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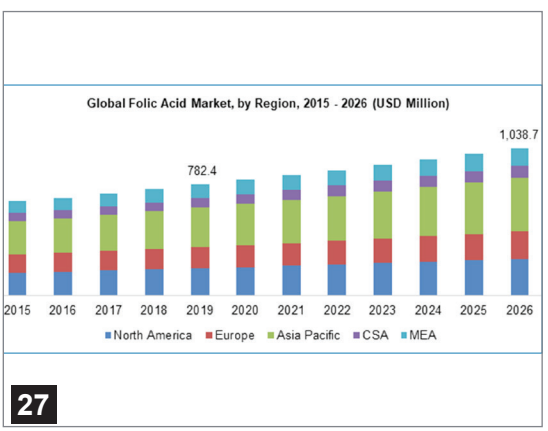

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Current State of Bioethics Relating to Biotechnology for Engineering Education

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Biotechnology provides a wealth of products which improve the lives of many individuals. Some improve the quality of life of the person while the others extend their lives. Another biology oriented research area is synthetic biology, which is a sub-category of biotechnology. Products from synthetic muscle tissue and medications to biofuels are the subjects of research today. Each product developed has to be evaluated as to whether it can be produced sustainably and economically while taking into consideration the effect on the environment and protection of human rights. With the introduction of new products and technologies, bioethics is evolving, which means the educational community has to be up to date with the current bioethical issues and accepted practice in order to prepare the engineering students to be involved in research as a student and in industry. The present study will investigate bioethical issues associated with biotechnology and synthetic biology. It will also touch on how these issues are handled globally.

Context

Biotechnology is "the study and manifestation of living bodies or their components (e.g., molecules, organs, cells, and tissues) in order to improve their living conditions." [1] Synthetic biology is a sub-category of biotechnology and is the "designing and combining of biologic molecules such as deoxyribonucleic acid (DNA), ribonucleic acid (RNA) and proteins in order to provide a better understanding of the biological phenomenon and produce biological systems with certain functions." [2] Synthetic biology differs from the biological sciences in that in the biological sciences the cell is studied in order to understand how it works and in synthetic biology they design and create a new cell. [2] Associated with these areas of research are concerns about bioethics, responsible conduct and safety.

Bioethics is "a relatively recent field of academic inquiry that deals with the ethical, legal, social and cultural implications of the biosciences and their application in biotechnology." [3] There are inherent safety risks involved with biotechnology and synthetic biology because these areas of research involve designing new materials which have the potential of having unintended consequences. This is especially true in synthetic biology since this involves manipulating the most elemental level of materials.

Historical Perspective

The World Medical Association adopted a form of the Hippocratic Oath called the Declaration of Geneva for all candidates wanting to join the medical profession in 1948 at the 2nd General Assembly of the World Medical Association, Geneva, Switzerland. [4] Although medical ethics has its roots in ancient Greece with the Hippocratic oath, bioethics came to the forefront as an issue at the end of WWII with the trial of 23 doctors for human experimentation in the concentration camps. The result of the Nuremberg Trials was a set of research ethics principles for human experimentation established in 1947 which was called the Nuremberg Code. The Nuremberg Code was meant to be used by countries as a guideline for their laws concerning bioethics. This code and the subsequent World Medical Association Declaration of Helsinki in 1964 is the basis for the ideas of informed consent, beneficence and minimizing the risk to the research subject in research involving human subjects. The Declaration of Helsinki states that "it is the duty of the physician to promote and safeguard the health, well-being and rights

of patients, including those who are involved in medical research." [5]

In the United States (U.S.) between 1947 and 1979 research involving human subjects without their consent or with questionable consent continued in spite of the code of bioethics adopted in this country to address areas of ethical concern. A few examples of this include research into treatments for hepatitis A[6], sexually transmitted diseases,[7] schizophrenia,[8] radiation exposure [9] and cancer studies. [10] The research subjects included prison inmates, mentally disabled children, hospitalized mentally ill and the elderly. In 1974 a story by a reporter outlining research initiated by the U.S. Public Health Service in Macon County, Georgia, which was called the Tuskegee Study, [11] caused public outrage over the unethical treatment of the human subjects in the trials.

The Tuskegee Study research started in 1932 when there was no definitive treatment of syphilis but continued until the story broke in 1972 even though penicillin was developed as a treatment in the early 1950's. In the study, 412 poor African-American men with syphilis were followed and left untreated while 204 men free of the disease were used for comparison in order to research and document the progression of the disease over the lifetime of the subjects. The subjects were deceived in order to get them to consent to participate in the clinical research and they were denied treatment even after an effective treatment was developed. [11]

As a result of the public outrage, the National Research Act which was passed in 1974 created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission would regulate research conducted by the then Department of Health Education and Welfare (HEW) and identify basic ethical principles to protect human subjects in research. The Belmont Report summarizes the ethical principles developed by the commission which are Respect for Persons, Beneficence, and Justice which should be applied with respect to the requirements of Informed Consent, Assessment of Risk and Benefits, and Selection of Subjects. [12]

In 1981 the Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA) revised their regulations to reflect the recommendations in the Belmont Report. The result was what is called the "Common Rule" which involved 15 Federal Departments and agencies and was published in 1991.[13] Under the common rule clinical research was defined and regulations were outlined. All research falling under the "Common Rule" was to be overseen by Institutional Review Boards.

The Council of the National Academy of Sciences formed a committee on the conduct of science and reported their findings in 1989. Their report, On Being a Scientist,[14] offers guidelines on how to conduct research using scientific methods while attempting to accurately gather facts and report them without prejudice. This can form a basis for a beginning researcher to develop and maintain responsible standards for scientific conduct.

Global Evolution

In the U.S. oversight of clinical research is accomplished through Institutional Review Boards which are responsible for making final recommendations regarding patient care ethical issues and ensuring that clinical research complies with the basic ethical principles. All research supported by a government agency which falls under the "Common Rule" is required to have an Institutional Review Board which complies with the Common Rule to review its research[15].

Although bioethics is more regulated and Institutional Review Boards oversee clinical research, there are still issues arising. It is logical to go to the areas where a condition is prevalent to research the signs, symptoms and progression of the condition as well as its effective treatments. This results in poor and impoverished nations being the subject of the research. This in itself can be looked at as exploitation and the ethics of it can be questioned. One such situation occurred from 1991-1993 in sub-Saharan Africa and Asia in the research of HIV treatments to prevent transmission of HIV to fetuses in pregnant females.[11, 16, 17] The double-blind clinical trials conducted were placebo-controlled studies which would mean giving a placebo to a segment of the research subjects. This would insure that treatment would be withheld from a percentage of the research subjects and their babies would not benefit from the treatment if effective. The reasoning of such a research project is that without the research there would be no effective treatment to prevent or reduce the incidence of infected fetuses, and therefore those babies who became infected with HIV through the pregnancy and/or breastfeeding would have been infected anyway. In this study, when the treatment was shown to be effective, further research which concentrated on the dosage and regimen of treatment did not involve placebo-controlled studies.[18]

An article in the New England Journal,[11] which criticized the HIV study as unethical resulted in a worldwide debate. The Global Forum on Bioethics in Research (GFBR) was formed by several organizations such as the National Institutes of Health, the Rockefeller

Bioethics is relatively recent field of academic inquiry that deals with the ethical, legal, social, and cultural implications of the biosciences and their application in biotechnology. There are inherent safety risks involved with biotechnology and synthetic biology because these areas of research involve designing new materials which have the potential of having unintended consequences.

Foundation, the Medical Research Council (MRC) United Kingdom and the MRC South Africa. The GFHR provided a forum between 1999 and 2008 for discussing the ethical issues associated with research conducted in developing countries. It was re-launched in 2014 to provide somewhere for individuals in low- and middle-income (LMIC) countries to bring their bioethics concerns regarding research in their country.[19]

Some countries are still developing their bioethical codes and regulations. In Iran biomedical research began in the 1970s but was halted in 1978 through the 1980s due to the Islamic Revolution and then the Iran/Iraq war.[20] In the 1990s research began again. By the late 1990s clinical research had reached a fast pace and bioethical concerns were emerging. A study of research proposals [21] showed that only 1% of the studies investigated mentioned ethical risks, and in only 11.8% were those participating aware they were participating in clinical trials. Of these trials, 32% were placebo-controlled. The cost of the biomedical research interventions that the participants were subjected to was paid for 80% of the time by the participants. When the results of the study were published in 1999 the National Research Ethics Committee was established. [20] In 2004 the Medical Ethics and Medical History Research Center (MEHR) was established. MEHR developed the National Ethical Guidelines on Biomedical Research. The development of biomedical research oversight in Iran was very similar to that experienced in other countries. Hopefully as this area continues to develop they will be able to benefit from the experiences of other countries and avoid further duplication of the painful learning process those countries experienced.

Research in synthetic biology is also being conducted in Japan, although it is not always referred to as this because the term is not widely accepted. The Japanese Society for Cell Synthesis Research was founded in 2007 and included in its purpose was the study of ethical and safety issues associated with this area of research. The organization promotes discussion and exchange on the subject of social and ethical issues among researchers internationally and in the Japanese public sector. The existing "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" has been satisfactory in regulating synthetic biology up to this point, but as this area of research progresses with new developments in the field, new regulations specific to this area of research are expected to be necessary.[2]

Current Biotechnology Research and Bioethical Issues

Over one hundred billion U.S. dollars are spent each year on biomedical research as shown in Table 1. Some research is funded by industry and some through government sources.

Biotechnology is expected to produce novel answers to societal needs. Biotechnology can increase the food supply by designing disease resistant strains of crops. It can provide new sources of energy, new medications, and treatments for disease.[22, 23] It is also a potential source of disaster, either accidentally or purposefully by terrorists, from the development of an organism deadly to the environment, animals, and humans.

Table 1: Expenditures in Biomedical research in 2012 in billions of U.S. dollars.[24]

Country	Total	Country	Industry
United States	119.3	48.9	70.4
Canada	5.3	3.3	2.0
Europe	81.8	28.1	53.6
Asia-Oceania	62.0	19.3	42.7
Total	268.4		

Biotechnology has the potential to develop a new energy source in biofuels that will comply with the new carbon emissions and carbon "foot-print" regulations. Biofuels are considered carbon neutral because their carbon content is being recycled by the plant process. Biofuels have the capability to replace the current carbon fuels and would be sustainable with an endless supply, but would not deliver the same BTU values as coal or oil. There are ethical problems associated with biofuels. The use of corn for biofuel decreases the corn supply for food and results in increased food costs.[22] In the U.S. over 30% of the corn crop was being converted into biofuels in 2005.23 Another avenue of biofuel research is algal energy for biofuels. This source of biofuel would not directly affect the food supply but could indirectly affect it by taking up acreage that would have been used for food production. If acreage not suitable for agriculture is used it could result in reduction of biodiversity by deforestation and reduced wildlife habitat. [22] Currently the rainforest is being razed for agricultural purposes.

Synthetic biology has its own ethical concerns. Though presented by some as being similar to building with LEGO blocks, the process is much more complex and less controllable than that. It has also been likened to programming a computer which is possibly more accurate than the LEGO blocks analogy.[25] Synthetic biology involves taking the building blocks in the biological world which randomly associate themselves in a highly predictable way and attempting to realign or remove and replace segments through controlling the process. In 2011, biologist J.

Craig Venter created the first viable bacterial cell that was designed in a lab by digitally writing its genetic code and synthesizing it in a laboratory.[25] Science is advancing with the goal of being the first, for instance, to engineer skeletal muscle that can be used to repair damaged human limbs [26] or develop a new strain of fungus resistant corn.[27] The behavior of a synthetic program cannot be completely and reliably predicted. Therefore, in designing a synthetic genetic program there is the possibility of unintended consequences. This causes concerns about the creation of organisms that may be harmful for humans and the environment and could potentially have devastating effects on the environment, wildlife and human populations. Therefore, an ethical research scientist takes measures

to protect researchers and the environment from exposure.[2]

The risks of exposure and contamination have to be considered in designing the research project. Sometimes the ethical thing to do is not to do the research because of the potential dangers.

This technology causes concern in the public sector mainly because of what they have seen in science fiction films. Public concern is also due to a lack of information or a lack of understanding of the available information on biotechnology and synthetic biology.[25] In order to address public fears educational programs should be developed to inform the public of what safeguards are in place to protect them and the environment.[12] Public education programs and discussion forums with panels of experts can help disseminate the required information to the public and answer their questions. Without adequate education they will be motivated by their fear and will probably resist the technology.[4]

The National Science Foundation funded the Synthetic Biology Engineering Research Center (SYNBERC) in order to responsibly advance synthetic biology. Their three-fold mission is: [28]

1) to develop the foundational understanding and technology needed to increase the speed, scale, and precision with which we design and build biological solutions; 2) to train a new cadre of engineers who will specialize in synthetic biology; and 3) to engage policymakers and the public about the responsible advance of synthetic biology.

As the area of bioethics matures and as policies and principles are developed, the scope of ethical concerns broadens. For example, in the past outside interests of the researchers were not required to be reported. It was left up to the researchers to determine if there were any conflicts of interest, but in today's environment research scientists are being asked to report their outside ties to industry and who their investors are.[29]

Implications for Higher Education

Seeing the complexities of bioethics and the historical perspective of the difficulty of research scientists in viewing their research in a bioethical and responsible manner, it becomes clear that training and education of the future engineers, researchers and research scientists in critical bioethical decision making are vitally important in order to ensure clinical research and other bioresearch will be conducted ethically. Although regulations and oversight are in place, it is the responsibility of the research scientist and researcher to comply with ethical principles and give safety top priority.[14] Future researchers and engineers must be trained to maintain standards of ethical scientific conduct.

The National Institutes of Health (NIH) has included in their requirements for institutions receiving Federal funding that students receive ethics training. They have also identified case studies and small group discussions as the best way to teach these principles. Another requirement is that there be at least 8 hours of face-to-face instruction because it has been identified as a necessary component of training. The National Academy of Sciences has identified personal contact with more experienced scientists as a necessary component for junior researchers to learn a code of professional conduct.[14] With these things in mind an institution would have to develop a program for ethics education. There is a source of curriculum assistance available at: http://www.fic.nih.gov/RESEARCHTOPICS/BIOETHICS/Pages/teachers-students.aspx.

Wichita State University, in Wichita, Kansas, has a general ethics offering required for all engineering students which conforms to ABET requirements. The catalog description of what is taught in this class is: "professional responsibility and integrity, whistle-blowing, conflict of interest, ethical issues in engineering consulting and research, engineering and environmental issues, and engineering in a global context." There is no offering for an ethics class which covers the specific areas of bioethics or nanotechnology ethics which are both areas of concern in relation to the environment and public safety. Ethical issues associated with these areas have historically been addressed in the research setting between graduate students and the more experienced research scientists/professors. Future research scientists need to be trained in how to address ethical issues before encountering these situations in order to resist industry and outside funding source pressures for quick results.

One way to assist the researcher in making responsible and ethical decisions when dealing with complex, difficult ethical dilemmas is to provide them with an ethical analysis tool. Two examples of analysis tools used for this purpose are the Four A's and the Four Quadrants or Four Boxes ethical analysis frameworks. The Four A's analysis approach Acquires the facts, assembles the Alternatives, makes an Assessment of the possible solutions, and arrives at a decision on a Plan of Action[30] which is more of a scientific approach. The Four Quadrant method is more of a clinical approach which looks at the medical indications, patient preferences, quality of life, and contextual features of the ethical dilemma in arriving at

Bioethics came to the forefront as an issue at the end of WWII with the trial of 23 doctors for human experimentation in the concentration camps. The result of the Nuremberg Trials was a set of research ethics principles for human experimentation established in 1947 which was called the Nuremberg Code. The Nuremberg Code was meant to be used by countries as a guideline for their laws concerning bioethics.

a solution.[31] Teaching an analysis tool with the use of case studies can be an effective way to teach students bioethics and prepare them for the issues they will face as research scientists and engineers. As biotechnology research is conducted in LMIC countries it is important that the stakeholders in these countries be included in discussions of bioethical policies to provide protection of their interests. In order to accomplish this, LMIC countries must have personnel trained in ethics principles to facilitate the discussion. NIH's Fogarty International Center has provided grants to establish ethics training programs in international research ethics. An example of the success of these ethics training programs is their training programs in Latin America and the Caribbean. In 1991 there was little oversight of clinical research or protection of research subjects, and international principles for bioethical research were not being applied in research programs. Four bioethics programs were initiated in that part of the world. One was developed in Latin America, one was coordinated from the U.S. in conjunction with Latin America and two were coordinated from the U.S with the cooperation of Latin American institutions. These programs have been very successful in changing the research environment in the countries through distance learning and online components provided by U.S. educational institutions.[32]

The success of the NIH's Fogarty International Center programs show that ethics programs in the U.S. should be developed to include a world view of bioethics in research. Students must be taught bioethics from an international perspective. More and more students are being employed outside the U.S. in these LMIC countries and can provide needed ethical expertise to protect the interests of those countries in policy development of research entities and local governments.

Conclusion:

Biotechnology is an emerging technology, and based on the technological developments it will be one of the most studied topics in the world. This is a valuable tool to make many new advancements on environment, health and science. In the present study, biotechnology, synthetic biology, bioethics, and their major impacts on human health and environment have been discussed. The primary issues associated with bioethics include current rules and regulations, historical prospects, future developments, legal limitations, morality, religious aspects, and safe practice and safety training of the engineering students. It is reported that many biotechnology products and practices are completely safe, whereas others can be highly toxic and harmful, resulting in serious diseases to humans, as well as surrounding environments. Bioethics mainly deals with all of these biotechnology related issues in order to create a safer work environment for students, scientists, engineers, health professions, and other individuals directly and indirectly participating in biotechnology research, development, and education.

Inspiration: 2015 ASEE Zone III Conference (Gulf Southwest – Midwest – North Midwest Sections)

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National Research Act which was passed in 1974 created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The commission would regulate research conducted by the then Department of Health Education and Welfare (HEW) and identify basic ethical principles to protect human subjects in research.

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Biomall Simplifies the Purchase Procedure through Aggregation and Online Portal-based Presence

e-Marketplace is an emerging concept at the Indian business landscape. Biomall has carved out a niche in the laboratory, life science, and diagnostic products segment. The author here narrates the emergence of Biomall with an emphasis on their USP and customer value proposition, global presence, future business expansion strategy, challenges & restraints, benefits of e-market place, and many other associated parameters.

Dr. S Jhaveri
Managing Director
Biomall.in

Conceptualisation of Biomall

Scientists in India and other developing countries usually follow the traditional purchase system wherein they need to contact numerous distributors to acquire different kind of laboratory products, as – in most of the cases – one particular distributor has limitation in their supply range. And from that point, a plethora of activities starts for the lab-in-charge in terms of – quotation receipt from each of the distributors, purchase order generation, experiencing the wait-time for the product delivery, and so on & so forth. The efforts don't stop here. Track-and-trace of quotes and orders from various distributors at times becomes tedious and time consuming. At times, buyers may even need to wait for months to get their product(s) delivered at their door-step.

To address this pain-point, Biomall emerges with an aim to simplify the purchase procedure for the laboratories by aggregating the suppliers on their platform and also with the implementation of online transaction facility. Here buyers can directly purchase the products of their choice and need without getting into the multiple sub-nodes viz inviting quotations, etc. This shortens the purchase cycle significantly from 7-10 weeks to 7-10 days. Not only is that, it also reduces the costs associated with buying the products offline.

Biomall as an e-Market Place

Biomall.in (www.biomall.in) is India's no. 1 ecommerce marketplace, specifically dedicated to laboratory, life science, and diagnostic products. It hosts over 100,000 products from more than 150 brands across 100+ categories such as chemicals, lab-equipment-and-consumables, microbiology, diagnostics, molecular biology, chromatography, etc. The uniqueness of Biomall is: researchers and laboratory users can buy laboratory items online and directly by using its secured payment gateway.

USP and Customer Value Proposition

The biggest USP of Biomall is – their online portal-based presence, dedicated only to laboratory, life science, and diagnostic products. This carves out a niche for them over several other contemporaries. Those contemporaries though are into marketplaces, are generic in nature. They sell all kind of products.

In addition to this, with Biomall, the buyers can enjoy the facility of purchasing multiple products of multiple brands at one go. Buyers get the option of quantity selection and the secured online payment. The lucrative part for them is the bagging the bulk discount for a purchase of more than 10 packs.

Other than pursuing the buying activity, purchasers do have the flexibility of

Message to the Young Entrepreneurs – "Don't be afraid to take risks and be creative".

posting any sort of enquiry, which can even encompass the products not found or products not available on the portal. Such queries then in turn get shared with all the registered sellers on the portal, who can then send an online quote to the buyers as per product availability.

Global Presence & Future Expansion Strategy

International buyers find it useful to get different kind of lab products from a single platform at a good price; and since Biomall consolidates the order into one single shipment, they also save on the shipping costs. Biomall has a high conversion rate for international leads, and has successfully exported to over 35 countries in Africa, Middle East, Asia, Europe, South America, and North America. As a part of their worldwide expansion plan, Biomall has been concentrating on channel partnering with distributors and agents.

Challenges and Restraints

As of today, certain major challenges that Biomall face are:

- Most institutes still rely on the old purchasing system. Aggregate purchasing will require a lot of awareness and marketing campaigns highlighting the benefit of online aggregate purchase for them.
- Dealers who offer credit facility and have deep relationships with various buyers also prevent people from buying online
- Logistics and delivery issues are prevalent for tier 3 and tier 4 cities due to inadequate infrastructure. Reaching out to those places is still a concern.

Suppliers' Benefit from Biomall over their Solo-Business Attempt

India is a good manufacturing hub for the chemical laboratory products, microbiology products, lab equipment, lab safety supplies, genomic kits, in vitro diagnostic kits, and many more. Biomall acts as a good marketing platform, especially for small- and mid-sized brands to promote and to sell their products online. It offers special marketing services like email marketing, SEO and SEM, online advertising, social media marketing, and video marketing to the suppliers to help create more awareness for their brands at the national and international level. To add more benefit-dimension to it, the digital marketing cost is just one-tenth of the offline marketing cost.

Also, Biomall helps their suppliers to address a major pain-point by waving out the traditional door-to-door visit for product promotion and lead generation. Such traditional procedure not only does require multiple follow-up visits, but also causes lengthy wait period to get the purchase orders. The story doesn't end here. Long wait period & several follow-up visits after supplying the product(s) to their customer(s), are also the teething issues. So, if we consider the entire process chain from lead generation to receiving payment, it takes close to 7 – 14 weeks for traditional purchase mode. With Biomall, suppliers are able to take the advantage of direct online selling. They get their orders in no time, and the timely payment is also ensured without the need of any follow-up. Suppliers / Vendors enjoy a seamless experience at the Biomall platform in terms of enquiry handling, as well as order-stock-dashboard-and-offer management.

Knowledge Sharing Initiatives and Business Rationale

With the help of the Biomall's blog (https://blog.biomall.in), the Company aims to bring up the scientific temperament in the country. In Dr. S Jhaveri's words, "We share articles about different laboratory technology, latest scientific research, upcoming scientific events, science jobs, etc. Through our webinar series, our endeavor is to enlighten the young minds in various stretches of scientific research. We are planning to have a new webinar series to guide scientists for buying laboratory equipment, wherein our seller partners shall also get a chance to promote their equipment". ■

"Being into the lab-and-chemical business for many years, provided us the opportunity to apply our past experience to form a new age business", says Dr. S Jhaveri, Managing Director, Biomall.in

Persisting Coronavirus Situation in China: Probable Threat to Indian Pharmaceutical Industry

Recent deadly outbreak of Corona Virus in China has captured everyone's attention. China being an important player in global economy and the business neighbor of India, the impact of such outbreak cascaded to India as well. Here in this article, the author narrates the probable threat upon global economy and more specifically, upon Indian Pharmaceutical Industry, in this context.

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Present Situation

The coronavirus outbreak in China and its spread has roiled the markets across the world in recent days and raised global economic growth concerns, given the size of the Chinese economy and the strong linkages that many countries and companies have with respect to their country's economy. Concerns over the virus-spread across the world have led to many global airlines halting their flights to the country; and the Chinese Government has issued unprecedented quarantine, as well as put 16 cities under lockdown. All this has impacted the movement of people, goods, services, and the financial market sentiments. Even though it is still in the initial stage, the impact is already being felt across a wide range of segments of the Chinese and certain neighbouring economies for their retail sales, travel and tourism, restaurants, cinemas, etc.

Impact on Chinese Economy

The epidemic has come right during the traditional peak demand period for China i.e. the Chinese New Year. The period is typically associated with high consumer spending. In 2019, it was reported that retail sales of USD 148 bn were recorded in the week of 4-10 Feb 2019; and revenues from domestic tourism were reportedly in tune of around USD 76 bn.

With domestic consumption expected to be a key driver for the Chinese economy in the prevailing environment of lower exports and investments, a decline in consumer spending could further exacerbate the slowdown of the country's economy. Economic growth in 2019 touched a 29-year-low of 6 percent and would have been likely to grow even at a slower pace in 2020, as projected by World Bank and IMF before this viral outbreak.

Global Impact

Past episodes of global epidemics (SARS, MERS, swine flu, zika virus, etc) have not had long lasting global economic impact and were tackled with medical expertise. The global economic cost of the earlier virus i.e. the SARS epidemic in 2003 has been estimated to be around USD 40 bn. In case the spread of the corona virus is not contained in the coming weeks, the implications could be far reaching and more severe, given that China's importance in the global economy has increased manifold and the global economy is experiencing the slowest growth since nearly a decade. As per World Bank data – in 2003, China's share in the global economy was 4 percent and its growth rate was 10 percent, while the global economy had been growing at a rate of 2.9 percent. China's share in the global economy currently stands at around 16 percent and the world GDP growth has dropped to a decadal low of 2.4 percent in 2019. If the viral spread is tackled in the next couple of weeks, there could be a possibility for revival in activity and sentiments.

The stimulus initiated by the Chinese Government in the aftermath of the 2003 epidemic aided the economic growth

Concerns over the virus-spread across the world have led to many global airlines halting their flights to the country; and the Chinese Government has issued unprecedented quarantine, as well as put 16 cities under lockdown. All this has impacted the movement of people, goods, services, and the financial market sentiments.

rebound there. However, this time, there could be limitations to the stimulus given the China's economic growth has slipped to a near-three-decade low; and the economy continues to be pressured by trade war uncertainties, sizeable debt overhang, and the lower investments.

Threat upon Indian Pharma Industry

Given that India and China have strong trade relations and see movement of large number of people between the two countries, the epidemic could have a bearing on the domestic economy too. Given the importance of China in the various facets of global trade, disruptions in the same for long durations can have severe implications on world trade and thereby the overall global economy.

The disruption caused by the epidemic – if prolonged – could have a bearing on India's imports from the country, which is critical for domestic economic activity as finding substitutes for imports from China in the near term could be a challenge. This could have implication for domestic economic output. Further, the slowdown in China's economic activity could impact their exports from India.

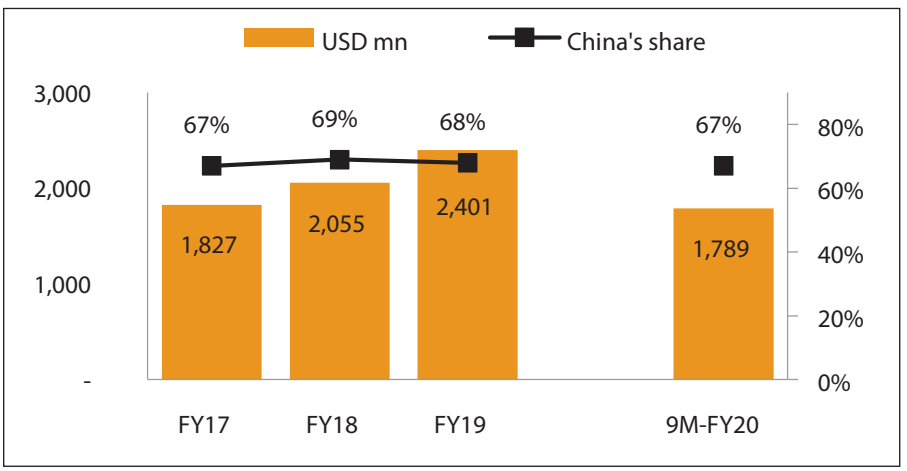
Exports of drugs and pharmaceuticals to China are minimalistic with 1.5 percent share, while imports contribute a gigantic 40 percent share. Product wise exports and imports are depicted in the below table. Amongst product-wise imports, India's dependence on China for procuring bulk drugs and intermediates has grown multi-fold over the years. While the import value has increased, the country's share has remained stable over the years. In FY19, India imported bulk drugs and intermediates worth USD 2.4 bn from China, contributing to 68 percent of the total imports.

Indian exports and imports to/from China in 9m-FY20 (USD mn)

Item	Exports	Imports
Bulk drugs, drug intermediates	178	1,789
Drug formulations, biologicals	-	147
Surgicals	10	57
Ayush and herbal products	9	1

Source: CMIE

Imports of bulk drugs and intermediates from China (USD mn)



Source: CMIE

Future Bearing

To safeguard from the current holiday period in China, Indian pharmaceutical players have sourced their raw materials and created buffer stocks for a period of about 3 months, hence the impact of spread of coronavirus in China is not expected on financials of FY20 of Indian Pharmaceutical companies. However, if the situation aggravates in coming months, the following could be expected:

1. Operations and production of bulk drugs and intermediates in China will be significantly inhibited, thus creating a demand-supply gap.
2. If shipping activity gets decelerated, then situation may worsen, thus creating a crisis for domestic pharmaceutical players due to dearth of raw material availability.
3. The dominos effect may lead to significant spike in the prices of bulk drugs and intermediates.
4. The Indian pharmaceutical companies which have entered into prescheduled delivery contract with various global and domestic clients at predetermined prices, would be forced to execute them while procuring the raw materials at a higher cost, which shall take a hit on their profitability margins as well as on the returns on capital employed.

Overall, the industry is expected to be negatively impacted if the spread of coronavirus in China not controlled and situation gets aggravated in coming months. ■

China's share in the global economy currently stands at around 16 per cent and the world GDP growth has dropped to a decadal low of 2.4 percent in 2019. If the viral spread is tackled in the next couple of weeks, there could be a revival in activity and sentiments.

The Next Generation of IoT – Addressing the Coronavirus and Preventing Future Outbreaks

Recent outbreak of deadly Coronavirus has posed a huge death toll at China. Initiated at Wuhan province, it has crossed the boundary of China and thanks to ease-of-commutation, has spread across the globe thus forming a dreadful pandemic. While catastrophe has been increasing at an alarming rate, the author in this article attempts to find an answer with a long-term perspective for the most pertinent question: what can be done as a preventive measure in future against such deadly infectious spread.

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The World Health Organization (WHO) has declared a global health emergency due to the rise in the number of infected people by the Wuhan coronavirus. As of the report dated 30-Jan-2020, over 8000 people have been infected with the virus. The virus has spread across every province of China and has been detected in over 20 countries.

The question of time is: how can technology aid in curbing the spread of infectious diseases that have the potential to create panic and to kill millions of people?

The Potential of IoT in Infectious Disease Control

The Internet of Things (IoT), a network of interconnected systems and advances in data analytics, artificial intelligence (AI) and ubiquitous connectivity can help by providing an early warning system to curb the spread of infectious diseases. In the Asia-Pacific region, China leads the way in IoT adoption followed by Japan, the country is anticipated to spend USD 254.6 billion in IoT by 2025.

The simple answer might be for enterprises, cities, and national governments to collectively create a massive global network of sensors to detect viruses. However, this would require planning and implementation on a global scale that would tax the very foundations of democracy and obligate governments to place the needs of the planet ahead of the needs of their citizens. The most logical solution is often the most difficult to implement. The amount of planning required to make this solution a reality would, arguably, make it one of the most significant achievements in the history of mankind. While I am an inherently optimistic person (while also realistic), I find this to be the "holy grail" of IoT opportunity in the long term.

So what are some of the practical ways that IoT can help in the near term? The first step in infectious disease control is detection. While a global network of sensors is unlikely to happen in the foreseeable future, China does have the ability to implement such a network in the country. China has a history of implementing wide-area IoT solutions (i.e. video surveillance) on a scale that has never been seen before. So why not to implement a network of virus-detection sensors? This can be coupled with facial recognition and location, existing surveillance cameras to identify, trace, and monitor people that may have contracted the coronavirus. An added layer would be to also track every individual that an infected patient contacted. While this may sound like a police state to many, ultimately, leveraging IoT and AI may be the most logical way to prevent highly

The question of time is: how can technology aid in curbing the spread of infectious diseases that have the potential to create panic and kill millions of people?

infectious diseases from spreading rapidly in a world that is getting smaller every day with air travel.

So what now?

There are some short and long term opportunities and recommendations to restrain the expansion of the coronavirus. In the short term, it can be through continued diligence in monitoring every 'compromised' individual as they go through customs at airports and/or border crossings, leveraging AI-sensors to help with targeted quarantines, and quick treatment to mitigate the spread of coronavirus. For the long term, the United Nations, World Health Organization (WHO), as well as other global agencies can start the process of gaining buy-in from governments across the world to develop an early detection system to uncover these infectious diseases before they become global emergencies. Global emergencies have a tendency to create economic uncertainty and increase volatility in stock markets. The global detection system can reduce the uncertainty in the market and thus can equip the Governments with the economic incentive to act fast to tackle the global health emergency issues and pandemics. ■

> The amount of planning required to make the solution a reality would, arguably, make it one of the most significant achievements in the history of mankind.

Developing and Manufacturing Accurate Reproducible APIs

The measurement of refractive index (RI) has been employed by a wide variety of industries to determine the level of dissolved solids in liquids. This is an important but relatively new measurement in the development and manufacture of active pharmaceutical ingredients (APIs) at laboratory scale, pilot plant scale, and industrial scale in pharmaceutical manufacturing and processing plants. In this article, the authors explain how RI measurement technology can be applied in pharmaceutical reactions, separation and purification processes, solvent swaps, and crystallisation operations.

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Background

As manufacturers of Active Pharmaceutical Ingredients (APIs) continuously implement the FDA's Process Analytical Technology (PAT) and try to comply with GMP guidelines, the requirement for continuous process monitoring grows. Real-time data provides insights and opportunities for process design, control, troubleshooting and optimization, as well as quality control and cost savings.

RI is a tool for PAT, capable of providing sufficient process understanding that helps in the design, analysis, and control of pharmaceutical manufacturing processes. Data collected through RI measurements can be used, for example, to identify and set deviation tolerances for critical process parameters (CPP) that have a direct impact on the quality and safety of the final drug.

In order to measurement technologies to be suitable for pharmaceutical processes, there are a number of essential requirements.

Firstly, documentation should be available to qualify the specification and performance criteria, as well as to confirm that all the materials are of pharmaceutical grade, with appropriate testing and traceability.

Secondly, the measurement should be accurate, reliable, and easily scalable. The technology and equipment used must be the same and capable of providing reproducible data that can ease process validation at lab, pilot, or full scale.

Thirdly, data authenticity should be protected, with all measurements permanently stored electronically, and with tracking and attribution of any additions or amendments.

Finally, evidence of traceable calibration should be available in addition to regular and documented performance verification.

The Refractive Index principle

Refractometers determine the concentration of dissolved solids by making an optical measurement of a solution's refractive index (nD) and temperature. The RI measurement is based on the refraction of light in the process medium, known as the critical angle of refraction, using a yellow LED light source with the same wavelength (580 nm) as the sodium D line (hence nD). The concentration is calculated taking pre-defined process conditions into account. So, Vaisala's refractometers are supplied factory calibrated to meet the specific process requirements. These

Refractive Index (RI) provides sufficient process understanding that helps in the design, analysis, and control of pharmaceutical manufacturing processes. Data collected through RI measurements can be used to identify and set deviation tolerances through critical process parameters (CPP) that have a direct impact on the quality and safety of the final drug.

instruments are also able to provide measurements in different scales, such as brix, liquid density, or concentration by weight.

Importantly, the refraction of light is not affected by particles, bubbles, crystals, or colours; so RI instruments can be employed in a wide variety of solutions for liquid identification and for monitoring the concentration of chemicals, solvents, and liquid pharmaceuticals.

Advantages of RI in Pharmaceutical Processes

In general terms, the monitoring of RI can improve the understanding of process conditions, reduce drug development time, increase production capacity and stability, improve product quality, and demonstrate compliance with regulations. Pharmaceutical manufacturers are required to demonstrate process validation from drug discovery to full production; this can be achieved through RI measurements which provide a unique process profile that can be used for validation at any scale.

All solutions have a specific RI value, which changes as the reaction proceeds. This means that RI monitoring can provide insight into the reaction and extraction processes as well as chemical identification. Changes in RI can therefore be used to track the progress of the reaction and to determine the end-point. For example, where products are extracted from natural materials, such as plants, RI measurements can be employed to determine the optimal time for extraction to finish.

In some processes, it is necessary to conduct a solvent swap in order to facilitate subsequent processes such as distillation. The correct mixture of original and swap solvent should be maintained during the various steps of this process; and RI monitoring is ideal for this application. For example, a Vaisala customer utilised an RI monitor during the scale-up of solvent swap operations from laboratory to pilot plant, and discovered that one of the swap steps could be eliminated, which resulted in an increased yield of over 6 percent.

Many processes produce APIs through crystallisation from the liquid phase. The aim of this process is to maximise the yield of high quality pure crystals that are easy to process, whilst avoiding fines and conglomerates by ensuring good particle size distribution. This can be achieved by maintaining the concentration and temperature above the solubility curve or supersaturated level. Continuous monitoring of concentration by RI offers major benefits for crystallization control because this method is not influenced by crystals or bubbles, so selective monitoring of the mother liquor concentration is simple. By monitoring mother liquor saturation, it is also possible to determine the optimal seeding point.

It is normally necessary to wash produced crystals with solvent to remove impurities and any remaining mother liquor from the filter cake. This process must be carefully controlled to maximise the yield and to avoid the product dissolution. By monitoring the RI of filtrate, it is possible to determine the end-point of cake washing which helps to maximise the yield, saves time, and avoids excessive solvent usage. These measurements also enable the differentiation between clean and saturated solvents with the API and between different solvents. This means that at the end of the washing process, if the RI value is closer to the saturated value than the pure solvent value, some of the product must have been washed out indicating that a process revision is required.

Conclusion:

The critical quality attributes of drugs must be identified, as well as the production variables that affect them, in order to set acceptable deviation tolerances and define the correct PAT tools for monitoring and control. RI measurements represent a simple but hugely valuable tool in the development and operation of API production processes, providing valuable insights into the key processes, facilitating optimization and process control to deliver accurate – reliable – reproducible products.

The Vaisala RI instruments that were initially developed by K-Patents have been designed for application in the pharmaceutical industry, with full scalability so that drug development and process design can be undertaken seamlessly from the lab to full-scale production. ■

Monitoring of RI improves the understanding of process conditions, reduces drug development time, increases production capacity and stability, improves product quality, and demonstrates compliance with regulations. Pharmaceutical manufacturers are required to demonstrate process validation from drug discovery to full production.

Creating a Workplace that Supports Mental Health

In today's increasingly stressful work environment, employees are often not at their sound state of mental health, which in turn affects their personal and professional lives. Employers have also become unable to derive the full value of the employees in such cases. Pharma industry has also got no escape from such incidences. This article gives a comprehensive view about the issue and what can be done at the end of employees as well as employers both.

Work is a pivotal factor around which our entire life revolves. The more we work, the more we will add to our income tally. Having said that income is directly proportional to our work, sometimes we prioritize work even ahead of our mental health. With most working-class, mental health is something which is neglected the most.

It is commonly believed that mental health has nothing to do with the working capabilities of a person, but that is not the truth. Mental health can have a devastating impact on the productivity of the employees. Moreover, it will attract absenteeism. Mental health affects the physical wellbeing and someone who is struggling in himself cannot work to his potential.

There is still a possibility for argument if there is actually a space for mental health evaluation programs at workplaces, when there are other areas where immediate attention is required. Mental health might not appear as a serious matter upfront, but it definitely something from which any organization will look to shield its employees.

A large number of mental health cases remain unreported.

Mental illness is still seen as a taboo, people generally don't prefer to talk about it openly. Psychiatric disorder is often made a huge fuss and the patients are likely to remain silent about it. They keep their illness to themselves as long as they can. They only consult an expert when the situation is out of their hands. 18 percent of the employees in the age group of 15-55 admitted that they had some kind of mental disorder in the past month. These are the statistics according to a survey conducted by the US National Comorbidity Survey.

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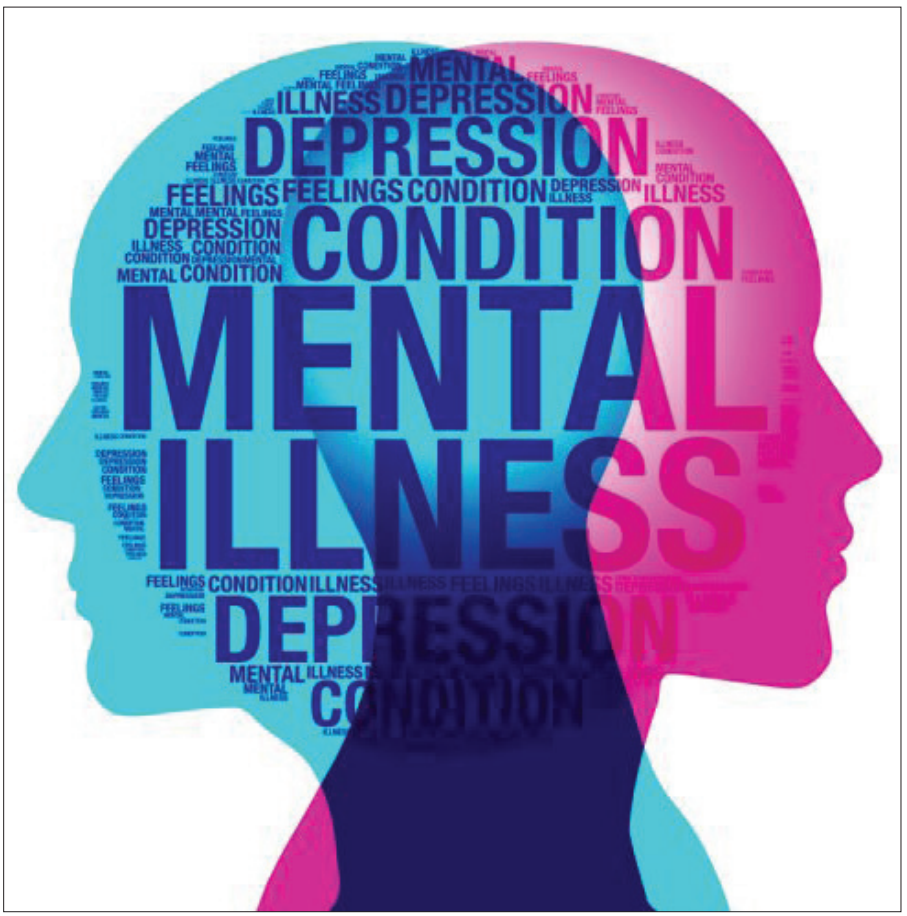

The awareness about mental illness has been increasing and those are promising signs. But the bitter reality is that people still have to face discrimination when they report the mental illness. They fear other's responses to their problems. The feeling of being left out and the fear of discrimination are among the reasons for people not willing to discuss their mental problems.

How to figure out if you are having a mental problem?

This is quite a tricky part, as mental problems show symptoms but not very clear ones. They might go undetected for months and surfaces when they have taken a severe mode. The onus is completely on the individual to identify if he's having some kind of problems with his mental state.

Components of mental illness

The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) contains an exhaustive list of all the mental problems. Here are the most frequently observed ones.

Depression- it is something that is common in the entire population and not just at the workplace. 6 percent of the workforce reported signs of depression at some point in the year. It is believed to be an outcome of low mood. Symptoms of depression may include nervousness, restlessness, or irritability with anger being at the top.

Bipolar disorder- mood swings can be taken as a reference to understand it. A person suffering from bipolar disorder feels highly energetic and cheerful in the manic phase while he will feel depressed at other times. In the whereabouts of 1 percent of the total population of America was reported suffering from bipolar disorder.

Anxiety disorders- They are quite difficult to diagnose, and they might even go undetected for years. There are instances when they were detected 5-10 years later. Some common symptoms are feeling restlessness, fatigue, lack of concentration, and worrying excessively.

ADHD- Earlier it was considered to be a problem only in the childhood phase, but recent studies suggest that adults too suffer from it. An international survey revealed that 3.5 percent of the workforce was suffering from ADHD. It may lead to a lack of management, failure to cope with deadlines, workload management, and difficulties in following instructions.

On what fronts an employee is likely to suffer due to mental problems

1. Getting tired earlier than normal: if you are feeling that your capacity to work has reduced significantly over time, and you are facing difficulties in performing the routine tasks, then mental problems might be the root cause.

2. Thoughts of suicide are striking your mind more often than not. This is a clear indication that something is very wrong with you and you need immediate medical attention.

3. If you have started to feel that there is something which is stopping you from getting on with life.

It is commonly believed that mental health has nothing to do with the working capabilities of a person, but that is not the truth. Mental health can have a devastating impact on the productivity of the employees.

4. Outbursts of anger are surfacing more often than not, while earlier it wasn't the case.

5. Lack of confidence: It is often noticed that people suffering from some kind of mental disorder try to save themselves from responsibilities they think that they won't be able to perform. This is certainly a worrying sign for an organization as having employees who aren't committing themselves to the fullest isn't enough.

6. Relationships are compromised. People with such mental issues corner themselves from relationships whether personal ones or the ones at the workplace with peers.

7. Worker safety might be compromised. When not in a healthy state of mind the person might not make the wisest choices available before them. They might lack at assessing possible hazards for them. Several distractions come into play when making future choices which might lead to taking the wrong decisions.

How to look after your mental health at the workplace?

Your mental wellbeing is in your hand and it's in your interest to start giving some time to look after your mental health. At least any prudent person would have done accordingly. You may argue that my mental health is perfectly top-notch and there's no need for all this. My friend, bad times never come knocking at the doorsteps, you need to be well equipped in advance to tackle them.

The feeling of being left out and the fear of discrimination are among the reasons for people not willing to discuss their mental problems.

- **Keep yourself active:**
  If you are having a desk job like most others, then this is for you. Add exercising and doing physical activities in your daily routine. We are not expecting you to be a gym freak, going to the gym isn't necessary at all. Doing some physical activities daily for 30 minutes in which you loosen up your muscles will be a great thing for you.

- **Relationships are must:**
  Cornering you from the rest of the world and living a life in isolation is not good for your health. There will be times when life will get hold of you and you will need someone to share your problems. Make some relations in life. They maybe your friends or family or anyone whose company makes you feel at ease.

- **Sharing your feelings, your ups and downs:**
  Sharing of feelings is often mistaken as a sign of weakness, but that's not the case. Sharing your feelings with someone actually helps in reducing the burden you are carrying. But the thing is that you cannot share your feelings with any random person. You need to look for someone who really understands you and will give you the right advice.

- **Have a healthy diet (with some cheat days allowed):**
  What we eat impacts us physically and mentally too in the long run. Mend your eating habits. Try to reduce alcohol and tobacco consumption as much as possible. Try resorting to public eating at the workplace, it will give your mind some time to relax while being with your peers.

Roles of employers in addressing mental problems in the workforce

As an employer, you will be the first person to be informed about the problems a particular employee of yours is facing, if informed at all. You need to tackle this

issue with care without making any rash decisions, because that will impact both the individual and the organization.

- **Dealing with absenteeism on account of mental illness**:
  While dealing with absenteeism on account of mental illness, it's the responsibility of an employer to enquire about the time frame the employee will be unavailable. Organizations with high standards can arrange for a statement of fitness to work, from a doctor. Avoid taking strict actions against the employees without knowing the issue in detail.

- **Performance appraisal by the management:**
  It is a well-known fact that a cordial relationship between the manager and staff are always fruitful. Regular staff meetings and supervision sessions have shown a positive impact on the mental health of the employees. If there is any competence case needs to be addressed that has arisen on account of mental illness, handle it with utmost sincerity.

- **Try to mitigate job-related stress:**
  Work stress is thus far the biggest contributor to mental illness. Employees take so much stress about their work that they end up hampering their mental state. This can be reduced by implementing healthier supervision, expecting realistic work demands from the employees, making ample resources available to the workforce, and making provisions for regular work breaks.

- **Raise worker awareness of mental health:**
  Make the importance of sound mental health felt to the employees, it will be in the interests of both the employees and the organization. Make them understand that mental wellbeing should be given equal importance. This can be carried out through experts led talk shows, seminars, calling someone to share real-life experiences, etc.

- **Help your employees establish a Work-Life Balance:**
  It falls in the share of duties for the employer to provide a healthy working environment for the workforce. Research has revealed that those workers who are exposed to work for long hours in the continuation are 33 percent more prone to depression, are 40 percent more likely to suffer financial woes, and 12 percent more chances of suffering from work-related stress.

- **Mental health policies will help:**
  Whether your organization is equipped to deal with mental health situations, needs to be addressed. You should have policies to tackle on-premises bullying, harassment, and discrimination in the workplace. If there are policies implemented already, have a timely review of those policies that they are still serving the intended purpose or are obsolete. Workers who have faced such problems can be asked for their opinions on such policies.

- **Encourage screenings:**
  There are numerous screening tests available online which will help the employee evaluate their mental state. They are absolutely free and don't reveal anyone's identity at all. The employers should provide resources to their employees to enable them to register into such programs.

Physical health of employees is important to ensure that they come to the workplace. However, mental health of employees is critical to ensure that they are engaged and are able to give their 100 percent. ■

Depression is something that is common in the entire population. 6 percent of the workforce reported the signs of depression at some point in the year

Transfer of Technology - An Indian Perspective

Technology transfer is the process of transferring scientific findings, knowledge, manufacturing process, technologies, processes etc. from one organization to another for the purpose of further development and commercialization. This article discusses the Indian scenario concerning transfer of technology.

Saurabh Anand
Senior Associate
K&S Partners

One of the most acceptable and unambiguous definitions of "Technology Transfer" or in other words "Transfer of Technology" is the process by which "commercial technology" is disseminated from one industry to another, and/or among different economies. In common parlance, the said terms are often misconstrued to be limited only to the transfer of a patent with respect to a particular product, which is patented. Meaning thereby, the product of the technology is often fused with the technology itself. However, in actual commercial terms, technology is often considered to be a blueprint, which once obtained would promise better commercial output and it largely depends upon the industry. For instance, in mechanical industries, transfer of technology might include transfer of an end product, involving multiple IP rights.

However, for pharmaceutical industries, transfer of technology might include transfer of know-how of a process to obtain a product, which will not always be a full-fledged transfer of IP rights, as certain IP rights will be developed upon development of that particular product. Thus, getting a patent is not always a pre-requisite for initiating or rather indulging in a "Technology Transfer" arrangement. This dynamic model often creates multiple hurdles for a transferor to enter into such transactions, due to the vulnerability of the "technology" at the whims and fancies of the transferee. This is often observed in cases of trans-border transactions, wherein the transferor who wishes to expand its footprint in a particular country, is hesitant to enter into such kind of arrangements due to the lack of confidence in the laws governing the importing country. However, at the same time such transfer of technology is often required to give a technological as well as economical boost to the importing country in an era wherein technology is changing overnight and the thrust of adopting to changing technologies is also increasing at the same pace.

At this juncture, the laws of the importing country play a vital role in preparing a ground to facilitate such transactions. Undoubtedly, strong IP laws play a crucial role for any transferor to prefer a particular jurisdiction over another, but simultaneously enforcement of such laws in order to protect the IP becomes the game changer. For instance, mere mention of provisions for remedies in cases of infringement would no doubt portray a positive image of the importing country and at the same time if such statutory provisions have actually been implemented by way of granting injunction or directing to pay for damages and so on, it definitely acts as a springboard for the transferor to actually start investing in such importing countries. Section 83 of the Indian Patents Act, 1970 which is in consonance with Article 7 of the TRIPS Agreement recognises this concept as under:

General principles applicable to working of patented inventions :
Without prejudice to the other provisions contained in this Act, in exercising the powers conferred by this Chapter, regard shall be had to the following general considerations, namely-

- *That patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay;*
- *That they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article;*
- *That the protection and enforcement of patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage*

of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations;

Thus, the Indian Patents Act, recognises the twin-benefit of Technology Transfer, that is, encouragement of innovation as well as protection and enforcement of patent rights. In addition to IP laws, the strength of ancillary laws like contractual laws, regulatory laws and so on, play a critical role in aiding such transactions. Further, various Government initiatives like FDI, tax exemptions, fast approvals, digitalization and the like are other factors which provides the impetus for Transfer to Technology. For instance, the pharmaceutical sector is one of the key 25 sectors identified by the Government of India under the ambitious 'Make in India' initiative, which is likely to provide the necessary momentum to the sector in order to achieve its true potential. Following this, is the nod by the Union Cabinet for FDI up to 100 percent under the automatic route sector for manufacturing of medical devices subject to certain conditions. Further, the implementation of the Goods and Services Tax (GST) is expected to be a game-changer for the Indian Pharmaceuticals industry as it will lead to tax-neutral inter-state transactions.

Till date, the Government of India has undoubtedly taken multiples initiatives towards improvements in the pharmaceutical sector however, they are mainly restricted to just that and do not focus on the concept of technology transfer to reduce the amount of input in such an industry. For instance, in the Union Budget 2017-18, the Department of Biotechnology (DBT) received Rs. 2,222.11 crore, an increase of 22 per cent, to continue implementing the Department's National Biotech Strategy. Later on, in an attempt to revive the active pharmaceutical ingredient (API) and the bulk drug market in India, the Government of India has proposed peak customs duty on the importing of APIs and also plans to establish mega drug parks to promote domestic production. It has also unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced simultaneously to boost investments. The Government has also introduced systems such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority in order to deal with the issue of affordability and availability of medicines. Against this backdrop, it is imperative to note that the concept of technology transfer can greatly help in reducing the cost of R&D in this sector if the government also provides incentives for the same especially since there has been a six-fold increase in the cost of R&D in this sector since 2010.

The high cost of development and rapid obsolescence may prevent the transfer of technology and the patent holder may prefer direct exploitation or import of products over transferring the technology or know-how. Fear of competition also dissuades the transfer of technology or demands a high royalty for the transfer, but huge royalties may have a negative impact on the expenditure on R&D. In the case of India in the pre'70s era, technology transfer by the big MNCs did not support indigenous technological abilities, although post '70s, a large number of small and medium size firms have also been transferring their drug technologies to India, thus encouraging an atmosphere of competition in technology transfer.

The Ministry of Science and Technology has issued the guidelines "*Instructions for Technology Transfer and Intellectual Property Rights*", which would help in enhancing the motivation of scientists, research institutions and universities in projects funded by the Department of Science and Technology, Department of Biotechnology, Department of Scientific and Industrial Research and Department of Ocean Development. The salient features of the guidelines are limited to ownership, commercial exploitation, royalty, norms for private industry, royalty free licenses for the government as well as patent facilitating funds.

India at this point has an immense potential for becoming a booming ground to facilitate and nurture the benefits of technology transfer. However, there exists a dire need to address this with guidelines to govern the same. The goals of technology transfer will only truly be met and be expected to cater to the needs of the public if there is a greater involvement of the Government. Despite the above, Government of India is on the verge of opening Technology Transfer Offices, universities, institutions that will be funded by the Central Government and will act as mechanisms for transferring or exporting the research conducted and its outcome to the desired place. It is pertinent to note that some Indian institutes such as the National Chemical Laboratory, Pune, CSIR-CDRI, have already been commercializing their research and have been successful in entering into technology transfer agreements vide which they have been licensed as technologies to industry.

It is only with adequate legal framework, guidelines and an increase of awareness that the issues of technology transfer can be encouraged. Although a number of Indian firms have been the receivers, a greater need of boosting this within the domestic markets is the need of the hour.■

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https://www.ibef.org/industry/pharmaceutical-india.aspx

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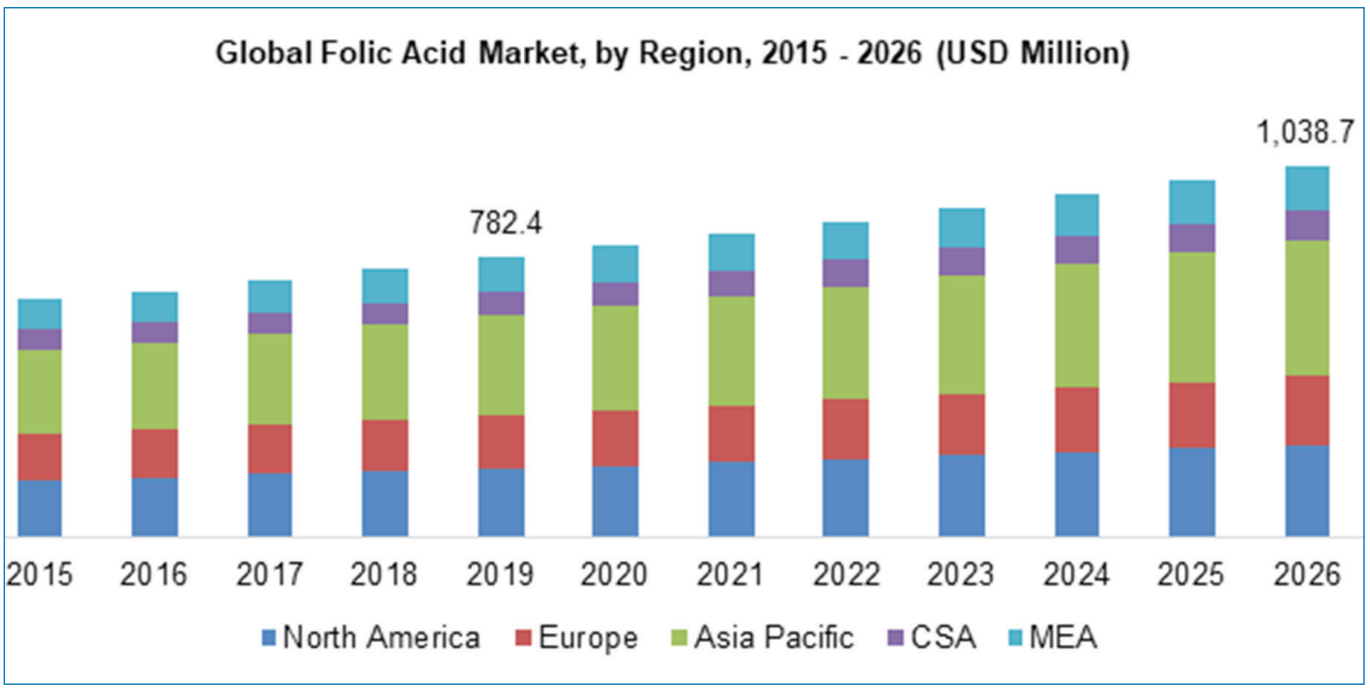
Comprehensive Industry Analysis: Folic Acid Market is on Growth Trail



Folic acid is an important water-soluble micronutrient for human body. It is synthetically produced and also found in fortified supplements and foods. It is naturally found in several plants such as dark green leafy vegetables. The natural occurrence is prevalent in the form of Folate in food, and folic acid is available in synthetic form. Okra, fruits, asparagus, mushrooms, meats, tomato juice, orange juice, lettuce, spinach, and broccoli are some of the natural sources of folate.

In its synthetic form, this vitamin is known in the market by several names viz. Folacin, Vitamin M, Vitamin B9, Acifolic, Folvite, Folcidine, pteroyglutamic acid, etc. The synthesized or artificially developed folic acid is structurally different than that of the naturally occurring ones. Being an absolute need for maintaining a healthy life style and balanced diet requirements, and human body's limitation to prepare it internally, the respective dietary requirement has to be fulfilled with food & supplement intake, which in turn fosters a good market growth across the globe.

The global folic acid market size is estimated to be of worth USD 1.04 billion by 2026 and is projected to grow at a CAGR of 4.1 percent over the period extended till 2026. Its demand has been increasing with the growing trend for a healthy lifestyle and balanced diet requirements. Development of enhanced drug delivery systems is one of the key measures to address the rising cases of folic acid deficiency in human body, thus in turn pushing the market demand upward.

Occurrence and Functionalities

Folate is needed for the proper functioning as well as the development of human body. It is instrumental for DNA production. Folic acid is abundantly available in natural sources. However due to various reasons viz. mal-absorption, poor dietary habits, prolonged illness, and side effects of drugs, many people are suffering from a deficiency. It is used for treating folate deficiency

Folic acid market size is expected to reach USD 1.04 billion by 2026 with a CAGR of 4.1 percent.

at the human body. The symptoms include anemia, and the inability to effective nutrient absorbance. Other diseases that can be prevented and treated with folic acid include kidney dialysis, liver disease, alcoholism, as well as ulcerative colitis. One more application of folic acid with paramount importance is dedicated to pregnant women. Folic acid helps them to prevent miscarriage. The intake of folic acid also reduces the occurrence of defects like spina bifida, a case in which the back and spine do not close. Folic acid is also used to treat cervical cancer and colon cancer. It can be effective in treating stroke among other heart diseases, and can be effective in lowering the levels of homocysteine in human blood. High homocysteine level results in high prevalence of heart disease. Folic acid is used to treat a variety of ailments relating to age. They are used to treat Alzheimer's disease, memory loss, hearing loss, as well as AMD or age related macular degeneration. It is also used to reduce the aging signs, weak bones, restless leg syndrome, nerve pain, sleep problems, depression, vitiligo, muscle pain, and rare diseases such as the Fragile X syndrome. It is also used to offset the harmful effects of medicines such as methotrexate and lometrexol.

Ever rising heart diseases across the globe and the effectiveness of folic acid in treating them are expected to benefit the overall folic acid market growth.

Recommended Dosage

Recommended dosage of folic acid supplement ranges in between 0.4 to 0.8 mg (which is 400 to 800 microgram), as endorsed by several Governments and health organizations including US Preventive Task Force (USPTF)

Market Growth Drivers

Various health applications of folic acid, ever rising heart diseases across the globe, and its effectiveness in treating various ailments are expected to benefit the overall folic acid market growth. The rise in geriatric population across the globe is expected to benefit the global folic acid market demand.

Segment Analysis

Pharmaceuticals, nutraceuticals, food & beverage, etc are some of the major application sectors of folic acid. With the growing demand for functional foods, food processors find folic acid an important investment instrument. Neutraceutical sector sees the fastest growth of this micronutrient. Recommendations by several Governmental agencies towards folic acid intake stirred the product demand and its use in nutraceuticals. Its various essential functional attributes has placed the product demand on an upward trail.

Regional Analysis

- Folic acid industry is moderately fragmented.
- As per the recent study, the lion share of consumption of synthetic folic acid has been happening at the Asia Pacific region with an estimated market share of around 31 percent. The region has witnessed increasing food supplement consumption and sales of high-end pharmaceuticals & nutraceuticals, being prominently driven by consumers' rising income levels and increasing purchase power parity.
- Companies and the manufacturing hubs based at Asia Pacific enjoy the easy access to abundant raw material supply and hence the prices are comparatively lower in this region.
- North America and Europe also occupy the prominent lead position at the consumption scale. However, here the driver is the endorsement of stringent policy for pregnant woman and children towards the essentiality of nutraceutical supplies for them.
- Presence of significantly higher number of companies belonging to folic acid value chain has made US a leading exporter of folic acid over several eastern European countries.

Key Players

Some of the notable market participants include BASF SE, Koninklijke DSM NV, Zydus Pharmaceuticals Ltd, Medicamen Biotech Ltd, Emcure Pharmaceuticals Ltd, Jiangxi Tianxin Pharmaceutical Co Ltd, Xinjiang Wujiaqu Xingnong Cycle Chemical Co Ltd, Changzhou Niutang Chemical Plant Co Ltd, Shandong Xinfa Pharmaceutical Co Ltd, and Hebei Jiheng Group Pharmacy Co Ltd amongst others.■

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2020
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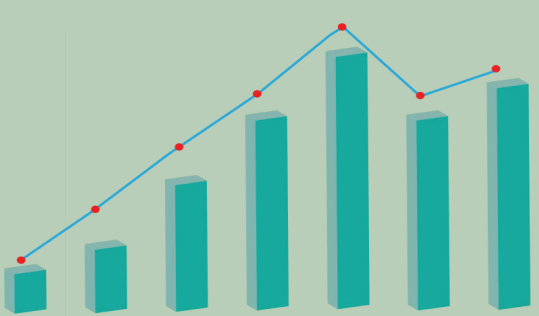


UNION BUDGET 2020-21

2020 Union Budget Snapshot: Health Sector

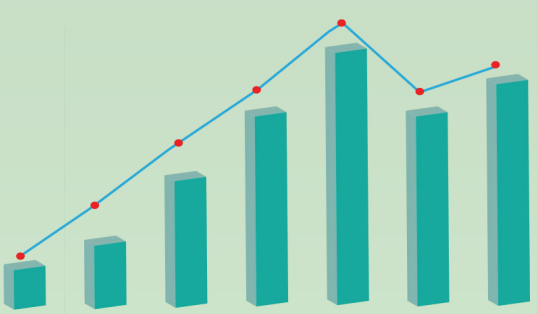
The budget is woven around three prominent pillars – 'Aspirational India', 'Economic Development', and 'Caring Society'. These three parameters have broadened the scope for Health Sector.

Enhanced disposable income for People of India, through revision in personal income tax structure, will invariably facilitate people's investment on health factorials and facilities.

Focus: Holistic Vision for Health & Wellness of the Citizen

The budget has taken a holistic vision for the wellness of the citizen.

- Health sector has been allotted to about Rs. 69,000 crores that is inclusive of 6400 crores for Prime Minister Jan Arogya Yojana (PMJAY).
- Mission Indradhanush has been expanded to cover 12 more communicable diseases including 5 new vaccines.
- FIT India movement is a vital part of fight against non-communicable diseases coming out of life-style issues.
- Expansion of Jan Aushadhi Kendra Scheme to all districts offering 2000 medicines and 300 surgicals by 2024.
- "TB Haarega Desh Jeetega" campaign: Efforts to be strengthened to realize the commitment of ending Tuberculosis by 2025.
- A very focused safe water (Jal Jeevan Mission) and comprehensive sanitation program (Swachh Bharat Mission) have been launched to support the health vision. This would reduce the disease burden on the poor.
- Presently, under Pradhan Mantri Jan Arogya Yojana (PMJAY), more than twenty thousand hospitals are empanelled. More hospitals are to be set up in Tier II and III cities for poorer people under this scheme.



UNION BUDGET 2020-21

2020 Union Budget Snapshot: Health Sector

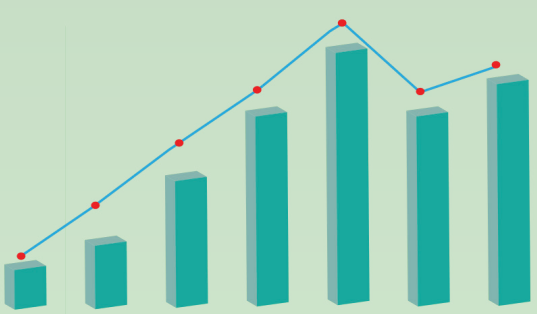
- Viability Gap Funding Window is proposed to set up hospitals in the PPP mode. In the first phase, 'Aspirational Districts' will be covered where presently no Ayushman empanelled hospitals are available. Proceeds from taxes on medical devices would be used to support this vital health infrastructure.
- Being empowered with machine learning and artificial intelligence, with Ayushman Bharat Scheme, health authorities and medical fraternity can target diseases with appropriately designed preventive regime.

Focus: Digital Revolution in India

- This budget aims to achieve seamless delivery of services through digital governance. This would be benchmarked to international standards and the indices would be announced soon.
- Data being the new oil and to take the advantage of analytics / fintech / IoT, the budget proposed to bring out a policy for the private sector to build Data Centre Parks throughout the country with a mission of enabling the firms to skillfully incorporate data in every step of their value chains.
- Using machine learning and artificial intelligence, in the Ayushman Bharat Scheme, health authorities and the medical fraternity can target for appropriately designed preventive regime.

Focus: Emerging Entrepreneurs

- The budget focuses on expanding the base for knowledge driven enterprises.
- A proposal announced to set up an Investment Clearance Cell to provide end-to-end facilitation and support to emerging entrepreneurs with pre-investment advisory, clearance service, and other associated features.



UNION BUDGET 2020-21

2020 Union Budget Snapshot: Health Sector

Focus: Manufacturing

- Revitalizing manufacturing activities is going to be one of the key focus areas.
- To implement zero-defect-zero-effect-manufacturing, this budget called for a time-bound adoption of all necessary & mandatory technical standards by the industry and their effective enforcement.

Focus: Export

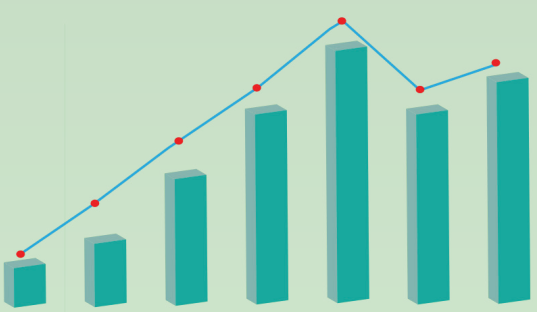
- Government has announced the launch of a scheme for reversion of duties and taxes on exported products. The Government has also been envisioning the development of an export hub.

Focus: IPR

- To facilitate the seamless application and capture of IPRs, this budget announces the forthcoming launch of a digital platform and an Institute of Excellence.

Focus: Research and Development

- The budget announces two new national level science schemes towards India's genetic landscape mapping.



Industry Leaders' Reaction

UNION BUDGET 2020-21

2020 Union Budget has recently been announced by Hon'ble Finance Minister Ms. Nirmala Sitharaman. Health sector has got a notable mention, which cascadingly impacted Pharma, Biopharma, Life Science, and allied industries. Here goes a few eminent industry leaders' reaction.

Rajesh Khosla,
President & CEO
AGI Glaspac

"Budget 2020 promises the right impetus to the manufacturing sector, thereby creating a well-laid roadmap for achieving India's goal of becoming a 5 trillion dollar economy by 2024. The corporate tax cut is a very bold move that will further help in strengthening the Make-in-India initiative. With the PM's Zero-Effect-Zero-Defect policy, this will act as icing on the cake as it will not only promote the manufacturing, but will also endorse the green manufacturing. The Government's gaits to focusing on India's spurring manufacturing will give a huge boost to all the subsidiary industries, and also create provisions for jobs at the same time. Additionally, the revision of the personal tax regime comes as a welcome measure, as it translates into the increasing purchasing power of the consumers, thereby bolstering the demand-and-supply parameter in the industry and improving the nation's economic growth".

Dr Sunil Singh
CHRO
Cadila Pharmaceuticals Ltd

"The Finance Minister has reiterated the Government's commitment to the health sector by allocating ₹ 69,000 crore for the healthcare sector. She has identified Access-to-Health for all sections of the society as a key part of Aspirational India, one of the three prominent themes around which this budget was woven. The Finance Minister has announced the expansion of Pradhan Mantri Jan Aroyga Yojana by creating an infrastructure for health services by facilitating the setting up of hospitals in aspirational districts. She has also proposed expansion of Jan Aushadhi Kendra schemes to all districts, which will allow citizens access to drugs to affordable prices. The focus on nutrition of children, adolescent girls, pregnant women, and lactating mothers will also help in improving health levels".

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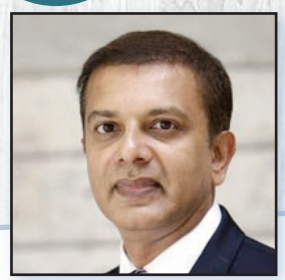

Satish Reddy
Chairman
Dr. Reddy's Laboratories Ltd
President, Indian Pharmaceutical Alliance

"The industry had high expectations of this budget as it was seen to be an opportunity to announce big, bold reforms given to the state of the economy. On that count, there is a degree of disappointment in some quarters as expectations have not been met.

However, I am happy to see that healthcare continues to be an integral part of the Government's key priorities. The announcement on the expansion of the Ayushman Bharat program by setting up additional hospitals in tier 2 and 3 cities is a welcoming move. Other measures in improving the healthcare infrastructure and capacity building in the sector are also commendable.

I would however have liked to see a significant financial incentive to boost exports and improve the competitiveness of the Pharma sector. I hope this will take shape with a new export incentive scheme. The overall thrust on ease of doing business, regulatory simplicity, and policy stability should help the pharma industry to scale new heights."

Vivek Sharma
Managing Director
Panasonic Life Solutions

"The Budget 2020 has some prudent steps towards improving consumption by the middle class and energizing the economy into a phase of recovery. The measures under ACE - Aspirations, Economic Development, and Caring Society - will be crucial for the betterment of the economy on the whole. Steps like boosting investments for development of smart cities, simplification of GST returns, making affordable housing more accessible, prominence of rural & skill development, Government's reform towards reduced Central Government Debt , and a much needed tax relief for consumers will not only uplift the manufacturing sector, but will also set India well on the path to become a 5 trillion dollar economy. Further in line with the Government's vision to eradicate poverty, so far we have been successful in bringing 271 million citizens out of poverty".

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Dr S Jhaveri
Founder and
Managing Director
Biomall.in

"The current budget shows a good encouragement to scientists and engineers, in addition to its continuous push for Make in India.

Finance Minister Ms. Nirmala Sitharaman embraced the national mission of quantum technology which has wide-spread applications in communication, cyber-security, data management, and many more. Finance Minister surprised everyone with a big 5-year allocation of 8000 crores for this mission of innovation and development in quantum technology. This will open roads to machine learning and artificial intelligence that can fast-track R&D, advanced machine development, supporting digital business, and disrupting the old models of business over the course of time.

Another clap goes to her for cheering the scientific community with an increase of about 13 percent funds in this budget as compared to last year's expenditure. Department of Biotechnology gets the highest 17 percent jump in fund allocation from 2381 crores to 2786.76 crores this year. This is followed by the allotment for Department of Science and Technology with 6301 crores (14.9 percent hike). The Ministry of Earth Sciences gets 14.3 percent increase, and the Department of Scientific and Industrial Research gets 10 percent hike with 5385 crores in comparison to 4883 crores of last year.

Although the budget allocation is not proposed yet, Finance Minister proposed two new national-level schemes for mapping of India's genetic landscape that will give data for the development of next-generation medicines, agriculture, and which can also be used for biodiversity management.

With Budget 2020, Finance Minister put forth the goal to make India ahead in technology and to soar high in scientific innovation. We can hope that such initiatives would boost India's economy in the long run".

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Zoya Brar
Founder and CEO
CORE Diagnostics

"It is encouraging to see over 10 percent increase in the allocation of funds to the Healthcare sector for the budget 2020-21. While there has been no significant announcement pertaining to diagnostics industry, it is good to see the government's growing focus on PPP mode ensuring accessibility and availability of quality healthcare services in remote locations. We are intrigued about how the government will use the fund of ₹ 6400 crores allocated exclusively to Ayushman Bharat to the benefit of the people residing in Tier II and III cities. The expansion of government's existing programme - Mission Indradhanush - to cover 12 new diseases and 5 new vaccines would be extremely beneficial in order to drive immunization across the country. The investment of ₹ 8,000 crore for National Mission of Quantum Technology and Application is another noteworthy announcement for the healthcare industry.

We, at CORE Diagnostics, agree with the government that Analytics, IoT, and AI are integral part for the growth of the industry and look forward to the implementation of this fund for R&D in the healthcare sector which will further result in innovations and advancements. As the Finance Minister rightly said, data is indeed the new oil. It is promising to see the improved attention from government on this subject in form of their support to the private sector in building data centre parks throughout the country. I've also spoken about the importance of genetic mapping. The announcement of two national level schemes will ensure protection and bring more structure to the abundant national level database that we as a country already possess".

Sandeep Toshniwal
CEO
Eurolife Healthcare Pvt. Ltd

Infrastructure improvements spending and ease of doing business have been easing the banking regulations to increase the money flow. Government sector, spending money on healthcare, stays at 1 percent of GDP. Healthcare sector will come within people's reach with Government's this initiative. Medical inflation has been growing at 13 – 15 percent every year, healthcare expenses of average household can easily exceed medical allowances of ₹ 15000 per annum. Companies usually cap medical allowance at tax free limit of ₹ 15k. If it gets revised upwards, company will also be encouraged to hike the allowance. The import of finished medical devices attracts custom duty of 0 – 20 percent, while the raw material import attracts 20 – 39 percent on customer duty. It adds strain on making the devices domestically

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Nikhilesh Tiwari
Founder & CEO
ColMed

"The Government's decision to use the proceeds from the taxes levied on medical devices to boost the health infrastructure in tier 2 and tier 3 cities is a smart move. It will help increase the access to quality healthcare in underserved areas, which will in turn increase the sale of medical devices. As such, the plan is sustainable and will be beneficial to all the stakeholders in the healthcare ecosystem. While the government's recent decision to regulate the price of medical devices and slash the import duties on raw materials is a step towards making healthcare more accessible, it should also incentivize research and development to support local manufacturing. Since most of the medical devices get replaced by a newer model once in every two years or so, the major medical device manufacturers spend more money on research and development compared to other industrial firms. Since the payback period is shorter, central incentive will help to foster innovation in the sector and will increase the quality of healthcare service delivery".

Mahendra Patel
Managing Director
Lincoln Pharmaceuticals Ltd

"Focus has been given on improving health infrastructure in the country and to ensure that quality medicines at affordable price are made available to the masses. Abolition of dividend tax will reduce the burden on companies. ₹ 1,000 crore allocation for technology upgradations, R&D, and business strategy will provide encouragement to mid-size pharma companies in increasing exports. Generic medicines will get a boost as Pradhan Mantri Jan Aushadhi stores would be expanded to every district. This would be a positive for both SME pharma manufacturing units as well as small domestic medical device makers who supply to the scheme. With the government's initiative, not only can the industry support the government in providing affordable and efficacious medicines, it will also help to mark its presence in the global markets".

Three Must-have Features to Ensure Your Pharmaceutical Metal Detector is Best-in-Show

Siddharth Kachroo
Business Manager –Product Inspection & Global Key Accounts
Mettler-Toledo India Pvt Ltd

When we speak about regulation, only a few industries are as heavily regulated as pharmaceutical industry. Manufacturers must do all they can to protect the customers' interest by ensuring the products contain what they stipulate on the label, so that they are free from metal contaminants. The repercussions of a product recall due to the fragments of broken sieve wire present in medicine can be catastrophic. Much more than bearing short-term downward impact on the profit margin, at its worst a recall can damage consumers' trust in the product, thus hitting sales and market share in the long term.

Quality control is vital for pharmaceutical production lines to safeguard against any sort of contamination. Companies can adhere to a number of strict safety standards to set the framework for manufacturing processes. These include the US Food and Drug Administration's (USFDA) Process Analytical Technology (PAT) guidance – a mechanism to design, analyse and control pharmaceutical manufacture; and Good Manufacturing Practice (GMP) aimed primarily to reduce the inherent risk associated with pharmaceutical production, including metal contamination.

To comply with these best practice guidelines, pharmaceutical manufacturers require reliable product inspection technology, such as – metal detectors, specially developed for pharmaceutical lines. Equipment such as Mettler-Toledo Safeline Metal Detection's Tablex integrates the metal detector and high-speed rejection system for inline tablet and capsule inspection. The Pharmaceutical Gravity Fall Pharma GF-PRO system, for free-falling powdered and granular materials, have been designed and built to address the challenges of an increasingly demanding and regulation-driven market.

When searching for metal detection machinery for their lines, pharmaceutical companies should look out for a number of design features to ensure the meeting of safety requirements by the equipment. These features have the ability to differentiate between a product inspection system offering best practice(s) and the one that simply meets the minimum standards. Below is a list of features that a pharmaceutical manufacturer should consider to guarantee their product inspection processes and products as best-in-show.

Best Practice 1: Generating Records

In compliance with Section 2.1 of the proposed updates by World Health Organization (WHO) on GMP for Pharmaceutical Products, from January 2013 principal records are to be made – either manually or using automated technology – during the manufacturing process to provide the proof-of-compliance. Manufacturers must also keep comprehensive data on batch history and distribution readily accessible to optimise traceability, and in the event of a product recall – to identify the source of any quality issue.

Metal detectors that have been designed and built to comply with FDA and GMP standards can satisfy pharmaceutical industry demands for data monitoring and traceability. The detectors, specifically developed for pharmaceutical applications, can arrive at the state where the production line is ready to connect the manufacturers' data collection devices, ensuring full compliance with industry regulations.

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Mettler-Toledo Safeline Metal Detection's Tablex-PRO pharmaceutical metal detectors, for example, incorporate a data storage function for machine operators to set up easily, with a colour touchscreen and Human Machine Interface (HMI) that is windows-styled icon-driven. This helps to reduce unnecessary downtime by making it simple for operators to navigate the machine's set up options with minimal training. On-screen histograms (graphical representations of the product inspection data distribution) provide an easy-to-understand visual breakdown of records pertaining to performance and historical inspection. Moreover, for multinational manufacturers, flexible interface connectivity simplifies the integration of the same with external data collection systems, thus enabling the monitoring of company's entire production process.

METTLER TOLEDO has developed ASNE 9000 series of conveyorized metal detector covering flexible range of fully integrated solutions designed for the inspection of tall, narrow packs such as bottles and mono cartons in pharmaceutical packaging.

Best Practice 2: Cleaning Up

To meet the GMP requirements, the highest hygiene standards must be upheld on pharmaceutical production lines. To facilitate this, production line machinery designs must – wherever possible – avoid the edges, corners, and flat surfaces that can act as dirt traps to accumulate excess layers of dust. In addition, systems must be easy to clean with modules that can be dismantled efficiently without the need for tools. At the same time, they must be made of robust materials, such as stainless steel, capable of withstanding harsh and repeated wash-downs without succumbing to corrosion.

Compact metal detectors, with rounded corners and curved surfaces can streamline the cleaning process, enabling pharmaceutical manufacturers to comply with PAT and GMP standards. Technologies, such as the Tablex-PRO, can easily be dismantled and reassembled without the need for tools or small parts, facilitating regular hygiene inspections of every aspect of the machine. With the electrical components removed, the fully waterproof modules – made from mirror-finished stainless steel – can be fully submersed in water for optimal cleaning.

Best Practice 3: Operator Training

To guarantee the best practice, simply integrating the data monitoring technologies or the easy-clean machines isn't sufficient. Machine operators on pharmaceutical production lines must also be properly trained to ensure comprehensive data monitoring and cleaning to take place; and not only is that, they are also to ensure the correct documentation of such procedures.

Pharmaceutical metal detectors incorporating advanced HMIs with icon-driven displays help manufacturers to ensure the easy navigation of their product inspection system's data collection process with minimal training. Not only this saves the time during product changeovers and boosts the productivity, but also reduces the risk of human error which otherwise affects the data monitoring.

In addition, advanced metal detectors – with built-in performance validation software – guide the operators by indicating when scheduled testing is due; and also walk them through the step-by-step test routines. This ensures the occurrence of product inspection performance monitoring as often as required being facilitated by GMP Best Practice guidelines and aiming to the standard expected.

Better than Best

Complying with regulatory and industry standards for quality, traceability, and safety is of paramount to ensure product safety, as well as to retain the access to lucrative international markets. By following the three best practice guidelines mentioned in this article, pharmaceutical manufacturers can ensure the right selection of metal detection systems that not only meet, but exceed the GMP and PAT standards, thus achieving the best practice(s) with regard to their product lines and maximizing the consumers' well-being. ■

The detectors, specifically developed for pharmaceutical applications, can arrive at the state where the production line is ready to connect the manufacturers' data collection devices, ensuring full compliance with industry regulations.

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Ultimate Vacuum Solutions for Power Consumption in Industries

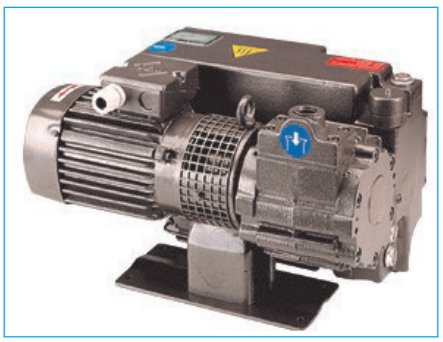
The application of vacuum holding is pick and place, etc, for battery, manufacturing. They are used in separator machine, red top placing machine and PVC sleeve insertion machine, bottom separator placing and body making machine. The approximate speed is about 760 batteries per minute. The operating level is 260-200 torr (abs).

The Problem

A battery manufacturing company was using centralized vacuum system in which they had oil immersed vacuum pump. The total installed motor capacity of the pump was 90-kW, which was placed approximately 200 metres away from the plant. Hence, due to conductance there was a lot of loss. This in turn got about very little effective utilization of the pumping capacity at the machine. Due to poor lubrication the sealing medium of the oil immersed pump got heated, thus emitting excessive smoke. This got about a lot of heat generation and oil evaporation. To set this problem right the company was using 100 litres vacuum oil per fortnight as a result bringing about high energy cost.

Toshniwal Vacuum Solution

The Company was in search for some solution, which would reduce the energy cost plus control the oil and heat evaporation.



They finally approached us after trying out other solutions. Taking into consideration their problem we decentralized the system and replaced it with ours, as our oil lubricated pump could be kept to the machine sight as it has pollution-free exhaust. With our expert engineers understanding their intricacy, supplied the present vacuum system of motor capacity 30-kW in comparison to 90-kW of centralized system. As a result, there was a lot of saving in the energy.

After replacing our pump with a much lower motor capacity to that of the other used pump, it faced a power saving of ₹ 10-lakh per year. Recently, their other plant at remote location has also undergone the similar changes after seeing the success.

Benefits

Over the years we have supplied suitable pumps providing our customers with the best solution, which in turn has improved the customer's manufacturing operation.

Summary

Providing suitable solutions helped the company save their power consumption. ■

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Syntegon Technology Appointed Dr Michael Grosse as Chief Executive Officer

Waiblingen, Germany: Syntegon Technology, a globally leading supplier of processing and packaging technology, has recently appointed Dr Michael Grosse as new Chief Executive Officer (CEO). Most recently, Michael Grosse was a member of the Management Board of Tetra Pak. He has relevant leadership and management experience in the international mechanical engineering industry, particularly in the areas of process and packaging technology for the food industry. Michael Grosse joined Tetra Pak in 2003 and was, among other things, responsible for expanding the global services business. Furthermore, he is an expert for new product development and process technologies. Thanks to his many years of experience, he has built an extensive network and close relationships within the food industry. Before joining Tetra Pak, he held several management positions in the automotive industry. Michael Grosse will take up his post on March 1, 2020.

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

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

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

In addition to the change at CEO level, Dr Walter Bickel will be appointed as a further Member of the Executive Board of Syntegon Technology as of March 1, 2020. In his new position, he will be responsible for driving the Group's transformation process forward decisively. Dr Walter Bickel has many years of leadership experience in top management positions within the mechanical engineering and automotive industry. He is a renowned expert in the implementation of holistic profit improvement programs, business model restructuring and leveraging additional growth potential. Between 2014 and 2018, he was CEO and CFO of the international foil manufacturer Treofan. Previous positions also include his role as COO and subsequently Member of the Supervisory Board of robotics manufacturer KUKA as

B&R Introduces New Digital Output Module with Pulse Width Modulation

B&R's new digital output module X20DO4332-1 has integrated pulse width modulation and is a cost-effective alternative to motor modules.

Pune, India: B&R's new digital output module X20DO4332-1 has integrated pulse width modulation and is a cost-effective alternative to motor modules. In addition, the module offers a dither function that prevents valves from sticking.

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

With its dither function, the module also prevents valves from sticking. This is particularly common when valves are held for extended times at a constant position, especially in liquids. The dither function oscillates the valve slightly around the position setpoint to prevent it from sticking. The X20 module is equipped with four outputs with three-wire connections and offers a nominal output current of 2 A.

Cadila Celebrated World Cancer Day by Organizing a Bike Rally

Mumbai, India: Ahmedabad-based pharma major Cadila Pharmaceuticals and N. K. Dhabhar Foundation, organized a Bike Rally in Mumbai on Sunday 2nd February, ahead of World Cancer Day on February 4.

This bike rally was organized as a part of the ongoing campaign "I Am and I Will" where the aim is to not only raise cancer awareness and also to encourage people to take action in the fight against cancer. The campaign began on 28th January and scheduled to continue for a month. Cadila shares tips and messages on their digital channel related to cancer and how everyone can do their bits to defeat cancer. Multiple awareness rallies have been planned across the country in association with various organizations to sensitize people about cancer patients on the occasion of World Cancer Day.

More than 30 bikers of Bajaj Avenger Group took part in the awareness rally which started at 8:00 am at Shivaji Park, and culminated at Nariman Point after passing through Worli, Mahalaxmi, and Girgaum Chowpatty.

"We all need to come together against cancer and not let it win. We need to make sure that the cancer patients and survivors feel safe and know that they are not alone in the difficult journey of cancer. Cancer if detected early is curable. It can be defeated if the right support and environment is provided to the patient. We all have a huge part to play in this", said Dr Dhabhar, Head of N K Dhabhar foundation.

Cadila Pharmaceuticals has been actively taking action to spread awareness towards various diseases. The activities are aimed at sensitizing people about various illnesses such as iron deficiency, Cancer, Schizophrenia, Epilepsy, and Depression. These campaigns are meant to help people to understand the ailments better and to support them to provide care to their loved ones.

Cadila Pharmaceuticals Ltd is one of the largest privately held pharmaceutical companies. Over the past six decades, we have been developing and manufacturing affordable medicines for patients around the world. Its innovation-led drug discovery processes ensure the health and well-being of people around the world. Being a care-focused, research-driven company, we are committed to comply the highest ethical standard in clinical research and medical practice.

Catalent Acquired Premier European Product Launch Site from Bristol-Myers Squibb

Anagni, Italy: Catalent recently announced the completion of its acquisition of Bristol-Myers Squibb's biologics, sterile, and oral solid dose product manufacturing and packaging facility in Anagni, Italy.

The state-of-the-art facility, designed for late-phase tech transfers and commercial product launches, has a track record of launching hundreds of new products across many therapies including cardiovascular, cancer, and hepatitis treatments. The facility provides Catalent customers the access to:

- Comprehensive commercial packaging solutions, with blister and bottling capabilities
- Serialization solutions to ensure product traceability throughout the global supply chain
- Integrated digital printing and RFID tracking
- Automated warehousing

The Anagni facility complements Catalent's existing European biologics, oral solid dose development and manufacturing network.

Jubilant Life Sciences Announced Q3 & 9M'FY 20 Results

Noida, India: The Board of Jubilant Life Sciences Limited, an integrated global pharmaceutical and life sciences company has recently announced their financial results for the quarter ended December 31, 2019. Commenting on the Company's performance, Mr. Shyam S Bhartia, Chairman and Mr. Hari S Bhartia, Co-Chairman & Managing Director, Jubilant Life Sciences said: "We reported stable performance Y-o-Y and growth in EBITDA with better margins sequentially and PAT was lower due to certain exceptional charges. Demand conditions across all Pharma businesses, Specialty Intermediates and Nutritional Products are strong. Overall we are confident of delivering strong performance going forward.

Pharmaceutical segment reported steady revenue growth during the quarter. We witnessed healthy growth in Allergy Therapy Products and API businesses with stable performance in Radiopharma, CMO and Generics. EBITDA at ₹ 411 Crore was up 6 percent Y-o-Y and 7 percent Q-o-Q with margin of 28.4 percent, an improvement of 112 bps Y-o-Y and 180 bps Q-o-Q. Adjusted EBITDA of Pharmaceutical segment at ₹ 414 Crore was 8 percent higher YoY with a margin of 28.6 percent.

LSI segment revenue at ₹ 797 Crore was lower 11 percent Y-o-Y, but up 6 percent Q-o-Q led by growth in Specialty Intermediates and Nutritional Products. Life Science Chemicals business' revenue at ₹ 381 Crore was down 30 percent Y-o-Y due to lower input prices of Acetic Acid. LSI EBITDA at ₹ 100 Crore was down 21 percent Y-o-Y, but up 10 percent sequentially with margins of 12.6 percent.

The Drug Discovery Services business reported robust growth of 26 percent YoY in revenue and a ~2.7x increase in EBITDA with margin of 25 percent during the quarter. In view of the strong demand, we are making significant investments in this business to double capacities over the next 2-3 years.

In our Proprietary Drug Discovery business, we are working on more than six programs targeting small molecule therapies in the area of oncology and auto-immune disorders with potential to fast track promising assets from discovery to clinical stage".

Q3'FY20 Highlights

Consolidated

- Revenue at ₹ 2,315 Crore, a decrease of 3 percent Y-o-Y and an increase of 2 percent Q-o-Q
- EBITDA at ₹ 513 Crore decreased 2 percent Y-o-Y but increased 7 percent sequentially. EBITDA margin at 22.2 percent vs. 22 percent in Q3'FY19 and 21.2 percent in Q2'FY20
- Adjusted EBITDA after one-off expenses at ₹ 516 Crore vs. ₹ 518 Crore in Q3'FY19. Adjusted EBITDA margin for the quarter is 22.3 percent vs. 21.8 percent in Q3'FY19
- Finance costs at ₹ 72 Crore vs. ₹ 53 Crore in Q3'FY19 and ₹ 72 Crore in Q2'FY20
- Exceptional charge of ₹ 23 Crore related to prepayment of high yield bonds and NCDs and ₹ 11 Crore related to write-off of fixed assets not in use. Q3'FY19 charge of 15 Crore is related to IFC Stock settlement charge
- PAT at ₹ 203 Crore down 22 percent Y-o-Y and 18 percent Q-o-Q. EPS of ₹ 12.8 for Re 1 FV
- Capital Expenditure of ₹ 111 Crore
- Gross Debt at ₹ 4,048 Crore and Net debt at ₹ 3,362 Crore
  - Net debt at ₹ 3,273 Crore on a constant currency basis
  - Average blended interest rate for 9M'FY20 @ 6.08 percent; INR loans @ 8.21 percent and USD loans @ 5.34 percent

Segment Wise Analysis

A. Pharmaceuticals Segment

- Pharmaceuticals revenue at ₹ 1,450 Crore, an increase of 2 percent Y-o-Y, contributing 63 percent to the company's revenue as compared to 60 percent in Q3'FY19
- EBITDA at ₹ 411 Crore increased by 6 percent Y-o-Y and 7 percent Q-o-Q with a margin of 28.4 percent as compared to 27.2 percent in Q3'FY19 and 26.6 percent in Q2'FY20.
- Adjusted EBITDA at ₹ 414 Crore increased by 8 percent Y-o-Y with a margin of 28.6 percent as compared to 26.9 percent in Q3'FY19
- R&D spent during the quarter of ₹ 72 Crore – 5 percent of segment's sales. R&D debited to P&L is ₹ 55 Crore – 3.8 percent of segment's sales

B. Life Science Ingredients Segment

- LSI revenue at ₹ 797 Crore, decreased by 11 percent Y-o-Y and increased by 6 percent Q-o-Q, contributing 34 percent to the company's revenues
- EBITDA at ₹ 100 Crore decreased by 21 percent Y-o-Y and increased by 10 percent Q-o-Q with margin of 12.6 percent as compared to 14 percent in Q3'FY19

C. Drug Discovery & Development Solutions1 Segment

- Revenue increased by 26 percent Y-o-Y to ₹ 68 Crore led by growth in Drug Discovery Services business
- EBITDA at ₹ 17 Crore with margin of 25.4 percent
  - Drug Discovery Services EBITDA increased to ₹ 21 Crore from ₹ 5 Crore in Q3'FY19. Margin improvement to 31.1 percent from 8.6 percent in Q3'FY19

9M'FY20 Highlights

Consolidated

- Revenue at ₹ 6,763 Crore, increase of 1 percent from ₹ 6,725 Crore in 9M'FY19

- EBITDA flat at ₹ 1,438 Crore as compared to ₹ 1,423 Crore in 9M'FY19. EBITDA margin at 21.3 percent against 21.2 percent in 9M'FY19
- Adjusted EBITDA after one-off expenses at ₹ 1,512 Crore vs. ₹ 1,432 Crore in 9M'FY19, growth of 6 percent Y-o-Y. Adjusted EBITDA margin in 9M was 22.4 percent vs. 21.3 percent in 9M'FY19
- Finance costs at ₹ 216 Crore as compared to ₹ 158 Crore in 9M'FY19.
- Exceptional charge of ₹ 23 Crore related to prepayment of high yield bonds and NCDs and ₹ 11 Crore related to write-off of fixed assets not in use. 9M'FY19 charge of 45 Crore is related to IFC Stock settlement charge
- Net Profit at ₹ 638 Crore down 5 percent Y-o-Y. EPS of ₹ 40.0 for Re 1 FV
- Capital Expenditure of ₹ 428 Crore

Segment Wise Analysis

D. Pharmaceuticals Segment

- Revenue at ₹ 4,231 Crore, increased 7percent Y-o-Y
- EBITDA at ₹ 1,127 Crore up 4 percent Y-o-Y with a margin of 26.6 percent as compared to 27.6 percent in 9M'FY19
- Adjusted EBITDA at ₹ 1,192 Crore increased 9 percent Y-o-Y with a margin of 28.2 percent as compared to 27.8 percent in 9M'FY19. One-off expenses of ₹ 65 Crore related to site remediation, litigation expenses and penalties on non-supply
- R&D spent during 9M at ₹ 186 Crore – 4.4 percent to segment sales. R&D debited to P&L is ₹ 157 Crore – 3.7 percent to segment sales

E. Life Science Ingredients Segment

- LSI revenue at ₹ 2,356 Crore, decrease of 11 percent Y-o-Y
- EBITDA at ₹ 313 Crore decreased by 9 percent Y-o-Y with margin of 13.3 percent as compared to 13.1 percent in 9M'FY19.
- Adjusted EBITDA at ₹ 321 Crore, with a margin of 13.6 percent as compared to 13.1 percent in 9M'FY19

F. Drug Discovery & Development Solutions Segment

- Revenue increased 18 percent Y-o-Y to ₹ 176 Crore
- EBITDA at ₹ 39 Crore a YoY increase of 108 percent
    - Drug Discovery Services EBITDA increased to ₹ 50 Crore up 168 percent Y-o-Y. Margin improvement to 28.3 percent from 12.5 percent in 9M'FY19
- In Q3'FY20 and 9M'FY20 Exceptional charge of ₹ 23.3 Crore was related to prepayment of high yield bonds and NCDs and ₹ 11.3 Crore related to asset write-off. Q3'FY19 and 9M'FY19 charge of 15 Crore and Rs 45 Crore, respectively, was due to IFC Stock settlement charge.

Particulars[1]	Q3'FY19	Q3'FY20	YoY Growth	9M'FY19	9M'FY20	YoY Growth
Total Revenue from Operations	**2,377**	**2,315**	**(3%)**	**6725**	**6,763**	**1%**
Pharmaceuticals	**1,424**	**1,450**	**2%**	**3943**	**4,231**	**7%**
Life Science Ingredients	**899**	**797**	**(11%)**	**2633**	**2,356**	**(11%)**
Drug Discovery & Development Solutions	**54**	**68**	**26%**	**149**	**176**	**18%**
Total Expenditure	1,884	1,819	(3%)	5344	5,364	0%
Other Income	29	6		42	28	
Segment EBITDA	**519**	**528**	**2%**	**1450**	**1,478**	**2%**
Pharmaceuticals	**388**	**411**	**6%**	**1087**	**1,127**	**4%**
Life Science Ingredients	**126**	**100**	**(21%)**	**344**	**313**	**(9%)**
Drug Discovery & Development Solutions	**5**	**17**	**270%**	**19**	**39**	**108%**
Corporate (Expenses)/Income	4	(15)		(27)	(40)	
Reported EBITDA	**522**	**513**	**(2%)**	**1423**	**1,438**	**1%**
Depreciation and Amortization	98	113	15%	276	333	21%
Finance Cost	53	72	36%	158	216	37%
Profit before Tax	**371**	**328**	**(12%)**	**989**	**889**	**(10%)**
Exceptional Items	15	35		45	35	
Profit before Tax (After Exceptional Items)	**356**	**293**	**(18%)**	**944**	**855**	**(9%)**
Tax Expenses (Net)	88	90	2%	266	217	(19%)
Minority Interest	7	0	-	4	0	-
PAT	**261**	**203**	**(22%)**	**674**	**638**	**(5%)**
Earnings Per Share - Face Value Re. 1 (Rs.)	**16.7**	**12.8**		**43**	**40.0**	
Segment EBITDA Margins	**21.8%**	**22.8%**		**21.6%**	**21.9%**	
Pharmaceuticals	**27.2%**	**28.4%**		**27.6%**	**26.6%**	
Life Science Ingredients	**14.0%**	**12.6%**		**13.1%**	**13.3%**	
Drug Discovery & Development Solutions	**8.6%**	**25.4%**		**12.5%**	**22.0%**	
Reported EBITDA Margin	**22.0%**	**22.2%**		**21.2%**	**21.3%**	
Net Margin	**11.0%**	**8.8%**		**10.0%**	**9.4%**	

Piramal Pharma Solutions Invested CA$25 Million to Expand its Aurora, Canada Facility

Aurora, Canada: Piramal Enterprises Limited's Pharma Solutions business, a leading Contract Development and Manufacturing Organization (CDMO), has recently announced their plans to expand the Aurora facility in Canada with the addition of a new state-of-the-art wing dedicated to manufacture Active Pharmaceutical Ingredients (APIs). A total investment of ~CA$25 million will be infused towards this expansion.

Known for its world-class lab services and production plants, the Piramal Pharma Solutions' (PPS) Aurora facility will enhance its offerings to customers with this new addition that features ~10,500 sq. ft. of new manufacturing space. The additional capacity will cater to increasing customer demand as well as support the facility's ability to provide APIs and HPAPIs down to an Occupational Exposure Limit (OEL) of 1mcg/m3. It will also include filtration and drying capabilities that will enhance service offerings at Piramal Pharma Solutions' Aurora facility.

Peter DeYoung, CEO, Piramal Pharma Solutions said, "We are delighted to announce the capacity expansion at our Aurora facility in Canada. This additional capacity will help us to strengthen our presence in Canada as well as service other geographies such as North America and Europe, whilst enabling us to support our customer's API requirements and market demand for integrated solutions. As a Patient Centric organization, Piramal Pharma Solutions is committed to serving the patient community and reducing the burden of disease."

Apart from the existing production scale reactors, this expansion will include two new reactor suites as well as a dedicated filter dryer room and a portable filter dryer. The expansion is expected to be completed and running by April 30, 2021. With successful inspections by the US FDA, the UK MHRA and the PMDA, Piramal Pharma Solutions' Aurora facility has a stellar track record of regulatory compliance and is committed to maintaining gold standards of environmental performance, health & safety.

This upcoming facility has been designed to meet the highest standards of global compliance and will employ highly qualified scientific, technical and professional staff, building on a business that has already seen staff numbers grow almost 2-fold to ~200 in recent years.

Agilent Teamed with IIT Delhi to Enhance Bio-therapeutics

New Delhi, India: Agilent Technologies Inc has recently announced its association with Indian Institute of Technology Delhi (IIT Delhi) to promote biopharmaceutical research. Agilent and IIT Delhi signed a memorandum of understanding(MoU). Under the scope of this MoU, Agilent, a leader in the biopharma space, is going to contribute funds to support the incubator at IIT New Delhi to support researchers at the institute in establishing global best practices for identifying and characterizing biopharmaceuticals. The research conducted by IIT Delhi examines and reports on the quality of bio-therapeutic products for the Indian market.

Visiting the campus, Agilent CEO, Mike McMullen, spoke about Agilent's history of innovation, focus on research and academia, and vision for the future. Likewise, the institute's Director, Prof. V. Ramgopal Rao, spoke about the institute's mission and role in promoting collaborations between academia and industry.

Agilent will be contributing funds to the IIT Delhi incubator site, as a part of its corporate social responsibility initiative, with the goal of enhancing the quality and safety of bio-therapeutics. The aim is to offer world-class training to researchers from academia and industry on protein characterization. The setup will be under the DBT Center of Excellence for Biopharmaceutical Technology (CBT) and will support incubated startups at IIT Delhi performing protein analysis, the result of which will provide critical information to policy makers for ensuring safe and efficacious bio-therapeutic products in India.

"We are happy to be associated with Agilent," said Prof. Anurag S. Rathore (IIT Delhi), Coordinator of the CBT. "Agilent's broad range of technologies will further boost our efforts at the Centre of Excellence for Biopharmaceutical Technology. This mutually constructive and productive partnership will hopefully lead to promising results for the entire biotherapeutics ecosystem."

"We are excited to embark on this initiative with IIT Delhi, an institute with the country's brightest minds engaged in research and technology," said Bharat Bhardwaj, country general manager, Agilent India. "Agilent's relationship with IIT Delhi goes back decades. The new memorandum of understanding that we have signed will further strengthen our relationship and will enhance the ability to do cutting-edge research, which can be used to improve the quality of life for the community at large, through the application of new innovations."

Conduent Market-Leading Disease Surveillance and Outbreak Management System to Fight Corona Virus

Bengaluru, India: Conduent Incorporated has announced a version of its disease surveillance and outbreak management platform, Maven®, to securely track, manage and report on cases of the coronavirus, 2019-nCov.

Maven is a software platform developed for organizations, including government agencies, to manage cases of more than 90 communicable diseases. Its flexible design gives organizations the capability to customize disease tracking most prevalent in specific geographies or communities.

Conduent will host the platform's coronavirus-enabled version of Maven in the company's secure cloud so public health agencies and other organizations can get immediate access to use it. Conduent expects its coronavirus module to be available within the month. Additionally, those with advanced training also can leverage the solution's flexibility to customize the Maven platform on their own to track coronavirus.

Based on an organization's need, Maven has the capability to track diseases such as influenza, tuberculosis and Ebola. More than 40 organizations are currently using Maven, and some have already taken advantage of the platform's flexibility by configuring it to track the coronavirus's spread within their respective locations. Conduent is also actively facilitating sharing of best practices between clients as they configure their systems to track the outbreak.

"Maven is a valuable tool that organizations can use to identify and follow up on people who may have come into contact with a person infected with a communicable or infectious disease," said Mark Brewer, President, Global Public Sector Solutions, Conduent. "In the absence of a vaccine, tracking and analyzing who is at risk from contact with an infected person is one of the most important methods available to contain diseases like the coronavirus and prevent widespread outbreaks.

"Maven's technology is scalable and can be quickly and easily configured to changing technologies, protocols and geographic locations — all of which are keys to effective disease outbreak response. It is also designed to allow for easier data sharing and integration among health agencies on the front lines of battling the disease."

Designed with rich contact tracing, outbreak management and detection, state and local health organizations can collaborate to quickly and effectively contain public health crises. Epidemiologists can use Maven's reporting capability to search and analyze the centralized data collected to discover trends and patterns. Maven can also be used to report externally, supporting the need for automatic case reporting to the Centers for Disease Control and Prevention in the United States, the World Health Organization, or local authorities.

B&R's Blackout Mode Enables High Machine Availability

The B&R drive technology portfolio now offers a Blackout mode.

Pune, India: The B&R drive technology portfolio now offers a Blackout mode that ensures safe machine control in the event of a network failure. Machine downtime can be avoided without costly redundancy solutions to ensure maximum machine availability.

The Blackout function enables the safe variants of B&R servo drives (ACOPOSmulti, ACOPOSmotor or ACOPOS P3) to continue operation in the event of a network failure. Safety functionality remains intact.

Controlled shutdown - Blackout mode allows configuration of simple safety sequences. Applications in lower-level systems continue execution even after a network failure. For example, axes can be brought to a stop or moved to a defined position.

Acquisition Positions Catalent as Premier Partner for Advanced Biotherapeutics, Now Including Cell Therapy

New Jersey, USA: Catalent Inc., the leading global provider of advanced delivery technologies, development, and manufacturing solutions has announced agreement to acquire MaSTherCell, a leading, technology-focused cell therapy development and manufacturing partner.

In combination with Catalent's deep experience in viral vector scale-up and production, MaSTherCell's expertise in both autologous and allogeneic cell therapy development and manufacturing, will allow Catalent to be a full-service partner for CAR-T immunotherapies and beyond.

MaSTherCell's advanced capabilities will supplement Catalent's industry-leading platform in biotechnologies including gene therapy, biomanufacturing, fill finish, clinical logistics and commercial supply, creating a comprehensive solution for advanced biotherapeutics.

Glenmark's Consolidated Net Profit Rises by 64 percent to ₹ 1,908.39 Mn. in Q3 FY 2019-20

Mumbai, India: Glenmark Pharmaceuticals Limited, a research-led global integrated pharmaceutical company, has recently announced its financial results for the third quarter ended December 31 of the financial year 2019-20.

In the third quarter ended December 31, 2019, Glenmark's consolidated revenue was at ₹ 27,355.61 Mn (USD 385.64 Mn) as against ₹ 25,550.45 Mn (USD 355.87 Mn) in the previous corresponding quarter, recording an increase of 7.07 percent.

Consolidated Net Profit was at ₹ 1,908.39 Mn for the quarter ended December 31, 2019 as compared to ₹ 1,163.41 Mn in the previous corresponding quarter, registering an increase of 64.03 percent.

Consolidated EBITDA was at ₹ 4,400.75 Mn in the quarter ended December 31, 2019 as against ₹ 4,346.80 Mn in the previous corresponding quarter, an increase of 1.2 percent.

"While the US business lost some of its momentum in the third quarter, the India business continued to grow at a healthy pace, consistently outperforming industry growth. We expect the ROW region and the European business to gain traction in the coming few quarters", said Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals. He further added, "Despite the challenging macro- economic environment globally, the organization still continued to record high single digit revenue growth and we hope that we can consistently grow the business every year."

India Formulations: Sales from the formulation business in India was at ₹ 7,888.39 Mn (USD 111.08 Mn) for the third quarter ended December 31, 2018, as against ₹ 6,675.30 Mn (USD 92.49 Mn) in the previous corresponding quarter, recording a growth of 18.17 percent.

The India business continued to outperform the industry growth; as per IQVIA Q3 FY 2019-20, Glenmark's India business recorded growth of 13.65 percent compared to IPM growth of 9.03 percent. As per IQVIA MAT December 2019, the India business recorded growth of 12.98 percent compared to IPM growth of 10.10 percent. Glenmark's India formulation business is ranked 14th, with market share of 2.21 percent. Glenmark has 9 brands among the 'Top 300 Brands in the IPM.'

USA Formulations: Glenmark Pharmaceuticals Inc. U.S.A registered revenue from sale of finished dosage formulations of ₹ 7,998.28 Mn (USD 112.70 Mn) for the quarter ended December 31, 2019 as against revenue of ₹ 8,556.75 Mn (USD 119.36 Mn) for the previous corresponding quarter, recording a de-growth of (6.53 percent).

In the nine months of FY 2019-20, the Company has received 13 ANDA approvals including 11 final approvals and 2 tentative approval.

Glenmark has 5 US FDA approved formulation manufacturing facilities (Goa, Indore, Baddi, Aurangabad and Monroe). In Sep 2019, the US FDA inspected the manufacturing facility in Goa, India. We have received an EIR regarding that inspection. In Sep 2019, the US FDA also inspected the manufacturing facility in Indore, India and we received an EIR regarding that inspection. The Baddi facility was inspected by SUKL (State Institute for Drug control), Czech Republic and was issued a certificate of compliance for the audit in Oct, 2019.

Europe Formulations: Glenmark Europe's revenue for the third quarter of FY 2019-20 was at ₹ 3,089.36 Mn (USD 43.59 Mn) as against ₹ 3,217.39 Mn (USD 45.09 Mn) in the previous corresponding quarter, recording a de- growth of (3.98 percent).

Glenmark Europe operations recorded strong growth in the third quarter of the previous financial year. Thus in the current third quarter, the growth is suppressed to that extent. However we still expect the European business to grow at a steady pace in the coming quarters. The European business however recorded growth quarter-over-quarter. Despite the high base effect, the Central Eastern and the Western European business recorded moderate growth as compared to the previous corresponding quarter.

Africa, Asia and CIS Region (ROW) : For the third quarter of FY 2019-20, revenue from Africa, Asia and CIS region was at ₹ 3,413.74 Mn (USD 48.15 Mn) as against ₹ 3,401.21 Mn (USD 47.57 Mn) in the previous corresponding quarter, an increase of 0.37 percent.

Latin America: Glenmark's revenue from its Latin American and Caribbean operations was at ₹ 1,563.18 Mn (USD 22.10 Mn) for the third quarter of FY 2019-20, as against ₹ 1,014.33 Mn (USD 14.11 Mn), recording an increase of 54.11 percent.

Glenmark Life Sciences (GLS) : For the third quarter of FY 2019-20, external sales for Glenmark Life Sciences was at ₹ 2,621.56 Mn (USD 36.95 Mn) as against ₹ 2,392.48 Mn (USD 33.29 Mn), recording growth of 9.58 percent over the corresponding period last year.

US and Emerging markets led the growth in the third quarter, with the US growing at excess 125 percent over the corresponding quarter in the last financial year and 60 percent over the previous quarter. The emerging markets sales grew at 25 percent. In the US market, the growth was led by key products such as Aprepitant.

Highlights for Q3 FY 2019-20

- India Business grew by 18.17 percent to ₹ 7,888.39 Mn
- US Business de-grew by 6.53 percent to ₹ 7,998.28 Mn
- Latin America Business grew by 54.11 percent to ₹ 1,563.18 Mn
- API Business grew by 9.58 percent to 2,621.56 Mn

Breakthrough Study Makes Cancer Detection Possible with a Simple Blood Test; Introduces a New Systemic Hallmark of Cancer

Mumbai, India: A new study by scientists from India, USA, and UK has presented clinical evidence for an innovative test that can detect clusters of cancer cells in the blood of asymptomatic individuals as a non-invasive screening and diagnostic method. The test makes cancer screening easier, efficient and affordable, and can potentially be a breakthrough in cancer detection and diagnosis. The test will soon be available commercially.

Commenting on the study, principal author Dr. Dadasaheb Akolkar, who is the Research Director at Datar Cancer Genetics, said, "This is the first study of its kind to investigate the prevalence of circulating tumor emboli or C-ETACs (Circulating Ensembles of Tumor Associated Cells) in over 16,000 participants, to establish the definitive new systemic hallmark of cancer. The technique we have used is a breakthrough innovation. When clusters of cells break off from an early stage tumor and enter the bloodstream, we can efficiently and accurately isolate a few hundred malignant cells from more than 100 million cells, using just 10 ml of blood. While almost all cancer samples had these cell clusters, they were seen in very few of the samples which were apparently without cancer."

Speaking on the breakthrough study and technique, Mr. Rajan Datar, Chairman and Managing Director, Datar Cancer Genetics, said, "Cancer is rapidly becoming a civilizational challenge. Importantly, cancer deaths are mainly because of late detection. We believe that this innovative blood-based test is a breakthrough in cancer screening and will impact outcomes through easy, patient-friendly detection and diagnosis in apparently healthy people who may have a silent malignancy in their bodies! It has the potential to eliminate the need for invasive biopsies and the risks associated with it. In the near future, a simple, inexpensive blood test that could be all that is required to reliably detect and diagnose cancer, even before any symptoms are seen."

The study involved 16,134 participants, including 5,509 patients with cancer (TrueBlood study) and 10,625 individuals with no symptoms (RESOLUTE study) and the test has shown an accuracy of more than 94 percent. The C-ETACs were seen in 89.8 percent of cancer cases and in only 3 percent of apparently healthy, asymptomatic individuals who had no abnormal findings in presently used screening tests. The study was the largest of its kind in the world.

Datar Cancer Genetics has also presented further data at several leading international conferences including AACR, ASCO and ESMO

Early detection of cancer is crucial but challenging, because of the lack of efficient and reliable screening methods. Most of the commercially available cancer-screening tests are invasive and expensive. Also, currently available cancer screening techniques such as mammograms and low-dose CT scans (LDCT) carry radiation risks, colonoscopies are invasive, blood based markers are non-specific and tissue biopsies for diagnosis have the same risks as general surgical procedures.

Sun Pharma and Rockwell Medical Entered into Licensing Agreement for Triferic in India

Mumbai, India: Sun Pharmaceutical Industries Ltd has recently announced that one of its wholly owned subsidiaries has entered into exclusive licensing and supply agreements with Rockwell Medical Inc. (Rockwell), to commercialize Rockwell's Triferic, a proprietary iron replacement and haemoglobin maintenance drug, for treating anaemia in hemodialysis patients in India. Triferic is approved in USA. As per the terms of the agreement, Sun Pharma will be the exclusive development and commercialization partner for Triferic during the term of the agreement, subject to its approval in India. In consideration for the license, Rockwell will be eligible for upfront and milestone payments as well as royalty on net sales. The financial terms of the agreement are confidential.

Kirti Ganorkar, CEO of India business, Sun Pharma, said, "We are excited to build a partnership with Rockwell who has developed an innovative product, Triferic for haemodialysis patients. Triferic is an innovative anaemia therapy for the patients who are undergoing haemodialysis and offers a unique treatment option. Triferic will help Sun Pharma expand its portfolio in its core therapy areas."

According to the 2017 Global Burden of Disease Study, chronic kidney disease was the 10th leading cause of mortality in India, having risen from 14th rank in 20071. In India, there are approximately 130,000 patients receiving hemodialysis, and the number is increasing by about 232 per million population.

Cipla Foundation Sets Up a Dedicated State-of-the-Art Chemistry Laboratory at IISER Pune

Pune, India: In continuance of its efforts to advance quality education and promote industry-academia collaboration, Cipla Foundation, the social responsibility arm of Cipla Ltd, has funded the set-up of a world class chemistry research laboratory at the Indian Institute of Science Education and Research (IISER) Pune.

The lab aims to provide practical training in Chemistry to undergraduates and researchers in the varsity campus along with support to the national outreach programme for school children. The centre and the labs will help strengthen science education in India by engaging with various stakeholders, including students, academicians, scientists, teachers of schools and undergraduate level science and mathematics.

Dr. Y. K. Hamied, Chairman, Cipla, Ms. Rumana Hamied, Managing Trustee, Cipla Foundation and Prof. Jayant B Udgaonkar, Director, IISER Pune were present at the campus for the unveiling of the facility along with senior leaders from Cipla and IISER Pune.

The expansive 27,000 square feet, ground plus two floor facility has been constructed in an eco-friendly zone in adherence with the green building GRIHA standards. In line with the international standards of chemistry practicals, four state-of-the-art four laboratories have been set up, each appointed with best-in-class equipment including virtual reality functionalities, interactive gadgets, demonstration facilities and more. In addition to academic learning, the facilities will also be utilized for real-life industry driven research projects and contribute to the latest scientific innovation taking place in the country.

Ultrasonic Level Transmitter

Ultrasonic level transmitters are used to measure level of all kinds of liquid. The sensor generates ultrasonic soundwaves which strikes the medium and returns. The electronic measures the time taken and then computes the distance of measured surface to the sensor. The transmitter generates an analogue output proportional to the liquid level or to the distance of liquid from sensor.

It finds application in diesel tank, solvent tank, STP tank, water tank (RO, DM, soft and raw), acidic and alkaline tank.

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Condensors

The condensor helps in reducing the process time of drying, distillation, etc, by effectively condensing the condensable vapours.

The condensor has been standardised with 1.5-m², 3-m² and 6-m² cooling surface area. The material of construction (MoC) can be given in Mild Steel/SS-304/SS-316 for Shell and Copper/Cu Nickel/SS-304/SS-316 for the cooling coil.

For more information, please contact:
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Peristaltic Pumps

Masterflex Ismatec Reglo Digital peristaltic pumps are ideal for the laboratory, with flow-driven technology that supports precision dispensing; functional versatility giving freedom in applications, and a space-saving compact footprint to conserve valuable benchtop space. In comparison to its predecessor, the new Reglo pumps have a wider overall flow range with the option of dosing between 0.00009- and 368-mL/min. The models pack in advanced features designed to deliver fluids accurately, including anti-drip technology to help conserve valuable samples, speed ramping to better accommodate fluids with varying viscosities, and touch-screen interfacing that supports powerful programmable performance - all while taking up very little space (178-mm (H) x 152-mm (L) x 165-mm (W)). The cartridge design synonymous with Ismatec Reglo pumps has been retained, with a choice of two or four channels, both of which fit three-stop tubing. The cartridge configurations offer a choice of 6, 8 and 12 rollers, allowing you to choose the optimal balance of flow rate and pulsation. For the first time in the Reglo family of pumps, the popular Miniflex pump heads have been integrated into the available options, giving you a choice of one- or two-channel configurations, both of which use continuous L/S tubing. Furthermore, these new Reglo pumps feature a 50-W BLDC motor instead of the 75-W PMDC motor used in older models. It is ideal for feed, transfer, perfusion, volume dispensing and time dispensing. These new Reglo pumps offer an easy-to-navigate and intuitive 5" capacitive touchscreen display so it can be used with disposable gloves. The Android platform on which the interface is designed helps the menu structure feel instantly familiar to most users. In addition, these are the first highly accurate micro-flow (<100-mL/min) models to receive MasterflexLive capability and 21 CFR Part 11 and EU Annex 11 compliancy. This secure, cloud-based platform allows you to control and monitor your pump via a PC, tablet or smartphone (iOS and Android). You can ensure that valuable sample loss is minimized, and your safety is optimized, due to the ability to control all pump parameters, including speed, flow rate, dispense volume, and more in real-time and remotely. Push notifications provide alerts for operating conditions and error messages.

For more information, please contact:
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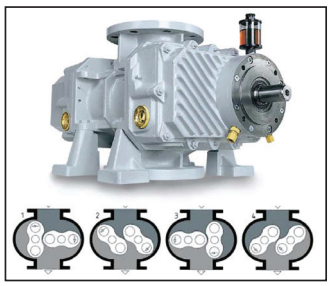
E-mail: response@coleparmer.in

Roots Vacuum Pumps



The Roots-type pumps belong to the group of positive displacement delivery pumps. Two symmetrical pistons having an eight feature, housed in the pump body, rotate in opposite directions with no contact neither between each other nor with the pump body, meshing continuously. The pistons are driven by a set of gears with synchronised rotation, which guarantees friction-free movement. During rotation, a progressively growing space is created with corresponds to the suction stage: phases 1 and 2, being gradually decreased phases 3 and 4, compressing the volume of gas. This cycle is repeated four times per each complete rotation of the drive shaft.

For more information, please contact:
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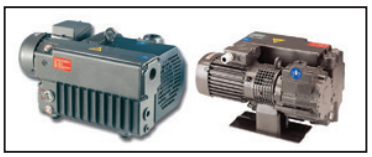
Oil-lubricated Vacuum Pumps



Toshniwal supplies oil-lubricated vacuum pumps. This oil-lubricated vacuum pumps of the TMS Series are single stage, oil-lubricated rotary vane vacuum pumps with oil re-circulation system. The lubricant system is rated for continuous operation of high intake pressures so that the pump may be used in a versatile manner in most rough vacuum applications. The pumps are used for suction of air also in presence of water vapour and for continuous industrial use. TMS Series pumps are made from high quality materials, has economical features which matches together to achieve: high pumping speed over the range of absolute pressure 1,000-0.5 mbar; high water vapour tolerance and low noise level; no pollution; air-cooled: built-in anti-suckback system. The pumping capacities available are:17-m^3/hr, 35- m^3/hr, 65- m^3/hr, 100- m^3/hr and 150- m^3/hr.

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Probes for Water Cut Monitor

AMETEK Drexelbrook has been working in the oil industry, helping eradicate this silent killer. The knowledge and experience that Drexelbrook holds has been integrated in our level and water cut monitoring instruments. These are manufactured to deliver trustworthy data, and to do so with proven quality even in harsh environments. One of the most reliable instruments on the market is the Universal IV water cut monitor. In fact, it is regarded as one of the toughest protectors of the production budget.

RF Admittance technology is used to ignore coatings and build-up that can plague day-to-day operations. All probes used for the Universal IV water cut monitors are manufactured with patented Cote Shield technology to ensure proper performance under these conditions. This means that even with the sticky materials measured at oil wells, the data is accurate and reliable. A wide selection of probes means customers have the ideal choice for any application. The length of the probe can vary. Drexelbrook probes typically measure across more than 15 inches of sensing area, whereas many competing products only measure 2 inches, meaning the Universal IV water cut monitor provides a more reliable evaluation of the passing media than the competition. RF Admittance technology measures the differences of dielectric constants of water and oil in the media passing by the probe. The monitoring can be performed at up to 1,500 PSI and 230°C/450°F. A primary application for water cut monitors is on LACT skids monitoring the quality of upstream oil flow post separation, ensuring trustworthy data for transferred oil.

For more information, please contact:
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Child-resistant Tablet Container

Sanner offers its new child-resistant CR TabTec tablet container. It has a new opening mechanism that protects children from accidentally taking painkillers, anti-depressants or medical cannabis. The patented Press & Flip closure is designed to prevent children from opening the container. However, it is still easy to handle for adults, who simply need to press and lift the cap simultaneously. It obtained excellent ratings in a consumer test regarding its functional characteristics and design. With its slim shape, the container fits in any trouser pocket and remains securely closed on the go. The innovative design with its distinct shape and design options makes the packaging solution stand out from many other products at point of sale. The new CR TabTec also offers pharma manufacturers an economic alternative to conventional tablet packaging.

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Hydrolysis-stabilized PBT Compounds

Compounds based on PBT need greater resistance to hydrolysis and aging in hot and humid environments when used in automobiles. Furthermore, additional thermal loads arise when charging the battery. In combustion engines, there is a trend towards turbocharged engines, which results in increased temperatures in the engine compartment. With this in mind, LANXESS has developed the new polybutylene terephthalate (PBT) product range Pocan XHR (Xtreme Hydrolysis Resistance). They have achieved outstanding results in the SAE/USCAR-2 Rev. 6 long-term tests of the American Society of Automotive Engineers (SAE). In the SAE/USCAR long-term tests, a finished part is exposed to temperatures from -40°C to +175°C (Class 5) at relative air humidities of up to 100 per cent in 40 eight-hour cycles. The finished parts then undergo various function tests. The test process is extremely demanding, as heat and humidity affect aging more intensely when the two factors are combined.

At present, there are four products in the Pocan XHR range. Pocan B3216XHR and B3233XHR have glass fibre contents of 15 and 30 per cent respectively, and attain Class 5 classification. Pocan TP155-002 is specially tailored for laser transmission welding. The laser-transparent compound with a glass fibre content of 30 per cent is suitable for resource-efficient production of sophisticated housings for electrical/electronic components, and achieves results between Class 4 and 5 in the USCAR test. Particularly interesting is the unreinforced Pocan B1205XHR, which achieves the second-highest grading in the SAE/USCAR test with Class 4. It can be processed with next to no distortion, thus enabling highly intricate geometries. LANXESS is currently working on adding further product types to the Pocan XHR range. As well as its outstanding hydrolysis resistance, Pocan XHR has other benefits. For example, its elongation properties and high resistance to alternating temperatures make it suitable for overmoulding of metal parts that are exposed to temperature fluctuations. Further strengths are its improved chemical resistance to substances such as caustic soda, and a much greater long-term temperature stability than standard PBT types, even in dry environments.

Pocan XHR is similar to the hydrolysis-stabilized PBT compounds in the Pocan HR Series that have become established in many Series production applications. In particular, the balanced processing characteristics so valued by the market have been transferred to the new XHR generation.

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Portable Sampling Pump

Versatility and portability are what the new Masterflex L/S portable sampling pump brings to operators who need to carry around a pump. The new portable pump features the latest Easy-Load pump head for faster tubing changes and flow stability. The variable-speed drive has a top speed of 400 rpm, allowing the operator to adjust the flow rate to the needs of the application. It can run up to four hours on the self-contained 12 V DC rechargeable battery, or indefinitely from any AC or 12 V DC power supply. Users can charge the internal battery from an AC power supply or a DC voltage source of lower voltaic potential than the battery itself. The pump is encased in high-visibility yellow housing for easy recognition and recovery in the field. It is ideal for rugged or remote pumping applications such as ponds and lake sampling in the forestry or the agriculture industries for applications like feed runoff sampling. It is also suitable for use in environmental testing labs and where a portable sampling pump is required.

For more information, please contact:
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Vacuum Mixer Homogenizer

The Ross turbo emulsifier consists of a counter-rotating turbine and a high speed rotor/stator. The rotor stator head is positioned in the bottom centre of the mix vessel to enable its use with very small volumes of material. During the mixing operation the outer turbine rotates clockwise and moves materials off the vessel wall and upwards. The inner blades rotate counter clockwise and move material downward and into the high speed homogenizing head. The turbo emulsifier is manufactured in many sizes from 10 through 4,000 litre capacity. Each machine is built for pressure and full vacuum operation, entirely in polished SS surfaces. The turbo emulsifier is used extensively in the pharma and cosmetic industries for the mixing of viscous materials. This processor is ideal for homogenizing, emulsifying, dispersion and particle size reduction. Typical applications include: antacids, biopolymers, collagen solutions, dental composites, gelatine compounds, gels and transdermal patches.

For more information, please contact:
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Stator Rotor

Tremendous amount of shear is required to produce stable emulsion and fine dispersion. Hence, all the impeller blades are designed at high tip speed and high shear rate.

For low and medium viscosity fluid premixing and de-agglomeration of particles to very fine and stable dispersion is a well-known use. For high viscosity fluids co-axial or multi-shaft agitators are recommended with stator rotor or pump may be used for flow through inline homogenizer. These machines are used for producing stable emulsions and fine dispersion in micron range. Ultra high shear mixers can be used for sub-micron range dispersion and emulsification (depending on the nature of the product). Trial on our pilot scale batch homogeniser or inline homogeniser is recommended for predicting the actual performance on the plant scale.

Standard machines can be used for most of the applications. However, a tailor-made custom design may be recommended to meet customer special needs. Rotor moves inside a stator at very high peripheral velocity, which produces intense hydraulic shear, which is required for emulsification and very fine and stable dispersion. Fluids are drawn at centre of the high speed rotor where it experiences very high mechanical and hydraulic shear due to centrifugal force and small clearance between the stator and rotor.

It finds application in de-agglomeration, dispersion, particle size reduction, droplet size reduction, emulsifying, homogenising, dissolving, hydrating powder, liquid mixing, etc.

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PharmaTech Expo —11th Edition

Event Date: 04 – 06 March, 2020
Venue: Bombay Exhibition Centre, Goregaon, Mumbai
About the Event: PharmaTech Expo is one of the largest pharma exhibitions in India and is a place for thousands of people from the business to share their experiences related to products, customers, business and sales. This pharmaceutical and lab expo brings together people from across the globe to one destination under one roof in Mumbai. It is one of the biggest B2B trade shows that involve people from the healthcare industry to participate and share innovation related to advanced technologies in the healthcare sector.

It will showcase pharma products, machinery and technological innovation to buyers from countries like India, China, USA & Germany which are a major market for this sector. This event will surely give you a huge platform to establish and enhance your business by meeting active suppliers from across the globe looking for collaboration with the Indian Pharma and Healthcare market. Meeting new investors and fellow businessmen from the same fraternity would definitely be a win-win situation for both parties. If you are from Pharmaceuticals and Healthcare industry and want to explore the involution of business, come and be a part of this mega pharma trade fair.

For More Information: https://pharmatechexpo.com/Mumbai

9th Annual Pharma IPR Conference 2020

Event Date: 4 - 6 March 2020
Venue: Taj Santacruz, Mumbai
About the Event: The pharmaceutical sector is complex and highly regulated in most economies. Intellectual property (IP) is a pharmaceutical and biopharmaceutical organizations' most valuable resource, and its protection is a key to the company's future success. Recent challenges over patents for varied newer drugs has emphasized that advancement is still required in balancing the opposing forces of innovation through protection of IP rights, versus the provision of affordable drugs for the emerging geographical regions across the globe. IP is the backbone to ensure development of new drugs. IP is extremely vital to improvise patient care, spurring economic growth and intensifying the innovation economy. In order to motivate researchers to explore new areas of medical innovation, modern IP systems and strong protections are crucial. The US pharmaceutical & biopharmaceutical industry drives the nation's Research and Development (R&D) economy, thereby keeping the country at the forefront of advanced technology development. The pharma and Biopharma industry hence is a key generator of new IP's across the globe. Intellectual Property (IP) is the backbone to ensure development of new treatments and cures. IP is extremely vital to improvise patient care, spurring economic growth and intensifying the innovation economy. In order to motivate researchers to explore new areas of medical innovation, modern IP systems and strong protections are crucial. The US pharmaceutical & biopharmaceutical industry drives the nation's Research and Development (R&D) economy, thereby keeping the country at the forefront of advanced technology development. The pharma and Biopharma industry hence is a key generator of new IP's across the globe.

With this overarching global theme of Ideate and Innovate, CPhI Conferences presents the 9th Annual Pharma IPR Conference.

Driven by powerful content and unmatched speaker profiles, the forum promises to provide an exceptional opportunity to bring all key stakeholders, IP Attorneys and Counsels from across the globe on a single platform to discuss, deliberate and share their thoughts on achieving the next phase of growth, recent trends and best practices in the Pharma IPR space!

For More Information: https://www.pharmaipr-india.com/

India Pharma 2020

Event Date: 5 – 7 March 2020
Venue: Mahatma Mandir, Gandhinagar, Gujarat, India
About the Event: The Event is organised by Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India in association with Federation of Indian Chambers of Commerce and Industry. This is an initiative to increase overall growth of Pharma sector including exports and focus on increase of Domestic production in the sector by Government of India & FICCI, with the active participation from all Stakeholders. This event provides a platform to global investment community to connect with the stakeholders of Pharma sector in India, Central and State Governments, principal business leaders, and top executives from the industry, academics, and experts from the world.

For More Information: http://www.indiapharmaexpo.in/

Medicall

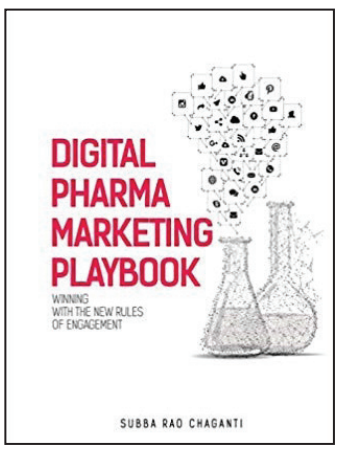
Event Date: 03 – 05 Apr 2020
Venue: Hitex Exhibition Center, Hyderabad, India
About the Event: Medicall is India's largest B2B Medical Equipment Exhibition and is organized by Medexpert Business Consultants Pvt Ltd. It brings all the equipment manufacturers under one roof. Medicall serves as a marketing platform wherein the equipment companies showcase their products and services to Hospital owners and decision makers. Since MEDICALL is being organized by people who have been in Healthcare field for many years, the content and the quality of the visitors are expected to be better than any other previously held event.

Highlights:

- Buying opportunity of equipment / services for the hospital / clinic.
- Dealership scope from International companies and reputed Indian companies.
- Update availability on innovations in the field of healthcare.
- Meeting collaborating partners
- Thought provoking conferences and seminars.
- One-on-One business meets.

For More Information: https://www.medicall.in/

Winning with the New Rules of Engagement



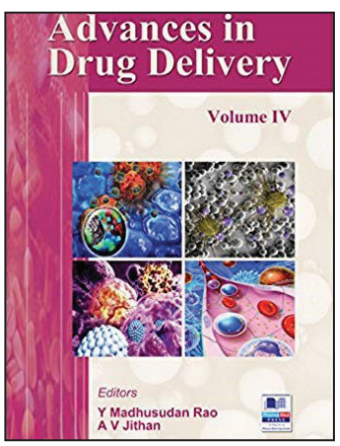
Author: Subba Rao Chaganti

Price: ₹ 1650.00

Publication: PharmaMed Press

About the Book: The book is a one-of-its-kind type and may be used by both, the practitioners as well as the students of pharmaceutical marketing. The value this book brings for its readers is the inclusion of 101 case studies. These case studies demonstrate how the leading pharmaceutical companies have taken the advantage of digital and social media channels. These case studies provide valuable insights and practical-based understanding for pharma digital-marketers with path-breaking digital and social media marketing campaigns. The book talks about five main concepts viz. changing scenario and new rules of engagement, digital revolution and big picture of technological changes impacting pharmaceutical marketing, essential aspects of digital pharma marketing, possibilities across multiple platforms and social networks, and also about the necessary steps to ride the tidal wave of digital transformation.

Advances in Drug Delivery Volume IV



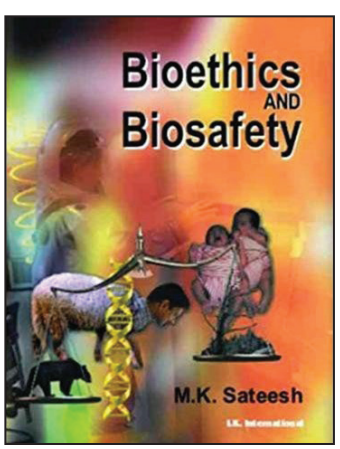
Editor: Y. Madhusudan Rao & A V Jithan

Price: ₹ 1526.00

Publication: PharmaMed Press

About the Book: The drug delivery is the process of achieving optimum drug reach to the targeted tissue, cell, or receptor through various means. This book incorporates latest information regarding drug delivery. This book describes the point-of-views of research scholars, teachers, R&D professionals backed by various application oriented case studies. This book discusses about spherical crystallization in solubility enhancement, self-emulsifying drug delivery system (SEDDS) & self-micro-emulsifying drug delivery system (SMEDDS), taste masking, ocular drug delivery system, prodrug – an approach to drug delivery, expandable drug delivery systems, nano-suspensions, lozenges, ungual drug delivery,and optimization techniques in product development.

Bioethics and Biosafety



Author: M. K. Sateesh

Publication: I K International Publishing House Private Limited

Price: ₹ 3153.00

About the Book: Bioethics revolves around the ethical controversies generated with the advances of biology and medicine. It encompasses the ethical issues related to life science, biotechnology, medicine, politics, law, philosophy, and theology. This book narrates the prevention of loss of bio-integrity at a large scale, with a focus on ecology and human health encompassing several fields viz ecology, agriculture, medicine, chemistry, and eco-biology. The entire content has been divided into twenty eight chapters covering different aspects of bio-ethics, biosafety, and their application in biotechnology.

AGI Glaspac Has Positioned Itself as a Lead Glass-Container Manufacturer in the Country

Rajesh Khosla
President and CEO
AGI Glaspac

Glass is a very important material for pharma packaging. As the pharma industry grows, the amount of the waste generated from the primary & secondary packaging of drugs grows. And, tackling it has been one of the most complex sustainability issues. Glass is one of the effective solutions to this problem statement. With an exclusive interview with **PharmaBio World,** Rajesh Khoshla spoke about AGI Glaspac's business footprint at the national & global landscape, further business expansion plan and the key drivers, current glass packaging trend, technology up-gradation initiatives, and many other associated aspects.

AGI Glaspac is a trusted name in the glass-packaging sector for over 47 years. Please acquaint our readers with AGI's national and global footprint.

Over the last 47 years, AGI has positioned itself as one of the leading glass-container manufacturers in the glass packaging industry. AGI glaspac, the packaging products division of HSIL Limited, was established in 1972. To talk about the manufacturing capacity, the organization started with a capacity of 80 tonnes per day (TPD). In 1981, HSIL Ltd acquired AGI and upgraded its furnace capacity to 180 TPD. In 1996, AGI achieved its first ISO 9000 certificate. In 2000, the first new furnace (F-2) colouring was added, thus increasing the plant capacity to 450 TPD. In 2004, the second new furnace (F-3) was added and the capacity was raised to 600 TPD. 2009 was embarked for AGI with a new greenfield plant at Bhongir. This new third furnace (F-4) has the capacity of 500 TPD, which raised the total capacity to 1100 TPD. In 2011, AGI exported its first consignment. In 2012, the fourth new furnace (F-5) was added, which increased the capacity from 1100 TPD to 1600 TPD with a colouring forehearth. It is also the largest container glass manufacturing facility at a single location in Asia. In 2016, electrostatic precipitators were installed to reduce SOX, NOX, and CO_2. In 2017, AGI introduced TPM, LEAN and Six Sigma. In 2019, AGI invested in natural gas to curb carbon emissions. AGI also installed machinery like end-of-the-line packaging for robotic case packer, case palletizer, cullet washing system, automated dry optical sorting system, etc.

While coming to the contribution to industry, AGI caters to at least 20 per cent of the glass container demand of the Indian market. With an utmost priority to the domestic market, AGI also has its global footprints in North America, Europe, Africa, Canada, and in the APAC regions.

What's AGI's plan for further business expansion? What are the key drivers?

As of the present scenario, AGI has positioned itself well as one of the leading glass-container manufacturers in the country with two manufacturing facilities – one in Hyderabad and the other one at Bhongir of Telangana. AGI today melts 1600+ tonnes of glass per day and has been heavily investing in R&D, machine-building, and business excellence capabilities to maximize the productivity and to upgrade the plant. AGI has also been investing in technology upgrades, inspection, packaging systems, warehousing, and logistics. Looking at the road ahead for coming five years, the Company has been aiming to increase its volumes by at least 50 percent to meet the rising market demand.

In terms of quantitative and qualitative expansion, glass is the major packaging material for providing solutions to the packaging industry. We are also planning to expand in the eastern and northern parts of India. We focus on : super light-weight packaging material, strong and thick bottles, special bottles with all types of shapes and sizes, different colours, and also the containers having surface protection.

When we talk about the key driving force that fosters organizational growth, the first & foremost factorial is the overall growth of the Indian packaging market. Pharma sector has been growing with a pace of more than 10 percent; and the hopeful part is: the usage of sustainable items viz glass becomes more preferable.

How do you designate AGI's competitive positioning over its contemporaries w.r.t Pharma Packaging? What are the strengths being explored and what are the improvement areas (intra-organizational and external) that are yet to venture out?

Glass packaging continues to face fierce competition from other forms of packaging in India for Pharma Industry for commercial reasons & the use of alternative materials is increasing. Among the reasons for some customers to switch are load-ability, breakages, and unit cost. In order to rebuff the competition, we have been developing more lightweight bottles and improve the durability of its finished products for pharma.

In the past, the local glass container industry has concentrated its efforts on objectives, such as traceability, to restrict counterfeiting. AGI has been taking such an initiative where we would involve the use of permanent engravings on containers, showing the quarter and year of manufacture. This system could be helpful to protect consumers from any harmful practices employed by fillers.

What are the current trends in glass packaging?

Glass packaging faces fierce competition from other forms of packaging in India. The use of alternative materials in the pharma industry for commercial reasons has been increasing. Prominent reasons for some customers to switch are – loadability, breakages, unit cost, etc. To rebuff the competition, we have been developing more lightweight and durable bottles. In the past, the local glass container industry has concentrated its efforts to restrict the counterfeiting. With a focus on this, AGI has been taking initiatives of introducing permanent engravings on containers, thus showing the manufacturing period in terms of quarter and year.

Glass packaging faces fierce competition from other forms of packaging in India. The use of alternative materials in the pharma industry for commercial reasons has been increasing.

How does AGI contribute to the Indian pharma packaging industry – both in terms of revenue and value addition?

With about 30 – 32 percent market share, AGI glaspac is one of the leading & the oldest players in the pharma packaging industry and has carved out a niche for it in this domain. With a wide range of product availability – to name a few, Medicine Glass Vials, Saline Glass Bottles, etc amongst others – the products are of topmost quality and are made from high grade raw materials with the use of cutting-edge tools & technology. Additionally, with the help of its in-house design studio, AGI provides customization services to its clients to help them offer best suited services for products at a market leading price.

As per the recent news, AGI would invest ₹ 130 crore in technology upgrades. Please acquaint our readers with this. How do you integrate innovation here?

AGI glaspac will invest up to ₹ 130 crores in technology upgrades to produce light-weight bottles and in glass reusage. The other major investment will be in setting up 'Cullet Systems'. The company is getting the sorting system from an Austrian firm. It helps in separating caps, wrappers, and glass systematically, paving the way for efficient reuse of collected bottles.

When we talk about innovation, we have incorporated it in weight reduction, which in turn contributes to CO_2 reduction. Not only is that, innovation is also used aptly for the variation of shapes, sizes, and colours of the glass container.

What distinct pharma-specific measures needed for designing and manufacturing the packaging devices?

Pharma containers are generally in amber-coloured glass in order to prevent the light transmission, as the light-transmission will adversely affect the formulation. With tamper-evident and child-resistant closures, glass is well-suited for pharmaceutical packaging. Glass is the only packaging material with GRAS status from the US FDA. Having a cleanroom environment is critical for pharma glass manufacturing to prevent contamination in glass bottles. As pharma bottles are non-returnable, they are produced at the lowest possible weights and with uniform thickness. With the help of advanced blow-blow and NNPB technologies, bottles are produced with airtight packaging and delivered to the customers.

How do you integrate technology & digitalization with production, operational excellence, and research & development?

We use latest technologies to integrate with its R&D and production. We have adopted Windchill, which is a product life-cycle management tool. It integrates all the operational stakeholders right from new product development to bottle packaging. The SAP system is in use to track everyday operations-metrics and quality parameters. The business excellence team is equipped with all the tools required for effective statistical analysis and developing the new methods for sustaining the improvements.

Recently, you have mentioned that AGI is forging partnerships with IITs and some foreign universities to augment its research initiatives. Please walk us through it.

AGI glaspac is actively exploring partnerships with industry and academia to bring innovative solutions. We have been working with IIT-Kanpur and other national-level institutes. We have collaborations with major glass equipment suppliers and service providers across the globe to bring new technologies and to improve operations.

Please tell us about AGI's initiatives towards eco-friendly glass packaging solutions to cater to the pharma industry. How does it contribute to the circular economy?

AGI glaspac has been at the forefront of offering innovative and lightweight containers to the pharma industry. The usage of glass containers contributes in a big way to build a circular economy as the glass is infinitely recyclable without any degradation. Right after its usage, it is collected, transported, and processed for cullet formation. This way, the used container is melted back to form a new glass container. Glass container is a model example of the circular economy.

Please acquaint our readers with your quality assurance and control practices.

1. We have a well-designed quality plan to ensure adherence to given specifications. To elaborate it further, we adhere strictly to the US Pharmacopoeia "USP 41" for testing all the parameters required for Type I & Type II glass container. In this connection, surface glass test and glass grain test demand a special mention.

2. We use advanced automatic packing machines to pack the container glass in poly packs without hand touch and any other chances of cross-contamination.

3. Our quality assurance system is designed in line with ISO 15378 standards, applicable for the primary packaging material manufacturing, which is meant for medicinal use. Implementation of this system ensures pharma sector specific cGMP requirements. We have also acquired the ISO 15378 certification.

4. We implemented a risk-based approach to identify the possible risks in the entire process of manufacturing and control measures to mitigate the risk.

What practices do you follow to ensure customer-centricity?

AGI glaspac proficiently caters to evolving customer needs, requirements, and preferences. We have adopted a bouquet of practices to ensure customer-centricity, such as - dedicated technical support for customers, conceptualization of 'First Time Right', improved performance on customer lines, quick complaints redressal (if any), etc.

Please throw light on the future of glass packaging in the context of the Indian Pharma Industry.

The glass industry in India is quite old and well established. It has been existed as a cottage industry for a long time. However, since recent few years, the industry has been going through a transformation – from using rudimentary mouth blown & hand-working processes, to adopt modern processes & automation in a big way. However, it's mention-worthy that Indian per capita consumption for glass packaging (1.8 kg) is much lower compared to other nations. AGI glaspac is going to set up a dedicated amber furnace and state-of-the-art machines for pharma. Along with all these initiatives, we also work closely with many agencies and check certifications for the pharma industry. ■

Pharma sector has been growing with a pace of more than 10 percent; and the hopeful part is: the usage of sustainable items viz glass becomes more preferable.

Moderator: Jayati Mukherjee

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- Manufacturers of Pre-treatment and Corrosion prevention chemicals
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- Hygiene & Cleaning Chemicals
- Laboratory Chemicals
- Surfactants
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FACTS & FIGURES - CHEMTECH WORLD EXPO 2019

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