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EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE JUNE 2021, ₹ 40

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Corporate Vice President,
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INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE
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Leadership
Interview
Lene Hylling Axelsson
Corporate Vice President,
Global Business Services,
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Preparing for the third wave

A recent International Monetary Fund (IMF) report's prediction that vaccine coverage in India could remain under 35 per cent of our population by this year-end, inspite of the government's claim that the full population would be covered, is worrying at several levels.

From a public health perspective, the under-vaccinated will still be vulnerable to the infection and therefore lead to many subsequent waves. From an economic perspective, while the pandemic is lowering business sentiment, it is also an opportunity for sectors like pharmaceuticals, medical devices and hospitals to scale up. Even if we need global help to meet today's needs, we have to shore up infrastructure for subsequent waves of this and future pandemics.

Indeed, even as overseas companies are holding out for pre-orders, advance payments and indemnity clauses, the government has finally given in and waived local clinical trials for "well-established companies". No company can ignore the size of the Indian population and the market it represents. Especially as it looks like annual SARS-CoV2 booster shots will be required for at least a couple of years.

Which is why Bharat Biotech has applied for approvals in more than 60 countries. Other vaccine manufacturers from India too will do the same, not just to shore up exports but to ensure that vaccinated citizens will be allowed to travel to as many countries as possible, once they have key approvals in place. The era of vaccine passports is already a reality today.

As the vaccine and medical device supply chains are being re-jigged, so must the API supply chain, especially for medicines required for COVID-associated conditions like mucormycosis, for example. Medicines to treat fungal infections were usually manufactured in small volumes as the number of cases were much lower. Now, Mumbai-based VAV Life Sciences, which is reportedly the only Indian company that makes the highly purified synthetic lipids needed to produce Amphotericin B formulations, the medication used for treating black fungus infections, finds itself scrambling to scale up from a monthly capacity of 21 kgs to 65 kgs by August, and a further increase to 130 kg per month by December, as per Arun Kedia, MD, VAV Life Sciences.

The clinical trials sector in India is also seeing a revival.

Even if we need global help to meet today's needs, we have to shore up infrastructure for future disruptions

Biotech and biopharma clinical trial sites in the Asia Pacific have increased by over 40 per cent each year on average, compared to just 11 per cent across the rest of the world, as per some estimates. Thus it is no wonder that major CROs like IQVIA Biotech recently announced their launch in India, along with across the Asia Pacific and Japan (JAPAC) region.

But as we rush repurposed medicines through clinical trials in the race to get emergency use authorisations for COVID-19 use, properly conducted clinical trials will be very important to determine the true value of such molecules.

Dr Arun Bhatt, a clinical research and drug development consultant points out the COVID-19 trials and tribulations in a recent article *(https://www.expresspharma.in/covid-19-trials-and-tribulations-for-treatments/)* explaining how a majority of clinical trials of repurposed drugs in India suffer from a high risk of bias. Most have been conducted in a small population of mild and moderate COVID-19 patients, using viral clearance, or clinical scale as efficacy endpoints. He points out that viral load reduction, as an endpoint is difficult to assess because of sensitivity and specificity limits of RT-PCR, and discordance between detection of virus from nasal and oropharyngeal swabs. Also, there is no established predictive relationship between the magnitude and timing of viral reductions and the extent of clinical benefit for a patient.

Dr Bhatt mentions the most recent example of such a trial, for 2-Deoxy-D-Glucose, which recently received the DCGI/ CDSCO nod. He flags one major concern as the safety in COVID-19 patients who can suffer from myocarditis and develop diabetes mellitus.

The WHO's recently released World Health Statistics report 2021 and global COVID-19 excess mortality estimates warn that the COVID-19 deaths could be at least two to three times higher, based on preliminary excess mortality estimates for 2020. Globally, and in India, deaths in 2021 have already surpassed cases and deaths reported in the whole of 2020. Thus, while we cannot afford to get complacent once more, neither can we rush through clinical trials or approvals.

VIVEKA ROYCHOWDHURY *Editor*
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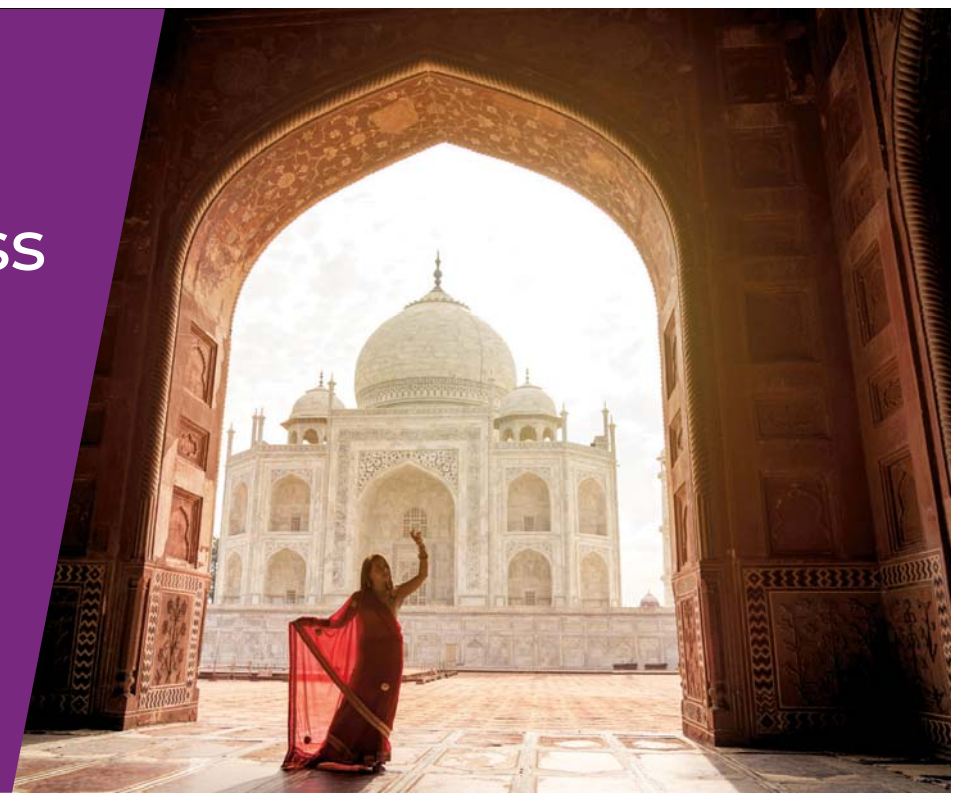

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INTERVIEW

More and more organisations in India understand and have diversity, equity and inclusion as a key priority

Lene Hylling Axelsson, Corporate Vice President, Global Business Services, Novo Nordisk shares details about the milestones and experiences in her career journey, evolution and progress of pharma Global Business Operations, challenges faced by the PHL industry during the pandemic, diversity, equity and inclusion in the workplace and more, in an interview with **Ashwini Prakash,** Managing Partner India, Asia Pacific Lead – Pharma, Healthcare, Life Sciences and Consumer products, Stanton Chase India

Lene Hylling Axelsson, Corporate Vice President, Global Business Services, Novo Nordisk

Ashwini Prakash, Managing Partner India, Asia Pacific Lead – Pharma, Healthcare, Life Sciences and Consumer products, Stanton Chase India

You are a global leader today; tell us about your career journey?
I have been working with the same company for 25 years and recently celebrated my 25th work anniversary at Novo Nordisk. Such a long time in a single organisation might sound boring to many, but at Novo Nordisk, I have worked in different functions including sales, marketing, finance, and production across different geographies - North and South Europe, the US, Japan and now in India where I am heading the Global Shared Services in India for the last two years. I feel 25 years have flown away quickly but I also feel that I got a lot of opportunities during my career. I never imagined I would be here for this long. Whenever I tried to explore opportunities outside Novo Nordisk, I have always come back with the feeling that the opportunities at Novo Nordisk are much more challenging and exciting. The company has since been on a wonderful journey in 25 years, expanding its services and reaching out to many more patients across the world. Today, we are among the top 10 pharma companies in the world. I feel my journey is closely linked with Novo Nordisk which itself has been very inspirational and interesting.

How are the pharma Global Business Operations (GBO) disrupting the Pharma, Healthcare and Lifesciences (PHL) industry?
I think the pharma sector and the GBOs are undergoing a huge transformation and COVID-19 has been one of the determining factors along with price pressures and a lot of change in regulations. As we know pharma products have a long life cycle management and it takes forever to build up a new product in the pharma sector if we look aside from vaccines, which is an amazing innovation in itself. Right now, all of this is very data-driven and we see digitalisation of the whole life cycle and across the life span of the product in the pharma industry. Large investments are being made not only in Novo Nordisk but the entire pharma industry to drive data-driven decisions and moving towards digital technology, both in the sales force, to improve our customer interaction, and also in our research & development (R&D). It is amazing to see how COVID-19 has accelerated the pharma industry's development and we took steps 10 years ahead within one year of the pandemic. It is also panning into the GBOs because, in our shared services, we see a lot of interest and approaching in digitalisation, innovation, and collaboration with start-ups. We are among the top pharma companies and we are placed in Bangalore which is a tech start-up and innovation hub in the world. GBOs are at different maturity levels in different locations, even within Novo Nordisk, and still,

70 per cent of the work we do is labour arbitrage. But a lot has been happening in getting the right competency in the field of IT, finance, and R&D. Our medical doctors here are some of the best in the world. With a focus on innovation and value addition, I see GBOs in India evolving and taking more prominent roles in the next 5 to 10 years.

What challenges have you faced and how companies are responding to meet the huge expectations from the PHL sector during the current pandemic?

The prime challenge that the pandemic posed to us was how to keep our employees safe and like everybody else, we remain focused on that. Secondly, we had to ensure the uninterrupted supply of our life-saving medicines to people who need them around the world. Coming originally from supply chain function myself, I know how stretched the supply chain has been, not only in pharma but across industries be it food, clothing or technology around the world. These days even procuring computers is getting difficult because the supply chain has been affected. We have people working round the clock to supply life-saving medicines to patients who are in dire need of them. So, in our company, we established a crisis response team and we continue to assess how our employees can work from home efficiently and also how do we help them with their health and wellness, both physical and psychological. With huge pressure on our employees, both personally and professionally, it can lead to stress and anxiety. We also continuously review our business continuity plan to see how we can remain resilient, and handle our business efficiently and provide more flexible ways of working once we resume working from the office. We are not only focusing on now but are looking ahead. As a leader, I believe it is about a lot about communication and I have spent a lot of time communicating with employees and our stakeholders during this crisis.

As an expat, did you observe any cultural difference in working style in the PHL industry across different geographies? What was your go-to strategy when you took over the mantle to manage Novo Nordisk Global Business Services (GBS)? How did you adapt and build?

As I mentioned earlier, I have worked in different geographies throughout my career and what I have learned is that all cultures are different. Our corporate culture is more or less the same across the globe. If I step into any of our Novo Nordisk offices across the world, it feels the same, like I am home, including in India. In my career journey, an important lesson that I have learnt is that in an organisation one must not only listen keenly but also ask questions. I have asked so many questions about culture, geography, gender, biases, about how we do work around here to understand how I fit in, and what do I want to keep and

what do I want to change. I have made my share of mistakes and learned the hard way. This is something we encourage across the organisation and I appreciate that our colleagues in India are open to provide feedback and also step up to a senior to ask the right questions.

We have heard women talking about inequality in opportunities at the workplace. What are your views?

I grew up in a family of four daughters and our father was the only male till we got our male dog. Growing up as girls we never experienced a bias of not being sons. In school too, we saw both genders being treated equally. So, it was a huge shift for me stepping into corporate life realising there is so much difference in how we treat genders. Throughout my 25-year career, I always felt I had to work much harder and more diligently than my male peers. This might very well be my own perception, but I still feel especially with maternity leave and changing geographies in different parts of the organisation, I had to spend a really long time proving myself. Even though a lot of work has been happening in India to promote gender diversity, it is a tough environment. I felt while coming here that I needed to prove myself before people actually accepted me and I think there is still a lot of work that needs to be done in the diversity space.

At home, it is women who take the leading role but in office, if we look at the statistics, the higher we get at the rank, the fewer women we have. But there is another dilemma which I still believe is an issue in India and to some extent other countries, women have to take a huge burden at home, so they work at home with children, often with parents and in-laws, and manage housekeeping, which is a huge task and then they get to the office and then they have to work again. So, it is like they are running two careers at a time. I have a lot of respect for Indian women, and I think they still have a long way to go in fighting their way to ensure there is more sharing of the tasks.

How do you see India on the DE&I maturity curve?

I am seeing more and more organisations here in India understand and have Diversity, Equity and Inclusion as one of their key strategic priorities. The topic is now a part of discussions among the top executives. Whenever I join any such meeting, no matter whether it's a man or woman, I see a very serious discussion around how we keep improving and how do we ensure to become diverse and have equity because it is absolutely necessary to succeed as a company. I actually believe there is a very strong culture of diversity and inclusion in the corporates in India because the Indian society is very diverse and in order to succeed, we should mirror society and we even need to show the way forward to how do we become more modern in handling D&I discussion. I think it is very critical that we manage to have dialogue and see how we incorporate other factors in the whole ecosystem including socio-economic factors and government regulations and it's also people we need to make sure come together and have a strong understanding of what still needs to be improved.

> COVID-19 has accelerated the pharma industry's development and we took steps 10 years ahead within one year of the pandemic

I see there is a persistent demand for organisations to walk the talk with these issues, not just being limited to training programs but translating into real action on the ground.

As a leader, what is your advice to the women who are entering the industry?

There are a lot of groups focussing on how we empower women more. In our GBO, we are still at a 43:57 ratio, where 43 per cent workforce being women. The ratio becomes more skewed as we move onto leadership position. So, I believe it is important that women must take ownership of themselves, take known risks from time to time and embrace the unknown. Take jobs that you might not be 100 per cent qualified for but can stand up with confidence to take it up and learn the process step by step. Raise your hand for these difficult jobs and be aware of your own strengths and development areas are and understand how you can contribute to the organisation. Look out for role models and seek a mentor at the workplace. A mentor is very critical in developing and grooming ones corporate and leadership style.

How do you maintain your work-life balance and what you like to do to de-stress?

I am a mother of three teenagers and that takes up a lot of my energy and thinking and they are always the centre of my life together with my husband. I have a tendency to simply work too much if I am not careful because I want to get work done well with high quality and delivered on time. So, I need to focus on balancing all the time. In India, I have started yoga with my husband and it helps me to breathe better and focus on something else than work. I am deliberate about setting aside some "me" time, use it to read books and do gardening. I also like to run, cycle or take a brisk walk with my dog and my husband. Most importantly, I also ensure my diet is healthy and that I get a good amount of sleep.

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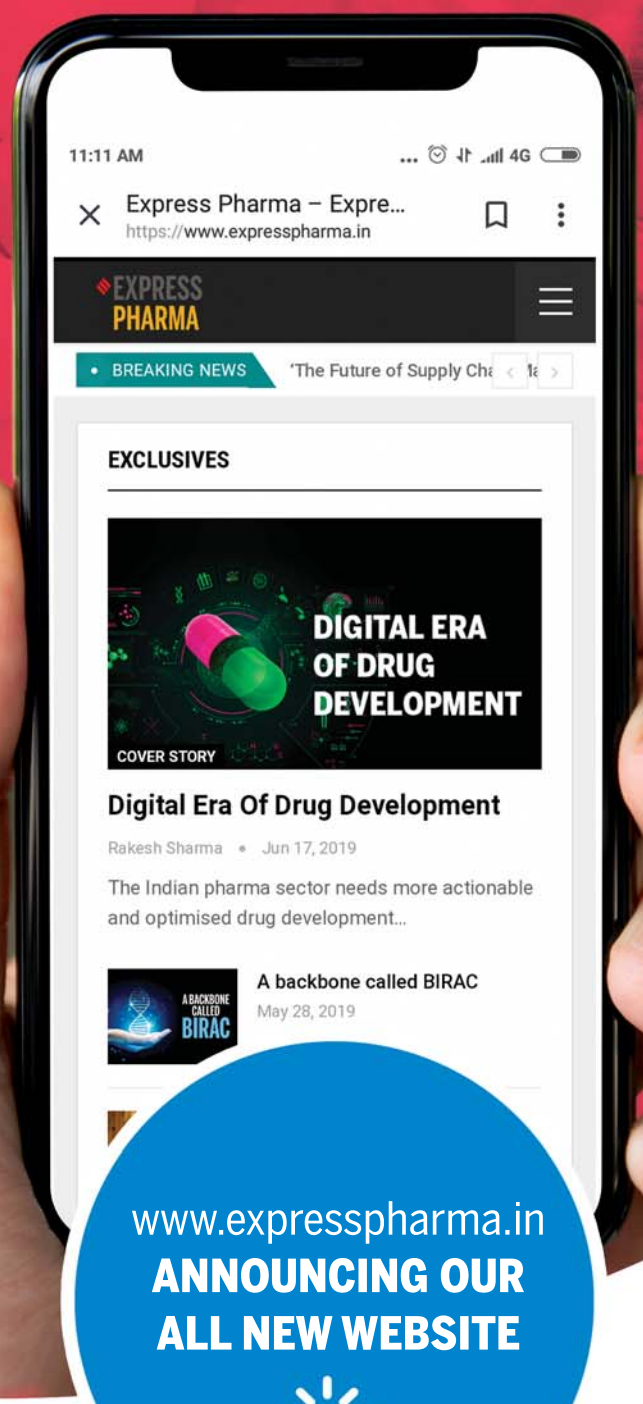

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REAFFIRMING COMMITMENT TO SUSTAINABILITY

As the pharma sector battles the COVID-19 pandemic and goes through a reset to defend the world against such crises in future, it needs to pledge allegiance to sustainability to ensure global welfare

By **LAKSHMIPRIYA NAIR**

Sustainability as a concept was gaining good traction across industries, globally and in India, before the onset of the COVID-19 pandemic. Be it reducing energy consumption or emission of greenhouse gases to curb environmental pollution, improving waste management or optimising water consumption, the pharma industry was identifying and implementing various measures to become more sustainable. Many companies were actively seeking to enhance their impact on the environment and society.

But, the focus of the world has shifted towards fighting the pandemic. For the pharma industry, in particular, identifying and developing new tests, medicines and vaccines at the earliest to fight COVID-19, while ensuring that the production and supply of other medicines remain unhampered, is the current priority. How has this affected sustainability agendas? Have they taken a back seat in this scenario? Let's examine.

The COVID-19 impact

A GlobalData report had anticipated last year, "Sustainability was the buzzword of 2019 and would have continued to increase in prominence in

TABLE 1: GLOBAL SUSTAINABILITY INITIATIVES

VANQUISHING AMR

Over 100 pharma firms and organisations that account for over a third of the world's global antibiotic sales collaborated to form the AMR Industry Alliance. It works to tackle AMR and its members have set voluntary targets to decrease the industry's environmental footprint.

The Alliance released a report In 2020, which divulges that15 of its 18 members who manufacture antibiotics had carried out assessments at their manufacturing facilities and 82 per cent of them had successfully adhered to the standards recommended by the alliance. The report also predicted that in three years, over 50 per cent of all products manufactured at facilities owned by these 18 members would meet targets for no-effect concentrations of antibiotics in the environment.

Source: AMR Industry Alliance 2020 report

ROOTING FOR RESPONSIBLE PROCUREMENT

Founded in 2005, the Pharmaceutical Supply Chain Initiative (PSCI) is a group of pharmaceutical and healthcare companies that have collaborated to promote responsible supply chain management and better business conditions across the industry. Today it has over 40 member companies across the globe.

The PSCI Benchmarking Survey Insights Report released in 2021 reveals very positive data about responsible procurement in the industry. It found, "responsible procurement is gaining more importance in member companies' business activity. Further demonstrating the increasing importance of responsible procurement is the fact that, over the years, higher levels of management are actively engaged in companies' Responsible Procurement Program."

The report states, "Supply chains have rarely had to grapple with more complex, changing conditions than during the Covid-19 pandemic. Even prior to the pandemic, however, there was an increasing understanding that having an overview of the risks present in a supply chain can help prevent business interruption and ensure resilience. In 2020, more companies segmented their supply base based on responsible procurement risk."

A higher proportion of member companies now also perform responsible procurement audits for suppliers assessed as high risk. Over the years, India, China, the USA and Europe have consistently been the regions where most responsible procurement audits are conducted, reveals the report.

Source: The PSCI Benchmarking Survey Insights Report

2020. However, the global outbreak of coronavirus (COVID-19) will bring progress to a halt."

This year, in another report, GlobalData highlighted, "Sustainability has been a big trend in the past few years and many companies in the Asia-Pacific (APAC) region have switched to more eco-friendly alternatives, such as replacing plastic materials and removing single-use packaging. However, since the outbreak of coronavirus, companies may resort to plastic packaging to combat the spread of the pandemic putting the sustainability aspect in the back seat."

Arvind Sharma, Partner, Shardul Amarchand Mangaldas & Co also states, "The present unprecedented situation since early 2020, as a result of the COVID-19 pandemic, has impacted the commitment towards the 17 SDGs. The process of achieving the 17 SDGs has slowed down and the approach towards these goals has weakened. There has also been a shift in the course of development."

He highlights, "Inequalities are increasing now more than ever before, and this threatens the overarching aim of SDGs, that is, 'leave no one behind'. Additionally, COVID-19 has largely impacted global economies, making financing for sustainability even more difficult. It was theorised in early 2020 that there is an apparent risk that COVID-19 will adversely affect the achievement of SDGs. The UN, World Bank and other international organisations warned that even the limited progress made towards countering poverty and malnutrition will be nullified."

Elaborating on the magnitude of the issue, he adds, "It is estimated by the UN Environment Programme that recovering from the fallout of COVID-19 may require a global investment of around $20 trillion. The investment decisions surrounding this money will affect the society for decades to come including our response to future and possibly greater environmental challenges."

If the growing use of plastics and the huge amounts of medical waste being generated are considered cases in point, the impact of the pandemic on sustainability has been adverse.

For the pharma industry, this means that endeavours undertaken and implemented over the years to make drug development, manufacturing and distribution more sustainable is at serious risk.

However, Santhosh Jayaram, Partner and Head, Climate Change, Sustainability and CSR Advisory, KPMG in India, has a different point of view. He states, "The fight to defeat the crisis has only strengthened the sustainability agenda. The capital allocation around the world towards sustainability has increased during 2020."

This opinion is reiterated by Antony Prashant, Partner, Deloitte India as well. He opines, "COVID-19 has accelerated the positioning of sustainability as an important agenda for organisations. One of the big impacts of COVID on companies has been the shifts in operating models which were near-constant for many years. As they build/redesign their operating models, the focus has been on creating them with the sustainability agenda at the core."

So, industry stakeholders and observers seem to be divided on the impact of COVID-19 on sustainability.

Challenges to sustainability in pharma

It is to be hoped that Jayaram and Prashant are proven true since it is clear that the pharma sector needs to reaffirm its commitment to sustainability. Otherwise, in the long term, this could also derail the world's efforts to prevent another health crisis of this scale and scope since the correlation between health and the environment is becoming disconcertingly clear.

But, a report from GlobalData titled, *'Sustainability in Pharma – Thematic Research',* gives a reality check as it points out, "The industry has deeply rooted environmental, social, end governance issues that challenge sustainability. This, along with the image of the industry itself, has created poor or even negative public perception about sustainability in pharma."

There is enough evidence to back this perception. For instance, a report titled, *'Carbon footprint of the global pharmaceutical industry and relative impact of its major players',* reveals that the pharma industry is 55 per cent more emission-intensive than the automotive industry.

And, some of the challenges have been aggravated as a result of the pandemic. Sharma informs, "A majority of the financial stimulus programmes that have been notified by various governments focus on sustainability to restore global economies from the impact of COVID-19. However, the change brought about by the pandemic is not simple and has created challenges in implementing/maintaining sustainable practices."

Our experts cite some examples of the challenges.

Jayaram states, "The big challenges that the pandemic

LANXESS: MAKING SUSTAINABILITY A GUIDING PRINCIPLE

LANXESS, a speciality chemicals company, is an organisation that is taking focused strides towards ensuring the safety of the environment.

Talking about the company's sustainability initiatives in India, **Namitesh Roy Choudhary**, Vice President- PTSE & Capital Investment, LANXESS India shared the following details of the measures implemented at their Nagda-based site and the benefits derived from them. They include:

Co-generation plant: The Nagda site has a co-generation plant that is fueled by biomass. It generates around 3.95 MW power and 45 TPH steam using Carbon Neutral Biomass Fuel and saves about 70,000 MT of Coal and thus saves 95,000 tons of CO2 equivalent emissions per year. This Co-generation plant is the largest consumer of biomass in the region which has eventually financially benefited the local farmers.

Wastewater post-treatment plant: The wastewater post-treatment plant was commissioned at the Nagda site to treat the discharge from the existing Effluent Treatment Plant (ETP) in a manner that virtually no liquid effluent is discharged from the site. The water recovered is re-used for production processes. This initiative not only prevented the contamination of the river Chambal, which is the primary source of water for the villagers downstream but also significantly reduces dependence on conventional water sources.

Off-gas Incinerator: The twin-chamber incinerator has been developed using best-in-class technology and is commissioned for the safe disposal of distillation residue generated from the plant production processes. Steam is generated using the heat recovered from flue gas, which is utilised for production processes. It has been designed with dual scrubbing systems for recovering HCL from flue gas. It complies with all requirements laid down by the Central Pollution Control Board and the Madhya Pradesh Control Board.

The site also efficiently recycles steam condensate which is economised in various processes.

Roy Choudhary added, "LANXESS believes in conserving natural resources through the most efficient possible use of raw materials and energies and identifying further potential for reducing emissions is an inherent part of its ecological responsibility. The Organization applies its expertise while taking into account local requirement to uplift environmental standards."

Among others, LANXESS India received the ICC award for Excellence in Management of Environment, 2020 for its work in areas of environment, water resource and waste management.

Source: LANXESS India

has created is the disposal of medical waste. The pandemic has also raised questions related to supply chain."

Sudarshan Jain, Secretary-General, Indian Pharmaceutical Alliance (IPA) also admits, "Pharmaceutical manufacturing and supply chain is complex in nature and requires collaboration with multiple stakeholders in the process. So, logistical disruptions were one of the key challenges in maintaining sustainable practices during the pandemic."

But, innovative ways and methods are emerging to tackle these issues. Take combination products for example. Packaging a drug and medical device together is an approach that is garnering a lot of attention as it could bring in a new paradigm in healthcare delivery and also lead to less packaging. Likewise, serialisation technologies are enabling efficiencies throughout the supply chain, and can also help find openings for simplification and waste reduction.

However, given the complexity of processes in the life sciences industry, pharma products could leak into the environment at any stage of their life, from development to utilisation to disposal. Therefore, tackling these challenges would call for collaborative, proactive steps from the industry. And, one of them would be to make environmental sustainability central to any project, right from the beginning.

So, what will drive sustainability agendas post-pandemic?

According to Jayaram, "Organisations have a better understanding that the centrality of sustainability is resilience. The pandemic has also given strength to the thought that sustainability goals can be achieved through partnerships."

He highlights, "The pharma industry is trying to restore/gain back the lost trust through this pandemic. The drug pricing issues and the Opioid crisis somewhat resulted in some damage to its image in 2019, especially in the US. With the response and agility the industry has shown during this crisis it surely would have helped to regain some of the lost image, but what it has also done is, it has helped to bring the importance of access to treatment and medicines to the centre of the agenda and this will be one of the biggest sustainability agendas for the pharma industry." Rebuilding its reputation and increasing access to key medicines will be crucial to India Pharma Inc as well.

Jain states, "Achieving sustainability while providing quality medicines to the country is one of the major priorities of the pharma industry." And, as India takes strides towards being truly *AatmaNirbhar* in the pharma sector, this is imperative.

He opines, "In light of the COVID-19 pandemic, the pharma industry went through various operational changes. A key agenda on priority is to accelerate India's domestic drug manufacturing capacities. While the industry plans to boost its capacities in API and bulk drugs, the industry consciously considers the quantities of liquid, solid and air pollutants generated during the process. The immediate need is to work at putting in place a mechanism to process this waste into less harmful substances. Being cognizant of the environmental factors is equally important to enable the success of the agenda and long-term impact."

Sharma advises, "The carbon footprint can be better managed by use of new, improved and technology-driven packaging techniques. Pharma companies need to consume resources like water efficiently and evaluate the environmental impacts of every stage of the product life cycle until its final disposal."

"Seamless integration of business objectives with sustainability goals is key," he asserts.

"The pandemic has significantly altered both the drug development cycle times and production lead times. This has brought in the need for pharma companies to drive the sustainability agendas around the environment, health and safety specifically around minimisation of waste, increase the safety for employees to ensure disruption-free operations and, optimisation of energy consumption all of which enable production at lower costs and ensure sustainability. Focus

LUPIN: MAKING BUSINESS OPERATIONS SUSTAINABLE

Lupin received certification for International Sustainability Rating System (ISRS), last year after audits were conducted at four of the company's manufacturing facilities located at Mandideep, Tarapur, Ankleshwar and Dabhasa, in India.

Speaking about Lupin's measures to ensure sustainability, a company spokesperson informed:

"Lupin has installed a solar rooftop at Lupin Research Park, Mandideep, Aurangabad, Dabhasa, Ankleshwar and Goa with a total installed capacity of 1.2 MW. Additionally, we purchase 3.7 MW and 1.5 MW of wind power at Ankleshwar and Dabhasa. Over the next five years, Lupin plans to increase its renewable uptake by up to 12MW from renewable hybrid power purchase under open access at Mandideep, and solar roof top installations at Pithampur and Nagpur."

"We have implemented several resource efficiency and energy savings projects," he adds. For example, installing energy efficient blowers in HVAC systems has reduced energy consumption and resulted in cost savings of Rs 2.3 crores in Aurangabad and Tarapur. In the last fiscal year, the company was able to increase their usage of renewable energy share by 7 per cent."

The spokesperson also shared a list of the other initiatives taken by the company. He said:

Reducing carbon footprint: We refer to The Intergovernmental Panel on Climate Change (IPCC) AR 4 emission factors for fuels and Central Electricity Authority (CEA) emission factors for grid electricity in India to estimate our carbon footprint. Over the years, our carbon emissions have consistently reduced owing to an increasing share of renewable energy such as solar and wind power in our fuel mix. Wherever feasible we are switching fossil fuel-based boiler fuel to emission neutral energy sources such as agro-waste. We have also implemented various energy efficiency measures in our processes. As a result, we have been able to reduce our cumulative GHG emissions by 9,775 tCO2e.

Water management and conservation: Effective water management is critical to the overall sustainability of our operations. Our plants focus on enhancing water use efficiency and implementing water conservation measures. Local utilities are the main source of fresh water, which is supplemented by groundwater and surface water. We aim to reuse, recycle and replenish water through technical improvements in our processes. This is achieved by installing water recycling plants, reusing AHU condensate and rainwater, water efficiency mechanisms, and raising awareness among our stakeholders about water conservation.

Our industrial by-products and waste streams are treated to ensure compliance with all applicable norms of the State Pollution Control Boards. Furthermore, all our sites are Zero Liquid Discharge. We also ensure that effluents form our processes are not discharged in water streams through run-offs. At nine of these sites, after the primary treatment of wastewater, it is further treated in state-of-the-art water recovery through Reverse Osmosis (RO), Multiple Effect Evaporators (MEE) and Agitated Thin Film Dryer (ATFD) plants.

In the past year, several measures have been undertaken at our plants to reduce our resource footprint and freshwater consumption. Approximately 29 per cent (7,42,179 KL) of the wastewater generated in our plants was recycled and reused in utilities, housekeeping, gardening, etc. Rainwater harvesting and AHU condensate water recovery have resulted in the collection of 3,178 KL of water which has replaced freshwater use. We also use steam condensation recovery and for reuse in our boilers.

Waste management: Waste management practices are implemented across our operations, divisions and supply chain based on the 3R principle – reduce, reuse and recycle.

Monthly reports track and categorise waste generated, which is reviewed by the EHS team. Waste generated during production operations are handled, stored, disposed and recycled in compliance with applicable environmental laws and regulations.

We transfer hazardous waste to cement plants for co-processing, waste mixing facilities for pre-processing or send it to the authorised recyclers for recovery and utilisation. This leads to a significant reduction in the resource footprint of cement plants by substituting fossil fuel use in their energy mix. Approximately 57 per cent of our incinerable hazardous waste is also sent for coprocessing to cement plants.

Aligned with our vision of resource conservation, our waste stream of spent calcium sulphate (7,561 MT) is sent to cement industries for co-processing as Alternate Fuel & Raw Material (AFR).

We also reuse our non-hazardous waste to make bio-compost or send it to piggeries and cattle farms for further use. Canteen wastes and mycelia waste (3,515 MT) is non-hazardous and is sent to piggeries or composted and converted into usable organic fertilizer. We have installed and commissioned bio-composters at two of our sites for converting canteen and garden wastes to organic fertilizer. This has helped derive value from waste and reduce the amount of waste going to the landfill."

for the future would be on dimensions around plastic neutrality, water sustainability and green infrastructure," says Prashant.

He adds, "There has been a shift in priorities towards social sustainability due to the pandemic and therefore the focus on environmental sustainability has been relatively less. The objective for organisations would be to balance both of these in the medium term post the pandemic."

Thus, multiple factors will impel the industry's strides towards sustainability.

Setting examples

The good news is that on a global level several pharma companies are pledging and taking very important steps towards key sustainability goals. *(Check Table 1)* Many companies with operations in India are also making it a priority. To cite an example, LANXESS, a chemical speciality company had released a statement in March 2021 which informed, "A new system of compensation for the Board of Management has been in place since the beginning of the year. Roughly one-third of the variable compensation is now linked to the company's sustainability performance. More specifically, the company's performance in the areas of climate protection and occupational health and safety will be factored into the system for 2021."

It also added, "This covers climate protection and energy, occupational health and safety, environmental

> Globally and in India, several pharma companies are making sustainability a priority and taking very important steps towards it

protection, products and circular value chains, employees and corporate culture, and transparent reporting on achievement of sustainability. Through its newly created Sustainability Committee, all member of the Board of Management will make joint decisions on major sustainability projects." *(Check LANXESS: Making sustainability a guiding principle)*

Another good example is being set by Lupin. Last year, it received certification for International Sustainability Rating System (ISRS), 8th edition. In a statement, the company informed that the certification was received after audits were conducted at four of the company's manufacturing facilities located at Mandideep, Tarapur, Ankleshwar and Dabhasa, in India. The results were declared on March 6, 2020.

ISRS is a global system to assess, improve and demonstrate the health of an organisation's business processes. The ISRS certification helps ensure that business operations are safe and sustainable. *(Check: Lupin: Making business operations sustainable)*

Making a pledge

Many others in the industry are also getting more conscious about their responsibility towards the environment. But, as part of a sector that touches countless lives, pharma companies have to renew their allegiance to sustainability with strategic approaches, management practices and investments.

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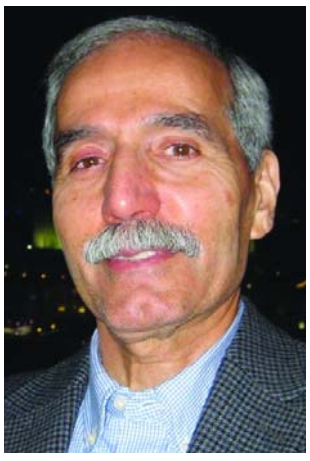
INSIGHT

Sustainability and sustainable development in pharma industry

Prasad Jaladi, Founder and Chief Facilitator, and **Mahmood Sabahi**, Sustainable Chemistry expert , Suraksha, point out that leading chemical and pharma companies or company associations have established sustainability programs to assess their products and manufacturing processes but it is also essential to create an agile, flexible workforce that thinks 'systems and sustainability'

It has been predicted that we will need enough water, food and energy to sustain a population as high as 9.8 billion by 2050 and 11.2 billion by the turn of the century. The key to meeting these challenges will be continued advances in chemistry, chemical engineering, and materials science and engineering. Their products are ubiquitous in our daily lives – from pharma and biomedical technologies to electronics, and communications to transportation and infrastructure. As discoveries continue to be made and technologies advance, how do we ensure the health and well-being of our people and the planet for generations to come?

Increasingly, the grand challenges identified in the 2016 United Nations report are driving new research initiatives. Reports such as that recently released from the 2016 NSF Workshop related to polymer science and engineering discuss those challenges within the context of a somewhat more focused discipline. Note one of the grand challenges identified in that report: "Achieve accessible, scalable polymers that match or exceed the property matrix of existing materials, yet have a green life-cycle." The authors go further to point out theimportance of life-cycle thinking.



Mahmood Sabahi

To continue to grow and support our economy, the chemical enterprise needs an agile, flexible workforce that thinks 'systems and sustainability'. Quite simply, global regulations require businesses/industries to adopt practices that support a circular economy. In a 2016 briefing, the European Parliamentary Research Service discussed "opportunities and challenges" for moving towards a circular economy. One of the four identified challenges was the need for technical skills "which are currently not present in the workforce"; namely, skills for scientists and engineers that would enable them to design products with circularity in mind. It emphasises that the lack of such skills would be particularly problematic for scientists, mathematicians, and engineers. Thus, the roles and responsibilities of chemists, chemical engineers and materials scientists and engineers extend not only to the life of products in the market but importantly, to the "end of life" and environmental fate of those products.

Leading chemical and pharma companies or, company associations have established sustainability programs to assess their products and manufacturing processes. In some cases, they have developed their own special toolboxes, while in others they have utilised existing tools and databases. *Table 1* presents a handful of examples that have been reported recently. All are used to assess the sustainability of existing products, manufacturing processes, and services as well as ideas in the early stages of research and development.

The American Chemical Society (ACS) Green Chemistry Institute (GCI) and a group of major pharma companies founded the GCI Pharmaceutical Roundtable in 2005 with the goal of promoting green and sustainable chemistry and chemical engineering believing that green chemistry and engineering are imperative, and the Roundtable is pursuing

Prasad Jaladi

the implementation of green chemistry and engineering into all facets of drug production from discovery and development to manufacturing. In a paper titled 'Expanding the Boundaries: Developing a Streamlined Tool for Eco-Footprinting of Pharmaceuticals' authors describe the development of "a streamlined Process Mass Intensity (PMI) and Live Cycle Assessment (LCA) tool" for use by chemists and chemical engineers in discovery and process development stages in pharmaceutical and chemical industries. The PMI is the quantitative measure of the mass of raw materials, solvents, catalysts, reagents, water, and anything else that is used for producing a specific amount of a target compound.

Alternatively, quantification of all the materials involved in the synthesis of a specific amount of material could also be achieved by capturing all these quantities in a spreadsheet and determining the fate of all materials after the separation of the target compound. The same approach could be applied to scale up and pilot plant operations. The resulting intensity numbers (mass, solvent, water, waste, etc.) identify the 'hotspots' in the synthesis or process and provide

$$\text{PMI} = \frac{\text{TOTAL MASS OF ALL RAW MATERIALS (KG)}}{\text{MASS OF PRODUCT (KG)}}$$

$$\text{SOLVENT INTENSITY} = \frac{\text{TOTAL MASS OF ALL SOLVENT (S) (KG)}}{\text{MASS OF PRODUCT (KG)}}$$

$$\text{ENVIRONMENTAL IMPACT} = \frac{\text{TOTAL MASS OF ALL WASTE (KG)}}{\text{MASS OF PRODUCT (KG)}}$$

opportunities for environmental and economical improvements. The mass intensities can be calculated for each step of a multistep synthesis or a manufacturing process.

The PMI tool was used by the Roundtable members for assessing synthetic and manufacturing processes and "internal benchmarking" and for collaborating with other companies and suppliers throughout the supply chain. This very valuable tool is available on the ACSGCI *website (https://www.acs.org/content/acs/en/greenchemistry/research-innovation/tools-for-green-chemistry.html)*.

LCA quantifies the environmental impacts of a product or manufacturing process and, also identifies the environmental 'hotspots' and opportunities for rendering the process more sustainable. As indicated in *Table 1*, leading chemical and pharma companies have developed their own tools for life cycle assessment of their products and manufacturing processes and expect such data from their suppliers throughout their supply chain. For example, pharma products are delivered to consumers in a wide range of materials including plastics. Although plastics have provided safe delivery of pharma products to the market, their persistence in the environment is a major concern. Search for biodegradable materials for safe delivery of pharma products has been underway for a few decades. The desired materials should meet a complex set of specification in addition to biodegradability and the search for biodegradable plastics to replace existing products continues. At the same time, major efforts are directed at recycling waste plastics into economically viable valuable products. For either case, it is necessary to apply cradle to cradle (CtC) life cycle assessment to better understand the environmental footprints and overall sustainability of these products.

TABLE 1: EXAMPLES OF SUSTAINABILITY TOOLS DEVELOPED IN THE ENTERPRISE

Company	Toolbox	Sustainability dimensions
BASF	Eco-Efficiency and SEEBALANCE®	LCI/LCA from cradle to grave, impact on environment and cost, impact on society
DowDupont	DCSFT (Dow Chemical Sustainability Footprint Tool)	economic, social, resource use, water, greenhouse gas (GHG), Dow organization
	Dow Dimension Tool	resource quality, renewable-recycled raw materials, conversion efficiency, process safety, chemicals management, water, energy, GHG.
GlaxoSmithKline (GSK)	GlaxoSmithKline (GSK) FLASCTM (Fast Life Cycle Assessment of Synthetic Chemistry)	synthesis route selection in early stages of pharmaceutical research: resource efficiency; materials environmental health and safety
GCI Pharmaceutical Roundtable	PMI/LCA (process mass intensity/life cycle assessment)	pharmaceutical industry mass-based green metric

Search for biodegradable materials for safe delivery of pharma products has been underway for a few decades. The desired materials should meet a complex set of specification in addition to biodegradability and the search for biodegradable plastics to replace existing products continues

In 2005, the National Research Council (NRC) of the National Academies released a report detailing eight grand challenges that must be addressed to secure a long-term sustainable future; and the broad concept of sustainability has caught the attention of many leaders in the scientific, engineering, industrial and regulatory communities. Sustainability education which was called out as one of the eight grand challenges in the 2006 National Academies report, is of paramount importance to instilling 'life-cycle thinking" into product and process design and development. Examples of how one might implement sustainability within science and engineering curricula are beginning to emerge. In 2009, Murphy *et.al.* reported the results of their benchmarking studies on the incorporation of principles of green engineering into engineering curricula across the US. Allen and Shonnard provided a perspective on the knowledge base required for chemical engineering education. As the American Chemical Society Green Chemistry Institute (ACS GCI) Roadmap vision statement aptly pointed out, "the practice of chemistry should change from chemistry focused on academic and economic value with minimal regard for environmental, safety, or health impacts; to process and product design to minimize adverse environmental, health, and safety impacts while enhancing desired performance throughout the product life cycle." To continue to grow and support our economy, the chemical enterprise needs an agile, flexible workforce that thinks 'systems and sustainability'. Quite simply, global regulations require businesses/industries to adopt practices that support a circular economy. In a 2016 briefing, the European Parliamentary Research Service discussed "opportunities and challenges" for moving towards a circular economy. One of the four identified challenges was the need for technical skills "which are currently not present in the workforce"; namely, skills for scientists and engineers that would enable them to design products with circularity in mind. It emphasises that the lack of such skills would be particularly problematic for scientists, mathematicians, and engineers. Thus, the roles and responsibilities of chemists, chemical engineers and materials scientists and engineers extend not only to the life of products in the market, but importantly, to the "end of life" and environmental fate of those products.

Motivated by the recognised societal need for the design and development of sustainable chemical, pharmaceutical, and materials technologies, coupled with the need for scientists and engineers to be educated in life cycle thinking, we developed a course entitled "Fundamentals & Challenges of a Sustainable Chemical Enterprise". It was first introduced in Spring 2015 at the Chemical Engineering Department of Louisiana State University and since 2017 at the School of Chemical & Biomolecular Engineering at the Georgia Institute of Technology. In 2018, this course was added to the Professional Masters in Manufacturing Leadership program at Georgia Institute of Technology which is offered to industry professionals as an emerging process in chemical and pharmaceutical manufacturing.

At Suraksha, we offer training and support to innovation, entrepreneurship, technology development, and commercialisation. Suraksha is an all-volunteer run organisation supporting sustainable innovation for protecting the environment. We offer professional training programs including ISO training and certifications, software, along with mentoring, consulting and commercialisation support. Suraksha is determined to empower one million entrepreneurs.

INTERVIEW

COVID-19 pandemic brought in a lot of focus to the medical refrigeration industry

B Medical Systems is a global manufacturer and distributor of vaccine cold chain and medical refrigeration solutions. **Jesal Doshi**, Deputy CEO, B Medical Systems, talks about the impact of the COVID-19 pandemic on the medical refrigeration sector, the shifts and transformations in the industry and the company, strategies for growth and more, in an interaction with **Lakshmipriya Nair**

The COVID-19 pandemic has brought about significant shifts across businesses. What were the major transformations that B Medical witnessed?

COVID-19 did trigger several changes for us, the major one being the significant increase in demand for reliable cold chain products. As we are directly involved in the fight against COVID-19 by providing the necessary equipment to store and transport test specimens (during the initial stages of the pandemic), vaccines, etc., suddenly, there was a huge requirement for our products across the globe forcing us to re-design our assembly lines and multiply our production by several folds. During a pandemic, this is not easy to achieve. But our employees ensured that the company quickly adopted these requirements. We invested several millions of Euros to expand our production capacity in Luxembourg. We were also able to set up our Indian subsidiary quickly, thanks to the support we received from the Government of India.

Even internally, there were several shifts. Safety of the workforce is our first priority and we introduced several initiatives to minimise the risk of infection to our employees. For this, we upscaled and fast-tracked several digitalisation initiatives. Some of these initiatives constituted a significant change in how we operate and create value for our partners and end customers. This helped us to continue our work in a safe, responsive and well-integrated manner.

> The roll-out of the first COVID-19 vaccine changed the vaccine cold chain landscape totally. We have been a market leader in the vaccine cold chain for the last 40+ years. But the scale of the global requirements was something that we never witnessed before

What kind of new opportunities and challenges did the pandemic bring about for your organisation? How did you tackle them?

COVID-19 pandemic brought in a lot of focus to the medical-refrigeration industry. In the initial days, it was more related to the storage and transport of test specimens. However, the roll-out of the first COVID-19 vaccine changed the vaccine cold chain landscape totally. We have been a market leader in the vaccine cold chain for the last 40+ years. But the scale of the global requirements was something that we never witnessed before. The pandemic necessitated the need for a broader cold chain spanning from -70°C to 8°C. And this requirement was across both storage and transportation. B Medical Systems was able to support the governments across the world by providing them with ultra-low freezers, vaccine refrigerators and freezers, and transport boxes. Our transport boxes are medical-grade boxes, contrary to the domestic-grade products a lot of companies are supplying in the market and has the unique benefit that it could transport vaccines at -70°C, -20°C, and +5°C. This helped several countries to scale up the cold chain infrastructure quickly and safely. Another important aspect that needs to be highlighted is the need for end-to-end monitoring. Some of the ultra-low freezers can store more than 250,000 doses meaning any failure of these units can lead to the loss of millions of Euros, making 24x7 remote monitoring very important. Even during transits, ensuring that vaccines are not exposed to a high temperature is important to maintain their efficacy. B Medical Systems provides end-to-end real-time monitoring capabilities, which further ensure safe storage and transport.

What are the major lessons your organisation learnt from this health crisis and

its management? How will it impact your future offerings, capabilities development for the life sciences sector?
The COVID-19 pandemic brought in unprecedented times and adapting to the conditions that seemed impossible during pre-COVID times made us all realise that 'versatility' is the first and the most important step towards resilience. We replicated this principle across our products and services. We started developing products that offer flexibility to our end customers. This led to the feature optimisation of our ultra-low freezers that now offer varying set point between -86°C to -20°C. This means that they can easily store Pfizer, Moderna, and Sputnik vaccines. Similarly, we can also provide multimode refrigerators and freezers that can operate at temperature ranges of -20°C to 8°C, thereby ensuring the storage of Moderna vaccine at sub-zero temperatures and storage of Covaxin and Covishield vaccines at 2-8°C. As there are uncertainties related to dose availabilities and temperature profiles, the best strategy for any country is to give its vaccine cold chain infrastructure this flexibility, so that it's well prepared to store any COVID-19 vaccine that it receives. We are also exploring and piloting new alternative financing schemes in some countries to empower the government to procure more vaccine cold chain products.

Innovation and collaboration are buzzwords these days. Please elaborate on B Medical's progress and initiatives on both these fronts.
Innovation is the core of our business. We are always looking for new opportunities to optimise the efficiency and effectiveness of the cold chain in order to provide the most reliable medical cold chain on the planet. We want to ensure that vaccines and specimens are stored and transported in the most reliable conditions at the lowest total cost of ownership. We, therefore, introduced remote temperature monitoring 6-7 years ago, much before it became a buzzword. The use of natural/green refrigerants throughout our product range is another innovative achievement that I am personally very proud of.

Collaborations are also very critical for us. This empowers us to bring different types of solutions into the market. For e.g, we recently developed the world's first WHO PQS pre-qualified refrigerated vehicle in collaboration with Toyota Tsusho Corporation. For us, collaborations are not just technology-related. We are also always looking for new commercial partners. Strong partners help us with the proximity to end customers and to serve them faster. Specific to the Indian market, we recently announced partnerships with Adani Group, Spicejet, Parikh Integrated Services, Omega Seiki and we will be shortly announcing a few more. Having them as our strategic partners helps us to cater to the needs of the Indian market more efficiently.

What will be the next frontiers for B Medical? What are your strategies to achieve them?
We are the world's oldest and largest vaccine cold chain company, having been established more than 40+ years ago. Our goal is to help vaccinate the entire world and to save lives through reliable and innovative technology. We will continue our efforts to develop new and innovative products and expand to new regions to achieve these goals. The next frontiers for B Medical are on expanding our vision and product offering; to emerge as the leading player in the medical temperature-controlled logistics space globally, leveraging on our manufacturing capabilities in India and Europe and our extensive presence around the globe including our subsidiary in the US.

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INTERVIEW

Training healthcare workers and pharmacists against fraudulent medicines is a must: ASPA

A continued immersive awareness and education programme is crucial for healthcare workers so that they can be vigilant towards the presence of a counterfeit product and be informed of the protocol if they come across the same, says **Nakul Pasricha**, President, Authentication Solution Providers' Association (ASPA). He reveals more about India's fight against counterfeit drugs to **Akanki Sharma** in an exclusive interview

On December 4, 2020, the European Union's crime agency Europol issued a warning about fake vaccines being sold online. Has something like this been reported in India?

Interpol and Europol had been issuing these global alerts to enforcement agencies across its 194 member countries for the last 12-15 months. One of the first alerts was released in March 2020 when the global operations saw a rise in fake medical products related to COVID-19. They also noticed that criminals were taking advantage of COVID-19 anxiety to defraud victims online. Even in December 2020, an alert was issued that terrorist groups are using COVID-19 to reinforce power and influence. The latest one was issued in March 2021 as the public is warned against online vaccine scams after recent operations in China and South Africa.

A Twitter handle operated by the Ministry of Home Affairs (MHA) @Cyberdost has issued alerts on a regular basis. On-ground incidents of fake COVID vaccines have surfaced in India, but no incident of online counterfeit sales has been reported so far.

As several COVID-19 vaccines come closer to approval and global distribution, ensuring the safety of the supply chain and identifying illicit websites selling fake products will be essential. The need for coordination between law enforcement and health regulatory bodies will also play a vital role to ensure the safety of individuals and that the well-being of communities are protected.

> Healthcare workers and pharmacists make for our first line of defence, and are the most important part of our defence against fraudulent medicines and essential products

As per a 2017 WHO report, 10.5 per cent of medicines sold in low and middle-income countries, including India, are substandard and falsified. What are the latest estimates about the extent of counterfeit medicines in India's pharma supply chain?

Understanding the exact magnitude of the size of counterfeiting in the healthcare system is extraordinarily complex. Realising this, in 2013, the World Health Organization (WHO) launched a global surveillance and monitoring system. It encourages the member states to report substandard, spurious, falsely-labelled, falsified and counterfeit medical products (SSFFC) incidents in a structured and systematic format, to assist in arriving at a more accurate and validated assessment of the scope, scale and harm caused by this issue. In between 2013 to July 2017, the system received 1,500 reports of cases of substandard or falsified products. Of these, antimalarials and antibiotics are the most reported. The findings you have mentioned are based on that alert system.

Globally, experts had noticed an increase in SSFFC from the last decade. The Pharmaceutical Security Institute (PSI), a trade group, had also reported that theft and counterfeiting of pharma products rose nearly 69 per cent over the past five years.

While varied statistics are reported, it is undoubtedly a huge issue threatening health and wellbeing. In the Indian scenario, as per ASPA Counterfeit News Repository, pharma products are among the top five categories which are at high risk of counterfeiting. Between March 2020 to December 2020 itself, over 50 cases were reported involving making SSFFC. There is more than one incident every week.

How can healthcare institutions and medical staff spot fake medicines/vaccines? Is there any way nurses and paramedical staff in hospitals, and pharmacists can be trained to identify counterfeit drugs and put a stop to them? Is such a thing happening anywhere at the moment?

There are two challenges – detecting counterfeit as well as stopping diversion. Healthcare workers and pharmacists make for our first line of defence, and are the most important part of our defence against fraudulent medicines and essential products.

Healthcare workers are amongst the few professionals who are well-versed and familiar with most medicine brands, usage and packaging. They can play a crucial role in detecting and preventing the distribution of counterfeit medicines. A continued immersive awareness and education programme is crucial for them so that they can be vigilant towards the presence of a counterfeit product and be informed of the protocol if they come across a fraudulent product. Information and reminder of a few simple, but crucial tips, can make a huge difference.

Many brands are using anti-counterfeiting solutions on their packaging. Sometimes, a close and careful look reveals authenticity. For example, checking if the security seal is intact, especially in bottled

medicines or the unique code printed on medicine blister packing or carton can easily be verified by sending an SMS or WhatsApp or by scanning a QR code. A crucial requirement is to nurture the culture of due diligence to ensure that the products are authentic.

Almost seven years ago, the World Health Professions Alliance (WHPA) released a handbook titled, "All you need to know about spurious medicines" together with inputs from the Indian Nursing Council (INC), Indian Pharmaceutical Association (IPA) and the Indian Medical Association (IMA). The booklet aims to provide healthcare professionals with a ready-reckoner and a "go-to" guide against spurious medicines in India.

There is a need to elevate and redesign the approach towards awareness on an ongoing basis, rather than a one-time opportunity. As per our information, the International Council of Nurses (ICN), WHPA and World Heart Foundation (WHF) have joined forces with the 'Fight the Fakes' campaign to raise awareness of the dangers of fake medicines.

What are the regulations to curb counterfeits, and what are the regulators like CDSCO and DCGI doing to combat this menace? Is any action being taken by pharma companies or pharma associations in this regard? What is ASPA's role in combating counterfeit medicines and vaccines?

India has no legislation dealing specifically with counterfeiting and piracy, but the legislators, through various statutes, have provided statutory, civil, criminal and administrative remedies. However, counterfeiting has been majorly dealt with by the Intellectual Property (IP) Law as it directly invokes the IP Rights of the aggrieved.

In a meeting held in May 2018, the Drug Technical Advisory Body (DTAB) deliberated the matter and agreed to the introduction of trace and track mechanism for major 300 pharmaceutical brands on a voluntary basis. However, in the absence of mandates, often pharmaceutical companies prioritise other projects – this is a trend we have seen across the world, where regulatory drivers have sped up the implementation of anti-counterfeiting solutions. India is no different, but, in addition, we have another factor to consider – the price controls imposed on certain products as part of the National List of Essential Medicines (NLEM). While we fully support the government's moves to make essential medicines more affordable for our citizens, we suggest that the quality and genuineness of the medicines should be factored in as well, and this can be done by having a dialogue with industry and ensuring that cost and margin pressures don't put a dampener on the adoption of authentication and traceability solutions.

> Regulators around the world, including in India (for exports) have mandated the use of barcoding (also called serialisation) and traceability for protecting medicine and vaccine movement through the supply chain. Similar measures need to be adopted urgently for the domestic public and private supply chain to ensure patient safety

ASPA is committed to build the authentication eco-systems in the country and enhance our relationship with other across-sector industry associations and other bodies working in the same space. We had signed a Memorandum of Understanding (MoU) with GS1 India to create awareness about counterfeiting problems and build knowledge through various tools, including training, publishing of articles, enriching websites, etc., to drive adoption of global standards for detecting and controlling counterfeits. From time to time, we are conducting information awareness webinars. On June 11, 2021, we are conducting a webinar on "Protecting Pharmaceutical lives and securing pharmaceutical Supply Chain during COVID-19."

Apart from this, we have built important tools for brand owners and policymakers. One such tool is the Counterfeit News Repository (https://www.counterfeitrepository.com/). The portal provides in-depth analysis and a one-stop source for all counterfeiting incidents reported in India. This helps in the assessment of the problem areas and the magnitude of the issue the country is facing.

Very soon, we are going to release the first edition of "Authentication & Traceability Source Guide" and a new portal providing detailed information on authentication technologies and solutions. Brands and organisations can use these as a reference guide for framing their anti-counterfeiting strategy.

What technologies are the vaccine and pharma companies deploying to take on fake/falsified vaccines and medicines? How much do these technologies like holograms, barcodes, etc. add to the cost?

According to sources, vaccine makers are deploying authentication and traceability measures. Pfizer reported using GPS software on shipments, Johnson and Johnson is using a security seal on vials' vaccine boxes, along with traceability measures on vials. Glassmaker Corning is equipping vials with black-light verification to curb counterfeiting. These are just some examples of various technologies, but the good news is that regulators around the world, including in India (for exports) have mandated the use of barcoding (also called serialisation) and traceability for protecting medicine and vaccine movement through the supply chain. Similar measures need to be adopted urgently for the domestic public and private supply chain to ensure patient safety.

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INTERVIEW

Companies are taking a fresh approach to be agile and efficient and are going digital on the shop floor

Sekar Udayamurthy, CEO and Co-founder, Jidoka Technologies talks about shifts and emerging trends in pharma manufacturing such as digitising the shop floor, techniques and technologies taking centre stage in pharma manufacturing, the company's plans for the Indian pharma market and more, in an interview with **Lakshmipriya Nair**

Tell us about the shifts and emerging trends in pharma manufacturing. What are the causative agents of these changes?

The two big emerging trends are - Pharma 4.0 and Big Data, and IIOT.

◗ **AI Partners with Big Data, harnessing human reasoning to provide cognitive insights**.

The large volumes of data available throughout the drug discovery and development process require high-performance systems to properly analyse the data and derive value from it. The advancement in analytical techniques is also turning historical and real-time data available with pharma companies into valuable assets for predictive, diagnostic, prescriptive, and descriptive analytics.

Robotic and industrial automation technology combined with artificial intelligence has become the key agent to help move manufacturing from a process-based (current practice) to knowledge-based manufacturing.

This allows organisations to transform from taking reactive decisions to predictive and proactive insights and actions - making manufacturing more consistent and accurate, with higher throughput. It also allows organisations to catch any potential problem before it damages a product that may cause a costly shutdown, a massive product recall, or equipment replacement.

◗ **Industry 4.0 and Digital Twin convergence of information technology and operational technology for manufacturing. Industry 4.0 can be considered the next generation of continuous improvement.**

Medicine spending in India is projected to grow 9-12 per cent over the next five years, leading India to become one of the top 10 countries in terms of medicine spending. To cater to this, the industry will need to upgrade and upskill its processes.

The old operational systems, when modernised and replaced with new digitising software, can reduce human errors and accelerate manufacturing processing. They will be able to make smarter decisions in real-time, 24 hours a day. Teams will be able to access the needed information immediately to maintain the required quality and compliance while improving speed and efficiency. The old manual platforms will have inconsistencies in decision-making due to lack of subject matter expertise in the manpower and also due to fatigue. Pharma manufacturers are finding that the new advanced software is making it easier to ensure compliance with regulations.

> Robotic and industrial automation technology combined with artificial intelligence has become the key agent to help move manufacturing from a process-based (current practice) to knowledge-based manufacturing

How should the players in this industry prepare themselves for a tech-driven future? What should be the prerequisites when they chart out a growth strategy?
With India becoming a major pharma manufacturing hub for many global markets, focus on quality has, today, become more important than ever. In keeping with this, the Indian government had begun "Pharma Vision 2020" with the goal of systematising processes, so that India could become the world leader in the end-to-end production of pharma products.

Artificial intelligence (AI) is a term that is becoming increasingly popular across all industries. It's essentially the use of computer systems to perform tasks that would otherwise require human intelligence. Apart from tasks like decision-making, speech recognition, visual perception, accelerating drug discovery and development, pharma companies can use AI to help increase the quality and rate of production. This will not only help to meet the forthcoming global demand but also ensure that the quality of our products is at par with larger manufacturing economies.

Digitising the shop floor seems to be a growingly popular concept. What does it involve? Can you elaborate on its potential, advantages and challenges?
The continuing evolution of IoT and Industry 4.0 has opened many opportunities for manufacturers. In a smart manufacturing survey, 65 per cent of all pharma manufacturers believe that the pandemic will increase adoption to Pharma 4.0.

Having said this, digitising as a solution is different for every manufacturer. Though for some it is the adoption of new technology and machines, for others it could be using technology to connect and automate their production line. The one thing that is common across all manufacturing companies though, is the urgent need for digitisation – to improve product quality, improve operational efficiencies, increase customer satisfaction, and of course improve revenues.

The one thing that is common across all manufacturing companies is the urgent need for digitisation – to improve product quality, improve operational efficiencies, increase customer satisfaction, and of course improve revenues

More and more companies, today, are taking a fresh approach to be agile and efficient at scale and are going digital on the shop floor.

Manufacturers are embracing technology in the form of cloud, IoT, robots and other automated machinery. They are leveraging artificial intelligence and machine learning to eliminate rote work, egging their workforce to upskill and upgrade to more specialised work. Smart organisations are also using data and analytics to improve planning, for predictive machine maintenance, process optimisation and so much more.

Digitalisation of the shop floor helps in
- Rapid detection of events on the shop floor.
- Standardisation of decision-making through centralisation of information and decentralisation of actions.
- Provides real-time visibility across ERP/MES and quality management systems for better tracking and predictive and proactive insights.

It can also benefit the organisation by way of:
- Great collaboration among employees and ability to work towards common goal.
- Standardisation and scaling of the knowledge of subject matter experts, consistency across various processes.
- Proactive and predictive actions based on meaningful insights.

There are two major challenges in going digital:
1. The legacy systems in the shop floor need to be modernised - which means:
- Retrofitting smart automation on current manufacturing lines.
- Seamless integration to existing systems.
- Generating data leveraging IIOT.

Most systems today are not IoT enabled. In order to meet Industry 4.0, the first step is to retrofit smart automation and this could lead to space constraint, require backward integration with current automation and also integration to current MES and ERP systems.

2. Challenges in acceptance of newer technologies
- Perceived loss of control due to modernisation- With digitisation, deviations can be detected immediately, and instant triaging can happen. Impact assessment management and action can be taken almost instantly. This could sometimes lead to a perceived loss of control.
- Need for extensive training of resources on the shop floor to process change.
- Security implications of wider availability of data and applications lend to vulnerabilities that can be exploited. This requires superior management.

What role does Jidoka Technologies envisage for itself in this transforming landscape?
Jidoka means automation with a human touch. We provide an innovative solution for the manufacturing industry that harnesses the power of human intelligence to automate visual inspection, in order to enhance quality and efficiency of the QC process. We add value, wherever there are visual quality checks, by reproducing human intelligence at scale, at speed. We also elevate the machine vision systems that you are using - to the next level of intelligence.

We have been able to make a positive impact in visual inspection of products for all forms of pharma dosages like tablets, capsules, liquid, creams, powders inline as well as at packaging stages.

With a minimum of 98 per cent accuracy and 100 per cent visual inspection at high speeds, we help decrease excess rejection and resultant wastefulness. Our scalable modular architecture allows for organisations to increase production at an incremental pace, meeting the growing demand in real-time, without the need to make large upfront investments in anticipation of future revenues.

What are your plans for the Indian pharma market? Tell us about your key collaborations, projects.
We are currently working on associating with Tier I, II and III pharma manufacturers in the country to help them deliver products with high quality and consistency, and enable their journey into Pharma 4.0's mandate for continuous quality improvement process. With Jidoka, manufacturing organisations can achieve greater productivity and simplify compliance. Also, our AI product enables faster identification of new defects and drifts in processes as well as generates analytics to capture community knowledge and process drifts. This helps them respond to problems as they emerge, change and iterate on the go.

Pharma is a highly regulated sector. How do your solutions ensure, facilitate regulatory compliance?
In our opinion, the qualification of vision systems is governed by cGMP 211.68(b) and guided by the International Society of Pharma Eng. (ISPE). Our Platform supports the compliance in:
- Calibration, data, audit and documentation needs.
- Providing appropriate controls, accuracy checks and backup requirements.

This combined with the process documentation/ validation; pharma organisations can leverage this capability, making the E2E process fully compliant with regulatory compliance requirements.

Can you share a case study in brief about how your solutions have brought better efficiencies with good ROI to the pharma manufacturing sector?
We are an early-stage start-up and are currently in various stages of discussion/ implementations with marquee pharma companies. We would be happy to circle back with you in few months with more accurate numbers. In the meantime, we would love to share our average numbers across other manufacturing industries, which we firmly believe we can replicate in pharma too:
- 33 per cent increase in throughput
- 30 per cent decrease in false positives
- 5 per cent increase in defect detection accuracy.

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INSIGHT

Is closed processing a reality?

Somasundaram G, Senior Consultant – Asia Pacific, Global BioPharm Centre of Excellence, Process Solutions, Merck KGaA and **Priyabrata Pattnaik**, Director, End-to-End Solutions – Asia Pacific, Process Solutions, Merck KGaA define the key drivers for adopting closed processing, detail the pros and cons of closed processing and some innovations happening in this sphere

Closed processing is considered to be a logical extension of single-use and involves the use of physical barriers to separate processing fluid from the external environment, including the operators. Materials enter or leave the system via predetermined control points.

International Society for Pharmaceutical Engineering (ISPE) defines it as, "A process condition when the product, materials, critical components, or container/closure surfaces are contained and separated from the immediate process environment within closed/sealed process equipment. A process step (or system) in which the product and product contact surfaces are not exposed to the immediate room environment." In this article, we will define the key drivers for adopting closed processing, what are the pros and cons of closed processing and how some of the innovations are happening in this direction.

Is closed processing the same as connected processing?

Biomanufacturing is steadily moving towards higher efficiency through process intensification. One of the key aspects of intensification is operational excellence through connected processing, resulting in functionally closed bioprocess. The advantages of closed processing are shorter processing time, less manual interactions in the process, reduced CAPEX, reduced resources for cleaning and validation, and reduced need for qualified manufacturing space.

Somasundaram G, Senior Consultant – Asia Pacific, Global BioPharm Centre of Excellence, Process Solutions, Merck KGaA

Drive to go for closed processing

One of the main drivers for closed processing is to achieve Contamination Control Strategies (CCS). Closed processing, when designed and implemented correctly, mitigates the risk of contamination by adventitious agents, reduces the amount of human intervention and manipulation and protects operators. In addition to a reduced risk of contamination, closed processing offers several benefits including reducing capital expenditures, reducing the classification of clean rooms and accelerating time to market.

What are the options available?

Critical enablers for closed connected processing are:

Closed bioreactor: Closed processing has always been mandatory in upstream processing to maintain sterility and to avoid contaminations. Also, an ecosystem of closed vessels or bags for media, feeds, glucose, antifoam, etc; have been well established. Continuous upstream processes (i.e., perfusion), have a long history in the production of unstable proteins and is therefore well-established.

Connectors: The connecting device or connection method may appear to be a small part of an overall system, however, connection and disconnection of tubing for process fluid transfer is a critical aspect of closed processing. Manufacturers need to carefully consider the available options because the connector can be the deciding factor in keeping the single-use bioprocess truly aseptic.

Sampling: Sampling of biopharma process intermediates and the final product is essential for manufacturing workflows where the final product cannot be terminally sterilised. Unfortunately, "traditional" sampling methods are not closed systems and therefore do not maintain a barrier to contamination entering the process during sampling. As a result, the sampling process itself, which is critical to the success and safety of the manufacturing workflow, can lead to contamination of a unit operation and possibly an entire batch. In contrast, aseptic sampling systems are disposable, closed units that always maintain aseptic conditions and ensure the security of the process, operator, and the sample. Due to the shortcomings of traditional sampling, many biopharma companies have adopted closed, single-use sampling technologies. A closed design ensures the process sample collected from a specific point for analysis, reducing the risk of losing valuable product while maintaining the integrity of the fluid samples.

Priyabrata Pattnaik, Director, End-to-End Solutions – Asia Pacific, Process Solutions, Merck KGaA

Fill finish assembly: For closed connected processes, it is important to consider the length of the tubing connecting the different unit operations carefully. It is beneficial from a contamination risk viewpoint to design the tubing length as short as possible, to make the setup easy to survey, facilitate the transfer of the liquid and minimise dead legs and losses in the tubing. This type of setup needs to be carefully planned and knowledge of the equipment used such as its appearance, size, contexture, etc., is necessary.

Potential pros and cons of closed processing

Pros:

- The risk of contamination is greatly reduced, due to the physical barriers protecting the product from human contact.
- Closed systems reduce operating time by relying less on operator handling and more on pre-assembled components. Single-use products may still be used, though unnecessary for sterilisation. If implemented, these products will also reduce time in the areas of cleaning, validation, setup, and operation.
- Manufacturing operations can take place in lower classified environments (able to downgrade production area to Grade B or lower).
- Reduced operating time and cost optimisations.

Cons:

- Due to the relative newness of closed operating technology, facility managers should ensure their equipment operators are capable of adjusting to the new process before adopting it. The new approach has reportedly been met with uncertainty by many engineers who preferred the more traditional process.
- Operating at high risk
- Large amount of Grade A space
- Increased operational costs

Future perspective

The aspiration of the biopharma industry is to move to fully integrated closed processing, either in batch, semi-continuous or continuous mode of operation. The intention is to remove aseptic manipulations that pose risk to bioprocessing with contaminations, to increase process efficiency and achieve a higher state of ultimate patient safety.

Though we aspire to achieve fully integrated completely closed bioprocessing, we are yet not there. There is a general confusion about how we define connected processing with closed processing and continuous/contiguous processing. Closed processing is the idea that the flow path of product and materials could be operated as a closed system,

reducing, or eliminating the dependence on a controlled cleanroom environment to prevent environmental contamination and assure quality. Closed processing necessitates connected processing and should not be confused with continuous processing.

TABLE 1: SUMMARY OF BENEFITS OFFERED BY CLOSED PROCESSING

Critical success factor	Impact of closed processing
Flexibility	◗Enable production in lower classification environment ◗Enable multi-product facilities with production of smaller batches run in parallel
Speed	◗ Reduce new facility build times ◗Reduce lead time between product campaigns
Quality	◗Ensure the integrity of process steps ◗Operate process in controlled, closed environments ◗Reduce risk of contamination of product and protect operators
Costs	◗Reduce capital and operating expenditures ◗Reduce or minimise cleanroom classification level ◗Enable gray space or controlled not classified (CNC) processing

Summary

The benefits of closed processing are compelling and regulatory agencies have encouraged this approach to mitigate the risk of adventitious agent contamination. As regulations continue to crystallise, the biopharma manufacturers are increasingly exploring their options as they consider evolving from open to hybrid to closed processing. While widespread adoption may be several years away, the pandemic has likely accelerated the pace of consideration and integration.

As in this article you have seen, many technologies are available today to facilitate closed processing including bioreactors, single-use systems, automated equipment, sterile connectors, and in-process sampling. The use of these technologies not only minimise the risk of contamination today but will also reduce the cost of facilities in the future, enable greater flexibility in manufacturing, accelerate workflows and help ensure high product quality.

INTERVIEW

Upskilling and rapid learning applications will lead the way in future

Ahmedali N, Mentor, Cornucopia - V5 Global - a unit of FirstMeridian talks about the shifts in pharma hiring and training since the onset of the pandemic and elaborates on the emerging trends and strategies in talent management, sourcing, retention in the pharma sector, in an interview with **Viveka Roychowdhury**

Pharma companies had to work through the lockdown as essential services. What were some challenges related to staffing, accommodation, training younger staff to perform without seniors who might have been in the higher age risk group, permits, etc.?
Pharma companies have both blue-collar and white-collar employees. They typically operate across different models and are involved in manufacturing, R&D, field sales and more.

In the last few months, many companies were operational around the clock to meet the demand for products. The industry, as a whole, had to adapt to newer ways of working in a very short period. There were various challenges with the supply chain, procurement, retaining quality and meeting production deadlines.

One of the biggest challenges has been staffing. All sectors have seen their share of attrition in the past few months, which has created challenges for training and maintaining quality and continuity of operations.

In pharma and other sectors, a solution to this has been adopting contract staffing and managed services. These services allow companies to expand their workforce without undertaking the pain of training and managing the staff.

In the current situation, while the industry needs to add people, constant disruptions are a challenge to training. Many companies have been addressing this issue by virtual training programmes for their employees.

With these challenges in place, upskilling and rapid learning applications will lead the way in future, which will help companies train their staff virtually.

> India is already becoming the hub for data analytics and clinical research operations. Staffing solutions are the new emerging trend that will support accelerated growth in a changing environment

A lot of pharma companies who worked through the lockdown had a sizeable section of staff getting the COVID-19 infection. How are they coping with staffing challenges, especially as the second wave looks to be worse than the first?
Every sector has had its share of challenges. The pharma sector adopted standard protocols like regular temperature checks, sanitising work areas, limiting contact, and face shields.

Like many other industries, the pharma industry also adopted a hybrid work model. About 30 per cent of the staff will be under the hybrid model, where they are required to be present in the office only a certain number of days. About 40 per cent of the staff will stick to traditional working in the office to execute strategic processes. R&D units are operating with 50 per cent staff.

Special leave policies were designed to help employees who had tested positive for COVID-19.

As mentioned earlier, pharma companies have begun adopting contract / temporary staffing services to meet staffing demand. Outsourced staffing helps meet the temporary shortfall or additional short-term increase in demand.

Outsourced staffing also provides companies with the flexibility of additional workforce on demand – they get the option to hire a skilled workforce for short periods without the hassles of hiring, onboarding, exits and the other tedious processes involved. In the functioning of Medical Affairs, Medical Liaison, product development and R&D, Regulatory and Pharmacovigilance, there exist many opportunities for outsourced staffing solutions.

India is already becoming the hub for data analytics and clinical research operations. Staffing solutions are the new emerging trend that will support accelerated growth in a changing environment.

Given that the pharma sector requires staff with specific skill sets and qualifications, how is the pharma sector different from other sectors when it comes to talent management, sourcing, retention?

The pharma industry requires highly qualified people with specific skill-sets. Depending on the company and the sector, there might be additional requirements that need specialised training. For instance, besides digital and technical skills, some companies require employees with skills like empathy and communication while dealing with the doctors on the field.

Managed Services can positively help here - right from recruitment and onboarding to training and expanding the team as needed. Having a suitably well-skilled workforce is notably vital because a skilled workforce is precisely what will help companies meet their targets and emerging demands.

Pharma companies are different from other sectors in terms of hiring. The difference is typically linked to a clash of old vs new culture and the changing nature of the expectations from external stakeholders.

The pharma sector hires both blue and white-collar staff. Has the pandemic impacted staffing services in these two levels of staff? Is temporary hiring a solution?

Pharma industry, as compared to other sectors, is a little different and slightly more conservative. Generally, they take time to try newer ways of working. At the same time, they are beginning to realise the severity of the COVID situation. The companies are in an observant phase and experimenting with different opportunities to stabilise their businesses. There is uncertainty of the future and hence they are reluctant to add on too many headcounts.

Therefore, contract staffing is the future in meeting employee shortage needs of employees owing to lack of skills and the ongoing pandemic.

What are the potential solutions to these staffing issues, especially as it looks like there could be recurrent waves of COVID-19?

The recurrent waves of COVID-19 will be a reality as assessed by experts worldwide; pharma companies have started to broaden their perspective and adopt contract staffing just as IT and Telecom industries have. The challenge could be the differentiation between permanent and temporary staff, employee relations, and employee engagement.

Companies that provide mature products and are well known in the market can utilise temporary staff to promote mature products, possibly becoming a prevalent trend sooner than later.

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KILITCH HEALTHCARE INDIA LTD.

Accrediations

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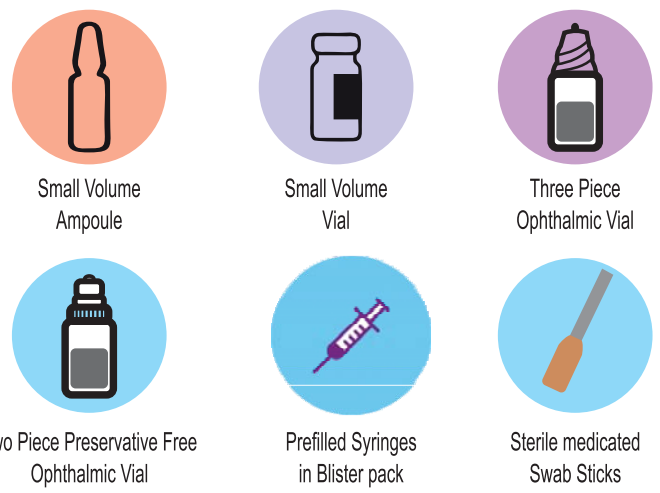
WHO

Manufacturing Sections



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HORPHAG

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AVISH SUBNIL

VEEGUM®: A key trouble shooting excipient!

An insight on Veegum® and the functions and applications of this excipient in various types of pharma formulations

Veegum® is a functional excipient and key ingredient for various Solid, Liquid and Semi-Solid formulations. The versatile 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.

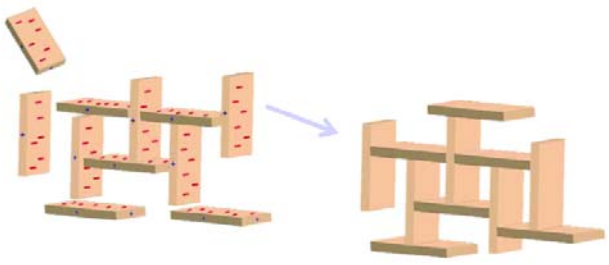


Fig: House of card structure

We say, 'If your tool is Veegum®, then every formulation problem has a solution!'

This article gives an insight into Veegum® and its 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, increasing 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.

We are talking about Veegum®, a versatile taste-masking agent. Veegum® (Magnesium aluminium silicate) - is an inert and flexible ingredient primarily used in Pharmaceutical applications. Veegum® is a type of natural smectite clay that are processed to optimise purity and performance and are 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, USA. 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.

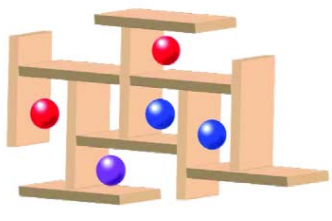
This ensures that VEEGUM does not form chemical bonds with the API or other excipient but works amongst its own particles to mask the bitter taste of the APIs and thereby protecting the integrity of the drug molecule. It is a US-DMF Certified excipient, a certification that speaks volumes about its safety, 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, Calamine to name a few.

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). This is 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 1-2 – will stabilise emulsions containing anionic or non-ionic surfactants and a wide variety of oils, fats, and waxes *(See figure below)*. 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.



Phase separation

No phase separation With Veegum®

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 a binder, disintegrant, moisture-controlling agents, 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 we all know 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. We at Pioma Chemicals, along with the consistent support from our valued supplier Vanderbilt Minerals LLC, are always on the lookout for new innovations which can make the product development an interesting task and ensure we come up with more user friendly ideas for our Customers and we hope to continue to do this 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!

New age offerings from Gandhi Automations

Gandhi Automations offers sectional overhead doors and dock shelters for all industrial and commercial needs

India's No.1 entrance automation and loading bay equipment company, Gandhi Automations offers sectional overhead doors and dock shelters for all industrial and commercial needs.

Sectional overhead doors from Gandhi Automations – Quality and safety

Porto: Porto Sectional Overhead Doors are ideal for all industrial and logistics needs. The design and different solutions offered ensure the door to be aesthetically pleasing and perfectly suited to any architectural environment - from modern and traditional industrial buildings to fine commercial buildings. As these doors slide vertically, stopping in the proximity of the ceiling, they blend in with the architectural features of the building. Porto doors are built to ensure the highest ease and flexibility of use which, in turn, ensures a quick, hassle-free and accurate replacement of old doors. Their compact size ensures more available space both inside and outside the premises. Depending on the structure of the building and the requirement a choice can be made from a standard lift, vertical lift, horizontal lift, low headroom or inclined lift. Porto range comprises a wide series of track systems, panel options and safety features. Special glazed doors provide excellent lighting and vision into the building where required.

Max Vista: Max Vista Sectional Overhead Doors are ideal for industrial and commercial buildings. The doors are made with a combination of aluminium panels and transparent acrylic, giving it a distinctive look and enhancing the look of a building. Max Vista Doors make the environment bright and pleasant to work in as it allows natural light to pass through the large clear areas.

Gandhi Sectional Overhead Doors provide heat insulation and soundproofing thus improving the working conditions on the premises and saving energy. The products are affixed with a CE mark making them reliable and safe.

Key features

- Reliable and low-noise operation
- Extreme robustness
- Safe operation in compliance with safety requirements
- Design-oriented surfaces and optimum light solutions
- Minimal bulk for more space indoors and outdoors
- Easy and practical to open and operate
- Energy savings and more comfort
- Bright indoor environment and attractive design
- Pre-painted, galvanised steel, sandwich panel of thickness 40 mm
- The gaskets made of a special non-ageing rubber that seal the perimeter of the door opening
- They produce a perfect seal, preventing water, air and dust infiltration
- Minimal bulk for more space indoors and outdoors
- Easy and practical to open and operate
- Energy savings and more comfort
- Bright indoor environment and attractive design
- Sectional Overhead Doors can be customised as Gas Tight Ripening Room Doors

Dock shelters from Gandhi Automations – Safe and environmentally friendly

Dock Shelters are installed mainly to seal the gap between the building and the vehicle in such a way that when the Sectional Overhead Door is opened goods and personnel are protected against the harsh weather conditions outside. Dock Shelters provide a seal between the internal and external environments, thus assisting in the reduction of energy consumption. The savings in energy costs are considerable.

Retractable Dock Shelters: The retractable PVC front panels of Dock Shelter are commonly used. With its simplicity and efficiency, it grants for a constant payback of the investment. These are available for dock level installation or ground-level installation for the protection of doors without dock. The front panels are made of high resistance black PVC reinforced with a double weaving of polyester that works like a spring to seal the vehicles of different shapes. The flaps are flexible and have very high wear and tear resistance. Designed to retract under the shock of any possible wrong maneuvers of the docking vehicles and extend when the vehicle drives away.

Cushion Dock Shelters: Due to its high insulation factor, the Cushion Dock Shelter is the ideal solution for controlled temperatures. The three cushions are made of elastic polyurethane foam, covered with PVC coated polyester fabric, supporting the vehicle pressures and perfectly sealing the three sides, including the space between opened rear doors and sides of the vehicle. The two vertical cushions have continuous overlapped anti-friction limpets allowing for the up and down heavy friction of the vehicle on its suspensions, during the loading. It is available with a fixed or adjustable horizontal top cushion, adjustable to the different vehicle heights.

Inflatable Dock Shelters: The Inflatable Dock Shelter is the best solution for insulating and improving the working environment. It can be rapidly inflated with a fan and it creates perfect insulation between the vehicle and the loading bay, sheltering from cold, rain, wind also dust and humidity. The Inflatable Dock Shelter is made of polyester fabric, PVC covered, a material that resists hot temperatures and bad weather conditions. Inflatable Dock Shelters provide the most versatile seal available to service the widest variety of truck and trailer configurations. Contrary to other types of dock shelters the vehicle does not push towards the shelter instead the shelter is inflated around the vehicle.

For more information contact:

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Profitable packaging for pharma manufacturing facility

Edge Controller, a comprehensive factory automation solution from B&R, enables pharma manufacturers to control the packaging line using a single system effectively

Pharma packaging has taken a paradigm shift and is recognized as a critical and essential process. Innovative packaging methods are consistently coming up to address the growing demands of the market. With a surge in demand for vaccination, vials, ampoules, and syringes, pharma manufacturers are under pressure to produce in high volumes with a shorter time to market. There is a strong need for the packaging process to be more flexible and efficient to cope up with growing demand. Moreover, an efficient packaging method becomes crucial to maintain the curative benefits of medicines and protect them from external factors such as temperature and humidity. It helps to keep the product intact during transport and while handling.

Comprehensive monitoring of the packaging process is a key focus for factory managers to increase efficiency and data generated from the process plays a vital role in it. Data-driven monitoring techniques have been gaining traction in the packaging process, which gives insight into operations to factory managers. Effective data management helps factory managers to harness data generated from the packaging process and gain complete visibility. With data available in real-time, it supports them in crucial decision making for process optimization and improving efficiency. Data curated during the packaging process is imperative in providing information on drug composition, necessary dosage details, expiry date, and the serial or batch number to simplify tracking.

With an emphasis on data at one end, pharma manufacturers also focus on increasing productivity, reducing downtime, and improving product quality. The packaging line is prone to handle multiple products with shorter batches. Liquid medications and injections, especially with glass packing, require different packaging methods due to their fragile nature compared to the packaging of blisters for tablets and pills that can be packed and stacked. An increase in operational demands has seen pharma manufacturers exploit automation solutions to make their processes agile and competent. This calls for a scalable factory automation system that can control and monitor the complete process simultaneously and not only handle field data efficiently but also convert it into valuable information for analytics.

Edge Controller enables factory manager to handle data efficiently from packaging line on a single system

Seamless data management using Edge Controller

Edge Controller, a comprehensive factory automation solution from B&R, enables pharma manufacturers to control the packaging line using a single system effectively. Edge controller is a scalable and flexible system consisting of core components for operation and data management, making it a more powerful and successful solution among pharma facilities. With its integrated PDA (Process Data Acquisition) features, manufacturers can seamlessly manage data from packaging lines in a central location. It consists of ready-to-use modules that enable data to be collected, analyzed, and processed on a single platform, making it convenient for factory managers to make decisions.

PDA is integrated with a powerful business intelligence suite that provides the framework for a manufacturing information system and offers key performance data to help identify the potential for optimization. The user-friendly report design tool allows the factory manager to create reports supporting all types of data sources, including MySQL, JDBC, XML, and CSV. The manager can also customize reports based on products and batches. PDA offers intuitive dashboards and graphs that reflect production performance in real-time. It offers powerful and long-time archiving, supporting in detail analysis of line performance. With the capability to handle up to several hundred thousand data points, PDA proves to be an ideal solution for manufacturers to address the increasing market demands.

Implement track and trace with minimum effort

Pharma manufacturing facilities require that the items produced are tracked seamlessly throughout all stages of its supply chain. International standards and regulations place strict requirements on manufactures regarding traceability and ensure product and packaging quality at the topmost level. To provide seamless process data, all relevant details are saved to the SQL server of Edge Controller throughout every stage of the process. This data forms a basis for tracking and tracing, which get logged-in documents with read-only access, thereby avoiding data tampering. Highly flexible reports with integrated analysis function support the factory managers in efficiently tracking the manufactured product.

Data protection as an integrated feature of Edge Controller

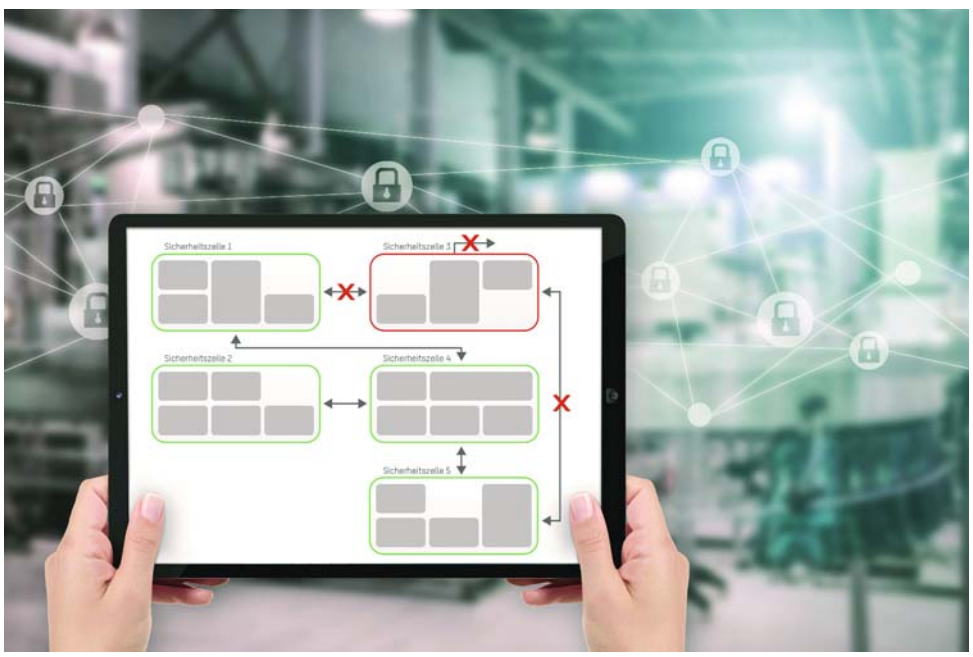
The Edge Controller is easily configured to handle multiple products on the same packaging line. With advance and modular software blocks, this PC based system can be programmed to handle batch production with ease. Integrated units such as recipe management, user management, alarms and trends, audit trail allow factory operators to manage batch information effectively. In addition, manufacturers are keen to protect data generated from the line and prevent access by unauthorized users. Edge Controller takes data protection as a serious function, and it has i nbuilt options to ensure data is safe. It consists of distributed, autonomous security cells that provide simple yet efficient protection for systems against malicious software and cyber-attacks. Edge Controller functioning over LINUX operating systems gives an added benefit to performing reliable and secured handling of process data.

Convergence of OT and IT

Edge Controller is a powerfully built system consisting of high processing capabilities and expandable storage that allows factory operators to establish end to end shop floor integration seamlessly. Edge controllers can connect with

different machines on the packaging line and at the same time exchange crucial data with enterprise-level such as SCADA/MES/ERP. It supports open communication protocols such as OPC UA and MQTT that enables packaging lines to connect and share data in a unified and easier way. With the extension of Fieldbus support, Edge Controller communicates with an auxiliary system such as barcode and RFID readers connecting devices to a single platform, ensuring ease of operation.

Edge Controller is integrated with functions for predictive maintenance, enabling factory operators to maintain the health of the line. The system monitors critical points in the line and supports the operator in scheduling maintenance to avoid unplanned downtime. Real-time monitoring of critical parameters increases the availability of lines and improves accuracy in operations. In addition, Edge Controller consists of modules to monitor energy consumption in the line. It enables factory operators to measure, record, and evaluate all relevant energy parameters in the process. It generates energy data using intuitive reports and trends that make it possible to visualize energy usage on the line and reduce energy costs.



Edge Controller provides effective protection of process data against cyber threats

Smarter packaging using smart automation from B&R

The pharma industry sees a growing trend in packaging techniques, and there is a constant need to innovate and adopt the latest technologies to stay competitive. With data becoming the epicentre of the packaging process and adhering to industry regulations becoming important, there is a need for a flexible automation system to make packaging operations suffice to the changing market demands and keeping innovations on track. Edge Controller from B&R enables manufacturers to easily scale the packaging line and give complete transparency of the process, maintenance, and energy consumption. Using powerful software and scalable hardware, B&R enables the pharma industry to become smarter, competent, and profitable.

Goldman Sachs invests in Aragen Life Sciences

It has taken a significant minority stake in the company by acquiring shares previously held by ChrysCapital and other existing shareholders

Aragen Life Sciences, formerly known as GVK Biosciences and a leading contract research organisation (CRO), announced that Goldman Sachs, an active investor in India, has taken a significant minority stake in the company by acquiring shares previously held by ChrysCapital and other existing shareholders.

Aragen is a leading provider of outsourced discovery, development, and manufacturing services across both large and small molecule platforms. The company serves a worldwide customer base which spans to the United States, Europe, and Japan. Aragen has demonstrated strong organic growth on the back of deep domain expertise, strong global delivery capabilities, and partnerships with global biopharmaceutical and biotech clients.

"We believe this new investment at this important juncture in our company's development underscores the tremendous opportunity ahead. Working with Goldman Sachs, we are well-positioned to address the opportunities in front of us to become a leading, global player with comprehensive end-to-end solutions for drug discovery and development. For more than five years, ChrysCapital has been a trusted investment partner. Following their successful exit, we are pleased to now enter a new phase in our continued evolution," said Manni Kantipudi, CEO of Aragen Life Sciences.

"Aragen is well positioned to benefit from the secular trend of increased outsourcing by the life sciences industry. With a clear value creation plan in place, we look forward to closely working with the management and shareholders of Aragen. Goldman Sachs is actively seeking to invest and foster leading, national champions of India who are building companies of a global scale," said Rajat Sood, a managing director at Goldman Sachs Asset Management.

> Aragen is a leading provider of outsourced discovery, development, and manufacturing services across both large and small molecule platforms. The company serves a worldwide customer base which spans to the United States, Europe, and Japan

"As an experienced global investor in the healthcare sector and India, we look forward to leveraging our worldwide network and experience to help expand Aragen's portfolio of differentiated offerings and client base to accelerate the company's growth." said Michael Bruun, a managing director at Goldman Sachs Asset Management.

Raghav Ramdev, Managing Director at ChrysCapital said, "We are proud to have seen Aragen grow and scale from providing discovery services to successfully expand into development and manufacturing, as well as biologics. It has evolved into an industry leader with a strong base of innovator clients."

Goldman Sachs is an active investor in India, deploying more than $3.6 billion in capital since 2006. Previous investments in Indian healthcare include Biocon Biologics, BPL Medical Technologies, CyteCare Hospitals, Max India and Nova Medical Centers.

Jefferies, Dimensions, and Shardul Amarchand Mangaldas & Co advised company, existing shareholders and ChrysCapital. Trilegal, Herbert Smith Freehills, and Deloitte advised Goldman Sachs.

Waters and Genovis collaborate to develop efficient workflows for biopharma characterization

Firms working to co-develop automated biotherapeutic characterization workflows, combining Waters LC-MS instrumentation and Genovis Smart Enzymes

Waters Corporation and Genovis AB are formally collaborating to develop and market complete routine biopharmaceutical characterization workflows based on the Waters BioAccord LC-MS System, Andrew+ pipetting robot and Genovis SmartEnzymes. The goal of the collaboration is to develop automated workflows for the rapid and consistent characterization of critical quality attributes (CQAs) of monoclonal antibodies (mAbs) and other protein-based drugs in bioprocess development, formulation, stability testing and quality control (QC).

"Biologics analysis is an area that is ripe for improvement. What takes analytical scientists several days to do, should take hours or minutes instead," said Jeff Mazzeo, Vice President, Global Marketing and Scientific Operations, Waters Corporation. "Today, up-front sample preparation is a major bottleneck to productivity, largely due to the number of manual steps involved and the outmoded technology by which samples are readied for analysis. By combining Genovis' SmartEnzymes with automation, liquid chromatography/time-of-flight mass spectrometry and application-specific software workflows from Waters, we intend to move biotherapeutic analysis forward in ways never thought possible."

"The BioAccord LC-MS system and the Andrew+ pipetting robot align perfectly with our strategies and vision at Genovis to bring simplified, robust and automated enzyme-driven workflows to the biopharma industry," said Fredrik Olsson, CEO, Genovis AB. "The enzymatic workflows that we will develop in collaboration with Waters will help our customers in their efforts to bring safe and novel therapeutics to patients, faster."

The workflows in development are based on the pairing of the Waters BioAccord LC-MS System, Andrew+ pipetting robot and Genovis SmartEnzymes and will focus on addressing the application needs of GxP laboratories in the following areas:

- Product variant analysis [e.g. glycosylation, oxidation]
- Bioprocess stability monitoring
- Biosimilar glycosylation analysis

Complete pharma solution: testo Saveris Pharma

Testo provides the best-in-class solution for comprehensive automated data monitoring management for equipment and environmental parameters in the pharma industry

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

- Holistic system comprising sensors, software, and services
- GxP&21 CFR Part 11 compliant system
- Provides seamless recording, automated documentation and reduces human efforts
- The data is stored in the probes, so even if software connectivity is lost the data is safe and can be downloaded once the software is logged in.
- Real-time alarm facility to highlight unexpected results

Testo Saveris Pharma system consists of testo Saveris base V 3.0 which is the core component of the system. It manages and evaluates data from all over the facility from 3000 channels. The four testo 150 data logger modules can be flexibly combined with the three communication modules (WLAN, LAN, testo Ultra-Range) making it a very convenient and user-friendly system along with the web-based, intuitive cockpit to detect alarms, initiate corrective measures and acknowledge them whenever necessary. Testo Saveris Pharma aids in uninterrupted monitoring of various applications in the pharma industry like:

testo Saveris Pharma is an automated system that is integrated into the facility and constitutes of wireless or Ethernet probes installed at different locations that are connected to one base station to document and monitor all measurement data of its own

For environment monitoring:

- Manufacturing/Production area
- Research and QC labs
- Cleanrooms
- Data centres
- Warehouses and packaging and many more

For equipment monitoring:

- Deep freezers, refrigerators
- Cold rooms
- Incubators, stability test and walk-in chambers
- Blood and tissue banks
- Autoclaves
- Nitrogen tanks
- Sterilisers and many more

Testo's specially GxP-trained service team supports you throughout the process in a very systematic way – from planning, documentation, system qualification and software validation through to service and support. Testo also has a NABL accredited service and calibration LAB that takes care of the after-sales support locally from Pune.

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

Beltecno Japan: Strengthening Indian pharma and healthcare industries

Ankur Verma, Global Sales and Marketing Manager, Beltecno India informs that his company has been strengthening the Indian pharma industry with their stainless steel panel tanks and talks about how Beltechno is supporting India to ramp up its production capacity of vaccines and medicines to defeat the COVID-19 pandemic

The Indian pharma industry is one of the largest providers of generic medicines globally. In 2017, the Indian pharmaceutical industry was valued at $33 billion and in terms of volume, its global export of generic medicines stands at 20 per cent globally.

The COVID-19 outbreak impacted the whole supply chain of the pharma industry and majorly impacted the vaccine producers in India. The Serum Institute of India and Bharat Biotech both have a huge responsibility to vaccinate a country like India which is highly populated and diverse in culture.

Global economies are coming forward and supporting India in this difficult time by providing all types of aids, whichever is possible. The second wave of COVID in India devastated the country with more than 30,00,000 daily new positive cases on an average in the first half of May. India itself is the fifth largest economy in the world and contributes a significant part to global economic growth.

Major challenges for the pharma industry during COVID-19

The pharmaceutical industry in India is the 11th largest globally in terms of value and the 3rd largest in terms of volume. Indian pharma exports contribute to a total of 3.5 per cent of total drugs and medicines export. Due to the sudden high demand for anti-viral drugs and other medicines, these exports are affected, which can create consequences for healthcare all around the world and therefore the global growth will be impacted.

In the current situation, Indian pharmaceutical industries are producing 70 per cent of the world's vaccines. The Serum Institute of India has provided all the manufacturing rights to produce AstraZeneca for low-income countries under the WHO's programme, Covax along with other exports.

The devastating situation of the country has already meant that these exports of the vaccine have been postponed or denied, and due to which so many countries are standing blank with the fear of upcoming waves of virus which will be impacting their business and overall economic conditions. If India is unable to provide vaccine supplies to other parts of the world, the whole world can expect more recurrent lockdowns in the coming future, which will ultimately slow down the global economy.

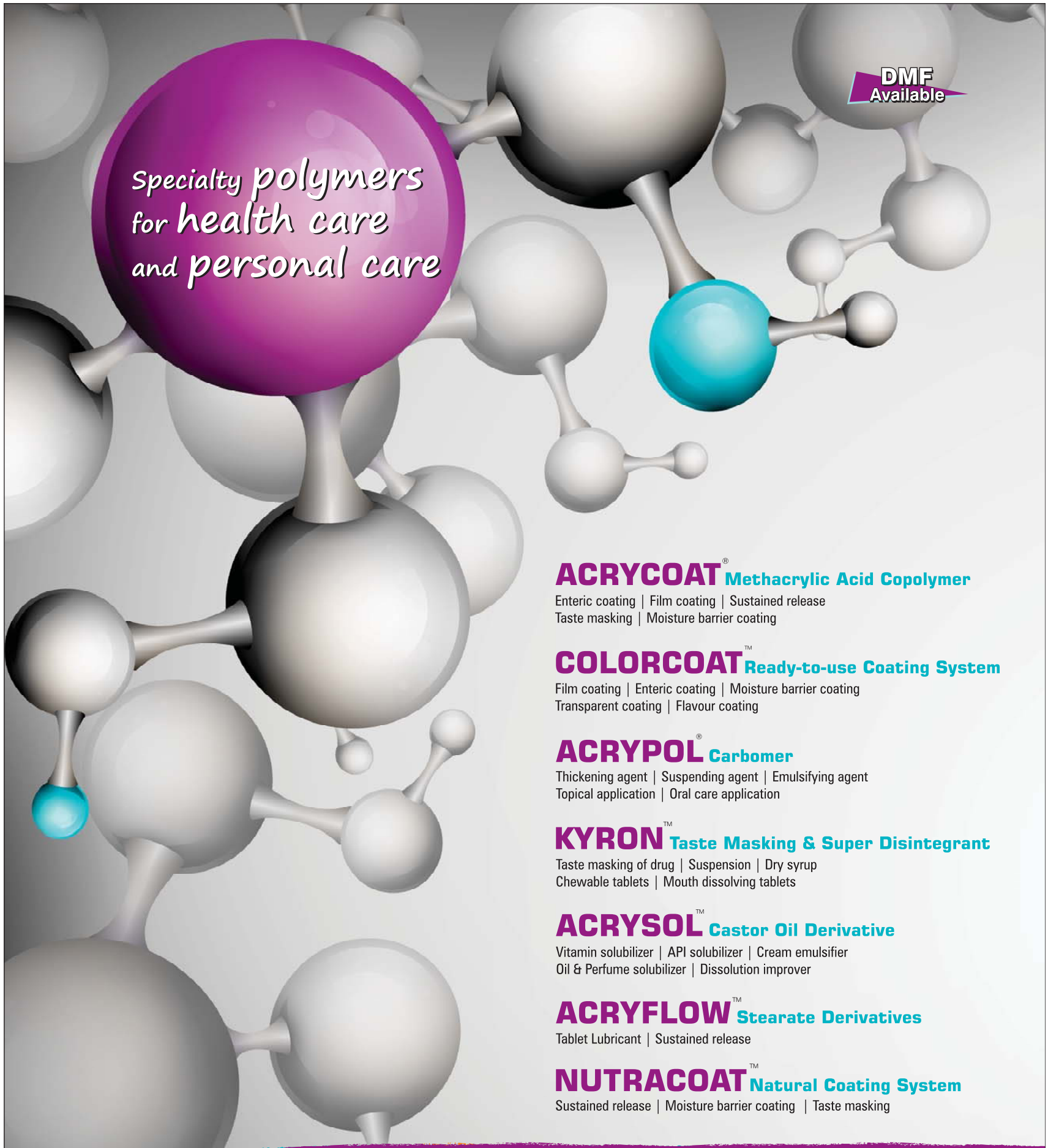
The current challenge for the pharma companies in India is to work on the highest of their capacity to produce more and more vaccines and put them in circulation, not only for our own country but for other countries as well.

We, Beltecno from Japan, have our stainless-steel panel tanks manufacturing plant at Neemrana, India. In the last few years, we have supplied multiple size stainless steel panel tanks for supporting vaccine producers, medicine producers like the Serum Institute of India, FDC and other pharma companies to support their expansion in India. We are standing with India in this tough situation and trying to strengthen the Indian pharma industries in terms of reliable utility and water supply 24/7 if required.

We, Beltecno from Japan, have our stainless-steel panel tanks manufacturing plant at Neemrana, India. In the last few years, we have supplied multiple size stainless steel panel tanks for supporting vaccine producers, medicine producers like the Serum Institute of India, FDC and other pharma companies

As water is one of the major commodity for pharma production, it has to be treated, used and stored in best industry practices. Beltecno Corporation is one of the oldest names in stainless steel water tank manufacturing in Japan and India we are supplying panel tanks for the last one decade.

Correct due diligence will definitely lead the Indian pharma industry in the right direction and make it one of the largest contributors in terms of total production, value and volume of export.



ACRYCOAT® Methacrylic Acid Copolymer
Enteric coating | Film coating | Sustained release
Taste masking | Moisture barrier coating

COLORCOAT™ Ready-to-use Coating System
Film coating | Enteric coating | Moisture barrier coating
Transparent coating | Flavour coating

ACRYPOL® Carbomer
Thickening agent | Suspending agent | Emulsifying agent
Topical application | Oral care application

KYRON™ Taste Masking & Super Disintegrant
Taste masking of drug | Suspension | Dry syrup
Chewable tablets | Mouth dissolving tablets

ACRYSOL™ Castor Oil Derivative
Vitamin solubilizer | API solubilizer | Cream emulsifier
Oil & Perfume solubilizer | Dissolution improver

ACRYFLOW™ Stearate Derivatives
Tablet Lubricant | Sustained release

NUTRACOAT™ Natural Coating System
Sustained release | Moisture barrier coating | Taste masking

COREL PHARMA CHEM

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