Jeff Price

Principal BFS Engineer

PERSONAL PROFILE

In 1993 when Jeff Price moved from aerospace engineering to pharmaceuticals manufacturing engineering and operations, he brought a deep passion for learning and innovation to his new field.

"Designing, engineering and creating are what I love to do," he says. "The closer I am to the development side of the business, the happier I am."

At ApiJect, Jeff serves as the Principal BFS Engineer, focusing on the Blow-Fill-Seal aseptic plastics manufacturing technology that will be used to produce components for hundreds of millions of ApiJect BFS Prefilled Injectors per month.

He provides manufacturing and operations guidance, facility setup knowledge, and wide-ranging contributions across component design, machining, process validation, testing, and product quality assurance.

Simultaneously, he is also setting up ApiJect's Florida-based Technical Center with a focus on new product development, along with a comprehensive BFS Operations training program. This program will train at least 500 future workers in ApiJect's planned BFS facilities.

Jeff earned two BS degrees, one in Mechanical engineering from the University of Illinois and the second in Industrial Technology from Western Illinois U. After his stint with Pratt & Whitney and GE, he entered the pharma business as Director of Engineering & Business Development for Vital Pharma, Inc. Next came a highly demanding job as VP of Operations & Engineering at Nephron Pharmaceuticals Corp., running a team of several hundred personnel on a 24/7 operation. "We made aseptically filled sterile liquids, which is probably the toughest thing you can do in pharmaceuticals because of the stringent quality requirements in addition to the regulations, which are very tight," he says today.

"After 27 years of constantly working with and even designing Blow-Fill-Seal (BFS) machines, you develop an intuitive understanding of the process."

— Jeff Price —

Ten years ago, Jeff launched his own independent consulting business, serving as the Principal Engineer at Icon Engineering, Inc. He designed, patented and licensed what became Rommelag's 434 BFS manufacturing machine. The 434 uses closed-parison, rotary technology which facilitates R&D through faster, lower-cost creation and testing of new mold designs and other capabilities.

Jeff also invented a Vial Inspection Machine (VIM) that performs extensive, sophisticated quality control checks on Rommelag machine output as containers are coming off the line at 500 units per minute.

"Learning new disciplines and tackling new challenges is always intriguing," Jeff declares. "That is why I look forward to getting up and working every morning at ApiJect. After all these years, I still love the challenge."

JEFF PRICE

"My core strength is design and operation of Blow-Fill-Seal machines."

BFS is a sophisticated hybrid of many kinds of technology. The results are amazing, elegant, and even inspiring—a "machine ballet" where "the science is everything," according to Jeff Price.

A good engineer becomes so attuned to a machine that he or she can sense, or intuit, certain nuances of its operations that even trained observers find difficult to detect.

Jeff Price, Principal BFS Engineer for ApiJect, has developed this kind of "rapport" with the machines he works on, and invents.

INTERVIEWER: Jeff,. Can you talk to us about your relationship to this complex and powerful technology?

JEFF: I have been working on, in, with and around BFS technology for 27 years and it still fascinates me. I find BFS machine operations positively hypnotic. I could sit and watch them all day, running thousands of units off the line with perfect machine precision.

What specifically makes BFS so compelling in your eyes?

For me it begins with the integration of functions and technologies. You've got plastic extrusion, heat transfer, molding, aseptic filling, all within a clean room, and all of these elegant motions as the molds come together, molten plastic is formed into a continuous tube called a parison and then formed into the mold and aseptically filled, and hermetically sealed.

What does it mean to become a BFS Expert?

When you learn all the different aspects of the BFS machine process, and how the inputs affect the outputs,

Jeff, an outdoor sports enthusiast, is seen during a hiking and camping trip that he made with his daughter Erika on the Appalachian Trail in the Roan Highlands of Pisgah National Forest in North Carolina.

and how to optimize performance by tweaking various parameters, it never becomes a mindless, purely mechanistic matter of "you just push a few buttons and it happens." You need to thoroughly understand the process to, adjust the right parameters the right amount to achieve the optimal results. There is a little "black magic" in that you need the "eye" to see what 's really happening.

Eventually, when you develop that level of understanding of the technology, you can look at a production batch of vials or containers and despite the lack of obvious outer indicators, you can tell exactly what's going on with the molds, with the processes, with the mechanisms. You gain almost a unique intuition, an ability to know what tiny adjustments or tweaks to make to maximize performance even more completely—temperature, speed, mold adjustment and other factors.

That's what I mean when I say that you become a BFS expert.

You began to develop this intuitive feeling for engineering from the earliest days of your career. But it was always based on hard-core, practical data.

It's true that I love learning and I'm always intrigued to master new knowledge. I began my career at Pratt & Whitney working on jet aircraft turbine engines. Talk about a complex combination of factors.

You have turbine blades spinning at 14,000 RPM at 2,100 degrees. How do they not shatter? What are the metallurgical properties that make it so strong? I am always hungry to learn, and when I worked in aerospace I learned as much as I could about the metallurgy of aircraft materials, because the science is everything.

And, obviously, the same is true in pharmaceuticals manufacturing. Tell us about your learning curve in that field.

I have been working with Blow-Fill-Seal (BFS) technology for 27 years. For quite a few of those years I ran operations at Nephron Pharmaceuticals, an organization of 500 people working at a 24/7 plant that makes sterile liquids. That is probably the toughest thing you can do in pharmaceuticals because the quality standards are so high and regulations are

so exacting. However, my real excitement about BFS comes in the design, engineering and creative side.

You're doing a lot of that kind of work at ApiJect Systems Corp.

At a certain point, machine design merges seamlessly into machine operation. My role with ApiJect covers everything that has to do with BFS machines—every aspect of operations, machine, container, and mold design, quality of the process, and quality of the product coming off the line.

You also designed, patented and licensed one of the two Rotary BFS machines that Rommelag builds and sells today.

For several years I had an idea bottled up in my mind that would not let me go. I am a great admirer of Rommelag's 460 machine, which is perfect for high-speed, high-volume production of a single design that you want to continue manufacturing 24/7 for years on end.

At the same time, if you're interested in performing R&D in a new Blow-Fill-Seal container, experimenting with different mold shapes and sizes, or changing your product from a two-milliliter container to a three-milliliter container, then it's a major investment to get 15 or 20 mold sets and it takes six to nine months' lead time. I kept imagining a different kind of BFS manufacturing machine that would allow the rotary technology but with a single mold. This would enable us to make a single mold quickly with a modest investment.

Jeff on a 9'6" Walden Longboard at New Smyrna Beach, Florida. He has been riding the waves for about a decade. Sometimes BFS is a status report on water and weather conditions: "Beautiful For Surfing."

What is the difference between a shuttle machine and a rotary machine?

A "shuttle machine" is where you cut the parison while it's in one position, then move it to another position for filling and sealing. A "rotary machine" is where you never cut the plastic. Instead, you fill through the parison into the newly-formed container within the mold. This has a lot of advantages, including the fact that you never expose the container to the outside environment.

This idea kept buzzing around in my head. Finally, I locked myself in a room with a 3D CAD program for a few months and worked out the design. It became the 434 model, which I patented and which now Rommelag builds.

To me, the beautiful thing about the 434 is that it requires only one mold. So you can turn that mold around very quickly and make a lot of different containers in a wide range of sizes and capacities, from half a ML all the way to, for example, 60 ML.

The 434 occupies a special niche in BFS manufacturing, with lower cost and lower output than a 460 unit, but greater versatility. I'm obviously very proud of it.

Will ApiJect have both types of Rommelag machines, the 460 and the 434?

Yes. We'll absolutely use the 460 for high-speed, high-volume production. It's perfect for turning out hundreds of millions of units of a single design, which is exactly what ApiJect plans to do.

At the same time, we'll probably use the 434 to run smaller-scale production batches and test different molds and different types of prefilled syringes. For example, we can quickly iterate many different designs and subtle variations for a dual-chamber prefilled injector that would support an adjuvanted vaccine, in cases where the vaccine and adjuvant must be kept separate in shipment, then mixed at the point of care, just before injection.

"No matter how completely you learn the many different parameters of BFS, the performance of these advanced machines always feels like a certain amount of 'black magic.'"

— Jeff Price —

Your love of BFS has come full circle. First you studied it, then you mastered it, and at last you created it.

3D design is one of my favorite things because I see things in three dimensions. I think things in three dimensions. But I could never fully express myself until SolidWorks came along with its 3D computer design program, and then I could design 3D models.

When I created the original design for what became the 434 machine, I built the model on my computer and animated the unique motion of all of its components, so there was no question what my design intent was. For me, being able to express yourself in that way was, and is, a wonderful tool and I absolutely love doing it.

Thank you, Jeff.