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Please introduce Voisin Consulting Life Sciences.

Dr Emmanuelle Voisin: Voisin Consulting Life Sciences (VCLS), was started in 1997 in order to assist the Pharma, Biotech and MedTech industry, especially the start-ups at that time, to place their products in the market. It is basically a product development and regulatory strategy consulting firm.

Over the years, the firm have evolved along two different areas. One, is we are regulatory driven, that is when a new regulation is been sought by the EC (European Commission) or US FDA (United States Food and Drug Administration) we are present and we try to understand the philosophy behind the regulations and prepare the services accordingly. So basically being regulatory driven means that when there is an orphan regulation in the air, be it orphan, pediatric etc, we know exactly what's going on and prepare the kind of services that our client will need. We once prepared for the geriatric regulation that never came up, but that's okay we are always prepared for everything and well ahead of time.

The number two is geography driven we really wanted to be an international firm and not just a network of consultants across the world. We are all employees in the different companies in different parts of the world. Europe is represented by France (Paris and Rennes), UK, and Switzerland. USA is represented by two main offices in Cambridge and San Francisco with more offices planed on the east coast, and of course Bangalore is our only and very important office in APAC.

What was the rationale behind setting up an office in India?

Dr Voisin: The rationale at the time, and it has evolved through years, was I discover that there were excellent Indian companies, which were growing and they wanted to place their products in the Europe and USA. So we focused on business

development with these companies and we attracted these companies to work with us in placing their products abroad. So we were oriented with the Indian companies expanding their operations overseas. After that, we did work with the local regulatory bodies, but most of our work is with the big Indian MNCs who wanted to grow in other parts of the world.

Please tell us about Voisin Consulting Life Sciences' operations in India.

Dr Rajashree Devarakonda: We started our Indian operations in 2008 and through this office we are operational in India and APAC. The services that we are providing form here are similar to our global counterpart but more so focused on the services related to Pharmacovigilance, clinical trial operations, clinical review of regulatory documents for Clinical Trial Applications/ INDs, Clinical review of MAAs/NDAs/BLAs, clinical/regulatory strategy, positioning of the product, assistance with formal informal meetings with regulatory agencies, preparation of clinical development plans, risk analysis from pre-clinical development stage to market authorization stage, registration procedure and lifecycle management.

We also support in conducting clinical trials in India through our local partners as a support office for our global counterparts. We have several Indian Clients and our own projects coming from India and also from APAC. We also act as a portal for our global clients to enter India or APAC and help them register their product here. We have several local partners for our various services for example; clinical trials, pre-clinical studies etc. In addition, we also identify service partners for our global clients.

How important is the APAC for your business?

Dr Voisin: The way we use Indian market is to bring Europe or American countries to utilize India's infrastructure like contract manufacturing, clinical research services or the Bio IT experience. We want to offer the Indian expertize to our foreign clients and help them to develop their products here and obviously there are lots of diverse patients in APAC including in India. We help foreign companies benefit from all that India offers - development capabilities in terms of manufacturing or clinical testing through our preferred local partners, as well as domestic market entry. VCLS Indian team is also a hub for our clients to the ASEAN region as well as excellent resources participating in a number of our clinical and Pharmacovigilance projects.

VCLS offers a number of services in development planning, manufacturing, quality and controls, nonclinical and clinical testing, etc among others where do you generally find your clients need the most help?

Dr Voisin: I think regulatory interactions with the agencies is our number one activity. This takes place non-clinical early development stage and also during clinical development including the chemistry manufacturing and control phase, when there is a characterization of the product. We also go beyond market authorization now from past two-three years, we are developing market access services. Thus, our major activity is regulatory and it starts as early as pre-clinical stage, during clinical development at the time of registration including pricing and reimbursement and beyond during life cycle of the product.

Dr Devarakonda: VCLS brings to Indian companies US and EU development and regulatory strategy and expertize in registration. VCLS anticipates and addresses challenges throughout health products life cycle. The company identifies and manages product-related risks, from the early definition of the target product profile through nonclinical and clinical development, registration, launch, and commercialization. We strongly believe that product development must be driven by a solid understanding of the science and environment within which the product will be launched, and the criteria by which elements of the development will be assessed by both regulators and payers. We start from science and medical needs, as we collaborate with our clients' teams to drive innovative products along development and commercialization.

VCLS also conducts due diligence to prepare for licensing, mergers and acquisitions. That is our team provides actionable recommendations with essential information that enable clients to make strategic decisions. VCLS helps define the roadmap to the developed market, complete with situation audit, milestones, and the strategy to drive tangible results in line with corporate objectives. We also provide insights and course correction along the way. We help expedite product development and optimize commercialization in long-term collaborations. We bring strategic recommendations and leave clients responsible for final decision. We do not just prepare submission packages either. We roll up our sleeves to guide and work with our client's project teams on implementation hands-on. We interact with regulators informally as well as formally on a regular basis on behalf of the client, as well we arrange scientific advice meetings, Pre-IND/IND meetings on a regular basis and we attend and prepare the clients for these meetings with the clients. Over 75 percent of our new assignments are with existing clients.

What are the biggest challenges that companies (your clients) have experienced when it comes to regulatory compliance?

Dr Devarakonda: The biggest challenge with Indian companies is interpretation of the existing FDA and EMA guidelines as well as difficulty in providing scientific rationale /justification in a manner that is acceptable by the agency during scientific advice meetings or in the dossier in the scenario where deviation from guidelines is required. To these clients, VCLS provides hands-on assistance in the preparation of development of briefing and submission packages. With a presence in North America, Europe and Southeast Asia, we design global strategies and adapt execution in each market - accounting for local medical practices, regulatory frameworks and reimbursement landscapes. Considering, we have been interacting for more than a decade with regulators, payers and key opinion leaders in these markets, we have privileged relationships that we have developed facilitate formal and informal dialogue between the industry and health authorities. We work with our clients in an educational manner; help them with the meeting preparations, interactions with regulators, to identify the kind of questions they should ask keeping in mind scientific rationale, help them with preparation of package so that our clients can make best of these meetings. In summary, VCLS provides hands-on assistance in the preparation of development of briefing and submission packages.
In summary, VCLS anticipates and addresses challenges throughout health products life cycle by providing strategic recommendations based on solid understanding of the science and environment within which the product will be launched, and the criteria by which elements of the development will be assessed by both regulators and payers.

How do you see regulatory climate in India? How does the firms trying to open offices in India sees it?

Dr Devarakonda: The regulatory scenario in India is definitely much better than what it was 1-2 year before. Of course, Indian regulations still have a long way to go to come to the stage of the US FDA or EMA standards where in several product specific, therapeutic area guidelines exist, process and timelines are defined. However, I would like to highlight that I strongly believe India has a lot to offer and Indian regulations are also being streamlined and are being fine-tuned in the right direction including tight processes to ensure good GCP practices are in place, quality standards are in place among others. Considering India has genetically diverse population which is an advantage to enrich the clinical trials I am positive Indian clinical trial industry will bounce back and become again the preferred destination for trials.

What we believe is what is really required is clarity in the existing guidelines, more disease specific and product specific elaborate guidelines, process clarity, transparency in the assessment and data requirement, stringent quality standards for approvals, customization to approval process based on scientific data and process for efficient risk/benefit analysis, more regulatory agency and industry interaction early in the development process, efficiency in approval process respecting critical timelines in order to not cause developmental delay. Agency should partner with companies in the development of critical products very early in the process especially for diseases of critical importance in India, for which there are no proper treatment; for example, Orphan diseases, and provide grants/ funds/ incentives/ongoing advice for the companies similar to US/Europe to develop and commercialize these orphan drugs to as quickly as possible. As well, it is important regulatory agency should; receive sufficient practical training in the assessment of the dossiers (especially considering the novel products, biologics, stem cell products that are coming in to the markets), receive more resource, be urged to hire more scientifically qualified staff with hands on experience in the industry so that efficient/thorough review of the application happens in a timely manner leading to approval of critical drugs with proven safety/efficacy in India. .

In summary, even though there is much more to be done for the Indian pharma industry, industry is heading in the right direction.

How is the regulatory scenario across the globe?

Dr Voisin: The word complex characterize the regulatory climate at present across the globe. The regulators are focused much more on safety of the patients.
Of course the zero risk does not exist. If you believe safety equals zero risk you will be working forever. Having said that, I believe there has to be a cursor placed on it, however that cursor now is more and more pushed towards infinite and that create a lot of work, so regulators are creating much work for the companies. Interestingly enough, more products are removed from the markets in the past decade after they are marketed, which is strange. Earlier they guidelines were less stringent and products would stay longer in the market, but now when the more stringent guidelines are placed, the more we see major scandals with the safety issues and problems with the products. That's a contrast which cannot be explained but it's quite visible.

The other key word would be more and more industry-regulatory interactions, regulators want early interactions with the companies/ industry so that they can put their expertize to the service of the new companies. They create regulatory pathways or mechanism through which we are able to interact with the regulators at the different stages of the development of the product and not just at the end, like it used to be earlier.

What is your international expansion strategy?

Dr Voisin: There are two kinds of areas that we look for expansion. First of all, if the economy is expanding than certainly it's a country of interest for us and we would like to explore and expand in that country. Secondly, we also go to places that are strategic in business, for example we want to be close to agencies. Our London office is located close to the EMA. Same thing with the FDA, we do not have an office in Washington DC at present but this could be another good thing to do, that could be one possibility.

In addition, I think the world belong to those who can work remotely. The idea is to identify the great professionals in our field around the world, wherever they are, we want to work and collaborate with them. We will in addition to our offices, recruit home-based persons, who believe in our values, even if they are located in the remote parts of the world. We want the best personnel for our company.

How the clients' requirements have evolved over the years?

Dr Devarakonda: Earlier the companies were developing the treatment for simple indications like fungal diseases or other infectious diseases and were mainly into generics and the simple small molecules. The procedure was thus standard and reverse engineering was possible. However, now the companies are looking for the treatment of cancer, genetic disorders, rare diseases, which were not explored before, and were assumed to be untreatable. Now companies are exploring complex generics, large molecules, innovative biologics, stem cell therapies and are aiming their development program at these complex diseases and personalized medicines. So when they explore these unchartered territories they don't have enough knowledge about it and find it extremely challenging to address all the aspects of development internally and turn to regulatory experts in the area of innovative products with parallel US/EU development expertise like us at VCLS.

Previous development strategies (set number of trial with set number of patients) are no longer valid for these life threatening diseases. Now it is possible to gain early approval for certain type of diseases and indications on a case by case basis if the companies can show risk safety efficacy in an abridged manner without compromising the risk benefit ratio with a commitment to monitor safety post marketing as a part of risk management plan. We have significant experience in designing such strategies. Recently, we have received approval for a study involving only nine patients.

Thus, with these new indications, it is becoming increasingly challenging to advice a clinical development plan. We work in partnership with the regulators and our clients to sort a strategic development plan so as to launch the product faster.

In terms of client portfolio which segment i.e. Pharma, Biotech or Medtech, do you think will be the key driver for your future growth?

Dr Voisin: I believe as big pharma is going to concentrate on development and commercialization and science and research, therefore new drugs are going to come from the small molecules. Today there is an explosion in the biotech industry worldwide, there are many biotech companies which are valued much higher and most of these companies or the product has been sold to the big pharma. So, I believe there will be a real growth of the biotech for innovations and invention. More statistic activities will be done by the big pharma but it will not grow extremely high.

Please tell us about your Future plans.

Dr Voisin: In the USA, biotech growth is huge, we want to be a part of this development, that's why we want to consolidate our presence in the US. So keeping in line with this, we have recently acquired B&H Consulting Services as a part of our expansion in the USA. We needed additional help in the areas of regulatory and specifically in the chemistry manufacturing and the control area which this acquisition will provide. Furthermore, B&H is bringing us a lot of expertize in interacting with the US FDA and it will also mark our presence in New Jersey where we did not have existence before.

Further, we want to offer integrated services. We want to go beyond the borders of our current activities and bring other services that are integrated or synergetic with the current ones. This is how we expand, it's not a conglomerate or a financial project. It's a project that has to make sense for a client whether it's as biotech, medtech or pharma, that's how we grow and

we plan to keep growing like this.