However, we cannot ignore the fact that there are individuals who are vaccinated, who can still be prone to infections with new SARS-CoV-2 strains, and a large part of the world still remains unvaccinated.

On the other hand, business and manufacturing automation also saw an unprecedented uptake to ensure that business continuity was in place and optimised, based on the challenges that they encountered. Repurposing of already approved molecules for additional indications, including the COVID-19 virus, was also looked into. During this period, digital acceptance grew to unprecedented levels across industries that changed the way research and

development, sales and marketing, learning and development, health care professional engagement, etc. were conducted. Almost all documentation from the laboratory, the regulatory departments, to the doctor's clinic, became paperless. Even audits were carried out in real-time and remotely. The pandemic is also estimated to have triggered the development and release of a tsunami of digital health apps in 2020.

The pandemic has underscored the need for global benchmarks of quality and supply reliability for pharma/biopharma products. So, as a major player, how is the Indian biopharma industry working towards global harmonisation for biopharma regulatory guidelines and drug discovery?

The rigorous and robust regulatory process in the biopharma segment can, at times, lead to uncertainties in approval timelines for products. During the pandemic, various regulatory bodies, governments and pharmaceuticals companies came together to find solutions to fast track development and approval timelines in view of the unprecedented situation. In doing so, they were able to collaborate towards regulatory transparency, continuous dialogue with regulators, advance mutual recognition agreements (like the FDA has with EU member states, etc), application and acceptance of digitisation of records. This is an ongoing process, and will potentially be the way forward to ensure an effective and streamlined regulatory system.

India has also been moving towards Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) membership, but needs support from across industry/stakeholders. The pandemic has also shone the light on the potential to accelerate regulatory processes as well as the importance of partnerships and transcending boundaries both in R&D (as we saw for COVID-19 vaccines) and on the regulatory front.

India has been working to address concerns around long approval timelines; for instance, setting up a new API manufacturing plant in India historically could require securing several approvals from multiple departments of state and central governments. With multiple regulatory bodies directly or indirectly engaged in framing rules and guidelines for the pharma and bulk drug segments in India, this can, at times, lead to sub-optimal allocation of resources at the policy-making level. However, for instance, the new Production Linked Incentive (PLI) scheme for active pharmaceutical ingredients (APIs)/key starting materials (KSMs) aimed at self-reliance and securing the country's medicine supplies, provides for time-bound clearances. Approval timelines have also been streamlined in the clinical trial segment in the country.

Access and innovation are the buzzwords in the lifesciences industry, not just in India, but across the world. So, which are the focus areas for the industry to build and accelerate progress on both these fronts? Why?

The most important buzzwords in the lifesciences industry globally are 'innovation' and 'access'.

While these have been well known in the industry earlier, the pandemic has spotlighted the multiple roadblocks to 'innovation' and 'access' to the forefront and full view of the world.

Innovation - The pandemic has served to spur biopharma research and development (R&D) backed by the multi-billion dollars provided by governments to support the development of vaccines and drugs. However, the 'Big Pharma' remains continuously in the hunt for new assets amid some challenges in late-stage development, as evidenced by continued targetted licensing deals and mergers and acquisitions, while investment flows into the biotech/bio-venture sectors remain strong.

Oncology remains the main R&D focus globally, with the now well-established immuno-oncology approaches and newer modalities such as gene therapy, and even "post-gene therapy" research continuing to progress. Rare diseases continue to generate interest given the high medical need and the possibility of profitable niche positions amid limited competition. Meanwhile, completely new options such as digital therapeutics continue to nudge the 'Big Pharma' interest, investment and deals.

The pandemic-related difficulties in recruiting and running clinical trials have accelerated the development of new approaches to this phase of development including decentralised trials, the use of virtual tools and remote monitoring, as well as the greater exploration of real-world evidence in the R&D process. Multiple initiatives are underway at major regulatory agencies globally to guide these changes and build them into processes in the future.

Access - Continuing inequities in global access to COVID-19 vaccines have cast a spotlight on wider issues around access to new medicines and medical technologies, and some of the existing global COVID vaccine distribution programmes have missed their targets. While companies have recently renewed their commitment to the COVID-19 Vaccines Global Access (COVAX) facility, the R&D-based industry continues to be generally opposed to intellectual property waivers around the vaccines, instead of focusing on increased production capacity and selected licensing deals.

More broadly, the innovative pharma industry continues to be involved in multiple individual company schemes, such as patient-assistance programmes, to improve access to selected products. At present, much of the access debate is focussing on the costs of newer and expensive, but often highly effective, technologies such as gene and cell therapies.

The industry faces the challenge of communicating the broader health and economic benefits of these one-time treatments. Part of its approach has also been to encourage holistic debate on the funding and efficiency of healthcare systems and the overall economic benefits of new medicines to create sustainability and the financial headroom to accommodate such treatments.

What is the strategic approach needed for India to move away from mere incremental innovation and become a global player in innovative drugs? What are the strengths to focus on and the challenges that can hinder the country from achieving its research and innovation potential?

It is well-known that investment in research and development across sectors is the only way to remain competitive in the age of globalisation. With a population of around 139 crore Indians, there is no dearth of talent. However, the focus on developing high-quality scientific breakthroughs has not been a focus area for many years. With the pandemic forcing individuals, organisations and institutions to bring out frugal and scalable solutions to solve the multitude of healthcare and other problems that the country was facing, there were a large number of solution providers that came forward to save the day.

Now that it's evident that talent is available but has to be nurtured, a long-term approach needs to be followed with:

- ◆ a focus on nurturing scientific talent at the entry-level as seen in the approach of the Indian Pharmaceutical Alliance (IPA).
- ◆ fostering more industry-academia collaboration for breakthrough research.
- ◆ building separate R&D set-ups/subsidiaries with sufficient funds and autonomy.

Innovative startups should be spotted and encouraged early on with financing, so they don't have to look offshore for support. Venture capital firms should step in where publicly-held companies are unable to. Another route for achieving the goal of accelerated high-quality research is through partnerships with global research-based biopharma companies, and companies like Biological E and Gennova Biopharma are set to bring cutting-edge mRNA technology via this route.

On the policy front, the Indian government has set the right tone by offering incentives for areas like cell and gene therapy, apart from building self-sufficiency in APIs. Now, the industry needs to follow through with the right intent and execution.

India has robust manufacturing capability, with sufficient skilled manpower to foster innovation and the COVID-19 vaccines developed by Bharat Biotech and Zydus Cadila are examples. The challenge lies in shifting focus from easy gains to a high-risk approach that might not always be welcomed by shareholders, but could yield dividends in the long term.

At the same time, one needs to remember that India's "Pharmacy of the World" status is on account of the economically viable drug options it engineers, without which several low- and middle-income countries would be bereft of options. The COVID-19 vaccines are a classic example of the invaluable contribution India makes globally.

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INTERVIEW

India constitutes about 80 per cent of world Ayurveda market

Dr Ram H Shroff, Director, Charak Pharma, informs **Akanki Sharma** about the market scenario of Ayurveda and the role played by his company nationally as well as internationally in boosting this market

Give us a brief on the overall Ayurveda market and its relevance to today's and future's unmet needs.

Ayurveda market is consistently growing and the growth is stupendous. The current world market of Ayurveda is around $6.5 billion, which is expected to grow by a CAGR of 15.63 per cent p.a., and is projected to reach $21 billion by 2028.

Ayurveda has, and will always be the most relevant and accessible and effective therapy in India, as it is rooted in our culture over centuries. It is becoming more and more relevant in today's environment. We have witnessed the increased acceptance of the efficacious Ayurveda remedies through the recent COVID times too.

The Ayurveda market in India is valued at about $5.2 billion at present and is expected to reach $9.2 billion by 2025, expanding at a Compounded Annual Growth Rate (CAGR) of 16.06 per cent.

Ayurveda encompasses the essence of good mental and physical health through

herbal formulas and adopting healthy lifestyles. Chronic lifestyle diseases and weak immunity are the current health hazards and the answer to them is Ayurveda. Going forward, acceptance of Ayurveda world over will only accelerate.

Right from babies to elderly, Ayurveda has natural solutions for all. It helps improve all chronic diseases, neurological issues, beauty concerns and the overall health and wellness conditions. So, the future for Ayurvedic products is promising and growing.

How are the current investment and competitive landscapes in Indian Ayurvedic medicine industry?

Ayurveda medicine industry is highly competitive with multiple players in the traditional and generic segment. However, adherence to the strict quality standards and good manufacturing practices has been the major issue for a majority of the smaller players. Further, recent advancements like use of standardised extracts in place of raw herbs, modern manufacturing techniques and quality control, and scientific validation are playing critical role in the competitive landscape of Ayurveda.

Charak, due to its dedication and experience of over seven decades, is well-known for its stringent quality norms and efficacious products that are patronised by the medical fraternity. Well-researched formulas made by Ayurvedic experts, standardised raw materials and state-of-the-art WHO-GMP-certified manufacturing facilities are the key factors that have contributed to the Charak's core competence.

With Ayurveda gaining accelerated attention, many areas of growth are opening up. Besides manufacturing of Ayurvedic medicines, Ayurveda tourism, ever-growing personal care and wellness and cultivation of medicinal plants are the promising opportunities of investment and growth.

> Ayurveda has, and will always be the most relevant and accessible and effective therapy in India, as it is rooted in our culture over centuries

Where does it stand when compared worldwide?

India constitutes about 80 per cent of the world Ayurveda market. Ayurveda today has its own standing in the world market and it will continue to grow as the increasing lifestyle diseases demand an alternative and effective holistic approach for better treatments.

Ayurveda is officially recognised as a system of medicines in 16 countries including Switzerland, Brazil, Cuba, Hungary, Nepal, Sri Lanka, Pakistan, Bangladesh, the UAE, Oman, Saudi Arabia, Bahrain, Malaysia and Mauritius. The World Health Organization (WHO) has selected India to set up a traditional medicine centre to strengthen research, training and awareness of Ayurveda.

Today, Ayush products are exported to more than 100 foreign countries as medicine or food supplements. The global market of Ayurveda is growing and will continue to expand further at a high growth rate in future.

Any exclusive achievements?

Charak has been manufacturing and marketing well-researched, proven, safe and effective health solutions for users across continents for 74 years and enjoys a strong equity amongst medical practitioners.

It has WHO-GMP, ISO-certified state-of-the-art manufacturing units to serve the customers with the products conforming to the stringent international quality standards.

Apart from it, we have a strong R&D infrastructure having hundreds of years of collective experience and expertise of the doctors. Our Laboratory is accredited by the Department of Scientific and Industrial Research, Ministry of Science and Technology.

In addition, we introduced herbal management for PCOS with Hyponidd tablets more than two decades ago. Our M2Tone has to its credit various unique clinical studies and is a leader in its category of female health and fertility ailments and is being trusted and prescribed by over three generations of the gynaecologists across the country. Our Addyzoa is the first line of treatment endorsed by doctors for male functional infertility. Currently, we have Endotone for endometriosis, unique in this segment.

What are the major factors influencing India's business scope in Ayurvedic medicine?

Growing inclination now of the general population towards natural products to manage lifestyle and chronic diseases, awareness of Ayurveda and herbs that they are free of side effects and that they can be used safely for children as well as elderly senior population, easy accessibility to information on Ayurveda and herbs and availability of branded Ayurvedic medicines from credible sources make it convenient for the customers' increasing preference for Ayurveda.

In addition, the well-informed consumers today demand natural products free from harsh chemicals, in particular, for beauty and personal care segment. The same is true for the demand for the supplements and nutraceuticals for the overall well-being and health.

Also, the positive policies of the government favouring Ayurveda through the Department of AYUSH are creating a favourable environment for the growth of the sector.

What are the business threats and impacts of the latest scenario on the Ayurveda medicine market and growth?

Threats are shortage of raw material and increase in their prices, and mushrooming of low-quality Ayurveda companies. Today, anyone and everyone is trying to market their products under Ayurveda's name without any previous trustworthy exposure. So far, only 16 countries have recognised Ayurveda as an acceptable system of medicine. To garner the worldwide acceptance for it, the Indian corporates need to come up to the norms of the international-quality parameters, including traceability, sustainability and documentation.

What steps are Ayurvedic players adopting to expand their regional footprint in growing economies?

Charak already exports in 30 countries. We have our manufacturing facilities approved by the authorities of various importing countries. What works is the scientific rationale combined with the age-old proven Ayurvedic formulas, well-studied and clinically-validated products and good ethical marketing practices and educating the countries about the science behind the natural herbal formulas and Ayurveda. The growing use of technology is helping to improve the reach of the Ayurvedic products to the international consumers.

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OPINION

How the nutraceutical industry is growing post-pandemic

Kamayani Naresh, Founder, Zyropathy, explains how the COVID-19 pandemic has made sure that the shift towards nutraceutical supplements is here to stay

During the COVID-19 pandemic, the idea of a salubrious body has evolved on a near-daily basis. People across the globe started making various changes in their lifestyles to stay safe. They started being open to all sorts of ways to nourish themselves. The different ways in which the virus affected people made it clear that every individual would need to enhance their health and personal levels of immunity. People realised they needed to depend on more than just medicines.

COVID-19 has proven to be an evolving virus that has proven to be challenging to be restrained and eradicated. No country has reached a fixed medical strategy plan that has had the same impact on everyone affected by the COVID-19 virus. The only way a population can fight the virus is through improving their immunity levels. A reliable, sustainable and prolonged immunity boost can be achievable only through dietary and lifestyle changes. Only then, can we reach a level of multitude immunisation that can help us subdue the spread of the COVID-19 virus and give the community a chance to fight and overcome any future health emergency.

The nutraceutical market is predicted to grow from $4 billion to over $18 billion by 2025

The nutraceutical market is predicted to grow from $4 billion to over $18 billion by 2025. The pandemic has made sure that the shift towards nutraceutical supplements is here to stay. In addition, nutraceuticals have been established through repetitious tests and studies as resistance boosters for the body's natural immune system. Thus, it supports in leading a healthier lifestyle for those who include the ingredients in their daily diet.

Indians alone bought supplements and immunity boosters worth over Rs 15,000 crores during the first wave of the COVID-19 pandemic. Having complete nutrition is an individual task that takes time to prepare. Unfortunately, we can hardly take time to ensure we intake adequate healthy food in our fast-paced life, and the world is unlikely to slow down anytime soon. Nutraceuticals go hand-in-hand with a fast-paced lifestyle and help you manage your diet and nutrition levels. People across the globe are opting to change their lifestyles to embrace more nutraceuticals in their daily diet. It further guarantees the growth of the nutraceutical industry.

Many companies are promoting different products to combat the virus as prevention is a nebulous umbrella term. However, none have proven to be an assured solution for everyone. The only way to overcome the virus's threat is to improve the immunity of everyone as a population. The home-grown Indian companies, which already had a grasp in the Indian markets, are now in demand in countries across the globe. Moreover, home remedies and dietary-must includes, which most Indians grew up with, have made their way into people's everyday lives across different cultures.

The nutraceutical industry in India has realised its potential to combat health issues in India amidst COVID-19 waves. The inclusion of potential nutrients and micro-nutrients like Vitamin A, Vitamin D, Vitamin C, folate, selenium and zinc in our daily diet has extensively increased our chances of better immunity. According to a Nutrition and Dietary Supplements study, many naturally-found ingredients and supplements can be included in a person's daily diet to gain immunity or strength against coronavirus and help prevent contracting any new strain of viruses. For example, everyone could incorporate plant-based compounds, leguminous seeds containing plant protease inhibitors and whey protein into their daily diet by including certain food ingredients.

India has a plentiful variety of ingredients for every nutraceutical, which helps generate income for local and indigenous businesses. Spices and herbs found only in India now have a global demand, making them a source of income. The Indian masalas and most of the recipes passed down through the generations include nutraceuticals and ingredients that have proven to help boost one's immunity levels and help their body recover faster from the COVID-19 disease.

With more and more recognition of Indian herbs and naturally-found ingredients as health and immunity boosters, the nutraceuticals industry is bound to get a worldwide audience. People have realised the importance of improving their lifestyles and dietary habits to help reinforce their immunity. The coronavirus was disruptive across the globe with the ease by which people contracted it. The possibility of a future with newer viruses has made the global population understand the consequence of a healthy diet that can help them stay immune against diseases and viruses. Along with the growing awareness that not everyone responds to all medication identically, it has been necessary for more people to include nutraceuticals in their daily diets and lifestyles. All this and more has given the nutraceuticals industry a surge in demand across the globe.

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PHARMA INFRA

GEARING FOR NEW REALITIES

As India Pharma Inc makes the shift from volume-based care to value-based care, it has to invest in robust R&D and manufacturing infrastructure, both physical and digital, to accelerate drug development and enable speed to market

By Lakshmipriya Nair

A complex and evolving regulatory landscape, the combined threat of existing and emerging diseases, innovative new technologies, need for agile R&D and manufacturing operational models, etc. are driving pharma and lifesciences companies to take diverse steps to increase their innovation potential, curb R&D and manufacturing costs, improve productivity and reduce time to market. Ramping up their physical and digital infrastructure is a key aspect of this endeavour and this requires careful design, equipment and technology planning and operation strategies.

For instance, animal facilities that are key to accurate R&D results or regulatory compliance of products need to be built by taking into account various aspects like compliance with standards in bioethics, animal and employee welfare, etc.

Likewise, building a combined GMP and bio-containment environment is a multifaceted undertaking that requires an equilibrium among various sets of requirements like biosafety risk assessment, use of new production technologies, use of modular solutions to ensure GMP and biocontainment, air management systems to maintain hygiene and biosafety procedures, etc.

So, in this article, let's examine some of the key considerations for the design and construct of multi-product pharma R&D and manufacturing facilities.

Flexibility and adaptability: It has become an imperative for new-age pharma facilities to be agile, adaptable and flexible, be it for research or manufacturing, to get the best outcomes, meet evolving market demands and regulatory expectations. Flexibility includes the ability to expand and allow reconfigurations easily to aid a variety of uses.

And, as companies expand their markets and product portfolios, it has become vital to be efficient and get rid of the need for new facilities for every new product. Thus, these facilities have to be multi-functional and multi-disciplinary, designed and built using optimised layouts and workflows, to encourage innovation, ensure the highest standards of quality and support the shift towards value-based care. As a result, the design of pharma infrastructure too is developing to meet budding demands and trends.

The need of the hour is to blend technical, healthcare and architectural concepts to create well-designed and effective pharma facilities that assist in optimal space utilisation and streamlining of workflows

Modern pharma labs and facilities have to be logically laid out and all the resources should be easily available. They have to be modular, flexible and scalable, said SM Mudda, Managing Director, Misom Labs, speaking at the Pharma LabNext Conclave 2021, recently organised by *Express Pharma*. He added that modern labs handle a lot of potentially hazardous compounds for highly potent drugs. So, lab design has to account for containing them while you're working in the lab. Likewise, in manufacturing, facility design should assure better controls, quality and safety measures.

Speaking at the same event, Naresh Narasimhan, Principal Architect and Managing Partner, Venkataramanan Associates, explained that designs for labs should not be inflexible spaces that will not be suitable five years later when an organisation's requirement changes. On the contrary, with the help of a lifecycle cost analysis, they should be modified or built in such a way that they can be refigured quickly to accomodate the extra services that will be needed in the times to come.

He asserted that flexibility balanced with functionality to change the very nature of the laboratory itself, indicating clever engineering, is crucial while designing a lab.

To cite an example, there are pharma R&D labs with movable benches and articulated arms fixed on the ceilings that travel along with the benches to deliver services. The aim is to rapidly and effortlessly restructure a lab to suit the change in workflows and shift to new projects without undertaking huge architectural and engineering overhauls.

Cohesive and collaborative: The lifesciences industry has understood the need to function in a collaborative milieu - both internally and externally. Therefore, apart from optimising cost, resources and technical performance, pharma facilities and laboratories also have to be holistic in design. As open science and R&D partnerships become increasingly important, pharma labs have to facilitate collaboration between individuals and teams, and provide integrated synergies to encourage creativity and innovation that support project goals.

Elaborating on this point, Narasimhan detailed how earlier labs were closed rooms with maybe fire doors or access doors, where each lab did its own thing and the interaction between scientists was fairly minimal. Now, as collaboration increases in the sector, one of the innovations is creating open labs with a lot of glass. Speaking about the work done by his firm, he said, "We put a lot of glass and the desk spaces of the scientists are very close to their workstations so they can move between them very easily. The goal is always to increase output and encourage innovation. We have created a lot of spaces in the laboratories, where scientists from these different disciplines, technicians as well as business leaders are able to meet and exchange ideas easily."

There are numerous such considerations about design, equipment and operation in new pharma manufacturing plants as well. Next-generation manufacturing, which is expected to be predictive and adaptive, will need design approaches and strategies that enable scalability, flexibility, innovation, quality and regulatory best practices.

Experts also reveal that the growing use of Internet of Things (IOT) in R&D and manufacturing environments are encouraging modular approaches in the design and construction of manufacturing facilities and labs in the lifesciences sector that will break down organisational and informational silos.

Design for technology

Pharma and lifesciences industries are in the course of upgrading processes, equipment and technology for enhanced efficiency and quicker product switches, especially since the onset of the pandemic. So, the need of the hour is to blend technical, healthcare and architectural concepts to create well-designed and effective pharma facilities that assist in optimal space utilisation and streamlining of workflows.

Yet, often it is found that the design of labs and facilities do not adequately plan for new equipment and technology solutions which can hinder productivity and cause glitches in the long run. Adoption of Lean principles in pharma infrastructure can help mitigate this challenge and usher new efficiencies.

Whether it is automation, AI or IoT or cognitive technologies, Industry 4.0 is playing out in the pharma industry. But Industry 4.0 has to

be supported by Quality 4.0. Therefore, we need smart quality management systems and digitally-enabled labs and facilities. Therefore, focussing on innovation and modern technology is the need of the hour. Consequently, pharma infrastructure trends are getting shaped by the need for smart and integrated labs and manufacturing facilities, opined Mudda.

Another speaker at Pharma LabNext Conclave 2021, Archana Salil, Founder Director and Principal Architect, Arena Consultants also stressed that digitisation of lab designing is the future. She said that the adoption of robots and cobots, increasing use of sensors, greener materials and technologies, etc. will grow increasingly in the design and build of pharma infrastructure.

She added that lab infrastructure costs will rise with digitization, but things are going to change drastically and will move in a positive direction.

Thus, the design and build of pharma infrastructure are beginning to reflect and imbibe the emerging technology/innovation trends. For instance, automation and digitalisation have brought in an era of smaller lab equipment that can integrate multiple laboratory functions, thereby saving bench space, resources and capital.

Sustainability

The pandemic has made the world sit up and pay heed to the fact that the global environment is sensitive to human activity. So, it is no longer possible to put sustainability on the back burner. And, the pharma industry, as a key stakeholder in global health security, needs to embrace it in a big way. Concerted efforts are required to build and operate greener labs and facilities in ways that either minimise or negate their effects on the environment, especially since many organisations' existing infrastructure are not designed for sustainability.

Strategies to design and green pharma labs and manufacturing plants, be it renovating the current space or creating a new building, involve assessing the function of the facility, identifying areas that can be improved from a sustainability point of view and implementing measures, be it optimal utilisation of resources, better waste disposal systems, measures to conserve energy and water, or reducing carbon footprint.

Sustainable design comprises both, architectural and engineering considerations. For instance, overhangs, glazing, insulation, use of photovoltaic panels can

help in energy efficiency. Similarly, the right HVAC systems, harvesting rainwater, sustainable lighting strategies, maximising the use of natural daylight, etc. can also help with sustainability goals. It also involves the effective use of technology to maximise the impact of eco-friendly initiatives.

Fortunately, the industry is already integrating these aspects into their labs and facilities. At a recent event organized by *Express Pharma*, in association with SAP, a few ESG leaders spoke about how pharma organisations are investing in physical and technical infrastructure to further their sustainability agendas.

Rajan Sharma, Vice President and Head Corporate EHS, Glenmark Pharmaceuticals informed that Glenmark has used smart sensors to control air control units, heaters and chillers installed at manufacturing facilities to maintain the right temperature and humidity at all times. This aids to optimise use of energy, reduce wastage, capture data and gain insights for further process optimisation.

TRENDS IN PHARMA DESIGN

- Open-grid ceilings where utilities drop down for better space management
- Movable HPLC systems and work benches
- Open labs for improved collaboration
- Innovative ventilation strategies
- Use of green materials

DRIVERS OF PHARMA LAB AND MANUFACTURING FACILITY DESIGN

- Evolving regulatory requirement
- Added focus on quality
- Growing patient centricity
- Shift to personalised medicines
- Move towards Industry 4.0
- Workforce and resources management

Thakur Pherwani, Global Head SHE & Sustainability, Dr Reddy's Laboratories, detailed similar measures implemented as part of the 'Digital Lighthouse' initiative at Dr Reddy's Laboratories. The company is banking on digitalisation, be it manufacturing, quality assurance, R&D trials, to facilitate energy saving, waste reduction, productivity enhancement or equipment efficiency. The company is also looking to adopt carbon capture technology to curb emissions and alter waste into energy that can be used in different processes.

Bhavesh Trivedi, Head EHS, Zydus Cadila, explained how water conservation has been taken up in a big way at his organisation at their plant in Gujarat and the company's implementation of different trackers for water and energy consumption, etc. to gain actionable insights.

In times to come

Design and construction of pharma infrastructure in India are evolving to blend functionality with creativity as it strives to keep pace with the industry's ventures into new areas of innovation across products, processes, tools and functions. In the years to come, we will see many more transformations and newer trends coming into existence.

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INTERVIEW

It's an era of digital transformation

COVID-19 has forced organisations across the globe to take radical steps towards adopting technological advancements to secure their businesses, tells **Suresh Pareek**, MD, Ideal Cures, to ***Express Pharma*** in an interview, while also throwing light on how his company managed business during the pandemic and the future trends in pharma formulation and drug delivery

It is almost two years since we first heard of SARS-COV2 and the subsequent COVID pandemic. How has Ideal Cures responded to this crisis?

This pandemic situation was already on a rise in other countries, and as per the news updates, we envisaged that we would soon have a lockdown to curb the situation and the Maharashtra government called for a lockdown from 20th March. For three or four

days, our operations were totally shut down after all-India lockdown. Under essential services, we applied for permissions from the Maharashtra government and within a week, we resumed our operations.

Our main concerns were for our employees' physical and mental health. Therefore, we immediately implemented Work From Home (WFH) for sales and marketing and other desk jobs. This also allowed employees to spend more time with their families. WFH also increased the efficiency of employees as the travel time and travel stress were reduced completely, thus, bringing an increase in the performance output. We also saw a great deal of effort from our staff and workers who voluntary came to the plant for production.

In order to have continuous production and not hampering our customer requirement, we also made arrangement for workers to stay at the manufacturing sites so as to minimise outside environment exposure. We also managed shift timings as per the government guidelines.

We completed the vaccination drive for all our employees on time. Supply chain being a challenge, we were able to stock up raw material and cater to those companies dealing with the

> We await more details on INSTACOAT™ 5G and INSTACOAT™ Super Rapid Performance (SRP) 6G

COVID-19-related medicines, and, hence, we prioritised all urgent orders.

During this pandemic, to spread positivity and stay connected, we conducted several webinars under " Ideal Cures Smile Initiative." As a part of the CSR activity, we distributed sanitisers to different communities, societies, police stations and other offices.

What have been the learnings that will be part of business practices beyond the pandemic?
It's an era of digital transformation. COVID-19 has forced organisations across the globe to take radical steps towards adopting technological advancements to secure their business.

The disruption created by COVID-19 was unlike anything the new world had ever seen. Nobody was prepared for the world's second-largest economy, China, to go completely off the grid and shut down every one of its external logistical connections. And that's why global businesses had no choice, but to reconfigure their supply chains.

Playing an expanded role in their employees' financial, physical and mental well-being as part of the work-life balance. Re-configuration of supply chains and making resources more accessible are also the lessons learnt during this pandemic.

What are the pharma formulation and drug delivery trends you foresee for 2022?
The drug delivery is segmented into oral, injectable, topical, pulmonary, nasal, ocular, implantable and transmucosal types of formulations. The area of vaccination continues to evolve at a break-neck pace with more effective and acceptable novel vectors and techniques making their way into clinical use. With the advancement of these new rationally-designed vaccines, improved and more patient-acceptable delivery mechanisms are being developed to better target and sustain the pain-free injection of antigen. Because the majority of vaccines are still delivered with a hypodermic needle, either intramuscularly, subcutaneously, or intradermally, delivery is critical.

We will also foresee pulmonary drug delivery segment like metered dose inhalers (MDI), dry powder inhalers (DPI) and nebulisers.

What are new offerings from Ideal Cures in line with these trends?
We await more details on INSTACOAT™ 5G and INSTACOAT™ Super Rapid Performance (SRP) 6G.

OPINION

COVID virus and vaccines ... a review

Siddhartha Mitra, retired pharma professional, reviews the doubts, controversies and unexplained fears about COVID-19 and the vaccines to fight the pandemic

The world, for almost the last 20 months, is going through a turmoil named COVID. It has not spared any country, whether rich, developing or poor. The human race has experienced the unthinkable uncertainties, suffering and agony of losing the nearest and dearest ones with severe economic depression all around. Vaccines have come as a succour - hope to life. Though it is the only major weapon to fight COVID at the moment, it's not free of doubt, controversies and unexplained fears. The problem with the COVID virus is its fast mutation and severity with high viral load and transmissibility. From the onset of COVID, it has already passed through multiple mutations and the latest Delta variant has been found to be quite severe as for viral load and high transmissibility.

With no specific drugs and various unspecified treatment protocols, the only solution to fight the epidemic is vaccines. Vaccines build the defence system to fight against specific pathogens by creating targetted antibodies against antigens as antibody-antigen reaction.

Different vaccines and their roles

Vaccines are expected to offer prolonged immunity and protection. Its efficacy is related to immunogenicity, tolerability, time coverage and overall safety. Immunities are of two types - humeral and cell-mediated. By now, we are having a number of vaccines -Covishield, Covaxin, Sputnik, Pfizer vaccine, J&J vaccine, Chinese vaccine, etc. to fight COVID-19. So far, the major vaccine that is being used is of AstraZeneca-Oxford (Covishield), manufactured in India by the Serum Institute. Covaxin of Bharat Biotech is a complete Indian product that has also been used in good quantity.

The vaccines are safe, well-tried and tested and help in bringing herd immunity amongst people.

The actual situation

When we try to analyse the present situation in our country - post COVID and initiation of vaccination, the following status emerges.

◆ India administered more than 180 million doses in August which is more than total of all G7 countries (the UK, France, Germany, Canada, the US, Italy and Japan). The country has plans to vaccinate all adults by 21st December.

◆ Although the vaccines are well tried and tested, some people still develop few unwanted side effects, known as 'vaccine break through cases.' Usual side effects like fever, body pain and headache are common for a day or two.

◆ There was resistance from some percentage of population based on certain wrong conceptions and myth. Nevertheless, with constant information and education, this percentage has reduced.

◆ There is a probability of development of vaccine-resistant strain because of the very fast mutation of the corona virus.

◆ Strength and length of immune response varies from person to person in relation to available antibodies.

◆ Seroprevalance is around 10 per cent.

◆ Plasma therapy had been introduced and tried, even the plasma banks have been established - but the overall result is not at all encouraging. It increases the O2 requirement, respiratory failure, creates either low or non-functioning antibodies, and variable antibody levels are also affected.

Major areas of problem and confusion

The second wave, which started sometime around March-April 2021 shattered the total emergency medical system, as India was not prepared for that deadly situation. However, after unprecedented human tragedy where lakhs suffered and died, and perhaps few are still suffering with associated health problems, one positive thing that happened is the availability of repeatedly tested and trialled vaccines to counteract COVID. Though vaccines are all effective, tried and tested on their own ways, but there are limitations.

Those who are affected with the virus, positively develop antibodies which protect them from future infection. Scientists have observed that people's antibodies' level rapidly decreases, making them prone to repeat infection. Recently, another positive study confirmed long-lasting immunity with activation of antibodies producing cells in the bone marrow after seven/eight months following infection. This obviously raises hope of longer immunogenecity of vaccines after two scheduled doses. Activation of memory T cells also plays an important role. Nevertheless, rapid mutation and identification of Delta variant causes further doubts on the efficacy of present vaccines. There were suggestions of the third booster doses to counteract and ensure further safety. A small percentage has been fully vaccinated, but even that population still develops repeated infection. Known as 'vaccine break through case," it does not conform to the need of the third booster dose. Israel was the first country to start administering the booster dose to people aged above 60 years, and later on to all adults. Later, the UK started with the booster in people aged above 50 years and suffering with co-morbidities. According to the World Health Organization (WHO), till date, evidence of booster and its benefit remaining limited and in conclusive; it recently recommended the same for immunocompromised people though. Last 20 months taught all of us a good lesson on how important life is and self-education and awareness are the utmost crucial things to be followed for a long and healthy life.

INSTACOAT SFC

INTERVIEW

"We've only just begun"

The first series-built machines featuring B&R's integrated machine vision system have hit the market, and many more are set to follow in the coming months. **Andreas Waldl**, Product Manager - Integrated Machine Vision, B&R, talks about his experiences of those first customers to get a glimpse of what lies ahead

Andreas, tell us about the reactions you're getting from machine builders when they first use the B&R vision system.
They're positive. The unique integration of machine vision into the automation system opens up a lot of possibilities they didn't have before. I know a lot of machine builders who were initially just looking into basic quality inspection. But then they realised they could also use our camera to control production processes in real time and significantly increase productivity.

What industries has the B&R vision system been used

THE ADVANTAGES OF THE B&R VISION SYSTEM

The strength of the B&R's machine vision is its complete integration into the automation ecosystem. The cameras, intelligent image processing algorithms and innovative lighting portfolio are an integral part of the B&R control system. That has many benefits:

- Cameras, lighting, motion axes and all other machine components are synchronised with microsecond precision. Because of that, image processing results can be applied to control commands in real time.
- There's only one engineering system for development, deployment and diagnostics. Controls programmers are able to solve many tasks themselves that would have previously required a specialist.
- Rather than traditional programming, they simply assemble a machine vision application from ready-made mapp technology software components.

in so far?
Our system has a wide range of potential applications, and it's being used in nearly every industry you can think of. And not just in machines by the way, we also have customers using it as a high-speed camera for R&D. Since our high-performance LED lighting is so tightly synchronised with the motion control system, they can capture crisp and clear images of extremely fast movements with exceptional positioning accuracy and repeatability.

What trends have shaped the progress of machine vision technology over the past few years?

> The strength of the B&R's machine vision is its complete integration into the automation ecosystem

The most fundamental trend is that vision applications are growing increasingly pervasive. Cameras are no longer being used just for inspection, but also as an integrated sensor that can directly influence the production process. And, that's exactly the type of application our system is perfect for.

Where do you see the next big developments happening?
There are definitely a number of exciting things on the horizon. We've been evaluating which developments are relevant for our customers and how we can shape our portfolio accordingly over the next few years. I can't reveal any details at the moment, but I can tell you this much, “we've only just begun”.

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INTERVIEW

We have supplied ground-breaking and eco-friendly disinfection solutions for various industries

Dev Gupta, CEO, Sanosil Biotech, tells ***Express Pharma*** how the company has been working hard right through the COVID-19 pandemic providing affordable and reliable disinfection solutions for numerous industries, while also mentioning about its past achievements and future plans

Can you explain briefly about your company's portfolio?

Sanosil Biotech has been a pioneer and market leader in the H2O2-silver based disinfectant and fumigant segment for over two decades.

Our products are trusted by some of the most discerning multi-national and domestic manufacturing customers and are commonly found in the SOPs of some of the world's leading and most trusted pharmaceuticals and vaccine brands.

We have supplied ground-breaking and eco-friendly disinfection solutions for various industries including

pharmaceutical manufacture, hospital operating rooms, food and beverage, and agriculture, to name a few.

A significant new segment was added to our customer base in the course of the pandemic that focussed on facilities management. Over 15 million square feet of industrial and office space has been treated with Sanosil Biotech products and treatment partners, helping corporate India make its warehouses and offices safe to reopen.

What are your plans for the Indian market in the forthcoming fiscal? What kind of investment would be made in this market?
Sanosil Biotech has been working hard right through the pandemic providing affordable and reliable disinfection solutions for numerous industries, and we expect to continue with this momentum in the forthcoming fiscal.

We have added distribution to make our products more easily and quickly available for our customers. We also enhanced our sales presence to be able to reach more customers in these times with what has now become a mission critical product.

We are also preparing to launch an innovative line of ready-to-use products. We are extremely excited about this launch, as for the first time,

our disinfection solutions will now be available in the form of sprays and wipes. Our line of products stands apart from the competition in their eco-friendly safety profile.

In addition to our products, we reaffirm our commitment to our people, and continue to invest in them aggressively, to ensure personal growth at the individual level and career advancement for all.

What kind of growth do you envisage in the next three years? What would be the factors driving this growth?
Sanosil Biotech is a market leader with a significant presence in overseas markets. We are in the process of expanding our footprint in the domestic market with expanded representation and distribution.

There is an increased demand for aerial and surface disinfection solutions that we expect to continue for the next 12-18 months. Several new customer segments have come on line that are looking for the safety and reliability that our products offer.

The increased focus and demand for good-quality fumigants and disinfectants coupled with our consumer ready-to-use lines of products gives us a great deal of optimism and confidence that we will be looking at robust double-digit growth over the next two-to-three years.

Tell us about your international presence. Any plans to expand your footprints overseas?
As mentioned, Sanosil Biotech already has a customer-base overseas. We supply our products to customers in countries including the Middle East, Singapore, Thailand, Dubai, Sri Lanka and Nepal, to name a few. Our discussions and search continue with international partners with experience in selling and promoting our products, in order to increase our international presence.

What are the growth opportunities opening up in the pharma sector both, globally and in India after the pandemic? How poised are you to leverage these opportunities?
The COVID-19 pandemic has created a new reality and never-before envisaged demand for healthcare-related products. The primary player who is at the forefront of the war on COVID is the pharmaceutical sector.

Pharma and vaccine manufacturers are running at the maximum capacity, and they rely on our product to keep their manufacturing lines disinfected and sterile. Demand for our products is steadily on the rise and we are in continuous contact with our clients and customers. Our focus is to ensure that they have all the necessary support they need from our end to guarantee the quality and safety on their manufacturing lines, and by extension the critical vaccines and life-saving medicines they manufacture for the world.

What are you showcasing at CPhI this year and what are your expectations from the event?
Sanosil Biotech is going to showcase its product "Virosil-PHARMA- an eco-friendly disinfectant and fumigant" which is a well-established brand in the pharmaceutical and healthcare industry for more than two decades.

We would like to take advantage of the diversity of CPHL's attendees and delegates to showcase our product lines to the new and existing customers alike. We look forward to interacting with various stakeholders including but not limited to director technical / production head / research head / quality (QC) persons / micro departments / SCMS and others.

Sanosil Biotech's expectation from CPhI is to be able to connect with the relevant stakeholders and our customers and business partners to answer their questions and build awareness around the quality and reliability that is synonymous with our brands and newly-released product lines.

InstaSpheres

Make in India

Amit Sehgal, Managing Director, Avantor India, explains how 'Make in India' recognises 'ease of doing business' as one of the most critical factors to nurture entrepreneurs and startups in the life sciences industry, and its impact on the post-pandemic scenario

Make in India (MII), launched in September 2014, is one of the major endeavours by the Government of India to transform the country into a global manufacturing hub. Its primary objective has been to create a conducive environment to attract foreign investments, make India digital, develop a strong and efficient manufacturing ecosystem, generate additional job opportunities, and empower secondary and tertiary sectors.

The initiative recognises 'ease of doing business' as one of the most critical factors to nurture entrepreneurs and startups that are considered to be major drivers for the success of Make in India. Therefore, various steps are being undertaken under the programme to support them, including eradicating the unnecessary laws and regulations, making

bureaucratic processes faster and easier, and making the government more transparent, responsive and accountable.

At present, the programme focusses on the development of 25 priority sectors, including pharmaceuticals and biotechnology, that have high potential of attracting foreign capital.

Impact of Make in India on lifesciences industry

The lifesciences industry constitutes sectors such as biomedicine, pharmaceuticals, biophysics, neuroscience, cell biology, biotechnology, nutraceuticals and environmental sciences, among others. Let us take a brief view on how the MII programme has impacted the various segments within these industries since its inception.

Pharmaceuticals: The Indian pharmaceutical sector enjoys its position as the largest generic drugs provider in the world. This sector caters to more than 50 per cent of the global demand for various vaccines. It also has a wide network of more than 3,000 drug companies as well as about 10,500 manufacturing units operating within it1. Under the MII incentive, to build a self-reliant pharma sector, the government has taken various steps to enhance end-to-end manufacturing with the support of emerging technologies and processes, incentivising the production of raw materials, established bulk drug parks, and provided other stimulus measures to boost local production of Active Pharmaceutical Ingredients (APIs) and Key Starting Materials (KSMs).

Additionally, it is found that globally, every third new drug approved is a biotech drug, and with patent expiries of key biologics, biosimilars play a huge role in boosting the growth of pharmaceuticals. To effectively deal with roadblocks in biopharma production such as limited capital, inadequate infrastructure and complex regulatory framework, world-class bio-manufacturing hubs under MII are being set up to aid in the development and manufacturing of innovative products in various streams of biopharmaceuticals, including vaccines and biosimilars.

The growth in pharma sector is also propelling the laboratory chemicals market. The demand for high-purity chemical production, distribution and sales for usage in pharmaceuticals and biotechnology sectors accounts for almost 21 per cent of the chemicals industry. MII's 100 per cent FDI incentive and de-licensing of most chemical products' manufacturing has provided the chemicals sector accelerated research and development efforts as well as modernisation and digitalisation of processes therein.

Medical Devices: Identified as a sunrise sector of India under the MII campaign, this sector puts India amongst the top 20 global medical devices market and as the fourth largest in Asia. With a current market size of $11 billion, this industry is at the brink of massive growth in the next five years. With the help of MII and other government initiatives, the home-grown medical devices manufacturing, including In-Vitro Diagnostic (IVD) solutions, has enabled better accessibility of products to the general public as well as increased exports, globally. The provision of 100 per cent FDI allowance under the automatic route for both brownfield and greenfield setups has helped the domestic medtech companies to scale up their capabilities, furthering their growth and resilience.

Changing lifesciences landscape post-pandemic

Meeting the global raw materials' shortages: During the course of the coronavirus pandemic, India stepped up to help navigate through the sudden shortage of APIs due to international trade coming to an abrupt halt and global pharma looking at alternatives for China, the biggest exporter for APIs in the world. The country ramped up its strategies to build a strong local capacity for specialised and novel APIs to cater for the sudden rise in domestic demand for bulk drugs. To aid this, under the MII scheme, the union government announced a Rs 30 billion project for setting up three bulk drug parks, as well as a 20 per cent financial incentive for the next six years to manufacturers for producing 53 critical bulk drugs, which would be further used to make medicines.

Significant growth in In-Vitro Diagnostic (IVD) solutions: With around 750–800 domestic medical device manufacturers in India, the contribution of medical devices and reagents during the ongoing COVID-19 pandemic has been significant. The IVD segment provided consistent supply of COVID-related medical devices and diagnostic kits, including ventilators, RTPCR kits, IR thermometers, PPE kits and N-95 masks.

Accelerated vaccine development: We saw governments, organisations, pharmaceutical and healthcare sectors, along with the scientific community, united together in fast-tracking the development of COVID-19 vaccines. Within merely a year and a half, India rolled out two vaccines, with more candidates in the pipeline, such as Sputnik V and ZyCoV-D. What has been truly exemplary is the fact that the typical 10-year-cycle of vaccine development was drastically reduced to a year and furthermore, a developing country like India came out with not only locally produced vaccines, but also an indigenously developed one. The Indian government provided resilient support with the launch of Mission COVID Suraksha in November 2020 to help accelerate the efforts made in research and development of Indian COVID-19 vaccines that are safe, efficacious, affordable and accessible to all the Indians.

> The initiative recognises 'ease of doing business' as one of the most critical factors to nurture entrepreneurs and startups that are considered to be major drivers for the success of Make in India

Developments in diagnostics and research: The lifesciences industry was seen ramping up and continuously evolving the diagnostics tools for virus detection, for detecting infections in symptomatic and asymptomatic patients, researching antibodies from the recovered patients, and for discovering a potential vaccine or therapy. Various existing therapies, including monoclonal antibody (mAbs), that are typically used to treat autoimmune conditions like rheumatoid arthritis, were seen being fast-tracked back through clinical trials to ascertain their effectiveness in treating symptoms of COVID-19 to save more lives immediately.

Development in biopharmaceuticals: Within the biopharma segment, the government announced an outlay Rs 1,660 crores ($ 227.94 million) for biotechnology research and development under the Union Budget 2021-22. Moreover, with the driving need to accelerate and promote local biopharma scale-up needs, the Telangana government partnered with a reputed global lifescience company to set up a 10,000 sq.ft. Fast Trak lab that would help the area's biotechnology hub increase production efficiency, reduce cost and speed to market. Further, with the increased demand for monoclonal antibodies for testing on COVID-19 patients, pharma giants in the industry are exploring biological therapies for treating COVID-19.

Providing global assistance: Being one of the biggest vaccine developers in the world, India exported more than 60 million doses to 76 countries before the second wave of the pandemic resulted in acute short supply within the domestic market, putting an abrupt halt on exports. However, the sector is ramping up its production capacity to resume export of vaccines to the severely impacted countries by 2022. The pharma sector also increased exports of drugs that had the potential of treating COVID-19 infection with Remdesivir exports doubling in March 2021 to $14.8 million from $5.75 million in February 2021.

The pandemic has been an example to reflect how all the stakeholders within the industry – the private enterprises, government, investors, academic and research institutions, and individuals- can transform challenges into opportunities by creating a collaborative ecosystem. To truly unlock the potential of the Make in India programme, stakeholders need to continue to work towards a common goal of creating a self-reliant and innovative ecosystem that is supported by integrating advanced digital technologies, a responsive and robust regulatory environment and strong global ties.

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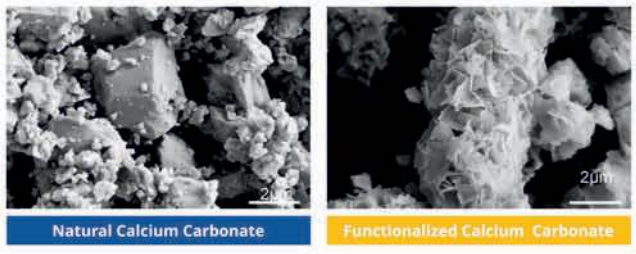

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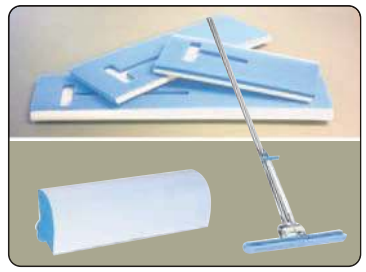

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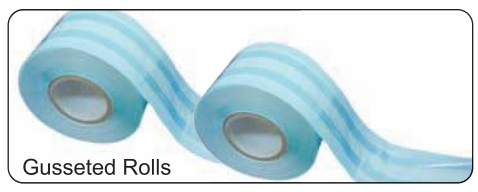

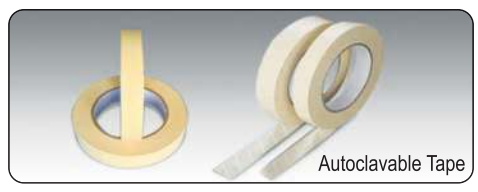

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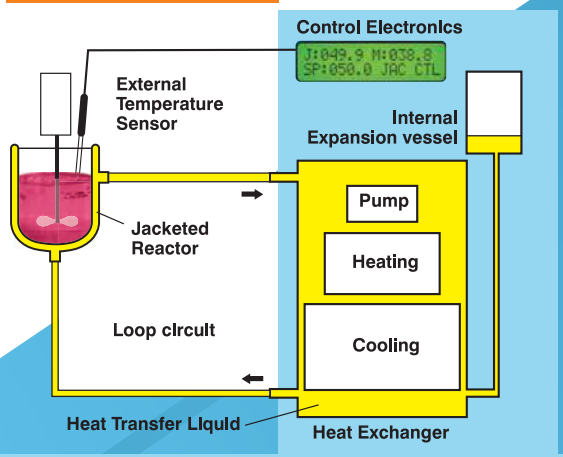

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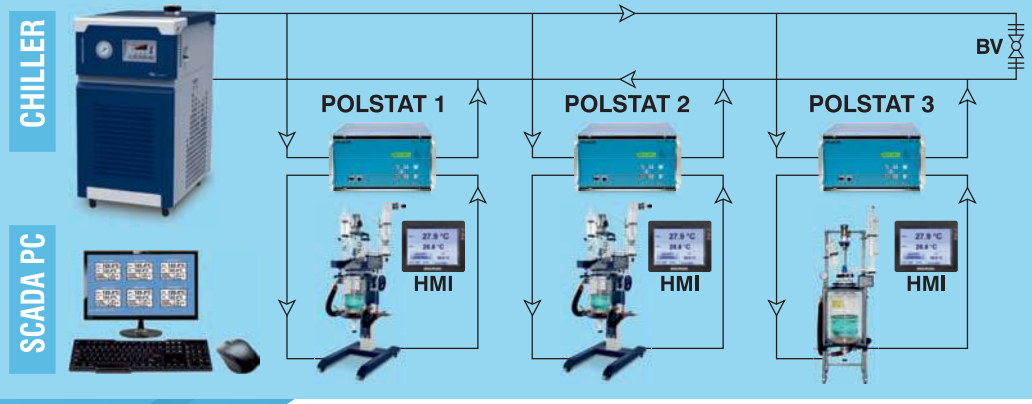

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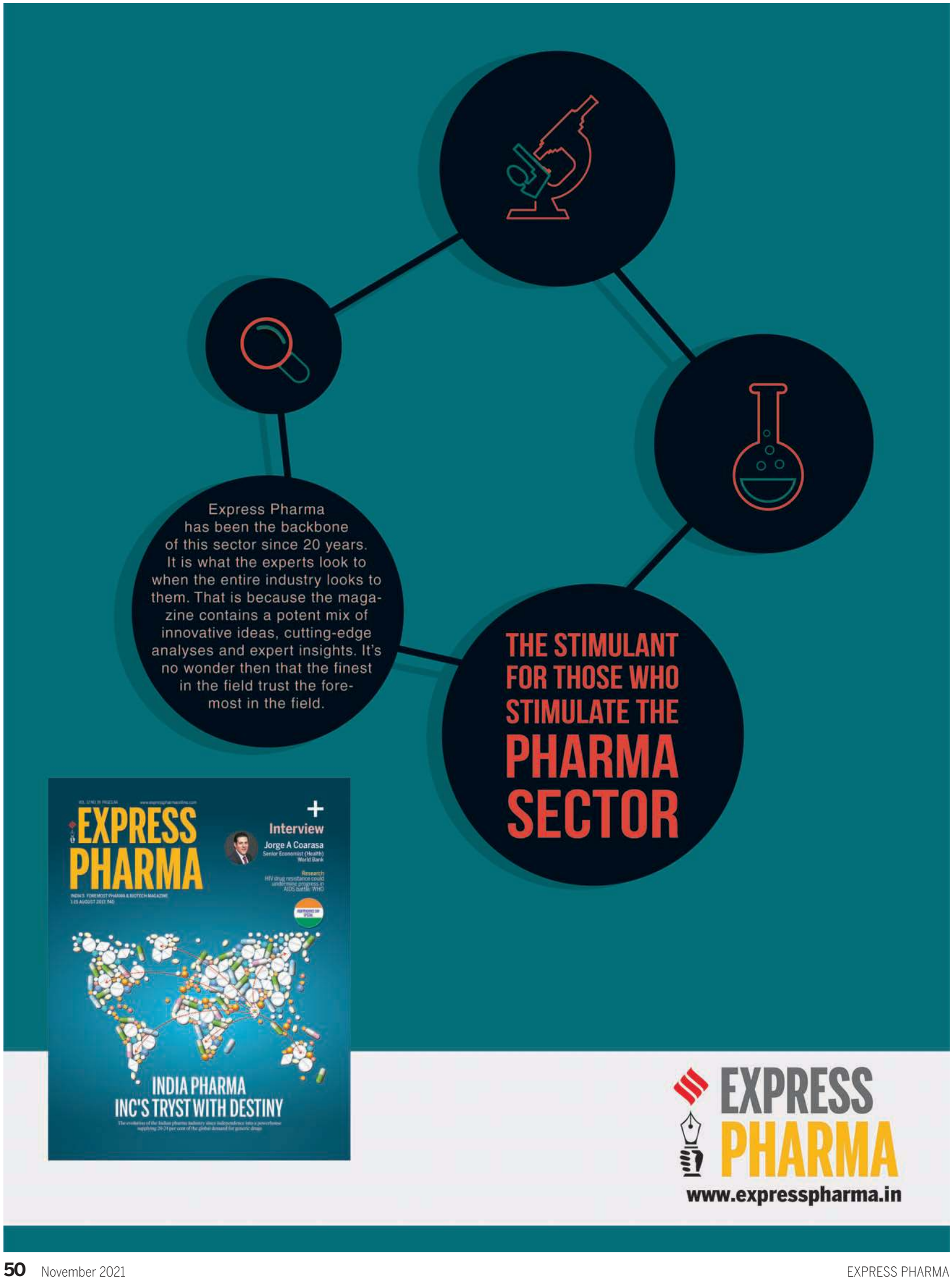
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Yokogawa enhances plant safety with IEC 61511-compliant Exaquantum Safety Function Monitoring

OpreX Asset Operations and Optimisation solution release delivers significant improvements in operational safety performance monitoring

Yokogawa Electric Corporation announced a major upgrade to its Exaquantum Safety Function Monitoring (SFM) software, an OpreX Asset Operations and Optimisation solution that helps to identify whether actual operating performance meets safety design targets. Improving health and safety is one of Yokogawa's six sustainability focus areas. SFM R3.35 provides continuous monitoring and evaluation of safety data to highlight deviations or failures in plant safety system performance.

Already in use across the globe in industries such as oil and gas, SFM collects all safety-related data to track and analyse key performance metrics, including Safety Instrumented Function (SIF) activations and maintenance (prooftesting), Independent Protection Layers (IPLs) and initiating causes and overrides. This new version now supports the International Electrotechnical Commission (IEC) 61511* standard and includes several new features to help SFM users identify potential safety issues, optimise maintenance activities and improve overall safety solution design.

Development background

Safety systems are designed to ensure that process plants are operated within tolerable limits, reducing risks to humans, the environment, assets and production continuity. To sustain the required safety integrity level, processing facilities must have a means for verifying the performance of their safety instrumented systems (SIS) during operations. Procedures need to be established and information must be collected that will ensure the quality and consistency of proof testing, demand rates and failure data of SIS. The challenge is determining if the real-time operating data can be verified against the analysis, design and assumptions to highlight deviations or failures in safety system design performance.

Yokogawa recognises the continuous challenges that plant owners face in trying to efficiently maintain process safety integrity over the entire life cycle of their plant facilities. As one component of a sustainable SIS solution, SFM automatically monitors operational safety data to quickly determine whether real-time operating data meets safety design targets and to track and analyse key safety performance metrics. Proof tests are recorded to track when they took place and identify when they reach their expiration date. SFM assists plant managers by identifying any potential safety issues, reducing unnecessary maintenance activities and improving the overall safety solution design.

Features

IEC 61511 compliant

IEC 61511 is a regulatory standard for functional safety in the process industry. It covers the design and management requirements for SISs throughout the entire safety life cycle.

SFM R3.35 employs a cause and effect matrix to quickly verify the logic of SIF activations and final element (valves, vents, actuators, etc.) actuations to see if they match their configured or intended safety design, as required by the IEC 61511 standard.

Enhanced proof testing

A proof testing status function has been added to SFM R3.35 for the monitoring of the expiration dates of proof tests on SIFs and final elements. Users can also claim proof test credit based on actual demand on the SIS during operation, with the functionality to record when proof tests have taken place, and their expiry date to help maintain the validity of the safety system.

PHA-pro compatibility

Safety configuration data for layers of protection analysis (LOPA) using PHA-Pro (a third-party software solution from Sphera) can be used to generate an initial SFM configuration file. A PHA-pro export template exports information from the LOPA in a format that can be imported into SFM.

Major target markets

Oil and gas production, oil and gas midstream, refining, petrochemicals, chemicals and power generation

Applications

Plant-wide monitoring, analysis and reporting of functional safety performance across SIS and final elements

More information:

https://www.yokogawa.com/solutions/products-platforms/solution-based-software/safety-management/safety-function-monitoring-exaquantum-sfm/

About OpreX

OpreX is the comprehensive brand for Yokogawa's industrial automation (IA) and control business. The OpreX name stands for excellence in the technologies and solutions that Yokogawa cultivates through the co-creation of value with its customers, and encompasses the entire range of Yokogawa's IA products, services and solutions.

This brand comprises the following five categories: OpreX Transformation, OpreX Control, OpreX Measurement, OpreX Execution and OpreX Lifecycle. Exaquantum is an OpreX Asset Operations and Optimisation family solution in the OpreX Transformation category, which delivers operational excellence throughout an enterprise's activities, from production through to supply chain optimisation and risk and business management.

For more information, visit https://www.yokogawa.com/solutions/solutions/oprex/.

About Yokogawa

Yokogawa provides advanced solutions in the areas of measurement, control and information to customers across a broad range of industries, including energy, chemicals, materials, pharmaceuticals and food. Yokogawa addresses customer issues regarding the optimisation of production, assets and the supply chain with the effective application of digital technologies, enabling the transition to autonomous operations. Founded in Tokyo in 1915, Yokogawa continues to work towards a sustainable society through its 17,500 employees in a global network of 119 companies spanning 61 countries.
For more information,
visit www.yokogawa.com

Reliable solutions for safe freezing and storage of blood plasma and its components

B Medical Systems' Contact Shock Freezers are designed for the quick freezing of blood plasma to a core temperature of -30°C

Blood is composed of many different components which interact constantly with each other and the rest of our body. Red blood cells bring oxygen to our cells, white blood cells protect us, platelets can help against bleeding in case of injury, nutrients from our digestive system are transported by the blood flow, and many different kinds of proteins with different functions help our cells survive, defend themselves and communicate with each other.

All these components interact with each other via chemical reactions. However, these reactions are often reliant on certain temperatures to be able to function normally and if the temperatures were to rise or fall, the molecules would start to break and lose their functions or slow down and stop interacting with each other, respectfully. Being able to slow down chemical reactions is critical in medicine: for example, once plasma is separated from red blood cells, it requires cold storage to maintain the integrity of its chemical components. These components include immunoglobulins, clotting factors and a wide variety of proteins, all of which are utilised in several medical procedures, making the safe storage of these samples critical.

Fresh Frozen Plasma (FFP) is indicated in the treatment of massive bleeds. Transfusion of fresh-frozen plasma replaces deficiencies of multiple coagulation factors and controls proteins in massive blood loss, liver disease and disseminated intravascular coagulations. This makes FFP an important raw material to obtain coagulation factor concentrates. To minimise the loss of coagulation activity, the production process of factor concentrates requires optimisation. Even though there are multiple factors influencing the recovery of coagulation factors, the time taken to freeze the plasma is an important one. For example, scientific literature has shown that quick and uniform freezing of plasma is essential for the optimal recovery of Factor VIII.

B Medical Systems' Contact Shock Freezers are designed for the quick freezing of blood plasma to a core temperature of -30°C. With the CSF61, blood banks and blood transfusion centres can achieve superior freezing times and improve throughput ensuring effective and efficient operations. Freeze times for 30 standard 350 ml bags from ambient temperature to -30°C are generally 30 minutes or less, thereby preventing any substantial loss of Factor VIII in the frozen plasma.

The CSF 61 features an innovative freezing technology that involves cooling plates inclined at 5°C. These ensure full contact with plasma and minimise the effect of air trapped in bags that negatively influences freezing cycle times. The freezing of plasma bags can happen on two levels operating independently, allowing simultaneous freezing and defrosting, if necessary. The linear actuators of the CSF 61 self-adjust to apply the proper force against the bags and act anti-parallel up to 10mm, thereby delivering homogeneous freezing of the bags even when they have slightly different fill volumes. All these features ensure the delivery of a fast and uniform cooling in the shortest time. Furthermore, the Contact Shock Freezer avoids the crazing of the bags by not exposing the plasma to extremely low temperatures.

The high-performance cooling systems, eco mode of operation, multiple injection valves and dual stage compressors used in the Contact Shock Freezers from B Medical Systems also ensure industry-leading and energy-efficient operations. Moreover, the CSF61 features an integrated monitoring solution, °B Connected, for complete traceability. With the °B Connected solution, healthcare workers can observe the status of the Contact Shock Freezer and the plasma bags being frozen at any given time, record every plasma bag via a bar code scanner and safely archive all the information. Finally, all operations can be accessed through a 7" touchscreen display, and all data can be easily exported via a USB drive or SD card.

It is also important to understand that the storage conditions of frozen plasma and blood components can impact their viability, functionality and lifespan. It is, therefore, vital that plasma bags are stored in plasma storage freezers that can maintain a stable temperature inside the cabinet and do not expose the samples stored to temperature excursions.

B Medical Systems offers Plasma Storage Freezers for the safe storage of fresh frozen plasma, enabling medical professionals to safely store these blood components reliably at a temperature of -27°C or below (down to -41°C). The company's products feature a controlled air-cooling system for uniform and stable temperature distribution, a fast temperature recovery even in case of frequent door openings, and a smart automatic defrost technology enabling a stable temperature inside the cabinet even during the defrosting cycle. Moreover, B Medical Systems' Plasma Storage Freezers can automatically switch off the evaporator fans during door openings to reduce the heat transfer and have an extended autonomy in case of power failures, thereby always ensuring the safety of all samples stored inside them. Finally, audio-visual alarms and the °B Connected software act as an extra layer of safety to safeguard the integrity of the biologicals.

By entrusting the freezing and the storage of blood plasma to B Medical Systems' reliable Contact Shock Freezer and Plasma Storage Freezer solutions, medical professionals can successfully obtain and manage large quantities of high-quality frozen plasma, supporting them in their efforts to deliver the best possible care to patients anywhere in the world.

Building capabilities in innovation space

Deepak Pahwa, Managing Director, Bry-Air (Asia), explains the need for pharma companies to take advantages of next-generation technologies to streamline their business processes in the near future to stay ahead of the curve for thriving in a digital world

Over the last decade, innovation in healthcare and pharmaceuticals has grown steadily. It is considered to be an important pillar for the pharmaceutical industry. The fast pace of technological advances has been driving the growth of the sector. With the potential advancements in hi-tech space, the industry is paving the way for a more cost-effective, energy-efficient, reliable, and most importantly, compliant to international standards' manufacturing facilities in the field of medicine and healthcare across the globe.

Technologies such as mobile communications, the cloud, advanced analytics, and the Internet of Things (IOT) are among the innovations that are playing a key role in transforming the healthcare industry. India is the largest provider of generic drugs, globally. Indian pharmaceutical sector supplies over 50 per cent of global demand for various vaccines, 40 per cent of generic demand in the US and 25 per cent of all medicines in the UK. The figures explain how Indian pharmaceutical companies play a crucial role worldwide. With such innovations, digitisation is not only providing opportunities to improve efficiencies, but playing a catalyst in taping new businesses and building effective relationships between patients and doctors.

The way Indian pharma market is going through rapid transformation, pharma executives are well aware of the disruptive potential and are experimenting with a wide range of digital initiatives. Companies are quite aware of the fact that without the help of technology, the business can't succeed. Hence, digital technology will drive the most value in the pharmaceutical industry. According to the Indian Economic Survey 2021, the domestic market is expected to grow 3x in the next decade. India's domestic pharmaceutical market is estimated at $42 billion in 2021 and is likely to reach $65 billion by 2024.

It is anticipated that by 2021, the global pharmaceutical sector will touch down $1,170 billion worth, with an impressive growth rate of 5.8 per cent. To achieve the momentum, companies need to set up the right environment for collaborative experimentation. The pharmaceutical industry needs to work on several factors such as investing in modern machines, upgraded diagnostic kits, manufacturing of medicines and proper use of data science. All these measures will lead to a successful outcome.

However, to thrive in a digital world, pharma companies will need to take advantages of the next-generation technologies to streamline their business processes in the near future to stay ahead of the curve. They need to keep upgrading at every possible step to cater to this huge demand. At the same time, reliability and consistency is a key factor in the health industry. Smart equipment need smart devices to maintain efficacy and reliability. We at Bry-Air understand the industry requirements and the need for developing innovative solutions.

In the last few years, businesses went through a transformation while exploring new technologies to make India future-ready as well as self-reliant. Believing in the same proposition, we launched our Bry-Air BrySmart Series (BBS) dehumidifiers that are embedded with patented BrySmart and BryTherm technologies.

These dehumidifiers integrate Industry 4.0-based concepts that reduce annual energy consumption by up to 48 per cent. The BBS modulates various critical components to optimise energy consumption continuously leading to less energy consumption thus making it a cost-effective solution. Therefore, the advanced dehumidifier is a step forward in energy conservation through enhanced automation. The Bry-Air BrySmart (BBS) dehumidifier series is the latest offering catering to the new-age requirement of energy-efficient moisture-control solutions, providing quicker ROI and the lowest cost of ownership.

Moreover, we have desiccant dehumidification, one of the most effective techniques to protect pharmaceutical raw material and products during processing, storage and packaging from moisture menace. Bry-Air desiccant dehumidifiers system ensures optimum moisture control in production areas, testing and RD labs, clean rooms, hospitals, etc, and help in maintaining hygienic conditions all-year round, regardless of the ambient conditions, at a very low dew point. Bry-Air is the fastest-growing adsorption technology in the world. We aim to reduce energy consumption and conserve energy for future purposes. Our objective is to focus on sustainable development, and with the help of our various patented energy smart technologies, we provide dehumidifiers and other latest solution offerings to manufacturers for their varied and complex quality air requirements.

For more information, visit
www.bryair.com

Bry-Air BrySmart Series (BBS) dehumidifiers

> It is anticipated that by 2021, the global pharmaceutical sector will touch down $1,170 billion worth, with an impressive growth rate of 5.8 per cent

Use of Single Use Technologies (SUT) for sterile dosage form processing and filling operations

Chandan Kumar Sah, Senior Manager- Quality/Technical Biotechnologist, explains the role played by Ami Polymer in supplying critical process consumables, that is, single-use assemblies, to parenteral formulation industries

Pharmaceutical drug products are produced to be efficacious. However, the presence of microorganisms or microbial by-products in these products may have adverse effects on their efficacy. Contamination of aseptically-filled biotechnological products is costly and can pose serious harm to the patient. Sterile dosage forms are those which are free from any microorganism, dust, fibers and foreign particles, and should be isotonic. Parenteral preparation, as the name suggests, (par-enteral) are those which are administered other than enteral routes. Enteral route involves oesophagus, stomach and intestines, but parenteral route bypasses all these. Sterile dosage forms include parenteral preparation and ophthalmic preparation. Parenteral preparations include injections, transfusions fluids, sterile suspensions, sterile solids, sterile solutions or emulsions. Ophthalmic preparations include eye drops, eye lotions, eye ointments, eye gels, eye suspensions and contact lens solutions.

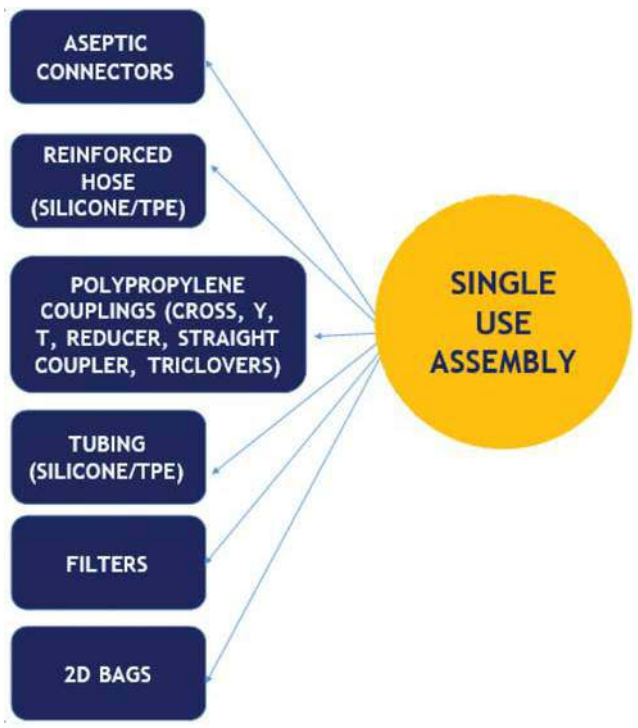
Ideal properties of sterile dosage forms:

Sterility: Sterile preparation shall be free from all types of microorganisms. Ophthalmic formulation must be especially free from gram-negative bacteria.

Free from pyrogen: Sterile formulation must be free from pyrogens and toxins. These products must pass pyrogen test.

Free from foreign particle: These products must be free from foreign particles, dust and fibres, and must pass clarity test.

To achieve these properties, Ami Polymer plays a vital role in supplying critical process consumables, that is, single-use assemblies to parenteral formulation industries. Single-use, sterile disposable technologies (sometimes referred to as bio-disposable technologies) are available in many different formats and confer various advantages for pharmaceutical manufacturers. Single-use disposable technologies are generally manufactured from plastic/elastomeric polymers involving process of injection moulding, extruding and blow moulding. The assembly of components should be undertaken in an ISO 14644 class 5 to ISO class 7 clean room. Once assembled, the items are sterilised using gamma irradiation.



Common Single Use Process Components

Single-use items are typically sterilised using gamma rays. Gamma irradiations kills bacteria, where there is sufficient energy, at the molecular level by breaking down bacterial DNA and inhibiting bacterial division. The sterilisation cycles are designed to achieve a sterility Assurance level 10-6.

There are several types of single-use systems. This article examines some examples that are applicable to biotechnological aseptic processing: aseptic connections, disposable product holding systems and bio container bags.

Application of Single Use Technology (SUT) for biotechnological aseptic processing

Aseptic connection: A critical clean room step is the aseptic connection, especially for aseptically filled products. An aseptic connection allows fluid to be passed from one vessel to another in a way that does not introduce microbial contamination. Ami Polymer provides one-step solution by providing high-quality customised single-use manifold which allows the operator to do connection in an easy mode and maintains the aseptic connection.

Cost savings: Cost savings are bound into process efficiencies. Although the initial cost of purchasing single-use assemblies is generally greater than the recycling of stainless steel components, the benefits of a faster turnaround, which potentially allows an organisation to produce faster and move between different product streams more quickly, deliver longer-term cost savings. Perhaps, the greatest cost saving of all depending on the valve of the product, is the elimination of contamination events, which will lead to batch rejection and process downtime.

Process efficiencies: SUTs present an opportunity for process efficiencies, several significant advantages over standard reusable stainless steel system, particularly in reducing process downtime and removing the need to clean and sterilise items. This eliminates the need to turnaround equipment thereby presenting opportunities to save on such factors as energy, waste disposal, cleaning chemicals used and labour.

Cross contamination: Cross-contamination in pharmaceutical processing can be a sterility assurance issue or a matter of product adulteration. Cross contamination can arise through the recycling of equipment where product residues are not adequately removed. Disposable components are single-use only and therefore not used for repeated operations, eliminating the chance of cross contamination or product carry over between process runs.

As a conclusion of all this, Ami Polymer offers wide range of gamma-irradiated single-use assemblies for various critical applications in biopharmaceuticals industry to support the campaign of large COVID vaccine drive of India. Our single-use assemblies are used to manufacture varieties of life-saving drugs {Covishiled vaccine, Covaxin, J&J vaccine (trial ongoing), Corbevax (trial ongoing). These are ranging from simple tubing with connector to complex manifold with several connections. All the assemblies are manufactured and packed in Class 7-certified clean room while critical components are assembled in class 5-certified clean room. Most of the key components used in these single-use assemblies are in-house manufactured and endure with high-quality standard.

Email: Chandan.s@amipolymer.com
Website: www.amipolymer.com

Mack PharmaTech: Devoted to excellence, care, safety and a matchless solution for environmental testing

Founders' experience, expertise and vision in the field of pharmaceutical equipment rendered Mack PharmaTech to be the youngest face to emboss the mark in India and abroad

Found in 1999 by a group of visionary professionals, Mack PharmaTech is a vision translated into reality. Founders' experience, expertise and vision in the field of pharmaceutical equipment rendered Mack PharmaTech to be the youngest face to emboss the mark in India and abroad.

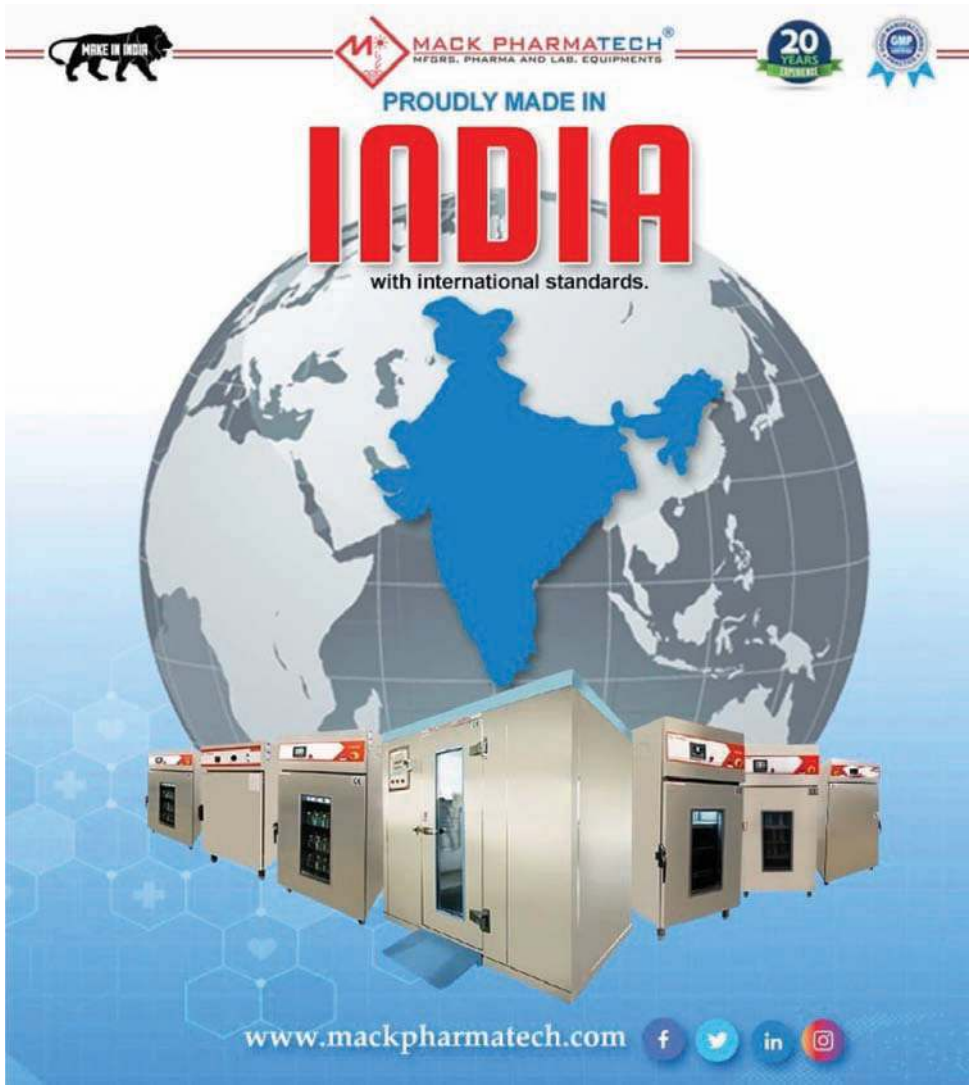
The company is relentlessly engrossed in benchmarking its products and services against globally-recognised quality standards. Mack PharmaTech, is one of the leading manufacturers and suppliers of laboratory equipment in India and in the international market in accordance with GMP guidelines. All the equipment manufactured by the company are as per FDA, GMP regulation and ICH guidelines.

The company adds one more feather to its cap by being the first company in India to provide CE (Compliance to European Standard)-certified lab equipment. All equipment are PLC-controlled with safety, automation, password protection and event recorder and data acquisition. 21 CFR Part 11 compliance software is used for monitoring and recording of data from chamber at one's computer.

Mack PharmaTech is an ISO 9001:2015 organisation certified by BSI for the scope of design, manufacture and servicing of environmental testing equipment of pharmaceutical industry and laboratory. It is serving to the sectors like pharmaceuticals, food, chemicals, medical, government research institutes and other industries.

The company even successfully implants its footprints in over 20 countries across the globe in territories like Asia, South East Asia, Gulf, West Africa, Canada, etc. Mack is always committed to its standards and ethics with all integrity. In discharging its responsibilities, the company never prefers professional or ethical shortcuts.

Mack PharmaTech is also having a young, dynamic and talented pool of professionals who are engaged in showcasing a wide range of products in domestic as well as international market and continues to promote brand awareness. It provides a complete set of documentation including Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification OQ) and Performance Qualification (PQ).



Mack PharmaTech is an ISO 9001:2015 organisation certified by BSI for the scope of design, manufacture and servicing of environmental testing equipment of pharmaceutical industry and laboratory

Besides, it offers the following service backup for all laboratory equipment:

- It has a technical expert team to handle complete after-sale services.
- Installation and commissioning of equipment.
- It undertakes after-sales services like AMCs, CMCs, and calibration and validation activities.
- 24x7 quality service by adopting devising advanced manufacturing technique to enhance quality.
- Online technical support, whenever required.

The company has its sales offices in Nashik, Delhi, Hyderabad, Gujarat and Bengaluru. Its service centres are in Nashik, Mumbai, Pune, Aurangabad, Hyderabad, Vishakhapatnam, Bengaluru, Chennai, Delhi, Baddi, Dehradun, Guwahati, Vapi and Vadodara.

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New launch by Neelikon of One World One Quality cosmetic colours

Under One World One Quality, Neelikon will offer colours meeting the different regulations of various countries. This new concept meets all the six regulations by reducing the impurity profile and with additional test parameters

Walk into a restaurant, a supermarket or a pharmacy; you are surely going to be awed by the chemistry of colours that are at play in them. Buy any food, cosmetic or medicine, colours have been proven to create psychological impact on our minds and our decision-making behaviour. Colour is considered to be the single-most important product - intrinsic sensory cue when it comes to setting expectations or building moods towards positive purchase intentions.

But, just imagine if these colours that we consume through the products we buy are not safe in the first place. If colours, that make something attractive, appetizing and compelling are made of harmful chemicals, and are not produced under proper control parameters; what would be the consequence of that? Just the thought of it can sometimes scare the hair out of its roots. It is beyond imagination what kind of damage it can cause to our skin, our organs and finally our health in the long run.

Therefore, it is important to check for their source, safety and suitability before using them in any application. It is the responsibility of the manufacturers of such consumables (foods, cosmetics or medicines) to produce and sell only the safest products at all costs using colour additives of the highest quality and fewer impurities. Over the years, a lot of research and experiments have been done to put together a series of regulations to ensure the best practices by different countries in their own capacity. Organisations like WHO and developed nations have invested heavily both in time and money to design legislations, specifications and test methods to monitor and manage the best practices, pushing the developing nations to adopt a similar charter for their people.

> Colour is considered to be the single most important product - intrinsic sensory cue when it comes to setting expectations or building moods towards positive purchase intentions

However, the times have changed, and with new technology, new breakthroughs are happening. In this scenario, there is one company - Neelikon - that has taken up this mandate quite seriously and after years of investing in R&D, it is now ready with a constructive disruption called as "One World One Quality" colour.

Neelikon is regarded as one of the top three producers in the world for food colours, cosmetic pigments and fluorescent dyes. Today, with the start of this decade and with over 35 plus years of impeccable service to this industry, Neelikon is ready to launch a one-of-its-kind product "One World One Quality" which is a range of high-purity colours with low impurities that will meet all necessary legislations of JECFA, the USA, Europe, Japan, China and India as applicable. Under One World One Quality, Neelikon will offer colours meeting the different regulations of various countries as mentioned above. This new concept meets all the six regulations by reducing the impurity profile and with additional test parameters.

Neelikon gives guarantee of One World One Quality to its current and prospective customers to use its colours in their applications and sell their products world-wide without any hurdle.

For more information on this range, please visit:
https://neelikon.com/

Ensuring pharma compliance with Testo data measurement technology

Testo data loggers can be used to test the optimum conditions for specific products or surroundings

Due to the crucial necessity and its direct impact on human health and welfare, pharma is probably the most important and critical sector, among others. As a consequence of which, it becomes essential to store pharmaceuticals, vaccines, laboratory samples or units of blood at the right temperatures to ensure that they remain effective and that quality is maintained. Also, sector like pharmaceuticals, which is governed by strict norms and regulations, must operate with the utmost efficiency. This elementary need for delivering safe vaccines, while adhering to stringent regulations, can only be ensured with right measurement technology at every stage. Testo being a market leader in testing and measurement sector provides the best-in-class measurement technology for different applications in the pharma division.

End-to-end climate monitoring – Testo Data Loggers

Pharma goods must be stored well in every situation as any deviation in the ambient temperature or humidity values may lead to deteriorated quality of the product. Testo data loggers can be used to test the optimum conditions for specific products or surroundings. In particular, temperature and humidity data loggers are often used in pharma industries to monitor the conditions in which drugs, medicines and vaccines are kept. Not only storage, but during the transit of goods, Testo transport data loggers are useful to measure the transport conditions.

The range of data loggers is extensive. A temperature and humidity loggers such as 174 T guarantees continuous monitoring in a storage or warehouse. Also, data loggers with multi channels for connecting external sensors and thermocouples, like Testo 176, are available for ensuring secured work process in labs. These data loggers are also critical for production-quality assurance where the temperature has to be frequently checked at various points in production processes. Using thermocouple probes, data loggers can also record data in the kinds of extreme temperature ranges. The probe's fast response also contributes in the validation processes and quality standard optimisation in QA units and clean-room applications. These instruments are the most convenient and pocket-friendly solution for all pharma application areas.

When transporting pharmaceuticals, clearly-defined temperature and humidity limit values usually need to be complied with – seamlessly and continuously. Breaching these limit values can result in irreversible damage to the active substances or to the composition of the pharmaceuticals. The Testo 184 transport data loggers offer uninterrupted control of the cold chain up to delivery with the highest data security while fulfilling relevant norms, guidelines and regulations.

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

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

Complete pharma solution

Testo provides the best-in-class solution for comprehensive quality management in pharma industry called as the Testo Saveris Pharma, a 21 CFR Part 11 compliant automated system that is integrated in the facility and constitutes wireless or ethernet probes installed at different locations that are connected to one base station which documents and monitors all measurement data on its own. The monitoring process is uninterrupted and the system provides number of alarm options in case the measurement values increase or decrease the standards. Some advantages of Testo Saveris Pharm-Data Monitoring System include:

Data compliance for audits and inspections: Testo offerings are majorly related to the data security along with comprehensive analysis and evaluation of all the recorded measurement data. Testo data loggers ensure continuous monitoring of temperature and relative humidity of pharmaceutical products during production, storage or transit of goods. Real-time data monitoring is important for the quality of pharma goods and also enables the supplier to improve the life of the goods. Transportation trucks, warehouses, cold rooms etc. can now be remotely monitored via Testo data loggers and data monitoring systems. Our data loggers are EN 12830 and 21 CFR Part 11 compliant which ensure complete documentation of parameters, be it humidity, temperature or absolute pressure. They come with professional software where the data recorded cannot be modified and the audits can be easily complied with.

Service and calibration made easy: Testo also has an established state-of-the-art NABL-accredited service and calibration LAB in accordance with the standard ISO/IEC 17025:2017, that takes care of the after-sales support locally from Pune. Testo service and calibration facility is highly cost-effective as it delivers international standards conveniently within a week's time. Instruments of any brand/make can be calibrated and serviced locally maintaining necessary standards. The accredited parameters include humidity, pressure, absolute pressure, contact type temperature, non-contact type temperature (infra red thermometer, thermal imager). In fact, Testo's is the first and only lab in India to get NABL accreditation for dew point temperature as well.

For more details, login to www.testo.com or write back to info@testo.in

Waters Corporation appoints John M Ballbach to Board of Directors

Dr Michael J Berendt to retire from Waters Board

Waters Corporation recently announced the appointment of John M Ballbach to its Board of Directors, effective 5th October, 2021. He currently serves on the Board of RPM International, Inc., a leader in specialty coatings, sealants, building materials and related services.

Waters also announced the retirement of Dr Michael J Berendt from its Board of Directors, effective 5th October, 2021. Dr Berendt joined the Waters Board in 1998 and has served on both, the company's Audit and Science & Technology committees during his tenure as director.

"Our sincere thanks and gratitude on behalf of my colleagues to Mike, for his service spanning more than two decades on the Waters Board. We wish him well and greatly appreciate his help ensuring a smooth transition of his seat to John Ballbach," said Dr Flemming Ornskov, Chairman of the Board.

He added, "After a thorough review of candidates, John stood out for his relevant industry, executive and operational expertise that is well-suited to advise Waters as the company continues driving sustainable long-term growth."

"I want to add my personal thanks to Mike for his guidance and camaraderie over the last year and especially his help during my onboarding at Waters," said Dr Udit Batra, CEO and President, Waters Corporation. "Also, welcome to John, who joins the Waters Board at an exciting time and during a critical period of growth and transformation at our company. He brings strong experience in M&A and driving operational excellence in the life science tools space. In addition to his global leadership experience, John also possesses deep expertise in building supply chains and robust e-commerce channels within the regulated sciences industries where we wish to strengthen and extend the reach of the Waters portfolio."

> John Ballbach currently serves on the Board of Directors of RPM International, Inc., as a member of its Corporate Governance and Nominating Committee

"The Waters brand is synonymous with deep scientific expertise and innovation throughout the industry, based on its pioneering innovations in chromatography, mass spectrometry, thermal analysis and chemistries that are used in laboratories worldwide," said Ballbach. "I'm grateful to be selected for this opportunity to work with a top-notch board of directors dedicated to helping Udit and the Waters team unlock the next level of growth and value creation."

John Ballbach currently serves on the Board of Directors of RPM International, Inc., as a member of its Corporate Governance and Nominating Committee. Ballbach is also the former chairman and chief executive officer of VWR International, LLC, a global leader in laboratory supply and distribution. With leadership experience in the chemicals and coatings industries, Ballbach was an independent director for Valspar from 2012–2017, when the company merged with Sherwin-Williams. In addition, Ballbach is a former corporate officer of Valspar, having served as President and Chief Operating Officer from 2002–2004 and in various senior management positions since 1990. He holds a bachelor's degree from Georgetown College and is an MBA from the Harvard University.

Ace Technologies now in upcoming pharmaceutical hub, Hyderabad

With this, the number of branches opened in India has gone up to four

The new office of Ace Technologies was inaugurated on 15th October, 2021 at Hyderabad by the directors Ajay Mehra, Hari Menon and Vijay Vaidya. The office was opened as part of the company's expansion to increase its presence in key growth markets. With this, the number of branches opened in India has gone up to four.

The company has been present in India since 2000 through its global connection of clients around the world. The opening of the new branch office here is expected to give a boost to pharmaceutical, healthcare, food & beverage and Horeca business in the region, enabling it to strengthen its relationship with clients and partners to provide technological solutions and services.

Ace Technologies has always focussed on building long-term business relationships through continuous innovation, better service and superior quality. With the vision and commitment to acquire and develop the best-in-class technologies globally through renowned partners, Ace continues its expansion in Hyderabad, the 'upcoming pharmaceutical hub.'

Ace Technologies, Hyderabad: 1002, 9th floor, Vasavi Mpm grand, besides Ameerpet metro station, Ameerpet, Hyderabad, Telangana - 500073.

Gandhi Automations earns recognition from the Government of India for being a Star Export House

The company headquartered in Mumbai is well-renowned as the global 'Made-In-India' brand across the industrial manufacturing domain

Gandhi Automations – India's number one entrance automation and loading bay equipment company, has earned recognition from the Government of India for being a Star Export House.

The company headquartered in Mumbai is well-renowned as the global 'Made-In-India' brand across the industrial manufacturing domain.

Since its inception in 1996, Gandhi Automations has been specialising in designing, manufacturing, exporting and installing industrial high-speed doors, dock levelers and dock shelters, sectional overhead doors, rolling shutters, aircraft hangar doors and shipyard doors, serving almost every industry across the globe.

Over the last 25 years, the company has evolved to have secured a 70 per cent market share in India. To date, Gandhi Automations have expanded their operations across 40 cities in India and 30 countries worldwide.

The company's three main guiding fundamentals of technical superiority, uncompromised quality and unparalleled customer service have been the real reasons for its success within India and globally.

By exporting their products to more than 30 countries, Gandhi Automations is actively contributing to India's growth through foreign exchange. They are also promoting India as the next manufacturing hub of the world by consistently delivering the best-in-class entrance automation products and loading bay equipment.

Samir Gandhi, Managing Director Gandhi Automations, confirmed this accreditation by the Government of India. He further commented, "We are thrilled to be a global Made-in-India brand. We are thankful to our dedicated employees and our customers for believing in us and our vision".

Gandhi is optimistic about the future and is looking forward to see Gandhi Automations as the world leader in this domain.

Ready-to-use coating solutions by Biogrund, Germany

Siddhesh Juvekar, Divya Prabhudesai, Geetanjali Laghate and **Dr Heeshma Shah**, Technical Services Department, Signet Excipients, explain the various types of coating solutions by Biogrund used in the pharma industry

Biogrund Group, since its inception in 1999, has been the specialist for offering simple, fast and reliable ready-to-use high-quality film coating, tableting, sugar-coating, colouring and printing solutions for oral dosage forms of pharmaceutical and nutraceutical industries. With a worldwide presence in Germany, Switzerland, America and Russia, Biogrund offers customer the best possible services and guarantees production and its supplies.

Biogrund's one-step coating blends are easily dispersible in water or organic solvents and find application in taste masking, film coating, enteric coating, moisture protection and release modification. Below is the list of coating premixes offered by Biogrund.

Category	Brand Name	Application
Film Coating	AquaPolish®	Film coating systems (functional and non-functional)
	NutraPolish® Organic	Organic certified coatings for nutraceuticals
	BonuWax®	Premix of waxes and lipids for hot-melt coating application
Sugar Coating	IsuPolish®	Sugar and sugar-free coatings

Grade	Composition	Applications
AquaPolish	Compound of Hypromellose (HPMC), hydroxypropyl cellulose (HPC) and other selected cellulose ethers	Aqueous or organic-based fast dissolving coating system
AquaPolish G	Compound of HPMC, HPC and other selected cellulose ethers with pearlescent pigments	Aqueous-based fast-dissolving coating system with a glossy and aesthetic appeal
AquaPolish HS	Compound of very low viscosity HPMC with selected cellulose, plasticising and colouring additives	Aqueous or organic-based coating system for faster process with high solid content
AquaPolish MS	Compound of HPMC, HPC and other selected cellulose ethers with hydrophobic additives	Aqueous or organic-based coating system for moisture protection
AquaPolish OM	Compound of HPMC, HPC and other selected cellulose ethers with odour-masking additives	Aqueous or organic-based coating system for odour masking
AquaPolish PVA	Compound of Polyvinyl alcohol (PVA), plasticisers and HPC (optional)	Aqueous-based coating system for moisture protection
AquaPolish TC	Compound of HPMC, HPC and other selected cellulose ethers with taste-masking additives	Aqueous or organic-based coating system for taste masking
AquaPolish PRO	Compound of PVA-PEG copolymer, talc and other pigments	Aqueous-based coating system with high flexibility and moisture-sealing properties
All the above grades are also available in titanium dioxide-free composition		

Category	Composition	Application
NutraPolish Organic	Compound of selected natural and organic certified ingredients	Aqueous-based fast-dissolving coating system for nutraceutical tablets

Category	Application
BonuWax	**Polishing agent:** A fine and homogenous mixture of beeswax and carnauba wax used to achieve an excellent glossy finish to sugar-coated tablets **Anti-sticking agent:** A mixture of different natural waxes providing excellent transparency and enhanced mechanical stability/flowability during processing and packaging of soft capsules **Hot melt coating:** A mixture of carnauba wax and/or beeswax plus two additional lipids having a suitable melting temperature which simplifies the coating process of particles or granules

Film Coating:

1. AquaPolish: AquaPolish is a one-step coating system designed to provide protective and fast release film coating for solid oral dosage forms. It is a unique, dry-milled and homogeneous blend of selected film-forming cellulose ethers with plasticising and colouring additives. It is produced with an innovative mixing and milling process which results in highest quality of a homogeneous and deagglomerated coating system. AquaPolish grades are easily dispersible and guarantees reproducible and high-quality films.

Customised ready-to-use premix coating system to meet specific formulation needs can also be provided.

Titanium dioxide (TiO_2)-free coating systems

As per the recent discussion on new classification and labelling of TiO2, and revaluation of TiO2 (E171) as a food additive in the EU by EFSA, formulators are looking out for TiO_2-free coating systems. AquaPolish range offers an immediate alternative to TiO_2-based coating systems without compromising the composition or functionality of one's existing system.

2. NutraPolish Organic: NutraPolish Organic is a ready-to-use film-coating system prepared from a mix of selected natural and organic certified ingredients. This aqueous clear film-coating system provides aesthetic appeal, moisture protection for herbal extracts and other nutritional supplements.

3. BonuWax: BonuWax is a three-in-one, easy-to-use premix for hot melt coating of particles, polishing of sugar-coated tablets and anti-sticking of soft capsules.

4.IsuPolish: IsuPolish is a unique, dry-milled and homogeneous blend of isomalt with pigments and additional excipients to speed up the production process. It is easily soluble and guaranteed to provide reproducible high-quality sugar or sugar-free coating. Clear, white and coloured preparations can be tailor-made according to customer requirements. It is used for nutraceuticals, confectionaries and pharmaceutical products.

Biogrund's 360° support with regards to consultation, development, testing and customisation of ready-to-use coating premixes has been appreciated by formulators working for competitive markets. They further assist in colour customisation with natural and light stable colours to enhance brand identity. The powder coating blend can be easily dispersed or dissolved in aqueous as well as organic solvents and works effectively in both conventional as well as the modern coating system.

All the above excipients meet official regulatory requirements for pharmaceutical products and for nutritional or dietary supplements. They are in compliance with the global EXCi-

PACT™ standards and pharmacopoeial specification.

Biogrund's support beyond coating

Biogrund also extends its support beyond coating applications by providing HME Cleaner Plus (GMP), a water-soluble purge compound with a micro-cleansing effect that solves the cleaning difficulties associated with hot-melt extrusion process using various polymers such as hypromellose acetate succinate, acrylic copolymers, copovidone, etc. It is manufactured in accordance with IPEC GMP guidelines meeting all requirements of USP/NF, EP and JP. Additionally, they also provide colour premixes (BonuTone), colour dispersion (TopMill) and co-processed tableting excipients (CompactCel). The company's solution-oriented product range helps to simplify formulation development activities to meet growing customer demands.

Grade	Composition	Applications
IsuPolish	Compound of isomalt, pigments and other selected excipients	Sugar-free sugar coating for smooth and glossy appearance
IsuPolish G	Compound of isomalt, mineral and non-artificial Candurin pearl effect colours and additional excipients	Sugar-free sugar coating for highly aesthetic glossy appearance
IsuPolish FSC	Compound of HPMC, isomalt or sucrose, pigments and additional excipients	Easy, fast and film-sugar-coating for excellent taste and odour masking and moisture sealing
IsuPolish S	Compound of sucrose, pigments and other selected excipients	Conventional sugar-coating for smooth and glossy appearance

For additional information on Biogrund products, do visit www.signetexcipients.com

Yokogawa invests in CyberneX, developer of a technology for measuring brainwaves with a high-performance earphone-type device

Accelerating the joint R&D of braintech to tackle challenges faced by industry and society

Yokogawa Electric Corporation announced that it has invested in CyberneX, a Japan-based startup that has developed a compact, light-weight and high-performance earphone-type device capable of measuring brainwaves in real time. CyberneX and Yokogawa will collaborate in the conduct of empirical research with the aim of constructing a platform for the visualisation of information on the mental states of individuals, based on brainwave data. The companies will work to develop applications that will lead to the effective utilisation of this technology by industry and society.

In recent years, there has been a rising interest in brain technology (technologies and solutions that collect and utilise brain information such as brain waves), a field that brings together neuroscience and IT. It is anticipated that there will be many different applications for this technology, and investment by government institutions and the private sector is on the rise around the world. Uses for this have already been found not only in medicine and healthcare, but also in product development and education, and the industrial sector too is now actively moving to adopt and make use of this technology in operations.

The earphone-type device developed by CyberneX is easy to put on and take off, and it can measure brainwaves in real time and with low noise even when the subject wearing the device is moving. As this device can be used in everyday situations and working environments, it is extremely practical, and enables the visualisation of previously difficult-to-capture information on users' sensations and emotions. Leveraging the features of this earphone device, users can receive auditory feedback that guides them to an ideal psychological and physical state. Moving forward, CyberneX is looking into the possibility of using physiological data such as blood pressure and heart rate to obtain deeper insights into the psychological states of human subjects.

Utilising its measurement, control and information technologies, Yokogawa provides cutting-edge products and solutions to customers in a wide range of industries all over the world. To help customers optimise their operations and sustain growth, it is necessary to quickly and efficiently research and develop solutions to the many issues they encounter at their sites. Through this collaboration between CyberneX, a startup company with innovative technology, and Yokogawa, a well-established company with a wealth of knowledge-in-process automation, synergy will be created that will lead to new innovations in the brain technology field.

Motofumi Baba, CEO/CTO, CyberneX, said, "Our mission is to pursue the potential that brain information possesses, and to make it more readily available in everyday life. I believe that gaining a deep understanding of humans will bring about brand-new forms of communication, and that this will lead to the development of a wide range of applications. By strengthening our relationship with Yokogawa and constructing a platform for the effective use of brain information, we will help to build a flourishing society and create new industries."

Tsuyoshi Abe, Senior Vice President, Yokogawa Electric Corporation and Head, Marketing Headquarters, said, "Against the backdrop of digital transformation, the extent to which technology can bring benefits to humanity will become increasingly important. And, in this context, I firmly believe that solutions leveraging brainwave technology will further increase human potential. Industry has seen a shift towards industrial autonomy, and I think that humans and machines will go on to coexist in a way that leverages their respective characteristics. In society, I think that these technologies will enable humans to live more prosperous lives. We will work to accelerate co-innovation with CyberneX, enabling the creation of new value not only for industry, but also in the lifescience fields."

Outline of CyberneX

● Established: May 22, 2020
● CEO/CTO: Motofumi Baba
● Main business: Support of R&D that leverages biometric data, support for effect measurement, development of brain computer interface devices and joint development of solutions
● Location: Tokyo, Japan
● Website: https://www.cybernex.co.jp/ (Japanese)

About Yokogawa

Yokogawa provides advanced solutions in the areas of measurement, control and information to customers across a broad range of industries, including energy, chemicals, materials, pharmaceuticals and food. Yokogawa addresses customer issues regarding the optimisation of production, assets and the supply chain with the effective application of digital technologies, enabling the transition to autonomous operations.

Founded in Tokyo in 1915, Yokogawa continues to work towards a sustainable society through its 17,500 employees in a global network of 119 companies spanning 61 countries. For more information, visit www.yokogawa.com

Confidently analyse nitrosamine impurities by LC-MS/MS & GC-MS/MS headspace methods

Shimadzu has standardised analytical methods capable of detecting problematic nitrosamines compounds for assisting pharma society to overcome the challenging market situation

Detection and control of nitrosamine impurities in drug manufacturing processes become critical to sustain the business of pharmaceutical industry. Shimadzu has standardised analytical methods capable of detecting problematic nitrosamines compounds for assisting pharma society to overcome the challenging market situation. Nitrosamine is an organic compound containing the group -NNO attached to two organic groups. Nitrosamines are found in tobacco products, tobacco smoke and many foods such as fried foods, fish, meat, beer and water. These are formed by the reaction of secondary or tertiary amines with a nitrosating agent and some of nitrosamines are classified as probable human carcinogens.

In July 2018, the US Food and Drug Administration (FDA) announced that the carcinogenic impurities: N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) had been detected in Valsartan bulk drug substances manufactured by Chinese drug manufacturers. Valsartan is used in the treatment of high blood pressure and congestive heart failure.

Subsequently, regulatory agencies, including US FDA, European Medicines Agency (EMA), Health Canada, Health Science Authority, Singapore (HSA) and Ministry of Health, Labour and Welfare, Japan (MHLW) are investigating the presence of nitrosamines in medicines. As a result, many medicines, e.g. Angiotensin II Receptor Antagonists (ARBs), Ranitidine, Nizatidine and Metformin, have been recalled till now. This global trend is revealing the necessity for rugged and robust analytical methods to detect nitrosamines in APIs and medicines.

Table 1: Summary of seven nitrosamines impurities by GC-MS/MS Headspace

Compound	CC range (ppb)	R2	LOQ		
			Conc. (ppb)	%RSD (n=6)	S/N*
NDMA	2.5 to 160	0.999	2.5	8.5	50
NDEA		0.999		12.6	472
NEIPA		0.999		6.6	651
NDIPA		0.999		9.5	399
NDPA	10 to 640	0.999	10	7.5	612
NDBA	5 to 320	0.999	5	9.2	58
NMPrZ	25 to 1600	0.999	25	14.6	28

Table 2: The sample spiked study for Losartan API at LOQ level by GC-MS/MS Headspace
(Results expressed are relative to sample)

Losartan API				
Name	Sample Amt. (ppb)	Amt. Spiked (ppb)	Found Amt. (ppb)	% Recovery
NDMA	Below LOQ	2.5	2.63	105
NDEA	Below LOQ	2.5	2.24	90
NEIPA	Below LOQ	2.5	2.44	97
NDIPA	Below LOQ	2.5	3.19	127
NDPA	Below LOQ	10.0	10.56	106
NDBA	Below LOQ	5.0	5.54	111
NMPrZ	Below LOQ	25.0	27.75	111

Note: Criteria for % recovery as per USP <1469> is 70 to 130%.

Required sensitivity for analytical methods

- FDA Control of nitrosamines impurities in human drugs-Guidance for Industry - FDA February 2021
  - Products with MDD < 880 mg/day: LOQ ≤ 0.03ppm
  - Products with MDD > 880 mg/day: LOQ as low as reasonably practical
  - LOQ < Test Result ≤ Acceptable Intake
- EMA Assessment Report - Nitrosamines impurities in human medicinal products - EMA 25 June, 20
  - LOQ ≤ Acceptable limit for the respective nitrosamine impurities, taking into account the purpose of testing
- Routine control: LOQ ≤ Acceptable limit
- Justify skip testing: LOQ ≤ 30% of AL
- Justify omission from the specification: LOQ ≤ 10% of AL
  - Exceptions may be needed depending on the maximum daily dose (MDD) or if more than one nitrosamine is expected to be present. Such cases should be discussed with the relevant competent authorities.

Shimadzu introduces rugged and robust analytical methods for nitrosamines in Sartans, Metformin and Ranitidine. The methods have been standardised on the Shimadzu GCMS-TQ8050 NX and LCMS-8045.

An HSGC-MS/MS method was developed and validated following ICH Q2 (R1) for the detection and quantitation of all seven nitrosamine impurities in Sartan API as per the proposed USP General Chapter <1469> protocol. The limit of quantitation (LOQ) and range of the method are summarised below:

Highlighted features

- **Enhanced sensitivity:** OFF-AXIS Ion Optics and

FIGURE 1: GCMS-TQ8050 NX WITH HS-20 SYSTEM

FIGURE 2: UHPLC WITH LCMS-8045 SYSTEM

Table 3: Summary of six nitrosamines impurities by LCMS

Comp.	CC range (ppb)	R2	LOQ		
			Conc. (ppb)	%RSD (n=6)	S/N*
NDMA	1.33 to 90	0.997	1.33	2.68	18.34
NMBA		0.997		15.66	17.54
NEIPA		0.997		10.3	37.10
NDIPA		0.997		1.85	46.80
NDBA		0.998		3.66	32.50
NDEA	0.66 to 59.4	0.999	0.66	5.90	22.10

Table 4: The sample spiked study for Losartan API at LOQ level by LCMS
(Results expressed are relative to sample)

Losartan API				
Name	Sample Amt. (ppb)	Amt. Spiked (ppb)	Found Amt. (ppb)	% Recovery
NDMA	Below LOQ	1.33	1.33	85.7
NMBA	Below LOQ	1.33	1.54	112.9
NEIPA	Below LOQ	1.33	1.19	92.5
NDIPA	Below LOQ	1.33	1.07	82.7
NDBA	Below LOQ	1.33	1.57	106.4
NDEA	Below LOQ	0.66	1.21	70.7

Note: Criteria for % recovery as per USP <1469> is 70 to 130%.

Regulatory agencies, including US FDA, European Medicines Agency (EMA), Health Canada, Health Science Authority, Singapore (HSA) and Ministry of Health, Labour and Welfare, Japan (MHLW) are investigating the presence of nitrosamines in medicines. As a result, many medicines, e.g. Angiotensin II Receptor Antagonists (ARBs), Ranitidine, Nizatidine and Metformin, have been recalled till now. This global trend is revealing the necessity for rugged and robust analytical methods to detect nitrosamines in APIs and medicines

newly-designed high-sensitivity shielded detector offers outstanding noise elimination, enabling the system to reliably detect at femtogram level.

- **Durable hardware:** The contamination-resistant ion source and the new detector with over five times longer service life ensures reliable and long-term analysis.
- **Superior performance:** A new turbo-molecular pump with higher evacuation performance results in higher sensitivity and improves analysis accuracy for ultra-trace concentration levels. UFSweeper technology achieves high-speed MRM analysis (800 transitions/sec).

An LC-MS/MS method was developed and validated following ICH Q2 (R1) for the detection and quantitation of six nitrosamine impurities in Sartan API as per the proposed USP General Chapter <1469> protocol. The limit of quantitation (LOQ) and range of the method are summarised below:

Highlighted feature

- The best-in-class sensitivity (UFsensitivity)
- The world's fastest scanning speed: 30,000 u /sec (UFscanning)
- The world's fastest polarity switching rate: 5 msec (UFswitching)

Veegum: A key troubleshooting excipient!

The product has played a key role in solving various formulation-related issues such as taste masking, dissolution, moisture control, to name a few, and at the same time, it has helped improve the quality and stability of the product

Veegum is a functional excipient and key ingredient for various solid, liquid and semi-solid formulations. The product has played a key role in solving various formulation-related issues such as taste masking, dissolution, moisture control, to name a few, and at the same time, it has helped improve the quality and stability of the product. This stellar product has found applications in varied types of industries such as pharmaceuticals, personal care, agro-science, animal care and more.

"If your only tool is a hammer, then every problem looks like a nail," said Abraham Maslow. Pioma Chemicals says, "If your tool is Veegum, then every formulation problem has a solution!"

This article gives an insight on Veegum and it's around-round applications in various pharmaceutical dosage forms. Let us look at some of the mind-boggling functions and applications of this simple yet effective excipient in various types of formulations.

What goes behind the taste masking of medicines using Veegum?

While popping a pill, we usually come across the bitter taste and the reason for it is the bitter Active Pharmaceutical Ingredients (APIs). Making medicines more palatable for paediatric patients and increasing the overall patient compliance and brand acceptance, the pharmaceutical companies have gone the extra mile to manufacture user-friendly medicines. Various products are being used today and the manufacturing process has seen a huge transformation in the way medicines are produced.

Veegum (magnesium aluminium silicate) - a versatile taste-masking agent - is an inert and flexible ingredient primarily used in pharmaceutical applications. Veegum is a type of natural smectite clay that is processed to optimise purity and performance, and is compatible with all APIs and excipients. The ores to manufacture Veegum are mined in Nevada, Arizona and California, which are milled in Nevada and shipped to the state-of-the-art GMP-certified processing plant in Kentucky, the US. The special feature of this product is its ability to form a "House of Card" structure (see figure above) around the API to mask the bitter taste of the API.

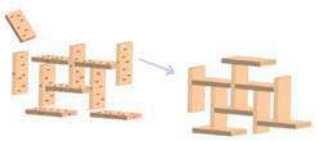


Fig: House of card structure

This ensures that Veegum does not form chemical bonds with the API or other excipients, but works amongst its own particles to mask the bitter taste of the APIs and thereby protecting the integrity of the drug molecule. It is a US-DMF-certified excipient, a certification that speaks volumes about its safety and acceptance for pharmaceutical formulations and standardisation.

Veegum has been used for taste masking of liquid suspensions and dry suspensions of widely-used APIs like Azithromycin, Clarithromycin, Ofloxacin, Cefixime, Cefpodoxime Proxetil, Cefuroxime Axetil and more for a long time now, and we continue to widen the use of this exceptional excipient for many other bitter-tasting drugs.

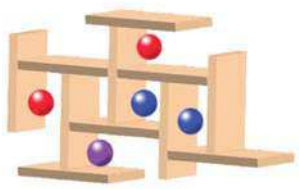
In liquids, this multi-tasking excipient has several roles to play.

Suspensions: By the virtue of its 'House Of Card' property, it is able to entrap and hold the other particles and prevent them from caking or sedimenting in suspensions (see figure below) - this will ensure that research scientists and product formulators can now do away with the tag 'Shake Well Before Use' for suspensions such as antacids, Bismuth Subsalicylate suspension, Azithromycin, Ofloxacin and Calamine, to name a few.

Phase separation

No phase separation With Veegum®

Emulsions: This same property also helps retain and trap particles of both phases (water and oil) in a single phase once it is mixed using an emulsifier and prevents the usual problem seen in emulsions of "bleeding" or "cracking" (ointments, creams, lotions, suppositories and more). One of the most useful features of this ingredient is its ability to stabilise oil-in-water (O/W) emulsions at low concentrations. The smectite colloidal structure effectively keeps the internal phase droplets suspended and separated. Since this structure is not affected by heat, these clays reduce the tendency of emulsions to thin out and break at elevated temperatures. Small amounts - typically one-to-two per cent- will stabilise emulsions containing anionic or non-ionic surfactants and a wide variety of oils, fats and waxes (see figure on the right).



These clays are also effective in fluid water-in-oil (W/O) emulsions that are otherwise difficult to stabilise; they inhibit coalescence by increasing internal phase viscosity and by strengthening the interfacial water/oil film.

Veegum is often used synergistically with gums and organic thickeners as it boosts their viscosity multiple times without increasing the dosage of these thickeners and gums. The viscosity or stability of formulations containing these mixtures is greater than that of the same formulation made with each component (separately) of the mixture. These combinations allow the formulator to fine-tune viscosity, yield value and flow properties beyond what is possible with either the clay or organic thickener alone. It has given wonderful results with thickeners like Xanthan Gum (Vanzan NFC), Sodium CMC, Hydroxyethyl Cellulose (Hydrocel - H) and Biopol - Carbomers, to name a few.

This versatile excipient has found to be multipurpose for solid orals.

In solid dosage forms, they are traditionally used as binder, disintegrant, moisture-controlling agent and lubricant, and for increasing the dissolution profile for tablets. These clays are also used in solid dosage forms as components of drug delivery systems, an application of increasing interest because these entirely natural excipients provide a unique combination of physicochemical properties for drug-clay interaction. Veegum, thereby improves the shelf life and stability of the product. Due to the nature of the clay and its particles, it has helped solve the issue of increasing the dissolution of tablets, especially Albendazole tablets.

With these features + compatibility with almost all APIs and raw materials + its active role in masking the bitter taste of the APIs, Veegum has proved to be quite efficient in its functionality and gives the formulators and research scientists multiple additional benefits and functions to work with making their life easier as the process of product development is quite tedious and draining. While aiding the process of development, it also ensures the developed product is stable and gives the product a luxurious feel throughout its shelf life and beyond.

Conclusion

With rising customer demands, varied weather conditions across the globe and increased demand for stable and safe products - all at the same time - Veegum has taken the centre stage and is popular amongst formulators and research scientists due to its versatile and adept applications across the globe. Pioma Chemicals, along with the consistent support from Vanderbilt Minerals LLC, is always on the lookout for new innovations which can make the product development an interesting task and ensure the company comes up with more user-friendly ideas for its customers for many more years to come. Veegum is the key win-win product for all entities and all personnel involved in product development and troubleshooting.

Not all carbomers are created equal: Why quality needs to come first when selecting excipients

In an industry where the global regulatory environment is fragmented, developers and manufacturers need to know the standard of their carbomers

Carbomers are widely used thickeners, controlled release polymers, suspending agents stabilisers and binders that ensure the performance of pharmaceutical products. However, growing competition as a result of globalisation is forcing many manufacturers to explore alternative carbomers to minimise production costs and potentially compromise on quality performance. This means many companies may be exploring cheaper excipients. On the surface, this may seem okay, but these carbomers are often lower-cost for a reason - they may be made using materials and techniques that render them toxic, low quality and unsafe for human consumption.

To penetrate the markets, manufacturers must ensure that drug products comply with the local regulations. This means ensuring that none of their products contain toxic solvents or impurities. In an industry where the global regulatory environment is fragmented, developers and manufacturers need to know the standard of their carbomers.

To penetrate the markets, manufacturers must ensure that drug products comply with the local regulations. This means ensuring that none of their products contain toxic solvents or impurities

Is your carbomer safe?

A fragmented regulatory environment has led to considerable differences in quality among carbomer manufacturers.

"Traditional" carbomers are synthesised in class-I (e.g. benzene, 1,2-dichloroethane) and class-II solvents (e.g. methylene chloride) that are likely to become more restricted for use in pharmaceutical applications.

Under USP467(ICH Q3C) guidelines, class-I solvents are to be avoided and class-II solvents must be limited. Benzene and 1,2-dichloroethane class-I solvents should be avoided in the manufacturing of drug substances, excipients and drug products because of their unacceptable toxicity.

Failing to address the removal of these excipients may:

- ◆ affect consumers' health.
- ◆ prevent companies from selling products in global markets.
- ◆ result in regulatory action by authorities.
- ◆ negatively affect sales and profitability.
- ◆ cause global reputational damage that could take years to repair.

Ultimately, choosing the wrong carbomer can lead to longer development, processing and manufacturing times and costs, ultimately leading to lower profitability, regulatory challenges and reputational damage.

Are you compromising on quality?

In addition to the safety implications, choosing the wrong carbomer can have a negative impact on quality and on manufacturing efficiency too.

For process and manufacturing, if carbomer properties are not optimal, the product development process will be negatively affected. This may lead to failed analytical testing and increased processing time and issues. Innovative actives and formulations are also often dropped in phase-I and -III trials as the carbomer chosen cannot support the novel formulation.

Know the carbomer landscape

Critically, there are carbomers available in the market that can address these safety and quality issues, provided you know how to look. In order to find a trusted and reliable supplier, it's important to focus on suppliers that offer the following:

- ◆ Comprehensive excipient characterisation, including residual solvents and elemental impurities
- ◆ Toxicity and stability data
- ◆ Manufacturing standards and customer support

Carbomer producers that may not have these available can bring significant risks.

Quality excipients matter

To bypass the risks associated with choosing the wrong carbomer, developers may turn to an experienced carbomer producer who can ensure these resources.

As the original carbomer producer, Lubrizol Life Science Health takes pride in manufacturing high-quality, non-toxic carbopol polymers. To find out more about how carbopol polymers can help find the right carbomer for one's product, contact the Lubrizol Life Science Health team today.

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Understand your wipes to maximise your performance

Wipes have been playing a significant role in safeguarding critical environments across a variety of industries including pharmaceuticals, medical device manufacturing, biotechnology, compounding pharmacies and electronics

It is important to keep cleanrooms to prescribed classification levels. Personnel following Standard Operating Procedures (SOPs) and the appropriate sanitisation solutions designed for specific applications play a huge role to sustain cleanroom hygiene standards. There are many consumables that are considered critical to cleanroom hygiene. However, wipes are one of the most popular consumables in a cleanroom environment.

Wipes have been playing a significant role in safeguarding critical environments across a variety of industries including pharmaceuticals, medical device manufacturing, biotechnology, compounding pharmacies and electronics. Cleanroom wipes have lower lint levels compared to ordinary wipes which help minimise contaminants at the facility. Designed and manufactured to have high absorbance, improved compatibility with a wide range of chemicals, low linting including controlled level of ions and NVRs, cleanroom wipes are preferred sanitisation solution at any facility.

What parameters and characteristics should you look for in a cleanroom wipe?

Selecting the right wipe for your applications is important from a practical and financial perspective. Wipes should meet particular performance criteria before making it into a cleanroom site. These criteria also need to be evaluated against the data and performance provided by the manufacturer. Here are a few factors that one should look at:

1. ISO classification: Every cleanroom wipe comes with a recommended ISO classification. Wipes with certain ISO classifications should be aligned with corresponding cleanrooms.

2. Low linting: The ISO recommendation for each wipe is largely dependent on how clean the wipe actually is. The cleanliness of a wipe is determined by its linting indicated by APC and LPC testing. Cleaner the wipe, lesser the deposition onto surfaces during wiping.

3. Absorbency: This measures the effectiveness of each wipe at picking up liquid or spills. There are two aspects to be considered i.e., rate of liquid absorption and total amount of liquid absorbed. A well-engineered wipe can not only absorb a sufficient amount of liquid, but can also release the liquid in a consistent manner onto the surface to maximise the coverage of each wipe.

4. Cleaning ability: This criterion measures each wipe's ability to remove a multitude of contaminants such as dust, stain, microbes, particles, etc. The wipes' capability is determined by a combination of the material and construction of each wipe and the chemicals that will be used for cleaning the contaminated area.

Knowing the wipes

Cleanroom wipes can be manufactured using different substrates. Each of those have their own unique performance characteristics and cost positions. Understanding the pros and cons of each material is a critical step while selecting an ideal wipe for a particular environment.

Non-woven polyester cellulose

It is a unique construct made out of a combination of polyester and cellulose where polyester provides the necessary cleanliness and cellulose delivers the required absorbency. A great choice for cleanrooms with less restrictive air particulate requirements.

Although it is cost-effective and boasts great absorbency, it also tends to release more particles and/or fibres in the environment.

Non-woven polypropylene

An industrial-grade thermoplastic, which, when combined with minerals and other additives during the manufacturing process, is malleable into synthetic papers and wipes. The melt-blown entanglement process forms a uniformly flat surface with exceptional particle removal characteristics. It has excellent compatibility with acids, bases and solvents.

It is clean and cost-effective, but has poor absorbency.

Polyetser knit

Knit polyester cleanroom wipes are made with 100 per cent continuous filament knit polyester. These are extremely low-linting and exceptionally soft, and has wide chemical compatibility range. However, it is expensive when compared to non-woven wipes.

Microfibre

Microfibre is gaining momentum in the cleanroom domain for its superior cleaning performance. Its extra fine fibres can remove various contaminants more effectively compared to other substrates. This wipe now acts as a bridge polyester cellulose and polyester knit. It is cleaner and softer, and has better absorbency and cost-effectiveness, compared to polyester. Further, it has lower absorbency than Polycellulose.

Pre-wetted cleanroom wipes

Manually wetting a wipe with a spray bottle makes the cleanroom worker a critical part of the process. But, it also means that every wipe is not saturated with the same amount of solution. A study published by The Society for Applied Microbiology in the Letters in Applied Microbiology compared the microbial cross-contamination on surfaces cleaned with dry wipes sprayed with alcohol against those cleaned with pre-saturated IPA wipes. The study showed that wiping with pre-saturated wipes minimised the spread of contaminants.

Benefits of using pre-saturated wipes

- Reduces solvent use from 15 to 50 per cent depending on the method of saturation
- Helps the cleanroom stay within emission limits
- Increases productivity and compliance due to its convenience
- More consistently repeatable compared to using dry wipes with a separate solvent

Conclusion

When choosing cleanroom wipes, it is important to establish key performance criteria for each cleaning environment and application. Select the right wipes that can deliver on those metrics. Each wipe substrate has its own advantages and deficiencies compared to others. Nevertheless, while there may not be the perfect wipe out there for everyone, one can sure pick the perfect wipe that comes close for his/her cleanroom requirements.

About Antylia Scientific

Antylia Scientific is a global leader with a diverse portfolio of life sciences products for the pharma, biopharma, healthcare and environmental markets. We have evolved from an instruments company to an organization that provides customers with mission critical products and services in the Life Sciences markets. The Life Sciences division includes our founding business Cole-Parmer®, home to more than 200,000 laboratory essentials that have become synonymous with unsurpassed quality and inextricable value to scientists in labs around the world; SPEX®, focusing on chemical and equipment products with more recent growth into chromatography, spectroscopy, and PCR; and Traceable®, a leader in applying IoT innovation to cold chain storage and transport, ensuring the high-quality products make it safely to every corner of the world. Environmental Express™ is the globally recognized leader for innovation, development and manufacture of sample collection, preparation, single use consumables and analysis equipment used in the environmental water, soil and air analysis laboratory. Rounding out our Life Sciences portfolio is the latest addition to our family, ZeptoMetrix®, which creates new standards in controls and verification panels used in pharmaceutical research and delivers expert technical services. For more information, visit www.antylia.com.

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