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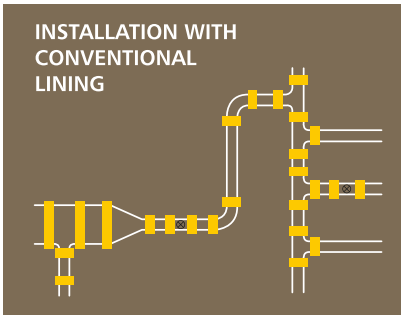

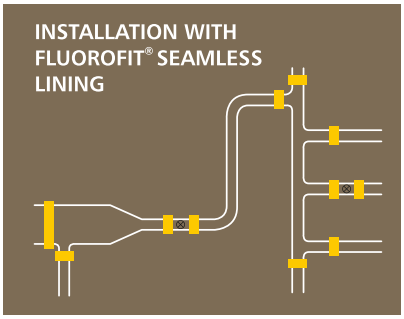

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Ahead of the Festive Season, Snowman Logistics Expands Its Operational Capacity

Prem Kishan Dass Gupta, Chairman, Snowman Logistics Ltd

Bangalore, India: Snowman Logistics Limited, India's leading cold chain & integrated temperature-controlled logistics service provider has completed the construction of a temperature-controlled warehouse at Siliguri and the facility has become operational from the 6th of September 2021. The total capacity of the facility is 4032 Pallets. It is a multi-temperature facility designed to store products ranging from ambient temperature to -25 Deg Centigrade with 8 chambers, 5 loading bays with related infrastructure that includes G+5 racking system, modern handling equipment, etc., and ample refrigerated truck parking space. The facility will mainly cater to the storage, handling and transportation of seafood, ready-to-eat food, ice cream, dairy products, quick service restaurants, confectionery & bakery products, fruits & vegetables, pharma, and other products.

A similar facility is under construction at Coimbatore and is expected to be ready and operational by the end of October 2021. Snowman also has built an e-commerce backend (fulfilment centre) for food and grocery in Mumbai. The facility is already operational. It is a 54,000 sqft warehouse with freezer, chiller, ambient storage with various value add facilities viz. sorting, grading, packing, labelling, etc. Another e-commerce facility is under construction at Pune and is expected to be ready and operational by mid of September.

Commenting on the development, Prem Kishan Dass Gupta, Chairman, Snowman Logistics Ltd, said, "I am happy that after a small pause, we are back with our expansion strategy. The expansions at existing locations are to take care of additional volume from customers, and the new locations are helping us offer larger geography to our customers."

Commenting on the expansion, Mr. Sunil Nair, CEO & Whole-Time Director, Snowman Logistics Ltd, said, "We see huge potential to profitably expand our business. With our SnowLink technology platform, we have been progressing well in our transport aggregation model. This is helping us offer end to end services to an additional set of customers. All these should help us optimise our overheads. Our IT systems are the best in class and are built to handle 3 lac pallet business. We are happy that we are optimising all our investments."

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Menarini India's New Era of Premium and Science Based Facial Contouring

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New Delhi, India: In response to the growing demand for minimally invasive aesthetic rejuvenation procedures, the world's leading biopharmaceutical company Menarini, and its dermatology and aesthetic medicine arm RELIFE have introduced Definisse™ Double Needle Threads in India. Definisse™ Double Needle Threads is a revolutionary solution in the minimally invasive techniques as it requires reduced procedural and recovery time, no general anesthesia with immediate and visible results leading to higher patient satisfaction. The aesthetic procedure using Definisse™ Double Needle Threads results in contouring, lifting, realignment of sagging tissue, and reinforcement of the middle and lower thirds of the face and neck.

This premier aesthetic medicine solution is used for supporting and repositioning soft tissue for cheek, jawline, and eyebrow. When placed under the skin, the barbs open like an umbrella to form a support structure that lifts the sagging skin. With a high level of safety, minimum downtime, instant and effective results, this novel medical aesthetic modality offers an excellent clinical outcome in achieving facial reshaping and treating sagging skin.

Anandh Balasundaram, Managing Director, Menarini India says, "With DefinisseTM Threads, a premium scientific-based innovation, Menarini has entered the medical aesthetic procedures sphere in India that promises cutting-edge solutions for aesthetic practitioners."

"However, to achieve this, one requires special training and a skill set to perform a thread lift successfully. These emerging trends necessitate upskilling of the doctors to learn these innovative techniques of newer aesthetic medicine procedures and address the needs of patients with more long-lasting results and high levels of safety. Addressing this need through training and workshops will help us achieve superior and reproducible results and a satisfied clientele", she adds.

Glenmark Concludes Post Marketing Surveillance (PMS) Study on Favipiravir

Mumbai, India: Glenmark Pharmaceuticals, a research-led, global integrated pharmaceutical company, announced the successful completion of its Post Marketing Surveillance (PMS) study on Favipiravir (FabiFlu®) in India. The PMS study commenced in July 2020 to evaluate the safety and efficacy of Favipiravir in mild to moderate COVID-19 patients. A total of 1083 patients were enrolled in the prospective, open label, multicentre, single arm study.

Results showed no new safety signals or concerns with the use of Favipiravir, and already-known side effects such as weakness,

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Alok Malik, Group Vice President & Head India Formulations

gastritis, diarrhoea, vomiting etc., were found to be mild in nature. The time for fever resolution was 4 days, while time for clinical cure was 7 days. Glenmark's PMS study is the first and largest post marketing study conducted in India on Favipiravir in mild to moderate COVID-19 patients. Thirteen sites – both Government and private institutions – across Mumbai, Bangalore, Hyderabad, Nashik, Nagpur, and Trivandrum took part.

The study was conducted in patients in line with the approved indication of the drug. Commenting on these findings, Alok Malik, Group Vice President & Head, India Formulations, said, "This study was crucial as it examined the safety and efficacy of FabiFlu® in real-world settings, where multiple variables can impact the results. Despite these factors, the PMS study demonstrated FabiFlu®'s consistent ability to provide symptomatic relief and improve clinical outcomes in patients with mild to moderate COVID19. It is a step forward both for Glenmark and the medical community, as it reinforces the oral antiviral's multiple benefits in tackling the pandemic." On June 19, 2020, Glenmark became the first company in India to receive restricted emergency use approval from India's drug regulator for Favipiravir (FabiFlu®), making it the first oral Favipiravir-approved medication in India for the treatment of mild to moderate COVID-19. The approval was granted as part of accelerated approval process, considering the emergency situation of the COVID-19 outbreak in India.

This PMS study continued to evaluate the safety and efficacy of Favipiravir (FabiFlu®) post its launch in the market. The average age of patients in the study was 40 years, with women comprising 40%, while men 60% of the study population. Hypertension (11%) and diabetes (8%) were the two most common comorbidities noted in these patients. Fever was present in all patients at baseline, followed by cough (81%), fatigue (46.2%), and new loss of taste (41%).

US Leads On Drug Device Innovation But Trails Europe on Sustainability

Paris, France: Ahead of the first Pharmapack Europe to be held in nearly 18-months, Informa has released the results of its global drug delivery and packaging survey, with the USA once again leading 'drug delivery and device innovation', but lagging behind all major European nations on sustainability.

Pharmapack Europe, which will be held at Paris Expo, Porte de Versailles, 13-14 October (2021), is expected to welcome up to 5000 people and 360 exhibiting companies. To

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enable access for those unable to attend in person, the event is being hosted in hybrid format, with online content and networking running from 27th September until 22nd October.

"We are incredibly eager to welcome back the pharma packaging, drug delivery and devices community after a year in which pharma's innovation has never been more prescient. Yet, our research also shows the pandemic has accelerated a number of important existing trends in terms of connected devices, sustainable supply chains and remote patient administration. What's exciting is that that with Pharmapack returning, we can provide the vital connections the industry relies upon to drive forward innovations and supply chains in 2022 and beyond." Sherma Ellis-Daal, Brand Manager for Pharmapack Europe.

In fact, the Pharmapack Innovation Index (scored out of 10) – a market perception measure of each country's drug delivery and device innovation – shows that globally the industry increased its outlook with a near 2% overall rise since 2020. Significantly, while the USA (8.26) again tops the rankings – followed by Germany (7.69) and Japan (7.52) – India (6.62) was by far the biggest mover, gaining nearly 13% on its score from 2020. This is particularly impressive improvement as it follows on India's 25% gain from its score in 2019.

"The Pharmapack agenda reflects these concerns and will explore 'patient-centred devices design', 'practical measure to improve sustainability', 'the impact of biosimilars on autoinjector development' as well as the usual cutting-edge innovations in the Learning Labs and the Innovation Gallery. But 2021 is also a reimagining of the entire Pharmapack experience, with content and learning available in advance. For example, networking and targeting of contacts can take place in the two weeks before you arrive to pre-qualify leads. So, I encourage everyone to take maximum advantage of the resources available, as we are at an incredibly important moment for industry innovation," added Ellis-Daal.

Pioneering Software Can Treat Virtual Tumours Using AI Designed Nanoparticles

Bristol, United Kingdom: The EVONANO platform allows scientists to grow virtual tumours and use artificial intelligence to automatically optimise the design of nanoparticles to treat them.

The ability to grow and treat virtual tumours is an important step towards developing new therapies for cancer. Importantly, scientists can use virtual tumours to optimise design of nanoparticle-based drugs before they are tested in the laboratory or patients.

The paper, 'Evolutionary computational platform for the automatic discovery of nanocarriers for cancer treatment,' is published in the Nature journal Computational Materials. The paper is the result of the European project EVONANO which involves Dr Sabine Hauert from the University of Bristol, and is led by Dr Igor Balaz at the University of Novi Sad.

"Simulations enable us to test many treatments, very quickly, and for a large variety

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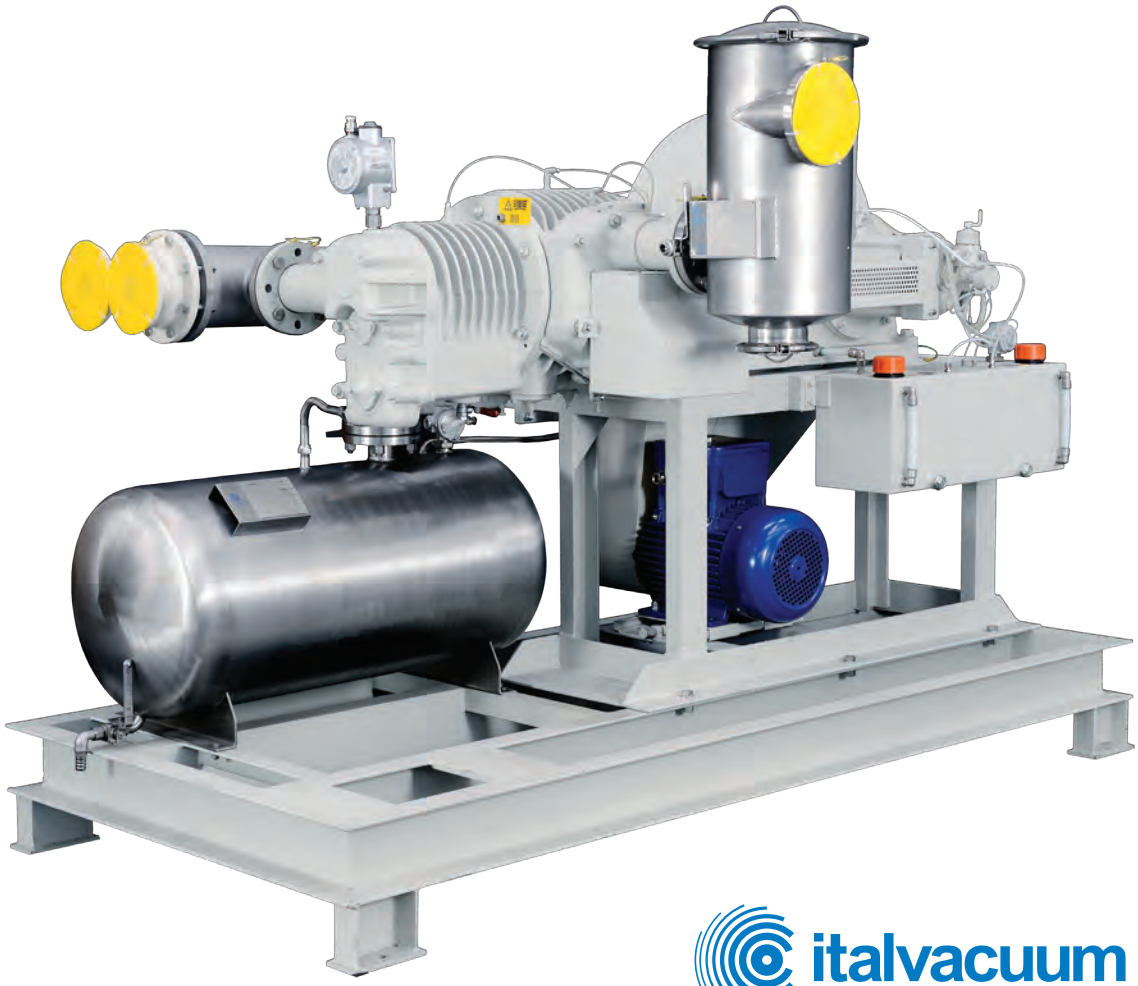

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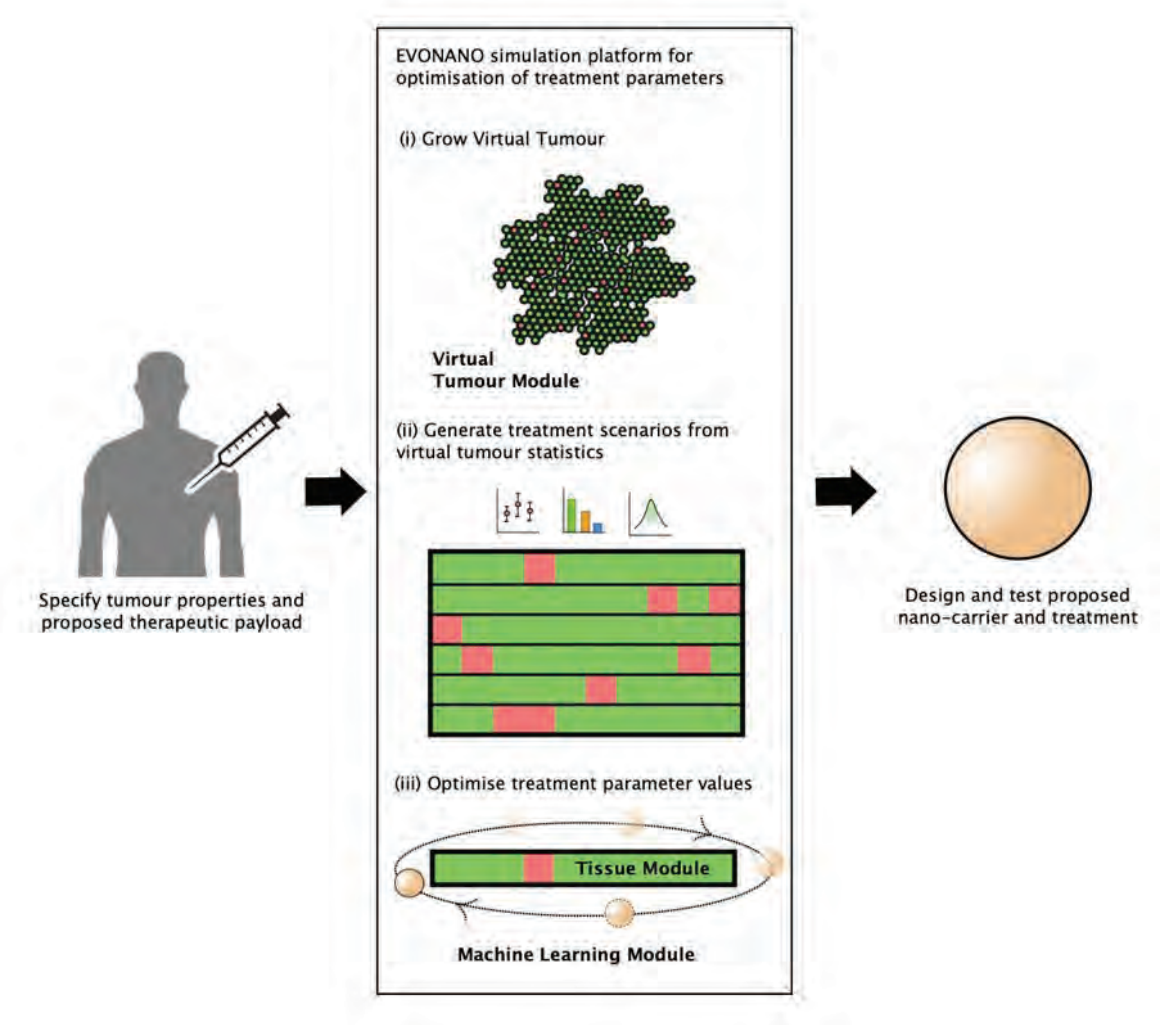

of tumours. We are still at the early stages of making virtual tumours, given the complex nature of the disease, but the hope is that even these simple digital tumours can help us more efficiently design nanomedicines for cancer," said Dr Hauert. Dr Hauert said having the software to grow and treat virtual tumours could prove useful in the development of targeted cancer treatments.

As Dr. Balaz highlights: "The tool we developed in EVONANO represents a rich platform for testing hypotheses on the efficacy of nanoparticles for various tumour scenarios. The physiological effect of tweaking nanoparticle parameters can now be simulated at the level of detail that is nearly impossible to achieve experimentally." In the future, the team aims to use such a platform to bring digital twins closer to reality by using data from individual patients to grow virtual versions of their tumours, and then optimise treatments that are right for them. In the nearer term, the platform will be used to discover new nanoparticle strategies that can be tested in the laboratory. The software is open source, so there is also hope other researchers will use it to build their own AI-powered cancer nanomedicine.

"To get closer to clinical practice, in our future work we will focus on replicating tumour heterogeneity and drug resistance emergence. We believe these are the most important aspects of why cancer therapy for solid tumours often fails," said Dr Balaz. ■

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The Indian pharma industry has already proved its mettle as a major supplier of generics globally with strong penetration in high-value healthcare markets. The initiatives like Make in India, announcement of Production Linked Incentive (PLI) scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs), Drug Intermediates and Active Pharmaceutical Ingredients (APIs) in the country is a strong boost for the pharma manufacturers as they plan their strategies for future growth.

To achieve the success in true sense would require all-inclusive growth of stakeholders across the value chain & overhaul of the ecosystem of pharma industry.

Retrospecting and speaking about the emerging opportunities and plans to drive the growth of India's most capable organizations, the September edition of Pharma Bio World is delighted to cover views of perceptive leaders on **'Make in India.'**

Emergent Technologies Developed in Reagene Biosciences

Uday Saxena
Co-Founder, Reagene Biosciences Pvt Limited

Dr. Subhramanyam Vangala
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What are the emerging opportunities for your organization over the horizon of next 5 years & how do you plan to leverage them?

We see COVID as an opportunity to produce products that could save human lives and are currently focussed on it. There is a window of opportunity for several products and we want to leverage that . In the future, we would like to focus on more chronic diseases such as type 2 diabetes and inflammation.

Walk us through the planned investments & key areas of focus for growth of your company.

We plan to invest in developing intellectual property based products as the key growth areas. We are a company which has vast experience in discovery and development of drugs and this will be a vehicle for our growth.

In your view, what are the key challenges that you will have to address as an organization & at the policy level to realize Make in India in the true sense?

The biggest challenges in getting our products approved are related to regulatory submissions and approvals. There is a dearth of high quality regulatory experts and consultants who can help a small company navigate thru regulatory submissions

Tell us about the latest innovations & products recently introduced & the ones in pipeline.

We are currently working on preventive and prophylactic products as well as differentiated diagnostics for COVID. We believe that while the pandemic may slowly phase out, preventive products and point of care and at home use diagnostics will still be needed for the next few years. ■

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in house

Concord Biotech's Precedence to Commercialize New Fermentation API's

Ankur Vaid
CEO, Concord Biotech Limited

Ankur Vaid, CEO of Concord Biotech *has been a driving force of the company by value adding to the R&D division, contributing market strategies, leading the organizations' business verticals and executing operational efficiencies which has boosted the growth of the company.*

What are the emerging opportunities for your organization over the horizon of next 5 years & how do you plan to leverage them?

Concord Biotech, a leading R&D based Biotechnology Company is recognized globally for its core expertise in manufacturing fermentation based API's. Concord manufactures fermentation API's across various therapeutic segments such as Immunosuppressants, Oncology, Anti-infective, Anti-fungal etc. and has a global leadership position in these products.

Concord plans to further strengthen its position through its recently commissioned facility, which is spread over 170 Acres of land and is one of the world's largest fermentation API plant. At the new site, Concord intends to increase the capacity of its existing products and also commercialize new fermentation API's to meet customer demands and cater to Indian and global markets.

Post Covid, Indian Government is now fully focused on reducing the dependency on imported API's. From beginning Concord has been working to develop and manufacture fermentation based products in India and making India self-dependent on the fermentation API's it manufactures. Keeping in mind the immediate requirement of Amphotericin B, Concord commercialized Amphotericin B

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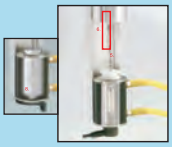
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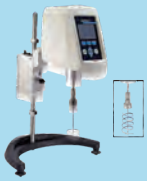
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API also, thus taking another step towards Atmanirbhar Bharat. Going forward, Concord intends to commercialize other fermentation based API's to reduce the dependency on import from other countries.

R&D has been a key growth driver for Concord. Concord has a strong pipeline of products and with our continuous R&D initiatives we will further strengthen our product basket, thus giving us an edge in manufacturing niche and complex API's. Concord is also working on several Contract Research & Manufacturing projects with global biopharmaceutical companies in the area of new chemical entities and patented fermentation products.

Concord also has state of the art formulation facility to cater to India, regulated markets like US, Europe and emerging markets with the highest quality products.

I am confident that with the support of the Government, Concord will build a leadership position for India in the area of fermentation based API's and niche formulation products.

Walk us through the planned investments and key areas of focus for growth of your company.

Concord continues to focus on its core area of expertise, which is fermentation. We have recently commissioned one of the world's largest fermentation facility, with which we intend to increase capacities of our existing products and also commercialize new fermentation API's.

As a part of our forward integration, we are manufacturing finished formulation products for India, regulated and emerging markets. Concord would continue to invest in this space thereby creating a leadership position in the area of fermentation and niche formulation products.

We intend to work closely with our customers thereby understanding their product requirements and catering to their needs in a timely manner by providing high quality products at competitive prices.

In your view, what are the key challenges that you will have to address as an organization and at the policy level to realize Make in India in the true sense?

Commissioning of a fermentation unit is a capital intensive project. Also, one of the major raw materials is electricity which when compared to some of the other Asian countries is expensive. These factors have a significant impact on the viability of the project. Also, we have seen that in spite of anti -dumping duty and other controls; certain countries are still able to find means to supply their product in India through different routes. Such issues significantly impact the sustainability of the fermentation plants. If India intends to regain its leadership position it had till the 80's, we need to work on how we can

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overcome these challenges and support the companies in their growth in order to make India self -reliant.

R&D plays a key role in the development and commercialization of fermentation based products and it is a time consuming and expensive process. If we intend to become Atmanirbhar, we need the Government to incentivize the companies investing in R&D.

Tell us about the latest innovations and products recently introduced & the ones in pipeline.

Continuous improvement to meet the growing domestic and global demand and to rise above the competition has been possible through our focus on R&D. Concord is continuously working on new fermentation products and the launch of Amphothericin B, Mupirocin, Teicoplanin are steps towards Atmanirbhar Bharat.

Concord has a strong pipeline of products in the area of fermentation and formulations across various therapeutic segments.

We are working with global biopharmaceutical players in the area of Contract research and manufacturing. This involves development of new chemical entities and other niche generic products.

Concord is also working on several P-IV opportunity products in the area of fermentation by developing non-infringing products. ■

Aragen Life Sciences' Nestling Salient R&D Programs

Manni Kantipudi
Director & CEO, Aragen Life Sciences

Manni Kantipudi *joined Aragen in 2007 as President. He is the CEO and member of the Board of Directors, in charge of the overall growth, strategy and culture of the company. In 2021, Mr Kantipudi spearheaded GVK BIO's brand transformation into Aragen Life Sciences.*

What are the emerging opportunities for your organization over the horizon of next 5 years & how do you plan to leverage them?

With significant capital flowing into life sciences industry, every company, whether a large pharma or a young biotech, has externalization as its key component of growth plan. Over the past few years, the CRO/CDMO market has been growing consistently and R&D outsourcing is now seen as 'must have' than 'good-to have' strategy. Pharma /biotech companies have also recognized the relevance of working with CROs located in other parts of the world to advance their programs. This paradigm shift in partnering for innovation bringing the pharma companies and CROs together is here to stay.

As a company, Aragen offers end-to-end integrated discovery-development-manufacturing solutions to our customers. We are rapidly expanding our scale of operations in small molecule discovery, development and manufacturing.

In large molecules, we are known for Cell Line Development where we help our partners succeed in expression of the most challenging proteins.

With Goldman Sachs on board, their investment will drive our growth strategy (inorganic and organic). Our investments will be in both small molecule and large molecule opportunities. We have a robust process in place to evaluate such opportunities to ensure judicious use of the access to this capital for expanding capacities and capabilities or strategic acquisitions of organizations to complement our capabilities.

Aragen has been recognized as 'Great Place to Work' twice in a row and we have been ranked second as 'Ambition Box Best Places to Work in India 2021' in Medium Pharma Companies Category. Our work culture/ environment continues to attract, retain and nurture excellent scientific talent globally and locally.

Walk us through the planned investments & key areas of focus for growth of your company.

As we look ahead, we are investing and expanding our infrastructure in Hyderabad and Bangalore for drug discovery, to cater to the increased outsourcing needs of our growing customer base. In Development and manufacturing, we recently invested significantly in expansions, and now have the capacity to meet our customer's immediate to near-term future needs. In Biologics, we are creating capabilities in downstream processing. We are investing in a manufacturing facility in the US to offer a single seamless solution to our customers that want to develop and manufacture their NBEs (New Biological Entities) in the West.

With Goldman Sachs team on our board, we have access to their global team, harness their intellectual horse power, lever their strategic thinking, and invest judiciously with our access to significant capital. We have some exciting opportunities that we will evaluate and prioritize over the next 12 months. We will continue to be only a company offering solutions to our customers with no conflict of interests against internal programs or stakes in any intellectual assets.

In your view, what are the key challenges that you will have to address as an organization & at the policy level to realize Make in India in the true sense?

We have identified the potential challenges ahead of our aspiration to expand and grow. As an organization, we are also developing and implementing strategies to address these challenges and mitigate their potential impact. Some of these challenges are Talent attrition, Managing

costs, Rupee v/s dollar fluctuation, Competition from other CROs, Ability to upgrade infrastructure and to bring new offerings to meet customer requirements.

There are also certain external factors which can impact our overall growth which are beyond the sphere of our influence. We will continue to stay agile and vigilant and continue to interact with the stakeholders in government to share our perspectives on how they can be develop /implement policies and guidelines that can enable the growth of this CRO industry in India. Policies, Incentives for R&D investment including tax holidays, Turnaround times for approvals/ clearances, access to infrastructure in industrial areas and simplifying policies are our keen focus.

Tell us about the latest innovations & products recently introduced and the ones in pipeline.

Aragen is primarily focused on offering solutions to drive our customers' R&D programs. We partner with our customers to enable them to bring new molecules in the market. We are driven by our purpose – "In every molecule is the possibility for better health". This is achieved by the innovative work carried out in our facilities with a team of 2800+ scientists. We create IP for our customers. ■

Government Initiatives, Market Conditions to Propel the Indian Pharmaceutical Industry

Dr. Suhasini Molkuvan
Associate Director, Healthcare & Life Sciences Practice
Frost & Sullivan

India is on a continuous growth trajectory towards becoming a global leader in pharmaceutical manufacturing. Globally, India ranks third in terms of pharmaceutical production by volume and 14th by value. The Indian pharmaceutical exports are valued at around $24 billion, and the domestic market is estimated to reach $71 billion by 2025 from $42 billion in 2021, according to India Brand Equity Foundation (IBEF).

India is one of the top suppliers of bulk drugs and formulations globally and has the highest number of US FDA-approved plants with state-of-the-art technologies. India supplies a majority of generic drugs globally to the US, UK, and several developing nations. India provides almost 40% of the total American generic drug demand and addresses nearly 25% of the total drug demand in the UK. According to Institut Montaigne, India also accounts for 60% of global vaccine production, contributing 50% of the WHO demand.

This success can be attributed to the advanced capabilities in formulation development, entrepreneurial ability, low manufacturing cost, government initiatives, and the industry's vision to establish India's footprint in large international markets. Contract research and manufacturing services and the biotech industry are the two fast-growing biopharmaceutical industry segments globally. Our analysis indicates that the global contract manufacturing services market was estimated at $109 billion in 2020, with the Indian sector valued at around $6.8 billion. Contract manufacturing contributes up to 60% of formulations and bulk drug manufacturing and presents a significant growth

opportunity. India is also moving towards innovation, with around 95 biosimilars approved to date. According to Frost & Sullivan's analysis, the biosimilars global market is estimated to be at $35.7 billion in 2021, with India capturing a market share of 1.7%. It is expected to grow at a compound annual growth rate (CAGR) of 34% in the next five years. The pharmaceutical industry will see a new wave of patent expirations between 2021 and 2026, leading to biosimilars, bio-betters, and bio-generics development.

Indian CROs are becoming more involved in developing biosimilars due to their expertise in streamlining biological products' research, development, manufacturing, and up-scaling. Indian vaccine manufacturers have emerged as significant players in the global market. India has been a substantial supplier of basic Expanded Programme on Immunization (EPI) vaccines to UNICEF. They currently produce new and more complex vaccines for meningitis, Haemophilus influenza Type B, rotavirus, influenza A (H1N1), and pneumococcal conjugate vaccines. The introduction of new vaccines in the Universal Immunization Program (UIP) is expected to promote investment and R&D in the vaccines sector in India. COVID-19 has also boosted the industry, resulting in the manufacturing of COVID vaccines for domestic use and exports. However, India lags in the active pharmaceutical ingredients (APIs) and bulk drug manufacturing segment. India imports around 68% of its API consumption by value from China and is highly reliant on China for fermentation-based APIs (antibiotics), feedstock, and many key starting materials (KSMs). With COVID-19 creating several challenges like restrictions on exports and imports, supply chain, and logistic issues, India's pharma sector is trying to reinvent itself and move forward from its long-standing dependence on the export of generics towards enabling the industry to become an end-to-end drug manufacturer. This includes a parallel thrust on localizing API and bulk drug manufacturing. Impact of Government Initiatives Amidst the pandemic, India has also seen a spurt in the growth of start-ups working towards accelerating lowcost development systems by leveraging the government's schemes like Make in India and Atmanirbhar Bharat. India has gained a significant competitive advantage as the cost of manufacturing in India is around 40% lower compared to the USA.

The Indian government has also set up a production-linked incentive (PLI) Ar t i c l e The G l o b a l G r o w t h P i p e l i n e C o m p a n y package focusing on APIs and the API Parks scheme to boost the competitiveness of India's manufacturing and promote domestic manufacturing of critical intermediates and APIs. In March 2020, the government approved the $1.4 billion (₹10,000 Crore) PLI scheme to

reduce India's dependence on China for raw materials and locally produce crucial antibiotics, anti-HIV drugs, vitamins, and cardiovascular diseases.

The Union cabinet cleared the new PLI scheme for the domestic pharmaceutical sector for 2020-21 to 2028-29. The scheme is expected to provide about $2.04 billion (₹15,000 crores) in incentives. This scheme expects total incremental sales of $41.2 billion (₹2.94 trillion) and incremental exports of $27.5 billion (₹1.96 trillion) from 2021 to 2029. In May 2021, the Department of Pharmaceuticals (DoP) issued revised Guidelines for the PLI scheme to promote domestic manufacturing of critical KSMs, drug intermediates, and APIs in India. The new PLI scheme is expected to boost the existing brownfield API units in the country and bring 20 priority molecules to be produced with scale; thereby, decreasing dependency on China. Additionally, under the Atmanirbhar Bharat 3.0, the government announced Mission COVID Suraksha to accelerate the development and production of indigenous COVID vaccines. In May 2021, to augment the capacity of the indigenous output of Covaxin under the mission, the Department of Biotechnology, Government of India provided financial support in the form of a grant to vaccine manufacturing facilities for enhanced production capacities, which is expected to cross ten crore doses per month by September 2021.

Bright Future Ahead for Indian Pharmaceutical Industry World-class capabilities and market conditions ensure that India remains one of the most lucrative pharma markets in the world. India is already an attractive destination for manufacturing pharmaceuticals due to its robust capabilities across the value chain. In the future, pharmaceuticals manufacturing in India has multiple opportunities for growth across formulations, bulk drugs, indigenous vaccines manufacturing, and contract manufacturing. Frost & Sullivan's analysis indicates that the Indian pharmaceutical industry is at the forefront of the Make in India initiative. Over the last few decades, the industry has experienced rapid growth. India has demonstrated commitment to ensuring affordable and accessible medicines globally, and most of the domestic demand for drugs is fulfilled by medicines made in India.

Many opportunities exist in the core businesses (formulations and bulk drugs) and new companies (e.g., complex generics, vaccines) that present a favorable outlook for the industry over the next 10-15 years. Despite the unprecedented times, the industry is working in close collaboration with the government to continue growing as the leader of pharmaceutical manufacturing and become the 'pharmacy of the world.' ■

Analyzing Indian Pharma Norms from Credit Risk Perspective

D Naveen Kumar
Associate Director
Corporate Ratings, CARE Ratings Ltd

With market size of around US $45.7 billion in FY21, Indian pharmaceutical industry globally ranks third in terms of volume and thirteenth in terms of value. Indian pharmaceutical companies, over decades of arduous efforts, have gradually developed the necessary technology, capacities and capabilities to meet the demand and to explore the opportunities provided by global regulated markets; and currently, United States of America (USA) contributes about one-third of the total Indian pharmaceutical exports.

Furthermore, Indian pharmaceutical manufacturing companies accounted for 42% of the total Abbreviated New Drug Application (ANDA) approvals by USA in 2021 (January-July) as compared with 39% in 2020; the total number of ANDA approvals were 168 and 293 during the said period, respectively. India has second-highest number of United States Food and Drug Administration (USFDA) approved manufacturing plants, i.e., about 891 units with over 2,500 ANDA-approved drug products during this decade, i.e., CY2011-CY2021* (* for CY2021, the data pertain to the period from January to June).

With all the aforesaid accolades and high dependency on US market, it becomes pertinent to analyze and understand about various observations made by USFDA in the recent past and the measures taken by the Indian Pharmaceutical companies to overcome them. It has been noticed in the past that adverse observations by regulatory authorities have considerably

restricted the supply of drugs to the US market from the affected facility, in turn resulting in decline in the revenue for the companies particularly to US market and also from other markets subsequently if the issues are not resolved at the earliest.

Sequence observed by USFDA in regulatory enforcement

USFDA's Office of Regulatory Affairs (ORA) is the lead office for all the field activities, including inspections and enforcement, which carries out the inspections of the manufacturing facilities approved by them at regular intervals. At the completion of inspection, a report is prepared by the agency and is termed as 'Establishment Inspection Report' which details inspectional findings. During an inspection, if investigators do not observe any objectionable conditions at the plant site, the said manufacturing unit (which is outside USA) can continue to export to USA, however, if any objectionable conditions are observed then based on the investigator's judgement, 'FDA Form 483' is issued to the manufacturer. Thereafter, the companies are fostered to respond to the 'FDA Form 483' in writing with respective corrective action plan and subsequently implement the plan expeditiously.

If the response to 'FDA Form 483' submitted by the company is deemed insufficient, a warning letter may be issued by USFDA to the respective firm. FDA then checks back to ensure that the corrections taken by the company are adequate, and in case they find the explanations or corrective measures taken by the company are inadequate, then they would issue an alert.

All the inspections carried out by USFDA are categorized in three buckets: No Action Indicated (NAI), Voluntary Action Indicated (VAI) and Official Action Indicated (OAI).

NAI = No Action Indicated, meaning no objectionable conditions or practices were found during the inspection (or the significance of the documented objectionable conditions found does not justify further action).

VAI = Voluntary Action Indicated, meaning objectionable conditions were found and documented but the agency is not prepared to take or recommend regulatory action.

OAI = Official Action Indicated, meaning objectionable conditions were found and regulatory action should be recommended. Out of the total inspections carried out during CY16 and CY17, about 11% and 17% of cases were categorized under Official action indicated and the same during CY18 and CY20 in this category were 7% and 6%, respectively,

which subsequently were converted into warning letters and alerts and the details of the same are presented in the tables below. However, during CY20, the number of inspections carried out by USFDA were less because of the COVID-19 pandemic, the FDA has temporarily postponed domestic and foreign routine surveillance facility inspections. Note: The import alert falling under the category 'Detention Without Physical Examination' (DWPE) 66-40 pertains to the Drugs from firms which have not met Drug GMPs.

The following table and graph delineates upon the entire classification of observations mentioned in warning letters received from USFDA into various categories and it can be inferred that about 50% of the warning letters issued to Pharma companies pertain to data manipulation, data integrity, lack of data documentation discipline and failure to maintain quality and purity.

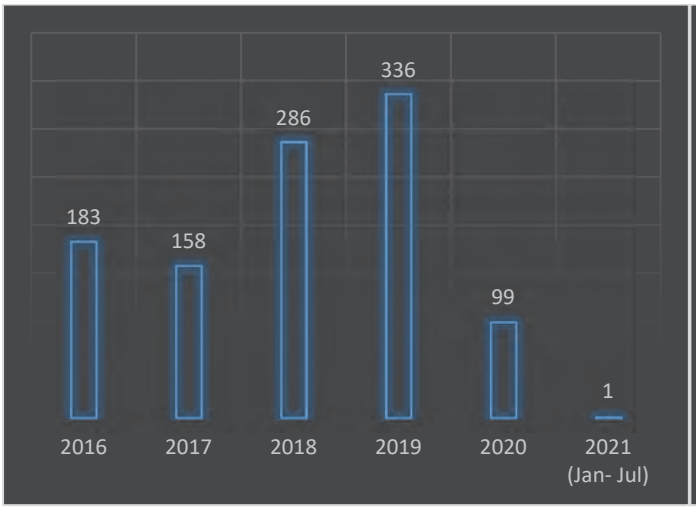
A warning letter restricts the ability of that manufacturing unit to supply new drugs to the US from that facility. In that case, the company needs to appoint consultants to advice on corrective actions and also monitor implementation of the same. After this, the company approaches the FDA and makes a request for re-inspection. If the regulator is satisfied with the corrective measures, it can issue a close-out letter.

However, FDA can also choose to issue Import Alerts immediately whenever it determines that it already has sufficient evidence to conclude that the products manufactured from a specific unit appear to be adulterated, misbranded, or unapproved, and has made serious deviations from Current Good Manufacturing Practices (cGMP), then they may be refused from importing. In such cases, warning letter would follow the issue of import alerts. The basic purpose of import alert is to prevent violative products from being circulated in the US; provide uniform coverage across country; and place the responsibility back on the importer to ensure that the products being imported into the US are in compliance with FDA laws and regulations.

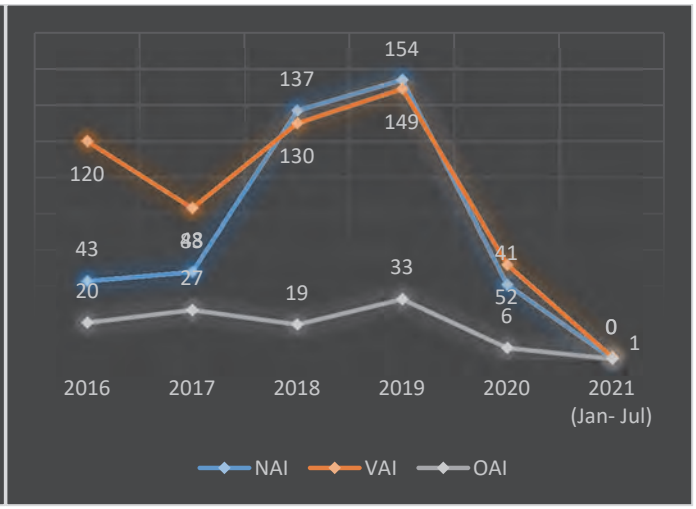
Post issue of import alert, the company needs to implement appropriate remediation process religiously. Once the company is confident about its processes, it can invite USFDA to carry out the inspection post implementation. Once the FDA finds that all the processes are in place then the unit can restart the export of the drugs to the US.

Following tables illustrate the total number of inspections that USFDA has carried out and the categories of the observations made by the regulatory authorities during those inspections:

Total number of inspections in India



Categories of inspections carried out in India

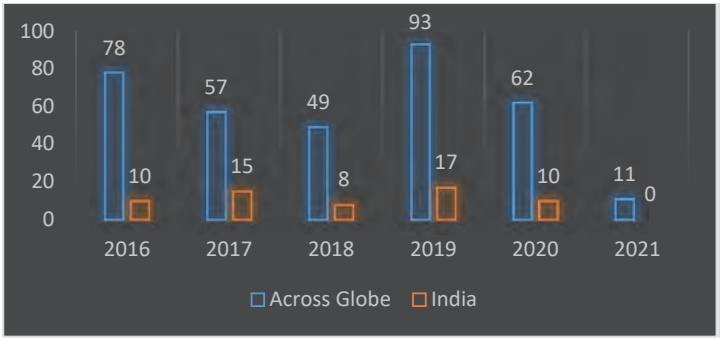


Source: USFDA

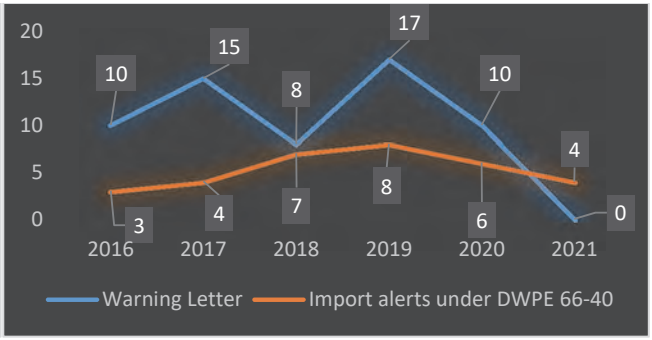
Out of the total inspections carried out during CY16 and CY17, about 11% and 17% of cases were categorized under Official action indicated and the same during CY18 and CY20 in this category were 7% and 6%, respectively, which subsequently were converted into warning letters and alerts and the details of the same are presented in the tables below. However, during CY20, the number of inspections carried out by USFDA were less because of the COVID-19 pandemic, the FDA has temporarily postponed domestic and foreign routine surveillance facility inspections.

Note: The import alert falling under the category 'Detention Without Physical Examination' (DWPE) 66-40 pertains to the Drugs from firms which have not met Drug GMPs.

Number of warning letters issued by USFDA across globe vis-à-vis India



Number of import alerts and WL

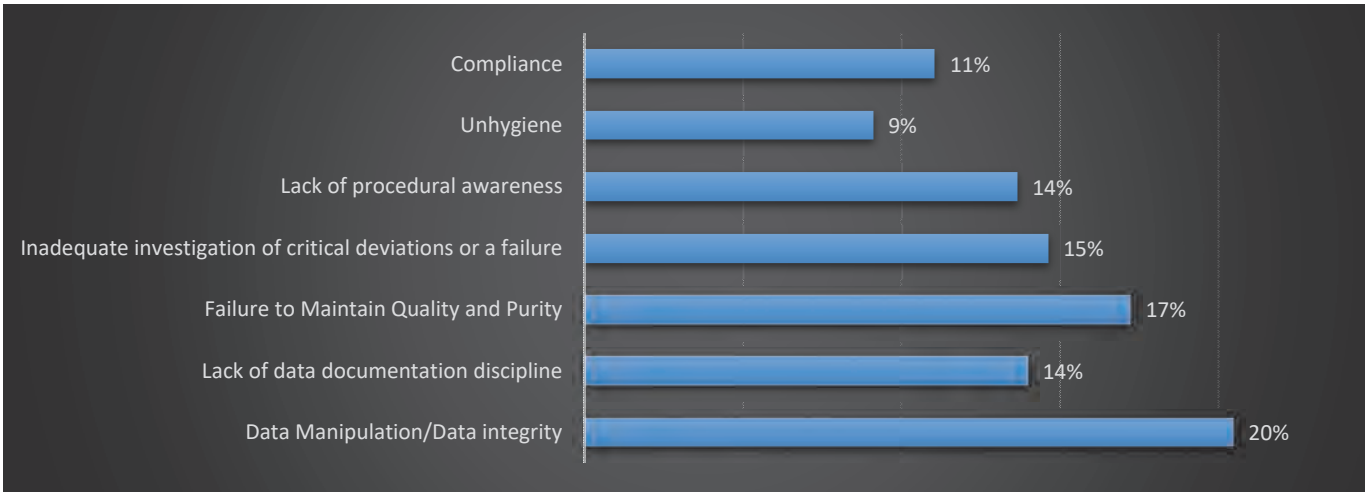


Source: Compiled by CARE Ratings Ltd
Note: 2021 data is for period Jan - Jul

The following table and graph delineates upon the entire classification of observations mentioned in warning letters received from USFDA into various categories and it can be inferred that about 50% of the warning letters issued to Pharma companies pertain to data manipulation, data integrity, lack of data documentation discipline and failure to maintain quality and purity.

Classification of Warning letters Global Pharma Co's	2016	2017	2018	2019	2020	2021	Total	% share
Data Manipulation/Data integrity	12	12	6	18	13	2	63	20%
Lack of data documentation discipline	4	10	12	8	8	1	43	14%
Failure to Maintain Quality and Purity	11	8	3	19	11	1	53	17%
Inadequate investigation of critical deviations or a failure	5	7	8	17	6	2	45	15%
Lack of procedural awareness	1	10	10	9	10	2	42	14%
Unhygiene	3	6	6	6	6	1	28	9%
Compliance	0	4	4	16	8	2	34	11%
Grand Total	**36**	**57**	**49**	**93**	**62**	**11**	**308**	**100%**

Categories of observations mentioned by USFDA in their warning letters (in %)



Following are some of the inputs provided by the regulatory authorizes and consultancies in order to avoid the observations and incorporate systems in place:

To maintain strong systems in place with proper qualified and designated personal to handle the data in order to prevent unauthorized access or changes to data, and to provide adequate controls to prevent omission of data.

As about 50% of the observations

pertain to data integrity, manipulation and/or discipline and failure to maintain quality and purity, USFDA necessitates a pharmaceutical manufacturing company approved by it to observe standard operating procedures meticulously. Furthermore, those SOPs have to be clearly written, modified, and maintained in a consistent and timely manner, and should be centrally accessible. Problems and accidents generally take place if the employees do not have current written instructions for their tasks or if they do not observe written instructions in toto.

To maintain complete data derived from all testing, and to ensure compliance with established specifications and standards as many data integrity observations fall under the category "Failure to provide records required to be readily available for authorized inspection".

To maintain the buildings used in the manufacturing, processing of a drug product in a clean and sanitary condition and keep them free of infestation by rodents, birds, insects, previous batch particles and other vermin.

While addressing the observations made by the regulatory authority, the company needs to take care that every observation should have a thorough root cause analysis performed and, if necessary present, one or more corrective and preventive actions identified very clearly with specific timelines of implementation.

It is in the benefit of the company to peruse to obtain closeout letter at the earliest for which the remediation process should start right from the day of receipt of Form 483 or a warning letter. USFDA generally looks for a response to most of its compliance notices within 15 business days. The USFDA, although does not conform to the company's response immediately but it would be appropriate to contact the agency and confirm receipt.

As majority (about 50%) of the observations fall under data integrity, manipulation and/or discipline and failure to maintain quality and purity category, the best approach for minimizing the human errors is to establish a system where each step has to be followed by implementing an enterprise quality management software system. The plausible and best-practice features include prompting users with selected data which is just required to be accessed or entered by the specific task performer. This would significantly reduce data entry-related errors and avoid mistakes common in manual document management and data entry. Apart from

the above, the implementation of the aforementioned systems would also take care of the procedural errors.

From credit risk perspective

The pharmaceutical industry operates in a highly regulated environment catering to various developed countries and it requires various approvals, licenses, registrations and permissions. The approval process for a new product registration is complex, lengthy and expensive. The time taken to obtain approval varies by country but generally takes from six months to several years from the date of application. Any delay or failure in getting approval for new product launch could adversely affect the business prospect of the company. Given India's significant share in the USA's generic market, the USFDA has increased its scrutiny of manufacturing facilities and other regulatory compliance of the Indian pharma companies supplying generics drugs to the USA. Non-compliance may result in regulatory ban on products/facilities and may impact a company's future approvals from USFDA. Any adverse observation from the regulatory authorities would not only lead to attenuation of the future business prospects but also can adversely affect the current cashflows and may strain the liquidity profile especially if the company has significant exposure to the country from where it has received the observations. It is being observed that the companies have spent considerable portion of their cashflows in implementing the remediation measures.

Furthermore, because of issues with regulatory authorities they were not able to build the product pipeline and had to rely upon semi-regulated markets where they took hit on profitability margins due to intense competition. Furthermore, the return on capital employed will be affected as the company would have incurred capex and incurred expenditure on R&D to develop the molecules and the regulatory overhang issues obstructs in exploiting the premium business opportunities present within regulated markets. Therefore, adhering to the cGMP practices laid down by the regulatory authorities and passing through the regulatory audits successfully on regular basis forms critical tool in accessing a company from credit risk view point. ■

An Overview on Biosimilars: A Review of Literature

Author

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The risk of chronic diseases like diabetes, cancer, rheumatoid arthritis, etc. has been increasing considerably at the global level. Biologics have been used for many years in treating chronic diseases, but their high cost leads to high financial burden on healthcare systems. This calls for affordable treatment, contributing to the development and commercialization of biosimilars across the world. The patent cliff of many biologics has provided opportunities for pharmaceutical companies to develop, manufacture, and market biosimilars. A biosimilar can be defined as "copied" and licensed versions of approved and authorized biologic products that have undergone patent expiration. It takes around 8-10 years to develop a biosimilar, at a cost of between $100 million to $250 million. According to the published reports, it is expected that sales of biologic drugs may lose up to $197 billion after the entry of biosimilars. Various regulatory bodies such as European Medicines Agency (EMA), US Food & Drug Administration (FDA), World Health Organization (WHO), etc. actively regulate biosimilars development and ensures that only high-quality, safe, and efficacious biosimilars are available on the market. Each country has its regulatory guideline for biosimilar drugs. The regulatory authorities play an important role in the success of the biosimilar development as they closely monitor the viability and balance between the reference product and biosimilar product. This article summarizes the approved status, market size, and comparison of the regulatory guidelines of biosimilars in Europe, the United States (US) & India.

1. Introduction:

The existence of biopharmaceuticals has been in the market for more than 20 years and Humulin was the first drug to be approved in 1982. There are nearly 300 biopharmaceutical products that have been approved and are available in the market. The global biopharmaceuticals market was at the value of $186,470 million in 2017 and is projected to reach $526,008 million by 2025, at a compound annual growth rate (CAGR) of 13.8% from 2018 to 2025. [1] Biosimilars are considered to be the new category of biotechnological drugs and represent a significant opportunity for healthcare systems to deal with the rising cost of biologics and access issues faced by patients. The biosimilar can be defined as an official approved medical drug that shares the same amino acid sequence but can never be identical. A biosimilar registration follows strict guidelines based on a totality-of-evidence approach emphasized on stepwise development. The initial development of biosimilar requires extensive studies and in-depth analysis to confirm that the product is identical to the originator in terms of structure, composition, and in-vitro activity. After the bio-similarity is confirmed, regulatory authorities may allow extrapolation to other licensed reference biotherapeutics (bio-originator) indications. Hence, a biosimilar may be approved in all indications (without multiple trials) for which the bio-originator has been approved. [2]

2. WHO Regulations:

According to the WHO, the biosimilar can be defined as "A bio-therapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference bio-therapeutic product." In 2009, WHO followed the guidelines on the evaluation of Similar Biotherapeutic Products (SBPs) and aligned its guidelines with those from the EMA. Most countries rely on WHO guidance to assure the safety and efficacy of biosimilars. [3] In 2019, WHO prequalifies its first biosimilar medicine i.e. trastuzumab which comes in the WHO Essential Medicines List. The global average cost of the trastuzumab innovator product is ~ $20,000, a cost that is too much of an expense for many women and healthcare systems in most countries. Hence, the biosimilar version of the trastuzumab has enabled women and healthcare systems to afford the drug as it is ~ 65% cheaper than the originator. It is expected that many products will come into the prequalification pipeline, as it assures countries of purchasing quality health products. [4]

3. Biosimilars in Europe:

3.1 Overview & Approved Status:
Europe was the first country to introduce regulatory guidelines for examination and approval of biosimilars via an abbreviated registration process from 2005 to 2006. After 2006, many guidelines were developed and released for biosimilars. Omnitrope (somatropin) was the first biosimilar to be approved in Europe in 2006. To-date approval of 64 biosimilars has been recommended by EMA within the product classes of human growth hormone (HGH), granulocyte colony-stimulating factor (G-CSF), monoclonal antibodies (mAbs), anticoagulants, erythropoietin, insulin, follicle-stimulating hormone (FSH), parathyroid hormone, and tumor necrosis factor (TNF)-inhibitor. Out of 64 approved biosimilars, six biosimilar approvals have been withdrawn after approval, leaving a total of 58 biosimilars approved for use in Europe. [5]

3.2 Biosimilar Market Size: Biosimilars have been on the market in Europe for more than 15 years. The biosimilar market in Europe reached a worth of $ 2,934.6 million in 2018. The market is further projected to reach a value of $ 11,663.1 million by 2024, growing at a CAGR of 24.9% during 2019-2024. [6] Europe has the world's largest biosimilar market accounting for approximately 87% of global biosimilars sales of $5 billion as compared to just 2% from the US [7].
In late 2018, the EU patent of Humira (adalimumab) got expired, opened the door for sponsors to develop cheaper biosimilars to hit the market. The originator product, AbbVie's Humira was one of the world's best-selling drugs, had worldwide sales of $18.4 billion in 2017, before the arrival of biosimilars. The global sales of Humira got to drop by 33.5%, after facing competition from biosimilars. [8] As per published reports, adalimumab has gained a high of 57% uptake across the European Union (EU) 5 nations, and discounts have reached levels of 70% to 80%. The total sales of Samsung Bioepis's three autoimmune biosimilars (i.e. Benepali, Imraldi, and Flixabi) in Europe alone accounted for $738.3 million (~35 % profit) in 2019. [9]

4. Biosimilars in US:

4.1 Overview & Approved Status: The regulatory framework for approval of biosimilars was established in 2009, via the Biologics Price Competition and Innovation Act of 2009 (BPCI Act). To date, the USFDA has approved 28 biosimilars within the product classes of TNF- α, monoclonal antibodies (mAbs), GCSF, and insulin. The USFDA approves its first

biosimilar product Zarxio (filgrastim-sndz) in 2015. The penetration of biosimilars in the US biosimilar market is very slow and is limited. Currently, there are only nine approved biosimilars in the US biosimilar market because anti-competitive behaviors, other markets, and regulatory dynamics discourage market uptake of biosimilars in the US. [10]

4.2 Biosimilar Market Size: Biosimilars currently make up only 2.3% of the US biologicals marketplace. On average, the biosimilars can cost 30% less than reference biologicals, with the potential to save the US up to $71 billion in the next 10 years. Also, the US could have saved $7.2 billion annually if the biosimilars penetration grew to 75% in the biosimilar market and even more savings could have been figured out if more categories of biosimilars are approved. [10] The US biosimilar market was valued at $737.2 million in 2019 and is projected to reach $ 22,966 million by the end of 2027. [11]

5. Biosimilars in India:

5.1 Overview & Approved Status: India released the draft of regulatory guidelines for 'similar biologics'(or biosimilars) at the BIO industry conference in Boston, USA, in June 2012, and implemented the same from September 2012. The Central Drugs Standard Control Organization (CDSCO) is responsible for the approval, i.e. marketing authorization of medicinal products, including biosimilars in India. The CDSCO introduced the revised biosimilar guidelines in August 2016. The first biosimilar was approved and marketed in India for a hepatitis B vaccine in 2000, well ahead of Europe which approved its first biosimilar in 2006. The number of approvals for biosimilars in the last 5 years represents a robust opportunity for biologics and biosimilars. Currently, more than 98 biosimilars have been approved in the domestic market of India. There are more than 2700 biotech startups, 600 biotech companies, and 100 biotech incubators in India which will be going to increase by 4-5 times in the next five years. [12]. The pipeline for biosimilars in India is robust because Indian government provides subsidies to Indian biosimilar manufacturers. In addition, global biopharmaceutical manufacturers are increasingly partnering with Indian biopharmaceutical producers. For example, Apotex (via its European marketing arm, Accord Healthcare) partnered with Intas Biopharmaceuticals Limited (IBPL) such that Apotex received the rights to market the product in North America (US and Canada), Europe, and selected other countries whereas IBPL expanded its ability to commercialize its products in Western markets. [2]

5.2 Biosimilar Market Size: The global biosimilar market will be worth of $240 billion and Indian biosimilars market will reach the value of $40 billion by 2030. India is considered to be one of the emerging hub for biologics and biosimilars. After CDSCO revised the biosimilar guidelines in 2016, several Indian pharmaceutical companies are making significant investments into biosimilar development and production into global markets. For example Cipla have made huge investments in India and abroad to acquire manufacturing facilities and potential product pipelines in the biosimilar segment in other countries like China [13]. Also, India is providing an affordable place to carry out research and development, more international players are partnering with Indian companies. India has shown that biosimilars have the potential to capture as much as 75 % of the available volume share. [2]

6. Comparison of Legal framework of biosimilars in Europe, US & India: The regulatory authorities play a significant role in enabling many biosimilar products to gain regulatory approval around the world. They develop a specific, appropriate, regulatory framework for approving biosimilars that is different from the previous regulatory policies applied to copy-version products, where the regulatory assessment was not well defined. [14] The summary of the comparison of the legal framework of biosimilars in Europe, the US & India is tabulated in Table no. 1.

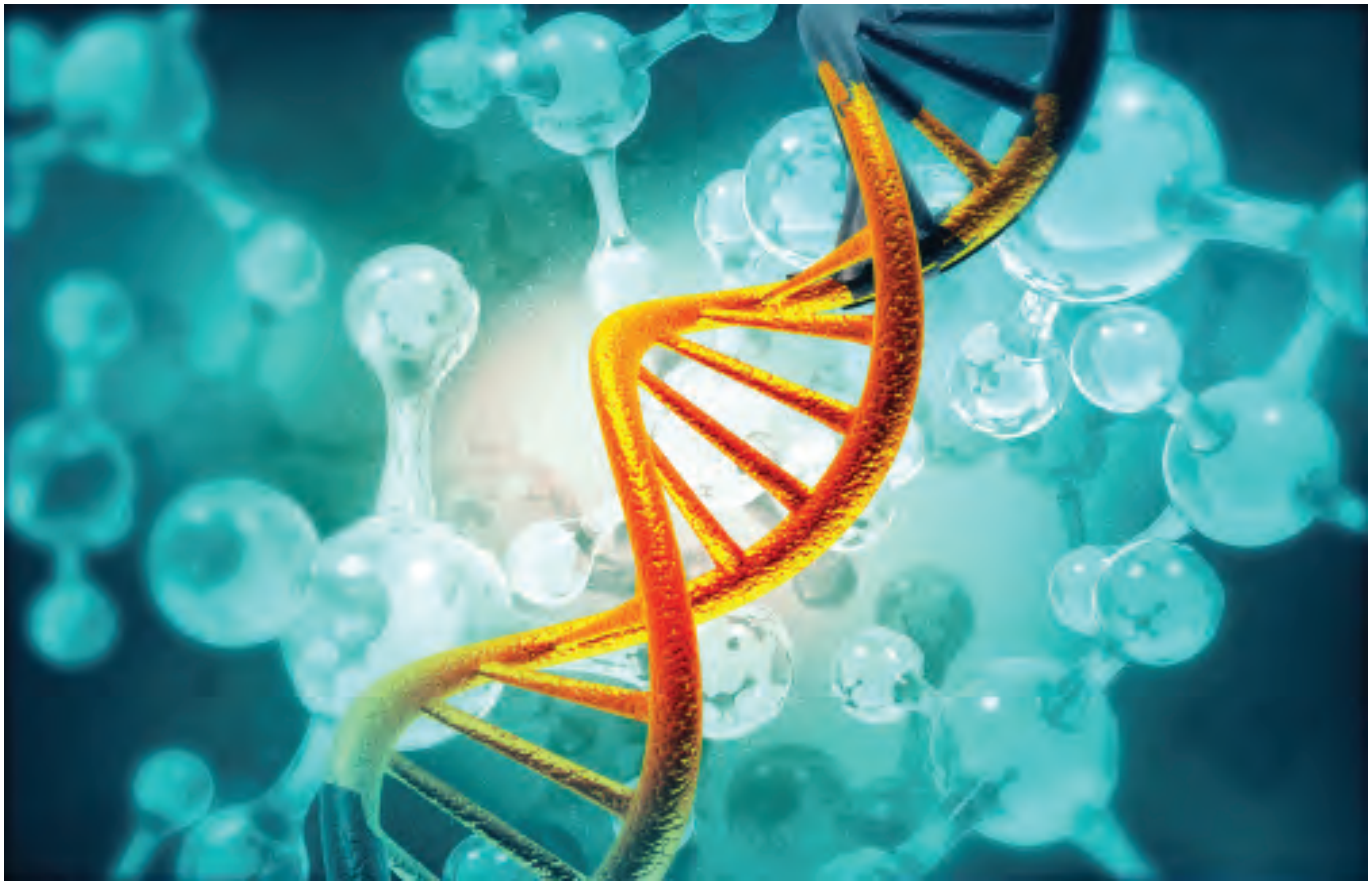
7. Discussion & Conclusion: The development of biological medicines has experienced continuous growth over the past three decades and it has transformed the treatment for several severe chronic diseases. Biosimilars are drugs that contain similar active components as biologics. The development of biosimilar drugs is a cumbersome process and the main driving force behind its development is the expiry of patents for approved biological products worldwide.

Table 1: Sum

S.No	Parameters
1.	Reference Pro (RP)
2.	Pharmacokinetics (PK) Studies
3.	Pharmacodynami (PD) Studies
4.	Safety (Immunogenicity)
5.	Extrapolation
6.	Exclusivity Period
7.	Interchangeability
8.	Post Marketing Surveillance (PMS

nmary of the comparison of the legal framework of biosimilars in Europe, US & India [2] [3]

	Europe	United States	India
oduct	RP which is not authorized in European Economic Area (EEA) can be used for certain clinical & in vivo non–clinical studies based on similar scientific and regulatory as per the EMA guidelines (CHMP/437/04 Rev Effective date: April 30, 2015) and representative of the reference.	As per 351(k) of the Public Health Service (PHS) Act, a sponsor must demonstrate the biosimilarity between the proposed product and single RP that previously has been licensed by FDA.	As per section 6.1 of the CDSCO & Department of Biotechnology (DBT) revised guidelines, biologics approved/licensed and marketed in a member country of The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human use (ICH) countries like EU, USA, Japan, Canada, and Switzerland can be used as reference biologic in India.
	PK studies are applicable to homogeneous and sensitive population (healthy volunteers or patients) to detect any possible differences between the proposed biosimilar and its reference medicine.	The sponsor should conduct comparative PK studies between proposed biosimilar and RP to measures of peak concentration (Cmax) and total area under the curve (AUC) in a relevant biological fluid.	Comparative PK studies should be conducted between proposed biosimilar and RP in normal healthy volunteers & patients and should consider some factors like half- life, linearity of PK parameters, route of administration and indications.
cs	The end points measuring PD activity ('PD endpoints') can be used when available and when relevant for the medicine's clinical effect.	In PD studies, PD biomarker(s) evaluated for the proposed biosimilar product and the RP and are compared by determining the area under the effect curve (AUEC).	Comparative PD studies are conducted between proposed biosimilar and RP in healthy volunteers when the PD properties of the RP are well characterized with at least one PD marker validated for a clinical outcome of the molecule.
)	Immunogenicity studies are mandatory for biosimilars as per EMA Guidelines.	Immunogenicity studies are compulsory and should able to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and for which licensure is sought for the biosimilar product.	Both pre-approval and post-approval assessment of safety is mandatory which has to be conducted for a biosimilar.
	Extrapolation is allowed and requires sufficient scientific justification in comparability studies (quality, non-clinical and clinical).	USFDA view is same with that of EMA in context of extrapolation of data to other indications.	As per section 8.5 of the CDSCO & DBT guidelines, both old & revised guidelines have the provision for approval of biosimilar for all the indications as that of the RP. However, the introduction of detailed description of "quality" and "clinical" similarity is an additional feature in the revised guideline.
	10 years of exclusivity to pioneered product.	12 years of exclusivity to pioneered product.	The concept of exclusivity period is not mentioned in the guideline.
y	EMA does not regulate interchangeability of a product. It is left up to the member states of EU.	The biological product may be substituted for the RP without the interference of the healthcare provider who prescribed the RP.	The concept of interchangeability is not mentioned in the guideline.
S)	PMS permits monitoring of knowns risks and detection of rare adverse drug reactions that arises when large numbers of patients have been treated for a long period.	PMS allows safety monitoring of all products with unknown safety risks as mentioned in Good Pharmacovigilance Practice guidance.	As per Section 10.3 of CDSCO & DBT guidelines, in PMS additional safety data may be collected by conducting a pre-defined single arm study of more than 200 evaluable patients and compared with historical data of the RP product.



Biosimilars have a product lifecycle that starts with inception (R&D) continues through manufacturing to regulatory approval and as well as post-approval in the form of pharmacovigilance. As a new wave of biosimilars is in the pipeline for development, and regulations in the EU and the US are simultaneously becoming increasingly more complex, manufacturers working on biosimilar development will need increasing guidance. Also, to establish a global strategy for biosimilars, sponsors/manufacturers have to make future strategies including "where to play" and "how to win".

The uptake and adoption of biosimilars in the EU vary greatly not only by country but by therapeutic area as well. The involvement of government, reimbursement systems, the regulatory and payer environment, and tender procurement policies also varies greatly among EU member states, the US, and India. In Europe, major awareness-raising initiatives have been taken on biosimilar drugs mainly focusing on physicians rather than on the patient perspective. Also, education remains a priority in the EU, which in turn will help healthcare members and patients to get updated information on the decisions related to

treatment options. The emendation of several biosimilar guidelines by EMA shows that the EU legal structure is moving stepwise in the direction of reducing the clinical requirements for biosimilars with the aim to have timely access to safe and efficacious biological medicines in Europe.

In the case of the US, USFDA is in continues to develop guidance on biosimilars, intentional educational efforts with various stakeholders, including continuous engagement of providers, payers, and patients will remain critical. It is estimated that the availability of biosimilars in the US could increase access to biological medicines and lowering out-of-pocket costs of ~1.2 million patients over the next 10 years, benefitting women, lower-income, and elderly individuals. Currently, the biosimilar market has been much slower in the US. It is expected that as more products get penetrated to the US biosimilar market, physicians will get more familiar with these products, resulting in a much larger uptake in the next 5-10 years. As more products get penetrated to the US biosimilar market, physicians will get more familiar with these products, resulting in a much larger uptake in the next 5-10 years.

India is emerging fast as a significant biotechnology sector across the world. In recent years the biotechnology sector has seen remarkable growth in terms of new companies registered, larger product pipelines, increased patent filings, and several product launches. The advent of biosimilars created huge opportunities for all stakeholders both in oncologic and non-oncologic disease areas. The Indian government took the steps to support the biopharmaceutical industry with the necessary infrastructure, funding, and global collaboration to bridge the technical knowledge gap, and further revision in regulatory policies of a biosimilar will help to capture the opportunity. As per published reports, India is likely to accomplish a $12 billion market size for biologics and biosimilars by 2025 and will grow at a CAGR of 22% [15]. This indicates that the Indian biosimilar market is lucrative, full of potential, and is always bullish for biosimilars. ■

Pharmaceutical Research in India:
New Models of Drug Discovery

The Indian Pharmaceutical Industry today is a highly organized sector with a growth rate of about 14 to 15 percent annually. It is technologically strong, totally self-reliant and the low costs of production with innovative scientific manpower will help it grow further. India has a very good track record for development of alternative processes for various drug molecules with improved yield and low costs. Many of these developments were based mainly on expertise and experience gained through integration of technologies/products developed elsewhere. Though many Pharma companies have initiated drug discovery research, none of them are anywhere close to releasing block-buster drugs. A variety of reasons contribute to this dismal performance of Indian Pharma companies. Globally also the drug discovery industry is in a critical condition with increasing R&D spending and high attrition rates, making drug discovery a risky business. Recent estimates indicate that it takes more than US$ 1 billion and a decade long year to bring a single drug molecule from concept to commercialization. This review highlights some of the recent developments in analytical instrumentation and presents new models of drug discovery that may overcome the present crisis in the drug discovery industry.

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I. Analytical and bioanalytical instrumentation in drug discovery

Drug discovery involves research carried by a multidisciplinary team composed of chemists, biologists, pharmacologists and clinicians. The drugs developed so far have been targeted not more than 500 disease linked genes or proteins. As a result of various analytical and bioanalytical technological breakthroughs in genomics and proteomics, it is anticipated that around 5000 relevant new targets will possibly be identified over the next 10 years. The automated sequencers and genome analyzers have brought the costs down more than 2X per year, making the entire human genome sequence affordable. The development in the microarray technology and proteomics tools have made it easy for the studies on gene/ protein expression profiles of the whole genome. Rapid advances in technologies such as mass spectrometry(MS), nuclear magnetic resonance (NMR) spectroscopy, fluorescence spectroscopy, dual polarisation interferometry and computational methods played key role in the field of metabolomics. These tools played critical role in the identification of novel targets, not only for known diseases but also for emerging diseases.

Similarly, rapid developments in molecular separation platforms, coupled with variety of detectors have revolutionized the separation and identification of not only small molecules but also large molecular proteins. Some of these include capillary electrophoresis (CE), gas chromatography (GC), HPLC, UPLC, LC-MS, LC-MS/ MS, MALDI-TOF and MALDI-TOF/MS. These separation platforms, however, rely on conventional particle-based technologies optimally designed for small molecule separation. Recent technologies involving renaissance of membrane and introduction of continuous bed or monolithic separation stationary phases overcome these problems. As a result, the separation of extremely large molecules like proteins, viruses or DNA can be achieved within seconds to a few minutes. High resolution-mass spectrometry (HR-MS) technology has made several breakthrough improvements in the past 5-7 years, including developments of new HR-MS instruments, data-mining tools and data-acquisition techniques. As a result, HR-MS has become the LC/MS platform of choice for drug metabolite profiling and identification in discovery and development.

Combinatorial chemistry and auto purification systems, along with separation platforms are immensely useful in developing compound libraries, of both

natural and synthetic, which are critical for drug discovery.

Instrumentation Driving Omics

- Genomics :Automated Sequencers, Genome analyzers
- Microarrays: Array Platforms
- Proteomics: Separation Platforms, MALDI-TOF-MS
- Metabolomics: Separation Platforms, MS, NMR spectroscopy, fluorescence spectroscopy, dual polarisation interferometry, MALDI-TOF-MS

Separation Platforms

- Chromatography: GC, HPLC, UPLC
- Combination Techniques : GC-MS, LC/MS/MS, CE-MS, SPE-LC-MS-MS

Rapid developments also have taken place in drug screening, cutting down the costs and time. From the manual screening of few hundreds of compounds per day, we have now reached towards screening of more than 2 million compounds in a day with robotic high throughput screening (HTS). HTS helps in reducing the time of screening, repetitive works and cost effectiveness.

Computer Aided Drug Design (in silico) approaches have been widely employed in Lead Identification and Lead Optimization stages of drug development against various targets over the years (Buchan et al., 2011). Molecular Modeling and Drug Design would be an important stream in the development of potential drug candidates for the pharma industry. In comparison to traditional drug discovery methods rational drug design methods bring down the time and cost involved in drug development process. It can be used to identify/design new inhibitors de novo or for the optimization of identified molecules from various sources. The development of more effective binding affinity prediction methods has made the application of CADD approaches in drug development process more invincible.

II. New models for drug discovery

Academia as the front-end player

The drug discovery industry globally is facing a considerable challenge due to increasing costs, decreasing productivity, and high rates of attrition of projects as they progress through the development process. These challenges can be overcome by developing novel models of drug discovery. One such approach would be to refocus the pharmaceutical industry research to involve academia as a 'front end' player. Universities/institutes with specialized core facilities, expert faculty, and talented young scientists should nurture innovation and provide

a pipeline of inventions and product ideas for licensing to industries for further development. This model should shorten the duration of drug discovery, enable the translation of publicly funded research, and lead the development of novel therapies at affordable prices. More importantly, this should promote innovative research in academic institutions.

The University-industry partnership models must be flexible and adequately funded by industry and/or Govt. agencies. Some of the recent initiatives of Govt. agencies to promote academia-industry tie-ups are:

- Drugs & Pharmaceutical Research program of Department of Science and Technology-DST (www.dst.gov.in/scientific.programme/td-drugs.htm),
- Technology Development Board (TDB, www.tdbindia.org),
- The National Science & Technology Entrepreneurship Development Board (NSTEDB, www.nstedb.com) of Department of Science and Technology (DST, www.dst.gov.in),
- "Promoting Innovations in Individuals Start-ups and MSME" (PRISM) is the erstwhile "Technopreneur Promotion Programme" (TePP) (https://step-iit.org/tepp.html), Technology Development and Demonstration Program (TDDP) and Industrial R&D Promotion Programme (IRDPP) of Department of Scientific and Industrial Research (DSIR, www.dsir.nic.in),
- Biotechnology Industry Research Assistance Council (BIRAC) set up by Department of Biotechnology, Government of India (https://www.birac.nic.in/), empowers the emerging Biotech enterprise to undertake strategic research and innovation, addressing nationally relevant product development needs through programs like e-YUVA, BIG, PACE, SBIRI, BIPP, CRS etc.,
- New Millennium Indian Technology Leadership Initiative (NMITLI) grants by Council of Scientific and Industrial Research (CSIR, www.csir.res.in),
- Biotechnology Industry Research Assistance Program by DBT in partnership with ABLE and BCIL (BIRAP, www.birapdbt.nic.in),
- Seeding Drug Discovery Initiative by Wellcome Trust (www.wellcome.ac.uk),
- Medical Research Council Development Pathway Funding Scheme set up by the MRC (www.mrc.ac.uk),
- The National Biopharma Mission (NBM) is an industry-academia collaborative mission for accelerating biopharmaceutical development launched in 2017 (https://www.birac.nic.in/nbm/).

Academia and industry should exploit the above incentives and work towards novel drug discovery processes.

Push and Pull models

Push and Pull models have to be created where 'push' from the owners of the IP and 'pull' from the pharma/biotech companies will help in more effective drug development processes. Many leading organizations have initiated programs to commercialize the outputs of their parent organization or funded components. These models would bring together key research and commercial players to identify and execute joint research activities more efficiently and more strategically.

Promoting & Nurturing Innovation

In addition to University-Industry tie-ups, there is a need to develop strategies for promoting innovation, protecting and enforcing intellectual property (IPR) and fostering entrepreneurship among scientists. This will be possible by promoting scientist- based enterprises across the country, which will focus on innovative translational research leading to IPR generation and commercialization of technologies. Even though Union Government had permitted the Faculty members to involve with such Science and Engineering driven Scientific Enterprises (vide a notification no. 3/3/2009-TU/ Knowledge to Equity dated May 25, 2009 by Department of Scientific and Industrial Research (DSIR), Ministry of Science and Technology, Govt. of India), it is not being implemented in most of the universities and institutes. Hence there is need to give wide publicity of the scheme and encourage for setting up of the faculty led enterprises so that innovations in academic institutions are taken up for further development.

The major constraint for budding entrepreneurs is the lack of mechanisms for venture capital (VC) support. Most VCs are interested in investments in companies with assured returns, and are not ready to finance drug discovery enterprises, especially in the early stages. In this connection, the announcement of the Rs. 100 crore "NASSCOM- ICICI Knowledge park Innovation Fund" for seed-stage investments to startups with a focus on creating intellectual property, and to academicians and researchers looking to commercialize inventions is a welcome trend. Such enterprises, set up with support from the Government/ Private agencies in University/Institute incubation centres, will become the centres of innovative discoveries to be exploited by big pharma companies. This will channelize the young pool of researchers in the country, who are otherwise unemployed or underemployed,

towards innovative drug discovery and nation-building.

Setting up of Biotech-Pharma Entrepreneur (BPE) Fund

A number of Government agencies (CSIR/ UGC/ICMR/DBT) have been offering fellowships for conducting doctoral/ postdoctoral research in publicly funded institutions. However, there is no agency that promotes young entrepreneurs from Universities/IITs/IIMs, coming up with innovative ideas. These are exclusively for students graduating from the Universities/ Institutes. Hence, there is need to setup 'BPE Fund' to support about 100 young scientists with innovative ideas every year, who are selected through a nation-wide competitive selection process. These BPE awardees may be given priority to locate their ventures in the Technology Business Incubators (TBIs)/BioNEST/TIDE incubation centers established by various Government agencies across the country. Those who are successful in this scheme may compete along with others for second round support through BIG/SBIRI/ BIPP/ CRS/TDB schemes of Govt. agencies.

This BPE Fund will form a channel to nurture innovation among the young scientists emerging from Universities/ IITs/IIMs. The leads coming from these innovators will feed established biotech/pharma companies for further development. If we promote about 100 BPEs every year, within a period of 10 years, there will be 1000 startup companies engaged in drug discovery and development.

III. Traditional systems of medicine

Natural products have provided important leads in traditional medicine. India has a rich legacy of traditional medicine such as Ayurveda, Unani and Siddha. These systems have given leads on important medicinal plants and formulations that are effective in treating several complex diseases, often with fewer side effects. Historically, natural products provide the oldest sources for new medicines. Natural selection during evolution provided every species with powerful biologically active natural products for self-defense, which can serve as leads to be refined by chemists as more effective drugs.

According to recent reports, phytochemicals as herbal drugs have an annual market of 100 billion USD all over the world. The herbal drug business dominated by the Northern Block, comprising of Germany, Sweden, Switzerland, UK and US accounts for 47 billion USD worth. Of the balance of 53 billion USD, China commands 57 percent of the market. India's share of this market

is only 2.3 percent and remains on the fringes. There is a need to focus on our age-old Ayurvedic system and develop herbal drugs in focused areas for global market. Towards this direction Council of Scientific & Industrial Research (CSIR) has initiated steps to first document the traditional leads and take up systematic studies to scientifically validate the claims in Ayurveda, Siddha & Unani systems of Medicine. Once validated, the products can be developed further as per international norms and marketed globally. This approach would provide India the advantage to emerge as global leader and contribute to the world with natural product based pharmaceutical products.

IV. The Road Ahead

Indian pharma and biotech companies have to quickly graduate from reverse engineering to innovative research leading to new drug discovery. The strong IT base and large pool of scientific manpower has to be exploited for the design and development of innovative drugs. There is need to refocus pharmaceutical research away from early discovery activities by involving academia and focus on later stages of drug development. This shift in the focus of the industry from early to late drug discovery will enable the translation of publicly funded research and lead to the cost-effective development of drugs. Moreover, they can overcome the challenges in drug discovery like increasing costs, decreasing productivity and attrition of projects. To make these novel partnership models successful, sustainable funding strategies are needed to create specialized core facilities within the academic institutions and driving them towards innovative research. In addition, there is need to create an ideal environment for scientist-based enterprises focusing on innovation and creativity. On the same lines nurturing the young graduates with innovative ideas with the BPE fund will help in channelizing the youth towards innovation and entrepreneurship along with the faculty. These efforts not only creates job opportunities for young graduates coming out of Universities and Institutes, but also channelizes them towards innovative translational research and nation building. ■

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The Vistop PP36 sterilisable range and applications include; 1684 One port perfusion cap with chlorobutyl liner and aluminium foil used for parenteral IV administration, 1482 Irrigation cap with PP Plug used for disinfection in operating rooms and hospital settings, 1866 Irrigation

cap with chlorobutyl liner for PP or glass bottle.

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"The availability of recycled resin for our Vistop® PP36 further increases the appeal of the closure, combining with the existing benefits of safeguarding product integrity and ensuring ease of administration that improve patient safety and enhance the overall patient experience," comments Franck Cordier South Europe Operations Director of Berry Healthcare. "Consumers are increasingly seeking sustainable solutions in all areas of their lives, and the sustainability credentials of the closure will help to further enhance a company's reputation and standing in the healthcare market." ■

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