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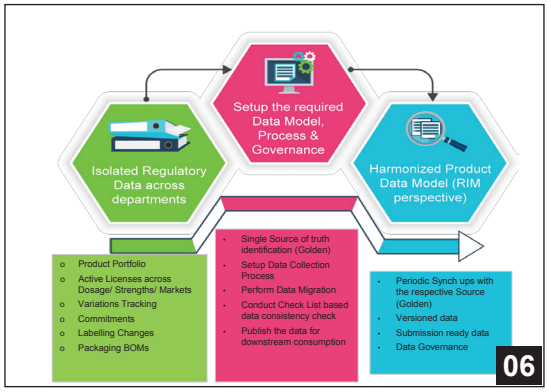

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Regulatory Data Migration – A Harmonious Approach towards a Centralized Product Database

For a Pharma Company, data migration is of extreme strategic importance in context of regulatory evolution. The author, in this article, has addressed the meaningful data migration strategy establishment and its successful implementation in order to have minimal surprises during the migration stage.

Sathish Sundaramurthy
Head of Product Development
Safety and Regulatory Technology
Navitas Life Sciences
(a TAKE Solutions Enterprise)

In an evolving regulatory landscape where a single-source-of-truth is paramount, the need for data migration is of extreme importance. We look at how a life science organization can strategically take their data from disparate legacy sources to a centralized product database. Investing in this single-source-of-truth can help to avoid the all too common data integrity challenges within internal operations which – as we know – not only cost an organization, but may cause heavy hindrance as well.

Let's begin by taking a look at a real-world scenario. Figure 1 presents a pharmaceutical company having one API and two formulations.

Figure 1 provides a high-level data structure that is prevalent for a typical 1 API and 1 Product with two formulations. We would consider this data hierarchy as an inverted tree structure that addresses multiple occurrences relating to:

- Markets
- Countries
- Doses
- Strengths
- Pack sizes
- Indications

We already know that compliance challenges exist owing to multiple markets and formulations, and these challenges must be addressed in order to meet Health Authority (HA) requirements. Further complications arise with the ownership of data. In most companies, we see a shift from central to local/affiliates and vice versa. Whilst this is okay, it needs to be fully documented and traceable. If done in a silo fashion, as we know it often is, this puts added pressure on regulatory operational resource. Adding to this, there is a requirement to track the licenses, agency correspondence, market expansion, renewals, and changes to name a few; hence the data sets held by regulatory operations are both exhaustive and multifaceted. The complications and challenges are clear for all to see; but what would be the answer? It lies in a holistic solution platform that can

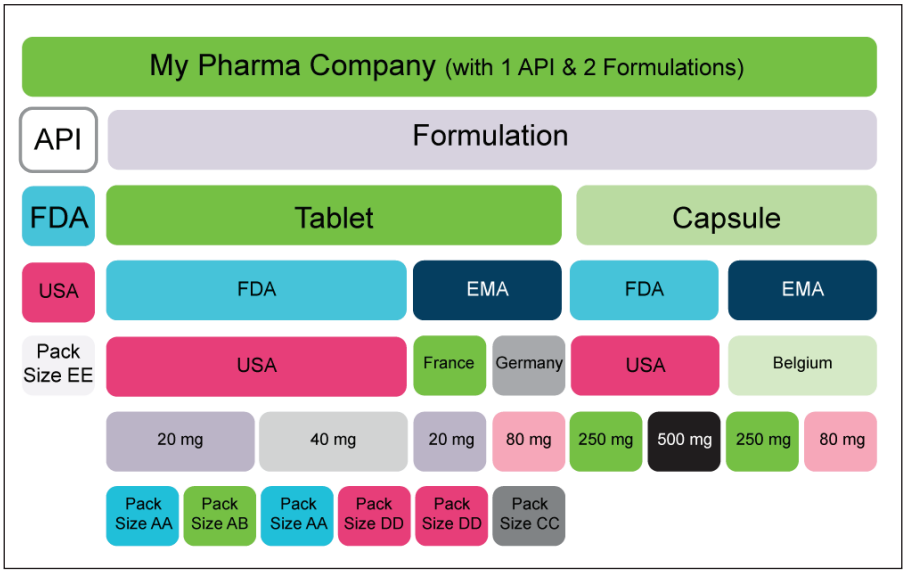

Figure 1 Real-World Scenario – A Pharma Company with one API and two Formulations

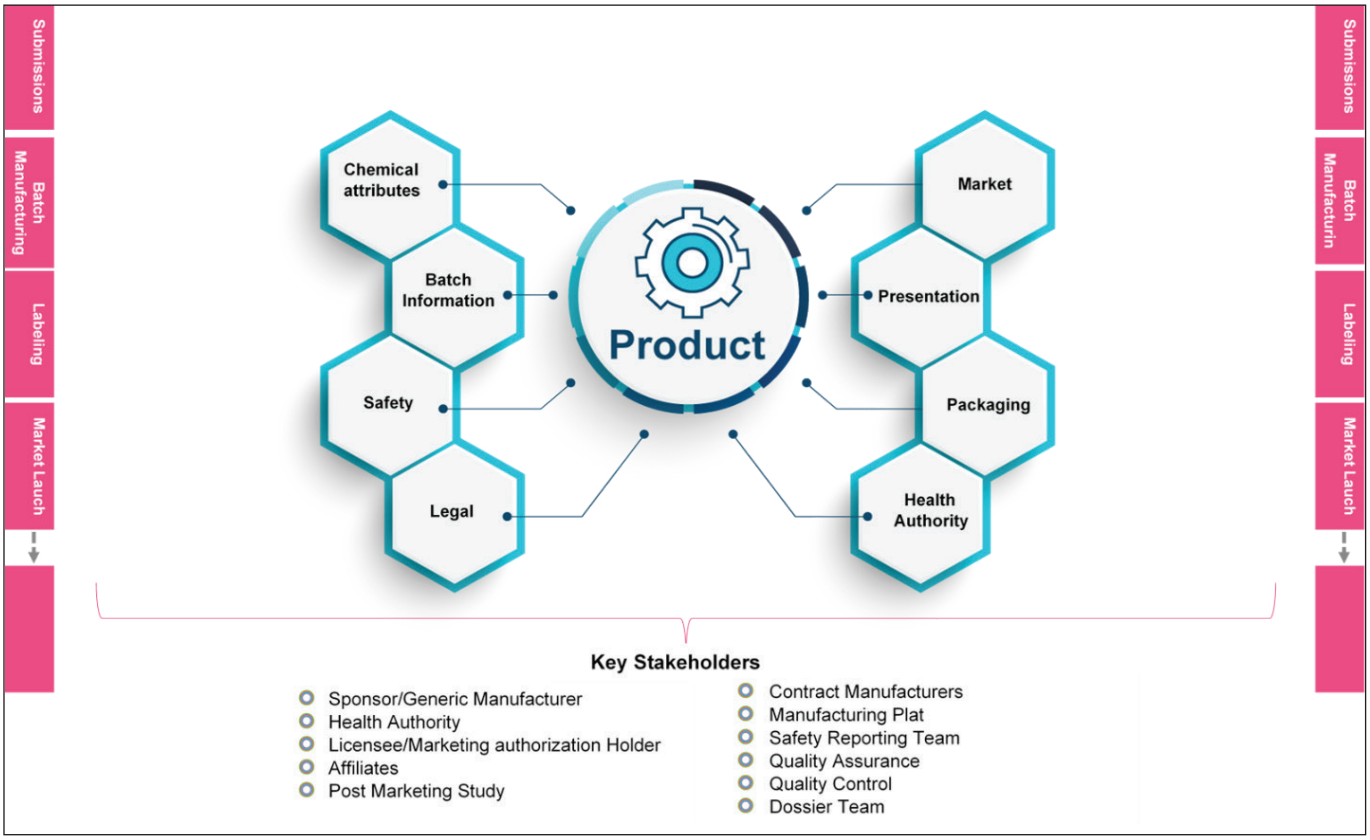

Figure 2 An illustrative example of some of the facets of a typical medicinal product and its accompanying data attributes[1]

manage the complexities of regulatory operations. Let's take a look at that in a little more detail.

Regulatory data availability situation

The regulatory domain related data is multifaceted. To that end, there are multiple distinct stakeholders who create and/or consume data in their preferred form in order to perform their day-to-day business functions. For example, medical product data-values are captured and recorded at different stages – starting from the clinical stage to post-marketing and beyond, right uptil the last batch is made available in any specific market. At each stage, the product data-attributes are different with minimal overlap and with continuously growing data. Figure 2 illustrates some of the facets of a typical medicinal product and its accompanying data attributes.

Additionally, an Enterprise can have globally dispersed business functions, and therefore may use multiple systems to manage their day-to-day operations. This can lead to further complex scenarios when it comes to holistic regulatory data; a few is mentioned below:

- Data is globally dispersed as data pockets with no single repository at the enterprise level.
- Some of the final data is available with Affiliates.
- If changes and/or variations are not properly managed, unwanted deviation in local submissions from the Core Data Sheets may occur.
- Multiple envelopes may be formed as data sits in different sources viz. paper, Microsoft Excel Open XML Spreadsheet (XLSX), databases, etc.
- Unavailability of required capacity to move data to a single repository, such as centralized Product database.

Compliance challenges do exist owing to multiple markets and formulations, and these challenges must be addressed in order to meet the Health Authority (HA) requirements. Further complications may arise with the ownership of data. In most of the companies, we see a shift from central to local/affiliates and vice versa. However, it needs to be fully documented and traceable.

Data readiness for regulatory submissions

Only being available somewhere-in-the-organization does not entail the data to be submission ready. The data identified for regulatory submission must go through a proper data lifecycle to meet the requirements as outlined below:

- A single-source-of-truth for data getting originated from varied sources must be identified.

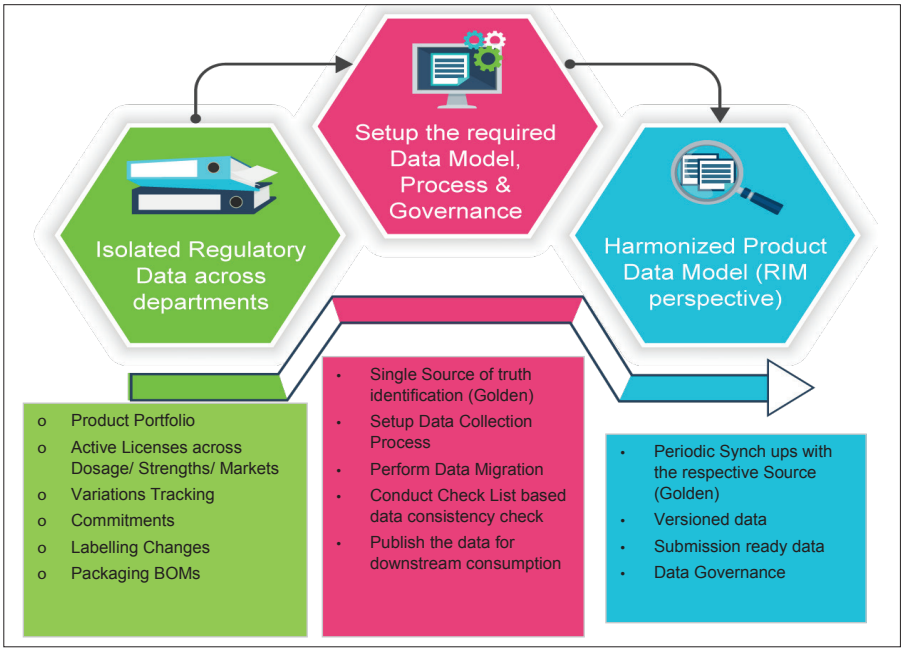

Figure 3 The journey to a harmonized Product Data Model

- The identified data must be fully traceable with a timestamp for future reference.
- Controlled revisions must be adhered to, while making any changes to the data entry value.

These requirements are critical to safeguard the data integrity. Hence, data readiness for regulatory submissions must be handled with due attention and diligence to avoid data mix-up or version conflicts. Once the data is available in a harmonized form, the next step is to make the data ready for regulatory submission(s). This, in practice, means managing potential non-compliance situations which could have a significant impact on both the brand and the economy. According to our experience, it is rare for a situation to occur that may have associated patient safety risk.

In order to standardize the data communication with HAs, there is a preference for data submission in an agency-prescribed format such as – eCTD, NeES, XEVMPD, SPL, and in future – IDMP, etc as much as possible for data consistency and verification. HAs have their own automated parsers to decipher the formatted data submission and to let the pharma company know quickly whether the data is readable and acceptable in principle for processing.

The Challenge

We appreciate that at the very first glance the data journey and its associated challenges may appear somewhat daunting. Therefore we often hear:

- How do I start my data migration? There are duplicate data sources with different owners across the locations. We need to shift from multiple data pockets to a harmonized data plane with a specific knowledge about how to manage potential non-compliance situations.
- Not all the data remains in a standardized format, which greatly restricts the automated data import with post-migration manual quality check.
- The indirect cost in duplicate data maintenance such as storage, manual time, and effort to find the right source and right version, ensuring the intactness of data integrity.
- How can a company ensure a compliant and effective migration to a new database?

The regulatory domain related data is multifaceted. To that end, there are multiple distinct stakeholders who create and/or consume data in their preferred form in order to perform their day-to-day business functions.

Therefore how do you get ready for data migration?

If a Pharma Company intends to set up a centralized Product Database, our advice would be to aim for global compliance and reduced data maintenance costs for the longer term rather than looking for the shorter-term benefits which may initially look attractive, but don't solve the real issues. For instance, don't settle with localized solutions for global problems. This may lead to quick periodic repair and cost up-gradation.

As you refer to Figure 3, you might find yourself at any of the three stages shown therein. However, here are some key considerations to achieve a harmonized product data model:

- Align and form a Data-Cell Team to lead the data change management program with a clear goal of achieving centralized and harmonized product database. Though it may seem obvious, the challenges do exist in the detailed preparatory work for team building.
  - The Data-cell team to comprise of well-informed team members who have very good understanding of pharma operations and the associated product data in its expected form. Typically it is found that the regulatory associates, publishers, and strategists become very critical to understanding, assessing, and defining the Go-To Data Model components. This team should include local as well as global players.
  - Centralized Product Data Model: The Data-cell is responsible for baselining / versioning the Product Data Model as per organizational policy and procedures.

- Avoid and eliminate the duplicate data collection: The Data-cell team to ensure that data duplication is eliminated. The team needs to identify the top three sources as Gold, Silver, and Bronze to ensure that the duplication of data sources are graded appropriately. By default, Gold is considered as the Single-Source-of-Truth. Silver and Bronze may be referred to, on the need basis, for reconciliation and review.
- Data mismatch: More often than not we run into a potential non-compliant situation wherein the data that has been submitted locally is different from what it should be based on the Core Data Sheet and the changes that published globally. These potential non-compliant situations may need to be investigated and appropriate resolutions may need to be exercised.
- Compliance-friendly data formats: The stored data and its associated formats should be as close as possible to the HA compliant formats to avoid any gap in compliance related data format transformation work. Data that bears submission candidature should be managed by the team who understands the HA based submission needs. This would ensure that the data migration requirement from one form to another is met whilst keeping the compliance in the mind.
- Controlled Data Life Cycle Management: Any revision of published data must go through a proper change control process before the change gets effected. This ensures that the changes are both well-planned and controlled.

- Classify the overall data hierarchy into respective categories:
  - Industry Standard Data (Global Term Store)
  - HA specific data (Agency Term Store)
  - Local Data (Local Term Store)
  - Operational Data (data generated and maintained as a part of internal operations)
  - Feedback Data (In-bound data that includes safety changes, regulatory correspondences, product complaints, and audit observations)
- Define organizational standards for each data point basis the following:
  - Data Category
  - Data Type
  - Length
  - Mandatoriness (Default or conditional)
  - Native Formats (predefined formats, pre-fixes, and suffixes)
  - Data Privacy
  - Data Source
  - Submission Formats (if any)
  - Data Version
- Baselining and Publishing Data:
  - For a specific data point, – identify, enumerate, and mark the multiple data sources such as Gold Source, Silver, and Bronze so that the preference is always given to the Gold data source and the other sources may be referred to only on defined conditions.
  - The data source can be manual, internal, or external system bound where in periodic data synchronization must be in place based on the expected data change frequency.
  - Any data that is meant for consumption needs to be in the published state. This is a well proven concept in terms of Standard Operating Procedure (SOP) of managing the Quality function wherein only the published and effective SOPs are to be considered for operational consumption; and at any point of time, there will be only one published version.
- The right technology option
  - The potential technology solution for data migration is to look at a holistic approach towards data harmonization at Enterprise Level.
  - The proposed solution is expected to have the following key features to facilitate the easy data migration:
    - A built-in option of the regulatory based product data model with potential extensions
    - Capability to process the multiple data sources with open architecture-based integration capability
    - Ability to transform the data from one or multiple sources to prescribed format
    - Ability to map the target data models against both internal and HA specific standards
    - Ability to process the data migration in batches (both time-based and event-based processing)
    - Ability to track the data changes, its associated versions, and to publish the effective and baseline data only for consumption
  - Data Migration process should have the below key aspects built-in:
    - Ability for pre-migration data processing
    - Ability for post-migration data processing with dependency checks
    - Ability for exception handling during the migration

If a Pharma Company intends to set up a centralized product database, our advice would be to aim for global compliance and reduced data maintenance costs for the longer term rather than looking for the shorter-term benefits which may initially look attractive, but don't solve the real issues.

Conclusion

When considering a Pharma Company, key drivers are to be addressed for successful & meaningful data migration strategy establishment as well as implementation in order to receive minimal surprises during the data migration. As far as the data migration is concerned, there is no single-stop solution. Multiple factorials, perspectives, and the right partner are to be considered to make the data migration journey a smooth ride. Therefore, the most significant question here is: where do you see yourself in the data migration process.

Reference

[1]Please be advised that this is an illustrative example only and does not provide a full and comprehensive product data set ■

Future of Healthcare in India: Role of Digital Technology

Healthcare organizations play a pivotal role for their patients. With an increasing patient-centricity, the Healthcare sector is on the transformational path being driven by technology upgradation and digitalization. The author here narrates the road for Healthcare organizations to follow for their future destination.

Amit Sharma
Founder and CEO
eExpedise Healthcare

These days' patients are ready to invest their time and money on multiple healthcare benefits and policies, which have made the industry to rethink its approach towards them. Health organizations, ranging from insurers to Pharma Companies, are now putting their customers at the first.

With this constantly building pressure on the healthcare organizations to make a paradigm shift in the way they work, even customers may feel the heat as they shall have to play an important role now in deciding the course for healthcare industry. Apart from the industry reformation in India, it is also promising to change our thought process about the various health services and the ways these services are being financed across the world.

Key Challenges

As these days patients feel more responsible for their healthcare decisions in accord to their wellbeing, insurance or arrangement, doctor, or the medicines they take, they have been searching for the organizations they can get associated with. Those organizations are to be trustworthy to the patients in order to enable them comprehending and dealing with their health-related expenses. These associations need to fight longstanding off beam recognitions in general. Healthcare service providers, for instance, have generally been viewed as the pocket-squeezing organizations keener on extracting cash than providing the quality service ensuring the wellbeing.

Pharmaceutical companies might be the organizations charging a lot for their products and more inspired by their primary concern as opposed to helping patients show signs of improvement. Even though these observations aren't completely valid, healthcare associations are striving to alter their clients' perspectives and be viewed as a trusted resource for treating and overseeing chronic diseases and conditions.

To Keep the Healthcare Approaches Customer-Centric

Customers these days request for a progressively comprehensive encounter, better results, and more open conversations as key variables driving the move towards the industrialization of healthcare. Conveying a customer driven model to help this move requires exceptionally applicable correspondences to meet the increased client expectations adequately. Exceptionally important

These days patients feel more responsible for their healthcare decisions in accord to their wellbeing, insurance or arrangement, doctor, or the medicines they take, they have been searching for the organizations they can get associated with. Those organizations are to be trustworthy to the patients in order to enable them comprehending and dealing with their health-related expenses. These associations need to fight longstanding off beam recognitions in general. Healthcare service providers, for instance, have generally been viewed as the pocket-squeezing organizations keener on extracting cash than providing the quality service ensuring the wellbeing.

correspondences are difficult to convey without framing a profound framework for fulfilling their clients' customized needs.

Payers, suppliers, and buyers are gradually turning to present day techniques to get the contribution from patients and to offer the effective basic leadership bolster devices to encourage a more grounded association with them. That relationship would enable them to explore the healthcare biological system which incorporates acquiring data, inclusion, participating in consideration, detailing the results, and paying for services in addition to other things.

Healthcare associations, hoping to embrace the standards of customer driven framework, are needed to look past their industry's accepted procedures. Retailers and other foundations have just moved into a buyer driven model. The capacity of retailers to customize their clients' experience depending on their previous history is the thing that should start to expand in client driven healthcare sector.

Personalized exercises for the retail business to follow could be another way. Although the retailers have less security rules than the health care associations, the conveyance of customized solutions in a retail setting is the feature what purchasers hope to get. Amazon, Walmart, and other retail brands have established the pace which these associations must pursue to achieve.

Binding together with the customer information set up may induce more doctors and retailers to funnel in. Putting in this sort of effort may viably prompt for a superior brand view, which confers to higher consumer loyalty for long haul. If separate gateways are created by the healthcare associations with right arrangement in order to make the information open, they place their patients as important.

Medical attendants and the doctors are the key supporters to their client(s) in order to receive seamless experience. To convey the experiences cultivating such principle, these experts should be permitted to stick to their occupational vows: working in service of others. Issues commiserating such reasons viz. authoritative pressure, excess work, and lack of staff-to-patient proportions must be decreased or wiped out. Projects satisfying the criteria of only being instructed, committed, and flexible are insufficient. Instead, correct devices and procedures must be set up to enable all concerned individuals to invest more energy with their patients to acquire a delightful experience.

Healthcare is one such industry that needs to stay rooted to its customers physically even in this digital era. When the technology is gradually being tampered, fragmented, and disconnected from its sources, it is the duty of a healthcare organization to make the entire experience worthwhile. Healthcare customers are not happy with the present situation and they expect an Amazon-like service & care.

Medical attendants and the doctors are the key supporters to their client(s) in order to receive seamless experience. To convey the experiences cultivating such principle, these experts should be permitted to stick to their occupational vows: working in service of others. Issues commiserating such reasons viz. authoritative pressure, excess work, and lack of staff-to-patient proportions must be decreased or wiped out. Projects satisfying the criteria of only being instructed, committed, and flexible are insufficient. Instead, correct devices and procedures must be set up to enable all concerned individuals to invest more energy with their patients to acquire a delightful experience.

Contribution of Digital Solutions

Hence, it is important for the digital solutions to join the marketplace and to let the healthcare organizations to engage with their customers as well as the concerned personnel just as how they should be. If the customers are asking for digital solutions, it is up to the healthcare setups to prioritize their medical services to proactively help the customers in managing their health and wellness. It is time that these care-providers and major healthcare associations make the digital platforms ready so that their customers' needs can be fulfilled.

Artificial Intelligence has been mastering several fields leading to a giant leap in tech-evolution; healthcare is also no different. AI induced reshaping of healthcare sector leads us to the results in terms of researches and applications which we thought never existed. It is difficult to think about the growth opportunities in healthcare without understanding the significance of Artificial Intelligence, which is nothing but a catalyst enabling the machines to sense, comprehend, act, and learn.

As opposed to conventional advancements based on algorithms to supplement a human, healthcare AI in present situation can genuinely enlarge the human advancement assuming the control over assignments that ranges from medical imaging to hazard examination in order to diagnose the healthcare conditions. Being enormously capacitated to release the cost-, quality-, and access upgrade, AI has acquired prominent detonate. Development of AI in healthcare sector

has been relied upon to reach USD 6.6 billion by 2021 with a compounded yearly development rate of 40 percent. The healthcare AI sector is expected to reach over 10x market-size in coming five years, which is to be counted as a big leap towards the future.

Even in recent past, the impact of AI on healthcare sector was beyond imagination. However, in the present scenario, it empowers numerous medical services which today's associations can't even live without, particularly when they suffer from various problems related to money, operational disturbance leading to rising work cost, computerized advancement requirements for buyers, and expanding the interoperability interest to name a few.

As an example, the new contestants' whirlwind and information blast when have joined with research, have been prompting for more intelligent frameworks. The case for AI selection is now more grounded. Healthcare AI enhances the opportunities which include health and lifestyle management, diagnostics, wearable-s, and menial helpers. To appreciate the opportunity in entirety, the medical associations must comprehend the full scientific classification of AI application and the potential worth which conveys monetarily, in addition to authoritative methods and work process upgrades.

So, what are the most recent patterns in clinical and restorative science that are exercising the genuine capability of AI?

Medical device organizations have been utilizing AI in order to help their intrusive careful tasks significantly along with complex life structure related activities. Prior to an activity, a patient's CT scan is stacked into a 3-D automated framework to demonstrate where a specialist should place embeds—all before even the patient arrives. The spinal surgery robot arm even manages the instruments that orthopedic specialists do use, and that too with an incredibly high level of accuracy.

Virtual sensor organizations have brought virtual healthcare to homes. Robotic medical caretakers are glad to respond to patients' inquiries. They are nurture specialists; however, a patient can likewise connect with doctors continuously by means of their telephone, tablet, television, or personal computer. The robots can even be incorporated through wired and remote restorative gadgets. Information from those gadgets so acquired may even be stored with doctors, thus empowering them to screen and evaluate the risk, triage, and facilitate an effective plan.

Artificial Intelligence is gradually becoming an Operating Software in the healthcare sector. While replacing old methods and introducing new forms of personalized capabilities, it has also enhanced healthcare's four most important areas:

1. Workforce - AI can ease the load on surgeons, specialists, and nurses to carry out their responsibilities better. For example, AI empowered symptom checkers help the patients to lower the costs involved as well as recommend the emergency only when it is fundamental. Computer based intelligence can address the neglected clinical interest with an expected accuracy of 20 percent more than that of without.

2. Institutional Readiness - To acknowledge more noteworthy benefits from AI, healthcare players may enforce AI advancement in their association's structure and administration.

3. Care Reach - Consumers need AI. Frankly speaking, they are keen to see the AI induced positive impact on society. Artificial intelligence can amplify care-reach by coordinating healthcare information crosswise over stages. If an inventive technology is introduced, it must be linked to empower the patients with consistent support.

4. Security – AI is effective as well as critical, pertaining to the risks for information storage. Every party in the ecosystem must work together to enhance the security of this valuable data. By and large, every penetrated healthcare record will cost USD 355. And not only do the healthcare setups lose the data, they also lose their customers' trust. As AI conveys advantages of more prominent productivity, straightforwardness and interoperability, associations must keep up a reasonable spotlight on enlightening security.

Conclusion

The market development is driven by the AI framework acceptance rate and the technological marvels in AI field. Furthermore, the capacity of these frameworks to improve patients' health, provision to drug accuracy, and increased coordination between the needs of healthcare personnel and patients are expected to fuel the market development. To be that as it may, absence of standard guidelines & rules and the inhibitions amongst healthcare experts to embrace AI-based advancements are expected to block the road of advancement in AI technology. ■

Healthcare is one such industry that needs to stay rooted to its customers physically even in this digital era. When the technology is gradually being tampered, fragmented, and disconnected from its sources, it is the duty of a healthcare organization to make the entire experience worthwhile. Healthcare customers are not happy with the present situation and they expect an Amazon-like service & care.

Sustainability in processing and packaging technology: Technological solutions for ecological challenges

The article analyses current ways of the pharma industry to make for more sustainable packaging and manufacturing processes, from utilising biodegradable plastics and fibre-based packaging to integrating energy-saving process equipment into their manufacturing lines. Further, the article takes a deep dive into how connected industry solutions can help reduce and optimize energy consumption.

Dr. Ing. Carsten Weiß
Vice President Engineering
Bosch Packaging Technology

Increasing urbanization, smaller household sizes and an ageing population are fundamentally changing the expectations for food and pharmaceutical packaging. At the same time, there is a growing need for more sustainable packaging solutions and processes. But according to Carsten Weiß, Vice President Engineering at Bosch Packaging Technology, no single company can rise to this challenge alone. In order to develop packaging concepts that are both truly sustainable and appealing to consumers, manufacturers, material and packaging suppliers, as well as mechanical engineering and waste management companies need to join forces.

In the majority of industrialized nations, the "Supersize Me" mentality is now a thing of the past. Given the demographic change and more responsible consumer behavior, the current trend is toward smaller portions. This can also be seen in the growing demand for convenience and on-the-go products. In many growth markets, small portions are also the number one choice due to consumers' limited financial resources. As a result, packaging sizes are becoming smaller, yet the number of individual packages is constantly on the rise. Although the sense of environmental responsibility among the general public is improving, every year more than eight million metric tons of plastic litter find their way into the ocean, due in part to insufficiently established or poorly implemented waste disposal processes. According to figures from the UN, this amounts to roughly one garbage-truck load per minute. In parallel, more and more effort is being put into the development of sustainable packaging and environmentally friendlier manufacturing processes.

In the future, there will be a greater focus on fulfilling the requirements of the circular economy. There is a greater demand for packages that are "designed for recycling", for example by using easily separable materials, mono-material packaging, and renewable materials. But what good does the most environmentally friendly packaging design do if it is not compatible with processing and packaging machinery? Or if the process steps involved in its manufacturing, filling, packaging and disposal involve much higher energy consumption? All parties involved in the production and supply chain have to work together to devise more sustainable solutions. The outcomes of key initiatives like Save Food, CEFLEX and European Bioplastics can offer valuable insights into future needs.

On the lookout for new packaging concepts

Some of the most important trends on the packaging market include the further development of conventional materials, research into new combinations of materials, and the introduction of more efficient processes. In this regard, various parties are already working hand in hand to find new solutions that reflect the spirit of sustainability. When it comes to achieving these goals, expertise from disparate, not directly related fields can be vital. For example, the automotive industry has been investing heavily in optimizing materials and processes for the past several years. With regard to products with extremely high barrier requirements, like battery cells, the spotlight is on optimizing flexible packaging materials. Lessons learned from these efforts can – provided they are available – be directly applied to the development of new packaging solutions and production concepts for food and pharmaceuticals.

Many research activities focus on the development of bio-based or biodegradable plastics that satisfy the requirements for food packaging. Bio-

Figure 1: Bosch Packaging Technology is investing in new technical solutions to ensure more sustainability in processing and packaging engineering.

based plastics often offer a better CO_2 balance than conventional plastics. Biodegradable plastics are particularly advantageous if they can easily be broken down by microorganisms. Compostable materials are an especially good choice for food packaging where the product and its packaging often enter the waste disposal cycle together – as is the case with coffee capsules or teabags.

Nonetheless, biodegradable plastics do not represent a cure-all for the pollution of our environment and oceans: as they break down, carbon dioxide, water and methane are released. Methane has a much more higher effect on global warming than CO_2, which is why it is burned to CO_2 and H_2O at managed waste disposal plants. Biodegradable plastics that are additionally bio-based offer a much better CO_2 balance, while those that are based on renewable raw materials can produce other negative environmental impacts, including eutrophication, increased soil acidity, and air pollutants. Generally speaking, rapidly degradable plastics are particularly advantageous for the environment when they are "marine degradable," that is when they break down in seawater. Needless to say, it should still be our goal to reduce the amount of marine litter to a minimum; in this context, good recycling solutions and smoothly running disposal systems are elementary.

First concepts already put into practice

Companies are also working intensively on new concepts in the area of fiber-based packages, so as to satisfy the circular economy's criteria for recyclability and the use of renewable materials without compromising product protection. For example, the first sealed paper packaging consists of mono-material paper instead of polymer film, making it completely recyclable. It is suitable for dry food like sugar, pasta, cereal or powder. Until recently, packaging products in mono-material paper was only possible with glued, premanufactured bags or with glued paper packaging produced by mandrel-wheel systems. With the new solution, food products can now also be packaged and sealed with vertical form fill seal (VFFS) machines, which translates into higher flexibility concerning the choice of format and packing style. Moreover, VFFS sealing delivers improved product protection and dust tightness. Thanks to the use of FSC- or PEFC-certified paper, this approach is truly sustainable – from the raw material to recycling – and offers a viable alternative to plastic for products with low barrier requirements.

In addition to mono-material packaging and compatibility with VFFS machines, additional future applications are imaginable. By suitably modifying current packages, the number of different materials needed could be reduced. Also, the increasingly stringent barrier requirements for product protection could be satisfied. However, a good deal of further development work will be needed to keep costs low while achieving a high degree of product protection and environmental protection, as a recent analysis (see graphic 1) shows. While the majority of materials are out of the question for use in the pharmaceutical industry due to the extremely high standards for product protection, the food segment also often has to sacrifice shelf life for the sake of higher sustainability. Accordingly, all parties involved will continue to have their hands full trying to optimally reconcile packaging requirements, cost efficiency and environmental protection.

Figure 2: The first sealed paper packaging consists of mono-material paper instead of polymer film, making it completely recyclable.

Although the pharmaceutical industry faces more complex challenges given the high barrier requirements for its products, some secondary packaging concepts are already available that may prove to be visionary. When it comes to fragile products like syringes, vials and ampoules, as well as applicators such as insulin pens, conventionally a mix of materials has been used to ensure their safety. However, a new, tray folding carton made entirely of cardboard and featuring variable inlays could offer an alternative solution. Thanks to the use of a single packaging material, there is no more need for plastic trays. Consequently, there is also no need to separate different classes of materials during recycling, which translates into better sorting and more efficient recycling outcomes.

Energy recovery during ongoing processes

Conserving resources is another key aspect of sustainability in the processing and packaging industry. In the energy-intensive pharmaceutical industry, for example, innovative energy recovery concepts are yielding significant savings. In the sterilization process, heating and cooling energy are recovered, which can mean up to 40 percent lower heating costs and 60 percent lower cooling costs. When it comes to ultra pure steam generation and distillation, the latest-generation systems use a preheater to reduce hot steam consumption by roughly 30 percent. In cleanroom production, up to 65 percent lower energy costs in connection with hot and cold water, steam and electricity can be achieved with the help of cutting-edge isolator technology depending on the air supply system used.

Similar concepts can now be found in the food sector: thanks to heat recovery, new systems used, for instance, to separate masses in the manufacture of jelly products consume only half as much energy. In addition to lower overall operating costs through reduced energy consumption, reducing the steam pressure in the separation process by 0.3 bar subjects the product to less thermal strain, helping preserve both quality and taste.

Keeping an eye on resource consumption with industry 4.0

The latest software solutions in the area of digitization show how manufacturers can conserve resources with their existing machines and lines, by asking questions

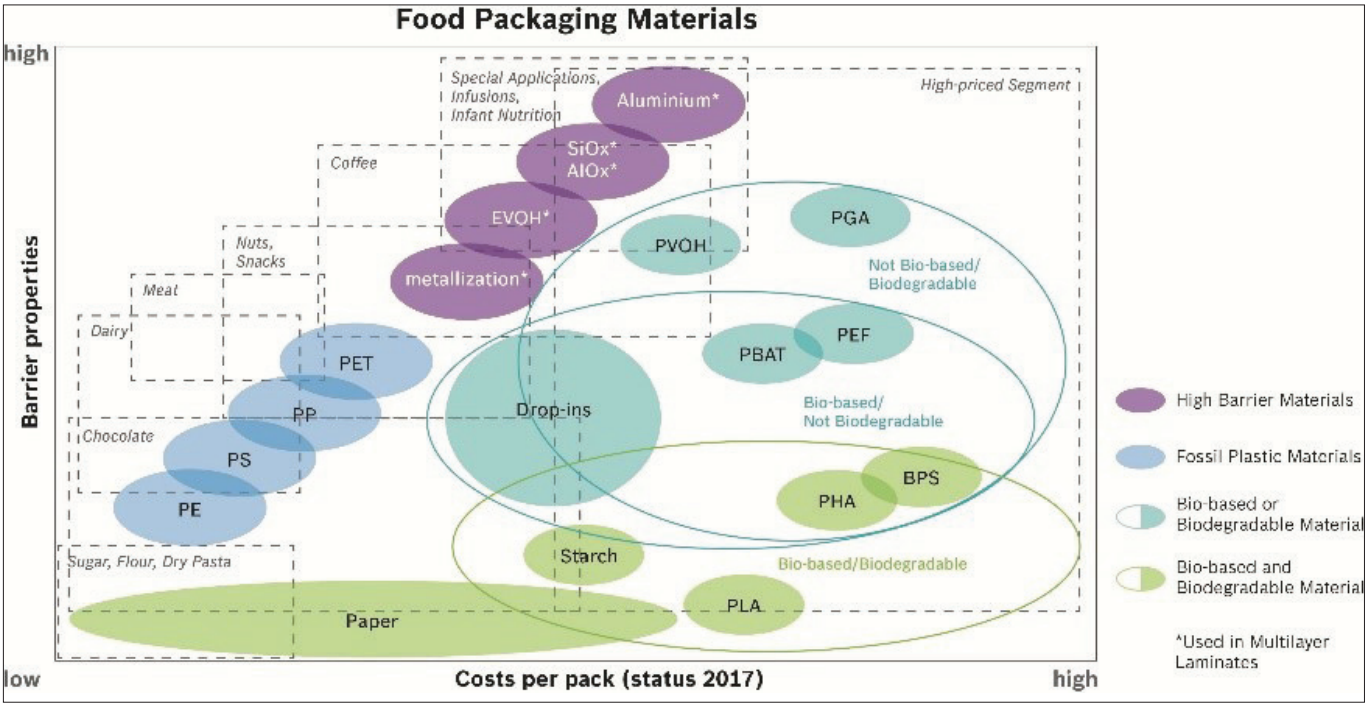

Figure 3: arious packaging materials are used in the food industry, depending on the specific product and barrier requirements.

like: which machines consume the most electricity? At which point in which process step do we use most energy? Thanks to the progressive connectivity of production, we now enjoy access to more and more data, which can also be used for consumption analysis: sensors provide data, for instance on energy and compressed-air consumption, allowing us to analyze these parameters over a given timeframe. These often very different types of data can be bundled and analyzed on a single platform, and displayed in real-time on the Human Machine Interface (HMI) of a given machine or line. In this way, fluctuations, peak loads and irregularities can be identified – and effectively remedied.

Thanks to industry 4.0, we will soon be able to use increasingly detailed data, paving the way for more fundamental analyses ranging from individual machines to entire plants. In turn, predictive analytics will help us spot potential sources of higher consumption and errors in advance – and identify corresponding potentials for optimization, leading to more efficient and resource-conserving production processes.

Trinity of design, material and machine

Several different aspects are important in the context of selecting suitable packages and processes: in addition to cost efficiency, more attention is being paid to barrier properties, processability, mechanical requirements, quality, and compliance with regulations. In this regard, sustainability will become more and more important in the future. When it comes to developing new packaging concepts and systems, factors like recycling, energy and resource efficiency have already become an integral part of performance specifications. Leading processing and packaging machinery providers are already working closely together with their customers in various pilot projects to develop comprehensive solutions based on a trinity of design, material and machine.

This can best be achieved by getting material manufacturers, brand owners and their customers on board at an early stage. As part of the UX (User Experience) approach, feedback is collected on various parties' expectations and needs, and is then directly integrated into further developments. In addition to individual customer needs, regional specifications like legal requirements, consumer mentality and the degree of automation in production also have to be kept in mind. Only then can solutions be found that will allow the emerging markets to establish ecologically sound production, packaging and disposal concepts in their own regions. And this can only succeed if producers and materials developers, packaging manufacturers and mechanical engineering firms, as well as logistics, waste management and recycling companies act in concert, so that the entire packaging industry actively contributes to more sustainability. ■

Pharma Technology will be Shaped by New Challenges for Product Manufacturing

Pharma technology is rapidly evolving due to requirements and challenges of new products and developments. Biologics and biosimilars and their packaging create more specialised demands for material performance. This article elaborates on the new developments in pharma technology and the Indian market playing a key role with research and development facilities being increasingly built in India.

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With the increasing demands for highly sensitive drugs such as biologics and biosimilars, the requirements for drug packaging and elastomer components are ever-evolving and rapidly changing. The number of biologics stored and administered in prefilled syringes today is constantly increasing. This also triggers a growing complexity of formulations and the surge in novel device designs. Due to the sensitivity of biologics during storage and their complexity during administration, packaging requirements of biologics and biosimilars are creating more specialized demands for material performance. Consequently, market trends indicate a growth in fluoropolymer coated elastomeric closures which help to mitigate risks related to drug compatibility and stability. For therapeutic proteins, the exact chemical make-up and three-dimensional conformation can influence the efficacy of the drug. As recognized by the (US) Food and Drug Administration[1], the interaction of proteins with silicone oil can present a risk to the safety and efficacy of therapeutic proteins. Conformational changes, degradation and / or aggregation can lead to the inefficacy or immunogenicity of the protein, ultimately impeding or preventing the success of the drug. Therefore, many manufacturers of biologics or biosimilars are already relying on fluoropolymer coated closure solutions today.

However, fluoropolymer coatings need special properties which make them as safe and reliable as possible. They are of particular importance to closures and components for pre-filled syringes. In storage, the drugs are in constant contact with the rubber component, e.g. the plunger of a prefilled syringe. When it comes to silicone oil migrating into a prefilled syringe formulation, the plunger has been found to be the larger source of free silicone than the barrel – despite the fact, that more silicone oil is applied to the barrel.[2]

Low levels of silicone oil particles in coatings for pharmaceutical packaging components provide advantages for every step of the way in terms of application. They not only make the products safer and more efficient; the reduction or elimination of silicone oils in rubber components and closures can also reduce time-to-market. As authorities such as the FDA recognise the risks which extractables and leachables are posing to sensitive medication, low particle levels can accelerate the approval process.

Cleanroom Manufacturing as standard for state-of-the-art facilities

To ensure that (coated) components for pharmaceutical packaging, particularly for biosimilars, are of the highest standard, a look at the manufacturing environment is often worthwhile. A cleanroom manufacturing environment, incorporating state-of-the-art solutions and standards, is crucial. The so-called fully integrated GMP (Good Manufacturing Practice) environment incorporates innovative automated processes and conforms to the highest industry standards. Each zone has been meticulously designed and constructed to prevent bio-contamination and is equipped with material airlocks. State-of-the-art pass-through washing equipment

has its automatic loading side in one zone and its automatic unloading side in a zone of even higher cleanliness. In addition, the latest generations of camera inspection techniques are used. It exceeds the most stringent quality standards of regulatory authorities and is certified to ISO 15378. All production lines operating under the First Line standard are designed to operate under a zero-defect philosophy. The process flow, gowning protocols, personnel and material flow, and state-of-the-art automation all result in the lowest endotoxin, bioburden, particulate, and defect levels available in the industry.

India is playing a key role

India is one of the most important drivers in the international pharmaceutical market and will continue to grow and strengthen its position. Currently, the market has the highest number of USFDA approvals and with more companies buying from Indian manufacturers, this development will continue.

Currently, India's role and the role of its pharma companies are quite centered around generic medication and the delivery thereof. However, this doesn't mean that they will continue on this path. Rather we will see a considerable shift towards establishing facilities for research and development. There are several reasons for this: one reason is certainly that the international regulatory authorities have long been observing Indian manufacturing sites closely. On the one hand, this guarantees quality products and a high aspiration for good manufacturing standards. On the other hand, it also creates the desire to further excel in production. The ambition to keep this position as a market leader is strong, resulting in more high-end and state-of-the-art facilities. This trend is here to stay, as global companies have started to recognize the market's potential. Many pharma majors are merging with or acquiring Indian pharma companies and are heavily investing in Research & Development. The main focus used to be on production, but now a substantial amount of the annual profits is going into R&D investments. Many of the major global players are also setting up own R&D facilities in India. Next to generics, R&D will become a major stronghold for India in the future.

Datwyler Sealing Solutions is a prime example for introducing high-end products to India. The newly built extension of the current facility in Pune already produces approx. four billion components per year. It will be fully aligned with Datwysler's state-of-the-art manufacturing standard First Line and produce highly complex Omni Flex coated elastomer components, eg, for prefilled syringes. This investment paves the way to introducing new pharma technology to the Indian market. As a result, the market and its biggest customers will be catered to with locally-produced components, proving that its future and perspectives are set out to be long-lasting and successful. ■

Reference

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Ethics in Clinical Trials: Its Role and Importance

Clinical trial ethics are the set of relevant ethics considered in the conduct of a clinical trial in the field of clinical research. It borrows from the broader fields of research ethics and medical ethics. This article discusses the role and importance of ethics in clinical trials.

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Clinical trials are a necessary practice in drug development to certify the safety and efficacy of a new drug and involve the participation of human subjects. Healthy volunteers and patients of specific diseases are considered legitimate trial units provided their free and informed consent is obtained under the law.

Exploitation in the Clinical Testing arena

Low and middle-income countries provide easy test subjects for clinical trials because in many cases, participating in a trial is the only way for the poor or needy to access expensive healthcare. However, this exposes them to the risk of exploitation. Experience has shown that unregulated practices in drug development can lead to unhealthy consequences for the people involved. In the 1960s, a chemical called Thalidomide was administered to pregnant women who had complained of morning sickness. The drug was marketed as a mild sleeping pill that was projected as being safe even for pregnant women. However, babies born to the mothers who took the pills were born with congenital deformities as a result. This spurred authorities and pharmaceutical companies to employ more rigorous testing standards before the introduction of a drug for human consumption.

Guidelines and Frameworks for Clinical Trials in India

Ethical concerns are to be addressed responsibly by all the stakeholders involved including doctors, pharmaceutical companies, ethics committees, regulatory agencies, CROs, patients and drug testing laboratories. Patients can help by honestly describing symptoms and therapeutic progression during testing. ICH-GCP (E6 guidelines) unequivocally declares that the rights of the individual, safety and well-being shall prevail over the interests of both science and society. The safety of the trial subject is an inalienable right to be protected at any cost. To ensure that this happens, stakeholders are required to undergo periodic training in order to comply with requirements of the Indian Council of Medical Research (ICMR) and the World Medical Association's (WMA) Declaration of Helsinki on the ethical guidelines for biomedical research on human participants. These principles themselves stem from the Declaration of Geneva, one of which binds the physician with the words, "A physician shall act in the patient's best interest when providing medical care".

The central concern of medical research is to study and understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Evaluation should continue beyond preliminary stages to as long as the tested molecule resides within the human subject. Nor does this declaration stop at lofty ephemeral ideals.

Comprehensive guidelines include the compulsory performance of medical research/ clinical trial by appropriately trained and qualified personnel with the requisite scientific and ethical bent of mind. Clinical trials should also minimize harm to the environment. Known adverse effects should act as a breach of preliminary conditions before subjecting humans to trials. Suitable compensation and treatment in case of subjects who have been harmed should be available.

The Ethics Committee (EC) in Clinical Trials

ICMR guidelines (2006) require the establishment of and oversight by an ethics committee. An EC is to be registered with the Central Drugs Standard Control Organization (CDSCO). Approval or disapproval of a clinical trial is in the hands of the EC. The EC examines the pros and cons of a clinical trial protocol before approval. The committee members including the Chairman, Member Secretary, Clinician, Pharmacologist, Lawyer, Layperson, etc, must scrutinize protocols,

investigate brochures, informed consent forms and other relevant documents thoroughly to ensure that the patient does not undergo any suffering due to negligence of document oversight.

Once the Ethics Committee nod is acquired, the principal investigator and her team members can begin recruiting patients according to inclusion and exclusion criteria. These criteria are to be strictly followed even if the numbers are low so as not to endanger the patient's life. All queries of a patient must be satisfied even after the informed consent form has been signed and received. All the benefits and adverse effects of the Investigational Medicinal Product (IMP) ought to be disclosed beforehand. Only when the patient or his/her relatives agree to all conditions should the participation in the clinical trial begin. The patient should have the freedom to discontinue with the experiment should she so desire.

Role of the Principal Investigator

It is the job of the PI to ensure that deprivation and vulnerability of the subject is not taken undue advantage of. An official report says that India serves 1.4% of the world's clinical trial needs while holding 16% of the world's population and 20% of its burden of disease. In the past, thousands of trials have been conducted here and several cases of death due to negligence or other serious accidents have come to light. Compensation to the victims has been a persistent bone of contention.

Recent Amendments

The CDSCO has been assigned the task of clinical trials regulator by the government of India as per the Drugs and Cosmetics Rules, 1945. GSR 53(E) dated 30-01-2013 inserted a new rule, 122-DAB and Appendix XII in Schedule Y to arrive at the compensation due to aggrieved patients and their relatives. Rule 12-DD of the DCR, 1945 mandating compulsory registration of ECs with it has enabled more transparency in the drug development regime. About 1200 ECs are currently registered. They are empowered to approve and implement ethics in clinical testing in India. Ethical measures have the ability to define and increase the reliability and authenticity of clinical research while at the same time pushing the limits of human understanding of disease.

Internet of Medical Things and changing Healthcare IP dynamics

The Pharma IoT concept involves digitalization of medical products and related care processes using smart connected medical devices and IT services (web, mobile, apps, etc.) during drug development, clinical trials and patient care. The outcomes of Pharma IoT in development and clinical trials can employ combinations of advanced technologies and services to create totally new kinds of disease treatment possibilities.

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What is IoMT

The Internet of Things (IoT) ecosystem provides a platform for bidirectional communication between enabling technologies such as sensor, actuator, and communication protocol networks. The feasibility of this technology trend appears to be successful in applications such as smart grids, smart homes, intelligent logistics, and smart towns along with healthcare.

The Internet of Medical Things (IoMT), a healthcare application of the IoT technology, would essentially comprise a network of connected components that monitor physiological data in real time and enables intervention. Figure 1 illustrates the architecture of patient and physician components of this technology.

The implementation framework would potentially transform the clinical practice areas in patient evaluation, clinical decision making and treatment follow-ups. The communication and storage component of system would enable efficient patient information storage, real-time data acquisition, wearable connectivity, and data transfers to control end user applications. Data analytics components enables data-driven decision processes for cyber physical systems, which remotely connects patients with computer-based systems and facilities at tertiary care centers.

Clinical technologies in IoMT environment would be realized in the form of multiple wellness and health monitoring devices, hospital care devices, wound monitoring swabs, drug delivery and pacing systems which will interact with other machines.

Table 1 lists the key benefits and limitations of IoT implementation in healthcare domain. The foreseen impacts of machine-to-machine interaction, data flow and real time intervention solutions will radically transform the healthcare delivery, affordability and reliability in near future. Additionally, increased patient engagement in decision making, personalization of treatment plans, and device performance optimization will boost compliance and overall service satisfaction. As a result of this, technology adoption rate will increase in coming years to grow this market to reach $156 Billion by 2020; a primarily growth driver for recent research in sensor, networks, cloud, mobility and big data domains.

Apart from their utility in managing regular health statuses, IoMT have also been used for disease prevention, fitness promotion, and remote intervention in emergency situations. Some IoMT end application areas are discussed as follows:

- Building family history at patient and community level
- Chronic disease management
- Remote assisted living (Tele health)
- Wellness and preventive care (Lifestyle assessment)
- Remote intervention in emergency
- Improved drug management

Shift in innovation focus due to IoMT implementation

The existing medical devices can be transformed into IoMT connected devices to monitor real-time data for patients through enhancements such as bio-sensors, signal convertors, and communication modems. IoMT devices have been conceptualized in various forms of smart wearable devices, home-use medical devices, point-of-care kits, and mobile healthcare applications, and are able to communicate with medical experts in remote locations. The macro-level architecture of such devices comprises three layers: local devices, connectivity, and data analytics and solutions as follows:

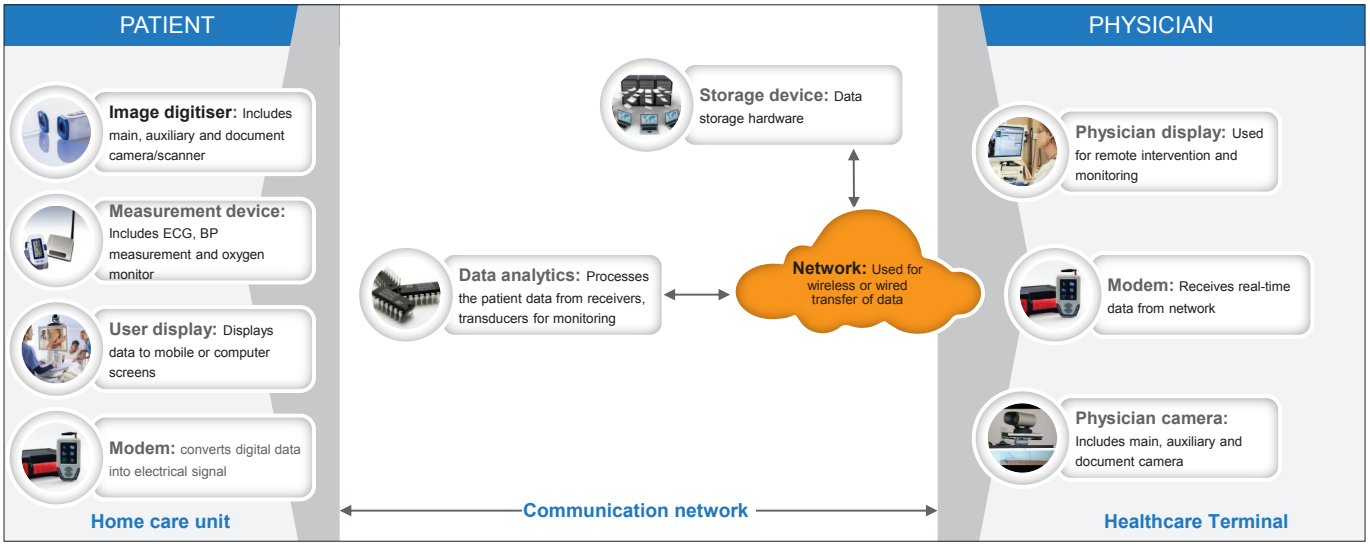

Figure 1: IoMT components

Advantage	Limitations
▪ **Patient benefits –** • Real time interventions in emergency situations • Cost reduction • Reduced morbidity and financial burden due to less follow up visits ▪ **Health care service providers –** • Optimal utilization of resources and infrastructure • Reduced response time in case of medical emergency ▪ **Device manufacturers –** • Standardization/ compatibility and uniformity of data available • Capability to sense and communicate health related information to remote location	▪ **Technical challenges –** • Security of IoT data - hacking and unauthorized use of IoT • Lack of standards and communication protocols • Errors in patient data handling • Data integration • Need for medical expertise • Managing device diversity and interoperability • Scale, data volume and performance ▪ **Market challenges –** • Physician compliance • Data overload on healthcare facility • Mobile hesitation • Security policy compliance

Table 1: IoMT Advantages and limitations

Local systems and control layer

Localized intelligence is among the key technological shift in IoMT devices. In localized intelligence, the prime objective is to build a medical device with intelligent sensing, predicting the next course of action, provides secured transmission and failsafe control capabilities. Current R&D efforts by hardware manufacturers are streamlined to develop innovative biosensors to measure operational parameters, converters to generate digital inputs, smart controllers to make real-time decisions based on physiological readings and network interfaces to share data with other machines / central servers. Innovations in this domain mainly covers devices in the form of wearable monitors, monitoring implants, and physician handheld diagnostic devices.

Device connectivity and data layer

The layer primarily focuses on transmitting data from the networked device and storing it in pre-defined data stores in secured manner. Criticality and sensitivity of the healthcare information demands mitigation of cyber risks, hence driving research in encryption technologies, block chain applications and new networking protocols. Networking firms such as Cisco

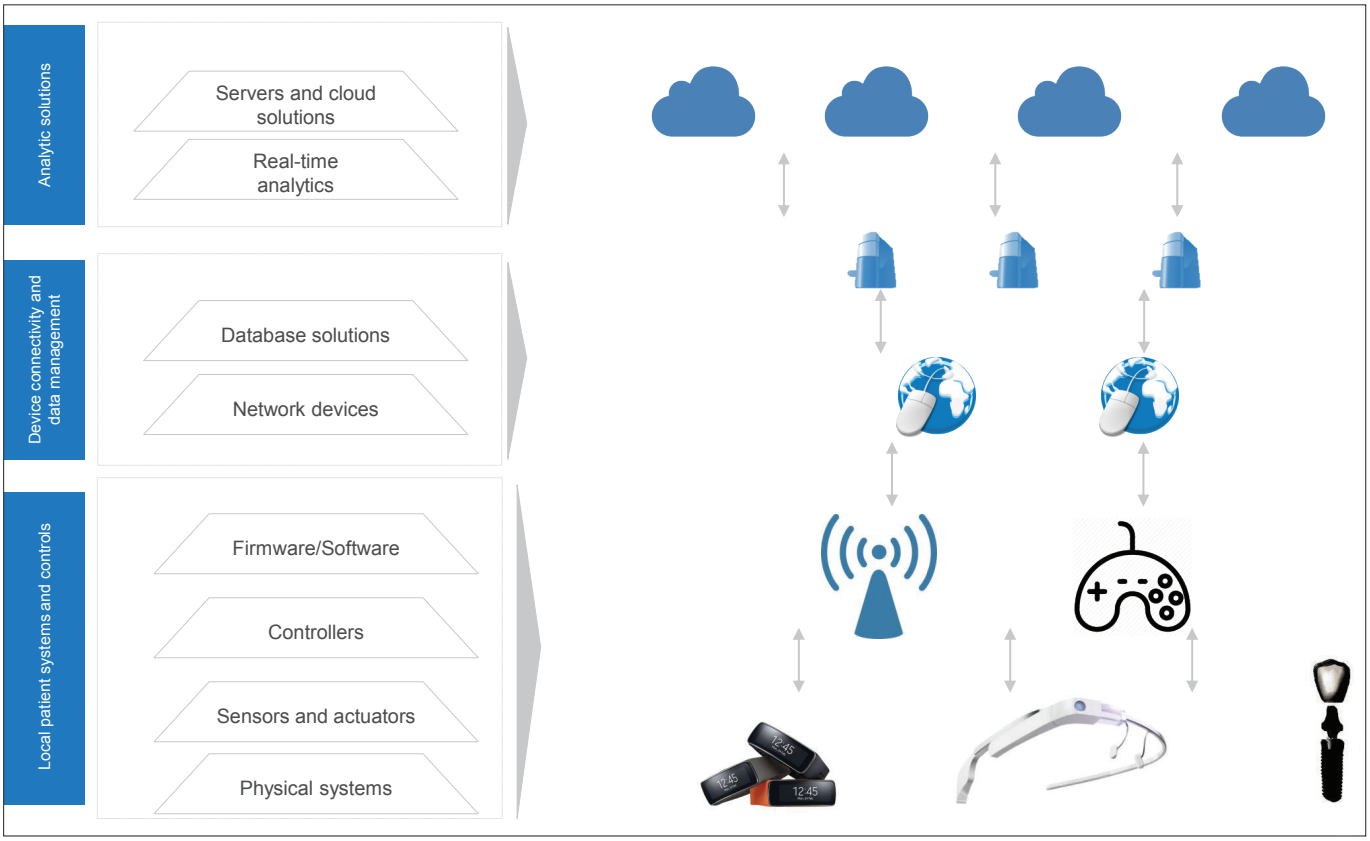

Figure 2: Architecture of IoMT system

and Qualcomm are quite active in providing advanced technologies at this level along with new entrants.

Analytic solutions layer

Irrespective of the types of healthcare solutions enabled, the remote server collects data from multiple devices over the networks. The key innovations at solutions layer are observed in built-in algorithms to analyze real-time operational data, and electronic health records to provide data driven suggestions to treating physicians. This data-driven diligence helps with diagnostic ability, disease prediction, and implementing preventive measures on mass scale.

The IP filed in this domain covers the softwares, and embedded systems for comprehensive evaluation of data from different sources such as implants and smart devices and teach machines to provide differential diagnosis and treatment options based on patient condition.

Changing Intellectual Property landscape

Major IP related to IoMT comprises the equipment, materials, design and software, as well as services and/or processes enabling remote monitoring and intervention capabilities.

Software IP related to IoMT includes the algorithms covering data acquisition, transmission and processing to support telemetry applications. Such control algorithms with embedded software are protectable by patents or copyrights. Copyright protection covers source code from proprietary applications and programming, but provides competitors the freedom to develop equivalent software by using independently formulated coding techniques.

The functional components of physical layers include hardware and embedded controls that perform sequential tasks in order to sense, convert and transmit vital information. Hardware patent primarily comprises of sensors, signal convertors, controllers and communication modems.

IP evolution

The IP in IoMT technologies were conceptualized in 1970 with a patent filed by both Warner–Lambert and Pacemakers Diagnostics clinic of America to disclose the telemetry and telephone transmission link system, to transmit healthcare data to remote locations. However, actual patent filing activities grew robustly after 1989, with the milestone improvements in bio-sensing and integration capabilities.

The bio-sensing and integration technologies in connectivity and solution layer captures dynamic physiological data and transmit it through wireless networks. The IP filings after 1989 marks evolution of telemedicine and IoT devices, which comprise a closed interdependent system of networked sensors, protocols, and cloud computing inventions.

Figure 3: Key IP assignees in IoMT

The Internet-based medical device and remote healthcare assistance segments first flourished in the US due to the country's major market share in conventional medical devices. Remote location-enabled technologies were rapidly adapted in the market due to their widespread clinical acceptance and healthcare policies. Due to this, major corporations opted to protect their inventions in North America, followed by Europe which constitutes 90% and 30% of IP jurisdictional coverage. Key players also adopted to protect their invention in Japan, Australia, and China market pertaining to growing demand and increasing reliance on tele-health services.

Key players

Philips, GE Healthcare, and Medtronic are among leading players in IoMT technology. Philips offers IoMT products that enable cardiac monitoring, remote patient communication devices, and sensors to detect physiological parameters. GE and Medtronic provide comprehensive integrated products that support cloud-based technologies in existing monitoring devices, implants, and cardiac pacemakers

Figure 2 shows the key players at various architectural level and their patent publication trend in last five years. Other players such as Siemens and IBM extend solutions in upper layers, which enable data analytics and cloud-based services to biometric data obtained from physical devices and sensors. Roche and Cerner focus on the integration of smart communication technologies that have the ability to connect diagnostic devices to remote locations.

Milestone innovations

Key technological innovations are classified under the medical data handling (US5924074A), remote networking technologies in medical devices (US5867821A), and data capturing sensor technologies (US6024699A) categories. The following key patents cover the landmark IoMT patents and have been cited frequentl. The Figure 4 shows total number of citing patents for each key patent family.

Recent IP filing focus

Analysis of IP filed in last five years reveals that applications in the areas of network connectivity, sensor integration, cloud based data solutions, artificial intelligence enabled diagnostics are on the rise. Synergistic technologies such as 3D imaging, augmented reality enabled patient education tools, encrypted patient record management, point-of-care devices and wearables are also witnessing the spurt in patent filing due to development of dependent technologies.

Aranca perspective

The IoT implementation in healthcare domain is currently in a nascent stage of development. Although implementation of this technology is likely to provide a number of advantages; device security, interrupted communication and reliability pose main

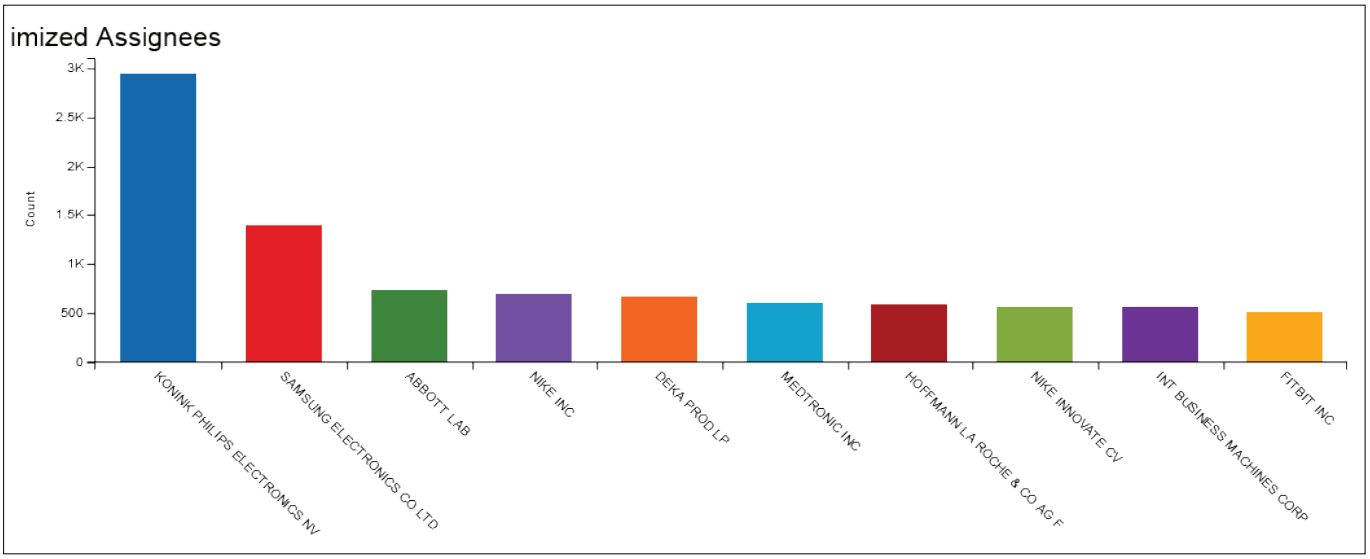

Figure 4: Key IP assignees in IoMT

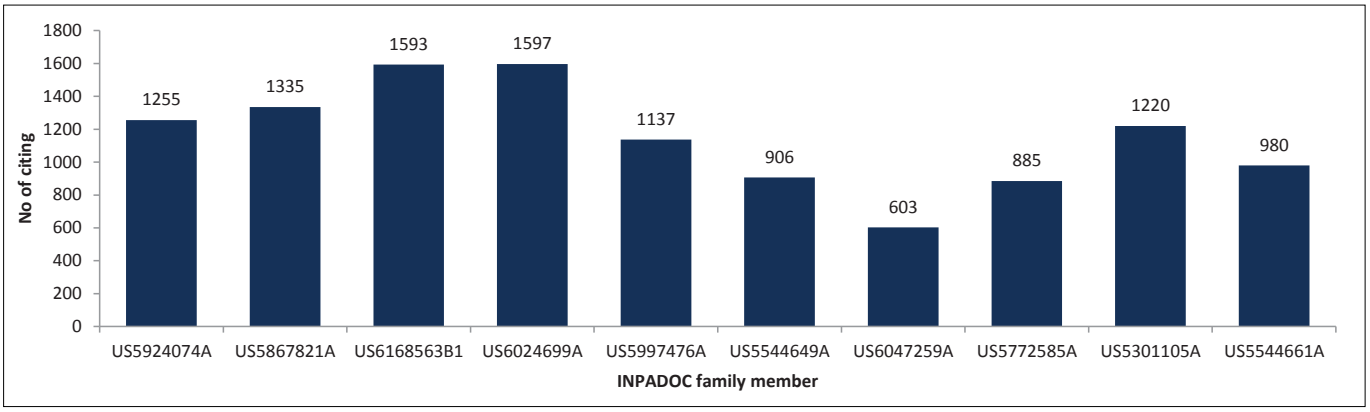

Figure 5: Key Inventions

concerns in mass adoption. The foreseen clinical practices advantages would drive the emergence of new innovations and IP players in this opportunity.

Currently explored areas such data-driven decision making algorithms, disease prediction capabilities, faster and secure data transmission, autonomous healthcare logistics, robot enabled interventions, deep-learning based professional assistance, large capacity storages and integration of device would be key focus in future IP filings. The connected systems are forecast to reduce cost for patients, increase treatment adherence, and offer the advantage of locally smart devices that can control health automatically, would be incremental solution offerings.

As long distance connectivity, secure transmission, uninterrupted storage and processing of high volume of data would be major factors governing successful implementation of IoMT; Hence companies providing these services (such as Telecom front end back-haul providers, Cloud storage service providers/ datacenter owners and security solution providers) would be major beneficiary of this trend and likely to emerge as leading IP filers in coming years.

On the other side, tier 2 supplier companies such as Vodafone, Verizon, AT&T, NTT, Sprint would also play a significant role in implementing IoMT. These companies could-

1. Collaborate with Implantable/ Wearable device manufacturers or doctors; or
2. Develop service business models such as:
   - One time fees for implantable device, per person
   - Monthly recharge for few devices, per person
   - Family based fitness plans to develop new IP and play a pivotal role.
   -

Considering the above benefits and challenges, IoMT seems a promising solution to improve healthcare monitoring and treatment outcomes. By leveraging core capabilities in data acquisition, transmission and processing, we believe that telecom front end back-haul providers, Cloud storage service providers/ datacenter owners and security solution providers are set to promote personalized care and improve living standards. ■

Cobots in the Pharma Industry: A Step into the Future

Collaborative Robots safely work alongside humans, without any danger of getting hurt, and more as a "worker's assistant" or "third arm" or "helping hand" or "portable tool" which traditional industrial robots cannot be used as. This is a perfect example of how manufacturing is becoming highly automated and IT-enabled or "Smart" and how Collaborative Robots (Cobots) are driving Industry 4.0 by Human-Robot collaboration paradigm.

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General Manager - India and Sri Lanka
Universal Robots

Automation in its broadest sense has expanded from its original industrial manufacturing base to laboratories and businesses. The application of robotics and automation has been successfully achieved in a wide range of industries dealing with well defined processes and products like the manufacturing industry, FMCG, automotive industry, the healthcare industry, the pharmaceutical industry, to name a few.

Technological advancements have revolutionized automation to the current level of complexity and flexibility; even so, the pharmaceutical industry faces a few issues like the commercial environment is getting harsher, as healthcare payers impose new cost constraints on healthcare providers who scrutinize the value medicines offer much more carefully. This leads to a sharp rise in the customer expectations for newer therapies, which are economically better than existing alternatives, while being medically superior.

The industry output has remained at a stable level for the past decade. Using the same discovering and developing processes, there's little reason to think its productivity will suddenly soar. Lastly, the prevailing management culture, mental models and strategies on which the industry relies are traditional, even though they've been eclipsed by new ways of doing business, leaving a huge margin for human error.

The many benefits of automation include efficiency, saving workers from hazardous environments or repetitive tasks, reducing training overhead, eliminating human error, increasing repeatability, reproducibility, and in clean-rooms, removing the potential for human contamination.

Automation also improves compliance and minimizes deviations by connecting instruments to electronic systems, so users don't have to manually enter data. Cloud- based software, with appropriate security protocols can be adopted to facilitate integration and automation. This reduces the paper work of the companies, making data manageable.

Robots, as are being introduced into every industry, the pharmaceutical industry too has begun adopting robotics in production and distribution. A study by the Association for Packaging and Processing Technologies (PMMI) found that robots are expected to handle 34 per cent of primary pharmaceutical packaging operations in USA by 2018, compared with 21 per cent in 2013. An increase in the use of robots is seen in dispensing, sorting, kit assembly, and light machine-tending as well as in more traditional applications associated with packaging. The global use of robotics in the Pharma sector has invariable increased in the past couple of years.

With the idea of higher production rate and the need for human interaction with machine automation, the Collaborative robots were first developed in 2008 by Universal Robots. Universal Robots are the leading manufacturers of advanced user-friendly and light industrial robotic arms from Denmark. Their latest technological advancement in collaborative robots or 'Co-bots' was brought out in the international market with a peculiar intention which is in line with Industrial 4.0; which is in sync with the automated revolution in the Pharma industry.

Robotic arms from Universal Robots are designed to meet the Pharma industry's specifications for accuracy, precision and hygiene. Robotics in the pharmaceutical

industry is performing a wide range of tasks: from packaging in medical devices and implants as well as assisting in surgeries. The robot arms from Universal Robots can be used for mixing, counting, dispensing and inspection to deliver consistent results for business-critical products. They can also be used for sterile handling and assembly of the small, delicate parts that are used in prosthetics, implants and medical devices.

Three robotic arms from Universal Robots namely UR3, UR5 and UR10 can incorporated into the processes so that engineers could easily adapt the software to the specific needs of the drugs and the required tasks. The easy programming, installation and collaborative nature of the industrial robot arms allow them to work side-by-side with the workforce for efficient, high-quality medicines.

Automation has been an indispensible part of the Indian manufacturing industry for decades now and has seen remarkable improvements in the efficiency and productivity of the industry.

According to IBEF, the domestic Indian pharmaceutical industry was estimated to be USD 36 billion in 2016 growing at nearly 20 per cent and is expected to reach nearly USD 55 billion in 2020. It is evident that a lot of internal factors are responsible for the growing Indian pharmaceutical industry. There are more than 200 companies' medicines for the largest population in the world which adds to the prevailing competition on the domestic front. The Indian Pharma industry is a success story in developing countries because within a span of three decades India has become one of the world's largest manufacturers of medicines.

The past decade has seen a change in the mindset of most pharmaceutical companies and a digital wave has swept the USD 36 billion Indian pharmaceutical Industry. The pharmaceuticals are now keen in adopting technology in every aspect of their operations.

Thus, the incorporation of collaborative robots will be a timely introduction to revolutionize the Indian Pharma industry which will bring optimization of processes, reduce waste, improve yield in production, with higher efficiency and precision. The functions that have already embraced automation will continue to prevail with incremental improvements from the normal cycle of technological innovation. Areas that are likely to witness quantum leaps will be in the integration between development work and manufacturing, efficiency and optimum utilization of robotics in the industry. ■

Contract Manufacturing

With the advent of multinational pharmaceutical organisations, and their rapidly growing presence in the country, the concept of contract manufacturing has steadily evolved and quickly adapted, so as to encompass services such as basic manufacturing of medicinal products, formulation development, stability studies, and various stages of clinical trials. This article look at the Indian scenario of pharmaceutical contract manufacturing, how the space has changed, upcoming trends, as well as what the industry will look like in the coming years.

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With snowballing growth of pharmaceutical industry in India, the concept and requirement of contract manufacturing is incessantly evolving. Now-a-days contract manufacturing has been extended to bring within its ambit various services, such as basic manufacturing of medicinal products, formulation development, stability studies and clinical trials. Off late, contract manufacturing is practiced in most of the industrial sectors, not limited to pharmaceutical sector alone. However, till date the concept of contract manufacturing has made significant impact in the pharmaceutical industry.

Indian pharmaceutical sector has witnessed a strong hold in the processes of manufacturing/production due to the encouragement/recognition of process patent alone prior to 2005. Post 2005, an additional recognition in the form of product patents led to exponential growth in pharmaceutical sector. This led to an increase of manufacturing through contracts.

This apart, India's allure as a viable outsourcing market lies in the fact of its resources including skilled labor, governmental incentives and WHO- GMP approved premises. In addition, contract manufacturing is expected to increase due to the fact that a number of patents over top-selling drugs are expected to expire, creating a profitable and differential opportunity to outsource to legally manufacture such drugs.

As per the Draft Pharmaceutical Policy issued by the Department of Pharmaceuticals in August 2017, cost of the drugs in India are about 50% lesser as compared to Western nations. Indian companies have around 1300 WHO-GMP, 262 USFDA (outside USA) and 253 EDQM approved plants being operational and functional till date, making India a preferred and safe business haven for contract manufacturing. Said policy further substantiate that the annual turnover of the Pharmaceutical Industry in India in 2015-2016 was around 30.76 billion dollars, out of which exports constituted around 15.38 billion dollars and the domestic consumption was 15.14 billion dollars, showcasing a brewing export in pharmaceutical sector.

The advantages of contract manufacturing is not alien to us and the primary reason behind entering into a contract manufacturing is to have a sustainable growth. For instance, an entity which is primarily engaged in the business of R&D can invest on labor, materials and other expenses related to production by outsourcing the same to another organization which is primarily engaged in the business of manufacturing and supply. Roughly, a substantial 40%-50% lower cost of operation and production is clearly operating as pulling-mechanism for multinationals to consider India for their outsourcing needs.

Further, contract manufacturing helps an entity in spreading its arm in another market, rather than spending billions of dollars and time in setting up its operations in that country. By entering into alliances/ agreements with already established manufacturers in India, these outsourcing companies can have their expectations met at a cost which is dramatically lower than the cost of establishing itself in a new location. In addition to this, contract manufacturing allows for exploiting manufacturing counterparts' pre-established marketing channels, which is a major consideration.

Contract manufacturing as a business model is not only serving the purposes of the parties involved but has also prompted the growth of research and development in India. As one of the ground realities which is a prohibitory factor in conducting R&D in India, is paucity of funds. Hence, off late several Indian companies have

entered into research partnerships with multinationals, and have established R&D facilities as separate units in order to scale up resources and attract focused investments. Such strategies have two-fold benefits: increase in R&D activities and a constant financial support.

The Government has encouraged such engagements by revising its FDI policy, which is effective from August 28, 2017, bringing significant changes in the amount of FDI allowed in the pharmaceutical sector. Where, under the erstwhile FDI policy, no FDI was permitted in brownfield pharmaceutical projects without government approval, the new policy allows 100% FDI in brownfield pharmaceutical projects, with up to 74% allowed in the automatic route and up to 74% allowed in the government approval route.

However, entering into an arrangement for contract manufacturing not only requires compliance with the quality standards but also requires cross-jurisdictional regulatory compliances. There could be a situation where an US entity has entered into an agreement for manufacturing a product which might be prohibited for manufacturing/production in India. In such situations, both the entities have to be cautious of cross-jurisdictional regulatory requirements well in advance before entering into such transactions.

One of the important aspects which entities should deliberate and negotiate beforehand, is the ownership and exploitation of IPRs generated thereunder, both in terms of the IP transferred and IP created during such process. It is inevitable that whenever an outsourcing company enters into a contract for manufacture with any manufacturer, there is an exchange of a large amount IP. The manufacturer is privy to information which is of a highly sensitive nature, the protection of which becomes extremely necessary, so that the outsourcing company does not lose its competitive edge. Thus, clear cut indication in the agreement that the information transferred to the manufacturer is "CONFIDENTIAL", is imperative. However, mere indication that certain information is "CONFIDENTIAL" without giving any clarity on the consequences of its disclosure will dilute the agreement. These situations play a larger role in cross border arrangements.

Regarding, ownership of IPRs, there could be several approaches to determine ownership of IP rights, namely

- Solely owned – either by the outsourcing company or the manufacturer or
- Joint ownership – subject to mutually agreed terms.

However, such arrangements only serve to prompt more questions such as ownership of the IP created by an employee/ independent contractor, ownership over improvements and customizations, exploitation of jointly held IP, consequences of termination of contract on the outsourcing company's IP, etc. Since a lot of the considerations stipulated hereinabove can only be decided upon negotiation, an IP due diligence, prior to execution becomes crucial.

Trade Secrets form a major chunk of the exchange of IP under contract manufacturing. A trade secret, by its very nature, remains significant only until it is protected by secrecy and quickly becomes obsolete once disclosed. Thus, such disclosure can lead to disastrous consequences, such as, the usage of such information for the advantage of the manufacturer or transferring such information to the competitors of the outsourcing company. Unlike the USA, India does not have any codified legislation for protecting Trade Secrets. However, Trade Secrets in India can be protected under a contractual obligation. The Indian Judiciary has observed the importance of Trade Secrets in multiple occasions. For instance, the Hon'ble Delhi High Court in Telefonaktiebolaget LM Ericsson(Publ) vs. Xiaomi Technology & Ors; CS (COMM) 434/2016, on October 24, 2017, observed:

"The reason probably is in today's world of globalization, where competition is at its peak, the organizations may not be inclined to disclose trade secrets/confidential agreements or its details, it had entered with different parties lest may cause serious prejudice to such parties because of competition involved. A trade secrets may make or break a company hence need to be protected. Once such disclosure is made or is misused by a competitor no order of the Court can save the company from loss or could retrieve it to its original position."

Thus, it is imperative to have express clauses for "Trade Secrets" in any contract of manufacturing especially in the absence of any existing legislation for the same in India.

In the absence of a codified legislation for protecting Confidential Information and/or Trade Secrets, the concept of "Confidentiality Clubs" have been devised by the Indian judiciary. These "Confidentiality Clubs" are constituted on a case to case basis to deal with any instances of breach of confidentiality and/or disclosure of Trade Secrets. This positive approach by Indian Judicial System, by regulating the access of the parties through their representatives and preventing further unauthorized disclosures, is a positive sign in recognizing and protecting the rights over Confidential Information and/or Trade Secrets.

As per recent reports, the contract manufacturing space in India is expected to grow around 20% on a compound annual growth rate. Thus, any entity should utilize this smart way of doing business but with water tight clauses. Such requirements are not only suggested to protect the interest of the parties involved but also to send a positive signal regarding the booming pharmaceutical sector in India.■

Unlocking Business Efficiency through Proactive Asset Management

This article discusses how the processes of asset redeployment, as well as the buying and selling of surplus and idle laboratory and production instrumentation can benefit the pharmaceutical industry.

Ben Potenza
VP Marketing
EquipNet Inc.

The global pharmaceutical market is growing 7.8 per cent year on year and is estimated to be worth around USD 1.6 trillion by 2020. As the world's population continues to grow and age, so will this industry[1]. At the same time, pharmaceutical companies are facing a range of challenges which are forcing them to reduce both time to market and costs. For instance, more stringent healthcare regulations are being introduced and payers are putting pressure on companies to adapt their pricing policies and commercial models.

Mergers and acquisitions are becoming more common-place, which means that equipment can fall out of use even though they remain valuable for a variety of uses such as drug discovery, manufacturing and the packaging of commercially available products. Additionally, new products are constantly being launched across the sector, meaning that instrumentation needs are also evolving.

An Innovative Solution

An increasing demand from pharmaceutical businesses for low-cost laboratory and manufacturing instrumentation solutions has resulted from the need for companies to focus on leaner production, as well as meeting the fluctuations in demand. These pharmaceutical companies are now beginning to purchase high-quality, used equipment in order to expand into new production areas, as well as to maximize budget; it is common to save between 50-75 per cent of the cost of new instrumentation. Furthermore, the advantage with purchasing second-hand equipment is that it is often available immediately, unlike new instrumentation[2].

In order to obtain returns from surplus machinery, time and expertise is needed. Many pharmaceutical companies do not have this however and implementing a partnership with a specialist provider can help to execute an asset management strategy. These asset management experts can provide useful information on budgets, specification and risk mitigation (how reputable a supplier is, for example). Industry experts can then guide companies through the purchasing process by helping them to obtain existing warranties on equipment and provide follow-up support allowing an efficient process for the purchaser.

EquipNet provides a holistic approach to surplus asset management for both buyers and sellers and this is illustrated in the EquipNet 'Value Control Model' (See Figure 1 on next page), which is based on time and can be customized using a central tracking platform. This provides communication and workflow tools and ensures the exposure of all assets throughout a business. A variety of disposition channels, which include redeployment, negotiated sales with managed pricing through an online market and competitive auctions can also be used. Other options include clearance, disposal and scrap programs, which can be customized for each specific customer.

To redeploy equipment and keep track of surplus assets, partners should possess a reputable software platform to list assets across a business. A company can then view all equipment across a variety of locations worldwide.

Figure 1: EquipNet's Value Control Model EquipNet's 'Value Control Model' shows how redeployment, negotiated sales with managed pricing through an on-line marketplace, competitive auction events and clearance programs fit together to deliver a consolidated service. This ensures a 'seller' company achieves maximum return and at the same time sees idle equipment become available to a 'buying' company. In many cases, a business is both a seller and a buyer at different times.

Redeployment

Redeployment of instrumentation allows businesses to gain the highest possible value from equipment and is hard to achieve without a central tracking platform. This software allows users to post, track, identify and then internally redeploy an instrument that is laying idle or not being used in its current location. Should this not be possible a company can then decide whether the external sale of equipment or the purchase of another instrument is necessary.

A proven example of a tracking platform used within this market is EquipNet's Asset Redeployment Management System (ARMS') platform, which features workflow management and multiple access levels for employees across a business, including plant managers and executives. ARMS can provide in-depth information on the equipment a business currently owns and which site it is located at.

Looking to Sell?

Should the redeployment of an asset not be possible, a company should then look to sell the instrument. An auction is a reliable way to sell equipment. Dealing with the auction process however is difficult and success depends on a number of factors. An asset management partner can provide advice on how to approach this process for each individual customer.

Therefore, using a company with specific industry experience and a good reputation is important. Options can include online auctions, live/webcast auction events, sealed bids and private treaty events. Further customized solutions for selling equipment include EquipNet's MarketPlace platform. MarketPlace lists used equipment available for purchase, however, in contrast to auctions, which are scheduled events for selling a large group

of used equipment from client facilities, MarketPlace allows price negotiation for an instrument at anytime.

Should it not be possible to redeploy assets as they have little or no value, clearance by donations, scrap and environmental recycling are the best options. It can be the case that the scrap value of idle equipment can achieve the highest return. It is common for EquipNet to advise clients in this area.

The purchase of second-hand equipment
Pharmaceutical companies now face the ever more difficult challenge of meeting rising demand, as well as more rigorous commercial targets. All kinds of businesses are now taking advantage of the savings to be made from purchasing pre-owned equipment from top-tier manufacturers. This is in contrast to constantly buying new instrumentation. Buyer companies therefore, often invest in high-quality second-hand instrumentation in order to maintain a low cost-base while continuing to improve company processes and services. Asset management partners can inform businesses of appropriate auctions, as well as how to use negotiated sales platforms such as MarketPlace. Collection and delivery are all that need to be organized following the purchase of equipment.

Summary
As the pharmaceutical sector continues to grow, businesses are keen to further reduce time to market, as well as costs. Redeploying and selling equipment with a reliable asset management partner can help businesses obtain the maximum returns on an instrument, as well as ensure operational efficiency. Buyers are also able to purchase unwanted, high-quality equipment for a fair price. An asset management partner can therefore provide important solutions for companies looking to redeploy, sell and purchase surplus assets.

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FORM IV

Statement about ownership and other particulars about newspaper **PHARMA BIO WORLD** to be published in the first issue every year after the last day of February

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I Hemant K Shetty, hereby declare that the particulars given above are true to the best of my knowledge and belief.

Date: 20th January 2020

Signature of Publisher

Ami Polymer Signs Master Distribution Agreement with Foxx Life Sciences.

Ami Polymer Pvt. Ltd. Pleased to announce that on 18th Nov. 2019 International Distribution Network was offered by signing an exclusive master distribution agreement with Foxx Life Sciences offering a service to customer in North America, Mexico and Canada by quick access to the company products.

"Foxx Life Sciences" Global leader in single-use technology having a strong presence in the Bioprocess market, through strategic planning and acquisition, commitment, and hard work, Foxx has developed an unparalleled reputation for technical expertise, quality and value.

"Ami Polymer Pvt. Ltd." is leader in rubber product manufacturing for food, pharma, Medical, and heavy engineering industries. Ami is enjoying the business growth through offering products with excellence in quality, ultimate customer satisfaction and being in business with ethics.

"This Imperative addition will allow Foxx Life Sciences to become a key global supplier to the pharmaceutical and biotech markets and for that our strategic Partnership will help businesses to create business plans that provide profitable, sustainable results" said by President and CEO of Foxx life sciences Thomas Taylor

"For the first time Ami is going to do long term business partnership. Ami is super excited to take a step forward with team Foxx and it will enhanced the wide business opportunities in pharma sector with technological advancement and Customer Satisfaction " said by Managing Director of Ami Polymer Pvt. Ltd. Mr. Alpesh Gandhi.

"An organization that helps business to develop strong leaders while creating a culture where self-improvement is an intrinsic part of the organization's value system" – Combined motive of "Foxx" and "Ami"

The Network allows full coverage of specialized Pharma Tubings (Platinum cured Silicone, TPE, FKM, and FEP tubings), O-rings, Manifolds, and Sanitary Gaskets for the markets such as Bio pharma, Medical and Lifesciences.

Established in 1996 at Mumbai (Maharashtra, India), Ami Polymer Pvt. Ltd. is an ISO 9001:2015, ISO 14001:2015 and OHSAS 18001: 2007 TUV Nord certified company having 375 employees (25+ polymer technologists) devoted to manufacturing and supplying the finest quality range of biopharmaceuticals grade elastomer tubing, reinforced hose, inflatable gaskets and all types of extruded & molded components. our product range is designed ,fabricated and distributed among 5000+ customers of various industrial sectors including; pharmaceutical, biotech, food processing, medical, solar, aerospace, engineering, textile, steel etc...For more information visit amipolymer.com.

Ami polymer is having 15 registered product brands with 7 Drug master files for USFDA and NSF-51 USA certifications on the products.

Located just 50 kilometers north of Boston, Foxx Life Sciences is a privately held world leader in custom single-use systems (SUS) including tubing, bag, bottle, flask and carboy assemblies, filtration, fluid management, laboratory safety products, and lab glassware for the research, biotech, and pharmaceutical industries. In addition to the Foxx Product line, the company distributes over 1,000 products from Borosil, Ami Polymer, and CPC. The company is Quality focused with ISO 13485: 2016 certified since 2010, ISO Class 7 cleanrooms, and three locations. For more information, call 617-320-1138 or visit FoxxLifeSciences.com ■

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Allergan, Sightsavers and the LAPB Announce the 'Keep Sight' Initiative to Address Glaucoma in Ganjam, Odisha

- A unique initiative which joins an innovative eyecare biopharma leader with international charities to train healthcare professionals to diagnose and treat patients with glaucoma --
- Glaucoma is the second most common cause of blindness worldwide1 and with adequate screening and diagnosis, vision loss can be prevented

Allergan, Sightsavers and the International Agency for the Prevention of Blindness (IAPB) announced the launch of its unique joint initiative - 'Keep Sight India' – a community based glaucoma screening progamme to prevent glaucoma-related vision loss in Ganjam District, Odisha. The pilot kicked off in October 2019 in partnership with Sightsavers local partner, Sankara Eye Hospital. Glaucoma is the second leading cause of blindness and a leading cause of irreversible blindness in India with at least 12 million people affected1 and nearly 1.2 million people blind from the disease. More than 90 percent of cases of glaucoma remain undiagnosed in the community.1 Glaucoma prevalence increases with age. Several studies conducted in India reveal that the estimated prevalence of glaucoma varies from 1.7% to 3.5% in people above 40 years of age, and the differences are largely because of the regional and methodological variations. It is estimated at 11.2 million people for the age group 40 plus which is quite high.

The progamme provides training for healthcare professionals to screen at-risk populations, ensure early and accurate diagnosis and provide appropriate treatment and long-term care in an effort to make a positive impact on people with glaucoma at all levels of comprehensive eye care.

The first outreach camp was organised on December 3rd, 2019 on World Disability Day and subsequently four outreach camps were conducted under the pilot project. The outreach camps included services like vision testing, refraction, IOP measurement, fundus photography, spectacle dispensing, cataract identification, referral services and counselling services. To date 8276 people have been screened for glaucoma in these four outreach camps, from which 749 glaucoma suspects were identified and referred to the base hospital.2

Sightsavers India CEO, RN Mohanty said: "We are excited to be partnering with Allergan, an organisation with a long legacy in eyecare. Sightsavers too like Allergan is committed in finding and providing effective solutions for patients suffering with glaucoma, which is one of the leading causes of irreversible blindness. The typical barriers we face on ground include inadequate human resources, a lack of awareness and limited access to medical treatments. The partnership between Sightsavers and Allergan is an example of the vital associations that are needed to fight avoidable blindness and deliver better services at the community level."

Dr SY Quraishi, Honorary Chairman Sightsavers India Board and former Chief Election Commissioner, India said, "Nearly 75% of sight loss can be cured or prevented, so it's an area where initiatives like this can have a strong impact where it is needed the most. I'm happy to know that people in and around Ganjam will become aware about Glaucoma and take adequate corrective measures which are now accessible via eye screening camps in the community and services at the Sankara Eye Hospital, Samarjhola."

"India will play a crucial role in meeting WHO's targets for eye health", said Joanna Conlon, Director of Development and Communications, IAPB**.** "The country is already at the forefront of delivering people- centered solutions for eye care. Keep Sight will work with Indian partners to support and extend India's successes around eye health and glaucoma. IAPB is committed to universal eye health. Sightsavers has decades of experience in delivering eye health in the region. Together with Allergan, they are keen to make a real difference for people with Glaucoma. Together, we will work to support India's eye care strategies".

"Allergan is honoured to partner with Sightsavers and IAPB on 'Keep Sight'; their wealth of knowledge and expertise, combined with our passion for science and solutions will have a real impact on our shared goal of reducing the high burden of irreversible blindness in the country. For almost two decades Allergan has been committed to developing novel approaches to preserve visual function and prevent blindness caused by glaucoma. 'Keep Sight' is an initiative that will make a real difference to people with glaucoma in India." said Gopinath Kesavan, Associate Director, Eyecare, Allergan India

Keep Sight India Project Update

The outputs of the programme achieved up until January 2020 are detailed below. The outputs include numbers from both outreach and hospital interventions.

Plan for next Quarter (Jan-Mar 2020)

The next quarter of the project will focus primarily on the following activities:

- Training of Ophthalmologists on glaucoma care/management through International Council of Ophthalmology

Particulars	Target	Achieved to date (Oct 2019 – Jan 2020)	%
Number of persons screened for glaucoma	30000	8276	27.6 %
Number of persons referred for glaucoma diagnosis	3000	749	25.0 %
Number of persons identified with glaucoma	650	259	40.0 %
Number of cases of glaucoma treated with medication	350	189	54.0 %
Number of glaucoma cases treated with surgery (including Yag PI)	370	116	31.4 %
Number of cases identified for low vision and rehabilitation	15	0	0.0 %
Ophthalmologists trained on basic glaucoma protocols		6	
Optometrists trained on basic glaucoma protocols		3	
Health workers trained on basic glaucoma protocols		18	

- Strengthening interventions for follow-up compliance of patients diagnosed with glaucoma or treated under the programme
- Strengthening outreach interventions in terms of reducing per patient time in camps
- Continuous learning, training and skilling of the project team
- Development and dissemination of project communication materials in local language

Sightsavers is an international organisation that works in more than 30 developing countries to prevent blindness, restore sight and advocate for social inclusion and equal rights for people with disabilities.

Research consortium set up to promote high quality primary health care across the globe

Seven international research organizations have come together to form a Primary Health Care Measurement and Implementation Research Consortium (RC). The consortium is funded by a grant from the Bill and Melinda Gates Foundation (BMGF) and will have its secretariat at the India office of The George Institute.

The other six global research organisations who are the founding members of the consortium are the American University of Beirut, Lebanon; Ariadne Labs, USA; George Washington University, USA; International Centre for Diarrheal Disease Research, Bangladesh; Primary Care and Family Medicine Network (Primafamed), Sub-Saharan Africa and World Organization of Family Doctors (WONCA).

The consortium has been set up to develop, conduct and disseminate research designed to address priority knowledge gaps in delivering high quality, person-centred primary health care in low- and middle-income countries, also known as LMICs. “The value of a research consortium that enables collaboration between research institutes in LMICs is clear. There is immediate potential for global reach, both to identify knowledge needs and to do effective country-based research and dissemination”, says Prof Bob Mash from Primafamed, Chair of the research consortium’s Steering Committee.

Additionally, the research consortium will develop and maintain a global primary health care research network. These organizations will conduct prioritized and policy-relevant research to support country and global efforts to build high-quality primary health care systems in pursuit of effective universal health coverage and health-related Sustainable Development Goals.

The consortium will bring together primary health care practitioners, researchers, and policymakers from multiple disciplines representing academic institutions, government agencies, international organizations, and non-governmental organizations to prioritize areas and define a way to accelerate progress in primary health care research. “The consortium will enable meaningful engagement with stakeholders, both knowledge users and beneficiaries. This engagement will integrate best practices in knowledge translation, dissemination science, and dialogue in the research process”, says Dr D Praveen, Head of primary healthcare research in George Institute, and Acting Director of the research consortium.

The research agenda will focus on answering questions raised by countries and regions in how to more effectively measure and improve primary health care, initially centring on the delivery mechanisms. Focus areas will be primary care governance, financing, organization and models of care, and performance management, quality, and safety. Partnering organizations have already conducted extensive work to develop evidence gap maps, prioritized questions, and potential research projects engaging a wide range of stakeholders from more than 65 countries.

“The formative work already conducted by the consortium combined with the extensive networks that the founding organisations currently participate in will support rapid engagement in multiple low- and middle-income countries through policymakers, implementers and academic institutions,” said Dr Praveen.

IIT Hyderabad Researchers make their own hand sanitizer in accordance with WHO standards

Indian Institute of Technology Hyderabad Researchers have developed their own hand sanitizer, in line with the standards recommended by World Health Organization (WHO) and Centers for Disease Control (CDC), a Federal Health Agency in the U.S, for the Institute Community.

Around ten liters of this hand sanitizer have already been deployed in the campus for the benefit of the students, staff and faculty. This makes it more likely that people will use it and this will help stop the spread of germs and promote good health and hygiene.

This has been developed by Dr. Shivakalyani Adepu, who was a Research Scholar at the Department of Materials Science and Metallurgical Engineering, IIT Hyderabad along with Dr. Mudrika Khandelwal, Associate professor, Department of Materials Science and Metallurgical Engineering, IIT Hyderabad.

Speaking about their effort, by Dr. Mudrika Khandelwal, Associate professor, Department of Materials Science and Metallurgical Engineering, IIT Hyderabad, said, “My research group has always believed in doing scientific research and outreach for the benefit of society. This is our small contribution at the time of need. I am glad we would make this happen and hope to make similar contributions in the future.”

The composition of this hand sanitizer is 70 per cent isopropanol with glycerol, polypropylene glycol to increase the viscosity and reduce the volatility so that the sanitizer stays on skin to allow action, as well as lemongrass oil for antimicrobial activity and therapeutic aroma. The 70 per cent IPA solution penetrates the cell wall, coagulates all proteins, and therefore the microorganism dies.

Adding on, Dr. Shivakalyani Adepu, said, “This was done purely to support the community at this time when it is critical to adopt safe and hygienic practices. We have not thought of commercialization. Our motto is to help people around us. We can assure that these are as safe as any commercial sanitizer, and possibly more effective. Our laboratory conducts a lot of microbiological studies and we have tested these kinds of materials before and have been using the same for several years now. Its efficacy is well known and has been reported.”

According to WHO and CDC, hands account for transmitting nearly 80 per cent of the infections due to frequent touching of eyes, nose, mouth and ears which leads to the entry of germs. Nearly one in five people do not regularly wash their hands. Of those who do, 70 per cent do not use soap. The alcohol-based hand sanitizers kill most bacteria, and fungi, and stop some viruses, present on hands within 30 seconds of application.

If 70 percent of alcohol is poured to a single-celled organism, the diluted alcohol also coagulates the protein, but at a slower rate, so that it penetrates all the way through the cell before coagulation can block it. Then the entire cell is coagulated and the organism dies.

Singapore eDevelopment Ltd makes breakthrough research on SARS-CoV-2

Singapore eDevelopment Ltd has announced that its wholly-owned U.S. biomedical subsidiary Impact BioMedical, Inc. has through its scientific research partner GRDG Sciences, LLC. conducted molecular docking studies utilizing advanced computational models, indicating that its Linebacker and Equivir compounds successfully inhibit infection by SARS-CoV-2, the virus responsible for the COVID-19 outbreak. The results indicate that the two compounds block 3 integral viral mechanisms for SARS-CoV-2 replication and infection: the viral spike interaction point, helicase, and protease.

Equivir and Linebacker are undergoing accelerated testing against the SARS-CoV-2 virus and data is expected to confirm efficacy based on previous work against other coronaviruses such as SARS and MERS. This research is part of a program conducted by GRDG to adhere to the principles and initiatives established by Project Bioshield and the Biomedical Advanced Research and Development Authority (BARDA) directives from the U.S. Department of Health and Human Services (HHS).

On 11 March 2020, the World Health Organisation Director-General, Dr. Tedros Adhanom Ghebreyesus stated that there are more than 118,000 cases of COVID-19 in 114 countries and 4,291 people have lost their lives to COVID-19. The World Health Organisation has therefore made the assessment that COVID-19 can be characterised as a pandemic and this is the first pandemic caused by a coronavirus, he added.

"Recent studies and analyses indicate that Angiotensin converting enzyme 2 ("ACE2") could be the host receptor for the novel coronavirus 2019-nCoV/SARS-CoV-2," says Dr. David Ostrov, PhD, a structural biologist / immunologist in the Department of Pathology, Immunology and Laboratory Medicine at the University of Florida, who previously discovered compounds that bind to ACE2, blocking interactions with SARS. "These new compounds with the potential to bind ACE2 and block coronavirus entry into cells were identified by simulation of structural interactions. New drug candidates will be evaluated for effects on coronavirus with GRDG."

Identifying ACE2 as the host receptor for SARS-CoV-2 is significant, however, inhibiting ACE2 is problematic as ACE2 is required to regulate cardiovascular system. Therefore, the intention is to modulate ACE2 through a conformational change to prevent interaction with the virus while simultaneously inhibiting the helicase and protease sites of the ACE2 which are necessary for viral replication.

The research is headed by Mr. Daryl Thompson, GRDG's Director of Scientific Initiatives. "The coronavirus presents a unique challenge in that it appears to exploit a 'hand shake' docking site to human cellular membranes that is atypical of Influenza and Rhinovirus. Influenza attaches to human membranes through the use of ICAM or intercellular adhesion molecules to download its genetic material.

"It's now becoming clear that the present strain of coronavirus is hijacking the ACE2 or Angiotensin Converting Enzyme pathway to accomplish the same goal. The issue is that ACE2 is essential for maintaining the health of the pulmonary system and may not be a straightforward target for inhibition. Instead, we are utilizing both Linebacker and Equivir therapeutics as molecular probes to identify methods to make the ACE2 resistant and less accessible to coronavirus infection," says Mr. Thompson.

"We are constantly pushing to stay ahead of this virus and look to provide meaningful solutions to the current pandemic situation at the soonest," said Mr. Chan Heng Fai, Executive Chairman and Executive Director of SeD.

Dalmia Group Launches "Corona Virus Preventive Capsule" for Prevention Against Covid-19

Dalmia Group launched Herbal Composition "dhl CoronaVirus Preventive Capsule" for prevention against COVID-19. The medicine will be launched on 16th March 2020 in New Delhi, to be available for purchase across all pharmacies in Delhi NCR. It will also be available all over India through the online retail platform, Dalmia Best Price (dalmiabestprice.in). The medicine is priced at Rs 480 for 60 capsules.

Mr. Sanjay Dalmia, Chairman, Dalmia Group of companies, said, DHL Coronovirus Preventive capsule, a polyherbal combination can be effectively used for the prevention against Coronavirus as it will work mainly on the immune system to further boost it and acts as a bronchodilator, decongestant, anti -inflammatory and lung detoxifier. It helps in eliminating the infection and regulating the allergic reactions. This has specific action on the mucosa of the respiratory tract and the muscular walls off the lungs that act as the airways. It has anti – inflammatory effect which reduces inflammation and congestion inside the lungs. Its continuous usage reduces the damage on lungs and the muscular walls and bring out significant reversal in their dysfunction.

Dalmia Centre for Research and Development (DCRD), after many years of extensive research developed a polyherbal combination of 15 herbs called Astha -15 and we have derived dhl CoronaVirus preventive capsule from the same composition and all the important herbs mentioned in the Indian System of Medicine. dhl CoronaVirus preventive capsule originally as Astha-15 has undergone a randomized double blind, placebo -controlled study on patients Speciality Govt. Hospital for Thoracic medicine, Chennai, India. under the watchful eyes of internationally recognized respiratory physicians who followed a peer reviewed ethically approved clinical protocol to assess the efficacy of dhl CoronaVirus in comparison to the modern medicines.

The unique blend of 15 herbs involved in dhl CoronaVirus provide immunity to the person. It also acts as a bronchodilator, decongestant, anti -inflammatory and lung detoxifier. According to the double-blind study using DCBT4567 – dhl CoronaVirus, it was found that the patients tested had significant reduction (95% significance) in dyspnoea, wheezing cough, expectoration, disability and sleep disturbances. dhl CoronaVirus which was originally taken from the brand Astha-15 did not exhibit any of the side-effects normally observed with allopathic drugs.

COVID-19 also known as Coronavirus has affected more than 87,000 people across the world. It has flu like symptoms which includes running nose, cough, fever, body pain and breathlessness. Lungs are exposed to approximately 7000 litres of air every day. The viruses being air- borne are inhaled through the nose and reaches the lungs where it attacks the cell machinery and starts the replication thus lowering the immunity of the host and causing flu-like symptoms in the body. The breathlessness caused by the virus is also due to the loss of the lining of the alveolar cells.

Herbs and plants naturally contain many active chemicals and thus drugs derived from such sources can have multiple health benefits when administered to patients. Due to the presence of multiple active compounds in phytomedicines, they are an ideal candidate for treating conditions with a variety of symptoms such as inflammatory diseases which affect multiple systems.

Herbal medicine-derived natural products can be considered as an alternative therapeutic potential for respiratory diseases since several compounds showed anti-inflammatory effects inhibition different inflammatory mediators involved in respiratory diseases.

It is believed that the natural products derived from plants inhibit the pulmonary inflammation by the inhibition of the transcription of NF-κB to the nucleus, thus preventing the development of all the inflammatory processes triggered by allergen, cigarette smoke, virus, or bacteria. Therefore, herbal supplements can reduce the inflammatory cytokines release and oxidative stress. These effects together culminate with the improvement of lung function and with the reduction of pulmonary inflammation.

Most of the studies are pointing out the effects of natural products on the inhibition of NF-κB and MAPK pathways, besides the antioxidant effects associated with these products.

Takeda Initiates Development of a Plasma-Derived Therapy for COVID-19

Takeda Pharmaceutical Company is initiating the development of an anti-SARS-CoV-2 polyclonal hyperimmune globulin (H-IG) to treat high-risk individuals with COVID-19, while also studying whether Takeda's currently marketed and pipeline products may be effective treatments for infected patients. SARS-CoV-2 is the virus that causes COVID-19.

Hyperimmune globulins are plasma derived-therapies that have previously been shown to be effective in the treatment of severe acute viral respiratory infections and may be a treatment option for COVID-19. As a leader in plasma-derived therapies with more than 75 years of experience in the development of plasma-derived products, Takeda has the expertise to research, develop, and manufacture a potential anti-SARS-CoV-2 polyclonal H-IG, which Takeda is referring to as TAK-888.

"As a company dedicated to the health and well-being of people around the world, we will do all that we can to address the novel coronavirus threat," said Dr. Rajeev Venkayya, President of Takeda's Vaccine Business Unit and co-lead of the company's COVID-19 response team. "We have identified relevant assets and capabilities across the company and are hopeful that we can expand the treatment options for patients with COVID-19 and the providers caring for them."

Takeda is currently in discussions with multiple national health and regulatory agencies and health care partners in the US, Asia, and Europe to expeditiously move the research into TAK-888 forward. This requires access to source plasma from people who have successfully recovered from COVID-19 or who have been vaccinated, once a vaccine is developed. These convalescent donors have developed antibodies to the virus that could potentially mitigate severity of illness in COVID-19 patients and possibly prevent it.

H-IG works by concentrating the pathogen-specific antibodies from plasma collected from recovered patients or vaccinated donors in the future. By transferring the antibodies to a new patient, it may help that person's immune system respond to the infection and increase their chance of recovery. Because the plasma needed for TAK-888 is unlikely to come from current plasma donors, Takeda will initially produce the therapy in a segregated area within its manufacturing facility in Georgia, and development and production of it should not negatively impact Takeda's ability to produce its other plasma-derived therapies.

"Plasma-derived therapies are critical, life-saving medicines that thousands of people with rare and complex diseases rely on every day around the world," said Dr. Chris Morabito, Takeda's Head of Research and Development, Plasma-Derived Therapies Business Unit. "Our heritage, combined with our scale, expertise and capabilities, uniquely position Takeda to realize the potential of plasma-derived therapies, such as TAK-888."

In addition, Takeda is exploring whether select marketed therapies and molecules in its drug library could be viable candidates for the effective treatment of COVID-19. These efforts are at an early stage but being given a high priority within the company.

An internal working group of in-house experts in public health, vaccines, plasma-derived therapies, and R&D will continue to seek opportunities to leverage our expertise and extensive network of global partners to address COVID-19. COVID-19 is the disease caused by severe acute respiratory syndrome coronavirus (SARS-CoV-2), which can cause pneumonia and has resulted in more than 3,000 deaths globally since its recent discovery. To date, there are no approved vaccines or therapies to prevent or treat COVID-19.

Zydus announces world's first drug for the treatment of Non-Cirrhotic NASH

Zydus Cadila, an innovation-driven global pharmaceutical company announced that the Drug Controller General of India (DCGI) has approved its New Drug Application (NDA) for Saroglitazar for the treatment of Non-Cirrhotic Non-Alcoholic SteatoHepatitis (NASH) in India.

NASH is a progressive disease of the liver, which starts with fat accumulation in the liver known as Non-Alcoholic Fatty Liver Disease (NAFLD). This condition could progress to cirrhosis and liver failure. It is a large unmet medical need as there is currently no approved drug for the treatment of NASH anywhere in the world, a disease that is highly prevalent with 10% to 30% of the global population being affected by it. The prevalence of NASH in India is estimated to be nearly 25% of the population. NASH ranks as one of the major causes of cirrhosis, behind hepatitis C and alcoholic liver disease. Liver transplantation is the only option for managing advanced cirrhosis with liver failure.

Pankaj Patel, Chairman, Zydus Group mentioned, "We are happy that our efforts to discover and develop a novel drug for patients living with NASH, an unmet healthcare need globally have been successful. Saroglitazar will provide hope and new lease of life for millions of patients in India suffering from NASH."

Saroglitazar was launched in India in September 2013, for the treatment of diabetic dyslipidemia and hypertriglyceridemia in patients with type-2 diabetes not controlled by statins alone. In January this year, Saroglitazar received an approval for the treatment of Type 2 Diabetes Mellitus.

Saroglitazar is uniquely poised with its dual PPAR alpha and gamma properties – reducing the comorbidities and causing NASH resolution. Zydus achieved positive results in EVIDENCES II trial, a Phase 3 liver biopsy trial of Saroglitazar 4 mg versus Placebo in Indian patients with NASH. The trial evaluated histological improvement of NASH using liver biopsy at the end of 52 weeks and successfully met primary and secondary endpoints. In EVIDENCES I, Saroglitazar demonstrated improvement in liver enzymes and lipids in patients with Non-Alcoholic Fatty Liver Disease (NAFLD). Phase 2 trial of Saroglitazar Mg in patients with NASH in the US met primary and secondary endpoints.

Additionally, 15 investigator initiated clinical studies of Saroglitazar have been presented and published in leading scientific journals and conferences.

Lincoln Pharmaceuticals forecasts export business to cross Rs.225 Cr in FY20

Lincoln Pharmaceuticals Limited, one of India's leading healthcare companies is betting big on export business. With presence in more than 60 countries, company has reported export sales of Rs. 174.7 crore for the nine months ended Dec 2019 and expect it to cross Rs. 225 crore in FY19-20. Company is also expanding portfolio in lifestyle and chronic segment especially in women healthcare and dermatology to complement its strong presence in acute segment. In the next 2-3 years company is targeting sales of Rs. 500 crore.

Mr. Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Limited, said, "Export business has increased many fold to 54% of the sales in FY19 from 11% in FY11. For the FY2018-19 company registered exports of Rs. 197.43 crore. Export is the focus area for the company as margins are better and also the fact that off-late a lot of issues like price control, ban on FDC drugs (fixed dosage combination), sale of generic drugs, etc. have cropped up in the domestic market. Company has received many product registrations in countries like East and West Africa, South East Asia and Latin America and will look to expand presence in more countries."

Company has presence in more than 60 countries encompassing Africa, Central America and Southeast Asia. Company's growth has been attributed to a strong performance in the domestic and international markets, new product approvals, healthy customer and product base and superior R&D capabilities supported by strong industry experience and improving market dynamics.

"Going forward, we are building a strong portfolio in lifestyle and chronic segment especially in women healthcare and dermatology to complement our strong presence in acute segment. Company has recently secured patent for its liquid Diclofenac Metered-Dose Rectal Spray (Diclofenac Rectal Spray). The company has necessary approvals from Drug Controller General of India (DCGI) and is set to launch it in Indian markets very soon. The Company is also planning to apply for a Global Patent for this novel solution. Over the next 2-3 years company is targeting sales of Rs. 500 crore and vision to enter the league of 'Top 50 pharma cos' of India in the near future," said Mr. Patel.

Company has recently approved amalgamation of Lincoln Parenteral Ltd (subsidiary) with Lincoln Pharmaceuticals Limited. The restructuring aims to bring synergies for both companies including competitive strength, operational efficiencies, productivity gains, and logistic advantages, thereby significantly contributing to future growth.

Going green, company has also set up a new Solar Plant of 1 MW at factory's rooftop with a capacity of producing 15 Lakh Power Unit Per annum in addition to two windmills. "This way we are producing renewable energy to nearly 65% of our consumption resulting significant saving in the electricity cost and helped the company to become a self-sustainable and environment-friendly organization," said Mr. Patel.

Lincoln Pharmaceuticals Ltd develops and manufactures affordable and innovative medicines for healthier lives. The company has developed 300 plus formulations in 15 therapeutic areas and has a strong product/brand portfolio in anti-infective, respiratory system, gynaecology, cardio & CNS, anti-bacterial, anti-diabetic, anti-malaria among others. Company has filled 20 plus patent applications and is awarded five patents.

Best in Class Facilities

Certifications: WHO-GMP Certified; ISO 9001:2015 Certified

R&D Center: Approved by Government of India; Team of 30 scientists for R&D

Green Energy: Windmill project for captive consumption

Dosage Forms Produced at Unit 1

Description	Annual Capacity	Unit
Tablet (Compression & Coating)	21,600 Lakhs	Tablets
Tablet (Granulation)	9,00,000	Kg
Capsule (Filling)	2,340 Lakhs	Capsules
Dry Syrup (Filling)	72,00,000	Bottles
Ointment (Filling)	336 Lakhs	Tubes

Dosage Forms Produced at Unit 2

Description	Size	Annual Capacity	Unit
Liquid Ampoules	1 ml to 5 ml	60,000,000	Ampoules
	10 ml	30,576,000	Ampoules
Liquid Vials	2 ml to 10 ml	15,600,000	Vials
	10 ml to 30 ml	15,600,000	Vials
Oral Liquids	60 ml to 100 ml	18,000,000	Bottles
	150 ml to 200 ml	18,000,000	Bottles
Dry Powder Injection	100 mg	22,464,000	Vials

LPL LINCOLN PHARMACEUTICALS LTD. HEALTHCARE FOR ALL

Bio-based Plastic Packaging

Sanner BioBase is the first effervescent tablet packaging that consists of more than 90 per cent bio-based material. The biopolymers used consist of various renewable raw materials such as corn, sugarcane or cellulose, which are converted into green ethanol. A major advantage of bio-based plastic packaging is its essential independence from fossil raw material deposits and its reduced CO_2 footprint. Bio-based plastic packaging has the same properties as conventional packaging solutions. They can also be processed on existing filling lines. From a chemical point of view, Sanner BioBase is almost identical to PE and PP from fossil raw materials.

The initial tablet tube will have a dia of 27-mm and can be combined with the appropriate desiccant closure.

The TabTec CR tablet container protects children from accidentally taking painkillers, anti-depressants or medical cannabis. The patented Press & Flip closure prevents opening by children's hands. However, it is easy to handle for adults and especially for seniors by pressing and simultaneously folding up the closure. The desiccant integrated into the bottom of the container and the appropriate colour selection protects the contents from moisture and light at all times. The integrated pouring assistance ensures hygienic and easy dosing of the drugs.

For more information, please contact:
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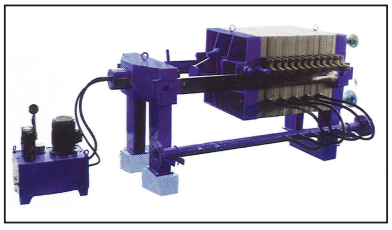
Membrane Filter Press



Membrane filter plates have a chamber below the drainage surface that may be inflated. The common method used is water pressure, which is generated by pumping into the squeeze cavity to inflate the face of the plate against the filter cake. Air may also be used.

Fixed membranes are most commonly 100 per cent polypropylene but thermoplastic is also available. The plate is manufactured by moulding a face membrane and a core plate separately. The face membranes are then joined into the core by heat welding to form a homogeneous plate. Although this type of membrane is suitable for many designs, it has particular advantages in food applications, where the lack of joints will prevent contamination.

Membrane plates are used to reduce the cake moisture content or shorten the filtration cycle time. Two types of membrane plate designs are used: fixed membranes and replaceable membranes. Mixed pack membranes are the most common configuration (one recessed plate, then one membrane plate alternate in the press plate pack). The final product produces savings in the overall plate pack cost.

Membrane plates usually operate at a feed pressure of up to 7 bar and squeeze pressure up to 15 bar. Special plates can be designed to accept higher feed and squeeze pressures. Replaceable membranes use a polypropylene core, which is machined to accept the connection and seal of a rubber membrane. These facts are easily changed. EPDM Thermoplastic and other compounds are used for specific conditions. Savings in operation can be achieved in difficult environments and the membrane's superior flexibility makes it the best design for many installations.

For more information, please contact:
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Pawane MIDC, Navi Mumbai 400 709
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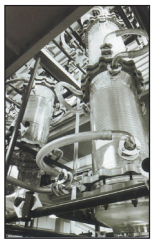
Process Engineering Solutions



Ablaze has concept and history of developing and supplying process systems to chemical industry and helps to improve environment by offering exhaust gas absorption and waste water treatments. Reclamation of chemicals/solvents from waste air or liquid streams often plays an important part in becoming economically viable process. All around the actual synthesis material flows accumulate in the chemical and pharma industry, which must be cleaned under environmental aspects or still contain resources. Requirements of the environmental protection laws also must be adhered to as well as the cost saving preparation and recycling of resources.

Ablaze offers basic and detailed engineering services to commissioning different project levels up to turnkey delivery using different MoC such as borosilicate glass, PTFE, FEP-PFA-lined components, Tantalum to arrive at cost-effective and environment-friendly solutions.

For more information, please contact:
Ablaze Glass Works Pvt Ltd
E-52 Sardar Estate
Ajwa Road, Vadodara
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E-mail: srshah@ablazeglassworks.com

Platinum-cured Silicone Tube

Imatech is platinum grade silicone tubing (non-regulatory market) designed for general purpose applications in food and pharma industries. Imatech is smooth bore tubing compared to peroxide grade tubing, which reduces risk of particle entrapment during transfer of fluid. Imatech meets all technical requirements related to non-regulatory market.

Manufactured by using general purpose platinum grade silicone rubber and packaged in clean room of Class 10000 facility audited by TUV Nord. It has better fluid transfer characteristics compared to peroxide silicone tubing. Available with FDA-approved silicone-based colour coding. It has better transparency and higher shelf-life compared to peroxide tubing. Free of any heavy metals and hazardous substances.

For more information, please contact:
Ami Polymer Pvt Ltd
319 Mahesh Indl Estate, Opp: Silver Park, Mira-Bhayander Rd
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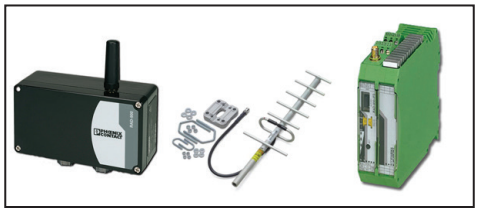
Wireless Communication for Level Measurement



AMETEK Drexelbrook offers an extensive line of wireless communication products for level measurement, level switches, floating roof tanks and other field instruments providing encrypted data transfer for distances of up to 32 km line of sight.

For this, Drexelbrook has teamed up with Phoenix Contact. By doing so Drexelbrook is now able to provide ideal wireless level measurement communication for industries such as oil and gas, chemical, and general industrial process plants. This new product line is the ideal communication option, especially for large plants where signal wiring can be prohibitively expensive.

The advantage of acquiring both wireless communication products and level measurement instruments from Drexelbrook is that Drexelbrook ensures that the data transfer works as intended and that the communication hardware will be covered by a comprehensive Drexelbrook warranty. The new Series of 900 MHz communication transceivers, I/O modules and antennas are available for indoor (DIN rail) as well as outdoor (NEMA4) mounting. Various I/O modules enable the engineer to set up the necessary support of analog and digital communication, secured by 128-bit encryption, and adjustable bit rates up to 500 kbps and signal gain up to 12 dBi.

For more information, please contact:
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E-mail: drexelbrook.info@ametek.com / bob.irving@ametek.com

Self-adhesive Profiles

Self-adhesive strip plays a crucial part in sealing and spacing throughout a multitude of different industrial sectors. Strips that are manufactured from EPDM make ideal seals against any ingress of water or air. Self-adhesive strip has a closed cell structure and therefore do not allow any liquid, gases or air to pass through them, creating a perfect airtight seal on your products. The compression of the EPDM base material allows for uneven surfaces to be securely sealed once clamped down. EPDM has excellent resistance to UV and ozone and is widely used in external applications when parts will be subject to weathering. EPDM is a relatively cheap sponge material choice making it a cost-effective solution to most sealing application.

EPDM self-adhesive strip is easy to install, just peel off the self-adhesive backing. The adhesive backing tape used is not fully resistant to water where large amount of moisture or water are present; it is advisable to use plain expanded EPDM and a good conduct adhesive. EPDM provide excellent resistance against oil, acid, alkalis and has good weathering against heat and ozone.

For more information, please contact:
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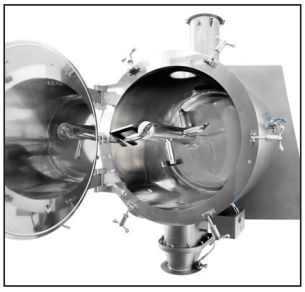
E-mail: mktg@amipolymer.com

Horizontal Paddle Vacuum Dryer



To offer the highest levels of productivity, while minimizing energy consumption, Italvacuum - international manufacturer of vacuum pumps and vacuum dryers – has realized Planex System. Planex System is a patented horizontal paddle vacuum dryer with eccentric agitator featuring two independent movements, allowing it to simultaneously revolve around its own axis and to rotate tangentially to the drying chamber. Planex System is ideal for the production of APIs, fine chemicals and intermediates.

The combined rotations of the agitator and its small size ensures perfect mixing and allows consuming at least three times less energy than conventional paddle dryers. This means a three-fold reduction in mechanical and thermal stresses on the dried batch. As a result, even the most delicate products are treated with maximum care. But there is more. Planex System control software allows to automatically command agitator movements with Stop & Swing Program. In this way, the agitator swings back and forth, thus remaining all the time immersed in the product, and guaranteeing its continuous mixing. This approach is particularly effective when processing small batches. Planex System, thanks to its agitator's ZeroFriction planetary movement, also prevents the product from being rubbed against the chamber walls and thus heating up due to friction, a typical problem in conventional systems.

In addition, the rotation of the paddles tangentially to the chamber walls conveys the product into the small clearance between the agitator and the chamber surface, preventing lumps formation and guaranteeing an even more effective drying and a controlled final particle size distribution.

For more information, please contact:
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Fax: +39 011 4701010
E-mail: marketing@italvacuum.com

Agitated Thin Film Evaporator

KEPs agitated thin film evaporator is an alternative and economical solution for heat sensitive products. KEP has developed agitated thin film evaporation technology with innovation at an optimised capital and operating cost.

Agitated thin film evaporators are used for the purification of liquid compounds that are heat sensitive, viscous and have high boiling points.

Features continuous operation; low maintenance; easy to start, operate and shut-down; heat transfer coefficient is high; one shot concentration no recirculation is required; can operate with flexible operating parameters; higher operating vacuums; efficiently processes viscous solutions; and low residence time eliminates thermal degradation.

For more information, please contact:
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6-A-52, Opp: Park, Nr Vedant International School
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Hyderabad, Telangana 500 055
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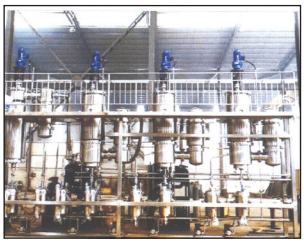
E-mail: info@kepengg.com

Short Path Evaporator



KEPs short path evaporator is an alternative and economical solution for high vacuum distillation/fractionation. KEP has developed short path evaporation technology with innovation and revolution at an optimised capital and operating cost. Short path evaporation is a thermal separation technique that provides minimum pressure drop, permitting high vacuum operation down to 0.001 mbar. Short path evaporation is excellent for gently processing heat-sensitive, high boiling products.

Features residence time of few seconds, important for heat sensitive products; operation pressure as low as 0.001 mbar (a). Hence, production can be distilled at lower temperatures to avoid degradation; suitable for viscous products; excellent turndown capability; low product hold-up, good for hazardous materials; and low power requirements.

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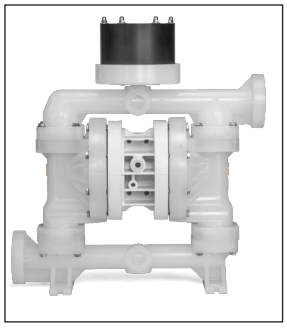
Equalizer Surge Dampeners



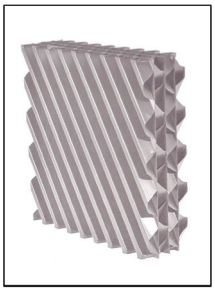
Wilden, part of PSG, a Dover company offers its new bolted plastic Equalizer Surge Dampeners – Integrated SD Series (ISD). The new ISD Series dampeners have been specifically engineered to help extend the life and reduce the noise of Wilden 13-mm (1/2") and 25-mm (1") Pro-Flo Series bolted plastic air-operated double-diaphragm (AODD) pumps while providing users with convenient installation and use.

Wilden ISD Series dampeners utilize an integrated design that allows them to be directly incorporated in the Pro-Flo Series bolted plastic manifold design. They easily screw onto the top of your Wilden pumps without any additional hardware required. There are no additional connecting elements or piping changes needed to install these dampeners, which helps keep operational downtime to a minimum.

These dampeners are available in 13-mm (1/2") and 25-mm (1") sizes in Polyethylene construction, with PTFE and EPDM diaphragm material options. They feature temperature ranges from -51°C to 138°C (-60°F to 280°F) for EPDM and 10°C to 137°C (14°F to 280°F) for PTFE. With a maximum working pressure of 100 psi, they are ideal for use across a variety of markets, including paints and coatings, chemical, hygienic, and general industrial applications.

For more information, please contact:
Dover India Pvt Ltd
No: 33, NH-4, Pazhanchur, Mevalurkuppam
Chennai 600 123
Tel: 044-67193000
E-mail: rajesh.shankar@psgdover.com / ravi.prasad@psgdover.com

High-effective Fill Media for Sedimentation Processes



Hewitech's media improving biological treatment efficiency is used for potable water application. The structure grants high process stability and an optimized sedementation. Adjustable foils thickness bearing all required loads of application process, eg, oil/fat removal.

Hewitech's film media made with a direct inline foil-forming and final thermo-welding assembly process grant a robust fill structure for a long lifespan.

Controllable foil thickness and multiple media structures allow to optimise fill stabilities, effective sedimentation processes and has a self-supporting character in various plant designs.

For more information, please contact:
Hewitech GmbH & Co KG
Am Langenhorster Bahnhof 16
D 48607 Ochtrup, Germany
Tel: +49 2553970260
E-mail: info@hewitech.de

Smart Probes

Vaisala offers six new smart probes for its Indigo product family, optimized for demanding industrial applications. New options for dew point and moisture in oil measurements bring more possibilities for industries to save energy, optimize processes, and improve product quality. The new probes will improve customers' process efficiencies by providing accurate and reliable measurement data for their industrial processes. The capabilities of the new probes are based on next-generation sensor technologies.

The new Vaisala DRYCAP Dew Point and Temperature Probes DMP5, DMP6, DMP7, and DMP8 are optimized for low humidity and high temperature or pressurized environments. Dew point measurements are particularly important in various industrial drying applications, eg, in ovens and compressed air systems. The dew point probes include Vaisala's DRYCAP sensor, which is immune to particulate contamination, water condensation, oil vapour, and most chemicals. Its fast reaction time gives it unmatched performance even in dynamic and low dew point applications, and the sensor's outstanding stability enables a long two-year calibration interval.

The Vaisala HUMICAP Moisture in Oil Probe MMP8 extends the Indigo product offering to include heavy industry applications such as measuring moisture in transformer or lubrication oils to protect engines from wear and shutdown. Also, Vaisala HUMICAP Humidity and Temperature Probe HMP3 is a general-purpose remote probe suitable for duct mounting in non-pressurized applications with moderate temperatures. The probe structure allows the sensor to be replaced in the field without tools, providing maintenance flexibility in demanding applications that might require periodic sensor replacement, such as paint booths. The HMP3 and MMP8 both include Vaisala HUMICAP thin-film capacitive humidity measurement technology, which has become the industry standard in humidity measurement.

All six new smart probes complement Vaisala's existing Indigo product family. The digital Modbus RTU connection enables both easy integration into other systems and standalone usage. The probes are also plug-and-play compatible with Indigo 200 transmitters, which offer various additional benefits such as a display for data visualization, easy access to probe configuration, and more options for connectivity, supply voltage, and wiring. For on-site configuration, diagnostics, and self-calibration, the Indigo probes can be connected to the Vaisala Insight PC software.

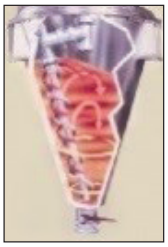
For more information, please contact:
Vaisala Oyj
Vanha Nurmijärventie 21, FI-01670 Vantaa, Finland
Tel. +358 50 555 4420
E-mail: comms@vaisala.com

V-Blenders

V-Blenders are most often used for the intimate dry blending of free flowing solids. The solids being blended in these units can vary in bulk density and in percentage of the total mixture. Materials being blended are constantly being split and intermixed as the shell rotates. Normal cycle times are typically in the range of 15 minutes, however, can be less depending on the difficulty of blending. V-Blenders are stocked in 5, 10 and 15 cu ft capacity. Each is constructed of type SS 316 and is internally polished to a 240 grit sanitary finish. The exterior is polished to an easily cleaned 150-grit finish. All Ross V-Blenders are supplied with intensifier bars to permit de-agglomeration as needed. Discharge is accomplished through a manually operated butterfly valve. The valve is positioned 24" from the floor when in the bottom position. All units are provided with appropriate safety railings and appropriately interlocked. Stop-Start and E-Stop Pushbuttons are included with all blenders.

For more information, please contact:
Ross Process Equipment Pvt Ltd
Plot No: D-233/3, Chakan Indl Area
Phase II, Village: Bhamboli
Tal: Khed, Dist: Pune
Maharashtra 410 501
Tel: 02135-628400, 628401, 628402, 628403

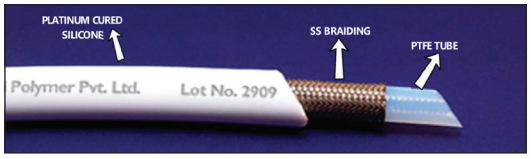
Vertical Blender



Vertical blenders are an excellent design alternative for applications that are shear sensitive or where space on the plant floor is at a minimum. The gentle blending action of the slow turning blending screw is far gentler than that of a horizontal blender. The blending screw orbits the conical vessel wall while it turns and gently lifts material upward. The materials are then thrust at the upper most batch level towards the centre of the vessel and then move slowly back down the centre, while mixing with materials being moved upward by the orbiting screw. When compared to horizontal blenders this design has several advantages: gentle blending action is ideal for friable or shear sensitive materials; one blender can be used for a wide range of batch sizes, ranging from as small as 10 per cent of the rated capacity; nearly 100 per cent of the blended materials are discharged through the bottom valve after completion of the blend cycle; use nearly 50 per cent less power per unit being blended; and less floor-space and are ideally suited to multi-story facilities.

For more information, please contact:
Ross Process Equipment Pvt Ltd
Plot No: D-233/3, Chakan Indl Area
Phase II, Village: Bhamboli
Tal: Khed, Dist: Pune
Maharashtra 410 501
Tel: 02135-628400, 628401, 628402, 628403

PTFE-lined with SS-304 Braiding, Covered with Platinum-cured Silicone



Imaflexxie is PTFE tubing covered with SS-304 braid reinforcement having outer layer of platinum grade silicone. Imaflexxie is having capacity to withstand high pressure along with greater chemical resistance. The product is having ultra-smooth bore which enhances superior flow properties and least adhesion to particulates. The outer layer of silicone cover acts as insulation to high temperature and keeps outer surfaces dust-free. Imaflexxie conforms to US FDA 21 CFR 117.2600 Food Grade Standard, USP Class VI and ISO 10993-1. It is certified by ROHS and Animal Origin Certification (free of animal derived material), free of restricted heavy metals. It is free of Phthalate/ Bisphenol/Volatile Plasticizer. It has USFDA DMF accreditation #26201. Complete validation package available upon request.

Imaflexxie has excellent chemical resistance. It permits easy cleaning. Its smooth silicone cover provides safety to operator while handling high temperature. It prevents operator from injury due to Frayed SS Braids. It is lot traceable. Its temp range is -80°C to 230°C. It is available with SS-316L Tri-clover end. It is sterilizable by autoclave.

For more information, please contact:
Ami Polymer Pvt Ltd
319 Mahesh Indl Estate, Opp: Silver Park
Mira-Bhayander Rd, Mira Road (E)
Thane, Maharashtra 401 104
Tel: 022-28555107, 28555631, 28555914
E-mail: mktg@amipolymer.com

Analytical Instruments and Separation Technique

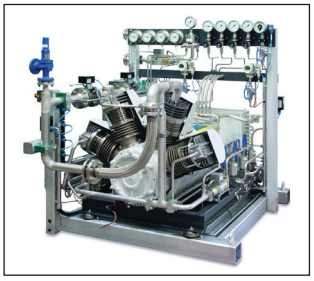
Lablink XtraPure Water System provides you reliable and compact system which produces ultra pure water system always ensures high comfort at low operating cost. XtraPure System is equipped with reverse osmosis and additional filtration system to produce de-ionised water. The de-ionised water can be dispensed straight from reservoir. Further ultra-pure water is produced with a combination of optimised cartridges with UV and polishers. Other special polishers and 0.2 um filter makes water XtraPure. System comes with touchscreen display and in-built printer (optional) for real time data printout. Display shows online conductivity and temperature of XtraPure water.

The input water required is DM water/RO water or municipal water. Easy to install, repair, plug and play. It is suitable for Indian conditions. Very low consumable cost. The system has calibrated conductivity meters.

Design of the instrument is electrically and electronically safe as the control box never comes in touch with water which enhances safety.

For more information, please contact:
LabLink
10/11 Pitre Compound
Mangaon, Manpada
Kalyan-Shil Road, Dombivli (E)
Thane, Maharashtra 421 204
E-mail: info@lablink.in

Oil-free and Gas-tight High-pressure Compressor



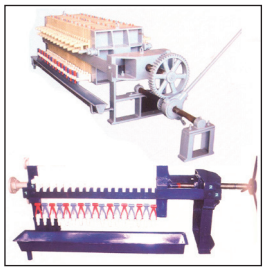
With the integration of the former HAUG Kompressoren AG, Sauer Compressors has significantly extended its portfolio to include solutions by the industry's leading expert in oil-free air and gas compression. The HAUG.Sirius NanoLoc marks the latest addition to the product range that combines high pressure with oil-free compression. Both the crankcase and the compressor stages operate without any oil. This ensures highest gas and process purity. Therefore, the compressors are an ideal choice for sensitive applications such as industrial gases, medical applications and bio technology as well as the chemical, pharma and food industries.

With its hermetically gas-tight construction, the HAUG.Sirius NanoLoc achieves extremely low leakage rates of <0.001 mbar l/s and enables 4-stage compression of almost any gas. The compressor delivers a flow rate of max 66 Nm^3/h and a final pressure of up to 450 barg with an inlet pressure of up to 30 barg. Depending on the configuration, it comes with a motor power of 11-30 kW. In addition, the HAUG.Sirius NanoLoc is ideally suited for booster applications of gases such as helium, natural gas or hydrogen. The well-proven magnetic coupling drive adds to the machine's exceptional gas-tightness both at standstill and during operation. The technology is a core feature of the HAUG.Sirius Series. Due to the newly developed and unique NanoLoc piston design's friction-free sealing, wear and friction losses in the cylinders have been reduced significantly. Likewise, all the compressor's components are designed for a particularly long service life.

Even in operations with long standstills, frequent interruptions and cold starts, the HAUG.Sirius NanoLoc is highly dependable. The absence of oil serves to significantly lower operating and maintenance costs. Due to its unparalleled process purity, the compressor reduces the need for gas treatment and filtration after compression to a bare minimum. Often, treatment and filtration are not required at all, resulting in significant time and cost savings.

For more information, please contact:
J P Sauer & Sohn Maschinenbau GmbH
Brauner Berg 15
24159 Kiel, Germany
Tel: +49 431 3940-0
E-mail: William.Koester@sauercompressors.de

Manual Filter Press

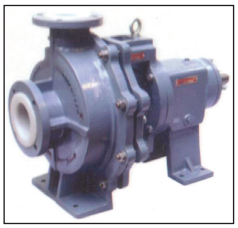


A manual filter press is simple and the basic form of the filter press. In manual filter press every operation is done manually. Manual filter press are available from 300 to 915 mm plate sizes. These machines are an effective, inexpensive choice for handling smaller quantities of material. In manual filter press, two types of mechanism are available: ratchet and capstan types.

In manually-operated filter press with ratchet closing device, the system consists of ratchet mechanism, pinion and gear wheel. By applying a ratchet lever to the pinion shaft the force is transmitted by small pinion to the larger gear wheel which provides the final lightening on the plate pack.

For more information, please contact:
Thorat Filtration Pvt Ltd
Gala No: 12, 3rd Floor, A-Bldg, Gami Indl Park
Plot No: C-39/A, TTC Indl Area
Pawane, MIDC, Navi Mumbai 400 705
E-mail: thoratfiltration@gmail.com / info@thoratfiltration.com

Non-metallic Centrifugal Pumps

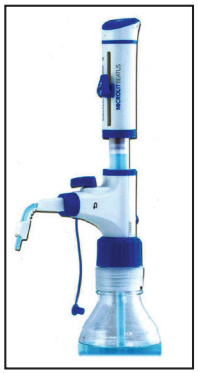


These pumps are designed for handling of most several industrial duties and available in variety of fluoropolymer to suit different requirement involving aggressive media at elevated temperature. The wetted parts of the pumps are moulded with following fluoropolymer: KYNAR PVDF (Polyvinyldene Fluoride), PPH – Polypropylene Homopolymer, FEP (Fluorinated Ethylene Propylene), PFA (Perfluoroalkoxy).

Polymer moulded with strong metal armour series – CMPV/CMPH/CMFE/CMPF to improve mechanical strength and avoid deformation. Shaft sleeve positively locked against impeller with positive locking technology. External seal cooling water not required. Back pull-out design. It finds application with all aggressive corrosive or toxic media up to 200°C with or without abrasive slurries.

For more information, please contact:
Chemitek Equipments
Plot No: 117, Nr GETCO SS, Old GFIDC
Gundlav, Valsad, Gujarat 396 035
Tel: 02632-236022
E-mail: sales@chemitek.co.in / info@chemitek.co.in

Bottle Top Dispensers



Traditional bottle top dispensers contain two valves with glass balls: Inlet valve is vertical. It operates under gravity and does not require a spring to hold the glass ball in its position, in order to keep the valve closed. The outlet valve is horizontal. It requires a spring to keep the glass ball in its position, in order to keep the valve closed while aspirating reagents in the barrel. It opens only when a reagent is being dispensed.

The spring, housed in the outlet valve, poses a lot of problems: The user has to procure different kinds of bottle top dispensers for different applications owing to spring metal reactivity. This proves to be an expensive proposition. Apart from this, the spring also offers a surface for deposition of chemicals. This results in a piston jam, thereby compelling the user to repeatedly clean the valve or replace it altogether.

Their product design engineers have expertly addressed these problems by designing a system where both inlet and outlet valves are vertical and hence do not require any spring. This Springlass Valve technology makes MICROLIT BEATUS a universal bottle top dispenser that can be conveniently used with both organic and inorganic reagents. It not only offers smooth, jam-free piston movement but also ensures service-free operation.

Recirculation valve prevents the loss of reagents during purging by re-directing them into the mounted bottle and facilitates bubble-free dispensing. MICROLIT BEATUS is available in six unique volume ranges.

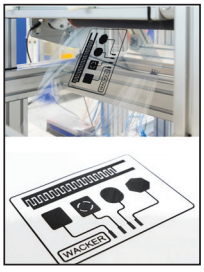
For more information, please contact:
MICROLIT
629 Pakramau, Kursi Road
Lucknow, Uttar Pradesh 226 026
E-mail: customercare@microlit.com

Fluoro Elastomer Tube (FKM)

Imachemton is fluoropolymer tubing (popularly known as Viton tubing) especially designed for highly corrosive chemicals and solvents used in pharmaceutical industries. It is manufactured in dedicated controlled environment to comply critical food and pharma grade standards. Imachemton has excellent resistance to alcohols, acids, halogenated solvents (Ex. IPA and MDC). It has greater flame and fire resistance. Its service temperature is -15°C to +250°C. It is available in 60 Shore A and 70 Shore A hardness. It is also available in black and off-white colour. It is double polybag packaged in standard pack size of 25 mtr (custom packing sizes available). Its extractable and leachable data available upon request. It is phthalate-free.

For more information, please contact:
Ami Polymer Pvt Ltd
319 Mahesh Indl Estate, Opp: Silver Park
Mira-Bhayander Rd, Mira Road (E)
Thane, Maharashtra 401 104
Tel: 022-28555107, 28555631, 28555914
E-mail: mktg@amipolymer.com

Ready-to-Use Electroactive Silicone Laminates



WACKER offers a novel silicone laminate with electroactive properties called NEXIPAL for the very first time. It consists of several ultrathin precision films made of silicone rubber. The films are coated with an electrically conductive material prior to lamination. The result is an actuator that creates movement, as soon as electrical voltage is applied. In addition, NEXIPAL can also be used as a sensor by measuring deformations electrically. The silicone laminate is wear-free, compact and energy saving and ideal for use in innovative applications. Tablet displays equipped with NEXIPAL create vibrations and haptic feedback which simulate the shape of keys or control panels that can be operated blindly by touch. Such a feature can be especially useful in automotive applications. The new laminate technology is based on ELASTOSIL Film. WACKER produces the extremely thin silicone film in thicknesses between 20 and 400 µm. The silicone rubber is a key component whose dielectric properties are an important prerequisite for the desired electroactive effects of the laminate. For the film to execute and/or measure deformations, however, it must be coated with an electrically conductive layer, and subsequently laminated to form a multilayer stack.

WACKER will produce such prefabricated laminates itself under the trade name NEXIPAL. NEXIPAL laminates are made of several ultrathin precision films coated with conductive material which acts as a flexible electrode. When voltage is applied, the positive and negative charge carriers of the electrodes attract one another, forcing the silicone film in-between to change its shape. As a result, the film flattens and at the same time elongates horizontally. The elongation of the surface is proportionate to the compression force. When discharged, the resilience of the highly elastic silicone film allows the laminate to return to its original shape. This process can be repeated indefinitely.

One of the most outstanding advantages of electroactive silicone laminates compared to existing solenoid technology is the fact that electric power is only applied during the short period of switching between ON and OFF status, not for holding it. This results in a significantly reduced consumption of energy as well as in sustainable and cost saving processes. Moreover, silicone laminates do not produce any heat when in use. This avoids investments into expensive thermal management systems. The electroactive component also acts like a sensor, since any movement or deformation alters the charge on the electrodes. This dual function makes NEXIPAL a genuine all-rounder and suitable for applications in medical technology, sensors and robotics. For example, the material is able to control the orientation of headlamps or mirrors in cars. Moreover, since fluid movements are possible with NEXIPAL, the laminate can also be used as an artificial muscle.

For more information, please contact:
Wacker Chemie AG
Hanns-Seidel-Platz 4
81737 München, Germany
Tel: +49 89 6279 1588
E-mail: agnes.froeschl@wacker.com

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Tel: 022-4037 3636 Fax: 022-4037 3635
Email ID: dilip_parab@jasubhai.com
Web: www.pharmabioworld.com

Jasubhai MEDIA

Medicall

Schedule: 03 – 05 Apr 2020

Venue: Hitex Exhibition Center, Hyderabad, India

About the Event: Medicall is India's largest B2B Medical Equipment Exhibition and is organized by Medexpert Business Consultants Pvt Ltd. It brings all the equipment manufacturers under one roof. Medicall serves as a marketing platform wherein the equipment companies showcase their products and services to Hospital owners and decision makers. Since MEDICALL is being organized by people who have been in Healthcare field for many years, the content and the quality of the visitors are expected to be better than any other previously held event.

Highlights:

- Buying opportunity of equipment / services for the hospital / clinic.
- Dealership scope from International companies and reputed Indian companies.
- Update availability on innovations in the field of healthcare.
- Meeting collaborating partners
- Thought provoking conferences and seminars.
- One-on-One business meets.

For More Information: https://www.medicall.in/

Asia Pharma Supply Chain Summit

Schedule: 07 - 08 Apr 2020

Venue: Bombay Exhibition Centre (BEC), Mumbai, India

About the Event: The Asia Pharma Supply Chain Summit will provide the attendees with the opportunity to gain insights relating to the Transformation of Life Sciences Supply Chains: The Emerging Imperatives, Demand-driven Clinical Supply Chain: A Paradigm Shift for System-wide Benefits, Leveraging the Digital Supply Chain to Deliver Personalized Patient Solutions, On Demand Supply Chain for Personalized Medicine, etc.

For more information: https://10times.com/

Annual Pharmacology Summit

Schedule: 22 Apr 2020

Venue: NIMHANS Convention Centre, Bengaluru, India

About the Event: Pharmacology Conference will provide a wonderful forum for you to refresh your knowledge base and explore the innovations in Pharmacology and Toxicological studies. Partaking and networking with Exploring the Novel Research and Advancements in Pharmacology and Toxicology will provide an opportunity for practitioners to know the ongoing research and inventions in the particular field.

For more information: https://10times.com/

PharmaTech Expo

Schedule: 17 - 19 Apr 2020

Venue: Parade Ground, Chandigarh, India

About the Event: PharmaTech Expo is a premier event dedicated to pharmaceutical innovation, technology, and knowledge which illustrates the latest cutting-edge technologies needed to cost-effectively develop and manufacture quality products. It focuses on pharma manufacturing and processing technology, pharmaceutical systems and services, pharma formulation, nutraceuticals, food & cosmeceuticals, and ayurveda. The highlights will be on Pharma Machinery, Lab, Analytical, Pharma Formulations, and Nutraceuticals.

For more information: https://10times.com/

Annual Pharmacology Summit

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Venue: NIMHANS Convention Centre, Bengaluru, India

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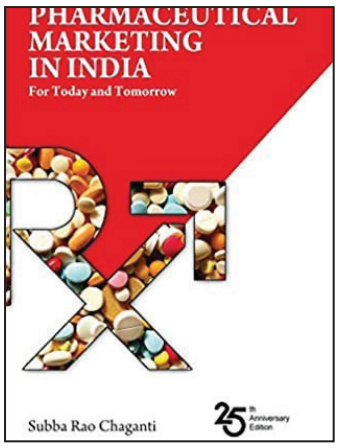
For more information: https://10times.com/

Pharmaceutical marketing in India: For Today and Tomorrow

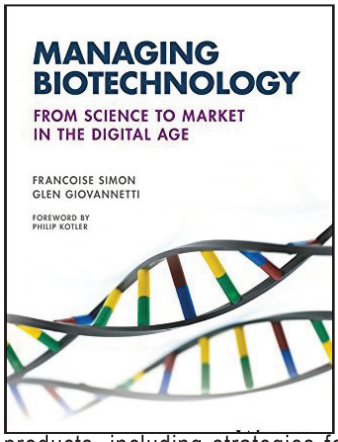


Author: Subba Rao Chaganti
Publisher: PharmaMed Press
Price: Rs. 2829.00

About the Book: This book is one of the front-row occupiers in sectoral marketing for Asia Pacific Region. The seventy plus cases in the book show how some of the highly successful practitioners of Pharma marketing in India have positioned their products, launched and promoted their brands and defended their therapeutic segments. The experiential insights these cases provide are immensely useful for both the practitioners as well as the students of pharmaceutical marketing in India.

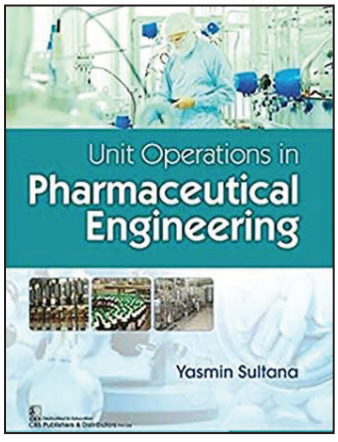
The book presents an introduction to all aspects of changes and initiatives that are happening in the first world markets and whatever baby steps that are being taken by Indian drug majors and their MNC counterparts in India. To name a few - Changing detailing practices such as e-Detailing, iPad detailing or tablet detailing, digital marketing strategies, social media strategies for the pharmaceutical industry, multichannel marketing, closed-loop marketing among others.

Managing Biotechnology: From Science to Market in the Digital Age



Author: Francoise Simon (Author), Glen Giovannetti (Author) and Foreword by Philip Kotler
Publisher: Wiley
Price: Rs. 2865.00
About the Book: Although Biotechnology has evolved as one of the key innovation driver for human healthcare, its development cost is clashing with aging demographics and cost containment policies of private & public players in spite of continuous growth of Biopharma industry. the development and increased affordability of sophisticated digital technologies has fundamentally altered many industries including healthcare. The arrival of new information technology (infotech) companies on the healthcare scene presents both opportunities and challenges for the biopharma business model.The author in this book provides a comprehensive overview of the new business context and marketing models for biotech companies. Informed by extensive input by senior biotech executives and leading consultancies serving the industry, it analyzes the strategies and key success factors for the financing, development, and commercialization of novel therapeutic products, including strategies for engagement with patients, physicians and healthcare payers. Throughout case studies provide researchers, corporate marketers, senior managers, consultants, financial analysts, and other professionals involved in the biotech sector with insights, ideas, and models.

Unit Operations in Pharmaceutical Engineering



Author: Yasmin Sultana
Publisher: CBS Publishers & Distributors Pvt Ltd
Price: Rs. 211.00
About the Book: Science and technology have been constantly changing fields. New research and experience broaden the scope of information and knowledge.
The author, in this book, has presented the basic principles of Unit Operations in a very effective manner. The book speaks about flow of fluids, size reduction, size separation, heat transfer, evaporation, distillation, drying, mixing, filtration, centrifugation, and pharmaceutical plant construction.

Raising Awareness in the Fight to Cure Rare Diseases

VINEET SINGHAL

"Our purpose is to enable people with life-altering conditions to lead better lives," Says Vineet Singhal, Country Head, Baxalta Bioscience India Pvt Ltd (Now part of Shire). In an exclusive interview with Mahesh Kallayil, he further talks about potential opportunities in rare disease market, ensuring affordability of specialty medicines, business strategies and much more.

Can you briefly explain about Shire's vision and its focus areas in India?

Shire is a leading global biotechnology company committed to serving people affected with rare diseases and other highly specialized conditions. These diseases (many of which are genetic) are often misunderstood, undiagnosed, and potentially life-threatening.

Shire keeps patients at the centre of everything we do. In India, we are focused on two therapeutic categories, one being Hematology with our portfolio covering anti-hemophilia factors. Hemophilia is an X-linked congenital bleeding disorder caused by a deficiency of coagulation factor VIII (FVIII) Hemophilia A or factor IX (FIX) Hemophilia B. The deficiency is the result of mutations of the respective clotting factor genes.

The second broad franchise in India is Immunology where we sell high-quality albumin and immunoglobulins, which are used under critical care by leading hospitals across India. We have widened our reach across the country and are present in every state.

How do you see rare disease market in India?

The biggest challenge that we see is that awareness and understanding of most rare diseases remains limited in India.

Therefore our primary focus will be on three areas: the first is to increase awareness of these conditions amongst the medical community. Our second focus will be to improve the means of diagnosis for rare diseases. Thirdly and most importantly we want to make therapies accessible to patients.

We are making a concerted effort to nurture an ecosystem that supports patients in rare diseases and ensure these specialized conditions can be treated. The good news is that there is a fair level of awareness about some rare conditions like Hemophilia across the country. Various efforts by the Government, patient bodies and healthcare companies have been instrumental in driving this awareness. It is thanks to these collective efforts by various stakeholders that the disease is addressed in a holistic manner.

There has been an increase in funding for Hemophilia around the country from three states 10 years ago to 21 states as of today.

The Government has played a pivotal role in this journey by ensuring that patients do not suffer from a lack of access clotting factors. Going forward, Shire is committed to supporting the Government in its effort to increase awareness of rare diseases, LSD (Lysosomal Storage Disorder) and specialized conditions.

What are the potential opportunities you see for Shire in India?

Given the current scenario of rising incidences of disease-burden in Hemophilia and other rare diseases it is an imperative and a responsibility for Shire to be able to bring therapies to India that can help patients lead a better quality of life. From our experience of having played the role of enablers providing access to the diagnosis and treatment of Hemophilia, we plan to play a similar role in the treatment of LSD.

Shire's extensive portfolio means we have the potential to help thousands of patients who need treatments , not yet available within the country. We want to make therapies accessible to patients so that they can start leading a near normal life.

We also plan to bring our Oncology portfolio into the country, including a first in line treatment for Acute Lymphoblastic Leukemia.

For Shire, it's critical we are a catalyst in creating an environment that supports Rare Disease patients with a comprehensive program that will encompass awareness, education, diagnosis, and infrastructure to provide the right treatment options. We believe the only way to make this possible is through meaningful partnerships that bring together policy makers, patient bodies, patient communities and other stakeholders around a common agenda, promoting awareness and accessibility to therapies.

At Shire, we ensure we build a sustainable platform for future innovation and growth. Keeping in mind the current scenario, the company has a significant role to play in building awareness among all these stakeholders.

Can you give us a brief overview of the Indian pharmaceutical sector and growth potential of biotechnology?

The pharmaceutical market in India is growing at a double-digit rate. Having said that, it is difficult to benchmark any specific data for the biotechnology market, although it has the potential to grow at a much faster rate than the mass pharma market. With rising in awareness levels and Government initiatives, we feel that the biotechnology industry will continue to grow, comprising bio-pharmaceuticals which will can contribute to the overall growth of the economy.

What steps have been taken by Shire to address the affordability of medicines of these highly specialized conditions?

Shire is dedicated to developing innovative treatments for rare diseases and specialized conditions, which make a difference to the lives of patients and their caregivers. Developing innovative medicines, particularly for rare diseases, is not easy. For every successful therapy that is brought to the market, there are many failures.

We are committed to pricing our treatments in a way that is responsible and sustainable for healthcare systems around the world and also ensures that our company makes a return on investment enabling us to develop the next generation of treatment for patients with high unmet needs.

To support decision makers, Shire generates evidence, both before and after our therapies are approved, to demonstrate the impact our treatments make to the lives of patients, their caregivers and to the healthcare system. We are solution-focused, actively seeking ways to engage constructively with healthcare providers, payers and policy makers to achieve together the best possible outcomes for patients from the resources available.

At Shire, we never lose sight of our focus on patients and our drive for high-impact. Our goal is to ensure that all patients prescribed a Shire therapy have access to it and that they have the support they need to achieve the best possible results for them. Shire has programs to support patients along their treatment journey offering early, supported or charitable access.

We believe our commitment to advancing innovation for rare disease and specialized conditions is how we are making a significant contribution to society through the impact we have on the lives of patients, their families and caregivers.

Shire has a very strong focus towards both global and domestic partnership. What are the basic criteria for partnership and how do you ensure success?

Shire's journey over the past few years has seen the company strengthened its position through partnerships and mergers, which in turn have helped us to achieve our mission. We are constantly seeking out new opportunities through strategic partnerships and our approach to business .

We have a good track record of partnerships with other organisations to develop innovative therapies which build on our existing rare disease portfolio. These partnerships help to combine the best of both companies and contribute to making Shire, a nimble, performance-driven organization through a collaborative approach with the patient at the centre of it all.

How important has the Baxalta acquisition been for Shire?

Our combination with Baxalta has been an important step to help us achieve our goal of being the leading global biotech for rare diseases, bringing us an expanded portfolio and increased capabilities that enhance the impact we can have on patients around the world with significant unmet needs. Shire and Baxalta's complementary portfolios mean that our global therapeutic areas now include Hematology, Immunology, Neuroscience, LSD, Gastrointestinal / Internal / Endocrine, HAE, and a small but growing franchise in Oncology. Globally, our two biggest franchises are Hemophilia (a Baxalta legacy) and LSD (a Shire legacy).

Following our combination, we have an expanded 37 programs in clinical development, our most robust pipeline in history. The combined company has nearly 24,000 employees and expanded geographic reach across more than 100 countries.

What are the major challenges you are facing and how are you gearing up?

From an India standpoint, our biggest challenge is the lack of awareness of rare diseases and specialized conditions. To overcome this, it is important to create more conversations at various levels, including patients, doctors, the medical community and policy makers. We have been working continuously with all stakeholders through patient outreach, awareness programs for the medical community and engagement with doctors and policy makers to increase awareness of these life affecting conditions.

What would be your business strategy for the current financial year?

Shire strives to support patients with rare diseases and other specialized conditions, and our strategy is to create and grow long-term value based on improved diagnosis and providing high impact medicines and therapies. We believe our commitment to advancing innovation means we are making a significant contribution to society through the positive impact we have on the lives of patients, their families and caregivers.

We continue to focus on commercial execution and new product launches, including geographical expansions to extend access to our portfolio. Our intent is to expand leadership therapeutic areas by enhancing our commercial capabilities, increasing our global footprint and broadening our portfolio of best-in-class products. Also, we want to focus on the effective execution of our late stage clinical development pipeline to support future growth. ■

Significant Growth of Indian Life-science Market is Expected in the Near Future, Thanks to Dynamic Environment

Dr. Philipp Marchand
IP Specialist and Portfolio Management
Vossius and Partner; Innosuisse Special Coach for Intellectual Property

Intellectual property right is pivotal for Indian pharma and life-science industry with respect to the protection of their new/existing innovations, for which the manufacturing companies and their respective scientists put in lot of sweat and toil for years to make their thoughts a reality. **Dr. Philipp Marchand,** in an exclusive interaction with **PharmaBio World,** speaks about the business footprint of Vossius & Partner, strategic portfolio management, expansion plan for India and engagement strategy with Indian companies, value derivation, IPR trends, cross-border difference in IPR regime, and the other associated aspects.

Please walk us through the business footprint of Vossius & Partner.

We are a leading European law firm with a sound focus on intellectual property protection and development on the international stage. Our clients make profit from our profound scientific and legal expertise, backed up by strength of over 300 employees including internationally qualified representatives; and therefore have placed their faith on us for years. The interdisciplinary collaboration amongst our teams ensures a fully comprehensive view of our client's intellectual property needs.

In terms of whom we cater to, our clients range from start-up businesses to multinational corporations, as well as academic and scientific institutions. We have established a global network of partner firms with a particular focus on the Asian market, including India.

In addition to our head office in Munich, we have offices in Düsseldorf, Berlin, and Basel (Switzerland), which are fully integrated so as to offer comprehensive consultation in any intellectual property matter at any dimension.

What's your expansion plan for India and engagement strategy with Indian Companies?

In terms of growth prospect, India is one of the most prosperous markets amongst the rest and we are convinced that Indian economy will continue to grow, basis the research & innovation attributed by Indian companies. With that context, we plan to increase our presence in Indian market. Not only is that, our focus is to establish ourselves as one of the main go-to firm for European Intellectual Property Law related services in entirety, with a diligent assurance

for new innovation and existing IP right protection for Indian companies.

When it comes to our engagement strategy, we usually associate with Indian companies through local IP law firms based in India. However, for European IP-related issues, we go for direct engagement.

How does Indian life science market will derive value from the association with Vossius?

In a dynamic environment, we expect significant growth of the Indian life-science market in the near future. Having special expertise to protect our clients' innovation, we follow such dynamic changes and expect to engage with as many Indian companies as possible who're seeking to enter and/or to expand their presence in European market.

Indian companies, being our potential clients, can expect to receive highest-quality IPR services from us. As one of the few European law firms, we are the one-stop service provider covering all the stages and aspects of IPR, ranging from initial filing to licensing, as well as the enforcement of such rights in court proceedings.

How do you comprehend the present IPR trend(s) in global context and its impact upon India?

The current trend, ranging from traditional innovation in the pharmaceutical industry to personalized and/or digital-based innovation, has impacted the strategy of successful securing and defending of IPR very profoundly. As an internationally engaged law firm, we are actively following such trends and offer current strategies for our clients which commensurate those trends.

As a special mention, with the recent trend to digitalize the diagnostics or treatment procedures, we see more and more software-based innovations in the pharma sector. Indian companies have developed strong expertise in this arena. Therefore, the current trend will likely to lead to an increasing number of innovations to be attributed by India.

Please walk us through the cross-border difference in IPR regime with respect to Life Science Vertical and how does Vossius deal with it.

One of the prominent purposes of our engagement with our clients is: to protect their interests, as most of them are active global market players. And therefore, our IP strategy encompasses cross-border differences in totality with respect to – the type of IP to be effective to protect life-science related inventions in the desired market, how best to obtain grant for such rights, and how they can be enforced most effectively.

In this regard, World Trade Organization (WTO) member states have ratified the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) to establish the minimal IPR

standards for national governments. Nevertheless, we are aware that not all the regulations are being effectively implemented by all the member states. However, having international experience allows us to take such differences into account in a tailored manner, specific to each client's needs and desires.

What are the concerns still existing for IPR implementation and how would be the respective addresses?

In life science sector, quite a few inventions do pertain to new chemical entities (NCE) and most of the countries allow such NCE related patent claims, unless the NCE was somehow derived from their national heritage as per Nagoya protocol. However, inventions are not only limited to NECs; these also relate to novel uses of existing compounds or inventive uses of such compounds in treatment regimens, such as the protection of treatment regimens. Most countries accept such claims and thus the grant of such patents directed to such "secondary" inventions, provided all the patentability requirements are fulfilled. Only a few countries deny such claims for formal reasons. A full IPR strategy takes into account the different regulations on a country-by-country basis and adapts the filing strategy accordingly, for example – with respect to the type of claims, the countries in which patent protections should be sought, and the alike.

How does Vossius generate value for start-up companies?

In pharmaceutical industry, strategies for start-up companies and that for global players are not the same, as the sameness does not make any sense here. Instead of developing a product for market entry, it may be advisable to out-license or sell a potential product after toxicity studies, and/or structure-activity-relationship (SAR) studies, or even before. The value attributed to a Start-up will largely depend on whether and how IPRs have been secured for that start-up. In other words, the value of the company will be determined based on the innovation-right-exclusivity made by the start-up companies for their potential buyers. We tailor the IP strategy according to our clients' needs, in order to optimize the IP protection scope and its value.

How does Vossius manage their strategic portfolio?

In line with the preceding, strategic management of IP portfolio is of utmost importance. Depending on the type of business, such as – drug development, diagnostics, medical devices, production, etc, the filing strategy may have to be significantly adapted. In general, the portfolio should be centered on the potential major markets identified for the planned product(s). However, depending on the identified markets, production sites, and distribution chains, – it may be advisable to pursue protection in additional countries. Again, acting on an international level, we can provide strategic advice with respect to all aspects of IP portfolio management.

What would be your message for Indian life science industry?

We are convinced that the Indian life science industry is currently the robust one and will continue to develop in the coming years. In order to secure further development, it will be important to secure intellectual property assets in the most important life science markets outside India, including the European market. As a one-stop law firm, we offer consultancy in all aspects of intellectual property law and would be happy to assist the Indian life science industry in its continuing growth! ■

Moderator: Jayati Mukherjee

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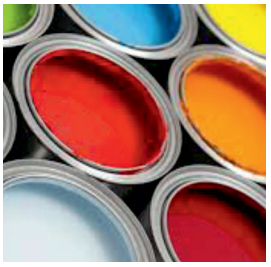

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