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INDIA'S FOREMOST PHARMA & BIOTECH MAGAZINE

16-29 FEBRUARY 2020, ₹ 40

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Bhavish Agarwal, Founder, FDAlytics.com

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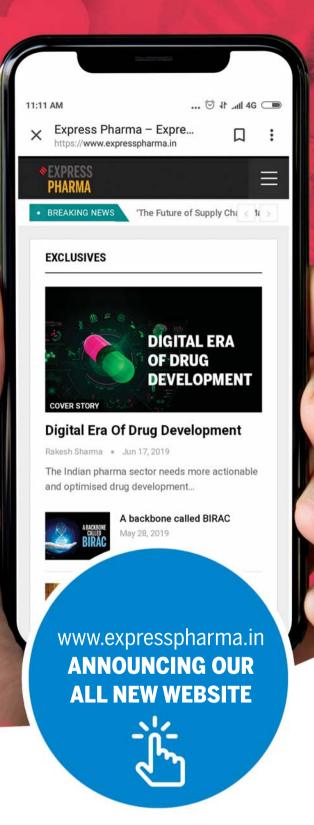
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# FDALYTICS IS AN INTELLIGENT ASSISTANT PLATFORM TO HELP IN GXP

As major pharma companies in India continue to grapple with GMP compliance issues, a startup combining deep learning, Al tech, and NLP models based on artificial neural networks is helping subscribers be better prepared for inspections, learn from the US FDA trends and improve their GMP processes continuously based on those learnings. With the official launch planned for February 20. Bhavish Agarwal. Founder, FDAlytics.com tells Viveka Roychowdhury how his company's algorithms can augment the analysis of pharma regulatory affairs personnel by providing them up-to-date and readily available data points | P24

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11TH ANNUAL KAIZEN CONGRESS - INDIA 2020 TO **BE HELD IN PUNE** 

**MINISTRY OF** MSME, GOI PARTNERING WITH **TELANGANA GOVERNMENT FOR BIOASIA 2020** 

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### **Express Pharma®**

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Editor: Viveka Roychowdhury.\* (Editorial & Administrative Offices: Express Towers, 1st floor, Nariman Point, Mumbai 400021) \* Responsible for selection of news under the PRB Act. Copyright @ 2017. The Indian Express (P) Ltd. All rights reserved throughout the world. Reproduction in any manner, electronic or otherwise, in whole or in part, without prior written permission is prohibited.

# 2019-nCoV must reform India Pharma Inc

s of February 9, 37564 laboratoryconfirmed cases of novel coronavirus (2019-nCoV) infection have been reported, including 813 deaths. The three confirmed cases so far in India seem to be doing well and under quarantine in various medical colleges in Kerala. But with a 14 day symptom-free incubation period, the government is taking no chances. All returnees from China and especially, from the ground zero, Wuhan, are being quarantined. Contact tracing too is on but there are worrying cases of a few returnees remaining untraceable.

The spread of nCoV is not just a medical and humanitarian tragedy. It will have major economic ramifications, impacting not just the industries which have shut down across China but also their clients in various countries across sectors.

The pharmaceutical sector in India is already feeling the pinch. It could be one of the most severely impacted, as many companies rely on China as a source of cheaper APIs. It is fortunate that most companies had larger than usual buffer stocks to last them through China's Lunar New Year holidays. But even these are expected to run out by February end. Sourcing alternate API manufacturers will take time and prices are already rising as per reports. The government is considering restricting the export of antibiotics and anti-virals to build up a stock pile in India in case 2019-nCoV is not contained.

But there could be a silver lining to these dark clouds. Will these shortages result in more proactive policies for proposed bulk drug and API parks? Will MSME players in India's pharma hubs see value in restarting manufacture of key APIs, which they had found non-viable due to cheaper products from China?

Companies like Cipla and Aurobindo Pharma are offering to ramp up production of existing medicines which are showing signs of being effective against nCoV patients. Given the lack of choices, regulators too are making exceptions to the rules. For instance, the Central Drugs Standard Control Organisation (CDSCO) has given an emergency approval to India Council of Medical Research (ICMR) to use a combination of anti-HIV drugs-lopinavir and ritonavir tablets for the treatment of nCoV patients in India.

But there are also ethical concerns. Protocols need to be iron tight, and clinicians and regulators need to be in 'research' rather than 'treatment' mode as there is not much evidence that this combination will continue to work. While we have good laws, like the New Drugs and Clinical Trials Rules, 2019, which were introduced in March last year, is there enough oversight to ensure that they are being followed in the right spirit?

Of late, the Department of Pharmaceuticals has been cracking down on the "unethical promotion of pharma products" by sending reminders to industry



Urgent regulatory reform is needed to spur more proactive policies for proposed bulk drug and API parks which will make the country self sufficient in the manufacture of key medicines

associations to ensure that their members adhere to the provisions of the Uniform Code of Pharmaceutical Marketing Practices (UCPMP). The latest reminder of February 4 mentions that the Department has "received a grievance alleging that pharma companies arrange hotels, accommodation in five-star hotels, local sight-seeing, etc. in conferences conducted by doctors." The reminder pointedly mentions the national conference of Indian Psychiatric Society 2020 to be conducted in Kolkata this year, perhaps to prove that such meets are already on their radar.

While the Code is still voluntary and not mandatory, the message seems to be that associations should pressurise their member companies to adhere to the code. While industry associations agree that such a code is necessary, a voluntary code remains "toothless", as many health activists point out. Perhaps policymakers know that enforcing such a code will be next to impossible, given the size of the country.

A day earlier, on February 3, the Ministry of Health & Family Welfare released amendments to a policy dating 1954 for comments. The draft of the Drugs and Magic Remedies (Objectionable Advertisements) (Amendment) Bill 2020 is open for comments for 45 days. The draft expands the list of diseases, disorders and conditions covered from 54 to 78, adding conditions like AIDS.

The draft also increases the penalties and fines for violations as well. Under the draft, the penalty for firsttime convictions is imprisonment up to two years and a fine up to Rs 10 lakhs (increased from jail time of up to six months, with or without a fine under the existing 1954 bill). Subsequent convictions will be liable for jail time of up to five years and a fine of up-to Rs 50 lakhs, which is substantially more than the current bill which awards imprisonment of up to one year for a secondtime conviction.

The draft expands the definition of "advertisement" to mean "any audio or visual publicity, representation, endorsement or pronouncement made by means of light, sound, smoke, gas, print, electronic media, internet or website and includes any notice, circular, label, wrapper, invoice, banner, poster or such other documents."While Ayurvedic and Unani systems of medicine were covered by the 1954 Bill, the 2020 draft adds the Siddha system as well.

Once again, are our regulatory systems geared up to enforce such a Bill? Will long drawn out litigation deter pharma companies from making such claims? While the intention to protect the patient/consumer is noble, will it be yet another toothless tiger? To be sure, policymakers are revamping regulation but the pace of reform needs to pick up.

> VIVEKA ROYCHOWDHURY Editor viveka.r@expressindia.com

# PRE EVENTS

# 11th Annual KAIZEN Congress – India 2020 to be held in Pune

The theme for this year's Congress, 'Thriving in Adversity through Business Excellence', talks about the current economical slowdown and trains organisations to equip themselves to face it

ndian economy is growing, and many industries are flourishing but the biggest hurdle has been inadequate utilisation of resources and wasteful activities. IMF has sounded an alert for a global slowdown, and India isn't immune from it. In fact, the Indian economy is going through one of the toughest challenges in recent times, with major sectors, such as the automobile industry, feeling the pinch. In such challenging times, it becomes even more crucial to maximise the utilisation of all the resources at hand.

The principles of KAIZEN help organisations adopt a lean approach, thus helping them become more productive. Since its inception, KAIZEN Institute has



helped with the exchange of ideas and information in the realm of operational excellence.

The theme for this year's KAIZEN Congress India – 'Thriving in Adversity through Business Excellence' also talks about this economical breakdown and trains organisations to equip themselves to face such

adversities with KAIZEN philosophies leading to operational excellence.

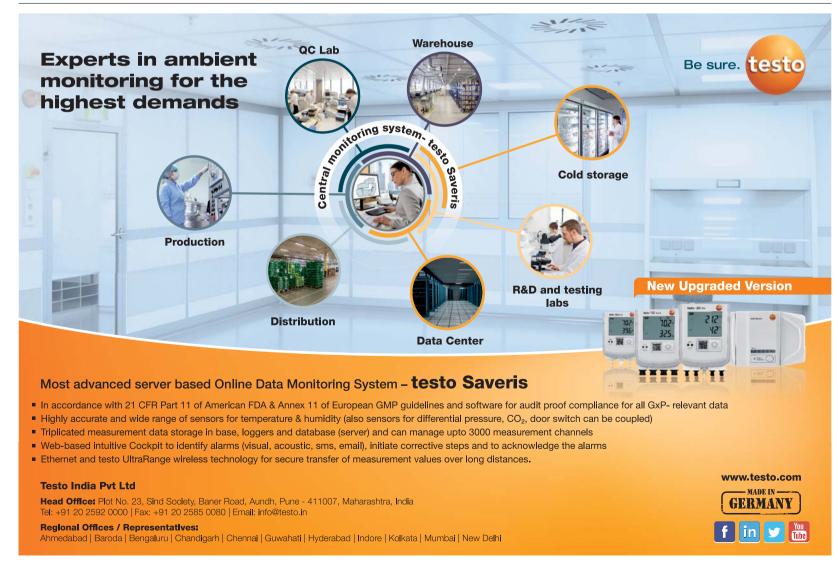
KAIZEN Congress India, one of the most sought-after events in the realm of operational excellence and lean methodologies, is back for its 11th edition. The annual event aims to demystify the concepts of KAIZEN and help

companies become more efficient. Spanning over three days, the gathering is replete with training sessions, benchmark tours, and more than 30 real-life case studies that is a treasure trove of practical information for KAIZEN practitioners and organisations. KAIZEN Congress India 2020 will have more than 100 companies gathering at one place to learn the latest lean methodologies and how companies have leveraged the principles of Kaizen to become more efficient. With more than 250 attendees and over 20 eminent speakers from varied industries, it is a lucrative opportunity to interact with some of the most successful Kaizen practitioners in the country.

### At the event you will:

- ▶ Learn about the tools that can help you transform any organisation into a lean, mean machine
- ▶ See real-life improvements through the KAIZEN Benchmark Tours
- ▶ Share insights into real time implementations through case studies presented by leading Indian organisations
- ▶ Get inspired through knowledge sharing sessions by stalwarts who practice KAIZEN

If you are looking for solutions to tide-over any adversities, 11th Annual KAIZEN Congress India 2020 is for you. Grab the super early bird offer before 31st October and get a flat 20 per cent off on all our packages.



# Ministry of MSME, Gol partnering with **Telangana Government for BioAsia 2020**

Given that the MSMEs contribute to over 80 per cent of the Indian Lifesciences industry and has been an important pillar for the job creation, the partnership is of extreme significance aimed at adding impetus to the growth of MSME sector in the country

THE MICRO, Small and Medium Enterprises (MSME) sector has emerged as a dynamic sector of the Indian economy over a few years. It contributes significantly to the economic and social development of the country by encouraging entrepreneurship and generating large scale employment opportunities. As per an Industry Survey, the MSME sector in India has created 13.5 million to 14.9 million new jobs in the past four years according to a CII's Survey on Jobs Creation and Outlook in MSME Sector. Also, another industry report suggests that the contribution of the MSME sector to the Indian economy is around 29 per cent of the GDP.

With the growing prominence of the MSME sector in the Indian economy, The Ministry of Micro, Small and Medium Enterprises, Govt of India has partnered with the Government of Telangana for BioAsia 2020 again from February 17-19 to help MSME organisations benefit from this global



platform. Given that the MSMEs contribute to over 80 per cent of the Indian Lifesciences industry and has been an important pillar for the job creation, the partnership is of extreme significance aimed at adding impetus to the growth of MSME sector in the country.

BioAsia has evolved as a pre-eminent global meeting benefitting from its extraordinary participant history including Nobel Laureates, Lasker Awardees, Breakthrough Prize winners, established scientific and industry leaders, amongst others. Switzerland will be the partner country, while delegations from various countries like Germany, Spain, Australia,

UK, USA, China, etc. will participate in the event. MSME companies will gain unparalleled access to explore new business opportunities with leaders representing about 50 Countries.

Commenting on the rising sector's participation, Jayesh Ranjan IAS, Principal Secretary, Industries & Commerce, and Information Technology, Government of Telangana said, "Micro, Small and Medium enterprises are one of the most important pillars of the economic growth of the country and is rightly called as 'The engine of the growth'. MSMEs have played a significant role in terms of creating employment opportunities along with innovation.

BioAsia which has emerged as one of the highly regarded platforms in the life sciences sector will bring together the cutting-edge, innovative and technologically oriented MSMEs from the realm of life sciences and healthcare sectors. We are delighted to partner with the Ministry of MSME for the second time for BioAsia and am confident that the platform will help MSMEs companies.'

BioAsia 2020 is set to host eminent global leaders from the life sciences industry including Vas Narasimhan (CEO, Novartis), Dr Carl June (University of Pennsylvania & CAR-T Expert), Dr Peter Piot (Director, London School of Hygiene and Tropical Medicine, and Co-Discoverer of Ebola), Ajay Piramal (Chairman, Piramal), Dilip Sanghvi (Chairman, Sun Pharma), Kiran Mazumdar Shaw (CMD, Satish Biocon). Reddy (Chairman, Dr Reddy's), among others

### **Objectives of the** partnership:

- To provide a platform for the MSME sector to showcase the strength and capabilities of Indian MSME companies to the global life sciences fraternity
- ▶ Offers unique marketing opportunities to MSME Entrepreneurs including access to diverse technologies
- lack Offers a platform to establish joint ventures, tapping into crucial supply chain partnerships, technology transfers, marketing arrangements and image building of Indian MSMEs across the world
- ▶ To foster awareness regarding international best practices that enhance their business prowess
- ▶ To provide a platform for MSMEs in understanding emerging global trends and learn about ways to safeguarding their innovation (Intellectual Property)
- ▶ To enhance marketing avenues for MSMEs by way of capturing new markets and expanding in existing markets.





For any queries, call 022-67440000/22022627

## POST EVENTS

# **Eminence Business Media concludes 3rd Annual** Pharma Project and Portfolio Management **Summit 2020**

The theme of the summit was 'Grooming Project and Portfolio Management teams for opportunities and uncertainties'

minence Business Media's 3rd Annual Pharma Project and Portfolio Management Summit 2020 concluded on January 23-24, 2020 at Hotel Hilton, Mumbai. The theme of the summit was 'Grooming Project and Portfolio Management teams for opportunities and uncertainties'. The event was attended by over 100 delegates. I2E Consulting, Innoventic Research and Business and ProductDossier Solutions India were present as the event partners.

The two-day event ensured the continuous engagement of the audience, speakers and exhibitors through various networking activities and discussions with regards to the ever-evolving challenges of the pharmaceutical companies related to project and portfolio management and how to overcome those challenges.

The event saw as many as

17 sessions and a panel discussion over the two days, attended by the CEO's, MD's, CXO's, Presidents, Senior VP's, VP's, Directors, Associate Directors and Functional Heads of Project Management, Portfolio Management, RandD and IP teams of pharmaceutical and

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### POST EVENTS



biopharmaceutical manufacturing companies.

The day started with Guneet Kaur Hayer, Managing Director, Eminence Business Media welcoming all the delegates and thanking all the partners for their contribution towards the event. She also spoke about Eminence Business Media's initiative towards women empowerment via Remarkable Women Camaraderie and girl child education.

The event was inaugurated with the opening remarks by Debasish Mitra- Vice President Project Management, Cipla in the presence of various eminent personalities from the Pharma Industry. The opening remarks were followed by the presentations by the chairperson and speaker John Robert, Sun Pharma: Javesh Khatri, Enaltec Labs; Sandeep Kumar, ProductDossier Solutions India; Dr Srini Srinivasan, PMI India; Anand Sinha, Innoventic Research and Business; Princy Achankunju, Lupin; Dr

Gazala Khan Koticha, Novartis; Purab Jajoo, Dr Reddy's and Manish Gumber, Cipla.

The panel was moderated by Dr Mahendra Shiradkar, Mylan and the panel members included Sudhir Nambiar, Hikal; Milind Wakaskar, LandT Infotech and Princy Achankunju, Lupin.

The day two of the event included presentations by Dr Laila Fatima, Dr Reddy's; Dr Paras Vasanani, Kashiv Biosciences; Dr Archana Badhwar. Cipla; Arunkumar

Mantri, Mankind Pharma; Abhishek Mittal, GSK consumer and a masterclass by Umesh Kunte, Pharma and Medical Concepts resulting into a standing ovation for him.

A unique moot court session was also held, led by Dr Bharati Nadkarni - Appropriate IP Services as the judge and jury, Dr Laila Fatima- Dr Reddy's, Dr Paras Vasanani-Kashiv Biosciences were advocating project and portfolio management teams respectively while Mr. Jayesh Khatri-

Enaltec Labs and Dr Mahendra Shiradkar - Mylan witnessing the real time responsibilities between these two highly important teams.

A special networking session was also arranged on day two for all the attendees where they interacted with each other and the partners also presented their solutions and services to the attendees. The event was concluded with the closing remarks by John Robert, AVP Project Management, Sun Pharma.

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# DEAL



# Healthcare industry reports 70 deals worth \$3.2-bn in Jan '20

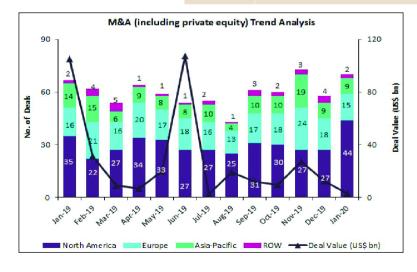
The healthcare industry reported 98 VC deals worth \$1.9-billion in January 2020, compared to the last 12month average of 103 deals worth \$1.7-billion

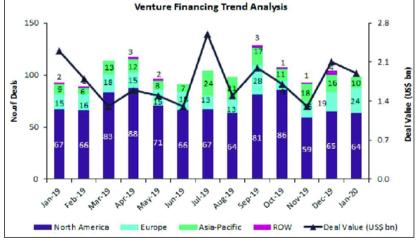
January 2020, the healthcare industry reported 70 deals worth \$3.2 billion as compared to the last 12-month average (January 2019 to December 2019) of 59 deals worth \$30.3-billion. One major deal by Eli Lilly and Company, a pharmaceutical company, announcing to acquire Dermira Inc, a biopharmaceutical company dedicated to developing new therapies for chronic skin conditions, for \$18.75 per share, or approximately \$1.1-billion has contributed 34 per cent to the total deal value in January 2020. The acquisition is expected to expand Lilly's immunology pipeline. Other notable deals in this month include Biogen Inc, announcing to acquire PF-05251749 from Pfizer for \$710-million.

The healthcare industry reported 98 venture capital (VC) deals worth \$1.9-billion in January 2020, compared to the last 12-month average (Januarv 2019 to December 2019) of 103 deals worth \$1.7 billion. EQRx Inc raising \$200 million in series A financing, Aligos Therapeutics Inc raising \$125 million in series B financing, and Generation Bio Corp raising \$110 million in series C financing are some of the major VC deals reported in January

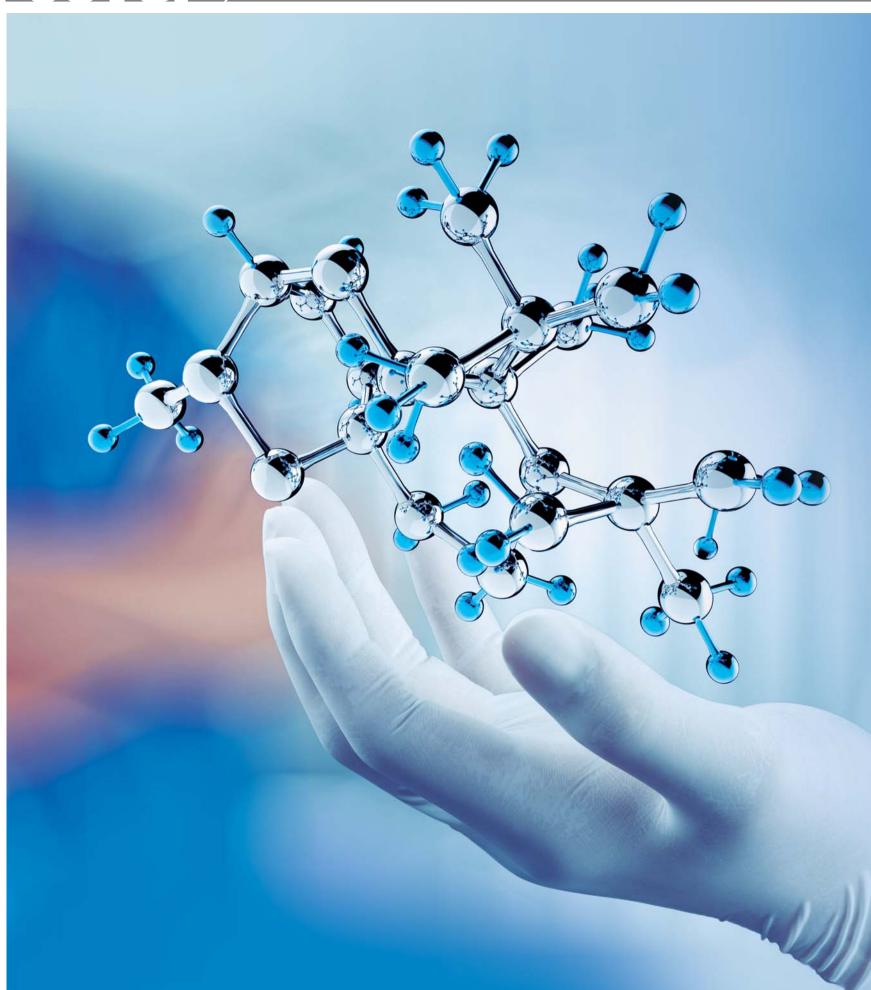
Deal Date	Acquirer (s)	Target	Deal Value (US\$ m)
10-Jan-2020	Eli Lilly and Company (US)	Dermira Inc (US)	1,100.0
13-Jan-2020	Biogen Inc (US)	PF-05251749 (US)	710.0
27-Jan-2020	Orbimed Advisors LLC (US)	Harmony Biosciences LLC (US)	200.0
28-Jan-2020	Yamma Investments (Luxembourg)	Sanovel Ilac San ve Tic AS (Turkey)	200.0
13-Jan-2020	PhaseBio Pharmaceuticals Inc (US)	Novel Oral Aldosterone Synthase Inhibitor (US)	147.7

Deal Date	Acquirer (s)	Target	Deal Value (US\$ m)
12-Jan-2020	Nextech Venture, L.P.; Undisclosed Investor(s); Arboretum Ventures LLC; ARCH Venture Partners LP; Andreessen Horowitz LLC; Casdin Capital LLC; Section 32; GV Management Co LLC	EQRx Inc (US)	200.0
10-Jan-2020	Wellington Management Company LLP; Undisclosed Investor(s); Roche Venture Fund; Versant Venture Management LLC; Boxer Capital LLC; Cormorant Asset Management LLC; Pivotal bioVenture Partners LLC; Novo Holdings AS; Vivo Capital LLC; Janus Henderson Investors; Logos Global Management LLC	Aligos Therapeutics Inc (US)	125.0
10-Jan-2020	Wellington Management Company LLP; Invus Group LLC; Atlas Venture Inc; T. Rowe Price Group Inc; SVB Leerink LLC; Deerfield Management Company LP; Farallon Capital Management LLC; Fidelity Management & Research Company; Foresite Capital Management LLC; Casdin Capital LLC	Generation Bio Corp (US)	110.0
8-Jan-2020	ChinaEquity Group Inc.; Sequoia Capital China; Temasek Holdings (HK) Limited; ARCH Venture Partners LP; Lilly Asia Ventures; Hillhouse Capital Group; Shanghai China Merchant Equity Investment Fund Management Co., Ltd.; Epiphron Capital Fund I LP; Fortune Capital; Teng Yue Partners LP; CR-CP Life Sciences Fund	Transcenta Holding Ltd (China)	100.0
2-Jan-2020	Undisclosed Investor(s); Suzhou Oriza Holdings, Co., Ltd.; Shenzhen GTJA Investment Group Co Ltd; CMB International Capital Management (Shenzhen) Co., Ltd.; New Alliance Capital; ShenZhen Co-Stone Asset Management Co Ltd; Lianxin Capital; CR-CP Life Sciences Fund; Langmafeng Venture Capital; Junxin (Shanghai) Equity Investment Fund Management Co., Ltd.; Yantai Finnova Investment Management Co., Ltd.; Suzhou Xiangcheng Financial Holdings (Group) Co., Ltd.; Suzhou Longmen Pharmaceutical Investment Partnership (Limited Partnership)	CF PharmTech Inc (China)	90.4





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# MAKING INDIA A \$100-BN BIOMANUFACTURING **HUB BY 2024**

Industry experts outline how Prime Minister Narendra Modi's dream of 'Make in India' for the biomanufacturing sector can be fulfilled in the stipulated time frame

By Akanki Sharma

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s the year 2020 began, Prime Minister Narendra Modi came up with good news for the biotechnology sector. Speaking at the inauguration of the 107<sup>th</sup> session of the Indian Science Congress at University of Agricultural Sciences in Bengaluru last month, Modi said, "We aim to develop India as a world-class \$100-billion biomanufacturing hub

"The growth story of India depends on its achievements in the science and technology sector. There is a need to revolutionise the landscape of Indian science, technology and innovation. My motto for the young scientists burgeoning in this country has been -innovate, patent, produce and prosper. These four steps will lead our country towards faster development. If we innovate, we will patent and that, in turn, will make our production smoother and when we take these products to the people of our country, they will prosper. Innovation for the people and by the people is the direction of our 'New India'," he added.

While the biotechnology sector is one of the key drivers for contributing to India's \$5 trillion economy target by 2024, the Indian biotechnology sector is poised to grow exponentially over the next decade. Further, the country is among the top-12 destinations for biotechnology in the world, with approximately three per cent share in the global biotechnology industry.

The biotech sector can be broadly divided into five major segments - biopharma (which accounts for around 55 per cent of the revenue of the total sector), bio-agri (22 per cent of market share), bioservices, bioindustrial and bioinformatics. According to Invest India, the National Investment Promotion and Facilitation Agency, the Indian biotechnology industry was valued at \$51-billion in 2018 and is growing at almost 15per cent year-on-year.



The government's aspirational goal of developing the country into \$100 billion biomanufacturing hub by 2024 is certainly going to give a fillip to the biotechnology sector

### Dr Renu Swarup

Secretary, Department of Biotechnology (DBT), Government of India (Gol):



A higher percentage of people employed in the biotech sector will have a ripple effect that increases per-capita incomes and gives a sustainable boost to the entire Indian economy

### Dr Rajesh Jain

Managing Director, Panacea Biotec and Chairman, CII National Committee on Biotechnology



States like Gujarat, Andhra Pradesh, Himachal Pradesh, Assam, Telangana and Rajasthan are actively attracting investments into the biotech sector through various initiatives like setting up pharma and biotech parks and offering other incentives. A hub could be created within these states or in others

### **Gaurav Kaushik**

Managing Director and CEO, Meteoric Biopharmaceuticals

### Potential that the biotechnology sector holds

Our country is currently ranked at 52<sup>nd</sup> on the Global Innovation Index (GII) 2019, with a jump of five places since last year, and 29 places in the past five years, informed Dr Renu Swarup, Secretary, Department of Biotechnology (DBT), Government of India (GoI). She also said that India has an immense potential to emerge as a global key player. "It is an important and exciting time for the industry. The challenges are as great as the opportunities. As we are moving forward, we are on the cusp of breakthroughs in medical innovations that will benefit patients as well as the societies for decades to come. The advancements through various innovations not only have vast implications for people and society, but these also help reshape the different sectors of the world economy. Innovations have come a long way in addressing challenges across varied sectors like agriculture, healthcare, pharmaceuticals energy, etc. The vibrant ecosystem offered to the innovators has been very helpful in addressing major societal problems and it also gives us the confidence that our innovators will be noticed globally," she said.

According to her, policy initiatives of the GoI such as Make in India, Skill India, Start-up India programmes are aimed to develop India as a world-class biotechnology and bio-manufacturing hub. She highlighted, "It is because of all these contributing factors that India today is a favoured partner for all global biotechnology collaborations. The government's aspirational goal of developing the country into a \$100-billion biomanufacturing hub by 2024 is certainly going to give a fillip to the biotechnology sector as well. For this, we have set up an ambitious target of \$150 billion. and the current growth rate and the enabling ecosystem has given us the confidence to achieve this."

Biotechnology is a multifaceted domain encompassing applications in agriculture, pharmaceuticals, scientific discoveries, etc. It has the potential to create innovative solutions to current challenges and healthcare problems. In this regard, Dr Swarup mentioned, "We at DBT are committed to creating an ecosystem for innovative and indigenous product development, which is globally competitive and involves participation from researchers, academia, start-ups, small and medium-sized enterprises and industry. Each of our schemes at DBT and its public sector unit Biotechnology Industry Research and Assistance Council (BIRAC) is uniquely designed and caters to a specific need-based application to support innovation and proddevelopment. These schemes, along with our partnerships like Grand Challenges India and national programmes like the National Biopharma Mission and 'Make in India' would be instrumental in achieving this goal. We have already been proactively working in this direction of achieving this goal," she further said.

Echoing the same sentiments as that of Dr Swarup, Dr Rajesh Jain, Managing Director, Panacea Biotec and Chairman, CII National Committee on Biotechnology, said that biotech has been recognised as the sunrise sector

among 14 champion sectors under 'Make in India' programme which has the potential to contribute to the \$5-trillion economy goal of India. He emphasised, "Biotechnology occupies a strategic position in the socio-economic advancement and development of the nation and the world at large. Biotech is an answer to various current and future challenges not only for India but the entire world. It has an impact on health and food security, along with environmental sustainability. Its socio-economic impact extends across demographics and the entire spectrum accrues its benefits. Our former Prime Minister Atal Bihari Vajpayee used to say that while information technology stands for 'India Today,' biotechnology stands for 'Bharat Tomorrow'."

Sharing his views on Prime Minister's goal of making India a \$100-billion biomanufacturing hub by 2024. Dr Jain said, "Considering that manufacturing in biopharma sector is capital intensive, such investments have been suboptimal in India due to limited access of capital, inadequate infrastructure and complex and ever-evolving regulatory framework. Biomanufacturing hubs under the flagship initiative of 'Make in India' are an answer to many of the challenges, and will enable worldclass facilities to boost development and manufacturing of innovative products in various streams of biopharmaceuticals including vaccines, medical devices, biosimilars, etc."

Dr Jain further opined that biotechnology is a high-people and high-value industry. "A higher percentage of people employed in the biotech sector will have a ripple effect that increases per-capita incomes and gives a sustainable boost to the entire Indian economy. Integrated hubs will also facilitate Foreign Direct Investments (FDIs), build the confidence of investors, enable technology maturation at a faster pace, enhance Indian export potential for quality products, boost in-house capacity towards import substitution, and nurture and support innovations to generate



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more IP for India," he stressed.

To help chart a robust and favourable policy framework for encouraging improved research, innovations, manufacturing and regulatory ecosystem so as to promote and position India as the hub for innovation and manufacturing in biotechnology, CII National Committee on Biotechnology has been very active.

In this context, Dr Jain said. "Higher innovation will mean increased costs and we need a more predictable system of governance and managing stakeholder returns while keeping affordability in mind. As a society, we have to find newer ways to address these systems. We acknowledge the government's need for lower costs but we also have to emphasise quality, reduce risk of reliance on a single supplier, reward innovation and enter into long-term supply agreements which ensure that companies can plan ahead while being assured of some market share - to keep the lights on."

According to him, some of the opportunities to enhance growth and innovation within the biotechnology sector in India are: government policies to attract global talent; government investment in new areas. eg. new vaccines for human and veterinary use, biosimilars, new medical device manufacturing in India; enforcement of IP; faster regulatory approvals; transparent and consistent drug approval process; expert committees to have global expertise; infrastructure for conducting clinical trials in India; adequate reward for innovation; private sector investment to substitute imports; and monitoring demand and capacity building, amid others.

Gaurav Kaushik, Managing Director and CEO, Meteoric Biopharmaceuticals, said that \$100-billion biomanufacturing hub by 2024, beyond bringing the benefits to the nation, in terms of employment and income, will be doing the world a great service as biotech India is the third largest biotech destination in the Asia Pacific Region and among the top 12 destinations for biotechnology in the world, growing at almost 15 per cent year-on-year

products are garnered from completely natural and biological sources - namely plants. animals and microbes, and tend to deliver higher efficacy. with almost no side effects. When asked about his company's plans to contribute towards this goal, Kaushik responded, "In the past 14 years of our existence, we have offered a bouquet of over 100 products, and have a strong and innovative presence in the specialised biological, biopharmaceutical and biotechnology products segments. We are exploring many healthcare and nutritional fronts through our enzymes and probiotics portfolio. We are currently exporting our products to over 28 countries across the globe -the USA, Japan, Brazil, the UK, Germany, South Korea, Japan and Canada, to name a few, and look forward to expanding our footprint in other parts of the world too."

### **Encouraging factors for** the making

The growth story of India depends a lot on its achievements in the field of science and technology and there is no dearth of talent. Biotechnology serves mankind in helping to move towards a biotechnology-led economy, transforming as many lives as possible, creating opportunities and promising development for all. "One of the major encouraging factors is the growth of the biotech sector and the number of new production and technology which instil in us the confidence of developing India as a world-class \$100-billion biomanufacturing hub by 2024," stated Dr Swarup. She, in addition, said, "Support from the government in terms of funding, policies and various schemes and programmes have fuelled the innovation drive and is helping in creating a conducive environment to solve some of the biggest challenges faced by India. The high demand for biotech products across the world has opened up scope for the foreign companies to set up their base in India. In fact, several foreign companies are joining hands with Indian counterparts due to the tremendous potential they see in the biotech sector. The biopharma and the MedTech sector have seen a strong growth which should now be scaled."

With startups being one of the major contributors to the growth of almost every industry today, the biopharma sector is also not untouched of these. "Today, we are one of the fastest-growing startup innovation hubs in the world. Our innovators and startups are our strength and it is their growth trajectory that encourages us, even more, to be confident about realising our dream of a \$100 billion bioeconomy. With over 2,500 startups in the country, a sizeable contribution is expected from them in achieving our goals as a nation. A lot of young innovators and entrepreneurs in the biotech space are inclined towards nation building by providing innovative solutions to unmet needs in the public health sector. We continue to facilitate and encourage innovations that leave an imprint on the international biotech space. I also urge the innovators/startups to assume greater responsibility in nation-building and carve the success stories for us as a nation by achieving the goal of 2024."

Expressing slightly differ-

ent views from Dr Swarup, Dr Jain said that being a high-risk business having a long gestation period, biopharma sector requires scale-up fund and marketing support from the government for generating success stories in the sector to build confidence amongst investors on India. "The industry has proposed needed reforms in current biodiversity and IP Act to boost the culture of innovations in the country through collaborative research. Such reforms will be encouraging for the industry to contribute to the \$5 trillion target on a fast track mode."

There are several factors that can come together to achieve the Prime Minister's goal. Kaushik said, "The government has already undertaken various initiatives to encourage innovative research. human resource development and an entrepreneurial ecosystem within the biotech space. Beyond announcing some facilitating policy initiatives under the 'Make in India' mission and various broader campaigns in the infrastructure and agriculture sector which will impact the biotech sector favourably, India is also one of the first countries to have a department dedicated to biotechnology. The DBT has also set up BIRAC that has been conceived to strengthen empower emerging biotechnology enterprises to undertake strategic research and innovation. At the same time, the industry is striving to innovate and make a mark in this field too."

### **Possible locations**

For any industrial hub, choosing a location is a mandatory and daunting task. On this

point, Dr Swarup's say was, "We are committed to cover all parts of the country in terms of establishing clusters and regional centres, so that the target audience in the adjoining areas can reach out and avail the facilities at these centres. We currently have about 45 bioincubators pan-India that function either as a stand-alone entity or as a part of the academia in order to connect and enable interactions for efficient exchange of knowledge as well as facilitate technical and business mentorship. The location of the hubs will depend on critical factors like research and technology development competence, market, industry poliinfrastructure. cies. investments, etc."

While Dr Swarup put emphasis on covering all parts of the country, Dr Jain felt that selection of locations will consider establishing new hubs in locations like Karnataka, Telangana, Maharashtra, Puniab and Himachal Pradesh. where various stakeholders like academia, research, industry, entrepreneurs, investors and regulators are already present, while also not ignoring those locations where few of these stakeholders are missing and require such facilitation to build on existing capa-

Kaushik also suggested the names of some states. "A number of states like Gujarat, Andhra Pradesh, Himachal Pradesh, Assam, Telangana and Rajasthan are actively attracting investments into the biotech sector through various initiatives like setting up pharma and biotech parks and offering other incentives. A hub could be created within these states or in others that evince fresh interest and offer a facilitating environment for biotech companies," he mentioned.

### Interpreting the achievability of the goal

As the Prime Minister aims to achieve the making of this biomanufacturing hub in the next four years, the industry people seem to be prepared to put in all their efforts and make this possible. "We are committed to achieving this target and are confident about achieving the same in the stipulated time frame. The government's will and policy framework have helped create an environment of trust and mutual understanding for all stakeholders to move ahead with one unanimous goal of achieving this target. We have moved from working in silos to working as a team to achieve this goal which is practically the only way ahead to build new partnerships, establish long-term collaborations and identify investment opportunities as well. DBT and BIRAC have, over the last few years, demonstrated the ability to achieve this. We have today a strong and vibrant industryacademia partnership, a translational ecosystem and a startup and entrepreneurial base of over 2,500," notified Dr Swarup.

Sharing that Indians are known to give their best when they work in an emergency situation, which is definitely challenging but not impossible, Dr Jain informed, "Indian biosimilar industry carries the most approved number of biosimilars in the world. This sector represents a vibrant ecosystem comprising innovative products and innovation pipeline with over 2,700 startups, 600 plus core companies, 200 plus biotech and research training institutions." He further said, "Present government policies have strengthened the institutional mechanisms for empowering innovation and ensuring scale up and sustainability. India understood the value of this sector long back and is the only one that established a dedicated department nearly three decades back to develop an ecosystem supporting innovation, investments, scientific and quality manufacturing skills. Following several years of strategic planning and actions, the Indian biotechnol-

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ogy sector has achieved a unique position."

According to research by Global Market Insights Inc., the global biotechnology marby 2024. This indicates the immense potential of the segment. India is the third largest biotech destination in the Asia Pacific Region and among the nology in the world. Although it's approximate share in the global biotechnology industry was just around three to five per cent at \$51-billion in 2018, it

cent year-on-year. If it continues to grow at this rate, it can expect to cross the \$100 billion mark by 2024.



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# HIV first-in-class pipeline sees high levels of innovation that targets drug resistance and latency reversal

There are 87 first-in-class products that act on a range of 50 molecular targets, which can broadly be classified as host or viral factor

he human immunodeficiency virus (HIV) pipeline is robust, with 450 products in active development that display a high degree of novelty and diversity. Promisingly, there are 87 firstin-class products that act on a range of 50 molecular targets, which can broadly be classified as host or viral factors, indicating a high level of innovation in comparison with the marketed products, says GlobalData, a leading data and analytics com-

The company's recent report, 'HIV: First-in-Class Therapies Target Major Unmet Needs Including Drug Resistance and Latency Reversal', reveals that the majority of the 10 highest-ranking targets have demonstrated evidence, either in vitro or in vivo, of latency-reversing potential and/or efficacy in drug-resistant HIV strains. This encouraging trend demonstrates that first-in-class innovation is centered on addressing these major unmet needs in the HIV market.

Sarah Elsayed, Pharma Analyst, GlobalData, commented, "The persistence of latent HIV reservoirs in antiretroviral therapy (ART)-treated patients represents a major barrier to the development of a functional cure, while the global rise in HIV drug resistance compromises the significant advances in disease management that have been achieved since the 1980s. However, the most pressing unmet need remains to be a cure that results in viral eradication."

First-in-class targets were integrated into a proprietary



matrix assessment that ranks them according to their therapeutic and commercial potential within HIV market. Interleukin 2 receptor subunit beta (IL2RB) was found to have the  $\,$ highest ranking. It has a role in stimulating the immune response by activating the potent IL-2 signaling pathway that results in suppression of viral replication eventually. Also, the drug candidate possesses latency-reversing potential as shown in the preclinical investigations. Other first-in-class targets with strong therapeutic potential include those targeting Toll-like receptor (TLR3) and Protein kinase C (PKC) family.

Furthermore, HIV vaccines have a strong presence in the overall pipeline (27.2 per cent). Preventive and curative vaccines have received high attention in research recently, since they may potentially translate into a cure that will eradicate the virus and help

control the HIV pandemic. Despite the promising outlook, vaccines have historically suffered from high failure rates due to the particular nature of HIV and the low clinical trial participation rates globally.

Cell/gene-based therapy is also being investigated in the early stages of development, with two first-in-class products, both of which are at the discovery stage. It is different from the conventional antiretroviral treatment, since it can potentially be translated into a revolutionary cure in the near future.

Elsayed concludes, "Although 60 per cent of these pipeline drugs are still in early development, the innovation of molecular targets is promising and presents the potential to expand the existing HIV drug classes, which have completely fulfilled the primary unmet need for long-acting therapies."

### STARTUP

### NTERVIEW

# We are proactively focusing on consumer awareness about the importance of right nutrition

Power Gummies, with its portfolio of vitamins and nutritional supplements in gummy format, has introduced a new fun way for consumers to keep up with their nutritional requirements, tells Divij Bajaj, Founder, Power Gummies to Tarannum Rana

### You have recently received a Pre-Series A funding by DSG Consumer Partners, How do you plan to utilise these funds?

With recent funding from DSG, we would be proactively focusing on consumer awareness triggering the importance of right nutrition. We plan to tie up with major influencers to communicate that message across because we've seen a robust response through influencer marketing, a new age media technique that we have deployed and the same has driven results for us. Our focus would also be around team building, improvising packaging, supply chain management and doing scientific research for future variants in the health and nutrition supplement market. The brand also plans to expand further in the OTC category, making Power Gummies a household name in the near future as far as the segment of adult nutrition is concerned.

### Apart from providing funds, will DSG Consumer Partners be involved with Power Gummies's development in any other way?

Yes, DSG has been more than just an institutional fund for us. They closely monitor and work along to improve management systems ranging from financing, accounting to legal support. They have been helping us through their network to get through the right industry experts. With them coming on board, a lot of opportunities have opened for Power Gummies in terms of market places, industry insights and distribution network. We have been able to

better manage our team and think of growth prospects, research, development as well as improve existing team structure and product line.

### Tell us about your growth story so far.

The response has been phenomenal in the domestic and international market. Assessing the scepticism that consumers have of long term allopathic medication, we decided to work our way around the anxiety of consuming pills/syrups with alternative sources of nutrition. The company's main focus from the behest was to bring nutrient supplements in a well researched and scientifically backed product which lead to the production of Power Gummies.

Before we launched the final product, a lot of research on possible barriers and challenges was done by us - we wanted to make sure that Power Gummies as a niche product is visually appealing, good to taste and something consumers do not need to be reminded of as compared to consuming pills or medicines in any form that might not be good to taste. A number of times, we have seen scenarios where people stop taking the prescribed medication due to lack of motivation, due to psychological fear of sideeffects Our USP, we'd say, is overcoming these challenges where people are selfmotivated to consume our products regularly. Also, since it's an over the counter product, consumers do not need prescriptions to purchase the same, making it accessible for



We are currently selling products worth above 80 million INR every month. We have a loyal brand following which can be seen through our social media pages where people of all demographics male, females, millennials, the 30-40 age group from Tier 1,2,3 cities - have been actively engaging with Power Gummies.

### After Biotin Power Gummies, what all other products are in the pipeline?

Talking about the big picture, we plan to launch one more variant soon - the Fat Loss Gummy variant which would bring in a tasty way to reduce fat. Currently, it is under the final stage of clinical trials as we want to make sure that we bring to the market a product that is scientifically backed and contains best-in-class ingredients to deliver the required results. We are creating a new standard for the

adult nutrition market for any new players/ products/ competition to follow suit when it comes to the science and precision required before any go-to market strategy.

Your brand's marketing seems to be focussed specifically on women. Do you have any products coming up specifically for men as well? Our product is gender-neutral, thus being fit for consumption for both men and women. Women comparatively face more hair loss and brittle nail issues as compared to men since estrogen production in the body goes down in middle age women. Not to mention that in today's age of millennial diets, stress and pollution it becomes more challenging for women to maintain and replenish their nutrition requirements.

Even for men, body image issues, mental stress and peer pressure make them conscious about thinning hairline, hair loss and we have seen a surge in men ordering our products.

### You claim that your products are plant-based, and do not contain gelatin or other animal-derived elements. What is the composition of Power Gummies?

Power Gummies have a base of Pectin which is 100 per cent vegetarian and are an amalgamation of Biotin, Zinc, Folic acid and 10 essential vitamins - a panacea for many hair and nail problems. Power Gummies supplements are 100 per cent vegetarian and completely gelatin-free, gluten and cruelty-free.

Recently, a similar US

product, SugarBearHair supplements have come under the scanner for containing a biotin dose much higher (over 160 per cent) than what is recommended. What are the permissible levels of Biotin recommended in India? What is the dosage composition of your product? Power gummies are FSSAI approved and FDA compliant, the percentage composition mentioned on our products is in sync to the guidelines provided by the government of India and does not exceed the recommended dosage in any way. We follow all guidelines and rules set by ICMR, and all our batches go through a series of clinical trials before getting to the market. We comply with all the rules and regulations governing the adult nutrition market and understand the sensitivity, trust and responsibility bestowed upon by the healthcare sector by government bodies and consumers alike.

### How is India's nutraceutical supplements sector growing? What kind of potential do you see in it?

According to a 2018 Assocham Knowledge report, the Indian nutraceuticals market is expected to grow from \$4 billion to \$18 billion by 2025. We see high demand as people are getting aware of the importance that vitamins and proper nutrition have in their lives.

As people now prefer quality products and don't mind paying for it, health supplement and nutraceutical space is expected to grow about 6 times overall in the next five years or so.

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### NTERVIEW

# FDAlytics is an intelligent assistant platform to help in GXP

As major pharma companies in India continue to grapple with GMP compliance issues, a startup combining deep learning, AI tech, and NLP models based on artificial neural networks is helping subscribers be better prepared for inspections, learn from the US FDA trends and improve their GMP processes continuously based on those learnings. With the official launch planned for February 20, Bhavish Agarwal, Founder, FDAlytics.com tells Viveka Roychowdhury how his company's algorithms can augment the analysis of pharma regulatory affairs personnel by providing them up-to-date and readily available data points

### Bhavish, thanks for talking to Express Pharma. Tell us something about your previous life before you turned entrepreneur.

Thank you. It is my pleasure to speak to you. I have been working in the field of Artificial Intelligence (AI) for the last 10 years in companies such as Microsoft, Zlemma and Hired.com. I met my cofounder Chakri Uddaraju at Hired. He was working at Facebook building the Marketplace before we decided to start Fdalytics.com.

### How did you find yourself starting an ML/AI startup for pharma companies in India after a career in Microsoft, etc?

It has been an interesting journey for us. We wanted to use our experience of working at big tech companies in cutting edge technologies in the field of healthcare and pharmaceuticals. During our interactions with multiple pharma players, we realised that GMP compliance remains one of the biggest and continuous challenges.

We identified the US FDA GMP regulation and compliance as the problem



and started thinking about the various ways we can use our experience in deep learning and AI tech to solve this problem. We found two opportunities: First in terms of India's growing position in the API and finished dosage exports to the US. By being in India, we are getting easy access to an industry which is looking out for innovative solutions to minimise or eliminate their compliancerelated risks.

Secondly, once we started capturing the US FDA data, we immediately understood how ML/AL can become a big differentiator and create value for our customers.

In summary, strict monitoring of GMP laid down by the US FDA and vast amount of data where

ML/AL can be used made it a no brainer for us to start an ML/AI company for pharma companies in India.

What is the basic rationale for FDAlytics.com? What are the features of FDAlytics.com like inspector analysis, etc? The aim of Fdalytics is to provide data and insight for GMP compliance to global pharma and medical devices companies. We want our customers to be better

prepared for inspections, learn from the US FDA trends and improve their GMP processes continuously based on those learnings

At a high level, Fdalytics features can be described in three categories: Data, Search and Intelligence.

As of today, the FDA inspection related data is either not available, scarcely available or if available, it exists in disjointed and siloed formats. It is virtually impossible to gather or combine these data points and gain insights from it.

If a pharma company wants to ask insightful questions like - what is the most frequently cited CFR violation last year? What area is a specific inspector more likely to focus on based on his or her behaviour? What are the global inspection trends based on all inspections? This is almost impossible to find out yet this is very useful for a company to go through the inspection.

Let me give first give you an overview of the data that we have before I tell you how we use ML/ AI to leverage these data points.

In Fdalytics we have gathered data points for all the inspections conducted by the US FDA since the year 2000. For each of these inspections, we have collected whether a Form 483 was issued, whether the inspection resulted in a VAI, OAI or NAI, how long that inspection lasted and who were the inspectors who conducted these inspections. We also have tens of thousands of 483s, EIRs, responses and Warning Letters.

Alternatively, the platform can also tell you the track record of each of these US FDA inspectors. For example: what inspections they conducted, how many 483s they have issued etc. Since we have these track records our users can also gain insight on each of these inspectors. Additionally, our users can use the advanced search features for each

inspector to drill down to a single observation made by the inspector during an inspection.

But this is just the surface. We are using Natural Language Processing (NLP) models based on artificial neural network. These models operate upon tens of thousands of Form 483, EIR, warning letters etc to pinpoint the specific areas that are the most relevant to an individual customer.

We are creating features where based on a company's profile and track record, Fdalytics algorithm can make personalised recommendations.

Pharma companies in India need to analyse the technical details of US FDA inspection reports, be they 483s or EIRs, on a daily basis. How does the ML/AI tool score better than regulatory affairs personnel in pharma companies who have had years of experience within the sector?

Yes, you are right. Regulatory affairs personnel need to go through a lot of 483s in order to learn from US FDA observations. However, there are many challenges to it - availability of data being the number one. With FDalytics, we solve this basic but foundational problem by providing the data in a click of a button. You no longer have to ask or call your friends or colleagues to get second hand or incomplete information or pay an enormous amount of money.

As you said, most of these personnel have years of experience within the sector. With Fdalytics, we aim to augment their analysis by providing them up-to-date and readily available data points. Since Fdalytics is a technology platform, we can scale it up which is very difficult to achieve without technology.

We are very confident that Fdalytics will become an example where AI

technology and professional experience come together to create a far more efficient environment for GMP compliance. In short, FDAlytics is an intelligent assistant platform for pharma companies and regulatory / compliance leaders to help them in GXP.

### Give us an example to illustrate. Suppose a company needs to look for all data integrity related 483s dealing with injectables.

This is an interesting example. Before Fdalytics, this problem would have taken a lot of manual efforts and resources, assuming someone has enough 483s. Then too, the chances of missing an important observation would have been high.

In the Fdalytics platform, our user simply has to search for the keyword 'Data Integrity' and chose the category 'Injectables' and our algorithm would go through almost 30-40 thousand individual observations and find the relevant observations.

You can even refine your search so that you can find specific issues by a particular inspector. For example, you can find all 'computer system validation' issues cited by say 'Thomas Arista' etc. Not only that, the search result can be filtered where you can filter those observations that resulted in a warning letter. All of this happens on Fdalytics in few milliseconds.

Our customers love the simplicity and the ease of use of the platform. But in the background, our AI algorithms are hard at work. For example, if some searches for 'Data Integrity' the algorithm also understands that phrases such as 'electronic data' or 'reviewed for accuracy' are closely related to data integrity.

One more example of a solution that we are providing is searching for observations by CFR

citations. Before Fdalytics, it was virtually impossible to search for issues related to say, 21 CFR part 11. Our powerful and accurate algorithms are capable of mapping all the individual observations with their corresponding CFR code. This is a powerful feature. and few of our customers are already using to update their training programmes and SOPs based on these CFR examples.

### What is your team size right now and how are you funding this venture?

We are a team of 10 passionate and energetic people, majority of whom are engineers and ML researchers. We have also onboarded pharma industry experts with vast experience and unparalleled domain expertise. We are completely bootstrapped and have already started generated revenues.

### With the official launch planned on February 20. what has been the response during the past few months in the beta launch stage?

We launched a few months back in the stealth mode and worked with select customers. The response has been phenomenal and provided testimony to the fact that there is a real demand for technology tools to help companies navigate the complex world of GMP compliance and regulation.

The feedback was very encouraging and gave us the confidence to launch Fdalytics officially. We also realised that the pharma manufacturers are very tech-savvy and are fast adopters of the latest technologies.

### How many companies have signed up? Are they all pharma companies or some are consulting companies as well?

We have close to a dozen companies both in India and overseas who are already are using the Fdalytics platform. We also have few pharma

consultants who are using the tools to keep abreast of the developments in US FDA conducted inspections. We are actively receiving demands and interests from new customers.

### Give us an idea of the subscription schemes on offer.

First of all, anyone can sign up to Fdalytics.com and start using certain search features for free. Fdalytics comes with a lot of flexible and affordable pricing option. We understand that each pharma company is different and will have different requirements.

Depending on the requirements, one can purchase Form 483 or an inspector's report. We also offer unlimited access to Fdalytics platform as a yearly subscription by paying a one-time yearly fee.

Our subscription customers get unlimited Form 483s, EIR etc download, access to all the inspector profiles and access to all the advanced features search as advanced search and recommendation. We also build custom machine learning models for our subscription customers that give specific insights for their companies.

### Who are your competitors in this space and what is your USP?

Fdalytics is the only pharma GMP compliance platform that uses AI/ML and operates on US FDA data. This is the first time that advanced NLP and neural networks are being applied in this space.

There are few websites which sell Form 483s etc but the customers have to pay exorbitant amounts to get just one such document. Our customers not only get these documents at a much cheaper rate but are able to leverage the power of big data and AI technology to get actionable insights. In essence, our USP is our data and technology.

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# "To end the HIV pandemic, we must continue to outthink this virus"

Mary Rodgers, virus hunter, Principal Scientist and Head, Abbott Global Surveillance Center explains to Viveka Roychowdhury the importance of tracking virus mutations in HIV and viral hepatitis across the world to update their diagnostic tests

Abbott's 20-year-old Global Surveillance Programme is the basis of the company's diagnostics research programme leading to commercial diagnostic test products. What is the significance of vour team's recent discovery of a new strain of HIV called HIV-1 Group M, subtype L? It has been 25 years since we established the Abbott Viral Surveillance Program to monitor HIV and hepatitis viruses globally to track mutations to help make sure our diagnostic tests remain up to date. The discovery of a new strain of HIV called HIV-1 Group M, subtype L by our team marks the first time a new subtype of HIV-1 has been identified in 19 years - since guidelines for classifying new strains of HIV were established.

This new strain is a part of the major group of HIV (Group M), which is responsible for 90 per cent of the pandemic, and has been traced back to the Democratic Republic of Congo (DRC). The new strain discovery helps researchers and healthcare providers stay one step ahead of mutating viruses and avoiding new HIV outbreaks. Since we live in a global village, we can't think of viruses being contained to one location. This discovery reminds us that to end the HIV pandemic, we must continue to outthink this virus and use the latest advancements in technology and



resources to understand its full scope.

### What are the other disease areas tracked by Abbott's Global Surveillance Programme?

At present, our program fo $cuses \, on \, HIV \, and \, viral \, hepatitis \,$ - both continue to be major global public health issues. India has the third largest HIV

epidemic in the world, with 2.1 million people living with HIV (2017 data).1 Globally, more than 257 million people are chronically infected with hepatitis B and 71 people are chronically infected with hepatitis C.2-3 As the only diagnostics company with such a unique, longstanding and large-scale Viral Surveillance Program, we provide a vital tool to keep pace

with these evolving threats to help make sure our diagnostic tests remain up to date.

Since such diagnostics research has a huge impact on public health, is the company collaborating with governments of countries most affected so that the research information can be used to detect and possible contain

### potential pandemics?

As a leader in blood screening and infectious disease testing, Abbott created its Global Viral Surveillance Program 25 years ago to monitor HIV and hepatitis viruses and identify mutations to help our diagnostic tests stay up to date. We partner with blood centers, hospitals and academic institutions around the world. We also partner with researchers in the Ministry of Health in some countries. So far, we have collected more than 78,000 samples containing HIV and hepatitis viruses from 45 countries, identified and characterised more than 5,000 strains, and published 125 research papers to help the scientific community learn more about these viruses.

Last January, Abbott announced its partnership with YR Gaitonde Centre for AIDS Research and Education (YRGCARE) to study the country's viral diversity to improve accuracy of diagnostic tests. What have been the outcomes of this partnership in this first year?

Our partnership with YRG Care aims to study the country's HIV and hepatitis viral diversity and to help make sure our diagnostic tests remain up to date to keep pace with these changing viruses. Abbott has provided study protocol and diagnostic equipment, while YRGCARE

has helped in screening and sequencing data from infected populations in India.

Our initial findings show diverse strains of HCV in India. Once we are closer to publishing our research, we can share details about the specific genotypes detected in the region. What's interesting is that the geographical classification of the HIV and HCV strains identified confirmed that higher levels of viral diversity were present in cities near borders with neighboring countries where drug trafficking routes exist. Notably, the HCV strains that predominated in the Northeastern region varied dramatically from those identified in the Northern border. These results support the hypothesis that new strains have been imported to India via the Golden Triangle and Golden Crescent

The new strain discovery helps researchers and healthcare providers stay one step ahead of mutating viruses and avoiding new HIV outbreaks. Since we live in a global village, we can't think of viruses being contained to one location. This discovery reminds us that to end the HIV pandemic, we must continue to outthink this virus and use the latest advancements in technology and resources to understand its full scope

opium trade routes.

How will these outcomes help diagnose, treat and maybe prevent HIV infection in India?

The UNAIDS 90-90-90 goals

are that 90 per cent of all people living with HIV will know their status, 90 per cent of all people with diagnosed HIV infection will get antiretroviral therapy, and 90 per cent of all who are on therapy will achieve viral

suppression.

Continuous research, including the new HIV virus discovery, supports the first and the most important pillar of 90-90-90goals. As we take it a step further to geographically classify

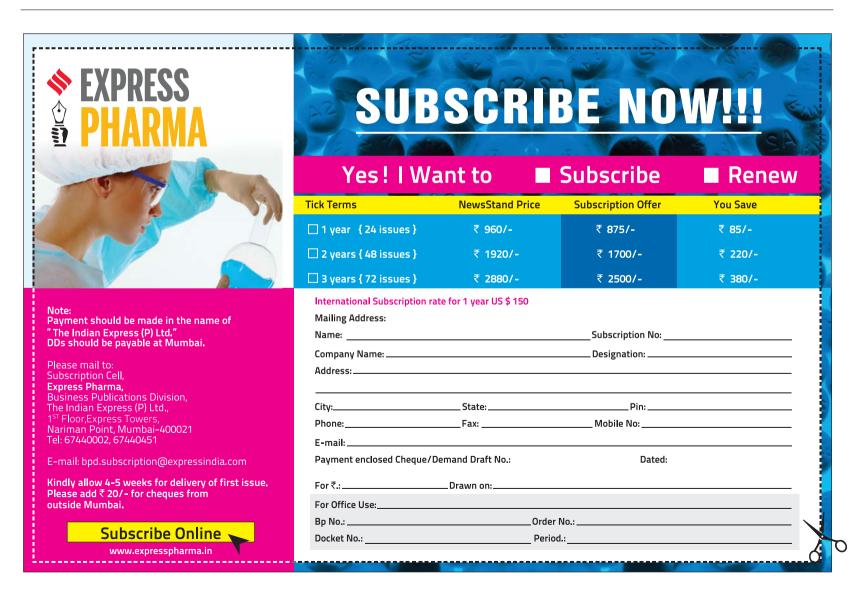
viral strains and map where these strains cluster, this information allows us to understand what might be driving viral diversity in specific regions. This information could give us insights, not only into how we can diagnose-and even preventthese infections, but also into where the global health community's efforts should be focussed.

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# IIT Hyderabad researchers find new molecule to potentially treat Amyotrophic Lateral Sclerosis

ALS is a neurodegenerative disorder that severely affects the voluntary movement of the muscles and can lead to paralysis and death and occurs due to changes in specific genes

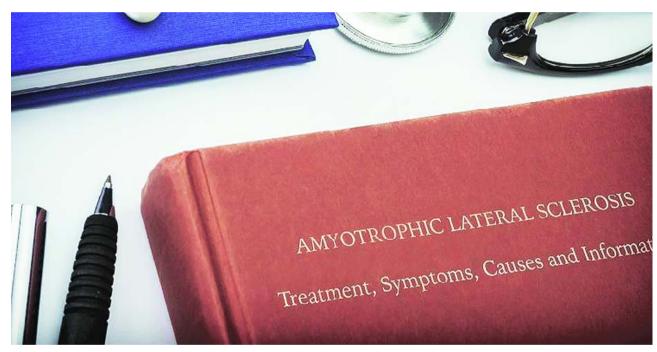
INDIAN INSTITUTE of Technology Hyderabad researchers have found a molecule called 'AIM4' that shows promise in the treatment of a rare and debilitating neurodegenerative disease called 'Amyotrophic Lateral Sclerosis' (ALS), also known as 'Lou Gehrig's disease.'

ALS is a neurodegenerative disorder that severely affects voluntary movement of muscles and can lead to paralysis and death. It occurs due to changes in specific genes, which may be triggered by factors such as smoking, exposure to toxins, metals and pesticides.

The results of this research, performed by a team lead by Dr Basant Kumar Patel, Dr Sandeep Singh and Dr Rajakumara Eerappa, faculty from the Department of Biotechnology, IIT Hyderabad, and Prof. Ganesan Prabushankar, Department of Chemistry, IIT Hyderabad, has recently been published in the reputed peer-reviewed International Journal of Biological Macromolecules.

The paper has been co-authored by these scientists along with research scholars – Amandeep Girdhar, Vidhya Bharathi, Vikas Ramyagya Tiwari, Suman Abhishek, Waghela Deeksha, Usha Saraswat Mahawar, and Gembali Raju.

There are no drugs available at present to cure ALS and treatment options are limited to two drugs only for management of the condition. Research is ongoing throughout the world to find better drugs that can arrest this disorder and not merely manage the symptoms. Such re-



search must first identify the causes for the onset of ALS.

Elaborating on this research, Dr Basant Kumar Patel, Associate Professor, Department of Biotechnology, IIT Hyderabad, said, "One of the causes of ALS is the alterations in the genes that code for a critical protein called TDP-43. The gene alteration modifies the protein, which results in its liquid-liquid phase separation. This phase separation in turn causes the proteins to be deposited on nerve cells, resulting in neurodegeneration."

The 'ice bucket challenge,' which went viral in the U.S. and the UK in 2014, created awareness about this disease among people. The disease is relatively unknown in India although Indians seem to have an earlier on-

set of this malady compared to people of the West and show longer lasting symptoms and disease progression.

In 2016, Dr Patel and Prof G Prabushankar found a small molecule called 'AIM4,' which seemed to be better than the other related molecules that have been studied all around the world, in its ability to inhibit abnormal aggregation of TDP-43 in vitro ALS disease model systems. Armed with this knowledge, the IITH scientists proceeded to analyse this molecule and study its action on TDP-43, to predict how it would potentially inhibit the deposition of the protein in nerve cells. The results of this work have recently been published in the above journal.

Dr Patel added, "We have shown that AIM4 prevents liquid-liquid phase separation of the modified protein, TDP-43-A315T. By this, AIM4 prevents aggregation of the protein and may potentially prevent the deposition on neurons."

The research group compared the ability of AIM4 to prevent protein phase separation with that of other molecules such as Dimebon. Dimebon is an antihistamine that was studied for treatment of neurodegenerative disorders by an American pharmaceutical company but failed clinical trials. The IIT Hyderabad Research team found that AIM4 was better than such earlier molecules in preventing protein phase separation.

The research team has also

discovered through computational studies that AIM4 has specific binding site on this protein and binding energy calculations have shown that the bond between AIM4 and the mutant energetically favourable, which makes it a promising drug for potential treatment of ALS. "This work is an important step forward in the area of therapeutics of the neurodegenerative disease ALS as current options for ALS are minimal or even non-existent", said Dr Patel. The work by the IITH researchers shows that AIM4 is a promising molecule that must be studied further for development of drugs for ALS and perhaps even other neurodegenerative diseases

EP News Bureau

## INFRASTRUCTURE

### INTERVIEW

# With HPTLC PRO, we have taken our tech to the next level with routine analytics

**Dr Markus Wyss**, CEO – CAMAG, Switzerland, who is in India for the unveil of HPTLC PRO System, talks about this latest addition to CAMAG's line of products

How has the CAMAG-Anchrom association shaped up over the years? The association with the

Charegaonkar family started almost a lifetime ago by CAMAG's founder Dr Dieter Jänchen. The owner Dilip Charegaonkar started to provide not only distributorship of this highquality instruments at an early stage of the collaboration to the Indian customers, but offered in his own laboratory, training and

method development to the HPTLC-community in India. Now the second generation of the family has taken over the company and all together are a trusted partner, with whom CAMAG develops the Indian market systematically and in depth.

Tell us about your latest product - HPTLC PRO?

HPTLC is a strong analytical technique, especially when matrix-loaded samples have to be analyzed, but compared to



other analytical systems, a major drawback of HPTLC was up to last year the relatively low level of system automation. Our patented HPTLC PRO System combines all the advantages of HPTLC in a fully automated solution, designed for high throughput analysis in routine quality control. Due to the approach of maximized process standardization and full automation throughout the entire process, the cGMP compliant HPTLC PRO

System is capable of delivering reproducible and reliable results, while a significantly reduced solvent consumption keeps operating costs lower than any other comparable analytical technology.

Can HPTLC replace HPLC for some applications? With  $\overline{\text{HPTLC}}$  PRO, we have initiated nothing less than a revolution in analytical chemistry, elevating our technology to the next level:



An entirely new generation of HPTLC System, specifically for Q.C. applications has been launched by CAMAG, Switzerland. There will be up to 5 identical looking instruments side by side with conveyerised movement of plates. Each instrument will perform one step of HPTLC viz.

- 1) Sample application
- 2) Chromatogram development
- 3) Derivatization
- 4) Detection by hyperspectral means
- 5) MS interface



A sixth will be for plate storage. Up to five plates can be chromatographed without manual intervention, with up to 3 mobile phases. As of Jan 2020, two instruments i.e. Application and Development have been released. Anchrom in Mumbai installed already the world's first Pro sold by CAMAG. Manufacturers for regulated markets, Indian regulatory authorities, commercial analytical labs will rely on HPTLC Pro, once they have evaluated it. Live demo in Mumbai on request.

> For full details about CAMAG HPTLC, list of users, application notes, HPTLC analysis of your samples, free training, further details, quotation, please contact: \_



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### **INFRASTRUCTURE**

routine analytics. We see a huge market potential in routine quality control, e.g. in pharmaceutical or food analysis and others. Due to the higher complexity in using the gas phase in addition to the solid/mobile phase of separation in HPLC, HPTLC PRO now offers a reliable solution to control all important factors during the analysis.

### Many analysts are giving more importance to HPTLC. What do you feel?

As mentioned, HPTLC is a powerful analytical technique, which has recently found its way into the USP and the Ph.Eur. The increasing importance of HPTLC is a direct result. We will see a renaissance of this analytical method also due to the fact that the analytes can be

detected in several detection modes (UV & fluorescense; derivatized and via MS) and adding a hypersprectral detector in the future will even further increase the interest in this technique by our worldwide customers.

### Is HPTLC an official pharmacopoeial technique?

Of course. There are general chapters describing parameters and proper use of HPTLC in the US, the European, and the British Pharmacopoeia. Since 2016 and 2017 respectively, all new monographs on plants feature HPTLC methods for identification. There are also chapters for identification of fixed oil by HPTLC. Last year the European Pharmacopoeia commission approved the use of HPTLC for tests on minimum content of marker

compounds.

The latest edition of the Indian Pharmacopoeia has added a chapter on HPTLC as

### **Apart from HPTLC** instrumentation, which other instruments do vou manufacture?

In 2012, we have entered the diagnostic field of dried blood spot (DBS) sampling by developing a patented, fully automated, high-throughput device - the CAMAG DBS-MS 500 - for the metabolite extraction of Dried Matrix Spot cards. The know-how gained from the elution process of the TLC-MS Interface was transferred to this device to extract target analytes online from Dried Blood Spots and analyze directly with LC-MS or MS, or to collect by a Sample

Collector. This technique will likely replace the whole blood sampling soon, e.g. the antidoping agencies announced to switch to this technique now.

### What are the main applications of this DBS-MS $\,$ 500 online extractor?

DBS analysis is well known in the field of newborn screening. With the sensitivity of modern Mass Spectrometry (MS) instruments, the technology has emerged into new markets and unleashed new application areas, for example forensic toxicology, especially doping analysis as already mentioned and testing for illicit drugs, and therapeutic drug monitoring, which aims at personalized patient care where drug dosage is adjusted individually in order to optimize the treatment outcome of a disease.

### Have you been successful in hyphenating MS with HPTLC?

Absolutely, since its introduction into the market some ten years ago, we have sold hundreds of MS-Interfaces to customers all over the world.

### What is your message to the large Indian HPTLC users?

With the introduction of HPTLC PRO, our Indian customers - and also any potential customer who has hesitated to invest into the technology - can now unleash the full power and advantage of the HPTLC technology when it comes to complex sample analysis at the best possible price per sample. Our partner Anchrom is happy to enable any laboratory in India the start using HPTLC PRO.



# Syntegon Technology appoints Dr Michael Grosse as CEO

He will succeed **Dr Stefan Koenig** who has been leading the company as CEO since 2017

### SYNTEGON TECHNOLOGY,

a globally leading supplier of processing and packaging technology, has appointed Dr Michael Grosse as new Chief Executive Officer (CEO). Most recently. Michael Grosse was a member of the Management Board of Tetra Pak. He has relevant leadership and management experience in the international mechanical engineering industry, particularly in the areas of process and packaging technology for the food industry. Michael Grosse joined Tetra Pak in 2003 and was, among other things, responsible for expanding the global services business.

Furthermore, he is an expert for new product development and process technologies. Thanks to his many years of experience, he has built an extensive network and close relationships within the food industry.



Before joining Tetra Pak, he held several management positions in the automotive industry. Michael Grosse will take up his post on March 1, 2020.

He will succeed Dr Stefan Koenig, who spent a 24 years working for the Bosch Group, ten of which at Syntegon Technology, or Bosch Packaging respectively. Since 2017, he has been leading the company as CEO. In 2019, he was in charge of the company's spin-off from Robert Bosch GmbH and its subsequent sale.

"We are very pleased to have won Dr Michael Grosse, an extremely experienced and successful manager, for Syntegon Technology. Almost two decades of management experience in the packaging machinery industry and an international industry network are excellent prerequisites to further advance the successful development of Syntegon Technology. At the same time, I would like to express my sincere gratitude to Dr Stefan Koenig. He has done Syntegon Technology a great service under his leadership, the company has not only become independent but also more profitable and more competitive." says Marc Strobel, Chairman of the Supervisory Board of Syntegon Technology.

"I am very much looking for-

ward to my new position at Syntegon Technology. Because of its high standards in quality as well as its long tradition, Syntegon Technology is an outstanding company in the packaging industry. Together with the Syntegon Technology team, I will particularly focus on further improving customer satisfaction and profitability," says Dr Michael Grosse. "In addition, we want to offer our customers even more innovative and sustainable packaging solutions in the future and make full use of the opportunities offered by digitalisation," he added.

Syntegon Technology is formerly the packaging division of the Bosch Group. Fields of application in the pharma industry are the production, processing, filling, inspection and packaging of liquid and solid pharmaceuticals (e.g. syringes and capsules).

# Pharma Authors Roundtable held in Mumbai

The event witnessed a gathering of like-minded experts sharing their unique ideas and held case studies discussions on project and portfolio management



### EMINENCE BUSINESS Me-

dia organised 'Pharma Authors Roundtable' on January 22nd, 2020 at Hotel JW Marriott, Mumbai inviting all the young writers & authors to present their ideas, success stories and case studies on how did they manage/handle a project successfully. This event was Eminence Business Media's initiative towards creating a platform for established and new authors to get their names featured as the co-author of an upcoming book on project management by John Robert, AVP Project Management, Sun

Robert also shared his thoughts on how to be a successful author and what does it take to get your book published

Pharma. The roundtable was led by Guneet Kaur Hayer, MD, Eminence Business Media. She set the expectations and rules for idea presentation and final paper submissions.

The event witnessed a gathering of like-minded experts sharing their unique ideas and success stories in the presence of Roberts, an author of three books on project and portfolio management.

Robert also shared his thoughts on how to be a successful author and what does it take to get your book published. He shared his ideas of his upcoming book and how to co-author it.

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# **ACG Inspection introduces groundbreaking** blockchain-based brand platform

Three-pronged solutions set combines Blockchain, geo-location identification and biometrics tracking through IIOT powered by AI for unsurpassed traceability and transparency.

ACG INSPECTION, one of the four businesses of ACG Group, has introduced an advanced blockchain-based solution that meets and exceeds traceability and anti-counterfeiting requirements in the pharmaceutical supply chain. The company's Brand Security Platform combines GS1 2D Data Matrix, smart contracts, geolocation identification and product biometrics tracking to ensure the whereabouts and contents of packaged medicines are tightly monitored through their entire supply chain journey from manufacturer to end-user.

The comprehensive new system provides a seamless, uncompromisingly transparent experience to all stakeholders along the supply chain, simplifying the overall process through distributed ledger technology and single ownership. It is designed to overcome several longstanding obstacles to advanced traceability, including the challenges of establishing single-owner data sets, and the prevalence of digitally broken supply chains stemming from, among other issues, struggles with GS1 universality, personnel error and new business models disrupting traditional procedures.

ACG Inspection's solution has three primary components, each of which can be incorporated individually or bundled per customer needs. The customizable products also are scalable, amounting to geolocation solutions that can provide everything from basic data management to full-scale, supply chain-wide transparency.

• Blockchain: With Distributed Ledger Technology (DLT) and smart contracts, all medi-



Romaco\_Siebler\_HM-1-350\_cmyk

cines and buyers, sellers, logistics partners and manufacturers are registered to one network, making it impossible for outsiders to manipulate the supply chain at any point without detection.

• Internet of Things (IoT): All participants in the delivery chain can be connected to the network using any GS1-compatible application, such as the ACG Inspection mobile application, the ACG Inspection web platform, or any other application integrated into the ACG Inspection platform. ACG Inspections Geo Location and product biometrics trackers tagged to the products always provide all the data required for monitoring the location information and biometrics of the package.

• Artificial Intelligence (AI): Participants can be alerted in real-time regarding any temperature breach if the temperature of the medicine/drug rises above or falls below the desired threshold level, Geo-Fencing breach, or any deviation in the route planning, enabling realtime decisions. If the steady stream of data determines unacceptable deviations, the corresponding package is automatically invalidated.

Combined, these elements lead to a supply chain setup with unsurpassed traceability and transparency. Upon obtaining a unique serial number, QR Code or datamatrix for each package, the manufacturer scans the codes to initiate the track & trace process. From that point forward, the system's trackers continuously monitor and transmit data concerning the package's temperature, humidity and location and any other parameter that is configured. Data is also analysed to ensure compliance with various domestic and/or international mandates.

Throughout, real-time data

is available to platform users via a dashboard, a unified space for clear and easy access to pertinent information. When the package eventually reaches the end-user, the receiving party can validate the drug prior to purchase by scanning its code with a POS scanner. Once the final transaction occurs, relevant data is immutably stored in a digital ledger for reporting or recall purposes.

The new solution is part of ACGI's VeriShield suite of services - which, in combination with its QualiShield portfolio, encompasses the full gamut of pharma serialisation needs through turnkey compliance with current and pending track & trace mandates in countries across the globe. VeriShield offers serialization and aggregation solutions for cartons and bottles at the primary, secondary, and tertiary packaging levels. QualiShield is a complimentary, extensive range of high-accuracy camera inspection solutions for pharma doses, labels, and cartons to help pharma companies consistently deliver best-possible products.

ACGI has an extensive portfolio for global Track & Trace requirements with complete coverage of Levels 1-5 serialization needs, from individual line implementation to enterprise IT coordination and government/third-party reporting capabilities. The company has a serialization solutions presence in more than 100 countries around the world; in the US, ACGI's Enterprise Management Suite is among the critical solutions deployed for compliance with the Drug Supply Chain Security Act (DSCSA).



# **Expert Report on automated climate** monitoring by Testo



### BOTH PHARMACEUTICAL

and medical technology products directly influence the health and well-being of patients and users. Efficacy, identity and purity are therefore the most important quality attributes applied to these products. In order to guarantee the required quality, the monitoring of the climate parameters of temperature (°C) and relative humidity (%RH) assume a key role in production and storage. There are also detailed requirements for this in directives and standards. In order to be able to meet the requirements of a wide range of measuring tasks, automated monitoring systems need to be implemented effectively at critical application areas in the pharma sector.

### **Objectives of climate** monitoring

The raw materials and substances involved, and also the end products, are very sensitive



to the wrong climatic conditions, such as temperature and humidity. However, it is not only the drugs per se, or their constituents, that are at risk when stored outside the permissible temperature range, their storage containers or packaging are also affected.

• Major fluctuations in temperature can cause hairline cracks in ampoules and glass contain-

- This can lead to contaminations and even loss of sterility.
- Too humid storage conditions can negatively influence the quality of drugs.
- Damp packaging or blurred and illegible labelling can also oc-
- Development of mould on and inside the boxes is also possible.

For these reasons, constant monitoring and documentation of the prevailing climate parameters in the relevant areas are indispensable and they are controlled by a really wide range of regulations and legal requirements. These for instance include -

- Specifications of the World Health Organization (WHO) regarding Good Storage Practice
- Requirements of the German Ordinance on the Manufacture of Medicinal Products and Active Pharmaceutical Ingredients (AMWHV),

- EU guidelines on Good Manufacturing Practice (GMP) and
- US requirements regarding Current Good Manufacturing Practice (cGMP) from 21 CFR

This means that sophisticated climate monitoring is an enormously important component of the whole product development and distribution process - starting in the research laboratory, via production and storage, through to the final transport of the goods. Cleanrooms are also very sensitive in this connection. Here, quality assurance also has to involve permanent monitoring and documentation of the differential pressure, airflow velocity and quantity of particles in the air, in addition to the temperature and relative humidity parameters. The exclusion of financial losses is another very important reason for permanent monitoring of the right environmental conditions. It is not possible to exclude all risks through

### **INFRASTRUCTURE**

monitoring, but they can be reduced to a manageable and safe level. Most importantly, in any pharma division regular internal and external audits are conducted, during which one can show the real-time data, as per compliance and the previous data can be retrieved from the system whenever required.

### Current measuring technologies

There are different ways to measure important climate parameters. Measuring values can be recorded using mechanical, analogue or digital methods. This process can be carried out manually or in a semi-automated or fully automated way. The technology which is used in each individual case very much depends on the sector and the directives in force. In some sectors, electronic measurement methods are prescribed by law, and rightly so for several reasons: Analog measuring instruments already have a high potential for errors, unacceptable ranges of fluctuation etc & thus cannot be used for extremely critical processes and areas of application - particularly as documentation which is carried out manually also has an enormous potential for errors and tampering.

With semi-automated methods, such as electronic handheld measuring instruments or data loggers, measurement is carried out digitally and automatically. However, manual steps are still necessary to analyse & document the data, which is again prone to human errors, high personnel expenditure, delayed reaction time & several other issues. Only automated systems can restrain such non-compliances. All the options described so far measure and document measurement data, but they do not monitor them. Automated climate monitoring systems regularly monitor the parameters, automatic transmit and document the measuring values & even provide alarms when there is a violation of limit values even at critical times of the day. The alarm notification itself can be provided either via acoustic or visual signals, but also by sending messages via Short Message Service (SMS) or emails. In addition, all the conditions that jeopardize the reliable operation of the system including for example connection problems, low battery statuses or an inadequate mobile phone network can be detected, reported and thus immediately rectified.

### Features of Automated Data Monitoring systems

Apart from the alarm indicators & monitoring of values these systems feature data transmission & report generation as their key highlights. Transmission of the measuring values from the measuring point to the database is possible both via radio and a wired connection. Many systems combine both these possibilities, which means the technology has a high level of flexibility and readiness for use. This process involving the automated transmission and analysis of measuring values prevents all errors which may occur due to the human factor in manual readouts and the interpretation of values. Furthermore, any tampering with the values is virtually ruled out. This is ensured by automatic documentation and reporting which is set up individually. This means that reports are generated from the raw data and

even directly dispatched, without there being any contribution from a user.

# Other Important aspects of data monitoring systems

Validation is required everywhere where documented proof must be provided that a process or system meets previously specified requirements in a reproducible way. For the pharmaceutical sector, this means that a measurement system is tested within the operational environment and together with all the influences that affect the system and must comply with all the prescribed directives and laws in the process, such as adherence to 21 CFR Part 11.

Another important aspect is data security and authorization access. This involves ensuring through detailed user management that employees and their authorizations can be individually configured. There is, therefore, a guarantee that individual system contents are only used by authorized employees.

Furthermore, control is crucial: systems must have the possibility of noting every move-

ment within a system and assigning it to an employee. This may, for example, involve login/logout, setting limit values or the acknowledgement of alarms. To achieve this, there are several methods such as the so-called audit trail, along with electronic signatures. Every action is unambiguously assigned to one person by these mechanisms.

### Testo Saveris – Solution that you need

A very large number of functions and methods have to be implemented in a system to enable all the requirements to be met. Thus, a system must offer both reliability and flexibility. Testo Saveris data monitoring system meets such needs in every aspect. It consists of a central base unit that communicates, through a combination of radio and wired network, to multiple probes installed at different areas of application. Multiple data storage, data integrity, continued operation along with a distinctive reporting system and indicative alarm features makes the Testo system a trustworthy component of the pharma sector.

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# **Designed for cleanliness,** engineered for performance

### **Prime Clean Reset-Air Tight Self-**Repairing

Clean room doors (Prime Clean Reset) are designed for inside applications requiring limitation of leak flow. The perfect sealing



properties of Prime Clean Reset provide environmental control and protect the inside environment against draughts, dust and dirt. Clean room doors provided by us also has self-repairing system. One of the most imperative aspects of clean rooms is the Door you choose for clean room facility. Time for which door is open will play a critical factor in avoiding dirt, temperature. humidity etc. Opening and closure of door has to quick enough to isolate the two areas. At Gandhi Automations, we provide Clean Room High Speed Doors specifically designed for above purpose. Our Clean Room High Speed Doors are best suited for pharma industries where you need to have controlled environment. The opening and closing of door are fast enough to separate two areas.

These high-performance clean room doors are designed and engineered for cleanliness. The tight seals and high speeds minimize air exchange between areas. Mechanical accessibility and the ability to clean are seamlessly integrated into the design. Collection points and conventional seams are minimized, and long life is ensured with corrosion-resistant and chemical-resistant materials.

### Common use-cases for these clean room doors:

• Medical Facilities, • Pharmaceutical Operations, • Food Storage, • Ensure compliance with CE and TUV Nord regulations and European standards

### **REDUCE AIR LOSS AND SAVE COSTS**

A Gandhi Automation's high-speed cleanroom door optimizes your cleanroom operation. Pressure levels are kept stable, air leakage is minimized and the exchange of contaminants and airborne particles is significantly limited.

The superior seal over the full

perimeter of the cleanroom door and its fast cycle, reduce the loss of conditioned air. Over the long run, this represents significant cost savings.

### **KEEP PRESSURE LEVELS STABLE**



High speed cleanroom doors are ideal to build airlocks. Their flexible PVC door curtain resists to pressure differences and keeps your cleanroom in under or overpressure.

Cleanroom doors have an aesthetical and slim design. They require little space and can easily be installed in tight places.

Prime Clean Reset is a high-speed flexible door in pvc for inside applications, with no rigid elements and with a perimeter structure made entirely of stainless steel.

Thanks to its special compact frame and to the special sliding system this roll up door has a low permeability to be suited for controlled environments, guarantees controlled loss of pressure and allows the ventilation systems and air purification to operate correctly.

The mechanical system of Prime Clean reset self-repairing doors is placed exclusively within the case of the upright and the crossbeam. This door ensures endurance and reduced air permeability, since the gear-motor unit and mechanical components are isolated within the upper crossbeam and side uprights.

Its patented sliding system guarantees safe operations: in case of an accidental collision, the curtain is released and reinserted after one cycle. The clean room doors of Gandhi Automations are perfectly adjusted to the requirements in controlled production zones. They guarantee the tightness of all accesses. The powerful high-speed doors have a smooth surface structure and no protruding edges. Therefore, they can be easily cleaned and depositing of particles is largely excluded.

Like all high-speed doors by Gandhi Automations, The Prime Clean Reset doors are enormously heavy-duty and require low maintenance thanks to their excellent quality. The most important argument for these doors is their air tightness which considerably contributes to saving costs in clean rooms, as well as their modular structure in a clinical design.

EXPRESS PHARMA 35

# Introducing **ADEIDT 101**











### 101 Stations - 3 Million Tablets per shift at 35 RPM

### **KEY FEATURES**

- Center drive without internal gear system
- 3 Chamber Bottom-Driven Rotary Feeder
- Multi-Chamber Gravity Feeder
- With Bi-Layer Capability
- Electronically controlled pressure monitoring system
- 21 CFR Compliant

Adept has been manufacturing Tablet Press since 1989. It is the inventor of Higher Station Turrets, R&D Turrets, 'A' Tooling and Multi-Chamber Feeder. Today there are over 500 Adept Tablet Presses in operation across 50 countries.







# Not all carbomers are equal

THE HEALTH business at Lubrizol Life Science partners with customers to speed their innovative medical devices and differentiated pharmaceutical products to market. Its dedicated team provides best-inclass polymers and excipients, along with state-of-the-art product design, development, and manufacturing services. with the ultimate goal of creating solutions that improve patient outcomes.

Carbopol, the first carbomer, was invented in 1958 and has been the market leader for more than 60 years. The Health business of Lubrizol Life Science (LLS Health) offers NF grade Carbopol polymers manufactured under cGMP conditions and are tested and certified to meet their respective monograph requirements according to USP-NF, EP and ChP. LLS Health meets these strict testing requirements in the monographs and general chapters to ensure that customers consistently receive quality products to keep patients safe around the world.

Compliance to the Pharmacopoeia requires conformance to standards from the relevant monograph, general chapters, general notices and manufacturing under GMP conditions. As a leader in this field, LLS

Health goes above and beyond monograph and general chapter requirements. It tests applicable residual solvents to aid drug product manufacturers in complying with USP general chapter <467> and also tests and reports all parameters required in the NF carbomer monographs.

Table 1 below summarizes characteristics of residuals and solvents in commercially available carbomers based on testing conducted by LLS Health.

### According to the specific **According to USP**

- The carbomer homopolymer. copolymer and interpolymer monographs are specific to carbomers manufactured without the use of benzene but require benzene to be tested and reported.
- The carbomer 934, 934P, 940, 941 and 1342 monographs apply to products produced with the use of ben-

### **NF Carbomer Monographs** General Chapter <467>

- Drug product manufacturers must identify and quantify any Class 1 solvents (e.g. 1,2 dichloroethane) likely to be present in their drug
- Residual solvents used in the production of an excipient will result in the presence of those residual solvents in a drug product.

### Table 1 Carbomer Homopolymers Type A, B, and C

	Carbopol® Pharmaceutical Grade Polymers*	Competitor A Product	Competitor B Products DCM Solvent
Solvents	Ethyl acetate (class 3) or a mix- ture of ethyl acetate and cyclo- hexane (class 2)	1,2 Dichloroethane (class 1)	Methylene Chloride (class 2)
Residuals	Low amount of solvent; Consistent, very low amount of residual monomer	Very high levels of residual solvent; not specified or reported	Unknown

Table 1 Carbomer Homopolymers Type A, B, and C

\*Carbomer Homopolymer Type A: Carbopol® 71G NF, 971P NF and 981 NF Polymers Carbomer Homopolymer Type B: Carbopol® 974P NF and 5984 EP Polymers

Carbomer Homopolymer Type C:  $Carbopol @980\,NF Polymers$ 

Table 2 summarizes the testing requirements for Carbomer Homopolymer Type A, B and C.

Testing required for Monograph Compliance - All polymers not manufactured using Benzene

LLS Health supports customers by providing data to aid in their formulation, validation and qualification processes. When selecting an appropriate polymer, companies should re-

view data like oral toxicity, stability, elemental impurities and more from their suppliers to ensure their finished drug product conforms to all regulatory standards. It is important to choose a partner with the expertise and knowledge to test and report on these data points.

### Table 2 Testing required for Monograph Compliance - All polymers not manufactured using Benzene

	Carbopol® Pharmaceutical Grade Polymers*	Competitor A Product	Competitor B Products DCM Solvent
Identification	Tested and Reported	Reported; test method not indicated	Reported
Assay - Carboxylic Acid Content	Tested and Reported	Reported; test method not indicated	Reported
Viscosity	Tested and Reported	Reported; test method not indicated	Reported
Loss on Drying	Tested and Reported	Reported; test method not indicated	Reported
Heavy Metals Content	Tested and Reported	Reported; test method not indicated	Reported
Residue on Ignition	Tested and Reported	Reported; test method not indicated	Reported
Limit of Ethyl Acetate and Cyclohexane	Individually Tested and Reported	Reported but not applicable	N/A
Limit of Benzene	Tested and Reported	Not Tested	Not Tested
Limit of Acrylic Acid	Tested and Reported	Reported; test method not indicated	Reported

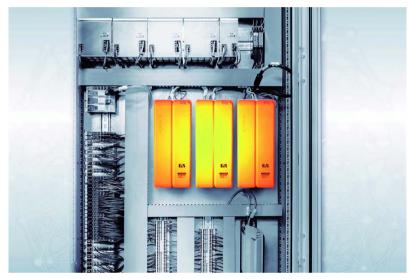
#### INFRASTRUCTURE

# **B&R's Blackout mode enables** high machine availability

THE B&R DRIVE technology portfolio now offers a Blackout mode that ensures safe machine control in the event of a network failure. Machine downtime can be avoided without costly redundancy solutions to ensure maximum machine availa network failure. Safety functionality remains intact.

#### **Controlled shutdown**

Blackout mode allows configuration of simple safety sequences. Applications in



ability. The Blackout function enables the safe variants of B&R servo drives (ACO-POSmulti, ACOPOSmotor or ACOPOS P3) to continue operation in the event of lower-level systems continue execution even after a network failure. For example, axes can be brought to a stop or moved to a defined position.

# B&R introduces new digital output module with pulse width modulation

**B&R'S NEW DIGITAL** output module X20DO4332-1 has integrated pulse width modulation and is a cost-effective alternative to motor modules. In addi-



tion, the module offers a dither function that prevents valves from sticking.

Pulse width modulation (PWM) is

mainly used for controlling larger loads, such as motors. Instead of using electronics to regulate a continuous input voltage down to the desired motor voltage, the motor is controlled by the width of the switching pulses. This process saves a considerable amount of

With its dither function, the module also prevents valves from sticking. This is particularly common when valves are held for extended times at a constant position, especially in liquids. The dither function oscillates the valve slightly around the position setpoint to prevent it from sticking. The X20module is equipped with four outputs with three-wire connections and offers a nominal output current of 2 A.

EXPRESS PHARMA 37

## Minimise Handling. Minimise Damage.



At Singhania Tableting, in addition to manufacturing precision tooling, we also offer products that help maximise tool life. The tool storage box provides a safe storing system for Punches & Dies while minimising tool handling.

#### **KEY ADVANTAGES**

- Made of polypropylene to prevent accidental tip damage. No metal to metal contact.
- Serial number on each pocket for easy identification
- · Special head support for easy punch removal
- · Minimum handling as the tray along with tooling can be used for transportation and ultrasonic cleaning
- · Inbuilt recessed handles for easy lifting











contact@singhaniatableting.com | www.singhaniatableting.com



# The many benefits of pycnogenol

Dr Frank Schoenlau, PhD, Director of Scientific Communication, Horphag Research writes about the results of the latest research done on the properties of Pycnogenol pine bark extract, applications of the research and its future prospects

#### **Venous Disorders**

Veins return blood from tissues back to the heart. Veins in the lower limbs transport blood passively, utilising any body movements, to propel venous blood upwards, alongside series of vein valves, to return blood to the heart. In hot weather and a sedentary lifestyle, vein vessels dilate, which adds additional pressure causing leg veins to dilate even further. Standard management consists of using compression stockings, which is effective, though not very pleasant to the patient, particularly in hot weather. Supplementation with Pycnogenol has been shown to significantly improve venous return, thereby relieving pressure and swelling in the limbs. Study authors conclude that Pycnogenol improves microcirculation, which leads to pressure relief and therefore releases edema [1].

Another study found that Pycnogenol helps prevent recurrent venous thromboses. This retrospective investigation evaluated different modalities for the management of post thrombotic thromboses.

The study concludes that Pycnogenol is - compared with two reference druds ticlopidine or sulodexide - the most effective and safe modality for prevention of recurring deep vein thromboses [2].

Pycnogenol has been shown to improve blood circulation during long sedentary periods, such as on long overseas air travels. In total 295 flight passengers participated in an investigation which was initiated to show that supplementation with Pycnogenol improves typical leg swellings during prolonged sedentary periods of eight hour

Furthermore, passengers

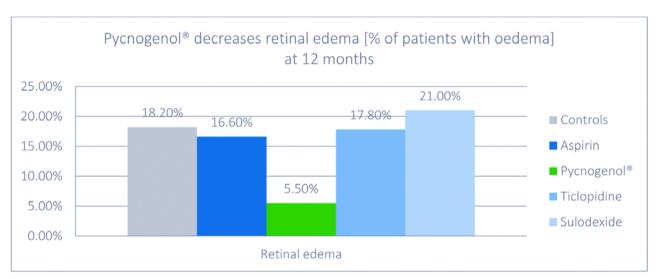


Fig. 1: Pycnogenol® controls edema in recurrent retinal vein thrombosis [6]

supplementing with Pycnogenol were protected from thrombotic incidents.

The study outcome showed that leg swellings were significantly less pronounced in travellers who supplemented with Pycnogenol prior to take off. The study authors conclude that supplementation with Pvcnogenol reduces leg swellings (edema) and provides protection from thrombotic events to travellers [3].

#### Joint Health

Pycnogenol has been shown repeatedly to improve joint health and improve mobility. Recent research suggests that applying Pycnogenol topically, such as by means of an adhesive patch relieves symptoms of osteoarthritis. A study with 67 participants verified the efficacy of Pycnogenol-bearing patches, in subjects suffering from osteoarthritis. Pycnogenol was added to a polycarbonate carrier, which is to be applied at the point where pain occurs. Study results confirm a faster improvement of joint pain. Furthermore, the ap-

The study concludes that Pycnogenol is, compared to two reference druds ticlopidine or sulodexide the most effective and safe modality for prevention of recurring deep vein thromboses

pliance of Pycnogenol patches helps to reduce pain medication

#### **Oral Health Care**

Oral hygiene in between periods of food consumption and snacking, or the next meal and the next opportunity to brush teeth again, may take long time in a busy day.

Pycnogenol was identified to arrest mouth bacteria, which decompose food particles in the mouth, thereby efficiently preventing the development of putrescent by-products, causing bad breath. A clinical investigation revealed that chewing

gums, fortified with Pycnogenol, proved to be remarkably effective for arresting growth of putrescent bacteria in the oral cavity within four weeks [5].

#### **Eye Health**

Pycnogenol is proposed to be one of very few active agents which are capable to reduce retinal vein thromboses

A clinical study evaluated incidences of retinal vein thromboses, with the aim to identify the most helpful agent. In comparison with Aspirin, ticlopidine and sulodexide Pycnogenol was identified to represent most effective active substance. Pyc-

nogenol proved to represent the sole active capable for reducing edema [6].

#### **Cognitive Function**

Pycnogenol is found to help improve cognitive decline already at the earliest time point of diagnosis. The diagnosis of cognitive decline is difficult though, because cognitive alterations typically progress very slowly and therefore often remain undiagnosed and hence untreated.

A clinical study with 87 subjects diagnosed with minimal cognitive function, participated in an investigation of cognition with Pycnogenol versus a control group, which had the same attention, yet void of Pycnogenol. Study participants who supplemented with Pycnogenol presented with improved cognitive function by 18 per cent, whereas the control group experienced a a small and insignificant improvement of cognition of 2.4 per cent [7].

A prestigious multi-centre, registered clinical study, is currently ongoing in Australia, which explores the virtues of

#### **INFRASTRUCTURE**

Pycnogenol for cognitive function improvement in depth of senior citizens. This study systematically explores all facets as involved in cognition, such as the influence of microbiota, faecal biomarkers, oxidative stress. gut microbiota composition. Furthermore, study subjects will be investigated over a time period of one year.

This study shall also provide insights to novel preventative therapeutic options and systematically explore in depth the cognitive function improvements related to Pycnogenol and the interactive affects with gut microbiota [8].

#### **Physiology**

Pycnogenol has been clinically shown to improve men's erectile function in several earlier studies, which applied complex formulae. Particularly the stimulation for greater nitric oxide release with Pycnogenol supports rigidity in clinical trials.

A most recent clinical trial demonstrates the merits of Pycnogenol for improving erectile quality in individuals who present with erectile challenges, related to diabetes mellitus. In a randomised, double blind controlled protocol a total 53 study participants, who presented with diabetes mellitus, were allocated to either the Pycnogenol supplemented group, or to the control group, which received placebo. Pycnogenol consumption significantly improved erectile function by 45 per cent in diabetics and 22 per cent in non-diabetics, monitored by applying the international index of erectile function (IIEF). The placebo group presented with a deterioration of erectile function of 12 per cent in non-diabetics and 20 per cent in diabetics[9].

Many patients depend on regular medication with anti-depressant medications, such as the commonly prescribed, serotonin re-uptake inhibitors. The side effects comprise a large number of very troublesome unwanted side effects to patients. Affected patients may suffer from diarrhoea, headache, dry mouth, sexual dysfunction and

A clinical investigation carried out at the University of

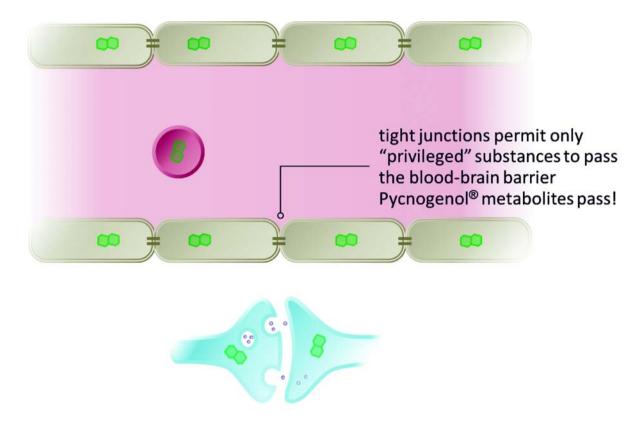


Fig 2: Pycnogenol® thus protects neurons from oxidative stress

#### Pycnogenol prevents oxidative stress and side effects in individuals presenting with hypothyroidism during levothyroxine (LT4) treatment

Bratislava, Slovakia, explored the possibility for reducing side effects attached to the serotonin-reuptake medications, by adding Pycnogenol French maritime pine bark extract as an adjunct daily supplement. The study, based on standardised psychiatric tests, revealed that additional supplementation of Pycnogenol to the serotonin-reuptake medications led to improvement of depressive symptoms and their severity including sexual dysfunction

The study authors conclude that Pycnogenol inflammatory and vasodilatory activities mediated the recorded effects [10].

Benign prostate hypertrophy represents a normal development in ageing males. However, the benign prostatic enlargement may be counteracted such as with regular supplementation with Pycnogenol, as shown in a study comprising 75 healthy men with benign prostate hypertrophy. Two comparable groups with benign prostate hypertrophy, were either provided standard attention, or a second group receiving the same attention, yet with additional supplementation with Pycnogenol.

Compared with the group of men which were not given Pycnogenol, the Pycnogenol benefitted group presented with a remarkable improvement to emptying their bladders after 60 days [11].

Pycnogenol prevents oxidative stress and side effects in individuals presenting with hyduring pothyroidism levothyroxine (LT4) treatment.

A study with 60 females, affected by primary hypothy-

roidism were investigated to verify whether supplementation with Pycnogenol is sufficient for controlling oxidative stress levels and in reducing the frequency and severity of side effects of levothyroxine.

The results found that occurrence of symptoms during the 30-day period with Pycnogenol supplementation was significantly lower than in the control group. Pycnogenol therefore may represent a useful tool in hormone replacement, in order to reduce LT4-related side effects in hormone replacement therapy for hypothyroidism [12].

#### **Bowel and Digestion**

A clinical study discovered that Pycnogenol may be beneficial to children presenting with Crohn's disease. Fourteen children diagnosed with Crohn's disease, were supplemented with Pycnogenol for ten weeks, another 15 healthy subjects represented the control group.

The study outcome finds that Pycnogenol supplementation reduces the dynamic forms of thromboxane, after ten weeks of supplementation with Pycnogenol, which is understood to positively influence clinical symptoms of Crohn's disease

Irritable bowel syndrome may be very bothersome, especially when symptoms persist for longer periods of time.

In a study with 77 participants, who suffer from irritable bowel syndrome, several products, which are commonly applied for soothing bowel aches and spasms were tested.

Pycnogenol administration was found to be more effective than the other products tested, including Buscopan and Antispasmina colica forte. The study authors conclude that Pycnogenol shows significant protective and preventative efficacy for a gentle approach for soothing an irritable bowel without side-effects [14].

#### Cardiovascular

Raynaud's syndrome is a medical condition in which arterial spams cause episodes of reduced blood flow to the extremities, predominantly the fingers, less commonly the toes and rarely the nose and ears. The inducers are predominantly stress and exposure to the cold. 67 women, aged 30 to 40 years of age, which were diagnosed

#### INFRASTRUCTURE

positive for primary mild Raynaud's disease, agreed to participate in a clinical investigation for the assessment of Pycnogenol ability to improve blood circulation. At the end of the study the group of women which were supplemented with Pycnogenol, presented with significantly increased fingertip skin flux, thus demonstrating a significantly improved tissue blood perfusion. Women who suffered from cold hands at trial start, experienced warmer hands in response to Pvcnogenol supplementation, as iudged from thermography measurements [15].

#### Inflammation

Sjögren syndrome represents an auto-immune disease, which most commonly affects glandular functions, such as disabling fluid secretion. Typically affected are the saliva glands, which leads to symptoms of a dry mouth. Pycnogenol exerts potent anti-inflammatory potency, which significantly contributes to dampen inflammation, which protects glands and helps maintain their secretary functionality.

A clinical study demonstrated the efficacy in 16 subjects, who supplemented with Pycnogenol, versus a comparative control group. The study authors conclude that supplementation Pycnogenol effectively helps control inflammation and reduce symptoms in Sjögren syndrome, such as mouth dryness and dry eyes

Pycnogenol is also shown to be helpful in the management of Behçet's syndrome.

Behçet's disease represents a rare disorder, which causes inflammation of blood vessels throughout the entire body.

Thirty-four subjects diagnosed with Behçet's syndrome were assigned to one of two groups, which both were treated, with one group additionally supplementing with Pycnogenol.

The group which supplemented additionally with Pycnogenol, further to the prescribed medication, appreciated a significant decrease of symptoms, such as burning pain. The study Researchers concluded A most recent study revealed that episodic primary migraine head ache benefits from supplementation with Pycnogenol for both treatment and prophylaxis. The study authors concluded that supplementation with Pycnogenol and applied as prophylaxis, reduces pain in migraine

that additional supplementation with Pycnogenol is useful for managing Behçet's Syndrome

A most recent study revealed that episodic primary migraine head ache benefits from supplementation with Pycnogenol for both treatment and prophylaxis.

Participating subjects, suffering from migraine, were supplemented with Pycnogenol in addition to further supplements, which comprised magnesium, Vitamin B2, lipoic acid, over a total observational period of eight weeks. The study authors concluded that supplementation with Pycnogenol and applied as prophylaxis, reduces pain in migraine [21].

#### **Future prospects**

As the clinical studies above have shown, French maritime pine bark extract Pycnogenol can be used in a very wide variety of ways, to support the health of everybody.

Clinical research at Horphag is an ongoing progress, which continuously leads to new discoveries. Therefore Pycnogenol French maritime pine bark extract is being continuously further researched for the identification of novel health contributions and new applications.

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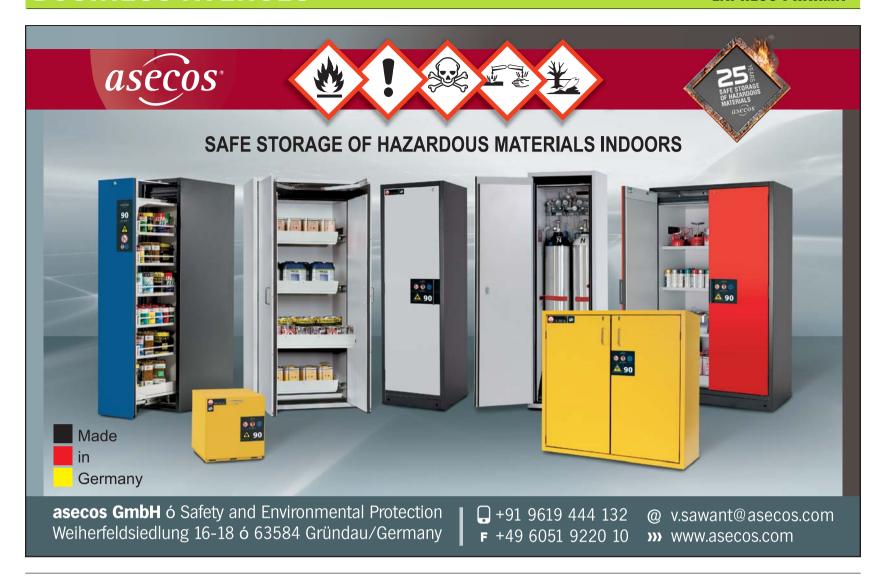
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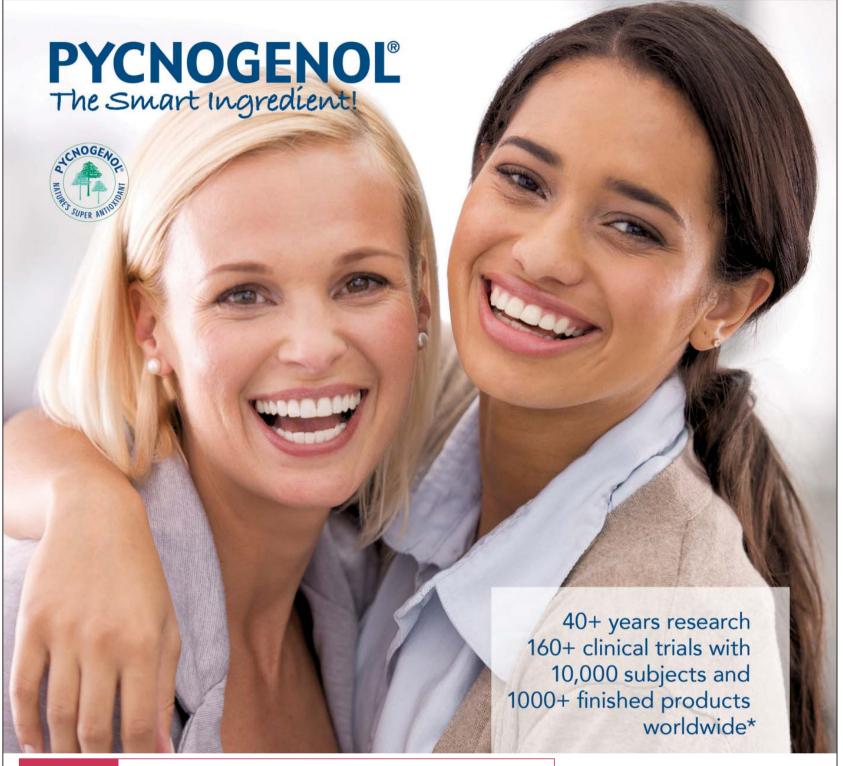
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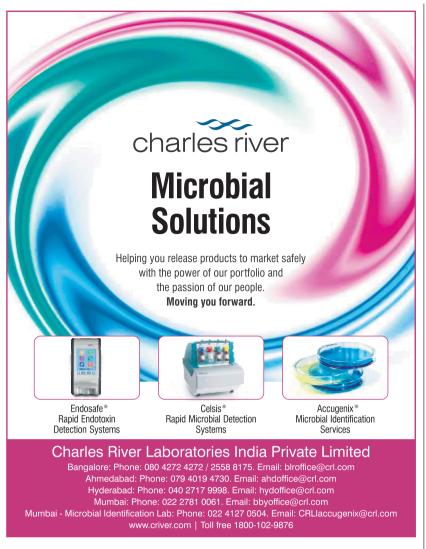
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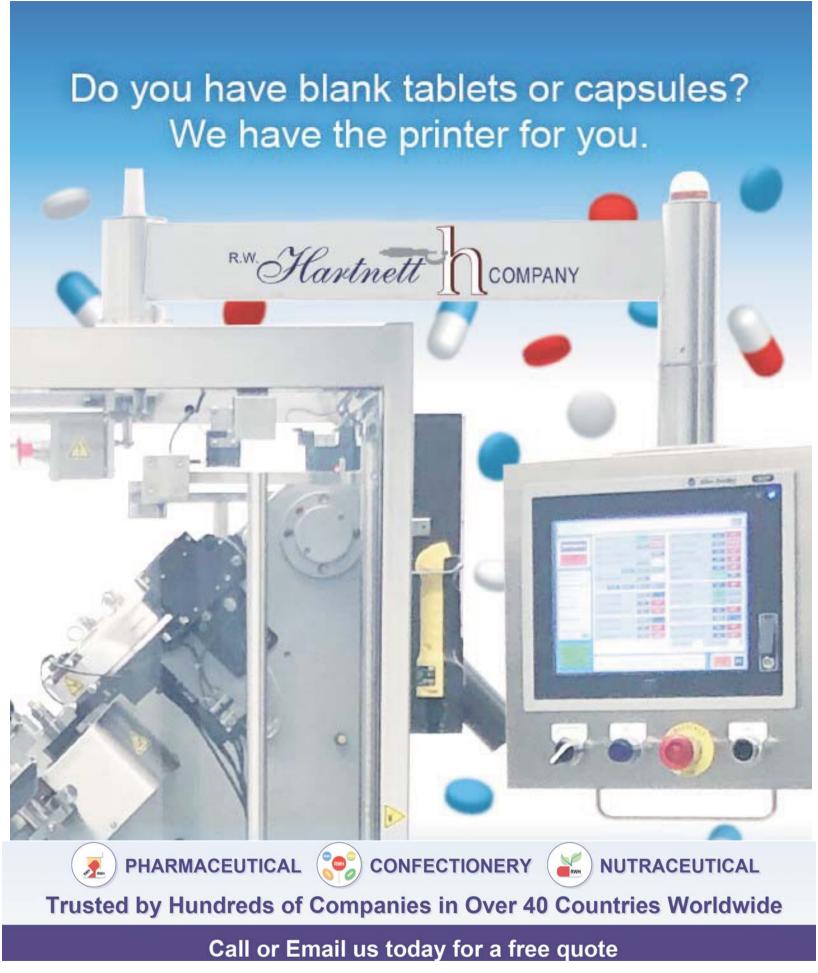
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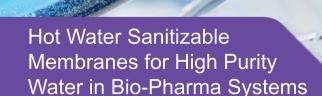
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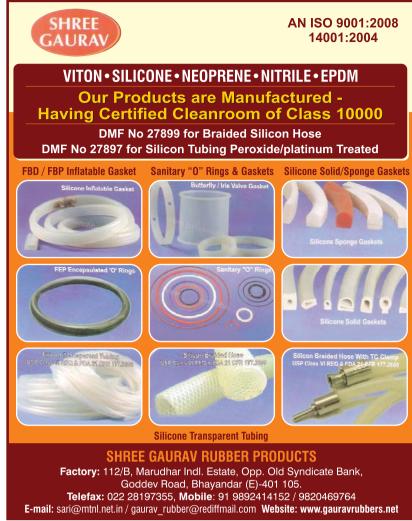
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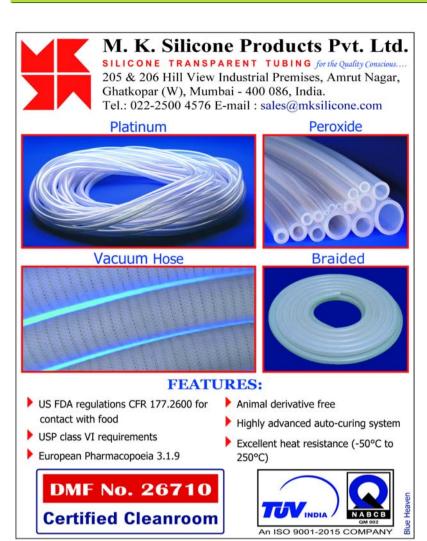
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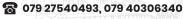














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