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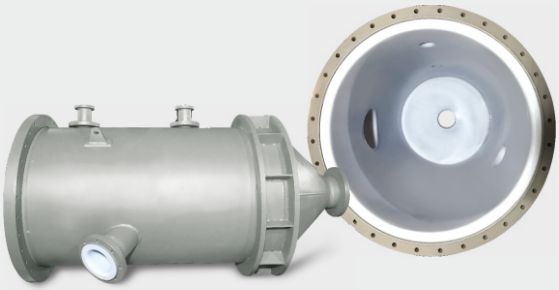


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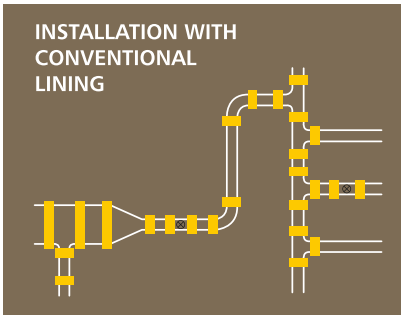

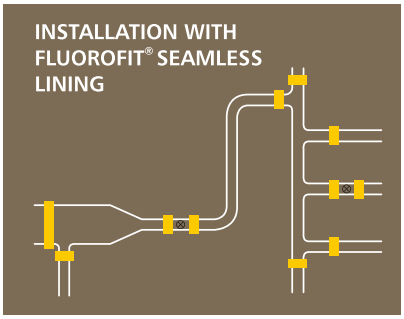

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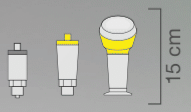

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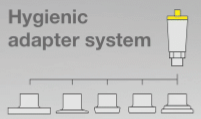

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Find a Viable Strategy to Maintain the Current Dominance and to Create Drugs that could help the Nation.

Mr Srinvas Lanka has worn many hats — Mentor, Industrialist, Corporate Boards and Government Initiative. He has played a major role in building India's mega pharma corporates like Sun Pharma, Aurobindo Pharma and held C-level positions in Novartis, Roussel, Ramky Group, etc. He has led over 100 mergers & acquisitions deals in pharma and biotech space and has bought over 25 entities globally and integrated them successfully into the mainstream of the organisations with zero failure.

As the former Chief Mentor of Prime Minister Bharatiya JanAushadhi PariYojana (PMBJP), Mr Lanka has been championing the cause of providing quality generic medicines at affordable price. Mr Lanka currently is a senior advisor & mentor for Pharmexcil, Ministry of Commerce - GOI, Mentor for scientific institutions like IICT & NIPER and Advisor to GoAP.

Mr Srinivas Lanka in his guest edit column for the anniversary edition celebrating Make in India, talks about the journey of the Indian Pharmaceutical Industry post-independence and how crucial it is to find a viable strategy to maintain the current dominance and to create drugs that could help the nation.

Mr Srinivas Lanka

Former Chief Mentor of Prime Minister Bharatiya JanAushadhi PariYojana (PMBJP)

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The Indian Pharmaceutical Industry – Post Independence to 2005

The Indian pharmaceutical industry is valued at approximately USD 40 Bn. India is an acknowledged leader on several fronts – be it the number of DMF filings, volumes of formulations exported, or the number of facilities inspected by USFDA. There is plenty to be proud of for our achievements, but also, a long road to travel before we can genuinely bask in our glory.

At the time of Independence, western MNCs controlled the pharmaceutical market, and it was heavily import-dependent. This led to medicines becoming unaffordable and among the priciest in the world. The Government of India set up Hindustan Antibiotics Limited (HAL) in 1954 to undertake commercial production of antibiotics like Penicillin, Streptomycin, Amoxycillin, among others. IDPL (Indian Drugs and Pharmaceuticals Limited) was set up in 1961 with a view of making our country self-sufficient and supply affordable medicines to the masses. The Government stressed the need to be self-reliant and the importance of domestic production, thus giving much-needed impetus to the industry. This decade also saw several new laws and regulations that supported the growth of the domestic industry. Manufacturers were encouraged to undertake end-to-end production of drugs, with clear guidelines for over 175 products.

The result was a pharma industry that could produce high-quality drugs at low prices. Within a matter of a few decades, India became self-sufficient in formulations manufacture, and almost self-sufficient in bulk drugs.

Pharmaceutical Industry undergoes change – some not so good

The Drug Price Control Order passed in 1970 ensured fair prices for most medicines, however, this meant that pharmaceutical companies operated at razor-thin margins. The country as of 2005 had more than 20,000 firms engaged in pharmaceuticals formally and informally as compared to around 2000 in 1970.

With razor-thin margins and high competitions, several companies started to look for ways to increase their profits. Companies began moving up the value chain and began outsourcing lesser profitable steps of the value chain.

The country also faced several other issues like an erratic supply of power and water, excessive government interference, cumbersome regulations and numerous laws that made doing business difficult. Eventually, most companies looked for offshore partners that could cater to their needs, at lower prices and higher reliability. This meant several therapeutic areas moved out of the country. Ironically, Fermentation, one of the first therapy areas to be researched, was also one of the first to leave the country.

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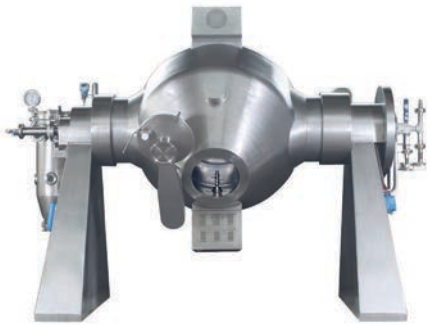

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Fermentation plants require a continuous source of power, water and vast tracts of land. Unable to procure these in the motherland, the technology and manufacturing shifted overseas. Several other technologies and manufacturing facilities were outsourced for similar reasons. PSUs were close to bankruptcy, and hence there was no innovation. Institutions were no longer working in tandem with the industry. This resulted in publications and patents that could not be licenced, which had no participation or correlation with industry success.

MSMEs suffered as there was no diffusion of technology from either the PSUs or government labs. They also had smaller budgets to cater to R&D. The larger companies shifted their focus to exports, marketing, patent wars and distribution.

The total of all these causes affected the chemistry expertise of the country—insignificant success in core novel chemistry, competitive chemical engineering and biology. By the end of 2019, India was importing more than 60% of its API and Intermediate needs from China. This has caused significant reason to be alarmed, and an urgent need to introspect and encourage domestic production.

We complete a circle – A new era of change

The current state of India is similar to its state at the time of Independence. Majorly import-dependent. This has shifted the focus of the Government and bureaucracy from "from "why manufacture, when we can import "to "health for billions, can't be outsourced abroad with uncertain relations ". The focus has resulted in several initiatives to change the situation, some of them being:

- BIRAC and DBT actively worked on start-ups and developed administrative mechanisms
- DoP has developed linkages with industry and made successful initiatives in removing bottlenecks to make in India
- MoC has developed aggressive ties with industry and captured strategic interventions required for Make in India
- Game changers:
  - DBT has announced a kit of initiatives in the area of Biologics
  - DoP has announced clusters and API manufacturing Incentives

Dependence on China

The final piece of the puzzle is solving the issue of excessive dependence on China. While the Government's initiatives so far have been promising, specific vital issues need to be addressed to resolve the issue in the long term.

India makes final stage APIs and formulations. We never had a policy that required a manufacturer to manufacture a product from its primary stage. This perhaps was the single most colossal

error in policy, wherein the incentive for domestic manufacturing is removed technically. As a result, we are now seeing an increased dependence on intermediates and basic chemicals. Should this policy change, it would go a long way to ensure that we develop the technical expertise to manufacture goods irrespective of our foreign relations.

Further, we need to develop technological expertise in six platforms to be self-reliant. These platforms ensure a domestic source of medicines available at all times.

- Flow chemistry to mitigate cost disadvantage in massive volume day to day products
- Fluorinated intermediates, complex KSMs, chiral chemistry, high-quality excipients
- Chemical Reagents and Catalysts
- Biocatalysis and Stereoselective catalysts, Membrane separation technologies
- Strain development and fermentation technologies

As important as policies are in encouraging entrepreneurship, it's important to create a favourable environment to manufacture in India.

- Make in India requires entry of chemical giants into required KSMs and intermediates. Scale and technology are critical. Without these, local companies cannot compete with prices in the global market.
- Make in India requires a sovereign fund based credit for national priorities. National priorities can't be achieved with private equity or stock market capital. Neither timelines nor returns will help the nation.

The primary focus is on low hanging fruits in drug discovery capabilities. This prevents India from being at the mercy of foreign pharmaceutical MNCs in the future for new & innovated drugs.

The next decade is crucial in finding a viable strategy to maintain the current dominance in chemistry, develop biology, and to create drugs that could help the nation.

The diffusion impact of such intense knowledge economy will help various sectors to think of global dominance following the example of the pharmaceutical industry. It would provide means and drive in such achievement. Due to the excellent regulatory and fiscal climate, we have travelled a significant distance.

India needs to protect what it has achieved. Government of India needs to more proactively nurture this sector by addressing the missing links and strengthening the policy environment to encourage industry to find its rightful place sooner than later. ■

The Indian Pharma & Biotech Industry - Will they graduate?

Dr. Reddanna, former Dean, School of life Sciences, is an established scientist from the School of Life Sciences, University of Hyderabad, working in the area of inflammation and cancer. He is the Founder member of Federation of Asian Biotech Associations, established in 2005, which provided a platform for academy, industry and Government to interaction and collaborations. BioAsia, a global biobusiness forum is the flagship event of FABA, being organised for the past 17 years.

He has recently established BioNEST incubation center funded by BIRAC, a public sector undertaking of the Department of Biotechnology, Govt. of India for promoting innovation and entrepreneurship (http://bionest.uohyd.ac.in/home), which is hosting more than 40 start-up companies.

His service to promote the Pharma and Biotech industries was recognized with "Outstanding Contribution Award (Pharma)" in 2005 by the ChemTECH Foundation and "Outstanding Scientist Award for benefit of Industry" in 2007 by Federation of Andhra Pradesh Chamber of Commerce and Industry (FAPCCI). He is the recipient of "The Rockefeller Foundation Biotechnology Career Award" and was visiting faculty at Penn State University, Johns Hopkins University and Freie University, Berlin.

Dr Reddanna, in his introductory Guest Edit essay gives the readers a glimpse of how Indian Pharmaceutical industry started its journey of 'Make in India' & the role played by Government of India as an Interface Agency to strengthen and empower the initiative.

Dr. Pallu Reddanna
Ph.D. BSR Faculty Fellow & Project Coordinator, BioNEST Incubation Center, School of Life Sciences, University of Hyderabad and President - Federation of Asian Biotech Associations

The success of Indian Pharmaceutical industry, though in the production of generics, paved the way for the Indian Biotech Industry also. Biotech revolution in India started with the production of recombinant Hepatitis B vaccine by Shantha Biotechnics Pvt. Ltd, which was followed by Bharat Biotech International Limited, Serum Institute of India and many other companies. Today India has become the epicentre for vaccine production in the world or Global Vaccines Hub, supplying to nearly 150 countries in the world. Though the journey started with the production and marketing of biotech products discovered elsewhere, the Indian Biotech industry has shown the capabilities of developing novel products through the discovery and development of Rotavirus Vaccine through academy — industry interaction and through global alliance by Bharat Biotech International Ltd. The Pharma and Biotech industry needs to graduate from generics and biosimilars to discovery and development of innovative novel products, if it has to become a global leader in healthcare industry.

Biopharmaceuticals: A shift from small molecules to biologics

With a shift in the global healthcare industry from small molecules to protein-based drugs, it became a challenge for the Pharma industry to adopt to the new challenges as it requires altogether different expertise and infrastructure. Again, kudos to the Indian Pharma industry, they have quickly transformed to build necessary infrastructure and expertise for the production of biologics developed elsewhere (Biosimilar) and present to the global market. Today a number of monoclonal antibody-based drugs, Mabs, are being manufactured and marketed by a number of Indian companies.

Development of Innovative Products- Still a challenge

Indian Pharma and Biotech industries have demonstrated their capabilities in developing “Me too drugs – generics and biosimilars” and became global leaders as manufacturing hubs. Microsoft co-founder Bill Gates statement “India is the manufacturing hub of vaccines as more vaccines have been manufactured in India than in the rest of the world” clearly points to the confidence in the Indian Pharma’s manufacturing capabilities once they are discovered elsewhere. With this journey Indian Pharma and biotech industry has to graduate from reverse engineering to discovery and development of innovative products.

Biotechnology Industry Research Assistance Council (BIRAC) is a not-for-

profit Section 8, Schedule B, Public Sector Enterprise, set up by late Dr. MK Bhan, the visionary Secretary, Department of Biotechnology (DBT), Government of India as an Interface Agency to strengthen and empower the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs. It played a key role in providing industry-academia interface and helped the country in building start-up ecosystem, starting from students (E-Yuva) to all the way to established companies for setting manufacturing units and conducting clinical trials. Today there are more than 3500 start-ups engaged in various sectors of life sciences, healthcare, and biotechnology. Many of these start-ups have come in handy to face the challenges posed by Covid-19 pandemic, in terms of indigenous production of PPE kits, diagnostics, therapeutics, vaccines etc.

Realising the importance of novel drug discovery, Government of India has come up with yet another scheme "National Biopharma Mission-NBM" with a slogan "i3 -Innovate in India". The main focus of NBM is to enable an ecosystem for preparing India's technological & product development capabilities in biopharma sectors to a level that will be globally competitive over the next decade and transform the health standards of India's population.

Drug Discovery is a relay race with discoveries from academic institutions passed on to Big Pharma/Biotech for later development.

Despite being global leaders in the production of generics and biosimilars, the real progress in discovery and development of innovative drugs/ biologics is still a challenge for the Indian Industry. Globally the innovative scientific discoveries, associated with high risk, have been coming mostly from the academic institutions in US and Europe, which are later taken up by big pharma for further development. These innovative biomedical discoveries have come from academic institutions with active collaborations between basic and clinical researchers, working under one roof. Academic institutions involved in biomedical research in India such as Universities, IITs, IISERs, NISERs, NIPERs and Institutes (CSIR, DST, DBT,ICMR etc), however, do not have such enabling environment of working together with clinician researchers. These two institutions have been systematically isolated with no interactions and collaborations. The basic scientists working on biomedical problems have no idea of clinical set up and clinicians have no understanding of underlying molecular mechanisms behind the pathogenesis of a disease. Unless this is corrected through policy decisions the

innovative discoveries will be elusive for India. Though Indian Pharma and Biotech industry are innovative in the development of generics and biosimilars, they will not venture into high risk novel discoveries. Globally the big Pharma also have closed their R&D labs and instead are scouting around the world for innovations from academic institutions.

Way Forward

The way forward for India is to strengthen academic institutions with teaching and research hospitals on high priority as follows:

- All Central Universities, IITs, IISERs and National Laboratories should have teaching and research hospitals attached, with basic and clinician researchers in equal numbers.
- The faculty entrepreneurship scheme, introduced in the country a decade ago, should be effectively utilised to start their ventures
- Incubation centres should form key units of all these premier academic institutions to accommodate faculty entrepreneurs
- Attracting Big Pharma and Biotech companies to set up their R&D units within the academic institutions
- Revamping the teaching programs in Science subjects with more practical orientation, hands on training and problem solving
- Strengthening of financial institutions that support high risk innovative projects

India needs to take radical steps in bringing academic institutions involved in biomedical research closer to teaching and research hospitals and thus promote translation of innovations into novel discoveries. Academic and Medical institutions have to be proactive in strengthening collaborations among them on one side and with industry on the other. Indian industry should exploit the resources in academic institutions with state of the art infrastructure, highly qualified faculty and human resources to identify the innovative discoveries for further development. I hope and wish that the Academy and Industry, with policy initiatives from Government, take these radical steps and place India on the global map of novel drug discovery. ■

Enabling the Growth of Indian Pharmaceutical Industry

Mr. V V Krishna Reddy is the National President of Bulk Drug Manufacturing Association (India) — an association that works for consolidation of the gains of the industry and serves as a catalyst between Government and the industry on the various issues for the group of the Industry. Thus BDMA(I) becomes a very important aspect of Make in India to build on India's existing strength in manufacturing and distribution. The association also plays a very important role to enhance the beginnings made in R&D in order to become one of the leading players in the global pharmaceutical market. Mr Reddy, via his article gives us an insight into the pharmaceutical boom that is awaited thanks to the initiatives taken by the government and efforts put in by the organizations and industries.

Mr. V V Krishna Reddy
National President, Bulk Drug Manufacturing Association (India)

Pharma industry's future is very promising and demand for pharma products is rising dramatically, with the global population increase and changing life styles. Many of the barriers to free trade have also been removed, bringing in a period of unprecedented growth in global trade. Indian companies are among the world leaders in the production of generics and vaccines. As both of these areas become more important, Indian producers are likely to take a large role.

The policies of the present Government are aimed at making quality healthcare affordable to all and also increase access to healthcare in rural and urban areas. Factors favouring the industry include low rural penetration, rising healthcare spending, rapid urbanization, lifestyle-related diseases, and growth in aging population, technological advancements and wide range of products manufactured. In the domestic market, generics are expected to fuel growth in this fiscal supported by govt. led initiatives promotion of Pharma industrial parks and Production Linked incentives for backward integration and import substitution.

India's pharmaceuticals industry is set for a solid long-term growth and is expected to witness a spur in investment activity during FY20-21. Foreign direct investment inflows are likely to increase as most of the multinational companies are looking at India. India's manufacturing clout is a massive threat to established generics firms. India produces more than 20% of the world's generics. India's pharma exports are estimated to rise approximately to US$20 billion by 2020.

During the last decade, Indian API manufacturers lost the competitive edge to manufacture the lower end of spectrum for APIs and fermentation technology to countries like China, primarily due to costly power, inadequate infrastructure, government restrictions clamping down on the volume of APIs that can be produced in the existing plants, delays in new drug approvals, lack of financial support and incentives from the governments, to match the Chinese government subsidization of exports. Realizing the fact that India now imports a lot of APIs from China, the Indian government has initiated a lot of steps to reduce our dependence on imports and strengthening indigenous production.

The Department of Pharmaceuticals under the Ministry of Chemicals and Fertilizers have planned to promote three dedicated Pharma Parks with a support of Rs 1000 crores for each park with wholly integrated infrastructure such as captive thermal

power generation, effluent treatment plant, solid waste disposal and landfill, road-rail-air connectivity - to encourage existing companies and new companies from within and outside India to invest and promote the manufacturing of APIs in a significant way.

API manufacturing being part of Life Sciences Sector, requires highly skilled scientists and technicians to manufacture globally compliant products. BDMA along with IPA, IDMA, OPPI, CIPI and other national industry bodies in the Life Sciences sector are playing a significant role in achieving this objective.

India has the potential to emerge as a cost-effective hub for R&D activities. The availability of cheap yet skilled manpower is a distinct advantage. The government's vision of making India the Drug Discovery and Global Pharma Innovation Hub by 2020 will work in its favour.

The clinical trials market in India offers high growth potential given the availability of a huge population base, bio-diversity and low costs involved in conducting the trials. However, guidelines issued by the government have not been encouraging to the segment unless the guidelines are reversed.

Contract manufacturing is a strong segment of the domestic market. Indian firms have several advantages over their Western rivals. Costs are very competitive. Indeed, they are only half of the cost involved in setting up and running a new manufacturing facility in the West. They can operate on significantly lower margins, given their low development and labour costs. Indian companies now have an opportunity to partner with global players from contract manufacturing and licensing arrangements.

Lastly, with all the new initiatives planned and support from the government, I am sure India will be a major force globally in the API sector. We also look upon not only becoming self-sufficient but also meet the growing demand of pharma products worldwide. ■

Invest in life sciences research and encourage development of private sector in this industry

Dr Prasanna Deshpande
Deputy Managing Director,
Indian Immunologicals Limited

Reliance on Chinese resources in the value chain

At IIL we do not have any great reliance on Chinese resources in our value chain.

Three steps to make India the hub for end-to-end drug discovery under the country's 'Pharma Vision 2020'

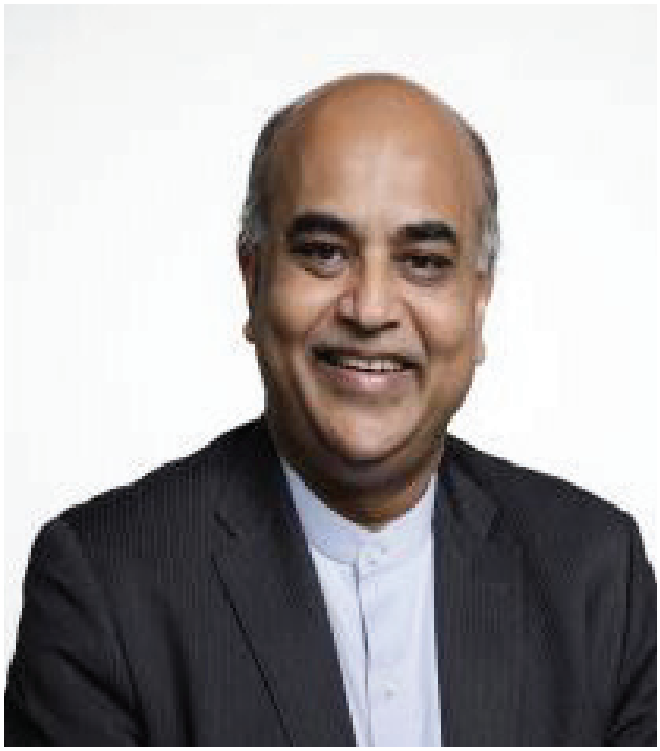
1) Encourage development of life sciences cluster in the country where companies, universities and research institutions converge and give rise to meaningful collaborations in drug discovery
2) Focusing on and funding the specific training required for workers to be ready to work in the life sciences industry
3) Invest in life sciences research and encourage development of private sector in this industry

Comment on achieving superiority in the domains of both knowledge and manufacturing.

It is true that supply of world class talent needs to grow for the life sciences industry to thrive in India. To enable this –

- Better educational and training opportunities should be offered to students
- Training infrastructure needs to be developed for workers engaged in drug manufacturing as well as scientists engaged in research
- Opportunities should be offered for overseas talent to return back to India and transition smoothly ■

Committed to making India one of the world's leading destinations for end-to-end drug discovery and innovation by 2020



Dr. Shirshendu Mukherjee
Mission Director, Grand Challenges India
Jointly supported by Department of Biotechnology (DBT), Ministry of Science & Technology (MoST), Govt. of India – Bill & Melinda Gates Foundation (BMGF) – Wellcome Trust and BIRAC

Rebalancing to manage the risks from an over reliance on Chinese resources in the value chain.

COVID-19, as we all know has posed an unprecedented challenging situation to humanity sans borders. The scientific community has been relentlessly working and striving hard to mitigate the challenges posed by the pandemic and is geared up to fight the challenges. As India has always been in the forefront of scientific knowledge and strength since decades, the country is fighting the pandemic with the best of its technological innovations in biotech, health, telemedicine, medical devices – thanks to the strong support of Government agencies such as DBT,

CSIR, ICMR, DHR, Niti Aayog, to name a few. The innovation ecosystem created by the aforesaid Government agencies have a strong base of startups, mid-size companies, large pharma groups within, which have fully realized the challenges posed by the pandemic and have reticulated their efforts, so as to minimize the impact created by the disease. Also, to reduce over reliance on the Chinese resources, these organizations have deployed business continuity strategies based on various Government initiatives particularly like Atmanirbhar Bharat.

Three stages to make India a hub for end-to-end drug discovery

The Indian Government is committed to making India one of the world's leading destinations for end-to-end drug discovery and innovation by 2020. Although we have achieved the distinction of being the world's leading supplier of generic drugs, we are still afar from accessing the global markets in respect of vaccines and targeted drugs, jeopardizing our efforts to become a drug discovery and innovation powerhouse. With this in mind, the Government announced the 'Pharma Vision 2020' with 100% FDI in the Pharma Industry to allow investment in R&D, enhance local capacities and to find solutions to endemic health issues. Three steps that could dramatically change the Pharma landscape could be:

- Building a strong scientific base, create foolproof validation platforms that are universally accepted and strong clinical trial sites to take on innovations especially in Pharma from the bench to the bed side.
- For the Pharma Industry to grow, both in terms of value and volume, India needs to strengthen its commercial capabilities, realize its R&D prowess and collaborate with stakeholders within and outside the industry, forge public-private partnerships to drive access and shape the market.

Basic building blocks to be 'pandemic ready' the next time around

Any pandemic which humanity faces is different in its impact and disease etiology. So, having a generalized mechanism/ strategy to address a pandemic is highly impractical. Generally, during a pandemic, we should understand the disease, mode of infection, control strategy and prevention. With a strong scientific resource base to understand the disease, a vibrant innovation ecosystem to manage the impact of the disease and a strong pharma platform to prevent the disease, a pandemic could be managed. However, to be 'pandemic ready' the basic building blocks could be:

- Disease forecasting capability through technological innovations - technology

innovations that help public health officials find and respond to threats as they arise, allowing them to get a much quicker handle on the size and scope of the potential problem

- Technologies for self-monitoring through health & fitness data - data from the devices is aggregated and analyzed, the emergence of an unusual disease cluster could become apparent before medical visits
- Technologies for public health monitoring and algorithmic telemedicine – the most important tool could be monitoring of public health situations in clusters with aggregated data on a single multi-access platform to be made available even before the actual outbreak by identifying differing vital statistics patterns of the population.

Healthcare and Pharmaceutical companies creating value to society for stakeholders

Of course, our healthcare and pharma companies are creating value to the society by developing innovative diagnostic tools, drugs and vaccines.

World class talent in the domains of both knowledge and manufacturing.

Pharma's increasing early engagement with biotechnology has been one of the themes of the industry in the last decade as companies prepare for a shift towards personalized medicines. Nobody knows exactly who will drive the change, and how the resulting wave of new treatments will be commercialized. Given the potential of molecular biology, there has been great interest in this area since understanding of human genome sequencing first came to the fore around 30 years ago, but it has spiraled upwards over the last decade as the capacity which new preventative and regenerative medicines could have for us all has started to emerge.

We need the translational medicine capability of academia, pharmaceuticals and biotech together in order to bring transformational innovation. Research requires new types of biomarkers, new pharmacology, new platforms, new ways of doing clinical trials, combination therapies, guiding therapies - it's a total new world where we have to go to. That being said, we should keep nurturing and creating institutes of scientific excellence which will continue to produce excellent intellectual outputs in turn helping India revolutionize the vaccine and drug race globally. ■

The strategy is to have a primary supplier of all KSMs in India and alternative suppliers in China and Europe.

Manoj Mehrotra
President –
Pharmaceuticals Business, Hikal

Pharmaceutical companies to rebalance or reset to manage risks from an over reliance on Chinese resources in the value chain.

Hikal is a leading manufacturer of intermediates and APIs. The pharmaceutical business has three manufacturing sites in India. Two of the sites are approved by US FDA, EU, PMDA and other global regulatory agencies. The third site is a cGMP site and is expected to be inspected by USFDA in the next few months

In the last three years, we have seen that supply of Key Starting materials from China has been difficult. The primary reason for the same are changes in environmental laws which have forced suppliers in certain provinces to either reduce production capacity or to shut

down entirely. We have faced several instances of supply failure, quality and inconsistent prices during this period. Supply problems from China again resurfaced during the COVID-19 crisis this year.

Hikal in the last 2 years has undertaken a structured supply chain de-risking program for all our products. The strategy is to have a primary supplier of all KSMs in India and alternative suppliers in China and Europe. We are also building a network of strategic manufacturing partners in India who will support Hikal in all the Key Starting Materials. Process Development will be done by Hikal R&D and technology transferred for commercial manufacturing to one of these strategic partners. Hikal's team is working very closely with these network partners to meet our expectations on EHS and Quality.

Three steps /stages to make the country a hub for end-to-end drug discovery

Drug discovery has very long gestation period and it costs upwards of $ 1 Bn from early research to final commercialization. No Indian company has been successful in this journey as yet.

- Financial support by Government of India in this long journey.
- Clinical trial protocols should be simplified
- Strengthen relationships between academic institutes and the industry

The basic building blocks to be 'pandemic ready' the next time around

Indian companies have to continue working on generic version of anti virals and anti retrovirals . This has helped in the current pandemic.

Are Healthcare and Pharmaceutical companies creating value to society and wealth for stakeholders at what should be an exponential pace – particularly today?

Indian pharma companies are the leading generic companies in the world and contribute to providing low cost quality medicines across the world. They also provide space for entrepreneurs to invest and create wealth and employment for the society. Indian pharma industry is forecasted to grow to $ 120-130 Bn by 2030.

Revolutionizing the domains of both knowledge and manufacturing for a supply of world class talent.

- Pharma Industry always requires good quality chemists and engineers. In the past few years, we have seen that all the bright students go in for higher education in Information Technology, Computer Science, Electronics & Communication. We have seen that some of the largest IT companies in the world are headed by people of Indian origin.
- Pharma /Healthcare industry should attract students early in their life . More students should get attracted to study basic science and core engineering so that there is a steady supply of good talent to the Pharma Industry. This is a very long and tedious path, but a beginning has to be made. ■

While self-reliance is the motto of our nation it is imperative that the Indian pharmaceutical industry strengthens its supply chain

Prashant Nagre
Chief Executive Officer,
Fermenta Biotech Limited.

Managing risk from an overreliance on China and dynamic balancing

The COVID-19 pandemic has exposed the heavy dependency of Indian pharmaceutical formulation manufacturers on external sources of raw materials. This has especially impacted our antibiotics production, as disruptions in critical APIs have led to disruptions in logistics of drugs for high-burden diseases.

At a time when self-reliance is the motto of our nation, it is imperative that the Indian pharmaceutical industry strengthens its supply chain. We, as an industry, need to ensure that our value chains are independent of the volatility that

surrounds us, by mitigating the risk of raw material supply.

At Fermenta, we are completely backward integrated as we manufacture our Key Starting Material (KSM), cholesterol. As the only manufacturer of Vitamin D3 in India, this allows us to cater to demand from our customers in a sustainable manner.

From vision to decision Pharma 2020

1. Innovation, not imitation: While India is the global hub of generic medicines, the industry also needs to invest in development of novel drugs that can be patented, through setting up R&D centres that focus on innovation and discovery of molecules.

2. Maintaining competitiveness: The Indian government has taken steps to boost the production of KSMs including APIs and drug intermediates through a proposed incentive package. Taking advantage of this, we, as an industry, need to leverage our high-quality low-cost manufacturing capabilities to ensure that we continue to provide the world with affordable medicines.

3. Shifting focus from treatment to prevention: As consumer awareness on maintaining health and wellness rises, pharmaceutical companies will need to realign their strategies to include products for preventative healthcare, apart from their therapeutic portfolios. Fermenta aims to capitalize on the increased demand for preventive health products through foraying into the nutritional ingredients segment.

Getting ready for the pandemic the next time around.

The unprecedented scale of the pandemic has disrupted lives and businesses across the world. Even as we struggle to gain back normalcy, the pandemic has exposed our vulnerability to disasters. As an industry, we need to take a lead on pandemic preparedness by inculcating the following steps:

(i) Invest in research: Increase collaborations for surveillance on new strains and to identify their resistance to existing drugs is required. Partnerships with governments, academic and global health bodies are required to win the race by outpacing the pathogens.

(ii) Leverage expertise: Newer technologies for drug delivery and formats to increase their efficacy should be brought in. More effective drugs for existing diseases not only reduce the chances of secondary infections during pandemics but also decrease the burden on our hospitals.

(iii) Spotlight on health: The COVID-19 pandemic has brought to light the vulnerability of large populations of diabetes and heart patients. Thus, the focus of our industry should be to help the immune-compromised through the right preventive medicine, and to boost health and immunity through proper nutrition. Nutraceuticals are therefore, the solution to tomorrow's problems, and the pharmaceutical companies should reinforce their portfolios by adding on products of nutritional value.

Healthcare and Pharmaceutical companies creating value to society for stakeholders at what should be an exponential pace.

The COVID pandemic has shown the essentiality of the healthcare sector. The shared value that arises out of the research into prevention and treatment is beneficial to multiple stakeholders. From affordable therapeutics to sustainable nutrition, there is a need to position business objectives to the requirements of the community, and ultimately, align with Sustainable Development Goals.

At Fermenta, we are proud to be providing the world what it needs, even as we continue our operations to manufacture Vitamin D, which has been shown to play a role in immune support as well as general health and wellbeing.

Revolutionizing the domains of both knowledge and manufacturing for a supply of world class talent.

The short-term economic shock will be replaced by a positive outcome for the industry in the long term, as more and more manufacturing facilities are set up to expand production capacities. As the world looks towards a sustainable alternative for procuring its drugs, India can emerge as a viable pharmaceutical sourcing option.

We can therefore expect a renewed demand for a workforce skilled in pharmaceuticals, biotechnology and life sciences. Post the pandemic, the working scenario will also no longer be the same, and organizations as well as individuals who adapt to technology will be at an advantage.

The leadership of organizations has been tested during these challenging times – it is essential to strategize for the new normal and rebound from the crisis. ■

Make in India with a strong presence in 19 countries across the world

Rahulkumar Darda
Chairman & Managing Director,
Brinton Pharmaceuticals

Opportunities to reduce the dependence on China

Currently over 63% of India's pharmaceutical imports are API and intermediates and almost 70% of it comes from China.

To reduce the dependence on China, India is considering importing certain APIs and intermediaries from alternative sources such as US, Italy, Singapore and Hong Kong. To address this problem, our Government has decided to set up three bulk drug parks for Rs.3000 Crs and approved Rs.6940 Crs production-linked incentive package for promotion of domestic manufacturing of critical intermediates and APIs. This will take

atleast five to eight years to show the results.

Brinton's exposure to Chinese bulk is very minimal and we are in the process of having "zero" dependency outside India.

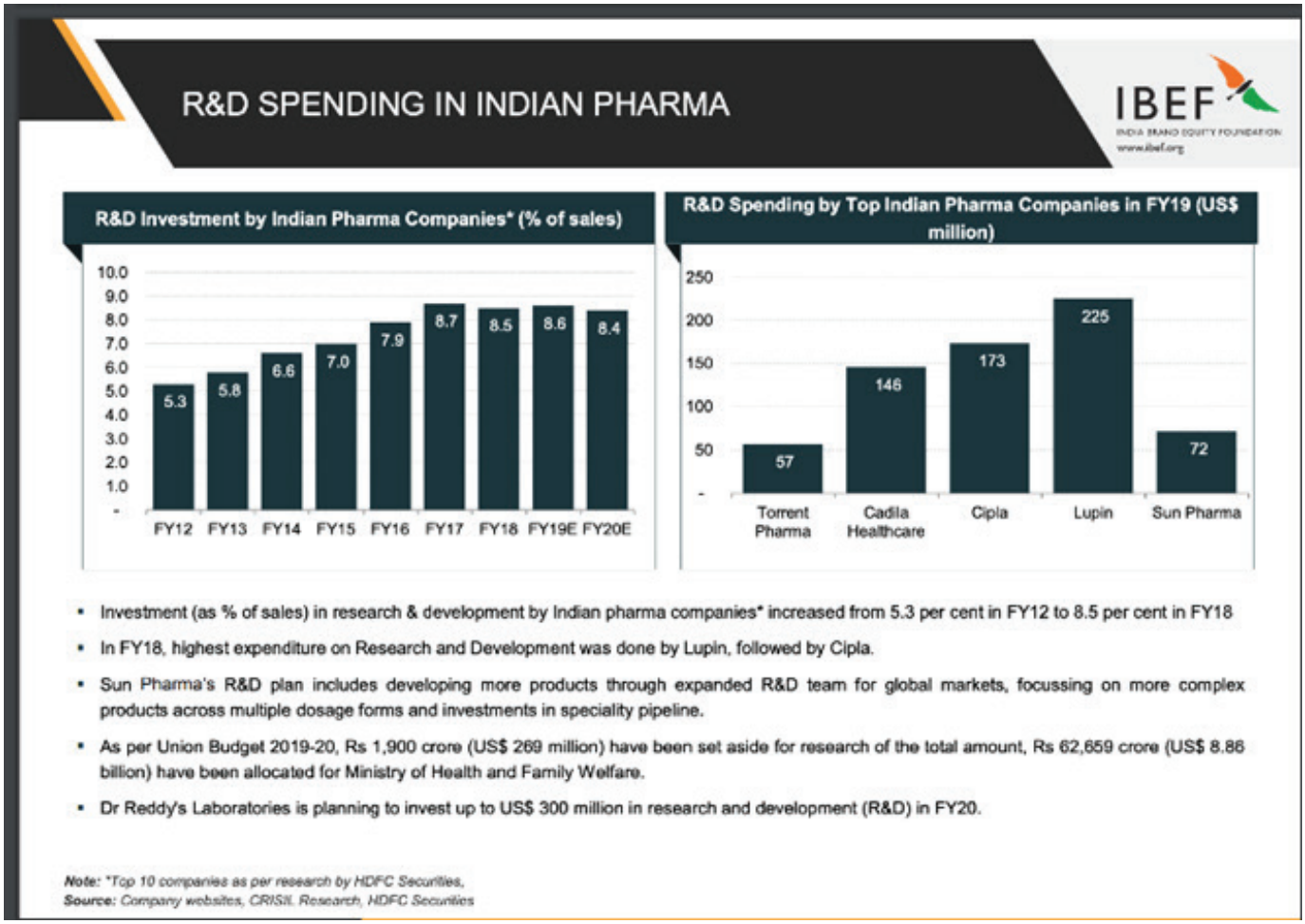
Three steps / stages which will make the country a hub for end-to-end drug discovery

To encourage more focus into R&D, the following need to be addressed effectively

- Reduction in approval time for new facilities through "one window" clearance
- Support for technological upgrades by setting up "Pharma parks"
- Tax free on R&D expenditure and relaxing FDI norms

Being pandemic ready in the future

As man built a better mouse trap, the nature built an even better mouse. Frankly we can't predict these types of events and that's why they are called as "Black swan events". Even the so-called advanced countries US, UK, Germany etc are struggling to battle this pandemic. However, we can work towards minimising



Current spend on R&D by Indian companies

the response time. For that Biotech will have to play a pivotal role.

During this period of pandemic, Brinton swiftly sprang into action by collaborating with manufacturers of PPE kits, N 95 Masks, RT PCR kit etc. We utilised our strong distribution channel and made available all these essential protective gears across the country for the protection of the COVID Warriors. Brinton will be the 2nd company to launch favipiravir in India, which is indicated for the treatment of mild to moderate COVID. Brinton has already received good amount of orders from abroad for export.

Healthcare and Pharmaceutical companies creating value to society.

Considering the current available infrastructure, policies etc., Pharma industry has done fairly a good job in creating value to society and wealth for the stakeholders. Even the current Stock market has given a big thumps-up to most of the Pharma scrips. Leading agencies like McKinsey have predicted Pharma sector has got the highest probability to bounce back from this pandemic.

Though the Indian Pharma Market showed a de-growth for the months of April & May, it has shown a positive growth of 6% for the month of June'20 (Source: IQVIA). Brinton's timely action to launch PPE kits, N-95 Masks, RT PCR kit etc helped manage the P&L effectively.

Now with "unlock" happening across the country, IPM should bounce back to strong double-digit growth and Brinton will continue to out-grow the industry's growth.

Producing & retaining knowledge and manufacturing talent.

Brain drain has always been a spot of bother. Off late things are changing very fast as the opportunity to learn and grow in our country itself. Government's initiative like "atmanirbhar" will encourage more participation in the Pharma & Biotech space, which will attract the best of the talents not only within India, even from abroad.

We need to derive inspiration from ISRO and IT industry to retain and grow with domestic talents. India is already considered as the "global pharmacy", will some support from the government, Pharma can replicate what IT and ISRO has done for India, globally.

Brinton will continue to play a pivotal role in shaping the therapy areas in which we are present. We will continue to innovate keeping the patients at the centre. ■

Ajit Singh

Chairman , ACG Group of Companies

"The Government of India is promoting skill building, investment and innovation. While the other two are short term, innovation is strictly long term. Innovation depends on good R&D."

Ajit Singh, Chairman ACG Group of Companies has played a prominent role in the development of the pharmaceutical and allied industry in India. He has been instrumental in bringing several global pharma associations to India, with much technology and learning disseminated to Indian pharma scientists and technologists. He has served on the Central Governing Council of the IIT's, and governing board of NITIE for several years.

Ashish U. Bhuta

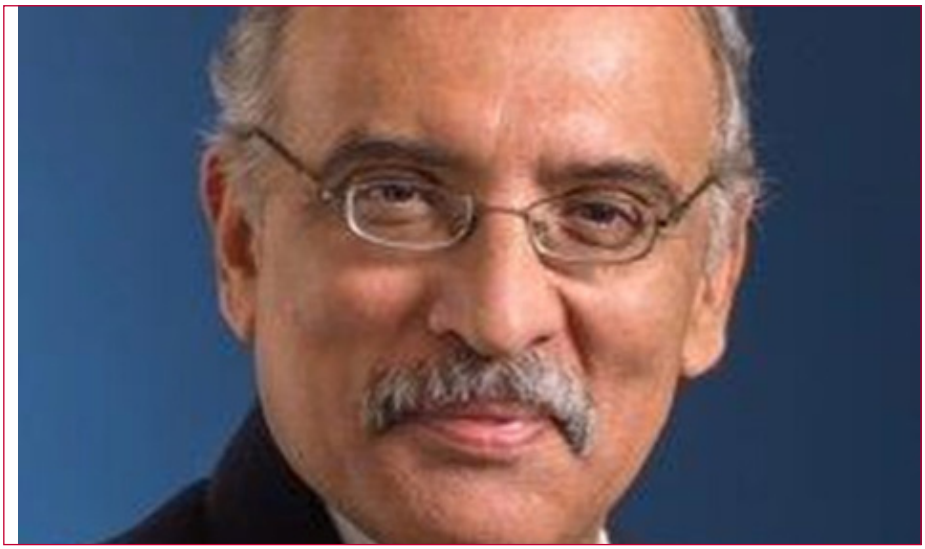
Chairman & Managing Director, Jenburkt Pharmaceuticals Ltd

"To me Make in India is a movement. it brings the whole industry together. it makes India very resilient. It gives the industry a momentum to try and make new ingredients which are not made in India."

Ashish U. Bhuta, Chairman & Managing Director, Jenburkt Pharmaceuticals Ltd, has many achievements to his credits like obtaining ISO 9002 and WHO GMP Certification of the Plant, setting up an R&D unit approved by the Central Government and International Business Department to foray into new countries.

Dr. Manjul Joshipura

Senior Vice President, Innovations and New Products,
Cadila Pharmaceuticals Limited



"The concept of Make in India & Cadila Pharmaceuticals go hand in hand. We were one of the 1st inian companies to establish manufacturing unit. Given the right ecosystem and right incentive this will be a huge opportunity that Indian pharma industry can benefit on."

Dr. Manjul Joshipura, in the role of Senior Vice President of Innovations and New Products, is responsible for Innovations, New Product Pipeline, R&D and sourcing of novel technologies in life sciences and international collaborations. Prior to joining Cadila Pharmaceuticals he was leading the health systems programme at World Health Organization in Geneva and contributed to research, policy development and advocacy efforts. He has been a consultant to the World Bank, Gates Foundation, NIH and various state governments on the issues related to trauma and emergency care.

Dr. Subhash Soni

Additional Secretary to Government of Gujarat, Science & Technology Department;
Director, GSBTM & Registrar, Gujarat Biotechnology University

"The Government of Gujarat has taken some steps to contribute to Make in India initiative. As Indian Biopharma industry is waking up Gujarat is ready to help and realize this dream of Make in India."

With a view to promote Biotechnology, State Government has constituted Gujarat State Biotechnology Mission (GSBTM) which acts as a state nodal agency for coordinating Promotional and Developmental activities on Biotech policy planning, Development of Biotechnology Infrastructure, Supporting Research, Human Resource Development, encouraging Biotech Entrepreneurship, development of Biotech Business, Biotech parks, Marketing – Networking, Information Dissemination, Biotechnology Works for Research and Recreation.

Mahendra Patel

Managing Director, Lincoln Pharmaceuticals Ltd

"We believe that there is an opportunity for the Indian pharma industry to play a larger role in the global drug supply and thus create a huge success of Make in India Initiative."

Mr. Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Ltd, believes in "Healthcare for All", so providing the medicines at concessional / affordable prices to the mankind. His vision has made it possible for Lincoln Pharmaceuticals to setup in-house R&D centre for New Drug Delivery System.

Mahesh Bhalgat

Chief Operating Officer, Syngene International Ltd

"Indian Pharma Biotech sector has been touted as world no.3 in production volume and world no.10 in value. I believe we can become world no.3 even in terms of value."

Mahesh Bhalgat, Chief Operating Officer, Syngene International LTD, a Ph.D. holder in Medicinal Chemistry from the University of Utah, the USA, and a bachelor's degree in Pharmacy from the University of Mumbai has over 25 years of experience in both biotechnology and biologics.

Rahul Guha

Managing Director, The Boston Consulting Group

"When it comes Make in India in the pharmaceutical industry, I like to use the acronym 'ASK' and that is really about how we build self-reliant India."

Rahul Guha, Managing Director & Partner, The Boston Consulting Group, has worked across the healthcare and industrial goods practices both in India and the US. He is also a part of the CII National Committee on Medical Technology and is the lead author of the Vision 2025 report for the Medtech sector in India. He is also a topic expert in Smart Simplicity and works on topics of organization design and strategy, particularly in the area of generics in the pharmaceuticals sector.

Vishwas Kulkarni

Founder Director, Spectralab Instruments Pvt Ltd

"We have been practicing Make in India for more than three decades. We have developed number of import substitution products. Now the Government of India has also started encouraging the Make in India movement and if government gives encouragement to talented and capable people, India can surpass global standards."

For Vishwas Kulkarni, Founder Director, Spectralab Instruments Pvt Ltd, Make in India initiative started 50 years back when he started developing analytical instruments as import substitutes. ble to fight all these odds.

Dr. Venkata Palle

Senior Vice President of Discovery Research at Lupin Pharma

"With strong pipeline Lupin's NDD is well placed to bring out more innovative medicines to treat diseases with huge unmet medical needs. And it's a perfect example of Make in India."

Dr. Venkata Palle is currently Senior Vice President of Discovery Research at Lupin Pharma. Prior to joining Lupin, Dr. Palle played a leading role in Medicinal Chemistry in the drug discovery efforts at Advinus Therapeutics (Pune, India), Ranbaxy Laboratories (Gurgoan, India), CV Therapeutics (Now Gilead Sciences, Palo Alto, CA, USA) and NeXstar Pharmaceuticals (Boulder, CO, USA). He is co-inventor of currently marketed drug Regadenoson (LexiScan).

Mr. Mahesh Doshi

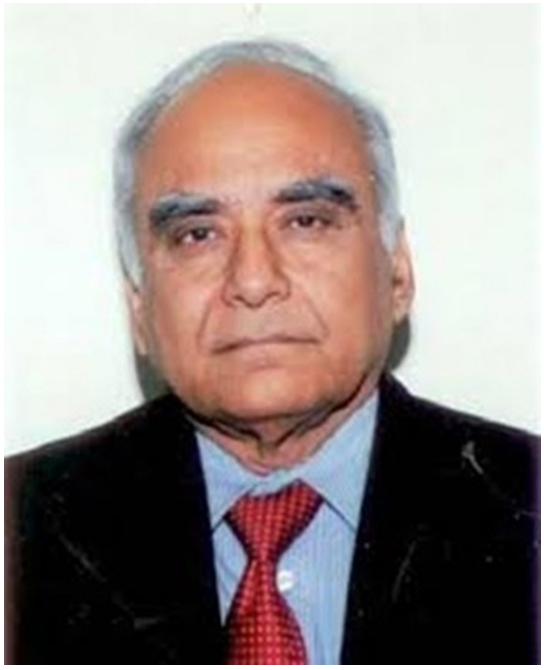
National President of IDMA is also the Managing Director & Partner of Dy-Mach Pharma

"IDMA has been in the forefront making our nation self-sufficient in the manufacturing of drug and pharmaceutical. With skilled workforce and globally recognized research institutions, India can do wonder in API sector."

Mahesh Doshi, National President of IDMA is also the Managing Director & Partner of Dy-Mach Pharma having two units in Maharashtra & Gujarat manufacturing APIs. He is also the Managing Director of Avesta Pharma, a US FDA Approved Plant.

Hydroxyquinoline use as Prophylaxis medicine for COVID 19 should be analyzed thoroughly

Padma Bhushan Prof. Nirmal K Ganguly, Former - DG, ICMR gives his perspective on Hydroxychloroquine or chloroquine, which was in the last few months often used in combination with a second-generation macrolide. It is widely used for treatment of COVID-19 despite no conclusive evidence of their benefit. Although generally safe when used for approved indications such as autoimmune disease or malaria, the safety and benefit of these treatment regimens are poorly evaluated in COVID-19.



Padma Bhushan Prof. Nirmal K Ganguly
Former - DG, ICMR

Hydroxychloroquine or chloroquine, which was last few months often used in combination with a second-generation macrolide, widely used for treatment of COVID-19, despite no conclusive evidence of their benefit. Although generally safe when used for approved indications such as autoimmune disease or malaria, the safety and benefit of these treatment regimens are poorly evaluated in COVID-19. Chloroquine (CQ) was first used as prophylaxis and treatment for malaria. Hydroxychloroquine (HCQ) is a more soluble and less toxic metabolite of chloroquine, which causes less side effects and is, therefore, was clinically much safer to administer. More recently, CQ/HCQ has been used to manage conditions such as systemic lupus erythematosus and rheumatoid arthritis. CQ/HCQ has been used in the treatment of HIV with mixed results. The ability of CQ/HCQ to inhibit certain coronaviruses,

such as SARS-CoV-1, has been explored with promising results. Subsequently Hydroxychloroquine, was found effective in inhibiting SARS-CoV-2 infection in vitro (Liu et al. Cell Discovery (2020) 6:16). Yao et al in his study found that HCQ was more potent against SARS-CoV-2 than CQ in vitro (EC50 of 0.72 μM and 5.47 μM, respectively. MOI = 0.01). Wang et al reported in vitro antiviral activity of CQ, with an EC50 of 1.13μM and CC50 >100μM at an MOI of 0.05, and with high selectivity for SARS-CoV-2 rather than host cells since it was evident that no COVID-19 new drugs for the novel virus hence it was felt that HCQ was good option to try out in patients suffering from COVID 19 illness on the serious. First clinical results were reported in a news briefing by the Chinese government in February 2020, revealing that the treatment of over 100 patients with chloroquine phosphate in China had resulted in significant improvements of pneumonia and lung imaging, with reductions in the duration of illness. No adverse events were reported. It appears that these findings were a result of combining data from several ongoing trials using a variety of study designs. No empirical data supporting these findings have been published so far.

On the 17th of March 2020, the first clinical trial data were published by Gautret and colleagues in France. The researchers conducted an open-label non-randomised controlled trial with 36 patients diagnosed with SARS-CoV-2. Six of these patients were asymptomatic, 22 had upper respiratory tract infection symptoms and eight had lower respiratory tract infection symptoms. Twenty patients were assigned to the treatment group, and received HCQ 200mg three times a day for ten days. The control group received usual care. Six of the patients in the treatment group were also prescribed azithromycin to prevent bacterial superinfection.

The main outcome of the trial was SARS-CoV-2 carriage at Day 6, tested using PCR of SARS-CoV-2 RNA from nasopharyngeal swabs. The results showed that patients in the treatment group were significantly more likely to test negative for the virus on Day 6 than patients in the control group (70% vs 12.5% virologically cured, $p<0.001$). Moreover, all of the six patients who were treated with a combination of HCQ and azithromycin tested negative on Day 6. The authors argue that this finding speaks to the effectiveness of HCQ and a potential synergistic effect of its combined treatment with azithromycin. A number of potential mechanisms of action of CQ/HCQ against SARS-CoV-2 have been postulated. The virus is believed to enter cells by binding to a cell surface enzyme called angiotensin-converting enzyme 2 (ACE2). ACE2 expression is also believed to be upregulated by infection with SARS-CoV-2. Chloroquine may reduce glycosylation of ACE2, thereby preventing SARS-CoV-2 from effectively binding to host cells. Furthermore, Savarino et al hypothesise that CQ might block the production of pro-inflammatory cytokines (such as interleukin-6), thereby blocking the pathway that subsequently leads to acute respiratory distress

syndrome (ARDS). Some viruses enter host cells through endocytosis; the virus is transported within the host cell in a cell-membrane derived vesicle called an endosome, within which the virus can replicate. When the endosome fuses with the acidic intracellular lysosome, this leads to rupture of the endosome with the release of the viral contents. Chloroquine has been found to accumulate in lysosomes, interfering with this process. Chloroquine is also believed to raise the pH level of the endosome, which may interfere with virus entry and/or exit from host cells.

Following the promising results of these first clinical trials, official guidelines recommending the treatment of COVID-19 using CQ/HCQ were allowed and guidelines for prophylactic use was published. The National Health Commission of the People's Republic of China published their recommendation mid-February, suggesting to treat patients with 500mg chloroquine phosphate (300mg for CQ) twice per day, for a maximum of 10 days. In Italy, the L. Spallanzani National Institute for the Infectious Disease published their recommendations for treatment on the 17th of March, which included the provision of 400mg of HCQ per day or 500mg CQ per day, in combination with another antiviral agent. Several other nations followed suit both in US and Europe HCQ was being used on compassionate grounds.

Some other Chinese studies from Wuhan also claimed to show signs of efficacy but patient were not very high. For example Zhan Zhang, Department II of Respiratory Disease and Intensive Care, Renmin Hospital of Wuhan University, Wuhan in China published that in 62 COVID-19 patients, 46.8% (29 of 62) were male and 53.2% (33 of 62) were female, the mean age was 44.7 (15.3) years were given HCQ. No difference in the age and sex distribution between the control group and the HCQ group. But for TTCR, the body temperature recovery time and the cough remission time were significantly shortened in the HCQ treatment group. While the results of these clinical trials sound promising, there are several limitations.

The trial by Gautret and colleagues also has some limitations. The authors state that an additional six patients were recruited to the trial, but were lost to follow-up for various reasons. The authors excluded these six patients and did not perform intention-to-treat analysis, which may have introduced bias.

Then subsequently On April 21, Reuters reported that an analysis by U.S. researchers of Veterans Health Administration (VA) data had found that hydroxychloroquine provided no benefit and led to a potentially higher risk of death for coronavirus patients at U.S. veterans' hospitals. The research, which was not yet been accepted for publication in a medical journal or peer reviewed, was not the result of a clinical trial. The study analyzed medical records from 368 men

hospitalized with confirmed coronavirus infection at VA centers who died or were discharged by April 11 2020.

An analysis of Veterans Health Administration (VA) data found that 28% of 97 patients given hydroxychloroquine along with standard care died, compared with a death rate of 11% for the 158 patients that did not receive the drug. The death rate was 22% for the 113 patients given hydroxychloroquine plus the antibiotic azithromycin.

In another recent study, researchers in France examined medical records for 181 Covid-19 patients who had pneumonia and required supplemental oxygen. About half had taken hydroxychloroquine within 48 hours of being admitted to the hospital, and the other half had not.

The doctors followed the patients and found there was no statistically significant difference in the death rates of the two groups, or their chances of being admitted to the intensive care unit.

A preliminary study out of Brazil on the use of chloroquine diphosphate to treat patients with Covid-19 symptoms ended early after several patients died and researchers found that a high dose of the drug was associated with a severe type of arrhythmia, or irregular heartbeat.

For the trial, patients either received a high dose of chloroquine, at 600mg twice daily for 10 days for a total dose of 12g, or they received a low dose at 450mg for five days, twice daily only on the first day, for a total dose of 2.7g. All patients also received the antibiotics ceftriaxone and azithromycin as part of their treatment. A limitation of the study is that there were no patients receiving a placebo.

By the sixth day of the trial, the researchers halted the study after 11 patients died — and even more deaths were counted in the study's updated data.

The nail in coffin for HCQ came from the Lancet paper published although it was not a randomized trial. The authors of the paper pulled together results for more than 96,000 patients in 671 hospitals, taking one of the drugs, with or without an antibiotic such as azithromycin, between 20 December and 14 April.

The death rate among all groups taking the drugs was higher than among people who were not given them. One in six of those taking one of the drugs died, while one in five died if they were taking chloroquine with an antibiotic, and one in four if they were on hydroxychloroquine and an antibiotic. The death rate among patients not taking the drugs was one in 11. The team also found that serious cardiac arrhythmias, which cause the lower chamber of the heart to beat rapidly and irregularly, were more common in all the groups receiving one of the four treatment regimens. The biggest increase was in the group treated with hydroxychloroquine in combination with an antibiotic, where 8% of patients developed a heart arrhythmia compared with 0.3% of patients not given the drugs.

WHO from new finding suggested worldwide stoppage of the use of HCQ in trials that going on in many countries in Europe. FDA had already around last week April had discontinued the use of HCQ for COVID 19 patients even on compassionate ground. Recently Lancet study has been criticized because this is not a randomized control trial and standardization between the patient's clinical information will be a challenge and some of the observation is because of the statistical analysis used. This size of the observational study means something. The HIS data these days from the good hospitals are linked to LIS data also which means data from images as well as data from laboratories with the new apps these data are now used for clinical decision making. Abbott already has one and Israeli also has one where the decision making even in individual patients is possible. Normally patient enrollment under various protocols occurs in the moderate, severe, critical categories. In all these conditions case definitions as well as the endpoints are all defined. Also the oxygen level whether below 95 or below 90 is critical. Going to ICUs and pressurized ventilators are also critical. In any study survival or death is very important, when you depend only on sofa scores it is not accepted as primary endpoint in many situations. The majority of patients severe and critical list in the western countries who are Covid-19 infected are older people and they normally suffer from comorbidities. That is why the death rate in this group is very high compare to overall death rate from a country. I will also stress that in any drug administration patient safety is paramount. It is without a doubt that hydroxychloroquine can induce cardiac arrhythmias or cardiac arrest. It is also known to aggravate renal conditions which are often associated with the cardiac condition and hypertension. In many countries, diabetes retinopathy as well as obesity is also a common denominator. Many obese women have silent Coronary artery disease. If Hydroxychloroquine causes more deaths in a group in which it was administered to compare to the group which didn't receive it, the safety will be a major concern. It is not critical whether it is beneficial or not beneficial, without patient safety it cannot be administered. One thousand patients is a huge number and it is fully legitimate to use this number to come to a conclusion.

Chemoprophylaxis with hydroxy-chloroquine (400 mg twice on day 1 or loading those of 800 mg thereafter 400 mg once a week indefinitely) since the COVID – 19 is there to stay for at least next 2 years, it could be toxic for the frontline workers. This is still in recommendation in India for asymptomatic healthcare workers treating patients with suspected or confirmed COVID-19, and for asymptomatic household contacts of confirmed cases. The document states "its use in prophylaxis is derived from available evidence of benefit as treatment and supported by preclinical data". But in the light of the current evidence and India having large population with silent CAD or congenital heart defects, pre diabetes

and diabetes, chronic kidney disease, hypertension and diabetic retinopathy with middle obesity as well as rheumatic fever and rheumatic heart disease if put on unsupervised prophylaxis may be endangered with severe adverse effects of HCQ. A large section of Indian population born in malnutrition which is subsequently later in life leads to development cardiac abnormalities. People are prone to infection Rheumatic fever an inflammatory disorder caused by a Group A strep throat infection. It affects the connective tissues of heart causing Rheumatic heart disease. There are many people with silent Coronary artery disease in India. With all this in mind in these times of pandemic, with no universal healthcare system in place we cannot screen such a large number of healthy contacts for concomitant QTc prolonging medicines, long QT syndromes, or glucose-6-phosphate dehydrogenase deficiency. Even a 0▪1% proportion of serious complications would amount to more than 10 000 severe adverse events in New Delhi alone and will cripple the health system. HCQ was used in malaria prophylaxis but mostly for those who visited endemic region from non-endemic western countries and it was primarily used for malaria treatment in India, however the age group most affected was children. Chloroquine was given in a syndromic approach in fever cases to control malaria, led to widespread resistance to chloroquine. Hence global fund recommended that chloroquine should be used in fever to treat malaria only when a diagnostic test has been performed. Hence discriminate use for prophylaxis in a largely endemic country having malaria may lead to chloroquine resistance very quickly as well as unintended adverse events. If the prophylaxis is to be pursued it should be done after counselling, health check before and after at periodic intervals and should be given to only those who have a greater chance of contracting disease and not to everyone. The Harvard group is a group of reputable scientist who have used a data gatherer company to access HIS data of 961 hospitals. None of the hospitals have said that the data was accessed illegally. HIS data these days are gathered in formats which could be used for research. The issue was the large number of serious adverse events in the chloroquine group compare to control. No study at the moment shown that the chloroquine group does not cause significant cardiac arrhythmias or retinal damage, it can also cause skin pigmentation.

On 3rd June' 20 New England Journal of medicine published a double blind randomized placebo control study in 814 subjects where the asymptomatic patient in one hour were given hydroxychloroquine. Placebo control trial was not given the drug. The end point was how many became symptomatic in each group. There was no difference between 2 groups although the time of post exposure was same. The adverse events in the

hydroxychloroquine group was 40.1% and the placebo control group it was 16%.

If the Lancet review comes out as conclusion drawn was acceptable every nation should take a policy decision. ■

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Yampolskii, Y.; Eliseev, A. Enhanced Gas Separation Factors of

Sanitizer formulations and Quality control

Sanitizing is most important than anything to protect ourselves in this global pandemic situation. In this current Pandemic situation of COVID-19 it has made every one use hand sanitizer to get rid of any bit of virus present on our hands due to direct or indirect contact with infected one. According to WHO guidelines washing hands every 2 hours or timely sanitizing them to protect her/himself. Now washing hands on the go is not possible for everyone, hence the use of hand sanitizer has been recommended.

While the world strives to cope with a global pandemic, the requirement of hand sanitizers has increased. FDA is allowing additional companies to manufacture alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency, But provided the following circumstances are present:

1. The hand sanitizer is manufactured using only the following United States Pharmacopeia (USP) grade ingredients, consistent with World Health Organization (WHO) recommendations:
   a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (80%,volume/volume (v/v)) in an aqueous solution or Isopropyl Alcohol (75%,v/v) in an aqueous solution.
   b. Glycerol (1.45% v/v).
   c. Hydrogen peroxide (0.125% v/v).
   d. Sterile distilled water or boiled cold water.

WHO recommends the local production of the following two formulations as an alternative when suitable commercial products are either unavailable or too costly, the formulations are as follows.

REAGENTS FOR FORMULATION 1:	REAGENTS FOR FORMULATION 2:
Ethanol 96%	Isopropyl alcohol 99.8%
Hydrogen peroxide 3%	Hydrogen peroxide 3%
Glycerol 98%	Glycerol 98%
Sterile distilled or boiled cold water	Sterile distilled or boiled cold water

Quality-control pre and post production is also very important.

Pre-production analysis should be made every time an analysis certificate is not available to guarantee the concentration of alcohol. Verify the alcohol concentration

with the alcohol meter and make the necessary adjustments in volume in the preparation formulation to obtain the final result.

Post-production analysis is mandatory if either ethanol or an isopropanol solution is used. Use the alcohol meter to control the alcohol concentration of the final use solution. The accepted limits should be fixed to ± 5% of the target concentration (75%–85% for ethanol).

Pre-production reagents quality can be verified in conformity of the respective monograph if an analysis certificate is not available. Density, Refractometry and Titration instrumentation are used to ensure compliance with pharmacopoeia requirements (e.g. European Pharmacopoeia).

- **Ethanol 96%:** alcoholometry or relative density 0.805 to 0.812 and R.I. 1.3636
- **Isopropyl alcohol 99.8%:** relative density 0.785 to 0.789 and R.I. 1.376 to 1.379
- **Glycerol 98%:** refractive index 1.470 to 1.475
- **Hydrogen peroxide 3%:** concentration can be determined by titration (oxidation of hydrogen peroxide using potassium permanganate).

We at Hanna instruments supply the instruments in refractometry as well as in titrometry. Our HI96800 refractometer and HI93X series of tiltrator series, is cost

friendly as well as easy to use. HI96800 is easy measurement with just 3 button operation. Titrators are state of art built to sustain in adverse conditions. Saves foot-print of your lab, gives accurate results. Durable, accurate, and simple to use, our fully supported autotitrators make switching to us the right choice.

Author: Kondiba

With more than a decade of experience in managing sales, marketing, customer support and business of Analytical Instruments. Kondiba has a vast knowledge of Instrument sales in new and remote markets. With his expertise and foresightedness, Hanna Instruments - a worldwide leader in analytical instruments has a strong hold in Indian market and witnessing growth every year.

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HRS Hot Water Systems

HRS brings the range of HRS Hot Water Systems, most efficient way for instant hot water generation for process industries. These are compact, pre-assembled skids designed with HRS' heat exchangers: tubular, corrugated tube or plate type heat exchangers, or a combination of heat exchangers as best suited to the process.

HRS hot water systems give superior efficiency. HRS heat exchangers Ecoflux* corrugated tube heat exchangers and HRS Funke plate heat exchangers give maximum output in have minimal energy. Corrugated tube heat exchangers are compact and enable turbulence in flow to reach high temperatures in short time, whereas PHEs are most suited to temperatures upto 1700C and 25 bar pressure. Accurate temperature pressure can be achieved instantaneously. HRS hot water systems are designed with proper safety measure, enclosures, fireproof/ insulated control panels of high quality to give operational safety, avoid intermixing of fluids and fast output. They enable the customer to reduce the hot water circulation cycle time to a substantial extent, thereby achieving higher economic efficiency also.

HRS hot water systems are customized with the best of heat exchangers and peripherals, pumps, valves, controllers, etc. yet are worth the investment due to lower capital cost, good installation and prompt service from the technical team of HRS. These skids require up to 75% less space for installation when compared with conventional hot water tank based systems.

HRS hot water systems are essential for pharmaceutical, chemical, textile plants, breweries, sugar refineries, food processing, HVAC, hotels, hospitals and more such industries. For special single fluid heating cooling applications, the heat exchangers can also be made in exotic materials like C276, C22, Titanium, etc. to ensure process compatibility. ■

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HyPerforma™

Single-Use Fermentor (S.U.F.)

The S.U.F. is engineered for optimal oxygen mass transfer, mixing, and temperature control, and performs comparably to traditional stainless steel systems. Using traditional, fundamental engineering principles, scale-up and process development work is streamlined – offering you cost savings and efficiency.

Some of the key features of the Single-Use Fermentor (S.U.F.) include:

Microbial Fermentation & Biological Fermentation: The S.U.F. is the first specifically engineered fermentor for scale up and production and is available in 30 L and 300 L sizes. It has been optimized oxygen mass transfer, mixing, and temperature control, and performs comparably to traditional stainless steel systems. Using traditional, fundamental engineering principles, scale-up and process development work is streamlined – offering you cost savings and efficiency.

Stainless steel performance, single-use benefits: The S.U.F. has been developed on standard stainless steel fermentation design geometry (3:1 height to diameter, 5:1 turndown ratio), making scale-up and process development activities easy. The single-use format helps reduce batch turnover activities, including the time-consuming clean-in-place and sterilization-in-place cycles, which helps to decrease costs and increase productivity. ■

Source: Thermo Fisher Scientific

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Spectralab Melting Point
Apparatus Check Melt Series

Spectralab is in manufacturing of Melting Point Apparatus since 2011. As per our philosophy of continuous R & D new models were introduced. Check Melt SB was introduced in 2019. This is again as per philosophy "Identifying the need & brining the solution at your door step". And now we are bringing "Check Melt VR" with latest technology as our top end model.

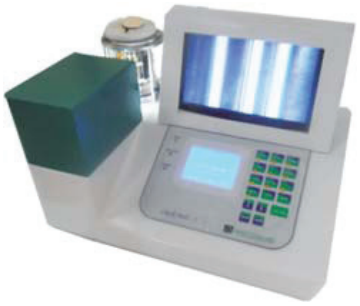
Spectralab offers Three models :

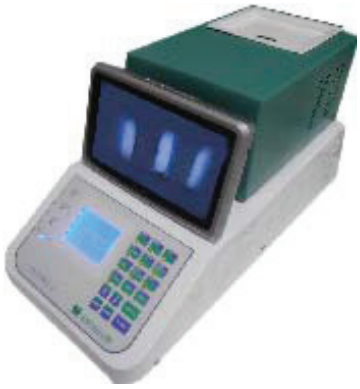
1. Check Melt OB Determines - Melting and boiling point. It is having heating media as Oil Bath. The Melting point Detection is Manual. Temperature Range is Ambient to 300°C

2. Check Melt SB Determines - Melting and boiling point. It is having Heating media is Heating block, The Melting Point Detection is Manual. Temperature Range is Ambient to 400 °C

Both these two model have 128 x 64 Graphic LCD Display.

Both these model meet GLP Compliance: Time & Date stamped... GLP compliant report, Password Protected Operation, Inbuilt RTC. These 2 models have both Serial & Parallel Interface to transfer Reports to Dot Matrix printer / PC.





Now we are pleased to introduce our new melting point model with video recording facility

3. "Check Melt – VR". Available as "Stand Alone" or "PC through operation"

- The instrument is compact and comes with 7 inch touch screen.
- Comes with password protection even in stand alone model.
- Upto 4 different samples can be analysed at a time.
- 21 CFR part 11 Compliance.
- Uses Solid Aluminium block
- Automatic Detection

It has Easy GUI access for editing:

1. Date & Time
2. Network setting
3. Display setting

4. Wi-Fi setting
5. Auto lock setting

Date, time, user name, reviewed by, approved by stamped GLP compliance report. Different types of reports are available as - result, parameter, document and graph are provided . User can use it for quick view, print report or save report to USB stick (pen drive) in pdf format.

Online video provides real time presentation of state of sample under process. Last video is recorded for offline observation of melting process.

Once the melting point is over you can get complete GLP report with full video which can be recalled any time. 1000 reports can be saved into the instrument or directly taken as print out or transferred to USB.

New method for each sample can be created. We can store * Sample name, * Batch no., * Sample no., along with start and end temperature. & ramp rate selected.

Selection Guide : If you want both melting point and boiling point — only choice is Check Melt SB or Check Melt OB. Oil bath has limitations on temperature up to which you can go. Most of the oils (silicon oil) are useful up to 250 °C only. Recurring expenses and extra work is involved in replacing the oil. Check Melt SB uses solid block hence the problems are eliminated plus temperature range is also wide up to 400 °C. Auto detection in Check Melt OB/SB is not available, however the visual images are very clear for manual detection with ease and accuracy. For Automatic detection & video recording use Check Melt VR.

Model Check Melt VR is Top End model with video recording and automatic detection. As the detection is based on image processing it can even detect coloured samples with some exceptions of too dark samples. With possibility of storing 1000 reports it is the ideal choice unless budget restrictions are there.

Choice between standalone & PC through Operation:

All the requirements of 21 CFR part 11 are available in standalone model. Video recording of only last sample is stored. PC through operation model can be chosen if large data storage for storing video recording of every sample is needed. A video recording of the melting process is also available and can be shown if required. ■

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Tablex MC Metal Detector

Tablex MC pharmaceutical metal detectors remove all metal contaminants in tablets and capsules from pharmaceutical and nutraceutical products. Offered with a compact material handling system, they feature adjustable conveyor infeed and outfeed heights enabling elimination of dedusters or vacuums employed to lift tablets to catch bins. Designed and built to comply with FDA, GMP standards and to satisfy the demands of the pharmaceutical industry, SAFELINE Tablex MC pharmaceutical inspection systems provide unrivalled metal detection sensitivity to all metal contaminants including non-magnetic stainless steels and difficult to find, minute sieve wire contaminants. This exceptional performance is further enhanced by robust construction for maximum on-line stability.

The intuitive membrane-driven operator interface provides rapid, easy set up routines and adjustment for maximized manufacturing uptime.

Source: Mettler-Toledo Product Inspection

Coperion K-Tron Modular Feeders For Bulk Material Processing

No two process applications are the same, and Coperion K-Tron offers the widest range of feeding solutions in the industry. From screw feeders to vibratory feeders, bulk solids pumps, weigh belts, liquid feeders and flow meters, all feeders are offered in a variety of configurations, which can be combined to create an optimal solution for any application.

Source: Coperion & Coperion K-Tron

iGene Labserve Pvt Ltd

iGene Labserve Pvt Ltd. is an instrumentation company having a complete range for biotechnology research institutes, pharma, food, FMCG and chemical industries. With emphasis on latest technology and after sales support, we are working to provide laboratories with innovative yet cost effective, high quality products and solutions designed to improve experimental efficiency, safety and results.

Source: Coperion & Coperion K-Tron

Biological Safety Cabinet- Class II, Type B2- Labgard 430

The Labgard 430 / 435 Combines the Ventilation of a Fume Hood with the Personnel and Product Protection of a Biological Safety Cabinet. The Labgard 430 / 435 Combines the Ventilation of a Fume Hood with the Personnel and Product Protection of a Biological Safety Cabinet.

Features

- 100% Stainless Steel Construction
- Evaluated for use with Flammable liquids
- Interlocked Blower
- Ergonomic Comfort.

Source: NuAire, Inc.

Natoli Tablet Compression Tooling

A global leader in manufacturing, Natoli Engineering Company delivers superior tablet compression tooling. Every punch and die is produced from quarantined steel and tested for hardness and exact chemical composition by stringent quality specifications.

For over 40 years, Natoli has manufactured punches and dies of unparalleled quality. Our company's advanced system of micro-precision engineering is designed to maximize the life of your tablet compression tooling and is regarded as the best in the industry. Before manufacturing begins, our team of experts extensively research and evaluate every tablet tooling design. This is done to make certain that every punch and die will be manufactured for maximum tooling efficiency, durability and superior performance.

Every punch and die is produced from quarantined steel and tested for hardness and exact chemical composition by our stringent quality specifications. Once the steel has been confirmed, it goes through our computerized vacuum internal quench heat-treating systems to guarantee batch-to-batch consistency.

Natoli's commitment to providing exceptional customer service, technical support and troubleshooting capabilities and pricing structure differentiates us from other solutions. Our staff has the knowledge and expertise to meet any customers' exacting requests and requirements. In addition, we offer competitive pricing by maintaining highly organized manufacturing facilities.

Source: Natoli Engineering Company, Inc.

HPVA II: High-Pressure Volumetric Analyzer

The HPVA II series of gas adsorption analyzers use the static adsorption method to obtain high-pressure adsorption and desorption isotherms utilizing such gases as hydrogen, methane, and carbon dioxide. The instrument can be used to study and determine the methane capacity of shale and coal beds at specific pressures and temperatures, as well as the hydrogen storage capacity of materials such as carbon and metal organic frameworks. It can also be used to simulate underground conditions for carbon dioxide sequestration studies.

Available in a single-station model or in a four-station version allowing up to four sample runs to be completed simultaneously Wide operating pressure range from vacuum to 100 or 200 bar Temperature capability from cryogenic to 500 °C Sample temperature control by means of a recirculating temperature bath, cryogen Dewar, or furnace Measures BET and Langmuir surface area, total pore volume, and corrects the non-ideality of gases with multiple equations of state.

Vertical Blenders For Manufacturing

Ross V-Blenders are most often used for the intimate dry blending of free flowing solids. The solids being blended in these units can vary in bulk density and in percentage of the total mixture. Materials being blended are constantly being split and intermixed as the shell rotates. Normal cycle times are typically in the range of 15 minutes, however can be less depending on the difficulty of blending.

All Ross V-Blenders are supplied with Intensifier bars to permit deagglomeration as needed. Discharge is accomplished through a manually operated Butterfly valve. The valve is positioned 24" from the floor when in the bottom position. Safety railings and appropriately interlocked safety interlocks. Stop-Start and E-Stop Pushbuttons are included with all blenders.

This versatile line of dry blenders is available from stock in 5, 10 and 15 cu.ft. capacity. All blenders include the following standard features:

- Intensifier bars for de-agglomeration
- Atmospheric construction
- Type 316 stainless steel parts
- 150 grit exterior finish, mirror finish on internal surfaces
- Stainless steel support stands
- Manually operated butterfly discharge valves
- Safety railings
- Fully integrated motors and controls

The units are available for sale or trial rental. Ross V-Blenders can all be customized to include special discharge valves and customer requirements.

Source: Charles Ross and Son Company

Branson's vibration welders

Vibration welding uses the frictional heat generated at the joint interface of two parts to be welded to melt the plastic. Two methods are available from Branson: linear and orbital vibration welding. With linear welding, the heat energy is achieved by moving one part relative to its mating piece in a reciprocating motion under pressure through a given displacement or amplitude. With the orbital process, the upper section is vibrated using a constant velocity circular motion. With both processes, once the desired amount of melt has been achieved, vibration is stopped, and the parts are held together under a clamp force for a short period of time, allowing the weld to solidify.

Branson's vibration welders are designed to withstand the abuses typically encountered in a rugged industrial environment. They offer state-of-the-art process control, improved ergonomic features, rapid setup capability, and meet all safety regulations. Several different-sized models are available. Depending on the model, standard linear vibration welders can assemble parts of any size up to 55" long by 20" wide. Multiple parts per cycle can also be welded. The Hy-Line Series linear vibration welders offer multiple control levels.

Standard features include closed loop amplitude control, adjustable frequency, and ergonomically designed optotouch sensors. Process verification software for validating weld quality on critical applications is available. In addition, Branson offers Mini II vibration welders; with a footprint of only 36" by 38"; these welder will handle parts up to 7" by 9". Orbital vibration welders can operate at low weld amplitudes – less than 0.030" in some applications, which reduces part clearance requirements and enables welding of unsupported vertical walls. Parts up to 12" in diameter may be orbital welded. Constant velocity orbital motion results in more welding power in short weld times. Omnidirectional motion enables welding of taller, unsupported vertical walls. No wall is ever perpendicular to welding motion since motion is in all directions.

MiR250

The MiR250 has a footprint of 580 x 800 mm and a height of only 30 centimeters while still being able to move as much as 250 kg with a speed of 2 meters/second. This makes the AMR more agile than any other AMRs on the market and highly adaptable for challenging environments. Thanks to the small footprint, it can drive in spaces as narrow as 80 centimeters. So, doors and elevators that can be an obstacle for other mobile robots, are not a problem for the MiR250.

The MiR250 is constructed for long lifetime, easy serviceability and work 24/7 with the option for fast battery swap. Further, it has been designed according to current applicable safety standards - we therefore believe it's the safest AMR on the market.

AutoGuide Max-N15 Tugger

AutoGuide Mobile Robots Max-N15 is the highest payload modular autonomous mobile robot (AMR) tugger, capable of transporting up to 15,000 pounds. AutoGuide created the Max-N15 configurable, modular autonomous mobile robot by combining and redesigning traditional material-handling systems into a common base. The Max-N15 combines a drive motor with sensor/steering/safety/communication features and a series of modular attachments that offer the most economical capital efficiencies for customers. The modular attachment approach enables volume production of the base units more quickly, which drives down costs, shortens lead times and improves reliability due to accelerated product maturity. Built on AutoGuide's patent-pending modular design, the Max-N15 provides a common base that can be adapted for multiple manufacturing and warehouse material handling tasks with modular attachments to create lift trucks, tuggers or high bay pallet lift trucks.

The Max-N15 extends AutoGuide's family of advanced high-payload industrial AMRs that are easy to deploy and program, improve safety, reduce costs and increase efficiency for a wide range of material handling operations. The company's Max-N10 tugger, Max-N10 pallet stacker and SurePath fleet management software—which provides an easy means to specify routes, coordinate autonomous lifting and transport of pallets, and manage the AMRs traffic to optimize customers' material transport. ■

SAPIEN - Human to Human

Dr. Sreedhara R Voleti
CEO, ASPIRE-BioNEST

In our second outing with the column PULSE - Presenting Unique Life Science Entrepreneur, Dr Sreedhara R Voleti, CEO, ASPIRE-BioNEST introduces us to SAPIEN Biosciences — India's largest and only commercial biobank. It puts 'medical waste' to use for healthcare innovation. The biobank has been established in a unique partnership with Apollo Hospitals, a pan-India network of 69 multi-specialty hospitals, hence avoiding regional or disease bias in the biobank.

SAPIEN Biosciences is a biotech company that originally started with Biobanking as a primary focus, later went into conducting its own research in oncology. The Company has evolved from solely an R&D-focused biotech entity diversifying based on the intended applications by providing biosamples from human patients. Being the first one of its kind in India (private biobank), it brought a lot of attention to the researchers requiring human samples from patientsof all diseases, and especially oncology.

SAPIEN Biosciences is India's pioneer in biobanking, being its largest and only commercial biobank. It puts 'medical waste' to use for healthcare innovation. The biobank has been established in a unique partnership with Apollo Hospitals, a pan-India network of 69 multi-specialty hospitals, hence avoiding regional or disease bias in the biobank. SAPIEN is expanding to other public and private hospitals to increase its capacity and diversity of patients. Challenges from streamlining & integrating multiple hospitals, each with its own workflow, IT databases and practices have been overcome using learnings from the past 7-years such that the synergy of scale is now evident.

SAPIEN has already acquired >200,000 cases and expects to cross 500,000 in 3-years. These biospecimens and associated digitized rich data have been used for establishing advanced cell and molecular research platforms needed by biotech, pharma & diagnostics companies for the development and validation of their products and marketing strategy. Clinical diagnostics e.g., myPLATELETTM test used to optimize anti-platelet therapy for PCI-plus-stent patients are also developed.

Due to it being the first of its kind in India, and forging a path in keeping with the rules for bioethics for R&D which can be used by various organizations, we have chosen to highlight elevate SAPIEN BioSciences in this article, PULSE.

Dr. Jugnu Jain is a molecular geneticist and cell biologist by training. She obtained her PhD from Cambridge University (UK), followed by a post-doc and Instructorship at Dana Farber Cancer Institute and Harvard Medical School at Boston. Her area of research was cytokine gene regulation.

After her post-doc, Dr. Jain joined Vertex Pharmaceuticals where she steered multiple drug discovery projects. She led Vertex's global Immune-Inflammation team, and has significant experience in cancer and diabetes area as well. Prior to founding Sapien and Saarum, Jugnu was a Research Fellow & Disease Area Expert for Multiple Sclerosis helping guide research strategy, evaluating innovative technologies and forging productive scientific collaborations.

Dr. Jain returned to India in 2011 to launch Sapien and Saarum along with her co-founders, Prithi and Sreevatsa. Jugnu has published over 20 papers in leading journals including Nature and Science and has two patents in her name.

In an exclusive interview for PharmaBio World, Dr. Jugnu Jain tells us about her inspiring journey in the Biotech domain.

Dr. Jugnu Jain, Co-Founder & Chief Executive Officer, SAPIEN Biosciences

INTERVIEW:

1. When and what triggered your Entrepreneurial journey gene? How was the ecosystem & family support for your journey?

The thought of initiating a biobank came to me in 2006. Biobanks weren't common in India, unlike in USA (where I was at the time), Canada and Europe. The thought of cancer on rise in India and no data availability was the birth of the idea of starting a biobank in India.

Most of the tissues collected in hospitals during surgeries, were used for diagnosis but the surplus tissue was thrown as a waste – but which had a huge potential for research. This invaluable resource of tissues if stored systematically in India and shared for research could be beneficial for translational research is what I thought. Conversations with an ex-colleague (Sreevatsa Natarajan) from Vertex brought synergy focusing on creating a drug discovery and diagnostics company founded on an organized biobank in India. During a 2009 visit to India the chance meeting with Sreevatsa crystallized this thought into a preliminary plan, leading us to start the groundwork to make our dream a reality. In 2010 for Vatsa, and 2011 for me, the time came to quit our job and take the plunge into entrepreneurial path of creating a Biobank-led personalized medicine company in India. We went to many hospitals to request samples and got traction at Apollo. It took two years of tireless efforts to convince Apollo not only to share their samples and data for the biobank but also the seed funding that led to the launch of SAPIEN Biosciences at Hyderabad, with a research lab infrastructure being available

Biobank Blocks Cupboard

at Apollo, its central location, easy access to life sciences talent, all of which made it attractive for us to build an ecosystem of Biobanking with the help of APOLLO.

Creating something out of nothing as an intent and biobanking as the need of the hour, my returning to Hyderabad was wholeheartedly supported by my Hyderabadi sibling family (sister) and my colleague Vatsa. Enjoying the company of and taking responsibility for my elderly mother were other reasons from personal angle that prompted me to start the entrepreneurial Journey in India. The ecosystem, family, and the collaborative spirit of my cofounder with Apollo's commitment kick-started my entrepreneurial journey in 2012.

2. How did you perceive the gap/unmet need back then?

Back then, and even now, the biobanks existing in India are limited to a few diseases and institutions that are typically academic and not accessible to healthcare and pharma industry. Their inaccessibility, non-multidisciplinary nature, and lack of longitudinal organized data with matched bio-samples, especially for oncology, was the biggest gap which we wanted

to address. We discussed many times whether we should start a not-for-profit enterprise but decided ultimately that a commercial biobank aimed at sustainability, independence and ability to fund internal research was important.

Knowing full well, the research and development in oncology from the biosamples obtained from cancer patients could be used to benefit other patients by generating enough knowledge, we named it SAPIEN. Thus, human cooperation was the fundamental thought that took shape in the nomenclature of SAPIEN (Samples From One Human to Help Another Human), and BioSciences to encompass the different services and products created through bio-samples.

3. What was your competition, challenges, entry barriers back then, which didn't fear your startup?

From 2006 to 2009, I toyed with the idea of a biobank, and explored many hospitals during my annual trips to India Quite interestingly, I found no competition. This was a unique, uncharted, and unexplored business proposition with two broad thoughts, one Service to Industry and Academic innovation, and Value proposition of Internal Research for novel personalized medicines and diagnostics. But, there were challenges like any entrepreneur faces. For over two decades, I had enjoyed a comfortable lifestyle and well-paid job in Boston, USA, and never expected to be an entrepreneur in my life. The thought of starting something from scratch especially in an area like Biobanking where I had no experience, with NO ENTREPRENEURIAL or business EXPERIENCE, and re-establishing myself in a new location (Hyderabad and India) did frighten me sometimes but I believed that we only live once hence should take risks and not regret later. Secondly, with Vatsa being in Hyderabad and more experienced in finance and business, I wasn't alone. .

Leaving all comforts behind and initiating a new chapter in my life was the discomforting aspect, but the entrepreneurial journey was the action-determining step. I took this challenge and opportunity upon myself and asked a question "who will do it if not me" especially with all the hard-work and groundwork done over the past few years with my co-founders, since 2010. The other challenges and entry barriers were mostly the , skepticism of doctors and hospitals in sharing samples, lack of clear ethical guidelines for biobanking and sharing of samples, lack of awareness and need for biobanking, lack of organized electronic data etc. I need to make a special mention of Dr. Hariprasad, our board member and President of Apollo hospitals, whose personal involvement and convincing skills brought the hospital pathology department, doctors and other stakeholders to start giving the samples

to the biobank. The version 1.0 of SAPIEN was creating the biobank with Hyderabad samples which happened by ~2015.
One of our most valuable collections is 15500 breast cancer biosamples with standardized annotated digitized treatment and survival outcomes data.

4. What are the Vision, Mission, Value proposition?

SAPIEN Biosciences started with the primary vision of building a world-class Biobank that systematically archives ethically consented, high quality human samples and associated coded data, digitizing hundreds of thousands of medical records. To harness the biobank resources towards the development of clinically important products, platforms & services for Pharma, Biotech, Diagnostics & Data science applications. To mine deep digitized data to improve patient care by maximizing efficacy and minimizing cost for patients. Hence, we created higher value proposition by developing our own platforms and technologies through internal research, and collaborative research programs with external research organizations such as Oncostem and Tech Mahindra for building better prognostic tools for Indian breast cancer patients using our samples and data. Examples of our products and platforms include Clinical Diagnostic (MyPlateletTM canAssist-BreastTM), OncoblocTM, OncoPrimeTM, TrucellTM, TrueScreenTM, TruDataTM. Our collaboration with Tech Mahindra uses digital pathology, multi-spectral imaging and AI to predict outcomes for cancer patients. We have used live cancer tissue to build lab models of cancer such as mammosphere and gliosphere, 3D cultures to test new drugs, antibodies, herbal extracts, nano-formulations etc., in primary human breast cancer and brain cancer. . These technologies have not only brought business to make Sapien sustainable, but also invaluable recognition for SAPIEN.

5. How is it now, when you look back, the entrepreneurial graph?

Very satisfactory, and gratifying experience! Had I not taken the step with leap-of-faith in entrepreneurship, probably it would have remained a dream. We started with a blank slate. Version 1.0 of SAPIEN which started in 2012, and lasted until ~2015, was the establishment of biobanking at Apollo Hyderabad with ~25000 patient samples in a proprietary EMR. Version 2.0 was expansion to many Apollos where we added another six hospitals as well as few non-Apollo partners across India by 2019, crossing 200,000 patient samples., We hope the version 3.0 of SAPIEN will not only reach 5X growth in samples but also development of clinically meaningful healthcare solutions for our patients such as non-invasive early detection of cancer by 2025. Critical challenges like normalization and coding of medical data

Mol Bio Lab

has been done. We have built critical mass , and put in the processes for sharing samples. We have established and registered ou biobank ethics committee (IEC). With TAC and IEC, we have brought in technical, medical, quality, and ethical experience to our projects.

6. How would you propose recommendations for the Govt. to endorse your Internal product/value proposition?

There is an artificial divide between public and private biobanks which needs to go if we are all to make optimal use of the precious samples given by patients for R&D into better medicines, diagnostics, treatments. So I feel government bodies like DST, DBT, CSIR, and ICMR should promote Public-Private Partnerships of biobanks wherein more funds could be available to researchers for validating their discoveries with high quality samples. Such partnerships could be benefit-sharing that help research as well as patients. Recently, Department of Biotechnology with its Institute of Life Sciences at Bhubaneswar as nodal center has initiated COVID-19 biobanking, while Council of Scientific and Industry Research through its institutions is also promoting biobanking for COVID-19. It is encouraging to see the governmental bodies recognizing the need for biobanking, yet these are not inclusive of private biobanks and hospitals which are also treating COVID-19 patients. If

all data from public and private was pooled, a pivoting data (normalized across all agencies) would bring a lot more applicability in understanding the etiology of disease, diagnosing it with appropriate and cost-effective measures, and treating it optimally at a larger and organized scale.

7. Highlight brief successful stories of SAPIEN.

At SAPIEN, we offer several advanced research services using the patient samples and data in our biobank that has benefited our partners. We have systematically curated and integrated cancer patients' treatment and survival outcomes data in breast, lung, H&N, Colorectal, renal, and many cancers. We are using our breast cancer dataset to develop a digital pathology and AI-led algorithm to optimize treatment of triple negative breast cancer cases in partnership with Tech-Mahindra; our project has been shortlisted by Frost & Sullivan for Technology Leadership Award. Our colorectal samples and data were used to validate a marker that could predict the response to a specific drug in colorectal cancer, which is in clinical trial now. Another example we have tested ayurvedic herbal extracts for their anti-cancer activity which has led to filing of IP by our client.

8. Punchline of SAPIEN:

Some of the punchlines of our organization are

"ADVANCING MEDICINE, PERSONALIZING TREATMENTS", "FROM ONE PATIENT TO HELP ANOTHER PATIENT", "UPCYCLING MEDICAL WASTE FOR MEDICAL INNOVATION"

9. Brief introduction of yours!

SAPIEN -I'm a first-time entrepreneur who moved from Boston, USA after 22 years to India, to co-found a unique company with Mr. Sreevatsa Natarajan, my ex-colleague from Vertex Pharmaceuticals. By training, I'm a molecular & cell biologist with extensive experience in drug discovery & translational research into healthcare solutions. Sreevatsa is a chemist and pharmacologist by training with global experience in drug discovery, clinical research, licensing & business development.

SAPIEN has been invited to speak at many national and international biobanking forums including ISBER in 2019. SAPIEN has been covered by India Today in 2016, by YourStory, by BioSpectrum and selected to present at BioAsia 2020. In 2019, SAPIEN was only one of the 3 companies selected in Healthcare Category to represent India at the Global Entrepreneurs Summit at Netherlands. In 2020, Dr Jugnu was awarded the Women Transforming India recognition by the Niti Aayog. ■

The Evolution of Law and Ethics in Pharma Sector:
Tracing the International Context - Part II

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

Mr R. S. Raveendhren, Advocate, High Court of Madras expounded on the Evolution of Law and Ethics in the Pharma Sector with respect to the international context in his maiden article. In this issue, he tells us about two of the worst experiments to be conducted on human subjects without so much as taking their consent. From there he goes on to elaborate the development of various conventions and the international bodies that have been imposing time and again the need for advancement of scientific research and clinical trials but only after completely studying the associated risks and with the expressed consent of its human subjects.

Mr Raveendhren who has completed 16 years at the Bar has also authored a book on Dr. Ambedkar's Contribution to Indian Constitution. He has been recently appointed as a Legal Expert on the Institutional Ethics Committee of SRM Medical College Hospital & Research Centre.

"Even the most rational approach to ethics is defenceless if there is no will to do what is right" *- Alexander Solzhenitsyn*

If at all there has been a significant milestone in the history of ethical clinical trials, then it has to be the Belmont Report. The report set forth three underlying principles of

- Respect;
- Beneficence and
- Justice for the volunteers

Immanuel Kant's "Act in such a way that you treat humanity, whether in your own person or in the person of any other, always at the same time as an end and never merely as a means to an end." stood reflected in the establishment of the Institutional Review Boards (IRB) that is also variously called the Independent Ethics Committee (IEC), Ethical Review Board (ERB) and the Research Ethics Board (REB).

One of the basic tasks of this board/ committee was to review research proposals and to determine if the projects concerned adhered to the ethical principles and regulations for the protection of its human subjects. The historical documents such as **The Nuremberg Code, The Helsinki Declaration and The Belmont Report** played a crucial role in the evolution of the said IRB.

Another important document that had a solid influence on it was the Universal Declaration of Human Rights that weighed the progression of modern scientific research and the need to protect the human-subjects equally and at par.

THE TUSKEGEE SYPHILIS STUDY 1938-1972:

The Syphilis Study is often regarded as one of the most controversial of experiments that were ever carried out on human-subjects; of course without taking any consent from them. The infamous study took place at Tuskegee in Macon County in Alabama, USA and was carried out on Afro-Americans who were then studied for the effects of untreated, later-staged but latent syphilis. What they were told was that they were being 'treated for bad blood'. The 'volunteers' were eventually left uncared for and even actively kept away from knowing about the availability of life-saving medical intervention.

This invisible study was exposed internationally in the year 1972 when 'Washington Star' came out with details exposing unethical treatment. It caused a huge furore that resulted in the termination of ongoing research on the disease. The outcome of this public outcry was also

that it led to the enactment of the National Research Act of 1974.

- The Act's main objective was to provide for the protection of human subjects involved in biomedical and behavioural research; and other purposes.
- It created a National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research to frame guidelines and regulate ethical practices in experimentation on human-subjects.
- It also mandated the role of Institutional Review Boards for research supported by the federal funds.
- In May 1997, President Clinton issued a public apology on behalf of the United States Government to all the victims of Tuskegee Syphilis Study.

THE GUATEMALA SYPHILIS STUDY

Guatemala Syphilis study was carried out at about the same time as the Tuskegee study, i.e. sometime between 1946 and 1948. The project was led by Dr. John Charles Cutler, United States Public Health Service, who ironically also played an important role in the Tuskegee misadventure.

The Guatemala study involved infecting soldiers, prisoners of war, prostitutes and mentally challenged with Syphilis and other Sexually Transmitted Diseases (STD) without any informed consent. The experiment was accidentally discovered

by Professor Susan Reverby of Wellesley College only in the year 2005 while studying the Tuskegee Syphilis Study from the archived papers of Dr. John Charles Cutler.

President Barack Obama rightfully apologized to Guatemala and in unequivocal terms called it a 'crime against humanity'. An investigation that was ordered by the Presidential Commission for the Study of Bioethical Issues concluded that the said experiment involved unconscionable violations of basic ethics that were also recognized by the medical community of the day.

COUNCIL FOR INTERNATIONAL ORGANISATIONS OF MEDICAL SCIENCES (CIOMS)

The Council for International Organisations of Medical Sciences is an international NGO that was founded in the year 1949 under the twin auspices of the World Health Organisation (WHO) and the United Nations Educational, Scientific and Cultural Organisation (UNESCO). CIOMS began its work on guidelines relating to bio-medical research. The Helsinki Declaration (1964) was also getting revised in the meantime. CIOMS rolled out its much-acclaimed 'Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects' in 1982.

Unfortunately, newer issues arose in the form of HIV/AIDS and trials for vaccine/ drugs warranted the widening of approach. The CIOMS-proposed guidelines were no match for the emerging scenario and fell terribly short of addressing ethical issues that cropped up because of rapid advances in medicine, biotechnology, research methodology and practices.

It necessitated revisions of the Declaration of Helsinki in 1983 and 1989. As an inevitable sequel, CIOMS revised its 1982 guidelines and released another set of two guidelines – one in the year 1991 titled 'International Guidelines for Ethical Review of Epidemiological Studies' and another in 1993 called the 'International Ethical Guidelines for Biomedical Research Involving Human Subjects'.

The period after 1993 posed innumerable ethical challenges in the areas relating to

- Controlled clinical trials,
- External sponsors and investigators,
- Experiments in low resource countries and
- Use of comparators other than established effective intervention.

The conflict pitted developed countries against the developing ones. After several rounds of discussions, CIOMS finalized the guidelines in the year 2002 that superseded the 1992 guidelines. It consists of a statement of general ethical principles, a preamble and 21 guidelines.

The 2002 guidelines assist in the

formulation of national policies on the ethics of biomedical research, application of ethical standards in domestic circumstances and creating adequate mechanisms for ethical review of research involving human subjects.

INTERNATIONAL COUNCIL FOR HARMONISATION (ICH) – GOOD CLINICAL PRACTICE (GCP):

The International Council for Harmonisation (ICH) formerly called the International Conference on Harmonisation famously contributed to the development of ICH guidelines on safety, quality and efficacy. It also played a significant role in developing MedDRA (Medical Dictionary for Regulatory Activities) and the Common Technical Document (CTD). Based on its successful track record, ICH is now an international association under the Swiss laws.

Good Clinical Practice (GCP) is a universally recognized ethical and scientific standard for designing, conducting, recording and reporting trials that involve human subjects. The regulations and guidelines that evolved into code of practice came to be known as the International Council for Harmonisation – Good Clinical Practice (ICH-GCP). It lay down:

(a) Good clinical practice

(b) Research ethics

(c) Investigator or Sponsor

(d) Trial protocol and

(e) Documentation of trials

The ICH-GCP comprises all member states in Europe, North America, Japan and Australasia.

EUROPEAN REGULATION – GCP:

The European Commission is the executive arm of the European Union. It comprises 27 member-states. The European Commission exercises control over legislation on pharmaceuticals in the European Union.

- **2001/20/EC Directive**
  In 2001, a directive was issued by the European Commission to make Good Clinical Practise (GCP) a legal requirement for all the member-states. The directive is popularly called 2001/20/EC
- **2005/28/EC**
  In 2005, the European Commission issued a second directive to make Good Clinical Practise as a legal requirement in all member-states. It mandated that the Helsinki Declaration be applied on all clinical trials carried out on human subjects.

(To be continued)

In next edition the author will be dealing about evolution of law and ethics in pharma sector in the Indian context. ■

Sanofi to invest 610 millions euros at two French vaccines sites

French drugmaker Sanofi on Tuesday said it would invest 610 million euros ($679.4 million) at two of its French sites to turn them into a hub dedicated to research, development and production of vaccines. Investments will help enhance the capacities of the group's sites at Marcy-L'Etoile and Neuville-sur-Saone, central France. The announcement came as Sanofi officials hosted a visit of French president Emmanuel Macron at Sanofi's Marcy-L'Etoile facility.

Catalent to fill and package AZ's COVID-19 vaccine

Catalent Biologics' manufacturing facility in Anagni, Italy will serve as the launch facility for the large-scale production and supply of the University of Oxford's Covid-19 vaccine candidate, AZD1222. The company signed an agreement with AstraZeneca, which is working with Oxford University on the development and production of AZD1222. The agreement will support the scale-up of capacity for the manufacturing of AZD1222. The facility will provide vial filling and packaging capabilities to AstraZeneca. It will be ready for production by August 2020 and the company aims to deliver hundreds of millions of doses of the potential vaccine. The production of the adenovirus vector-based vaccine will continue until March 2022, subject to the approval by regulatory authorities.It will also accelerate the launches of customers' biologics and oral drug products and broaden Catalent's network in Europe. Catalent plans to invest further in the facility for its growth.

Vaccine candidate AZD1222 details:
Developed by the Jenner Institute at the University of Oxford and the Oxford Vaccine Group, the recombinant adenovirus vaccine technology-based AZD1222 is backed by the US government. AZD1222 utilises a replication-deficient chimpanzee viral

Catalent's Anagni manufacturing facility will provide packaging services for AZD1222. Photocredit: Catalent Pharma Solutions Inc.

vector derived from a weakened version of a common cold adenovirus that infects chimpanzees. The vaccine contains SARS-CoV2 spike protein genetic material. Vaccination will produce the surface spike protein and prepare the immune system of the patient to attack coronavirus if the body gets infected by it later. It will be a single dose vaccine to create a strong immune response in individuals. Vaccinated individuals will not suffer from ongoing infection as it does not replicate. The drug is currently in clinical studies. It entered Phase I / II clinical trial to evaluate the safety, immunogenicity, and efficacy of the drug in more than 1,000 healthy individuals aged between 18 and 55 years in southern England in April 2020.

Cipla expands partnership with Roche Pharma India to further improve access to key oncology medicines

Cipla Limited and Roche Products (India) Pvt. Ltd. announced that the two companies have entered into an agreement to provide better access to innovative medicines for patients in India. Under this agreement, Cipla will be responsible for marketing and distribution of Roche Pharma's key trademark oncology drugs viz.,Trastuzumab (Herclon), Bevacizumab (Avastin) and Rituximab (Ristova). Commenting on the partnership, Cipla said, "Enabling access to high quality life-saving treatments is core to our purpose of 'Caring for Life.' We are pleased to strengthen our partnership with Roche towards bringing innovative oncology medications to India. This represents our unwavering commitment to address the unmet needs of cancer patients through an enhanced portfolio of offerings in this space. We look forward to leveraging our solid marketing and distribution strengths in India to provide broader access to such transformative treatments in the country.

Roche and Cipla had previously entered into a similar agreement in February 2018 for promotion and distribution of Tocilizumab (Actemra) and other products.

"We have been working as a partner with Cipla for some of our products and it has been a great journey working with them in ensuring access to our innovations in India. We hope to extend the same support to patients in India through this new agreement.", said V. Simpson Emmanuel, General Manager, Roche Products (India) Pvt. Ltd. "This deal will ensure that our focus on providing Roche innovations in India remains steadfast in this portfolio and we will keep on collaborating with the relevant stakeholders in Indian healthcare system to ensure better outcomes for patients."

New leap forward for SARS-CoV-2 detection

PCR Biosystems, the UK-based PCR experts, announced the launch of qPCRBIO Probe 1-Step Virus Detect, a high-concentration 4x RT-qPCR kit designed specifically for ultra-sensitive, high-throughput detection of viral RNA sequences, including SARS-CoV-2. The new kit, which marks the latest addition to PCR Biosystems' specialized RT-qPCR offering, enables users to add more sample to their reactions to boost analytical sensitivity, even when working with small volume reactions.

Consistent with their commitment to supply global healthcare systems with the critical reagents required in the fight against COVID-19, PCR Biosystems has validated the new qPCRBIO Probe 1-Step Virus Detect kit for qualitative detection of the SARS-CoV-2 nucleic acid. Validation has been performed

using the Charité (Germany) primer-probe sequences targeting the RdRp and E genes, as well as the Centers for Disease Control and Prevention (USA) recommended sequences targeting specific regions of the N gene. The kit is ideally suited to high-throughput testing of COVID-19 clinical samples, either with laboratory developed assays or as a component of diagnostic testing kits.

"RT-qPCR reagent kits are pivotal for successful research and molecular diagnostic projects that aim to establish the course of viral infections," explains Alex Wilson, Co-Founder of PCR Biosystems. "Drawing on our PCR expertise and our commitment to delivering best-in-class technologies, we developed qPCRBIO Probe 1-Step Virus Detect to offer researchers and diagnostic kit manufacturers flexibility in their assay development and ultimate confidence in the quality and accuracy of the results generated."

qPCRBIO Probe 1-Step Virus Detect has been developed with the company's UltraScript Reverse Transcriptase enzyme, benefiting users with fast and efficient cDNA synthesis over a wide range of reaction temperatures. Reverse transcription can be performed in only five minutes and at temperatures up to 55ºC, enhancing the detection of difficult viral RNA sequences. The PCR step is powered by PCRBIO HS Taq DNA Polymerase, which employs antibody-mediated hot start technology for specific amplification of virus-derived cDNA, with improved tolerance to the common PCR inhibitors found in clinical samples. Combined with a specially formulated buffer system developed using smart screen technology, qPCRBIO Probe 1-Step Virus Detect gives accurate and ultra-sensitive RT-qPCR over a broad range of template concentrations.

qPCRBIO Probe 1-Step Virus Detect is multiplex-compatible and can be used with all qPCR instruments. Furthermore, this universal kit is developed for use with a variety of probe technologies, including TaqMan®, Scorpions® and molecular beacon probes, for optimal application flexibility.

The introduction of qPCRBIO Probe 1-Step Virus Detect comes as PCR Biosystems continues to scale up operations to ensure uninterrupted global supply of RT-qPCR reagents to support COVID-19 testing and diagnostic kit development.

Lonza and CELLINK Join Forces to Offer Complete 3D Cell Culture Workflows

Lonza and the Swedish company CELLINK have partnered to offer a comprehensive 3-dimensional (3D) bioprinting solution designed to optimize and increase access to complete 3D cell culture workflows. The solution integrates CELLINK's 3D bioprinting instruments and bioinks with Lonza's broad selection of human-derived primary cells and supporting culture media. Cell biologists can now rely on this high-performing product offering to successfully execute even the most demanding 3D bioprinting work and boost their scientific research.

Under the agreement, CELLINK will be delivering the complete 3D bioprinting solution through its global sales channels, supported by Lonza's well-established logistics processes.

Cell biology laboratories on a global scale are increasingly adopting 3D over 2-dimensional (2D) cell culture approaches, as they more closely resemble the cells' in vivo environment offering a more accurate and reliable means of predicting and analyzing cell behavior. However, as researchers look to create increasingly complex 3D

constructs, finding solutions to structural and material engineering challenges is becoming progressively more important. 3D bioprinting has emerged as a powerful technology for engineering complex 3D tissues for in vitro drug discovery research.

Ginger Lohman, BioDispensing Product Manager, CELLINK, said, "Everything we do at CELLINK, from live cell imaging to our innovative bioprinting systems and bioinks, is meant to support our customers with the products and services needed for them to more effectively and efficiently research solutions to some of the most important challenges of our time. Challenges such as cancer therapeutics, regenerative medicine and the testing and development of drugs, to name a few. When it came time to expand our portfolio into complete 3D cell culture workflows, we knew it was critical that we brought the right partner onboard. We're confident that Lonza is that partner."

CELLINK provides a wide range of user-friendly and flexible 3D bioprinting systems, designed to offer improved levels of sterility, precision and versatility. Furthermore, the company's Bioink is the world's first universal bioink designed to print complex 3D human tissue constructs with any 3D bioprinting system. Offering superior biocompatibility, cell viability, printability and consistency, this biomaterial can be modified with peptides and growth factors to develop a series of customized bioink formulations to meet varying application needs.

Robust, viable cells are an essential component of any successful 3D bioprinting and cell culture application. Lonza offers an extensive array of high-quality human-derived primary cells and culture media specifically developed to improve experimental reliability and validity. All cells are ethically sourced and authenticated by thorough quality control testing, while the media are optimized for each cell type to support optimal, consistent growth and maintain the tissue-specific characteristics.

Parexel Launches New 'KeepingPatientsFirst' Integrated Research Platform to Access Critical New COVID-19 Data

Parexel, a leading provider of solutions to accelerate the development and delivery of innovative new therapies to improve world health, from Clinical through Commercialization announced the launch of the #KeepingPatientsFirst integrated Real-World Evidence (RWE) research platform collating critical evidence and accelerating patient and physician access to insights on treatment and outcomes in COVID-19. The platform is powered by Microsoft Azure in

collaboration with the company's Parexel Informatics division, enabling physicians and researchers to better understand and adjust treatments in real-time. The robust and patient-centric technology solution reflects learnings from both organizations resulting from their cloud technology alliance established in 2017.

"Applying the traditional process of executing randomized controlled clinical trials that require in-person subject availability over a period of months and years to execute is simply not feasible in today's landscape," said Jamie Macdonald, Chief Executive Officer, Parexel. "As such, our industry must innovate to validate and approve these therapies at the earliest possible moment. Our #KeepingPatientsFirst platform leverages advanced technology capabilities along with industry-leading expertise to expedite the processing and analysis of information to work with regulators to save lives."

Patty Obermaier, US VP of Healthcare at Microsoft said, "As the global health pandemic has evolved, we've seen the industry come together with a range of innovative solutions emerging. We are pleased to see that by using Azure, Parexel has been able to accelerate their work to help provide rapid access to COVID-19 therapies."

#KeepingPatientsFirst is focused on aggregating, analyzing and predicting real-world COVID-19-related disease progression and outcomes using state-of-the-art machine learning, artificial intelligence and analytics. The study is now available to provide patients and healthcare providers a leading reliable source for rapid access to pooled real-time analyses on multiple COVID-19 therapies thus facilitating informed, individualized treatment decisions and accelerating the identification of promising therapies. This epidemiological approach will also help to characterize and define an unprecedented worldwide event, including documenting the real-world patient journey from awareness to diagnosis to disease resolution, speeding the evaluation of potential COVID-19 therapies.

Takeda and Neurocrine to Collaborate on $2-Billion Deal for Pipeline Program Development

Takeda and Neurocrine Biosciences announced on June 16, 2020 that they have entered into a collaboration worth up to approximately $2 billion to develop and commercialize seven of Takeda's pipeline programs, including three clinical-stage assets for schizophrenia, treatment-resistant depression, and anhedonia. Through the agreement, Takeda will receive a total of $120 million in upfront cash and will be entitled to development milestones of up to $495 million, commercial milestones of up to $1.4 billion, and double-digit royalties on net sales, a Takeda press release said. Additionally, Takeda will have the option to opt in or out of a 50/50 profit share on all clinical programs on an asset-by-asset basis, while Neurocrine will be responsible for developing and commercializing all pipeline compounds included in the collaboration.

"We are excited to collaborate with Takeda to bring life-changing therapies to people living with serious, challenging, and under-addressed psychiatric disorders who are in need of better treatment options," said Kevin Gorman, PhD, CEO at Neurocrine Biosciences, in the press release. "With our deep understanding in the fields of psychiatry and neurology, we look forward to developing

new treatments for schizophrenia, treatment-resistant depression, and anhedonia as part of our diverse clinical development pipeline. This strategic partnership enhances our growing pipeline and strengthens our position as a leading neuroscience-focused biopharmaceutical company."

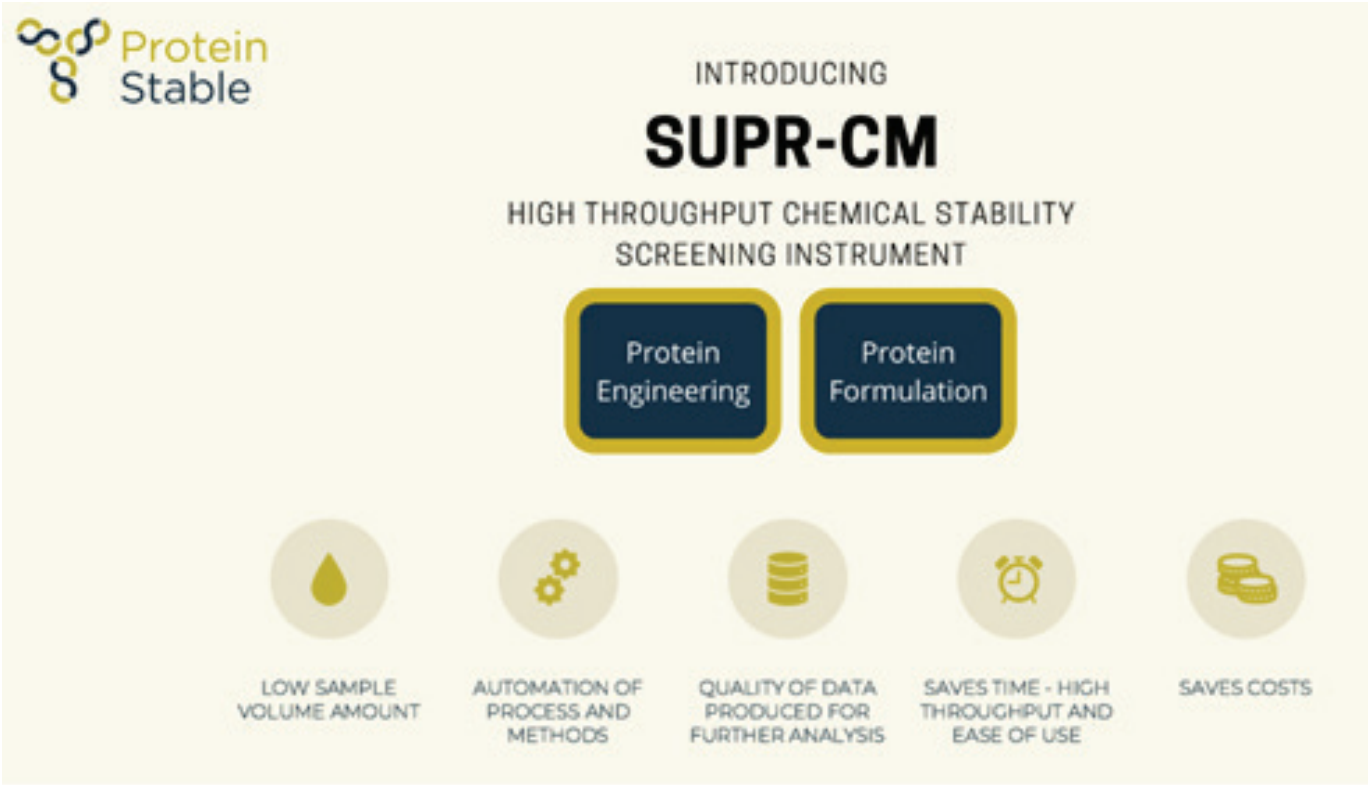
"With longstanding experience developing and commercializing therapies for serious neurological and psychiatric disorders, Neurocrine Biosciences is the ideal partner to continue to develop our early-to-mid-stage psychiatry portfolio and bring these potential new therapies to patients," said Sarah Sheikh, MD, head, Neuroscience Therapeutic Area Unit at

Strategic Alliance between Applied Photophysics and Fluorescence Innovations

Applied Photophysics (APP) and Fluorescence Innovations (FI) have entered into a joint venture agreement to develop and produce protein stability systems for leading researchers and industries around the globe.

The two firms said they will be equal partners in the new initiative. The joint venture will be autonomous and independent, with APP and FI continuing to compete in all other business areas, the companies said. They anticipate that joining forces on protein stability systems will lower development costs and bring forward a cutting-edge technology centered around a chemical melt protein stability system.

Both companies aim to offer their specific expertise with FI handling the development of the technology and APP offering streamlined sales and manufacturing support to produce the system. Both companies have significantly played a vital role in the success of the newly-founded Protein Stable Ltd.



Batavia Biosciences to Partner with Valneva Sweden AB for Polio Vaccine Development

Batavia Biosciences, a biopharmaceutical contract development manufacturing organization, and Valneva Sweden AB, the Swedish subsidiary of Valneva SE, announced that they have entered into a collaboration to accelerate market access of a low-cost inactivated polio vaccine (IPV).

Through the agreement, Valneva will manufacture the Sabin vaccine strains (sIPV) for clinical trials in its manufacturing facility in Solna, Sweden, using Batavia's process, according to a press release. Valneva will receive an upfront payment and monthly service fees while Batavia will be responsible for the release and supply of the vaccine to developing country vaccine manufacturers (DCVMs).

Batavia received a grant from the Bill and Melinda Gates Foundation in 2019 to use its low-cost vaccine manufacturing process HIP-Vax, in combination with Nevoline manufacturing equipment from Univercells, to produce clinical grade IPV bulks to select DCVMs for phase I and II clinical studies, the press release said.

"As a company focusing on high unmet medical needs, Valneva is proud to make another important contribution to polio eradication through this agreement with Batavia," said Thomas Lingelbach, CEO, Valneva, in the press release. "Our site and team in Sweden has significant experience working with poliovirus. This new contract underscores Valneva's technical expertise in clinical manufacturing and bio-risk management."

"We are excited to be working with Valneva, who can leverage their GAPIII polio facility and polio know-how to accelerate the development of this important vaccine as well as offering an important step forward in the application of our HIP-Vax technology for vaccine manufacture," added Chris Yallop, chief operating officer, Batavia Biosciences.

Yokogawa Innovation Switzerland as Center for Bio Business

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To accelerating R&D and market development activities for the bioeconomy, Yokogawa Electric Corporation has established Yokogawa Innovation Switzerland GmbH to build a strong base for its bioeconomy business through the provision of quick and proactive market research and development activities, and the introduction of cutting-edge biotechnologies. The new subsidiary was officially registered on June 26th, and business operations will start from August.

Switzerland is ranked high in global competitiveness and is a gathering point for highly talented professionals. Yokogawa Innovation Switzerland is located in Allschwil, directly next to the city of Basel, which is the European center of the biotechnology and life science industry. In this ideal location, the new company will promote Yokogawa's bioeconomy business through research and development and partnerships. It will focus on discovering research themes, promoting open innovation, and searching for business partners. To coincide with the opening of the new subsidiary, Yokogawa Europe's existing Swiss branch for its industrial automation

business has also moved to the same location as the new company.

The bioeconomy is considered to be an important pillar for building a sustainable society, and governments and corporations in many countries are concentrating on this field. It is one of the focus areas defined in Yokogawa's long-term business framework, and through its bioeconomy business and other initiatives, the company is working to achieve the sustainable development goals (SDGs) and contribute to the development of a circular economy. To acquire technologies and expertise in the bioeconomy field, Yokogawa has already taken steps such as investing in AlgaEnergy, a Spanish company that is a leader in the production and application of microalgae.

As this market expands and grows more competitive, Yokogawa aims to secure the knowledge and human resources required for developing the bio-related business, explore new business opportunities, and forge alliances with other entities that have world-leading technologies by establishing operations in a region with dynamic bio-related innovation.

BioAscent appoints Nick Moore, PhD to steer growth in US

To support its ongoing growth in the US, BioAscent has appointed Nick Moore, PhD to head up business development in North America. BioAscent works with companies of all sizes and already supports a number of US biotech customers with both compound management services and drug discovery projects.

Dr Moore, is an internationally recognized drug discovery specialist with over 35 years' experience in all aspects of discovery &

Dr Peter Djali

development, from early compound identification to clinical Proof of Concept. He has directed a range of drug discovery programs spanning multiple therapeutic indications, including leading the preclinical development of the $5bn blockbuster Zyprexa (olanzapine) for Eli Lilly, and has worked with the pharmaceutical, biotech and academic drug discovery/development communities. Dr Moore has held senior roles in the US and the UK, and with both in-house and contract research organization experience - most recently including Charles River Discovery Services - he is ideally placed to support BioAscent's customers and develop the company's North American business.

Honeywell expedites development and production of vital vaccines and medical therapies with fast track automation

Honeywell announced Fast Track Automation, a combination of proprietary technology innovations for the life sciences industry that enables vital vaccines, treatments and therapies to move from regulatory approval to full production in as little as two months depending on process requirements. The solution incorporates process automation elements that can be configured in a virtual environment, then implemented rapidly once a therapy is approved and ready to be produced

for public distribution.

Fast Track Automation is a response to the global COVID-19 outbreak, which has highlighted the need to accelerate delivery of medical solutions and devices to patients by focusing on ensuring more efficient production and testing capabilities along with facilitating strengthened supply chain. Life sciences manufacturers are leading the race against time to overcome the pandemic through innovative science. At the point in time when clinical trials are nearing completion, the ability to rapidly pivot and scale up to meet production demand will severely test existing technology infrastructures.

The most efficient way to ramp up the production of potential therapies is to facilitate development of commercial-scale manufacturing earlier, while treatments and prevention therapies are still in clinical trials. Fast Track Automation has been designed to be used in development applications in as little as two months, and then to help manufacturers scale up to full production immediately after the appropriate regulatory approvals are granted.

"Honeywell has provided the pharmaceutical / life sciences industry with consistently innovative advancements in automation and digital software technologies, systems and services for over 30 years, and Fast Track Automation offering is one of our most valuable and latest offerings to date," said Ashish Gaikwad, vice president and general manager, Honeywell Process Solutions, India. "Our solution allows for end-to-end manufacturing process. It offers intuitive data visualization, providing real-time information and predictive insights while offering benefits like enhanced audit-readiness and data integrity, minimized regulatory risk, increased operational efficiencies and reduced rejects and waste. This offering simultaneously enables manufacturing automation designs in parallel with clinical trials, to ensure production is ready to go once a medical therapy is approved."

Fast Track Automation leverages the power of the cloud, virtualization, batch software running in the controller, flexible assignment of computing power, remote asset management from a data center, and efficient, fast-track lean project implementation. Manufacturers can even use the system to digitize manual steps during clinical trials to better consolidate and analyze data and more seamlessly prepare electronic submissions for regulatory body review and approval. Manufacturers can then use that data to prepare the final production automation design. Additionally, the system can be quickly scaled up or down depending on needed changes and demand. ■

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