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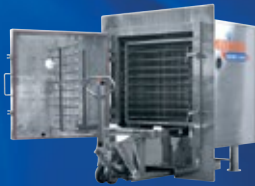
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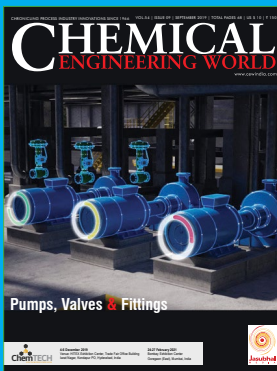
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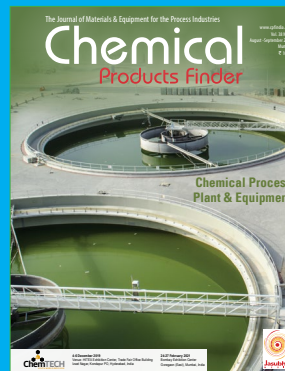
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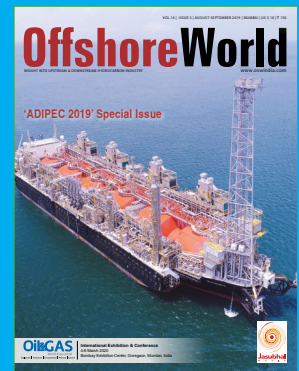
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# PHARMA BIO WORLD

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Single Copy Price: ₹ 150/-, Annual Subscription: ₹ 1620/-, Foreign: US\$ 180

**Jasubhai Media Pvt Ltd**  
Registered Office: 26, Maker Chambers VI, 2<sup>nd</sup> Floor, Nariman Point,  
Mumbai 400 021, INDIA.  
Tel.: +91-22-4037 3737 | Fax: +91-22-2287 0502 | E-mail: sales@jasubhai.com

Printed and published by Mr Hemant K. Shetty on behalf of  
Jasubhai Media Pvt. Ltd., 26, Maker Chamber VI, Nariman Point, Mumbai 400 021  
and printed at The Great Art Printers, 25, S A Brelvi Road, Fort, Mumbai 400 001  
and published from 3<sup>rd</sup> Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.  
Editor: Ms. Mittravinda Ranjan, 3<sup>rd</sup> Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.



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# Injectable Drug Delivery Market Analysis

*Forecast is that the injectable drug delivery market will see growth from USD 362.4 billion in 2016 to USD 902.3 billion by 2027, at a Compound Annual Growth Rate (CAGR) of 11.5% during the forecast period. The major factors responsible for the growth of this market are the increasing use of biologics, increase in the prevalence of chronic diseases, increasing occurrence of needlestick injuries, and the benefits of injections (convenience, ease of use, and reduced pain). These factors have increased the demand for devices such as safety syringes, prefilled syringes, and autoinjectors. The objective of this market analysis compilation is to define and describe the injectable drug delivery market size.*

The Injectable Drug Delivery Market is projected to reach USD 902.3 billion by 2027 from USD 362.38 billion in 2016, at a CAGR of 11.5% during the forecast period. Growth in this market is mainly driven by increasing prevalence of chronic diseases, rising aging population, increasing use of biologics, and increasing number of needlestick injuries. On the other hand, growing use of alternative delivery methods, safety concerns, and risk of transmission of blood-borne infections and needlestick injuries may hinder the growth of the market.

The injectable drug delivery is segmented based on type, formulation packaging, therapeutic application, usage pattern, site of administration, distribution channel, facility of use, and regions.

By therapeutic applications, the market is segmented into autoimmune diseases, hormonal disorders, cancer, orphan diseases, and other therapeutic applications (pain management, allergies, hepatitis C, aesthetic treatment, and hemophilia). Cancer segment is expected to register the highest CAGR during the forecast period.

Based on formulation packaging, the market is segmented into the ampules, vials, cartridges, and bottles. Ampules are expected to dominate the Injectable drug delivery market, in 2016. The large share of this market segment can be attributed

majorly due to its good barrier properties as compared to other types of packaging; moreover, they offer better protection at a lower cost. Ease of transportation and low cost of manufacturing are the factors driving the growth in this segment.

Based on region, the injectable drug delivery market is segmented into North America, Europe, Asia, and the Rest of the World (RoW). North America is further sub-segmented into the U.S. and Canada; while Europe is further subsegmented into Germany, France, the U.K., Italy, Spain, and the Rest of Europe (RoE); Asia is further subsegmented into Japan, China, India, and the Rest of Asia (RoA). Along with this, the rise in disposable income, the growing awareness of safety and comfort, and the increasing number of partnerships in this market space are also contributing to the growth. In 2016, North America is expected to dominate the market, followed by Europe. The large share of North America is attributed to the increasing prevalence of chronic diseases and the number of companies that are focused on collaboration and partnerships to ensure the availability of high-value products.

Asia is projected to be the fastest-growing region in the injectable drug delivery market from 2016 to 2021, due to the rising incidence of chronic diseases and the growing aging population. Moreover, high

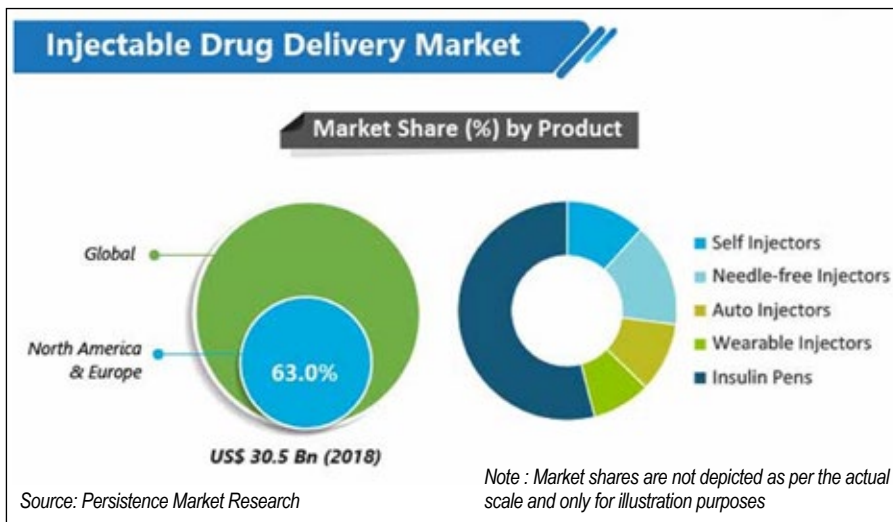
penetration of self-injection technologies in Asian countries such as China, Japan, and India adds to the demand for injectable devices.

### Drug Delivery Market Growth Drivers:

- Increasing incidences of chronic disease such as cancer across the world is majorly driving the global drug delivery market owing to the effective and targeted drug release along with minimal side-effects on the body.
- Rising population of the old-age majority demands greater supply of generic drugs and doses. Growing age accompanies several diseases resulting in an upsurge of the drug delivery market.
- Incrementing global biologics and biosimilar market is inducing a positive influence on the global drug delivery market owing to a lucrative market revenue.
- New innovations, technological advancement, and promotion of new products propelled by the key manufacturers in the global market, wide scope of development and profitable outcome is accomplished by the drug delivery market.

### Drug Delivery Market Challenges:

The nanoparticles of drug delivery systems are made up of certain substances which reacts with the cellular membranes



## Drug Delivery Market Trends:

### • Advanced Prodrug Implants

Prodrug therapy offers two-step solution for cancerous cells and is used as an alternative treatment to chemotherapy. Antibodies are delivered to the particular cancer sites in the body, thereby targeting the enzymes of the cancer cells and releasing prodrug to kill the cancer cells without affecting any normal cells.

### • Chip-Based Drug Delivery

Microchip drug delivery is an advanced medical technology which when injected into a body system or consumed orally remains inside the body and releases drug doses at regular and fixed intervals over a great time span. Without any interventions of the bearer, this modern drug delivery system is gaining large scale demand from different end-users owing to its potential benefits in treating chronic diseases.

### • Cellular Delivery Technology

The potentiality of cells as carrier of drugs is exploited by modern medical science and technology. Cellular drug delivery emerges as an alternative to nano and micro drug delivery particles with efficiency in the treatment of HIV, cancer, cardiovascular diseases, and other body abnormalities.

## Drug Delivery Market

The drug delivery market is generally divided into segments by technology, application, and end users. On the basis of technology, the market is bifurcated into syringes, inhalers, intrauterine devices, powered injectors, and others. Based on application types the segmentation includes oncology, cardiology, gynecology, asthma, diabetes, and others. By end users this market is categorized into patients, hospital, clinics, and many others.

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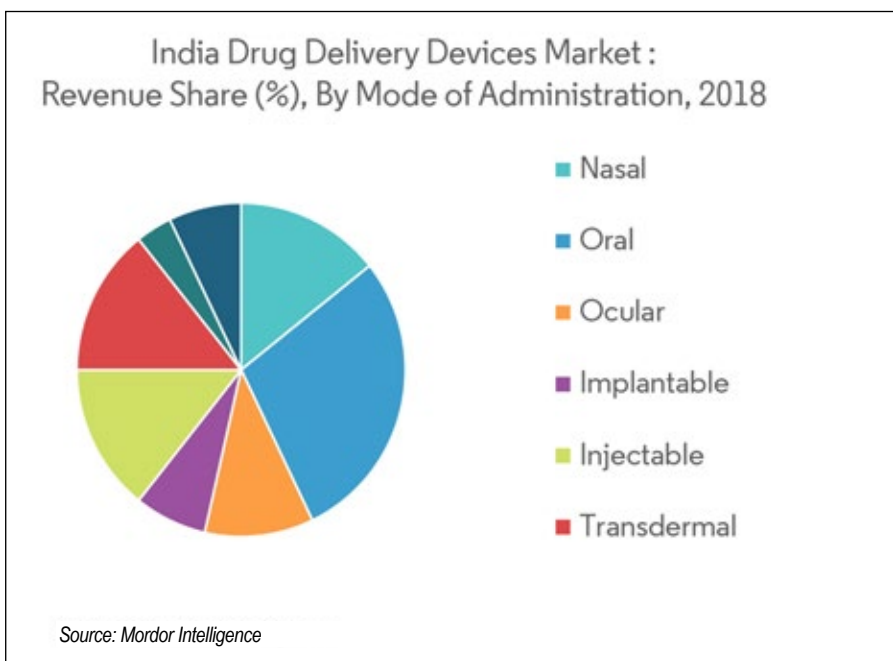
resulting in morphological changes. Moreover, certain drug delivery devices are partially or completely insoluble in nature becoming a barrier in the blood streams. This may lead to several other health issues creating severe problems. Medical researches executed and other biotechnological advancements conducted by the pharmaceutical industries are constantly limiting these drawbacks through their innovative and cost-efficient drug delivery systems.

### Drug Delivery Market Key Players:

The pioneers in the global drug delivery

market include companies like Becton, Dickinson and Company, Baxter International, Pfizer, Gerresheimer AG, Schott AG, Eli Lilly and Company, and Terumo Corporation, and others.

Dickinson and Company is an American based leading medical technology company delivers various ergonomic drug delivery systems including prefillabe syringes, self-injection systems, safety and shielding devices to more than 500 companies, which reduces pain and enhances the delivery span to ultimately provide the patients a healthy medication.



# Key Trends in Injectable Drug Delivery

*The global drug delivery market is anticipated to grow at a CAGR of 11.26% between 2018 and 2026. The important drivers increasing growth in the global drug delivery market is the technological advancements and the increasing use of biologic drugs. Technological advancements in the drug delivery technology are one of the key factors for the market growth. In the drug delivery industry, the introduction of new delivery platforms is expected to introduce technology that optimizes a drug's therapeutic value in order to find a better way to get a drug into the patient's body with a safe and in a consistent way that may lead to better compliance and outcome. Biologic drugs are widely used for the treatment of diseases and conditions such as chronic diseases, ulcerative colitis, rheumatoid arthritis and other autoimmune diseases are one of the most advanced therapies.*

*However, the factors restraining the market growth are high cost involved in development of drug delivery devices and product recalls. PBW with the focus on Drug Delivery Systems will cover the current condition and future possibilities of the segment.*

*Significant factors driving the market growth include:*

- *Technological advancements*
- *Increasing use of biological drugs*
- *Swelling demand for effective drug delivery mechanisms*
- *Increase in the prevalence of chronic diseases*

## **B** iologics Driving Longer Syringes & Wearable Technology

Wearable devices are changing the paradigm in drug dispensing. Today's smart, advanced self-injectable devices aim to provide therapeutic value to patient and physicians, and commercial value to the drug makers and payers. With the growth of the biologics market, four of the world's top-five selling drugs are delivered by injection. Because these drugs are complex, biologics often require robust design efforts and present delivery challenges. Over the last decade or so,

the trend toward self-administration of injectable drug therapies has grown in an increasing number of disease states.

## **Compliance through Connected Technology**

In addition to wearable devices, experts see a trend toward connected devices. Here, a device is connected to a smartphone and tracks and reports injections to doctors and healthcare providers. The connected smartphone may remind the patient when to take the next injection, improving compliance, and if the patient forgets to inject, the

caregiver could receive an alarm from the system.

The benefits of connected drug delivery are still being explored, but remote tracking and improved compliance are among the big ones. There is overwhelming evidence that these tools have a significant impact on the health of patients.

## **Self-Injection with a Human-Centric Focus**

Until connected devices reach maturity, device developers will continue to seek more mainstream ways of enhancing the injection experience. Many are



their shelf- life and constrain the manufacturing and supply processes of manufacturers.

Listed down are some of the leading device developers and their products:

## Bespak Europe Ltd: VapourSoft™

Bespak works closely with biopharmaceutical partners to develop customized device designs that are suited to the needs of specific patient groups. Those designs reflect inputs from a range of key experts and stakeholders, including healthcare professionals and patients. Data generated in-house and by the company's biopharmaceutical partners' studies are also considered.

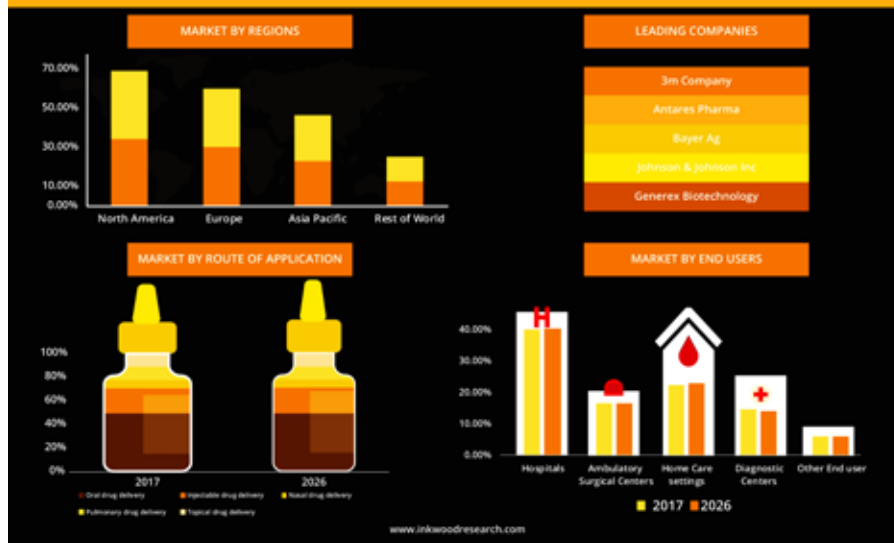
Bespak Europe's new proprietary product VapourSoft™ is a compact energy source containing liquefied gas. Through gentle release of a pressurized vapour, it powers viscous drug delivery with minimal user effort. This technology came about from proven expertise in metered dose inhaler valves.

Bespak has focused on three specific features with these devices: customizable, empowering, and universal. Devices also need to accommodate the most common primary containers. Most of Bespak's devices are designed to allow for universal standards and ensure that if the body of the device needs to be changed for different patient groups, one device could easily be used for a number of different injectable products. The VapourSoft range of devices addresses issues of injection volumes and higher viscosity liquids to allow self-administration.



Bespak Europe Ltd

## GLOBAL DRUG DELIVERY MARKET FORECAST 2018-2026



turning to Human Factors Engineering. Design plays a uniquely important role in healthcare as it accounts for the needs of multiple system stakeholders, brings focus to existing challenges, and inspires solutions grounded in people's lived experiences. Tata Elxsi which specializes in the core designing of drug delivery devices and surgical equipment for leading Indian pharma and medical technology companies, aims to consolidate its presence in the life-saving injectables. The global self-injection devices market is also driven by a significant rise in demand for home health care, owing to low cost of treatment and improvements in overall patient experience.

### Qualities of Future Devices

- **Universal:** They will operate with any primary container without the need for a drug transfer step.
- **Customizable:** Embedded electronic features will allow customization depending on the intended user type.
- **Upgradable:** Connectivity capabilities will allow devices to be remotely upgraded, making the task of lifecycle management easier.
- **Green:** Devices will further align with the increased requirement for greener

technologies. Energy harvesting technologies will replace batteries and make the end-of-life management of devices much easier and greener.

- **Empowering:** Injectors will allow patients to take control of their disease state by monitoring their drug performance and recording relevant everyday activities. Access to real-time and historical data will empower patients who want the ability to better manage their disease state. Drug delivery devices will also be able to give feedback to patients and this information will be followed up with instructions on how to improve.
- **Intelligent:** Delivery devices will be able to distinguish between the different types of drugs they deliver, how much they deliver, and when they deliver them. They will be used as authentication devices for drugs administered, providing extra control to the supply chain of drugs.
- **Likable:** Drug delivery devices will adopt design features that resonate with patients and increasingly look more like consumer accessories.
- **Extended Shelf-Life:** Devices will have limited features that may limit

## Credence MedSystems: Connect™ Auto-Sensing Injection System

The award winning Credence Connect™ Auto-Sensing Injection System incorporates automatic real-time monitoring of critical injection data and user feedback into a reusable ergonomic finger grip. The Credence Connect™ brings digital connectivity to any pre-filled syringe for the delivery of injectable medications. It incorporates automatic real-time monitoring and transmission of critical injection data into a reusable ergonomic finger grip. The Connect™ enables healthcare providers and self-injecting patients to automatically collect data and receive feedback on the success of the injection, while improving usability of the syringe.

The Credence Companion platform of reconstitution devices shares common themes across the products: the user



Credence MedSystems

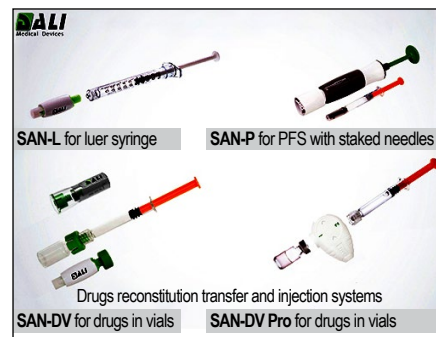
completes the injection (marked by an end-of-dose click) and then the needle automatically retracts through the stoppers and into the plunger rod and syringe barrel, preventing the syringe from being reused. However, each product can play a different role in a manufacturer's strategy and a drug's life cycle. Credence's needle retraction technology allows this mixing procedure to occur without any potential for premature activation of the safety mechanism. Additionally, because the drug manufacturer can choose from readily available syringe and elastomer primary package components, and because Credence components do not interface with the drug product during storage, the development and regulatory path to market is shortened and simplified.

## DALI Medical Devices: Safe Auto-Needles (SANs)

DALI focuses on the development of injectable drug delivery technologies -- from product concept to regulatory approval -- that meet the needs of patients, physicians, and healthcare systems.

DALI's unique, creative and innovative injectable drug delivery devices are designed for ease of use self-administration. By reducing "needle phobia" and the fear of injections, patient compliance to prescribed therapies increases and their quality of life improves. Treatment success is achieved using DALI's safe, user-friendly and high-quality injectable devices. DALI has developed the unique Safe Auto-Needles (SANs). The SANs feature automatic needle insertion and safe automatic needle shielding after use. The proprietary SAN family is single-use disposable devices combining an extremely simple user interface with an innovative hidden needle for safety in a cost-effective design.

The SAN™ (Safe Auto-Needle™) family of injectors delivers easy injection of a wide



DALI Medical Devices

range of formulations for patients with a wide range of needs. The injectors are designed — and can be customized — for use with all types of syringes or primary drug containers: conventional plastic hypodermics, single- or dual-chamber pre-filled syringes made of glass or plastic, or vials.

All SANs feature automatic needle insertion, passive-automatic sharps protection, and a needle that is hidden at all times. And SAN products combine these features with manual control of injection speed.

## Gerresheimer: New PFS Addresses Biotech Needs

Gerresheimer Medical Systems produces prefillable syringes and cartridges (primary packaging) made of glass and plastics, as well as customized injection-molded plastic assembly units like insulin pens and autoinjectors. Gerresheimer currently offers a range of prefillable Cyclo-Olefin-Polymer (COP) syringes produced by long-time partner Taisei Medical Co. Ltd. in Japan. COP syringes are distinguished by a high degree of break resistance, glass-like transparency and very low oxygen permeation compared to other plastics. They can be used directly for aseptic filling. COP releases no alkali ions, which means that the risk of a pH value shift is eliminated. Production with injection molding process enables flexible designs - even customer-specific designs are possible. In comparison to glass more precise production tolerances are possible thanks to the exact injection molding. This



Gerresheimer

makes a higher degree of customized solutions possible, for example, when a lower remaining volume is required. Additionally, COP has a high pH tolerance and, unlike glass, does not change the pH value while in storage.

Gerresheimer also produces 1-mL Gx RTF ClearJect syringe which is siliconized with a precisely controlled amount of high-viscose silicone oil, which generates lower amounts of subvisible silicone oil particles while providing good functionality.

**Haselmeier: Flexibility is Key to Next-Generation Devices**

Haselmeier specialises in the development and manufacture of innovative self-injection devices with proprietary designs and technology. The company covers all of the steps in the creation of its award-winning devices from design, to planning and industrialisation. Haselmeier also offers a range of early-stage development activities to ensure all products are high quality. The company conducts human factors studies and consults with user focus groups to provide successful administration. This is combined with a qualified design control process, certified quality system, regulatory expertise, a solid network of partners, and strong manufacturing operations designed to meet and exceed client expectations. Development of pharmaceutical devices



Haselmeier

depends on the understanding of technical, regulatory and operational requirements. Haselmeier develops and manufactures innovative self-injection devices that feature company designs and state-of-the-art technology.

A detailed pre-development process is used at Haselmeier to properly evaluate the technical requirements and create devices that are easy and intuitive to use. This structured process allows for engineering and design exploration, as well as Human Factors testing, to verify that the product design will be effective. Combined with a final risk assessment, a complete package is then released for full-scale development. Haselmeier is developing connected technologies that can be applied across its device portfolio, which will allow customers to deliver intelligent solutions for clinical trials, commercial use, or both.

**Insulet: Omnipod**

Insulet is an innovative medical device company dedicated to making the lives of people with diabetes and other conditions easier through the use of its Omnipod product platform. The Omnipod Insulin Management System provides a unique alternative to traditional insulin delivery methods. With its simple, wearable design, the disposable Pod provides up to three days of non-stop insulin delivery, without the need to see or handle a needle. Insulet also leverages the unique design of its Pod, by tailoring its Omnipod technology platform for the delivery of non-insulin subcutaneous drugs across multiple therapeutic areas. Founded in 2000, more than 100,000 users across the globe rely on Insulet's Omnipod Insulin Management System to bring simplicity and freedom to their lives. Omnipod platform can modify dosing and delivery times, as well as monitor patient adherence. Additionally, the Omnipod has a remoteless option for preprogrammed dosing regimens. Its auto-cannula insertion means patients



Insulet

never have to handle the insertion needle. Omnipod is discreet, tubeless, and waterproof to help reduce life interference and improve drug adherence.

**Medipacs, Inc.: Wearable Device Delivers Biologics Subcutaneously**

Medipacs has developed a patent protected, injectable drug delivery technology that is precisely controllable and fully programmable. The Mini Infuser™ is a miniature, disposable, programmable drug delivery device designed to significantly lower the cost of patient care while improving a patients lifestyle with increased pharmacological



Medipacs

safety, patient mobility and fewer needle sticks. Medipacs is currently developing the second generation ready for commercialization prototype shown in the images and will submit it to the FDA for approval once testing is completed. The Medipacs Mini Infuser™ is a unique medical device that the electric motor and mechanical pump components have all been eliminated and replaced with a Smart Polymer Actuator that responds to changes in pH. The Actuator is controlled by a programmable electrical current that allows it to expand up to 500% of its original volume in order to accurately meter out a liquid medicine.

### Nemera: Safe'n'Sound®

Parenteral is often considered as the default route of administration, but is also known as a non-intuitive process. To respond to these issues, Nemera has developed Safe'n'Sound®, a customizable platform of add-on passive safety devices for prefilled syringes, which aims to prevent potential needlestick injuries and facilitate the injection process. To ensure adherence and user well-being, Nemera has developed Safe'n'Sound®, a fully passive safety device for prefilled syringes. With an ergonomic and robust design, it helps in preventing needle stick injuries, providing a user-friendly protection for



Nemera

healthcare professionals or patients. This add-on device has been developed for healthcare professionals, patients with self-administered prescribed medications, or individuals that assist self-injecting patients. Safe'n'Sound® is a customizable platform, compatible with prefilled ISO standard glass syringes as well as Plajex COP syringe, for 1ml or 2.25ml.

### Noble: Training Devices

Noble has developed and launched many new autoinjector and prefilled syringe training devices using a device-comparable approach. This approach means training devices are engineered to replicate the same form and functionality as a real device, including functions like plunger speed, needle simulation, safety mechanisms, and additional technologies that improve proper use and memory recall.

### Ompi Integrated Safety System Syringes

The new technology guarantees patient's safety and reduces the customers' Total Cost of Ownership through:

- prevention of needle stick injuries
- reduction of non-quality costs (missed activation and wrong functionality)
- reduction of logistic space (incoming and outgoing)
- lower impact on secondary packaging (blister and carton box)
- minimization of regulatory impact
- investment for safety device assembling machines

The ISS Platform is designed to be customizable to meet the needs of different drug products applications such as Biotech, Heparin, Small Molecules, and Vaccines.

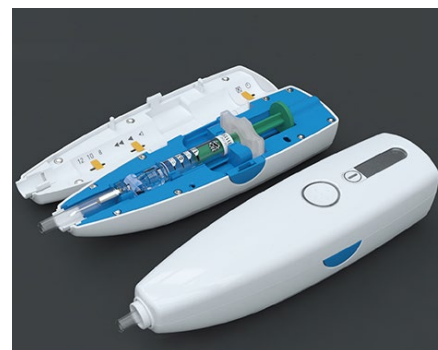


Ompi ISS

### Phillips-Medisize

Phillips-Medisize has developed and launched a user-friendly autoinjector as part of a first-of-its-kind connected health system for their patients. The company's existing autoinjector was an all-mechanical, spring-based device. Typically, devices of this type have a number of usability issues which can make injecting unpleasant for patients. To speed product development, Phillips-Medisize used the Technology Accelerator: customizable building blocks combined with deep technology expertise. A series of proposals, refinements, block models and tests led to a connected design that offered:

- Ergonomic design with a button in the middle of the device, operated with one hand and light pressure, making for a gentle experience.
- Secondary control functions hidden on the inside, so they don't interfere with the day-to-day operation of the device.
- A dashboard for healthcare professionals to easily monitor patients and determine who needs support.
- Bluetooth connectivity that ensures data on injection time, volume and body location are synced with the patient app and dashboard.
- Personalized, localized messages and reminders for patients on their device and in the app.

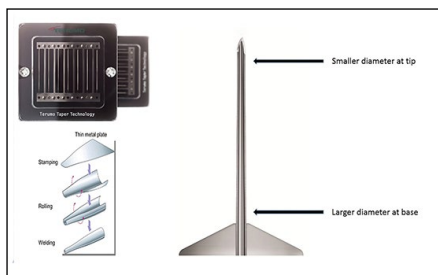


Phillips-Medisize

**Terumo®: Tapered Needle Technology (TNN)**

Patients have long been in search of virtually painless injections. Terumo has made this possible with the advanced NANOPASS® 34 - The World's Thinnest Pen Needle.

Terumo® launched the 33 gauge (G) x 4 mm Nanopass pen needle provide better injection comfort for diabetic patients who have to self-administer daily insulin injections. This micro-tapered needle had larger diameter at the distal end and a smaller diameter at injection tip. Based on the same principles, Terumo launched the 34G Nanopass pen needle.



Terumo

The Tapered needle can be used with PLAJECTM syringes. PLAJECTM (COP polymer syringe) is a ready-to-use prefilled syringe with i-coating™ technology on the plunger stoppers to create a silicone oil-free system. It is also free of tungsten and glue and has low sub-visible particles.

**Ypsomed: Building a Platform that is Customizable to Meet Current & Future Needs**

Pharma companies increasingly focus on self-injection devices as a mechanism for differentiating the drug product. Responding to these emerging requirements, Ypsomed has built up comprehensive platform products that each meet key customer needs yet are specifically designed to be modified into customer-specific products. The platform products enable flexible customisation while minimising project risks and

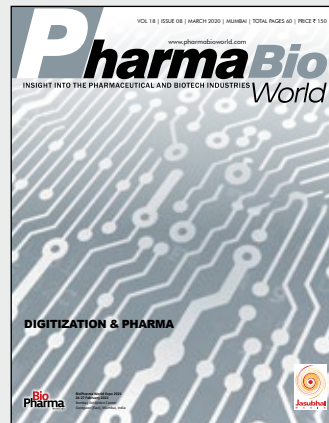


Ypsomed

shortening time to market. Examples of Ypsomed's platform products are YpsoMate, the 2-step autoinjector, and UnoPen, a disposable pen, both of which have been tested for usability in extensive formative human factor studies on a platform level.

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**PBW Spotlights**

- ★ Indian Pharma and Biotech
- ★ Industry Globalisation
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- ★ Future Trends of the Industry
- ★ Current Indian and International Corporate News
- ★ Novice & Updated R & D Strategies
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- ★ Event Alerts and Many More.....



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# Exosomes and Exosome-Inspired Vesicles for Targeted Drug Delivery

*The similarities between exosomes and liposomes, together with the high organotropism of several types of exosomes, have recently prompted the development of engineered-exosomes or exosome-mimetics, which may be artificial (liposomal) or cell-derived vesicles, as advanced platforms for targeted drug delivery. In this review, we provide the current state-of-the-art on the development of exosomes, as well as artificial nanoparticulate systems that aim to mimic their properties as innovative nanocarriers with high drug targeting efficiency.*

The most recent discoveries in the field of extracellular vesicles are unravelling exciting concepts on intercellular communication pathways. The fast growing literature in this field is showing that nano to micron sized vesicles budding from cells and named exosomes display specific organotropic behavior as part of their active role in cell-to-cell communication and material (protein and/or nucleic acid-cargo) transfer pathways. Besides local cell-to-cell communication, in some cases, the secreted factors play a key role in the interactions between cells located far apart from each other. The tremendously high and specific organotropism of some types of exosomes is one of the major goals of all the types of nano-based drug delivery systems (DDSs) that have been screened to date, which remains unmet. By providing important insights into the key elements that dictate the biological fate of vesicles and their ability to interact and be taken up by specific cells, the novel and fast-growing field of exosomes is now inspiring the design of ex-novo nanovesicles as targeted drug carriers for therapeutic applications.

Due to the numerous similarities between liposomes and exosomes, the application of liposome engineering technologies to engineer exosomes has been proposed as a way to overcome their limitations. The

many similarities between the two systems is also the reason why liposomes are of the nanoparticle type, which is preferentially used for the construction of artificial exosomes or EX-mimetics as drug carriers.

In order to understand why exosomes can be used as targeted drug carriers, we need to initially clearly define what they are, and additionally, review their basic functions. Exosomes are one of the types of a broader category of cell-derived vesicles characterized as extracellular vesicles (EVs).

In more detail (Figure 1): Representation of the biogenesis of extracellular vesicles from eukaryotic cell.

- (i) Apoptotic bodies are released during cell death and are heterogeneously shaped vesicles with sizes between 50–5000 nm. They are formed from the plasma membrane, and they contain DNA, RNA, histones, and signalling molecules.
- (ii) Micro vesicles are formed by blebbing of the cell membrane with concurrent incorporation of cytosolic proteins, and their sizes range between 20–1000 nm, depending on the origin cells and the method applied for their isolation from cell media. Their formation can be triggered through Ca<sup>2+</sup> influx, phorbol esters, ATP, etc.

- (iii) Finally, exosomes include a more homogeneous population of vesicles compared to microvesicles, with sizes that range from 50 nm up to 120 nm. Their biogenesis is initiated by inward budding of the plasma membrane which results in the formation of intermediate endosome-vesicles, the multivesicular bodies (MVBs).

Microvesicles and exosomes are smaller compared to apoptotic bodies. They differ from apoptotic bodies in their content, since they rarely contain DNA. Although these two vesicle-types, microvesicles, and exosomes, are separate classes of vesicles, due to the fact that they overlap in size, and since the commonly used non-specific protocols for exosome isolation and purification rely solely on the vesicle size differences. Because of this, it has been proposed that the term “extracellular vesicles” (EVs) be used as a general term for all small vesicles/particles, including both vesicle types, and excluding only apoptotic bodies.

As a result of the above-mentioned functions, extracellular vesicles may serve as novel tools for various therapeutic and diagnostic applications, such as (a) anti-tumour therapy, (b) pathogen vaccination,

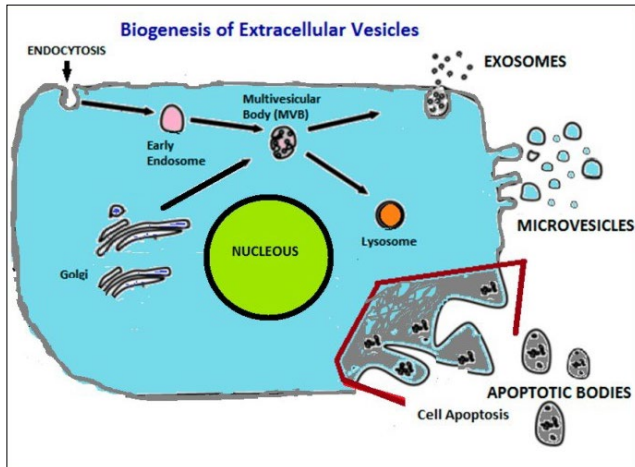


Figure 1: Representation of the biogenesis of extracellular vesicles from eukaryotic cell.

(c) immune-modulatory and regenerative therapies and (d) drug delivery.

Indeed, in the last 5 years, extracellular vesicles were proven to have high targeting potential for specific cell types, but in most cases, following systemic administration, they failed to demonstrate the anticipated therapeutic results. It is well-known today that the main pre-requisites for using any type of vesicle for the targeted delivery of drugs are that: (i) they can be loaded with a sufficient amount of drug, in order to elucidate a therapeutic response; (ii) they are stable during circulation in the blood stream before reaching their therapeutic target in the body; (iii) they can avoid uptake by the macrophages and circulate for prolonged time periods so that they can reach their cellular targets; and (iv) they are biocompatible, or else non-toxic and non-immunogenic. In accordance to these requirements, the main problems identified for the successful translation of extracellular vesicles into targeted drug carriers are the following: (i) drug loading and/or retention of drugs in exosomes is not sufficient; (ii) the poor pharmacokinetics of natural extracellular vesicles when loaded with bioactive agents, and (iii) the fact that a big problem for such systems to be included in industrial roadmaps still remains, giving very low yields of isolation from biological media or cell cultures.

Due to the aforementioned shortcomings, other approaches are currently being exploited, such as the use of exosomes- or

extracellular vesicle-mimetics, which are, in most cases, liposomes constructed after appropriate selection of their components in order to mimic the composition (and hopefully) the structure of organotropic extracellular vesicles.

**Current Bottlenecks in Nanoparticle-Assisted Targeted Drug Delivery and Liposomes**

Several types of nano-based drug delivery systems (DDSs) have been, over the last 4 decades, and are currently being considered for drug targeting applications. Among all the nano-based DDSs, liposomes—that first reached clinical approval—are the most biocompatible and least toxic artificial systems, which is logical since they are constructed by phospholipids and cholesterol, the main components of cell membranes.

Liposomes have made great impact on therapeutics due to their advantages as DDSs. Indeed, in addition to their non-toxic and biocompatible nature that can accommodate high payloads of drugs, they have the capability of loading multiple drugs in order to provide protection of drugs from degradation, and to enhance drug endocytosis into cells. It is well known that Liposome-assisted drug delivery has a major impact on many biomedical areas, and that several liposomal formulations are proven to stabilize therapeutic compounds, overcome cellular/tissue uptake obstacles, and improve biodistribution, enabling thus the effective delivery of encapsulated drugs to target sites and minimizing their systemic toxicity.

In addition to the bottlenecks of insufficient targeting efficiency and translation difficulty due to their complexity, which have been identified for ligand-targeted liposomes, other types of targeted nanoparticles also suffer from poor biocompatibility and biodegradability, as well as immunogenicity, factors that could be resolved by exosome-

based drug delivery systems. Currently, the need for superior targeted-drug carriers is further increased due to the fact that the tremendous therapeutic potential of biopharmaceuticals will become available only after formulation and delivery issues are resolved.

Additionally, the development of drugs that act on the central nervous system is presently severely hampered by the lack of efficient methods to deliver the drugs into the brain. It is well known today that only a very small fraction (<1%) of injected antibodies enter the brain by passive diffusion, while other large molecule-drugs can be only administered by peripheral injection or invasive intra-cranial procedures, approaches that failed in the clinic. The extremely challenging issue of blood-brain-barrier (BBB) crossing is an urgent need, taking into consideration the worldwide rise in neurodegenerative disorders, as well as the yet unsolved problem of treating brain cancers, both situations having at present no recognized therapeutic solution.

In addition to the approaches mentioned above, other advanced methodologies have been exploited with the aim of further increasing the targeting potential of ligand-targeted-liposomes. In this context, phage display methodologies have been utilized for the selection of high affinity ligands. Additionally, multi-targeted liposomes which can target two or more receptors simultaneously have been constructed, with the aim of increasing liposome targeting efficiency. Other approaches employ the use of physical stimuli to further increase the targeting efficiency of ligand-targeted-liposomes, such as magnetic- or ultrasound-enhanced targeting. Nevertheless, in addition to other potential problems, the multifunctional systems may be too complicated for translation into drug products, a factor that should also be seriously taken into account when seeking solutions to the bottlenecks of actively-targeted liposomes, or nanoparticles in general.

**Similarities and Differences between Exosomes and Liposomes**

Exosomes have many similarities with small unilamellar, vesicle-(SUV)-type liposomes

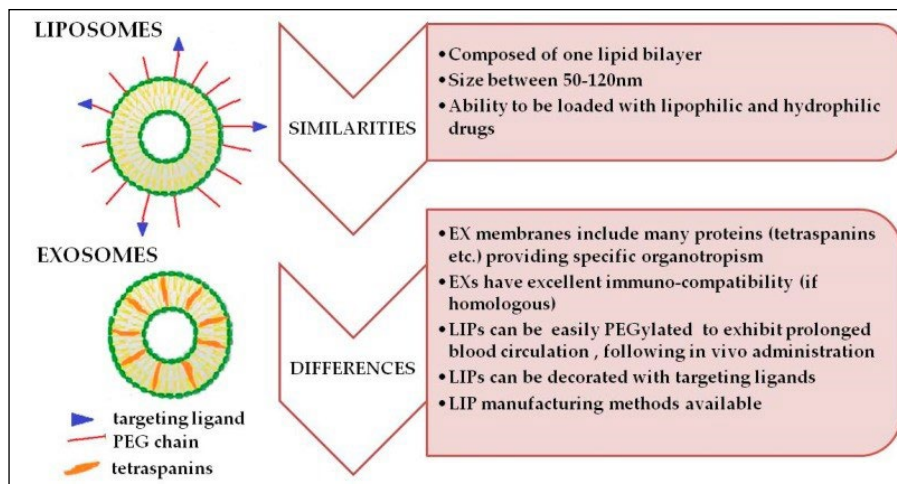
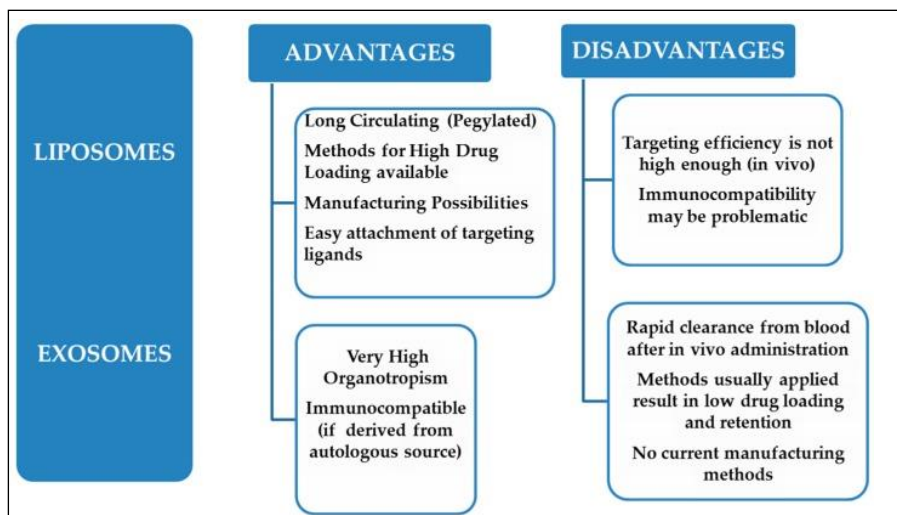


Figure 2: The basic structural characteristics, as well as the main similarities and differences of liposomes and exosomes are presented.

(Figure 2), which explains why most types of artificial exosome-mimetics are mainly based on liposomes. These similarities could allow researchers to engineer exosomes, using the methodologies developed in the liposome technology field. Indeed, both exosomes and SUV-liposomes, are vesicular structures consisting of one lipid bilayer, with mean diameters ranging from 50 nm to 120 nm. The major difference between SUV-liposomes and exosomes is the complex surface composition of exosomes, and more specifically, the characteristic array of membrane proteins such as tetraspanins, which are present on the membrane of exosomes, whereas SUV-liposomes do not usually have proteins in or on their lipid bilayer. These exosomal

proteins are required for facilitation of their efficient targeting and uptake by recipient cells.

When comparing the advantages and disadvantages of exosomes and liposomes, with respect to their applicability as targeted-DDSs, it becomes evident that the two systems are complimentary, since the advantages of the one system are disadvantages of the other and vice-versa (Scheme 2). Thereby, the incorporation of the advantageous features of the two vesicle types into one hybrid vesicle, if possible, would most probably result in the realization of an advanced system for drug targeting applications.



Scheme 2: Advantages and disadvantages of liposomes and exosomes.

## Sources, Methods of Isolation and In Vivo Clearance of Unmodified Exosomes

### Sources of Exosomes

Most cell types have been demonstrated to be able to release exosomes. Most of the in vivo-detected circulating exosomes (about 80%) are derived from platelets. Mesenchymal stem cell (MSC)-derived exosomes are currently being exploited for numerous applications since they have been shown to play a role in cell-free therapy of many diseases, including myocardial infarction, drug addiction, and status epilepticus. They are also thought to be able to ameliorate liver injury, inflammation-induced preterm brain injury, and various types of cancer. Exosomes are also found in many physiological fluids.

The cellular origin of exosomes strongly determines their contents, and as a consequence, also their functions. Exosomes which are produced by B lymphocytes contain functional MHC I, MHC II, and T cell co-stimulatory molecules, and can thus stimulate T cell proliferation. Alternatively, exosomes from cancer cells contain cell adhesion related molecules, such as gelatinolytic enzymes, and thus, they have the ability to enhance the progression and metastasis of tumors. Cancer cell-derived exosomes are actively incorporated by mesenchymal stem cells (MSCs) (in vitro and in vivo), since the transfer of exosomal proteins and miRNAs depends on the physical and functional characteristics of tumor-supporting fibroblasts.

### Isolation Methods

Several methods have been developed to efficiently isolate exosomes from cells and biological fluids. Each method exploits a specific trait of exosomes, such as their size, shape, density, or surface antigens to aid isolation. However, the most challenging task of all methods employed is to specifically purify exosomes from the wide spectrum of extracellular vesicles, cellular debris, and interfering molecular components. For this reason, the quality of each batch of isolated exosomes should be examined before any further application is pursued.



In all the exosome isolation methods, the first general step is to culture parental cells in serum-free media and allow the cells to condition the media. Conditioned media is then collected and processed in different ways based on the specific isolation method applied. For bodily fluids or other types of fluids, the principle for exosome isolation is the same as when starting from cell culture conditioned medium, but because of the viscosity of some fluids, it is necessary to dilute them, and in some cases, to pre-clean them from large bioparticles, as well as to spike them with protease inhibitors in order to prevent potential degradation of the exosome proteins.

**Ultracentrifugation:** Ultracentrifugation (U/C)-based exosome isolation is considered as the gold standard, and is one of the most commonly used and reported techniques for exosome isolation. There are two types of methodologies based on the principles of separation: differential and density-gradient U/C.

**Immunoaffinity:** Immunoaffinity capture-based techniques exploit interactions between antibodies and selective exosome surface proteins in order to isolate them. Higginbotham et al. recently demonstrated the feasibility of using fluorescence-activated vesicle sorting to analyze and sort individual exosomes from DiFi cells (human colorectal cancer cells).

**Other Size-Based Isolation Methods:** The most popular size-based exosome isolation technique is ultrafiltration. Based on their size, exosomes can be isolated with sequential filtration using membrane filters with defined size-exclusion limits (specific membrane pore sizes). Another size-based separation technique is size-exclusion chromatography that uses a column packed with beads that have smaller pores to those of the exosomes. Fractions are eluted sequentially in order of decreasing sizes, and exosomes can be thus isolated, from larger and smaller particles.

**Precipitation:** Exosomes can be isolated from biological fluids by altering their solubility. Various methods use polymers

that can precipitate exosomes according to their surface characteristics.

### **Yield of Common Isolation Methodologies:**

A common aspect among isolation methods is that they all involve multistep procedures, and thus, they finally provide a low production yield and/or a low purity of exosomes. The U/C method for instance, which is currently the most classical and reliable isolation technology, can isolate only a small portion of extracellular vesicles (~20–25%). On the other hand, immune affinity methods require expensive antibodies and matrices, but finally lead to similar yields to those acquired when using U/C. Size-exclusion methods are often used in combination with U/C or other techniques, but the complex-methods finally realize low yields due to the fact that a large fraction of the (extracellular vesicle) sample is lost due to its adhesion to the gel materials or the filters. Polymeric precipitation instead might achieve a higher yield than the other methods, but cannot purify the exosomes from the polymeric material used. Altogether, the very low production yield of exosomes imposes a tremendous impediment to their utility in research, thus delaying their potential clinical translation for any type of therapeutic application.

### **Types of Systems**

In this review, we will use the following categorization and naming for the various types of exosome-like systems which have been tested to date as drug carriers (Scheme 3).

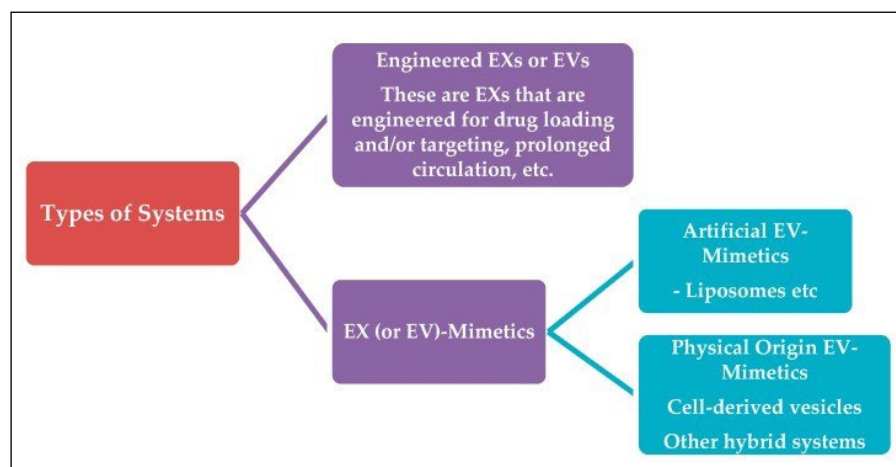
The two main categories of exosome-evolving-vesicles that are being currently used for drug delivery will be defined as:

- 1 **Engineered-Exosomes or Extracellular Vesicles:** This first category will include vesicles derived from isolated and purified exosomes or extracellular vesicles.
- 2 **Exosome or Extracellular Vesicle-mimetics:** This second category of vesicles includes all the vesicle-types that are not formed using exosomes or extracellular vesicles as their starting material. Such approaches have been explored in order to overcome the low yields of exosome isolation/purification methodologies, or to develop drug carriers for broader applicability.

**Artificial Exosome-mimetics,** when the starting material is of synthetic or semi-synthetic origin. In most cases, artificial exosome-mimetics are actually liposomes with or without specific proteins in their membrane.

### **Engineered-Exosomes or Extracellular Vesicles**

Several studies have exploited the potential use of extracellular vesicles for drug delivery/targeting, or, in general, for theranostic applications, after being engineered for drug loading, surface modification, or both.



*Scheme 3: Classification of EV-like vesicles used for drug delivery applications.*

## Exosome (or Extracellular Vesicle)-Mimetics

As mentioned above, there are two types of Extracellular Vesicle-mimetic systems: (a) Artificial exosome-mimetics and (b) Physical-origin Extracellular Vesicle-mimetics. The main theoretical basis, and some examples of the potential applications for drug delivery of the two different types, are presented below.

### Artificial Extracellular Vesicle-Mimetics

While pure populations of exosomes can be isolated from exosome-secreting cell lines, these exosomes, unlike those released from autologous primary cells, have immunogenic and oncogenic potential, inhibiting their broad use as drug delivery systems. Moreover, extracellular vesicles play multifaceted roles in health and disease, including the intercellular transfer of pathogens and disease-associated proteins, introducing major barriers for the translation of naturally secreted exosomes to the clinic. Extracellular vesicle-mimetics may help circumvent these barriers.

### Physical-Origin Extracellular Vesicle-Mimetics

Due to the low yield of extracellular vesicle isolation from cell media or other sources, extracellular vesicle-mimetics have also been composed by using other types of physical-origin media as starting material. Most of the physical-origin extracellular vesicle-mimetics studied to date are derived from whole cells.

Cell-derived vesicles or cellular vesicles (CVs) are a new and rapidly evolving class of biological drug delivery systems. Cellular vesicles retain the surface characteristics of their parental cells, and are thus highly biocompatible with efficient intrinsic targeting ability; additionally, they don't need any further surface functionalization. This offers a clear advantage over other (synthetic) drug delivery systems. Cellular vesicles are obtained by subjecting cells to physical processes producing vesicles of nano-dimensions. Cellular vesicles are derived from the cell plasma membrane. They are composed of a lipid bilayer and

have a final size between 50 and 200 nm. They are closed vesicular structures that incorporate many cellular contents from the parental cells, such as membrane proteins, intracellular proteins, and RNAs.

## Methods of Preparation and Engineering of Engineered Exosomes and Exosome-Mimetics

### Drug Loading Methodologies

The drug loading methodologies applied to date in the case of exosomes, and their physical mimetics (Cellular Vesicles), are categorized in two main groups, the pre-loading methods and the post-loading methods. The recently-developed microfluidic approaches are separately discussed (Scheme 4).

In pre-loading methods, the drug is initially produced or loaded in the parental cells, and thus, the extracellular vesicles or cellular vesicles isolated or produced by them are already pre-loaded with the desired drug. Such methodologies are particularly useful when oligonucleotides or proteins are to be loaded in the vesicles, in which case the cells can be programmed to produce "a-la-carte" extracellular vesicles or cellular vesicles (after applying particular cell engineering techniques).

In post-loading methods, the drug is loaded in the extracellular vesicles after their isolation. In recent years, scientists have been trying to apply high yield drug loading methods that have been used for liposome engineering, and in some cases,

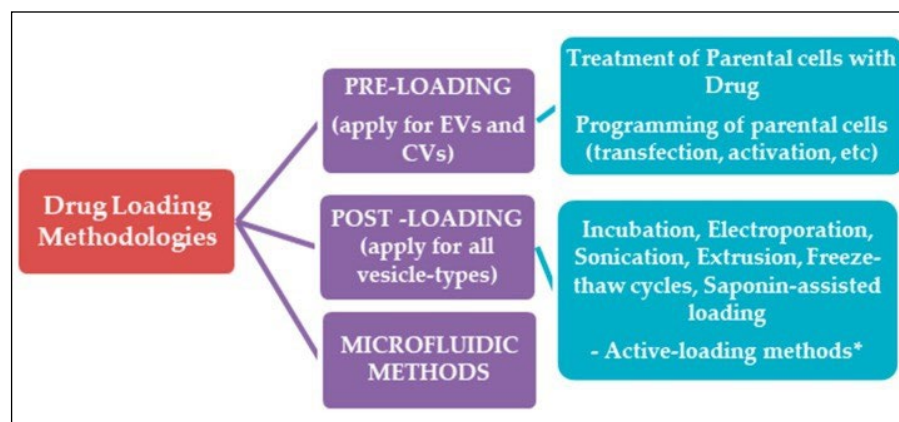
the loading efficiencies acquired are significantly improved

**Incubation with Drug:** The simplest way to incorporate any cargo into exosomes is their co-incubation, simply by mixing the isolated vesicles with the drug. The driving force for the loading is the different concentration of the drug in and out of the vesicle membrane. Hydrophobic drugs interact with the vesicles lipid layers, and the drugs diffuse into the exosome cavity along the concentration gradient.

**Electroporation:** By this technique, an electrical field disturbs the phospholipid bilayer of vesicles, creating small pores in their membrane, and thus allowing the passage of the drug into the vesicles. The integrity of the vesicle membrane is then recovered, resulting in the formation of drug-loaded vesicles.

**Sonication:** In this method, exosomes derived from donor cells are mixed with drugs and subsequently sonicated by a probe sonicator which allows the drug to flow into the exosomes due to the sonication-induced deformation of their membrane.

**Extrusion:** In this method, exosomes are mixed with a drug, and the mixture is loaded into a syringe-based lipid extruder and extruded through membranes with 100–400 nm porous size, at controlled temperature. During the extrusion, the exosome membrane is disrupted and vigorously mixed with the drug, resulting in drug loading into the exosomes.



Scheme 4: Categories of methods used for loading drugs into EXs and EX-like vesicles.

**Freeze/Thaw Cycle Method:** In this method, drugs are mixed and incubated with exosomes at RT, and the mixture is subsequently frozen at  $-80\text{ }^{\circ}\text{C}$  or in liquid nitrogen, and re-thawed at RT. This process is repeated for at least 3 cycles to ensure drug encapsulation. However, by this method exosomes, may aggregate, while the drug loading efficiency is generally lower than that of sonication or extrusion.

**Saponin-Assisted Loading:** Saponin is named from the Latin “sapo” which meaning “soap”; it is a surfactant molecule that, upon incubation with exosomes, generates pores in their membrane through interactions with cholesterol, leading to increased exosomes-membrane permeability. Saponin can also assist in loading other hydrophilic molecules into exosomes.

**Potential Clinical Applications of EXs and EXs-Mimetics**

To date, most of the reports related with the use of exosome-like vesicles for drug delivery concern the use of exosomes derived from cells, such as cancer cells, dendritic cells, from biological fluids or from other types of sources such as milk of fruits. Most of the studies are actually early preclinical proof-of-concept studies, to prove: (i) the possibility of exosome-like vesicles being loaded with sufficient amount of drugs; (ii) their capability to retain the drug under in vivo simulating conditions; and (iii) their potential to deliver the drugs in a functional state to the target cells of interest, at higher amounts compared to the free drug or other types of nanocarriers. In several cases, in vivo studies have also been carried out in appropriate disease models, verifying the in vitro findings. The pre-clinical studies performed to date concerning the usage of exosome-like vesicles for drug delivery aim to treat several potential diseases such as different types of cancers, cardiovascular diseases, Parkinson's and Alzheimer's disease, as well as other neurodegenerative diseases, musculoskeletal diseases, kidney and diabetes-related pathologies, and others.

**Challenges and Future Perspectives**

The main challenges towards unlocking the potential of exosome-like vesicles, regardless of their type, towards the development of novel targeted drug delivery systems with enhanced targeted efficiency, are related to the following factors: (i) the abundance of starting material for their construction and their preparation yield; (ii) the loading efficiency of drugs; (iii) the blood circulation time, assuming that this determines their targeting efficiency; (iv) the inherent targeting efficiency of the selected system, and how this may be affected by various engineering methodologies; (v) methods/roadmaps for scalable, repeatable manufacturing.

Between exosomes and cellular vesicles, the latter seem to have several advantages for clinical applications, the most important of which are: (i) the high yield, and (ii) the simple purification processes required for their production. These two advantages may be the ones that will perhaps facilitate the construction of a roadmap for the rapid manufacturing of engineered cellular vesicles from autologous sources for drug targeting systems.

Finally, several other issues have not yet been considered, such as the stability of engineered-exosomes, engineered-cellular vesicles, and artificial-exosomes, since it is not straightforward to predict how stable the protein parts of their membrane will be during storage. Furthermore, nothing is known about the potential to lyophilize such vesicle dispersions. ■

*First published in MDPI. To read the full version of the paper, please visit [www.mdpi.com](http://www.mdpi.com).*

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# Indian CDMO Industry: A Rising Star in the Indian Pharmaceutical Industry

*The fast growing Indian Contract Development and Manufacturing Operations (CDMO or CRAMS as popularly known in India) industry is attracting Investor interest. The 70 bn USD global CDMO industry is growing at 10 percent pa, driven by increasing generic utilisation, and need to enhance R&D productivity and reduce costs. Many Pharmaceutical companies have stated their desire to enhance outsourcing levels as they build drug pipelines and rationalise existing manufacturing/R&D assets.*

*Here, Puneet Goyal, Vice President at o3 Capital and Saumya Kothari, IB Associate at o3 Capital shares their considerations on the key patterns they hope to find CDMO industry in the coming decade.*



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Vice President  
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**Saumya Kothari**  
IB Associate  
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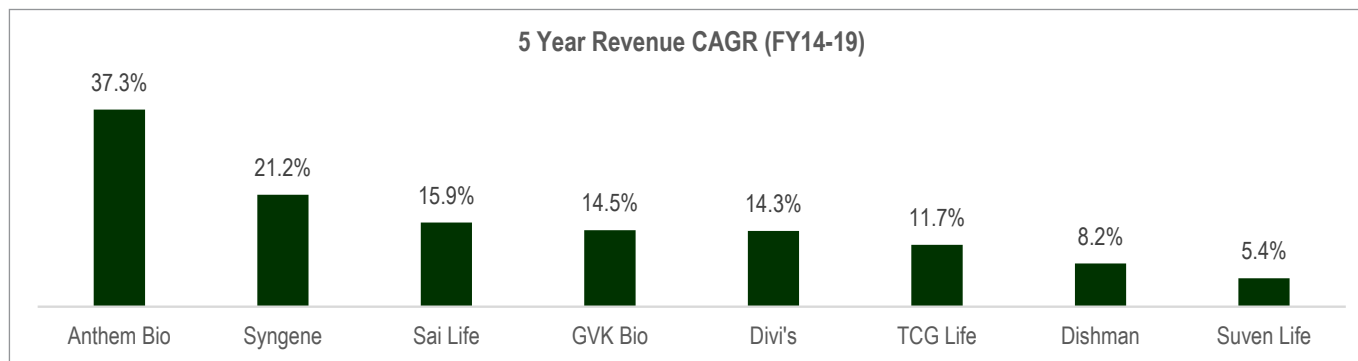
In an environment where the Indian pharmaceutical space has been grappling with various challenges, including pricing pressure and stricter USFDA regulatory vigilance, the Indian contract development and manufacturing organization (CDMO) industry has nevertheless been a growth story. While the Indian domestic pharma story largely remained range-bound with a revenue CAGR of 9.3 percent over FY15-19, the Indian CDMO industry grew at a CAGR of 15.9 percent during the same period. Globally, the prescription drug sales are expected to grow to USD 1.06 trillion in 2022, and R&D outsourcing business is expected to almost double from USD 41 bn in 2017 to USD 73 bn in 2022, growing at a CAGR of 12.2 percent. For pharmaceutical

companies, keeping spare resources and building expensive capacities for innovative drugs has proved inefficient, resulting in increased outsourcing of their early drug development activities to some of the leading CDMO players.

## Indian CDMO Market

India is amongst the preferred destinations for outsourcing of research as well as manufacturing activities as it offers several distinct advantages, such as lower manufacturing cost, ample talent pool to deal with ever increasing drug complexities, strong R&D capabilities and high IP adherence. Besides, India has already established itself as a significant player in the global pharmaceutical industry, especially in solid dosage form manufacturing.

A lot is at stake for a pharmaceutical or a biotech company and hence selecting a right R&D partner is important. Also, it is expensive and time-consuming to switch the CDMO once a manufacturing process is established, making it a long term and sticky relationship. For small biotech companies the decision is even more critical as they typically tend to partner very early, and outsource the end to end process, starting with drug discovery to development and later manufacturing. Factors such as fully integrated services, large scale manufacturing capabilities, R&D infrastructure, USFDA approval, access to newer technologies, track record of regulatory compliance, quality standards and financial strength play a significant role in influencing the decision of the R&D partner. Large Indian CDMO players with a proven track record and fully integrated services offerings are likely to be the beneficiaries of this future growth in outsourcing.



Overall, the Indian CDMO industry grew at a healthy growth rate and the chart below shows five-year growth track record of the key Indian CDMO players. It continues to be a fragmented industry, much like the global CDMO industry and has seen emergence of a few successful players on the global platform.

The Indian CDMO industry has seen several success stories in the recent past. Players like Syngene, Anthem Biosciences, GVK BIO and Sai Life Sciences have demonstrated strong revenue growth and established track record of quality and delivery. Syngene, a subsidiary of Biocon Limited, started operations in 1993 and today has revenues of more than USD 260mn. It has established a name in the global biopharma industry and boasts of having eight of the top ten pharma companies globally as its customers. Similarly, Anthem Biosciences which started operations in 2007-08 as just a drug discovery service provider, is today a fully integrated platform with state-of-the-art manufacturing plants, 700 plus scientists and capabilities across chemical as well as biopharma drugs. Both these companies also cater to speciality chemicals, animal health, agrochemical, consumer goods and nutrition companies along with the pharmaceutical clients.

The top Indian CDMO companies have grown at a CAGR of 14.1 percent over the last 5-year period compared to the top global CDMO companies which grew at a CAGR of 9.7 percent. Even in terms of profitability, the Indian companies

outperformed global peers, with the top Indian companies having EBITDA margins in the range of 20-30 percent as compared to the 10-25 percent range for the top global ones, thus delivering excellent returns for their stakeholders.

**Biopharma: A Game Changer for Indian Biopharma CDMO Players**

Use of Biologic drugs has increased in the recent years as it has superior clinical results as compared to Chemical Pharma, in terms of clinical efficacy, safety and bioavailability. Biologics are one of the top selling drugs worldwide with 11 of the top 15 drugs globally being biologics. However, a major drawback of biologics are high development costs, making them unaffordable and inaccessible to many patients worldwide. Biosimilars are generic versions of Biologic drugs which have no clinically meaningful difference in term of safety and effectiveness but cost much less than the innovator biologic drug. Given their cost advantages, experts believe the Biosimilar market is expected to witness an exponential growth of over 50 percent CAGR in the next five years.

India made early strides in this burgeoning segment and got its first Biosimilar drug way back in 2000, much before Europe and the US, when there were no specific guidelines available. Indian companies like Biocon seized this opportunity early on and were the first to make early strides in developed markets such as Japan and the US. In 2016, Biocon received approval for Insulin Glargine in Japan and in 2017 it received approval in the US for Trastuzumab, a drug

used to treat certain types of breast and stomach cancer.

Emergence of Biopharma in the overall pharmaceutical market has led to an increased R&D spend by the large pharma companies as well ample funding for emerging Biotech companies. Led by these factors, outsourcing of R&D in Biopharma is expected to grow at 19 percent CAGR over the 2016-24 period. India has a thriving ecosystem for biopharma, low cost of operations and ample talent and infrastructure to reduce time to market for development and large-scale manufacturing of Biologics and Biosimilars, thus making Indian CDMO companies an ideal partner for R&D in Biopharma.

**Conclusion:**

Global pharma players continuing to witness cost pressures and looking for ways to shorten time to market would look for well-established CDMO partners, particularly in India and China. Regulatory headwinds in China, incidences like Covid-19 and political confrontations with the developed economies of the world is likely to dent confidence in partnering with CDMO players in China. On the other hand, Indian CDMO companies in the last decade have demonstrated their capabilities on the global platform and are best positioned to benefit from increased R&D outsourcing in pharmaceutical industry. ■

## India's future healthcare landscape looks promising

*The sudden onset of coronavirus has brought healthcare as a paramount factor in everyone's life. People have realized that our medical services can't contain the infection spread among people right now. Seeing such a drastic impact on life and livelihood everywhere has proven the importance of healthcare infrastructure in a country like India. Mr Rajat Garg, Co-founder, myUpchar shares his opinion on building a promising foundation overnight.*



**Mr Rajat Garg**  
Co-founder  
myUpchar

With lockdown and hospitals not conducting OPDs, non-COVID related treatment has taken a backseat. Existing institutes are being pushed to cater the demand of such consultations. However, there is still a gap left to be filled. This pandemic has brought into light, few leading technologies which can fulfill these ever increasing demands for consultations. Telemedicine technology is one such facility that was earlier scarcely used but has come into the spotlight after the lockdown announcement.

Lockdown has proved as a forceful push in the adoption of teleconsultation technology by patients and doctors alike. myUpchar is such a healthcare startup that is offering its teleconsultation services to help people get quality consultations at home. The biggest advantage of this system is that it saves both travelling for consultations as well as money involved in this due process. Further, it minimizes the risk of getting infection for both the patient and the doctor.

According to a report of the Medical Council of India, the doctor patient ratio in India is 1: 1445 which is far behind the prescribed WHO (World Health Organisation) standard of 1 doctor for every 1000 people. With 78% doctors serving only 22% of the population, this ratio is far worse in Tier 2 and 3 areas. Use of teleconsultation will assist in eradicating this disparity and make the access of healthcare universal.

Currently, the ground reality of the healthcare system in India is that we

have several inferior quality clinics and quacks operating in every nook and corner. These health facilities do not have the required provisions or trained staff with knowledge pertaining to the disease which the patient has. The mediocre diagnosis which they provide sometimes even put the patient at higher risk of not recovering from their current illness.

On the other hand, the online consultations are very structured in the way that they work e.g. standardized prescription writing, treatment algorithms etc. As online players are working well on their record keeping practices and giving the best of their service, offline institutes in turn will also be expected to play well on the documentation part. This major advantage of the online system will in turn force offline institutions as well to adopt more structured practices as they will be challenged by the growth of online healthcare systems. The standardisation brought into practice by these online players will eventually build a strong pillar in the healthcare sector for India. We can expect platforms like myUpchar offering telemeds services to be on the rise as there will be consultation demand in the market even after this tense situation ends.

With the onset of coronavirus, several of the small and medium sized hospitals, nursing homes are under a lot of economic pressure. They will either close or merge with larger hospitals to survive as the economy would be cash-stricken in the near future. The mergers of these institutions will in turn require



implementation and use of tools like HIS, EMR (Electronic medical records) across the whole institution in order to replace the traditional paperwork with the latest digital systems.

If the Government mandates standard protocols for storing and retrieving healthcare information, it will make all

that patient's revenue is well captured in the local ecosystem, it deprives patients of high quality medicines especially in Tier 2 and Tier 3. With teleconsultations, standardized prescriptions will have drug names, which will make above practice a thing of the past. Patients can get a prescription online, walk to any pharmacy and take a medicine based

transparency. Gaps in the supply chain can be quickly identified and plugged by software solutions. Pharmaceutical companies will have an end to end visibility of the consumption patterns and can plan better.

With a slight nudge from the Government like issuance of telemedicine guidelines, Indian healthcare ecosystem has moved 10 years ahead in a matter of months. Covid 19 pandemic has brought an opportunity for the government and industry to revamp, adopt the digital processes and automation, and bring the much needed transparency, accessibility and accountability which a patient needs. ■

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*Lockdown has proved as a forceful push in the adoption of teleconsultation technology by patients and doctors alike.*

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hospitals talk to each other on a common health platform. This will allow any patient's information accessible to any doctor across the country with suitable permissions from the patient.

Next big pillar of healthcare in India is the million pharmacies available even in smaller towns. However, availability of high quality medicines is an issue as pharmacies partner with local pharmaceutical companies and doctors to make a mini nexus. While this ensures

on drug name vs brand name. Chemists all over India can also be brought onto a common platform to procure high quality medicines from authorized pharmaceutical companies. myUpchar chemist app already provides such a platform to over 10,000 chemists across northern India.

Smaller pharmacies surviving due to current nexus will either collapse or merge into pharmacy chains which will bring digital processes and

# Pharmacovigilance in India: An Undervalued Growth Opportunity

*Pharmacovigilance is now accepted to be a continuous process of evaluation accompanied by steps to improve safe use of medicines which involves pharmaceutical companies, regulatory authorities, health professionals and patients. The methodologies have broadened to encompass many different types of study, with spontaneous reporting remaining the cornerstone. In a vast country like India with a population of over 1.2 billion with vast ethnic variability, different disease prevalence patterns, practice of different systems of medicines, different socioeconomic status, it is important to have a standardized and robust pharmacovigilance and drug safety monitoring programme for the nation. The involvement and the role of pharmacists will increase in the area of pharmacovigilance.*

*The article by Amartya Bose and Khushbu Jain, Industry Analyst, Transformational Health Practice, Frost & Sullivan aims to bring forth the undervalued growth opportunity for PV in India.*



**Amartya Bose**  
Industry Analyst  
Transformational Health Practice  
Frost & Sullivan



**Khushbu Jain**  
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**P**harmacovigilance (PV) is defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. According to Frost & Sullivan, the global PV market is almost US \$5 billion; APAC accounts for approximately 25 percent and projects the fastest growth. India has been a key contributor to this growth in APAC, flourishing on the back of increased domestic drug consumption as well as outsourcing of services for data processing and monitoring to a certain extent.

India has come a long way in establishing PV systems and protocols from 1986 to

2010 with AIIMS and WHO working in conjunction. The Indian Pharmacopoeia Commission - Pharmacovigilance Programme of India (IPC-PvPI) with 250 established adverse drug monitoring centers all over India is now a WHO Collaborating Centre for PV in Public Health Programmes and Regulatory Services. The Central Drugs Standard Control Organisation (CDSCO) has also made efforts to simplify the adverse drug reaction (ADR) reporting process in India by offering a toll-free number and the ADR PvPI mobile app, in addition to the standard protocols. The reported adverse drug reactions are recorded and analyzed at the centers in Vigi-flow software, which are reported to CDSCO and WHO for further regulatory action. This has been adopted by domestic pharma companies and their western counterparts. AstraZeneca, Pfizer, and Novartis have set up PV centers in India using independent units or by forming strategic alliances with PV service providers like contract research organizations or business process optimization providers. As part of the continued efforts, pharma companies have also taken it upon themselves to advance the health literacy among patients and engage with them through customized solutions, like Bayer's SafeTrack tool.

However, this is not enough when compared to the global average. Despite an established framework, India lags with only 3 percent adverse events reported, as opposed to the global average of 6 percent-20 percent. ADR is considered to be the sixth-leading cause of death. This



implies that out of 500,000 to 700,000 adverse event occurrences captured each year, low- to middle-income countries representing more than two-thirds of the world's population account for a small portion of all the adverse drug reaction data. Lack of health literacy is not the only culprit. Less/delayed reporting, non-availability of trained staff to handle reported issues, imprecise documentation system, non-adherence to the schedule and confidentiality issues contribute to the deficiencies in the PV system.

But as India moves on an expanded growth trajectory, excellence in PV systems can give the necessary boost to accelerate this growth. India is already the world's third-largest producer of drugs in terms of volume and 13th by value, thereby accounting for approximately 10 percent of global production by volume and 1.5 percent of the world's production by value. India is the chief contributor of generic medicines globally, with a 20 percent share in global supply by volume, and also supplies 50 percent of global demand for vaccines. India provides 60,000 generic brands covering 60 therapeutic categories, manufacturing more than 500 active pharmaceutical ingredients. But under Pharma Vision 2020, India is taking a different path, with rapid induction of new chemical entities (NCEs) and high-tech pharma products, which will make India a hub for new research and clinical trials.

This creates an urgent need for companies to advance post-marketing phase IV trials to evaluate the long-term effects of the drugs. Doctors, pharmacists, other healthcare professionals, and patients must be encouraged to continue reporting serious suspected adverse drug reactions, whether unknown or known, to manufacturers and respective local regulatory agencies. Some of the adverse drug reactions can be avoided by accelerating spontaneous

reporting and adopting a targeted spontaneous reporting methodology at ADR Monitoring Centres located across India.

Although India is relatively new to new drug development and PV, it does have a distinct advantage of strong IT infrastructure and an enviable talent pool.

In the current system, India is already a preferred hub for outsourced PV activities, like the collection of adverse drug reaction data, individual case handling, periodic reports, signal management, and risk management. Within these segments, the PV outsourcing market in India is dominated by case handling activities that involve case processing and medical review of individual case safety reports (ICSRs). Apart from commonly outsourced PV functions like case management and data entry, the other high-end, niche actions like signal management and aggregate reporting set the country's service suite apart.

However, a stronger IT infrastructure offers promise in process automation. India is well-positioned to take the lead in adopting newer technologies such as harnessing AI to transform PV into a sustainable and scalable operating model, which can eventually free up resources and allow them to focus on innovation and advance the knowledge base associated with newer products.

BPOs such as Accenture, TCS, Cognizant, and Wipro focus on core PV activities, like case handling, ICSRs, etc., provide PV Software-as-a-Service (SaaS) and have already paved the way for growth in the Indian PV sector. This software using AI and machine learning resolves industry problems with cognitive automation. By leveraging advanced Optical Character Recognition (OCR)/ Intelligent Character Recognition (ICR), Natural Language

Processing (NLP) and Robotic Process Automation (RPA) technologies, players like TCS and Genpact are unlocking the potential of unstructured data, reducing the cost and effort of processing adverse events, and providing real-time predictive analytics with a cutting-edge visualization-analytics-interaction workflow framework. Companies like Linguamatics, an IQVIA company, are changing the dynamics of data mining by providing access to a vast library of content, e.g., MEDLINE® containing journal citations and abstracts for biomedical literature from around the world, FDA Adverse Event Reporting System and DailyMed publishing, and up-to-date and accurate drug labels for healthcare providers and the general public. The NLP platform converts unstructured text into actionable data, providing structured results at every stage of the drug development process. These results can be presented in a wide choice of formats, allowing the user to analyze relationships between entities.

There is no doubt PV is driven by automation, AI, and robotics. In an era of Industry 4.0, digitizing business models is one of the top priorities for many sectors, and the PV outsourcing industry is no exception. Also, government-led initiatives such as the PvPI, primarily to amplify the safety and awareness related to the use of a medicinal product and adverse event reporting will further encourage the growth of the PV market in India. This will not be restricted to outsourcing but will include "insourcing" as well. As India opens its gates to cross-border collaboration on drug research, testing, and clinical trials, it will call for harmonized reporting systems and agility to adjust to evolving guidelines. ■

## Innovation for Parexel: A Right Mix of Driving Efficiency, Improving Quality, Lowering Cost, and Meeting Patients' Needs



**Peyton Howell**  
Executive Vice President  
Chief Commercial  
& Strategy Officer  
Parexel International



**Sanjay Vyas**  
Senior Vice President, India  
Country Head & Managing Director  
& Global SBU Head - Clinical Trial  
Supplies & Logistics  
Parexel International

In an exclusive in-person interaction with PharmaBio World, Peyton Howell – Chief Commercial & Strategy Officer of Parexel International and Sanjay Vyas – Senior Vice President, India Country Head & Managing Director; & Global SBU Head - Clinical Trial Supplies & Logistics, Parexel International speak about Parexel's business footprint, expansion plans for Indian corridor, positioning over its contemporaries, regulatory guidelines, technology & innovation, patient-centricity, and many more intertwined aspects.

**Being a Global name in CRO World, please walk us through Parexel's business footprint.**

**Peyton Howell:** Parexel is one of the largest Clinical Research Organizations (CRO) globally, with a 35-year history that includes being one of the first CRO organizations. The suite of biopharmaceutical services we provide to our clients across the globe ranges from clinical trials to regulatory, consulting, and market access to transform scientific discoveries into new treatments. Our

global regulatory expertise, Phase I-IV clinical research services, integrated e-Clinical technologies, and advanced commercialization services all work together to move our customers and through the development journey smoothly and cost-effectively from the beginning to the end. While we have dual headquarters near Boston, Massachusetts and in Durham, North Carolina, we work with clients in more than 100 countries across Asia, Europe, Middle East & Africa, North America, and South America.

**What is your expansion plan for Indian Corridor?**

**Sanjay Vyas:** In the Indian Life-science market over last 5 to 6 years, it's evident that there has been double-digit growth in the range of 12 percent to 15 percent and we hope that Parexel will reflect that growth. India has been proved as a fast-growing segment, country-wise, for us in terms of jobs, investments, and talent-pool. As a global clinical research provider, we consider India as a very important hub. Our Indian operation reflects Parexel globally,

comprising of all the globally operating functionalities. In India, we have presence in six major locations across Bangalore, Hyderabad, Chandigarh, Mohali, Mumbai, and Delhi. What differentiates us from our contemporaries is our global scale including our strength in India. Amongst almost 20,000 employees of Parexel, 25 percent count – which calculates as over 5400 people – comes from India. This acts as a huge differentiator for us in being able to provide global services to our customers.

**Parexel being a Global Lead as a Biopharmaceutical Service Provider and CRO, how has Parexel positioned itself over its contemporaries?**

**Peyton Howell:** The most important thing for Parexel is that we continue to innovate with a constant focus on patients. Our philosophy revolves around patient centricity. When it comes to recruiting and retaining our patients, we believe in making it as easy as possible for the patients to learn about and participate in clinical trials. This means incorporating the needs, views, and experiences of patients and caregivers at all stages of clinical development. All of our colleagues globally live this focus every day – we put the patient at the heart of everything we do.

From the perspective of our services, Parexel provides a breadth and depth of support for customers from the introduction of molecule to the patients to commercialization and post-approval studies. Parexel also has a strong capability in regulatory consulting, with more than 1000 regulatory-related experts on staff. We have several adjacencies in managing clinical trial supplies and logistics, and our technology platforms and offerings that support clinical development with applications through our Informatics

division. This integrated approach of services brings real value and innovation to our customers.

Our focus on innovation is all about getting the right mix of driving efficiency, improving quality, lowering costs, and delivering the medicines that meet the patients' needs.

**When it comes to regulatory guidelines for Biopharmaceutical companies, how do you compare it in between global context and Indian context?**

**Sanjay Vyas:** Regulatory consulting is actually where Parexel started. We were founded as a regulatory consulting company and today, in addition to our significant clinical research capabilities, we have over 1000 consultants globally in regulatory and market access, many of whom came to us with direct experience working within global regulatory agencies. It's worth mentioning that about 30 percent of our regulatory experts are based in India. Having this first-hand perspective of regulators is critical to success for many of our biopharmaceutical customers.

In India, between 2013 and 2019, we saw a reversal of existing regulatory guidelines and introduction of new regulatory guidelines that had a tremendous impact across the industry. Today, we are seeing two types of development paths happening in India:

- Global clinical trials, with international sponsorship, being conducted in India
- Indian biopharmaceutical companies who want to go global and having local as well as global aspirations

These changes have brought in a big impact for growth in India. In 2019, the highest number of clinical trial applications were registered since 2013. The regulatory changes have benefitted

patients and have also been helpful in driving industry growth.

In terms of comparison between Indian and global landscape, clinical trial regulatory guidelines now follow global standards. This is to ensure that global companies can make their entry to India and they can have the same experience across the globe. Indian companies are also expected to follow international regulations in order to catch up on what they missed out in last 5 – 6 years. China has followed a similar path. All of these changes have been beneficial to patients.

**Technology, innovation, and digital transformation play a great role in clinical research and drug development. What are the emerging trends and how is the Indian industry going to adopt it? And how will it impact the entire clinical & drug development sector in the coming days?**

**Peyton Howell:** It's a very broad yet interesting topic. However, the most important question in context of CRO industry is: are the innovations happening keeping the patients in mind? Also when it comes to technology innovation, it's not just about digitalization - it's about how digitalization positively impacts the customer experience. For example, how does the industry use artificial intelligence for predictive analysis? How can the entire lifecycle of study design be reduced through prediction?

With the COVID-19 health crisis we have observed how global situations can unexpectedly impact the ability of patients to physically visit a site which is paving the way for the increased consideration of decentralized clinical trial (DCT) approaches. The key to success in moving to a decentralized approach is prioritizing trial standards and consistency to ensure patient safety. Many sponsors have a renewed interest in DCTs as they work to maintain patient safety and data quality and Parexel is working closely with sites and members of our Patient Advisory Council to ensure that we're keeping both the site and patient input top of mind as we shift a number of traditional trials to the home.

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*In the Indian Life-science market over last 5 to 6 years, it's evident that there has been double-digit growth in the range of 12 percent to 15 percent and we hope that Parexel will reflect that growth. – Sanjay Vyas*

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COVID-19 also has made access to data and the effective use of data in clinical development even more critical as we look to reduce the time to market for new diagnostics and therapies, as well as reduce the burden on patients. Leveraging data enables us to take a more patient-centric and patient-friendly approach in identifying and developing potential cures when compared to randomized controlled trials. Another potential benefit may be the faster and near real-time evaluation of decision-making based on the data that, in turn, will help save lives and result in identifying effective therapies faster.

Parexel also has a multi-year partnership with Datavant that enables linking of anonymized data across the entire patient journey, including electronic health records, claims and diagnostics, as well as emerging sources such as genomics, wearable devices, socioeconomic and behavioral data and more. Connecting these data sources yields a more holistic view of patient health than clinical trial data alone. By linking real-world data sources with other sources of study data, biopharmaceutical customers will be better equipped to generate and submit real-world evidence for regulatory assessment.

**Since over a decade, the evolution of data science has been impacting the clinical research services to a great extent. How do you experience this evolution and impact in Parexel? What do you do which gives you an edge over your competitors?**

**Peyton Howell:** Parexel has been leveraging data as a critical part of the clinical trial process for some time, through real world evidence (RWE) studies, decentralized and hybrid trial approaches.

Through our partnerships with leading data and analytics companies, we have

the ability to access diverse data sets, and to anonymize and link the data to make connections and insights that enhance the clinical development process. Data can also be used for modeling and simulation in the early stages of development to help reduce risk and increase the likelihood of success by producing a more informed trial design. Our recent acquisition of Model Answers provides Parexel greater access to the specialized talent and processes necessary for effective modeling and simulation for our customers.

The COVID-19 situation has made access to data and the effective use of data in clinical development even more critical as we look to reduce the time to market for new diagnostics and therapies, as well as reduce the burden on patients during these challenging times. Leveraging data enables us to take a more patient-centric and patient-friendly approach in identifying and developing potential cures, when compared to randomized controlled trials. Another benefit may be the faster and near real-time evaluation of decision-making based on the data that, in turn, will result in identifying effective therapies faster.

**'Patient First' is one of your prime attention areas. What are the practices that you follow to ensure patient-centricity?**

**Peyton Howell:** Patients are at the heart of everything we do. We are focused on engaging and supporting the patients throughout the development cycle by incorporating their input at every stage - pre-study, during the study, and post-study: market access & beyond. Pre-study includes study design – with Patient Centric Protocol Optimization (PCPO). We use PCPO to incorporate the needs, views,

and experiences of patients and care givers into trial planning. This helps to create a more patient-friendly study design. This also supports the development of a more practical protocol to ease the patient burden. Throughout the study we work to reduce the visit burden and promote ongoing trial engagement. Post-study, we work to demonstrate value and support evidence generation and patient access. Our decentralized clinical trial (DCT) offering is also driven by the need to enhance the clinical trial experience to improve patient safety.

**These days leading companies do follow the 'employee-first' concept. What is your point-of-view towards it? And how do you amalgamate it with 'customer-first'?**

**Sanjay Vyas:** Our employees here in India have embraced patient-centricity and our "Patients First" approach. We emphasize everyday why we do what we do, and it resonates with our colleagues in India and globally. We also have been recognized with several awards globally and in India for our Diversity and Inclusion initiatives.

It is important that our employees feel proud for their purpose to work for Parexel. Every day we focus on the patient and keep the patient at the heart of everything we do. That purpose is felt throughout the organization across the globe.

**What would be your message for Indian Biopharmaceutical Companies / Industry?**

**Sanjay Vyas:** Parexel sees great potential for growth in the Indian biopharmaceutical market, and we are excited about the opportunity to bring our significant clinical development, regulatory and technology expertise, along with innovative approaches and a patient focus to customers in the market. We also see a need to continue to educate the Indian population in general about the clinical research. We also see a need to work closely with sites and investigators to ensure alignment of all aspects of clinical research, to ensure continuity in our industry today, and going forward. ■

**Interviewed by:** Jayati Mukherjee

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*We innovate with a constant focus on our patients. Our philosophy revolves around patient centricity. When it comes to recruiting and retaining our patients, we believe in making it as easy as possible for the patients to learn about and participate in clinical trials – Peyton Howell*

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# Neuberg Diagnostics Private Limited -Taking on the COVID-19 Challenge



**Aishwarya Vasudevan**  
Group COO  
Neuberg Diagnostics Private Limited

Neuberg Diagnostics Private Limited, a StartUp in the PathLab chain segment, has commenced COVID testing in its Neuberg Ehrlich Laboratory, Chennai post the approval from ICMR. Neuberg is the only Lab Chain in India, whose four facilities have been approved by ICMR and will offer COVID-19 RT PCR tests through its. The COVID-19 testing in Neuberg's labs will follow guidelines by ICMR and other competent government agencies. As per the guidelines issued by ICMR for COVID-19 testing in private laboratories, Neuberg will provide the test to an individual only when prescribed by a qualified physician, while also adhering

to the sample collection and testing guidelines set by ICMR. All COVID-19 positive samples will be transported to ICMR-NIV (National Institute of Virology), Pune under suitable Biosafety and Biosecurity precautions as laid down by ICMR.

PharmaBio World interviewed Aishwarya Vasudevan, Group COO, Neuberg Diagnostics Private Limited to discuss and offer insights into Neuberg's adherence to quality and protocols. With over 16 years of experience, Aishwarya has a rich background in P&L, Sales, Marketing, Operations, Training, Customer Engagement and Quality. She has strong credentials in consumer healthcare and has successfully developed and launched sales strategies, innovative marketing & branding solutions, and is very passionate about ensuring flawless adherence to quality and protocols.

**Congratulations! Neuberg joins an exclusive clique, garnering ICMR approval in testing for COVID 19. What efforts drove toward this timely achievement?**

Thank you! We are the first laboratory chain in India to get approval for 4 labs for COVID19 testing. This is due to the strategic development of our regional reference laboratory network which are NABL/CAP accredited, with BSL2/BSL3 classification, good technical expertise and experience in the RT PCR technique which is the preferred method for COVID19 testing. Our strict adherence to ICMR guidelines and GLPs were key contributing factors for us to be chosen as their partner in this crucial endeavor of national importance.

**How do you see an accolade of such timely prominence shaping Neuberg's journey, in the near five years?**

We currently view this as an exercise of National duty and are yet to evaluate the long-term implications. However, this will add to our recognition as a global diagnostic consortium with several centers of excellence in the fields of Pathogen Identification, Proteomics, Genomics, Metabolomics, Digital pathology, Personalized Medicine and Data analytics powered by great team of visionary leaders, reputed domain experts and competent workforce.

Our vision from day one is clear- the patient is the center of our universe, doctors and other healthcare professionals are our partners in ensuring patient care through affordable and accessible diagnostics and research.

The journey so far has been one of tremendous satisfaction and learning I am confident the coming years will see us garner further reputation as a leader in quality diagnostic services.

**What is a single most prominent opportunity in Pharmaceuticals and Biotechnology, that you wish could facilitate future growth?**

India is a vast country and is home to a large pool to genetic resources due to its ethnic diversity. I believe the future is in precision or personalized medicine which has been gaining tremendous momentum since the completion of the Human genome project. This will help in reducing cost of treatment, eliminating one size fits all approach and ineffective treatment plans.

But in my opinion, we are yet to make the best of genomics, the impact of this science can have on the health of an individual as well as a population is tremendous. There is still a lot of scope of awareness and education about this field in general public including the doctors.

With center of excellence for Genomics in Ahmedabad and we aim to lead the movement of awareness of this science. We are the first lab in India to bring highest throughput DNA sequencer which will support us in the study of human genes at an unprecedented scale by sequencing more number of samples to discover rare and novel genetic variants.

**What are the top three forays you see soon for the Pharmaceuticals and Biotechnology world? Are these different when considering a national and international market?**

There too many to pick but currently I see Companion diagnostics, Clinical Research and Precision medicine using both conventional techniques and advanced tools such as Flowcytometry, Next Generation sequencing, Mass Spectrometry especially in a synoptic fashion is a good foray both in the national and international market.

Our ability to customize services, adopt novelties and engage effective SMART teams will ensure our success. Our Mantra is Constructive partnerships with defined priorities- Patient, Science and Customer satisfaction. I am sure the commerce will follow.

**What impacts and / or transformations do you see digitization and digitalization making in the Pharmaceuticals and Biotechnology industry?**

Digital transformation and machine intelligence (Artificial Intelligence or AI) is helping companies to achieve cost effective medicine and superior health outcomes. Digitization has allowed us several luxuries including cross consultations between domain experts, accessibility to experts across geographies, using AI tools to make decisions more objective and data driven.

We are running several neuronal networks and AI tools to solve simple problems such as using peripheral smear and CBCs to differentiate between several forms of anemias to complex problems like diagnosis of genetic diseases. A gene sequencing generates more than 100 GB of data and with the help of AI it has become easy to screen and analyze this vast amount of data in a matter of time. It is helping the industry in reducing the cost, streamline R&D efforts and time for the clinical trials.

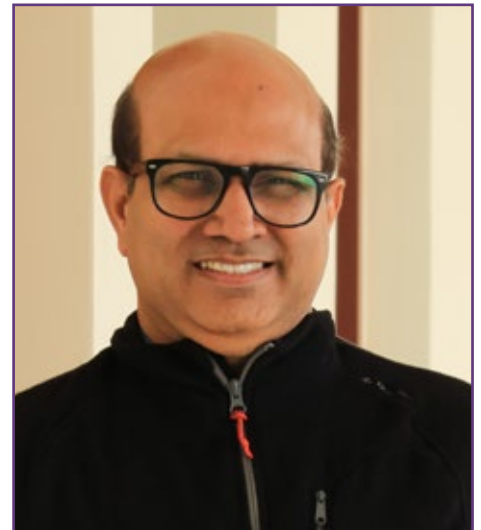
We are in the digital age and healthcare is at the forefront on adopting these tools however one must always remember medicine is an empirical science and not an exact science like mathematics and all digitization should be done with sure diligence in accordance with clinical guidelines and requirements. ■

## “PULSE” - Presenting Unique Life Science Entrepreneur

*The India pharma industry is adapting novel technologies and medicinal practices steadily. Pharma and Lifesciences, while a critical pillar of any economy, is a highly competitive and regulated sector. The Pharma and Lifesciences segment has witnessed a strong traction, with a large number of startups entering this domain.*

*Dr Sreedhara R Voleti, CEO, ASPIRE-BioNEST will be curating a new column on Pharma and Lifesciences start-ups. Titled “PULSE” - Presenting Unique Life Science Entrepreneur, the column every month will feature a Unique Life Science Entrepreneur. On the prime edition of this column, Dr. Voleti will be introducing the readers to Dr. Subhadra Dravida, MD & CEO, TRANSCCELLBIO and a group of companies under it.*

*For more information about ASPIRE-BioNEST: <http://bionest.uohyd.ac.in>*



**Dr. Sreedhara R Voleti**  
CEO  
ASPIRE-BioNEST

Entrepreneurship, especially in healthcare is a long-drawn challenge for variety of reasons. Let them be discovery of pharmaceutical drugs, biologicals, biosimilars/betters, or tools like prototypes for instruments, microfluidics, wearables, and healthcare diagnostics viz. kits, standards etc. all related to healthcare are the opportunities one can undertake. Past decade, in all, excepting discovery of new drugs of chemicals or biological nature, India has been raising its entrepreneurial bar in innovations with the governmental, venture, and capital funding support. According to DBT's BIRAC and other funding agencies for science and technology of Govt. of India, an unprecedented number of startups in life sciences have been funded – albeit, the total funding done is small when compared to the rest of the developed world. Focusing on the opportunities available, many startup innovators have jumped the entrepreneurial band-wagon “to-make-a-difference” than continuing the conventional journey of job-searching in academia or industry. In-order to make a mark of their own, the hunt for innovating novel products by India, for India, made in India has started and mushrooming quickly for bringing self-goals with vision and mission to help society – waking the innovation gene of society becoming an entrepreneurial society, for generations to come. The unprecedented current generation of entrepreneurs and innovators, especially in life sciences, brings an awe for the job-seekers.

This change now has led the society to believe not just “Success is not just a measure of reaching valuable product after efforts”, but the number of sustained efforts made by numerous players

aiming to bring useful outcomes to society. Hoping the tribe-culture of entrepreneurship grows over-the-period of sustained efforts - leading India to become a knowledge-based economy with a valuation that each entrepreneur/startup innovator brings to society.

“Untiring Entrepreneurs Unlocking the Innovation Potential in Healthcare”, is a new series that PharmaBio World is bringing to its audience, viewers, and members - through interviews/article format, with a focus on divulging cutting edge technologies made through research outcomes with translatable, scalable, and commercialisable potential by various startup innovators. A monthly report on key differentiating innovative entrepreneurship with a USP focusing on knowledge-enhancement leading to an entrepreneurial economy will be brought into limelight by the magazine.

PharmaBio World brings new dimension to its audience, the feel of PULSE that presents a narrative with entrepreneurs in life sciences, especially wanted to make a difference in bringing wishful thinking into reality with unique scientific proposition for society. A stimulating discussion with Dr. Bindu Balan, a long-standing friend of Dr. Voleti, brings life to the series, PULSE!

Watch this space for exciting information of “knowledge-for-society” in healthcare!

In this edition we bring forth the journey of Dr. Subhadra Dravida, the Founder & CEO, TRANSCCELLBIO and how she and her team is transforming the space of stem cell research and applications.

### TRANSCCELLBIO - Disrupting Biopharma industry through Stem Cell Technologies

Transcell Biologics is an innovative biotech company with continuous discovery and process development as its central theme to deliver unique disruptive stem cell based solutions to treat chronic and debilitating diseases that have otherwise no options available to manage. The passionate leadership team is committed to developing therapies to address important medical needs through adult stem cell technologies by collaborating with clinicians and patient communities. Among the company's landmark innovations is the development of a novel proprietary process for maximizing the therapeutic stem cell yield that also maintains the native pluripotent properties and inherent functionality. The Company has evolved from solely an R&D-focused biotech entity diversifying based on the intended applications of stem cell technologies.

There are few companies that can boast of being insightful, cost-effective in the first year of operations and Transcell is one such. At present, the group comprises 40+ members including technologists and sales personnel taking in-house research based service and product offerings to the market.

Having kick-started its operations nine years ago, the growth of Transcell Biologics, a Hyderabad-based Biotech company from being an R&D unit that translated adult stem cell technologies into clinical reality to become a group that has launched the first indigenously developed stem cell storage products as services in India, has been nothing short of inspiring. The story of Transcell in truth is also the story of a strong woman, Dr. Subhadra Dravida, the Founder & CEO of the company who is leading to cut her own niche in the competitive Biotech global industry.

Dr. Subhadra set her own success points, or milestones as she calls it, and ensured that every stride she takes is towards that predefined vision. Her success has been quite exemplary with its discipline of execution from establishing labs to handpicking teams, undertaking R&D towards productization, protecting the company's intellectual property (IP), launching certain products as services generating revenues to the company, strengthening the IP portfolio, entering into multiple geographies attracting strategic partners, and even being able to take the deep science IP to make road shows. She lived many lives in her journey with the company.

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

### INTERVIEW:



#### Dr. Subhadra Dravida

Founder & CEO  
TRANSCCELLBIO

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

Speed matters as Science can't wait. My dream was to translate the stem-cell technology prowess into an application and reality, which was the toughest challenge faced during my initial entrepreneurial days. My formal technical training with a relevant work experience from global industry perspective led my entrepreneurial journey begin. Ecosystem in India in this specific field was virtually non-existent that gave me the fast-first-mover advantage. My family ecosystem was most supportive including my parents, and sister (practicing lawyer) who is inspiration beyond par for making me assertive, positive, and progressive even today, and my son and husband (globally renowned chemist) for being the reason and cause for internal peace.

#### What was the gap/unmet need that forced you on-board of the entrepreneurial track? How the name "TRANSCCELL" originated?

Advanced applicative outcomes of stem cell technologies back then weren't a gap but weren't existing in India especially covering the therapeutics and non-therapeutics. As a fast mover, the patents and technical know-how were to my advantage, where the story began. Stem cells understanding from academia and industry are poles apart, while Transcell® (Transdifferentiating Stem Cells) group with related entities in toto is an instrument that deals with adult stem cells to intended



translational outcomes. Transcell has been operational since 2011, and all its entities have evolved during the past decade.

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

There were established government funded labs doing research and established biopharma industry with deep pockets, but not a-scientist-driven knowledge based spin out enterprise/s built on the foundation of intellectual property in India in this field during that time. The confidence that has stemmed to start and continue to operate was from the intellectual property on the defined path and my technical background to deal with any perceived risks and competition associated with the business part of science. Life has taught me to be prepared for the worst always and so my chase was to realize the vision set while Transcell is a journey.

**Describe the different entities of your parent organization, the eulogy, reasons for starting them (Knowledge-based and service-based)?**

Transcell Biologics is the parent entity built on Adult Stem Cell Technologies for the intended applications as the central theme. To source adult stem cells, one should have a repository because the source material is human specific, and, accessing the source material involves ethics and regulations. But, there is a parallel industry on ethically immuned sources like human biological discards like Umbilical cord, Milk teeth, Lipoaspirates, Bone marrow where adult stem cells were known to be residing that Transcell got into. Creating a biobank as a function was the brainchild, while it became source of revenues from privately stored units gave me the freedom to feed the in-house R&D in productizations. In the context of Transcell Biologics, we had therapeutics and non-therapeutics as two broad divisions imparting stem cell applications: (a) Regenerative medicinal and (b) Role in Cancer Research. In 2017 August, Transcell Biologics underwent desubsidiarization and gave birth to two- spinouts: (a) Transcell Biolife (a pure play biobank), and (b) Transcell Oncologics (Developing next generation first-in-class druggable formulations for debilitating cancers). Transcell Biologics continues to be the parent entity with it's own IP and related clinical collaborations to address Neurodegeneration and Periodontal diseases.

**What are the Vision, Mission, Value proposition for your different entities?**

**Transcell Biologics ([www.transcellbio.science](http://www.transcellbio.science)):** A technology investing entity translating adult stem cells into application reality.

**Transcell Biolife ([www.transcell.in](http://www.transcell.in)):** A next generation biobank in making to offer transformative medicine.

**Transcell Oncologics ([www.transcellonco.science](http://www.transcellonco.science)):** A

biotech developing first-in-class chemical space combined with unique biological platforms to develop all new druggable formulations as cure options for cancers. The unique biological cell-based platforms are being offered as a dedicated portfolio named [www.transstoxbio.com](http://www.transstoxbio.com) - It is supporting drug and cosmeceuticals preclinical research addressing domestic and global market opportunities. Oncologics's own configured platform technology is being marketed as a clinical tool (Transchymal-RM) in standard care of offering approved stem cell transplantations by Hemato-Oncologics.

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

Graph is a mirage for me till I reach the finish line, while, I was told that finish line is a mirage like in the book "The Alchemist" by Paulo Coelho.

**How are you bringing the value proposition closer to societal understanding?**

Transcell group is working on the technologies to offer cure options to Alzheimer's disease and Cancers. Bio-banking addresses preserving the precious bio-samples of the donors (families with expectant mothers and kids aged between 5 and 11) to support predictive and personalized medicinal requirement.

**How would you propose recommendations for the Govt. endorsement to your Internal product/value proposition promotion?**

I sincerely believe Indian government's support in the form of adopting and making it mandatory to practise indigenously developed technologies and products by the domestic market would be a game changer for companies like Transcell to establish it's niche and value proposition with offerings reaching the Indian market – the most deserving for Transcell.

Government can play a crucial role with the technologies and products developed with the knowledge-base of the companies under Adopt-in-India-First program, in order to encourage the bio-entrepreneurship spirit. This will help improve the confidence and the appetite to invest in this domain as a back drop. This is the only solution for creating, cajoling, and encouraging the ecosystem of entrepreneurs.

**Punch line of Transcell:**

Powered by Passion to Translate; Driven by Dedication in Science

**Brief introduction of yours!**

An experimentalist turned bio-entrepreneur with revenant mind is my Identification Card. I have masters and doctoral degree in Biotechnology from Canada with work experience from India and the USA in the areas of biobanking, stem cell research and commercialization. I am one of the very few with hands on experience handling wet lab experimentation to managing the commercial face of it. ■

## Damping vibrations, shocks and noise

**E**lesa+Ganter vibration-damping elements represent an easy and effective solution to damp unfavourable vibrations produced by moving bodies or non-balanced vibrating masses which can also affect adjacent equipment improving operator safety and comfort. They are ideal for use with compressors, fans, vibrating feeders, rotary pumps or electric motors.

Manufactured with natural rubber NR, hardness 40, 55, 60 or 70, combined with zinc-plated steel or AISI 304 stainless steel threaded inserts, Elesa+Ganter damping elements are from now available in a wide range of dimensions and shapes.

In addition to the already well-known series with cylindrical (DVA.1, DVA.2, DVA.3 –

DVA.4, DVA.5) or parabolic shape (DVA.6, DVA.7), Elesa+Ganter has recently introduced on the market new solutions.

DVB.6 and DVB.7 rubber bushes with conical shape, which are generally used as bumpers or limit stops for the absorption of vibrations. Standard executions are available with Ø from 20 to 60 mm and stiffness from 49 N/mm to 975 N/mm.

New DVC.1, DVC.2, DVC.3 vibration-damping elements with bobbin shape. Under pressure, they allow more lateral movement as well as vertical dampening. Available with Ø from 10 to 95 mm, they provide stiffness from 15 N/mm to 903 N/mm.

In addition, DVE series bell-shaped mounts,

composed of two metallic elements joined together by a rubber anti-vibration body. A round element with a boss and a threaded pass-through hole constitutes the base for fixing to the vibrating machine. Another element, oval or square shaped, constitutes the flange for fastening to the floor. Suitable for applications with rotary machines that do not present big dynamic imbalances, where elasticity is required both vertically and transversely. These damping elements provide stiffness from 13 N/mm to 448 N/mm.

Elesa+Ganter buffers GN 454 are used as end-stop buffers, e.g. conveyor trolleys. They can be fixed on the damping side with socket head cap screws DIN 912. They absorb most of the kinetic energy development on impact. They act as dampers and prevent damaging shock and rebound. They also act as sound dampers. These buffers are also used as levelling feet.

Last, but not least, LW.A vibration-damping levelling elements, composed of base, plate, stem and washer in zinc-plated steel, NR rubber damping element with NBR synthetic rubber packing ring. Their max. limit static load is up to 40,000 N and contributes to the stability of the machinery even in the presence of strong vibrations. ■

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## COVID-19 vaccine: key components are vital to a rapid response

*As biopharmaceutical companies focus tirelessly on developing a vaccine for the COVID-19 virus, they are expected to both rapidly develop vaccines and then scale up into mass production. In order to achieve to these goals, they must have access to critical components used in their operations.*

According to the WHO, some 60 vaccine candidates are now in the pre-clinical trial stage, with current estimations indicating a vaccine may be 12-18 months away. Key players are accelerating this process around the world, including Indian companies such as Zydus Cadila, Serum Institute and Bharat Biotech.

Under such circumstances, it is vital to reduce time-to-market. Single-use technologies deliver the operational flexibility required to meet increased demand. In India, single-use technology has already played an important role in the successful R&D and mass manufacturing of many biologics. Vaccine development for Zika was carried out on a single-use platform.

Pavan Urs, Applications Development Specialist in India at Colder Products Company (CPC), a global leader in single-use connection technology, commented: "As companies race to provide a vaccine to combat the alarming spread of COVID-19, we have to consider everything possible to accelerate the process – down to a component level. Single-use connectors are an example of the kinds of products that

can support biomanufacturing speed and efficiency without sacrificing performance. Aseptic single-use connectors are pre-sterilized, effectively "outsourcing" cleaning and sterilization activities that would otherwise be required in a traditional stainless-steel operation. This reduces validation and operations expenses and helps improve the speed and safety of drug development and delivery." CPC (Colder Products Company) is the leader in single-use connection technology, offering a wide variety of connectors for biopharmaceutical manufacturing. Innovative, flexible designs easily combine multiple components and systems including process containers, tubing manifolds, transfer lines, bioreactors and other bioprocess equipment. The company's well-known AseptiQuik® connectors provide quick and easy sterile connections even in non-sterile environments.

Through aseptic connection and operations in a closed system – for example, in post filtration, when product goes for blending and filling – manufacturers can move from Grade A to Grade C or D levels, making the process much easier to maintain and validate

In addition to supporting sterile manufacturing, aseptic genderless connectors offer simple installation, eliminating the need for clamps and fixtures as in the case with tube welding. The genderless design is flexible and efficient because male and female components are not required to create a secure connection. This streamlines both inventory management and installation, which is especially important when operations are moving quickly and cannot afford to stop production for missing parts, misconnected lines, leaks or potential sterility breaches.

Aseptic connectors also provide benefits to biomanufacturers beyond fast, efficient production. For example, Mumps Measles Rubella vaccines were manufactured and stored for three years in disposable bags with aseptic connectors attached. Aseptic connectors also enabled the manufacturer of Insulin to gain USFDA approval by providing the assured sterility advantage required to complete the process.

In these challenging times, the biopharmaceutical industry has proven its readiness to act, and act quickly. Where a reactive approach is required, speed is of the essence, but that speed must be accompanied by an unerring commitment to producing vaccines that are safe, efficacious and available in the quantities required. "Both CPC and the industry as a whole focus constantly on these levels of readiness, and are acting with the utmost commitment to push the boundaries of our combined capabilities at this difficult time," Pavan reaffirmed. ■



## Changing landscape of Medical Devices industry in India

**Author: Mr. Anand Srinivasan, MD, Covestro India**

The Healthcare Industry in India is one of the most important sectors not only for its social significance, but also in terms of generating revenue and employment. Due to increasing health awareness, penetration of health insurance and government healthcare schemes like Ayushman Bharat, the Indian Healthcare Sector is experiencing a new wave of opportunities. There are, however, some important challenges that the sector needs to address in order to make healthcare accessible, affordable and of consistent quality. As per a FICCI-KPMG report, India's healthcare sector is poised to touch a whopping \$280 billion in size by 2025 and grow at a compound annual growth rate of 16 percent. Medical Devices industry is one of the most important industries in the healthcare sector to ensure safety and well-being of patients across the world. Currently, India imports 80 percent of its medical devices and efforts need to be made to encourage manufacturing of medical devices locally. With the right use of innovation and technology, medical devices need to be constantly improvised and upgraded to meet the highest quality of standards and global norms.

The Government of India made a very positive move last year by proposing a single regulatory framework for all medical devices to meet certain standards of quality and efficacy. India has approximately 800 medical device manufacturers, but standard regulation for materials used in medical devices still remains a major concern for the health sector. Currently, only 23 categories of medical devices are regulated in India under the Drugs and Cosmetics (D&C) Act and the recent concerns raised over the safety of patients requires bringing all medical devices under regulation. While the recent development from the Health Ministry to reach a consensus on the Medical Devices Bill to improve safety and promote domestic manufacturing of Medical Devices is underway, it will be equally important to ensure the right use of raw materials to maintain the highest quality standards.

Selection of the right material for developing a medical device is the primary step considering parameters of functionality, logistics, budget, and prior standardization set. Physical properties like density, transparency and electrical conductivity are essential for many devices and chemical properties like resistance to degradation through contact with lubricants, solvents, moistures or electromagnetic radiations also need to be critically noted. India is among the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China, and South Korea. As per the industry estimates, the medical devices industry in India is poised to

reach \$50 billion and keeping in mind the potential of future economic growth from the medical devices industry it is evident that India is on its way to becoming future-ready.

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## Intas Pharmaceuticals Ltd. donates up to two million tablets of HCO

Intas Pharmaceuticals Ltd., the largest supplier by volume of generic medicines to the UK NHS, is collaborating on a World Health Organisation-endorsed study into the prevention of COVID-19 infection using hydroxychloroquine, a drug that may have an effect in preventing and/or reducing symptoms of COVID-19. The global COPCOV (chloroquine / hydroxychloroquine prevention of COVID-19 in the healthcare setting; a randomised, placebo-controlled prophylaxis) study involves 40,000 frontline healthcare workers who are caring for COVID-19 patients and is due to start shortly. Mr. Binish Chudgar, Vice Chairman and Managing Director, Intas Pharmaceuticals Ltd. said: "I am extremely proud that Intas is leading the way and playing an important part in the current COVID-19 pandemic. In addition to providing scientific advice, our teams are working around the clock, in challenging times, to manufacture the required hydroxychloroquine and matching-placebo for this vital study. This is a great demonstration of Intas' mission to provide essential medicines to people in need, helping to make things better for healthcare professionals on the frontline, patients and society in general."

COPCOV will be led by scientists from the University of Oxford and funded by the Wellcome Trust; the study pools the resources of international experts across multiple continents. Intas will provide up to two million tablets of hydroxychloroquine to the trial, free of charge, along with two million tablets of matched placebo.

Dr William Schilling, co-lead investigator, Research Physician and Infectious Diseases/ Microbiology Registrar, Mahidol Oxford Tropical Medicine Research Unit, Thailand explains what prompted the rapid initiation of this global trial: "We are in a race against time to find effective treatments and preventive measures as the COVID-19 pandemic grows. What we already know is that chloroquine has antiviral activity against SARS-CoV-2 in cell culture, as it does for the related SARS-CoV."

Professor Sir Nicholas White, Wellcome Trust Fellow and consultant in infectious diseases at the University of Oxford continues: "The hypothesis for this study is that chloroquine and hydroxychloroquine might both slow viral replication in exposed subjects, attenuating or preventing the infection. Given the extensive experience in clinical practice, established safety and tolerability profile, if it proves effective then it would be a readily deployable and affordable preventive measure for high risk individuals such as healthcare workers".

## Virtual Show: Syntegon Technology showcases expertise for producing and processing liquid pharmaceuticals

In May 2020, Syntegon Technology provides insights into the future of liquid pharmaceutical processing: from May 7 to 13, customers can discover new developments at the Virtual Show. Based on digital machine presentations, concept studies and pilot projects as well as numerous opportunities to contact the experts, Syntegon shows how pharmaceutical manufacturers can prepare for future trends: new, targeted drugs for small patient groups require greater flexibility in the configuration of filling lines. At the same time, valuable data is generated, which can be used for traceability and increased product safety thanks to new software solutions.

### Flexible Filling Portfolio: the modular small batch solutions from Syntegon

At the Virtual Show, Syntegon presents its new Flexible Filling Portfolio. "The individually configurable, modular machine concept for processing small and medium batches is the answer to the increasing demand for drugs for smaller target groups, for example in the treatment of cancer," explains Klaus Ullherr, senior product manager at Syntegon. "The modular approach bundles our entire line competence for liquid pharmaceuticals and offers our customers maximum flexibility". Whether syringes, vials or cartridges: pharmaceutical manufacturers can select the different modules individually and obtain a filling line completely tailored to their needs, including an integrated isolator for aseptic and high-potent active ingredients – and benefit from more than 25 years of experience of the system supplier for machines and isolators.

### Micro Batch: robotic competence on the smallest scale

For even smaller batches, Syntegon presents a concept study for the processing of aseptic and high-potent micro batches, which was developed in cooperation with a long-standing customer. "For very small batches, the focus is not on output, but on loss-free filling and fast batch changes," Ullherr explains. "The biggest challenge was to design the isolator of the production cell without glove ports, which requires an extremely high degree of automation." The result is a highly flexible and fully automated production cell with the smallest possible dimensions and a complete batch-to-batch changeover of less than two hours.

### Filling & Capping – new monobloc solution

Another premiere at the Virtual Show: the new version of the FLK 9000 piston filling machine, a monobloc solution consisting of the linear FLK filling and the rotary VRM capping machine for liquid pharmaceutical and cosmetic filling. The newly developed three-axis drive for the FLK's filling pipe carrier makes sure the bottles are now continuously filled, before being capped in the synchronously running VRM capping machine. This significantly shortens the length of the line. Furthermore, the filling tubes can now be moved fully automatically to the cleaning position. Improved accessibility to the filling tubes also makes format changes easier. "The monobloc solution combines all the advantages of linear filling with rotary capping technology and fulfils the high demand in the medium output segment from 80 to 150 bpm," says Frank Jansen, head of product management at Syntegon.

### SODA: traceable data makes production safer

Pharmaceutical processing lines generate a large amount of diverse data, which often remains unused. "Until now, object-specific data could no longer be assigned to individual batches or containers as soon as they left the machine," Markus Heinz, product manager at Syntegon, explains. The new "Single Object Data Acquisition" (SODA) system from Syntegon provides a remedy: a data matrix code attached to the container or closure contains all object-related and process-specific data of the container and can be read with a scanner. "This means that valuable information collected during production can now be assigned to individual containers and traced in a structured manner. This opens up a wide range of possibilities for our customers to make their production safer and to react individually in case of complaints," says Heinz.

### Syntegon and SCHOTT – a smart team

Combined with the Smart Containers from primary packaging manufacturer SCHOTT, the Syntegon SODA system offers a very special advantage: the primary packaging materials are initially provided with a unique data matrix code to ensure traceability throughout the entire manufacturing process. The codes are scanned by cameras that can be used to equip and retrofit filling and closing machines such as the ALF 5000 as well as upstream and downstream equipment. If required, the recorded information can be retrieved and analyzed for each individual container at any time. "The combined know-how of the packaging and the equipment manufacturer provides pharmaceutical producers with unlimited access to valuable production data," says Diana Löber, product manager vials at SCHOTT.

### Artificial Intelligence for visual inspection

The use of Artificial Intelligence in visual inspection, one of the most demanding steps in the pharmaceutical manufacturing process, is another major innovation from the software sector. Many industry branches already use the required software solutions and algorithms. Hence, manufacturers of automated visual inspection machines do not necessarily have to develop their own deep learning algorithms or neural networks. In fact, minor adjustments to existing software solutions are sufficient. What's much more important is the know-how in software implementation and process validation. In contrast to many other industries, the deep learning model in pharmaceutical use must be statically fixed after the development phase and is not allowed to change in order to meet the corresponding validation requirements. Syntegon is currently demonstrating how this can be achieved in several pilot projects together with customers and at the Virtual Show.

### Flexible assembly of auto-injectors

Another premiere: the presentation of the modular platform RRA for the assembly of auto-injectors. The advantages include the assembly of different auto-injector types as well as fast, tool-free changeover times of less than two hours. The machine has been specially tailored to current customer requirements: on the one hand, it can react quickly to new market requirements thanks to its high flexibility. On the other hand, the scalable platform is available in both a semi-automated and a fully automated version and can be used for all known auto-injector types. Further adaptations and retrofitting, such as the integration of robotic systems, are easy to realize. In line with Syntegon Technology's pharmaceutical line competence, the RRA can be extended with additional equipment for container handling, inspection, labelling and packaging.

## Thyrocare has slashed down COVID-19 test pricing

Thyrocare, the diagnostic giant in the country, also happens to be one of the first private laboratories approved by ICMR (Indian Council of Medical Research). With effect from 7th April 2020, the laboratory has made the COVID –19 PCR test much more affordable at ₹ 3,500 to customers and at ₹ 1,800 to Hospitals for already collected samples. Thyrocare, one of the leading Preventive Health Care Diagnostic Laboratory in India makes COVID-19 test affordable and available to everyone.

The lab has now slashed down COVID-19 test pricing starting at ₹ 1,800 for Hospitals for already collected samples, ₹ 2500 per person for group collections and ₹ 3500 to customers for home collected samples.

A valid prescription from your doctor will be needed to book your Test. Currently the services at this cost is available within 300 km radius of its Mumbai based state of the art laboratory. Soon the lab plans to start PAN India collections based on lockdown restrictions. The doorstep collection service now only costs ₹ 3500 to the customer instead of the existing price of ₹ 4,500. Also, the lab has made COVID 19 test available at ₹ 1,800 to Hospitals for already collected samples. The offer for institutions for group collection in batches is ₹ 2500 per person. Not only that, Thyrocare has also started mobile ambulance collection service at ₹ 2,500, where a mobile ambulance will be available at public places for sample collection.

Dr. A. Velumani, Chairman and Managing Director of Thyrocare Technologies Ltd said, “ It is really important for everyone with the symptoms & doctor prescription to get the COVID-19 test done. Being a leading Diagnostic Laboratory in India, it is our responsibility to make it accessible and affordable to everyone in India. ”

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## Glenmark Pharmaceuticals receives ANDA tentative approval for Dapagliflozin and Saxagliptin Tablets, 10 mg/5 mg

Glenmark Pharmaceuticals Inc., USA (Glenmark) has been granted tentative approval by the United States Food & Drug Administration (U.S. FDA) for Dapagliflozin and Saxagliptin Tablets, 10 mg/5 mg, the generic version of Qtern®1 Tablets, 10 mg/5 mg, of AstraZeneca AB.

According to IQVIATM sales data for the 12 month period ending February 2020, the Qtern® Tablets, 10 mg/5 mg market2 achieved annual sales of approximately \$10.4 million\*.

Glenmark’s current portfolio consists of 162 products authorized for distribution in the U.S. marketplace and 44 ANDA’s pending approval with the U.S. FDA. In addition to these internal filings, Glenmark continues to identify and explore external development partnerships to supplement and accelerate the growth of its existing pipeline and portfolio.

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## Multifaceted Blister Control with POLYPHEM wt

Sectors such as the pharmaceutical, cosmetics and food industries in particular rely on blisters for packaging their sensitive products. With the camera system POLYPHEM wt, Laetus offers a high-quality solution for comprehensive inline quality control on blister machines. Regular advancements, as for instance the module POLYPHEM wt 3D for three-dimensional inspection, enable meeting all individual process requirements as well as new security standards.

Whether medication, toothbrushes or chocolate confectionary – intact packaging of high quality is one of the prerequisites for presenting a product successfully. The camera system POLYPHEM wt convinces with a variety of control options for blister packaging that is filled with coloured tablets, capsules, dragees, syringes and vials or applicators. Beyond merely checking the presence, the system reliably detects errors in colour, form, dimension and position of the contents. It also recognises contaminations, damages or overfilled pockets.

A GAMP-compliant industrial computer with a touchscreen and a lighting unit with one or more integrated cameras build the basic structure of POLYPHEM wt. Various optional modules adapt the system to customer-specific process requirements. POLYPHEM wt 3D uses stereoscopy to evaluate height and colour and thus detects double or broken content. Moreover, the module is particularly useful for inspections in low-contrast surroundings. POLYPHEM wt Pro TWIN+ allows for controlling blisters successively from above and below, before and after sealing. Both modules can be combined with each other.

POLYPHEM wt inspects objects of the most diverse materials lying in blisters for errors and therefore ensures that faulty objects are reliably discharged from the production process. Laetus configures the modularly expandable system directly according to individual customer requirements and without additional programming effort. For more than 40 years and with more than 2,300 installed systems, POLYPHEM

## Multifaceted blister control with POLYPHEM wt



Among others, POLYPHEM wt inspects colour, form, size and positioning of tablets, capsules and dragees in blister packaging



The camera system POLYPHEM wt ensures reliable fill inspection on blister machines

Sectors such as the pharmaceutical, cosmetics and food industries in particular rely on blisters for packaging their sensitive products. With the camera system POLYPHEM wt, Laetus offers a high-quality solution for comprehensive inline quality control on blister machines. Regular advancements, as for instance the module POLYPHEM wt 3D for three-dimensional inspection, enable meeting all individual process requirements as well as new security standards.

### Versatile inspection solution

Whether medication, toothbrushes or chocolate confectionary – intact packaging of high quality is one of the prerequisites for presenting a product successfully. The camera system POLYPHEM wt convinces with a variety of control options for blister packaging that is filled with coloured tablets, capsules, dragees, syringes and vials or applicators. Beyond merely checking the presence, the system reliably detects errors in colour, form, dimension and position of the contents. It also recognises contaminations, damages or overfilled pockets.

### Tailor-made adaptation

A GAMP-compliant industrial computer with a touchscreen and a lighting unit with one or more integrated cameras build the basic structure of POLYPHEM wt. Various optional modules adapt the system to customer-specific process requirements. POLYPHEM wt 3D uses stereoscopy to evaluate height and colour and thus detects double or broken content. Moreover, the module is particularly useful for inspections in low-contrast surroundings. POLYPHEM wt Pro TWIN+ allows for controlling blisters successively from above and below, before and after sealing. Both modules can be combined with each other.

### Always up to date

POLYPHEM wt inspects objects of the most diverse materials lying in blisters for errors and therefore ensures that faulty objects are reliably discharged from the production process. Laetus configures the modularly expandable system directly according to individual customer requirements and without additional programming effort. For more than 40 years and with more than 2,300 installed systems, POLYPHEM wt has met the highest demands in fill inspection and is constantly being refined.

## Virtual acceptance test for a Noack blister machine

Romaco is responding to the corona crisis by taking new approaches with the factory acceptance tests for its machines. The first Romaco Noack blister machine for a pharmaceutical producer in southern China has now passed its virtual FAT, which was carried out via a live stream.

In the light of current travel restrictions due to the COVID-19 pandemic, Romaco is now organising its day-to-day operations in virtual space. Since the pharmaceutical machinery manufacturer's customers are not allowed to attend the factory acceptance tests for their new equipment in person at present, Romaco has begun carrying out FATs via a live stream or a video conferencing facility instead.

The first live remote FAT for a Noack blister machine was recently completed successfully at the Romaco manufacturing facility in Karlsruhe (Germany). This machine for a pharmaceutical producer in southern China can now be shipped and put into operation as planned. Apart from the fact that the customer was not physically present, the virtual FAT followed exactly the same procedure as its conventional counterpart. According to the FAT report, all tests relevant to production and safety were performed on the machine and streamed live.

Only half a day was required for the virtual acceptance of the Noack 623 blister machine, which will be used to seal ultra-lightweight and almost transparent hard gelatine capsules in aluminium-aluminium blisters. The people responsible at the customer end in China monitored the various functional tests closely during the live broadcast. The project manager in charge at Romaco China was at their side to translate any questions and answers straight away and ensure problem-free communication.

### Virtual day-to-day activities

“The only things we have to do without when carrying out digital acceptance tests are the meals we normally eat together and of course the group photo standing next to the machine after it's passed the FAT”, explained Markus Frey, Area Sales Manager at Romaco Pharmatechnik GmbH in Karlsruhe. “We intend to catch up on all of that later on after the pandemic is over.”

In the meantime, Romaco is developing a certain routine when it comes to streaming factory acceptance tests live. A blister line, complete with cartoner and case packer, is currently being acceptance-tested via a live link for a French manufacturer of contract packaging. Parallel to this, preparations are also under way for the FAT for two Romaco Siebler effervescent packaging lines destined for a pharmaceutical group in the US.

## Workflow Optimization is a Key Priority for Pharmaceutical Labs in India, Reveals Agilent Survey

Agilent Technologies Inc. has unveiled the results of its most recent Pharma Lab Leaders Survey, conducted in association with the global research firm Frost & Sullivan. The survey gathers insights from pharmaceutical, biopharmaceutical, and contract research laboratories around the world.

Respondents included 650 laboratory managers, directors, and supervisors from China, Germany, India, South Korea, Switzerland,

Austria, and the United States. The laboratories surveyed are involved in a range of activities from disease research to manufacturing.

Respondents highlighted their unique industry challenges, laboratory pain points, and goals for the future. Globally, the primary focus was on achieving quicker results (55 percent), superior quality (44 percent), and data integrity (43 percent). Over half of the respondents indicated that quality standards are getting more stringent in their laboratories, with over 80 percent finding that their current workflow requires further optimization.

In India, it was found that sustainability goals were a key priority for pharmaceutical and biotech companies, especially reducing carbon emissions (70 percent). With regard to challenges, 85 percent of lab managers felt that more reliable and accurate instrumentation would be crucial to further optimizing workflows. More lab leaders in India are concerned about increased demands to get generic medicines to market quicker than any other region (3rd ranking in India's regional survey).

"At Agilent, we endeavor to enhance our offerings in line with the evolving needs of the industry," said Bharat Bhardwaj, India Country General Manager, Agilent Technologies. "This survey has helped us better understand key pharmaceutical objectives, requirements, challenges, and operational pain points in a laboratory setting. Based on the new insights, we will continue to design and deliver solutions that help our customers drive efficiency across their labs.

The top strategies being deployed globally by lab leaders to more efficiently move drugs through the pipeline are:

- Buying more sophisticated instruments that deliver a greater degree of specificity (85 percent)
- Improving documentation of the sample chain of custody (70 percent)
- Employing better-qualified staff (56 percent).

In comparison to other regions, 54 percent of the surveyed lab leaders in India felt that increasing the existing number of instruments would improve and optimize workflow procedures. This is one of the top strategies being deployed to progress drugs through the pipeline and to market faster.

Overall, the primary concerns of pharma lab leaders are:



"Quality of results is among one of the top priorities in the laboratory, we have to make sure that the products are up to the mark from the in line testing to the finished products..."  
**China, Biotechnology, Laboratory Manager**

"One of the major challenges which we face in the daily operations is streamlining all the processes..."  
**USA, Biotechnology, Lab Manager**

**Achieving quicker results** is the number #1 concern for pharma lab leaders (55%)



**65%** say the most important type of laboratory innovations are those that **increase efficiency**



**38%** of those who work with generic medicines say one of the most common challenges is the **increased demand to get these medicines to market quickly**

**Achieving better results is more crucial than ever before** with increased performance expectations placed on laboratory technologies and innovations



**41%** cite innovations that **improve instrument performance and sensitivity** as being one of the most important innovations for their labs



**85%** said that they are looking to buy **more sophisticated instruments with a greater degree of specificity**, in order to progress medicines through the pipeline more quickly

**Challenges around data integrity** have a significant impact



**43%** of lab leaders say data integrity is one of the **key pain points** in their labs



**54%** of lab leaders cite **data integrity as being very important** to their work



**70%** say improving the **documentation of the sample chain of custody and data integrity** is one of the most important strategies that labs are employing to progress drugs through the pipeline quicker



## Indian Immunologicals to Lead Research Collaboration to Develop Vaccine for COVID-19

Indian Immunologicals Limited (IIL), a leading vaccines manufacturing company, has announced that the company is going to commence research for developing a vaccine for Corona Virus (COVID-19), the pandemic which has infected more than a million and killed about 55,000 people across the world so far. The Hyderabad, India, headquartered vaccine maker joined hands with Griffith University of Australia by entering into an agreement for research collaboration to conduct exploratory research to develop a lead vaccine candidate for Coronavirus.



*Dr K Anand Kumar, Managing Director, Indian Immunologicals Limited*

In this significant cross-continental collaboration, scientists from Indian Immunologicals Limited and Griffith University (Australia) will develop a 'Live Attenuated SARS – CoV-2 vaccine' or Covid-19 vaccine using the latest codon de-optimization technology. The technology looks promising for developing a vaccine for prophylactic, active, single dose immunization against coronavirus in humans, with an enhanced safety profile. The vaccine is expected to provide long-lasting protection with a single dose administration with an anticipated safety profile similar to other licensed vaccines for active immunization.

Speaking on the development, Dr K Anand Kumar, Managing Director, Indian Immunologicals Limited said, "IIL is committed to addressing critical public health needs by engaging in this research collaboration. The mission at IIL is to develop and supply vaccines that support the One Health initiative. IIL has taken up this initiative to develop a vaccine candidate for the pandemic – COVID-19. IIL's leadership in producing safe and affordable human and veterinary vaccines will enable us to progress well in this endeavor".

Upon completion of the research, the vaccine strain will be transferred to Indian Immunologicals Limited and the vaccine maker will work accordingly with the country's regulator – CDSCO (The Central Drugs Standard Control Organisation) - to further conduct clinical trials which will be taken up in a phased manner. IIL intends to use its existing Vero cell platform technology for mass production of the virus.

Commenting on the research collaboration, Dr Prasanna Deshpande, Dy. Managing Director, Indian Immunologicals Limited said, "After evaluating various options being followed across the world, we decided to develop a Live Attenuated Covid-19 vaccine based on codon de-optimization technology. With our dedicated research and

development capabilities supported with excellent team of scientists and engineers, IIL is committed to developing high-quality vaccines that are affordable. We are confident that this new cross-continental collaboration will yield the desired results".

"We are very excited to be able to work closely with Indian Immunological Limited for development of this important vaccine to solve this urgent public health crisis. Our live-attenuated vaccine will be developed using codon de-optimization technology and is expected to provide long lasting immunity against SARS – CoV-2 following a single immunisation and cross-protection against other coronaviruses (e.g. MERS, SARS-CoV-1). As this vaccine will be a live attenuated vaccine it is expected to be highly effective by providing very strong cellular and antibody immune responses against the virus. The other benefit of a live-attenuated vaccine is a proven track record for economical large-scale manufacturing and well-known regulatory approval pathway." said Professor Suresh Mahalingam, Menzies Health Institute Queensland, Griffith University, Australia on the research collaboration.

Indian Immunologicals Limited is already working with Griffith University, Australia for conducting research and development of Zika virus vaccine which is currently at pre-clinical toxicology testing stage. The joint project has been progressing well and Indian Immunologicals Limited is expected to submit the application for conducting clinical trials in due course.

The codon de-optimization technology has been successfully employed to reduce the virulence of several RNA viruses including Enterovirus C (Poliovirus), Human Immunodeficiency virus type 1, Zika virus etc.

## Atlas Copco completes medical gas pipeline project at Sassoon Hospital in record time

Atlas Copco - a leader in medical and laboratory gas systems completed the medical gas pipeline system project at Sassoon Hospital, Pune in a record time of 11 days. Where it normally takes 4 to 5 months planning and executing a project of such magnitude, the company undertook to complete the project in a much shorter time to provide support to the hospital in treating COVID-19 patients.

Amit Kumar Srivastava, Business Line Manager, Atlas Copco Compressor Technique, said, "We were actively involved in the process to ensure that we deliver our best services to the hospital in view of this pandemic. The project required flawless collaboration, along with strategic planning to accomplish the task within the almost impossible timeline. We as an organization feel very proud and humbled that we were able to contribute our bit to the fight against COVID-19 and complete the medical gas pipeline project in a record time of 11 days."

All parts of the medical gas pipeline system by Beacon Medaes, such as medical oxygen system, medical air system, medical vacuum system, medical gas outlet and other accessories, are as per international medical standards. Atlas Copco has employees working remotely, and also at sites supporting essential services, following all health and safety guidelines, and is committed to strengthening and maintaining support to customers and partners at all times

## NiceLabel to Provide Free Label Cloud Software to Organizations Fighting COVID-19



NiceLabel, a leading global developer of label design software and label management systems, is offering free subscriptions of its cloud-based labeling solution and technical consulting services to organizations that have joined the fight against COVID-19.

NiceLabel has launched the non-commercial and non-profit-based initiative in order to help these organizations get much needed deliveries of medical equipment and supplies; respirators, disinfectants, masks or other critical supplies to those in need as quickly as possible.

Having the cloud-based labeling solution in place will enable these organizations to produce new labels quickly and rapidly add them to the packaging used on their new product lines to ensure that equipment and materials arrive on the front line without delay.

Organizations likely to qualify include manufacturers re-focusing on the production of critical healthcare supplies; farms and other food producers who must meet new labeling requirements to supply critical food to supermarkets; hospitals and other organizations involved in fighting COVID-19.

In delivering a free labeling solution to these organizations, NiceLabel will engage with them both directly and, where appropriate, through value added resellers and other IT solutions partners.

Ken Moir, NiceLabel VP of Marketing said: "We wanted to help eliminate any delays in the delivery of supplies by ensuring that labeling is never an obstacle to getting critical items to the front line as fast as possible. Our multi-tenant cloud platform allows us from a remote location to get labeling anywhere around the world - and to do it ultra-fast.

"We plan to use our capability to help manufacturers rapidly switch their product lines to key equipment and products needed in the fight against COVID-19 and to support the rapid delivery of those supplies to those battling this new virus on the front line. We are here to help, so we would encourage any organization seeking out labeling support as they look to get key materials and equipment deliveries out to those who need it most, to get in touch with us today".

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## Kaka-Ba Hospital and Gujarat Police Come Together to Fight COVID-19

Kaka-Ba hospital in association with Gujarat Police on 20th March, distributed masks and sanitizer bottles to the police team in the vicinity of Dholka in the wake of COVID-19.

Kaka-Ba hospital, the CSR wing of Cadila Pharmaceuticals arranged for the distribution of masks for the protection of all police team in Dholka. Since gathering of people is not advisable in the current scenario, along with the masks, an awareness video talking about the virus, how it spreads and the importance of hand washing was sent to the staff through WhatsApp. While self-quarantine is not possible for the police staff, they were informed about the importance of social distancing and what all steps they can take to protect themselves through infographic pamphlets. Kaka-ba hospital responsibly distributed the masks and sanitizer by providing to the leader of the team and not gathering complete team for this.

"We salute all these heroes who are out there serving the nation in the time of need. It is our duty to give them the right information and help them in any way we can. With the help of this step we hope to help them serve the country better" Mr. B.V. Suresh, Head of Corporate Social Responsibility, Cadila Pharmaceuticals.

"During these tough times, it is an honour to serve our country. The masks distributed by Cadila Pharma will definitely help us perform our duty better. The awareness video in Gujarati and pamphlets will act as a great source of information for all our staff and help them keep safe while on field" Nitish Pandey, ASP, Gujarat Police said.

Cadila has always been active in its CSR initiatives. The Kaka-Ba hospital has been conducting multiple free health check-up camps for the people who can't afford. The patients who require medical attention are then taken to the Kaka-Ba hospital near Ankleshwar where their procedures are done for minimal costs. The CSR team also organized a self-help group amongst the women of Bhat to help them make a livelihood for themselves through embroidery techniques.

## ProteoGenix Announces a New Human COVID-19 Antibody Library

ProteoGenix, a global leader in antibody production, is pleased to announce the first Human Immune COVID-19 library for the fast discovery of potent antibodies against SARS-CoV-2.

"Highly sensitive and specific antibodies are critical for the development of diagnostics, therapeutics, and prophylactics to fight against COVID-19," says Philippe Funrock, Co-founder and President of ProteoGenix. "The new Human Immune COVID-19 antibody library developed by ProteoGenix represents an exciting opportunity to solve the current pandemic."

The library, created using blood samples from dozens of recovered COVID-19 patients, is adapted for screening with phage display and strives to meet the rising demands for effective antibodies for a broad range of applications.

The library's vast diversity (1.2 x 10<sup>10</sup> different clones) allied to the fast turnaround time and sensitivity of the screening technology, are intended to fast-track the discovery of antibodies with the strongest affinity, specificity, and viral blocking activity.

"Compared to the hybridoma technology, phage display saves time by allowing us to directly screen highly diverse and human antibody libraries. In addition, when developing therapeutic antibodies, this technique also helps us reduce the time-to-market by avoiding complex antibody humanization processes," says Raphaël Hopfner, Co-founder and CSO of ProteoGenix. ProteoGenix further fast-tracks the process of discovery by offering a broad diversity of ready-made SARS-CoV-2 antigens, as well as fast custom antigen development services (proteins, peptides, small molecules).

Within 8 weeks or less, clients can receive 3 to 10 unique and royalty-free antibody sequences with an optimal affinity. Being the first to propose this service, ProteoGenix aims at supporting the outstanding efforts of teams fighting the COVID-19 pandemic around the world.

## CytoSMART to donate 100 live-cell imaging systems to assist COVID-19 researchers

CytoSMART Technologies is to donate 100 mini live-cell imaging systems to researchers in high containment labs worldwide. Labs working to combat COVID-19 will benefit from this initiative, as CytoSMART aims to reduce the huge workload currently facing researchers on projects vital to controlling the disease.

"We aim to do our part to assist researchers in minimizing the time they have to spend in high-contamination labs, by providing them with remote video access to evaluate the status of their cell cultures. The video data is used to remotely monitor the cytopathic effect, this way researchers know when it's the right time to harvest the virus", said Joffry Maltha, CEO at CytoSMART Technologies.

According to guidelines by the CDC and the WHO, isolation and characterization of COVID-19 should be performed in BSL-3 laboratories. Performing research in Biosafety Level 3 and 4 laboratories (BSL-3 or BSL-4) means working in a highly controlled area. Many precautionary measures must be taken to ensure the safety of researchers and help prevent the diseases they are working with from spreading outside the lab. Removing and replacing the protective clothing and apparatus can be time consuming and expensive, so entering the lab should ideally only occur when absolutely necessary.

CytoSMART's unique and compact live-cell microscope films living cell cultures without disturbing their growth or behaviour. The device operates from inside cell culture incubators and is accessible from an online environment. This enables researchers to analyse their cell cultures remotely and assess e.g. the cytopathic effect, which is caused by virus replication. Using the CytoSMART Lux2, researchers will know when to take action for the next step and harvest the virus.

Maltha further explained, "We need to help scientists who are working in BSL-3 and BSL-4 laboratories to combat COVID-19. We know that our system can help researchers in monitoring cell growth and deciding when they need to go to the high containment labs and run further experiments."

The work of such labs is absolutely essential in the fight against COVID-19 and it's important to us as an organisation to help where we can. This useful tool can support them in their hard work, by helping to save precious time and equipment by knowing exactly when to enter the lab.

## Covid 19 Vaccine: Hope through Challenges

While the World is severely affected by Covid-19 outbreak followed by isolation and quarantine, numerous attempts have been initiated for the invention of a vaccine against this deadly virus. However, the most likely timeline to develop a vaccine for COVID-19 causing virus SARS – COV – 2 is 12 to 18 months, if everything goes right.

A recent article in Bloomberg Businessweek mentioned, "For that to happen in the next year or so, an almost equally implausible set of circumstances has to occur: flawless scientific execution, breakneck trials and a military-style manufacturing mobilization unlike any the pharmaceutical industry has put in place before".

One such company, which has gained a spotlight to work on this area is: Moderna, a Cambridge Massachusetts-based organization. They have had a headstart with a novel technology and their proposition mRNA – 1273 is already in clinical trials. This mRNA vaccine encodes for a prefusion stabilized form of a Spike(S) protein. The differentiating factor of this vaccine is: it's almost like a form of Gene-Therapy and it codes for Spike(S) protein's genetic sequence. Upon injecting in the body, it causes patient's own cells to produce the protein – not the virus – that triggers an immune reaction to combat with the virus. Though the technology is interesting, it's unproven. Neither Moderna brought such kind of medicine before in the market.

Source: Biospace Genepool ([www.biospace.com](http://www.biospace.com))

## Transpact Enterprises develops COVID-19 telemedicine screening, testing solution

As India grapples with a rising number of COVID-19 cases, a Mumbai-based startup Transpact Enterprises has developed a telemedicine solution and mobile app that it hopes can help manage the spread of the pandemic. The COVID-19 Online Screening and Evaluation Telemedicine Services (COSETS) will allow monitoring and engaging with patients remotely in their homes by use of a computer or smartphone. It facilitates a line of communication between quarantined people and health care services, and helps maintain visibility of those recently discharged.

The mobile application uses questionnaire-based classification suggested by the World Health Organization for suspected COVID-19 patients, it will allow users to do the initial screening remotely without needing them to travel to primary healthcare, thereby maintaining social distancing.

The data captured through the mobile application is stored on a common cloud repository accessible by telemedicine the system at primary as well as secondary healthcare distributing the diagnosis workload, The app captures authenticated information and grid location. The company expects the platform will use Artificial Intelligence (AI) overtime to allow providers to identify patients at risk of deterioration and optimize their care.

Aslam Khan, Founder and Managing Director of Octaware Technologies "In India, COVID-19 test and treatment cases are assigned to designated public and private hospitals and diagnostic centres. Our primary objective is to help public health authorities at the national, regional and community levels by identifying who is most vulnerable," He added that the solution could help the government plan containment strategies and prepare necessary resources to tackle any emergent the situation on a war footing.

He also said "We have developed the complete architecture and prototype of mobile app and telemedicine for COVID-19. The solution is the design of a telemedicine system integrated with a personal assistant mobile application to manage the possible spread of the pandemic. our company's solution integrates the personal assistance mobile app with telemedicine system into a centralized data storage on the cloud. The other apps just allow you to self-test with no provision for storing or pooling that data. Whereas, our application allows data to be collected and stored on the the cloud that can be accessed by health professionals for further analysis and treatment" said Khan.

The company is taking the service of Dr Suleman Merchant, a former dean of SIO Municipality hospital and Dr Zahoor Patanker from (KEM Hospital)

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## Electronic Patient Record provider PatientSource to offer 'slimmed down' version

PatientSource has announced that it will be offering an adapted version of its Electronic Patient Record (EPR) software to healthcare organisations across the globe, completely free of charge with minimal cloud hosting costs, to help combat the Coronavirus pandemic.

With the priority to ease the burden on healthcare services now reaching critical levels, PatientSource is offering a 'slimmed down' version of its software, which can be installed and ready to go within as little as an hour, in a move to keep a 'digital eye' over the ever-increasing number of COVID-19 patients.

Founded by a practising NHS doctor and recognised as a 'leading innovator' by the Department of International Trade, PatientSource offers a cloud-based interoperable patient record system with an intuitive interface, designed for use on the frontline of care. The clinician-designed solution works cross-platform on any device with a web browser – desktops, laptops, tablets and smartphones. The company has an international footprint, with clients in the NHS and private sector.

The adapted version of the PatientSource software will feature a cloud-based electronic observation module complete with patient trackers and ward whiteboard tools that are attuned to COVID-19 patients, and will be able to quickly identify the most critical, frail or deteriorating patients in a challenging setting.

Dr Michael Brooks, Chief Medical Officer and Co-Founder of PatientSource, said: "COVID-19 is a virus that spreads quickly and causes an appreciable minority of people to need hospital care. Put those two figures together, and you get a virus that will easily overwhelm any country's healthcare system. Hospitals across the globe are going to be saturated and will struggle to cope.

"PatientSource brings case tracking, clinical noting, vital signs, test requests and results, team messaging, and prescribing together in one place. A doctor or nurse can walk onto a ward with just one tablet and access everything they need."

"Our PatientSource COVID-19 tracker will show you which affected patients are in your hospital or ward, what their latest vitals are, the plans for escalation, and who the expected incoming cases are in real-time. This allows you to identify the patients who need oxygen bays and the patients who need critical care input, allowing you to allocate limited resources to those who need them quickly."

Recent announcements from the Department of Health and Social Care have revealed that they will soon call upon private hospitals and possibly requisition hotels to help deal with the ever-growing number of NHS patients, meaning that resources are to be spread thinly and widely. PatientSource hopes that the capabilities of its EPR solution in providing digital oversight over a rapidly expanding patient cohort will support overstretched medical services both in the UK and across the globe.

Its experience of working across both sectors and the interoperable capabilities of its EPR solution will help providers to maximise the efficiency of their available resources by applying them appropriately to the most critical patients.

Dr Brooks added: "As an Emergency Department Clinician I acutely understand the challenges faced by my peers in caring for large numbers of patients with limited staff resources. This offer aligns to my founding ethos for PatientSource of better patient care; I hope we can help."

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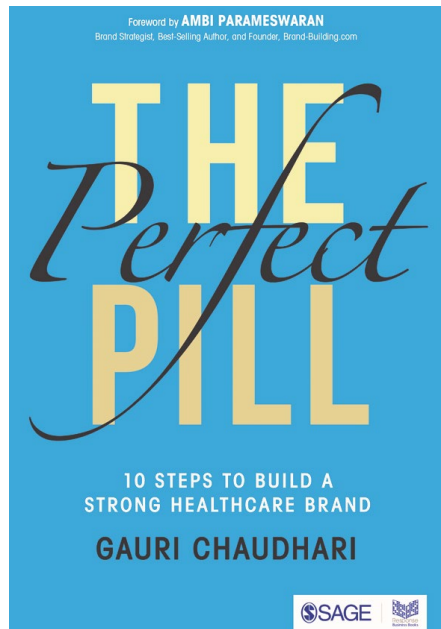


## The Perfect Pill: 10 Steps to Build a Strong Healthcare Brand

**Author:** Gauri Chaudhuri

**Publisher:** SAGE Publications India Pvt Ltd

**Price:** Rs. 343.00 (Kindle Edition)



The book elaborates on brand building concepts and suggests necessary steps to apply of such concepts. It focuses on three aspects of marketing –

- Understanding the brand, market, customer, and competition
- Developing the brand value proposition and brand articulation
- Strategy for media, metrics, and evaluation.

On its release in March 2020, author Gauri Chaudhuri said, “Different patients need different solutions depending on their physical, rational, and emotional needs & the generic approach rarely takes patients’ day to day challenges into account while creating and marketing the respective brand(s). So strong is the influence of these generics marketing practices in the industry, that even the patented brands echo the same strategies. So, that was one of the key motivations for me to write the book and address these challenges. My book offers a combination of theory & practical guidelines with a rare blend of case studies from Consumer, International pharmaceutical, and Indian healthcare industry”.

The book is foreworded by Ambi Parameswaran, Brand Strategist and a Best-Selling Author. In his foreword to the book, he mentioned: “By referring to multitude of examples from the

non-pharma space, Gauri has made the book so much more approachable. At the same time, the book is replete with examples from the pharma space, of both medicines and devices marketed in India and abroad.

### Core Concept of the Book:

The only place the brand needs to occupy lies in the consumers’ minds. The distinctiveness of the position decides the fate of the brand. Brand positioning is the most important milestone on the journey towards building a strong brand. The customer’s perception is the ultimate truth about the brand; the positioning helps the organization(s) to build it.

The book exemplifies the Sundrop, a brand of edible oil, which was launched in 1989. The brand was made up of sunflower oil which is known for its cardiac health benefits. It has polyunsaturated fats that keep the heart healthy by reducing bad cholesterol. The product understanding gave the oil its name: Sundrop, suggestive of purity and goodness. Sundrop was operating in the market comprising of homemakers who believed in branded edible oil. Having health advantages associated with sunflower oil, the company decided to target the health-conscious households where the main competition was Saffola from the house of Marico.

Saffola, the brand of safflower and rice bran, too had health benefits. Similar to Sundrop, this brand too has been promising heart health to its customers. The TVC for Saffola was based on an insight that men are reluctant health enthusiasts. They shy away from making lifestyle changes and always procrastinate physical exercise. The common phrase used by all the men concerning exercise was “kal se” (from tomorrow). This often was the cause for worry for the housewives. Saffola offered a solution to the worried wife. Instead of pushing husbands for exercise, the housewife could use “Saffola aaj se” (from today) and ensure their husbands’ cardiac health.

The Sundrop team decided to dig deeper into the mindset of health-conscious households. On carefully listening to the woman of the house, they realized the very strength of Saffola was its weakness. While interviewing the housewives, the team came across some startling facts. The brand was closely associated with people with a heart problem. If there was a Saffola at home, it was a clear sign of having at least one cardiac patient at home. Thus, the perception was that “Saffola; a brand for SICK and not the healthy beings”. Saffola used the fear appeal, and people bought the brand.

Sundrop positioned itself for healthy people. It was ‘healthy oil for healthy people’. It appealed to the health-conscious mindset of the people. The oil was for everybody who wanted to stay healthy.

Taste is a critical criteria for the edible oil category. It is a point of parity criteria. In the case of Saffola, the taste association was missing. The first association with anything medicinal is that it can’t be tasty. There is a belief in the human mind that ‘medicines are always bitter’. Sundrop knew this negative association of Saffola, and that was an opportunity for Sundrop.

It used larger-than-life visuals of food items in the commercial. It depicted taste in a uniquely creative way. While positioned on the health platform, Sundrop managed to keep taste association intact.

Sundrop dominated the market and remained an undisputed leader for several years. Thus, the right positioning for the brand can change the fortune of the brand.

When the housewife was buying Sundrop for health, she was buying multiple benefits. She was getting: Health, Lightness, Taste, Quality, and Purity. The brand was offering multiple values, yet the single-minded space it had occupied in the minds of the customers was that it was a healthy oil for healthy people. Thus, positioning is the subset of the values brands can offer.

Positioning is single-minded, focused and sharp; like a laser beam capturing the most relevant benefit for the target segment. It picks up the most important benefit in the context of the market landscape. Positioning is unique to the target segment(s) we have selected in Step 2 of the brand-building journey. It captures an understanding of the customer as we have done in Step 3, and it contrasts the brand from its competitor as we have done in Step 4.

It is essential at this stage to understand that positioning is all about perceptions. It is not only about what brand offers but it is all about what customers think and feel that the brand offers. It’s not about what the competitor brands factually provide, but it is about impressions of the competitor’s brand in the minds of the customer.

Positioning is the ultimate differentiation tool. Sharper and clearer positioning helps the brand stand strong among the crowd. ■

## Nanopharmaceuticals: Volume 1: Expectations and Realities of Multifunctional Drug Delivery Systems



**Edited by:** Ranjita Shegokar

**Price:** ₹ 12,073.27

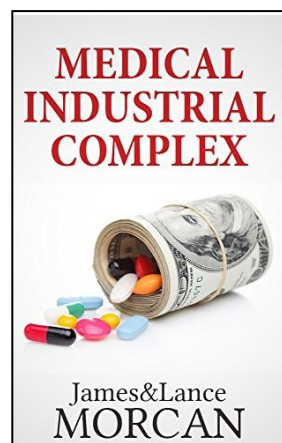
**About the Book:** (Paraphrasing Required)

In this book, the author talks about the advancement in the drug delivery field with a niche focus on nano-vehicles and nano-carriers.

The series expectations and realities of Multifunctional Drug Delivery Systems covers the fabrication, optimization, biological aspects, and regulatory & clinical success of wide range of drug delivery carriers. This series reviews multifunctionality and applications of drug delivery systems, industrial trends, regulatory challenges and in vivo success stories. Throughout the volumes discussions on diverse aspects of drug delivery carriers, such as clinical, engineering, and regulatory, facilitate insight sharing across expertise area and form a link for collaborations between industry-academic scientists and clinical researchers.

Expectations and Realities of Multifunctional Drug Delivery Systems connects formulation scientists, regulatory experts, engineers, clinical experts and regulatory stake holders. The wide scope of the book ensures it as a valuable reference resource for researchers in both academia and the pharmaceutical industry who want to learn more about drug delivery systems.

## MEDICAL INDUSTRIAL COMPLEX: The \$ickness Industry, Big Pharma and Suppressed Cures (The Underground Knowledge Series Book 3)



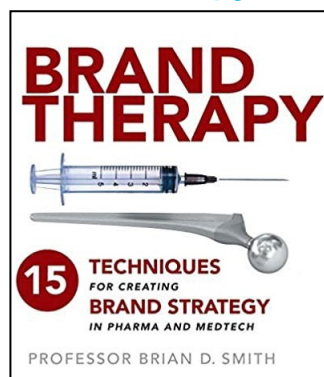
**Authors:** James Morcan and Lance Morcan, forwarded by Denis Toovey

**Publisher:** Sterling Gate Books

**Price:** ₹ 116.82 (Kindle Edition)

**About the Book:** This book addresses the corrosive influence of Big-Pharma Corruption through a broad and insightful overview of the corrupting practices of Corporate Medicines. Being a part of the Underground Knowledge Series of James & Lance Morcan, the book raises very pertinent questions concerning the state of modern medicines and the major players in the highly profitable medical sector. The authors cover the following topic: the sickness industry, the political impatience that kills patients, do drug companies make drugs or money, so how much is too much, dangerous drugs big pharma doesn't want you to know about, and many more associated topics. The objective of the book is to guide the patients for not falling through the cracks of health system as a direct result of healthcare solution providers focusing on high-patient-turnover on a free-for-service basis with no guarantee of results.

## Brand Therapy: 15 Techniques for Creating Brand Strategy in Pharma and Medtech



**Author:** Brian Smith

**Publisher:** Practical Inspiration

**Price:** ₹ 499.00 (Kindle Edition)

**About the Book:** The book acts as the 21 century strategic marketing bible for pharma and med-tech brand leaders and their teams.

This book is for the readers who work with a Brand Team catering to pharmaceutical, medical technology, or other life science companies. Competing successfully in the life science market is difficult and require a range of expertise, from medical and technological to marketing and other commercials. The book addresses such problem arenas.

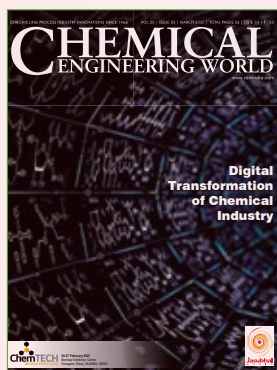
The book covers various topics, viz. strong brand strategies using the right tools, customer-centric market definition to frame analysis & brand strategy, Drucker's Definition to clarify brand strategy, Using SWOT alignment to guide brand strategy, using reality filters to gain strategic objectivity, and many other associated topics.

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4	Vacuum Drying Technology India LLP	3

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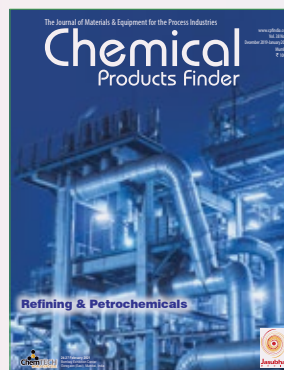
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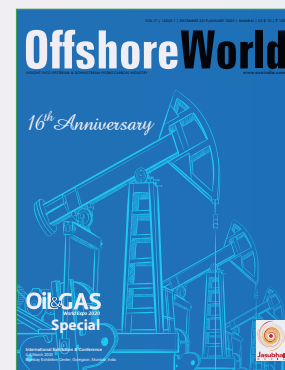
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# Paint & Surface Coating

World Expo 2021

**24-27 February 2021**

Bombay Exhibition Center, Goregaon (East), Mumbai, India

## Major Highlights

- Paint & Surface Coating World Expo & Conferences will be a comprehensive platform servicing the needs of every facade of the Paints, Coating & Surface Engineering industry right from raw materials, formulation, application, technology, finishing, quality assurance, recycling, disposal and end consumer.
- Innovation Pavilion showcasing latest developments by various Paint and Coating manufacturers, Raw Material manufacturers, Equipment and Tools manufacturers, Testing Equipments and Labs services etc.
- Green Pavilion showcasing Eco Friendly and Sustainable Paints & Coating Solutions.
- Emerging Technology Pavilion showcasing New Technology which will shape the future of Paint & Coating Industry in next decade.
- Pavilion on New Applications in Coating Industry & Surface Engineering.
- Product Presentation Lounge & Demo Zones.
- Two Days Technical Conference on Surface Engineering, Paints & Coating Industry.
- Over 20,000 Buyers from user Industry .

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Comprehensive platform servicing the needs of every facade of the Paints, Coating & Surface Engineering industry.

### EXHIBITORS PROFILE

- Paint manufacturers and formulators for liquid and powder applications
- Manufacturers and distributors of paint raw materials for paints: Pigments, Additives, Resins, Solvents, Monomers, Bulk Chemicals & Intermediates, Specialty Chemicals, Stainers, Pigments Dispersions & Machine Colorants.
- Manufacturers of Pre-treatment and Corrosion prevention chemicals
- Manufacturers of Spray-guns and other paint application equipment
- Paint booths for OEM applications and quality assurance systems
- Decorative Paint Manufacturers
- Decorative Paint Applications Tools and Devices
- Paint Mixing, Conveying and Handling Systems
- Colour Matching Tools
- Dispensing Machines and Systems
- Manufacturing & Capital Equipment
- Analytical Instruments
- Testing Equipment
- Testing and Research Services

### BUYERS PROFILE

- |  |  |  |
|--|--|--|
| <ul style="list-style-type: none"> <li>→ Aerospace</li> <li>→ Architectural</li> <li>→ Agriculture Industry</li> <li>→ Automotive OEM</li> <li>→ Automotive components</li> <li>→ Automotive Refinish</li> <li>→ Building Segment – Residential, Commercial, Industrial</li> </ul> | <ul style="list-style-type: none"> <li>→ Chemical &amp; Pharma</li> <li>→ Construction Equipment &amp; Heavy Duty Equipment</li> <li>→ Food &amp; Beverage</li> <li>→ General Engineering</li> <li>→ Marine Coating</li> <li>→ Metal Working</li> <li>→ Measuring &amp; Test Technology</li> </ul> | <ul style="list-style-type: none"> <li>→ Oil &amp; Gas</li> <li>→ Paint &amp; Coating Manufacturers, Dealers &amp; Distributors</li> <li>→ Packaging</li> <li>→ Power &amp; Thermal</li> <li>→ Textile &amp; Paper</li> <li>→ Research &amp; Environment Technology</li> <li>→ Wood Coating</li> </ul> |
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For more details:

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### Concurrent Events



#### Scope for CHEMTECH + Biopharma World Expo 2021

- Refining & Petrochemical products
- Biotechnologies
- Chemical & Pharma Processing Equipment
- EPC Services
- Automation Technologies
- Environment Solutions
- Water & Wastewater Treatment Technologies
- Pumps & Valves
- Pipes & Fittings
- Packaging Solutions
- Material Handling Systems
- Analytical & Laboratory Technologies
- Consulting Services
- Equipment Fabricators

#### Scope for Specialty Chemicals World Expo 2021

- Agrochemicals Intermediates
- Adhesives & Sealants
- Agrochemicals & Crop Protection
- Bulk Drugs & Intermediates
- Enzymes
- Colorants, Dyes & Pigments
- Cosmetics & Personal Care Ingredients
- Hygiene & Cleaning Chemicals
- Laboratory Chemicals
- Surfactants
- Water Treatment Chemicals
- Catalysts
- Electronic Chemicals
- Flavours & Fragrances
- Contract Manufacturers

#### FACTS & FIGURES - CHEMTECH WORLD EXPO 2019

<b>612</b> EXHIBITORS	<b>18962</b> VISITORS	<b>18</b> COUNTRIES	<b>6</b> CONFERENCES	<b>85</b> SPEAKERS	<b>923</b> DELEGATES	<b>2150</b> STUDENTS
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### International Supporting Associations



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