# End-To-End Partnerships Are Leading The Way In Drug Development

Manufacturing and supply chains have been a key topic of interest in the pharmaceutical industry during the course of the COVID-19 pandemic. Equally, the speed at which new treatments have come to the market for patients during this time has placed great expectation on the potential for future development.

In Vivo spoke with Dr. Stephan Haitz, President, CDMO Sales and Marketing at Cambrex, about the role that outsourced providers can play in creating efficiency in the drug development process, the importance of leading sponsors through disruption, and what the future holds for small molecule therapeutics and the US-based CDMO's capabilities.

**In Vivo: The contract manufacturing industry is growing rapidly. What key trends in outsourcing small molecule drug development has Cambrex observed in the last two years?**

**Haitz:** I think foremost it is the closer relationship needed between our customers and us. Despite COVID-19 putting distance between us, I think we all saw that we need to work closer together in a virtual world. There is a strong trend towards having many more interactions on technical and commercial levels, and using modern technologies like RealWear to give our customers the ability to actually be at the reactor in the manufacturing plant, or in the lab where their drugs are produced.

We are also seeing the consolidation of manufacturing service lines. Companies like Cambrex have a wide range of capabilities and nowadays our customers prefer to work with one supplier who can offer most, if not at all, of what they need in the development cycle of their products.

**What are the main benefits of working with an end-to-end drug development partner?**

**Haitz:** I think for most it's the ease of working. A good example is quality audits. Instead of a pharmaceutical company needing to have ten different suppliers and audits for one development project, with a company like Cambrex, customers can really reduce those efforts based on one quality system.

There is also a project management benefit. Rather than having information packages passed on from one supplier to another everything is in our system, so our team have a holistic view on development. This also allows us to plan capacity accordingly, so we know where the project is at any given time and nothing comes as a surprise.

Finally, with end-to-end capability providers there is access to support. Every project needs additional assistance, we just don't always know exactly when. However, if you work with a company like Cambrex that support is always available, whether it is from our network of 12 sites or general analytical and technical expertise.

**During the pandemic the importance of supply chain resiliency was highlighted. Is Cambrex prepared for future disruption?**

**Haitz:** During the pandemic we all learned a lot, but did what we had to do to keep things moving. At Cambrex, we had done everything we could to prepare ourselves for disruption and learned that transparency between multiple sources is key. We know when our suppliers produce, when they ship, and we have the ability to track these shipments.

The most difficult part at the moment is transportation capacity, but this issue is not isolated to our industry. Again, transparency is important here, but it is also better to receive supplies earlier where possible, even though there are additional costs to this. These include capital and storage costs, but it's better for the overall project to put financial resource here and be prepared. Prior to COVID-19 we were used to

everything arriving just on time, sometimes to the minute, but this does not work anymore.

**How is Cambrex expanding to grow its capabilities and further support small molecule drug developers?**

**Haitz:** As I mentioned before, we have a holistic view on development because we can provide early-stage services as well as commercial manufacturing, so all our investments are driven by supporting that chain. As an example, we recently announced a $30 million investment into our High Point, NC facility which produces Phase II and Phase III material. We also invested $50 million in our Charles City, IA site to support our commercial manufacturing capacity.

These are large expenditures, but we are also doing more targeted investments, such as upgrading our Tallinn site for GMP, and in Longmont and Durham we have invested in our analytical services. We are not only adding capacity, but also capabilities across the continuum of development through to clinical phases. These decisions are based on close interaction with our clients, so we understand what they will need tomorrow as well as today. This enables us to be prepared for their requirements in the near future.

**The regulatory landscape with regards to chemistry, manufacturing and controls (CMC) can be challenging to navigate, especially during the pandemic when in-person interaction was limited. What should sponsors be thinking about when approaching these requirements?**

**Haitz:** We have had experience with virtual inspections, which was quite a change in what both the regulatory agencies and suppliers were used to. However, I think it will be a continuing trend moving forwards that a lot of audits and inspections will be virtual or partly virtual.

We are also having discussions with experts on our side regarding what the agencies will be asking two years from now. As we are developing and expanding our capabilities we have to have that in mind, so having that deep in-house regulatory knowledge is important.

Lastly, there are benefits to our end-to-end setup. We have all the data available, meaning it is easier for our sponsors to respond to questions from the agencies because they do not need to go to multiple sources. Instead, they can just talk to our project management team who have all the information in our systems.

**What are your predictions for the future of small molecule manufacturing and how is Cambrex leading the way for innovation?**

**Haitz:** The need for medication and new treatments is unbroken by COVID-19. We need to support our customers in developing new medications, and this is also driving innovation. For instance, we asked ourselves: can we do something faster than we are now? As a result, we have built continuous flow capabilities that are helping to develop drugs at increased pace. Another question is: can we do our chemistry with the right quality and purity? This is something we are looking into as well.

Another trend which will be important for all of us is sustainability. This is something which is only possible with sponsor buy-in and means that when we are taking on programs, we want to make them less environmentally burdensome. We have to look at things like electricity efficiency and consider how our wastewater treatments work. It will force us, on top of the quality of our products, to think about the environment much more, which will trigger new technologies.

**Is there anything else you would like to add?**

**Haitz:** I think it's important to recognize the performance of the pharmaceutical industry in providing a vaccine 13 months after the initial outbreak of COVID-19. This will have two implications. First of all, I think that society and communities have realized the value pharmaceuticals bring to daily life. However, this great achievement now comes with heightened expectation.

There are so many other unmet medical needs that the pharmaceutical community must tackle. These include orphan drugs, where there are indications that may have 10,000-20,000 people waiting for treatment. While these expectations are based on how excellently the industry helped us through COVID-19, we now have to do the same for other diseases and conditions. This comes back to what I hope for the future: for us to provide more solutions for as many illnesses as possible. Seeing patients that are able to access new treatments makes everyone going to work proud, and motivated to continue their efforts.