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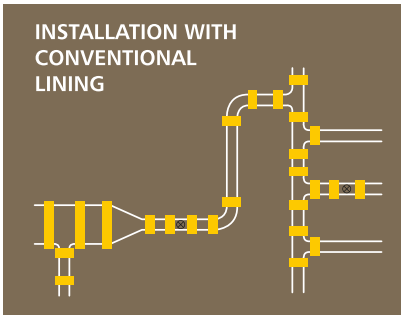

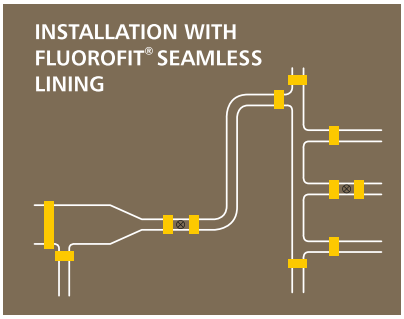

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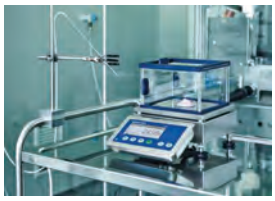

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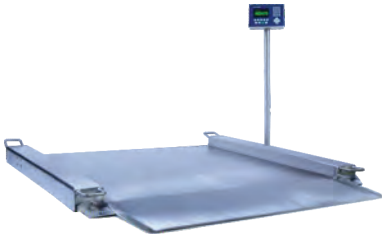

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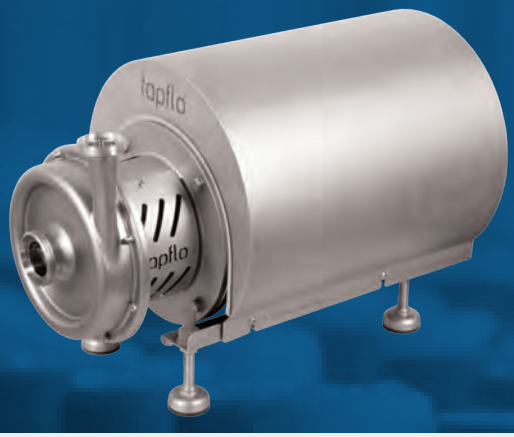

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Jubilant Pharmova's Subsidiary, Jubilant Pharma, Announces The Development Of A Novel Oral Formulation Of Remdesivir

Shyam S. Bhartia, Chairman, Jubilant Pharmova Limited

Hari S. Bhartia, Co-Chairman & Managing Director
Jubilant Pharmova Limited

Noida, India: Jubilant Pharma Limited, a subsidiary of Jubilant Pharmova Limited, successfully completed the safety and pharmacokinetic/absorption studies in animals and healthy human volunteers in India using a novel oral formulation of remdesivir against the commercially available injectable formulation of remdesivir.

Jubilant has sought authorization for additional studies for this novel oral formulation from the Drug Controller General of India (DCGI). Jubilant is hoping to provide an affordable, more convenient, easy-to-administer and potentially effective treatment option for COVID-19 patients. The proposed oral treatment is expected to be for 5 days, a duration similar to the injectable dosage form. Remdesivir is the first and the only anti-viral drug fully approved by the US FDA for the treatment of patients with COVID-19 requiring hospitalization.

This innovative formulation is likely to ease the capacity constraint that injectable formulation faces and ensure wider and timely availability for the patients of COVID-19.
It is specifically designed to avoid hepatic metabolism which results in almost complete first-pass clearance/elimination of remdesivir when it is administered by the traditional oral route. The findings from both preclinical and human studies indicate that the drug is able to undergo absorption when administered using the novel oral formulation. The novel formulation was well tolerated by all the study subjects with no additional safety/ tolerability profile as compared to the injectable product.

In May 2020, Jubilant entered into a non-exclusive Licensing Agreement with Gilead Sciences, Inc. (NASDAQ: GILD) that granted it the right to register, manufacture and sell

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*From an FDA presentation in May 2013; Impurities and drug degradation were among the top three recall reasons in 2010, 2011 and 2012.
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Gilead's remdesivir in 127 countries including India. On July 20, 2020, Jubilant received approval from the Drug Controller General of India (DCGI) to manufacture and market the antiviral drug remdesivir ("JUBI-R") for 100 mg/vial (lyophilized injection) for restricted emergency use in India for the treatment of severe COVID-19.

"We are pleased to announce the ongoing development of a novel formulation of Remdesivir to address the pandemic at this critical juncture. Once approved, this will not only provide a more convenient and easy-to-administer formulation but also support an increasing demand of COVID-19 treatments." stated Mr. Shyam S. Bhartia, Chairman and Mr. Hari S. Bhartia, Co-Chairman and Managing Director, Jubilant Pharmova Limited.

VAV Lifesciences Inks Deal To Supply Crucial Ingredient For M-RNA Based COVID-19 Vaccines

Mumbai, India: India's research-driven biopharmaceuticals manufacturing company, VAV Lifesciences, through its subsidiary VAV Lipids, has agreed with a US-based multinational contract development and manufacturing organization (CDMO), to manufacture and supply highly purified synthetic phospholipids suitable for vaccine manufacturing. The CDMO will use lipids made by VAV to produce gene-based lipid nanoparticles (LNPs) on behalf of brand owners namely Pfizer-BioNTech and Moderna.

VAV Lifesciences Pvt Ltd, which is headquartered in Mumbai, is the only Indian company whose lipids will be used in the

Arun Kedia, Managing Director, VAV Lifesciences

mRNA-LNP technology-based vaccines. The company will play a vital role in the global mRNA-based vaccine supply chain It will thus play a vital role in the global vaccine supply chain. The company has already initiated a commercial supply of phospholipids for large-scale vaccine manufacturing through its EU cGMP certified facility under its subsidiary company, VAV Lipids, based at Ratnagiri in Maharashtra.

Phospholipids are crucial biomolecules used in the manufacturing of m-RNA based COVID-19 vaccines. These synthetic lipids are used in the formulation of lipid nanoparticles (LNPs), very tiny lipid particles which enclose submicroscopic mRNA strands. These LNPs effectively deliver the mRNA to the target cellular sites and help bind these to the relevant cells. Since mRNA, on its own, is extremely sensitive to degradation and rapid breakdowns, lipid nanoparticles (LNPs) ensure the protection of the mRNA until

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its uptake in cells. This results in a better cellular response and efficacy against virus replication, significantly enhancing the overall immunogenic response of vaccines.

Speaking about this development, Arun Kedia, Managing Director, VAV Lifesciences said, "While a lot of importance has been given to the bottling and distribution of vaccines, there is little understanding of the science behind the formulation of lipid nanoparticles (LNP). LNP technology is considered a medical breakthrough in vaccine-based delivery systems. It has enabled the development of mRNA-based Covid-19 vaccines at a blistering pace. We are proud to be the first and only Indian company to produce high-quality phospholipids that have been approved for use in these novel vaccine delivery systems."

According to the company, contrary to what most people think, the volume of lipids utilised in vaccine delivery is very small and measured in micrograms. Hence the mRNA-LNP concentrate is produced in small amounts. Each order volume is about 250 kg and is roughly valued at Rs 50 lakh (approximately USD 67000). However, the platform of gene delivery is transformative to human health and offers profound possibilities of disease elimination and cure.

VAV has already started receiving orders on a regular basis from the CDMO. Of this, about 80% of the order quantity has been either delivered or is in the supply chain with new orders already under discussion. VAV will manufacture all its synthetic phospholipids at its EU cGMP certified facility at Ratnagiri in Maharashtra.

Evonik Delivers First Lipids From German Facility To Biontech

Christian Kullmann, Chairman, Evonik Industries

Essen, Germany: Evonik is helping to accelerate the production of the COVID-19 vaccine from Pfizer-BioNTech by suppling an essential component. Evonik is delivering first batches of the urgently needed lipids for the mRNA-based vaccine to BioNTech months earlier than planned. Specialists at Evonik's Hanau site had set up the lipid production in just eight weeks, meeting the high-quality requirements for the component. Initially, delivery was scheduled to start in the middle of the year.

"Setting up production at this speed is a great achievement," says Christian Kullmann, chairman of Evonik's executive board. "Increasing lipid production in Germany will also allow us to further accelerate the manufacturing of larger quantities of the

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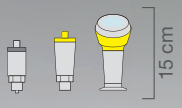

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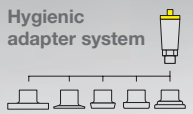

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vaccine. In this way, we are contributing to the fight against the pandemic."

As part of its strategic partnership with BioNTech, Evonik produces two different lipids for the Pfizer-BioNTech COVID-19 vaccine. Together with other lipids, they encapsulate to form a lipid nanoparticle (LNP), which serves as a protective shell around the mRNA to transport it safely into the cell. There, the mRNA is released to allow the vaccine to take effect.

"This is a complex production process that only a few in the world master," says Dr. Thomas Riermeier, head of Evonik's Health Care business line. "We're demonstrating once more that Evonik is a superior and reliable partner for the pharmaceutical industry, far beyond COVID-19.

Yokogawa Bio Frontier And Bloom Biorenewables Ink Agency Agreement To Develop Lignin Biomass Materials Business In Japan

Tokyo, Japan: Yokogawa Bio Frontier Inc., a subsidiary of Yokogawa Electric Corporation "Yokogawa", and Swiss startup Bloom Biorenewables SA ("Bloom") announce the signing of an agency agreement to promote biomass material in Japan. Under the agreement, Yokogawa Bio Frontier will provide Bloom's products to potential customers in Japan in the chemical, food, cosmetic, and pharmaceutical industries who are interested in alternatives to petrochemicals, and develop market opportunities. The agency agreement builds on the investment and partnership agreement signed by Yokogawa and Bloom in August 2020. It will enable Yokogawa Bio Frontier and Bloom to evaluate customer needs and market demand in Japan and expand the sales of Bloom's products in the region. It is the first initiative for the newly established Yokogawa Bio Frontier, and marks the company's first step as a provider of biomass materials to a range of industries. Bloom has developed ground-breaking technologies to manufacture chemicals and fuels from plant-based raw materials.

The startup focuses on valorizing underutilized parts of plants, such as hemicellulose or lignin* found in all non-edible agricultural wastes or in wood. These new biomass-based products are expected to substitute current fossil-based materials in applications such as fragrances, flavorings, cosmetics, and pharmaceuticals. The potential of these biomass materials continues to attract strong attention, and Bloom has received additional investment led by the Breakthrough Energy Ventures-Europe investment fund to accelerate the market entry of its bio-based chemical products.

Mitsuhiro Iga, President and CEO of Yokogawa Bio Frontier, commented, "This agency agreement marks the starting point for concrete business collaboration with Bloom. For Yokogawa Bio Frontier, we plan to make this 2 initiative a key pillar of the environmental business portfolio we will

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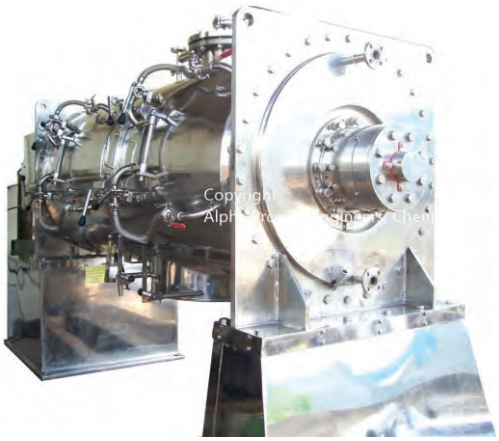

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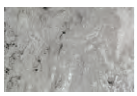
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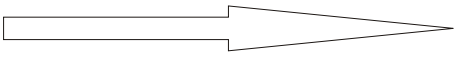


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build over the long-term. Moving forward, we will work closely to achieve the goal shared by both companies the adoption of environmentally friendly materials on a global scale."

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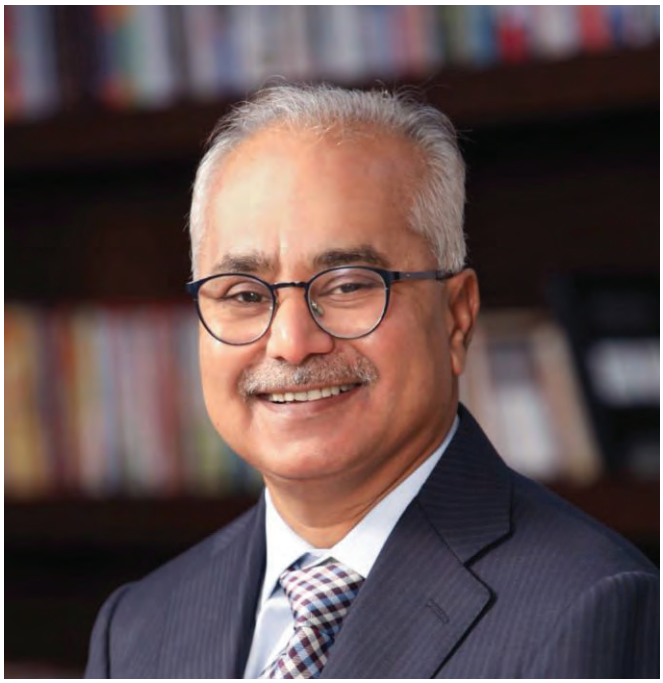
Dr. Reddy's Laboratories Gets Emergency Use Authorisation For Sputnik V In India

Hyderabad, India: Dr. Reddy's Laboratories Ltd. announced that it has received the permission from the Drug Controller General of India (DCGI) to import the Sputnik vaccine into India for restricted use in emergency situations as per the provisions of the New Drug and Clinical Trials rules, 2019 under the Drugs and Cosmetics Act.



GV Prasad, Co-chairman & Managing Director
Dr. Reddy's Laboratories Ltd

In September 2020, Dr. Reddy's had partnered with the Russian Direct Investment Fund (RDIF) to conduct the clinical trials of Sputnik V and distribute the vaccine in India. In addition to the trials conducted in Russia by RDIF. Phase II / III clinical trials of the vaccine were carried out by Dr. Reddy's in India.

Dr Reddy's Laboratories Co-chairman and Managing Director, GV Prasad said, "We are very pleased to obtain the emergency use authorisation for Sputnik V in India. With the rising cases in India, vaccination is the most effective tool in our battle against COVID-19. This will enable us to contribute to our nation's effort of vaccinating a significant proportion of our population."

Sputnik V is now approved for use in 60 countries around the world. It ranks second among coronavirus vaccines globally in terms of the number of approvals issued by government regulators. Sputnik V uses two

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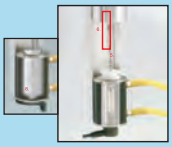
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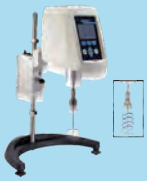
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RHEOLOGY VISCOSITY TEXTURE IN-LINE POWDER MOISTURE GAS

different vectors for the two shots in a course of vaccination. The efficacy of Sputnik V was determined to be 91.6% as per a published article in the Lancet, one of the world's oldest and most respected medical journals.

Hester Acquires Technology From ICAR – IVRI To Commercialise Classical Swine Fever & Sheep Pox Vaccine

Rajiv Gandhi, CEO & MD, Hester Biosciences Ltd

Ahmedabad, India: Hester has signed two agreements with ICAR-IVRI (Indian Council of Agricultural Research – Indian Veterinary Research Institute),for acquiring technologiesfor the production and commercialisation of Classical Swine Fever Vaccine and Sheep Pox Vaccine.

These vaccines are the first that have been developed within the country by using locally isolated strains, a step towards making India self-sufficient, Atmanirbhar, for the country's requirement of Classical Swine Fever Vaccine and Sheep Pox Vaccine.

The agreements were signed on 26 March 2021, followed with a virtual ceremonythat took place on 7 April 2021. The technologies were developed by ICAR-IVRI and the commercialization of the technologies was facilitated by Agrinnovate India, a company owned by Department of Agricultural, Research & Education (DARE), Ministry of Agriculture, Government of India.

Both the vaccines have been extensively tested by IVRI for safety and potency and have been found to provide 100% protection.

Classical Swine Fever Vaccine has been found to induce protective immunity up to 24 months. Sheep Pox Vaccine has been found to induce protective immunity up to 48 months.

The vaccines hope to prevent economic losses in swine and sheep farming in India. It is Hester's endeavour to produce good quality vaccines, at low cost in order to enable the immunisation of animals against these diseases.

Hester has targeted to launchboth the vaccines commercially in approximately 8 months. The swine population in India is estimated to be 9.06 million (90 lacs).The sheep population in India is estimated to be 74.26 million (7.42 crores).With a focus on livestock as a source of income, the over-all population of swine and sheep is expected to grow rapidly thereby increasing the demand for vaccines.

Dr. Reddy's Laboratories Launches Sapropterin Dihydrochloride Powder For Oral Solution

Marc Kikuchi, Chief Executive Officer, North America Generics, Dr. Reddy's Laboratories

Hyderabad, India, Princeton, USA: Dr. Reddy's Laboratories Ltd. Along With Its Subsidiaries Announced The Launch Of Sapropterin Dihydrochloride Powder For Oral Solution, 100mg, A Therapeutic Equivalent Generic Version Of Kuvan® (Sapropterin Dihydrochloride) Powder For Oral Solution, 100 Mg, USP, Approved By The U.S. Food And Drug Administration (USFDA).

"We Are Pleased To Launch This Generic Version Of Sapropterin Dihydrochloride Powder For Oral Solution, Illustrating Our Continued Commitment To Bring Affordable Generic Medicines To Market For Patients," Says Marc Kikuchi, Chief Executive Officer, North America Generics, Dr. Reddy's Laboratories. "At The Same Time, This Product Demonstrates That We Are Actively Expanding The Breadth Of Our Portfolio With A Treatment For A Rare Disease."

Dr. Reddy's Sapropterin Dihydrochloride Powder For Oral Solution Is Available In 100 Mg Unit Dose Packets In A 30 Count Carton.

Emcure Pharmaceuticals Launches 'Uncondition Yourself' An Initiative Dedicated To Women's Health And Wellness

Pune, India: Emcure Pharmaceuticals, among the top 15 pharmaceutical companies in India, announced the launch of 'Uncondition Yourself' – an initiative dedicated towards women's well-being. The campaign launched on the occasion of 'World Health Day' will seek to identify and address the prevalent notions and misconceptions about women's health and well-being from cultural and social context in India. In the first phase, the campaign aims to put forth the challenges and connect with relevant influencers to initiate a step towards building a supportive ecosystem for women in the workforce. The campaign will involve on-ground engagement and online activities at a national level.

Speaking on the occasion, Ms. Namita Thapar, Executive Director, Emcure Pharmaceuticals, said, "Despite the economic advances we have made, even today, issues related to

Namita Thapar, Executive Director, Emcure Pharmaceuticals

women's health are associated with irrational taboos. These lead to stigmatization and more worryingly holding back among women about their health issues. Through the 'Uncondition Yourself' initiative we hope to bring to light important health issues India's significant women workforce face, and to educate them to make informed choices in their day-to-day actions."

The campaign is an outcome of an online talk show 'Uncondition yourself with Namita' featuring candid heart to heart conversations on women's health issues, giving accurate information and dispelling various myths. This programme received a tremendous response which encouraged the company to launch its 'Uncondition Yourself' initiative to engage with a wider audience.

Promoters Of Lincoln Pharma Increases Promoter Group Holding By 4.9% During FY 20-21 To 37.25%

Mahendra Patel, Managing Director Lincoln Pharmaceuticals Limited

Changodar, India: Promoter group of Lincoln Pharmaceuticals Ltd, one of India's leading healthcare companies is gradually increasing their holding in the company. During the FY 2020-21, the promoter group has bought 9.8 lakh shares from the secondary market - at an average price of Rs. 225.6 per share. With this, promoter holding in the company has increased to 37.25% - rise of 4.9% (490 bps) from 32.35% as of 31 March 2020. Rating agency ICRA has recently upgraded the company's long-term and short-term bank facilities to A and A1 respectively.

The Securities and Exchange Board of India under creeping acquisition allows promoters of a listed company to enhance promoter group holding by 5% in a financial year. Share price of Lincoln Pharmaceuticals Ltd was Rs.

222.6 per share on 30 March 2021. Share price of the company have risen 160% from March 2020 low of Rs. 85 per share and also made a high of Rs. 283 per share.

"We are committed and plan to gradually up the promoter holding ideally to a majority mark over the next 3-5 years. Our company is growing from strength to strength and delivering robust operational and financial performance while maintaining healthy growth in revenue, margins and profitability and expects to continue the growth momentum in the coming years. Our strategic growth initiatives, product and geographical expansion, EU approval and operational efficiency are likely to maximise value for all stakeholders in the near to medium term. The recent upgrade by ICRA for the company's long-term and short-term ratings further testifies the strong foundation of the group," said Mr. Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Limited.

Rating agency in its report has stated that the upgrade in ratings takes into account the improvement in the group's financial risk profile in FY2020 and 9MFY2021, backed by steady growth in scale and margins. The report further states that, Healthy profitability and limited capex outgo have improved the coverage indicators and liquidity, resulting in healthy built up of free cash/liquid investments.

During FY20, the company has become a zero net-debt company. Company has received EU approval and plans to enter the EU markets very soon with its dermatology, gastro and pain management products. Company currently exports to more than 60 countries and plans to expand to 90 plus countries.

For the nine months ended December 2020, the company has posted a net profit of Rs. 48.6 crore as against net profit of Rs. 40.3 crore, growth of 20.7%. Net revenue also grew by 10% Y-o-Y to Rs. 339.8 crore in nine months ended December 2020.

Augmentation Of Manufacturing Capacity For COVAXIN Production Under Mission COVID Suraksha

New Delhi, India: Under Atmanirbhar Bharat 3.0 Mission COVID Suraksha was announced by the Government of India, to accelerate the development and production of Indigenous COVID Vaccines. This is being implemented by Department of Biotechnology Govt of India.

Under the Mission the Department of Biotechnology Govt of India is providing financial support as Grant to vaccine manufacturing facilities for enhanced production capacities. The current production capacity of indigenously developed Covaxin vaccine will be doubled by May-June 2021 and then increased nearly 6-7 fold by July - August 2021 i.e increasing the production

from 1 crore vaccine doses in April, 2021 to 6-7 crore vaccine dose/month in July – August. It is expected to reach nearly 10 crore doses per month by Sep 2021.

Few weeks back, Inter-ministerial teams had visited the sites of 2 main vaccine manufacturers in India to get their inputs on how production can be ramped up. In this period, there have been extensive reviews and feasibility studies on the plans being discussed with vaccine manufacturers.

As a part this augmentation plan, capacities of Bharat Biotech Limited, Hyderabad as well as other public sector manufactures are being upgraded with required infrastructure and technology. Financial support is being provided as grant from GoI to the tune of appx Rs 65 Cr to Bharat Biotech's new Bangalore facility which is being repurposed to increase the capacity of vaccine production.

3 public sectors companies are also being supported to increase the capacity of vaccine production.

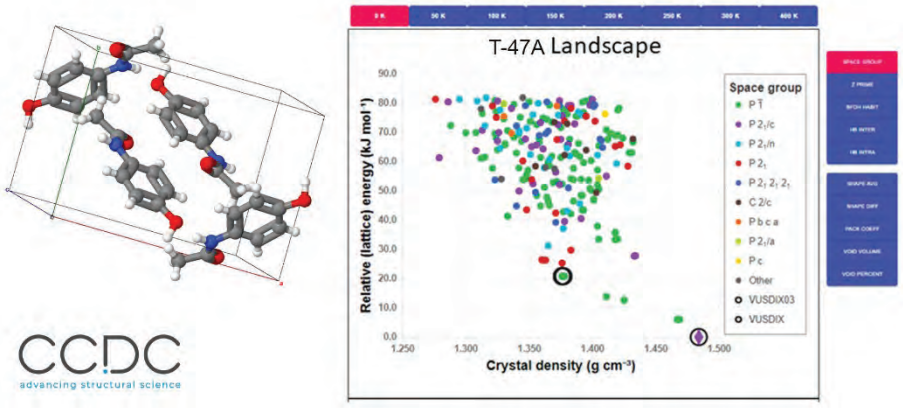
Haffkine Biopharmaceutical Corporation Ltd , Mumbai –a State PSE under State Govt of Maharashtra. Financial support as grant from GoI to the tune of appx Rs 65 Cr will be provided for this facility to be made ready for manufacturing.The Haffkine Biopharmaceuticals Ltd had asked for around 12 months to complete this task.However, the Central government has asked them to expedite and complete the task urgently within 6 months. The facility will have a capacity of 20 million dozes per month, once functional.

Indian Immunologicals Limited (IIL), Hyderabad –A facility under National Dairy Development Board and Bharat Immunologicals and Biologicals Limited (BIBCOL) , Bulandshahr a CPSE under Department of Biotechnology ,Govt of India will also be supported to prepare there facility to provide 10-15 million dozes per month by August - Sepember 2021.

Cambridge Crystallographic Data Centre Simplifies Management Of Complex Crystal Structure Prediction Data

Cambridge, UK : The Cambridge Crystallographic Data Centre (CCDC) announces the launch of CSD-Theory software for use in small molecule pharmaceutical development. This latest addition to the CCDC's software toolbox delivers easy storage, management, search and display of crystal structure prediction (CSP) results alongside experimental structures on a web-based platform and an API interface. The new software, developed in collaboration with six major pharmaceutical companies, will enable organisations to incorporate and share CSP knowledge earlier and more easily in small-molecule drug development—reducing risks and shortening the time to market.

Small molecule therapeutics are regularly administered in crystalline, solid forms which undergo extensive testing to ensure stability, efficacy and safety. However, the 3D structure and packing of the crystalline form significantly impacts the properties of the therapeutic and, to further complicate matters, it is possible for a small molecule to have multiple crystal forms (known as polymorphs).



These polymorphs have the same molecular structure, but different packing. Predicting alternative polymorphs is both very important and very complex; predictions can produce hundreds, if not thousands, of possible crystal structures. Varying polymorphs can be unstable in storage, ineffective, or at worst unsafe, which can, and has led to, drugs being pulled from market—costing millions. For example, rotigotine, the active ingredient in transdermal patches for Parkinson's disease, was withdrawn for reformulation due to an unexpected polymorph in 2007.

The ability to reliably predict the occurrence of polymorphs in silico would enable pharmaceutical companies to identify and mitigate such risks earlier, as well as identify and progress suitable candidates faster with less issues. While CSP is already a key part of the drug development process for many companies, the science and tools are still evolving. Exploration of CSP data is a bottleneck, with data often confined to a handful of computational specialists.

As a registered charity, an active centre of research and a producer of leading informatics software, the work that the CCDC does in collaboration with academic institutions, pharmaceutical companies and external software providers is critical to advancing methods in structural science, developing new approaches and expanding the utility of existing tools.

The new CSD-Theory software provides a user-friendly, interactive web interface that simplifies the CSP data storage, management, search and display, enabling users of all levels to access and share critical information across teams. The additional API component allows CSP data to be stored ready for AI or ML analysis. Capable of handling the full spectrum of CSP-data types and providing a platform to easily share results, CSD-Theory is set to drive forward the data-first approach in pharmaceutical drug development.

As well as the new software, the CCDC has an extensive and growing suite of tools to aid molecule discovery and materials design—including the Cambridge Structural Database (CSD)—the world's repository for small-molecule organic and metal-organic crystal structures. The CCDC also runs collaborative initiatives to drive advances in CSP such as the CSP Consortium and CSP Blind Test.

Similar to the CASP protein structure predicting challenge, which saw tech giants such as Google push the boundaries of protein folding prediction in 2020, the CSP Blind Tests enable researchers to test

novel methods for small-molecule CSP in a controlled, unbiased setting—facilitating the development of computational techniques to predict crystal structures. The chemical systems tested are unpublished crystal structures sourced by the CCDC, overseen by an external referee from crystallographers across academia and industry. Previous years have demonstrated that these Blind Tests translate to real world results that have the potential to revolutionize the pharmaceutical industry.

Highlights of the Drug Discovery and Development Workshop

Prof. P. Reddanna, Eicosanoids, Inflammation & Cancer Research Group, School of Life Sciences University of Hyderabad

Hyderabad, India: The Federation of Asian Biotech Associations (FABA) in collaboration with the Science Gurus (sciencegurus.org) and the University of Hyderabad (uohyd.ac.in) conducted a 21day virtual workshop on drug discovery and development from the 15th of March to the 4th of April 2021. The workshop was sponsored by NATCO Pharma, co-sponsored by Jackson Laboratories and the awards were sponsored by Cytiva Life Sciences. Nearly sixty-eight participants from various universities and industries of the country and abroad registered for the workshop. The workshop had 5 participants from Bangladesh, 2 from Israel, 1 from Iran, and 15 industrial participants from Syngene, NATCO Pharma, Aragen Life Sciences and Hetero Pharma, and the remaining were from the elite Indian universities such as The Indian Institute of Technology, the Center for DNA Fingerprinting (CDFD) Hyderabad, the University of Hyderabad and JNTU to name a few.

The Inaugural address on the 15th of March was initiated with welcome address by Prof. P. Reddanna, Executive President, FABA and Dr. Asadulghani, President, FABA followed by the inaugural address by Ms. Anuradha Acharya who spoke about the advances in personalized medicine and Dr. Jagath Reddy Junutula, Board Chairman, Science Gurus who introduced the participants to the main features and schedule of the workshop and a final vote of thanks by Dr. Bindu Madhava Reddy from university of Hyderabad.

The highlights of the workshop were the speaker sessions which were held as two to three sessions per day spanning the period of the workshop. The 45 invited speakers included accomplished scientists, from the academia and industry from the US and India. The topics and sessions were designed so as to equip the participants with the required knowledge of how drugs

against diseases are first discovered then extensively tested, developed and industrially manufactured before making them available to the public. Sessions were held on Targeted drug therapies, Personalized medicine, Gene Therapy, the advances in CADD, AI and Bioinformatics for the purpose of discovering drug targets and designing drugs, Animal models for drug testing, Industrial manufacturing and large scale production of drugs, legalities of drug manufacturing, IPR and Regulatory issues, and Capital, Funding required for Pharma and Drug Startups. Prominent speakers in these sessions included, Dr. Rami Reddy Mutyala (RR Labs), Dr. Ajith Kamath (Pandorum Technologies), Dr. Chakk Ramesha (Medhus Bio), Dr. Uday Saxena (ReaGene Innovations), Dr Eswara Reddy (DGCI) and Dr. Mohan Vemuri (Thermo Fisher Scientific).

In addition to the speaker sessions the participants presented a 15 mins presentation on relevant disease and drug development topics such as Alzheimer's, B-cell Lymphoma, Hepatitis, and the best presenters were awarded at the end of the work shop. Senior industrial representatives from Syngene, NATCO Pharma and Aragen Life Sciences enthusiastically took part in all the participant activities and presentations. Their initiative motivated the participants especially the young graduates and postgraduates in the direction of industrial research. The evaluation was done by the participants and the final awards were distributed based on these scores in addition to the participants' attendance and active participation in the workshop.

The sessions and presentations for the workshop concluded on the 4th of March 2021. The closing ceremony began with Dr. P Ratnakar and Dr. Surya Sankuratri who introduced FABA and the Science Gurus respectively to the audience. The keynote speaker Dr. Anula Jayasuriya engaged the invited guests, participants and organizing members with her talk on capital funding. The highlight of the closing ceremony includes a panel discussion on "Pharma and Biopharma Industries in India: Challenges and Opportunities in Innovative Drug Discovery and Development", involving the panelists from the academy, industry and the Government agencies and moderated by Dr. Uday Saxena, ReaGene Innovations. The panel discussion highlighted key challenges such as lack of interactions between the basic scientists and clinicians, lack of academy – industry interactions, risk averse of the Indian Pharma and Biopharma industries, and lack of effective venture financing ecosystem. It is opined that the startup ecosystem, supported by the Government agencies such as BIRAC, has played key role in promoting innovation and entrepreneurship in the country but to take it to the next level the country needs a robust venture financial ecosystem and drive of the Indian industry taking a risk for innovative drug discoveries to the next stage. The panel discussion was a highly interactive session and panel members such as Dr. Anand Anand kumar (Bugworks), Dr. Tanjore Balganesh (GangaGen), Dr. Srikar Raman (Levim Biotech), Dr. Manish Diwan (BIRAC) and Dr. Nishith Tyagi (Novartis) addressed the questions posed to them by the invited guests, participants and attending students.

The workshop drew to a successful close with Dr. Jagath Reddy Junutula's closing address to the audience, where he highlighted the main

features and topics covered by the speakers, the participant presentations and the efforts of FABA, the Science Gurus and the University of Hyderabad to make this 21day virtual workshop a success. He also thanked the sponsors for their generosity and the organisers made a commitment to carry out more such workshops, which could be held in the future.

Trulymadly's Matchmaking Engine To Help COVID-19 Patients Find Right Plasma Donors

Snehil Khanor, CEO & Co-founder, TrulyMadly

Delhi, India: As the country records the highest number of daily COVID-19 cases in the world, the scarcity of oxygen and plasma among other resources has led to demand outstripping supply. In lieu of this, TrulyMadly, India's leading dating app has deployed its matchmaking algorithm to help COVID patients match plasma donors with patients. The feature has been added to TrulyMadly's initiative Corona Clusters, which was launched last year to update people on latest pandemic related data and is used by more than 30-Lakh users each month.

The 'Plasma matchmaking' feature helps both plasma donors and patients find the right match thereby bringing relief to families of patients, who have to undertake a frantic search for plasma donors and also help plasma donors help people in need.

To make the process fast and more efficient, the Plasma Donation feature captures and matches all critical information from both the patient and donor, including their blood group, COVID-19 diagnosis date, location, contact details, and phone number.

TrulyMadly CEO & Co-founder Snehil Khanor said, "The second wave of the pandemic has severely affected the country and despite information being available, it is largely unverified or dated in nature and only adding to the information overload. We decided to use the underlying technology of our matchmaking engine for couples to also help COVID-19 patients meet the right plasma donor. This feature has been launched on CoronaClusters.in, we appeal to people, who have recovered from COVID-19 to come forward, and register on the platform to help save lives of those whose immune system is unable to fight the infection. We wish to help as many people as possible with this initiative and contribute meaningfully in fighting this pandemic."

Early in the pandemic, the dating app launched the nationwide multilingual website to apprise users about COVID-19 related information, including state-wise segregation of cases and district and state level health bulletins, among others. Corona Clusters uses verified crowdsourced data & APIs from Covid19India.org and shares updates on the number of total active, recovered, and death cases on a real time basis. ■

One-Pot Batch-mode Synthesis – A Veritable Challenge to Continuous-mode Synthesis

N Muralidhar
Technical Director
Alpha Process Engineers

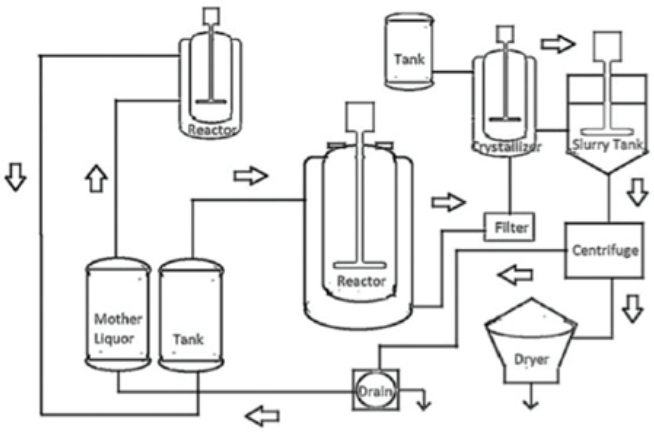
Batch-mode synthesis is the most adopted route in the Chemical and Allied Industries the world over; these industries include Bulk Drugs/APIs, Drug-Intermediates, Fine Chemicals, Speciality Chemicals, Agro-Chemicals (including Pesticides & Insecticides) & Dyes and Dye-Intermediates. Here, each step in the synthesis is characterized by a Unit Operation and the equipment that executes the step is unique in its ability to perform the desired unit operation.

Since its inception, the process industry has embraced batch-mode synthesis centred around unit operations because of their identity with lab-scale synthesis and utter simplicity and naturally enough, plant-scale technologies have evolved around these unit operations; with every advancing generation, scientists and researchers worked towards technology upgradation in each of the established unit operation steps in the synthesis of the chemical. So much so that it is still inconceivable, today, to think of setting up a new Chemical Plant without enumerating the unit operations in the production route to be adopted and identifying the equipment (for investment in) that will optimally fulfil the processing needs to profitably reach the products to their respective markets.

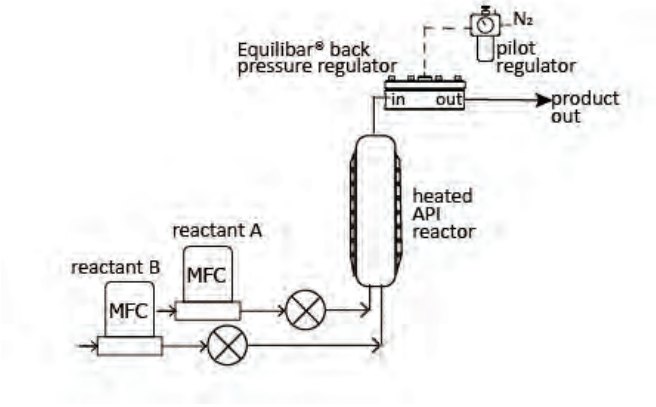
Over the years, an alternate synthesis route, founded on the principles of Flow Chemistry, has received increasing attention. While this alternative route also recognizes the fact that synthesis of most chemicals follow definitive steps that are also characterized by Unit Operations, the manner in which it executes these steps fundamentally differs from that adopted by a batch-mode of synthesis, essentially

in the time dimension, while the rest of the process parameters of pressure, temperature, stoichiometric composition, concentration etc governing each step largely tend to remain consistent with that of the batch mode, with some caveats. Flow Chemistry technology is still evolving. It must however be noted that, given the state of this technology today, Flow Chemistry has been successfully adopted in the synthesis of only a few chemicals. It is not viable in situations where, for example, the product is a low volume product, or a company needs to switch to synthesis of many products every month. A high-volume product, as of now, appears to be better suited for adoption of Flow Chemistry in its synthesis. If viable, it then becomes a dedicated line for that product.

The figures below give a basic picture of the batch-mode and continuous-mode (Flow Chemistry based) of chemical synthesis.



Batch-mode (Ref-1)



Continuous-mode (Ref-2)

The conventional advantages of Batch-mode synthesis remain its main attraction and economies of scale continue to justify its large-scale adoption in the Indian Process Industry. Synthesis consists of one or more Reaction(s) together with associated Work-ups / Purifications steps and usually requires several independent and distinct steps. Each step is usually carried out in a separate equipment. This results in multiple transfers of intermediate masses between equipment. Also, quality parameters at the beginning / end of most of these discrete steps are defined to help ensure repeated achievement of consistency in quality of the end product. However, in industries such as Bulk Drugs/APIs and Intermediates, Speciality Chemicals, Fine Chemicals etc that cater to the requirements of regulated markets, the requirement of stringent quality adherence and associated audits have necessitated achievement of quality parameters at almost every

intermediate stage of the synthesis. This entails requisite documentation-support that help trace quality non-performance to a particular intermediate step, in the event of failure on quality front of a product. Conforming to such defined quality parameters and the maintaining of multitudes of documentation in support of such quality conformance has remained a key sore point for the manufacturers.

Another typical feature of batch-mode synthesis has been the use of several equipment in the synthesis and work-up/ purification. There are almost as many equipment involved as there are number of processing steps. It is not uncommon to notice manufacturers investing in batteries of each unit-operation equipment (like several Reactors of varying capacities, several Separation Equipment like Distillation Columns, Filters, Extractors etc, several Crystallizers / Precipitators, several Dryers etc) when setting up a plant to manufacture several products. Such a configuration invites complex equipment planning / scheduling / cleaning tasks. Associated with this complex task is the engagement of more labor, movement of material between equipment, yield loss, susceptibility to quality deviation due to contamination etc, etc. Despite these issues with Batch-mode synthesis, investment in a new Chemical Plant continues to reliant on this mode of synthesis.

In the debate, Flow Chemistry or Continuous-mode synthesis Vs Batch-mode synthesis, there is an increasing shift towards the Continuous mode internationally, on the backing of the big-league players, but the debate has only just begun and is far from over. In India too, the situation is not any different. Proponents of Continuous-mode synthesis cite certain key arguments to support their leaning. These essentially are :

- Continuous, without break, synthesis, reducing human error
- Better Quality
- Less Space
- Lower Yield loss
- Lower operating costs

While Flow Chemistry or Continuous-mode Synthesis is seeing more of industrial-scale implementation, that appear to be throwing up evidence in favour of as well as against the new Technology, more and more data is getting generated for the protagonists to work upon the shortcomings and improve the implementation criteria of this technology. The batch-mode protagonists, on the other hand, do not appear to be much concerned about the erosion in support for this long-standing, proven technology.

Time has therefore come to address this issue (shortcomings of batch-mode synthesis) in a manner that draws upon all available engineering and technology resources to mitigate the associated

pain and distress attributed to the batch-mode synthesis, in a definite, consistent and wholesome manner. Batch-mode synthesis can be improved upon to match the benefits, if not exceed them, of the Continuous-mode synthesis. There is no reason to believe that, with paradigm shift in batch-mode definition and its implementation, continuous-mode synthesis would replace the batch-mode technology in the industry yet.

We need to begin by re-visiting the synthesis of Chemicals. Chemistry has taught us that the most efficient synthesis of any chemical product is by adoption of "One-Pot Process". Since it is considered an ideal condition and therefore 'impossible' to achieve, the multi-step-multi-equipment format in synthesis found ready acceptance as the next best. We need to question this. We need to subject this hypothesis to rigorous evaluation.

'One-Pot Synthesis' & 'One-Pot Reactions' are terms commonly used, many times interchangeably. In reality, 'One-Pot Synthesis' goes beyond 'One-Pot Reactions.' In addition to Reactions, if one can do the work-ups in the same equipment then we would be closest to 'One-Pot Synthesis.' If all of work-up stages cannot be executed in the same equipment, then the next best thing would be to execute as many as possible in the equipment. Even this step, to begin with, would mean process economy and result in a far-improved batch-mode synthesis. Some of the issues with the current practice of batch-mode would have got resolved.

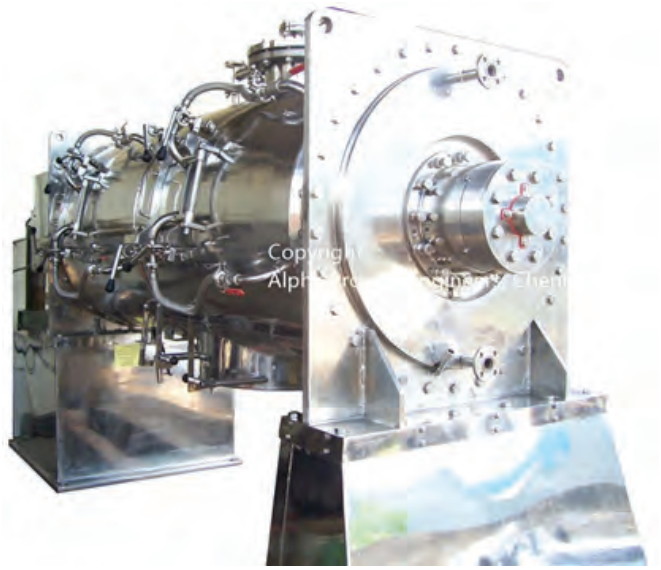
One-Pot Reactions result when one re-designs Reactions such that the desired product, requiring several Reactions in their synthesis, is obtained as a result of just one multi-step Reaction, instead of several independent Reactions. This is easily said than done. This has been researched extensively and success reported in synthesis of many molecules / chemicals. This has helped cut down on several work-up steps and save on avoidable usage of solvents. This is also said to promote 'green' chemistry.

A more significant gain can be realized if, together with this 'One-Pot Reactions', one can carry out one or more work-up/ purification stages in a synthesis in the same equipment, thereby minimizing mass transfers, reducing other solvent usage, recovering solvents where used, increasing contained operations, reducing yield loss, reducing batch cycle-times and achieving greater consistency in quality of the end-product. Need for cleaning substantially reduces to cleaning fewer equipment, thus eliminating instances for cross-contamination. Production scheduling also gets simplified. This emphasizes the need to design equipment such that several unit operations, subsequent to Reactions, can be carried out in the same equipment (Reactor), with requisite controls. To achieve this, a need to re-visit the underlying principles of Extraction, Distillation, Phase-separation, Crystallization, Precipitation, Filtration and Drying becomes apparent. Theory of Reactions and Reactor Design too need to be worked upon to help re-design agitation systems to achieve optimum efficiency in the combined sequence of synthesis-steps.

One-Pot Synthesis would thus eliminate breaks (pauses) between steps, reducing occasions of human error during a batch process – an important advantage attributed to Continuous Synthesis.

More than 3 decades ago, the introduction of Filter-Dryer (eg, Rosenmund's ANFD) was the first attempt to move towards One-pot processing. Though very successful, this did not provide impetus to combine other work-up / purification steps in a single equipment. In a limited sense, where the synthesis only involved Reaction and Drying, One-pot Reactor-Dryers were introduced successfully on industrial scale. The rest of the work-up processes remained independent and separate equipment continued to be used to carry out these steps. Thus Batch-mode synthesis continued to be equipment-intensive.

Today, a paradigm shift towards batch-mode One-Pot Synthesis has already begun. M/s Alpha Process Engineers (APE) is offering 2 distinctly independent Processors that come close to delivering One-Pot Synthesis. In one version, a Reactor-Dryer is offered where Reaction and Drying unit operations can be carried out in a sequence. The Processor incorporates feature of micronization too. As a result, lump formation is broken down effectively and fine dry powder is discharged. In the same category, APE offers a Reactor-Filter-Dryer wherein, in a single sequence of operations, Reaction, Extraction, Crystallization/ Precipitation, Filtration, Washing, Drying and Micronization can be effectively carried out, without the product leaving the system. This would symbolize the best of containment in any synthesis.



In the second version, a combination of 3 Processors together constitute the apparatuses for total synthesis. These 3 equipment can together execute the entire synthesis. This configuration becomes essential when phase-separation becomes necessary and the lighter phase leaves the equipment first, carrying the product with it.

Typically, synthesis of an API or Drug involves more than one stage and each stage consists of Reaction followed by work-ups or purification steps. Each stage becomes a fit candidate for One-Pot synthesis. And therefore, typically, an API or Drug synthesis can be executed in a couple or minimal number of One-Pot Processors, one for each stage at worst.

When the product of a reaction stays in the solid state throughout the synthesis, the first version of the Processor finds application. This is a Reactor-Filter-Dryer, a true One-Pot Processor. When as a Reactor, the agitation system brings the reactants together very efficiently and creates conditions for quick transformation of the reactants into products. This Reactor-Filter-Dryer is of horizontal configuration. It has been found to even obviate the need for a solvent-based medium for completion of a reaction (eg, the reactants, dimethylamine hydrochloride and dicyandiamide, combine to form metformin hcl without the aid of any solvent).

The agitation system does not stop due to load during reaction, as that in the conventional, vertical configuration Reactor is prone to, in the synthesis of several organic compounds. From gentle mixing to intense, turbulent agitation, the impeller system generates appropriate conditions for efficient reaction. Every type of Reaction, be it Combination, Decomposition, Neutralization, Single-displacement, Double-displacement, Precipitation, Redox or Combustion, is handled efficiently.

If the product of reaction does not go into dissolution during the entire synthesis, the first version of the Processor can handle the subsequent purification / work-up steps without the need to transfer the mass. Extraction, Crystallization, Precipitation, Filtration, Washing and Drying can be effectively executed in the same Processor in one appropriate

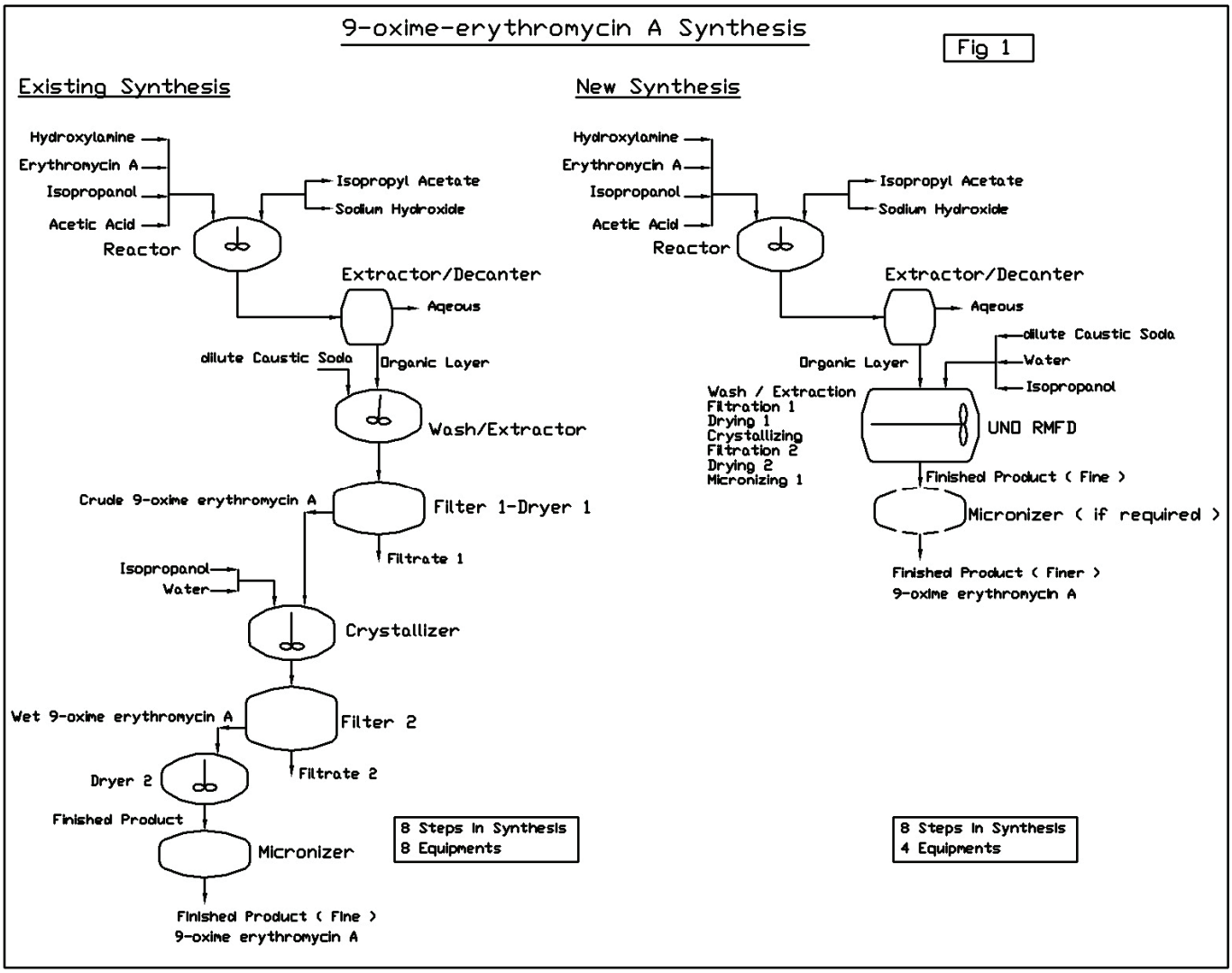


Fig. 1

sequence. This would represent a true One-Pot Processor, and the synthesis a true One-pot synthesis.

If the product of reaction enters into a liquid phase (dissolved), the second version of the Processor kicks in. Steps subsequent to Reaction cannot be continued automatically within the same Processor. Every time the product is carried into a dissolved state, it becomes necessary to separate product-carrying liquid in an external filter outside of the Processor, empty the Processor of the other bye-products and clean the Processor of residues, re-introduce the product-bearing liquid back into the Processor and complete the subsequent steps in the same Processor. A minor deviation from a literal One-Pot-synthesis, nevertheless, the complete synthesis can be completed in a minimum of 2 equipment.

Two illustrations would clarify the distinction between the two versions of

One-Pot Processors introduced by APE.

In the first illustration, referring to Fig. 1, the product dissolves in a solvent / aqua medium

at the end of the Reaction and leaves the Reactor, only to enter a One-Pot Processor where rest of the work-up / purification procedures are completed in a single equipment.

And in the second illustration, referring to Fig. 2, the product remains in solid state in stage 1 and 2 of synthesis and goes into solution in stage 3 of the synthesis.

In both the illustrations, the steps of synthesis (unit operations) are retained while achieving equipment economy, together with reduced space, reduced batch-cycle time, significantly improved yield, more consistent quality, reduced labor and significantly reduced production cost by adoption of One-Pot Synthesis.

APE has supplied several Reactor-Dryer versions. Applications include propionate metal salts as supplements for the poultry industry, Sodium and Magnesium Valproates and Divalproates (APIs in the treatment of Epilepsy etc) and others. The second version of One-Pot Synthesis involving a single Reactor-Filter-Dryer has been demonstrated successfully on pilot scale. Also, the 3-Processor application has been successfully demonstrated on a pilot scale for several products, including Metformin HCl for Industrial Clients. In this latter case, a batch was produced where the Reaction was carried out without solvent medium. This gave better quality end-product.

As is obvious from the two illustrations

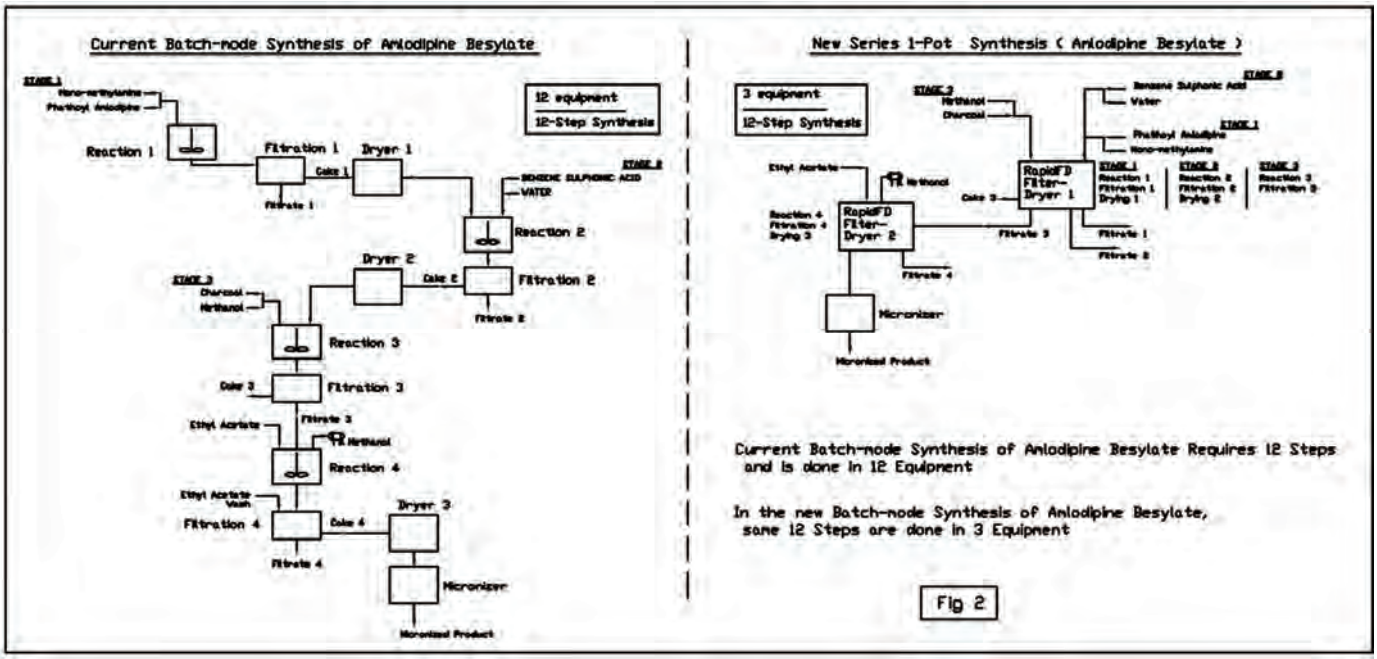


Fig. 2

above, adoption of One-Pot Processing in batch-mode synthesis results in the following tangible benefits :

- Higher yield.
- Substantial reduction in process / synthesis cycle time (15% to 60% of current cycle time).
- Elimination of some steps in the manufacture of APIs / Drugs / Intermediates.
- Lower energy costs.
- Reduction in Material handling.
- Reduction in space for manufacture of a product.
- Reduction in manpower required in the synthesis.
- Possible elimination of use of solvent in some stages of synthesis
- Overall equipment cleaning times greatly reduced compared to current practice.
- Improvement in the bottom-line of the Company.
- Lower Investment outlay for a given capacity Plant, compared to Investment in current practice.

To give a sense of the benefit this One-Pot batch-mode Synthesis offers, consider the setting up of a small-to-medium scale Bulk Drug / API manufacturing unit for synthesis of 12 products and their intermediates. A Company, adopting the conventional batch-mode synthesis route, made an estimate of Investment in Land, Building and Machinery which is given below under 'Conventional Batch-mode' column (column 2). To produce same batch-sizes of the 12 same products and intermediates considered in the original project, an estimate of Investment on facilities based on the new One-Pot synthesis described above is listed in column 3, for comparison. The Production-capacity of such a project based on the new One-Pot Synthesis is also given below.

It can be seen that the new One-Pot-Synthesis-based Investment would not only be lesser by Rs 65 Lacs but would also mean a higher Production capacity of plant since the batch-cycle times would be lesser. Lesser Operating Manpower would

"Table 1 : Benefit from adoption of One-Pot Synthesis Technology (Ref-3)
(In Setting up of New Plant to manufacture APIs / Bulk Drugs & Intermediates)"

	Conventional Batch-mode	New One-Pot Batch-mode
Land 14000 sq. ft.	Rs. 46.0 Lacs	Rs. 46.0 Lacs
Building	Rs. 90.0 Lacs	Rs. 90.0 Lacs
Plant & Machinery	Rs. 365.0 Lacs	Rs. 300.0 Lacs
Total Cost	Rs. 5.01 Crores	Rs. 4.36 Crores
Production Capacity	280 kgs/day or 8.5 Mts/month	500 kgs/day or 15 Mts/month
Operating Manpower	60	45
Mean Utilization	65%	80%

be required and, since lesser equipment would be needed, lesser cleaning times would result leading to higher productive utilization of equipment.

The example considered was of a small-to-medium scale plant. The benefits would be significantly larger for larger capacity Investments. The plant size as also the building size would be significantly smaller, translating into lesser Investment value.

The new route to batch-mode processing, One-Pot Synthesis, justifies the continuance of use of batch-mode synthesis in the years ahead, taking the sheen off the Continuous-mode Synthesis. The Continuous-mode Synthesis would no longer offer same advantages as claimed today over the Batch-mode. It would therefore do the Chemical and Allied Industries a whole lot of good to quickly upgrade their batch-mode technology and incorporate more of One-Pot synthesis into their existing production stream (while also considering new Plants on the basis of One-Pot Processing) and reap the benefits of continuous-mode synthesis. ■

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Technology Driving Pharma In A New World Order

Richard Porter
Global Director, Pharmaceuticals
Aspen Technology

Abhinav Choudhary
Country Manager
Asia South, Aspen Technology

For pharmaceutical manufacturers, an issue that the pandemic has highlighted is the need to be ready and quickly meet demand spikes. The requirement for vaccines to be brought to market and production scaled up at a much higher velocity is shaking up traditional research and development (R&D), clinical trials, and the supply chain, with their well established and often protracted processes. In recent months, the profile of drugs in demand has changed significantly. Some drugs have seen spikes as a result of induced or panic buying, others have seen troughs, along with shortages due to supply chain disruption.

While legislative compliance and process control remain critically important, the rapid development of Covid-19 vaccines has set a positive precedent with the ongoing expectation that drugs will continue to come to market faster than in the past. The pandemic has disturbed the equilibrium and Pharma 4.0 is well underway.

Finding a solution

When a pharmaceutical manufacturer discovers a new drug, in most markets they typically own its patent for 20 years. Many factors can affect the duration of a patent. Exclusivity laws depending on drug and market, mean actual market exclusivity from generic competitors is often far less.

Coupled with the high probability that it will take the manufacturer some time to bring a new product to market means the race is on.

The speed with which manufacturers can bring a drug to market can directly impact the lead time provided to drive up return on investment. A faster time-to-market translates to far-reaching commercial benefits to manufacturers. How can improved velocity best be achieved? The timeline required for clinical trials is often the key element. Product development can be a factor.

We expect the industry's experience with Covid-19 to permanently reset expectations, including the belief that innovation may compress the clinical trial timeline and put increasing pressure on product development to accelerate processes and ensure parallelization. Rapid batch release requires electronic batch records to be verified instantly. Analytical techniques need to be fast enough to allow corrective actions before quality is affected. Clean data allows for faster, better insights. That equates to faster, better decisions to be made.

The latest digital technologies can provide decision-makers visibility on product quality and consistency faster than before, but also providing them with unprecedented, deeper insights. This reduces the time taken and number of iterations to get the manufacturing process correct and validated, enabling them to reduce costs and improve public health. The effect on time-to-market depends on whether important data access is critical to product launch, which increases the robustness of the manufacturing process and reduces the risk of the product launch being delayed.

Process simulation tools can help select and deploy the right processes and assets to scale from pilot to full-scale manufacture. Simulation tools allow users to look across their supply chain for the right asset, or to understand that with some tweaking or re-engineering of the existing processes, they will be able to manufacture a new drug product in their existing plant.

Another trend is the increased use of multi-purpose plants. Historically, plants were built for specific drugs, even if global demand was tiny, in some cases, to the extent that such plants ended up mothballed when annual drug production was complete. As a result, there is a growing trend toward multipurpose and continuous plants, which can streamline drug throughput, reduce capital expenditure, and save money and time through better use of resources.

Challenges include demand from multiple different drug lines for the same equipment. Manufacturers need to consider if they can fit processes in, and where and when they have the necessary bandwidth or time in the day to do so. ■

Sturdy Yet Not Prevailing – The Pharmaceutical Supply Chain: An Engrossed Review

Mohd Riyaz Beg
Pharmacology Research Scholar
Student Placement Coordinator

The pharmaceuticals industry, since the beginning with its major investments in research, reliance on complex chemistry, and sophisticated understanding of human biology — has long been a technologically advanced sector. But with emergence of new technologies, ever increasing innovations, edge to edge competitions and exploding stakeholders and consumers demands, are now pushing operations (especially supply and distribution) to the top of pharma's agenda. From continuous manufacturing to digitization, from biopharmaceuticals (including vaccines) to novel gene therapies and even 3-D printing, there will be major changes in pharma production and supply chains. But there is a dire need of absolute clarity whether the industry is enforcing the right actions in the right direction.

Supply chain management describes the management of all activities in any of the companies involved in a supply chain to provide the highest possible level of customer service at optimum total supply chain cost and investment. Over the last 30 years, supply chain has undergone a tremendous change. From purely operational logistics function that reported to sales or manufacturing and focused on ensuring supply of production lines and delivery to customers has now become an independent supply-chain management function that in some companies is already being led by a CSO (chief supply-chain officer). The whole world is already at

Supply Chain 4.0 and heading towards 5.0 due to humongous disruption by COVID-19 pandemic.

Globally, we have observed the use of Internet of Things (IoT), advanced robotics, analytics, and big data—to jump-start performance, and customer satisfaction in supply chain management around many industrial sectors whether it may be automotive, or food, or electronics, etc. Industries around the world are adopting the changing trend with an equally fast pace. Every industry has its unique characteristics, but those working in pharma would always say that the effective adoption of contemporary supply chain management is difficult due to the regulatory environment that they work in.

R&D is the major focused area of pharma world since the early ages and that strong product focus of R&D implies a hard impact on the supply chain. In other sectors, R&D is increasingly aimed at improving processes, as well as developing new product and both these factors have contributed to the pharma industry arriving late to the game in terms of supply chain process innovation. Secondly, the sluggish decampment of regulatory compliance is another factor which hold-down the growth of supply chain processes in the pharma sector.

Any supply chain improvement uses six main drivers to leverage the innovations, i.e., Strategy, Planning, Physical flow, Performance management, Order management, and Collaboration. All along with utmost requirement to recognise the complexity and value of securing the entire value chain for medicines, from production to distribution to patients as well as the drivers that hinder supply security. A predictable and sustainable access to quality medicines fundamentalized the concept of universal health coverage and UN's Sustainable Development Goals.

There are four vitals or absolutes of supply chain management as per Ed Sweeney: the objectives, philosophy, flow and customer/supplier relationships. Objective defines an absolute clarity about what the objectives of the supply chain are. That can be achieved by enabling high levels of customer service in targeted markets/segments while also optimising total supply chain investment and cost. The whole concept of value and how the supply chain as a collective entity, or as a network of companies, creates that value, works on this basic principle. A High level of integration between companies upstream and downstream in supply chains marks the second absolute i.e., Philosophy. This can be rectified by replacing the fragmented approaches with those that are characterised more by integration. Strengthening linkages between functions can also help to fulfil this target. Logistics has taken a huge step forward through better

connectivity, advanced analytics, additive manufacturing, and advanced automation, upending traditional warehousing and inventory-management strategies. The key flow is the flow of information – it is impossible to imagine any 21st century supply chain being able to operate without a sophisticated and complex IT backbone. Apparently, by working on relationships and creating an ecosystem with high level of mutual trust and benefits, openness and shared goals and objectives the perfections and advancements can be manifested.

Now, after discussing the supply chain basics, question arises that where is the gap that need to be filled? The simplest yet powerful and justified answer to this question is, "Pharma Industry — just not an early adopter". Perhaps, pharma companies face different competitive pressures to those in the consumer electronics or the automotive industry may be the reason for this. But in the last decade, the level of supply chain professionalism that is quite visible in the pharma sector has increased beyond recognition.

Amid coronavirus crisis, on one hand the evident modulation and amplified efforts of the industry to meet the challenging demands, boosted the whole infrastructure of the pharma supply chain. On the other hand, it added complications too like the temperature-controlled logistics to distribute the approved COVID-19 vaccines. The need of the hour is to design and eliminate out the complexities with such a supply chain that can take care not only the distribution of the vaccine to patients, but the pre-manufacturing, manufacturing and everything in between.

At last, diversification of the supply chain will remain important and systemic and sustainable policy reforms will underpin such ambition. The pharma supply chains are need to be re-imagined in a very logical and systematic way. Also, it is equally important to prepare it for large scale responses with sufficient value proposition. Along with the improvement and investment in R&D pharma sector has to charge their supply chain and roll-out a trending and robust value chain model which maximizes the productivity, profit, healthcare, customer satisfaction and more oriented towards the synergistic collaborations. ■

Effectively Securing Cell and Gene Therapies with Closed Systems

Jayanthi Grebin
Senior Business Development CGT
Cold Products Company

The cell and gene therapy (CGT) industry is growing rapidly, due to their potential to target chronic and rare diseases that previously had limited treatment options. Yet, there are many challenges to developing these innovative new therapies that cannot be addressed using traditional manufacturing models and processes. Historically, these therapies are produced for small patient populations in clinical trials using laboratory scale equipment and utilizing manual, open processes completed under laminar hoods. An increased focus on efficiency and flexibility from the biopharmaceutical industry has accelerated the adoption of novel technologies and solutions to manufacture cell and gene therapies. Among these advancements is the implementation of a closed system design utilizing single-use technology (SUT).

Lab equipment originating from medical processes are quick and open to the environment and must be performed under laminar hoods to prevent contamination while closed systems are self-contained in order to prevent exposure from and to the environment. Thus, a closed system in cell and gene therapy manufacturing provides the protection of a cleanroom against outside contaminants without the costs associated with maintaining it. Although closed systems are already in use in SUT facilities for monoclonal antibodies, recombinant protein, and vaccine production, there is still a lag in the adoption of closed systems

at lab scale for smaller batches, for CGT manufacturing.

As the demand for CGT grows, the need for scale up to larger volumes has led to the utilization of SUT with open connections as well as other methods such as tube welding, multi-purpose connectors, quick connects, luers, and luer locks. These approaches are cumbersome and inefficient, though, leading to a greater need for closed manufacturing in CGT to protect and provide effective therapies.

COMPARISON WITH BIOPROCESSING

Single-use technologies (SUTs) are expected to play a huge role in CGT commercialization. CGTs have many of the same needs as biopharmaceutical manufacturing, where SUTs have proven to effectively meet the needs at the commercial scale. Some learning can be adopted from bioprocessing, a process with similar needs.

To make biologic products using genetically modified organisms, cells are modified to produce the biologically active molecules. The cells are the process. The active molecule is the product.

To produce CGTs, the cells are the raw material, the process, and the product.

Biopharmaceutical drugs utilize SUTs at all stages in the development and manufacture, from bench-scale research through all phases of clinical testing and into commercial manufacturing. SUTs are used for the development and production of both large and small molecule drug products. The wide range of processing technologies are supplied as either discrete components or more often as pre-validated, pre-sterilized single-use systems ready to use once opened. SUT adoption provides many well-documented benefits for commercial operation.

Similarly, for cell therapies and personalized medicines, SUTs are widely used and accepted for development and production. The reasons for using SUTs for CGTs are strikingly similar to those for bioprocessing — cost, speed, and sterility.

There are also some marked differences to be considered. Scale is one significant difference between bioprocessing and CGT processing. Bioprocessing scales are larger than those used in the development and production of autologous cell therapy products. The smaller scale of autologous products requires smaller equipment.

The type of SUTs used is the second important difference. For biopharmaceuticals, SUTs include filters, cell culture systems, mixing systems, storage vessels, tubing, sensors, valves, sampling systems, and connectors. For cell therapies, single-use systems are traditionally employed for clinical and R&D

uses for such devices as pipettes, blood collection bags, and T-flasks. The use of these products will continue but is being supplemented with the expansion of SUTs to include collection sets, fluid transfer sets, small-volume cell culture systems, and specifically with the widespread utilization of single-use bags and bag assemblies for media, washing, rinsing, cell harvest, waste collection, and even cryopreservation.

Furthermore, filtration steps used in biopharma manufacturing cannot be utilized in most cell therapy as the cells that are required for the therapy will be filtered out. With the industry facing issues with low yields, there is an increased need for a safe alternative that allows for a closed system design for every process of CGT from upstream to final fill without creating new challenges for an already complex area of the market.

While SUTs are used to manufacture CGTs for clinical trials today, there are limitations. Many of those SUTs cannot be transferred from lab scale into commercial scale for a variety of reasons, including extractables, leachables, supply chain security, reproducibility, and scalability. The industry needs to overcome these issues and develop solutions in the near future to meet the pace of CGT development and expected demand.

Single-use Connectors offer an easy-to-use method for maintaining flow path sterility and integrity while enabling the protection needed to avoid costly failures from contamination. SUT's plug-and-play assembly eliminates the convoluted process for connecting tubes via tube welding, where a cart must be brought into the production suite and, along with all the necessary components, moved to the biosafety cabinet to be put together. With single-use connectors, manufacturers no longer experience the costs and delays associated with the extra time needed for open manual processes. This is critical with CAR-T and other autologous therapies where time is sensitive and patient immune systems are low. The faster the patient gets the therapy, the better. The approval of FDA of two CAR-T therapies by Norvatis and Kite Gilead has created a demand for these therapies that the industry is currently not able to meet. Any delays in making these therapies only compounds the growing problem. And in an industry where labor costs are already high, the time to train operators to consistent welds contributes to the final price tag for manufacturing CGTs. Assembly also reduces operator error, which can pose additional costly risks.

The other option – tube welding, while considered by the FDA to be a sterile connection, requires the use of pressure

and heat to connect two pieces of tubing together. The tubing does not contain product at the time of welding; however, once the tubes are welded and product begins to flow through the tubes, any foreign particulates left behind could get into the product. If the weld is not done properly, there is also risk of occlusion, which is when the flow path in tubing is partially blocked during the sealing process. When this happens, any extrinsic particulates are now in the flow path. In addition, depending on the material the tube is made from, i.e, PVC, heat, and pressure during welding can also create extractables that can affect healthy cell population. And since tube welding is done in GMP processes, there is no pre-validating testing done to ensure contamination did not occur. Furthermore, tube welding requires longer tubing meaning product are held up in long tube sets instead of being part of the final product.

And unlike tube welding, extensive extractables studies have been completed on SUT, so CGT manufacturers gain peace of mind that the equipment they are using will not impact the safety and quality of their product. The threat of extractables has become such a concern with the rise of SUT that regulators have increased scrutiny about testing for the presence of these materials. While specific testing requirements have not been provided by the FDA, a white paper written by the BioPhorum Operations Group (BPOG) has become an industry guideline for extractables testing by single-use suppliers. CPC recognizes the critical need for extractables testing and has adopted and executed the BioPhorum Operations Group protocol on its single-use connectors.

The market is growing rapidly, with an anticipated value of over $35 billion by 2026. In its Technology Roadmap to 2025, the National Cell Manufacturing Consortium clearly identified in the section on Standardization and Regulatory Support that establishing standards with the appropriate regulatory authorities is required for both open and closed systems. The type of system required and the environment in which each process step and connections for each step will be undertaken determine the type of connection technology that should be used. While this opens up exciting new opportunities for patient care, it also drives a greater need to develop processes that can deliver these life-saving therapies efficiently and economically. The industry and regulators are dedicated to exploring ways to do this, but it is difficult with CGT manufacturing still in its early stages of development. ■

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Sustaining India's drive to accelerate BioTech initiatives

Video Link: https://youtu.be/3TflyWLxkKQ

Kris Gopalakrishnan
Chairman, Axilor Ventures Co- Founder , Infosys

Kris Gopalakrishnan talked about his reasons to dedicate his work in Healthcare, Bio Firm and Brain Research. He envisioned and encouraged taking Healthcare goals of making the industry of Bio Tech, 5% of India's GDP and 10% of India's exports by moving to accelerate Bio Firm industry and recognizing start-up initiatives.

Grand Challenges India & National BioPharma Mission

Video Link: https://youtu.be/ZWkMKWKTgko

Dr. Shrishendu Mukherjee
Managing Director, BIRAC

The innovation ecosystem changing past few years and technology evolving to greater paths were keenly discussed. Pushing innovation, strategies to build bigger picture, people finding key elements of developing ideas, challenges faced in innovative spaces like writing grant applications, telling compelling stories, were intriguingly discussed in the session.

Clinical Research- Capacity Building to support BioPharma innovation to marketplace

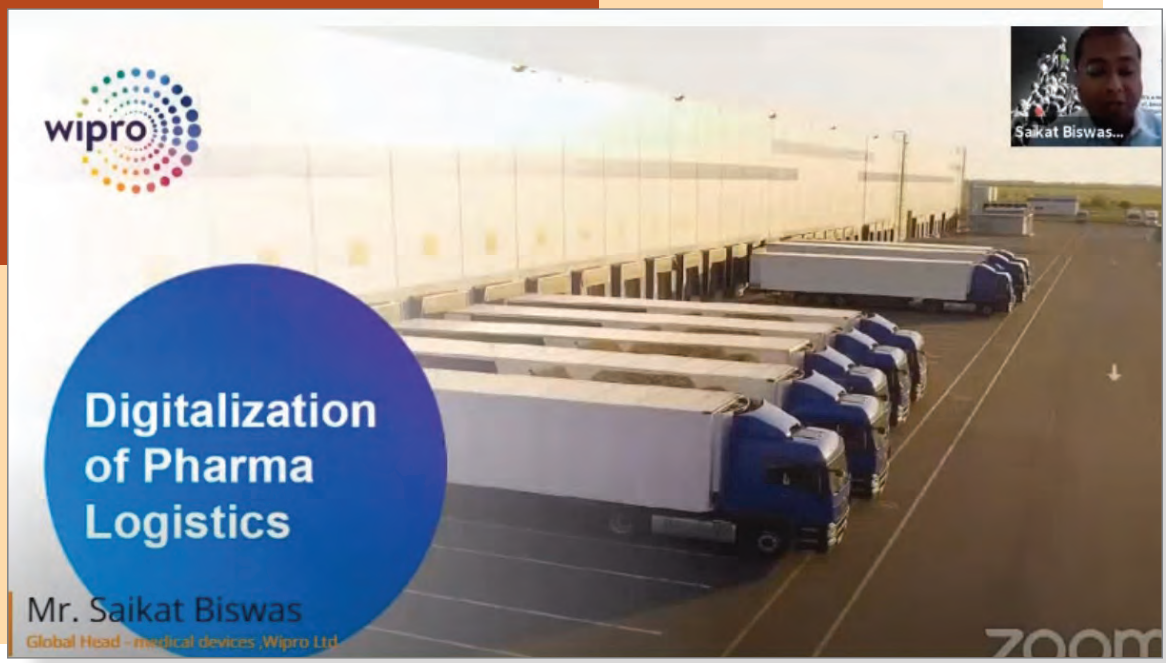
Video Link: https://youtu.be/VbQOym744PI

Dr Sucheta Banerjee
Director Training,
CDSA, THSTI, Department of Biotechnology

Dr Sucheta Banerjee talked about clinical research, Building capacity and capacity to support Biopharma innovations. National dissemination of stem cell research guidelines, Strengthening Trial research capacity in neighbouring countries like Afghanistan, Bhutan, Bangladesh, Nepal, Sri Lanka, Maldives, Mauritius, In 2019 an online courses were conducted which saw 1707 participants and 4944 participants in 2020, 2671 participants in 20221. When new drugs and clinical trial were released national workshop on regularity compliance for accelerating innovation were conducted in New Delhi, Pune, Bengaluru, Hyderabad, Guwahati and Vadodara. In national Biopharma Mission training programs training programs of good clinical practise, ethical consideration in clinical research.

Digitalization of Pharma Logistics

Video Link: https://youtu.be/QA0g6U_W9f8

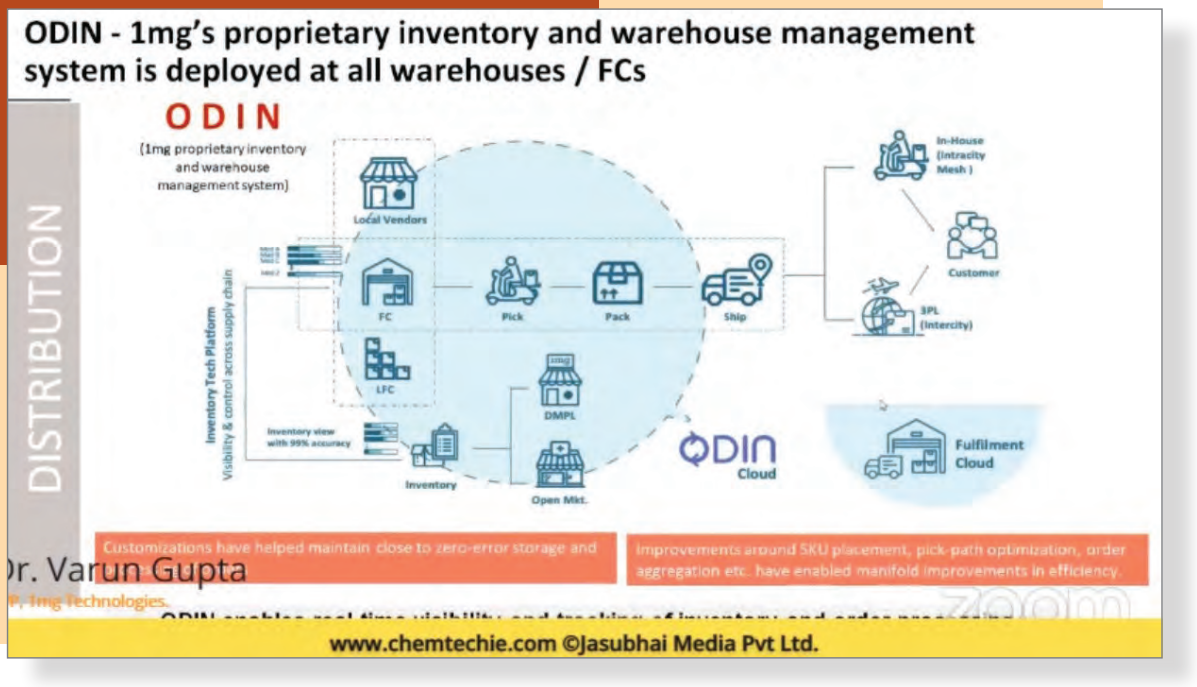


Saikat Biswas
Global Head - Medical devices, Pharma Services, Manufacturing, Energy and Utilities,
DOP Wipro LTD

Saikat Biswas talked about the key challenges of Logistics and Distribution are extreme product handling requirements, high propensity for counterfeiting, fragmented supply chains and logistics, limited visibility of end to end supply chain, inadequate technology interventions and high cost of logistics and distribution. Wipro helps digitize and manage end to end logistics and distribution supply chain and specializes in Securing cold chain, Logistics control tower and Supply Chain Risk Management. It results in Safe and Secure product level condition visibility, Transparent cross organization product tracking, Risk Free managements, intelligent tool usages like AI, ML, Cognitive, Automation, IoT and block chain and earnest efficiency.

Role of e-Pharmacies in Last mile delivery of Bio-Pharmaceuticals

Video Link: https://youtu.be/orlo89BBtK8

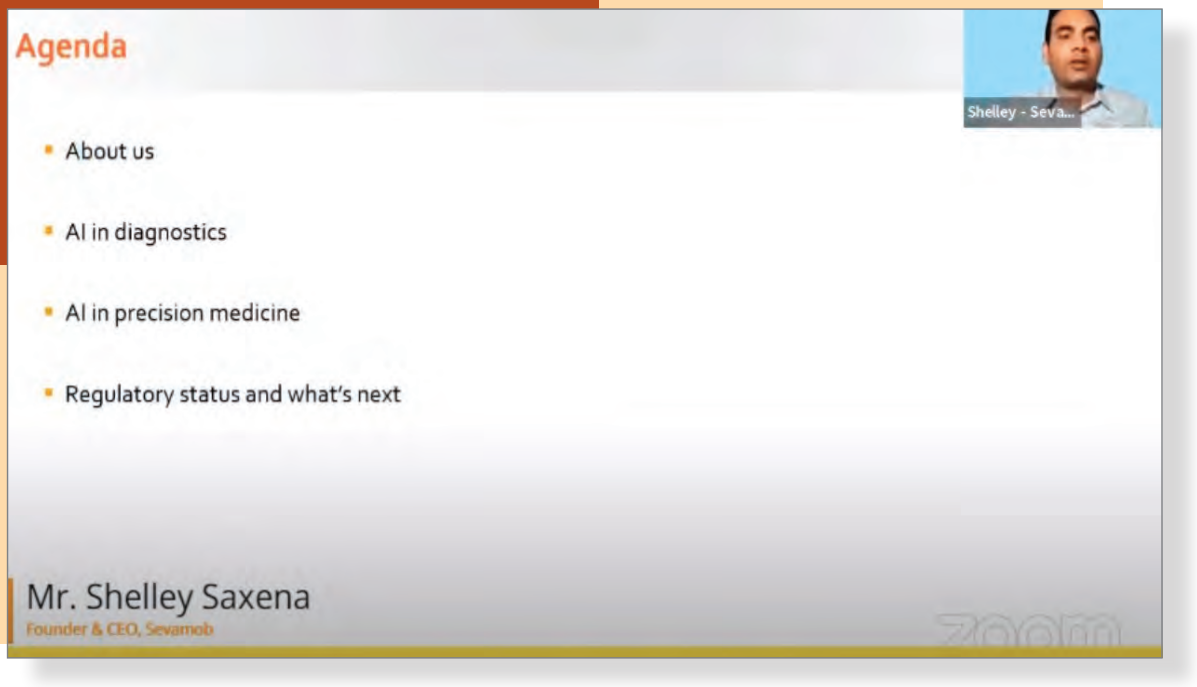


Dr. Varun Gupta
SVP, 1mg Technologies

Dr Varun Gupta talked about how 1mg has built the largest consumer-centric digital healthcare platform in India. The company started as a Healthcare Information & Digital Health Tools, and moved towards e-Pharmacy, e-Diagnostics, e-Consultation and Ecosystem Solution. India uses 1 mg for health. There are 140 million annual unique, 6.0 Billion Pageviews, and 46% Category shares. There has been far reaching and strong recognition in the national and global ecosystem. The supply and distribution side has enabled the distribution network of pan India cold chain network. There are 3 billion healthcare data points with integrated data sources and user health profiles of deep patient health profiles. Post-vaccination assistance for employees and dependents is also provided with over 40 lakh consultations, 22 specialties, 3 thousand daily consultations and 100k doctor network.

AI in Biopharmaceuticals

Video Link: https://youtu.be/JBH5em21vdw



Shelley Saxena
Founder & CEO, Sevamob

Mr Shelley Saxena, briefly talked about how Artificial intelligence in diagnostics has been strong and constantly evolving and AI in Diagnostics and Precision Biopharmaceuticals. Precision medicine is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment and lifestyle. Intel developed a deep learning model that was able to achieve 85% accuracy on disease in prediction. Atomise uses machine learning algorithms for drug discovery and development. Notable Labs uses FDI approved treatment recommendations based of tumour.

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Eppendorf introduces multipurpose centrifuge 5910 Ri to accelerate research

Leading life science company Eppendorf introduced a new centrifuge designed to increase efficiency in the laboratory, Centrifuge 5910 Ri. The new centrifuge is the successor to the popular Centrifuge 5910 R, the flagship of Eppendorf multipurpose centrifuge portfolio that has been providing customers worldwide with outstanding versatility and ease of use since its launch in 2018.

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