



Nick Robinson

Vice President of Manufacturing

PERSONAL PROFILE

Supplying the U.S. Government with hundreds of millions of prefilled syringes in a matter of months, once a COVID-19 vaccine becomes available, is the ambitious goal of ApiJect.

Achieving this objective, says Vice President of Manufacturing Nick Robinson, requires the company to perform a four-way balancing act of speed, scale, quality, and cost. Population-scale product volume must be achieved with unprecedented manufacturing speed, yet with the highest standards of quality and safety—all at a production cost that the company can sustain going forward.

Adding another layer of complexity, the specific vaccine that will go in ApiJect prefilled syringes is yet to be determined. Accordingly, dozens of vital factors are unknowns, including specifics of temperature controls, dose size, sterilization requirements, and many more – yet manufacturing capabilities must be established now to meet those requirements, whatever they may turn out to be.

“It’s an enormous challenge, obviously driven by the urgency of the pandemic,” says Nick. “At the same time, it’s an extremely exciting challenge to take on, because the mission—enabling quick, reliable, safe vaccination of the entire U.S. public—is so crucial to the



“In a pandemic, when you’re manufacturing what is literally a lifesaving device, speed is paramount but quality is non-negotiable.”

— Nick Robinson —

health, wellbeing and even survival of millions of people.”

To this challenge Nick brings more than 20 years’ experience as a CEO and operations executive, with a track record of leading innovation and

profitable growth for mid-market companies, implementing business transformation and restructuring strategies, while managing risk, improving productivity and containing costs. In brief, he’s accustomed to complex balancing acts.

After taking his MBA from Columbia University’s Business School, Nick served as Senior Vice President of North American Communications, Inc. before becoming President and CEO of Directcom, Inc., a database marketing and modeling agency.

Since then Nick’s focus has been large-scale, highly sophisticated direct marketing for global financial, insurance and consumer lenders, among others, plus the manufacturing to support it.

Nick spent 20 years at North American Communications, Inc., one of America’s largest vertical integrated direct mail manufacturers, first as CFO for four years, then as CEO for 16 more years. “On an annual basis we produced over a billion pieces of mail a year or for clients,” he said.

“With ApiJect and its BFS Prefilled Injector, we’re breaking new ground,” he points out. “In a market sector long dominated by traditional technology, we are providing bold new leadership.”

“We’re doing something that hasn’t been done before.”

BFS Prefilled Injector components can be manufactured by streamlining and combining multiple complex processes into a flexible, integrated operation, according to Nick Robinson.

As the world races against the clock to produce and disseminate a vaccine to combat COVID-19, ApiJect VP of Manufacturing Nick Robinson is keenly aware that the urgency of the crisis has vastly shortened the timetable.

Yet that same urgency has also changed the rules for funding, manufacturing, technology, regulation and other factors.

The result: speeds that were previously unthinkable, are now entirely possible.

INTERVIEWER: Nick, you have said that manufacturing components for the ApiJect BFS Prefilled Injector, using Blow-Fill-Seal technology for the first time in combination with a Needle Hub, requires a four-way balancing act. Can you explain?

NICK: In this pandemic environment, the requirement is to balance speed, scale (production volume), quality and cost.

All four factors are clearly critical. Yet if there is a “first among equals,” then speed seems to drive everything else.

Speed is certainly always on our minds. The clock is ticking.

At the same time, drug discovery, testing, careful regulatory assessment, and then the operational design of manufacturing and fill-finish processes, is normally a process that is



Nick relaxing at Lake Placid, New York, home of the 1980 Winter Olympics and a popular spot for outdoor recreation.

spread out over 10 to 15 years. Sometimes longer.

Can you quantify the speed requirement?

With COVID-19 vaccine, the world is attempting to accelerate the typical 10- to 15-year timetable by 90% or better, if possible. ApiJect is a core part of this very aggressive effort. The pandemic has created real urgency at every stage of drug development, from research and development, clinical trials, regulatory approvals, through productions and distribution.

Accelerating the execution of all of those functions to deliver a vaccine in months rather than years is something that hasn't been done before. So we're

going to be breaking some new ground and moving at a pace that none of us have experienced but that the situation demands.

Keeping in mind this relentless requirement for speed, how do you see your responsibilities in supporting ApiJect to carry out its mission?

My responsibilities are to help the company operationalize the mission on the manufacturing level. That means turning large goals into specific, achievable blueprints. It means developing and defining the optimal production process and scale of operations to match our objective: producing prefilled containers for single-dose injectors with a proven



Lisi is all smiles while Nick gives a “father of the groom” speech at their son’s wedding in New Orleans. They have three kids.

vaccine as soon as one becomes available, at a pace than can cover the entire U.S. population within a month. If we can accomplish that, then we and the government together can be confident that the U.S. will have the domestic surge capacity required to respond the current pandemic or future bio-emergency with exactly the population-scale injections needed.

It's no wonder that you describe this challenge as "enormous, yet exciting."

It's absolutely both. These four factors—speed, scale, cost and quality – obviously don't always work in lockstep. It really is a balancing act from start to finish.

Yet while speed is definitely important, at the end of the day quality is the value that cannot be sacrificed. You can understand why. In a pandemic environment, with lives at stake, when you are making a product that is designed to save those lives, quality is absolutely paramount. There isn't any choice.

You have stated that one of the keys to this balancing act is finding ways to streamline various processes. Can you explain that a bit?

Streamlining means that to the extent that you can simplify a very complex process, you try to do that. I would say another, equally important, key to the balancing act is flexibility.

If we can design our manufacturing operations to give us ultimate flexibility to be able to respond to whatever the marketplace eventually needs, and to meet the future requirements that any manufacturing operation will have for predictability and stability, then we are way ahead of the game.

Vaccine production, manufacturing and fill-finish to combat COVID-19 is the short-term objective for ApiJect. What about the long-term objective?

It certainly adds to our challenges that

we have to think a long way beyond today and even well beyond tomorrow. We're looking at emergency crisis response this year and next year, hopefully followed by a transition into an orderly, shall we say "peacetime" economy in a couple of years.

Under ordinary circumstances, you would structure your business differently for each one of those market segments. And yet, we're going to do both and we're going to do them both at the same time, as we build our facilities and design our operational strategies. One more factor amplifies our long-term commercial challenge, and that is the market disruption factor.

"It usually takes years to bring a new drug or vaccine to the market. But we're doing it at unheard-of speed."

— Nick Robinson —

Please explain.

Blow-Fill-Seal (BFS) technology has not been deployed in the prefilled injectables marketplace. For more than 100 years, that sector has been dominated by the traditional technology of glass vials and disposable syringes. But we believe this is the moment for BFS to come into its own, driven by necessity. Obviously, the U.S. Government shares that view, which is why the Department



Nick with his wife Lisi, a social worker and therapist. They've been married 32 years.

of Defense and the Department of Health and Human Services have partnered with us. As you know, the RAPID Consortium is a public-private partnership between the U.S. and ApiJect Systems of America.

You seem quite confident about ApiJect's future, no matter how large the challenges.

What I've learned over the years is that everybody has their turn in the barrel.

Everybody goes through periods of their professional life where things are extremely difficult. That's true for individuals, and it's also true for countries and for the world.

Ultimately what counts is not the size or severity of the challenge; it's how you manage yourself and your team through those challenging times that determines the outcome.

These are defining moments in life, and this pandemic crisis is one of them. The urgency of our mission is always top of mind for me, and I think everyone at ApiJect feels the same way.

What we are trying to accomplish is so vital, that the importance of the mission is more motivating than anything else.

Thank you, Nick.