Interview: Susanne Picard â?? President, SPharm, Canada

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Susanne Picard, founder and president at SPharm, speaks about how her passion for regulatory affairs led her to found her own consultancy in 1997 and how the company can look back at an impressive track record of success over the last 21 years. Here, she outlines key priorities to further internationalize the scope of her activities and discusses the sector at large.

Can you please introduce SPharm to our international audience?

SPharm is a Quebec-based, Canadian, strategic product development and regulatory affairs services company that I founded in 1997.

I have always loved regulatory affairs and the proximity to drug research opportunity that the field offers. Having worked in the pharmaceutical sector for some time, I decided to seize an opportunity to establish my own business; gradually hiring local professionals and support staff interested in developing the business where we are headquarteredâ??an area that offers a very high quality of life.

The regulatory landscape in Canada is a rather complex one. How would you assess Health Canadaâ??s competitiveness today?

The regulatory landscape is actually not more complex in Canada, today.

When I started in the industry a few years back, reviews of regulatory dossiers supporting market access of new drugs could take years and at the time, the process was much more complex.

Presently, Health Canada works with fixed target review timelines that are competitive with those of foreign markets. These review targets are respected, if the quality of the dossiers allows a streamlined review. A standard new drug submission review time takes close to one year. If submission strategy and content are well planned out, dossiers well prepared and submitted, the review should take place within the target timelines. Shorter target review periods apply for drugs to be used in life threatening diseases.

When we look at the clinical trial application process, Canada is even more competitive than other countries. A standard 30-day review period applies 100 percent of the time and no preclinical nor clinical study reports need to be submitted. Key summary documents with the clinical protocol are required and used by Health Canada for the assessment along with the complete quality dossier. Compare that with the USA, for instance, where the same review timeline applies but with the possibility of a clinical hold and there is a requirement to include both nonclinical and clinical reports; making the submission content more complex. Turning to the EU, there too we see that submission requirements are also more complex and review timelines are longer. Overall, putting together a clinical trial application in Canada for authorization to conduct a clinical study with an investigational drug is easier and faster than elsewhere; the content being less complex, and a final go/no go decision given in 30 days by the authorities.

How would you characterize the openness of Health Canada during the review process?

There can be challenges during any dossier preparation that we as experts aim at resolving ahead of submission time and during the review period. In my close to 30 yearsâ?? experience, I have found Health Canada to be always open to discuss either in scientific advice meetings, in pre-submission meetings or through telecoms.

At any point in time when questions are raised that require clarifications during the review process, I invite transparent discussions between my clients (sponsors), ourselves and the authorities. Results do speak for themselves as close to 100 percent of the dossiers that myself or my team have supported through the Health Canada review process were eventually approved.

More important challenges have been observed when there is lack of dialogue or transparency between government and industry. In my experience, when you can demonstrate scientifically sound approaches in your drug development and your drug is safe and efficacious, you can reach approval. For example, I have seen instances where SPharm worked on new drug submissions or new indications submissions which were approved in Canada, while they were refused in other jurisdictions.

[Featured_in]

How does SPharm set itself apart from competitors?

When considering competition, we need to understand: Who are they? Are they equal in skills or in the scope of the services? What is the depth of knowledge and degree of investment in success used to serve their clients.

At SPharm, we offer very high quality and diversity of services (including provincial reimbursement initiatives), with *â??out of the regulatory boxâ??* strategic thinking. We keep abreast of the regulatory environment in Canada, which is the core of our expertise, but also beyond Canadian borders.

Possessing this dual knowledge and keeping an open mind of the global regulatory environment helps us to assist our clients, which sets us apart from competitors. We have experienced very little client turnover. Our depth and broadness of knowledge and acquired experience makes our clients

come back to SPharm and as a result, we experience high repeat business. Most clients that have gone forward without us, we have supported in their initiative to build their own internal autonomous regulatory departments.

We have a stellar reputation on both the client side and the authority side, which serve us well and I believe does give our clients, a competitive advantage, and which has ensured our continued success over the last 21 years.

Indeed, our clientele is very diversified and our passion in serving them is what drives us to adapt to their culture and needs. For example, we work with universities, research institutions, CROs, start-ups, and mid- to bigger-sized pharma companies, with a high proportion of which are located outside Canada.

Another advantage for your clients is the size of your company: you are smaller and more approachable.

As matter of fact, we are a team of nine employees working at SPharm. I have always wanted to maintain a relatively small business structure, in order to maintain a humane and responsive approach with our clients; we can truly make a difference for them and have a positive impact on their businesses. We have been praised for being very responsive at SPharm, at all levels and with any of our team members, and this is something we take to heart.

Our core expertise is Canadian. Nonetheless, we do work with strategic alliances in Canada and abroad when needed, to offer an even wider range of services. Essentially, we are a one-stop-shop that clients can count on when wanting to register a product in Canada as well as in other jurisdictions, where our allies can help fine-tune the foreign local approach, when needed.

We also support eCTD (Electronic Common Technical Document) submissions in Canada and in foreign jurisdictions. We offer a competitive cost structure with equivalent if not even better expertise. Therefore, working with a Canadian company that not only knows Canada but also international markets, can be very advantageous. By understanding the Canadian as well as the foreign regulatory environments, a Canadian expert can provide the best strategic initiative for timely access to the Canadian market, keeping the global regulatory initiatives in mind.

In which area does SPharm truly excel?

We excel in the area of orphan drugs despite there being no framework for orphan drugs in Canada as yet. There are regulatory paths to use with these drugs, to agree to with Health Canada ahead of submission time, since the regulatory dossiers for orphan drugs do not have the same type or quantity of data that is usually expected from Health Canada. This is where our knowledge is crucial to coordinate discussions with the authorities and efficiently drive submissions for this type of drugs.

We also excel with oncology and other niche products in which the clinical and or quality development is new or unfamiliar to the health authorities. In fact, our most gratifying successes have been with non-standard dossiers. We are very good with pushing boundaries and presenting sound scientific and strategic approaches that differ from what is expected.

One of our most recent examples of this is having successfully and efficiently supported market access of an orphan drug from conceptual phase to regulatory approval through Priority Review, in a record-setting timeframe of less than 3.5 years â?? this is unprecedented in the area of orphan drugs.

We supported our client through the strategic regulatory approach, the complete manufacturing initiatives, the literature review, the drug development strategies and with all their communications with Health Canada.

This shows that success is possible with challenging dossiers, it is a matter of putting together the right resources, being engaged as an expert and engaging the regulatory authorities through an open communication channel.

Also, companies that do not have regulatory expertise in-house also benefit from our wide range of services as well as companies with regulatory departments, in their peaks of activities.

Tell us about your business development initiatives.

We are exploring ways to attract more multinational companies to bring their health product clinical trials to Canada and help them penetrate the Canadian market at the end of the clinical development.

We are also looking to attract more Canadian companies that work to introduce additional products to Canada as well as abroad. To that effect, we have structured a preferred rate for Canadian companies who are developing drugs in Canada for Canada and for foreign countries.

We currently focus on the smaller sized companies and start-upâ??s as they are the ones that usually need the most input early in the process to optimize and streamline their drug development to reach the market efficiently.

Engaging regulatory experts with local expertise can help significantly with streamlining market access through the recommendation of the most strategic regulatory path forward that will optimize registration process and reduce cost consequences of potential market entry delays.

How do you scout for new clients?

I am actively working on creating new business opportunities as we speak. I attend conferences, either as a speaker, an exhibitor or an attendee to network, increase visibility and attract additional clients. I am also looking alternative ways to increase SPharmâ??s visibility and identifying alternative business opportunities with my marketing team. Ultimately, I want my company to be able to serve global submissions and we are certainly on the right track in expanding our footprint.

What our potential clients and clients need to understand is that right experts can turn a seemingly complex or intimidating regulatory process into a more manageable and predictable one, with successful outcome.

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