

Ravinder S. Singha, Firmlink Pharma, Philippines

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Ravinder S. Singha, the Managing Director of Firmlink Pharma, discusses the unique business model they offer to their clients, their key success factors in entering new and sometimes challenging markets, as well as his views on the potential seen in many of the dynamic pharma markets around the world. He also shares his vision for the company's continued success in the coming years.



As an introduction for our readers, how would you define the business model of Firmlink Pharma?

"The number one motivator [for setting up Firmlink Pharma's regulatory hub in the [Philippines](#)] was that the [Philippines](#) scores high on evolved regulatory practices and registration process transparency."

Firmlink Pharma is a young multi-national firm that uses the domain knowledge and relationships of its consultants to become the extended business development arm for its partner companies wanting to export their products overseas in their geographies of interest. We handle the entire gamut of work from product and partner identification to supply agreement firming to dossier vetting and filing to product approval from respective regulatory bodies to sales ordering post approval.

Firmlink Pharma also does selected work as an extended vendor sourcing arm for large generic companies wanting to get site due diligence & site approvals, regulatory dossier and BE assistance in sourcing countries and commercial tying up in areas that may need a foot on the ground by our partners.

We have consciously positioned ourselves as a hardcore service organization that is clearly distinct from being a trader with a focus on sharing the incremental value gained in costs, processes and time with our partners. We are now known for transparency as our bottom line in our dealings and we want people to know that we are not making a shameful amount of money since they monetize us, thus making them more open with us.

Firmlink Pharma shares its local market grasp and cognizance with companies and takes them to markets they may not venture on their own. We lay out the path and drive their entry into these markets to better allow them to focus on their core competencies. We also get incremental value for our customers and vendors. More often than not we are able to get our exporting partners a higher realization than their base prices offered to us or get lower prices than the wish prices of our sourcing partners. Unlike a typical trading mindset to maximize and retain all these margins to ourselves we proactively share the incremental value with our partners. This makes us build a sustainable FIRM-LINK with them since we directly add to their profits. All this while saving them precious travel costs and hit and trail costs in an unknown territory.

As for our target partners, we only go to vendors who have at least a PICs site approval, and additionally we have a list of boundary conditions for companies: besides the minimum one PICs approval, flexibility in terms of batch sizes and packing changes, basic dossier capability and the key is their vision to go global. We carefully assess their broad plans to see if they want to do more than 50 percent of their sales globally in their vision. Since, if it is just going to be domestic focus and exports is just an appendage, then we may not be the right people for them. We try to map a company and see whether they will fit with us in terms of values and the business plans, so we do all of that work and come to them with our proposition. Additionally, we try to focus as much as possible on suppliers with differentiated dosage forms and or products.

In terms of market selection, we are sharply focused on select pharmerging markets, specifically the ones

difficult to enter. Our number one market in terms of regulatory footprint and revenues is [Taiwan](#), which has more regulatory mazes and higher fog index in terms of entry compared to even the much vaunted markets of USA and Japan, as there are many steps you must take before getting a product into the market. The difficulty is the opportunity for us! Besides the [Philippines](#) which is relatively easy to enter but tough to sustain, we are also well equipped to get companies into [Indonesia](#), where there are limitations on imports, and Korea, which has started to open up to supplies from the less developed areas. We also have on our radar Brazil, Gulf Cooperation Council countries, Vietnam, Singapore, Malaysia and Bangladesh, all of which are high-profit markets fitting our model.

What were your motivations behind setting up your regulatory hub here in the [Philippines](#)?

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The number one motivator was that [Philippines](#) scores high on evolved regulatory practices and registration process transparency. In ASEAN, after Singapore and Malaysia, they are the best performers on these count. Additionally, it is an English-speaking country, which in terms of dossier and document capability handling is a major asset. Thirdly there is quality pharma education and institutes when benchmarked in the region and a young talent pool of Pharmacists. Fourthly [Philippines](#) has a head start in terms of adoption of ACTD formatted dossiers which helps us get our local team to vet product dossier across the region and even distant geographies following CTD format, with ease. The fast growth in the adoption of generics is a big plus to replicate our practices here to other neighboring markets. Lastly the sound sourcing practices followed by large players here coupled with the top-of-the-line GDP growth rate of 7.1% (Q3, 2016) makes us sustain the team from the profits we can get from this market. Firmlink may well be a pioneer in setting up a global regulatory hub here and to not just be PFDA-focused but outsource regulatory work from here. We see more people bucking this trend in the future.

You had the foresight of seeing the [Philippines](#) becoming a dynamic and growing market, and now are active in almost a dozen markets. What were the reasons for choosing the markets that you did?

A very considered and experienced view weighing in a number of factors has been used by the team to expand to the markets we are presently in. We have objectively done this exercise and are data driven tempered with our rich experiences. Foremost in selecting the markets is the fact that 46 percent of the global pharmaceutical market growth until 2020 will be coming from Asia, which translates into roughly a 35 percent share of the global pie size, a USD 340 billion opportunity!

Asia is also where profitability despite the price pressures is still attractive for the suppliers and where the market, especially in generics, is growing in double digits. The center of gravity of global pharma business is now Asia. This has made us select most of our target markets here like [Taiwan](#), [Philippines](#), [Indonesia](#), Korea, Vietnam, and GCC markets. Within Asia the shortlist was made keeping in mind the less crowding, low price erosion, higher branded sales, greater difficulty to enter the market and low present genericization.

Thirdly, 10 of the top 15 markets by 2020 are expected to be Pharmedging markets and based on the projected growth rates we have additionally identified Brazil, Ukraine & Jordan outside of the core Asia region.

And fourthly, the Least Developed Countries as per WTO provisions, are countries which allow manufacture of patented products now until 2033, and keeping this in mind, and the low cost of production, Bangladesh made the cut into this list. We work with 7 of the top 10 companies there. At the cost of being immodest we can say we are front runners in Bangladesh to get some of the major players to get their sites approved by highly regulated bodies like TFDA, [Taiwan](#); BPOM, [Indonesia](#). ANVISA, Brazil & PFDA, [Philippines](#). Firmlink is a pioneer to get

Bangladeshi companies to export to the [Philippines](#), [Taiwan](#), [Indonesia](#) and soon to Brazil. We have identified clearly the country as the hidden jewel while others do not want to go there thinking of it as a quality-compromised geography that is messy and unstructured, for us its India 20 years ago! A less developed country or a relative greenhorn in exports also by default is a more reliable country with easier and more trustworthy dealings- another big fitment with Firmlink values.

Another factor that we take into consideration is healthcare reforms and insurance coverage, which are just starting here in the [Philippines](#) and several of our other selected markets and thus growth is a given over next half a century.

Lastly, any market which is completely dispensing is not on our list. We classified markets based on their prescription habits. Prescription-driven markets with brands where the price erosion is slow and thus are naturally interesting. [Taiwan](#), though a dispensing market, qualified purely on account of the difficulty to enter factor which overruled all other considerations. Even though it is a pure reimbursement market but with the second highest prices in the region after Japan it has sufficient incentives to be a key market for us.

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What markets do you see being most promising for Firmlink Pharma in the coming years?

Over the last three years we have worked to consolidate our foray into [Taiwan](#) with more than 100 quality products tied up with over two dozen vendors across the globe. In [Taiwan](#) we are the number one overseas generic player in terms of products registered or under registration. Also we are still working to expand our customer and product reach in the other key market for us, the [Philippines](#). For these two markets after pioneering Bangladesh market entries we are now exploring working with medium sized generic players in US and select generic players in Japan to take a lead to get these big market companies to look at these interesting markets.



Going forward our eyes are set on the two other new pharmerging markets to set our foot on the ground. We are working to begin supplying to and sourcing from Brazil. We are targeting to set up our next base in Sao Paulo by 2020. Then we have Ukraine and the Baltics on our radar. They are highly attractive and fit our strategy, however, due to the political turmoil, we put this initiative on hold, but we still have plans on going there. Lastly, some of our sourcing will come from the Middle East and Maghreb region, especially [Algeria](#) and GCC, which has the regulatory readiness and is yet not present in most of our strong customer- territories.

Considering the diverse group of markets you are operating in, how do you adapt your services to those very different markets?

The cornerstone of overseas business is to tailor-make your package to fit the specific needs and nuances on the ground. We have carefully tried to look at the specifics of each of those markets and adapt to each country. We first look at the regulatory practices, and we have a checklist to classify the opportunity areas and then we look at the sourcing practices and licensing possibilities to make out our value proposition for the potential customers. While [Philippines](#), Vietnam and Singapore become prime candidates for pure registration and

supplies business, markets like Bangladesh, [Taiwan](#) and Brazil have holes to plug in terms of supplies and yet simultaneously offer attractive sourcing options with their well evolved local manufacturing and R&D bases. On the other hand, given the Decree 1010 in [Indonesia](#) and the restrictions on imports in Jordan, dossier sale, tech transfer or supplying of locally unmanufactured dosage forms becomes the natural way forward. Markets like India, US, [Algeria](#) and Korea are for us essentially only as strong sourcing hubs.

How do you position yourself as the partner of choice for your clients around the world to truly highlight the qualities that differentiate Firmlink Pharma?

Firmlink has assiduously worked to develop a value proposition which is so different from what anyone else offers in the generic pharma space. In fact, at the cost of sounding a bit brazen there really no one else competing with us in our offering!

First is the fact that our monetization model in which we share the incremental value over the base prices proactively with our partner companies. In essence our partners cover for their margins and then we give them an icing on the cake with even better realizations.

Secondly is our belief that APAC is the center of gravity for all action of generic pharma business over the next couple of decades. Thus we pointedly get companies to work with us in our tried and tested markets where all the action is moving to.

Third is the way we do our Tripartite Agreements (TPA) between us, vendor and customers balancing power and making firmer engagement with Brand Name owned by the customer and IPR by the vendor, thus both sides needing each other for good. Additionally, our TPAs are exclusive so that no threat from the same vendor is felt by the customer for the product. This is despite regulations allowing for to give the same MA to different players in the market. This gives all parties concerned the security to invest in the relationship.

Fourthly, I would say our focus on newer and difficult to formulate or register products and dosage forms like Metered Dose Inhalers, Dry Powder Inhalers, Oral Dissolving Films, Transdermal Patches, Specialty Injectables, Suture Closing products, Hep C products to name a few make us a company people like to work with to energize their product portfolios.

Lastly, we work with vendor companies who do not have the knowledge or wherewithal to go into the markets that we specialize in but yet have proven regulated quality. This gives us untapped potential to build on. These are never the largest suppliers or companies but typically are medium sized companies that offer quality products (which our customers want us ensure) and under more flexible arrangements. We then can work to fill the regulatory gaps, and be their Business Development engine handling all aspects of overseas pharma business for them. This is a tremendous opportunity area. Most importantly, they need to be focused on building themselves globally, and we believe that we can be the partner to help them accomplish this.

This is where our experience comes in. We have over a hundred years of hardcore international experience amongst the lead team across our offices. This helps to give our value proposition a sound foundation and not just be advisers but key actors in their foray into overseas pharma business.

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How are you going to attract new partners and highlight your ability to fill gaps and provide them value added services?

There are clearly two initiatives we are taking to expand our partner network. Foremost we are going to add any qualifying company which has new products and differentiated dosage forms. So companies with newer combos coming off patent over the next 5 years or suppliers who have Inhalers, Patches and Biosimilars in their range

are prime targets.

Secondly, we are going to the medium sized generic players in USA and select generic players in Japan to try and get them to be in this exciting playing field, Asia. Like any pioneering initiative this is a tough task because these are big markets, and typically companies do not want to look at smaller pharmerging markets to expand their revenue. So clearly it is an exercise to use our experience to show them the opportunity gaps in our major markets and get them firm customer enquiries for their products and start the ball rolling. We already have a considerable interest from a couple of American companies and we are all set to be yet again the first to conduct business with Japanese generic companies in our territories.

Since you co-founded Firmlink in 2009, what are some of the accomplishments that you are the proudest of?

It has been a path-breaking and exciting journey so far for the organization. While there is no one giant step but there are several pioneering steps and firsts in the industry that our team is proudest about. We became the company with the largest generic registration foot print in [Taiwan](#) with over 100 products and site approvals by TFDA arranged by any company at 17 sites. We have over more than 170 filings done with PFDA of which 72 products approved at average of 14.5 months. We have multiple product supply agreements with the Top 5 generic players in [Philippines](#) and are the first company to take major Bangladeshi companies into markets like [Taiwan](#), [Philippines](#), Brazil & [Indonesia](#). Additionally, we have launched over 50 products thus far across 6 markets: [Taiwan](#), Philippines, [Indonesia](#), Vietnam, Singapore and Bangladesh and are drastically improving the timeliness of our signed deliverables to over 85 percent from partners' average level of on-time completion of less than 30 percent.

As Firmlink is a pioneer in this industry, where do you hope to lead the company in the coming years?

We at Firmlink have a clearly defined vision set for the team which is "To be the most admired overseas business development company in the global generic pharma space by 2025." By ensuring we use our domain knowledge to increase the value for our partners we have a unique model that needs to only gain traction across more territories and newer product lines. It is also our firm belief that anything worth doing is worth doing fast and this core value will help us to keep the organic growth pace with our vision. The idea behind the organization to focus on building the partners' business will always be the foundation for all our action as is encompassed in our slogan "Our Business Building Yours". We see the set-up of two more offices in two new continents, Latin America and CIS taking shape in the coming years and making us realize our vision.

These are exciting times to be in the generics space in the Pharmerging markets specially in APAC. We are confident as long as we are not generic in our approach to the generic business, success will keep happening for us!