Interview: Maryse LalibertÃ© â?? Vice President & General Manager, Halo Pharma, Canada

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Halo Pharma, a US-based one-stop-shop CDMO (Contract Development and Manufacturing Organization), operates out of a site in Mirabel, close to Montreal, that boasts 30 years of experience in developing and manufacturing medicine. Maryse LalibertÃ©, Halo Pharmaâ??s vice-president and general manager, highlights the companyâ??s differentiation factors of quality delivery and flexibility, and presents the companyâ??s ambitions for the further international expansion of its business in Europe and Asia.

Maryse, can you please give us an introduction to Halo Pharmaâ??s history and presence here in Mirabel?

Halo Pharma was founded in 2008 and started its operations in Mirabel, Canada in August 2012, at a site with a rich 30-year heritage in pharmaceutical development and manufacturing. Our facility was mostly built by Ratiopharm and the German Merckle family owned it until the company was acquired by Teva in 2010. While under the Ratiopharm name, the site in Mirabel would submit 10 to 14 ANDA for the European and Canadian markets per year. After I started at Halo Pharma in 2013, as we took over the plant, we retained a majority of its employees. Therefore, we did not only acquire a site in which major investments had previously been undertaken, but with it the experience and knowledge of people who have now worked on the Mirabel premises for 20 to 25 years for some of them. To this day, our employee turnover is very low, under one percent, which allows us to maintain invaluable know-how at Halo Pharma.
Today, building on the historic advantages we acquired, the plant operates as a fully integrated CDMO, alongside our facilities in Whippany, New Jersey in the U.S., where we are headquartered.

Five years after its start in Canada, what is Halo Pharmaâ??s service offering today?
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As a CDMO, we try to be a one-stop-shop for our clients. Halo Pharma has the ability to accompany its clients from the very start of product development, at phase I or II of clinical research, and bring it successfully all the way to commercialization. Our services include: pre-formulation, formulation, development, the production of registration batches, clinical batches and commercial batches.
The variety and range of the batch sizes we offer span from laboratory-scale batches to 1,000-kilogram batches. Likewise, we are able to service development and production of a multitude of different dosage forms: liquids; solids such as capsules, tablets and mini tablets; semi-solids; creams and ointments.
Our capabilities include shipping to Europe through the Mutual Recognition Agreement and to the Canadian market, of course, and we also have an FDA approval since 2014. This was an important step in our development, as it is very difficult for a Canada-based CDMO to survive without the access to the U.S. market.
What has been the more recent evolution of Halo Pharmaâ??s scope of activity?
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Many of our customers choose to work with us because of our proximity to the U.S., our knowledge of the market and, of course, the ability to distribute products there through our FDA approval. This global capacity allows us to attract clients from Asia as well, and today we work with three companies from South Korea amongst others. Many of our clients come from the American West coast, others are of Canadian origin, which displays the diversity we have come to master in our client roster. In 2013, we started out with one customer, and after five years we have been able to build a solid foundation and have on-going relationships with more than 25 companies.
2017 was a good year for Halo Pharma, and one where we began to see our growth accelerate as we doubled our product development in one year. We further continued to invest in our Mirabel site and put in place a new technology platform allowing us to produce an alcohol-based coating, in order to render our production explosion proof. Thus, we are now able to do solvent coating, an important feature when preparing pediatric dosage formulations, as much of the taste-masking is often done with alcohol-based coating.
Differentiation is key in an increasingly competitive CDMO landscape. What differentiates Halo Pharma from other CDMOs and allows it to stand ahead of the curve?
Our main differentiation factor remains our highly personal customer service and our willingness to accommodate our clientâ??s needs. We match our customerâ??s requirements, not the other way around. Further, we of course also need to be productive in order to be able to offer a service at good cost and attract clients. In the end, price is a big part of the decision, in parallel with good service and product quality.
Finally, we emphasize innovation to differentiate ourselves, and we strive to innovate in everything that we do. This includes venturing into new technologies where we meet little competition, such as the explosion-proof area and the investment in tablet-coating technology we just undertook. Sometimes, innovation also simply lies in anticipating and adapting to a specific situation.
As a Canadian CDMO, we are not attempting to compete directly with giants in the U.S. or India. Rather to trying to do the same mass production as they have scale to do, we have, from the beginning, focused on positioning Halo differently. While large plants in many countries are allocated entirely to the production of one single product, we produce 400 different products in Mirabel, and develop and manufacture more than 100 different formulas.
We will continue to focus not on commodity products, but niches such as complex generic formulations, fixed-dose combination products, pediatric products, and multiple batch-levels. Those allow for an opportunity to demonstrate our skills.
Overall, our differentiation factor does not reside in economy of scale but in our capacity to deliver reliably high quality, to be flexible and quick on our feet, and with a rapid turnover. Those complex products also allow us to share our knowledge with our clients, which is something we are very dedicated to. Because our ultimate goal is product commercialization, our ideas have to be good

beyond the laboratory level of operations.

What is the value the Canadian manufacturing facility can bring to the U.S. headquarters of Halo Pharma?

The Canadian siteâ??s contribution to the global revenues of Halo Pharma is about 50 percent. What we bring to the company is access to the European market and also, out of our very specific location in Quebec, our ability to work in a bilingual environment. I think that we are able to adapt quickly to different cultures, and that this is a key advantage in working with the European Union. Our work also includes a lot of collaboration with our U.S. site. Often, they will, for instance, take charge of the development process of a drug, and we will be responsible for its commercial launch. In general, our Canada facility has more experience in the commercialization of a diversity of products, and the New Jersey site has strong expertise in certain areas of product development, so that we are able to complement each other well and can attribute tasks according to our individual strengths. Ours lie in the conception of commercial batches for which we have great on-time delivery.

In the pharma world, Canada is sometimes overshadowed by the U.S., as it is the biggest market globally. Where do you see Canadaâ??s unique strengths in terms of manufacturing?

First and foremost, the talent pool in Canada is incredible, and fosters an environment of knowledge and experience that manufacturers can easily leverage. In Montreal alone we have four universities, and as a country, we boast a rich history of development in the biotechnology and pharmaceutical industries. And while we will never be able to scale up to the U.S., our smaller size and to a degree acknowledgment of this disadvantage has allowed us to focus on what we *can* do. The running of smaller batches is one such capacity, packaging multiple labels from a same bulk and adapting to the European market for instance, a market we are already in a privileged position to service for historical reasons of mutual attachment.

How do you explain the raising interest of foreign companies to work with Canadian CDMOs in Canada?

From my understanding, I see that much of the demand from Europeanâ??especially Frenchâ??companies that has been coming towards us recently is due to difficult experiences some players have had with partners in Asia or Eastern Europe. They thus decide to bring back their business to Canada or the U.S., where they can rely on the stability, quality and constant on-time delivery they were missing before.

You have been around this industry for many years, working with some of the largest global pharmaceutical companies. What are the main developments afflicting CDMOs in the Canadian life sciences environment today

The main challenges during the last ten years have always been of a regulatory nature. We have lived through some major changes which, to a point, impacted our interactions with our customers. I hope for a normalization of regulations between the U.S., Canada and the European Union, because I do not think that Canada can continue to increase its list of requirements as a lone mover, with no other country following in that path.

Everyone agrees that compliance is essential and that no compromises should be made on quality. However, every time Health Canada adds another layer of regulation â?? as for the importation for drug substances recently â?? it becomes more complicated for Canadian site to explain these additional constraints to our clients. The entrance barriers for potential customers increase, sometime itâ??s difficult to entirely compensate with even the greatest of customer services and quality.

What will be the key priorities you will be pursuing over the coming years?

Halo Pharma has built a strong pipeline, with a good mix of revenue and product development. Now, the time has come to bring the development-stage products to commercial launches, as quickly and as efficiently as possible.

We will further look to expand our business by finding new customers, as success in the CDMO business is always about striking the right balance between the number of customers and the volume per customer. Thus, we will focus on realizing part of our business growth with existing

customers, to leverage the existing partnerships we have that allow for smooth collaboration. International expansion will remain on top of our list. Asia and Europe will remain our main focal points in terms of market development; Japan and South Korea in particular in Asia, and France in Europe.
Overall, Halo Pharma will not lose sight of our mission to service our clients in development, manufacturing and packaging, and selling our know-how and expertise as a one-stop-shop contracting partner for life.

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