


In the business of **saving**

A portrait of Nik Mongroo, Director of Manufacturing, wearing a light blue button-down shirt. He is standing in a modern office or factory interior with a circular light fixture on the ceiling and a staircase in the background.

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lives



TEXT JEANNETTE CÉZANNE PHOTOS BILL TRUSLOW

US based Lonza Biologics is an expert in the field of mammalian cells. Successful enough to defy the present economic decline in the US and in the process of a large expansion. Alfa Laval's separators are central to this project.

The first thing one notices upon arriving at Lonza Biologics in Portsmouth, New Hampshire, is the construction.

"We're very excited about it," says John Machulski, Director of Engineering. The plant is prepared for adding 3 x 20,000 litre bioreactor production capacity. It is a breathtaking step forward."

"We're adding 277,000 square feet of space," Machulski says. "It's one of the largest biotech project in the world at this time. It will be a four-year process, and we're wrapping up one phase of it – the construction – in the next three months." After that, there will be extensive validating testing before the service officially goes online.

In the meantime, a visitor to the facility in Portsmouth navigates a parking lot filled with construction crews. They all seem brisk and motivated, which is due at least in part to Director of Manufacturing Nik Mongroo's unique approach to teamwork. "People work best when they understand where their work fits in with the whole. So early on in the expansion we brought many of the construction workers on a tour of the production facility," he explains. "We showed them what we do, and how we do it. That way, everyone is fully engaged."

A different dimension That engagement extends far beyond the construction crews working on the new production facility. What is truly striking about Lonza Biologics is how everyone seems to enjoy their work.

"We're in the business of making materials that save people's lives," says Project Engineering Manager Gerry Coey. "That brings work into a new dimension. On a personal note, last year, my grandmother was dying. Lonza produced a drug that saved her life. How can you not like coming to work when that's what we're about?"



The new entrance to Lonza Biologics' renovated and expanded facility in Portsmouth, New Hampshire, reflects the changes that are happening throughout the plant.

It's a workforce that is not only committed, but highly educated as well. "The people are what costs us the most here," Machulski points out. "We have college graduates working on the production floor." That level of education is necessary, says Anne Moschella, Director of Sales and Marketing and herself a biochemist. "All of our salespeople have graduate degrees," she explains. "It's essential to know what you're talking about when you go out to meet with a potential client. What you know is what the company knows." She smiles. "We may be in marketing, but we still talk science all the time!"

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Understanding that science is no small feat. Lonza Biologics is a leading contract manufacturer of therapeutic monoclonal antibodies and recombinant proteins derived from mammalian cell cultures. The company provides its clients with complete process development, manufacturing, and analytical services, including cell line construction and development through cell banking to large-scale cGMP (current Good Manufacturing Practice) manufacture. “No one else offers this kind of continuity,” says Machulski. “We take it all the way from the beaker to the commercially-viable product.”

One-stop shopping What is happening at Lonza would have seemed like science fiction a few short years ago. Single cells are

frozen in liquid nitrogen and then placed in an environment designed to increase the volume of cells. This inoculum has nutrients for growth added to it, then is moved into the fermenter. Nutrients are constantly being added to the product, hence the name – fed batch fermentation – given to the system.

After the protein has been expressed, the cell culture is transported to a centrifugal separator that clarifies the culture. Depending on the nature of the final product, it then goes through a number of stages to remove impurities before being ready for shipment to the customer. And there’s more in store in the future. “We might eventually do packaging as well,” says Mongroo. “It would make us a fill-finish facility – sort of one-stop shopping for the customer.”

The customer is where Lonza’s technology intersects with real life; it is the customer that is developing the drugs that are changing the way the pharmaceutical and biotechnology industries are doing business – and the way that the world is benefiting. Lonza Biologics is working on approximately 40 projects and with twenty customers at any given time, some of which are in the public domain; most of which are not.

Customized production With twenty years of experience with mammalian cells behind it, Lonza is producing the essential ingredients for tomorrow’s life-saving medicines. Therapeutic drugs used to fight cancer, HIV infections, neurological disorders and sepsis are being brought to market faster and more efficiently through Lonza’s work. And, as Gerry Coey’s grandmother can attest, it’s not only making lives better – it’s saving them. “One of the fire-fighters who was injured at the Pentagon on September 11 went septic from his wounds,” says Nik Mongroo. “Our work saved his life.”

While Lonza is a multi-product facility,

none of the products being worked on here belong to the company itself. Clients may bring their own cell lines or have Lonza develop cell lines for them; but all of the work done is on a customer’s behalf and for a customer’s project. “There’s a certain risk level here,” acknowledges Coey, “in that we’re not producing any products of our own.”

Instead, Lonza takes the customer’s requirements—including its timeline, budget, regulatory package, and product quality and quantity—and transfers those requirements into its own process, which includes development (expertise in cell culture and process scale-up), testing, compliance, validation, regulatory requirements, manufacturing, sales and marketing, and logistics. The batch records, the data, and the final product all go back to the customer.

This position has stood Lonza in good stead in uncertain economic times, as the company is not dependent on any one product’s success. “We’ve been seeing pretty much continuous growth since 1996,” says Mongroo. There are only between five and eight other large contract manufacturing organizations that can do mammalian cell work worldwide, with others doing some smaller-scale projects as well. “It’s not exactly a really mature industry with a lot of other companies lined up,” agrees Coey.

But it is not a lack of competition that makes Lonza Biologics stand out; it is Lonza’s own striving for excellence and its willingness to take on challenges. The company has made a commitment to be the pre-eminent supplier to the life sciences industry, and is working toward that vision by fostering a culture that is driven by values that consider people first. Nik Mongroo’s facility tour for the construction workers is only a small example of how the company includes the human factor in the way it does business. And it is working.



The Alfa Laval BTAX 215 large-scale separator will play an important roll in Lonza’s expanded production.

►► www.alfalaval.com/here/cells/lonza



An important partnership

Separators are an extremely important element in Lonza's process. Alfa Laval has pioneered the development of advanced separators for the production of pharmaceuticals from mammalian cells. These separators fulfill all necessary sanitation and quality control requirements and are capable of handling the fragile living cells without damaging them.

"I can honestly say that now we see Alfa Laval continuously focusing on our needs," says Nik Mongroo of Lonza Biologics. "Our relationship has come a long way. It's been a learning curve for both of us, so obviously there have been bumps on the road." Lonza didn't just take Alfa Laval's capacity to deliver what was needed at face value: "The disk stack separator is integral to Lonza," Mongroo says. "So we evaluated everyone who can do them. We were impressed by Alfa Laval, with what they gave us in terms of materials and support. We don't even consider anybody else now: Alfa Laval is absolutely our only vendor. They can discuss process-specific issues. They know what we're doing here." Gerry Coey agrees. "They have sent people here overnight," he says. "When we say we need them, they're here for us."

Alfa Laval's partnership with Lonza Biologics began in 1996 when a BTUX 510 separator was placed in Lonza's 5000-liter production line. "We've worked very closely with Lonza personnel to ensure that they get the most out of their investment," says Richard Mathies of Alfa Laval's life science segment in the USA.

The new Portsmouth facility features Alfa Laval's BTAX 215 separator, "just out of the box," as Nik Mongroo proudly describes it. Alfa Laval is also working on a Preventative Maintenance plan tailored for Lonza's needs in order to maximize use of the separator and minimize—or even eliminate—any risk of downtime. "Right now we're working closely with Lonza to ensure that together we pay attention to training, spare parts, and maintenance needs," says Mathies. "Lonza will commit themselves to stocking some of the long lead critical spare parts and Alfa Laval will provide training support."

Lonza Biologics is prepared for adding large bioreactor production capacity.