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Samina Hamied
Executive Vice-Chairperson
Cipla

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The online pharmacy sector has seen many deals but the announcement of PharmEasy’s impending acquisition of diagnostics major Thyrocare on June 26 took many by surprise. However, the synergies between the two are undeniable and are in line with the general trend over the past year.

The PharmEasy-Thyrocare announcement comes on the heels of Tata Digital’s deal to acquire majority stakes in 1MG earlier in June. This consolidation in the e-pharmacy segment is bound to continue as the sector is still very fragmented. The same logic holds for the diagnostic segment.

The COVID-19 pandemic has only accelerated a trend that was already in the works. In August last year, interest in the e-pharmacy sector swelled, with big-ticket deals like Reliance Retail’s acquisition of NetMeds. Health tech startups MedLife and PharmEasy too announced merger plans in the same month, with the former selling operations to the latter, to reap the benefits of scale.

Even as biggies like Reliance Industries and the Tata Group bulk up against global peers like Amazon and Walmart for a slice of India’s online retail sector, e-pharmacy has proved to be an easy and logical entry into customers’ wallets. And mind space.

Consumers were forced to move to online purchase of almost everything, including medicines, during the COVID-19 lockdowns. They then also booked their diagnostic tests online and tried teleconsultation, all through the same apps. Most health-related purchases and decisions moved online since the pandemic struck and industry pundits are predicting that at least a major proportion of these consumers will continue online for some time.

E-pharmacies have come some ways from their initial days when they attracted a backlash from their offline peers. If the interest and subsequent investment of venture capital legitimised the e-pharmacy concept in India, the entry of corporate giants should continue the mainstreaming process. PharmEasy’s takeover of Thyrocare clearly shows that they are no longer part of the ‘upstart start ups’ brigade. E-pharmacies have proved their mettle and value during the COVID-19 pandemic, delivering medicines to harried patients, many times at decent discounts.

Which is why it is high time e-pharmacies get their own set of regulations. Still governed by the same rules as their offline counterparts, framed in the pre-internet era, there have been numerous examples of unscrupulous players who are exploiting the loopholes.

Though policymakers did take the first steps on this front, nothing has moved much since the Ministry of Health and Family Welfare’s draft amendment of the Drugs and Cosmetics Rules, 1945 of August 28, 2018. This is the first draft to introduce and define terms like ‘e-pharmacies’, while prescribing certain restrictions.

However, the draft Rules to amend the D&C Rules have not yet been notified and thus cannot be enforced. Ending the ambiguity will be good for patients, as well as the industry.
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You are leading Cipla from the front, was joining the family business always a plan?

Before joining Cipla, I worked at Goldman Sachs as an investment banker for almost five years across their London and New York offices. I joined the firm right after completing my Masters at the London School of Economics.

My entry into Cipla in 2011 was at a time when the company was on the cusp of change. I took a call to switch over from my career as an investment banker in London to my family business here in India. Given that I had practically no experience in the pharmaceutical sector and that Cipla was also at a critical turning point, it was a big leap to take and a massive responsibility. But I saw it differently. For me, it was an opportunity to infuse fresh thinking into the organisation and refresh the existing mindset to lead it towards future growth. In hindsight, I couldn't have asked for a more opportune time than that.

Coming from the founding family, did you face any stereotype challenges?

While I was very happy to join the family business, I had apprehensions about foraying into a new domain.

A company that is ready to re-imagine their businesses to stay relevant in the evolving times, while staying true to their core purpose is a future-ready organisation.

My first challenge was to develop a solid understanding of how pharma functioned as an industry. Consequently, I spent a lot of time with strong mentors to understand how the generics business runs.

When you are working for a company that has eight decades of legacy behind it, it is imperative to drive the organisation with a humanitarian approach to healthcare, keeping up with its legacy of caring for life and fast-forwarding its journey into the future. While I was empowered to transform the company through my position on the Board, keeping the purpose of Cipla, on which it was founded by my late grandfather Dr KA, intact, was also my priority. As a leader, having a clear-cut vision is essential. The bets that I undertook at the time may have been new to many within the system, however with conviction and a well thought through strategy it has today, led Cipla onto a new path of becoming a holistic healthcare solutions provider focused on wellness, instead of limiting ourselves to manufacturing medicines alone.

What disruptions do you foresee in Indian pharma, healthcare and life sciences sector? How is Cipla poised to ride the wave?

The pharma industry has started evolving from its current role of being seen as traditional drug manufacturers, to an industry that is focusing on being holistic healthcare providers. Going forward, one of the disruptions we see is the shift from illness to wellness wherein patients are empowered about their health needs and are transitioning to a more preventive, and curative behavioural change. Pharma companies will have to re-imagine their roles in the lives of patients and play a larger part in their lives. At Cipla, we took major steps towards growing Cipla Health into a holistic wellness player. This business has achieved an all-around play across multiple, large OTC categories. Cipla Health launched an entire range of products including hand sanitisers, surface disinfectants, face masks, etc. to cater to the increasing market demand for hygiene essentials due to the ongoing COVID-19 pandemic.

The second disruption is embracing digitisation. In pharma, digitisation has not only played a crucial role in bringing about operational efficiencies and managing supplies but has also enabled more meaningful and convenient engagements with stakeholders. For...
instance, today pharma companies are able to reach a much wider base of doctors and patients beyond cities alone through the use of virtual engagement platforms. From a value-add point of view, we see digital as a tool that will empower each and every stakeholder in the healthcare ecosystem to actively participate along the care continuum. We recently launched an initiative ‘Healthcare Superstars’ that provides a unique virtual learning experience comprising LIVE interactive sessions, global collaborations of, world-renowned speakers, interview and case-based learning for medical professionals.

Last but not least is access through collaborations. This pandemic is a great example of how the power of the collective has worked towards combating this crisis. Governments, public and private institutions and individuals came together and pooled in their strengths to strengthen the response to COVID-19. The pharma industry, in particular, came together in solidarity by forging global partnerships to make drugs accessible, some lending their innovations and others their manufacturing capacities and distribution networks. Cipla has been the partner of choice given our large portfolio of COVID-19 treatments through our multiple strategic partnerships with innovators such as Gilead, Roche, MSD, Eli Lilly and CSIR-IICT to provide access to life-saving treatments.

Building an inclusive, diverse and equitable workplace is on top of the agenda for most corporates today. Where do you position Cipla on this maturity curve?
Companies have a lot of scope to embrace a workplace that is not just diverse but inclusive. And this starts with inculcating a mindset shift, i.e., going beyond numbers play to bring about true equality. Gender equality and inclusiveness cannot be ensured by enhancing women representation alone but also introducing policies and initiatives that empower them within the system to effectively contribute to their roles. The right approach is to take steps towards inclusiveness. Additionally, it is equally important to nurture and chart out development for diverse talent at all levels within the organization that will equip them to become leaders in the future. Gender diversity and inclusiveness should not be limited to the Board alone.

At Cipla, we strive to ensure that our people practices and systems are gender-inclusive. In FY 2019-20, we set up an Inclusion & Diversity Council, led by me, to give additional support to our efforts to build a truly diverse and inclusive workforce. It acts as an advisory body on all matters related to diversity and inclusion such as recruitment,
LEADERSHIP

leadership development, the launch of new initiatives, building a healthy work-life balance, and so forth. Maternity Leave, Paternity Leave, Adoption leave, Crecche facilities, institutionalisation of POSH, initiatives like Meri Saheli (Women employees-only forum to share women related issues at the workplace), are some examples of the policies that we have in Cipla to build a more inclusive culture. We also recently extended our group Medilclaim policy to cover LGBTQ and live-in partners.

Building a diverse culture gives a competitive advantage? Your take on it, please.

An organisation with a diverse talent pool not only makes for good social sense but also makes for perfect business sense. Welcoming new thinking and developing a culture of looking at things from a fresh perspective and a refreshed lens definitely gives a competitive advantage to the company. With diverse mindsets at the table, the company can operate in an all-encompassing way rather than adopting a traditional approach to their decisions; which is necessary with the evolving times. For example, at Cipla, we are not just looking at the industry from a typical lens of how a pharma company exists. And one of the major benefits that we have seen by bringing in diverse talents, is that we have been able to evolve in our role beyond traditional notions of being a drug manufacturer.

In today’s world, talent is attracted to companies that are not just diverse but inclusive too, making these companies the ‘employer of choice’. Organisations that take that on the front foot in being inclusive and diverse are companies where employees have a sense of belonging, making them want to be a part of a company that is future-focused while having a strong sense of purpose.

What does future-ready organisation mean to you? In my experience, a company that is ready to re-imagine their businesses to stay relevant in the evolving times, while staying true to their core purpose is a future-ready organisation. Cipla, being a part of an industry that is at the forefront of fighting the pandemic, we had to ensure an uninterrupted supply of medicines for COVID-19 and other illnesses despite the industry-wide challenges in raw material procurement, operations and logistics and subsequent nation-wide lockdown in India. Given the nature of the pandemic, we had to also ensure that employee health and wellbeing was not compromised in the bargain.

What helped us successfully overcome these roadblocks was the business-wide ‘Re-imaginaion’ exercise that was already underway at Cipla towards making our business future-ready and resilient on all fronts. As a business leader, making your core business growth drivers resilient to these changes, addressing and smoothly working past the changes while keeping the big picture in mind to secure the next leg of growth are questions we grapple with every day. For me, the answer lies in changing with the times. And therefore, the last few years at Cipla has been about embracing change, expanding and consolidating strategically, innovating, diversifying, finding the right partners, and staying alert to the latest business trends. These approaches have held us in good stead and will help us sustain our growth through the pandemic and beyond.

On the talent front, we have always welcomed individuals from diverse backgrounds with new thinking and developed a culture of looking at things beyond the traditional approach. This too adds to what forms the basis of a truly solid yet agile and future-focused organisation.

Given the tight work schedule, how do you maintain a work-life balance?

I try to allocate an equal amount of time to my family and work and treat both as equally important. It also helps me a great deal to have a strong support system both professionally and at home to help me do justice to both my roles. It is not easy to have a work-life balance when you are bearing responsibilities as a mother and as a professional. That said, maintaining a balance between work and personal life needs to happen on a daily basis. While there are some days that work takes the front foot, there are also days wherein our personal lives must be given priority. As a leader; it is imperative to understand how the two must be balanced and a conscious call needs to be taken on a day to day basis.

One should try and reach out for help whenever required. Fortunately for me, I don’t have inhibitions in asking people for help. My family and friends have always supported me by weighing in on various occasions and that has made the journey easier.

Personally, what are you passionate about and how do you pursue your interest?

I am extremely passionate about fitness. I love running as it refreshes my mind and helps me focus better, while also ensuring physical fitness. I usually aim to run at least three to four half-marathons every year. In order to gear up for these marathons. During the pandemic, I have been particular about my fitness regime as it boosts immunity. I ensure a regular exercise schedule and running on the treadmill.

What message do you have for professionals with diverse backgrounds venturing into the pharma and healthcare industry?

Drawing from my personal experience, while the industry I came from was completely different from the role and space I currently am in, it is the fresh perspective that worked in favour. What people could think is a drawback, may actually be the greatest advantage, if leveraged correctly. To those with diverse backgrounds venturing into the pharma and healthcare industry, I’d say never be afraid to take the leap and try something new or pursue your passion. And I see a lot of young professionals doing so, which is great. Also, always be game to learn and unlearn throughout your life. An open mind will help you grow not just professionally but also personally as opposed to rigidity.
Pharma industry’s digital maturity has accelerated with the adoption of digital engagement channels

Shashin Bodawala, Director – Business Excellence, Boehringer Ingelheim India, updates Viveka Roychowdhury on the evolution of digital pharma marketing strategies. He also explains the need for new regulations as the current code of conduct was not designed for a world of data, software, and digital, as well as the importance of data-driven insights and robust analytics to derive actionable outcomes from such initiatives.

Pharma companies have been criticised in the past for allowing marketing budgets to be bigger than R&D spend. While this may not be strictly true, has the shift to digital initiatives cut down on marketing spends? Where have the savings come from?

Up until 2020, pharma had fallen behind other industries for their investments in digital marketing. The pandemic served as a wake-up call, leading to a change in outlook. Business leaders have come to understand the potential of digital by looking at digital investments as a ‘growth-driver’ rather than a ‘cost-saver’. This, in turn, led to a rise in personalisation in terms of content creation and delivery along with new capabilities.

While this personalisation at scale required massive funds, our investments to realise these objectives have not seen a dip. Our momentum continues to stay strong, only our channels of delivery have seen a change. Digital is no longer viewed as an enabler, but an essential and integral part of the business model. This disruption has proven that only companies which are able to pivot to innovative ways of working, will emerge successful.

What are the regulations covering such digital marketing initiatives in India? Does the Uniform Code for Pharmaceutical Marketing Practices (UCPMP) hold for these initiatives too and are these sufficient? Any global benchmarks on this?

The code of conduct set by the...
UCPMP meant for ethical pharma marketing was not designed for a world of data, software, and digital. It was designed for a world of trade with limited focus on one stakeholder – the doctor. Already under pressure due to pandemic-induced changes, this code is inadequate to face critical challenges that new technologies pose. Critical aspects such as digital privacy and data protection is practiced by pharma companies out of volition rather (than) it being a mandate. In some cases, platforms providers define terms of use. Simply put, UCPMP does not spell out much on digital marketing initiatives.

A prompt and appropriate response to changes and the rush to capitalise on growth opportunities calls the need for greater coordination and updated nation-wide regulations. General privacy focused regulations, permission-based marketing models that respect customer preferences, and judicious use of digital channels (e-mail, SMS, WhatsApp, online ads, website) are a much-needed requisite.

What was the fallout of the pandemic on pharma marketing channels? Did doctor engagements suffer in FY21 as compared to FY20? While a digital strategy has been a part of organisational plans, we are now witnessing a move towards digital-only strategy, to survive and to move towards digital-only plans, we are now witnessing a growth. The pandemic has led to an evolution of the interactions. This change has led to an increased emphasis on being given to the role of technology and new channels, like emails, remote calls, messaging, webinars and social networks available to enable new modes of CX (customer experience).

Digital channels, have been directly in touch with the network of over 50,000 HCPs nation-wide, along with over 20,000 HCPs through our partner channels, making the total reach over 50,000. We have continued to emphasise on quality of interactions rather than quantity; and deploy a mix of complementary channels such as Veeva approved e-mails and phone calls. Through our initiatives, we have been able to maintain close to 90 per cent pre-pandemic HCP interaction levels.

Is digital the new normal for pharma marketing in the post-pandemic era, especially with some hospitals charging consultation fees for MRs to meet with doctors? Are doctors now more open to digital CMEs and MR e-meet s? Doctors are more receptive to digital channels, and time spent on these channels has also increased, improving our opportunities to reach them. Digital channels give an undivided attention and allow the HCP and the company to not use time allotted for patients. As of now, hospitals charging consultation fees is still rare and is not spreading as far as we see.

What parameters can pharma companies use to identify the right digital marketing initiatives? What are the means to judge RoI and cost-benefits of these initiatives? Digital is no longer viewed as an enabler, but an essential and integral part of the business model. This sudden disruption has demonstrated that only companies which are able to pivot to innovative ways of working, will emerge successful. The digital medium is also expanding as a platform for information, interactions, awareness and solutions about healthcare. As a result, a pool of better-informed patients and better-networked doctors will emerge.

For successful implementation of digital projects, marketers must take into consideration customer preferences, their affinity towards digital channels and content types. Every channel has a different role to play in the customer journey and the end objective must be expanding reach and increasing depth based on brand maturity. Digital engagement rates are metrics which are similar to KPIs used for measurement of RoI. Like in any other engagement method, RoI, in this case too can also be used by comparing measurable growth seen by digital v/s traditional. Such projects, if not possible on a full scale, can always be done through pilots.

How should pharma cos determine which initiatives can be scaled up and how? Which are the technologies that have already caught on in India and what more could be expected? Perhaps, the best part of deploying digital initiatives (in comparison to P2P) is that it leaves behind a permanent footprint in the form of accessible records which can be tracked, monitored and measured over time. Pharma marketing teams are realising the gaps in their customers’ data, and the gap in digital focus in their marketing strategies. Initiatives such as customer preferences, desirable content and its frequency, e-mail, messaging, remote meetings, webinars, etc. are aspects much of the industry has already caught up on.

With adoption of digital tech, we now have more and more data available and accessible to understand doctor preferences on therapies, treatments, disease areas, engagement timing, and preferred channels of communication. As pharma marketers, we need to equip ourselves with data-driven insights and robust analytics to derive actionable outcomes.

Have digital marketing initiatives helped sustain/exceed pharma companies’ growth of pre-COVID levels? What is your assessment of the pharma industry’s digital maturity in India versus global markets? The pharma industry’s digital maturity has accelerated with adoption of digital engagement channels, on a fast-track, and is going to continue even once the lockdown is lifted. The industry, as a whole, has adopted multiple interventions to engage HCPs through virtual ad-boards, podcasts and webcasts to discuss scientific aspects of medicines. Boehringer Ingelheim has continued to support medical practitioners to engage with global experts in these times of need, to provide much needed support on the impact of COVID-19 in patients, and has seen a majority of our HCPs adopt digital ways at an accelerated pace.

We expect that digital and virtual engagements will become a regular and an important part of the new normal even as we move out of lockdowns. This will help us offer improved access to global experts and scientific knowledge and trends and will enable us to offer scientific knowledge on medical advancements to our network of HCPs in India.
We will look at further expanding our footprint in India by relying on innovative new products

Shripad Joshi, President - India and South Asia, PerkinElmer talks about his company's plans for the India market and informs that a stream of new product introductions across life sciences, pharma and food testing will help PerkinElmer strengthen its positions in these key end markets, in an exclusive interview with Lakshmipriya Nair

The pandemic and subsequent lockdowns have posed unprecedented difficulties to businesses worldwide. They had to adapt to massive shifts in market dynamics. What were the biggest challenges for PerkinElmer and how were they dealt with?

Much of the conventional wisdom around the way business is done was turned on its head these last 15+ months. While the pandemic and lockdowns posed new challenges, providing solutions to our customers who are fighting the pandemic itself as well customers in pharma, food testing and other essential markets required us to be more agile and innovative to ensure that they continue to get the service that they have come to expect of us. We've sped up and improved many of the initiatives around customer service, be it ramping up our remote service capabilities, utilising high-end technology for a greater customer experience for virtual demos or the tools and training available for our sales teams to become more effective in selling.

What were your key learnings from the upheaval caused by the pandemic? How did they help in restructuring the company's growth strategies?

PerkinElmer is exiting the pandemic stronger and in faster-growing markets - and I couldn’t be more excited about the future. Outside of the great performance, we are having today and our strong outlook for the future, I am proud and excited for what PerkinElmer has been able to contribute to society over the last year and a half. The company’s success is a byproduct of the great work our employees do each and every day.

While our Applied Genomics portfolio enabled us to support COVID-19 testing across the country, our stream of NPIs across life sciences, pharma and food testing helped us to strengthen our positions in these key end markets. As we move forward, commercial execution of our NPIs, market-focused solutions and unmatched customer experience will be the key pillars of our growth strategy.

How big will be your focus on the life sciences sector in the next few years? What are the opportunities that you seek to leverage in pharma and healthcare?

Pharma is a very important market for us. We are seeing many exciting opportunities. The recent Production Linked Incentive (PLI) schemes for pharma will further bolster our position in the pharmaceutical industry.

How can the new LC 300 HPLC/UHPLC systems help Pharma laboratories who have been using other makes, traditionally, through the years?

The LC 300 HPLC/UHPLC is an outcome of the tireless efforts of our team. The product is a result of our countless interviews listening to customers explain their needs, challenges with existing platforms and areas where they wanted us to focus upon. Further, our new software platform “Simplicity” was built keeping in mind all the regulatory requirements that a pharma lab needs while ensuring a new age GUI and ease of use. LC 300 HPLC/UHPLC will continue to be a key aspect of our portfolio. We believe this solution not only meets today’s challenging laboratory needs but also strengthens our position in the chromatography market.

Where does India fit into PerkinElmer’s global vision? What are the unique opportunities and challenges offered by the Indian market?

India is a very important market for PerkinElmer and our footprint here goes beyond being a sales, service and application set-up. With the acquisition of Tulip Diagnostics in 2017, we also have a significant manufacturing footprint in the country. Furthermore, we believe that the commercialisation of technologies for local consumption will play a very important role in driving future growth in the country.

What are the key goals for the company in the next three years? What is the roadmap to achieve them?

We strongly believe in the potential of India and our key end markets, including life sciences, diagnostics and food will continue to provide many exciting opportunities. Our organic expansion with new product introductions (NPIs) in analytical and food portfolio, coupled with series of recent acquisitions of Horizon Discovery Group PLC, Oxford Immunotec Global PLC, OMNI International, Nexcom Bioscience and Immuondiagnostic Systems Holdings PLC in the life sciences and diagnostics space has positioned us to meet our customer needs today and down the road. We will look at further expanding our footprint in India by relying on innovative new products while continuing to focus on enhancing the customer experience.

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EQUIPPING PROGRESS

The lab equipment market is expected to boom as investments in life sciences R&D increase to deal with existing and emerging health threats

By LAKSHMIPRIYA NAIR
As pharma companies invest in building the labs of the future, the pharma lab equipment market is expected to boom in the coming decade. A 360 Market Updates report predicts that the global pharma lab equipment market size is expected to gain market growth in the forecast period of 2021 to 2025, with a CAGR of 4.3 per cent in terms of revenue and the global market size will touch $11850 million by 2026.

Let’s take a look at some of the primary drivers of growth in this segment.

The COVID-19 pandemic
In the near future, one of the key factors for the growth of the pharma lab equipment lab infrastructure and equipment to aid and accelerate R&D efforts by private players and governments. India’s lab equipment market is also going to see a growth spurt as a result of government initiatives to make India Pharma Inc stronger and self-reliant, increasing funding for life sciences, expansion of clinical capabilities, and growing along with a rapid increase in the number of sample tests have further led to an increased demand for lab equipment in various countries. In addition, the rising funding by the governments of various countries to boost the R&D for the development of vaccines and numerous medicines to meet the response of COVID is also anticipated to significantly drive the lab equipment market in the coming years.

Growing R&D spend
Even before the pandemic, spurred by the increased volume of drug discovery research, pharma lab equip-

The pandemic has underscored the importance of innovation, investment, and access. It has opened new avenues for the pharma laboratory equipment market from areas higher up in the value chain such as drug discovery, development, and API manufacturing.

Amit Chopra
Managing Director, India and South Asia, Thermo Fisher Scientific

India is one of the geographies for Agilent where we see great potential and we will continue to focus on expanding our local footprint. One of the focus areas for Agilent is to expand its capabilities and offer a complete biopharma workflow solutions portfolio.

Samir Vyas
Country Manager, Agilent India

Lab equipment related to cell/microbial cultures, biosafety, sample preparation, sample processing, storage are expected to grow in research, pilot or small-scale production while demand for large volume shakers, fermenters, bioreactors, single use culture vessels, large volume or continuous centrifuges are expected to stay high.

Dr D Murugananand
Head of Operational Marketing - India, Middle East & Africa, Eppendorf India

With Indian pharma expected to grow at a very impressive CAGR over the next few years, we are very well positioned to serve our customers. Our solutions span across the entire pharma value chain from disease discovery to quality control and manufacturing.

Shripad Joshi
President - India and South Asia, PerkinElmer
the demand for new drugs. Now, the COVID-19 pandemic has also underscored the importance of increasing R&D endeavours to deal with emerging infectious diseases and enhance preparedness of the sector to deal with such crises.

The growth potential of the lab equipment market is set to increase due to the growing demand for biologics as well. In 2018, as per WHO’s International Clinical Registry Platform, biologics comprised 40 per cent of the total trials in the pharma pipeline comprising over 50 countries.

Thus, mounting investments in pharma R&D is expected to impel progress of the pharma lab equipment market globally. Reports reveal that global life sciences companies are already spending over 20 per cent of their sales into new drug development.

India too is likely to witness a lot of growth in this segment due to similar reasons. “The pandemic has not just triggered the necessity of therapeutics but largely introduced the novelty and confidence in recombinant vaccines and monoclonal antibodies. Unfortunately, not all pharma is equipped to adapt new technologies and the ones that had the infrastructure and expertise in biologics benefited the most. Many more will expand into biologics, controlled processes using microbes or cultured mammalian or insect cells to produce therapeutics or other life-saving products instead of synthetic drugs. Investment in research is expected to increase substantially in areas of genomics, cell biology and proteomics,” informs Dr D Muruganand, Head of Operational Marketing - India, Middle East & Africa, Eppendorf India.

A report from Research and Markets also predicts, “The Asia Pacific region is anticipated to show robust growth opportunities during the coming years owing to the rising prevalence of chronic diseases and the growing investments in pharma research.”

Technological innovations
The pharma industry needs to be in a state of continuous, steady improvement, to spur medical advances. And, as the life sciences industry evolves and progresses, advancements in lab equipment too will rise. Pharma laboratories will have to be at the cutting edge of science and technology to be more efficient, improve time-to-market and reduce costs. Be it spectroscopy, chromatography, DNA amplifiers and sequencers, lab automation,
immunoassay analyzers, flow cytometry or any other process in the pharma sector, the demand for sophisticated equipment and instruments to aid and accelerate the process of drug discovery, development, analysis and modelling of the compounds will continue to grow.

Companies will also have to invest in emerging technologies and equipment for laboratory process optimisation, integrated automation for key data insights and even IP protection. Lab equipment will also be powered by digital technologies and be more connected to improve data traceability and integrity.

Beroe, a provider of procurement intelligence and supplier compliance solutions, in one of its reports, lists down technology trends that drive growth and progress in the life sciences lab equipment space. As per the report, some of them are as follows:

◆ **Sustainability:** Energy efficiency, minimising operating cost, increasing researchers' productivity and decreasing waste productions, would continue as focus points of lab equipment buyers in future

◆ **IP Protection:** Increasing popularity of cloud computing and mobiles in analytical and quality laboratories is demanding the organisations to redefine the information access protocols

◆ **Automation:** Lab equipment automation would be more focused towards enabling the continuous flow and decreasing the batching requirements during experiments

◆ **Portability of services:** Suppliers are focusing on developing the portable equipment, which can work as a supplement to the primary lab equipment that makes things easier for field scientists. It is cost-effective, as all samples would not be required to send to labs

◆ **Increased focus on data integrity:** Demand for efficient software for managing clinical workflow, in terms of regulatory compliance and data security, is increasing. Life science, healthcare industry contributed to the major share in the overall laboratory informatics (LIMS, CDS and others) market.

Industry players’ views and their offerings validate the report’s findings.

Elaborating on the tech trends, Dr Muruganand says, “Lab equipment related to cell/microbial cultures, data are archived.” He adds, “We have also built automation capability into the sample preparation side, as manual sample preparation can be variable and error-prone leading to time-consuming rework and poor results. While automation is becoming an integral part of each advanced laboratory, we also ensure that it comes with ease of operation as well as affordability.” (Check the whole interview at https://www.expresspharma.in/agilent-continues-to-focus-on-strategic-ma-rd-investment-to-expand-product-portfolio/)

**Growth in CRO services market**

Pharma and biotech players are increasingly relying on strategic partnerships with Contract Research Organisations (CROs) for drug discovery and development. The pandemic has also spotlighted the importance of such collaborations. They have become key partners at all stages of drug development, from target selection to clinical trials. This has created opportunities for CROs and as a result, this segment is poised for growth.

“The global CRO services market is projected to reach $73.77 billion by 2025 from $47.77 billion in 2020, at a CAGR of 9.1 per cent during the forecast period. Market growth can be attributed to the growing R&D expenditure, increasing outsourcing of R&D activities, and an increasing number of clinical trials,” forecasts a MarketandMarkets report. As a result, CROs would be among the lead buyers for lab equipment.

**Strategic Directions International (SDI),** a firm providing business intelligence on the market for analytical and life science instruments, forms that the companies in this segment are “eyeing a market opportunity in the Contract Research Organization (CRO) industry.”

The report states, “As demand for CRO services increases, the market opportunities for suppliers of analytical instrumentation used by CROs will see significant growth, even in the face of the global COVID-19 pandemic and subsequent recession.”

**Gung ho on growth…..**

India’s lab equipment market is going to see a growth spurt as a result of government initiatives to make India Pharma Inc stronger and self-reliant, increasing funding for life sciences, expansion of clinical capabilities, and growing academic-industry collaborations.
Dr Muruganand states, “Eppendorf as a one stop solution for pharma workflows, especially for biologics customers, is our plan for next few years. And to delight their journey further with us by offering our service support such as installation, maintenance, repair, calibration services and our IQ, OQ, PQ performance plans for GMP facilities are the key initiatives.”

“Eppendorf offers solutions to support various workflows for pharma and biopharma with wider product ranges in liquid handling, centrifuges, shakers, CO2 incubators, ultra low temperature freezers, PCR cyclers, fermenter and bioreactors. The Eppendorf - himac range offers ultracentrifuges and floor large volume centrifuges that suits for various applications. Digital solutions from Eppendorf such as VisioNize and eLABInvertory and eLABjournal are best fit for connectivity needs.”

Shripad Joshi, President - India and South Asia, PerkinElmer shares, “With Indian pharma expected to grow at a very impressive CAGR over the next few years, we are very well positioned to serve our customers. Our solutions span across the entire pharma value chain from disease discovery to quality control and manufacturing. The recent Production Linked Incentive (PLI) schemes for pharma will also trigger further investments. PerkinElmer has a strong leadership position in pre-clinical animal imaging, high throughput and high content screening, atomic and molecular spectroscopy as well as gas chromatography. Our recently launched liquid chromatography platform LC300 will further bolster our position in the life sciences and pharma segment.”

He adds, “India is a very important market for PerkinElmer and our footprint here goes beyond being a sales, service and application set-up. With the acquisition of Tulip Diagnostics in 2017, we also have a significant manufacturing footprint in the country. Furthermore, we believe that the commercialisation of technologies for local consumption will play a very important role in driving future growth in the country.

…but challenges exist
While the growth potential is huge, challenges like the financial crisis caused by the pandemic and high acquisition cost can decelerate the pace of growth. Likewise, the life sciences industry’s hesitancy in adopting advanced technology and automation can also put the growth story at risk. The disruption to R&D activities due to the pandemic is another challenge to be dealt with.

Outlook for the future
The pharma industry has a compelling need to optimise efficiency and efficacy of its complex and critical lab operations, thereby offering lab equipment players armed with a strategic roadmap, great product portfolios, significant investments and meaningful collaborations, tremendous opportunities for growth.
India underinvests in science

Unless we build more than simply two or three global centres of scientific excellence and training, and unless we reward our scientists to work in those institutions, it will be hard for us to compete with countries like China, informs Dr Swami Subramaniam, CEO, Ignite Life Science Foundation to Akanki Sharma in an exclusive interview.

Give us a brief about Ignite Life Science Foundation - the story of its origin, its goal and target audience, etc.

Ignite was launched formally at an event in January 2020 but its story had begun prior to that. It is the brainchild of Professor Ramaswamy Subramaniam, who was at that time heading C-CAMP in Bengaluru - a part of the Bangalore biocluster. During his working years in India, he recognised many problems Indian scientists were facing and it was not simply a matter of quantum of funding; there were multiple factors.

Research productivity thrives in a complex ecosystem. Very few countries in the world have succeeded in building such self-sustaining ecosystems consisting of multiple factors - government funding, academic institutions (that are often private) that consider research an important purpose for their existence, ability to attract the best students from the global pool, private philanthropists willing to support science through large endowments and the co-existence of research universities with communities of investors, start-ups and large company R&D facilities - The Boston-Cambridge (Harvard) area and the San Francisco Bay Area (Stanford), Cambridge University (Cambridge, UK) and the Stockholm area (Stockholm University) are some examples.

Building out such ecosystems takes time, but Rams and his scientific peers got together with leading business persons and academics in India to find Ignite as an organisation that would nurture good science using philanthropic money. Connecting uHNIs to science in Indian universities is the first step towards getting widespread acknowledgement of the challenges facing Indian science and pooling resources and capabilities to solve some of these challenges - funding is only one among those.

So, Ignite is an organisation with the purpose of building - not just good science in the country, but also building research capacity because there are critical areas of research where a capacity in the country is missing because of historical reasons. For example, we don’t have good fundamental vaccinology research going on in India as we noticed during this last pandemic. The only vaccine launched used an older technology. There was nobody in India, ready with messenger RNA technology for developing vaccines, and this is important because the fastest route to launch a vaccine is using messenger RNA technology, which is why the Pfizer vaccine got launched way before the Bharat Biotech one.

So, if we see, this is a gap that we identified; but, like this, there are many other missing pieces in the overall puzzle of Indian science. Unless those pieces are filled, Indian science will always find it hard to deliver to the expectations and requirements of India.

There are other healthcare needs in India, which are unique to the country. The second one could be antimicrobial resistance, and the third would be nutrition. So, in some of these areas where India faces unique challenges and problems, Indian capacity needs to be built. Hence, Ignite was found with these two purposes in mind.

Biocan has invested Rs 5 crores in Ignite Life Science Foundation for life sciences research. Share details about the project for which this fund has been received.

Our first set of projects is related to pandemic preparedness and antimicrobial resistance. The specific project for which Dr Kiran Mazumdar-Shaw’s funding will be used is to be determined in the coming weeks because all our proposals go through a rigorous external review. So, we will, within the next two to three weeks, decide which project specifically gets funded from the initial set of proposals received.

Then, as we grow our donor pool, we will expand the portfolio of projects. We will also be bringing forward projects in the area of antimicrobial resistance. So, as and when we receive good proposals that get good external reviews, we will be ready to fund those, and, hopefully, additional funding will then come in to Ignite from new donors. Therefore, we can increase the number of projects we fund. The more we do, the better the outcomes will be, and the more effective we can be in terms of creating changes or new developments that are favourable in Indian science.

So, we do hope that we will get support from more donors.

How active is ISFL in life sciences research? What all has it done to date and what does it intend to do in the upcoming days?

Ignite is a startup. We are only getting going with the funding that has just come in. We really had not started any project work until this initial round of funding from Dr Shaw. Now, what we plan to do with this funding, I have briefly alluded to. We have identified other areas for research, including the ones mentioned earlier. I just mentioned some of them could be based on donor interest. I mean, while we can find to fund.

I don’t want to get ahead of the story by saying that we would raise so much money for sure, but I think we would raise enough money to fund all the good projects that we can find. While some of these will make a huge difference, some will make a smaller one; but all will be executed in a manner that ensures that excellence in research output is maintained.

As things change in the environment, we will also make adjustments in what we do. One of the things we do want to do in addition to funding projects is to consciously bring scientists together, not just as collaborators on projects, but as communities of practice. For example, if we take pandemic-preparedness, we would like all the scientists who are, in some way or the other, doing work on pandemic preparedness to come together on a common communication platform that Ignite will build for them. We believe that the exchange of ideas between, and maybe some collaborations among scientists across institutions, can strengthen Indian science in a manner that simply funding science cannot achieve. So, apart from funding science, we want to be an active promoter of collaborations and we also see opportunities for Indian scientists to collaborate with counterparts overseas.

We would like to facilitate that so that the best practices, the best knowledge, the best ideas, the best technologies,
the best reagents and the best research tools are available to, and in some instances, generated by Indian scientists. So, I think research and science is ultimately a global activity and we want to make sure that Indian scientists are a key part of the international research community in science in at least a few chosen areas, if not in every area.

Do you think India lags behind when it comes to investing in science and innovation? If yes, what losses has it brought to the country? If not, how strong has the sector been and what achievements has the country witnessed? Explain in detail.

India underinvests in science. More importantly, India underinvests in its scientists. Unless we build more than simply two or three global centres of scientific excellence and training, and unless we reward our scientists to work in those institutions, it will be hard for us to compete with countries like China. We also cannot take the China route of super funding science since our resources are comparatively limited. Nevertheless, we have impressive human resources and we need to invest in its development. Unlike China, we are a free society where research and inquiry of the highest level can flourish. However, many players - private donors and the government must each do their part to make this happen. Hopefully, Ignite can play a role in enabling this on behalf of the major stakeholders, including the scientists.

How do you intend to create and sustain a robust environment that promotes world-class scientific research and productivity in India?

Ignite is in the business of creating the facilitating mechanisms and processes that allow scientists to do their best work, and when appropriate, rapidly convert their ideas into products for the benefit of the community. We see ourselves as seeding these efforts. At some points, the seeds will develop and grow self-sustainably. Today, for a good scientist who can compete globally, there is no shortage of funds. For good and great scientists to emerge, we need to create an enabling environment. That is what we will do.

What steps are you taking to upgrade your R&D space?

We do not run our own laboratories. The investigators we fund and the host institutions provide this. We will support specialised equipment to reagents that they need.

What kind of aid do you seek from industry stakeholders - philanthropists, scientists, policymakers, etc. for the growth of ILSF?

First, we need them to believe in what we do and support us with their words of encouragement. As a next step, for those who are able, we ask them to reach out to us to understand how they can support our mission - through funds, partnership, whatever. We will do the same by reaching out proactively to our stakeholders and when there is an opportunity, we will collaborate with like-minded institutions. The task is huge and no one player can do this. We hope other Ignites will also arise and we can all do together what none of us can accomplish individually.

Are you in talks with any organisation or government authority with regards to further investment in your foundation? If yes, kindly share details about the same.

We are in the very early stages of discussions with several potential donors. None of these is at a stage where it would be meaningful to disclose. We will keep you posted about any developments, as they happen.

What is your business plan for the next five years?

As I said earlier, it is good to have plans, but it is much better to execute on a small plan and then reveal the big plan. Our ambition is to raise over Rs 100 crores and become a partner of choice for both donors and scientists. Time will tell if we live up to this commitment.

To know more call us Toll Free 1800 22 8884 / 1800 10 28460 or email sales.mtin@mt.com

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Express Pharma 25
July 2021
Key process elements to achieve successful artwork

Nooru Raju. Artwork - Senior Manager, Freyr Software Solutions, explains and addresses some of the pressing critical artwork challenges and the implementation of key process elements to produce error-free artworks consistently with minimal effort.

Pharma and life sciences companies are governed by the global Health Authorities with stringent quality norms. With years spent on innovating new drugs, the life sciences organisations, due to tight timelines, sufficient time may not be available for artwork design processes, which may result in an compliant product presence. In such scenarios, a company's well-defined artwork management system plays a key role in curtailing the possible compliance setbacks. With defined regulatory artwork processes, organisations can sustain such critical situations, especially in time-bound pressures.

Being an intrinsic part of the pharma product supply, the Artwork process always goes through constant pressure to deliver accurate output in a compressed time frame. Even minuscule errors (such as misplacement of a decimal point) can be costly, damaging, and puts companies at risk owing to the threat of product recalls, health authority warnings, and fines. According to the data by the US Food and Drug Administration (USFDA) over a six-month period, there were a total of 455 recall notices, of which 51 per cent were attributed to faulty packaging, which sometimes root back to Artwork inefficiencies.

Due to tough regulatory requirements and heavy investments in innovative or generic products, pharmaceutical and life sciences companies across the world must have established and defined artwork processes in place that guarantee zero errors and secures timely approvals for quick market entry of the products. These can truly be possible by implementing technology-driven robust processes that help to efficiently integrate the areas of repository management, data management, label regulatory control, authoring, and design control.

**Artwork process challenges**

It is quite evident that when it comes to Artwork management there are certain challenges. If these challenges are not timely addressed, there is a risk of regulatory fines and recall, increased time-to-market, loss of competitive position, and damaged brand equity. Here are a few of them:

1. **Compliance burdens:** Artwork and labelling compliance is probably the biggest challenge for pharma companies of any size. From keeping abreast with the ever-evolving local or regional regulatory authority updates to adapting to the new market requirements is a huge and complex task. A company, whose core focus is to innovate medicinal products, is challenging to track the regulatory updates.

2. **Recall risks:** Product recall is a terrible experience for a manufacturer. As per research, it is believed that more than 50 per cent of product recall are due to labelling or artwork packaging, and more than 60 per cent of all recalls are caused by human errors. The consequences of product recalls are dire. Also, such errors may cause serious risks to patient safety, which may result in fines, reputation damage, and even job losses.

3. **Multiple artwork revisions:** Reworks can be costly, time-consuming and ultimately cause delays in the artwork review and approval process. When a job card is initiated without much information on the drug, there will be delays and errors, resulting in rework. Also, reactive and poor communication are the major reasons that cause unnecessary revision cycles that consume resources bandwidth and delay the artwork design output.

4. **Poor tracking of the process:** The artwork process flows across many facilities and regions globally making it difficult to track. Hence, it is challenging to track accurate information and report and measure performance. It calls for a necessity for process centralisation, to enable visibility throughout the product lifecycle for identifying any bottlenecks and process inefficiencies.

5. **Difficulty integrating with partners:** Integrating with partners and global expansion will be highly difficult to achieve without a standardised artwork workflow. Also, improper communication with the partners results in more reworks that delays the entire process, which in turn may cost much to a partner.

6. **Delayed time-to-market:** Poor stakeholder visibility, inefficient processes, and difficulty in ensuring the completion of mission-critical tasks along with all the challenges mentioned above can put the artwork creation and approval process at a source of risk resulting in delayed market entry. The consequences of delays can be significant and costly.

**An ideal artwork process workflow**

To secure a compliant market-place manufacturers must follow an ideal workflow for artwork. *(Check diagram on Page 28)*

- **Implementation of key process elements for successful artwork:** Pharma artwork is a complicated and lengthy process as developing the product itself. Implementation of standardised processes and automation can protect organisations from vulnerabilities and accelerate their existing workflows. Here we discuss some of the key elements to achieve successful artwork.

- **Aligning unstructured data:** Many pharma and life sciences companies are still using traditional methods to manage their artwork and approval processes. It necessitates routing of printed documents, which host a lot of risks and inefficiencies, through emails and folders. These documents can easily be lost, damaged, or misplaced, costing valuable time and resources. Also, therein such cases, it becomes difficult to find out which document copy is the most recent. Without a proper version, it is never clear that your spreadsheet has been routed to the right parties for approval.

- **Streamline artwork process:** Pharma must have an ideal artwork process to come up with error-free artwork with quick time-to-market. Therefore, organisations must move towards standardising and harmonising the existing processes. It helps in creating and developing artwork under a common platform in a standard way.

- **Transform to automated/digital artwork management:** The traditional Artwork management process has been cumbersome. There are still many companies using the old manual processes for Artwork management. Incorporating an automated artwork approval process into your product lifecycle can help you deliver on-time, quality work consistently. Automation acts as an aid for manual
Electronic automations and process optimisations for first time right submissions

Balaji A, Manager, Regulatory Operations, Navitas Life Sciences (a TAKE Solutions Enterprise) informs that we are witnessing a new era for eCTD submission publishing with a push towards first-time-right submissions with a short-turnaround time, 100 per cent quality, and zero per cent HA rejection

The aim for any pharma company is to submit First-Time-Right Submissions to the Health Authorities (HA) to reduce the approval timeline and go-to market as early as possible. We know that the publishing process is complex, with pharma companies using various publishing tools to both compile and publish documents in eCTD, Nees, and paper formats as specified by the HAs. In our experience, over 70 per cent of small to medium companies are still following a manual process to process and add documents to the Document Management System (DMS) and, subsequently to the Publishing tool. This is not only time-consuming, but it also expends additional efforts both pre and post publishing.

In adopting such manual processes and ways of working, pharma companies are facing challenges relating to:

◆ Effort: With additional time necessary to complete the submission, there is the potential to not meet the HA timeline, there is an impact on the utilisation of resources, as well as the timeline forecast for complex submissions.

◆ Document changes: Last minute amendments to the published document, or inclusion of additional documents, will lead to rework and/or additional efforts which, in turn, affects both the timeline and quality.

◆ Quality: Additional time spent by senior publishers and/or the QC reviewer often means that multiple reviews are required for a simple submission owing to manual errors.

Pre-Publishing

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To ensure that the document is submission ready

Post-Publishing

| Once the submission is compiled, there is a need to provide external hyperlinks to documents which might reference previously submitted sequences. Publishing tools have the functionality to execute this, but manual effort is required |

Mapping the current process steps together with their associated dependencies. Figure 2 provides an example of the typical manual process steps that are seen within Publishing.

With automation, manual process steps can be dramatically reduced, as depicted in Figure 3 with some 27 manual steps, decreasing to just eight manual steps, with the remaining 19 becoming automated.

By implementing automation in the eCTD submission publishing process, manual intervention is eradicated and the ability to auto build is achieved using the publishing software to generate an XML backbone with metadata applied, and submission ready documents are prepared with the appropriate PDF mapping.

Continued on Page 28
Electronic automations and process...

Continued from Page 27

properties applied per ICH guidelines.

In our experience, there are numerous advantages to eCTD process automation including:

◆ Up to 40 per cent reduction in the usual effort(s) consumed by manual processes
◆ A gain in overall productivity
◆ First Time Right Submissions
◆ Rapid turnaround time

We are seeing something of a new era for eCTD submission publishing with a push towards First-Time-Right submissions with a short-turnaround time, 100 per cent quality, and 0 per cent HA rejection. This, in turn, avoids any “Refuse to Review” for not adhering to eCTD specifications and, therefore, reduces the approval time and minimises HA queries.

Periodic review and streamlining of existing global SOPs help to identify any gaps as well as enhances the process to help produce quality submissions. Figure 4 below provides a high level illustration of use cases for publishing.

Figure 4: Future State Regulatory Submission Strategy, process, organisation, and technology

Key process elements to achieve...

Continued from Page 26

With this future state strategy enabled, organisations can:

◆ Progressively achieve better value through long-term investments while transitioning from the current model to a more data and knowledge centric model to maximise automation capabilities with process bots
◆ Improvise or re-engineer the current process in parallel to optimise the current system to achieve higher benefits

Figure 3: Example of process steps with proposed automation

Figure 3: Example of process steps with proposed automation
Our greatest contribution has been in making the last-mile cold chain viable and reliable

Tessol solutions allow pharma companies/logistics providers to offer end-to-end transportation of vaccine packages from source to end customers without breaking the cold chain up in a highly temperature-controlled environment, informs Rajat Gupta, founder and CEO, Tessol, to Akanki Sharma

Give us details about the solution that you have launched recently for vaccine delivery across India to aid the COVID-19 vaccination drive.

Tessol took up the challenge to build products for safe transportation of vaccines at the beginning of the pandemic. We have all the required expertise and technology in-house to build these solutions that we believed will be critical for the large-scale rollout of the vaccine.

We tied up with Koolex logistics, the largest pharma trucking company in India and built solutions for long-distance and last-mile movement of pharma products. Our products cover all temperatures from -20 degrees Celsius (required for Moderna and Sputnik V vaccines) to two-to-eight degrees Celsius required for other vaccines like Covaxin and Covishield. We have already validated our solutions with several pharma companies and logistics players. In order to facilitate the industry, we have also opened our doors to sell the Phase Change Material (PCM) - our core technology - product to companies engaged in making cold chain solutions, especially for the pharma industry.

What made you take this step and since how long have you been doing this?

We have launched the vaccine delivery solution keeping in mind the massive ongoing drive in India to inoculate each and every Indian. The entire world is facing a challenging situation due to the ongoing pandemic. Therefore, vaccinating the maximum number of people in the country is the only way to halt the ongoing growth in infection. Tessol is contributing its bit by launching vaccine delivery solutions for pharma companies, logistics companies and organisations. With the help of our technology, we are supporting this huge cause of vaccinating many Indians.

As of now, how many areas/small towns/cities/states have you catered to? Kindly name these and also tell us about the contribution that you have made there.

Tessol is present in all major cities in India like Mumbai, Bengaluru, Delhi, Chennai, Cochin, Coimbatore, Ahmedabad, Pune, Nagpur, Hyderabad and many others. With over 500 vehicles and 300 home-delivery units in operation, our solutions cater to clients on a pan-India basis. Our greatest contribution has been in making the last-mile cold chain viable and reliable for our customers. Given the nature of the last-mile retail and home delivery market, the cold chain is invariably not viable for most customers forcing them to either break the cold chain or rely on unsafe options such as dry ice. Customers who do not wish to do either, choose not to cater to the segment. We have effectively addressed this problem by enabling our customers to not only expand their reach but by also ensuring that product quality and safety is not compromised till the last delivery point.

What are the major challenges faced by the Indian supply chain when it comes to delivering pharmaceutical products to the last mile and what immediate steps must be taken to overcome these?

In my view, the biggest challenge in the supply chain in India is the viability, given low price points. In many cases, it is cheaper to waste the product than to save it. Harsh but true. We see this not only in commodities like food and vegetables, liquid pouch milk, etc. but also frozen food, etc. at the last mile.

Even if the product has a high price point, given the scenario of fragmented retail fabric in India, having the throughput to one location or shop is small, and even the smallest refrigerated vehicle is too big for carrying that load. Therefore, there is a tremendous price pressure on the cold-chain operators while the basic cost is fixed with the minimum CAPEX and OPEX (especially with increased diesel prices). In most cases, they end up subsidising the local movement through storage or use unorganised players who have limited cold chain experience.

Briefly explain the solutions built by Tessol for long-distance and last-mile movement of pharma products.

Tessol solutions allow pharma companies/logistics providers to offer end-to-end transportation of vaccine packages from source to end customers without breaking the cold chain up in a highly temperature-controlled environment. The company’s proven thermal battery and technology provides the desired temperature control (from -25 degrees Celsius to +25 degrees Celsius) across enclosures ranging from a five-litre bag to 20-feet (10 ton) truck. Its core technology uses proprietary PCM heat exchangers and chargers that store thermal energy (therefore, the term thermal battery) and releases it as required during the transport period.

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We have active partners in Dubai, African Continent, Sri Lanka and New Zealand. We have also have 25 active Tamsys units running in New Zealand and have powered the country’s first zero-emission refrigerated van. We also partnered with Tata to supply the first PCM-based ice cream truck in Mozambique. Further, our bike delivery solutions have been used in Dubai by our partners.

While we are already investing in growing our capacities, at this point in time, we are also actively looking at investments and strategic partnerships that can help scale our technology and solutions to a global level. It is no longer a small play that we are sitting on - our solution is critical for the growth of pharma and food retail not only in India, but globally. The incoming demand from overseas is an evidence of that.

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<table>
<thead>
<tr>
<th>Sr.No.</th>
<th>Grades</th>
<th>Description</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>HiCel™ 50M</td>
<td>MCC 101</td>
<td>Since it has small particle size, can be used for both wet and dry granulation. Effective when used with large particles because of its binding properties. Primary use is in the wet granulation applications.</td>
</tr>
<tr>
<td>2</td>
<td>HiCel™ 90M</td>
<td>MCC 102</td>
<td>Has larger particle size, improved flowability, especially with smaller particle size components. Most popular grade of MCC used in direct compression.</td>
</tr>
<tr>
<td>3</td>
<td>HiCel™ LP200</td>
<td>MCC 200</td>
<td>Large particle size used with poorly flowing actives. Improves flowability &amp; facilitates high speed tableting of direct compression blends and reduces tablet weight variation.</td>
</tr>
<tr>
<td>4</td>
<td>HiCel™ XLM 90</td>
<td>Low moisture MCC 102</td>
<td>Equal to grade 102/90M, but low moisture content (&lt;1.5%) It is recommended for extremely moisture sensitive active ingredient.</td>
</tr>
<tr>
<td>5</td>
<td>HiCel™ 25M</td>
<td>MCC 105</td>
<td>Finest grade for chewable tablets. Improves texture and compressibility.</td>
</tr>
<tr>
<td>6</td>
<td>HiCel™ HD50M</td>
<td>MCC 301</td>
<td>Similar to HiCel™ 50M &amp; HiCel™ 90M in particle size, but with higher densities.</td>
</tr>
<tr>
<td>7</td>
<td>HiCel™ HD90M</td>
<td>MCC 302</td>
<td>Both grades have improve flowability and facilitate thinner tablets.</td>
</tr>
<tr>
<td>8</td>
<td>HiCel™ 90M SCG</td>
<td>Coarser than 90M</td>
<td>Coarser than HiCel™ 90M, this grade has been specially developed for high density with fine particles API's.</td>
</tr>
</tbody>
</table>

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Hydrocel-CR, USP Hypromellose (HPMC), is designed for a hydrophilic matrix agent having tighter specifications, which is especially suitable for wet granulation and direct compression application. Consistency in every batch is of the highest level, as Hydrocel HPMC is developed with stringent in-house specifications with a narrow limit. All the Pharmacopeial Monographs as well as manufacturers offer product with 75-140% result of declared value for viscosity. However, our Hydrocel HPMC is developed such that we can provide you material with 90-120% result of Declared value (Narrow range = Higher Consistency). This ensures the Drug Release Profile is consistent and almost a replica of results for each subsequent batch.

**Information for best results with Hydrocel HPMC**

- Drug solubility is one of the most influential factors for designing a drug release pattern. Highly water-soluble drugs require higher amounts of HPMC in the tablet.
- Suitable types of HPMC are the Hydrocel AW and CW grades, especially CW-CR grades, which have a characteristic of quick hydration and gel formation.
- The higher viscosity of HPMC or amount of HPMC in the tablet can decrease the drug release rate. Generally, an optimum content of Hydrocel in the tablet is at least 20%. If the content is below 20%, there is a risk for initial erosion or excess dissolution in the first stage. This is applicable for a drug like Metformin HCl. Of course the dosage will differ based on the API, label claim of the API and type of release profile (Monographed or In-House).
- Various Sustained Release / Controlled Release / Extended Release formulations such as Aceclofenac, Nifedipine, Metoprol, Pregabalin & many more have been developed using Hydrocel HPMC by our Team and has gained commendable appreciation from Customers across the Industry Worldwide.
- Preparation method also affects the dissolution profile due to the difference of HPMC particle distribution in the tablet. In the case of wet granulation, most of the water can be taken up by Hydrocel, resulting in the separation of Hydrocel and the other components. (i.e. large particles with high Hydrocel content and ungranulated drug in the fine particle fraction.). Hence, ideal moisture content must be available post drying of granules.

**Adjusting the dissolution profile with Hydrocel HPMC**

Sustained release dosage forms have number of advantages over conventional dosage forms. It results in less fluctuation of steady state levels of the drug in patients and allows for improved patient convenience and compliance due to less frequent dosing. The oral dosage form should be designed and formulated for the optimal sustained release dosage for your specific purpose.

- In case dissolution is too fast:
  - Increase the content of Hydrocel in the tablet formulation.
  - Select higher viscosity grade of Hydrocel.
  - Increase the tablet size.

In case dissolution is too slow: Opposite adjustments of too fast dissolution. Also, you can always get in touch with our Team Pioma who will be happy to assist you on the technical guidelines related to Hydrocel HPMC.

**Safety Standards and Pharmaceutical Compliance**

HYDROCCEL - HPMC is supported with complete documentation. Our product is US DMPF certified and our site is US FDA Registered. This speaks volumes regarding the products standards, safety, pharmaceutical compliance. Since it is multi pharma-copeial (USP/IP/BP/Ph. Eur./JP) compliant, it is being used for Regulated Markets as well as Domestic market formulations. In addition to all these features & benefit, the cherry on top is that HYDROCCEL - HPMC is cost competitive as well.

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Because of its superior performance and narrow limit, Hydrocel HPMC has found acceptance across the globe within the pharmaceutical industry. Its multiple benefits including consistency of results, stability in terms of supply and cost effectiveness makes it popular amongst the formulators and research scientists worldwide as well as its ease of use has garnered tremendous support from the Operations Team at various pharmaceutical plants across the industry. Contact us for more information about Hydrocel HPMC today.

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B&R’s PharmaEdge is an integrated, out-of-the-box, optimised offering for the pharma industry to meet increasing demands of FDA compliance. It helps to achieve advanced functionality of detailed reporting, analytics, and business intelligence while ensuring top class cyber-security.

Pharmaceutical industry is facing unprecedented challenges with an increase in regulatory compliances. On top of that, the complexity of regulatory compliances has increased substantially as well over recent years, and it is expected to grow further in the near future.

On the other hand, the silver lining is that advanced automation technologies have become an essential part of pharmaceutical processes. From lowering production costs to simplifying data collection, compliance and management between various machines, lines, plants and processes, automation solutions have ensured consistent product quality, flexible production-alongwith strong adherence to ever changing regulatory compliances.

B&R’s PharmaEdge is an integrated, out-of-the-box, optimised offering for the pharma industry to meet increasing demands of FDA compliance. It helps to achieve advanced functionality of detailed reporting, analytics, and business intelligence while ensuring top class cyber-security. PharmaEdge is a unique solution which offers all benefits of SCADA and a robust control system in one device. On top of that, the possibilities to add energy monitoring, condition-based predictive maintenance, and MES / ERP connectivity enable the implementation of intelligent and futuristic machines.

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Yokogawa Releases Platform for Advanced Control and Estimation R5.03

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Yokogawa Electric Corporation announces that Yokogawa and Shell have jointly developed Platform for Advanced Control and Estimation R5.03 and will release it on June 2 as a solution under the OpreXTM Asset Operations and Optimization family.

Platform for Advanced Control and Estimation is a software suite that brings together Shell’s advanced plant process control technology and Yokogawa’s real-time control technology to help customers improve productivity by increasing product yield and reducing energy consumption. This version upgrade supports Open Platform Communications Unified Architecture (OPC UA)*, the latest version of a communication standard that improves plant systems interoperability and security, and provides the basis for digital transformation to help customers transition to industrial autonomy.

* OPC is the interoperability standard for the secure and reliable exchange of data in the industrial automation space and in other industries. OPC UA is recognized as a communication standard for Industry 4.0, benefiting from high security and scalability without hardware or OS dependence.

Development Background

Advanced process control (APC) systems improve product yield and reduce energy consumption by maintaining temperature, flow rate, pressure, and other process values within a set range and keeping them as close as possible to their optimal set points. Such systems are increasingly used in facilities such as oil refineries, petrochemical plants, chemical plants, and LNG trains.

Yokogawa’s Platform for Advanced Control and Estimation suite delivers the following functionalities:

- Multivariable model predictive control (the control of multiple variables based on predictions made using models of the dynamic characteristics of plant responses)
- Soft sensing for estimating quality in real-time based on temperature, flow rate, pressure, and other process values
- Customization of calculations

Yokogawa has continued to enhance this suite in response to changing customer requirements. The release of version R5.03 meets urgent industry needs for enhanced plant systems interoperability and security.

Enhancements

1. Feature expansion

A) Support for OPC UA

Version 5.03 conforms to OPC UA, the latest version of the OPC communication standard. OPC is the prevailing data exchange standard in the industrial automation field. Support of the latest OPC version enables users to securely exchange data with OPC UA devices and work with data from a wider range of sources.

B) Addition of new Base Layer Control (BLC) model

A new BLC model that employs proportional integral differential (PID) control logic has been added. This model uses the PID parameters of a distributed control system (DCS) to represent the dynamics of a PID loop. This improves control by reducing mismatches with the process described by the BLC model.

C) Expansion of Shed Logic to Event Logic

Shed Logic is a function that customizes how applications operate. It gives users the freedom to customize the behavior of their applications to suit the operating conditions of a plant. Shed Logic is now called Event Logic, with expanded functionalities that eliminate the need for custom code and enable event-based processing for measurement validation, model change, etc.

2. Improvement of maintenance features

A) Design-Time advisor

This function verifies the parameter values for applications, processors, and variables that have been set using Design-Time and displays a warning message for any invalid parameter settings. By making it easier to identify and correct configuration errors, this helps to improve applications.

B) Automatic trend scaling

The scale of the trend pen (upper and lower limits of the trend display) can now be adjusted automatically. This feature reduces the time and effort required for setting the trend scale.

C) Visualization of OPC performance data

It is now possible to view OPC performance metrics such as read time when accessing data from an OPC data access/unified architecture (DA/UA) server. In addition, a list can be displayed that shows all accessible OPC items. This feature makes the diagnosis of OPC DA/UA access easier.

3. Improvement of execution speed and robustness

Applications are more robust and run faster. Also, lab updates take significantly less time to perform and are more robust.

Major Applications

Advanced control of continuous plant processes in the oil, petrochemical, chemical, gas, and other industries

Sustained-release (SR) dosage forms: The Matrix system

Mayuresh Sainkar, Technical Manager, Shin-Etsu Chemicals, India informs that his company offers application-specific selection of suitable HPMC viscosity grades

Oral drug delivery has been known for decades as the most widely utilised route of administration among all the routes that have been explored for the systemic delivery of drugs via various pharma products of different dosage forms. Nowadays most pharmaceutical scientists are involved in developing an ideal DDS. This ideal system should have the advantage of a single dose for the whole duration of the treatment and it should deliver the drug directly at a specific site. Scientists have succeeded in developing a system that can be as near to an ideal system and it encourages the scientists to develop a controlled release system.

Sustained Release Drug Delivery System (SRDDS) is designed to release a drug at a predetermined rate by maintaining a constant drug level for a specific period of time with minimum side effects. Now a day’s focus on the development of SRDDS has increased, as very few drugs are coming out of research and development and already existing drugs are suffering the problem of resistance due to their irrational use specifically in case of drugs like antibiotics. The major goal of designing SR formulations was intended to modify and improve the drug performance by increasing the duration of drug action, decrease the dosing frequency, reduced side effects, decreasing the required dose employed and providing the shortest possible time by using the smallest quantity of drug administered by the most suitable route.

Polymers used in sustained release (SR) design of dosage forms
Over the past 30 years, polymers have been one of the most widely used options for the formulation of sustained-release compounds with a view to modulating the release profiles of drugs in a satisfactory way; and in this scenario, it is common to discover mixtures of different kinds of polymers. This is why a profound knowledge of the factors affecting the release rates of drugs is critical for the correct scientific development of sustained-release systems. The following are the general categories of polymers that are used in controlled release drug delivery:

<table>
<thead>
<tr>
<th>Polymer class</th>
<th>Coating polymer</th>
<th>Chemical structure</th>
<th>Elongation value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulosic polymer</td>
<td>Ethyl cellulose</td>
<td></td>
<td>&lt;5%</td>
</tr>
<tr>
<td></td>
<td>Hypromellose (HPMC)</td>
<td></td>
<td>Around 40%</td>
</tr>
<tr>
<td>Acrylic polymer</td>
<td>Ethyl acrylate and Methyl Methacrylate copolymer dispersion</td>
<td></td>
<td>&gt;365%</td>
</tr>
<tr>
<td></td>
<td>Ammonia Methacrylate copolymer dispersion</td>
<td></td>
<td>&lt;50%</td>
</tr>
<tr>
<td>Vinyl polymers</td>
<td>Polyvinyl acetate dispersion</td>
<td></td>
<td>&lt;1.1%</td>
</tr>
</tbody>
</table>

Source: Oral Modified Release Multiple-Unit Particulate Systems: Compressed Pellets, Microparticles and Nanoparticles Nihad Al-Hashimi 1, Nazish Begg 1, Raid G. Alany 1, Hany Hassanin 2 and Amr Elshaer 1

<table>
<thead>
<tr>
<th>Drug/s</th>
<th>Polymer used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indomethacin</td>
<td>HPMC 100cps, HPMC 4000cps, HPMC 15000cps</td>
</tr>
<tr>
<td>Metformin HCl &amp; Gliclazide</td>
<td>HPMC 4000cps, HPMC 15000cps, PVP K90 D</td>
</tr>
<tr>
<td>Ambroxol HCl</td>
<td>HPMC 15000cps, Eudragit RSPO</td>
</tr>
<tr>
<td>Metformin HCl</td>
<td>HPMC 100000cps, HPMC 4000cps, HPMC 15000cps, PVP K30</td>
</tr>
<tr>
<td>Repaglinide</td>
<td>HPMC 15000cps, HPMC 1000000cps, Guar gum</td>
</tr>
<tr>
<td>Carbamazepine</td>
<td>HPMC 100000cps, Eudragit RLPO, Eudragit RSPO</td>
</tr>
<tr>
<td>Glimepiride &amp; Metformin HCl</td>
<td>Eudragit L100, Eudragit RSPO, PVP K30</td>
</tr>
<tr>
<td>Amisulpride</td>
<td>HPMC 4000cps, PVP K30, Polyox, Carbopol 71G, Cross Povidone, Kollidon SR, Xanthene’s Gum</td>
</tr>
<tr>
<td>Tramadol HCl</td>
<td>HPMC 15000cps, HPMC 1000000cps, PEO N80</td>
</tr>
<tr>
<td>Metformin HCl &amp; Glimepiride</td>
<td>HPMC 150000cps, HPMC 1000000cps, Guar gum, Sodium alginate, Carbopol 934, Carbopol 940</td>
</tr>
<tr>
<td>Galantamine HCl</td>
<td>HPMC 1500000, HPMC 10000000000, PEO N80</td>
</tr>
<tr>
<td>Isosorbide mononitrate</td>
<td>HPMC 4000cps, Polyox WSR 303, PVP K30</td>
</tr>
<tr>
<td>Flupirtine Maleate</td>
<td>HPMC 4000cps, HPMC 10000000000</td>
</tr>
<tr>
<td>Diclofenac Sodium</td>
<td>HPMC 4000cps, Sodium CMC, Sodium alginate, Cashew gum, Xanthan gum, Sodium CMC</td>
</tr>
<tr>
<td>Diclofenac Sodium &amp; Tramadol HCl</td>
<td>HPMC 4000cps, HPMC 15000000000, HPMC 10000000000</td>
</tr>
</tbody>
</table>

METOLOSE SR, USP, EP, JP, Hypromellose (HPMC), is exclusively designed for a hydrophilic matrix agent having tighter specifications by Shin-Etsu Chemical. Various viscosity grades are introduced for the simplicity of the formulation.

The matrix system has several advantages as follows:
1) It is very simple and easy to establish a formulation.
2) The tablet is completely dissolved and thus achieves good bioavailability.
3) It is easy to control the dissolution profile by selecting a specific grade.
4) The matrix system is an economical method for obtaining controlled release products.

METOLOSE SR Grades
METOLOSE SR has a tighter specification for substituents with finer particle size as compared with regular METOLOSE, therefore METOLOSE SR is exclusively suitable for matrix tablet applications, especially direct compression. Various properties of Metolose SR made it a perfect candidate in selection as matrix polymer for SR applications. Particle size as is very crucial and hence promising property of Metolose SR as depicted in the chart.

Note: Particle size in the table expressed as based on standard sieve analysis. Chart generated by a laser diffraction analysis, which gives larger particle size in comparison with standard sieve analysis.

<table>
<thead>
<tr>
<th>Grades</th>
<th>Viscosity (mPa.s)*</th>
<th>Substitution type</th>
<th>Methoxy content (%)</th>
<th>Hydroxypropoxy content (%)</th>
<th>Particle size (µm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>90SH</td>
<td>100SR</td>
<td>80 - 120</td>
<td>220B</td>
<td>22.0 - 24.0</td>
<td>8.5 - 10.5</td>
</tr>
<tr>
<td></td>
<td>4000SR</td>
<td>3000 - 5600</td>
<td></td>
<td></td>
<td>D20:20-40</td>
</tr>
<tr>
<td></td>
<td>15000SR</td>
<td>11250 - 21000</td>
<td></td>
<td></td>
<td>D50:50-80</td>
</tr>
<tr>
<td></td>
<td>100000SR</td>
<td>75000 - 140000</td>
<td></td>
<td></td>
<td>D90:100-160</td>
</tr>
</tbody>
</table>

*Viscosity of 2% w/w aqueous solution at 20 °C

Particle size of METOLOSE SR grade (laser diffraction method)
Metolose SR offers various advantages and is preferred choice of polymer for SR applications as enlisted:
- Smaller Particle size
- Different Viscosity grades
- Tighter specification of Substituents
- Special control for SR grade

For more info, please contact pharmaindia@setysin.com or visit https://www.metolose.jp/en/
Waters launches SARS-CoV-2 LC-MS Kit (RUO) for clinical research of infectious diseases

New LC-MS method offers a versatile research tool in the fight against SARS-CoV-2 as it enables reproducible results with three unique peptide biomarkers.

Waters Corporation introduced a new RUO LC-MS test method to advance critical infectious disease research. Waters’ SARS-CoV-2 LC-MS Kit (RUO) uses an orthogonal analytical method that directly detects and quantifies SARS-CoV-2 Nucleocapsid (NCAP) peptides that initial studies have shown to yield highly accurate, quantitative results.

"For biomedical and clinical research laboratories that are involved in fighting the pandemic, this kit offers a useful research tool for deeper study of the virus and the versatility to enable pioneering research of other infectious pathogens. The accelerated development of this method shows what's possible through collaboration and represents an important step towards equipping scientists around the world with a highly versatile, reproducible, and quantitative platform capable of providing new insights into this and future pandemics," said Dr Udit Batra, CEO and President, Waters Corporation.

Waters developed the SARS-CoV-2 LC-MS Kit (RUO) in support of a coalition of academic, commercial and government research scientists. This coalition worked to develop an alternative test method on LC-MS platforms in support of the United Kingdom’s National Health Service (NHS) Test & Trace program.

The Waters SARS-CoV-2 LC-MS Kit (RUO) has been optimised on the ACQUITY™ I-Class Plus System and the Xevo™ TQ-XS System. It comes in an adaptable automation-friendly format with liquid handling protocols for the Andrew+ Pipetting Robot on OneLab™ Software.

This kit is for research use only and has not been approved for use in clinical diagnostic procedures. This RUO kit has not been tested with clinical samples.
Waters Arc Premier System delivers increased precision and certainty in chromatographic results

New system sharpens chromatographic peaks for metal-sensitive compounds by eliminating secondary interactions, maximising reproducibility and efficiency of separations without compromising performance

Waters Corporation introduced the Waters™ Arc™ Premier System, the first liquid chromatography system optimised for chromatographic separations on 2.5 - 3.5 micron columns to also feature Waters' novel MaxPeak™ High Performance Surface (HPS) technology. The new system complements Waters' best-selling MaxPeak Premier Columns to virtually eliminate the surface interactions that occur between sample analytes and instrument and column hardware, saving laboratories time wasted on costly passivation and providing greater confidence in separations results.

Analytical scientists working in method development and quality control laboratories can typically waste hours and days re-running or troubleshooting analytical methods that fail to reproduce an expected test result, such as missing low concentrations of a target analyte known to be in the sample or that fail to detect an impurity. The Waters Arc Premier System and Columns are designed to help increase speed, consistency and confidence in analytical results for scientists working to develop, transfer and run chromatographic assays that are central to business and laboratory operations.

“With liquid chromatography results, there is no room for error. Laboratories cannot afford to overlook or under-report an impurity in a drug formulation for example, or miss product release timelines because of assay variations. Laboratories both big and small have long suffered the frustrations of analyte/surface interactions, which degrade sensitivity, reproducibility, and of separations methods that can require several days for passivation. The combination of the Arc Premier System and Columns sets a new standard for pharmaceutical analysis, giving scientists the confidence they need while reducing the cost and time to market,” said Udit Batra, President and CEO, Waters Corporation.

The Arc Premier System delivers reproducibility and repeatability for scientists developing methods for stability testing, impurity profiling and product release data in compliance with regulatory requirements. The combined solution provides reproducibility without sacrificing performance along with system ruggedness for delivering consistently accurate chromatographic results in test after test.

“Mitigation of deleterious analyte interactions with chromatographic columns and systems has always plagued separations scientists striving for perfect peak shapes and recoveries. Material modifications that maintain all the best properties of stainless steel while reducing or even eliminating these secondary binding events will be transformative. Removal of internal passivation procedures and skipping mobile phase additives to address chelation is exciting and very promising,” says Jonathan Shackman, Associate Scientific Director, Bristol Meyers Squibb.

Removing analyte to-metal interactions for improved results

MaxPeak HPS technology is a unique hybrid organic/inorganic surface technology exclusive to Waters’ MaxPeak Premier Systems and Columns. It forms a barrier between the sample and the metal surfaces of both the system and column, mitigating, or eliminating altogether, non-specific adsorption. It offers many benefits including:
- Increased analyte recovery for more accurate and precise quantification
- Up to a 5X increase in detector sensitivity depending upon the degree of metal sensitivity
- Up to a 10X increase in system-to-system reproducibility
- Potential savings of 2-3 days/assay by eliminating system passivation and column conditioning, increasing productivity and profitability

MaxPeak Premier Columns - Stop Looking and Start Seeing

MaxPeak Premier Columns are designed to be the most universal column platform for chromatographers who need to reduce variability risks and save time, while increasing recovery and sensitivity. The column offerings now available for the Arc Premier System include MaxPeak Premier 2.5 µm columns in the Atlantis™ Premier, XBridge™ Premier and XSelect™ Premier Product families.

The Arc Premier System and MaxPeak Premier Columns are now available worldwide from Waters.
Platinum-cured silicone resin: Rising demand in pharma, biotech and medical industries

Vinay Pandey, B-Tech Rubber Technologist, Ami Polymer explains that silicone rubber is the most widely used polymer in pharma and biotech industries due to its inherent properties like biocompatibility and inertness to cells/human tissues.

Polymer industries have been serving pharmaceutical industries through various polymeric product compositions to meet critical requirements of food, pharma and biotech industries.

Silicone resin formulations very easily meet with FDA and USP requirements with ultra low extractable and leachable properties.

Silicone rubber is the most widely used polymer in pharma and biotech industries due to its inherent properties like biocompatibility and inertness to cells/human tissues.

Every product puts a demand on the material used, but none so more than the medical industry.

In terms of meeting both the regulatory requirement and performance, the answer is thermosetting liquid silicone rubber (LSR).

Let’s try to understand world of silicone rubber used for healthcare products intended in pharma and biotech applications.

Overview of silicone rubber chemistry

Silicone Rubber is chemically known as PDMS (Polydimethylsiloxane). It contains Si-O Backbone Structure in polymeric chain, which is responsible for its superior performance as mentioned below:

- Flexibility at lower temperature up to -80°C
- High heat resistance up to 250°C
- Greater weather and oxidative resistance

Key properties of product made of silicone resin

Silicone resin is translucent polymer widely preferred for pharma industry because of below reasons:

- Nonreactive and inert to biological tissues/cells
- Excellent biocompatibility
- Smooth surfaces tend to prevent contamination of fluid on its surface
- Easy to clean and sterilize by any standard sterilization process
- Free from toxic ingredients
- Free of Phthalate and Bisphenol content
- Low level of extractable compared to any other polymers
- Excellent flexibility to facilitate dynamic applications (Peristaltic Pump)
- Transparent compared to other rubbers to visualize flow of material

Types of available silicone rubber

Based on chemistry of cure mechanism, there are two types of silicone rubber available as stated below:

A) Peroxide Cured Silicone Rubber
B) Platinum Cured Silicone Rubber

Understanding peroxide cured silicone rubber

While processing of silicone resin, catalyst is added to strengthen its physical properties. When peroxide catalyst is used for processing, it is called as peroxide cured silicone rubber. Most common catalyst is DCP (Dicumyl Peroxide).

The peroxide curing process leaves behind by-products in the form of volatile organic acids. To remove by-products, peroxide grade silicone products are treated in tray drier (hot air circulating oven) at 200°C for three to four hours. This treatment is called post curing process, which eliminates the by-products by converting it into gaseous form. But still, ineffective post curing process may lead to leaching of by-products in food contact and medical applications.

Understanding platinum cured silicone rubber

Platinum complex based catalyst is added in silicone resin while it’s processing. Chemically it is known as addition reaction. There is no generation of any kind of by-products in platinum curing system of silicones. Prevention of by-product generation makes it safe to use in critical application of food, pharma and biotech industries.

Advantages of platinum cured silicone products

- Superior transparency to see visibility of fluid flow transfer
- Free of by-products and odour
- Smooth surface resists stickiness of transfer fluid. It prevents contamination and bacterial growth
- Better physical properties like tensile strength, tear resistance.
- By-product free silicone resin contains low level of extractable and leachable enhances its usage of critical product transfer in pharma and biotech industry
- Maintains physical characteristics in storage condition of long period enhance its shelf life. Doesn’t turn yellowish during prolonged storage period

Above listed features make platinum cured silicones the center of attraction among R&D specialists of the pharma and biopharma industry. Awareness among polymer industries has been improved to provide silicone solutions to their clients.

Contact:
tech@amipolymer.com
Yokogawa Electric Corporation announced that it has obtained ISASecure CSA Level 1 certification from the ISA Security Compliance Institute*1 (ISCI) for its ProSafe-RS safety instrumented system, a product in the OpreX Control and Safety System family. This is the first time a safety instrumented system has obtained this certification. Yokogawa has long emphasized the importance of cyber security with its safety instrumented systems, and this certification is expected to give customers even greater confidence in the use of this product.

Cyberattacks are on the rise worldwide, and are growing ever more sophisticated. In recent years, a number of attacks have targeted industrial control devices, resulting in lost production and the theft of information. In August 2017, a malware attack on a safety instrumented system was reported, and this has led to a call for enhanced cyber security measures to deal with the threat to these systems, which play a pivotal role in ensuring plant safety.

Yokogawa’s ProSafe-RS safety instrumented system is certified for use in safety integrity level 3 (SIL3) applications. With regards to cyber security, it has held ISASecure EDSA certification since 2013. Replacing this certification program, ISASecure CSA certifies compliance with the IEC62443-4-2 and IEC62443-4-1 international standards pertaining to control device security. Receipt of this certification indicates that a product has been recognized by a third party as having security controls that conform to these international standards. Yokogawa also plans to obtain ISASecure CSA certification for the ProSafe-RS Lite SIL2 safety instrumented system, which was released in January of this year.

Through its development of highly-secure control devices and systems as well as the provision of support services, Yokogawa offers its customers a wide range of security solutions. Yokogawa will leverage this certification to accelerate its efforts to enhance the cyber security of its customers’ plant operations.

*1 ISA Security Compliance Institute & ISASecure CSA
Developed by the ISA Security Compliance Institute (ISCI), the ISASecure CSA certification program focuses on the security of embedded devices and related components (software applications, host devices, and network devices). The ISCI’s members come mainly from the International Society of Automation, and the principal activity of this organization is the promotion of security certification for industrial control systems and control devices. The ISASecure CSA certification program was launched in August 2019, replacing the ISASecure EDSA certification program. It complies with the International Electrotechnical Commission’s IEC 62443-4-2 and IEC 62443-4-1 international standards for security in control devices.
Rolling shutters have always been considered as one of the most dependable additions to any building due to its safety, durability, maintenance and ease of operation. Along with safety and other mentioned features to the building, it also provides optimal privacy without compromising the aesthetic appeal of the property. Modern rolling shutters are outperforming the traditional doors and erstwhile prototype rolling shutter option. This is due to its innovative designs, handiness and material strength which are far better than its earlier roller shutter models. Gandhi Rolling Shutters are ideal for situations where side room is at a premium and security is required. They require very little headroom above the structural opening. Their strength, elegance, durability and other salient features are designed for both external and internal applications. Gandhi Rolling Shutters are fabricated of interlocking galvanized insulated and non-insulated profile, stainless steel profile, patented aluminum profiles and patented MS rolling grills.

Gandhi Automations, India’s No. 1 Entrance Automation & Loading Bay Equipment Company, is the only manufacturer of Rolling Shutters certified to ISO 9001: 2015, ISO 14001: 2015, ISO 45001: 2018 quality management system. This has resulted in the implementation of continuous improvement in personnel training, production technique, inspection, equipment calibration, machinery maintenance, logistics and customer relations. The product engineering team uses the latest software combined with technologically advanced machinery to offer to the customer a well-engineered product.

Over years of meticulously working on the design, fabrication and installation, Gandhi Automations has developed technical expertise in manufacturing various kinds of Automated Rolling Shutters. The Research and Development team with its extensive knowledge and experience are able to produce specific types of Rolling Shutters unique to certain sites and client requirements. A consistent quality product has thus become the hallmark of Gandhi Automations' manufacturing process right through installation to after-sales service.

Each of Gandhi Automations’ Rolling Shutters are designed to client’s specifications and solidly constructed to promote trouble-free operation and long life. All Rolling Shutters are automatic using vigorous drive expertise with manual override in case of power failure and are dense, noiseless and dependable.

For further details contact: Gandhi Automations Pvt Ltd Chawda Commercial Centre Link Road, Malad (W) Mumbai - 400064, India Off: +91 22 66720200/66720300(200 lines) Fax: +91 22 66720201 Email: sales@geapl.co.in Website: www.geapl.co.in
2021 marks a key milestone for anyone working in a lab. Sixty years ago, Eppendorf changed the ways of handling liquids by introducing the world’s first piston-stroke pipette. Launched in 1961, the Eppendorf ‘Marburg Pipette’ featured the same basic elements as those found in today’s labs: a spring-loaded piston that stops precisely at a set volume level and a removable pipette tip made of plastic. This alternative to cumbersome and risky mouth pipetting changed scientific research forever and laid the foundation for Eppendorf’s position as a market leader in liquid handling today.

**Continuing innovation**
Since then, by applying their proven expertise and innovation, Eppendorf has continued to set industry standards in precise manual and automated pipetting and dispensing of small volumes. In 1978, for example, the company redefined liquid handling again with the introduction of the Multipette dispenser with Combitips tips system - the first handheld repetitive dispenser and an entirely new concept of disposable tips with integrated pistons.

**Still accelerating research**
Eppendorf has always worked closely with customers to understand their precise needs and develop the right pipette or solution for every application. Over the years, Eppendorf has continued to evolve the pipette through the advent of electronic pipetting and automated liquid handling systems to maximise reproducibility when working with micro- and nanoliter volumes.

Over the years, Eppendorf has continued to evolve the pipette through the advent of electronic pipetting and automated liquid handling systems to maximise reproducibility when working with micro- and nanoliter volumes.
Virosil Pharma: A revolutionary, eco-friendly fumigant

Virosil Pharma has proved to be effective in controlling aerial bacteria and fungus present in sterile rooms. The area becomes completely sterile within 60 minutes of spraying without causing any irritation to the eyes, nose and skin - unlike conventionally used formulations.

ABSTRACT
In the past years, the pharmaceutical industry has witnessed tremendous growth and there have been tie-ups with a number of multinational companies for production and R&D facilities to be nurtured in India. Organisations are applying for ISO standards and upgrading themselves to the latest norms related to health and hygiene.

Microbial contamination and pollution play a significant role in the pharmaceutical industry. Control of microbes has always been the biggest challenge to these industries. A load of microbes are present in areas such as production, storage/packaging, R&D, QA/QC, filling etc. They are present everywhere in the air, surface, water, instruments, linens etc.

Hence the disinfectant used should be so precise that it should not only take care of the microbial contamination but also be user and eco-friendly. Virosil Pharma meets all the required standards for the pharmaceutical industry.

ABOUT US
Sanosil Biotech, a Mumbai-based company, has launched a range of multipurpose disinfectants which are eco-friendly, chlorine-free and completely biodegradable and have applications in the pharma and healthcare industry as well as in the food processing industry.

It is manufactured in India in technical collaboration with SANOSIL AG of Switzerland. SANOSIL AG in Switzerland is the patent holder and has joint venture agreements in more than 15 countries such as France, Italy, Spain, Holland, Norway, South Africa, Australia, Saudi Arabia, Oman, the UAE, etc. The product is being used in various countries by reputed institutions and has been thoroughly tested under strict regulations imposed by European Health bodies.

PRODUCT DISCRIPTION
Virosil Pharma is a multicomponent fumigant and disinfectant. The oxidizing agent used is hydrogen peroxide, which is bonded with stabilizing agents to form a complex solution. A long-lasting effect is ensured by the addition of silver, which acts as a catalyst in trace amounts. The bactericidal effect of silver is based on the fact that the monovalent silver ion Ag+ binds very firmly to bacterial proteins by a covalent or co-ordinate bond, and thus inactivates or precipitates these.

- Its effectiveness against bacteria, viruses, amoebae, fungi and algae; i.e. its extremely wide range of application makes it easy to handle for the end user; i.e. only one product is needed, where so far 2, 3 or various products were necessary.
- Owing to the good stability of the product, a long storage time can be guaranteed. As the product remains stable at high water/air temperatures, and as its effectiveness is even increased at high temperatures.
- Due to its long-term effectiveness and pronounced characteristics to prevent recontamination, this product is perfectly suited for disinfection of drinking water and wells.
- Virosil Pharma is ecologically harmless. Its principal constituent - hydrogen peroxide - does not pollute waste water, because it breaks down into water and oxygen (H2O2 and O2), i.e. it produces no noxious by-products.
- The two basic substances (H2O2 and Ag) enhance their advantages (*synergism). The bactericidal effect comes into action quicker and more intensively than if either substance was used on its own.

Fumigation with Virosil Pharma, the perfect alternative to Formalin
Fumigation is one of the most

---

**USFDA DRAFT GUIDELINES**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Microbial limit (cfu / 10 cu.ft.)</th>
<th>Microbial limit (cfu / 10 cu.ft.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Less than 1</td>
<td>Less than 1</td>
</tr>
<tr>
<td>B</td>
<td>5</td>
<td>7</td>
</tr>
<tr>
<td>C</td>
<td>100</td>
<td>18</td>
</tr>
<tr>
<td>D</td>
<td>500</td>
<td>&lt;88</td>
</tr>
</tbody>
</table>

*a* = samples from class 100 environments should normally yield no microbiological contaminants

**WHO 2002 MICROBIAL LIMITS**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Max. no. of microorganisms permitted / m3</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Less than 1</td>
</tr>
<tr>
<td>B</td>
<td>5</td>
</tr>
<tr>
<td>C</td>
<td>100</td>
</tr>
<tr>
<td>D</td>
<td>500</td>
</tr>
</tbody>
</table>

**EU GMP 2002**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Air sample cfu / cu.m.</th>
<th>Settle plates (90mm) cfu / 4 hours</th>
<th>Contact plate 55mm cfu / plate</th>
<th>Glove print cfu / glove</th>
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**ADVANTAGES**
- Eco-friendly - It is totally biodegradable since (H2O2) breaks down into water & oxygen
- Chlorine free
- Non-toxic (no irritation to skin or eyes
- No effect on pH
- Non carcinogenic and non-mutagenic
- Excellently rinseable with water & oxygen

**PROPERTIES**
- Can easily be dosed
- Does not foam
- Decomposes into water and oxygen
- It is excellently rinseable with no remains
- Treats any other material with consideration

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PHARMA PULSE
A glimpse at the standards put down by various would monitoring agencies would help an individual or an organization decide on choosing the most appropriate control procedure/methods. The important microbial limits which have been prescribed by various agencies is as follows:

To meet those requirements aerial disinfection (fumigation) with formaldehyde was the most convenient method. With the regulatory having restricted the use of formaldehyde and also putting into place the monitoring levels of formaldehyde after fumigation makes it a procedure with its own limitations.

Formaldehyde is a known carcinogen (IARC & NTP). Formalin is toxic by inhalation, toxic if swallowed, may be fatal if swallowed, causes eye burns, may cause blindness, strong sensitizer, causes irritation to skin, eyes, and respiratory tract. Repeated or prolonged exposure increases the cancer risk.

Virosil Pharma has been a direct alternative to Formalin Fumigation. Virosil Pharma has proved to be effective in controlling aerial bacteria and fungus present in sterile rooms. The area becomes completely sterile within 60 minutes of spraying without causing any irritation to the eyes, nose and skin - unlike conventionally used formulations. Virosil Pharma can even be successfully used in AHU which are responsible for optimal and steady air exchange in production facility, of which the ducts, air shafts, humidificator, filters, etc. are often contaminated with loads of bacterial and bio-films.

The main aim of Virosil Pharma is to increase productivity by cutting down disinfection time while at the same time providing a totally microbe-free environment.

Virosil Pharma is also very effective in disinfection of all critical surfaces that come in contact with pharma products. There is no requirement to wash equipment and surfaces disinfected with Virosil Pharma since it is H2O2 based and decomposes into water and oxygen.

Virosil Pharma has been tested by several reputed and renowned institutions in India with respect to its disinfection and fumigation applications in Pharmaceutical Industry because of all these factors, Virosil Pharma has attained maximum satisfaction of the customers in controlling the microbial contamination in their respective applications. The introduction of an eco-friendly, non-carcinogenic and totally biodegradable versatile product, like Virosil Pharma, has not only brought an end to the era of conventional biocides but has completely solved the disinfection requirements which these healthcare industries were prone to.

**Targets**
Sanosi Biotech is marketing this disinfectant under the ‘Virosil Pharma’ brand name and is targeting the entire industrial belt of India. The company has already set up a distribution and infrastructure network having establishments in Maharashtra, M.P., Hyderabad, Chennai and Delhi.
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Calibration of weighing instruments
Weighing in the safe weighing range

Calibration is one of the key activities that must be performed periodically when instruments are used for quality relevant measurements. Internationally, there are many standards which stipulate this requirement, e.g. ISO9001, GMP regulations or standards concerned with safety. Unfortunately, there is no common understanding on the definition, the implementation and the specific activities that comprise calibration.

The International Vocabulary of Metrology (VIM) provides the official definition of calibration: "Operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication."

It is evident that the relation between the known and the measured values can only be established if the associated measurement uncertainties are derived. Basically, measurement uncertainty describes how far away from the true value a measurement result reasonably might be. Besides calibrating, an instrument can also be adjusted.

Adjustment is defined in the VIM as "Set of operations carried out on a measuring system so that it provides prescribed indications corresponding to given values of a quantity to be measured."

In other words, when adjusting an instrument, its indications are modified in a way so that they correspond - as far as possible - to the quantity values of the measurement standards applied. Unfortunately, many users apply the words calibration and adjustment interchangeably, incorrectly or even randomly. Quite often, they talk about calibrating a weighing instrument, however they mean adjusting it.

The VIM also emphasises this by stating, "Adjustment of a measuring system should not be confused with calibration, which is a prerequisite for adjustment. After an adjustment of a measuring system, the measuring system must usually be recalibrated."

The tough reality is that a balance calibration without measurement uncertainty is meaningless. Measurement uncertainty is an integral part of any calibration; it is the quantified doubt about the result of a measurement. If not reported in the certificate, the calibration is incomplete. Besides of calibration, measuring instruments can also be verified. Usually, instruments need to fulfill predefined requirements, quite frequently expressed as tolerances. The VIM defines verification as follows: While calibration only establishes the relationship between measurement standards and indications ("how well performs the instrument"), verification assesses the instrument on whether or not it meets specific requirements ("does the instrument perform well enough"). Usually, the outcome of verification is a "pass" or a "fail". In respect to weighing instruments, the requirements can come from the manufacturer who specifies tolerances for each balance or scale model, international or national testing recommendations, and handbooks for weighing instruments used for applications involving commercial transactions as well as industry specific regulations. However, even more importantly, the user needs to specify weighing tolerances that assure that the instrument performs well enough to fulfill his specific process requirements. In view of the application of the weighing instruments, these tolerances are the most important ones as they have a direct impact on the quality of the final product.

METTLER TOLEDO Accuracy Calibration Certificate (ACC) provides calculation of Measurement Uncertainty at site and Good Weighing Practice Verification (GWPv) provides Safe Weighing Range by comparing relative measurement uncertainty with required weighing tolerance for given applications. GWPv also provides Routine Test Plan based on selected weighing tolerance and Risk assessment at site. ACC and GWPv ensure that the weighing equipment is fit for its intended purpose throughout the life cycle of the equipment.

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Choosing the right type of desiccant is quintessential for your product’s shelf life

CILICANT understands how critical it is to choose the right desiccant and offers a variety of sorbents developed for different applications.

Active packaging is a primary concern when developing and packaging pharma products, particularly, when it comes to the sorbent or desiccant, you use. Desiccants are an essential part of active packaging as they prevent degradation through moisture, extending the lifetime of the product.

While the cap/closure mechanism and the bottle will physically protect medicines, the type, quality and quantity of the desiccant used will also play a vital role in determining the quality of the formulation for the end-user. Use a generic desiccant and, in all likelihood, you won’t see the best results. In fact, the wrong type and quantity of desiccant can result in over-desiccation of the formulation and may be detrimental to patient safety.

So you can see the importance of choosing your desiccant carefully. The cheapest or most convenient option may not be the most valuable solution.

Use a desiccant that’s fit for purpose

CILICANT understands how critical it is to choose the right desiccant. That’s why it offers a variety of sorbents developed for different applications. The two most commonly used are silica gel and molecular sieve.

Significantly, the moisture adsorption properties of molecular sieve and silica gel differ when it comes to how they perform. While molecular sieve has an excellent adsorptive capacity at low humidity levels, silica gel tends to perform poorly in low humidity. Both, however, have similar moisture retention capacities at room temperature (25°C) at a relative humidity of 40 percent.

Silica gel is the most suitable desiccant to use in products with stable storage temperatures and high relative humidity. With its inert, non-toxic, and highly stable properties, understandably, silica gel is a popular desiccant choice for many pharma products.

On the other hand, the molecular sieve is more aggressive and rapid when it comes to moisture adsorption, so performs better in products that require instant protection from moisture degradation. Molecular sieve is also stable over a large temperature range maintaining its higher moisture retention properties. However, caution should be exercised when selecting the proper dosage for use in products with specific RH requirements.

Packaging specialists also need to consider the following in order to get optimal results from the desiccants they use.

While choosing the right adsorbent is important, it’s equally important to choose the right product within the desiccant range, as each serves different purposes. In the case of molecular sieve, there are several variants commonly used, including 3A, 4A and 13X. Type 4A is a popular choice for pharma packaging.

Likewise, there are several types of silica gel. Type A, B, C are the most common. Here, type A has been specifically designed for the adsorption of moisture in pharma packaging.

To get the optimum results from the desiccant one selects, users should examine a number of testing parameters, such as LOD (loss on drying), MAC (Moisture Adsorption Capacity) at low RH and high temperatures, along with other parameters such as packaging headspace and the regional climate at the product’s destination, etc.

Clearly, inert products, such as medical devices, diagnostic kits and API’s will be more compatible with silica gel, while thermal-sensitive medicines will be protected better by using molecular sieve desiccants. As both over-desiccation, as well as under-desiccation, can impact the life span and efficacy of formulations, companies involved in development and packaging of these products need to ensure that they’re using the most appropriate form of adsorbent technology.

For more information on the best desiccants for your product, get in touch with CILICANT’s technical sales representative now!

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The Ideal Cures Smiles Initiative was born out of an intrinsic desire to spread joy. It starts with our CSR activities and goes on to help uplift under-privileged, tribal sections of society, especially in the sphere of education. It goes on to our customer and partner programs and employee programs as well. So we make everyone associated with Ideal Cures Smile.

Right from our community of pharmaceutical fraternity, to our employees, partners, well-wishers and our customers - we want to invite everyone to be a part of these programs under the Ideal Cures Smiles Initiative.

A significant part of Ideal Cures Smile Initiative includes Smile webinars. Some of our Smile Webinars so far have been:

- Yoga and Breathing Techniques Session
- Musical Evening
- Comedy Night with Sunil Grover
- Webinar on Nutrition by Rujuta Diwekar