Beth Totin

Chief Commercial Officer

PERSONAL PROFILE

Beth Totin did not intend to make her career in the pharmaceuticals industry. But when the doors opened, she swept right in.

"Yes, it can be a tough, competitive, highly complex market," she acknowledges. "But if you have the right people and the right mission, this industry also offers opportunities to do incredibly worthwhile things—like saving lives. With the ApiJect single-dose injector, we and our partners in The RAPID Consortium will bring vaccines to the U.S. at population scale with incredible speed to help combat this pandemic, and later we want to do the same for the rest of the world."

After earning her degree at West Chester University of Pennsylvania, Beth spent her early career as something of a turnaround artist. "It was so rewarding to step in and find ways to restructure struggling companies so that people could remain employed and keep putting food on the table for their families," she said. "Ultimately it's about helping people, and it feels great to be able to do that."

Today, as Chief Commercial Officer for RAPID USA, Beth's role centers on business development and strategic planning. To these functions she applies a wide range of industry-, technology- and product-specific management skills, including assisting pharma companies with drug development and contract manufacturing, drug formulation, production scale-up, strategic positioning, acquisition, customer management and market analysis. She also possesses world-class expertise in the sterile industry including Blow-Fill-Seal (BFS) manufacturing for medicines and biologicals.

"I truly like having a cause and giving back to the world."

— Beth Totin —

Beth acquired these skills beginning her sterile career at Holopack US/The Ritedose Corporation, where she learned BFS manufacturing from the company's facility in Columbia, SC (previously owned by Rommelag, the inventors of BFS technology). She continued over the next decade while holding a series of key management positions with leading pharmaceutical CMOs covering facilities around the world. The list includes three-plus years as Business Development Manager for Catalent Pharma Solutions; two years as Director of Drug Products North America for Siegfried; and three years as Commercial Director North America for Unither, the largest global BFS manufacturer.

"I've been working on injectable BFS my whole career—it's been a driving passion to offer affordable injectables globally," she declared. "BFS is an advanced, proven aseptic process and it's being used in the global injectable market space. Adding the ApiJect Needle Hub provides a market advantage, based on an established concept with reliable technology."

Looking beyond COVID-19, Beth sees a worthwhile future in helping RAPID leverage the long-term potential of the ApiJect BFS single-dose injector.

"Once we have helped to make vaccinations quickly and universally available, and when this pandemic is hopefully under control," she said, "I'm also excited about the opportunity for ApiJect's BFS single-dose injector to help bring more routine vaccinations, as well as many injectable drugs, to parts of the world where they currently are difficult to access, and to do it on a low-cost basis. That will save a lot of lives too."

BETH TOTIN

"No challenge is impossible to overcome."

Saving countless lives by delivering more drugs and vaccines in Blow-Fill-Seal plastics technology is an ambitious goal. For years, it has been Beth Totin's dream.

Beth Totin is not afraid to say that she became the Chief Commercial Officer for RAPID USA because she wants to make the world a better place.

She wants to save lives. In addition, she wants to work with a team of outstanding individuals who are as committed, passionate and professional as she is.

Beth Totin-Lee with husband James Lee. They live near Philadelphia, PA, where winter temperatures have been known to drop to minus 15 degrees Fahrenheit, giving the city its own cold chain.

INTERVIEWER: Beth, you have described yourself as a creative problem-solver. True?

BETH: Yes. I like to work with people in situations where I'm helping make a better world. Situations where important values are at stake, not just dollars.

Your passion for making a positive difference, and for saving lives on a large scale if possible, is an important reason why you got excited when you first learned about the growing potential of Blow-Fill-Seal (BFS) plastics manufacturing. Can you tell us about that?

BFS has been widely used for decades, including respiratory, ophthalmic and biologicals and, more recently, oral vaccines. But some years ago, I realized that BFS had a large history in the parenteral space. The technology is well known for larger format IV bottles, luerlock and therapeutics injectables throughout the world. I knew this technology could provide even more game-changing solutions because it could be used for single unit dose injectable drugs, too, the question was more so—how.

> **"We can unquestionably make a major contribution to the world's health, and finally make the world a better place."**
>
> — Beth Totin —

When did that light bulb come on?

In 2008 I started looking at injectables in BFS when I was working at Holopack, (now The Ritedose Corporation). They are a Contract Manufacturing Organization for the pharmaceuticals industry. Working on the company's website I learned the history of large bottle format injectables and started digging and researching. I learned there was a push in Europe to remove glass ampoules for safety reasons and one company was pushing plastic luer lock ampoules, using the BFS technology. A little more research showed a few BFS injectables with luer locks on the U.S. market. From there, I never let up with this quest.

Why was that a big deal?

To people outside the pharmaceuticals industry, it may not sound like a big deal. But to people inside the industry, it is a tremendously big deal.

Because…?

Because industry members understand how long change can take, and how difficult it can be to adopt new technologies. So I got really excited, thinking if they're changing to more use of BFS in Europe, it would be easy to do it in the U.S. too.

What happened?

I learned it's not that easy. Ritedose was formerly known as Holopack International; they were owned by Rommelag, the German inventor of BFS technology. But even though Rommelag and BFS had a successful long-term track record of reliability and low cost in Europe, I discovered that U.S. and global manufacturers were largely wedded to their existing systems for drugs and vaccines in glass vials.

Presumably because they had made large investments in glass technology, and because they had all the necessary regulatory approvals in place?

Yes, but I refused to let go of the idea. As a result I've been working on injectable BFS my whole career, first at Ritedose and Catalent, then at Unither. From the very beginning, when I realized what BFS could do and the advantages it offers, it has been a major passion of mine.

Beth with Rommelag USA General Manager Tim Kram. Germany's Rommelag invented BFS technology in the 1960s. Components for ApiJect BFS single-dose injectors are produced with Rommelag machines.

Even though it can be very difficult to change a multi-billion-dollar industry with 150 years of momentum behind an established technology?

No challenge is impossible to overcome if you have the right people in place and a passion to save lives.

And that brings us to ApiJect and The RAPID Consortium.

I'm putting my heart and soul into the ApiJect BFS single-dose injector. I am excited about it because now we'll finally be able to provide low-cost, safe injectables to the marketplace, first in the U.S., and then in the rest of the world, with reliable, aseptic delivery for every single product.

> **"Ever since I realized what BFS could do and the advantages it offers, it has been a major passion of mine."**
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> — Beth Totin —

The design of ApiJect's single-dose injector is new, but the technologies of BFS containers and Needle Hubs are well-established. And, there is a very experienced team in place at RAPID, although from diverse backgrounds. How much confidence does all this give you?

I have always done business on the basis of loyalty and trust in fabulous people, and that will never change. When I look around the table at RAPID, I see fabulous people and companies. That includes our in-house team, of course. It also includes our key allies, from people at the U.S. Department of Health and Human Services to Rommelag, which will supply our BFS machines.

Saving lives with technology is a theme that runs through much of your career. Early on, you worked for a company that took this approach, including immediately after Sept. 11th. How did that come about?

Almost every manufacturing process creates a certain output of colorless, odorless gas. It's supposed to be contained, but our company made equipment to detect leaks. Preventing fatalities in a factory setting was awesome all by itself.

Then, right after the attacks of September 11th, 2001, we started sending our products to the firefighters in New York City as personal protective equipment. It was such a great feeling to know we were helping those men and women, helping to save their lives while they saved the lives of countless others.

Looking ahead a few years, what future do you see for ApiJect and RAPID?

I am confident that ApiJect and RAPID will be a huge success, initially in the U.S. with vaccine and therapeutics for COVID-19. Later I think we'll be a huge success around the world for routine vaccinations and generic drugs. There are definite needs for a prefilled injector, so we can unquestionably make a major contribution to the world's health, and finally make the world a better place.

Which is exactly what you have always wanted to do.

Yes.

Thank you, Beth.