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EXPRESS PHARMA

INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE MARCH 2022, ₹ 40

INTERVIEW

Girisan Kariangal
MD,
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Interview

Dr ANIL KUKREJA
Vice President, Medical Affairs and Regulatory, AstraZeneca India

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Mandatory QR codes on APIs: Benefit or burden?

THE EVOLVING LANDSCAPE OF WOMEN'S NUTRITION

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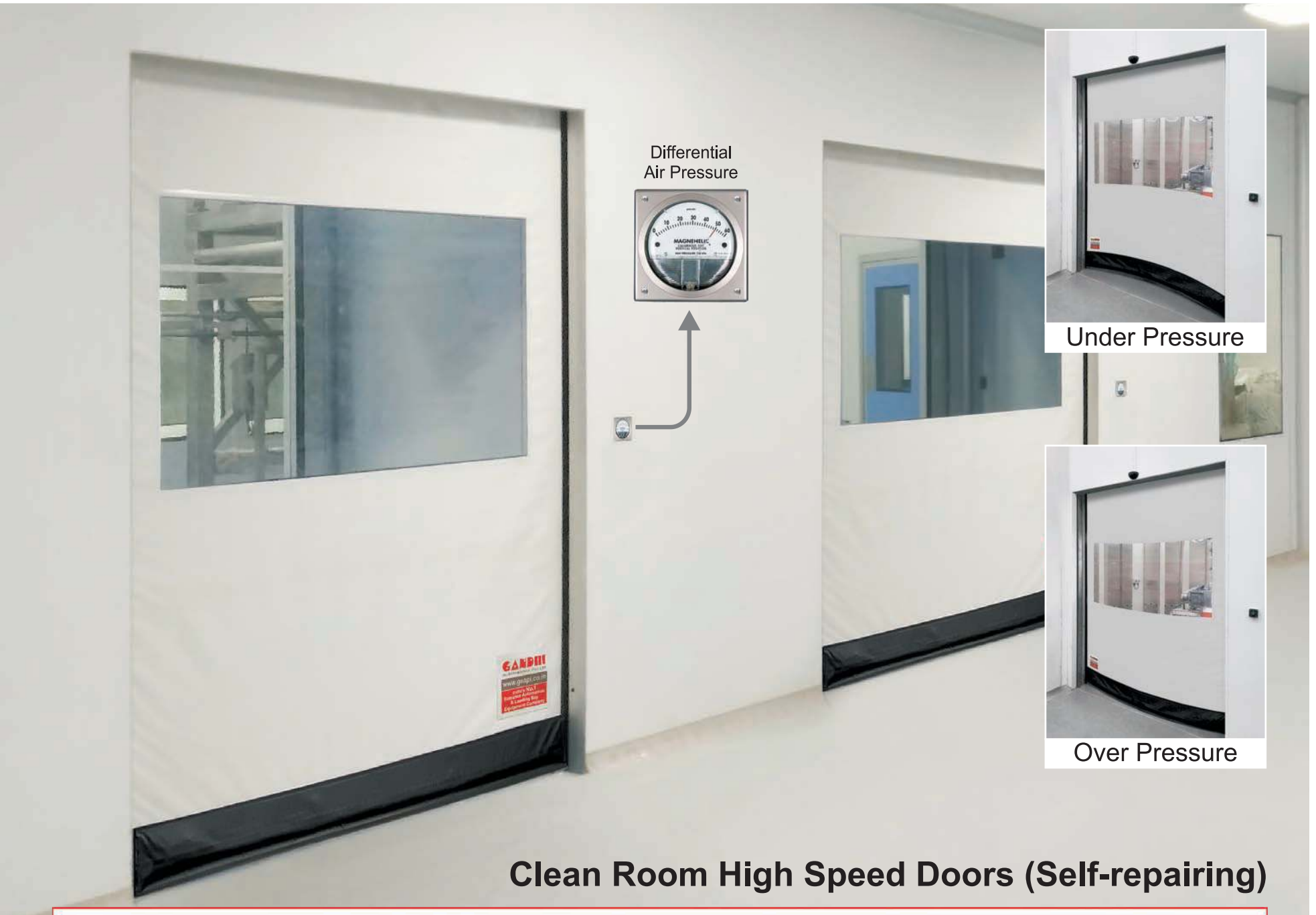

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Express Pharma®
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Still tripping on TRIPS

In the run-up to the WTO TRIPS Council meeting on 22nd February, a letter backed by over 200 global, national and regional civil society groups to the WTO Director General, has stressed that for the WTO response to the pandemic to be credible, it must deliver a bold and meaningful outcome on the TRIPS waiver proposal and address concerns about the impact of intellectual property (IP) on timely and affordable access to medical products.

The letter re-states the main purpose of the waiver proposal which is the prevention, treatment and containment of COVID-19 and expanded and diversified supply, affordable prices, and more equitable access to the full range of medical products needed to achieve those goals.

The letter goes on to highlight the irony that some WTO members are supporting an IP waiver only for vaccines, even though domestically, these same members have emphasised the significance of testing and treatment in controlling COVID-19 infections. The letter, thus, makes the point that the IP waiver must extend to diagnostics and therapeutics as well as vaccines.

Even more worrisome is the news that some developed nations are suggesting a TRIPS waiver that is geographically limited. It is ironical that India, one of the main proponents of the TRIPS waiver, could well be left out. Experts also recommend that should this happen, India should be ready to exercise the compulsory licensing option, even though this is a legal rabbit hole that comes with its own complications.

Another school of thought proposes that India should start by sharing IP on its own Made in India vaccines and therapeutics for the duration of the pandemic. This 'India waiver' could then put moral pressure for a more equitable TRIPS waiver. However, is India Pharma Inc ready for this step? Are the companies investing in new research labs and vaccine manufacturing plants ready to sacrifice revenues on these products, at least as long as the pandemic lasts? Are we ready to do what we expect of others?

MSF has also issued yet another appeal that the TRIPS waiver be extended to cover not just vaccine jabs, but tests and medicines as well. Besides criticising the move to make it geographically confined, MSF also asked that the TRIPS waiver be extended for five years, as transfer of manufacturing technology is a lengthy process in the pharma sector.

Another important virtual workshop was slated for 28th February, with WTO, WHO, and WIPO on accessing and using information resources for the pandemic response. The Council for trade-related aspects of Intellectual Property rights has two meetings in March as well. So, we can expect more discussion and debate on this topic in the days ahead.

If India, one of the main proponents of the TRIPS waiver, is left out, is it time for an 'India waiver' to show the way forward?

Pressure is mounting for a TRIPS waiver, even as world leaders acknowledge the worth of work that is IP-protected. For instance, on 23rd February, Dr Tedros Adhanom Ghebreyesus, Director-General, WHO, remarked, "We must now turn our attention to addressing the crucial question of how we turn vaccines into vaccinations – or how we get vaccines from ports to arms." He reasoned that the flexibilities in the TRIPS agreement are there to be used in emergencies and asked, "If not now, then when?"

Mentioning how the WHO is trying to smoothen and speed up vaccine research and manufacturing, to "turn vaccines into vaccinations – or how we get vaccines from ports to arms," he said the whole process "would be accelerated if manufacturers were willing to share their intellectual property and know-how" with the collaborative manufacturing hubs funded and created, like the mRNA Technology Transfer Hub in South Africa.

The worry is that low vaccine coverage in some countries increases the chances of new variants emerging and spreading throughout the world. WHO's 22nd February statement on the Omicron subvariant BA.2 points out at a global level, the proportion of reported sequences designated BA.2 has been increasing relative to BA.1 in recent weeks, even though the global circulation of all variants is reportedly declining. As per an assessment of the WHO's Technical Advisory Group on SARS-CoV-2 Virus Evolution (TAG-VE), the BA.2 differs from BA.1 in its genetic sequence, including some amino acid differences in the spike protein and other proteins. Studies have shown that BA.2 has a growth advantage over BA.1 and initial data suggest that BA.2 appears inherently more transmissible than BA.1, which currently remains the most common Omicron sublineage reported. However, this difference in transmissibility appears to be much smaller than, for example, the difference between BA.1 and Delta.

This data only goes to prove that even as we evolve our versions of a post-COVID normal life, we cannot let our guard down. At an individual level, this calls for masking and taking our shots. At a health policy level, governments must collaborate and work towards a more equitable access to medicines, vaccines and diagnostics to tame the COVID pandemic.

VIVEKA ROYCHOWDHURY, *Editor*
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INTERVIEW

We remain optimistic that Evusheld will retain its efficacy against Omicron variant

Dr Anil Kukreja, Vice President, Medical Affairs and Regulatory, AstraZeneca India, tells **Akanki Sharma** about Evusheld, which was designed by combining two potent antibodies with different and complementary activities against the virus, to evade potential resistance with the emergence of new COVID-19 variants

What is a monoclonal antibody cocktail? How is Evusheld different from Covishield vaccine or any other vaccine in the market?

Evusheld is a combination of two long-acting monoclonal antibodies (mAbs) – tixagevimab and cilgavimab – derived from convalescent patients after SARS-CoV-2 virus. Combining two monoclonal antibodies allows them to work synergistically to enhance the potential for improving the effectiveness of treatment, and to evade the potential resistance that might emerge with the

appearance of new variants and strains of SARS-CoV-2.15.

It is the only antibody therapy authorised for emergency use in the US for the pre-exposure prophylaxis (prevention) of COVID-19. The cocktail is intended to help protect the most vulnerable populations, such as the immunocompromised, who may not mount a sufficient immune response to COVID-19 vaccination.

Preventing immunocompromised individuals from getting COVID-19 rather than waiting to treat this vulnerable population once they become infected is an important goal in the fight against the pandemic.

Evusheld is also authorised for emergency use for prevention of COVID-19 in several other countries, including France, Spain, Germany, Italy, Bahrain and Egypt, with rolling reviews underway in the UK and the EU.

Tell us about the recent developments of this monoclonal antibody cocktail. Is this effective against all the variants of corona virus?

By combining two potent antibodies with different and complementary activities against the virus, Evusheld was designed to evade potential resistance with the emergence of new COVID-19 variants.

> We are conducting additional studies to further evaluate Evusheld against the Omicron variant. Data from this research is anticipated very soon

A new independent study by the US Food and Drug Administration (FDA) shows that Evusheld retains neutralising activity against the Omicron SARS-CoV-2 variant (B.1.1.529). The pre-clinical data was generated by pseudovirus testing of the full Omicron variant spike and showed that the combination of the antibodies comprising Evusheld, retains neutralisation activity against the Omicron variant.

These data add to the growing body of pre-clinical evidence demonstrating that Evusheld retains activity against all tested variants of concern to date.

The Omicron variant was not in circulation during the Evusheld clinical trials. Further data are needed to understand the implications of this observation in clinical practice. We are conducting additional studies to further evaluate Evusheld against the Omicron variant. Data from this research is anticipated soon.

We remain optimistic that Evusheld will retain its efficacy against the Omicron variant and continue to provide a robust level of protection.

What went behind making this long-acting antibody (LAAB)? Tell us in detail

about what was found in the Provent and Tackle trials.
No one vaccine or therapy can eliminate COVID-19, but multiple approaches could help to reduce the spread of the virus, defend those most vulnerable to infection, deliver better outcomes for patients and ultimately allow the world to return to normal. Despite the roll out of vaccines across the world, there remains an unmet need for vulnerable populations, including those who might receive little to no protection from vaccines or prior COVID-19 infection, such as those with suppressed immune systems.

These vulnerable populations may need added defence or more immediate protection than vaccines can provide, e.g., those with weakened immune systems, sub-optimal vaccine response, those that require immediate protection, high-risk patients with increased risk of exposure due to work or living situations.

The need for targetted prophylaxis will still be there even if we have multiple effective vaccines. There is also the need for treatment of both outpatients and sicker, hospitalised patients.

Evusheld showed robust, long-lasting protection against symptomatic COVID-19 that continues for at least six months, as demonstrated in the Provent phase-III trial. In Provent, it reduced the risk of developing symptomatic COVID-19 by 77 per cent at the primary analysis and 83 per cent at a six-month analysis compared to placebo.

In the Tackle phase-III outpatient treatment trial, it reduced the risk of developing severe COVID-19 or death (from any cause) by 50 per cent compared to placebo in non-hospitalised patients with mild-to-moderate COVID-19 who had been symptomatic for seven days or less (the primary endpoint), 67 per cent when patients were treated within five days of symptoms, and 88 per cent when treated within three days. Ninety per cent of Tackle participants were at high risk for developing severe COVID-19.

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Can this antibody cocktail be used as a third dose for people of all age groups?
Evusheld may offer added protection to a range of different groups where there is currently an unmet need, including those who, it may not be possible to vaccinate, for example, those with allergies or other intolerance of the vaccines; and those who have an inadequate response to vaccines, for example, the immunocompromised.

Most US guideline recommendations, including those put forth by the National Institutes of Health (NIH), are aligned to the US FDA EUA indication/fact sheet and are largely supported by Provent results.

This vaccine is developed for immunocompromised patients. When do you think it can hit the Indian market?
Regulatory dossiers are being compiled as per the requirements of various countries, including India. We are sharing this emerging therapeutic option as evidence generated with stakeholders and seeking their insights to arrive at our strategy, regulatory filing and timelines.

Further plans regarding the dissemination of this LAAB? Which all markets do you intend to cater to in the upcoming days?
AstraZeneca is in discussions with several markets on agreements for Evusheld now that data from Provent has demonstrated AZD7442 can significantly reduce the risk of developing COVID-19. Based on available near-term supply and ongoing discussions, we are prioritising discussions with markets and regions where there is demonstrated interest and clear unmet need and early access mechanisms in place.

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I, Vaidehi Thakar, hereby declare that the particulars given above are true and to the best of my knowledge and belief.

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Vaidehi Thakar
Publisher

INTERVIEW

We envision being a leading global dermatology company in India in next 10 years

Menarini India has a presence in the dermatology and primary care segments in the Indian market with its own brands. Recently, the company decided to increase its focus on the dermatology market. **Girisan Kariangal**, MD, Menarini India, shares more details about the directional shifts underway in the company's business strategy, his vision for accelerated growth, plans for the Indian market and more, in an exclusive interaction with **Lakshmipriya Nair**

Menarini India recently announced its foray and focus on the dermatology segment in India. Is the company changing its strategic direction in India? Is it looking at diversification as its growth strategy?

Menarini was always present in the dermatology sector, and it continues to be a core therapy for us. Until recently we were directly marketing our products in other therapy areas also including primary care, gastroenterology, urology, pain management and respiratory. However, with effect from July 2021, we have entered into a marketing and distribution agreement with a leading Indian company for the promotion of these products in India. With this change in strategy, Menarini India will significantly step up its focus to build the dermatology portfolio and to establish an aesthetics segment through the launch of our Global Relife portfolio. To widen the reach of our cosmetic segment, we are well-positioned to leverage the digital and e-commerce platforms with direct-to-consumer plans in the pipeline.

What is the dermatology market outlook in India for the next five years? What makes it a lucrative market?

As per the IQVIA prognosis report published in September 2021, the dermatology market is forecasted to grow in double digits and increase its market share within the pharma market. The numbers of dermatologists is relatively less, and are more located in the metros and tier 1 cities, making it easier and affordable to reach out to them. Moreover, the patients'/consumers' say in the choice of treatment is much higher and we could leverage the digital media to educate them and increase their awareness.

Dermatology becomes an interesting market for Menarini considering the innovative global product pipeline that we have from the Relife portfolio, which we would be launching in India. In the past, Menarini's partnership model has been highly successful across Europe. Initiating the same model in Asia -Pacific, we will partner with other global dermatology companies that are not present in India and

> Menarini India will seek to expand its product range by collaborating with leading formulation vendors to launch line extensions and will continue to build capabilities to consolidate within the dermatology segment in both RX and OTC space so that we are able to establish ourselves as a 'Partner of Choice' for the leading global dermatology companies

bring their innovative products to the Indian market. Through this, we believe Menarini would be able to cater to medical needs and help patients and consumers lead a better quality of life with confidence.

Can you please elaborate on the other priority areas of growth at Menarini India in the near future? What are the market factors prompting these decisions?
Menarini aims to strengthen its dermatology portfolio in India that will offer international innovative solutions for overall skin health. Menarini India will seek to expand its product range by collaborating with leading formulation vendors to launch line extensions and will continue to build capabilities to consolidate within the dermatology segment in both RX and OTC space so that we are able to establish ourselves as a 'Partner of Choice' for the leading global dermatology companies. In the next few months, Menarini India will continue to expand its aesthetic franchise with the launch of Definisse fillers and Definisse Free Floating threads and the dermatology franchise through the launch of innovative global skincare products that include a sunscreen with a novel patented technology, hair serum with unique proven ingredients and an acne scar serum specially formulated for the Indian skin.

What are the changes you would seek to implement as Menarini India's MD? What will be your strategy to decide on which segments to back and which to drop?
The immediate priority would be to communicate about the new strategy and vision to all the employees and get them aligned and excited to be part of this journey. I plan to bring an infinite mindset within the organisation whereby each employee can walk in as an individual and contribute to their fullest. The strategy would be to strengthen our existing key segments namely scar management and hyperpigmentation and make a strong entry into aesthetics and haircare segments, which are expected to grow faster than the dermatology market.

Where does India fit into Menarini's global vision? Any big tie-ups or investments, in the offing?
As we continue to position ourselves for growth in the Indian market, our focus on dermatology is a testament to Menarini's commitment towards investment and growth in our well-diversified dermatology portfolio in India. Dermatology is a cornerstone of Menarini India's brand promise, to invigorate lives through our products and services. Given our globally acclaimed, patient-centred and science-based approach to dermatology, we envision being a leading global dermatology company in the country in the next 10 years.

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THE EVOLVING LANDSCAPE OF WOMEN'S NUTRITION

This Women's day, *Express Pharma* examines the expanding arena of women's nutrition and seeks to understand its growth drivers and restraints

By **Lakshmipriya Nair**

A study released in 2021 by the Tata-Cornell Institute for Agriculture and Nutrition, New Delhi revealed that the COVID-19 pandemic has adversely affected women's nutrition in India. It pointed out that women's dietary diversity saw a decline during the lockdown compared with the same period in 2019. The drop was due to decreased consumption of foods such as meat, eggs, vegetables and fruits, which are rich in micronutrients that are crucial to good health and development.

"Women's diets were lacking in diverse foods even before the pandemic, but COVID-19 has further exacerbated the situation," said Soumya Gupta, a research economist at TCI who coauthored the study along with Prabhu Pingali, TCI director; Mathew Abraham, assistant director; and consultant Payal Seth. She added that any policies addressing the impact of the pandemic on nutritional outcomes must do so through a gendered lens that reflects the specific, and often persistent, vulnerabilities faced by women.

This is an imperative for various reasons including the fact that there is a clear link between women's health and economic growth and productivity of communities and countries. As Anjula Masurkar, Clinical Director, Entod Pharmaceuticals explains, "Promoting female health helps to achieve other desirable targets apart from economic development, such as greater fairness in access to healthcare, promoting female empowerment, and improving the physical well-being of women and children. Women can be powerful instruments of social change. When women are healthy, educated, and empowered, they are more likely to take leadership roles in the community. The time has come to put women's health and wellness at the top of the investment and science research lists, or at least equal with other opportunities, because to do so not only affords investors the opportunity to make meaningful returns, but also because of the positive impact such investments will make on society in general."

The time has come to put women's health and wellness at the top of the investment and science research lists, or at least equal with other opportunities, because to do so not only affords investors the opportunity to make meaningful returns, but also because of the positive impact such investments will make on society in general

Anjula Masurkar
Clinical Director
Entod Pharmaceuticals

Women, unlike men experience multiple health problems, including gynaecological health and disorders such as menstrual irregularities, urinary tract health, uterine fibroids, PCOS, etc. An increased number of experts suggest consuming nutraceuticals that provide extra health benefits in addition to the basic nutritional value found in foods

Shanil Bhayani
Executive Director
Sudeep Nutrition

To say that the women's nutrition market is ever-evolving would be an understatement. Every year, we see a new selection of ingredients and trends rise to prominence in this industry. With each passing day, women are becoming more and more conscious towards their lifestyle choices

Ameve Sharma
Co-Founder
Kapiva

Fortunately, since stakeholders and consumers have seen the need and opportunity to expand access and availability of nutrition to women. Experts have been rooting for 'gender budgeting' for sustainable progress in women's health. The industry too has seen the huge growth potential in this segment and is striving to cater to the rising demands.

In an article carried by *Express Pharma* last year, Suchi Ray, Partner Deloitte India quotes, "Overall, women's health therapeutics have established a strong presence in the global pharma market over the last few decades and the market is expected to grow moderately. Innovations coupled with technology focusing on correct nutrition and safety i.e. prevention is the key to women's health." *(Read https://www.expresspharma.in/is-womens-health-gaining-momentum/)*. In turn, the market for nutraceuticals and dietary supplements for women has seen a huge boost.

Understanding the market for women's nutrition

A Data Bridge Market Research report informs, "On the basis of type, the women nutrition market is segmented into sports nutrition, additional dietary supplements, personalised nutrition and others. On the basis of product, the women nutrition market is segmented into vitamins, proteins, minerals, fluids, probiotics, omega 3 and others."

The major players in the Asia-Pacific women nutrition market are Abbott, GNC Holdings, Amway India Enterprises, ADM, Bayer AG, Danone, BHI Biohealth

International, Swisse Wellness, Uniliver, Nestlé, GlaxoSmithKline, General Mills, Kellogg Co. among others, as per the report.

However, the women's nutrition market in India is also seeing a lot of newer entrants. While companies like Kapiva and Sudeep Nutrition have products that cater to women, brands such as Chicnutrix, Oorah Nua etc., are wellness and nutrition brands that exclusively focus on products that serve women's needs ranging from PCOS to pregnancy, menopause, motherhood and other challenges.

Reports reveal that vitamins and minerals segment grew the fastest due to various diseases in women and growing vitamin deficiencies in women. However, proteins and amino acids segment is also likely to see robust growth in this decade. Likewise, dietary supplements segment will acquire a major chunk of the women nutrition market due to swelling demand of healthy lifestyle choices and healthy food habits.

Giving a more detailed overview, Shanil Bhayani, Executive Director of Sudeep Nutrition says, "Women are growing aware of the importance of consuming essential nutrients in the right quantity. They, unlike men experience multiple health problems, including gynaecological health and disorders such as menstrual irregularities, urinary tract health, uterine fibroids, PCOS, etc. In addition, adult women are at risk of developing ovarian and cervical cancer too. An increased number of experts suggest consuming nutraceuticals that provide extra health benefits in addition to the basic nutritional value found in foods. As it stands, many women have incorporated nutraceuticals in their daily lives to treat menstrual disorders as it has anti-inflammatory and smooth muscle

Reports reveal that vitamins and minerals segment grew the fastest due to various diseases in women and growing vitamin deficiencies in women

relaxing properties."

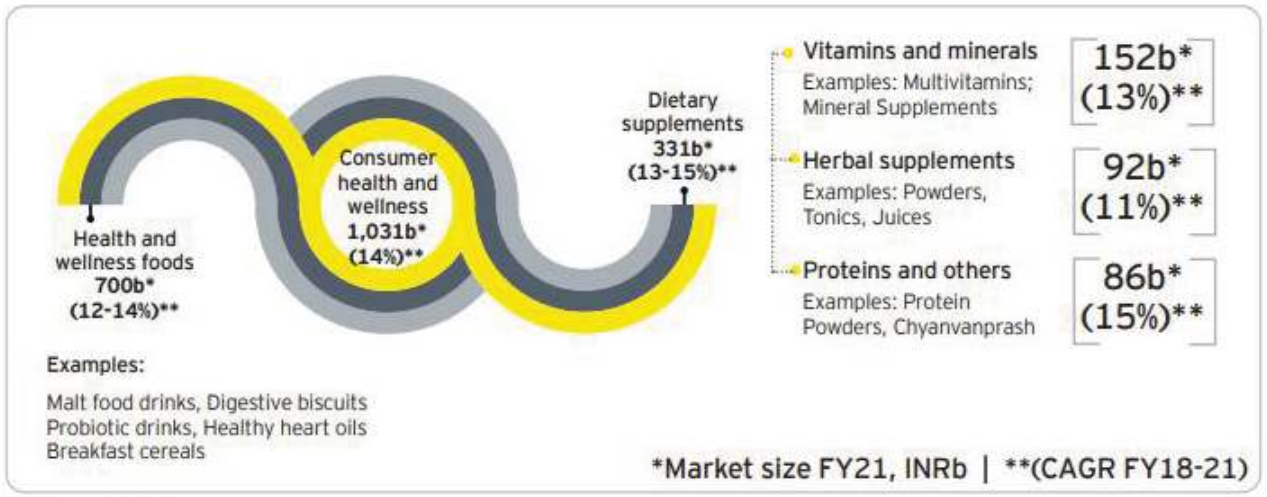
He informs, "We are witnessing a growing trend for cranberry and bearberry-based nutraceuticals that are preferred by young adults to treat urinary tract infections, a common bacterial infection in women. Focused on prenatal vitamins, nutraceuticals loaded with iron, calcium, iodine, and vitamin A, C, D, as well as probiotics etc. that help to bridge the gap by providing extra micronutrients are also high in demand during pregnancy. We have seen many women who have turned to nutraceuticals to stimulate milk production in pregnancy. A lot of women are opting for nutraceuticals such as melatonin, vitamin E, chasteberry, flaxseed, etc. to manage life-altering symptoms of menopause."

Ameve Sharma, Co-founder, Kapiva states, "To say that the women's nutrition market is ever-evolving would be an understatement. Every year, we see a new selection of ingredients and trends rise to prominence in this industry. With each passing day, women are becoming more and more conscious towards their lifestyle choices."

Adding that "modern, easy to use formats that serve nutrition at ease such as juices, powders, effervescents that

Figure 1

Dietary supplement including herbal supplements, vitamins, minerals and proteins is estimated to be an INR331b in FY21



Source: EY analysis

BOX 1: GROWING DEMAND FOR CONSUMER HEALTH PRODUCTS

COVID-19 has created the biggest seismic shift taking health and immunity to the centre stage. Approximately 94 per cent of Indians are worried about their family's health against 82 per cent globally. Indian consumers have opened their wallets towards fitness classes and activities, consuming natural foods, health supplements, and following specialised diets.

The consumer health products market size in FY21 was Rs 1.03t and witnessed a compound annual growth rate (CAGR) of 14 per cent over the last three years (FY18-21). This, on one hand comprises healthy variants of foods and beverages such as digestive biscuits, low fat snacks and on the other hand comprises dietary supplements. In the first wave of adoption, consumers have opted for healthy variants of food, which represents ~70 per cent of the health products segment. Dietary supplements at Rs 331b is a fast-growing market, and manifests itself in herbal supplements, vitamins and minerals and proteins. COVID-19 has acted as catalyst to fuel the demand of dietary supplements, as consumers increasingly are adopting these specialised products for preventive health and well-being.

Excerpts from 'The Sunrise Consumer Health and Nutrition Sector report by EY'

BOX 2: WOMEN'S NUTRITION: THE GLOBAL OUTLOOK

As per Data Bridge Market Research analyses, "The women nutrition market is expected to gain market growth in the forecast period of 2021 to 2028, globally. The market is growing with a CAGR of 8.2 per cent in the forecast period of 2021 to 2028 and is expected to reach $63,215.20 million by 2028."

According to the report published by Allied Market Research, the global women health and beauty supplements market generated $57.28 billion in 2020, and is expected to hit $206.88 billion by 2030, registering a CAGR of 12.4 per cent from 2021 to 2030. Another report from DataM Intelligence, released in 2021, updates, "Asia Pacific accounted for the highest revenue share of in 2020. Rising disposable income, increasing prevalence of chronic diseases like cancer and diabetes, rising digestive tract diseases, and growing consumer awareness about nutritional products is propelling the regional product demand. Increasing focus on a healthy diet to maintain fitness levels is also boosting the demand for women's health and beauty supplements. Initiatives by countries like India, China, Australia, Singapore, and Japan to create awareness and to educate women regarding nutrition is also boosting the growth of the Asia Pacific market. For instance, In September 2016, Ministry of Health, Australia announced to raise AUD 5.6 million in funds till 2019 to Jean Hailes, a health organization for women. This initiative is undertaken to help the organization in expanding its education and outreach." Giving an overview on the global market for women nutrition, the report informs, "The global women nutrition market is highly fragmented with many local as well global players. Some of the key players in the market include: Abbott, Optimum Nutrition, Inc., GNC Holdings, LLC, Amway, ADM, Hamilton Thorne Health Solutions, and Bayer AG among others. Increasing investments in R&D, mergers and acquisitions, collaborations with other industry players, geographic expansions, and product and flavor differentiation are among the key strategies adopted by the market players for gaining a competitive edge. For instance, in October 2020, to help stronger bones and healthier joints in females, Oziva has introduced HerBones. The formula has an impressive array of 100 percent plant-based & vegan ingredients aimed at strengthening bones, encouraging healthy joints and preventing female calcium loss by maintaining optimal female hormonal balance. HerBones is aimed at women with possible calcium deficiency aged 25 years and over. In September 2020, Bayer AG completed the acquisition with KaNDy Therapeutics, a biotech company in the UK. This acquisition extends the drug development pipeline in women's healthcare. Bayer AG is completely integrating KaNDy's NT-84 compound into women's healthcare drug development pipeline.

are the preferred product forms," he emphasises, "Consumers are more health and wellness-conscious than ever before and the major focus has shifted towards health and nutrition. Therefore, we are excited to bring more and more ayurvedic superfoods to the nutrition industry."

Restraints to growth

Women's nutrition is an advancing segment and has been seeing steady growth but there many challenges that could derail progress. To cite a few examples:

◆ **Societal taboos and stigma:** Women's health has been an area which has been ignored and neglected. Often, they are disadvantaged by discrimination rooted in socio-cultural factors. Emcure Pharmaceuticals, released a report in 2021, on notions and misconceptions about women's health/issues/concerns prevalent in India. It reveals that as a result of cultural and social context in India, nearly 50 per cent women are still hesitant to discuss about women health issues such infertility, endometriosis, menstrual struggles and uterine infections. Women also face pressures and taboos that are part of the societal structure and interdict women from behaving in a certain way. The expectation to prioritise family over work is one of the most common of such pressures. Women also face discrimination in getting married if they face any gynecological issues.

◆ **Inadequate investment, policies and regulation:** Investments in women's health and nutrition, both at the public and private stakeholder level, is inadequate despite a few measures in the right direction. For instance, though at the public health level, POSHAN 2.0 has been launched by the FM to "strengthen nutritional content, delivery, outreach, and outcomes", confusion over the objectives and implementation of the new programme, has led to under spending in this arena.

The regulatory landscape related to nutraceuticals needs more clarity and streamlining as well. For example; compliance to regulations pertaining to particular ingredients and their processing may increase complexities and impact the overall cost in the women nutrition market. These kind of issues are could become serious restraints to growth of the market. Likewise, there is a need for nutrition companies to improve their R&D capabilities to become more evidence-based.

◆ **Lack of proper supply chain:** Companies dealing in women's nutrition need to build robust supply chains

and develop strategic relationships to build strong retail and distribution channels which will be crucial to growth.

◆ **Low focus on sports nutrition:** Though there are many companies and brands catering to women's nutrition these days, the needs of all categories of women are not being met. For instance, despite growth in the women's nutrition segment, the nutritional requirements of female athletes remain overlooked, not just in India but globally. Though participation of women in professional sports has increased significantly, the market is completely catering

Figure 2

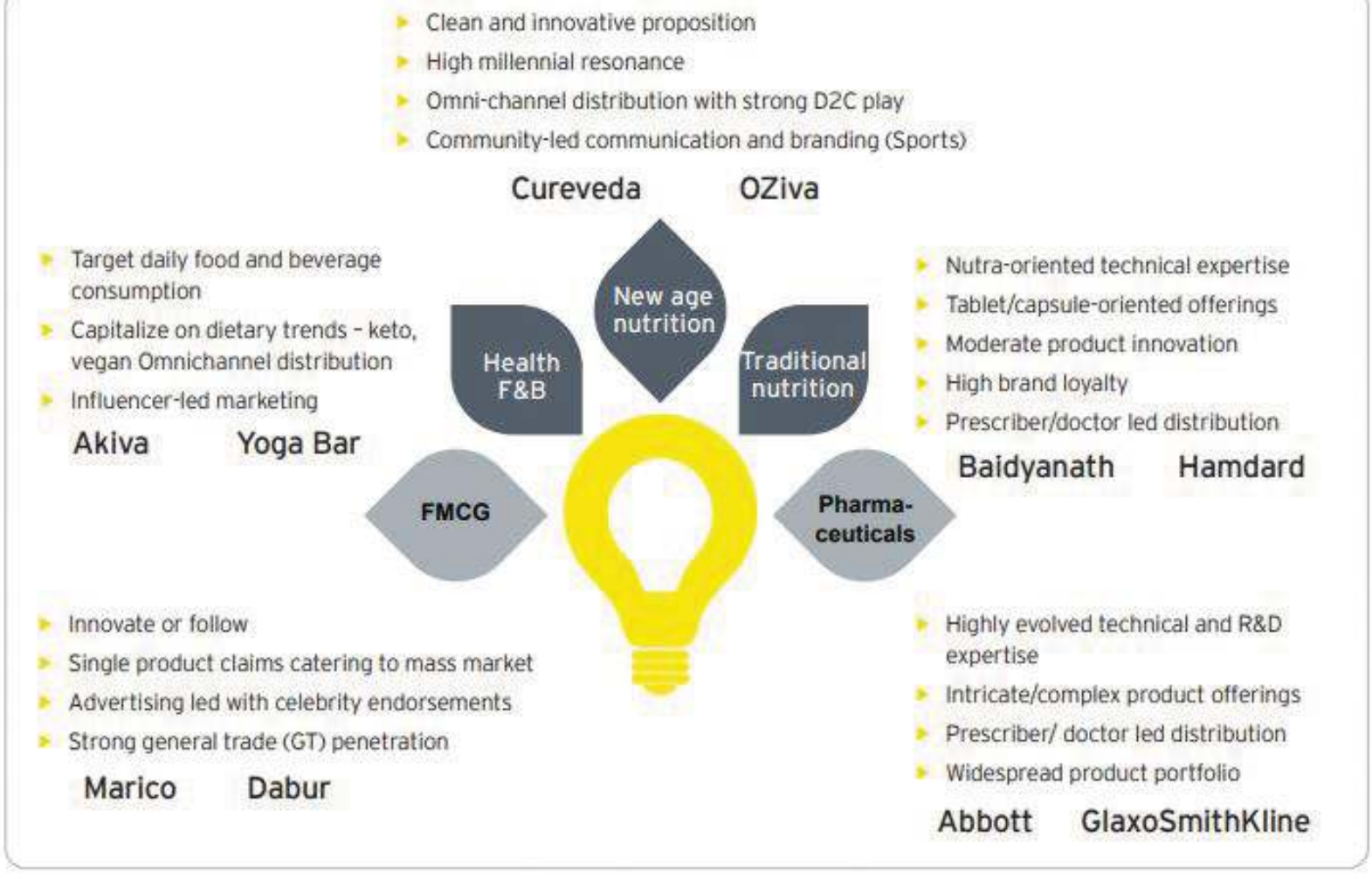
Notable transactions in the space

Month	Company	Investors	Funds raised ($ million)
Jul-21	The Whole Truth	Sequoia, Matrix	5.5
Jun-21	Wellbeing Nutrition	Fireside, ACG	2.0
Mar-21	OZiva	Eight Roads, F-Prime Capital, Matrix	10.5
Feb-21	Man Matters	Sequoia, Matrix, Elevation	7.0
Jan-21	Kapiva	Vertex Ventures, 3One4, Others	11.0
Jun-20	FastnUp	Sixth Sense, Rekha Jhunjhunwala	4.0

Source: press articles and EY analysis

Figure 3

Market players have chosen distinctive "ways to play" with each requiring a distinct set of capabilities to succeed



to the distinctive needs of athletic and active women. As a result, only very few sports nutrition products target women and those products tend to be more expensive.

The path ahead

There is a lot of scope and opportunity to grow in consumer health products and nutraceuticals *(Check Box 1 and Figure 1)*. An EY study titled 'The Sunrise Consumer Health and Nutrition Sector report' points out, "Many companies from pharma and FMCG industries want to discover the sweet spot. From a category attractiveness perspective, the gross margins of formulation driven products are much higher than foods products, making this play interesting. From research and development on fortifying packaged food, usage of natural grains across categories like cereals and noodles, innovation in categories such as vitamins and dietary supplements, to beauty and personal care products, companies are working hard to establish differentiated planks on the concept of inner and outer wellness. Additionally, the growing interest in Natural and Ayurvedic products has encouraged companies already active in the area to assert their credentials more strongly, while it has also attracted the attention of players from pharmaceuticals. For example, in vitamins, established companies such as Herbalife Nutrition without an Ayurvedic positioning have started using traditional Indian ingredients, such as amla, turmeric, and black pepper in their products. The company has launched a separate label called Vritilife to position it as amalgamation of ayurvedic principles and modern science. Several FMCG players with an Ayurvedic positioning have also worked to highlight their local heritages through their formulations, packaging, and marketing." *(Check Figure 2 and Figure 3)*

> Greater investment is required in women's health including more research to unlock new insights that could lead to new and innovative solutions for women

But, in the case of women's health and nutrition market, the working population of women have realised new need for nutrition and thus has started consuming of more nutritional products. But, as the report from Emcure concludes, "There is a need for women, organisations and the society at large, to become proactive when it comes to managing their health and normaliase conversations around critical aspect of women's health. For every being, physical, mental and sexual health is inter-related. Greater investment is required in women's health including more research to unlock new insights that could lead to new and innovative solutions for women."

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Mandatory QR codes on APIs: Benefit or burden?

Reportedly, 20 per cent of the medicines that are manufactured in India are counterfeit. As per a government report, three per cent of medicines are of substandard quality

By **Akanki Sharma**

In a notification dated 18th January, 2022, the government of India has made Quick Response (QR) codes on its label mandatory at each level of packaging on Active Pharmaceutical Ingredients (APIs) to facilitate tracking and tracing of the products. The new rule will be effective from 1st January, 2023.

Even though the industry has less than a year for its implementation now, pharma experts and stakeholders, shedding light on this decision, primarily emphasised that this is a crucial step taken by the government that will lead to a number of benefits for the pharma manufacturing domain.

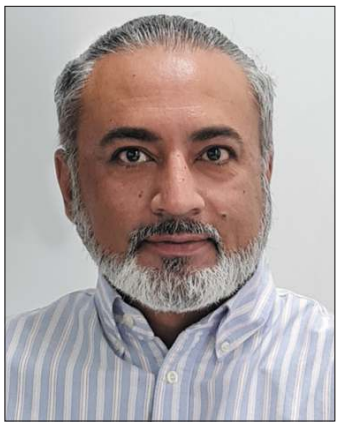
Reportedly, 20 per cent of the medicines that are manufactured in India are counterfeit. As per a government report, three per cent of medicines are of substandard quality.

Highlighting that the mandatory QR codes on APIs will be a huge move in eliminating the sub-standard and falsified medicines, Nakul Pasricha, President, Authentication Solution Providers' Association (ASPA), said that this decision will facilitate the identification of authentic products, making the system more efficient by weeding out sub-standard and falsified medical products.

"QR codes are a practical solution readily available and easily workable at a nominal price. On the other hand, the benefits are considerable, especially the significant impact it will have in making the supply chain in the pharma industry secure. The Indian authentication industry is capable and capacitated to provide the required solutions," he said.

QR Codes are a practical solution readily available and easily workable at a nominal price. On the other hand, the benefits are considerable, especially the significant impact it will have in making the supply chain in the pharmaceutical industry secure

Nakul Pasricha
President
Authentication Solution Providers' Association (ASPA)



The benefits of this technology are numerous. The first element is the connectivity between brand and consumer through Onspot. The brand can connect directly with the end consumer once the consumer scans the QR code on the product

Lokesh Harjani
Co-Founder and CEO
Onspot Solutions

This might seem like an insignificant step or something that may be dismissed as a prerogative for the industry, but the real winner would be the end users and patients. It will facilitate the identification of authentic products, making the system more efficient by weeding out sub-standard and falsified medical products. Moreover, considering India's increasingly important role in the global healthcare system, this step will support its endeavours in securing world health. This will reinforce India's commitment to medicines safety in India and globally. This step will help distinguish spurious and original drugs and make the ecosystem vulnerable to substandard and falsified products. However, it would be advisable to adopt a robust and comprehensive approach, Pasricha further added.

The Drugs Technical Advisory Board (DTAB), in June 2019, had approved the proposal for mandatory QR codes on the APIs in order to combat falsified drugs.

Later on, a high-level panel was set up in July 2020 to build a framework for implementing QR codes on drug packs. In addition, India had also made it compulsory from 1st April, 2020 that all medicines procured under public procurement will have barcode/QR code at primary level of packaging.

Lokesh Harjani, co-founder and CEO, Onspot Solutions, while explaining about the technology for implementing QR codes on APIs, mentioned that the tracking portion of the system has individual, as well as bulk packaging traceability. The QR codes are linked between the Onspot platform and the manufacturer's ERP systems in most cases with all dynamic information being added, and stored at the actual point of manufacturing.

In addition, stating the advantages of this technology, he said, "The benefits of this technology are numerous. The first element is the connectivity between brand and consumer through Onspot. The brand can connect directly with the end consumer once the consumer scans the QR code on the product. In real time, the end consumer comes to know the authenticity of the product, any ingredients used, as well as other related information, including MRP, expiry date and more."

He also said, "Consumer

gets the information in real-time, and brand also gets a bird's-eye view of its supply and distribution chain, including the confirmation that goods were sold for intended markets through geo location."

Sanofi is one of the pharma companies that is using the technology offered by Onspot Solutions. The company has been deploying the solution for many years and has patents in India and abroad.

"The cost of this technology varies depending upon the customisation and the specific requirements of the brand, it is quite cost-effective. There is no major capital cost, and very low costs towards platform expenditure. Recurring costs are absolute minimum, and in volumes, the system pays for itself in a short amount of time," mentioned Harjani.

Moreover, according to S Sridhar, President, Organisation of Pharmaceutical Producers of India (OPPI), the move taken by the government will be highly advantageous for the pharma industry.

"QR code technology is led by our smartphone apps, and is a highly efficient way of testing the authenticity of any product. In the pharma industry, QR codes are extremely beneficial, as it helps in combatting spurious ingredients, raw materials, and other APIs' integration in the supply chain, by providing real-time information, which also helps in tracking and tracing the products in the market. Since the unique non-duplicable QR codes are essentially integrated into the primary packaging of the product, it will be highly advantageous to the industry, as it validates the genuineness of the products. As an industry, we must consider evaluating this," he emphasised.

Pasricha also opined that the ideal solution must include a mix of physical and digital features providing authentication and increased digital security to reduce system vulnerability.

For formulations where the packing is small, QR code will serve the purpose by encoding the detailed information in a small square which is machine readable. APIs are usually packed in LDPE bags (primary packing) and the labels already have all relevant information in writing as proposed in the notification. Further, these APIs are then packed in aluminium containers/fibre drums/HDPE drums (secondary packing).

"In the notification, it is mentioned that QR code labels are required on both primary as well as secondary packings. The notification does not give clarification about what 'unique product identification code' means," Daara B Patel, Secretary-General, Indian Drug Manufacturers' Association (IDMA), said.

He further stressed, "These QR codes are not recommended for serialisation by global regulatory agencies. These appear to facilitate a safe and secure supply chain. However, it is not clear how applying a QR code label secures the supply chain. The imposition of the requirement of fixing QR codes on the labels of API packs would be another cost burden imposed on the manufacturers of APIs, and will serve no purpose without any quantifiable benefits. Use of barcodes will increase the cost of drugs without any benefit to consumer."

Apart from it, he had the view that the SME members may not be able to afford the costs in setting up the machinery that costs above Rs 1 crore and also requires additional skilled manpower. Especially, for MSMEs, it is not possible to implement the system as, apart from being financially unviable, acute lack of requisite manpower and equipment add to the problem.

As of now, no country has commenced implementation of track-and-trace systems. Even the US and Japan, the two largest developed pharma markets, have not been able to ensure the implementation of automated supply chain fully, i.e. from manufacturer, C&F, distributor, stockist, retail chemists, thus rendering it

meaningless. Therefore, Patel suggested to keep implementation of the track-and-trace systems either in abeyance or made voluntary till an international consensus is arrived or such time as specific importing countries demand them in the form and format they will finalise.

"Taking advantage of the confusion created by MNCs over fake and counterfeits, the so-called anti-counterfeit solution providers that sell barcode and other technologies are propagating and lobbying for the use of such expensive and impractical methods by making them legally compulsory. Use of barcodes will increase the cost of drugs without any benefit to consumers," he claimed.

Manufacturers continuously face problems during custom clearance of export consignments. The consignments are being opened and physically examined to verify barcoding. There have been instances of shipments not being allowed to be exported and sent back to manufacturing site.

"Shipments which have been allowed to be exported are being given provisional approval and duty drawback benefits, for such provisionally approved exports, are given only if exporters upload barcode data on the DAVA portal. Further, it may be noted that repacking activity (with inclusion of barcode) is with the State Licensing Authority and they are in a position to ensure that all repacking is done as per the Drugs and Cosmetics Rules and Regulations. Any repacking activity that is not licensed is illegal and all users must ensure that they do not use repacked material from such source. This severely impacts the manufacturer," he notified.

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President
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Secretary General
Indian Drug Manufacturers' Association (IDMA)

On one hand, national authentication and traceability projects have been trending internationally for some years now, with China, Brazil, Turkey, the US, and the EU and India (for exports) being pioneers in this area, helping reduce fraud and prevent losses caused by counterfeiting and illicit trade. It has helped these countries to reduce the shadow market in many industries, improved tax collection, and considerably reduced losses incurred by businesses from counterfeit products and illegal trade. India should also implement these measures on formulated drugs as well as in other sectors to join the league of advanced digital economies.

On the other, to execute this, manufacturers will have to buy new machines, digitalise huge data and set up a whole new team which requires large investments. The change in artworks to incorporate barcoding cannot be done unless approval by regulatory authorities of importing country is received. This is a time-consuming and costly affair, which will impact the exports as manufacturers have to wait for such approvals.

The pharma experts and stakeholders need to deliberate whether the move is a security benefit or cost burden for the industry.

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NEWS

IPA organises seventh Global Pharmaceutical Quality Summit

The event brought together leaders from the industry, regulatory agencies, academia and subject experts from India and across the globe to facilitate discussions on "Making quality pharmaceuticals in India, sustainably, for the World

The Indian Pharmaceutical Alliance (IPA) hosted the seventh Global Pharmaceutical Quality Summit (GPQS) last month. The event brought together leaders from the industry, regulatory agencies, academia and subject experts from India and across the globe to facilitate discussions on "Making quality pharmaceuticals in India, sustainably, for the World." Day one highlighted the importance of sustainable operations in pursuit of quality excellence and strategies that will enable the Indian pharma industry onto the pedestal of a global leader.

In her keynote address, S Aparna, Secretary, Department of Pharmaceuticals (DoP), said, "It is imperative that we maintain the trust and credibility the pharma industry enjoys today. Quality and affordability need to be complemented by innovation and modernity. It is important regulators and stakeholders are aligned to improve access to quality healthcare."

In his special address, Dr V G Somani, Drugs Controller General of India (DCGI), said, "COVID-19 has been challenging and India has demonstrated its commitment in drug delivery and vaccine

supplies by collaborating with relevant stakeholders. Sustainability is the buzzword in the industry and IPA is taking the right efforts in this direction."

While setting the context of the summit, Sudarshan Jain, Secretary-General, IPA, said, "IPA has been organising the quality summit since the year 2016 and has consistently been working towards pursuing quality excellence. This year's focus is on sustainability as it is the key to a better future."

Samir Mehta, President, IPA, said, "Achieving quality excellence and improving patient centricity in pharma operations has always been a priority for the Indian pharma industry. The industry should evolve from 'Make in India' to 'Make and Discover in India' and making quality pharmaceuticals in India, sustainably, for the world. We are entering a new paradigm in quality management and this summit aims to cover some important topics in quality with a focus on sustainability."

Samina Hamied, Vice President, IPA, and Executive Vice Chairperson, Cipla, said, "I strongly believe that quality is a culture, not just a function, and needs to be embedded across fundamental pillars of the industry like operation, our workforce and management systems. A collaborative effort among industry, regulatory bodies, policymakers and healthcare drivers is the key. The seventh edition of GPQS is a step forward in this regard by enabling a knowledge-sharing networking platform on pivotal themes."

The session on "Future of Pharmaceutical Operations and Quality" was deliberated by Dr Douglas Throckmorton, Deputy Director, Regulatory Platforms, US FDA and Joseph Hughes, Senior Partner, McKinsey and Company.

Dr Sotirios Paraschos, Inspector, Certification of Substance Department, EDQM, delivered a session on "CEP Holder Responsibilities towards EDQM and their Customers."

Dr Atul Dubey, Director, Pharmaceutical Continuous Manufacturing, USP, spoke on USP's initiatives for capability building and advancing continuous manufacturing, while Geena Malhotra, Global Chief Technology Officer, Cipla, spoke on Quality by Design – Design to Delivery.

A panel discussion on "How can we achieve Quality Excellence in Pharmaceutical Operations?" saw participation by Kristan Callahan, International Relations Specialist, US FDA India Office; Dr Paraschos, Dr Manisha Shridhar, Regional Adviser, WHO – SEARO and Dr Rubina Bose, Deputy Drugs Controller India, CDSCO. This was moderated by Dr Rajiv Desai, Executive Vice President, Global Quality Head, Lupin.

On the second day of the summit, a panel discussion was held on 'Sustainable end-to-end Operations and Quality Excellence – Path Forward' moderated by Gautam Kumra, Senior Partner, McKinsey & Company.

Umang Vohra, CEO, Cipla, shared his views on newer modalities such as biosimilars with the audience. "We have developed our technologies internally for generics and now we have to collaborate with the ones who have already done it and then leverage those. The talent required for some technologies is not present in India. So, collaboration with global partners will help address this issue," he said.

Speaking about challenges in the digitisation journey, G V Prasad, co-Chairman, Dr Reddy's, said, "While digitalisation is inevitable, there is still a challenge to digitise since underlying processes need to be mastered and understood to enhance efficacy of the digitisation process. Industry leaders will have to be more agile, make data-driven leadership decisions with science and common sense coming together."

Elaborating on crystallising his vision on quality, Nilesh Gupta, Managing Director, Lupin, said, "Quality and compliance was a company-specific issue, and it has changed due to forums such as this, which have allowed us to work towards a collective goal. Information sharing has been a support system. We are known to be pharmacy of the world, and we are fortunate to have achieved this position. In the next five years, it will be great to be known as the best in class with the help of forums such as this which promote open dialogue."

Addressing the issue of supply chain shock during COVID-19, Dilip Shanghvi, Managing Director, Sun Pharma, spoke about building resilience. "Creating options is important to have a backup. Government PLI schemes are helping to create a self-contained supply chain and helped in efficient supply during the pandemic. Yet, there is a long way to go, and we shall gradually bridge the gap," he said.

Talking about the biggest trends in operations and quality in the industry, Pankaj Patel, Chairman, Zydus Lifesciences, said, "COVID-19 has brought the focus on technology and automation, and ushered our digital entry into manufacturing and supply chain. Even on the API front, newer technologies for manufacturing have emerged and entry into the biosimilar market can be envisaged."

The panel further discussed environmental, socials and corporate governance.

Earlier, in a special address, Dr Rogério Gaspar, Director, Regulation and Prequalification Department, WHO, spoke on the "Future of Pharmaceutical Operations and Quality."

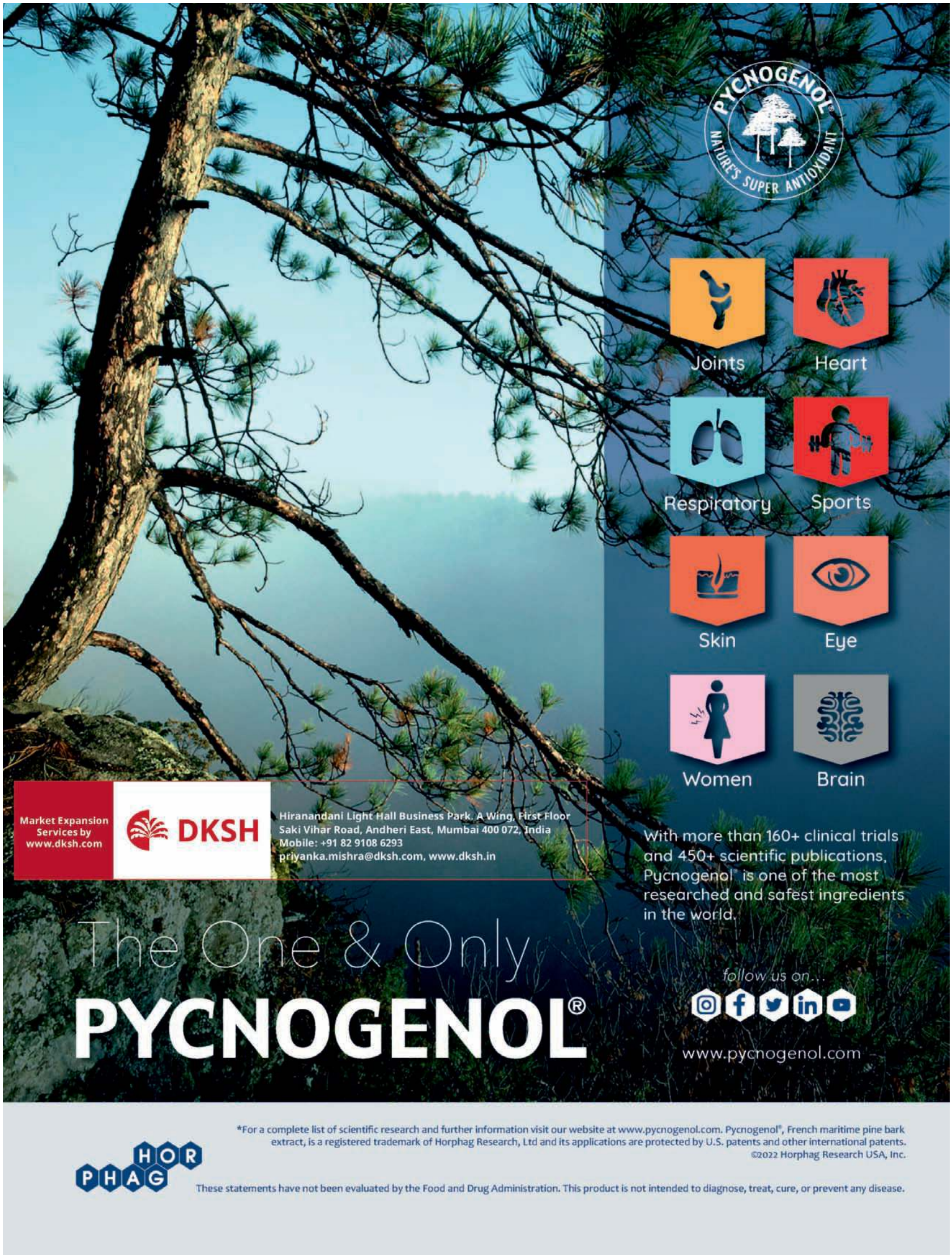
A panel discussion on "Vaccine Development: Design to Delivery in Vaccine Manufacturing" was addressed by Dr Nivedita Gupta, Scientist F and Head, Virology Unit, ICMR, and saw participation from Dr Kapil Maithal, President, Vaccines and Diagnostics, Zydus and Dr Sanjay Singh, CEO, Gennova Biopharmaceuticals. This was moderated by Shirish Belapure, Senior Technical Advisor, IPA.

Another panel discussion was on "Quality Excellence across Industries and Potential Learnings for Pharmaceuticals" which was addressed by Adil Zainulbhai, Chairman, Quality Council of India (QCI), and saw the participation of Dr Ranjana Pathak, President, Global Quality, Medical Affairs and Pharmacovigilance, Cipla; Nandkumar Kulkarni, Senior Director, Integrated Supply Chain, Mondelez and Vijay Kalra, Head, Mahindra Institute of Quality and Chairman, Central Safety Council, Mahindra Group.

Naveen Unni, Partner, McKinsey & Company, delivered a session on "Sustainability in Operations."

The final session of the event was on "DnA Roadshow of Latest Technological Advancements in Pharmaceutical Quality and Operations" which saw the participation of Dr Rajesh Kuppuswamy, Health Sciences Industry Adviser, SAP; Lalitha Surabhi, Associate VP, Strategy and Business Development, Caliber and Samuel Samson, Head, pharmaceuticals and life sciences vertical, Siemens. This was moderated by Dr Navneet Tewatia, Associate Secretary General, IPA.

The event concluded with closing remarks by Nilesh Gupta and vote of thanks by Sirish Belapure.



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These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

KILITCH HEALTHCARE INDIA LTD.

Accrediations

9001:2015

14001:2015

WHO

Manufacturing Sections

Small Volume Ampoule

Small Volume Vial

Three Piece Ophthalmic Vial

Two Piece Preservative Free Ophthalmic Vial

Prefilled Syringes in Blister pack

Sterile medicated Swab Sticks

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Machine Vision for regulated environment

One-way manufacturers are increasing quality controls with machine vision technology

In pharma manufacturing, quality has always been the most significant concern. Stringent regulatory or statutory requirements of the FDA mean high liabilities for mistakes in production. The pharmaceutical industry is continuously in quest of innovative ways to validate quality. One-way manufacturers are increasing quality controls with machine vision technology. Quality control is one of the essential drivers of intelligent vision systems and vice versa. Along with delivering reliably high-quality products, machine vision can also bring productivity, efficiency and competency improvements within the limits of strict quality demands. Overall, to fit in the growing competition, the pharmaceutical industry cannot afford to fall back or slow down.

New possibilities with advanced technologies

The governments and regulators worldwide are pushing advanced technologies to tighten up and standardise the distribution of pharma medicines. Digitisation and advanced automation have opened the door to protect consumer safety and avoid diversion, theft and counterfeiting. The advanced machine vision technology plays a significant role in achieving and maintaining these compliances and staying competent throughout the manufacturing and packaging stages involved on the production floor. Machine vision can be used to inspect different processes like code validation, matching, shape identification, QA for the filling and capping, liquid-filling level, contamination, sealing, labeling, QR code identification etc. Machine vision leads to productivity through lower operating costs by utilising less labour in the inspection process.

Production lines in the pharma industry generally operate at high speeds, and machines are often pushed to their extreme levels to achieve production goals. Regular servicing of machines does not provide 100 per cent protection against unexpected failures. Faults do not only cause downtime on the affected machine or whole production line; they also hamper the quality of drugs. Maintenance engineers invest a lot of time and spend money in solving unseen problems in fast processes. The comprehensive machine vision solution can capture images of mechanical processes that work at high speeds. This quality of high-speed imaging can lower the maintenance cost and increase the quality by reducing downtime and change over time.

Quality and packaging benefits

Traceability, packaging and quality are critical challenges

manufacturers face where the possible departments could benefit significantly by using machine vision technology.

In the packaging departments, the machine vision technology can be used in quantity and condition detection, an inspection of packaging items like dose applicators and printed instructions. Manufacturers can utilise machine vision on the production and packaging lines to ensure that their production units meet their organisational quality requirements and other compliances.

Pooja Patil, Corporate Communication, B&R Industrial Automation

It is imperious that medicines and other products should be trackable in the pharma industry while transporting them to distribution centres and stores for maximum compliance and accountability. In case of any issues like defects or unforeseen side effects are seen by patients, the drugs or any other medical products must be traceable from the patient's possession back to the manufacturer.

Pharma manufacturers are responsible for providing all the necessary tracking and manufacturer information with their products. Machine vision solutions can help consolidate all this information and deliver it across channels during many steps of the shipping process.

Companies can utilise machine vision technology to ensure their tracking information is accurate and readily available across the distribution channels. This could be in the case of an emergency or a simple customer service inquiry.

Productivity benefits

Along with meeting the quality requirements, machine vision enhances pharma application's productivity through the speed of inspection. Manual inspection processes are usually slow and are prone to errors. As machine vision advances and cameras become faster, the pharma inspection process also speeds up, leading to a more productive and efficient manufacturing process.

Usually, machine vision provides ease of use, creating further productivity improvements. Machine vision technology is becoming easier to implement and practice, resulting in lower operating costs.

Once the machine vision system is in place, they further automate pharma production. For example, inspecting package integrity on a conveyor can inform an automated material handling system, which faulty packages are to pull off the production line. This also leads to faster manufacturing and gains in productivity.

There are many additional ways that machine vision systems lead to more productive pharmaceutical production, but ease of use, accuracy and speed are the main sources of productivity.

Machine vision by B&R

B&R's machine vision is an embedded vision system whose flexibility and unprecedented integration eliminate the drawbacks previously associated with these systems. These cameras can perform an extensive range of machine vision tasks that are presently being supported by PC-based systems.

An essential factor of B&R's machine vision system is its intelligent lighting technology. Lighting elements are integrated into the camera, as an external device, or even as a combination of the two. The possibility of automatic lighting modulation prevents stray light and other challenging lighting conditions from compromising performance. It also makes it easy to achieve exact synchronisation for high-speed image capture or implement object-specific requirements such as bright-field or dark-field illumination.

B&R has taken machine vision to a whole new level with integrated solutions. The cameras, intelligent image processing algorithms, and innovative lighting portfolio are an integral part of the B&R control system. At the heart of B&R's vision solution is a broad selection of intelligent cameras. Options at the lower end will replace simple machine vision sensors, while the top of the range will harness the full potential of high-end smart cameras. For the entire portfolio of cameras, there are easy-to-configure machine vision functions for creating applications with minimal programming.

For more information, visit
www.br-automation.com

More safety for less money

B&R servo drive with integrated torque determination reduces costs

Safe torque determination is based on an internal current measurement and enables the safety functions Safely Limited Torque (SLT), Safe Speed Observer (SSO) and Safe Brake Test (SBT). The functions are suitable for applications up to SIL 2 / PL d / Cat. 3.

Safe prevention of overload

The SLT function can be used, for example, to reliably limit the torque applied to the power transmission system. Mechanical overload conditions can thus be avoided and safely averted. In addition, mechanical designs can be made more cost-effective with SLT. SLT also minimises the risk of operators being injured via pinching or crushing while working on a machine.

Ensuring operator safety

The SSO function is a virtual speed sensor that makes it possible to use the SLS safety function without needing a safe encoder. This is particularly helpful when using linear or torque motors, since these types of motors usually do not have an integrated safe encoder.

Reliable holding brake testing

The SBT function can be used to safely monitor and evaluate the performance of a holding brake. The data it collects provides insight into the condition of the brake and any damage or wear.

B&R has equipped the ACOPOS P3 servo drive with safe torque determination, enabling numerous integrated safety functions.

About B&R

B&R is an innovative automation company with headquarters in Austria and offices all around the world. On July 6, 2017, B&R became a business unit of the ABB Group. As a global leader in industrial automation, B&R combines state-of-the-art technology with advanced engineering to provide customers in virtually every industry with complete solutions for machine and factory automation, motion control, HMI and integrated safety technology. With Industrial IoT communication standards like OPC UA, POWERLINK and openSAFETY as well as the powerful Automation Studio software development environment, B&R is constantly redefining the future of automation engineering. The innovative spirit that keeps B&R at the forefront of industrial automation is driven by a commitment to simplifying processes and exceeding customer expectations.

For more information, visit
www.br-automation.com

More safety for mobile machinery

B&R introduces new safety relay module for X90 control system

Mobile controllers with safe, floating outputs have previously not been available on the market. With B&R's new safety relay module, external safety components such as drives or laser scanners can now be connected to the X90 controller via a floating-ground emergency stop circuit. A safety level of PLe /SIL3 can be achieved. The option board is particularly suitable for autonomous agricultural and construction vehicles.

Modularity makes the difference

With its powerful, expandable X90 controller, B&R offers design freedom that is unique in the market. The range of option boards opens up new possibilities for implementing customer-specific automation solutions. In addition, the controller comes in a rugged IP69K housing. Since it does not require a control cabinet or complex wiring, easy service is guaranteed.

The new safety relay module from B&R makes mobile machinery even safer.

About B&R

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For more information, visit
www.br-automation.com

Antioxidants in pharma formulations

Sredstva Regionale Chemie offers a diverse range of antioxidants that comply with various regulations and standards, allowing its customers to protect their formulation. Here's why picking the right antioxidant is so essential...

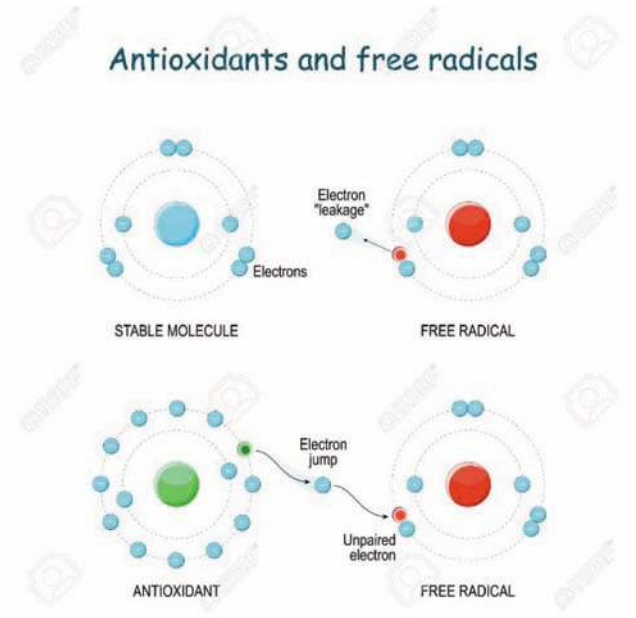
Antioxidants, or free-radical scavengers, are molecules that will reduce or prevent the oxidation of other molecules. Antioxidants are currently used as efficient excipients that delay or inhibit molecule oxidation. After hydrolysis, oxidation is the second most common pharmaceutical degradation pathway. Excipients are prominently associated with adverse reactions.

Safety and efficacy are critical aspects of drug research and development, formulations must be designed to make sure appropriate bioavailability of a drug as well as its physicochemical stability over the determined shelf-life.

Drug stability affects the safety and efficacy of the drug product/formulation, degradation impurities may cause a loss of efficacy and generate possible adverse effects. The chemical stability of a drug is an intrinsic property that is determined by its chemical structure. The dosage form can lead to drug instability because of the presence of other compounds (e.g., excipients). In addition, drug stability must be evaluated throughout the production, packaging and storage processes. In this context, drug product stability is a critical issue in drug research and development, not just for new medications, but also for generics.

Properties of an ideal antioxidant

◆ Effective at a low non-toxic concentration
◆ Stable and effective under conditions of use, over a wide pH and temperature range
◆ Soluble at the required concentration
◆ Compatible with a wide variety of drugs and pharmaceutical excipients
◆ Free from objectionable odour, objectionable taste or stinging



◆ Colourless in both original and oxidised form
◆ Non-toxic and non-sensitising, both internally and externally at the required concentration
◆ Reasonably priced
◆ Unreactive with containers or closures

Why use antioxidants to protect formulation?

The process of preparing a formulation is time-consuming and expensive from manufacturing to supply and storage. A longer shelf life enables a wider window for consumption, thereby reducing waste and costs. Drugs are stable in their pure form, with instability arising due to their mixture with excipients. Certain factors contribute to degradation of a drug over time such as moisture content, storage temperature, change in chemical composition, microbial growth and potency, etc. The efficacy of an antioxidant can be assessed by creating several formulations with the APIs and single or multiple antioxidants in order to place each of these formulations on stability under accelerated conditions. The trial-and-error selection process is costly and time-consuming, often taking weeks before the oxidation is observed at a detectable level. Stability testing the formulation ensures a rational correlation with antioxidant activity in a solution thereby enabling a prudent use in oral, parenteral and liquid formulation.

ANTIOXIDANTS LISTED IN THE USP30/NF 25 CLASSIFIED ACCORDING TO SOLUBILITY AND LISTING USUAL CONCENTRATION RANGE

	Solubility			
Antioxidant	Water	Alcohol	Oil	Concentration Range (%)
Ascorbic Acid	Yes	Yes	No	0.02-0.1
Ascorbyl Palmitate	Yes	Yes	Yes	0.01-0.2
BHA	No	Yes	Yes	0.005-0.02
BHT	No	Yes	Yes	0.005-0.02
Monothioglycerol	Yes	Yes	-	0.1-1.0
Potassium Metabisulfite	Yes	No	No	0.01-1.0
Propyl Gallate	Slightly	Yes	Slightly	0.001-0.15
Sodium Bisulfite	Yes	Slightly	No	0.05-1.0
Sodium Metabisulfite	Yes	Slightly	-	0.01-1.0
Tocopherol	No	Yes	Yes	0.01-0.1
Tocopherol Excipient	No	Yes	Yes	0.01-0.1

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For more information on this range, visit www.srchemie.com or contact on sales@srchemie.com

Imaweld™ TPE Braided Tubing: Designed to meet demands of pressurised critical applications

Imaweld™ TPE Braided Tubing is a specially designed product with the thermopolymer material, which is worldwide accepted in the bioprocess industry for the high press fluid processing applications

Are you looking out for solutions to your critical demands of high-pressure fluid processing application in the biopharma industry?

Know more About - Imaweld™ TPE Braided Tubing – designed to meet the demands of the pressurised critical applications.

Imaweld™ TPE Braided Tubing is a specially designed product with the thermopolymer material, which is worldwide accepted in the bioprocess industry for the high press fluid processing applications.

Imaweld™ TPE Braided Tubing is translucent braided tube manufactured in cleanroom with Imaweld formulation, Animal Derived Component Free (ADCF) resin, and is reinforced with polyester braiding, which exceeds the properties of those with the non-polyester braided TPE tubes.

It is manufactured with the finest grade of TPE materials, which is fully inspected, controlled from the stage of the raw material production to the final product development. Ami Polymer has its own facility for the TPE raw material processing which is validated and tested with accordance to different compliances and specifications that meet the USP Class VI biocompatibility requirements.

Outstanding features of Imaweld™ TPE Braided Tubing

- ◆ Light weight
- ◆ Supports increased pressure ratings
- ◆ Improved bend radius and ultra flexibility
- ◆ Greater kink resistant
- ◆ Compatible with autoclave and gamma irradiation
- ◆ BPOG extractable studies available
- ◆ Temperature range -45ºC to 135ºC (-50ºF to 275ºF)
- ◆ Available in customised length and PP sanitary triclover fittings

Certifications

- ◆ USP Class VI
- ◆ ISO 10993-3/4/5/11
- ◆ USP Class 87
- ◆ FDA 21 CFR 177.2600
- ◆ Phthalate free
- ◆ ROHS compliant
- ◆ Extractable and leachable studies available

Ami Polymer is ready to work alongside its customers to secure their supply chain, by offering:

- ◆ its support in determining its customers' requirements and supply needs
- ◆ stock piling on demand
- ◆ attractive lead-times
- ◆ 24x7 support system

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https://www.linkedin.com/posts/amipolymerindia_cellculture-usabusiness-biopharmaceutical-activity-6871395634163908608-5EiA

Thanks & Regards

CHECK OUT HERE FOR THE SIZE SELECTION

Part No.	ID in Inch (mm)	OD in Inch (mm)	Working Pressure (in Bar)	Minimum bend\ radius(in mm)	Coil length in feet)
06-13-IWB	0.237(6)	0.512(13)	7.58	38	25
09-16-IWB	0.354(9)	0.63(16)	5.5	63.5	25
12-20-IWB	0.472(12)	0.787(20)	8.96	76	25
16-24-IWB	0.629(16)	0.944(24)	7.58	100	15
19-29-IWB	0.748(19)	1.106(29)	7.58	140	15

Yokogawa enhances cybersecurity and safety for OpreX Control and Safety System Lineup

The company has developed an enhanced version of ProSafe-RS Lite that meets both explosion protection and marine standards, and an updated version of the Plant Resource Manager (PRM) software that supports this latest version of the ProSafe-RS Lite

Yokogawa Electric Corporation (TOKYO: 6841) has obtained ISASecure CSA Level-1 certification from the ISA Security Compliance Institute* (ISCI) for its CENTUM VP integrated production control system, a product in the OpreX™ Control and Safety System family. With this certification, Yokogawa's CENTUM VP integrated production control system and ProSafe-RS safety instrumented system, now, both conform to the latest international security standards. In addition, the company has developed an enhanced version of ProSafe-RS Lite that meets both explosion protection and marine standards, and an updated version of the Plant Resource Manager (PRM) software that supports this latest version of the ProSafe-RS Lite.

Due in part to factors such as the increased reliance on remote system access during the COVID-19 pandemic, cyberattacks on production facilities are on the rise worldwide and are growing ever more sophisticated, and this is driving a rising awareness of the need for compliance with international standards. Components that receive ISASecure CSA certification conform to the IEC 62443-4-1 and IEC 62443-4-2 international standards pertaining to security for industrial automation and control systems. The ProSafe-RS safety instrumented system, which conforms to safety integrity level SIL3, and the ProSafe-RS Lite, which meets SIL2 standards, obtained ISASecure CSA Level-1 certification in May and July 2021, respectively.

For CENTUM VP to qualify for ISASecure CSA Level-1 certification, a cyclic redundancy check function has been added that periodically diagnoses the integrity of the programmes and databases on a plant's field control stations. If an error is detected, a system alarm is issued. Upgrading to the latest CENTUM VP, R6.09 also enables operators to access collaborative information server screens from their human interface stations, thus enabling the acquisition in real time of data on the operational status of equipment and devices.

In line with efforts to enhance safety, ProSafe-RS R4.07 has been developed, as a result of which, ProSafe-RS Lite now meets both explosion-protection standards (ATEX/IECEx/ECAS-Ex) and marine standards. This means that this SIL2 system can be installed in plants and facilities where there is a risk of explosions, and on LNG carriers and other vessels. By using it together with the SIL3-certified ProSafe-RS, which also meets both sets of standards, it is possible to optimise the cost of plant safety instrumentation based on the application. In addition, PRM R4.05 has been developed to support devices that are connected to ProSafe-RS Lite. PRM uses IT to detect signs of impending equipment malfunctions so that operators can be notified and take pre-emptive action, thus reducing the risk of failures.

With the development of highly secure and safe devices and systems, and the provision of support for their operation, Yokogawa is able to offer a wide range of control system solutions. The certification and functional enhancement of these solutions will contribute to safe and robust plant operations in many industries.

*1 ISA Security Compliance Institute & ISASecure CSA eveloped by the ISA Security Compliance Institute (ISCI), the ISASecure CSA certification programme focuses on the security of embedded devices and related components (software applications, host devices and network devices). The ISCI's members come mainly from the International Society of Automation, and the principal activity of this organisation is the promotion of security certification for industrial control systems and control devices. The ISASecure CSA certification programme was launched in August 2019, replacing the ISASecure EDSA certification programme. It complies with the International Electrotechnical Commission's IEC 62443-4-2 and IEC 62443-4-1 international standards for security in industrial automation and control systems.

About the CENTUM series

Yokogawa released its CENTUM Distributed Control System (DCS) in 1975, a world first. CENTUM VP is the ninth generation in the CENTUM series. Known for their rugged performance, CENTUM systems set high standards for engineering and technology excellence while ensuring backwards compatibility with previous system versions and support of the latest technology applications. Knowledge-driven engineering lies at the heart of CENTUM, a Yokogawa flagship product that has been proudly serving the process industry over the past 40+ years.
https://www.yokogawa.com/solutions/products-platforms/control-system/distributed-control-systems-dcs/centum-vp/

About ProSafe-RS

TÜV Rheinland, an independent certification body, has certified that ProSafe-RS can be used in SIL3 applications. Unlike conventional safety instrumented systems and Distributed Control Systems, which are regarded as having different roles and functions and operate separately, the operation of ProSafe-RS and the CENTUM distributed control system can be fully integrated.
https://www.yokogawa.com/solutions/products-platforms/control-system/safety-instrumented-systems-sis/process-safety-system-prosafe-rs/

About PRM

The PRM software centrally manages large amounts of status and maintenance information from automation assets as well as production assets. PRM supports the FOUNDATION™ fieldbus, HART®, ISA100 Wireless™, and PROFIBUS field digital communication protocols. PRM has various maintenance support functions, including online functions for monitoring and diagnosing devices and equipment.
https://www.yokogawa.com/solutions/products-platforms/solution-based-software/asset-management-softwares/field-device-management-prm/

About OpreX

OpreX is the comprehensive brand for Yokogawa's Industrial Automation (IA) and control business. The OpreX name stands for excellence in the technologies and solutions that Yokogawa cultivates through the co-creation of value with its customers, and encompasses the entire range of Yokogawa's IA products, services and solutions. This brand comprises the following five categories: OpreX Transformation, OpreX Control, OpreX Measurement, OpreX Execution and OpreX Lifecycle. CENTUM VP and ProSafe-RS are part of the OpreX Control and Safety System family, which is aligned under the OpreX Control category. With its various OpreX Control solutions, Yokogawa is able to quickly effect changes for its customers that lead to a transformation in such areas as management and operations, and provides highly reliable control technology that ensures high efficiency, high quality, and safe and stable plant operations. PRM is an OpreX Asset Management and Integrity family solution in the OpreX Transformation category. OpreX Transformation delivers operational excellence throughout an enterprise's activities, from production through to supply chain optimisation and risk and business management.

About Yokogawa

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

For more information, visit
www.yokogawa.com

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Gandhi Automations' High Speed Doors

High Speed Doors designed and manufactured by Gandhi Automations are sturdy, dependable and are the ideal solution for medium and large entrances. The doors are manufactured with European collaboration and technology with innovative and creative engineering

Fast-moving functional and reliable doors are needed in industrial and commercial contexts. Gandhi-designed and manufactured High Speed Doors are versatile and solid ensuring long-lasting reliability. The modular structure of the curtains, assembled and joined by anodised aluminium extrusions, provides for a wide range of polyester sections available in a variety of colours. Wide, full-width window panels ensure a safer traffic and allow more light in. Their fast and easy replacement, in case of accidental tearing, saves money and time. The alternating metal tubular structure there inserted ensures high wind-resistance.

Prime High Speed Doors are the ideal solution for internal and external entrances and effectively operate in any situation, even when strong winds are blowing, and in rooms with high volume traffic. Sturdy and dependable, Prime is the intelligent door for medium and large entrances.

High Speed Doors for external entrance are equipped with spring steel wind lock in curtain pocket that ensures silent door travel, higher wind loads and curtain stability.

High Speed Door - Prime Reset

It is a unique High Speed Self-Repairing Door with the latest technology that prevents downtime of the door system. In case, the curtain is impacted accidentally. It will cause the curtain to move out of the guides without damage. The movement of the door is designed in such a way it can be recovered with a simple opening and closing operation. Gandhi Automations manufactures doors of the highest quality that meet the issue for greater flexibility desired by clients. High Speed Self-Repairing Door in PVC is the most suitable solution in the field industries, it lowers the time of transition from one facility to another, avoiding any human error which can cause damage to the High Speed Door and all this can be achieved due to the innovative ANTI-CRASH SYSTEM. Gandhi Automations provides a world-class product with great security.

Below are the features of self-repairing high-speed doors offered by Gandhi Automations:-

- ◆ Flexible and self-repairing door
- ◆ Functional, safe, quick and resistant
- ◆ Innovative anti-crash system
- ◆ Can be equipped with PVC vision windows
- ◆ Self-lubricating maintenance-free guide
- ◆ Smooth and silent opening and closing
- ◆ Protects traction unit, enables rapid wiring and safety photocell
- ◆ Flexible curtain in self-extinguishing material
- ◆ Self-resetting without intervention
- ◆ Quickly back to operation
- ◆ Control panel designed for an intensive continuous service

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Email: sales@geapl.co.in
Website: www.geapl.co.in

Ensuring pharma compliance with testo data measurement technology

Testo the best-in-class data loggers and data monitoring systems for the pharma division

Due to the crucial necessity and its direct impact on human health and welfare, pharma is probably the most important and critical sector, among others. As a consequence of which, it becomes essential to store pharmaceuticals, vaccines, laboratory samples or units of blood at the right temperatures to ensure that they remain effective and that quality is maintained. Another reason for the pharma division to ensure safety measures and controlled environment is stringent regulations and inspection of the facilities. This elementary need for climate control can only be ensured with right data monitoring systems. Testo being a market leader in testing and measurement sector provides the best-in-class data loggers and data monitoring systems for the pharma division.

Ensuring end to end climate monitoring – Testo data loggers

Pharma goods must be stored well in every situation as any deviation in the ambient temperature or humidity values may lead to deteriorated quality of the product. Testo data loggers can be used to test the optimum conditions for specific products or surroundings. Temperature and humidity data loggers are often used in pharma industries to monitor the conditions in which drugs, medicines and vaccines are kept. Not only storage, but during the transit of goods, testo transport data loggers are useful to measure the transport conditions. The range of data loggers is extensive. A temperature and humidity logger such as 174 T guarantees continuous monitoring in a storage or warehouse. Further, data loggers with multi channels for connecting external sensors and thermocouples, like testo 176 are available for ensuring secured work process in labs.

These data loggers are also critical for production quality assurance where the temperature has to be frequently checked at various points in production processes. Using thermocouple probes, data loggers can also record data in the kinds of extreme temperature ranges. The probe's fast response also contributes in the validation processes and quality standard optimisation in QA units and clean room applications. These instruments are the most convenient and pocket-friendly solution for all pharma application areas.

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

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

Data compliance for audits and inspections

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

Service and calibration made easy

Testo also has an established state-of-the-art NABL accredited service and calibration LAB in accordance with the standard ISO/IEC 17025:2017, that takes care of the after-sales support locally from Pune. Testo service and calibration facility is highly cost-effective as it delivers international standards conveniently within a week's time. Instruments of any brand/make can be calibrated and serviced locally maintaining necessary standards.

The accredited parameters include humidity, pressure, absolute pressure, contact type temperature, non-contact type temperature (infra red thermometer, thermal imager). In fact, Testo's is the first and only lab in India to get NABL accreditation for dew point temperature as well.

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

Compliant and profitable pharma packaging with Checkweighing

As manufacturers need to remain certified in order to produce pharma products, compliance is also critical

High demand in pharma industry is a constant. Manufacturers both large and small must look to optimise their production lines in order to ensure production quotas are met in a timely, profitable and, above all, safe manner. Larger producers running single product batches seek outstanding reliability and accuracy in checkweighing, while smaller contract packagers – who are likely servicing multiple clients – need the flexibility to effect quick changeovers in order to keep throughput to a maximum. As manufacturers need to remain certified in order to produce pharma products, compliance is also critical. Products entering the supply chain that do not meet the required standard threaten patient safety, retailer confidence and in the worst case scenario a company's ability to continue production. All are damaging to profit margins to varying degrees and the risks can be mitigated with a well-executed product inspection programme. Automation is a given in these environments and it is universally recognised that checkweighers play an instrumental role in day-to-day production. A checkweigher's main function in a pharma environment is to check the package for missing components such as the leaflet or complete blisters. This is a vital part of the package, as a box of tablets, for example, will not be considered safe or compliant without it. End-of-line applications are also commonplace, where systems are used to check the completeness of secondary and tertiary packaging, ensuring that what is sent into the supply chain is exactly what is expected. Checkweighers automatically inspect 100 per cent of products on the line – which is highly recommended compared with random off-line sampling, as the latter gives a sample size that is now considered to be of little statistical significance.

Checkweighing solutions can help pharma manufacturers to maximise productivity

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

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

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

In addition, there is an easy-

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

Compliance with Good Manufacturing Practice (GMP) guidelines

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

Minimising changeover downtime with checkweighing technology

Minimising changeover downtime is critical. Advanced checkweighing systems offer useful features such as digital positioning control. Due to a plausibility check, the system does not allow users to enter false parameters. Users are immediatley alerted if settings are entered incorrectly and the system will not start if the parameters are wrong. Another factor that influences the usability of the GUI also helps users to save time and therefore minimise changeover times - key factors when looking to increase productivity. Statistical Process Control (SPC), in addition, is possible via software functions that can be utilised to predict issues on the line. SPC measures and refers to industry standard values of process capability CP and CPK. Standalone or integrated systems allow users access to the statistical data needed to understand, document and control profitability and production efficiency. This way, early detection of problems can be achieved ahead of any major issues that may have a significant impact on uptime. The ability to monitor performance is directly linked to OEE, and the net effect of reduced machine downtime is that higher production levels can be achieved using the same amount of resources. This leads to a faster return on investment with regard to capital purchases such as checkweighers.

Tracebility of process changes

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

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

Mettler Toledo is a leading global supplier of precision instruments and services. The company has strong leadership positions in a wide variety of market sectors and holds global number-one market positions in many of them. Specifically, Mettler Toledo is the largest provider of weighing and analytical instruments for use in laboratory and in-line measurement in demanding production processes of industrial and food retailing applications.

The Product Inspection Division of Mettler Toledo is a leader in the field of automated inspection technology. The division incorporates the Safeline Metal Detection and X-ray Inspection, Garvens and Hi-Speed Checkweighing and the CI Vision and PCE Track & Trace brands. The solutions provided by the business increase process efficiency for manufacturers while supporting compliance with industry standards and regulations. Systems also deliver improved product quality which helps to protect the welfare of consumers and reputation of manufacturers.

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