VOL 18 | ISSUE 10 | MAY-JUNE 2020 | MUMBAI | TOTAL PAGES 64 | PRICE ₹ 150

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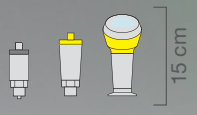

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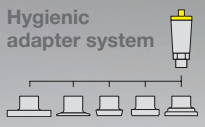

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CHEMICAL ENGINEERING WORLD
RNI REGISTRATION NO. 11403/66

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Subscription Rate (per year with effect from 1st April 2013):
Indian - ₹ 1620; Foreign - US$ 180
Student Concessional Rate: ₹ 800; Price of this copy: ₹ 150

Jasubhai Media Pvt. Ltd.

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Jasubhai MEDIA

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 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001. Editor: Ms. Mittravinda Ranjan, 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

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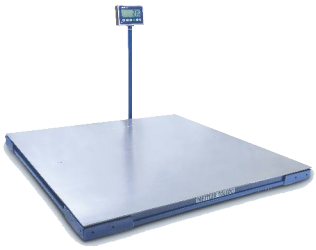

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Looking into the future of Pharma Packaging

Mr. Ajay Bapat, a veteran Pharma Packaging Professional, and now an independent consultant in field of pharma packaging, has been involved in development of packaging materials for more than 33 years. Mr Bapat in this exclusive feature for PBW takes us through how pharma packaging will be most interesting, and challenging task in near future, which demands for use of best of the skills, knowledge and aptitude and be ready for any challenge anytime.

Author: Mr. Ajay Bapat
Independent Packaging Consultant and Director – Packaging Concepts

If this topic was to be discussed a few months ago, the text would have been different. The thought processes of packaging professionals in all the fields have changed, apart from Pharmaceutical packaging.

Since the start of this year, people have been joking about formatting the year since it has caught a virus.

Jokes apart, the thinking worldwide has changed post COVID 19 pandemic. The typical definition of Packaging will remain same; however, the application may change.

The latest buzz word of sustainability has taken a back seat in this post pandemic scenario. People are more worried about the availability of material, ready to use material, and avoid a crisis in supply chain. Demand for packaged product has grown tremendously and the supply industry who are fighting with the reduced work force and closure of some manufacturing units because of the lockdown, has been working like a see-saw. When demand was highest the supply rate was lowest.

The bakery products, which had least demand of wrapping materials, also have started asking for packaged items, no human intervention etc.

Suddenly every part of the world has started producing sanitizers and whoa what a demand. If you would have thought of using sustainable material for this product, the market would have gone for toss. Masks share the same story. I'm actually not sure how many masks were produced worldwide in the last three months. Now that people have started using masks, a bigger threat has been in the offing, how do you dispose them? Are we going to increase our load on ocean?

Everyone in industry is talking about automation and pharma industry will not lag behind. We expect an increase of automation to the tune of 30 % just to avoid human intervention. With increasing automation in the industry, our focus needs to be on the flexibility and adoptability of machines, accurate material feed and planning, increase in capital expenditure and operational cost.

So a sea of change in the thinking and usage of material in the last three months. Packaging has a profound impact across the entire supply chain. The new products that are being developed for COVID 19 cannot be imagined without the inputs of the packaging industry. Whether it's a new molecule in a tablet form or a vaccine under

development that needs to be maintained and marketed from -40°C to + 40°C, at the same time.

We as packaging professionals need to bring back the situation to normal, no not the new normal, our old normal. We need to bring back sustainability to the forefront again.

In that case, the trends of the future prove to be an interesting topic.

Package Optimization as a growth factor

The Indian pharma industry has steadily grown year after year. If we see the growth rate it is always been between 10 to 20 % depending on the market shares, the product range etc. The Indian pharma industry is the world's 3rd largest by volume. It is also the world's largest supplier of generic drugs and a leading producer of vaccines catering to about 50% of global vaccine demands.

The Indian pharmaceutical industry is undergoing significant growth, thanks to 40% lower cost of production in India as compared to US and EU. Even at current rates of seven to eight per cent CAGR, the industry's annual revenues can grow to about USD 80 to 90 billion by 2030. This continuation of growth factor could also be possible because of molecules going off patent, more and more generic medicines are being promoted, new markets opening up for genomics, cell therapy and biological products.

On the other hand, as we enter in the new decade, pharma industry will continue to face the challenges of the past. Particularly, the globalization of drug supply, delivering new product types, meeting demand from emerging countries, the rise of chronic lifestyle conditions such as obesity and diabetes, and the growing threat of counterfeit and falsified medicine with variety of regulations and tab on cost.

What could then be the reason, for Pharma packaging industry, not to achieve a yearly growth, as packaging is an integral, ever evolving, and an interesting segment of the pharma industry?

As mentioned, most of the new products being worked on, are injectable dosage form and glass is definitely the preferred material of choice. However, some drug products which are not compatible with glass and tend to delaminate it, need to be worked on with alternate material while developing the product. In most of the cases, the product walks hand in hand with packaging and gives an equal opportunity for growth of packing material manufacturers, however, hardcore packaging material manufacturer may find this industry a challenge but at the same time, it is very interesting as well.

As the world is coming closer, newer technologies worldwide are available to everyone. Still we find there are preferred packaging styles and requirements in each market. For example, in the US they still prefer to have bottle packs whereas, typical commonwealth nations including the EU prefers blisters. It depends on habits, distribution system and even the weather conditions prevailing there. However, as compared to the last decade, markets have started accepting newer packages, thereby reducing the cost and number of SKUs for the manufacturer.

In the coming years, there is every possibility that the manufacturer can offer a single type of SKU for all markets depending on volumes and market penetration. Hospitals have started preferring unit dose blisters and this can be one of the areas where smaller or emerging markets, including Asian markets, adapt to this type of packaging with small batch manufacturing concept. For example, Myanmar does not specifically ask for unit dose blisters or with cross perforations, however, they ask to print a batch detail with every tablet or capsule in blister.

In India, we have a typical practice of chemist cutting a strip at retail sell, even to single unit, as required by the customer and do not bother if the remaining part has the batch number printed on it. This concept of having batch identity on each pocket should pick up here as well.

In my opinion, the coming decade may be the decade of compliances as regulators across the world are coming with newer guidance and complying to them will be a challenging job for packaging engineers, be it related to primary packing materials, testing, serialization or labeling. We may expect a new guidance from World Packaging Organization as well, as being discussed.

Regulatory compliance to Serialization or Track and Trace requirements

Fake Drugs' business is one of the most damaging businesses in all the countries, irrespective of controls that regulators

have set in that market. It has direct repercussions on the reputation of the Pharmaceutical Brand, dilution of brand value, risk of associating with poor quality, recalls, and adverse competitive advantage of the brands in the market.

In view of the growing issue of counterfeit medications and deaths all across the globe, a million per year as per WHO, most of the regulatory agencies have started working on adopting to some standards, which can be easy to implement but difficult to copy.

As Regulatory compliances are one of the most important driving factors for innovations or changes in packaging / repackaging, a major compliance being discussed and implemented is related to serialization or a job related to anti-counterfeit issues.

The past decade, as it all started in 2011 has seen a tremendous change in Indian pharma packaging, and it was not for any "wow effect" or any special feature for patient, but the changes related to packaging systems, modifying artworks, adopting to newer software etc., and all this is to take the challenge of implementing Track and Trace / serialization compliance head on. We in India, should take pride in saying, yes, we were the ones who have implemented the tracking way back in 2011 successfully, though partially, when most of the developed markets were still formulating the course.

Post COVID19 outbreak, we Indians have again proved that we are the pharmacy of the world and almost all countries are looking forward to India for supplies either of HCQ, Remdesivir or the vaccines that are still in making. In view of this global supply chain initiating in India, the efforts taken by Indian pharma industry to complete the challenge of Serialization is commendable.

The supply chain needs to be made more secure and robust and packaging plays the most important role in making it more difficult for counterfeiters to eat in our product share.

Pharma packaging thus is proving to be in support of business development which is continuously evolving at an accelerated pace. The motive has been defined differently from time to time, ranging from containment and protection, to branding to patient centricity.

Next challenge to pharma packaging can be gelling with e-commerce or more precisely e-pharmacies and it's challenges. This business is expected to grow to US$ 2.7 billion by 2023

There will be continuous effort to make this serialization more robust as this was developed with the idea of selling solid oral products mainly. Now with the entry of genomics, cold chain supplies for plasma, cell therapies and smaller batch sizes, we definitely have to amend the laws.

Going forward complying with requirements from different markets and still maintaining the uniformity in pack size and design can be a task by itself. Our near future demands us to figure out how to make supply chain more secure and whether the digital identity that is recognized as of today is enough or to have a combination of technologies of physical identity along with digital technology, which will make it perfect security. Making use of big data from serialization with block chain technology for physical identification, should be helpful in a secured supply chain. Should we call it Serialization 2.0 ?

Patient centric focus

With the newest buzz word of patient centricity and specificity for a patient, all of us have already started working on patient-centric packaging and as a medium of communication; it is packaging, which is going to play a major role.

Pharma manufacturer's desire to build direct relationships with patients is not new. Rapidly changing technology helps those connections more possible than ever and important.

Health apps, 24/7 call centers that depend on machine learning. Voice-enabled artificial intelligence or may be adoptable intelligence that helps manage chronic conditions. Digital therapeutics with automated reporting. They are few of the tools, indispensable in pharma marketing, not just because of value addition, but also the data analytics it provides to have better patient centric business model.

Pharma companies as well as packing material manufacturers will have to work on very attractive, sustainable and at the same time a cost-effective options keeping in mind the specific customer who is going to use it. With the growing availability of information and awareness of intellectual property, the new material being developed in future will surely be covered under IP.

With an increase in the ageing population worldwide, the demand for innovation, to be intelligent or smart in packaging, to help geriatric patients is on rise. While digital medicine with in-built sensors is making inroads in compliance monitoring and connected care, daily dose markings on the pack is becoming a regular feature, however, advanced features such as digital timers and alarms on packaging itself, reminding patients of the time for next dose are the need of an hour. What needs to be worked upon, is package has to interact with the patient. Actually it has to listen to the patient sometime.

Dose monitoring features in packaging are playing an important role in missing doses as well as patient adherence, as the study shows that only 50% of patients take medicines as per advise of doctor. Simple metered dosing systems to calendar-enabled closure technologies tracking and counting pills as they are dispensed and the sending of data to a smart phone. Scanning of codes on each Unit-dose packaging with key drug details incorporated in every dose is gaining popularity in hospitals and clinics as a convenient and safe option, driving allied trends in packaging.

While a lot of work is being done on geriatric patients, equal attention must be given to pediatric patients to curb the unintentional poisoning due to high or wrong intake in children. Tamper protection and Child Lock is required as per the law Depending on the product characteristics, the right balance is to be done with child resistant and senior friendly packaging.

With better awareness and digitalization, patients or customers are also getting aware of the newer trends of features which are more focused on customer centricity. Even in domestic (Indian) market, where the features are not so common, people have started demanding more and more. This may raise a competition in industry, in satisfying the customers. Why do you think otherwise the most robust drug products are being supplied in Alu/Alu pack and thereby increasing a value (cost?) of the product.

Forget the old definition of packaging, to protect, preserve, etc, as, now is the era of smart packaging which with the help of sensors provides a significant functionality. The packaging then becomes not only a way to protect and provide information on medicines but can add value to package like never before. The smart packaging can reduce supply chain losses through enhanced environmental monitoring. A Bottle label uses Biometric authorization to ensure that only required patients are using this product. If someone tries to open it forcefully, it may not work.

Another avenue in smart packaging is it can speak to the patient and even be able to listen. It will induce a level of psychological impact, wherein the same drug product can do wonders especially in a critical and prolonged illness. The current form of patient information or medication guides can be replaced by easy ways of audio-visual communication with advantage of smart phones. Packaging can play a commendable part in e-pharmacy that is gaining popularity in India day by day.

In the era of make locally and sell globally, Indian drug manufacturers will have to play a balancing act, as at global level, we need to exceed the international standards of safety, patient compliance and quality. Thanks to “Bottle of Lies” which has made a dent in image of India pharma industry in regulated market. Identifying requirements of patients, retailers and hospital pharmacist and satisfying them will be a great challenge for brand building and patient loyalty and on other hand while making for domestic market, we must think first of the cost for DPCO and affordability by market.

With globalization of healthcare services and hospital as hospitality service, growing demand of digital communication between doctor and patient and packaging and patient needs to be worked out.

Devices

With the rise in self medication and few therapies designed towards patient centricity, the near future will be dominated by devices; a packaging suitable and complimentary to these new devices will be a challenging job. A connected device with healthcare providers or manufacturers will be useful in connecting patients for drug delivery reminders, monitoring at real time. A monitoring of patients with recognition as incentives or rewards will be a new business model. These connected devices will give a real time feedback on sales and support in demand supply planning.

With increasing use of devices and possible misuse, FDA will ask for unique device identification system to adequately identify medical devices sold in the United States from manufacturing through distribution to patient use. We as a manufacturer will have to work out a system to identify and include a unique device identifier. Depending on repeated use of single device or single use or if the device is to be processed before use, the device needs to be identified accordingly. Such information is also to be submitted to the database like we do for 2 D barcodes.

Automation

Post COVID, more and more companies have started working on automation and increase in productivity thereby reducing the dependency on manpower.

Internet of Things and Industry 4.0 is gradually becoming an everyday requirement in the industry. Pharma industry is not at all behind and we are already talking of Pharma 4.0. Though inventory and supply chain management are the biggest adopters, amalgamation in drug delivery devices is also being worked out.

Few of the areas that are catching up and will be a need of an hour are:

- Using technology for better information of the medicine, dosage, precautions.
- Smart or intelligent packaging which is connected to manufacturers for patient adherence

With the barcode being placed on each package and scanning it at retail level will give the manufacturers clear indication on area wise sales and will help in patient adherence. Thanks to adoption of GS1 standard by regulators and compliance from Pharma packaging world, we have definitely put a step forward in reducing counterfeit.

As manufacturers struggle to continue producing everything they need to produce, Robotics and Automation play a key role in making sure machines stay running. Companies will be paid with benefits, of some technologies adopted, like more digital approach to robotics and their cloud capabilities. Flexible automation has also been instrumental in helping customers, as many of them have made last minute changes on line, - in some cases for social distancing and in some cases to make a switch to the products that are needed to combat the pandemic.

Now with a new look of India as pharmacy of the world, adoption of these global standards, use of newer technologies and competition with industry in any country with highest quality levels will pay in near future.

With a push from the government for price control under DPCO and promotion of generics, we will need to have a better control on cost of goods. Automation will play a role in reducing the cost. While many of us are working on using high speed lines and maximizing the output, we also need to give attention to input material.

This automation and high quality also needs to be worked out as material manufacturers cope up with new demands of pharma manufacturers.

Sustainability

As said in the beginning, with the outbreak of COVID 19, the most talked about subject, of sustainability has taken a back seat. Unless we have a control over the pandemic, this word cannot be brought back to the driver's seat.

We as packaging professionals and pseudo environmentalists need to bring it to forefront again as early as possible.

Of the 8.3 billion metric tons of plastic that has been produced in the world, a recent study states that a whopping 6.3 billion metric tons has become plastic waste either as landfill or ocean fill. A meager 9% of this plastic waste gets recycled. Reports indicate that by 2050, there will be 12 billion metric tons of plastic dumped on this planet, if there is no eco-system built to recycle plastic waste. What are we doing on this? Building fresh mountains in ocean ? Disturbing the environment ? I am really happy to applaud a girl in Singapore, who has hit the headlines in last week, for developing a plastic material which is real bio-degradable in just 33 days (details are to be studied though.)

Many people have started promoting paper as replacement to plastic. Those who been in the industry for a long time will remember what kind of propaganda was done on use of plastic to save wood/jungles. We are going back to same old square1 without even properly working on aforestation.

Of course, FMCG or retail markets with e-commerce making the most of business, will attract most volumes, but pharma packaging is not a smaller contributor either.

Post pandemic, there will be a new business world. Lot many changes will be happening, joining of new hands and few of the products like ready to use or customer focused material will be used more. We have opportunity to make a change in packaging which can be designed and reformulated to have a big "R" with three small "r's"

Make it a habit of "RECYCLE" with Reuse, Reduce and Replace

Materials like Glass, PP, PET which are single component materials, made from single material and easy for recycling are to be promoted more. Plastic suddenly cannot be ruled out and why it should be? So, plastic needs to be optimized where possible and try to avoid over-packaging. The lami-tubes which replaced aluminium tubes in a big way in yesteryears cannot be thrown out, but as per recent development they are made of 100% biodegradable material. This should solve the purpose.

Incidentally, COKE very recently came out with the idea of using recycled material for few of the products and it is a really welcome move.

Reduce – Need to reduce the carbon foot print by reducing or down gauging or using lighter versions of traditional packaging or material with less material. In pharma industry we have seen a trend of using high wall or heavier HDPE bottles. Are they really needed or can they be made stronger with reduced material weight?

We have recently seen an initiative taken for removal of cartons from toothpaste. Why is it really required? There will be few more items where this can be implemented. Gone are the days where everything needs to be displayed and cartons have definitely played a role of salesman. Can we apply this in pharma packaging for Rx products where selling is done by doctors and you have no choice of selecting the product?

Replace – As mentioned above, can we replace the existing material of plastic

with biodegradable or recycled material. Everyone talks of ocean fill, but we have never tried to remove plastic waste from ocean and recycle it. Can we make it compulsory under CSR for an industry to have a forestation, if paper is to be used by a particular industry? Can we consider moving to fully recyclable material. 100% monolayer in place of multilayer films. A thin liquid layer on monolayer can give the same barrier properties.

Reuse – Actually we Indians are good in making use of all material and generally we do not throw away anything unless it is reused for some household thing. In our typical kitchens the ladies are really masters of this art. When it comes to pharma packaging, we cannot apply the same logic; however, will it be possible to make use of glass or wood material to reuse.

Under sustainability header, world is also talking about Circular Economy. Today, products are designed to reduce the overall impact on human health and the natural environment. Lot of packing material convertors are working out on usage of energy, water and other resources efficiently. Even fire safety audit has become regular point. We are trying to reduce use of plastic, however, there is a huge unorganized sector which still uses plastic or PE coated paper board, which can be easily replaced with water base coating.

Packaging material as such will have a major impact on reducing the cost and reducing the carbon footprint. Effective changes in packaging with desired functionality will have an impact on handling, shipping and have optimum costing.

With the awareness to nurture the environment and reduce the damage already done due to the industrialization and urbanization, the reduction in the use of plastics will require the development of environment-friendly biodegradable packaging materials.

Quality

When we talk of building good packaging for future pharmaceutical products, we just cannot keep aside the most important aspect of development i.e. quality of material.

We just discussed automation in the pharma industry will be a compulsion as it will play a major role in reducing the cost. While many of us are working on using high speed lines and on getting maximum output, we also need to give attention on input material. We will have to re-educate our purchasing teams and even material vendors that AQL can be a part of contract but emphasis has to be on total defect free material. One odd rejection and you end up in recall of product in market. So a cost v/s value analysis has to be done to have a precise and perfect input packaging material.

While taking a look at the primary packing material which is critical as it is in direct contact with the drug product, not only the industry but even regulators are very demanding on its quality. The bible of pharma industry, the pharmacopoeia, is also being updated regularly on maintaining and adhering to quality. The container /closure system, use of plastic, glass and rubber compounds are being worked out to the highest level. We as pharma manufacturers need to adhere to these quality standards for all the incoming material. For example the latest requirement from USP, to comply with plastic packaging systems to meet overall quality. A newer trend of establishing extractable and leachable and to have toxicological studies to document that they are safe for use apart from general chemical testing.

It is one of the important responsibilities of pharma packaging technologists to facilitate 100 per cent transparency with packaging material vendors in translating these regulatory requirements and ensuring all are being complied to. Re-education of all stakeholders in the new situation is must and all of us need to follow the rules of game.

As all of you are aware that the maximum recalls in US are because of labeling issues, emphasis is also required on avoiding wrong claims, update labeling as per guidance, and strictly follow the norms.

With all these aspects in mind, a pharma packaging professional involved in material development will have the most interesting, and challenging task in near future, which demands for use of best of the skills, knowledge and aptitude and be ready for any challenge anytime. ■

Improved Patient Outcomes through Innovative Packaging

Innovative packaging solutions could make a real difference for the brand and product. The demands placed on medical and healthcare packaging are intense. The packaging must protect its content from shock, puncture, temperature fluctuations, vibration, tearing and busting.

Gauri Chaudhari, Co-Founder of Brand Innerworld, a healthcare brand consultancy, who is also an author of the recently released book, 'The Perfect Pill: 10 steps to build a strong healthcare brand', explains about the importance of Innovative Packaging for pharma products.

Author: Gauri Chaudhari
Co-Founder of Brand Innerworld

"We are not in FMCG market, why should we have a special packaging strategy? Our packaging protects brands throughout the supply chain without hampering product quality. Is it not enough?"

I often hear this response from my pharma clients when I ask them about their packaging strategy. There are many reasons behind this response and I perfectly understand them.

Firstly, many brands in the pharma industry are under price control. This has made companies adopt cost conscious mindset. Keeping packaging to basic helps companies keep the costs under check.

Secondly, the pharma brands are promoted to doctors but are bought by the patients. Obviously the doctors don't get to see the sales pack unless patients show it to them. Hence companies doubt the ability of packaging to influence doctors.

Thirdly, unlike FMCG brands, those who buy the medicinal pack (patients) are not the decision makers. So even if the pack impresses patients, it cannot be purchased by them unless it is prescribed.

Yet, the reality of any healthcare ecosystem is that it exists only because patients do. The purpose of any such ecosystem is to

improve patient outcomes, and the only way to do so is to ensure patients take the right medicine at the right time and for the right duration. Packaging can play a significant role in this process if we adopt the right packaging strategy.

Packaging has the potential to create an ultimate win-win situation for all the three stakeholders of the healthcare ecosystem; patients, doctors and the pharma companies. Doctors breathe a sigh of relief when patients remain compliant with their prescriptions. Pharma companies make higher revenues when patients complete their prescribed course of medicine and give positive feedback to their doctors.

Closer home, in India, packaging has yet another important role to play. The Indian pharmaceutical market is crowded with branded generics. There are hundreds of brands operating in the same market with the same molecule. In such a scenario, a brand needs to create value-added differentiation to stand tall in the market. Packaging provides this much-needed opportunity. It can help not only in creating differentiation but also in improving patient outcomes. Such brands are often revered by the doctors and quickly get on to their prescriptions.

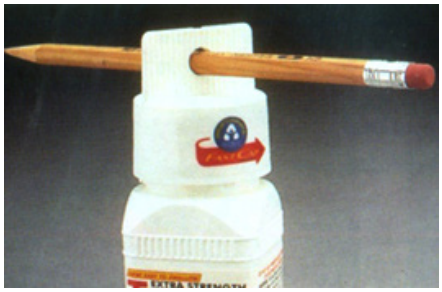
Improved patient outcomes through pharma packaging

Medicines don't help those patients who do not take them. Improved patient outcomes are achieved if and only if patients take their medicines as prescribed. There are many reasons why patients do not take medicines as prescribed. Lack of awareness, unclear instructions, forgetfulness or inertia are some of the reasons often sighted. But the list is long.

The first step is getting value-added packaging is to listen to the customers and understand their problems. "What are the pain points of patients, caregivers', doctors and other stakeholders? Which of those problems can be solved by packaging?" Brand development teams must brainstorm to get an answer to these questions.

A few years back, McNeil Consumer Company wanted to launch a Tylenol line extension for arthritic patients. While listening to the patients, brand teams realized that the biggest hurdle for any arthritic patient is to open the pack of his or her medicine. Reason? Unbearable pain in finger joints.

The team decided to resolve this problem with innovative packaging. Instead of



packing the medicine in a strip or a bottle, the brand team created a unique pack. As shown in the adjacent fig , the pack was designed with a hole in the cap. A pencil could be easily inserted in the hole and the bottle could be opened without bending fingers. Such pack was a huge relief for an arthritic patient. It was not an expensive innovation. All it needed was to have empathy towards patients and commitment towards improving patient outcomes.

Closer home, in India, Human Mixtard is yet another example. Human Mixtard is a brand of Insulin. The insulin market has many players with similar formulations. Yet Human Mixtard, a leading brand of Human Insulin, stood apart by creating a simple but highly effective packaging solution.

While talking to chemists, the brand team realized that the insulin formulations across the brands were available in multiple strengths. There was a significant chance for patients or even chemists to mix up the strengths. Insulin is a highly potent drug. A wrong dose of insulin can be fatal to the patient. Human Mixtard figured out a simple yet highly effective packaging solution to resolve the problem. It coded the caps of different strength vials in different colours. Now, the patients and chemist could recognize their Human Mixtard strength just by looking at the cap of the vial. A simple change in packaging ensured that the right medicine with the right dose reached the patient.

This simple but effective packaging strategy aimed at improving patient outcomes, changed the fortunes of the brand. Doctors saw great value in this packaging. They preferred Human Mixtard over other similar brands that were not color-coded. Human Mixtard went on to become the number one prescribed brand in the pharmaceutical industry.

Each disease and its treatment has a unique challenge. Need is to listen to patients and other stakeholders with empathy and create solutions.

Improved patient outcomes through Packaging Design

In addition to rational or functional needs, patients have emotional needs. Illness is an emotional subject. We feel sick. We feel better. There are a lot of feelings associated with illness and treatments. Understanding these emotions is critical to developing a strong bond with patients which often results in better patient outcomes.

The colours, fonts, visuals, mnemonics and symbols used to design pack together help brands create an unbreakable bond with the patients.

Research has shown that the colour of packaging has a positive impact on health outcomes. For example, a patient suffering from anxiety and depression is positively inclined towards medicine, which is packed in soothing colours. Yellow packaging

design for an antidepressant performs a lot better on patient acceptance criteria than dull brown packing. An analgesic that is expected to be strong and effective performs better when given in a red colour pack.

Fonts, too, have an important role to play. There are numerous fonts available for packaging designer. Each font makes a statement about the brands personality. While the sharp, bold font helps patients receive medicine as strong and powerful , a softer, curvier font gives a feeling of it being gentler and smoother.

Ulcikit, a brand for peptic ulcers, came up with a unique design. The strip of Ulcikit comprises six tablets; three to be taken in the morning and three at night. The pack is designed in such a manner that

patients instantly understand the regime of administration. The pack design colours and fonts bring out the friendly personality of the brand. Such designs often build a strong bond with patients and improve overall treatment outcomes.

Voveran, a leading analgesic brand, is meant for the skeletomuscular pain in the

body. It uses blue and red colour on its pack to communicate effective yet gentler brand personality . The mnemonic used on the brand provides much-needed sense of mobility. Moov, another topical analgesic gives the same sense of mobility through the fonts it uses on the pack.

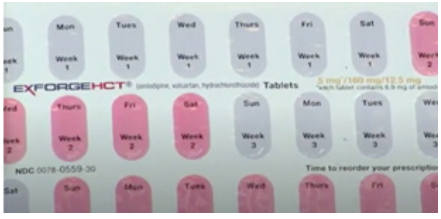
Improved patient outcomes through therapy Adherence

Packaging can play an important role in ensuring patients' adherence to medication. It has been estimated that one third of the Indian patients are non-adherent to the prescribed treatment. Non -adherence often leads to complications and results in higher economic burden.

Medicines for chronic illnesses require long term therapies. Remembering to take medicine every day, ordering a new pack before the previous one is over can be challenging for many patients. Often such lapses result in poorer health outcomes.

Packaging has a unique role to play in providing solutions that improve adherence. There are several examples of calendarized packaging designs wonderfully acting as pill reminders.

Exforge HCT, a cardiac medicine manufactured by Novartis, comes in an



interesting monthly pack. It labels not only days but also weeks of the month. It also has instruction for patients to reorder medicine by clearly indicating 'Time to reorder your prescription' above the fourth week. This definitely enhances patient's compliance with treatment.

Non-adherence to medicine to therapies, at times, puts the entire society at a disadvantage. India has a unique problem of antibiotic resistance. Since the patients often stop their antibiotics without completing its full course, antibiotic resistance in India is on the rise. By 2050,antibiotic resistance is expected to be the leading cause of death.

Packaging played an important role in educating/ warning patients to complete the prescribed antibiotic dose. Every strip of antibiotic has a red line indicating this medicine cannot be self-medicated and the patient is mandated to complete its entire course as per doctor's advice.

Improved patient outcomes through technology

Technology often makes the most complex problems simple. Today's technology can add several features to packaging that aid in improving patient outcomes.

Patients often like to know more about their medicines. What is the dose? Should it be

taken with food or empty stomach? What are the side effects? What precautions need to be taken while on the treatment. Putting all this information on the pack is practically not possible. But technology is here to resolve

this issue. A QR code on the pack can give all this information to patients without taking up space on the pack. In India, CDSCO is advising pharma companies to print QR codes on the packs to inform channels and patients about the batch size, manufacturing date, expiry date etc.

Yet the application of QR code can be far more engaging.

- QR code can direct patients to brand website to know more about the brand.
- A patient education e-leaflet can be attached to QR code advising patients on various aspects of medicines.
- QR can open in a video. This can be a boon for complicated therapies like Insulin. Self- injecting insulin can be difficult. A video can instantly educate patients on various subjects including lifestyle modifications, exercises and diet.
- QR code can act as a pill reminder. On scanning QR code patients or caregivers can add recurring events to their calendar and get suitable reminders.

Future trends in Packaging

-Interactive pack: Technology can convert a pack into a content channel. An interactive sample pack can augment the efforts of the medical representative in a doctor's chamber

- Temperature sensor pack: Many medications are temperature sensitive. Digital technology today can alert chemists or patients if the medicine is stored at the temperature outside the range.
- NFC technology to record when the pack is opened each day. If patient forgets to open the pack at the expected time of the day, alert is sent to his or her phone for reminding the dose.
- Microprocessors and conductive inks RFID can record the date and time at which the medicine is taken. Such packs are already available and being used in clinical trials to get the accurate data.

Of course, some of these inventions are expensive and are unthinkable in the country like India. Yet, technology tends to get cheaper over a period of time. Hence pharma brand marketers need to keep a tab on the latest technology.

In the coming decade, the packaging will become more and more important in the pharma industry. We are going to see packaging playing a critical role in improving health outcomes. Need is to put in sincere efforts to understand customers' pain points. Packaging strategy has the potential to build pharma product into a strong brand. But of course, that would be just a by-product. What would count the most? Blessings from patients. ■

Child Safe Packaging Today

With creative solutions abound in the packaging industry, manufacturers are able to address all manner of consumer and regulatory concerns, and health and safety is no exception. There's regular 'safe packaging', however, and then there's child-safe packaging: a sector with its very own demands and challenges. Richard Quelch, head of marketing at Origin Pharma Packaging, discusses child-resistant packaging and how to prevent incidences of medical poisoning.

Author: Richard Quelch
Head of Marketing, Origin Pharma Packaging

As physicians become more reliant on prescribing medications to treat illness instead of advocating preventive measures, the risks associated with accidental medication poisonings is increasing. In the UK, approximately 50%[1] of our population take prescription medicine whilst in the US the figure is over 60%[2]. These figures are not quoted to in any way reflect on cases genuinely requiring prescription medication, they do however provide an insight into the volume of medicines in circulation and with this, the scale of potential risk to children. Poison centres in the US treat between 60,000 and 70,000 children each year for accidental ingestion.

Advancements in packaging technology such as soluble packs, films etc are undoubtedly to be viewed as a progression, it is questionable however whether there is a parallel effort in creating the child resistant packaging necessary to ensure these products are safe for the environments they occupy. Whilst Mercola[3] reports that pain medications are the single most frequent cause of fatalities from accidental medication poisonings in children, household products still present an alarming number of ingestion cases. In medicine terms the category

of substances with the largest number of deaths across all ages (including intentional use of opioids in teens), are medications containing acetaminophen, sedatives, sleeping medications, stimulants, and cardiovascular drugs. In terms of household products the most common issue is becoming the soluble packed alkaline detergents.

There is an abundance of information and even some creative solutions available to the packaging industry, with the ease of access to online information manufacturers are able to appraise themselves in consumer and regulatory concerns and safety is no exception. There is however possibly a lack of understanding what truly constitutes child-resistant packaging and also a preparedness to await regulatory obligation before introducing protection.

One question we hear raised from time to time is whether the effectiveness of some of the conventional child resistant packaging of today is to be assumed appropriate for today's world. Some of the established institutions will feel strongly that it is, however it is arguable whether the combined impact of freedom of information, intelligence of today's children, and the tragic increase in cases of diminished responsibility are effectively measured.

Non-medicine packaging

Whilst Origin's work of over 50 years has revolved largely around medicine packaging and drug delivery devices, there is perhaps a sharper increase in casualties from the non-medicine product categories.

The advance in soluble packaging is an example of a welcomed and convenient technological development, in our opinion it has been delivered upon with an apparent disregard of the potential harm to children. Soluble dishwasher tablets for example contain aggressive and corrosive alkaline salts. Ingestion of these products is becoming a common occurrence yet apart from warnings printed on the box, there is no physical barrier provided in the packaging to protect children. These oftencolourful capsules are attractive to young children as is evidenced in the ingestion cases. How many of us in reality have these accessible to children in our homes? and how many of us have located and read the product information?

Unlike medicines, there are virtually no defined regulations to control the packaging of such products, guidance notes on packaging enforce only our impact on the environment but stop short of enforcing child safety values. If this situation continues little is likely to change on commercial scales to develop packaging to reduce these risks, yet without apportioning the burden unfairly, should we really wait for regulations to be imposed to meet the need? Regulation supports good practice and no doubt it will be pronounced on one day, in the meantime we wonder if our moral and ethical obligations are being fairly considered?

Child Resistant is Not Child Proof

An important consideration is the terminology used in matters pertaining to child safety, rarely if ever is packaging child proof. The balance between child resistance and senior accessibility restricts just how far we can restrain children and the senior friendly challenge is something of an interminable debate. Accommodating both aspects in design is a significant challenge, regulating such a conflicting scope is probably harder still.

Child resistance should, according to the ISO8404 Standard (non re-closable) be considered the last line of defence, not the first line. Whatever packaging is developed

to meet the fine balance of abilities between children and seniors it should be always remembered that "child resistant" is never "child proof" and therefore the practise of keeping medicines out of sight and reach of children should be mandatory.

There will no doubt exist some interesting papers on child psychology that will substantiate this comment, but the fact is that for all our experience we still tend to underestimate the innocent, inquisitive nature of children. An article by VWA entitled "children see things differently"4 gives a simplistic message of how things appear to young children and provides thought-provoking questions about what consideration should be made when designing safety into these packages. Even the bright colours used as a means of retail marketing or shelf impact attract young children in an entirely different way to how they are intended.

Senior Friendly Child Resistance

Accommodating both Senior Friendly and Child Resistant values in design is a significant challenge, whilst regulating such a conflicting scope is probably harder still. In many ways, the senior accessibility aspect is less definable than the child resistance. With children, we have fairly prescribed parameters of ability in the child safe testing age bracket of 42 to 51 months. The scope of abilities present in the adult test panel however of 50 to 70 year olds presents a hugely different picture.

The loss of dexterity and in some cases the ability also to coordinate is often diminished in our latter years. The key principles required in achieving effective child resistance are by definition the same principles needed to enable the aging population. As our aging population is also increasing and advances in medicine is enabling us to retain our independence longer, questions could be raised as to whether 70 is still a relevant top end age for the testing protocol.

Storage of Harmful Substances

The storage of medicines and other potentially harmful substances therefore requires a responsible approach. As already stated, child resistance is the last line of defence. The most secure way without doubt to ensure children to not access these products is to ensure they never see them in the first place.

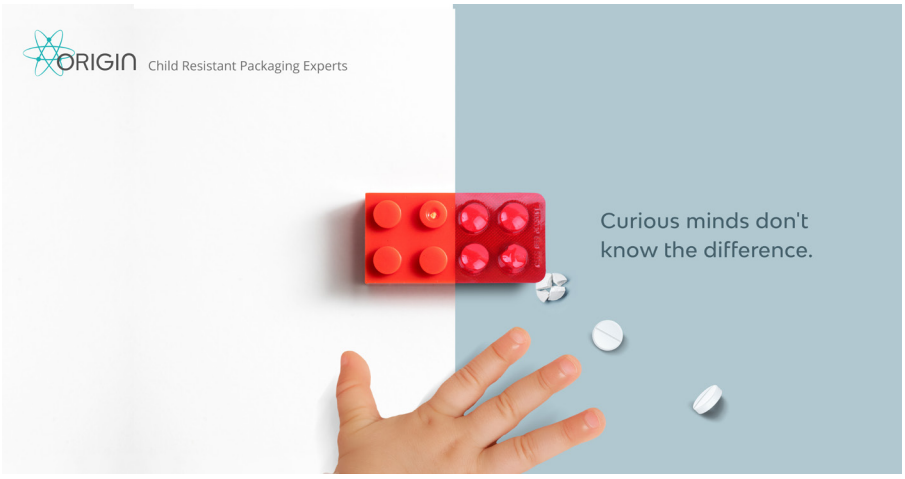
The deliberate misuse of opioid substitute has been the greatest cause of child ingestion of pharmacy-dispensed child medicine ingestions in the UK that have led to actual fatality. It is important to recognise that these tragic instances have rarely (never in our experience) proved to be the result of non-compliant packaging.

A report from Alder Hey hospital, Liverpool5 found that of 30 methadone ingestion cases; 22 involved re-closable screw cap bottles and only 2 of these were found to be original and child resistant. Such evidence sadly proves that even compliant packaging cannot be expected to provide the intended protection if medicine is transferred to non-child resistant packaging. The cause

of these breaches in security after police investigation have always proved to be the outcome of diminished responsibility on behalf of the adult. One simple measure that could be enforced easily in our opinion is to provide education to patients using such medication that the product must be stored in the container it was supplied in.

Regulations and Testing

We have effective and well recognised regulations for the safe containment of medicines and the necessity of a common test protocol has long been considered essential for these products. Reclosable packaging to BSEN ISO8317 and its American equivalent, 16CFR 1700.20 are still effective and the 2015 version of the ISO Standard has cleared up some areas of confusion.



To gain approval the complete pack must be tested – container and closure. Whilst many closures are produced to provide child resistance it is not possible to assume that because one pack combination passes another will pass also.

Testing in the UK is carried out at UKAS approved test centres in accordance with the relevant test protocol. Marginal differences apply between the European and US procedures but there is no meaningful difference in our opinion between the two with the exception of the re-securing aspect of the US test 16CFR1700.20.

Some test centres provide an expedited 'pre-application' test service providing a smaller test panel for a lower cost (Origin can advise regarding this). The test conditions are as per the protocol and the results helpful in ascertaining whether there are any fundamental issues in the pack design. Successful pre-app tests can usually then be scheduled quickly to full protocol testing if there appear to be no issues. A further benefit from such preliminary testing is that we are able to 'weight' the test panel to include more or less of certain age brackets to create robust test conditions.

The official test protocol requires 200 able-bodied children between 42 and 51 months and can be carried out either with the full 200 contingent or by a method of sequential testing. For the adult test a panel of 100 is required between the ages of 50 and 70 years.

Compliance – how do I know?

With over 50 years' experience in child safe packaging we know there are an increasing number of packs in circulation that cannot be considered child resistant, as might be expected a number of these are imported. Research suggests to us that an assumption is often made that because a cap appears to have a push-and-turn mechanism it must be child resistant, however this is not a wise assumption.

We suggest a common practise should be to ask your supplier for a technical file and certificate of child resistance for the pack you are using. Remember that technically there is no such thing as a "child resistant cap" as for a pack to be child resistant you should have a certificate which specifies the container and cap.

If your product is sold within the UK and EU then the BSEN ISO8317 certificate is the correct document for your activities. If your product is to be sold in the US you will need the 16CFR1700.20 certificate to comply with the regulations currently in force in the US.

If you require support in design and supporting your packaging formation transition into child safe compliant packaging Origin Packaging Limited (originltd.com) can help. ■

Functions of packaging and labeling in pharmaceutical perspective

Packaging & labeling are vital and need to be done correctly in new product development, production, and supply chain, until the product reaches the consumer. Jayanti Sawant, Pharma Packaging Consultant explains the functions of packaging and labeling in the pharma industry.

Author: Jayanti Sawant
Pharma Packaging Consultant

The pandemic has had devastating impact on almost all industry sectors and so on the global economy. The pharmaceutical and healthcare sector, however will continue to grow as the need of medication remains and cannot be ignored at any cost.

In such a crisis, the pharma and healthcare sector successfully are delivering essentials to the suddenly grown demand .There is a continuous demand of one time use packaging or disposable packaging. The scenario will surely be different for packaging materials after the world is done dealing with Covid-19 .Most of the medicines are being ordered online during lockdown and hence, cardboard packaging , plastics will be in demand. Shortage of waste paper may result in hiked prices of cartons during this phase and glass will continue to be dominating injectable sectors.

The use of masks and sanitary products has caused a sudden demand and a pressure on packaging industry. Packaging is under essential services for all kinds of industries. Labeling is a vital part of packaging, and both, packaging and labeling need to be done correctly in new product development, production, and supply chain, until the product reaches the consumer.

Functions of packaging and labeling in pharmaceuticals.

Over the last two decades, pharmaceutical packaging has evolved . At one point it was a simple packing operation of finished goods which has now emerged as a separate, intricate process. The term ' packaging technology' is appropriate to indicate that this process is an amalgam of art, science and technology .

The development gained momentum in last decade due to availability of various kinds of materials , upgradation in printing technology , availability of professionals in this field , and even changed regulatory requirements. Globalisation resulted in complete transformation of pharma packaging and labeling .

Pharma packaging and labeling are two sides of the same coin, fused or merged to complete the definition of a package of any product. It is an integral part of product development and remains crucial until the consumption of the drug by the customer . Hence packaging and labeling have defined functions which if not identified correctly during product development , can result into serious complaints and ruin the brand image in the market .

Packaging

For packaging operations, Once the bulk drug or the batch is ready, all the operations like washing, filling, sealing ,packing will be treated as 'packaging' .For instance, the silicon tubing for injectables or any such material in direct contact with the product during production, may call for the detailed studies of extractables and leachables with respect to regulation compliances. These are packaging compliances. Hence the word 'packaging Technology' emerged and replaced 'packing'.

There are certain regulatory requirements that have to be fulfilled, such as suitability, safety, protection, convenience, compatibility, quality control, vendors and stability. The content of the dosage forms are often very sensitive towards external elements such as light and moisture. Hence, once the product

is packed it is to be completely safe from direct exposure to light and moisture. Simultaneously sealing the pack should be excellent and shouldn't allow reactive gases like oxygen, as this might lead to dangerous consequences like failing of the product in stability. Moreover, if any leakage is found in this sealing, it might raise a question on sterility and closure integrity of the container.

Labeling

Labeling on the other hand is the factor that determines the safety and briefly introduces integrity of the product. This operation includes both printing on the carton and pack inserts provided individually with the pharma products.

The primary purpose of labeling is to make identification of the product unambiguous.

Labeling information is important for both healthcare professionals and patients to prescribe and consume, respectively. This is crucial also because people have an obvious belief on medicines' company that they will provide right information on the product. Hence, the faith of the customer or end user is associated with the brand which is created by packaging and labeling. Thus , with evolution from packing to packaging , functions of packaging and labeling evolved.

FUNCTIONS OF PACKAGING .

1. To carry the product: It is the first and foremost function of the pack and his been right since the time we have evolved as humans, from the zeitgeist of wrapping food in leaves to carrying it in modern day revolutionary packaging.

2. To protect a product from damage or contamination: The product must be protected from any damage during transit or storage The product must also be protected against the climate, including high temperatures, humidity, light and gases in the air.

3. To act as a marketing tool: It identifies and represents the brand . Packaging is the main way products are advertised and identified. To the manufacturer, the package clearly identifies the product inside and it is usually the package that the customer recognises when shopping .Thus it helps to sell the item and create a brand identity.Marketing communications and graphic design are applied to the surface of the package and often to the point of sale display. Most packaging is designed to reflect the brand's message and identity on the one hand while highlighting the respective product concept on the other hand.

4. Protection during Transport and Ease of Transport. A package should be designed to make it easy to transport, to move and lift. A regular shaped package can be stacked without too much space between each package without space being wasted. This means that more packages can be transported in a container thereby systemising logistics and supply chain.

5. Stacking and Storage: In stacking and storage, symmetric packs lead to minimum errors in the transit and in distribution.

The choice for a packaging material usually depends on:

1. The level of protection required: Highly hygroscopic dosage forms like amoxicillin and clavulanic acid tablets need high barrier packaging.
2. User friendliness: The size ,shape and weight matter. It should be easy to carry, accorded to taste of the product , and dispensed carefully.
3. Filling method of the dosage form
4. Compatibility with the dosage form
5. Sterilization method: The pack has to withstand the sterilization process.
6. Reusability of the pack: Refill packs should be sturdy as they undergo multiple use at the hands of the end user.

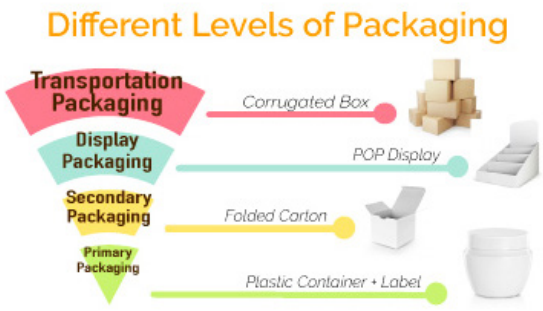
Functions of packaging materials also vary for different packaging materials.

These types can be divided as:

1. Primary Packaging Material (PPM)
2. Secondary Packaging Material (SPM)
3. Display Packaging Or Intermediate Packaging (Mainly Used For Food Products)
4. Tertiary Or Transport Packaging, (TPM)

Here we consider primary, secondary and tertiary packaging which are mainly used in pharma .

The display or intermediate packaging holds secondary units , for example, a bunch of cartons, tetra packs or bottles and



facilitates distribution channels , displays brand , supports consumer in bulk purchasing . It also provides strength to the main pack while in storage and during display .

The image below is self explanatory, showing different levels of packaging .

1) Primary packaging: it includes blisters, ampoules ,vials etc. This is the material that is in direct contact with the product and holds/envelops the product. It is, therefore, the most important and undergoes difficult selection for sensitive products .

The most important function of primary packaging is to protect and preserve the product from external damage, contamination, spoiling and spillage . It also serves the purpose of keeping the product in storage, often for a long period of time .It also defines shelf life of the product and contributes to shelf life studies .

It should be able to withstand the product sterilization process , develop good barrier against microorganisms and environmental contamination .It should support the product in WVTR ,MVTR and OTR as the more the migration through PPM to product , more will be damage to product in terms of shelf life .

The objects enclosed in the package may require protection from mechanical shock, vibration, electrostatic discharge, compression, temperature, etc.

A barrier to oxygen, water vapor and dust is often required. Permeation is a critical factor in design. Some packages contain desiccants or oxygen absorbers to help extend shelf life. Modified atmospheres or controlled atmospheres are also maintained in some cold packages. Keeping the contents safe for the duration of the intended shelf life is a primary function.

2) Secondary packaging: Cartons have been used to put together single products or many primary packages. It does not come in direct contact with the product.It:

- Markets the brand by creating brand identity : Since this pack is directly seen by the end user , its design and aesthetics get registered in consumers while browsing through shelves in medical shops or pharmacies . Thus it is one of the P's of marketing since it displays the brand . .
- Protects the primary pack and provides mechanical support to the product and primary pack thereby enhancing product protection , product appeal and safety .
- Is an intermediate block for the supply chain ,hence a low quality grade shipper can damage the entire product if it fails to withstand the transit hazards like shocks ,vibrations , multiple handlings and compression due to stacking during storage .
- Provides convenience and security to the pack at the consumer's end .This concept has given entry to small portion packs or one time use sachets like vitamin D pouches, rehydration solution pouches .

3) Tertiary packaging: Shippers are mostly used for bulk handling, warehouse storage, and transport . They are the backbone of the supply chain.

Tertiary packs are generally not seen by the customer . most of the shippers are tertiary packs which give protection to the product by safeguarding the primary and secondary packs .

Thus it protects the product from damage , moisture and environmental hazards while in transit and in storage warehouses

If the product is not delivered on time, notwithstanding the fact that it is a successful product, it will become useless to market. Hence, timely delivery of the product with the intact product is the tool for success in supply chain and hence for marketing also. Many a times , quality of the tertiary packs is still a last minute development in many organizations . Even now, the problems include hidden or invisible damages which crop up suddenly in transit. Damages to the shippers, buldging of shippers in new product launches are a phenomena.

Hence transport packs are important for any business. We can categorically define functions of these packs:

• Most important tool of transport:
Optimum size transport pack or shipping box helps in successful transition of goods anywhere in the world and there by makes the product available where it is needed the most .Thus , it's a building block of any supply chain .

• Protects goods inside:
It protects the primary , secondary packaging and the product . During transport ,when goods arrive from a supposed port A to port B in a damaged condition , it may have to undergo replacement of damaged goods, which then becomes an additional cost .

Apart from the extra cost , it will beget sour relationships with customers , distributors which can affect the image of the organisation .

• Conveys important information:
There can be a lot of important information that distributors need to know about your product. Your transport packaging is the perfect place to display this information.

A lot of different things can be printed on your boxes. It could be something simple, like the order in which the packages need to go, or a declaration that the contents are fragile. You can also

specify more detailed handling instructions, such as temperature range your products need to be stored at.

• Makes storage and transport possible:
Perfectly designed shipper or transport box uses optimum space on pallets .These boxes on pallets fit perfectly in containers , providing safety from damage to the goods till they reach the destination port and are further distributed .Hence, while designing shippers, following technical specifications is important .

GSM, Burst Factor , Virgin Or Recycled, Edge Crush , Compression , Bursting Strength , Type Of Flute Used . With correct use of combinations the strength of 7 ply box can also be obtained in 5 ply box

Image below shows perfectly designed shipper -optimum utilization of pallets .

• Helps to sell:
Good logistics are preferred by the retailers , distributors as they help in protecting the goods in storage and such packs are always preferred by the supply chain personnel.

The display labels carry detailed information about the product which helps in identification of the brand, thus helping in selling the product . We will see labeling in detail under the labeling section.

Functions of labeling:
Pharmaceutical labeling is a complex and stringently done process with increasing global quality compliances , regulatory requirements.

For local markets ,it is governed by Drugs And Cosmetics act 1945 has to be updated in accordance with the updated provisions .For export , labeling is governed by the concerned regulatory body or ministry of health of the countries. The term label refers to all labels which display content of the medicines along with other important matters about the drug or its formulation .

A label may be of paper , printed packaging materal like foil or laminates , sleeves , ceramic or screen printing on ampoules ,paper tags .Label matter should be approved by FDA , Hence the content of the artworks shall also be FDA approved .

The minimum legal information that needs to be on the label is :

- Brand name and generic name of the product
- Composition
- Storage
- Strength and dosage form
- Quantity or pack size
- Instructions for use
- Mfg Lic No , B.no, Mfg Date ,Expiry date ,MRP
- Name and address of Manufacturer.
- For prescription drugs : The pack should display Schedule G,H,H1 and X warnings in accordance with latest updated guidelines of Drugs and Cosmetic Act, 1945 .These guidelines are released in Gazette of india as and when updated .

Pharma labeling:
- Provides detailed product information to the consumers , doctors , pharmacists about the product's content .
- Helps in safe usage of the product by providing detailed such informative labels .
- Secures the brand by providing anticounterfeit measures .

For instance, Betadine gargle pack has got a tamper evident cap with a holographic label, helping the brand to be secured .The shape of the bottle is unique combination of square and round which creates an intricate mold which is difficult to copy .Thus packaging and labeling are effectively used to protect and secure the brand .

• Helps in brand development and acts a marketing tool since it identifies the brand: For instance, a customer can easily choose or identify Crocin among all other paracetamol brands as the design and pack are easily distinguished by consumers for years .Hence the brand name Crocin has become a synonym for Paracetamol .

• Aids brand development: Packaging and labeling combined together create a brand identity in market . A standard pack with various label shades segregates variants of the same brand . A few images will help us understand this concept. For example,.

Iodex pain balm, Headfast balm, Iodex gel

:Shipping boxes are crucial to supply chain since they carry significant information right since warehouse storage, till distribution.
It is labeled or printed with brand name , generic name , batch number, manufacturing date, expiry date ,storage , gross weight, net weight, shipper number, address of the manufacturer, and that of the importer and exporter .

It also displays 1d code label adhering to DGFT compliances for export and it has to be treated as per the guidelines released by the DGFT . This label has a relation with the secondary packaging, which can track the goods in transit and is considered to be one of the most powerful tools to arrest spurious drugs . That also makes it an anticounterfeit tool.

It also displays common instructions for handling it since the shipper undergoes tremendous handling, loading and unloading during the entire cycle of distribution .

Packaging and labeling together offer product security and are largely used as anticounterfeit tool. Let's look at anticounterfeit techniques.

Counterfeit products are growing day by day and are a nuisance for businesses all over the world .These are fake products that have been copied exactly like the original in every sense , resulting in huge economic losses and harm to the consumer. Pertaining to pharmaceutical products ,if the drug is spurious , it will be certainly life threatening to the consumer or end user .This need of protecting the drug and its pack from being spurious or prevent it from being copied has led to demand of anticounterfeit packaging which can protect brands from being easily replicated .

Packaging and labeling in pharma have to protect the brand and the product , also tell apart the brand from other brands with unique anticounterfeit features included in the pack . Day by day , the demand of such packaging material is increasing, and the anti-counterfeiting labels and packaging market will continue to grow and evolve.

One of the first steps brand owners can take towards protecting their brand is learning about various anti-counterfeiting techniques so they can find suitable and cost effective solutions for them.

Most widely used Anti-Counterfeit Labels and Packaging Techniques:

There are two main types of anti-counterfeiting techniques for labels and packaging which are often used together to create a comprehensive security solution. Overt and covert features are noticeable and hidden details, especially, make it easier to detect fakes and increase traceability across the supply chain, and make it harder to counterfeit products.

1) Track and trace: A two-dimensional (2D) barcode looks like a square or rectangle and contains many small, individual dots. The two most popular types are Quick Response (QR) Code and Data Matrix,but there are other options available. According to GS1, "A single 2D barcode can hold a significant amount of information and may remain legible even when printed at a small size or etched onto a product.

Track and trace works like parental child tracking methods where every secondary unit will have a unique serial number under the main or parent shipper or pallet which helps in tracking the shipment or a particular pack in transit. This is a directive from DGFT for export.

2) Watermarks: watermarks are images or patterns that are embedded into the design of a package or paper to authenticate products and support brand identity. Watermarks can be generic or customized using a logo, brand name, or other symbology.

3)Microtext: Like watermarks, microtext is used to authenticate

products. Extremely small text, codes, or symbols are tricky to replicate or copy without using advanced detection and printing equipment. Microtext can be inserted into overt images, larger text, and other design elements without being noticeable to the naked eye. Since microtext is not easily noticeable, counterfeiters would be unaware that it exists in the pack.

4)Holograms: A hologram is a three-dimensional image formed by the interference of light beams from a laser or other intense light source. Hologram technology is popular for anti-counterfeiting because it can incorporate various data forms and product tracking information.

It can be used as a label to close a carton, thus acting as a tamper evident seal also.It can be a part of a blister embedded in a foil.

5) RFID Tags: Radio frequency identification (RFID) technology uses radio waves to automatically identify people or objects.

6)Tamper Evident Seals: Tamper evident seals can be printed in different styles to fit your security and packaging needs. shrink sleeve labels with a perforated seal or shrink bands are full-body labels that make products stand out with visually attractive graphics that completely wrap around a container. They are more than a pretty face – they are harder to counterfeit than pressure sensitive labels because they're more complex and need high volume products to be cost effective.

Shrink bands are film strips that are shrunk to fit around the cap and neck of a bottle or jar to show the product has not been opened. You can choose between non-perforated or perforated for easy removing, and blank or custom printed design (recommended for brand identity and anti-counterfeiting).

Tamper evident seals and anti-counterfeiting techniques offer brand owners many benefits like product security, brand identification, and product authentication.

7) E pedigree : The E Pedigree label tracks the origin of prescription drugs through an electronic pedigree and provides data on the history of a particular batch of a drug. When the system is set up, this tracking is done during the reception and dispatching of batch.

Thus Anti-counterfeit packaging is mainly intended to prevent brand reproduction. It enables brand protection and enables clients distinguish between original and counterfeit.

Conclusion:

All in all, it is difficult to imagine pharmaceutical industry sans the functions of packaging and labeling which are integral part of production activities once the new pack has been developed and commercialised .The products meant to safeguard human beings will be useless if they are not packed and labeled in accordance with the compliances .It is of utmost importance that the drug retains its original quality until consumed by the end user . Packaging and labeling ,though different activities , intermingle and together lead to the creation of a quality pack .

The success and failure of any product depends on how the end user or the customer has responded, especially the healthcare sector. While the end user reacts, he /she is educated enough to check the packaging and labeling of the pack, hence packaging and labeling are crucial and important factors of the pharma domain.■

Finding a Therapy for Pandemic COVID-19 quickly – Challenges and Solutions

The world is suffering from a pandemic currently, the likes of which have not been seen in recent history. Dr. Uday Saxena, Co-Founder & Dr. Subrahmanyam Vangala, CEO of ReaGene Biosciences Private Limited through this feature explains the urgent need for finding a therapy for COVID-19.

Dr. Uday Saxena
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Dr. Subrahmanyam Vangala
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1. Introduction to COVID-19

The world is suffering from a pandemic currently, the likes of which have not been seen in recent history. The virus causing this pandemic is called novel severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2, 2019-nCoV) and the disease caused by it is called COVID-19. It is believed to have initiated in Wuhan, China and rapidly spread from there to other parts of the world thru individuals traveling. COVID-19 has been impacting a large number of people worldwide, being reported in most countries with fatalities in millions globally.

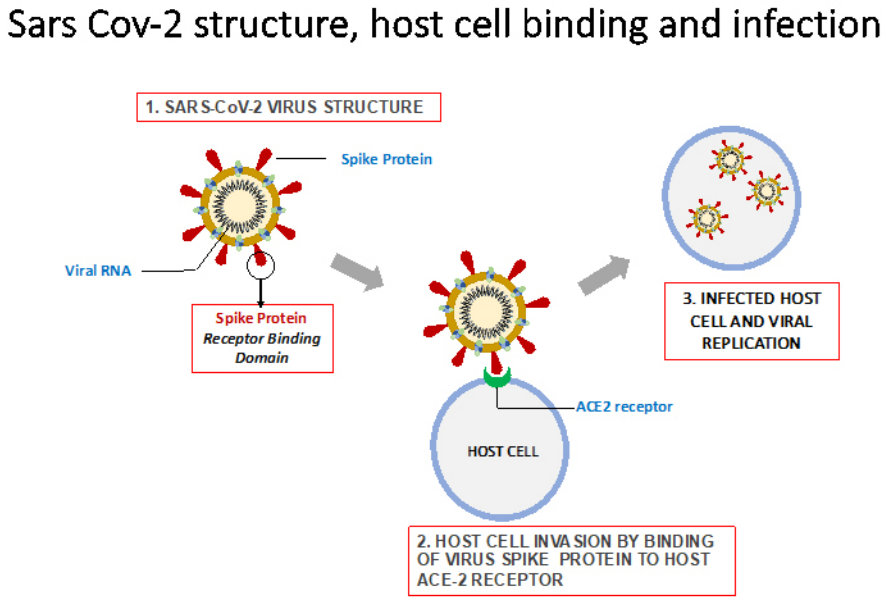
SARS-CoV-2 virus mainly impacts the respiratory system, but now it has been shown in patients to have impact on other organs such as kidney, heart, digestive system and possibly the CNS system. Typical symptoms including high fever, dry cough and difficulty in breathing. In addition mild symptoms of headache, dizziness, generalized weakness, vomiting and diarrhoea are also observed.

There is an utmost sense of urgency in trying to find a therapy for this disease since it can be fatal. Epidemiological observations have shown that mortalities are higher in elder population and much lower to none in children. It also appears that males are more severely impacted by COVID-19 relative to females.

Unfortunately since the disease COVID-19, is so new, there are no targeted therapies available. Current medical management is mainly symptomatic and existing anti-viral drugs marketed for other viral infections are being put to use, such as lopinavir-ritonavir, remdesivir, hydroxychloroquine and azithromycin which have been used in patients for other indications previously. Thus, there is an urgent need to find a disease modifying cure for patients that have been infected by this virus as well as a vaccine for rest of the population to prevent the spread and reoccurrence.

2. Approaches to new therapies for COVID-19

For any virus to cause damage, it has to enter host cells (e.g., human lung airway epithelial cells, endothelial cells, intestinal cells) and then rapidly use host cell machinery for replication. In case of SARS-CoV-2, its surface spike (S) protein facilitates viral entry into target cells. The spike protein has two units S1 and S2. Entry depends on binding of the surface



unit, S1, of the S protein to a cellular receptor, which facilitates viral attachment to the surface of target cells. In addition, entry requires S protein priming by a specific host cell proteases, which entails S protein cleavage at the S1/S2 and the S2 site and allows fusion of viral and host cellular membranes, a process driven by the S2 unit. The spike protein binds to a specific receptor on the host cells surface called angiotensin converting enzyme -2 or ACE-2. Shown below are the steps that occur for the virus to infect a host cells involving virus spike protein and human host cells.

The spike protein has become a major target for new drug discovery efforts that have been launched . Some of the approaches that are being used are using it as an antigen to design vaccine protocols, designing small molecule drug or peptide antagonists that can block the interaction of spike protein with ACE-2 receptor, finding inhibitors to the protease that process the spike protein during its interaction with ACE-2.

3.Typical drug discovery process may be too long a wait for COVID-19

Typical process for new discovery and development of vaccines or drugs is very time, resource and cost intensive. The process for discovery and development of any vaccine or new drug, peptide or biological is composed of three stages:

a) Discovery (3-5 years)
b) Preclinical Toxicology (1-3 years)
c) Clinical Trials (3-7 years)

Shown in figure below are the typical stages of drug discovery development, timelines and cost:

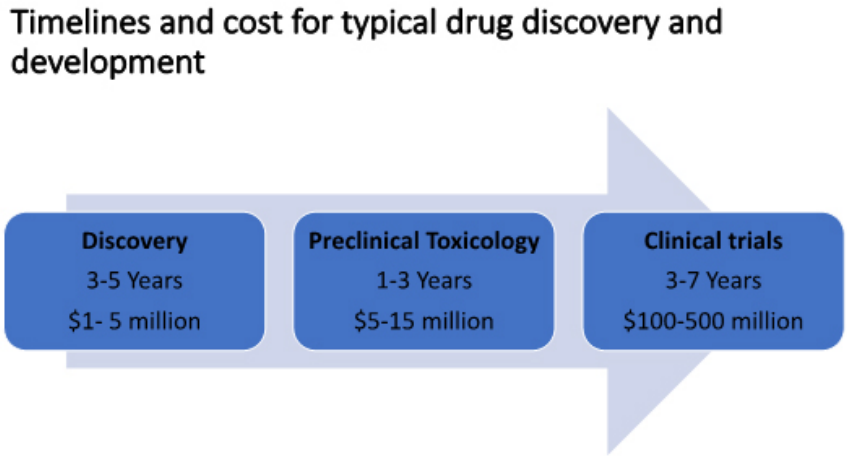
4. Challenges in finding a drug quickly for COVID-19

There are many challenges in the discovery and development of a new drug especially for a new disease. Let us look at the challenges in each stage separately especially with application to COVID-19.

A) Discovery stage

The major challenges in the discovery stage where the work is mostly done using isolated cells and animal models is to be able to reproduce the human disease in the lab and complete understanding of the disease process itself. Both of these aspects severally impact new drug/ vaccine discovery for COVID-19 simply because a) there are no well-established lab/animal models for it and b) our understanding of the disease itself is very rudimentary. The cell/animal models used to reproduce COVID-19 in the lab are still being developed and validated.

An excellent solution to find better models for human diseases is to use organs recreated by a new technology called



3D bioprinting. This technique uses a computer aided, robotic process to layer human cells in the same manner as seen in human organs, thus creating a more human like model e.g. of liver, kidney skin etc. For COVID-19, drug discovery approaches could consider data derived from such alternate 3D human cell based organ models for successful design of therapies that may have high probability of success in humans. This may be especially relevant for this disease since no fully validated animal models are available yet.

Potential avenues for acceleration of timelines

ACTIVITY	ACCELERATION STEP
Discovery activity	Use lab models such as 3D bioprinted human organs that better reflect human disease and bypass animal studies
Preclinical toxicology	Regulatory agencies may allow accelerated safety studies for diseases that are rare, are to be used for terminal patients and for diseases for which animal toxicology studies may not reflect safety concerns of a particular disease.
Clincal Trials	Perform one single well controlled clinical study in patients that combines efficacy and safety Repurpose known drugs approved for another disease and use these for the disease of interest

B) Preclinical Toxicology

Any novel, new drug must undergo clinical trials before it is marketed for human use. However, regulatory agencies require detailed acute and sub-chronic safety assessment studies termed "preclinical toxicology" before going into first-in-human (phase 1) clinical trials. Similarly, they also require extensive chronic (at least one year or more, depending on therapeutic indication) non-clinical animal safety studies for intended duration of efficacy of the drug in humans. In extreme cases agencies may also request 2-year carcinogenicity studies in rodents if they suspect a non-genotoxic mechanism of carcinogenicity.

Safety pharmacology especially cardiovascular safety studies are a must for small molecule drugs before submitting IND application.

Thus, for regulatory agencies safety is of primary concern whether the new drugs are marginally efficacious or have excellent efficacy. However, agencies may accelerate the drug discovery/ toxicology programs if:

a) The drug is a first-in-class with well differentiated mechanism action and there are no treatment options available other than surgical intervention.

b) The drug is to be used for terminally ill patients where all other treatment options do not prolong survival of patients

c) Diseases for which no animal models available to reproduce human disease and safety. In this case a rational justification can be made to the agencies on lack of animal model availabilities and providing critical data using alternatives especially non-animal human models

For COVID-19, the regulatory authorities could consider shortened preclinical toxicology program because of items shown above - b) i.e. there are no other treatment options for this pandemic currently that can cure the disease and c) it's a disease for which there are no validated animals to study the disease or toxicology as mentioned above.

C) Clinical Trials – Potential Innovative models

The failure rates of new drugs in clinical trials is very high. It is well known that the productivity of drug discovery is very poor with more than 90% drugs those enter clinical trials do not ever reach market. 90% of phase 3 clinical trials fail due to lack of efficacy. About 3-5% of marketed drugs are withdrawn or have black box warnings due to unanticipated serious adverse events. The last three decades have shown that human drug metabolism is quite different from animal metabolism. Current alternate cell/animal models used in preclinical drug studies do not consider physiological variables, communications between different organs etc and are limited in their predictivity for what may happen in humans. Thus there is a requirement of more sophisticated models to predict both human safety and efficacy to improve success rate of clinical trials. In addition human drug metabolism enzymes are highly polymorphic with high inter-ethnic and/or intra-ethnic variabilities resulting either in loss of efficacy or increased toxicities in specific human populations. Agencies are requiring such human data for all submissions to ensure scaling of safety and efficacy data derived in animals to informed and calculated design of clinical trials.

Given the challenges of large amounts of data being needed for a drug to enter clinical trials, the options to reduce clinical trial timelines for COVID-19 are limited. One option is to devise new clinical

trial formats. For example currently the drug needs to go thru three separate clinical trials, Phase I in healthy human volunteers to establish safety, Phase II in small patient population and Phase III in larger patient population to demonstrate safety and efficacy. It is possible that the drug could directly be tested in only ONE pivotal human trial to demonstrate both safety and efficacy, thus saving potentially years in time and millions of dollars in cost. Under this format, most of the safety and efficacy monitoring can be done as post marketing surveillance.

The other strategy that is currently in practice for other diseases is to repurpose drugs that are approved for another diseases but may be efficacious in the disease of interest due to similarity in disease mechanisms. Because the repurposed drugs are already approved, their safety in humans is established and much less of a concern. The primary thing that remains to be shown is efficacy of the repurposed drug in patients suffering from the disease of interest. This approach is called drug repurposing. This clearly is the fastest approach to get a therapeutic drug for a new disease provided it actually intervenes in the disease process and is not just providing symptomatic relief (e.g. paracetamol to bring down high fever in COVID-19).

5. Summary of solutions for accelerating timelines for COVID-19 new drug discovery

Shown in the Table below are some innovative ideas discussed above to circumvent the typical long timelines for finding a new drug. As can be seen there are some solutions that can be used. Specifically, to discover and develop a drug rapidly, all of the solutions listed to accelerate time to bring a new therapy to the patient can be utilized. 3D bioprinted human lung and other organs can be used to ascertain drug efficacy and safety of a drug thereby potentially cutting down time spent is discovery and preclinical toxicology studies. Similarly, for clinical trials, the drug can then be directly tested in one pivotal trial to demonstrate safety and efficacy and then approved for use in humans followed by stringent post marketing surveillance. Finally drug repurposing which is already being used for COVID-19 (e.g. remdesivir, a drug originally for Ebola virus is now being used for COVID-19) is an excellent way to bring a drug to patients very quickly.

To fight this pandemic quickly and successfully, scientists, clinicians and regulators will have to think outside the box and be more innovative than ever because the stakes in COVID-19 pandemic are very high both in terms of mortality as well as breakdown in world's economy. Paradigms used in the past of bringing a drug to the patients may not serve any purpose in the fight against this pandemic since time is of essence. COVID-19 also provides the pharma industry an opportunity to create newer paradigms and improve their declining productivity as an added inducement. ■

COVID 19 unveils strengths and pain points of Indian Pharmaceutical Industry

D. Naveen Kumar
Senior Manager - Corporate Ratings,
CARE Ratings Ltd.

The Indian Pharmaceutical Industry (IPI) is ranked third globally in terms of volume and thirteenth in terms of value. Majority of the biggest pharmaceutical companies in the world rely on global supply chains of which India plays a key role in supplying of both Active Pharmaceutical Ingredients (APIs) and finished drugs. D. Naveen Kumar, explains how pandemic has had a positive and negative impact on the growth chart of domestic pharma market.

The Indian Pharmaceutical Industry (IPI) is ranked third globally in terms of volume and thirteenth in terms of value. The lower market share in terms of value can be attributed to the predominance of IPI in generic medicines which command lower prices. As per CARE estimates, the industry size is expected to grow at a compound annual growth rate (CAGR) of about 10% from around USD 40 billion in 2020 to about USD 65 billion by 2025 given the huge export potential coupled with steady growth in the domestic formulation market. Growth in the domestic pharma market is expected to be driven by increase in the penetration of health insurance, improving access to healthcare facilities, rising prevalence of chronic diseases and rising per capita income. The export growth is expected to be led by increasing generic penetration in the regulated markets on the back of enhanced focus on the niche and complex product segments, patent expiries, medicine patent pool announcing licensing agreement with pharmaceutical companies and growing demand from semi-regulated pharma markets. In the long term, growth in the export market will be sustained by emerging markets such as Russia, Brazil, and South Africa, etc.

The strengths unveiled by Covid 19:

Majority of the biggest pharmaceutical companies in the world rely on global supply chains of which India plays a key role in supplying of both Active Pharmaceutical Ingredients (APIs) and finished drugs. As mentioned earlier IPI is ranked third in terms of volume and it supplies 20% of generic drugs globally which indicates the capability of the industry to supply the drugs in large scale. Even in the current pandemic situation hit by Covid-19 while inventing the vaccine for the virus in a short span is definitely critical but more crucial factor lies in the capability to produce the vaccine and to make it reach to entire populace across the affected parts of the globe. And this is where IPI could play a vital role to fill the gap immensely. Even at the preliminary stage when the health experts have indicated the benefits of some of the drugs such as Paracetamol and Hydroxychloroquine (HCQ) to treat Covid 19, India has supplied them to over 120 countries in the last two months i.e. during March and April 2020 as these two medicines are in huge demand. India accounted for 70% of global production of HCQ. In April 2020, USFDA (US Food & Drug Administration) gave emergency approval for one of the most watched drugs i.e. Remdesivir for treatment of Covid 19. Post to that Gilead Sciences the patent holder of Remdesivir has

signed licensing deal with three Indian Pharma companies (Jubiliant, Hetero Labs and Cipla Ltd) to make the drug available for 127 countries across the globe. This is because India has such manufacturing capacity and capabilities to scale up the production of the drug to an extent that it would suffice the global demand to certain extent.

Even currently India is the major producer of vaccine for example Serum Institute is the world's largest vaccine producer by volume, it makes 1.5 billion doses a year, 80% of which are exported and is UNICEF's largest vaccine supplier. India also produces 65% of the World Health Organization's requirement of DPT (diphtheria, pertussis and tetanus) and tuberculosis, as well as 90% of its measles vaccines. Further it is stated that Serum Institute of India is investing $100 million on a potential COVID-19 vaccine being developed at Oxford University.

Thus whether it is HCQ or Remdesivir or any other upcoming vaccine the world depends on production and supply of these drugs from India which would play critical role if the current pandemic situation is to be brought under control.

Pain points unveiled by Covid-19

Inadequate support extended by Indian government Vs support by Chinese government to their respective pharma cos:

Following table illustrates the contrast between the benefits offered by Chinese government versus Indian government to their respective pharma industry.

On account of all the above favourable policies the Chinese pharma players during last two decade have become the largest global suppliers of bulk drugs. And during the same time unable to withstand the pricing pressure many of the Indian Pharma players operating in formulation segment have started procuring the required raw material from China which eventually has discouraged the domestic bulk drugs thus leading to close down of several units. Currently out of the total imports of bulk drugs by IPI about 68% is procured from China indicating high level of geographical concentration risk. Further most of these intermediates and APIs pertain to critical and essential drugs.

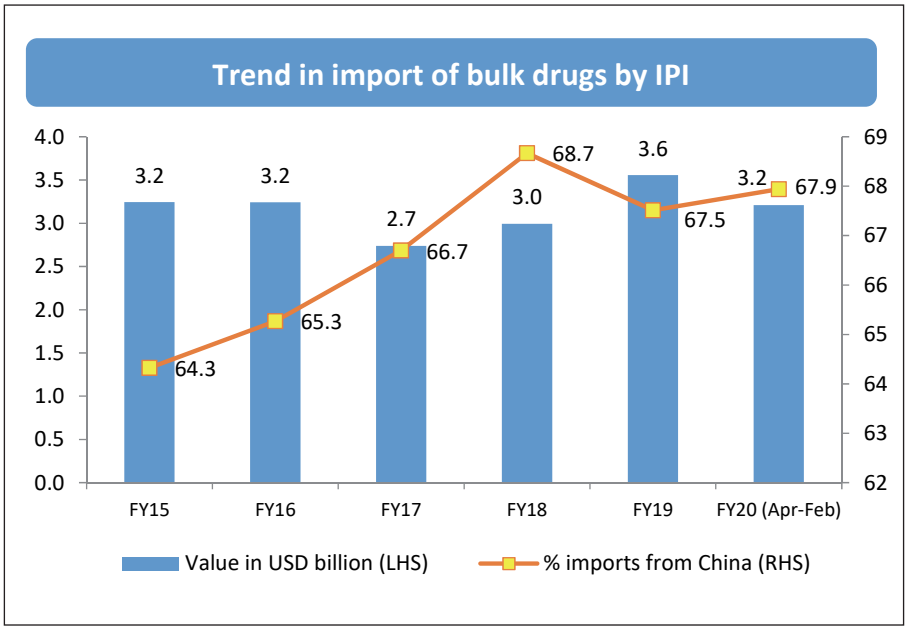
The spread of Covid 19 in China and eventual lockdown issued by the Chinese government had taken place at the time during which the country is in holiday period. And by virtue of experience the Indian pharma players have procured and kept buffer stock to meet their requirement for entire Q4FY20. Therefore even though the recovery of operations at Chinese units were ramped up gradually combined with various logistics issues leading to increase in operational cost, the Indian pharma players were not significantly affected in terms of maintaining the optimum operation levels. However if the same situation had occurred in any other quarter of the year then it would have considerably affected the operations and dented the profitability margins of Indian Pharma cos.

The Indian government thus understanding the pain point of the industry and the precarious state the above situations could lead to has approved following schemes:

CHINA	INDIA
✓ The Chinese government has been providing various incentives and sops to the industry such as subsidized debt, tax and duty breaks on capital equipment.	× The support from Indian government towards the industry in terms of providing incentives has remained inadequate especially towards bulk drug manufacturing companies.
✓ The corporate tax rate in China is about 25%.	× The corporate tax rate in India is about 30%.
✓ The financial institutions lending interest rates in China is about 4-5%.	× The banks and financial institutions lending interest rates in India is about 10-12%.
✓ As per World Banks Ease of Doing business rankings report in 2019 amongst 190 countries China is ranked 46th.	× As per World Banks Ease of Doing business rankings report in 2019 amongst 190 countries India is ranked 77th.
✓ Chinese government for considerable period of time has offered industrial land to the industrial enterprises without any consideration in return or imposed time limit for its usage. This significantly reduces project cost for both greenfield and brownfield projects and improves returns on investment.	× First of all to set up an industrial unit in India the land has to be acquired from Government for a consideration and it does not have uniform policy to acquire land, adding to above woe is the complex process and time consuming nature has overall led to increase in the project cost thus lowering the returns on investment

Factors effecting operational efficiency:

CHINA	INDIA
✓ In China the government has developed and nurtured the SEZ with fiscal and tax incentives. Further the SEZ area in China are large and sprawling thousands of hectare each. And many of these parks derive operational synergy with common effluent treatment plants, R&D infrastructure, data storage platforms etc,. The above factors helps in deriving the benefits for larger economies of scale thus improving the operational efficiency immensely.	× The Indian government although has approved about 420 SEZ parks and out of which 14 SEZ parks are dedicated to pharmaceutical industry, the area of these parks remain very limited with average size of about 300 hectare which is about 1% of the average size of Chinese SEZs.
✓ China has abundant natural resources for manufacturing of basic chemicals, Key starting materials and intermediates which contributed about 50% of their chemical sector.	× The India's focus on the manufacturing of basic chemicals had been weak which account of about 30% of the chemical sector thus leading to dependency on China for procuring the same.
✓ China contributes about 80% i.e about 2000 APIs manufactured across the globe, on accord of which it is recognized as the world largest API producer.	× On contrary Indian API producer manufacture only about 400 APIs.



a) The scheme on Promotion of Bulk Drug Parks for financing Common Infrastructure Facilities in 3 Bulk Drug Parks with financial implication of Rs. 3,000 crore for next five years.

b) Production Linked Incentive Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates and APIs in the country with financial implications of Rs. 6,940 crore for next eight years.

In light of the above the pain point with respect to procuring of raw material from China can be addressed if government continues to support the industry by way of rolling out various schemes benefitting the KSM, drug intermediate and API manufacturers. Secondly the domestic formulators should either go for backward integration for developing the necessary intermediates or APIs or procure part of them from other domestic players especially considering the vicissitude of fortune the industry is going through, this would eventually reduce the geographical concentration risk. ■

The Ticket to Quality and Safety: Optimising your metal detection system

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

The latest food and pharmaceutical industry trends show that consumers, whilst attracted by low prices in uncertain financial times, are nonetheless increasingly drawn to product safety and quality re-assurance. Siddharth Kachroo, Business Manager – Product Inspection & Global Key Accounts, Mettler-Toledo India Pvt Ltd, explains why it is important to ensure the highest safety standards possible for products intended for human consumption.

When dealing with products intended for human consumption, like foods and pharmaceuticals, every care must be taken to ensure that they meet the highest safety standards possible. It is simply not an area where brands can afford to take any risks, or gamble with their reputations.

Due to their impact on consumer health, harm to brand reputation and the financial implications of legal proceedings, even minor quality shortcomings in the production process can be hugely damaging, perhaps irreversibly so for consumer brands. Product recalls are a particularly embarrassing and costly outcome for a producer to endure. The detection of hazardous foreign objects, such as ferrous metals, non-ferrous metals and stainless steels, is hence an area of massive importance.

The latest food and pharmaceutical industry trends show that consumers, whilst attracted by low prices in uncertain financial times, are nonetheless increasingly drawn to product safety and quality re-assurance . It is vital that brands find a cost-effective way to meet these contemporary demands and advanced metal detection systems provide a solution.

A necessary process

"Every company needs to perform a hazard analysis for every product it produces to assess the risk of metal contamination in their products. If the hazard analysis shows there is a risk of metal contamination, then, a metal detector will be required." British Retail Consortium (BRC) - Global Standard Guidelines

An optimised metal detection programme is not a matter of choice for food and pharmaceutical producers – it is a matter of legal necessity.

To identify and remove contaminated products from the production line, metal detection solutions use either "balanced-coil" or "ferrous-in-foil" search heads. Balanced coil heads can detect all types of metal contaminants, including ferrous, non-ferrous and stainless steels, in fresh and frozen foods, while multi-simultaneous frequency heads are used to detect ferrous metals and magnetic stainless steels within fresh or frozen products packed in aluminium foil wrapping. Balanced coil systems are by far the most common metal detectors in use. Systems of this type recognise any trace of metal through a three-coil arrangement that generates a high-frequency field, the voltage of which is disturbed by the presence of any metals in any material passing through it. Products can be inspected in the bulk processing phase or in their finished form, although a combination of the two is most effective.

Producers faced with choosing a metal detection system must sort through numerous parameters that influence which system is ideal to handle the varied potential sources of contamination, so partnering with an experienced supplier is important to guarantee food safety. They must choose a supplier that can tailor solutions to their specific product and application needs, and provide the highest quality equipment and assistance without the burden of unnecessary cost.

Fitting the bill

The key to an effective metal detection programme is rooted in optimisation around certain key areas: product type, packaging used and the particular working environment. The array of available system options means that virtually any type of food, in any unusual shape or size, or any type of specialist package, can be inspected with equal rigour. A top-level metal detection supplier will take all of these into account, working with the producer at all stages so that their requirements are fulfilled.

The product being inspected will govern the search head design and aperture which is the opening through which the product passes. Detectors with a "balanced coil" search head can inspect unwrapped or wrapped fresh or frozen products, even products wrapped in metallised film. Detectors utilising the latest multi- simultaneous frequency technology to push metal detector performance to another level. This technology incorporates a product signal suppression technique to effectively cancel out the product signal from difficult to

inspect products. Cancelling these product signals or the effect of the package makes it easier to detect metal contaminants up to 50% smaller than previously possible.

For meeting local and global compliance needs, the processed food manufacturers are implementing data collection software which maximizes rigorous quality regimes and optimizes their production. It significantly reduces complexity and sources of error caused by multiple operating systems and proprietary machine software .

The choice of the most appropriate automatic rejection system to remove contaminated items also depends on the product and application and several options are available. A pneumatic air blast is ideal for light, single-file, discrete products running on a narrow belt, while a punch/pusher design suits light- to medium-weight discrete packs that are spaced and oriented on a narrow belt. A sweep or diverted arm is suitable for light- to medium-weight, discrete, random non-oriented products running on a narrow belt, typically up to 350mm wide. An end flap/dump suits random, small discrete items or loose bulk items (dry or sticky) running on a wide flat or dished inclined conveyor belt, while a retracting belt is reliable for most applications when more than one product passes in-line across the width of the conveyor. Lastly, for bulk loose, dry or sticky products, or multiple random items, a reverse belt is ideal.

During the manufacturing process, products come under threat of contamination from numerous sources, from the processing of raw materials through to in-house filling and packaging. For instance, mince meat products are at risk of metal contamination from metal tags in the raw material stage, from personal effects such as jewellery and buttons in handling, and metal fragments from in-house milling machines. An appropriate metal detection solution must be devised to take account of these factors – finding the right balance between in-process and finished product inspection.

The manufacturing environment is no less important in dictating the specific detection solution required. In some plants, the slightest temperature variation or vibrations from motors and pulleys can induce false rejection of a perfectly safe product when inferior metal detectors are used. Microscopic movements of the coils relative to each other as small as one micron can cause a signal sufficient to result in a false rejection. One way to negate this problem is by “potting” the detector case - filling it with an appropriate material, the weight of which prevents relative movement of the coils. Similarly, temperature changes, build-up of product in the aperture, ageing of electric components and slow changes in the mechanical structure will also contribute to an out-of-balance voltage. This can be eliminated by electronic techniques such as Automatic Balance Control or quartz crystal control, which enable the detector to permanently maintain this sensitivity without operator attention and without the generation of false rejects.

One feature that all metal detection systems must observe is a metal free zone (MFZ) in the area immediately adjacent to the detector head. The MFZ is necessary to negate the magnetic field leaking from the detector’s metal case through the aperture. It is therefore necessary to have an area containing no metals around the opening. Technological expertise and experience are required to find the absolute optimum size for the MFZ. Also, producers with limited space are now able to install a compact unit utilising “zero metal free zone” technology, where the MFZ is much smaller.

To ensure that a reject device is operating properly, that contaminated packs are accurately rejected and the metal detection system is operating effectively, additional devices can be included. These customized features may include a container or rejected product bin to collect contaminated product, failsafe systems and alarms to indicate the occurrence of faults in the detector or rejection device or reject confirmation systems to confirm that the correct product has been rejected from the production line. Producers also have the option of adding further features such as high level warning beacons or audible alarms that can signal when a problem occurs. These additional features allow food producers wide scope in customizing their setup – taking account of product type and, crucially, available budget.

Clearly, manufacturers must consider every last detail in order to optimise the performance of their metal detection programme. They must be able to rely on experienced, reliable and flexible machinery suppliers to ensure all specific criteria are met – whether dealing with fresh or frozen, wrapped or unwrapped products.

Keeping standards high

Technological innovation and efficiency optimisation are all well and good; but without proof of due diligence and regulatory compliance, they count for very little. Plant inspections require that safety standards are met at all stages, and the penalties of any deviation can be severe. Metal detection equipment must have features such as condition monitoring, record keeping and traceability to support compliance.

When a contaminant is found, current metal detection systems allow highly accurate record keeping and traceability. Metal detection systems allow preventive action to be implemented rather than having a dependence on reactive maintenance and frequent verification testing. The detection process is therefore constantly refined. Similarly, the latest metal detectors are designed with general hygiene in mind, constructed using materials that be easily cleaned and re-assembled without excessive downtime. Sealing standards to prevent water ingress to electronic components and enclosures is also very important, particularly in harsh aggressive environments.

The full package

Perhaps surprisingly, stringent safety standards do not have to come at the expense of line efficiency. The eradication of potential threats posed by stray metal through the introduction of a sophisticated metal detection programme actually pays huge dividends to those companies who seek to put the long-term success of their business ahead of ill-advised corner cutting.

Wise investment provides peace-of-mind, strengthens consumer trust and protects brands from complications arising from failed plant inspections. There is no better method for complying with food safety trends and regulations than through the installation of a reliable, consistent metal detection programme.

How drug delivery can impact treatment

Alagu Subramaniam
Managing Director,
West India

The human body is complex, and while we are still learning about the impact various drugs can have on it, the search for more effective treatments for common ailments to more complex diseases is ongoing. Researchers are studying how medicines interact with and move through the human body, how much time the medicine can take to reach the affected cells and the impact those drugs may have on the surrounding healthy cells. Mr Alagu Subramaniam, Managing Director, West India, in the article expounds on how drug delivery can impact treatment.

Not every medicine will react the same way for everyone, and certain drug combinations may react with healthy tissues leading to serious side effects. In fact, this is a concern that is limiting the ability of pharma researchers as they work to develop suitable treatments for a variety of diseases. Additionally, the quantity, the time/frequency of dosage, the rate at which the drug is administered into the body, the location where it is administered and the distance it needs to travel to reach the affected area – are additional concerns faced when designing a drug. The more targeted a drug is, the lower its chance of triggering any adverse reaction or resistance, which is a serious concern surrounding the use of broad-spectrum antibiotics.

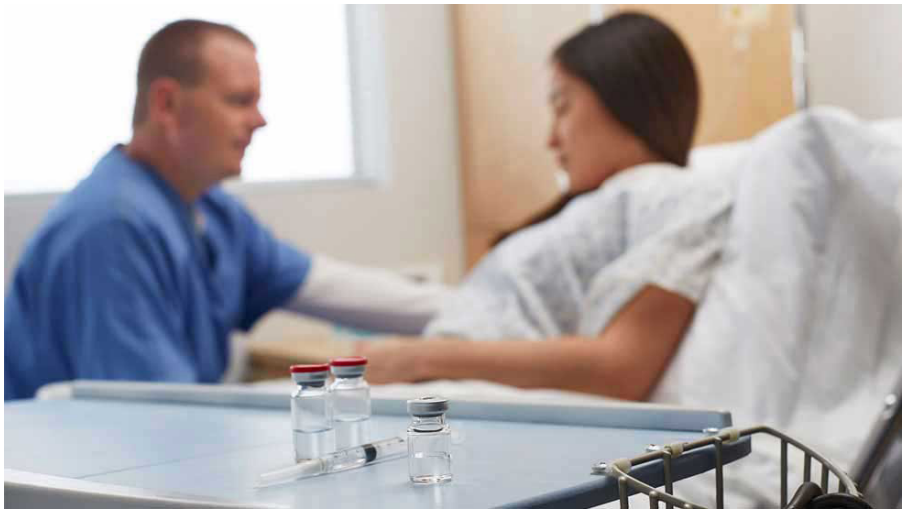
Additionally, when bringing a new injectable drug product to market, the packaging is quite important, especially considering the potential problems that can result with stability, manufacturing, or use. In today's regulatory climate, it is essential to have a heightened awareness of all the risks that can occur, from development through lifecycle.

Keeping the above in mind, it is no surprise that over the last couple of decades, science has been focused on developing better and more effective drug delivery mechanisms.

Evolution in the landscape

As the healthcare landscape evolves and technology continues to play a greater role in both drug discovery and drug delivery, patient care is increasingly becoming an area of collaboration between healthcare professionals and the patients themselves. Other key trends in the landscape include digitization of healthcare, innovation in healthcare devices, greater reliance on data analytics, remote care becoming a reality and precision treatments.

As digital technologies find more pervasive application in the healthcare space, researchers and medical professionals find themselves in possession of valuable data not just about the patient but also about the treatments, recovery patterns and other key metrics. Artificial Intelligence and Machine Learning are making it possible to derive valuable insight from these datapoints. Innovation in design of healthcare devices is making heavy machinery portable,



making it possible to take treatment to the patient's doorstep. Remote care and online consulting are now possible too, as with patients being treated at-home this would take some of the burden off the shoulders of the overworked healthcare professionals in a country like India, where the last mile is still a challenge for healthcare services.

Patient-centric care

Innovations in interactive applications and technology have made it possible to provide information about health concerns and care literally at the patient's fingertips. This has led to greater participation of the patients in their own treatments.

As patients become more knowledgeable and play a greater role in their own care decisions, there is need for the drug delivery mechanisms to be simple and self-administrable. The delivery mechanism should also be designed in a way that it does not cause unnecessary discomfort to the patient and does not require extensive medical or technical knowledge to use so that the patient finds it easy to adhere to the prescribed therapeutic routine.

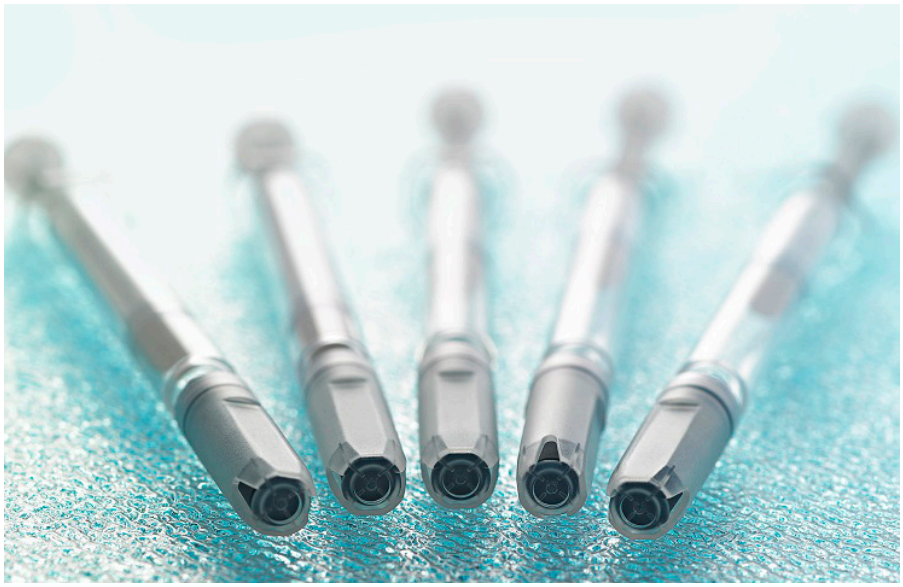
Improving the efficacy of delivery mechanism

Developing a new drug is an expensive and time-consuming exercise. The current thinking is that by improving the efficacy of the existing drugs, better results can be achieved from the same treatment at a much lower investment and time cost. As a result, pharma industry is giving equal importance to different means of drug delivery, that can then have a marked impact on the treatment cycle such as dose titration as well as therapeutic drug monitoring. Delivering the dose at a controlled rate and targeted delivery are goals that are being pursued by the pharma packaging manufacturers.

In fact, there are many drugs that are capable of effectively treating various health concerns. However, it may be possible that these drugs are limited by delivery issues or bring with them side effects that need to be mitigated. This is exactly what has been driving the researchers to find better and more effective delivery mechanisms. For example, at present the drug delivery routes that are garnering increasing amount of interest include nasal and pulmonary routes. They are being explored to see if they can provide promising alternatives to drug delivery compared to routes such as parenteral, that require the use of a needle, syringe, or an intravenous infusion set. Parenteral route is usually taken when the medication is poorly absorbed internally by the body or when enzymes deactivate it as it passes through the digestive tract.

Additionally, for treatments that require regular injections, manufacturers are evaluating alternative injection platforms that reduce the need for use of IV in large volume doses. Case in point being the SmartDose® Platform. Drug therapies are only effective when patients follow a prescribed treatment. For those suffering from chronic conditions, daily or even weekly injections can cause pain and fatigue, resulting in patient non-adherence. New options in biologic therapies have enabled single-dose options, but those options require higher dose volumes administered over a long period of time. Such was the case with a cholesterol-lowering drug offered by one of West's customers. While a once-a-month dose could work, effective delivery of the large-volume dose posed a challenge.

The SmartDose® platform of wearable injectors allows patients to self-administer large volumes of medication in accordance with their prescribed treatment over a longer period of time. Extensive human factors testing and analysis was undertaken to understand the interaction between the patient and the delivery system while designing this platform. The SmartDose injector adheres to the patient's body, usually on the abdomen, so the patient can



be hands off during administration. The injector comprises of a silicone-free Daikyo Crystal Zenith® cartridge and a FluroTec ® coated piston containment system.

Delivery challenges faced when it comes to new drugs

The legacy challenge

In the case of new drugs coming to the market, in particular biologic drug products, many manufacturers use legacy components for packaging, i.e., components they have used over time and with other drug products. This is based on the assumption that packaging components are inert, or that issues can be overcome by reformulation. These legacy components appear to offer the benefits of known performance and supply chain and resultant smooth production with minimal downtime. But legacy components may not meet the quality and regulatory standards of today, which require understanding of potential risks for each individual pairing of drug product and Container Closure System (CCS). In particular, an understanding of the factors that impact protection, compatibility, safety, and performance, is required.

Pace of innovation adoption

Although the industry is very interested in innovations, its ability to adopt them is quite slow.

One might argue that the barriers to innovation adoption lie in the drug R&D process itself, particularly in the way that scientists and engineers relate to supporting functions such as information technology, intellectual property, legal, procurement/ supply chain, operations, regulatory and quality assurance. This challenge, coupled with the frequent lack of clarity as to decision making ownership, and the normal risk aversion due to potential regulatory challenges, is central.

Components may be part of a combination product

Historically, the industry has been focused on the drug product and package – not the delivery device. Therefore, there was limited understanding of the technical, developmental, and regulatory requirements to meet current combination product best practices, which means combining both the drug and device CGMP regulations. Failure to do so can put many products at risk from the standpoint of regulatory approval.

Failure to Understand Special Challenges of New Molecular Entities

There is a growing complexity to the molecular entities in the industry's pipeline. Many manufacturers, who had focused on small molecule drug products, are expanding into large molecule biologics, such as monoclonal antibodies (mAbs). mAbs comprise the majority of biologics both in development and already commercialized. This pipeline is becoming more diverse, with the emergence of therapies based upon technologies such as gene, siRNA, oligonucleotides or stem cells. There may be unique needs for these new drug products, and packaging/delivery requirements (sensitivities, storage/ delivery) may be quite different from those of small molecules or mAbs. Thus, it is essential that the starting point for all packaging be the needs of the molecular entity – to ensure suitability and ultimately safe delivery to the patient.

Manufacturers today are paying greater attention to delivery mechanisms – be it for existing or new drugs – for the role they can play in drug impact on treatment. ■

Creating Innovations in Packaging

Amitava Ray
Executive Director, UFlex Ltd

UFlex is India's largest multinational flexible packaging materials and Solution Company and a leading global player in Polymer Sciences. Since its inception back in 1985, UFlex has grown from strength to strength to evolve as a truly Indian Multinational with consumers spread across the world. UFlex Ltd. has recently developed a Personal Protective Equipment (PPE) Coverall 'Flex Protect' in joint collaboration with IIT-Delhi and INMAS, DRDO, Delhi. Flex Protect that comes with Four-layered Protection and Anti-microbial Coating has been approved by The Defense Research and Development Organisation (DRDO) for use by the front-line health workers who are fighting the battle against COVID-19.

Mr. Amitava Ray, Executive Director, UFlex Ltd in an exclusive interview with PharmaBio World gives our readers an insight into the successful development of this revolutionary kit as well as into the various achievements of UFlex Ltd.

Q: Congratulations. UFlex and IIT-Delhi have jointly developed a Personal Protective Equipment (PPE) Coverall 'Flex Protect' in joint collaboration with IIT-Delhi and INMAS, DRDO, Delhi. Please share with our readers about the idea and the achievement.

Ans- Thank you very much! Indeed, it was an innovative effort from our R&D team along with the team from IIT-Delhi. I also extend my special thanks to ace designer Manish Tripathi for his innovative thought behind designing multi-layered security in 'Flex Protect Coverall'.

The idea that triggered the development of 'Flex Protect' Coverall was the lack of breathability in PPE kits that are being used so far by our frontline workers, to treat the coronavirus patients. The kits used are quite thick and cause discomfort during long wears. It was also observed that the PPE kits which are currently used have certain gaps that provides limited barrier against the virus from entering through the stitches and openings.

'Flex Protect' Coverall is an answer to these shortcomings and enhances the safety of health workers. It allows 30% better breathability and confirms to ISO 16603 standards. I am also glad to share that with Flex Protect' Coverall we have enhanced the safety of the health workers up to 100% as the fabric is coated with anti-microbial properties and certified by South Indian Textiles Research Association (SITRA)

Q: Can you provide our readers an overview of the company?

Ans- UFlex is India's largest multinational flexible packaging materials and solutions Company and a leading global player in Polymer Sciences. Since the inception back in 1985, we have evolved as a truly Indian Multinational with consumers spread across the world. Integrated within our core business profile of Packaging and Packaging Films are our allied businesses like Aseptic Liquid Packaging, Engineering, Cylinders, Holography and Chemicals that create a value chain across packaging cycle to help brands fulfill consumer needs. As on date UFlex has state-of-the-art packaging facilities at multiple locations in India with installed capacity of around 1,35,000 TPA and has packaging film manufacturing facilities in India, UAE, Mexico Egypt, Poland and USA. We are expanding our global footprint further with new plants for Packaging Films in Russia, Nigeria and Hungary.

Today, we cater to markets spanning across the globe in over 140 countries. We offer technologically superior packaging solutions across multiple industries such as FMCG, Pharmaceuticals, Agriculture, Automotive, Engineering, Construction, Beauty and Skincare, Brand Protection, Packaging films, Printing inks etc.

UFlex is a winner of various prestigious national and international awards for its products' excellence including Dow Packaging Innovation Award in 2018 and PrintWeek India 'Packaging Company of the Year 2019'. We were also the 'first company in the world to recycle mix plastic waste' for which we earned recognition at Davos Recycle Forum in 1995.

Q: UFlex is one of the world's leading organizations providing brand protection and anti-counterfeiting solutions to its customers globally. What are the cutting edge technologies provided by UFlex to develop and produce its anti-counterfeiting solutions for brand protection?

Ans – The world of packaging is entrusted with the responsibility to safeguard business interest of the brand owners from malpractices such as duplicity and counterfeiting. It is alarming to know that the drugs counterfeit market is almost double the size of legitimate pharmaceutical market, which is why at UFlex we have developed cutting-edge and non-duplicable overt and covert technologies in purview of 'Brand Protection', such as Fast Tear Strip Foil, PET based Cold Form Blister, Child Resistant & Senior Friendly Foil and Branding Solutions.

The packaging solutions for pharmaceutical are complemented with holographic anti-counterfeit offerings such as Registered Holographic lens for cartons, Self-adhesive holographic product labels, Metalized Holographic PVC, Tr**ans**parent Holographic PVC, Holographic Aluminium lidding foil, Holographic Stamping Strips for PVC, Alu foil, Shrink Sleeves & Alu-Alu foils, etc. The solutions can be customized for all packaging needs for Pharmaceutical segment.

Q: How vastly and methodically has UFlex invested in its Research and Development team, considering its multifarious range of offered products?

Ans– Packaging is an ever-changing and dynamic concept that is triggered by shifting needs and buying behavior of the consumer, brand focus and innovation. Serving our clients with customized, high-quality and unique packaging

solutions is of utmost importance to UFlex. Recognizing the increasing demand from customers for our various offerings, we are steering the path of innovation by developing cutting edge technology and products that meets the needs of our patrons. This requires continuous focus on innovation and investment in R&D. We have a robust team of scientists and engineers working on developments of products for all the verticals that we house. They help us develop at least 10-12 new products every year.

To highlight a few milestones, we have developed Alu-Alu blister packs, which is a replacement to the conventional Cold Form Laminate. Alu-Alu packaging is a special polyester film that has replaced the conventional Nylon and PVC while retaining Aluminum in it. For this unique development, UFlex has also been granted a US patent.

Then a Green film 'Asclepius' has been developed by UFlex which blends up to 100% of post-recycled content thereby helping brand owners have a packaging that is green sourced without any compromise on its attributes and create a loop economy.

We have also developed FlexFreshTM, a modified atmospheric packaging that provides extended shelf life to perishable produce.

Our Engineering Business has developed RELAM 250 machine, a one of its kinds recycling machine induced with a technology that makes all types of multi-layered flexible plastics (MLP) bags, carry bags etc. be recycled homogeneously into granules, without separating layers of plastic and aluminum.

Our chemicals business has also launched multiple path-breaking products that revamped the scope of chemicals and inks in printing over packaging. We launched Water-based Ink for paper printing for flexible packaging, paper & board segments. Some others like FlexSeal HSL-WBHS 18, a heat seal lacquer that is water-based and balances low seal initiation temperature with high seal strength was developed. Keeping in view our sustainable nature, we launched Flex Seal Blister Coating (Water based PUD), Aqueous narrow web ink and Aqueous water resistant OPV to name a few.

Our R&D team at Holography has developed various brand identity and protection solutions that have proven to be extremely beneficial to pharma companies in arresting counterfeiting.

UFlex R&D is developing a technology that will make plastic films bio-degradable as well recyclable. Thus, the plastic waste that remains uncollected and seeps into landfills shall become biomass at the end of its assigned life.

Q: UFlex Group has been a trendsetter when it comes to sustainable innovation and commitment towards the 'Circular Economy'. Could you tell us more about the 'Project Plastic Fix' – the initiative designed to make the UFlex a part of a solution to keep plastic in the economy and out of the environment.

Ans– Project Plastic Fix is UFlex Group's global sustainability initiative which is intended towards keeping the plastic in the economy and out of the environment. The Project Plastic Fix will convert plastic waste into products that have an economic value. In essence, 'waste becomes wealth'. UFlex will have a mix of various methodologies as part of Project Plastic Fix.

1. Recycling plastic waste into granules which can be further used to make household and industrial essentials products such as dustbins, paver tiles, outdoor furniture, road dividers etc.

2. Converting plastic bottle waste and MLP into Green plastic packaging. Asclepius is our special range of BOPET film having as much as 100% PCR content and has the same properties and application as any standard fossil-fuel based substrate twin. This method creates an endless loop of polymer that is reused to make a new product each time.

3. Reprocessing plastic waste into fuel through Pyrolysis, which emits zero carbon emission So what could have been incinerated is reused to produce energy employing an anaerobic system that ensures zero carbon emission.

4. UFlex is working to introduce a Biodegradable and Recyclable renewable solution product that will convert uncollected plastic waste/ laminate waste into biomass, upon degradation.

The first leg of it has already been launched in India with the commencement of our PCR and PCPR lines in Noida that washes and recycles post-consumer PET Bottles and Multi-layer Packaging waste collected from Delhi-NCR thereby helping reduce plastic waste and turn them into valuable commodities. UFlex is working on similar models to be implemented across our facilities globally.

Q: What impacts and / or transformations do you see digitization and digitalization make in the Pharma Packaging industry? How do you think it is changing the today & tomorrow of the industry?

Ans– Digitisation and Digitalization are the buzzwords in the packaging industry. Compared to other sectors, pharmaceutical production and packaging underlies more demanding regulations. Changes in Pharma packaging production mean changes to the machines and processes which could ultimately impact the whole value chain. Nevertheless, it is today 'A need, not greed.'

For a while now, pharmaceutical brands and converters have been contemplating on fully digitizing and digitalizing their packaging. One might say that this COVID19 is the 'straw that broke the camel's back,' but both Digitization and Digitalization are going to drive the growth of packaging industry in the near future and so on. As the dependence on man-driven processes will get automated, packs will become self-communicative and a huge quantum of supplies will be easily met. I am sure, that the relevance of both these terms in pharmaceutical packaging will be ascertained in no time, once the vaccine of Novel Coronavirus is found.

Q: How do you think that your products, services and digitalization methods will impact maintaining sustainability in this dynamic industry?

Ans– At UFlex, sustainability is the first focus. We are an environmentally responsible organization and each of our product, process and service comply to the sustainable norms and beyond. With more digitalization methods coming into picture, we can surely look up to lesser industrial waste and achieve economies of scale while continuing the sustainable practices of converting 'waste to wealth' in parallel so that the offerings retain their utility for a longer time and in loop but it's impact on environment and the surroundings can be nullified

Q: Make in India is a major new national program of the Government of India designed to gain momentum for investment, innovation and enhance skill development and build best in class manufacturing in the country. What is the impact of this program on Pharma packaging sector?

Ans – The Make in India initiative gave a thrust to strengthen the self-dependence notion within the country. Much as many sectors got a boost, so did the packaging for pharmaceutical sector gained impetus. With the initiative by GoI the local manufacturing of medicinal drugs witnessed a rise and so did our dependence on foreign manufacturers lessened.

A study by IBEF (Indian Brand equity foundation) Indicate Indian domestic pharmaceutical market turnover Rs 1.4 lakh crore (US$ 20.03 billion) in 2019, growing 9.8 per cent year-on-year (in Rs) from Rs 129,015 crore (US$ 18.12

billion) in 2018 and is likely to reach $ 158 bn by 2025 Packaging that carries pharmaceutical from the point of manufacturing till point of consumption also had a proportionate rise as a matter of sector growth. However the growth also led to fake drugs manufacturing and counterfeiting on the other hand, which has been well curbed by the development of track and trace technology by the offerings as part of pharma packaging.

Q: Your views on the future of Pharma Packaging in India and where do you think the market is heading under the current circumstances?

Ans– Being under the umbrella of pharmaceutical sector, the growth of pharmaceutical packaging market is also exponential. A recent study by Markets & Markets underlines pharma packaging sector's growth at a CAGR of 6.27% to reach up to $ 111.9 bn by 2024. However the packaging sector faces the warmth of business challenges as there is always a constant pressure form the companies to curtail the cost of final packaging without compromise on the packaging quality and aesthetics.

It is noteworthy to state that the global trends in pharma packaging are moving towards compliance packaging which provokes use of high quality barriers and solutions to pack pharma produce which aid to make it easy for the patient to use them. The trends in pharma packaging are also tr**ans**formed as a result of business focus of Pharmaceutical drug manufacturing companies, which are speedily turning towards adopting eco-friendly packages to overcome environment related concerns arising due to packaging materials. Hence it is a backward integration of analysing the demands and constituting deliveries.

Q: The Pandemic has caught us all off guard and pushed us to the edge of a new normal. Being the market leader in your domain, how do you think it has impacted UFlex's work process as well as operation?

Ans – Coronavirus is unique and every one was unprepared as anyone else. It would be apt to state that 'believing in ourselves' was the biggest strength we had while coping up with the current pandemic. Being an essential commodity to FMCG and pharmaceutical sector, we were prompt to get necessary permissions to operate during the lockdown; however the challenges that we faced in the initial phase were related to movement of raw material, finished goods and shortage of manpower. As India is gradually unlocking, we are back to normal and are operating at almost full capacity with increased hygiene, proper sanitization and safety protocols.

Q: Though there are still lots of uncertainties, there is also a new opportunity to do better. How is UFlex looking at this unfamiliar challenge?

Ans– The outbreak of COVID-19 has left everyone bewildered, like many other organizations the initial few days were a matter of struggle for UFlex as well. However since we are an into packaging of essential commodities for lifeline sectors such as Pharmaceuticals and FMCG, we were able to avail necessary permissions to continue our operations. We relied upon the three Ps of Production, Planning and Productivity to lift our capacity utilization and as on date we are operating at almost full capacity to meet the needs of the essential sectors with the belief to 'Do More with Less' now and going further.

I am sure that in times to come there will be more innovation and findings to make packaging thinner yet sustainable, which has always been a preference by pharmaceutical companies hence I foresee use of mono-layers in packaging for pharma products.

In addition to this, anti-microbial and sustainable packaging will play a major role in strengthening the scope of packaging in the pharmaceutical space. UFlex has already been focusing on creating sustainable pharmaceutical packs, our Alu-Alu Blister Packs being one of the best examples of that. We would now want to see how we can blend anti-microbial pharma packaging into this and other pharma packaging formats that we manufacture, so as to address pharma companies' need and allay consumers' fear.■

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

The current socio-economic scenario has pushed most industries to their brink. The same is also true of the pharmaceutical industry. There has been a recent spate of enactment that market leaders and participants feel are difficult to adopt given the inadequate institutional support mechanism that is present. It is anyone's guess that the risks are going to be very high and will far outweigh all possible advantages if the judicial practice poses inconsistencies.
Beginning from this edition, in this column, Mr. R S Raveendhren will be focusing on the legal aspects of the pharma sector. Mr. Raveendhren is an Advocate practicing at the High Court of Madras with a good track record of 16 years at the Bar. He regularly writes columns in newspapers and magazines on various topics and has also recently published a book on Dr. Ambedkar's contribution to the Indian Constitution.
From this month onwards he will be expounding on the evolution of law and ethics in the pharma sector from an international perspective and its impact in general.

Mr R. S. Raveendhren
Advocate , High Court of Madras

Justice Earl Warren once said, "In civilized life, law floats in a sea of ethics." The word 'ethics' is derived from the Greek word 'ethos' meaning custom or character. Because of its close connection with a lot of other social sciences, it has often been considered a parallel to Philosophy. Therefore as a philosophy there are two things that ethics is mainly concerned with:

1. How a man should live and
2. The difference between the right and the wrong.

Since the ancient times, every civilization worth its salt has its origin in a code of conduct that was a reflection of the things that it strongly believed in. To quote a very famous example, Moses was presented with the Decalogue or the Ten Commandments

by God on Mount Sinai which contained ten ethical rules that He wanted to convey to the Israelites after being freed from the Egyptian slavery.

The Modern society has gone one step further and classified ethics into four major components

- Duty
- Utilitarianism
- Rights and
- Virtue.

Simultaneously, it also devised laws for regulating human conduct and subordinating the individual's need to that of the society at large.

In ancient times, there was no clear cut distinction between laws and ethics. The Greeks were the first people to formulate an ethical foundation of law; During the Middle Ages, Christian morality was considered as

the law of the land. It was only towards the end of the European Reformation that law and ethics came to be known and treated as distinct and separated.

With endless progress made in the course of history, there arose lots of conflicts and undesirable practices that often led law and ethics to mould each other to improve the situation at hand. This is how justice, equity, good faith and conscience penetrated into the fabric of the law.

GENESIS OF CLINICAL TRIAL IN PHARMA SECTOR:

World Health Organisation (WHO) defines clinical trial as 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.'

The history of clinical trials is a tumultuous journey marked with instances of not just human ingenuity and triumph but also full of folly and moral deviousness as you will see below.

THE EPOCHAL MOMENTS IN CLINICAL TRIAL:

(i) Cure for Scurvy

The first ever clinical trial was conducted aboard a ship on 20th May, 1746 by a Scottish naval surgeon named James Lind. Lind successfully demonstrated that citrus fruits completely cured scurvy. He is called as the Father of Clinical Trials and May 20 is celebrated as the International Clinical Trial Day in his honour.

(ii) Sulfanilamide Tragedy

It was the year 1937 and a drug called Elixir Sulfanilamide had invariably caused the death of a 100 people in the different states in the US. Sulfanilamide, drug chiefly used to treat streptococcal infection was converted into liquid form from its tablet/capsule formulation. However, the new formulation was not tested as the Food and Drugs Act (1906) did not require any safety study to be carried out on new drugs.

The unsafe drug caused poisoning in patients and as a result many people lost their lives. There was a huge uproar in the country and as a fallout, a new enactment, Food, Drugs and Cosmetic Act of 1938 which gave powers to the Federal Drug Agency (FDA) was formulated to promote public health and to monitor safety of newer drugs.

(iii) Randomized Controlled Trial (RCT)

The credit for RCT or Randomized Controlled Clinical Trial goes to an English Epidemiologist and Statistician, Sir Austin Bradford Hill who in the year 1950 collaborated with Richard Doll to successfully demonstrate the link between cigarette smoking and lung cancer.

(iv) Nazi Human Experimentation

Man's inclination towards savagery and aggrandizement laid the foundation for the world's first instrument on the ethics of medical research called the Nuremberg Code, 1947. This is the code that laid down the basic principles for clinical trials.

The Nuremburg Code, 1947

Towards the end of the Second World War, an International Military Tribunal was constituted on 19.11.1945 to try the offences committed by the war criminals and Nazi sympathizers. It came to light that many physicians from Germany had carried out dangerous, inhuman and cruel experiments on unwilling prisoners and detainees. The trial of physicians famously came to be known as 'Doctors' Trial'. The charge made against the physicians, inter alia, was the commission of crimes against humanity by planning and conducting medical experiments without the subjects' consent; and in the course of experiments they committed murders, brutalities, cruelties, tortures, atrocities amongst other inhuman acts.

The heart-numbing medical experiments carried out were:

(a) High Altitude Experiments
(b) Freezing Experiments
(c) Malaria Experiments
(d) Lost (Mustard) Gas Experiments
(e) Sulfanilamide Experiments
(f) Bone, Muscle and Nerve Re-generation

and Bone transplantation Experiments
(g) Sea Water Experiments
(h) Epidemic Jaundice Experiments
(i) Sterilization Experiments
(j) Spotted Fever (Fleckfieber) Experiments
(k) Experiments with Poison and
(l) Incendiary Bomb Experiments

The exercise of setting up the Tribunal and bringing the culprit doctors to book helped see the obnoxious nature of human experimentation that were carried out on the prisoners of war as also on civilians. The Nuremburg Code thus laid down a strict standard for research and inter alia made voluntary consent a basic requirement for clinical trials.

(v) Thalidomide Tragedy, 1960

The drug 'Thalidomide' was marketed as an aid for patients with sleeping problems such as insomnia. In course of time, the drug began to be prescribed to pregnant women. What the drug unfortunately did was that it interfered with the normal development of the foetuses causing them to be born with serious birth defects such as absence of ears, complete deafness, severe under-development or absence of arms, defects (shortening) in femur and tibia (bones of the legs) amongst many more.

This event prompted the government and the regulating agencies to sit up and review the policies for the approval of pharmaceutical drugs.

In the USA, the Kefauver-Harris Amendments were passed in 1962 casting heavy burden on the sponsor of the drug as well as on the company that planned to investigate that drug clinically. They were required to provide the FDA with a detailed outline of their study. It ensured that the sponsors and researchers would be responsible for keeping meticulous records of the findings and that they reported periodically to the FDA.

In course of time a universal concurrence was reached that drugs that were intended for human use could no longer be approved purely on the basis of testing on animals alone.

In the aftermath of the Thalidomide tragedy, the United Kingdom passed the Medicines Act, 1968 also regulating the pharmaceutical licensing policies and the sale of prescription drugs distinguishing it from the sale of general drugs.

(vii) Helsinki Declaration, 1964

The General Assembly of the World Medical Association adopted the Declaration of Helsinki containing guidance to physicians in biomedical research involving human subjects. It contains 12 fundamental principles in relation to the planning and performance of all research on human beings. It signified a major development of observing ethical practices and for the submission of the research protocol to an independent specially appointed committee for advice, consideration and for comment. In effect, the Helsinki Declaration restated the Nuremburg Code with extensions.

(viii) Belmont Report, 1979

In the USA, the National Research Act of 1974 was passed creating a National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. The report derived its name from the place where the document stood drafted in part. The commission enunciated the three broader but basic ethical principles

(a) Respect for persons,
(b) Beneficence, and
(c) Justice towards human subjects that were involved in the clinical trial.

Watch out this space for continued discussion of legal aspects of Pharma sector. ■

Staying Compliant and Profitable in the Pharmaceutical Packaging Process with Checkweighing

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

High demand in the pharmaceutical industry is a constant. Manufacturers both large and small must look to optimize their production lines in order to ensure production quotas are met in a timely, profitable and above all safe manner. Larger producers running single product batches seek outstanding reliability and accuracy in checkweighing, whilst smaller contract packagers – who are likely servicing multiple clients – need the flexibility to effect quick changeovers in order to keep throughput to a maximum.

As manufacturers need to remain certified in order to produce pharmaceutical products, compliance is also critical. Products entering the supply chain that do not meet the required standard threaten patient safety, retailer confidence and in the worst case scenario a company's ability to continue production. All are damaging to profit margins to varying degrees and the risks can be mitigated with a well executed product inspection programme.

Automation is a given in these environments and it is universally recognized that checkweighers play an instrumental role in day to day production. A checkweigher's main function in a pharmaceutical environment is to check the package for missing components such as the leaflet or complete blisters. This is a vital part of the package, as a box of tablets for example will not be considered safe or compliant without it. End of line applications are also commonplace, where systems are used to check the completeness of secondary and tertiary packaging, ensuring that what is sent into the supply chain is exactly what is expected.

Checkweighers automatically inspect 100% of products on the line - which is highly recommended compared with random off-line sampling, as the latter gives a sample size that is now considered to be of little statistical significance.

Checkweighing solutions can help pharmaceutical manufacturers to maximize productivity

Downtime is the enemy of any manufacturer, therefore identifying

areas that affect this directly is important when looking at Overall Equipment Effectiveness (OEE). System setup is one such area that can be optimized, and checkweighing features such as digital position control help to verify this is carried out correctly - otherwise the batch cannot be run at all. Running a batch with incorrect inputs can be very costly to correct due to the wastage involved. Also, should these products enter the supply chain it could have significant consequences, both in terms of consumer safety and brand reputation.

Another feature that increases OEE is In-Process-Testing. The test procedure, to be followed step by step, is normally written down on a separate instruction document and the results are manually entered on separate documents. Such testing procedures are very labour intensive, cause operational downtime and rely heavily on the operator consistently testing for reliable results.

In-Process Tests significantly reduce the risk of errors during test procedures and are highly flexible - so are able to adapt to customers' specific requirements. They are easy to operate, generate automatic reports for each test scenario, and – most importantly of all – require no shutdown of production. In-Process Tests are carried out with the help of special screen prompts, which guide the operator through the complete procedure and automatically record the results, which can then be saved and printed. Clear guidance during testing reduces labour time and possible operator errors and manufacturers benefit from more consistent, reliable results and higher operational uptime. In-Process

Tests enable several configurable test scenarios.

In addition, there is an easy to operate, intuitive Graphical User Interface (GUI), that helps the user to make changes easily. Mettler-Toledo also offers ProdX, a product inspection data management software application, which can significantly increase OEE as it enables nearly all processes on the line to be monitored from a central point.

Compliance with Good Manufacturing Practice (GMP) guidelines

Pharmaceutical checkweighers in particular are designed to meet the regulatory requirements of the pharmaceutical industry. First of all, GMP offers a broad guidance, although GMP regulations are not prescriptive instructions but consist of guidelines based on general principles. These include, for example, the validation of processes, record keeping, operator training or prevention of cross-contamination. It is always up to the manufacturer to design the production process and quality programs in accordance with GMP principles, to interpret the guidelines and asseses process risks accurately. Mettler-Toledo, in order to maintain process safety, offers equipment qualification, which is a huge benefit to users as it reduces the qualification and validation time in order to comply with FDA or CGMP (Current Good Manufacturing Practice) requirements. Equipment qualification comprises all aspects of design, installation, operational and performance qualification.

Minimizing changeover downtime with checkweighing technology

Minimizing changeover downtime is critical. Advanced checkweighing systems offer useful features such as digital positioning control. Due to a plausibility check the system does not allow users to enter false parameters. Users are immediatley alerted if settings are entered incorrectly and the system will not start if the parameters are wrong - another factor that influences the usability of the GUI also helps users to save time and therefore minimize changeover times - key factors when looking to increase productivity.

Statistical Process Control (SPC), in addition, is possible via software functions that can be utilised to predict issues on the line. SPC measures and refers to industry standard values of process capability CP and CPK. Standalone or integrated systems allow users access to the statistical data needed to understand, document and control profitability and production efficiency. This way, early detection of problems can be achieved ahead of any major issues that may have a significant impact on uptime. The ability to monitor performance is directly linked to OEE, and the net effect of reduced machine downtime is that higher production levels can be achieved using the same amount of resources. This leads to a faster return on investment with regard to capital purchases such as checkweighers.

Tracebility of Process Changes

Individual boxes, for blister packs of pills for example, are lightweight, therefore the load cell of a checkweigher has to be very precise. The checkweigher helps to check for product completeness, to reject falsely produced products and ensure the safety of the processes comply with FDA requirements. Another demand is the legal compliance with CFR 21 Part 11, which describes the way access to information is managed and changes made to the checkweigher. Everything has to be traceable and logged. This is integrated into the audit trail feature that the pharmaceutical checkweigher offers and a local audit trail operates completely automatically in the background and usually requires no user intervention.

Another useful feature is the domain login server, which enables the manufacturer to use accounts, passwords and rules issued and administered by the company's IT department for the checkweighers. Operators, maintenance personnel, supervisors and quality managers can use their normal network log-in name and password for tasks at the checkweigher just as they would with a network PC. This is not an FDA requirement but is a very valuable addition to the system.

Regulations: looking to the future

A challenge for pharmaceutical manufacturers will be the European Falsified Medicine Directive (EUFMD), that is expected to be implemented by the first half of 2018. Two years may sound like a long time, but depending on how many products the manufacturer has, how they are produced and whether they are produced using internally owned facilities or with external partners, it really isn't a great deal of time at all. Manufacturers generally deal with multiple facilities, that will all have to be enhanced with hardened serialization software to comply with these regulations.

Overall serialization is the key to success here and the EUFDM will require a unique serialization number on every salable unit of drug product intended for dispensation to a patient. So, for instance, a batch of 60 boxes of blister pack pills will have 60 different identifiers, not just one at the lot level. During production every aggregation level will have to be integrated into the serialization process and can be supported by checkweighing technology. Added value can be generated either by checkweighers with integrated serialization functionality, tamper evident sealing or aggregation solutions for the secondary and tertiary packaging at the end of the line.

If a pharmaceutical manufacturer works together with contract packagers, which is quite common in Europe, it should keep in mind that those contractors may not be ready for serialization when it needs them to be.

In addition to upcoming regulatory requirements, the US Drug Supply Chain Security Act (DSCSA) is in development for the pharmaceutical industry, which is to be applied in three phases for the US market up until 2023. First is to ensure lot traceability, followed by unique serialization and last, but not least, a combination of the two. Like the EUFMD this act will involve an increase in work, and systems such as checkweighers will be instrumental in helping manufacturers to remain both compliant and profitable as the regulatory landscape continues to evolve.■

Accurate Weighing in Hazardous Areas

Accidents in hazardous areas can have dramatic consequences for businesses in terms of both human life and profit. METTLER TOLEDO'S intrinsically safe equipment is designed to ensure process safety and to comply with hazardous area standards and regulations.

Two primary considerations must be taken into account when choosing the right weighing equipment for hazardous areas. They must be approved for the defined hazardous area classification and they must feature an appropriate method of ignition protection. When it comes to weighing applications in hazardous areas, the two most common ignition protection types available are intrinsic safety and flameproof (or explosion proof). Intrinsic safety is one of the safest ignition protection types. It provides a range of benefits which sets it apart from other protection types.

Hazardous Areas and their Classifications

An explosion is the sudden exothermic chemical reaction of a flammable material with oxygen and the simultaneous release of high energy. To eliminate the risk of explosion, one of the three elements must be removed.

Flammable substances may be present in the form of gases, vapors, mists or dusts. Together with oxygen these substances can form an explosive atmosphere. It can be ignited by an ignition source such as flames, sparks, hot surfaces or electromagnetic fields.

One approach to prevent an explosion is to eliminate the ignition source by keeping the system's active ignition energy below the minimum ignition energy. The minimum ignition energy is the smallest amount of energy required to ignite a combustible vapor, gas or dust cloud. The minimum ignition energy is measured in joules.

For example, the explosive "hydrogen-air" mixture can ignite with very low energy input; its minimum ignition energy at atmospheric pressure is about 10-5 joules. The minimum ignition energy of dusts is in the range of several milijoules up to 100 milijoules.

Businesses conducting collection, transformation and production processes with inflammable substances are obliged to conduct hazardous risk analysis to identify the potentially hazardous areas where dangerous concentrations of explosive mixtures of flammable or explosive materials can occur. Such areas are called "hazardous areas." When electrical equipment is used in a location classified as hazardous, it must be appropriately certified and provide the required level of protection. The selection of an appropriate protection method is based on the classification of the hazardous area. That is why it is important to understand area classifications and their differences.

Mettler Toledo offers a host of weighing equipment and systems, which are compliant to relevant guidelines applicable to hazardous area classification ensuring safety of business, equipment and human lives. ■

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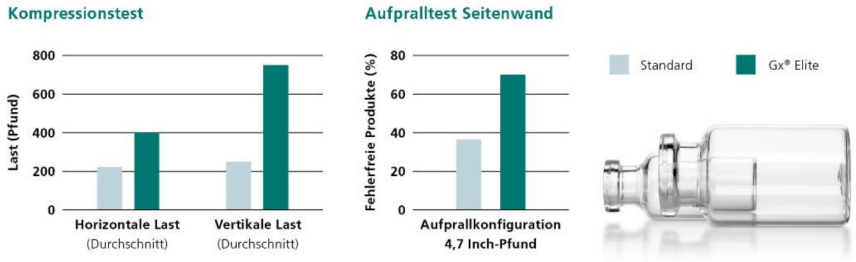
Injection vials for vaccines for protection against Covid-19

The vaccines under development to protect against Covid-19 are, like many other drugs, filled in so-called injection or vials made of type 1 borosilicate glass, also known as vials. The large worldwide demand for vials is met by the Gerresheimer Group's plants in Europe, America and Asia, where they are manufactured to high quality standards for customers in the pharmaceutical industry. The Company has already received initial orders for vials for drugs and vaccines against Covid-19.

Our injection vials, manufactured according to ISO standard, have been successfully used by our customers for decades and have proven themselves in the use with vaccines. Thanks to the continuous development of our portfolio, we are now able to produce a portfolio of injection vials that is geared to the increased needs of our customers. The keyword patient safety is at the heart of all our developments," says Hans-Ulrich Pieper, Senior Director Sales Pharma Parenteral Solutions Europe & MENA, who is responsible for tubular glass products (Tubular Glass Converting).



Gx Elite Vials are clearly superior to standard products. They perform significantly better in the com-pression test and side impact test

Gerresheimer's product range includes vials for conventionally manufactured pharmaceutical drugs as well as for biotechnologically produced and other specialty pharmaceutics. In order to meet the different requirements of the applications, Gerresheimer produces not only standard vials but also a corresponding range of different qualities of injection vials, also known as vials.

All Gx Vials (Standard, Pharma-Plus, Gx Elite and RTF) are manufactured and inspected using the latest technology and image processing techniques. The quality level of the agreed specification is decisive. Gerresheimer can use its camera systems for a wide range of parameters with or without restricted tolerances and for differently agreed quality levels, also known as AQLs (Acceptable Quality Levels).

Standard Vials - classic and proven In addition to glass ampoules, injection or piercing vials are the standard for the primary packaging of parenterally administered drugs and vaccines. They are the classic packaging material for numerous vaccines and medicines. Gerresheimer produces the vials in all sizes in accordance with international standards and the requirements of pharmacopoeias.

Pharma Plus Vials - injection vials - exceeding the standard Pharma Plus injection bottles are designed to exceed the pharmaceutical industry's requirements for critical dimensions and cosmetic quality. The Pharma Plus Type I injection vials have a high standard that is critical to meet customer requirements. The vials are manufactured using state-of-the-art technology and are inspected during production using image processing technology.

Gx Elite Vials - Extremely stable and free from cosmetic defects A Gx Elite Vial is a flawless container (cosmetic defects less

than 100 microns) with two to three times the strength, a high process capability (Cpk) for critical features and improved delamination resistance. Gx Elite is a product development that exceeds all known market requirements for a Type I borosilicate injection vial. These vials increase patient safety while reducing the total cost of ownership (TCO).

Gx RTF Vials - sterilized and ready for filling The Gx RTF injection vials are made of borosilicate glass type I and meet all current requirements of the applicable ISO standards and pharmacopoeias (USP and Ph. Eur.) They are formed according to cGMP, washed in a clean room, packed in trays or nest and tub and sterilized. Gerresheimer offers its own packaging configurations, but also the wellknown Ompi EZ-fill packaging format. This means that the vials are ready for the subsequent process steps in filling. The advantages are obvious: sterile delivery, a simplified filling and finishing process, the highest quality standards, flexibility through different packaging configurations and a wide range of filling and sealing technologies. All of these factors together ensure an improvement in overall manufacturing costs throughout the product life cycle.

Modern inspection systems All tubular glass plants producing vials work with standardized control, inspection and packaging technologies. These are mainly the Gx G3 and Gx RHOC technologies. The inspection systems are in-house developments and part of a tightly meshed inspection system that ensures the highest precision and quality assurance according to the most modern standards. For example, the Gx G3 inspection system uses state-of-the- art HD cameras to ensure reliable detection of cosmetic defects. The intelligent software detects and classifies the defects in fractions of a second. Gx RHOC ensures dimensional quality with high-resolution matrix cameras and a hyper-centric ID camera.

All Gx Vials are the patient-safe packaging material of choice for vaccines The Gerresheimer Vial portfolio leaves no customer wishes unfulfilled because it can be tailor-made. All vial qualities are suitable as packaging material for numerous vaccines and have proven this many times over. The future vaccines for protection against Covid-19 will be equally patient safe. ■

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New GSv9 TM Media and Feeds Maximize Yield and Batch-to-Batch Consistency

Lonza has expanded its cell culture media portfolio with the addition of the GSv9™ Media and Feeds, providing a fully integrated solution specifically designed to optimize recombinant protein production using Lonza's GS Gene Expression System®. The new chemically defined, animal-component free media and feeds are easy to implement, highly robust and enable greater batch-to-batch consistency. As a result, biopharmaceutical manufacturers can more easily develop streamlined and scalable bioproduction processes.

Recombinant proteins derived from mammalian cell lines are a key source of biopharmaceuticals designed to treat many complex human diseases. However, in such a highly competitive market, biopharmaceutical manufacturers must ensure that they maximize protein yield and consistency whilst also expediting production times. One way to achieve this is by using specially developed, simple-to-use media and feeds that improve cellular productivity, streamline processing and eliminate sources of product variability.

With a focus on ease of implementation, Lonza is introducing the new GSv9™ Media and Feeds that deliver high performance with a simple and easy to use protocol. Furthermore, the solution has been developed using response surface optimization and multivariate propagation of error analysis to increase the intrinsic robustness of the production process. Additionally, the overall culturing time is designed for high facility throughput.

Cadila Pharma Launches Anti Allergic Drug Bilastine in India

Cadila Pharmaceuticals Limited has announced the launch of Bilastine syrup (30 ml) and Bilastine tablets in the strength of 20mg. It is indicated that Bilastine, an antihistamine drug is used in the treatment of allergic rhinitis.

Bilastine is an antihistamine which addresses the current gap in the treatment of Allergic Rhinitis and meets the expectations of

doctors to treat their allergic rhinitis patients. The Bilastine has an advantage over other molecules available in the category, as faster onset of action, non-drowsy, cardiac safe. Cadila Pharmaceutical's product under the brand name Bilacad also ensures better safety and efficacy.

India has seen a growth in the number of cases of allergic rhinitis induced due to tobacco smoke, exposure to air pollutants, vehicular pollution, and other air pollution. Moreover as per a recent study published in Lung India 65% of the Indian allergic rhinitis patients also suffer from Asthma. Improved control of nasal allergies can help gain better control on Asthma.

Cadila Pharmaceuticals Ltd. is one of the largest privately-held pharmaceutical company of India. It has recently concluded USFDA inspection successfully in February 2020. Over the past six decades, Cadila Pharmaceuticals is engaged into development and manufacturing of affordable medicines and make them available for patients across the world. Its innovation-led drug discovery processes ensure the health and well-being of people around the world.

Hetero announces the approval and launch of first generic 'COVIFOR' (Remdesivir) in India for the treatment of Covid-19.

Hetero, one of India's leading generic pharmaceutical companies, announced today that it has received the manufacturing and marketing approval for the investigational antiviral medicine 'Remdesivir' from the Drug Controller General of India (DCGI) for the treatment of Covid-19. Hetero's generic version of Remdesivir will be marketed under the brand name 'COVIFOR' in India.

Dr. B. Partha Saradhi Reddy, Chairman, Hetero Group of Companies, commented, "In the light of increasing COVID-19

cases in India, the approval of 'COVIFOR' (Remdesivir) can prove to be a game-changer given its positive clinical outcomes. Backed by strong backward integration capabilities, we can ensure that the product is immediately made available to patients across the country. We are prepared for ensuring enough stocks required to cater to the present needs. We will continue to work closely with the government and medical community to make a difference in the fight against COVID-19."

The drug 'Remdesivir' has been granted approval by DCGI for the treatment of suspected or laboratory-confirmed cases of COVID-19 in adults and children, hospitalized with severe symptoms of the disease. COVIFOR (Remdesivir) will be available in 100 mg vial (Injectable) which has to be administered intravenously in a hospital setting under the supervision of a healthcare practitioner. The product is launched under a licensing agreement with Gilead Sciences Inc. to expand access to COVID-19 treatment in low and middle-income countries.

Bostik launches solvent-free HERBERTS™ 700 series product line for retort and metalized film applications

Bostik, a leading global adhesive specialist for industrial, construction and consumer markets, is proud to announce a new series of high-performance flexible lamination solutions. The Bostik HERBERTS™ 700 series, is a smart adhesive solution that aims to improve performance while being environmentally friendly. HERBERTS™ LF794/H180 and LF728/H128 are mainly designed for food packaging applications, and can also be used in industrial and medical markets. HERBERTS™ LF794/H180 is a polyurethane solvent-free retort adhesive solution for flexible packaging in food sterilization, stand-up pouches made with foil and spouts for boiling, lidding and facial mask packaging applications. HERBERTS™ LF728/H128 is a polyurethane solvent-free adhesive for metalized film, which is commonly applied in flexible packaging.

"There is an upward trend in consumer demand for convenient packaging, and manufacturers need to constantly innovate their materials to be able to meet this demand or risk being left behind. Our new solvent-free solutions, the HERBERTS™ LF794/H180 and LF728/H128, are made using the latest, high performance flexible lamination technology and are designed to provide a similar level of performance to solvent-based adhesives. In addition to their features, HERBERTS™ LF794/H180 and LF728/H128 also check the cost-effective box. This combination is especially important in light of these unprecedented and challenging times that the world is facing. We want to ensure that our customers continue to have access to the best quality solutions regardless of market challenges," said Daniel Thong, Regional Market Manager for Flexible Packaging, Industrial Adhesives Asia, Bostik.

The introduction of HERBERTS™ LF794/H180 and LF728/H128 comes at the right time for Asia Pacific, which has emerged as the leading consumer as well as producer of adhesives due to increased demand domestically, rise in income levels, and availability of cheaper raw materials.

Fermenta Biotech Limited and Indchemie Health Specialities Private Limited pledge Vitamin D3 (DV 60K®) for 250,000 Maharashtra Police personnel

Fermenta Biotech Limited and Indchemie Health Specialities Private Limited have jointly committed to supplying Maharashtra Police personnel 250,000 strips of DV 60K®, each strip containing sufficient dosage for an individual's recommended regime of 60,000 IU of Vitamin D3 per week for two months. Mr Krishna Prakash IPS, Spl. Inspector General of Police (Admn), Maharashtra State, said, "Maharashtra Police highly appreciates this gesture to support our police forces in their daily battle

against COVID-19. The Vitamin D provided to us will aid our colleagues to maintain their health, which is a major concern in this pandemic. Once again, we thank Fermenta and Indchemie for enabling us in our collective fight against COVID-19."

Around 90% of the Indian population suffers from low levels of Vitamin D, a vital nutrient with documented evidence for its important role in enhancing immunity as well as reducing the incidence, severity and risk of flu-like illness and pneumonia. Commenting on the initiative, Mr Krishna Datla, Managing Director, Fermenta Biotech Limited said: "We, at Fermenta, are proud of our Corona Warriors including Maharashtra Police fraternity, who are at the frontline of the battle against COVID-19. Through this initiative, we hope to thank them for their relentless efforts to protect us every day. Now, more than ever, is the time to develop a resilient community and emerge stronger, together."

The initiative will be a part of the Joint Corporate Social Responsibility programme of Fermenta, India's only manufacturer of Vitamin D3 and a leading player globally along with Indchemie, one of the pioneers in the Indian pharmaceutical industry and the first to launch Vitamin D3 in India in soft gelatin capsules.

Mr M K Singh, Managing Director, Indchemie Health Specialities Private Limited, commented: "Indchemie is extremely proud to associate with this noble cause. We are extremely happy to partner with Fermenta to enable the Maharashtra Police personnel to build their immunity & combat COVID-19. We take this as an opportunity to express our gratitude to the Police Force, our unsung heroes & our Protectors. Indchemie is proud that our products are helping millions of people, both within the country and abroad, to lead a healthier life."

Eris Lifesciences brings in Boman Irani as the brand ambassador for Circa

Eris Lifesciences has announced association with the well-known theatre and film actor, Boman Irani, for their circa range of devices. The association is aimed at highlighting importance of an accurate and validated BP monitoring device. The focus of the campaign is to encourage hypertensive patients to measure their blood pressure at home using a validated device while making an appeal to share their readings with doctor. The campaign theme #ShareYourPressure, urges users to stop worrying about getting false reading and trust the device to share their pressure.

The campaign will go live on social media channels this week in the form of short videos.

Commenting on the development, Amit Bakshi, Chairman and Managing Director, Eris Lifesciences said, "Hypertension therapy is our second largest therapy and with cardiovascular being the No. 1 Chronic therapy, we are upping our ante by closing the loop with one of the most validated device for blood pressure management. We have world class data in the form of 'India Heart Study' conducted on the same 'Circa' device further validating our commitment to Hypertension therapy. "

The corona virus outbreak has highlighted that patients with co-morbidities, E.g. Hypertension, are vulnerable to developing serious complications. Hence, accurate measurement of blood pressure at home becomes extremely crucial. Any error in the measurement of blood pressure because of non-validated devices can put life of the patient at risk.

Naari completes acquisition of ANDAs from Intas Pharmaceuticals

Leading women's health company Naari Pte Limited ("Naari"), a Singapore-incorporated wholly owned subsidiary of Naari Pharma Private Limited, has entered into a definitive asset purchase agreement to acquire 10 Abbreviated New Drug Applications (ANDAs) for the U.S. market from Intas Pharmaceuticals Ltd, the largest privately held pharmaceutical company in India.

Naari is a vertically integrated global women's health pharmaceutical business focused on hormones and has development and manufacturing capabilities across

intermediates, active pharmaceutical ingredients and finished dosage forms (FDFs). The strategic acquisition follows a period of significant growth and investment for Naari. Through the newly acquired portfolio, Naari will gain market access to USD900 million (per IQVIA data), accelerating its path to becoming one of the top women's health companies in the world. The acquired portfolio comprises eight U.S. FDA approved ANDAs and two products pending approval. It includes generic products in female hormones which will be manufactured at Naari's dedicated female hormone facility in India and commercialized over the next 24 months.

Prithi S Kochhar, Co-Founder and CEO of Naari, said: "This is another important milestone in our journey towards becoming a leading global player in women's health, enabling us to continue providing vital products to support women across the globe. Our journey into the U.S. market is well charted and we expect sales and a positive growth trajectory in the next 12 months. With 13 ANDAs, Naari will be amongst the top few Singapore pharmaceuticals with a large portfolio approved in the US."

With a presence in more than 50 countries and over 30 hormonal generics currently available or under development, Naari has one of the most comprehensive hormonal portfolios in the world.

New leap forward for SARS-CoV-2 detection

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

Consistent with their commitment to supply global healthcare systems with the critical reagents required in the fight against COVID-19, PCR Biosystems has validated the new qPCRBIO Probe 1-Step Virus Detect kit for qualitative detection of the SARS-CoV-2 nucleic acid. Validation has been performed using the Charité (Germany) primer-probe sequences targeting the RdRp and E genes, as well as the Centers for Disease Control and Prevention (USA) recommended sequences targeting specific regions of the N gene. The kit is ideally suited to high-throughput testing of COVID-19 clinical samples, either with laboratory developed assays or as a component of diagnostic testing kits.

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

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

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

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

Ortho Clinical Diagnostics (Ortho) launches two COVID-19 Antibody Tests

With 6,287,771 confirmed cases worldwide and 379,941 deaths due to the novel coronavirus scourge —2,16,919 cases /5,815 deaths in India — healthcare professionals, researchers and

government officials in the country and across the globe are racing against the clock to find solutions to better manage Covid-19 and save more lives and families...ICMR has asked states to conduct antibody tests on large scale.

Study results show that even with 97% specificity, there is a chance of getting 30 false positive results out of 1,000 and with 99.6%, 4 false positive results out of 1,000. Only with 100% specificity can one be fully confident that the antibody positive test result is a true positive, such as with the one developed and launched recently by Ortho Clinical Diagnostics.

Unlike many commercially available antibody test kits, Ortho's high-throughput, automated VITROS® Anti-SARS-CoV-2 antibody tests are highly reliable and have demonstrated 100% specificity in assay validation studies. The tests can help to identify with high accuracy a previously infected patient who can donate antibody-containing plasma to treat severe COVID-19 patients. This is important because any inaccurate test result could lead to a plasma therapy without antibodies to SARS-CoV-2, the active ingredients in the convalescent plasma therapy.

Both VITROS® Anti-SARS-CoV-2 antibody tests target the S1 subunit of the Spike (S) protein of SARS-CoV-2. The virus uses the S1 protein to bind to the angiotensin-converting enzyme 2 (ACE2) receptor to facilitate viral entry and infection. Antibodies that can bind to S1 and block S1-ACE2 interaction can inhibit viral infection, which are called neutralizing antibodies. The VITROS® Anti-SARS-CoV-2 antibody tests can detect neutralizing antibodies that bind to the S1 protein.

Ortho's 100% specificity-compliant antibody assay for Covid-19 testing — the VITROS® Immunodiagnostic Products Anti-SARS-CoV-2 Total and IgG Reagent Packs and Calibrators — have now been included in the updated list of approved Rapid/ CLIA/ ELISA kits the Central Drugs Standard Control Organization (CDSCO), under the Ministry of Health and Family Welfare, GoI. (*No other company has 100% specificity).

The recent guidelines from the Centre for Disease Control and Prevention (CDC) for Covid-19 antibody testing emphasizes on the serological methods/antibody testing towards monitoring and responding to the Covid-19 pandemic. Antibodies most commonly become detectable 1-3 weeks after symptom onset, at which time evidence suggests that infectiousness is, possibly, greatly decreased and that some degree of immunity from future infection has developed. Serologic assays for SARS-CoV-2 with very high specificity, now available, can play an important role in understanding the virus's epidemiology in the general population and identifying groups at higher risk for infection.

In the current pandemic, maximizing specificity, and thus positive predictive value, in a serologic algorithm is preferred in most instances, since the overall prevalence of antibodies in most populations is, possibly, low. Choosing a test with a very high specificity, perhaps 99.5% or greater, will yield a high positive predictive value in populations tested with prevalence >5%. Ortho Clinical Diagnostics' VITROS® Anti-SARS-CoV-2 antibody test offers 100% specificity, providing high confidence to positive test results. These kits have received EUA from U.S.FDA and are CE marked too. The VITROS® Systems that have already been installed in hospitals and laboratories in India and the neighboring SAARC countries are self-contained and do not require any external water source to run, offering labs placement flexibility.

BSVL gets permission to conduct phase III clinical study of Ulinastatin

Bharat Serums and Vaccines Limited (BSVL), a leading biopharmaceutical company with presence in India and emerging markets, today announced that it has received approval from the regulatory agency DCGI to conduct phase III clinical study on Ulinastatin for mild to moderate Acute Respiratory Distress Syndrome (ARDS) patients with COVID 19. Clinical trial is expected to start at hospitals shortly.

The mortality risk is higher when an individual with COVID-19 infection develops ARDS and pneumonia. ARDS causes dry cough, heavy breathing, breathing difficulties and increased heart rate. Ulinastatin, in such cases, can be used as a remedy to combat the underlying inflammatory condition related to ARDS in COVID-19 patients.

According to Sanjiv Navangul, Managing Director and CEO, BSVL, "Identifying effective antiviral agents and therapies to combat underlying pathology of COVID-19 is the need of the hour. As one of the leading biopharmaceutical companies in

India, BSVL has a legacy of using scientific resources to treat patients in critical care, and we are channeling our efforts towards the ongoing fight against the COVID-19 pandemic. We began our innovation journey 3 decades ago and we are committed to continuing our efforts in developing and marketing innovative products to transform patient lives."

While there is no approved treatment against the SARS-CoV-2 virus yet and experimental drugs are presently being used as a supportive therapy, Dr Swashraya Shah, Chief Medical Officer shares heartening data points, "Meta-analysis of 2300+ ARDS patients treated with Ulinastatin has shown significant improvement along with four parameters. Those parameters typically are an improvement in oxygenation index (PaO2/FiO2), shortening duration of mechanical ventilation, and reduced mortality & ICU stay as compared to conventional therapies."

Intensivists currently use Ulinastatin in India for severe sepsis and other critical clinical condition (acute pancreatitis). "This drug is a serine protease inhibitor. It exhibits anti-inflammatory activity by suppressing the infiltration of neutrophils and release of elastase and other chemical mediators of inflammation [tumour necrosis factor (TNF)-α, and interleukin (IL)-1, 6 & 8] from them. Patients with severe COVID-19 infection can develop fatal lung damage from a cytokine storm due to increase in pro-inflammatory cytokines. Ulinastatin could combat underlying inflammatory condition in COVID-19 patients experiencing mild to moderate ARDS", Dr Shah explains.

As per the approved clinical trial protocol, subjects with mild to moderate COVID-19 will be randomized in the study in a 1:1 ratio with Ulinastatin and standard supportive care or standalone standard supportive care. Ulinastatin is currently manufactured at BSVL Ambernath facility in Thane, Maharashtra, India.

Thermo Fisher Scientific Launches New MAS Omni Infectious Disease Quality Controls

Thermo Fisher Scientific announced the availability of the Thermo Scientific MAS Omni Infectious Disease quality control sets for monitoring serological assays for analytes such as HIV 1&2, Hepatitis B & C virus, Syphilis and HTLV I/II.

Serology testing for infectious diseases continues to be on the rise and newer instrument platforms are offering serology markers with improved sensitivity than previously available. In addition, there is continued progression with infectious disease screening protocols requiring serology testing for diagnosis, monitoring and treatment of infectious agents.

The Thermo Scientific MAS Omni Infectious positive and negative quality controls are third-party, independent external controls used to assess the performance of serological assays for infectious diseases. Our new control set supports assays for HIV, Hepatitis C, Hepatitis B, HTLV and Syphilis. As with all Thermo Scientific MAS Quality Controls users can efficiently monitor assay performance, streamline operations and potentially reduce your spending without sacrificing quality or throughput.

"We are expanding our quality control offering into a space which continues to increase each year as new pharma drugs are developed and enabling better identification and treatment for infectious diseases. Our team is committed to providing innovative solutions to support our customers' productivity," said Fernando Beils, vice president and general manager, Thermo Fisher's niche diagnostics business. "The Thermo Scientific MAS Omni Infectious Controls are the first in a line of products we are continuing to develop to support the monitoring of in vitro diagnostic tests."

Syntegon joins OPEN-SCS Group

Syntegon Technology recently joined the Open Serialization Communication Standard (OPEN-SCS) Group. Joint goals include the fight against pharmaceutical counterfeiting and the establishment of interoperable interfaces for the implementation of adequate serialization solutions.

The OPEN-SCS Group was initiated in 2014 to define, publish and maintain an OPC UA based standard and companion documents for the integration of serialization solutions. Syntegon fully supports the mission statement of the working group, to "allow functional interoperability of serialization solutions in order to seamlessly integrate the operations and business processes across organizations and regulatory bodies, aligning with other industry groups and standards whenever appropriate."

"Apart from the fact that saving lives through anti-counterfeiting measures is an excellent reason to joint OPEN-SCS, we also firmly believe in open digital worlds and open platforms", says Jörg Willburger, product manager for Track & Trace systems at Syntegon. "Customers should have no constraints and a high flexibility to choose. Mixed systems with machines and software from different suppliers, combined with common interfaces will become standard. And that's exactly what we want to achieve with our commitment in OPEN-SCS."

Syntegon will contribute to the success of OPEN-SCS with long-standing experience in Track & Trace and serialization solutions, as Jörg Willburger explains. "We know that successful serialization projects usually consist of many different applications. In the end, it's all about having the right interfaces to combine them – and to realize the individual solution for each customer", Willburger said.

Syntegon Technology is proud to join the OPEN-SCS Group in its fight against pharmaceutical conterfeiting and for standardized industrial interfaces for serialization.

With its long-standing experience in Track & Trace and its comprehensive Industry 4.0 portfolio, Syntegon has realized numerous successful serialization projects across the globe

Cadila Pharma announces the launch of FDA registered immunity booster syrup

Ahmedabad based Cadila Pharmaceuticals Limited launched its immunity booster syrup under the brand name 'Cadimmune' by distributing the immunity booster syrup to 150 AYUSH practitioners fighting on the frontline against COVID-19. AYUSH ministry has released multiple guidelines on the steps that people should take to boost immunity. The company has introduced an immunity booster syrup in an endeavour to promote safety and precaution during these times. The syrup helps further augment immunity and supports in prevention of life-threatening complications in the case of viral infections.

The formulation will be available in syrup form, for adults and

for paediatric use, and will help in boosting the immunity. Cadimmune works mainly on digestive fires to produce the mature and good quality Sapt Dhatus. Processed with advanced modern extraction method to maintain the aromatic principles, Cadimmune majorly contains, Nagarmustha (nut grass), Ushir (Khus), Rakt chandan (sandal wood), Adrak (ginger), Kalmegh, Haritaki, etc.

Cadimmune is alcohol and preservative free and is packaged in a glass bottle to keep the efficacy intact. It works to produce the potential Ojus which is responsible for immunity. The immunity booster syrup is available in 110 ml and 220 ml packs. As the country enters into unlock 2.0, it is essential that people take care of their immunity, so that they step out with full strength and carry their protection against the pathogen. Cadimmune helps to prevent viral infections such as common cold, recurrent attack of viral or bacterial infections and also acts as adjuvant therapy in viral infections, allergic rhinitis and dengue.

Cadila Pharmaceuticals Limited has recently launched a range of sanitizer to promote safety and sanitization across the communities. The organisation also donated thousands of essentials kit, to underprivileged families across Trasad, Dholka, Ingoli and Virdi villages.

Emcure Pharma offers hope to patients with chronic kidney disease

Emcure Pharmaceuticals an Indian integrated global pharmaceutical company has launched India's first generic version of sucroferric oxyhydroxide for the control of increased serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis. The drug will be sold under the brand name Dynulta. Its active component is sucroferric oxyhydroxide developed indigenously by Emcure. Dynulta will be manufactured at Emcure's state-of-the-art plant at Jammu and will be marketed at less than 70% cost of the innovator brand. "The incidence

of CKD is on the rise in India. Dynulta will provide efficacious and cost-effective remedy for Indian patients" said Ms. Namita Thapar, Executive Director, Emcure Pharmaceuticals ltd.

Recent data from the International Society of Nephrology's Kidney Disease Data Centre reported a prevalence of 17% of CKD in India. Diabetes and hypertension accounts for most CKD cases. By 2030, India is expected to have the world's largest population of diabetes patients. There are several other issues that contribute to the high prevalence of CKD in India.

Hyperphosphatemia is a serious and common consequence of advanced CKD. Hyperphosphatemia is associated with increased risk of cardiovascular events and mortality in patients undergoing dialysis. Dietary restrictions and dialysis alone are usually insufficient to control hyperphosphatemia therefore an effective phosphate binder is needed to control increased phosphate level.

Sucroferric oxyhydroxide displays a high phosphate binding capacity, resulting in effective serum phosphorous control. This was demonstrated in a phase III study of sucroferric oxyhydroxide versus sevelamer. Real-world studies show that patients who switch to sucroferric oxyhydroxide from another phosphate binder achieve better long-term serum phosphorous control with a lower number of pills. A lower pill burden can translate into better patient compliance to treatment. Studies have shown that sucroferric oxyhydroxide is effective in the reduction of serum phosphorous in a broad range of dialysis patients.

The innovator company for sucroferric oxyhydroxide is Vifor Fresenius Medical Care Renal Pharma Ltd, a joint operation between Vifor Pharma and Fresenius Medical care, providers of dialysis services. It is marketed internationally as Velphoro, which is not available in india. Emcure Pharmaceuticals ltd has made it available/accessible Dynulta, for the first time in India.

Oncomine Precision Assay receives device designation by the U.S FDA

Thermo Fisher Scientific received breakthrough device designation for its Oncomine Precision Assay by the U.S. Food and Drug Administration (FDA). The assay can be used to identify low-grade glioma (LGG) patients with isocitrate dehydrogenase IDH1 and IDH2 mutation.

Thermo Fisher recently expanded its strategic partnership agreement with Agios Pharmaceuticals to co-develop the companion diagnostic (CDx) for vorasidenib, an investigational, oral, brain-penetrant, dual inhibitor of mutant IDH1 and IDH2 enzymes currently under evaluation in the Phase 3 INDIGO study for IDH mutant LGG. Over time, Thermo Fisher seeks to receive premarket approval (PMA) for the Oncomine Precision Assay as a companion diagnostic for multiple therapies, as well as approval for liquid biopsy tumor profiling in lung cancer and solid tissue tumor profiling in multiple cancer types.

In November 2019, the Oncomine Precision assay was first introduced as a research product to run on Ion Torrent Genexus System –the world's first fully automated next-generation sequencing (NGS) platform with a specimen-to-report workflow that delivers comprehensive genomic profiling results in one single day.

Mr. Amit Chopra, managing director, India and Middle East, Thermo Fisher Scientific, said "Quick access to comprehensive genomic profiling data will open a lot of possibilities to probe accurate treatment decisions in the current treatment regimes. The multi-biomarker profiling that is generated onsite and available in about a day is game-changing for healthcare professionals, by accelerating their assessment and prescribe the most appropriate treatment for their patients faster than before. We have taken a great step forward by equipping the healthcare industry with faster access to comprehensive genomic information, which exemplifies our Mission to enable our customers to make the world healthier, cleaner and safer."

The Ion Torrent Genexus System is the first turnkey next-generation sequencing (NGS) solution that automates the specimen-to-report workflow and delivers results in a single day with just two user touch points. The Oncomine Precision Assay on the Ion Torrent Genexus System is a next-generation genomic profiling solution that can allow every laboratory to deliver a genomic profile with a one-day, hands-free workflow. Featuring the most prevalent and potentially relevant cancer driver variants across 50 genes, the Oncomine Precision Assay is ideal for fast genomic profiling in clinical cancer research. When combined with the Genexus System, molecular testing laboratories can generate comprehensive NGS results within the same timeframe as single-gene tests. Additionally, these features set the stage for molecular pathologists in the future to analyze NGS information in parallel with first-line testing modalities, such as immunohistochemistry (IHC).

With its unprecedented speed to results, the Genexus System is positioned to accelerate a broad range of application areas, including oncology, infectious disease, inherited disease and reproductive health, among others. Since its launch in November 2019 as a research only solution, the integrated sequencer has also been enabled to analyze SARS-CoV-2 samples to support epidemiology or contact tracing studies.

Practo salutes the doctors with its #BeingADoctor campaign

Practo, India's leading digital healthcare company has launched a campaign #BeingADoctor on the occasion of National Doctors' Day. The campaign is a tribute to doctors by shining light on the sacrifices they've made in their lives; it portrays the commitment, grit, and determination it takes to become and be a doctor to patients every single day. This campaign is Practo's effort to showcase and acknowledge the struggle, the trials and tribulations, responsibilities, and above all, the joy of being a doctor.

The video narrates the journey of the doctor from being a student to becoming an invincible warrior bringing life and hope to mankind during turbulent times. The film highlights the passion behind the purpose and the unsurmountable struggle and challenges one faces during the journey of becoming a doctor and their path to fulfilling their oath of showing compassion, care, and commitment to patients for the rest of their lives. On this doctor's day, everyone at Practo proudly acknowledges the services of all the doctors, on behalf of the indebted public. The video is live and can be viewed on Practo's Youtube, blog, and social media channels.

Cipla and Boehringer Ingelheim forge partnership

Cipla Limited and Boehringer Ingelheim India Pvt. Ltd. (BI) announced their partnership in India to co-market three new oral anti-diabetics drugs Oboravo® (Empagliflozin), Oboravo Met® (Empagliflozin+Metformin) and Tiptengio® (Empagliflozin+Linagliptin).

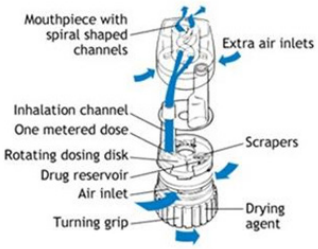
Empagliflozin is approved for glucose-control in patients with type-2 diabetes; it is also approved for reducing the risk of cardiovascular death, in patients with type-2 diabetes and established cardiovascular disease. The Empagliflozin + Metformin combination Oboravo Met® can be given to newly diagnosed patients of type-2 diabetes who have higher baseline HbA1c levels.

The Empagliflozin + Linagliptin combination Tiptengio® is the world's first approved combination of an SGLT-2 inhibitor and DPP4 inhibitor. In addition to a strong effect on lowering blood sugar levels, it also addresses multiple pathophysiological defects in type 2 diabetes, and is a big step towards improved management of type 2 diabetes. It will also help in reducing the pill burden for patients and help improve adherence to the prescribed treatment.

As per the International Diabetes Federation, India is home to 77 million adults aged between 20 and 79 years with diabetes, ranking second behind China; and is poised to reach 134.2 million patients by 2045. Fortunately, while the number of patients is increasing, so is the awareness among the public to address it. The Indian diabetes market is valued at INR 1,45,451 million and is growing at 10.35% (IMS MAT May 2020) with the oral anti-diabetic market being valued at INR 1,07,354 million and growing at 11.34% (IMS MAT May 2020).

Clariant introduces static reducing compounds for drug delivery devices

Clariant Plastics & Coatings Healthcare Polymer Solutions recently launched static-reducing functional plastic compounds which, when used in drug delivery devices, enable increased dose reliability. The resins are part of the wider 'medical grade' MEVOPUR® line of color and additive concentrates and 'ready-to-use' polymer compounds, covering polymers from PE to PEEK.



Plastics are insulators, and therefore prone to build-up of static charges. In applications where plastics are in contact with powders, the powder can stick to the surface. In drug delivery devices, such as dry powder inhalers, this sticking effect reduces the dose reliability and repeatability. MEVOPUR permanent antistatic compounds reduce the surface resistivity and dissipate charges quickly, thereby eliminating sticking. However, since the plastics often have direct drug contact, and inhalation is considered as a medium-to-high risk drug administration route, the plastic materials need to be evaluated for biocompatibility and risk of potential leachables.

In a recent development program with a leading European pharmaceutical company, members of Clariant's global Healthcare Polymer Solutions team provided technical support and compounded materials covering ABS, COP (cyclic olefin polymer) and PP resins that the development team planned to use. The critical areas in contact with the drug flow needed to avoid static charge build-up, and the MEVOPUR antistatic agent,

combined with the chosen polymer, demonstrated antistatic functionality that significantly reduced this problem. In other development programs, antistatic functionality was combined with the chosen color in one compound product.

Although many resins are now widely available as 'medical grade' products with supporting regulatory declarations and change notification, this usually only covers the resin, and not colors or additives that are introduced by compounding or masterbatch concentrates. It is these colors and additives that present the higher risk of potential leachables that could end up in the drug. The problem is particularly acute as these added materials change routinely over the life time of the product.

The MEVOPUR family significantly reduces this risk by using pre-tested ingredients that support compliance to medical and pharmaceutical standards such as ISO10993 and USP Class VI, manufactured in EN- ISO13485:2016 certified production facilities and change control.

Other examples where MEVOPUR anti-static compounds are applied in drug delivery is in transparent plastic 'spacer' accessories used with metered-dose inhalers (MDI). These spacers which act as 'accumulators' to aid in correct dosing, are mainly used by very young or elderly patients who have difficulty to use an MDI unaided. Although anti-static functionality is needed, the materials used are often not 'medical grade', and so they can present the same risk as the described above. MEVOPUR antistatic compounds are available both in opaque colors and in transparent MABS (methyl methacrylate-acrylonitrile-butadiene-styrene) delivering the same quality and regulatory compliance.

OMRON forays into telemedicine in India with PhableCare

Leading healthcare monitoring brand, OMRON Healthcare India, has partnered with PhableCare – the artificial intelligence (AI) enabled healthcare management player- to provide a one-stop remote hypertension management services at home.

The platform aims to bring technology and healthcare together, enabling hypertensive patients to avail all kinds of services right from diagnosis to monitoring to treatment under one roof. It's an amalgamation of doctors' expertise, patients' data, health devices and the power of artificial intelligence and machine learning (AI/ML) onto a single platform.

Speaking on this development, Mr. Masanori Matsubara, MD, OMRON Healthcare India said, "With autonomous & AI based healthcare becoming a reality in the new normal, the association will usher in India's first-of-its-kind remote hypertension management service. So far, OMRON has been contributing towards empowering people to keep track of their heart health by providing quality digital blood pressure (BP) home monitoring solutions. However, with the merging of our synergies with PhableCare, we will be able to make millions of patients utilise the monitoring services efficiently under the supervision of doctors from the comfort of their homes. The patients will get access to an accurate monitoring device, proper diagnosis, prescription, real time tracking and monitoring, and even efficient drug delivery & risk analysis under this solution."

The endeavour is a step ahead for OMRON Healthcare in India to realize its vision of "ZERO HEART ATTACKS and ZERO BRAIN STROKES" by making people realise the importance of timely and accurate blood pressure monitoring.

The users would have to download the app PHABLE on their mobile devices and choose the right subscription packages to start the journey. As of now, the app has a subscriber base of 65,000+ patients with 800+ doctors on board. The association will be instrumental in scaling up the reach to 1 Million hypertension patients in the next 12 months.

On this association, Mr. Sumit Sinha, CEO and Co-Founder, PhableCare said, "The last few months have brought a major shift in consumer behavior where a large population is accessing their basic needs through smartphones. Healthcare is a basic need and PhableCare truly believes that good healthcare access is a fundamental right for every citizen. At PhableCare, we are focused on bringing better healthcare outcomes for chronic disease patients; helping doctors save hundreds of lives and women deliver healthy babies. This partnership brings together the world's leading digital BP monitoring device manufacturer, OMRON, with India's largest hypertension management company PhableCare together. The effort is to bring about a fundamental change in how healthcare is accessed and outcomes are driven for Hypertensive patients."

Hypertension is a primary risk factor for cardiovascular diseases such as stroke and heart attack. Recent studies indicate, about 33% urban and 25% rural Indians are hypertensive. Also, only one-tenth of rural and one-fifth of urban Indian hypertensive population have their BP under control.

Roche Diagnostics India's Elecsys IL-6 test to help identify high risk of severe inflammatory response

Roche Diagnostics India today highlighted its commitment to enabling access to reliable diagnostic solutions in India. Given the growing need to manage respiratory failure, Roche's Elecsys IL-6 test measures levels of the biomarker interleukin 6 (IL-6) in human body and can be used to help identify patients who could be at high risk of development of severe respiratory illness.

The test can support physicians, in combination with other examinations and vital signs, to decide early on about treatment management for severe respiratory illness. The levels of IL-6 also helps identify patients who might be at high risk of disease progression.

Dr. Sandeep Sewlikar, Medical and Scientific Affairs Head, Roche Diagnostics India, said, "Roche Diagnostics India has been proactively working on addressing the country's diagnostics need across a whole range of diseases and conditions. Responding to the need to address patient management relating to increasing cases of respiratory distress, I believe that our IL-6 biomarker plays the role of early indicator for acute inflammation in the management of critically ill patients."

Hospitals and laboratories can run the Elecsys IL-6 test on Roche's cobas e analysers which are available in around 500 cities across India. These fully automated systems can provide test results in approximately 18 minutes, with a test throughput of up to 300 tests/hour, depending on the analyser.

West Launches AccelTRA® RTS/RTU Product Line in India

West Pharmaceutical Services, Inc. a global leader in innovative solutions for injectable drug administration, recently announced the launch of the AccelTRA® Ready to Sterilize (RTS)/Ready to Use (RTU) product line in the Indian market, under the AccelTRA components program.

The AccelTRA components program was designed to provide generic drug manufacturers with components for injectable drug delivery that meet the challenges of today's fast-paced market. West designed AccelTRA components around the ideas of quality, speed and simplicity to help address the unique needs of generic drug manufacturers to be able to quickly respond to un-forecasted market demand while meeting increasing quality standards. The RTS components were made available in India earlier this year, and the RTU gamma sterilized components are now available.

Elaborating about the new product launch, Alagu Subramaniam, Managing Director, West India said, "The AccelTRA component program offers delivery times and a single next-generation formulation that helps our customers in India stay competitive and move product to market quickly. By partnering with West, customers receive reliable and safe products that may help to mitigate risks as they navigate the regulatory approval process."

West is highlighting its expanded innovations for global customers and their patients with the introduction of an AccelTRA component line extension. "This product line provides greater flexibility in a stricter regulatory environment to customers who need a high-performing elastomer that leverages West's 4031 formula, with optimized product lead times, and global warehousing to help our customers get their products to market quickly," added Subramaniam.

Launched in March 2017, the AccelTRA component program's high-quality 4031/45 elastomer formulation enables optimized lead times, extremely low particulate levels and can withstand multiple punctures. These features help to reduce patient risk and ensure the drug and its packaging meet strict standards for quality set by regulatory agencies. Through the AccelTRA component program, West can provide generic drug manufacturers with sample components for injectable drug packaging in as little as one week and commercial quantities in six weeks. Available globally, the high-quality components are offered either Ready to Sterilize (RTS) or Ready to Use (RTU), have an industry-leading extractables profile and meet United States Pharmacopeia (USP) and European Pharmacopoeia (EP) compliance requirements.

AccelTRA products are currently stocked in India to deliver speed to the local generic drug manufacturers. West's presence in India began in 2004 with a commercial office in Hyderabad, and has since expanded with the establishment of a manufacturing plant in Sri City in 2014 and a Digital Technology Center (DTC) in Bengaluru in 2019.

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R.N.I. No.: MAHENG/2002/08502. Date of Publication: 26th of every month. Postal Registration No: MCS/207/2020-22 Posted at Patrika Channel Sorting Office, Mumbai 400001, on 27th of every month. Total Pages:- 64

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