

Interview: Peter Soelkner

A conversation with the managing director of Vetter Pharma International GmbH

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IN NOVEMBER 2009, VETTER PHARMA INTERNATIONAL announced that it was launching Vetter Development Service with a new facility in Skokie, IL. To find out more about the German company's new foothold in the U.S., as well as further expansion plans and perspectives on branded vs. generic injectable manufacturing, I spoke with VPI's managing director, **Peter Soelkner**, who will head up the new initiative.

—GYR

Contract Pharma: *What was the impetus for Vetter Development Service and the new site?*

Peter Soelkner: We are in the business of manufacturing and producing prefilled injection systems and a full array of primary packaging materials, specifically single- and dual-chamber syringes, and cartridges and vials. We stand out with our expertise and high quality in manufacturing compounds with little API or substance loss. With our Key Account Management concept, we work with clients from early development all the way through commercial manufacturing. So, in order to focus more on development, we began a strategy at the end of 2008 to expand our capacity through Vetter Development Service. This resulted in the new Chicago site.

CP: *Why did you choose Chicago?*

PS: Chicago definitely has several advantages. It's an international hub, reachable by almost every major airport in the U.S., Europe, and other parts of the world. The Illinois Science + Technology Park is just 30 minutes away from O'Hare, 20 minutes from downtown Chicago, and 20 minutes from Chicago's main lifescience community, with direct train access. It's in-between for both east coast and west coast clients, and in the midwestern region, there's a cluster of pharma and biotech companies. Within an hour's drive, there's a workforce potential of 70,000 to 80,000 people who are currently working in the pharma, biotech or biomedical industries. Baxter, Abbott, Hospira, Takeda and Astellas are working in that locale. I don't have to explain to a client why we're there.

It's "only seven hours away" from central Europe, as opposed to the west coast, where I'm located right now, which is nine hours. That gives you more time in the work day to synchronize while offices are open.

We definitely want to be closer to our customers. Half of our client base is already coming from North America,

especially the U.S., so there's definitely a need to be closer to that marketplace. Two-thirds of Phase I and Phase II projects are coming from the U.S. We hope that by operating in the same time zone, we can speed up the time to market. It boils down to a partnership approach, to having a good handle on project management, that you have your i's dotted and your t's crossed.

This is particularly true when you work with an emerging biotech company. Frequently, they will have a great vision of their molecule and its effect on a new indication, but not necessarily the knowledge of how to bring a product to a primary packaging container that will fulfill all the regulatory requirements of international agencies.

The new site will help further internationalize our company, enabling us to attract more talent from an international market, and not just around Lake Constance. The Illinois Science + Technology Park where the new center will be located is in close cooperation with Northwestern University, and there are other major academic institutes (six medical schools) nearby (including University of Illinois-Chicago, Rush, and University of Chicago).

CP: *How much will the Development Center cost?*

PS: We're projecting \$15 million, not including project management work.

CP: *What's the composition of the workforce? How many staffers are coming over from Germany?*

PS: We're bringing 15 full-time-equivalents coming over from Germany. Seven or eight of those positions will be permanent, while others will have project assignments. We're looking to hire 10 to 15 local individuals. We picture approximately 25 heads in place by the end of the year. Once the site is really up and running, we could entertain a second shift. The site can accommodate 50 to 60 employees. Most of those will be highly qualified staff.

CP: *Are you going to show off the new digs at BIO in May?*

PS: We hope to! The lab space is already operating and the cleanroom infrastructure will be completed by early May. Long-lead items like our filling equipment will be in around summer and be operational by beginning of Q4 2010. Still, we plan to show the place off during BIO.

There was a takeover event on Dec. 1, 2009. It wasn't exactly an inauguration, since some of the cleanroom suites and laboratories are under construction. The filling machine we're

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bringing in from Bosch offers great advantage in disposable components, extremely low yield losses, and more, but it won't be in the building until around May 2010. It'll then need to be validated and qualified within the cleanroom suite.

CP: *When are you bringing clients in?*

PS: From summer onward. We plan to ramp up project work in the second half of this year, to familiarize clients with our work. And if someone is interested and needs a project done yesterday, we can certainly talk to them about accomplishing their goals with our existing services.

We'll be fully operational by the end of the year. In the meantime, our microbiology lab is up and running, as is the chemical analytical lab. There are around 24,000 sq. ft. for the technical disciplines. It's not a whole factory, but with three filling rooms, it definitely covers all the tasks one needs to handle projects in early clinical phases.

CP: *What's the site's history?*

PS: The new site, which dates back to 1941, is a legacy facility from Pfizer (through a series of acquisitions and mergers): it was first a Searle R&D campus, then a Pharmacia R&D site, then a Pharmacia site, and then it was closed down by Pfizer at the end of 2003. It was later bought by Forest City Science + Technology Group, which has a big retail real estate presence. Forest City decided that it would get into this area to diversify from retail malls with "life science malls." The park currently has 18 companies and almost 1,000 people on campus including such companies as the Astellas Research Institute of the Americas. Forest City has four other bioscience parks in the U.S.

This building used to be Pharmacia's clinical manufacturing site for parenterals, so there was some cGMP thought that went into the site's design. It was revamped in 2001 and '02, and was still manufacturing in 2003. So the basic structure needed a minimum of work, outside of the WFI system, which hadn't been operated in five years.

At the Science + Technology Park, the floor plan and the infrastructure were ideally suited for our needs. We had to revamp the HVAC and WFI, but it's a huge advantage for the layout of the rooms — in terms of the size of the suites and the material flow of the place — is geared toward this kind of operation. The city of Skokie and the state of Illinois have been very supportive in helping us along the way.

CP: *Does the same rationale for launching development in the U.S. hold up for commercial work? That is, would commercial clients need the same level of "hand-holding" that characterizes early-stage work?*

PS: I don't feel that it is, from my experience. Vetter is already working with 19 of the top 20 big pharma and biotech companies, and those commercial needs are taken care of at our three sites in Germany. In Lake Constance, we have a safe environment, politically and economically speaking, with no exposure to earthquakes, hurricanes and tornadoes.

Since a commercial injectable tends to get launched in North

America and the EU, it's going to get shipped regardless, so there's less of an imperative for local geographic reach. With development work, there's revamping and other changes that require that sort of flexibility, but with commercial work, it's about consistency in reaching millions of vials with the same precision. So we're presently covered by our existing commercial facilities in Germany.

CP: *How about Asia? Do you have expansion plans in that region?*

PS: We're working on an Asia strategy this year, but we haven't settled on specific countries and objectives in that region. We know we cannot neglect Asia in the next five or 10 years, and that Vetter must become a truly global company with a presence there. Chicago was our first ex-Europe expansion, and we may look at other moves, including Asia.

CP: *What are the drivers for Asia? Market access? Labor savings?*

PS: Vaccines are certainly growing in importance in the emerging regions, and other medicines are also gaining share. Operations in Asia would be more centered on regional access and distribution for clients' products than for labor savings. Clean room operations are all about removing people from the area, to reduce contamination risks, so Asian facilities would not represent any great cost savings in terms of labor.

For example, in our Ravensburg South site, we're in the process of bringing on line a third clean room with a line that can handle more than 36,000 syringes an hour (north of half a million syringes a day), yet it can be operated by three individuals. So the contribution of labor costs to that equation isn't as important as quality, since the economies of scale rise with automation.

With labor-intensive analytical work — extractable/leachable or stability studies, for example — perhaps the equation would be different.

CP: *How does a deal like Pfizer/Aurobindo, in which Pfizer will sell generic injectables in the U.S. market, affect Vetter? Is that perceived as a new field for you to enter?*

PS: Vetter always focuses on new and innovative drugs; that is our major direction. However, the market has shifted in the last two or three years. Some big pharma companies wouldn't touch generics and biosimilars with a 10-foot pole five years ago, but that's all changed thanks to pipeline failures and financial pressure. The net result is that we all talk about generics and biosimilars now. With the potential for U.S. healthcare reform and everything else that's going on in the U.S. and EU, then we have to evaluate these opportunities on a case-by-case basis. We don't want to cherry-pick from clients' pipelines; if we want to be a partner, we handle the latest and greatest projects from development and if they are pursuing something like biosimilars, then we look to add innovation and value to that. In those terms, we'd be talking about more patient-convenient delivery devices, for example. Being a partner means being there for all their needs. We have to react to the changed circumstances within the pharmaceutical market. ■