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Government has 69 taken cognizance and has passed the Bulk Drug and Medical Devices policy focusing on domestic manufacturing of APIs/KSMs.

Sudarshan Jain

Secretary General, Indian Pharmaceutical Alliance (IPA); Senior Advisor, APAX Partners, India; Visiting Faculty, IIM, Ah'bad

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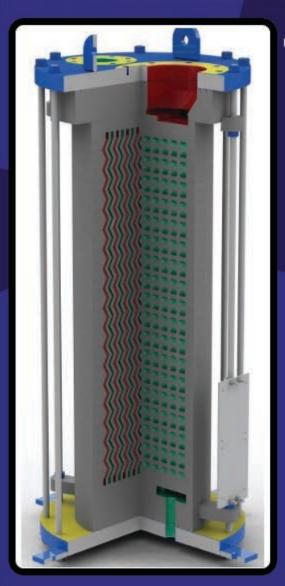


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R. S. Raveendhren

Advocate, High Court of Madras & Legal Expert in the Institutional Ethics Committee of SRM Medical College Hospital & Research Centre.



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Comparision Table of CAPEX, OPEX of MREPL MES v/s conventional MEE, Capacity : 10 KPLD

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1.	Operational Cost/KLPD	Rs. 1000/KLPD	Rs. 100/KLPD	Rs. 80/KLPD	Rs. 500/KLPD
2.	Saving on OPEX	Nil	Rs. 900/KLPD	Rs. 920/KLPD	Rs. 500/KLPD
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4.	Plot Size	3 m²/KLPD	10 m²/KLPD	6 m²/KLPD	6 m²/KLPD



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FDC Limited launches two variants of favipiravir Drug for Covid-19

Home-grown pharma major, FDC Limited, today announced its foray in the fight against COVID-19 by launching two variants of the COVID-19 drug, Favipiravir – PiFLU and Favenza – which will be used to treat mild to moderate cases of COVID-19 in India. With the third largest number of cases globally, at close to three million, and a daily increase rate that is on the rise, the Indian economy and populace have both seen major hits over the past two quarters.

Earlier this year, the Drug Controller General of India (DCGI) approved the use of Favipiravir, an off patent, oral anti-viral drug that has been shown to quicken clinical recovery in COVID-19 patients with mild to moderate symptoms. It is a broad spectrum anti-viral agent, and selectively inhibits RNA polymerase of influenza and SARCOV-2 virus

10 polymerase of influenza and S and prevents viral replication.

> Commenting on the development, Spokesperson of FDC Limited, Mr. Mayank Tikkha said, "With over 2.7 million cases of COVID-19, now is the time to provide healthcare warriors in our country with viable affordable options to fight the battle against this disease. Early diagnosis and treatment will help in arresting the deteriorating condition of patients, and we will be working with the government and healthcare fraternity to make Favenza and Piflu available across the country".

FDC's PiFLU and Favenza is currently available across the country.

FDC has also increased the production and availability of its brand of balanced electrolyte drink 'Enerzal and Electral as according to ASPEN guidelines, 03 litres of fluid intake in a day (60 to 120 ml in every 30 min) helps in speedy recovery of people who are home quarantined.

Bristol Myers Squibb Provides Update on Phase 3 Trial in Patients with Relapsed or Refractory Acute Myeloid Leukemia

Bristol Myers Squibb announced that the Phase 3 IDHENTIFY study evaluating IDHIFA® (enasidenib) plus best supportive care (BSC) versus conventional care regimens, which include best supportive care (BSC) only, azacitidine plus BSC, low-dose cytarabine plus BSC or intermediate-dose cytarabine plus BSC, did not meet the primary endpoint of overall survival (OS) in patients with relapsed or refractory acute myeloid leukemia (R/R AML) with an isocitrate dehydrogenase-2 (IDH2) mutation. The safety profile of IDHIFA was consistent with previously reported findings. The company will complete a full evaluation of the IDHENTIFY data and work with investigators to present detailed results at a future medical meeting.

"While we are disappointed by the outcome of the IDHENTIFY study, we remain confident in IDHIFA's established role as a treatment option for patients with relapsed or refractory AML with an IDH2 mutation and are grateful to all those who participated in the study," said Noah Berkowitz, M.D., Ph.D., senior vice president, Global Clinical Development, Hematology, Bristol Myers Squibb. "AML is one of the most difficult-to-treat blood cancers, and we're committed to furthering our research and improving on the standards of care for patients living with this aggressive disease."

In August 2017, Bristol Myers Squibb received full approval in the U.S. for IDHIFA for the treatment of adult patients with R/R AML with an IDH2 mutation as detected by a U.S. Food and Drug Administration (FDA)-approved test. IDHIFA is the first and only FDA-approved therapy for patients with R/R AML and positive for an IDH2 mutation, which represents up to 19 percent of AML patients. IDHIFA is also approved in Australia and Canada.



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Asalyxa Bio Launches with Novel Neutrophil-Targeting Drug Delivery Platform Technology and Lead Candidate, ASX-100, for ARDS and COVID-19 Patients

Capricor Therapeutics, a clinical-stage biotechnology company focused on the development of first-in-class cell and exosome-based therapeutics for the treatment and prevention of diseases, announced today that the U.S. Food and Drug Administration (FDA) has accepted its investigational new drug (IND) application for a Phase 2 clinical trial of CAP-1002 in patients with COVID-19. The study will enroll patients who have a confirmed diagnosis of SARS-CoV-2 and require supplemental oxygen. Enrollment is expected to commence shortly.

The INSPIRE trial is a randomized, doubleblind, placebo-controlled study that will enroll up to 60 patients from multiple, geographically diverse trial sites across the United States. Patient participation will be a maximum of 13 weeks from screening.

"We greatly appreciate the continued support and encouragement by the FDA as we advance our CAP-1002 program for treatment of COVID-19," said Linda Marbán, Ph.D., Capricor's president and chief executive officer. "Based on the data from the initial emergency use individual patient compassionate care cases, we see continued momentum and support for CAP-1002 for the treatment of COVID-19. It is important to remember that many patients are suffering from long term cardiac consequences from COVID-19. As CAP-1002 directly targets cardiac dysfunction, CAP-1002 potentially may also be an important tool in the treatment of the cardiac complications of COVID-19, which represents a patient population with an unmet medical need."

The promise of CAP-1002 in COVID-19 is its immunomodulatory properties, which have been demonstrated in multiple clinical trials as well as in critically ill COVID-19 patients. Multiple published peer-reviewed studies of CDCs have demonstrated favorable modulation of various inflammatory cytokines and regulation of the immune response. The current understanding of COVID-19's later stages are thought to be due to overstimulation of the immune system, which triggers a cytokine storm in which the body is overwhelmed with pro-inflammatory molecules. This immune response may become excessive and pathologic, inducing ARDS, multi-system organ failure and death.

HMD Scaling up Production to 1 Billion Auto Disable Immunization Syringes to help in Covid-19 Vaccination

Hindustan Syringes & Medical Devices Ltd (HMD), one of the largest manufacturers of Disposable Syringes in the World and the largest for Auto Disable syringes with annual capacity of around 700 million autodisable syringes for vaccination is scaling up production to a billion in the first half of 2021 as India gets ready for COVID-19 Vaccine.

"We have received orders from UNICEF to increase our supply of immunization AD syringes to the organisation to around 300 million to build up a stockpile of around 140 million syringes for Covid-19 by the end of the year" said Mr. Rajiv Nath, Managing Director of Hindustan Syringes & Medical Devices Ltd.

"We are waiting on the Indian government to start creating a stockpile of syringes as being done by other Countries. Should the government need 100 million auto-disable syringes for Covid-19 vaccines by the end of



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this year, we can easily offer them to lift the outstanding orders placed with us. We have nearly 50 million in stock that the government has not timely lifted as standard immunisation injection campaigns had been suspended at onset of Covid. Though the campaigns have been restarted recently, the pace is still slow," added Mr. Rajiv Nath.

As the race for a 'safe and effective' vaccine against coronavirus infection is on the horizon, Pune based drug-maker Serum Institute of India is all set to start the advance clinical trial of University of Oxford vaccine while continuing to work alongside on 4 more vaccines candidates. In addition, Covaxin, India's first coronavirus vaccine has been developed by Bharat Biotech, Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV). The clinical trial to verify the safety of the potential COVID-19 vaccine started about two weeks back. If successful, it may be available by end of the year. Zydus is the 3rd of the 7 vaccine Manufacturers in the running.

The outbreak of COVID-19 has taught the importance of infection prevention practices like hand-hygiene to all. The focus has shifted to single use disposable consumables from reuse consumables and especially a change has been seen in higher deployment of autodisable syringes even for curative injections. WHO and. UNICEF also recommend that auto-disable syringes be used for administering vaccines— particularly in mass immunization programs. Moreover, WHO has suggested the use of auto-disable syringes to collect blood samples of Covid 19 patients, which in turn, helps to avoid the transmission of disease through healthcare equipment.

Mr. Rajiv Nath also raised concerns of the poor status of PPE, Masks & Ventilator manufacturers who are saddled with surplus inventory & excess capacities after the supply chain mismatch crisis got over in June 2020. With over 9 plants, HMD has created a niche for their disposable syringe —DISPOVAN which is today the most popular brand in syringe market in India with over 60% market share with Dispovan Needle and Disposable Insulin Syringes having over 70% Market Share and thereby displaced renowned MNC's – an inspirational case study for other Indian entrepreneurs.HMD is one of the largest suppliers to UNICEF for Auto Disable Syringes for immunization and is the first Company in India to manufacture Auto Disable Syringes for Curative Segment.

INTAS Develops COVID-19 Hyperimmune Globulin - A New Treatment

Intas Pharmaceuticals Ltd is a leading Pharmaceutical company from India. As per IQVIA (IMS), Intas is the 9th largest company in India having a strong presence in chronic therapeutic segments. Intas also has expertise in blood plasma products through its wide range of Albumin, Immunoglobulins and Coagulation Factors used in the treatment of various lifesaving conditions. It has been the first to launch 4 plasma products in the country.

The R&D team at Intas has developed COVID-19 specific Hyperimmune Globulin as treatment for patients suffering from moderate to severe COVID-19 infection. Hyperimmune Globulin also has potential for use as prophylaxis for all high-risk population in contact with COVID-19 patients. This could be an important therapeutic option that can potentially help combat the disease until a vaccine is available. Intas is among the world's first to adopt this approach for treating COVID-19 patients. This will be a Corporate Social Responsibility (CSR) initiative from

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Intas in collaboration with all Indian Blood Banks that will help to procure convalescent plasma (plasma extracted from patients recovered from COVID-19 infection).

Intas has received permission from the Drug Controller General of India (DCGI), to conduct clinical trial by using the newly developed COVID-19 specific Hyperimmune Globulin. After establishing its usefulness in the clinical trial, this product will be available for use in treating COVID-19 patients. Commenting on the development, Dr Alok Chaturvedi, Head of Medical & Regulatory Affairs, at Intas, mentioned that "This endeavour is a testament to Intas' commitment towards meeting unmet medical need of the society through research driven solutions."

Dr. Suma Ray, Vice President & Head of Plasma Operations at Intas mentioned that Hyperimmune Globulin will provide purified and enriched preparation of COVID-19 specific neutralizing antibodies in high concentration, free from blood transmitted viruses and other plasma proteins. Hyperimmune Globulin will also enable consistent, precise dosing and predictable response early in the treatment of COVID-19 infections. Being a specific antibody treatment manufactured specially, it does not require blood group matching or donor selection while administering to the patient besides having huge benefits in terms of assured antibody administration. Unlike Plasma therapy, Hyperimmune Globulin can be readily administered to the patients anywhere even in the remotest part of the country.

Intas is establishing an alliance with medical and research institutions, blood donation groups to collect the plasma from recovered COVID-19 patients. Intas will shortly launch a website to help recovered COVID-19 patients to locate the nearest Blood Bank where they can safely donate plasma. The company seeks government support to facilitate the supply of convalescent plasma for the manufacturing of these enriched Hyperimmune Globulin and thereby help more patients conquer COVID-19.

AnteoTech creates high-sensitivity 15-minute COVID-19 antigen test to support rapid clinical decision making

AnteoTech Ltd has successfully developed proof-of-concept COVID-19 antigen and Flu A&B point-of-care lateral flow tests that can detect the presence of SARS-Cov-2 and influenza in less than 15 minutes. The tests utilize AnteoTech's patented AnteoBind™ activated europium technology and provide significantly higher sensitivity than that offered by currently available COVID-19 tests. AnteoTech intends for the tests to be combined into a single multiplex test platform and be available in as little as 6-9 months following clinical trials and regulatory approvals. AnteoTech is currently looking to build strategic partnerships with medical device manufacturers to expedite commercialization. Once deployed, the portable test could significantly reduce COVID-19 spread by enabling detection and guarantine of infected individuals before symptoms develop. AnteoTech is a Brisbanebased company that specializes in leveraging next-generation surface management technology to address challenges in a range of markets, including point-of-care diagnostics.

With COVID-19 causing unprecedented economic and social devastation worldwide, governments and health services continue to seek effective ways to mitigate its spread. Mobilization of rapid and accurate testing is a crucial part of a comprehensive disease containment strategy, allowing for swift identification of active cases and, as a result, early quarantine. However, analysis of standard swab tests currently requires costly equipment, highly trained staff and must generally be performed in large hospitals or pathology laboratories. Further, testing in this way may take several hours to generate results, undermining prompt clinical responses.

To overcome this, AnteoTech's new platform will make use of a patented AnteoBind assay surface that, with the use of a portable Axxin lateral flow reader, will allow for rapid, reproducible, and high-sensitivity results without the need for highly trained personnel and complex testing infrastructure.

"The development of this new platform marks a critical step in our collective journey to halt the spread of COVID-19," said Derek Thomson, CEO of AnteoTech. "By leveraging many years of expert insight in the form of our AnteoBind europium nanoparticle technology and applying it to this unique challenge, we're enabling detection of the lower viral particle levels seen in earlier stages of COVID-19 infection — levels which aren't detectable with current gold-based diagnostics. As a result, we're opening the possibility for better clinical decision-making and earlier direction of patients into quarantine to curtail disease spread."

AnteoTech's COVID-19 development program was initiated in late March 2020 and is supported by more than 10 years of rich expertise in the creation of cutting-edge bioconjugation and coating solutions. Over the coming months, the COVID-19 antigen dual testing platform will enter the next stage of development to optimize function, further improve the lower limit of viral particle detection and conduct clinical studies for targeted populations and settings. AnteoTech is currently preparing for outsourced scaled manufacturing to ensure it can meet growing market demand.

J&J to Acquire Momenta Pharmaceuticals for \$6.5 billion

Johnson & Johnson (J&J) announced that it has entered into a definitive agreement to acquire Momenta Pharmaceuticals, a biotechnology company based in Cambridge, MA, for \$6.5 billion. According to a J&J press release, the deal is expected to close during the second half of 2020. Until then, Momenta will operate as a separate and independent company.

"The agreement with J&J recognizes the value created by years of commitment and dedication to our mission by the many current and past Momenta employees. Programs such as nipocalimab have the potential to improve the lives of countless patients suffering from autoimmune and fetal maternal diseases," said Craig Wheeler, president and CEO of Momenta, in the press release.

AstraZeneca Initiates Phase I Trial of Monoclonal Antibody Combination for COVID-19

AstraZeneca has dosed the first participants in its Phase I clinical trial assessing the safety, tolerability, and pharmacokinetics of a combination of two monoclonal antibodies (mAbs) for the prevention and treatment of COVID-19. AZD7442 is a combination of two mAbs that have been derived from patients with SARS-CoV-2 infection. The trial is expected to include up to 48 healthy participants in the United Kingdom, who will be aged between 18 and 55 years.

"This trial is an important milestone in the development of our monoclonal antibody combination to prevent or treat COVID-19," said Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca. "This

NEWS

combination of antibodies, coupled to our proprietary half-life extension technology, has the potential to improve both the effectiveness and durability of use in addition to reducing the likelihood of viral resistance."

DWK Life Sciences to Acquire Müller + Müller

DWK Life Sciences announced that it has acquired Müller + Müller, a German manufacturer of primary packaging materials made of tubular glass for the pharmaceutical industry. Under the terms of the acquisition, Müller + Müller will become part of DWK upon closing in September 2020, a DWK press release said. Müller + Müller will continue to function under the same name and will be managed by its current CEO, Florian Müller-Stauch. "Acquiring the family business Müller + Müller is a significant strategic step for us in expanding our activities in the market for pharmaceuticals packaging," explained CEO of DWK Life Sciences, Armin Reiche. "We are not just investing in an important growth market here, but also in a company that boasts first class production technology and highly reliable products."

Dinesh Chauhan stepping up as Chief Executive Officer of CORE Diagnostics

Gurgaon based CORE Diagnostics has announced that Dinesh Chauhan, the current Chief Operating Officer of the company, will be stepping up as the Chief Executive Officer starting September 1st, 2020. He will also join the board of directors of the company. Dinesh is a founding member of the company and joined CORE in 2013. He has over 30+ years of experience in the diagnostics industry.

Dinesh expressed his thoughts at the announcement. "I am humbled at the



Dinesh Chauhan, Chief Executive Officer CORE Diagnostics

confidence that the board has put in me. I have seen the organization grow from a small start-up to a 400+ strong team. Taking over from a Founder-CEO is never easy but I am looking forward to all the opportunities and challenges this next phase will bring. This is an incredibly exciting time for our industry in general and for CORE in specific. The role we will play in the next few years in healthcare will be key to determining where healthcare will go in the future. Diagnostics and the underlying data that we generate and analyze has a tremendous impact on healthcare outcomes. This has only become more evident during the current pandemic."

Zoya Brar, the current CEO and the Founder of the company is moving on and will also resign from the board. She will continue to support the company as an advisor to the board and the CEO.

Yokogawa Signs Investment and Partnership Agreement with Swiss Startup Bloom Biorenewables

Yokogawa Electric Corporation has signed an investment and partnership agreement with Bloom Biorenewables SA (Bloom), a Swiss

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startup company focusing on the utilization of biomass, with the aim of developing business opportunities in the bioeconomy field. The two companies will collaborate on the commercialization of a breakthrough technology from Bloom that maximizes the extraction of lignin* from plant material to replace petrochemicals in a range of chemical products.

Yokogawa and Bloom are both undertaking initiatives to promote the bioeconomy, which involves the utilization of biomass and biotechnology to solve global issues such as the depletion of natural resources and climate change and enable long-term, sustainable growth. The agreement brings together Bloom's lignin extraction technology with Yokogawa's advanced technologies and knowhow related to the automation of industrial production processes, as well as its global sales network.

Bloom was established in January 2019 as a spinoff from EPFL, the Swiss Federal Institute of Technology in Lausanne. With the mission of making biomass a true alternative to petroleum, the startup is initially focusing on commercializing it's new, far more efficient method of extracting lignin, especially monolignol, from biomass material such as wood. Its immediate goal is to demonstrate the technology in a pilot-scale plant.

Bloom's CEO, Dr. Remy Buser, commented, "This new collaboration will help strengthen interactions with large industrial groups, drive internationalization, and ultimately accelerate market entry, which are all essential factors for countering climate change and having a significant impact."

Tsuyoshi Abe, a Yokogawa Senior Vice President, and Head of the Marketing Headquarters, added, "Yokogawa aims to contribute to the UN's Sustainable Development Goals through its core business activities, and the bioeconomy is a focus area in our long-term business framework. Lignin has huge long-term potential as a petroleum replacement, and we have high expectations that together we can contribute to the increased utilization of biomass by integrating Bloom's outstanding technology and Yokogawa's decades of experience in industry."

Cadila Pharmaceuticals Launches Biosimilar Rituximab

Ahmedabad-based Cadila Pharmaceuticals has launched Ritucad, its biosimilar product referencing Roche's blockbuster MabThera/ Rituxan (rituximab) originator biologic, for the Indian market, Cadila announced in a July 29, 2020 press release. Ritucad is used for treating blood cancer, including Non-Hodgkin's lymphoma, and rheumatoid arthritis. Roche's MabThera/Rituxan had nearly CHF 5 billion (US \$5 billion) in 2019 sales (1).

Ritucad will be made available in a singledose vial of two strengths, 100 mg and 500 mg. Ritucad marks the second biosimilar in a series of biosimilar products planned by Cadila in 2020. The company also recently launched Bevaro, a biosimilar referencing Roche's top-selling Avastin (bevacizumab), a cancer-treating biologic that had CHF \$7 billion (US \$7.6 billion) in 2019 sales (1).

Henlius and Accord Healthcare Receive European Approval for Biosimilar Trastuzumab

Shanghai Henlius Biotech (Henlius) and partner Accord Healthcare have received approval from the European Commission for

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Zercepac (HLX02), a biosimilar referencing Roche's originator biologic, Herceptin (trastuzumab), that was developed and manufactured by Henlius. The approval covers the treatment of HER2-positive early breast cancer, HER2-positive metastatic breast cancer, and HER2-positive metastatic gastric cancer, the companies announced in a July 29, 2020 press release. Roche's Herceptin is one of the company's blockbuster drugs, reaching over CHF 6 billion (US\$6.5 billion) in 2019 sales (1).

Henlius stated in its press release that Zercepac (HLX02) is the first monoclonal antibody (mAb) biosimilar developed in China that has successfully entered the market in the European Union (EU). The development and manufacturing process of Zercepac (HLX02) is in line with international standards, the company stated in the press release. The company's manufacturing facility in Xuhui, China, and quality management system have been certified by the EU as being good manufacturing practices (GMP) compliant.

Samsung Biologics Expands Manufacturing Facilities and Launches Cell Line Technology

Samsung Biologics has announced facility expansions and a new cell line technology in several recent moves that boost its manufacturing capacity and cell culture services. In one move, the company is preparing to break ground before the end 2020 for its fourth biologics manufacturing plant, and in another move, it is expanding an aseptic fill/finish line in its drug product manufacturing facility. Both facilities are located in Incheon, South Korea. Meanwhile, the company has also launched a new Chinese hamster ovary (CHO) cell line technology that it says improves titers. The construction of the fourth manufacturing plant (Plant 4) in Incheon is part of Samsung Biologics' long-term strategy to maximize operational efficiency and scale up its development and manufacturing capabilities as demand for bio-manufacturing grows, the company stated in an Aug. 11, 2020 press release.

Glenmark appoints Dipankar Bhattacharjee to its Board of Directors

Glenmark Pharmaceuticals, a research-led, integrated global pharmaceutical company, announced the appointment of Mr. Dipankar Bhattacharjee as Independent Non-Executive Director on the Board of the organization for a period of five years with effect from 14th August, 2020.

Mr. Bhattacharjee comes with over 30 years of global experience in leading Generics, Specialty and OTC Pharma, Medical Devices, and FMCG businesses. He has led high performing teams to develop and execute business strategies across all stages of business cycles, driving growth and value through commercial innovation and focused R&D investments.

In his previous role, Mr. Bhattacharjee held various senior leadership positions at Teva Pharmaceutical Industries, including President & CEO - Global Generics Medicines, Officer and Member Teva Executive Committee (TEC), and Co-chair in JVs with P&G and Takeda Pharmaceuticals. With strong orientation towards stakeholders including investors, customers and consumers, and deep understanding of payers and regulators, he has consistently delivered short term and long term results across multiple geographies and business environments.

SCHOTT AG delivers pharma vials to package 2 billion doses of COVID-19 vaccines; Indian JV SCHOTT KAISHA leads the supply of vials from India

German glass manufacturing giant SCHOTT AG is supporting the world's fight against COVID-19 with vials capable of holding up to 2 billion vaccination doses. The pharma glass and packaging specialist has reached agreements with leading pharmaceutical companies, including key players in India. The global agreements became effective last month and first vials are already being delivered to companies in Asia, North America and Europe.

In India, SCHOTT's 50-50 joint venture, SCHOTT KAISHA is supplying vials for COVID-19 vaccines to Serum Institute (India) and several other players. The joint venture operates four manufacturing facilities in the country located in Jambusar and Umarsadi in Gujarat, Daman, and Baddi in Himachal Pradesh. In addition, the company produces the pharmaceutical glass tubing for the packaging itself at its global sites including one in Jambusar in Gujarat.

"SCHOTT KAISHA has been known to scale up extremely fast in order to meet customer demands over the past decade, which is also evident from its two new facilities in Umarsadi and Baddi. Thanks to our strong supply chain and support from SCHOTT's global sites, we are in a very strong position to meet our customer's current and anticipated requirements. We are confident that we can quickly expand our production capabilities further, in case demand arises", shared Rishad Dadachanji, Director, SCHOTT KAISHA.

The specialty glass pioneer is ideally positioned to meet the challenging demand situation since it had started an investment program into its pharma business of 1 billion USD in 2019 already. In India, this includes a three-digit million-euro number for new Borosilicate glass melting tanks, and for its packaging operations an entirely new production site as well as new modules and lines.

All of SCHOTT's 20 production sites for pharma glass and packaging are validated by regulatory bodies and pharma companies. This means that additional capacities can be used immediately without further regulatory efforts. Even before the expansions, SCHOTT already produced more than 11 billion pharma containers globally for life-saving drugs per annum, of which a nine-digit figure is manufactured locally in India.

More importantly, all major pharma companies and many other players in the market have been processing the company's vials on their fill and finish lines for many years. "Hence, no time consuming adaptations of fill and finish equipment will slow down vaccine distribution. As time is a luxury the industry doesn't have at the moment, it is common sense to rely on tried-and-true packaging solutions," Dadachanji said.

Cadila Pharma launches osteoporosis biosimilar in India



Ahmedabad-based Cadila Pharmaceuticals Limited has announced the launch of NuPTH an Osteoporosis biosimilar of Forteo in India. The Forteo biosimilar is used for the treatment of osteoporosis and in patients with increased risk of fracture.

India is the Osteoporosis capital of the world. It is a very common problem. As per a study in 2003 the number of osteoporosis patients in India were approximately 26 million. It is estimated that by 2050, half of the world's fractures will occur in Asia.

"Difficulty in use and early drop-outs is often cited as a common reason for noncompliance of osteoporosis medication. The medication is primarily used by people of 50 years and above. We realized that if the delivery system is complex, people stop using it. The ease of use of delivery device is as important as the development of new drugs. The biosimilar NuPTH aims to be a costeffective solution for patients and will be sold as an easy to use, pre-filled disposable pen," shared Amit Ajmera, Vice President, Cadila Pharmaceuticals Limited.

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NuPTH is the third biosimilar announced by the organization in the past one month. The pharma giant has recently launched Rituximab and Bevasizumab biosimilars, recommended in multiple indications under the brand names Ritucad[™] and Bevaro[™] respectively.

Verizon Business to create nextgeneration global network infrastructure for Bayer

Verizon Business has been chosen by Bayer to build a next-generation global network infrastructure to underpin the company's global business operations. Verizon Business will enhance Bayer's existing network capabilities to enable easier and cost-effective network management, and will also deploy next-generation network technologies, including software-defined networking, to further improve resilience, flexibility and scalability. Historically, Bayer's in-house team looked after its global IT real estate, supported by a variety of different technology companies, including Verizon. As Bayer continues to move to a cloud-first, digital business model, the company decided to outsource management of the majority of its global network environment to a single service provider. The objective was to free up its own resources to focus on supporting its core crop science, pharmaceutical and consumer health business activities, while also further developing a secure, stable but flexible network platform to improve connectivity and collaboration around the globe, and support ongoing digital business transformation.

Verizon Business will deliver managed network services to over 700 sites in 91 countries around the world. This includes a managed global Private IP network, a managed software-defined Wide Area Network, and Professional Services support and governance. Verizon Business was chosen for the strength of its expertise and experience, its position as a global leader in network delivery and its proven track record in delivering efficient networking services for global clients.

Bijoy Sagar, Chief Information Technology and Digital Transformation Officer, Bayer, said: "Our network is foundational to our future business success, and Verizon has the global technology and innovation capabilities and expertise to support us as we continue to digitally transform our company. Most importantly, with our network management safe in Verizon's hands, we are able to focus our internal IT competencies on generating value for our core Life Science businesses."

Tami Erwin, CEO, Verizon Business, said: "Verizon is well-positioned to deliver innovative and seamless network solutions for our customers at a global scale. We are looking forward to this next chapter with Bayer, as we ramp up our ability to build a future-ready infrastructure to support their ongoing growth." The five-year contract is effective immediately and has an additional two-year extension.

Thermo Fisher Scientific has expanded deployment model options for SampleManager LIMS software

Under a contract agreement, Thermo Fisher will manage the entire deployment process from installation and maintenance to backup and recovery. As a result, laboratories will benefit from significantly reduced financial and human resource investment associated with setting-up, running and maintaining traditional on-premise deployments or deployments to their own cloud hosting service.

At the same time, laboratories will retain control over the software upgrades and validation schedule, while taking advantage of unlimited and secure access to data from anywhere at any time, which will drive wellinformed decision making and easier crosscollaboration. Furthermore, AWS Cloud deployment will enable unparalleled levels of scalability, with the LIMS expanding to meet evolving business needs.

"Life science and industrial laboratories are increasingly adopting a cloudfirst approach to enterprise-wide LIMS implementation," said Richard Milne, vice president and general manager of Digital Science. "However, managing deployments to a laboratory's own cloud hosting service can be a costly and resource-intensive process. We have developed the new cloud services to alleviate this burden and enable SampleManager LIMS software customers to use the system's superior functionality and integration capabilities without having to invest significant resources into the setup and ongoing management of a cloud environment."

The Cloud Services offering has been designed to provide optimal data security and protection. In addition to the security features available through standard AWS Cloud deployments, Thermo Fisher also implements its own robust Corporate Information Security (CIS) program, which outlines additional measures in line with security-by-design principles to maintain the confidentiality and integrity of data.

Eli Lilly and Healthcare Pharmaceuticals Launch Once-aweek Drug TrulicityTM for Type 2 Diabetes in Bangladesh

Healthcare Pharmaceuticals Ltd. (HPL) and Eli Lilly and Company announced the launch of Trulicity[™] (dulaglutide) in Bangladesh. Trulicity[™] is the first once-weekly, injectable medication designed to improve blood sugar control in adults with Type 2 diabetes. "Trulicity[™] will be marketed and distributed in **Bangladesh by Healthcare Pharmaceuticals** Ltd., a leading life science organization that believes in innovation, patient benefit and compliance. The launch of Trulicity[™] will open newer avenues in diabetes management and provide health care professionals with an additional tool to manage diabetes," said Mr Halimuzzaman, DMD & CEO, Healthcare Pharmaceuticals Ltd.

Trulicity[™] offers patient benefits beyond glycemic control and the convenience associated with a once-weekly dose. Studies done on Trulicity[™] have established its

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cardiovascular safety and weight reduction potential. Trulicity[™] comes in an easy to use, single-dose pen that does not require mixing or measuring and can be administered at any time of the day, independent of meals. It is available in 0.75 mg and 1.5 mg doses. Special care has been taken in concealing the injector needle to address the fear of needles that some patients have.

Trulicity[™] is part of a class of drugs known as a glucagon - like peptide (GLP-1) receptor agonists. It is not insulin and mimics the effects of GLP-1, a natural hormone that helps keep blood sugar levels normal, by helping the body release its own insulin after food intake.

"Diabetes is a big burden on the healthcare system in Bangladesh. More than 8 million people live with diabetes in the country and their treatment needs vary," said Luca Visini, Managing Director for India, Bangladesh,

Sri Lanka and Nepal, Eli Lilly and Company. Trulicity[™] is a prescription drug that should be taken only on advice from a registered MD (Internal Medicine) and Endocrinologist. When prescribed, it should be used as an adjunct to diet and exercise.

ELGi's AB 'Always Better' Series powers the Indian Pharmaceutical Industry

India's leading pharmaceutical companies rely on the ELGi AB series range of oil free screw compressors, to deliver pure, clean, class "0" oil free air. With high reliability, consistent air quality, better return on investment, lower cost of ownership, and fast, efficient service support for sensitive applications with moisture content between +3°C, to -20°C PDP; the AB series range of air compressors meets the ISO 8573–1 compliance requirements. In addition, the ELGi AB Series delivers unmatched air quality in line with the



ISO8573-Class 7 compliance norms ensuring zero traces of microbial contaminants. With the IS:10500:2012 certification for water quality, the AB series also guarantees the safest pneumatic air for the pharmaceutical industry. The sheer performance of the ELGi AB Series, coupled with its compelling value proposition has resulted in India's leading pharmaceutical companies replacing existing machines with the AB series, while successful installations, have prompted pharmaceutical companies, across the country, to revisit their entire fleet of air compressors.

India's pharmaceutical industry is forecasted to grow at 22.4% annually, to US \$100 billion by 2025; addressing over 50% of the global demand for vaccines, 40% of generic demand in the US and 25% of all medicine requirements in the UK. Dr. Jairam Varadaraj, Managing Director, Elgi Equipments Ltd said "In light of the pandemic, India's pharmaceutical industry has a tremendous opportunity to play a pivotal role in global healthcare. With growing FDA scrutiny, strict warnings over toxic impurities and delicate pharmaceutical manufacturing processes, the quality of compressed air meeting the highest standards, is of quintessential importance. On the other hand, continuous air supply must be guaranteed, since a disruption can lead

to an immense loss of production. At ELGi, we endeavoured to address the needs of the pharmaceutical manufacturing industry in a new way. The ELGi AB 'Always Better' series is a disruption in oil free compressed air technology, and we're delighted to witness its growing adoption as the customer's choice for sensitive pharmaceutical applications."

Pharmaceutical customers traditionally buy oil lubricated compressors for requirements below 500cfm (90kW) owing to low capital investments, and conventional oil free compressors, to meet stringent air quality requirements. The flip side of using lubricated screws is the multi-layer filtration systems which increase pressure drop and cause down time due to the replacement of oil filters resulting in increased lifecycle costs. On the other hand, conventional oil free compressors in this range, are normally air-cooled and also face reliability issues and temperature trips at high ambient temperature conditions (above 45°C), resulting in significant downtime and operational losses, in addition to excessive initial and running costs.

The ELGi AB Series has a unique air cooling system which ensures ample condensation of water from air particles, aiding the selfreplenishment of water in the closed loop. This eliminates the need for external water top-up and also reduces the load on the driers and the water management system. The in-built microbial inhibition system prevents microbial growth, across all scenarios of operation, thereby ensuring microbe free air.

The ELGi AB Series operates with a single airend, as opposed to conventional oil free machines that operate with dual airends. This results in lower foot print, fewer rotating components and lower maintenance costs. Fitted with stainless steel rotors for better performance, every ELGi AB series air compressor comes with standard bearings for ease of maintenance. Additionally, the AB series range operates at a lower RPM, resulting in less wear and tear of rotating parts, low noise levels and reduced power consumption. Additionally, the low noise levels ensure the AB series does not require a dedicated compressor room and can be placed right next to the application area, thereby reducing costs involved with the build-up of additional infrastructure and compressed air supply systems.

Cherwell launches new support hub for growing Redipor® prepared media distributor network



New online resource centre for distributors ensures Redipor customers receive quality support for environmental monitoring applications internationally. Cherwell Laboratories, specialist suppliers of environmental monitoring and process validation solutions for the pharmaceutical and related industries, has launched a Redipor[®] prepared media distributor resource centre website. Developing this online knowledge hub supports Cherwell's growing international distribution network within Europe and now Asia. This means that all Redipor microbiological media customers will receive quality support for their environmental monitoring, sterility testing and process

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validation applications, whatever their location.

The new Redipor distributor resource centre securely houses lots of useful material, including prepared media product information, safety data sheets, guides and updates which are readily accessible to the distributor at all times. This detailed information in turn enables them to help ensure the controlled environment monitoring efforts of Redipor users run as smoothly as possible. Further supporting in-house expertise, Cherwell invests time in developing a Redipor product champion at each of its distributors; training them in its processes and the complete range of Redipor culture media products, including features, benefits and applications. This is all key to ensuring customers are advised on the right solutions for their needs.

"We are proud that the Redipor range has for many years been associated with quality products supported by an efficient, responsive and truly flexible service for small and large users alike. We therefore take great care in selecting the right partners to work closely with us to supply our products internationally," said Andy Whittard, Managing Director, Cherwell Laboratories.

Sun Pharma launches FluGuard[®] (Favipiravir) in India at Rs. 35 per tablet

Sun Pharmaceutical Industries Limited announced that it has launched FluGuard[®] (Favipiravir 200 mg) at an economical price of Rs. 35 per tablet, for the treatment of mild to moderate cases of Covid-19 in India. Favipiravir is the only oral anti-viral treatment approved in India for the potential treatment of patients with mild to moderate Covid-19 disease. Commenting on the launch, Kirti Ganorkar, CEO of India Business, Sun Pharma said, "With over 50,000 Covid-19 cases being reported daily in India, there is an urgent need to provide more treatment options to healthcare professionals. We are launching FluGuard® at an economical price to make the drug accessible to more and more patients thereby reducing their financial burden. This is in line with our continuous efforts to support India's pandemic response."

The company will work closely with the government and medical community to ensure availability of FluGuard® to patients across the country. The stocks of FluGuard® will be available in the market from this week.

Michael Van den Bossche appointed new joint Managing Director of Romaco Innojet



Michael Van den Bossche, Managing Director of Romaco Innojet GmbH

Romaco Holding GmbH has just announced the appointment of Michael Van den Bossche as new Managing Director of Romaco Innojet with effect from 1 August 2020. In his new role he will be responsible for Sales, Laboratory, Customer Service and Product Management. Van den Bossche will share the management of Romaco Innojet with Bastian Käding, who has been at the helm of the company since 2018 with responsibility for Project Management, Engineering, Operations and Administration.

Prior to joining Romaco Innojet, Belgianborn Van den Bossche, who holds a master's degree in biochemical engineering, worked for various leading international players in the business of processing technologies, process design and development.

Lincoln Pharmaceuticals Ltd launches Vitamin C + Zinc Tablets to boost immunity in the fight against COVID 19



With a commitment towards "Healthcare For All", Lincoln Pharmaceuticals Limited, one of India's leading healthcare companies has launched Chewable Vitamin C + Zinc Tablet for the markets in India. The tablet is an evidence-based bio-active for natural immunity in the combination of zinc that boosts antiviral activity and protection against COVID 19. Market size for Vitamin C and Zinc tablets is estimated at around Rs. 150 crore in India and growing at 15% per annum. Mr. Ashish R. Patel, Whole-Time Director, Lincoln Pharmaceuticals Limited, said, "During this COVID 19 Pandemic, Immunity & immunity boosters are the only way to protect against the Virus. Vitamin-C & Zinc tablets have become a necessity and important part of all human being in their day to day life. With this launch, we aim to fill the gaps in serving the healthcare requirement of the masses with our wide range of 600 plus formulations." Lincoln Pharmaceuticals Limited is of the leading companies in pharmaceutical industry, engaged in the business of manufacturing of Tablets, Capsules, Dry Syrup, Liquid Vials, Injectables and Ointments etc.

Hetero announces the launch of 'Favivir' (Favipiravir 200 mg) in India to treat mild to moderate Covid-19



Hetero, one of India's leading generic pharmaceutical companies and the world's largest producer of antiretroviral drugs, today announces the launch of generic Favipiravir in India under the brand name 'Favivir.' Hetero has been granted the manufacturing and marketing approval for Favipiravir from the Drug Controller General of India (DCGI).

Favivir is the second drug developed by

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Hetero after Covifor (Remdesivir) used in the treatment of Covid-19. It is an oral antiviral medication that has demonstrated positive clinical outcomes. Favivir improves treatment accessibility to a significant amount of Covid 19 patient population, which usually sustains mild to moderate symptoms. Hetero's Favivir is priced at Rs. 59 per tablet and is marketed and distributed by Hetero Healthcare Limited. The product is available from today at all retail medical outlets and hospital pharmacies across the country and will be sold only on prescription.

Backed by strong vertical integration capabilities, the drug is being manufactured at our world-class formulation facility in India, which has been approved by stringent global regulatory authorities such as USFDA and the EU, among others.

28 Cytel announces East Alloy for easy access to verified Bayesian and innovative methods

Cytel Inc., an advanced analytics leader providing sophisticated quantitative insights to decision-makers in clinical investigation, has today announced the launch of East Alloy[®]. This new platform is a web-native extension of Cytel's world-renowned East® software for adaptive clinical trial design and analysis. By leveraging the speed of cloud computing and the pace of SaaS delivery, East Alloy enables easy implementation of computationally intensive Bayesian methods that may be otherwise impractical. The launch of East Alloy builds on Cytel's time-tested record of delivering cutting-edge Bayesian tools and engines to the pharmaceutical industry for optimized clinical trials. To support the launch, Cytel will also host a 60-minute webinar on July 29 introducing East Alloy and detailing how it can be used to adopt

Bayesian and innovative methods with speed and confidence.

Amidst the rapid pace of modern clinical development, drug developers are increasingly seeking greater clinical trial efficiency and probability of success while also minimizing costs. This often means turning to sophisticated and innovative clinical trial designs, including Bayesian methods. However, underpowered on-premise technology can make execution of such methods challenging under routine statistical design timelines. Furthermore, publicly available solutions often rely on unverified bespoke coding, which can introduce risk to clinical programs.

"As trial designers turn to open-source or home-grown trial design solutions to meet the demands of modern drug development, they're experiencing a range of challenges, from a lack of user-friendliness and quality control, to difficulty accessing the computational power needed to deploy these complex methods," commented Yannis Jemiai, Chief Scientific Officer at Cytel. "With East Alloy, we're combining Cytel-curated public solutions that we've subjected to our robust verification program with Cytel's own cuttingedge engines, and then accelerating their delivery via SaaS and cloud computing. This enables our customers to avoid extensive IT infrastructure and confidently deploy powerful innovative techniques and Bayesian methods with ease."

Bayesian methods are of growing interest to the drug development industry, as they allow clinical investigators to leverage historical trial data as well as learnings from new data as it accrues throughout a trial. The result is betterinformed decision making, greater program flexibility, and the ability to run smaller, more resource-efficient trials.

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The release of East Alloy follows the launch of East Hosted® in 2019, which brought Cytel's East software into the cloud for the first time to simplify the deployment of software updates, reduce on-premise IT burden, and ultimately broaden access to Cytel's trusted trial design and analysis engines.

Patent awarded for Concarlodeveloped therapeutic to tackle treatment-resistant breast cancer



Concarlo Holdings LLC, has announced that US Patent 10,702,570 was issued by the United States Patent and Trademark Office on July 07, 2020, marking the latest step in Concarlo's journey to commercialize revolutionary medicines for metastatic breast cancer. The patent, for which Concarlo is the exclusive licensee, covers IpY, a novel therapeutic peptide that addresses drug-resistant breast cancer by targeting a unique cellular pathway - p27Kip1. Concarlo has also announced that a new provisional patent application has been filed for modified versions of the therapeutic peptide that are believed to exhibit enhanced bioavailability. Concarlo is a Brooklynbased biotechnology innovator dedicated to developing sophisticated, targeted therapies and diagnostics in the oncology space. The IpY technology is the first to address the high incidence of drug-refractory disease that develops with currently available CDK4

inhibitor (CDK4i) treatments. Such a solution has the potential to drastically increase overall survival of breast cancer patients.

"Despite the clinical efficacy of CDK4 inhibitors, we're seeing that primary or secondary resistance to therapy is presenting a significant challenge to overall survival," commented Dr. Dominique Bridon, Chief Development Officer at Concarlo. "With the IpY technology and its unique mechanism of action, we're effectively targeting CDK4 while simultaneously inhibiting another target CDK2 — which has been found to be a key molecular player in the development of drug resistance. In doing so, we are the first company to successfully address the CDK4i resistance issue to provide long-term durable tumor arrest. Combined with its highly specific targeting and low toxicity profile, the positive impact of this drug on the breast cancer treatment landscape is hard to understate."

Concarlo was formed in 2016 and is supported by a team of internationally renowned experts forming its Scientific Advisory Board. To date, the company has raised more than \$3.1 million to support the development, improvement, and commercialization of its IpY and ApY technologies to bring a precision medicine approach to breast cancer management. The newly issued patent for IpY and the provisional patent application for modified versions of the peptide are the first key milestones in Concarlo's plan to build an extensive patent estate to maintain market exclusivity for its clinically relevant therapeutics. ■ 30

New Age Technologies: AI/ML/Blockchain in Drug Discovery

Artificial Intelligence (AI) and Machine Learning (ML) has taken a leap in the pharmaceutical industry. AI has wide-reaching potential to fasten the overall drug development process and can dramatically shorten clinical trials. AI has the potential to fasten molecular and material research to discover and explore new drug like molecules which need to be examined to find all possible drug targets. The growth of the AI in the drug discovery sector is primarily driven by an array of factors of cross-industry collaborations and partnerships, the increasing need to control drug discovery & development costs and reduce the overall time taken in this process. AI technologies are going to be truly transformative. Dr.P.Ratnakar, Vice President & Practice Head- Life Sciences, Tech Mahindra gives us a sneak peek into the role of an initiative such as Make in India for new age technologies of AI/ML/ Blockchain in Drug Discovery.



Dr. P. Ratnakar Vice President & Practice Head - Life Sciences Tech Mahindra

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rug Discovery research involves identifying new medicines to treat a particular condition or disease for which there are no medicines available in the market like the Corona Virus or identifying medicines which may have better efficacy or less side effects or ones which are at affordable cost as compared to the existing approved therapies. These drugs bind to a specific target molecule in the body which is related to the disease in order to elicit the pharmacological response. The complete process involves identifying a target, validating the target, pre-clinical / screening in animals (invitro and in-vivo) and clinical trials/ screening in human. The facts related to drug development are quite alarming. The whole process may take 10-15 years and may cost US\$2.8 bn for bringing a new drug to market. Less than 10% of drug candidates succeed following Phase I trials.

According to market research firm Bekryl, Artificial Intelligence (AI) has the potential to offer over US\$70 billion in savings for the drug discovery process by 2028. Realizing the potential applications of AI, pharma companies are exploring the potential of AI tools to drug discovery and development either through in-house R & D or through collaboration. The global artificial intelligence in medicine market is valued at US\$18 billion. New Age Technologies like AI-ML and Blockchain can help the researchers' speed-up the drug discovery process leading to huge cost savings, improved efficiency and potential to identify new drugs by having a deeper understanding of effects on biological pathways by biochemical entities and molecular entities of the drug.

Al is being used at various stages of drug discovery. It can help identify new targets, find good molecules from data libraries, suggest chemical modifications, identify candidates for drug repurposing, biomarkers development etc. Leading **Biopharmaceutical companies are** collaborating with niche companies to reap the benefits of AI. Genentech announced a research partnership with GNS Healthcare to identify and validate novel cancer drug targets. GlaxoSmithKline (GSK) formed a collaboration Insilico Medicine, to explore for identification of novel biological targets and pathways of interest to GSK. It is also signed a \$43 M drug discovery collaboration with U.K-based AI-driven startup Exscientia to identify small molecules for ten selected targets across undisclosed therapeutic areas. Santen Pharmaceuticals, a Japanese leader in

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the ophthalmic field, entered a strategic research collaboration with TwoXAR aiming to find new drug candidates for glaucoma treatment by screening large datasets of molecules to unique diseasedrug associations. Berg Health is applying advancing deep-learning techniques for screening of biomarkers from patient data and "multi-omic" modeling approaches. It is collaborating with AstraZeneca for identification and novel approaches for treating Parkinson's disease and other neurological disorders. Sanofi in an attempt to polypharmacology discovery "multitarget drug discovery" has tied up with Exscientia to discover and develop bispecific small molecules that treat diabetes and its comorbidities.

Repurposing drugs developed for a different therapeutic condition and positioning for a new area has an advantage of already available vast amount of safety and toxicity data and therefore less R&D time and spend. Sanofi has collaborated with Recursion Pharmaceuticals in 2016 with the purpose to identify new uses for Sanofi's clinical stage molecules across dozens of genetic diseases. Repurposing is turning out to be the best approach in the current situation to treat Corona virus. Known anti-viral agents are being studied with docking interactions with COVID-19 enzymes. Drug – Repurposing or Drug –Repositioning powered by AI is a faster and effective approach for identifying drugs to create COVID-19.

Blockchain which is known for its immutability, security and transparency is also aiding drug discovery and development in many ways such as data management, drug authenticity, Intellectual property authentication. Clinical Trials is a complex exercise and involves various stakeholders making the process error-prone. Blockchain provides a single sharing platform for all parties ensuring proof-of-existence, authenticity, efficient data sharing and data security leading to effective clinical trials. The Mediledger project was designed to apply blockchain to track and trace prescription medicines and prevent drug counterfeiting. Boehringer Ingelheim has collaborated with IBM Canada to explore blockchain technology in clinical trials.

India is the largest provider of generic drugs globally. 40% of the generics demand in the USA and 25% in the UK are met by India. The global Pharmaceutical companies spend an average of 20% of their revenue on research and development (R&D), whereas the Indian pharma companies R&D spend is around

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6%. While Indian Pharmaceutical industry is having a lot of potential to innovate new drugs, most of the innovator drugs are from the multi-national firms. India has well-developed scientific base with advanced research in stem-cells, cell engineering, cell and gene based therapeutic R&D.

As part of "Make in India" initiative, Indian Pharma sector will be able to disrupt the industry by innovating new medicines/ therapies for treating diseases with unmet medical needs with the help of New age technologies. The huge potential of new age technologies like AI/ML and Blockchain will create a drastic impact in the drug discovery process and is ought to change the traditional way of laborious and mundane processes to smart and intelligent technology aided drug discovery. Adoption of these new age technologies can be the biggest enabler for the Indian Pharma who can start disrupting the Innovators who were always the torch bearers in the drug discovery foray and place the industry in the level playing field with the Big pharma.

Disclaimer: The views expressed in this article are those of the author and do not necessarily represent those of his employer.

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Will Quantum Computing Transform Biopharma R&D?

Of the many industries in which quantum computing is expected to have a farreaching impact, biopharma is among the most promising. Quantum computing has the potential to significantly accelerate, enhance the quality of, and reduce the costs of data-rich R&D processes. The earliest uses are likely to involve the early stages of R&D (drug discovery and design), but the impact will extend into the later stages of R&D, thanks to higher clinical success rates from better early design.

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uantum computing is still very much an emerging technology, and the pathway to practical application remains under construction. However, the technology is graduating from the lab and heading for the marketplace. Google announced that it had achieved "quantum supremacy" in October 2019, IBM has committed to doubling the power of its quantum computers every year, and numerous other companies and academic institutions are investing billions toward making quantum computing a commercial reality. Biopharma companies have the potential to benefit significantly from this technology-and those that begin taking

"Biopharma companies that take the right approach to quantum computing now may gain a lasting advantage."

the right steps now may gain a lasting advantage.

As with any emerging technology, much of the potential value lies in how commercial enterprises apply new capabilities to improve core processes. We believe that quantum computing is very likely to transform the early stages of pharmaceutical R&D over the coming decades-and that it will provide nearterm benefits as the technology matures. But its actual impact will depend in large part on how biopharma companies learn to use it. Aside from quantum computing hardware and software, keys to success will include talent, new ways of working, and partnerships. Early movers will almost certainly gain advantages that followers will have a tough time matching.

Current Challenges in Pharmaceutical R&D

The biopharma R&D process—from drug discovery to development—is a costly, lengthy, and risky endeavor. A new drug typically takes 10 to 15 years to progress from discovery to launch, and the capitalized costs exceed \$2 billion. The success rate is less than 10% from entry into clinical development to launch. For these reasons, biopharma companies count on a few blockbuster drugs to realize payback of the more than \$180 billion that the industry spends each year on R&D.

Computational tools are already key components of drug discovery and development. In many instances, they have significantly shortened the time companies spend on drug optimization. Researchers rely on high-performance computing-using powerful supercomputers or massive parallel processing-to perform in silico modeling of molecular structures, mapping of the interactions between a drug and its target, and simulations of the drug's metabolism, distribution, and interactions in the wider human system. For example, computational chemistry algorithms aim to predict how a potential drug molecule will bind to specific target proteins, by modeling the binding energy of interaction. Because many of these algorithms do not scale well with the number of atoms, however, they are often limited to relatively simple molecular structures. For example, IBM has estimated that fully and accurately modeling the base-state energy of the penicillin molecule, which is composed of 41 atoms, would require a classical computer with more transistors than there

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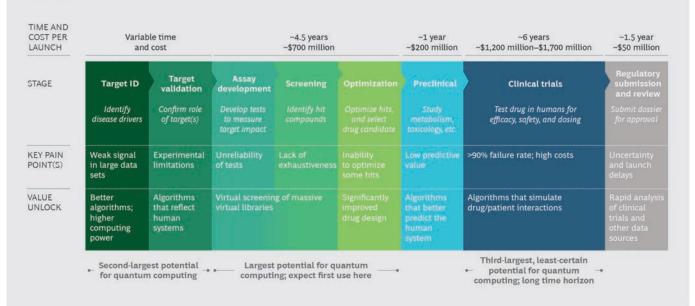


EXHIBIT 1 | The Potential for Quantum Computing's Impact on the Drug Discovery and Development Process

Sources: Paul et al., "How to improve R&D productivity: The pharmaceutical industry's grand challenge," *Nature Reviews Drug Discovery* 9(3):203–214 (2010); BCG experience and analysis.

are atoms in the observable universe.

How Quantum Computing Can Reshape Drug Discovery

Quantum computers work fundamentally differently than classical computers, and these differences give them the power to solve certain classes of problems that classical computers cannot. Classical computers are built on bits that have values of zero or one. In contrast, a quantum computer uses quantum bits (or qubits), which can be overlays of zeros and ones (meaning part zero and part one at the same time). Rather than working in isolation, qubits become entangled and act as a group, which helps enable quantum computers to achieve an exponentially higher information density and computing speed than classical computers. This gives them an advantage over classical computers in solving four types of problems: combinatorial optimization, differential equations, linear algebra, and factorization. Whereas modeling penicillin on a classical computer would take 1086 bits, it could take as few as 286 qubits on a quantum computer.

Quantum computers provide powerful tools for studying complex systems such as human physiology and the impact of drugs on biological systems and in living organisms. We believe that quantum computing will have numerous uses in pharmaceutical R&D, especially in the early phases of drug discovery and

"Quantum computers can achieve exponentially higher information density and computing speed than classical computers."

development. Take optimization. Currently, the process of modifying the physiochemical properties of hit compounds to produce lead compounds and, ultimately, drug candidates still mostly relies on expensive and time-consuming experimental methods. The biopharma industry already applies quantum mechanics for energy calculations and structural optimization, especially in molecular docking and quantitative structure-activity relationship analyses. Quantum mechanics-enabled synthetic chemistry gives researchers the tools to preclude potentially inactive compounds and to support the synthesis of more challenging compounds. As quantumbased virtual screening and optimization leverage molecular simulations, it is possible that researchers will someday be able to combine both into a single in silico workflow.

Or consider screening. Virtual screening tools tend to be cheaper and faster than chemical processes for screening large compound libraries against a target of interest. But the usefulness of virtual tools depends on their ability to accurately predict hits, especially for complex molecules. Quantum computing has the potential to transform virtual screening through physically precise modeling of drug-target interactions and efficient screening of massive virtual libraries. Another complication is that building a tool to test compounds for the desired impact on a target during screening is a slow, labor-intensive lab process. By improving in silico screening and compound validation, quantum computing could reduce the need for costly and timeconsuming in vitro testing. Eventually, quantum computing could permit end-toend in silico drug discovery.

Quantum computing may also be useful in the target identification phase by enabling deeper exploration of complex multifactorial diseases that require the modulation of multiple targets. In addition, there could be applications in clinical development.

The possibility of step changes in capability is not a distant dream. Hybrid quantum-classical approaches that can predict molecule structure should be available within the next five years, allowing more-effective structurebased drug design of small molecules. A number of startups are developing virtual screening tools that use 3D representations of molecules derived from quantum mechanics to determine interactions between drugs and their targets. 38

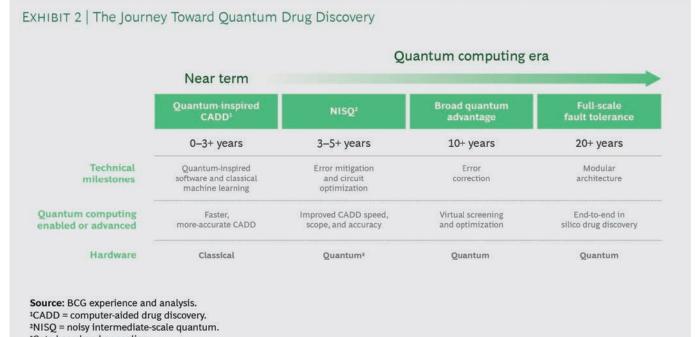
How Biopharma Can Get Ready for Quantum Advantage

While the long-term promise of quantum computers may be transformative, the machines available today have serious shortcomings related to capacity, stability, and reliability. These issues must be overcome before companies can put quantum computers into practical service. We expect this journey to develop through four distinct phases, during each of which capabilities, applications, and business income will steadily increase over time.

The earliest uses involve the computeraided drug discovery (CADD) applications described above. The next decade will be defined by so-called noisy intermediatescale quantum (NISQ) devices, which increasingly will be able to perform useful, discrete functions, but will also be plagued by high error rates that limit their functionality. In three to five years, error mitigation techniques, along with better hardware and algorithms, should begin to support useful business applications.

Error-corrected machines will achieve true quantum advantage, outperforming classical computers in time, cost, or quality for the applications we have outlined. But error correction is still at least a decade away. The next milestone after that is full-scale fault tolerance, at which point quantum computers could enable full in silico drug discovery and design.

Harnessing technology during the NISQ decade requires mastery of four areas: quantum hardware- and software-based solutions, talent, new ways of working, and partnerships.



³Gate-based and annealing.

"Makers of quantum computing hardware aim to develop circuits optimized to solve problems such as molecular docking."

Quantum Hardware- and Software-Based Solutions. In addition to the hardware advances that large end-toend providers such as Google, IBM, and Honeywell are pursuing, emerging companies such as D-Wave, Rigetti, and Xanadu are active. As happened in the early days of the semiconductor industry, quantum computing hardware manufacturers are aiming to develop circuits optimized to solve particular problems, such as molecular docking. For example, IBM is taking this approach to produce specialized circuits for "hidden shift" and quantum Fourier transform algorithms. "When it comes to nearterm applications, the beautiful work will happen at the cross-section of business needs and quantum circuitry so that the circuit itself determines the application," IBM's head of quantum computing, Jay Gambetta, told us.

Because they work differently from classical computers, quantum computers require new software and algorithms. Specialists such as ProteinQure, GTN, Rahko, Menten AI, and Qulab are pioneering quantum drug-discovery algorithms. By partnering with these and larger companies, biopharma companies may be able to shape optimized circuitto-application solutions and realize value more quickly.

In the meantime, the massive classical computing industry continues to deliver performance improvements (through supercomputers, HPC, and GPUs) and better algorithms that will help bring value to biopharma companies even sooner. Quantum computing has introduced new ways to approach problems, inspiring new algorithms that run on classical hardware. Microsoft, which has dubbed these new techniques "quantum-inspired," has just released a quantum-inspired chemistry library with 1QBit to run on Azure Quantum. Companies such as Silicon Therapeutics, XtalPi, Qubit Pharmaceuticals, Atomwise, Turbine, and Benevolent AI are using quantum-inspired approaches, often in combination with machine learning, and aim to achieve quicker and more-accurate drug discovery. Proven quantum computing algorithms boost machine learning training, so this approach will accelerate as NISQ machines become more powerful.

Talent. How companies decide to tackle specialized software development internally, externally, or with a combination of the two—will have major implications for **COVER STORY**

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their talent needs and their organizations. Companies will need skilled scientists and technicians, including hardware and software experts, to handle these tasks. Such talent is in short supply—and the supply is shorter still for jobs that require quantum computing knowledge or experience. Early movers have the opportunity to establish a skills advantage by becoming recognized centers of commercial advances in quantum computing. Companies such as Airbus already offer quantum training programs to prepare their engineers for the future.

New Ways of Working. In order to derive value from new approaches such as quantum computing, companies may need to change their processes. Building internal quantum computing capabilities requires not only relevant quantum skills but also collaboration between research scientists and pharma businesspeople and, work with talent in other technical fields such as artificial intelligence and machine learning. The new solutions promise a step change over current CADD tools in both accuracy and speed (for example, Atomwise claims a 10,000x improvement in hit rates and 100 times faster screening times, and other players point to similar improvements) that will

open up radical new ways to design drugs. But to capture the value, companies must change their processes and, potentially, their organizational structure, as well as adopting agile ways of working. An agile approach enables faster and more efficient testing and iteration of promising therapeutic candidates and technological advances. In other industries, early leaders that have adopted agile have seen as much as a doubling of the speed of their new product development.

Partnerships. Innovation is a much more fragmented and varied endeavor today than ever before. More young companies in more places are pursuing more new avenues. One result of this fragmentation and diversity of effort is that although knowledge, skills, and information are much more accessible, they are also harder to harness because they reside in more numerous and more disparate places—geographically, industrially, and functionally. Investing in partnerships dedicated to building custom solutions that address the most crucial drug discovery challenges is an effective way to gain a foothold in the emerging quantum computing ecosystem. As BCG has observed before, deep technologies require a more thorough analysis of the

"Quantum computing solutions promise a step change over current CADD tools in accuracy and speed."

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"Computing may encourage tech players to enter drug discovery, competing with pharma companies."

stakeholders' interdependencies and more precise value creation models in order to accurately determine how to align goals, set strategies, and organize for interaction with others.

How to Get Started

Quantum computing is likely to have a profound impact on biopharma R&D, potentially changing the competitive set and dynamics of drug discovery. A quantum-advantaged world will probably witness a race to find and patent the best molecules for a given target. This in turn will set off a "landgrab" of the most promising molecules, targets, and biological or clinical mechanisms for subsequent exploration. It's also possible that tech players will enter drug discovery, competing with pharma companies. In an extreme scenario, biopharma companies risk being relegated to focusing mainly on clinical development, medical affairs, and sales.

Biopharma should take the necessary steps now to prepare for quantum computing's role in R&D. A sensible first step would be to conduct an assessment of the probable impact of quantum, featuring a workflow analysis to identify key friction points and solution mapping to determine whether these challenges fall into quantum-advantaged problem archetypes. Companies can then identify "lighthouse" use cases and build out early.

As they move forward, biopharma companies should look for early wins that will demonstrate the value of new approaches (such as a speed-up over previous, nonprobabilistic algorithms) to the rest of the organization. Quantuminspired algorithms that emulate quantum concepts on classical hardware or specialized NISQ-era quantum circuits are good places to start.

Ultimately, quantum computing is likely to yield greater speed and efficiency in drug discovery, improvements in existing drugs, and faster development of new drugs. It should also accelerate time to market. The technology's long-term potential is vast, but quantum computing also offers biopharma companies tangible benefits in the near term. Companies that want to play need to prepare for a quantum future now. ■

New Frontiers of Growth in the Life Sciences Industry

The life sciences industry is on the cusp of change. While this change does give rise to some challenges, it throws open doors for new opportunities and possibilities. In order to capitalize on these opportunities, an organization must be on a dual mission of 'renew - new' – one that simultaneously focuses on renewing existing systems and processes for greater efficiency and adopting new advancements in technologies to gain value. In this paper, we discuss these opportunities and the way forward for the life sciences industry.



Subhro Mallik SVP & Head of Life Sciences Infosys

R ecent scientific and technological advances coupled with an aging population, expansion in the emerging markets, and an exponential increase in mainstream adoption of digital technologies have set the ball rolling for the life sciences industry, providing it with a renewed platform to revive its fortunes.

With an explosion of digital data availability – electronic health records, social, genomics, clinical, insurance, and more digitally engaged consumers, the stage is set to derive benefits from an integrated drug development and manufacturing environment. Such an environment not only provides the best care for patients but also generates



significant revenue growth. Furthermore, there is significant focus on personalized healthcare from both the Life Sciences industry and policy maker perspective. A case in point is President Barack Obama's precision medicine initiative. Personalized healthcare, however, would require a complete shift in how the industry evaluates the market (focus on an individual instead of a population), analyzes higher volumes of data, and puts in place newer processes and methods to complete their studies. The spate of recent investments in the immuno-oncology therapies is pointing towards a significant growth in the coming decade.

Technology is playing a massive role in enabling the industry to achieve these objectives, be it analytics in personalized medicine, cloud computing in collaboration, or wearable devices in remote and self-health monitoring. As the world becomes increasingly connected, information and communication technologies will fundamentally reshape both the consumption and delivery of services in life sciences. The industry must prepare for the future by embracing next-generation technologies and systems throughout the life sciences value chain.

We believe life sciences companies must adopt a more proactive strategy, one that allows them to maximize value from prior investments by renewing existing solutions and processes and generate new value by embracing new technologies, systems, and best practices.

Opportunities for 'renew' in Life Sciences

The Life Sciences industry is undergoing a major transformation. A large part of this is fueled by the integration of digital that has driven a powerful re-imagination of the Life Sciences industry landscape.

This transition has opened up new opportunities for development, but also comes with its own challenges.

 Innovate through cloud: Cloud's greatest impact is in facilitating innovation through increasing accessibility of both internal and external data. While initially the reasons for cloud adoption were



centered on reducing the cost and the time for infrastructure provisioning, it is now providing many more strategic benefits such as enhancing collaboration and providing much greater computing power across the entire value chain from R&D, sales & marketing to enabling functions such as HR and finance.

In pharmaceutical research where large volumes of data (notably nextgeneration DNA sequencing systems and genomic tools) needs to be mined and the cost of obtaining this sequence is rapidly decreasing, data has further increased the number of both, instruments being used and labs using them. Through cloud's agility of provisioning and pricing (pay-peruse), setting up massive infrastructure resources for data crunching, analysis, or simulation is no longer an impediment.

Similar cases are happening in clinical research. A large pharma company is setting up a cloud-based solution to integrate clinical data across all its global trials and provide it to its global operations team for analysis. These big data solutions that receive clinical data instantly from all the current trails will reduce the time taken to

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analyze and predict the path of the trials, while decreasing the operating expenses substantially. On a broader application, the scope of collaboration is expanding to include R&D processes outsourcing, exemplified in virtual laboratories where thousands of researchers from contract research organizations can seek and provide help. Overall, by opening the doors of collaboration, exploding analytical power, and making information more accessible and manageable, the cloud is encouraging new practices such as open innovation in life sciences.

The industry must leverage these to the fullest.

 Smarter and transparent supply chains: Due to globalization and the ever increasing size of organizations, the need to integrate supply chains and gain visibility into them has become critical. Wide diversity of the product mix (biologics versus small molecule) will further compound the need for supply chains that can handle this mix. Furthermore, regulatory policies on transparency are evolving and several states in the U.S. have passed product pedigree laws, and many others are contemplating such legislations. In summary, supply chains will need to transport an increasingly diverse range of products in a challenging environment with resources that are

much more geographically scattered while simultaneously optimizing costs.

As technology erases the distinctions between the virtual and the physical, it sets up the opportunity to create intelligent, analytics-driven, nextgeneration supply chains that provide real-time, end-to-end visibility and control. A smart supply chain, integrated across all business processes and systems, can also leverage real-time data and analytics to enable more accurate forecasting, shorter response times, optimized supply chain processes, and faster decisions.

To enable transparency, pharma organizations are not only implementing global track and trace solutions but are also experimenting with cloud-based, leaner supply chain management solutions. While more prevalent in the CPG Industry, discussions in the pharma community on these lean solutions that can provide visibility on their products after they leave their warehouses have taken place. These solutions are being used in the developing nations that have a more complex network of distributors and wholesalers. Such solutions will promote growth by preventing stock-outs and allowing further optimization of inventory and support recalls.

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Renew through automation and modernization: Most large pharmaceutical organizations are born out of numerous mergers and acquisitions and have inherited portfolios of IT applications in various stages of modernization. In our experience, a substantial part of the legacy portfolio is either outdated or manual, creating high cost burden of managing them while ensuring they meet the complex and evolving regulatory compliance standards. While legacy systems are integral to the continued operational maintenance, they hinder the adoption of newer digital solutions.

Best-in-class companies are standardizing business processes, measuring manufacturing, focusing on visibility, and using the right tools. They are using automation to manage the processes and drive increased business value. Automation is being welcomed in the industry as an alternative to manual steps, especially across processes that have repetitive steps. Automation not only reduces the time taken to execute a task but also frees up time for valuable resources to focus on productive tasks. In manufacturing, **Process Analytical Technologies** (PAT) are being integrated across the assembly line to automatically capture unit operations data and integrate it with the plant quality

equipment. This automation allows instant feedback on the batch quality based on the analysis of data while preventing waste and reducing costs. In R&D, numerous research labs are going paperless by integrating their critical solutions such as ELNs and LIMS with their high throughput chromatographs.

This has not only reduced the time taken, but also minimized errors and allowed scientists to collaborate more effectively leveraging digital data. Additionally, in core IT services, a novel use of automation is in enabling testing of large and complex enterprise solutions. Panaya, which was recently acquired by Infosys, uses artificial intelligence to provide impact assessment and execute automated testing of their enterprise solutions. As a result, it can achieve 75-80% reduction in time and resource consumption. This is now being utilized across a number of large organizations with substantial time and resource savings. Automation is also being effectively utilized in executing the many repetitive tasks in application support services resulting in greater than 35% efficiency savings for organizations.

We envision that the automation of IT processes will soon become a key component of the life sciences operations and new-generation

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leaders will mandate these efficiency savings within their lean organizations.

New opportunities for life sciences

Populations are aging. Chronic illnesses are increasing. New disease strains are emerging at an alarming rate. Add to this mix, the soaring number of patients in a greater spread of geographies. Top it with global regulatory mandates. Then, factor in the variable dosage needs. Think about the shelf life of pharmaceutical drugs and medications. And, we are looking at skyrocketing global healthcare costs. At the same time, there is pressure to develop innovative drugs to save more lives.

Here are the opportunities that await the life sciences industry:

 Connected patients and partners: In today's socially connected world, pharmaceutical companies have a clear opportunity to play a greater role in delivering a better experience for patients and their providers. Patients are becoming demanding about how they want their care. This has precipitated a major transformation in business and technology and has led organizations to adopt a patientcentric model. Earlier attempts at creating these solutions were exclusively focused on adherence to



the medication. However, an emphasis on continuity of care provides an opportunity for pharma companies to play a bigger role. Digital solutions are facilitating patient education, behavioral change, and better communication with clinicians. There is also a wide variety of solutions that facilitate this connect including web portals, body sensors, and apps. These help the patient self-monitor and get needed support, between visits to the physician.

These solutions now provide health advice anytime, anywhere, by developing patient-centric smart tools and devices. These devices also detect and track data regularly and accurately and relay the same to physicians.

Mobility is another key feature of these solutions, making it easier for the patient to communicate. A hospital network in Boston empowers patients to use their home devices to track and report data to their doctors.

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Patient and physician- centric portals, where comprehensive information about treatments and drugs is actively shared, are also on the rise.

In the future, pharma companies will design holistic Medical-health (M-health), platforms that connect the patients and physicians across the globe, drive patient and physician engagement, and activation - all with the objective of improved care experience for patients, better clinical outcomes, and lower total cost of care. In the new collaborative, omni-access data world, this will be a key factor in attracting and retaining patients, partners and clients. To keep pace with a rapidly changing technology landscape, organization, would need to develop a deeper integration, collaboration, and synchronization of activities across all channels.

 Adoption of IoT and wearables across the value chain: Ubiquitous presence of smartphones and substantial investments in Internetof-things (IoT) are providing an exciting opportunity to reduce the gap between the patients and the pharmaceutical industry. While still in its nascent stage, higher adoption of IoT has already started to facilitate at-home diagnostic testing, selfmanagement of chronic diseases, and remote patient-health care provider interaction in the healthcare industry.

For life sciences companies, the adoption of IoT can improve medication adherence and reduce time by capturing critical clinical indicators directly and sending them to the EDC system, produce better outcomes based on analytic insights such as in clinical trials where patient data through wearables has been found to be useful for tracking recovery from cardiac surgery, judiciously replace physical interaction with digital intervention, and lower the cost of treatment. Doctors are turning to wireless devices such as Fitbits to understand the factors that help the recovery of patients. A report published in the Annals of Thoracic Surgery says, "Wireless monitoring of mobility after major surgery was easy and practical. This opens the door for changing recovery models and improving outcomes in surgical practice."

Early market movers already see the use of pill-shaped micro-cameras that traverse the human digestive tract, sensors in pills that track concordance, hip replacements that detect falls and send messages to care providers, and thousands of health-monitoring applications that send messages and data from the home to the hospital or patient to the HCP to improve early diagnosis and treatment solution. One critical innovation in this area is the advancement by Proteus Digital Health. It has created an FDAapproved small pill that consists of a pinhead- sized sensor embedded in the pill and a battery-powered patch that monitors various health indicators such as sleep, activity, respiration, and heart rate. The recent announcement by Novartis of partnering with Google on developing contact lenses that will monitor blood sugar levels and even correct impaired vision will further transform eye care and exemplify another frontier in adoption of IoT.

The adoption of IoT is yet to pan out in the life sciences industry. The industry must work cohesively to overcome the barriers to wearable technology adoption – concerns of security and privacy, data sharing and protection, regulatory compliance, among others – to take life sciences to the next level. In our view, companies that are proactive in using IoT will be the leaders of the future.

 Effective big data utilization to generate insights: From nextgeneration sequencing data and patient information to supply chain monitoring, pharmaceutical firms have been managing massive amounts of data for years. In recent years, rapid digitization has made access to larger volumes of data (EMR, clinical, genomics, wearables), an everyday



reality. The need to design solutions that will systematically analyze and generate real-time insights from these mountains of data more effectively is critical for success. To develop and deliver the next generation of successful therapies, the industry must simultaneously minimize the cost of processing / managing data while maximizing its value. This is complicated by the need to continue integrating new data types and sources from around the globe and to glean insights from unstructured data, while complying with multiple complex regulations governing drug safety, supply chain security, patient privacy, and other sensitive information.

Since early 2000, research units within biopharmaceutical organizations have been actively harnessing the powers of big data by leveraging the advancements in next-generation sequencing. This includes a variety of studies including whole-genome sequencing, targeted re-sequencing, discovery of transcription factor binding sites, and noncoding RNA expression profiling, among others. Organizations are now able to leverage the vast library of available molecular and clinical data, utilize predictive modeling techniques, and identify new potential candidate molecules with a high probability of being successfully developed into drugs while ensuring efficacy and safety.

Clinical development now is also benefiting from big data solutions. We have already mentioned earlier how a large pharmaceutical company is creating a cloud-based aggregated clinical data solution that will house results from all of its global trials.

Faster access to and analysis of this data will reduce the time-to-market and enable rapid decision-making capability. We envision that a further integration of clinical operations data with safety data will allow near realtime monitoring of trials and provide the ability to rapidly identify safety or operational signals demanding action to avert adverse events and unnecessary delays.

We believe that the need to uncover valuable relationships within the existing data is the key to boosting innovation and driving new value. With computing power and storage becoming cheaper, as well as increase in cloud adoption, the life sciences industry stands to benefit tremendously from big data solutions.

Conclusion

There are several reasons for the conservatism of the life sciences industry. But given the current dynamism in the sector, occasioned by regulatory, market, and technological forces, life sciences companies can no longer hold back. We believe this is a time of great opportunity, albeit with some challenges, for this industry. As the industry looks to grow while managing existing investments, it must adopt a dual strategic approach towards technology- renew existing systems and processes for greater efficiency while adopting completely new technologies and practices for value creation.

Digital collaboration in the pharmaceutical and biotech industries

For a pharmaceutical plant to operate in the digital world, integration of the distributed control system (DCS) and the manufacturing execution system (MES) is essential. Critical to this integration is the replacement of traditional tag-oriented peer-to-peer communication with a new message-based communication format that simplifies validation and engineering effort. The message-based method is applied to installed equipment by modelling the application. The model enables the smart equipment integration and message-based communication to be simulated and tested before being implemented.

This feature describes how the integration of the MES and DCS, together with the message-based communication, is set to meet the challenges faced by the pharmaceutical sector. It shows how the newly created solution saves up to 75 percent engineering effort while increasing data integrity and productivity.

Challenges facing the pharmaceutical and biotech industries

Today's life science companies need to be more agile and scalable than ever. Companies need to manufacture greater product varieties, with shorter production runs, partly driven by the demand for personalized medicines. The end products need to be brought to the market quicker. The challenge is to create efficient workflows that fulfill FDA 21 CFR part 11 by following GAMP5 guidelines outlined by the International Society for Pharmaceutical Engineering (ISPE). These guidelines are for engineering and validation to ensure data integrity and conformal production.

Many pharmaceutical companies are challenged by the need for digitalization in a validated production environment. Even more so, the installed equipment may not be ready to deal with the modern digital world and will need to be upgraded accordingly. While vertical integration of the different levels is key in a modern production environment, it is even more critical in the pharmaceutical industry. Here data integrity is an imperative for product quality and mandatory to assure compliance with regulation bodies like FDA and EMA.

While integrating Level 3 to Level 4 (ERP) is quite common and well standardized, it is less so between Levels 0-2 and 3.

Achieving integration based on the standard OPC DA – i.e. "soft wiring" – requires much engineering and validation. Moreover, should a recipe change, it impacts the master batch record (MBR) for the MES and/or the batch management in the DCS. Thus, integration cannot always deliver the highest productivity or quickest time to market as the engineering effort needed to keep the MES and DCS batch level updated remains high.

Pharmaceutical companies need to rise to the challenges of today's validated production environment. They need to recognize that Industry 4.0 and the benefits that digitalization brings to all devices, machines and systems throughout a facility is the key to unlocking the future.

Realistically this can only be achieved by integrating automation and the quality management system/ electronic batch recording. The uncompromised data integrity comes with improved operational expenditures (OPEX) and easier implementation of efficient CAPA management through much higher transparency of the production process.

Principles of plug and produce integration

What is plug & produce?

Incorporating new machinery into the production network used to be highly complex, time consuming and unproductive with endless I/O lists, configurations and qualifications necessary for pharmaceutical compliance. Today everything is simpler with the introduction of the plug & produce concept.

The term plug & produce is used to describe the next level of connecting software and hardware throughout a pharma facility. In the context of the pharmaceutical industry, the International Society for Pharmaceutical Engineering (ISPE) is encouraging this term to describe and achieve a standardization in the production environment.

The aim is to provide a fast and easy integration of machines and automation systems into a pharmaceutical production environment. This is a prerequisite for those companies striving towards implementing Industry 4.0 solutions.

What is the role of ISA95/S88?

At the heart of the plug & produce concept is the ISA95 model. The model consists of the three levels, shown in Figure 1.

Level 0-2 (shop floor) is where the distributed control system (DCS) is positioned and is often isolated within the operational technology (OT) department. Level 3, meanwhile, is the layer for the manufacturing execution system (MES) and is often isolated within the information technology (IT) department. Level 4 provides the connectivity to enterprise resource planning (ERP) functionality.

A digital factory of the future, will see a convergence of the IT and OT systems and departments. As such, there is much discussion on how best to ensure this integration is seamless. The aim of plug & produce is to simplify how different parts and levels of a production communicate with each other within the ISA95/ S88 layer. This is achieved by providing cost effective, standardized, cyber secure and robust solutions throughout the complete life cycle of a facility's operations.

The key is for all levels to communicate digitally. In a good manufacturing practice (GMP) environment this is even an imperative, as data integrity is key for quality production.

What are the benefits of plug and produce integration?

By integrating the MES (Level 3) and the DCS batch (Level 0-2), engineers, shop floor workers and plant management gain from increased flexibility and higher productivity. The integrated solution achieves:

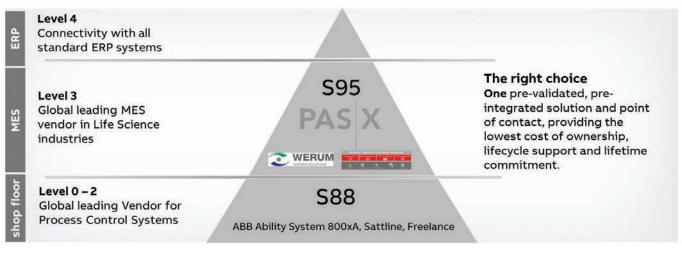


Figure 1.

 Standardized and transparent process flow from ERP production order to batch control recipes

 Simplified communication structures between automation and quality management system

 Significantly reduced engineering effort creating recipes and master batch records (MBRs) with up-load, download and synch functionality between DCS and MES

 Higher flexibility to apply changes to the process

 Ability to connect any equipment to the message bus even based on classic OPC

 Combined/integrated concept for data handling (master data, users, data collection)

For pharmaceutical companies this translates to:

 Significantly reducing the time to market for setting up new production plants and processes

 Improved agility and speed for new product introduction

 Significantly reducing the operation cost by avoiding manual interactions and by automating operations

 Considerably reducing efforts and cost involved in regulatory compliance and validation Using a modern message-based architecture that is designed to be highly secure and reliable

Principles of integration

The principle behind plug & produce is to successfully connect the MES system to shop floor systems such as batch, DCS and SCADA in a common way. Analogous to a printer integration, connecting the MES to DCS should be as easy as plugging in a USB into the computer whereby the driver installs automatically. While this scenario may be some way off, the effort of integration shall be system agnostic and based on cyber secure communication methods.

Integration in the past

Previously, integration used OPC DA for tag-based communications, relaying data back and forth between the shop floor and the MES (see Figure 2).

Engineering of tag-based communications involves defining all the OPC tags at both the Level 0-2 (DCS) and Level 3 (MES). Then all the interface handshakes must be defined in the MES, along with the state and logic.

Similarly, with the DCS, all the handshakes, towards the MES, along with the state and logic need to be defined. And finally, the steps required for the interaction need to be defined, both in

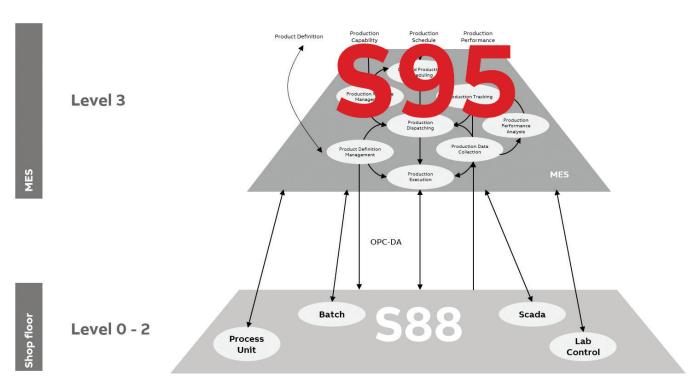


Figure 2.

the MES/MBR (master batch record) and within the batch recipe in the DCS.

The challenge with tag-based communication is that it entails much engineering work, which can be difficult to build and validate. Moreover, any time a change of the recipe is requested, it must then go through the similar definition and adaptation routines as described, impacting the MBR for the MES and/or the batch management in the DCS.

Integration using tag-based communication, therefore, does not deliver the highest possible productivity nor address the quick to market demands. It can also be cumbersome and time consuming and thus inflexible to easily cope with production changes. Because of this, the pharmaceutical industry has been reluctant to prioritize MES and DCS integration, resulting in poor implementation across the industry. Those that have attempted the integration have documented it using SOPs on paper i.e. via manual operations, double signature, etc. For most cases the state of the art is "paper on glass", which just replaces paper, but does not eliminate the risk of human errors.

A typical OPC tag interface includes the following steps:

- OPC tags
- MES interface handshake
- MES interface state and logic
- DCS/ Batch interface handshake
- DCS/ Batch interface state and logic
- MES/ MBR interaction steps
- DCS/ Batch interaction steps

Integration in the future

The newly introduced integration concept is a plug & produce message-based communication between the shop floor and MES systems, see Figure 3. This is a qualified method of interchanging data between the different system levels. This concept is being driven towards a standard by the ISPE in a special interest group (SIG): a forum in which ABB and Werum are actively planning to establish a message-based interface as an open industry standard.

With the message-based communication interface, the synchronization messages are firstly defined and then the interaction steps are further detailed inside the MES/ MBR and in the DCS batch system.

From an engineering standpoint it is much

easier to validate, with up to 75 percent engineering savings on the MES side, while savings on the DCS-side depends on the complexity of the process and the interactions between the systems. However, much time can be saved as it is easier to integrate the messaging. Engineering of MBR and recipes can run much more independent with a qualified method of ex-changing data and synchronizing recipe execution and electronic batch recording (EBR).

Typical message-based interface includes the one time effort of:

- Defining the messages
- Defining MES/ MBR interaction steps
- Defining DCS/ Batch interaction steps

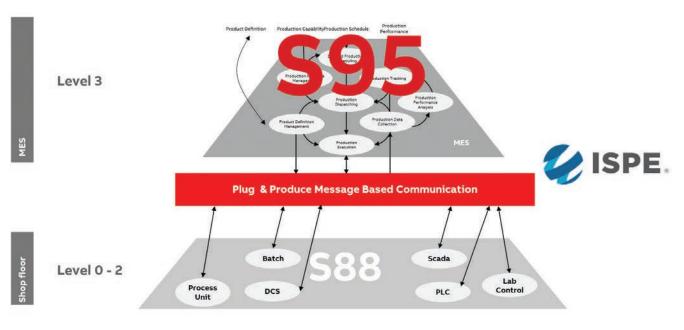


Figure 3.

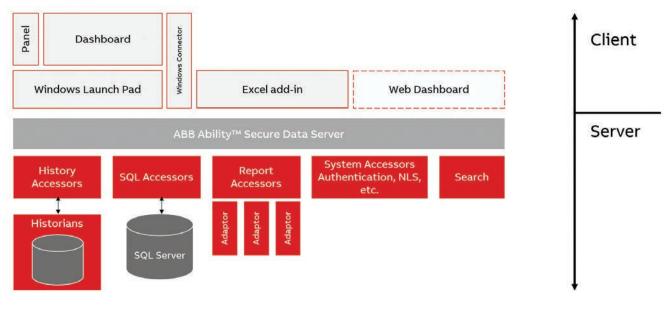


Figure 4.

Plug and produce implementation Shop Floor Integration for Life Sciences

How plug and produce is implemented

Figure 4 shows the view from both the client and server side. On the server side is the ABB AbilityTM Manufacturing Operations Management (MOM) which is the back bone for the secure data server. This server enables secure communication towards the client side with access to a variety of functions, shown below in red. From a configuration point of view, a new panel or App is added to the client side to configure the interface.

In Figure 5, the MOM server integrates towards the System 800xA Batch Management (shown left) and the smart equipment implementation (shown right). To carry out messaging, back and forth, and in a secure way, OPC UA is used. The MOM server features both OPC UA server and client, and the client is used to send messages to the MES. The OPC server is used to receive messages from the MES.

How plug and produce works in practice

Connecting a new machine to the manufacturing IT system is possible because the machines on the shop floor and the MES software communicate directly via the new standardized message-based interface.

The MES automatically receives all relevant information and electronically executes and documents all production steps. The plug & produce standard interface ensures that the software and the machine speak the same language.

COVER STORY

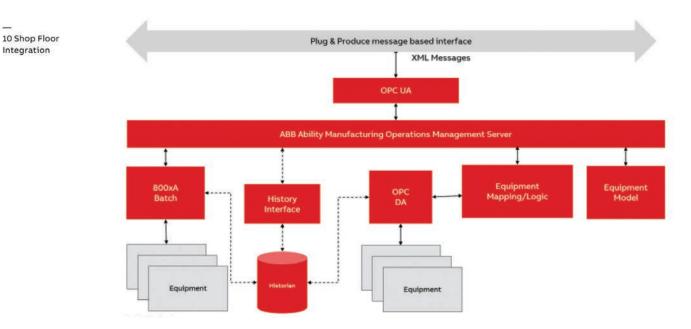


Figure 5.

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The plug & produce solution offers several advantages. The engineering and configuration workloads are significantly lower. Also, far less qualification efforts are needed to satisfy compliance requirements.

Installation is easy and therefore extremely reliable, greatly diminishing the likelihood of set up errors. Finally, project run times are significantly reduced as the MBR design is simplified and can be conducted at an earlier stage. Compared to tag-based communication, a company's workload for integrating a new machine into its production environment will be cut by some 75 percent.

Case study:

Digital plant tackles changing customer demands while reinforces security of supply

Background

A new facility is the first site to use a message-based communications approach that connects a MES to a DCS. Traditionally, the DCS is often isolated within the OT (operational technology) department. Meanwhile, the MES is often isolated within the IT (information technology) department.

A digital factory of the future sees a convergence of the IT and OT systems and departments, such that MES system is successfully connected to shop floor systems in a common way. In a GMP environment this is even an imperative, as data integrity is key for quality production.

Challenge

The facility wanted to avoid the need for the intensive engineering efforts previously required to integrate MES and

automation systems. The facility wanted to move to an MES to meet customer expectations, dictated by industry standards, compliance and operational excellence. Furthermore, the company was seeking a tighter integration between the ERP and the DCS. It was not just a replacement for the paper to tablet solution - which carries no integration instead it wanted a solution that would be fully integrated. Prior to the installation, the company did not have an MES. All MES functions were paper-based and all the control processes were carried out from the System 800xA, straight to the operator control stations.

Solution

The plant connects the Werum IT Solution's PAS-X MES to the ABB Ability[™] System 800xA Batch Management. Together with ABB's expertise in batch production, ABB and Werum are the only companies capable of offering such a solution. Collectively, the entire solution is called "Shop Floor Integration for Life Sciences".

The Shop Floor Integration for Life Sciences solution sends and receives messages from the MES, straight down to the DCS batch system (Figure 11). It shows the configuration featuring one PAS-X MES linked to one ABB Ability MOM server and up to five interfaces towards the System 800xA Batch Management. This provides a regular synchronization between the two systems. Such synchronization is critical as some of the batches run for between one to two weeks. It will transfer data from System 800xA to PAS-X MES such as quality data, set point, consumption or whatever is

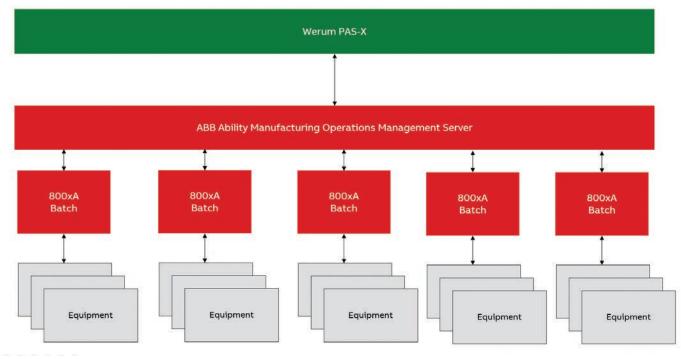


Figure 11.

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needed to report back into the production report.

System 800xA Batch Management is one of the most important applications for the bio-medical industry, enabling the electronic recording of the entire production chain, from raw materials to packaging, ensuring that that client meets stringent requirements for traceability.

Benefits

The Shop Floor Integration for Life Sciences solution prevents production bottlenecks and reduces cycle times so as to lower inventories, free up capacity and increase efficiency.

By fully integrating the MES and the DCS, engineers, shop floor workers and plant management gain from increased flexibility and higher productivity. The integrated solution achieves:

 Standardized and transparent process flow from ERP production order to batch control recipes

 Simplified communication structures between automation and quality management system

 Significantly reduced engineering effort creating recipes and master batch records (MBRs) with upload and synch functionality between DCS and MES

 Higher flexibility to apply changes to the process Ability to connect any equipment to the message bus even based on classic OPC

• Combined/integrated concept for data handling (master data, users, data collection)

For the facility this translates to:

 Significantly reducing the time to market for setting up the new agarose plant

 Improved agility and speed for new product introduction

 Lowering the operation cost by avoiding manual interactions and by automating operations

 Considerable reduction in efforts and cost involved in regulatory compliance and validation

• Using a modern message-based architecture that is designed to be highly secure and reliable

Conclusion

Currently the quality of pharmaceutical processes is achieved. Many production facilities use paper validation, which requires a lot of paperwork and does not provide any digital transparency (e.g. for track & trace). Data is buried in reams of paper.

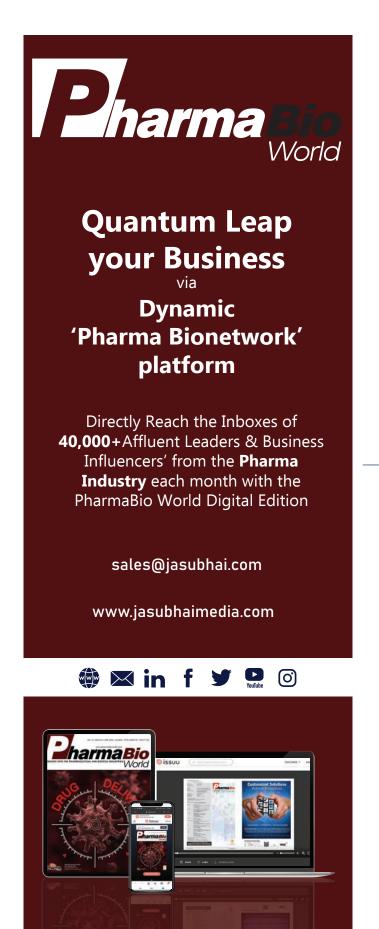
While paper on glass provides a digital storage, it still requires personnel to manually type in data, which was available in digital form before. Tag-based communication takes the data without manual interaction, but is very hard to maintain. It also takes a lot of engineering to set it up and to keep up to date and validated when recipes change.

Message-based communication provides a validated method to relay the information and needs no adaption when recipes need to be altered or changed.

Author

ABB

ABB is a leading global technology company that energizes the transformation of society and industry to achieve a more productive, sustainable future. By connecting software to its electrification, robotics, automation and motion portfolio, ABB pushes the boundaries of technology to drive performance to new levels. With a history of excellence stretching back more than 130 years, ABB's success is driven by about 110,000 talented employees in over 100 countries.



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Journey as an innovative, transformative solutions provider in the global healthcare industry

Silji Abraham, Senior Vice President & Chief Digital and Transformation Officer at West Pharmaceutical Services, Inc., since February 2018 oversees West Pharmaceutical Service's Information Technology (IT) and Enterprise Business Systems organizations. In this exclusive conversation with Pharma Bio World, Mr. Abraham talks about the USP of West Pharmaceuticals and the company's journey as an innovative, transformative solutions provider in the global healthcare industry.



Silji Abraham Senior Vice President & Chief Digital and Transformation Officer at West Pharmaceutical Services, Inc.

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Can you introduce our readers to West Pharmaceutical Services, Inc. and its history?

West Pharmaceutical Services, Inc. ("West") is a global leader in innovative and high-quality solutions for injectable drug packaging, containment and delivery systems. For more than 97 years, we have been a trusted partner to the world's top pharmaceutical, biotechnology, generic and medical device companies, working together to improve patient health worldwide, by creating products that promote efficiency, reliability and safety of the world's pharmaceutical drug supply.

Founded in 1923 by Herman O. West, West's spirit of collaboration, innovation, and partnership are a part of its DNA. In the early years, West produced rubber components for packaging injectable drugs, providing a sterile environment for the producers of penicillin and insulin. Today, West has a strong presence in more than 50 locations, with 25 manufacturing facilities and a diversified global workforce of 8000+ employees across the Americas, Europe, and Asia Pacific. West's 2019 net sales of \$1.84 billion reflect the daily use of approximately 100 million of its components and devices.

In India, West has been operating since 2004 when we opened our commercial office in Hyderabad to serve our B2B customers throughout India. West also set up a 15,300 square meter manufacturing plant in Sri City in 2014 that manufactures various offerings from our product portfolio of seals, elastomeric components, and other offerings in response to regional market demands.

Most recently, in 2019, we established a 17,000 square foot Digital Technology Center (DTC) in Bengaluru that serves as a global center of excellence for the company's Digital and Transformation (D&T) team, alongside teams based in Exton, Pennsylvania, Eschweiler, Germany and Taiwan. This DTC allows our team to create compelling digital experiences for our global customer base across hemispheres, source talent from India's fast-growing technology industry, and bring forward the latest digital advancements to create insights and value for our customers and team membersultimately delivering better business results.

You are responsible for driving a digital transformation at West to improve business performance across the enterprise. Give us a brief overview about your role.

Accelerating digital transformation and, thus, enhancing business performance across the enterprise has been my focal area of expertise at West. Being associated with digitization in multiple industries and organizations over the past 20 years allowed me to learn and refine strategy, tactics and methods for successful digitization. I believe that expanding the company's digital footprint is instrumental in creating a unique opportunity to build tremendous value for our partners on a global scale. A central priority is building a strong IT infrastructure, cyber security, business systems and platforms that provide compelling digital experience to all our 8000+ colleagues, our customers and partners globally.

We methodically approach this digitization journey across 3 logical pillars. These are (1) External Experience, (2) Internal Experience and (3) Digitization of our products.

At an abstract level, this journey is a fusion of science, technology and digitalization to automate and simplify the human to human and/or human to machine interactions to an always contextual and highly effective near real-time for the promotion of effective collaboration and problem solving with precision and speed.

As the Chief Digital and Transformation Officer, what impacts and / or transformations do you see digitization and digitalization making in the healthcare and Pharmaceuticals + Biotechnology industry? Across the world, researchers, scientist and technologist collaborate and partner with a common goal of improving quality of life every day. The global pharmaceutical industry is leading this and hence growing at an unprecedented pace, with no signs of slowing down anytime soon. Though the adoption of emerging technologies in this industry has been traditionally slower as compared to other customer-centric industries, a large number of players in this segment have already put on their "thinking caps." There is a clear recognition of the ubiquitous nature of software, displays and microcontrollers together providing a compelling experience across diagnostics, delivery systems, hospital systems, homecare systems and digital heath systems, to name a few. This reality and other digital opportunities have acted as a catalyst for organizations in creating roadmaps for digital transformation or adopting the various transformative innovations that digitization has to offer.

Digital transformation, for West, is not a term or a business strategy; it is a paradigm shift in behaviour and processes that promotes innovation and new business models, advocating higher adoption of latest technologies to enhance the experience of our employees, customers, suppliers, partners and stakeholders. This transformation encompasses advanced software

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platforms , data integrity, cloud/Edge computing, machine learning, cognitive services, Internet of Medical Things, robotics and many more inventive ways of collaborating and supporting the healthcare industry.

What is the company's current strategy?

The ongoing COVID-19 pandemic has left many regions and countries grappling with immediate, medium-term and long-term impacts. Since West is deemed an essential service provider, our plants around the world continue to operate, largely to schedule, to meet the requirements of our customers. Our immediate priority is to maintain the ability to support healthcare systems globally through undisrupted production and supply of our products. The strong tenants of our market-led strategy and globalization of the manufacturing network are contributing to the resiliency of our business in today's climate.

The growth trends we experienced in 2019 have continued into 2020 and the outlook for the balance of the year remains positive. West sees the trend of growing demand for digitization within the global healthcare manufacturing industry. Digital transformation is a key strategy to enhance customer engagement through digital marketing, digital manufacturing and automations to accelerate internal and external business processes so that West is well-positioned to continue to address increasing customer demand across all locations.

What technologies does West offer, and what makes the company unique?

Our company is committed to advancing our capabilities to meet customer needs not just in India, but worldwide. We are a leading global manufacturer in the design and production of technologically advanced, high-quality, integrated containment and delivery systems for injectable medicines. Partnering with top global pharmaceutical and biotechnology companies, we provide approximately 100 million components and devices to companies around the world.

With an unmatched global business landscape, West has our finger on the nerve of ever-evolving market trends and challenges, and we have responded through continuous innovation in our extensive product portfolio. These include the SelfDose[™] Patient-Controlled Injector and the AccelTRA[®] Components Program.

Further, at West, we understand the impact of digital technology on the way our customers perceive information and conduct business with us, and also on our potential to improve productivities with technology. Our global online store offers customers a one-stop solution to access 66

small quantities of a limited number of West's high-value products. Additionally, we have also created our Knowledge Center, an online repository to provide customers with the latest insights and data relating to the quality and safety of our injectable systems. Our recent acquisition of Exosite LLC's license of certain software technology and solutions aims to further accelerate West's digital transformation initiatives in the healthcare marketplace.

What is your vision for the company, and what are the critical success factors?

We are a critical part of the pharma industry and have been working together with our clients for 97+ years, delivering industry-leading quality to our customers. West as an organization is driven by quality with a patient-first focus that guides our mission and vision. We have a diverse global team with an immense collaborative spirit and a dedication to make a real difference to patients' lives. Believing in and working for the communities where we live and work is what drives our people, with the strong spirit of giving back to the society.

A pioneer in the industry with cuttingedge products to offer to our customers, I envisage West's digitization journey being executed across strong strategic pillars with primary focus on creating unique customer experience, improving the internal experience, and enhancing effectiveness and digitalization of products. We aim to build a distributed multi-geographical platform for subsecond experience around the world for customers. Through the optimum utilization of software and platforms, we are creating value for our customers and stakeholders across Biologics, Pharmaceutical, Generics and Contract Manufacturing segments.

Our first Digital Technology Center (DTC) is a key milestone in our endeavour to stay ahead of the market trends in digital transformation. The DTC plays a pivotal role in the company's ongoing efforts to enhance customer engagement through digital marketing, digital manufacturing and automations to accelerate internal and external business processes. Also, our collaboration with Exosite LLC and opening West's DTC in Taiwan are significant steps in expanding the company's digital landscape.

During the unprecedented global health crisis, our teams are also partnering with a wide range of customers working to support efforts to develop solutions that address the pandemic such as diagnostics, anti-viral therapeutics and vaccines.

INTERVIEW

Which products will be your drivers in the near future?

Our High Value Products (HVP) continue to be the company's growth driver globally, driven by the trends of demand for higherquality products and stricter regulation requirements. HVPs (components and devices) represented 63% of segment sales and generated double-digit organic sales growth in Q1 2020. Also, the proprietary segment saw good demand for Westar®, Daikyo®, NovaPure® and FluroTec® components, as well as for devices such as Daikyo Crystal Zenith® syringes and cartridges and our SelfDose[™] and SmartDose® self-injection platforms.

In India, rapid growth in generics and biosimilars as well as biologics and an increasing demand for combination products is driving the need for innovation and quality in injectable drug packaging and delivery. To address this demand, West has launched its AccelTRA® brand, a new packaging component, for generic drug manufacturers in injectable category. AccelTRA components offer customers a rubber formulation compatible with the needs of generic drug manufacturers seeking quality, speed and simplicity.

Make in India is a major new national program of the Government of India designed to gain momentum for investment, innovation and enhance

skill development and build best in class manufacturing in the country. Your views on how it has impacted Pharma sector in India.

Today, India is the third-largest pharmaceuticals industry in the world by volume. It is a global leader in generics both globally and in domestic markets, accounting for 20% of global exports. Made-in-India drugs supplied to developed nations such as the US, EU and Japan are known for their safety and quality. With annual revenues of about \$38 billion, the industry's tremendous growth can be attributed to world-class capabilities in formulation development, the entrepreneurial ability of the firms, and the vision to establish footprint in large global markets.

In September 2014, the Indian Prime Minister Narendra Modi launched the 'Make in India' initiative with a singleminded focus to make India a global manufacturing hub. Various measures are taken under this initiative to facilitate investment, cultivate innovation and thereby promote a strong business environment in the country. These government initiatives have been imperative to the pharma sector's growth. One example is the FDI policy that allows 100% FDI for greenfield pharmaceutical projects and up to 74% FDI for brownfield pharmaceutical projects. Total foreign

INTERVIEW

direct investment in the drugs and pharmaceutical sector in the country rose to INR 2,065 crore during the April to September period of fiscal year 2019-20.

Additionally, reduction in approval time for establishing new facilities has boosted investments. It enabled West to scale up our Indian manufacturing operations for the domestic market as well as for exports. As part of 'Make in India', pharma/ biotech parks across different locations in the country in partnership with state governments have been established, and in 2019, the Central Drugs Standard Control Organisation (CDSCO) amended the 'clinical trial rules' that streamlined the clinical trial process to accelerate drug approval and favor domestic and international pharma companies.

The pharma sector is a sunrise industry, with a competitive advantage for India. Healthcare in India is on the verge of significant transformation - demographic, regulatory, technological, and financial. Therefore, it is crucial that we leverage the country's global position by giving a free rein to entrepreneurial spirit through policy stability and ecosystem. Private Indian healthcare providers are contributing towards the country's economic growth by creating employment opportunities, attracting medical tourism, enhancing delivery care with the adoption of digital innovations, and promoting the trend of patient-centric care and service.

With the world under siege and a country-wide lockdown due to COVID-19, the lives & economies are going through tough time. What is your message for boosting Pharma and Healthcare Sector to emerge through this tough time?

The impact of the COVID-19 pandemic is being felt across the world by people in their personal and professional lives. Given the magnitude of this virus, I expect that post-COVID-19 era may witness most countries' global commitments and priorities stressing greater public health security for its citizens.

Once the pandemic wanes, India's existing advantage of large-scale pharmaceutical production can be significantly leveraged to promote further inward development as well as outward growth of the healthcare sectors of other nations. This entails boosting exports in pharmaceutical products and stimulating medical tourism in the country. An important aspect for the Indian pharma and healthcare sector to emerge in the forefront lies in its capability to pursue medical diplomacy -to provide medical training and technical expertise to other developing nations whose healthcare systems trail behind that of India. To this end, it is vital for our global diplomatic priorities and commitments undergo a radical acclimatization, starting from regional to international channels.

Government has taken cognizance and has passed the Bulk Drug and Medical Devices policy which focuses on increasing the domestic manufacturing of APIs/KSMs.



Managing the risk factor from over reliance on Chinese resources

COVID 19 pandemic posed unprecedented challenges including the realisation that many of APIs coming to India are from a single country source. However, the Government took cognizance of the issue and has passed the Bulk Drug and Medical Devices policy which focuses on increasing the domestic manufacturing of APIs/KSMs. The approved scheme will

Sudarshan Jain

Secretary General, Indian Pharmaceutical Alliance (IPA); Senior Advisor, APAX Partners, India; Visiting Faculty, Indian Institute of Management (IIM), Ahmedabad; Formerly Managing Director, Abbott Healthcare Solutions, India Board member, Healthcare and Education Sector

promote Bulk Drug Parks for financing common infrastructure facilities in three Bulk Drug Parks with the financial investment of Rs. 3,000 crores in the next five years. Additionally Rs 7,000 crores have been allocated for Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical KSMs/Drug Intermediates and APIs in the country. Going forward, the execution of the policy on the ground will be important to accelerate the 70

process, and this step over a period of time will help reduce reliance on - imports from China.

Necessary steps/stages for India to aim for being the hub for end-to-end drug discovery under its 'Pharma Vision 2020'

Three key areas that will enable a resilient Indian Pharma industry would be to launch policies to increase investment in innovation by enhancing scope of government incentives for R&D;, 200% weighted deduction on R&D expenses to increase thrust of the companies on novel research and drug discovery programs and incentives on exports.

Being pandemic ready if a situation arises the next time around.

Boost domestic production of medicines by streamlining policy framework, implementing streamlined and accelerated regulatory and testing pathways, for all drugs (including COVID-19), enhance overall innovation / R&D to provide a longterm thrust to Indian Pharmaceuticals and strengthening API API/KSM domestic manufacturing. Likewise, access to low cost capital, ease of doing business especially in environmental clearances and reforms in price control are also imperative to expedite the achievement of self-reliance and ensure the Pharma industry's invulnerability.

Healthcare sector creating value to society

The Healthcare and Pharmaceutical industry rose to the occasion to address the various challenges and worked in tandem with various stakeholders including the Government to ensure an uninterrupted supply of medicines in India and across the world. IPA is committed to an uninterrupted supply of quality medicines to patients in India and globally. We take pride in being of service to the nation and the world at this time.

Creating world class talent in the domains of both knowledge and manufacturing for the pharmaceutical and biotechnology

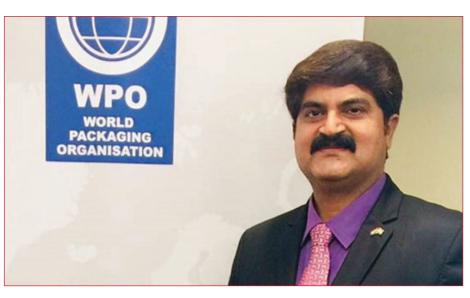
Indian pharmaceutical industry has been playing a key role in improving access to affordable medicines in India and across globe from last few decades. Up skilling the talent pool in pharma sector will be key to its growth and make the sector future ready. Digitization and technology advancements are taking place rapidly in Pharma operations and companies are increasingly engaging in digitization and automation to transform quality control work in the lab and on shop floor by introducing new ways of working. COVID 19 pandemic has further accentuated the digitization aspect. With the restriction in headcount at the workplace, emphasis is to maintain the productivity. This will see massive and rapid adoption of automation. Hence, need is to focus on upskilling and re-skilling in automation.

Secondly, as industry's product portfolio shifts towards more complex products, the demand for operations and highly skilled personnel for the manufacture of these products will also increase. There is a limited supply of experienced talent for such operations. Industry-Academia collaboration will be important. We have taken this up and working to make the talent future ready.

Chakravarthi AVPS

Global Ambassador - World Packaging Organisation

"The Indian packaging industry is doing their best and we do not have to import a lot from the other countries to meet all the requirements of pharmaceutical sector especially when we talk about various kind of packaging requirements."



Chakravarthi AVPS, Global Ambassador - World Packaging Organisation, is the first Asian to be appointed as global ambassador. With an experience of over three decades in printing and packaging field Chakravarthi has been actively associated with Packaging activities, worldwide for a long time and has been on management committees of various national and international organizations. Chakravarthi is Managing Director of Ecobliss India, a company that offers innovative packaging solutions.

Srinivasa Chary Dingiri

Vice President-Business Development, Innovare Labs Private Limited

"The R&D efforts need to be encouraged. Investments has to be channelized to build global level capacities and competencies. Unless we derive the economies of scale it is very difficult to stop our dependence on imports."



Srinivasa Chary Dingiri, Vice President-Business Development, Innovare Labs Private Limited, is an experienced Business Development professional with 20+ years in the healthcare and pharmaceutical industry. Currently actively involved in preparing business plan for Start-up Company and executing go-to market strategy.

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Avoiding bad investments: Future-proof blister packaging machines

The modern servo technology that enables flexible and economical system designs provides individual solutions that allow for future modifications and upgrades with no problems. Mediseal GmbH, an internationally active company specializing in the development, design and manufacture of blister, stick-pack and sachet machines, cartoning solutions and entire packaging lines for the pharmaceutical and cosmetic industries talks about the focus on meeting customer requirements for pharmaceutical safety, technologically mature systems and economy.

Solida and parenteral blister packs are often produced on monobloc machines designed for specific applications. Format changes are complex and expensive procedures. In packaging medication, the pharmaceutical industry must not only meet the highest quality standards, but also increasingly cope with

minimal production times, and so be able to use packaging systems very flexibly. This demands new machine designs, so Mediseal GmbH has developed a flexible blister and cartoner machine portfolio based on a modern modular system. The future-proof Blister Expert platform makes it possible to configure a machine for a



Solida and parenteral blister packs are often produced on monobloc machines designed for specific applications. Format changes are complex and expensive procedures. In packaging medication, the pharmaceutical industry must not only meet the highest quality standards, but also increasingly cope with minimal production times, and so be able to use packaging systems flexibly. Source: Tim Reckmann / pixelio.de, stux / pixabay.com

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Mediseal GmbH has developed a flexible blister and cartoner machine portfolio based on a modern modular system. The future-proof Blister Expert platform makes it possible to configure a machine for a specific need by choosing from among multiple modules, and assemble the machine immediately using these pre-produced components. Source: Mediseal GmbH

specific need by choosing from multiple modules, and assemble the machine immediately using these pre-produced components. Special components and modules can also be designed and built. By switching out and/or adding modules, a Blister Expert machine can be comprehensively modified at a later date to address new products or future challenges. The only real limitations are the available space and the predefined interfaces.

Blister packs are used in the pharmaceutical industry typically to package individual doses, especially of solida like tablets and capsules, as well as parenterals in ready-to-use hypodermics, ampoules and the like. "Many manufacturers offer monobloc machines for this purpose, which users purchase for a specific application," explains Ulf Leineke, Director R&D at Mediseal GmbH, a company in the Körber Group with over 11,000 employees worldwide. If requirements change, these machines are all equipped to be easily modified. Typically it requires a lot of engineering effort and consequent down time. But in many cases, it cannot be modified at all or only with great effort. In many cases, it then becomes necessary to buy a new blister machine."

With the 100% modular Blister Expert platform from Mediseal, which includes

FEATURES

blistering as well as cartoning solutions, this is no longer necessary. "In a modular system, existing machines can be adapted to meet future needs, since their functions can be altered within the limitations of the available space and previously defined interfaces," according to Ulf Leineke. "For example, if there is an innovation in the sealing function after the machine is taken into production, the old module can be replaced with a new, improved version, since both are designed to be interchangeable." This lets manufacturers address the ever shorter innovation cycle times in the pharmaceutical industry.

74 Retrofit capability including extending machines in the field

For companies such as contract packagers, whose dependency on orders means they cannot predict their needs years in advance, the ability to purchase options or modules later provides a high level of future safety. This can be illustrated with an example from ampoule packaging. Normally, ampoules are presented in blister packs without needing to be sealed by a lidding foil. With a modular system like the Blister Expert platform, a company that takes in such an order can acquire a machine specifically for this purpose. The company doesn't need to include the components necessary for sealing with lidding foil.

However, if a later order requires lidding



By switching out and/or adding modules, a Blister Expert machine can be comprehensively modified at a later date to address new products or future challenges. The only real limitations are the available space and the predefined interfaces.

Source: Mediseal GmbH

foil sealing, for example due to subsequent sterilization, a sealing station can be added. Standardized modular attachments even let the machine be expanded in the field. "This makes it possible to separate the blistering machine and cartoner, and insert another module between them," explains Stefan Kemner, System integration & Portfolio manager at Mediseal GmbH. On conventional nonmodular blister machines, the inability to retrofit presents companies with the need to cover possible future requirements at the time of purchase by including expensive functions that they may not end up ever using.

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The modular system helps keep machine downtime to a minimum. When changes need to be made, replacing old modules with new ones or retrofitting others significantly reduces validation effort. The pharmaceutical manufacturer doesn't need to revalidate the entire machine, just the new module. Source: Mediseal GmbH

Shorter delivery times through configure-to-order

Building blistering lines with a modular design has other advantages. With the Blister Expert platform, it enabled Mediseal to implement a full configureto-order approach. "The customer gives us basic information which we enter into a configurator, for example which solida and/or parenterals are to be packaged, and what performance category is needed. The customer can then choose from among various package options, for example optimizing the machine for easy conversion, ergonomics or productivity," explains Stefan Kemner. "This configures the system exactly for the target product." The configurator identifies the necessary modules, and based on this information the production order is placed. Mediseal then sources the necessary components or assembles premanufactured modules. This differs from the conventional process, in which a designer first brings together the individual parts and assemblies based on the customer order, and the production order is then prepared from that. This step, which is costly and error-prone, is eliminated in the Blister Expert system. Furthermore, any Mediseal cartoning machine can be configured downstream of the blister machine, unlike many other systems where only one cartoner fits the chosen blister machine.

In addition, Mediseal can build special systems. "For example, if a customer wants a UV disinfecting station or another option that we haven't yet included as a standard component in our module pool, we'll develop the necessary element," says U. Leineke. "We can do this because either there is the space for it at the proper point in the machine we already configured, or we simply extend the machine length a little." While the additional module is being designed, the standard modules are already in production so the system as a whole can be taken into operation sooner.



76 Foil rolls can be replaced on the fly without needing to stop the machine. Source: Mediseal GmbH

Modularity for less downtime

At the same time, the modular design helps keep machine downtime to a minimum. When changes need to be made, replacing old modules with new ones or retrofitting others significantly reduces validation effort. "The pharmaceutical manufacturer doesn't need to revalidate the entire machine, just the new module," explains Ulf Leineke. "Thus, during upgrades, the machine is out of use for much less time than systems that do not use a modular design." Furthermore, if a machine in use malfunctions because a component is defective, with a modular system it can be replaced by a module that the machine manufacturer has previously

fully commissioned. By contrast, with conventional blister packaging lines, it is usually necessary for a technician to take the machine apart and determine which parts are affected. Typically, only then can the necessary parts be drawn from stock, which takes much more time.

The Blister Expert Platform helps reduce downtime in another way as well. Mediseal's solution is designed so that a format change needs no tools, and only a few light parts need to be switched out. This noticeably reduces format changeover time. The ergonomics have also been improved. The design works mostly with curves and rounded edges and avoids corners and angles. This makes cleaning much faster, for example during

FEATURES

a line clearance or product change. By reducing dirt traps, it increases machine availability.

Compatibility with Pharma 4.0

The Blister Expert system is ready for Pharma 4.0. For example, a predictive maintenance package is available that shows the user the regular maintenance intervals as well as immediate needs, such as when wear parts like the suction cups on the suction wheels no longer function well and need to be replaced. If there are frequent changes in format or operating personnel, the Guided Format Change option is recommended. This features augmented-reality goggles that guide the operator through the format change step by step, showing the operations on the goggles' display. Mediseal's proprietary HMI used to operate the Blister Expert series is also very user-friendly. The user interface is reminiscent of a smartphone, and is based on self-explanatory symbols and graphics, with task-oriented jobs that can be individually adapted. "The production manager is presented with pre-programmed elementary actions, and can assemble them into a job by dragand-drop," says S. Kemner. "Additional actions can be entered or defined as well." This intuitive structure prevents errors and incorrect machine operation, especially if the guided mode is used.

In addition, the machine can be equipped with all-digital interface solutions that let

machine data be provided to Level 2,3 and 4 systems in a standardized manner. Thus, in plug-and-produce scenarios, monitoring systems present at the site can capture machine status in a standardized way, so that the company can better asses the condition and productivity of its machines, and perform maintenance as needed. "Within our company group, there is also the option of equipping the entire line with a line manager called – LION. This provides a consistent data flow for the blister and cartoning machines, and can incorporate a third-party scale and bundle packer," explains Stefan Kemner. "This enables guided format change on the third-party machines as well." Thus, the Blister Expert platform provides a high degree of future safety in blister packaging for many years.■

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Breakthroughs in Medical and Pharmaceutical science



Dr. Uday Saxena

PhD, Reagene Biosciences Private Limited

The practice of health and medicine is changing fast. There are increasing frequency of global crises that would lead to wide scale disturbances and force healthcare leaders to collaborate and deliver health solutions that are truly global. The current pandemic being one such instance.

Imagine the future of health innovation and factors that could determine its success or failure. Sequencing of the first "working draft" of the human genome was one of the greatest scientific breakthroughs in history and has made possible a string of transformative subsequent discoveries.

What are the current technological advances that are bringing in the change? What will the next decade bring? What are the envisioned medical discoveries and technological trends that will change the landscape of health innovations?

A decade or two from now, in the wake of the changes that may or may not happen, what are the impacts that will influence the pharma and biotechnology sector?

Dr Uday Saxena, an experienced drug discovery scientist who has held several executive positions in the pharma industry in his new column series "Breakthroughs" will expound on various innovations in the sector and how they impact lives.

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BREAKTHROUGHS

S ince the 1800's to now, 2020, there has been almost a 100% increase in human longevity (average worldwide longevity was 35 years in 1800 to currently it is about 70 years). Why has this happened? Is it just a normal case of evolution, adaptation and accompanying increased survival? I am afraid that's not the likely reason!

In the 1800 and 1900's the majority of deaths worldwide used to be due to infections and epidemics and pandemics. Now less than 20% of people die of infectious diseases and more die of chronic life style disease like cancer and cardiovascular disease. So, what has changed now? The big change in longevity is because of the advancements made in medical and pharmaceutical sciences. Most pandemics have been eradicated due to vaccines and other methods. Even in the incidence and deaths due to cardiovascular disease (heart attack and stroke) there is a continuing decrease due to new medicines, surgical procedures and devices that can treat, detect and prevent the disease much better than the last few decades.

So clearly medical and pharmaceutical breakthroughs have made a very

significant contribution to help improve human life and longevity. The breakthroughs have come from both academic and Industry scientists' efforts. While academia pursues ideas for the pursuit of knowledge, the industry aims to translate the ideas into products. Interestingly most breakthroughs are now coming from start -ups whether as spin offs from academia or entrepreneur-initiated companies.

The breakthroughs have come in many forms from early stage discovery of antibiotic penicillin to modern day spectacular CART technology to fight certain cancers. The core of all this is a mindset of innovation, betterment of human life and of course business opportunities. Innovation can come in many forms from finding a new drug to optimizing the process chemistry to make the drug itself so that it is scalable and cost effective. Even incremental innovation can be termed as a breakthrough if it ultimately helps the patient improve quality of life and longevwwity.

There are many contributors to betterment of human health from physicians, pharmacologists, organic

BREAKTHROUGHS

PHARMA BIO WORLD

and process chemists just to name a few. India has had a major role to play especially in making medicines more affordable globally. From making generic drugs to manufacturing vaccines, vast majority of innovations have come from Indian pharma industry and it has become the dominant player in these areas. This has happened because of their understanding that innovation can either be applied to discovery of new medicines which is expensive, risky, time consuming and uncertain OR to make existing medicines affordable (generics) by devising new chemical process to synthesize the drugs at lower cost, i.e. the lower hanging fruits. This is a classic example of understanding the global business scenarios and playing to your strength to compete. This also shows that breakthroughs are not just limited to novel drug discovery but can also present themselves - for example in the form of new process chemistry being applied to make the drug synthesis faster, scalable and cheaper.

In this new column being introduced, which will appear regularly in this magazine we will highlight breakthroughs that have made human lives better either through cutting edge science for novel drugs or using innovative ideas to make them more affordable.

The overall idea is to give the readers a flavor of how breakthroughs in pharmaceutical research has extended human longevity through the years and continues to do so.

The first column in this series will be focused on Type 2 diabetes, the silent Indian endemic — the causes of this disease, the treatment options and showcase new technologies for detection and treatment of this global problem. ■

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The Evolution of Law and Ethics in Pharma Sector: Tracing the Indian Context - Part I

In the previous editions, the author has dealt with the impact of clinical studies that were carried out on humans without gaining their consent. After a close scrutiny of the evolution of international norms pertaining to legal ethics in the pharma sector, here is a new series that recounts the position in India.



Mr R. S. Raveendhren

Advocate, High Court of Madras & Legal Expert in the Institutional Ethics Committee of SRM Medical College Hospital & Research Centre.

Medical Ethics in Ancient India:

Medical ethics has always been considered as an integral part of our moral philosophy. The ancient Tamil literature Tirukkural that was written 2000 years ago by Sage Thiruvalluvar also talks about ethics in medical practice.

"Let the physician enquire into the (nature of the disease), its cause and its method of cure and treat it faithfully according to good medical practice." (Couplet 948)

Ancient healing practice:

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Ayurveda is of the ancient healing practices that originated about 5000 – years ago. 'Ayurveda' means the 'science of life'. It is unanimously considered to be the mother of all healing systems and has its source in the Vedas. The three scholarly texts by Charaka, Sushruta and Vagbhata may not have a separate section that is dedicated to ethics but an ethical undercurrent indisputably runs through the texts.

- Charaka who is also called the Father of Indian Medicine is one of the pioneers of Ayurveda. His 'Charaka Samhita' stresses on the need for a healthy lifestyle to prevent diseases. The code of conduct for physicians was spelt out in the Charaka Samhita itself.
- 2. Sushrutha, another well-known physician in ancient India is also the

author of one of the world's foremost text on Plastic Surgery that goes by the name 'Sushrutha Samhita'

3. Vagbhata wrote the famous treatise 'Astanga Hrudaya' Vagbhata believed that "all activities of man are directed toward the end of attaining happiness. Happiness however is never achieved without righteousness. It is the binding duty of man to be righteous in all his action."

Presence of Code of Conduct:

From what is accessible, there is enough evidence to pin that:

- History was taken down with utmost care from the patient, his family and also the messenger of the news;
- Only after a thorough diagnosis was done, the physician would be in a position to decide further course of action;
- The Ved or the doctor was under strict obligation to inform the patient and his family about prognosis and before the treatment.
- If the medical procedure contemplated was considered dangerous, the physician was duty bound to obtain royal permission in advance. Chanakya's political and administrative treatise called the 'Arthashastra' prescribes death for a physician



who undertook surgical procedures without seeking prior permission from the king and that which lead to the death of his patient.

As can be inferred, the principles of ethics in the field of medicine in India carried the quintessence of ancient wisdom. It will not be wrong on our part to think that modern developments have only fortified the timetested principles of the ancient in a way expanding their scope and codifying them.

Medical Ethics in Modern India:

A lot of medical developments happened during the early 1900s. The most remarkable one was the discovery of the carriers of Malaria by the Ronald Ross, a British scientist who was born in India. Modern India saw the setting up of some of the pioneering institutes, viz., Plague **Research Laboratory** in Bombay, the King Institute in Madras, the National Institute of Nutrition in Hyderabad and the Virus Research Centre in Pune.The Indian Research Fund Association was also established in the year 1911 which was later rechristened as the Indian **Council for Medical** Research (ICMR) in 1949.

The role of ICMR:

The ICMR is an autonomous body funded by the Government of India through the Department of Health Research, Ministry of Health and Family Welfare. It is the apex body to formulate, conduct, coordinate and promote biomedical research in India and it is one of the oldest medical research bodies in the world. Its mandate is to undertake and support all kinds of research whether it is basic, applied, epidemiological oroperational in areas of national public health.

First Policy Statement on Biomedical Research:

The ICMR brought out the first policy statement on biomedical research in February of 1980 as 'Policy Statement on Ethical Considerations Involved in Research on Human Subjects' for the benefit of all those involved in clinical research in India. It was used as a guide not by ICMR alone but also by other governmental and non-governmental research institutions.

Chronology of Events that Influenced Indian Policymaking:

1982 - WHO and CIOMS (Council for International Organisations and Medical Sciences) issues a 'Proposed International Guidelines for Biomedical Research Involving Human Subjects'.

84 1991 - CIOMS follows it up with
"International Guidelines for Ethical Review in Epidemiological Studies"

1993 – There is yet another report from their desk called the 'International Ethical Guidelines for Biomedical Research involving Human Subjects'.

1997 - UNESCO brings out a document on ethics called 'The Universal Declaration on Human Genome and Human Rights'

2000 –The ICMR revises guidelines on biomedical research requiring all institutions that carry out any form of biomedical research that involve human beings to follow its guidelines in letter and in spirit to protect the subjects. It also requires that any proposal on biomedical research involving human subjects be cleared by the Institutional Ethics Committee (IEC). 2003 - 'The International Declaration on Human Gene Data' is brought out.

2005 – The 'Universal Declaration on Bioethics and Human Rights' sees the light of the day.

India as a clinical trial hub:

The new millennium saw rapid advances in the field of genetics and molecular biology in India. However there was laxity in formulating stringent protective mechanism for the human participants that were subjected to biomedical research. The fag end of 2004 saw several pharmaceutical companies setting up shop in India and exploring clinical trials. India seemed to be a good place for them because it had a lot of population with majority of them from lower incomes and a pronounced inefficiency in enforcing regulations concerning biomedical research. The ICMR since has come a very long way from being a policy making body to a responsible institution.

(To be continued)

In the next edition the author proposes to deal with the role of ICMR in detail and the events and disputes that have moulded it into a game changer.

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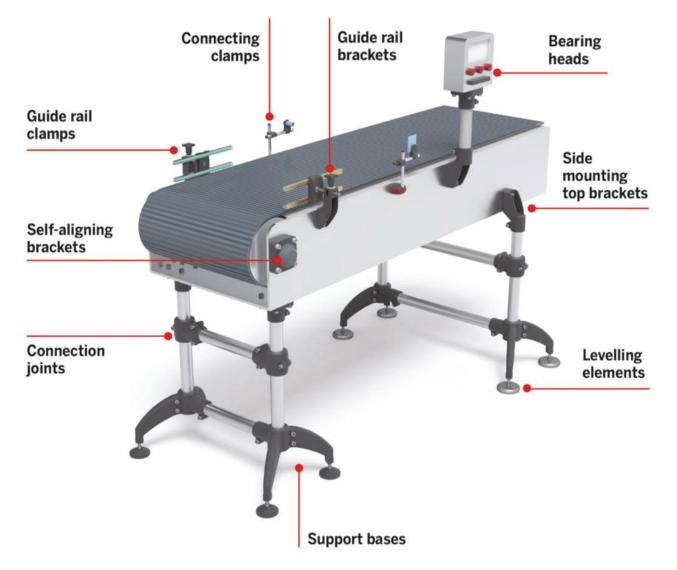
New range of components for conveyors

he new range of conveyor components allows the creation of support structures for production lines in diverse industrial sectors, such as bottling, packaging and material handling.

To the already available range of supports and guides, rail brackets and clamps, support bearings and connection joints, Elesa+Ganter now offers new roller sides and central guides, linear guide rails, also with shaped profile and a series of accessories.

The side and the central guides together with the articulated side guides have polyethylene based (PE) technopolymer, grey colour rollers.

GLA (side guides) and GCA (central guides) series are available with anodized aluminium body, acetal resin based (POM)



technopolymer support and AISI 304 stainless steel pins.

The articulated side guides GLB-1 and GLB-2 are modular self-supporting structures for the side guide of products on conveyor belts. The body is in acetal resin based (POM) technopolymer and the pins in AISI 304 stainless steel. These guides are also particularly suitable for use in environments in the presence of liquids, subject to frequent washing or in filling areas. The joint in the roller side guides allows an external curvature radius 500 mm, internal curvature radius 350 mm.

For all standard solutions, rollers can be with spherical contact area, for the guide of products in cans or in plastic containers; cylindrical rollers, for the guide of cardboard products; rollers with cylindrical contact area, for the guide of glass products. The guides are available single or double, suitable for side guide of products with limited or important vertical dimensions.

The linear lateral guides, GLP, GLR and GLT series are used for the side guide of products with different dimensions on conveyor belt. Brackets are in AISI 304 stainless steel; the guide profile in polyethylene based (HMWPE) technopolymer, natural colour.

The natural colour of the material leaves no traces on the containers, while the stainless steel inserts (pins, screws and nuts) guarantee a high corrosion resistance.

The linear lateral guides are characterised by a high wear resistance and the

low coefficient of friction makes them particularly suitable for high-speed movements.

GLP-HT series in polytetrafluoroethylene based (PTFE) technopolymer is designed for environments where resistance to higher temperatures is required, such as ovens, fryers, steam chambers.

GLS linear guide rail with shaped profile in polyethylene based (HMWPE) technopolymer, natural colour and AISI 304 stainless steel support, together with GLC series with shaped profile in black colour, are suitable for the side guide of products with different dimensions on conveyor belts, even vertical.

The range is completed by a series of accessories, including closing caps, separation blocks and technopolymer supports, as well as stainless steel profiles.

Once again Elesa+Ganter proves its attention in the customer care, offering a wide variety of components with all advantages of being standard.

Product technical data sheets, along with drawings and tables with codes and dimensions are available on the website www.elesa-ganter.in

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Conserve Precious Samples and Save Costs with the Newest METTLER TOLEDO XPR **Analytical Balance**



xpensive, rare or toxic substances must be used sparingly. To conserve them, you need to be able to weighout very small samples with a high degree of accuracy. The innovative design of the new XPR Analytical balance simplifies sample handling and helps you ensure right-first-time results, even at the lowest minimum weights.

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can be weighed on a balance within the uncertainty range becomes crucial.

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Selecting the right balance is crucial

IMPACT FEATURES



With the new XPR Micro-Analytical balance from METTLER TOLEDO, it just became even easier to conserve materials, ensure accuracy, and save costs in your lab.

to choose the balance that meets the requirements for accuracy, conformity and quality. Our GWP® Recommendation service is available free of charge around the globe. GWP® is a unique scientific approach linking customer process requirements with a suitable balance selection that includes concrete maintenance recommendations to keep it accurate. This gives the certainty that the selected balance complies with necessary regulations and is a fit for your environment. Discover how easy it is to ensure accuracy, reduce waste and save costs—even when working with your smallest samples. Check out the new XPR Micro-Analytical balance from METTLER TOLEDO today. ■

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Taking Innovation to the Next Level: Introducing UVC Lighting Technology for The Healthcare Sector In India

J Group, a pioneer in the hospitality and healthcare sector has introduced a wide product range with UV-C



Disinfection system, which has been validated to effectively inactivate SARS-CoV-2, the virus that causes COVID-19. The company has taken a fresh approach by offering

Piyush Agarwal CEO, RJ Group of Companies

products that are designed with UV-C light sterilization technology. The product is especially curated for healthcare facilities.

RJ Group has ensured strict quality control on every single product. All its products are 100% designed from the homegrown tested technology with ISO certification to manufacture UVC systems and the testing report generated from Haffkine Institute. Made in India, this new product is another step in the company's support to the government's call for 'Aatmanirbhar'. The UV-C technology in this is designed in accordance with the norms suggested by medical and research bodies to disinfect surfaces from germicidal bacteria. The UV-C light is germicidal – i.e., it deactivates the DNA of bacteria, viruses and other pathogens and thus destroys their ability to multiply and cause disease. Thus, when the organism tries to replicate, it dies.

To meet the growing demand for products in the health security space, RJ Group has developed this defense range for fighting efficiently against COVID-19. UVC disinfection is often used with other technologies in a multi barrier approach to ensure that whatever pathogen is not "killed" by one method (filtering or cleaning) is inactivated by another (UVC). In this way UVC could be installed now in clinical or other settings to augment existing processes or to shore up existing protocols where these are exhausted by excessive demands due to the pandemic. These devices actively reduce the bacterial and viral charge of the air in closed environments. This truly innovative design can provide fast sterilisation for hospitals and clinics by illuminating the pathogens from air and surfaces around/in rooms and personal protective equipment.

Mr. Piyush Agarwal, CEO, RJ Group of



Dev Anand Director - Marketing, RJ Group of Companies

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Companies, said, "As India is uplifting lockdown in phases across the country and people resume work in the 'new normal', health security has become a priority for everyone.

COVID-19 infections can be caused by contact with contaminated surfaces we are all aware of this fact. Thus, minimizing this risk is key because COVID-19 virus can live on plastic and steel surfaces for up to 3 days as per the research. Normal cleaning and disinfection may leave behind some residual contamination, which UVC can treat suggesting that a multiple disinfectant approach is prudent. UVC has been shown to achieve a high level of inactivation of a near-relative of COVID-19's virus. By its usage, we are not only eliminating the viruses that are responsible for this pandemic but also creating a future safety net of protection for possible stronger viruses that could affect life."

Mr. Dev Anand, Director - Marketing, RJ Group of Companies commented, "Today, there is a rise in the demand for disinfecting products in the market and being a pioneer in the segment with over two decades of experience with a highly skilled team; it was incumbent on us to launch products that can help our countrymen in this fight. UVC technology used in our products helps effectively to disinfect surfaces from germicidal bacteria that fuel the growth of viruses. We truly believe in Aatmanirbhar, thus we are heavily relying on homegrown technologies, talents and our inhouse R&D to create world-class products. UV-C based Disinfective systems will be effective Disinfectants for Most types of Virus and Bacteria's. These products are made with utmost safety to Human, Long Lasting Usage and Economical. We will reach across all the local Hospitals and Hospitality industry to equip them first. Then we will plan on the national and global expansion."

Since its inception the RJ Group has always been at the forefront of designing innovative products for the healthcare and hospitality sector. As we are entering into a new era, the company ventures into this new segment by extending its support to the government by supplying UV-C products. Furthermore, they are also planning to install UV-C light systems at hospitals, hotels, airports, malls, theatres, schools, restaurants, public toilets, corporate houses and residences.

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R J Group Website: rjgroupindia.net



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