

Elena Bejan

Head of Research and Development & Project Management Charles City, IA, USA

HIGHLIGHTS

Ph.D. in Organic Chemistry from Paris-Sud University (Paris XI), Paris

MBA from Rotman School of Management, Toronto

25+ years of industry experience focused on scientific innovation and R&D

SUMMARY

Driven to connect the dots between science, clients, and business, Elena leads research and development at Cambrex.

AREAS OF EXPERTISE

- Organic chemistry
- Research & development
- Business management and leadership

LINKEDIN

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Along with two post-doctoral fellowships, you have an MBA—how has this informed your career?

Along my career path with previous organizations, I realized that as a leader, I would like to know more about business, and hence, I went back to school to do my MBA. I thought that it's really business training—in marketing, business, finance, etc.—that would fit quite well as skills and expertise for CDMO and the role that I had at the time and the role that I have now.



"When we undertake a program, it's not just about the science. It's also about the client, the partnership, the business, and the ultimate stakeholders, the patients. It's about how we work together to create future opportunities."



What are the benefits of working with a CDMO like Cambrex?

There are multiple: first and foremost, the extensive technical expertise in process, analytical transfer, development, and validation, along with impressive GMP manufacturing capabilities and our commitment to safety, environmental, quality, and operational excellence. Cambrex represents a team of passionate professionals with advanced scientific and technological experience committed to providing superior customer experience with a focus on partnership, engagement, milestones, timelines, and communications.

How does the Cambrex culture impact clients?

I would describe the culture at Cambrex as a team focused on providing the best customer experience through the excellent execution of API programs that our clients have entrusted us with. The leadership team promotes a culture that's dedicated to safety, quality, commitment, and delivering the best results for our clients.

Last year, we were focused on a program of extremely high importance for one of the big pharma clients. It has an indication that it is essential for patients around the world, so Cambrex Charles City was committed to successfully executing the program and accelerating timelines. The complexity of this program included the execution of two validation campaigns at the same time, at different scales to support client clinical trials for various indications. Towards the end of the year, not only did we successfully complete the campaigns within the accelerated timelines, so ahead of schedule,

but we were also deemed by the client, the CDMO, that represents the standard for them to build their other relationships upon.

How important are client relationships?

Client relationships in the CDMO space are one of the most important aspects of what we do at Cambrex. Just as important as what we do, i.e., advancing and accelerating therapeutic solutions for patients around the world. But coming back to clients, I think the focus of the Charles City Cambrex team is to provide an outstanding customer experience. We do execute science, and science is sometimes challenging, but at the end of the day, how do we resolve together, and how do we advance the program? That is probably what stays with the client. That is a testimony of the commitment that we have, our problem-solving abilities, and our dedication to resolving challenges in order to advance their program accordingly.

What role does collaboration play in your work?

The collaboration with the other Cambrex site is integral to who we are as an organization. We do really collaborate with most of our drug substance sites as well as our generic sister site in Milan, Italy. As an example of the collaboration, I can emphasize the transfer of processes from the High Point to the Charles City site. We have a seamless process that we follow that was established years ago, and that includes scientist-to-scientist discussions, technical visits to ensure that the technology is transferred accordingly, brainstorming to resolve technical issues, etc.



Furthermore, we have biweekly and weekly calls with the engineers and the scientists, and we all work together with the clients on a regular basis to make sure that the technology is transferred from High Point (and/or client) sites to Cambrex Charles City for scale-up purposes.

What makes the site in Charles City so unique?

Charles City is a remarkable site. I've seen several sites in my career, and this is definitely the most impressive manufacturing site that I've seen. It focuses on phase three and commercial manufacture with 13 work centers with multiple reactors as large as 4,000 gallons. There is a vast power in terms of manufacturing capability, scale, and opportunities as well as various reactor sizes and materials of construction. There's a lot of expertise in manufacture with numerous validation and commercial programs that we're executing routinely.

Our Pharma 4.0 manufacturing facility was a \$50 million investment by Cambrex. It took probably about two years to build. It is absolutely impressive and mind-blowing! Another important capability and expertise is the ability to execute high-potency API projects in our facility. Last but not least, we also have continuous flow capabilities. We have run commercial programs, I believe maybe a year or two ago at the commercial scale using continuous flow.

In summary, Charles City is a unique and amazing site based on its impressive technological abilities, manufacturing expertise, and assets, as well as our commitment to excellence in quality, environment, and operations.

How do Cambrex experts share knowledge, advancements, and trends across the organization?

The scientific program established at Cambrex Charles City has the objective of expanding scientists' expertise in process, analytical development, and scale-up, enhancing knowledge sharing within the team, elevating scientists' awareness of recent trends, methodologies in synthesis and analytical areas as well as establishing collaborations with academic, business partners focused on innovation and research. The scientific program has two components: an internal and an external one. The internal obviously includes brainstorming and poster sessions, as well as case studies presentations by our experienced scientists. The external component includes conferences held by academic speakers or industry experts as well as presentations by our research fellows to the community in conferences like the American Chemical Society and Organic Process Research and Development.



At what stage does your team get involved in the process?

The technical teams at Charles City. including the analytical, process scientists, process engineer, and quality, were brought into the program from the get-go when the program was awarded to us by the client. During the initiation of the program. teams are defined to include process and analytical scientists, process and analytical leaders, a lead process engineer, a quality expert, and a project manager. This technical team, as well as the project manager, will be responsible for leading the project execution with client support throughout the life cycle of the program. They're also responsible for ensuring that we resolve challenges collaboratively and escalate any concerns or issues identified during program execution.

What's your approach to integrating scientists into clients' programs?

The scientists at Charles City are integrated right from the beginning of a client's program. They are responsible for reviewing clients' technical packages and executing the experimentation, both process and analytical. They're obviously responsible for making the technical decisions on the process and analytical matters in alignment with the client. They are working together with the process engineers and the manufacturing team to ensure firsttime right execution in the manufacturing campaigns. Last but not least, they are also involved in creative problem-solving during the execution of the campaign and the life cycle of the program. And they will continue to chaperone the program along the life cycle of the program.

