



# PREPARING THE WORKFORCE PIPELINE

**Biomanufacturing is a constantly evolving industry. And with rapid development comes a need for a highly trained and prepared workforce. State leaders met virtually to discuss the biggest changes they are seeing in the industry, how they are working to prepare the worker pipeline and what they are doing to adapt to developments around the COVID-19 pandemic.**

Panelists:

**Samuel M. Taylor**, *president, North Carolina Biosciences Organization (moderator)*

**John Balchunas**, *workforce director, National Institute for Innovation in Manufacturing Biopharmaceuticals, assistant director, Prof. Dev. Programs, Biomanufacturing Training & Education Center, North Carolina State University*

**Brent Harpham**, *executive director for BioNetwork and Life Sciences, N.C. Community College System*

**Rick Lawless**, *training manager, AveXis*

**Martin Meeson**, *president and CEO, FUJIFILM Diosynth Biotechnologies*

**Hernán Navarro**, *director, Biomanufacturing Research Institute and Technology Enterprise, N.C. Central University*

**Mike Renn**, *director, instructor, N.C. Pharmaceutical Services Network at Pitt Community College*

**Kimberly van Noort**, *senior vice president for academic affairs, chief academic officer, UNC System*

Due to social distancing efforts, this month's round table took place via videoconference. The event was sponsored by BioNetwork, NC BIO, National Institute for Innovation in Manufacturing Biopharmaceuticals, Golden LEAF Biomanufacturing Training and Education Center, Pitt County Development Commission and AveXis. The transcript was edited for brevity and clarity.

**HOW HAS THE PROCESS OF BIO-MANUFACTURING CHANGED AT YOUR FACILITY OVER THE LAST FIVE TO SEVEN YEARS?**

**MEESON** We've moved a lot more away from the traditional stainless-steel type of operation. [Previously,] there has been a lot of stainless steel, a lot of cleaning, and we've moved now to the more disposable systems.

We are predominantly, nearly totally, in the disposable systems for all of the small-scale cell culture antibodies, which in our case is 2,000L, that we make across the whole of the network, including this facility in North Carolina. That's been quite a big change, and something that's been mainly in the upstream. We've all heard of the single-use bioreactors, but we now have many more items in the downstream which are moving to single-use as well.

In our facility in Texas, we are almost exclusively single-use throughout the

whole of the process, from the opening of the vial all the way through actually putting the drug substance in the bottle.

The other big [change] is around analytics. You know from your interactions with the [U.S. Food and Drug Administration] that one of the things they are extremely focused on is analytics, around the molecule when you go to get it registered.

We did an analysis the other day where we looked back over about 10 years, and virtually all of the equipment and some of the techniques that we're using today for analytics weren't even around 10 years ago.

**BALCHUNAS** When I looked back 10 to 15 years ago, "single-use" was a buzzword, and now it is a reality and very much the reality everywhere.

I think one area we are definitely seeing significant change is around the use of data analytics and automation, and it's a paradigm shift in ways. As companies begin leaning more heavily on data to make decisions, it

impacts the workforce as a whole. It trickles all the way down to operators and technicians as a different cadre of person is needed to interface with that data to know how to react. As a result, companies are actively seeking out data analytics talent to build a more intellectually diverse workforce.

**HOW HAS YOUR WORKFORCE ADAPTED TO NEW MANUFACTURING TECHNIQUES?**

**LAWLESS** We are a gene therapy company. Our gene therapies treat genetic diseases such as spinal muscular atrophy, Rett Syndrome, genetic ALS. Other companies make products for hemophilia and Duchenne muscular dystrophy. Genetic diseases are caused by a mutation in a patient's DNA, so that they can't produce an important functional protein.

So many of the gene therapies use vectors, sometimes virus particles, to deliver good DNA to the target cells so





## BRENT HARPHAM

N.C. Community College System

that they can produce functional protein. Often, this requires only a single dose. So our product is basically DNA in a vector, which was a little different than the other biotech products.

The thing that we look for the most — especially in new hires — is a good background in biology and chemistry. The processes aren't as well-defined, so sometimes it requires a lot of information and investigation to figure out how to proceed. The other skills that we look for are biomanufacturing skills.

As Martin mentioned, we are all in disposables. So some background in disposables. Automation has been mentioned before. Some of the companies in our industry use some old-school technology such as adherent cell culture, which is different than the suspension. That's kind of a step back in technology, but it's sometimes a requirement.

A lot of times, our vectors are intracellular, so we have to get them out of the cells. So we require a little bit of a different biomanufacturing background. The regulatory is a little bit more important than it was before, especially with new products. And then our QC testing would be on

DNA using PCR techniques instead of techniques looking for proteins.

But those skills are needed in our quality control laboratories that maybe are not available in the general industry at the existing companies.

**A SURVEY LAST YEAR SHOWED THAT WE'RE EXPECTED TO CREATE, AS AN INDUSTRY, MORE THAN 5,000 JOBS BY THE END OF 2024. HOW IS OUR UNIVERSITY SYSTEM PREPARING TO COPE WITH THAT DEMAND FOR EMPLOYEES?**

**VAN NOORT** Our universities are in a constant process of scanning workforce needs and working hard to respond. The UNC System has recently completed a study of workforce needs in the STEM and health sciences areas and of our future capacity to meet those needs. We looked at enrollment projections, seat availability projections in key areas, capacity of critical facilities, and other key considerations. Across the system, universities are starting up new programs in emerging fields such as data science, supply chain management, and data curation, among others. We are also helping to facilitate conversation between our institutions and industry to inform the development of new programs and the evolution of existing programs.

**WHAT ARE YOUR COMPANIES OR SYSTEMS DOING TO PROVIDE TRAINING IN THEIR RESPECTIVE AREAS AND SPECIALTIES?**

**RENN** East Carolina University and Pitt Community College got a \$1.75 million grant, from the Golden Leaf Foundation, to develop training facilities to provide training services in support of the pharmaceutical industry. The university received \$1.1 million and has built on the great program they already had in their chemistry department around [good lab practices], while also adding additional equipment to help with training and troubleshooting within the industry. They've implemented

short courses and also held its second annual two-day pharmaceutical chemistry seminar program.

The community college received \$650,000 from the grant, and \$400,000 from Pitt County Economic Development Commission with which we established the Pharmaceutical Services Network at Pitt Community College, a 6,000-square-foot facility to teach people how to make tablets and capsules. Since we went active in October 2017, we have completed about 45 classes, training more than 350 individuals, many of them from local industry, which was the reason that this all came together with Mayne Pharma and Thermo Fisher Scientific. We've also trained a number of public classes through the community college. A number of those people ended



## SAMUEL M. TAYLOR

North Carolina Biosciences Organization

up employed at Mayne Pharma and Thermo Fisher Scientific.

Last summer Pitt Community College, Pitt County Schools, Thermo Fisher Scientific and the N.C. Biotechnology Center partnered to launch a pilot for the newly created program called the Pharma K12 Workforce Development Training Initiative. Together the team identified seven graduating



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**SAM  
TAYLOR**  
NCBIO  
President

The Life Science Industry in North Carolina is driving innovation to improve our health, strengthen our agriculture industry and provide good paying jobs for employees. The industry is investing in communities and supporting education and training to equip incumbent workers and students for the jobs of the future.



**KIMBERLY VAN NOORT**  
UNC System

seniors that were good students, met the established minimum testing requirements, with no immediate plans to further their education. Upon graduation, the students attended the two-and-a-half day training session, receiving their certification, allowing each to be invited for interviews with Thermo Fisher, [from] which two of them were employed.

This year, we're opening it up to all seven Pitt County high schools. Unfortunately, given the circumstances, it's been kind of a bumpy road getting the young people lined up. But our goal is to hopefully train up to 12 students again this summer. They'll graduate on a Saturday, train the following week and then interview the following week at Thermo Fisher.

At about the one-year-and-a-half mark, we had follow-up meetings with the manufacturing leads with Mayne Pharma and Thermo Fisher to see if there was anything else we could do. What we heard back from them was very exciting: Their production rates were up, their reject rates or issue rates were down and [there was] a greatly improved attitude, because people had a little better understanding of what they were doing.

**WHAT ARE THE COMMUNITY COLLEGES DOING TO ADDRESS THE GROWING NEED FOR SKILLED WORKERS IN BIOMANUFACTURING?**

**HARPHAM** From the BioNetwork side, we work closely with community colleges and customize training directors across the state, to ensure that biopharmacy industry partners have customized training content that they need. It's a pull system rather than a push. We offer training on multiple disciplines including aseptic processing and quality systems, validation, upstream and downstream.

On the certificate side, we recently completed a revamp of the BioWork program. We had industry reps as well as community colleges represented during that revamp. The BioWork program is a 136-hour certificate program, and we have increased the number of community colleges offering this program up to 10. These are the 10 colleges that have a concentration of biopharma companies in their service areas.

Across the 58 community colleges, there are several associate degrees offered. Some of them are coupled with specific certificates in the areas of biotechnology, bioprocess technology



**JOHN BALCHUNAS**  
North Carolina State  
University

and biopharmaceutical technology. And there are also additional community colleges bringing these types of programs, which is providing not only a skilled workforce but the ability for these individuals to transition into the higher educational programs.

**WHAT IS THE GOLDEN LEAF BIOMANUFACTURING TRAINING AND EDUCATION CENTER AT N.C. STATE DOING TO MEET THE DEMAND?**

**BALCHUNAS** I think it's critical to frame the nature of this demand. In talking to companies, we hear encouraging words that we are well poised to meet their technical training needs. By and large, I'd wager that many of the biopharma-oriented education programs in the state are well positioned to deliver education and training aligned with biopharma skill needs. Yet, what becomes clear is that most companies are afraid there will be a shortage of talent five to seven years from now. As cell and gene therapy takes off, for example, these companies will be in a pinch for talent. And I think COVID-19 is only going to intensify that need for talent as [we see] more products coming online.

BTEC has undergraduate and graduate programs that are training students at different levels. Our undergraduate programs are reaching chemical engineering majors as well as microbiology majors and life science majors.

I oversee the hands-on technical training for the industry and bringing in incumbent workers for training.

**NAVARRO** One of BRITE's missions is workforce development, and it centers around a four-year pharmaceutical sciences degree where the students get a broad exposure to the biomanufacturing industry. And we have an advisory committee that has members in the private sector, and we're soliciting feedback from them to adjust our curriculum so it meets their needs when the students come out.

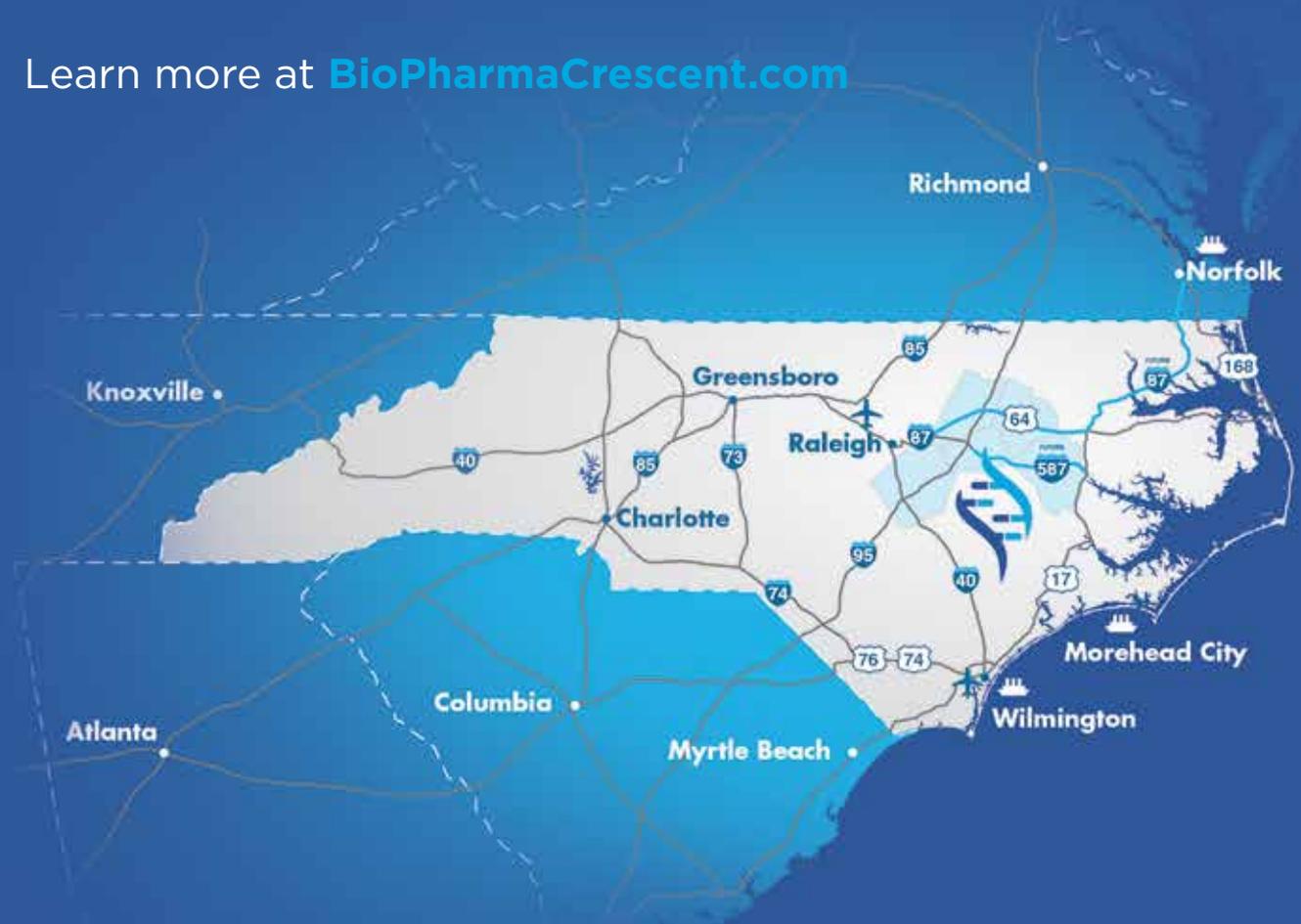
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## LIFE SCIENCES ROUND TABLE

When we work with NCBIImpact and NCBio, we also get great feedback as far as what the industry is looking for. We've adjusted some of our coursework based on that information. For example, we started to add disposable tubing in our bioprocessing labs now.

And we're hiring a full-time recruiter. We had a part-time recruiter, but part-time is not as good as full-time. Her goal is to go out to high schools and the junior highs and spread the word about how good a career in biomanufacturing is.

When I talked to the students at BRITE, some of them say, "I'm a scientist, but I'm not so sure I want to work in a lab."

What I want the recruiter to do is let people know that these are great jobs.

**MIKE RENN**

Pitt Community College

You'll work for great companies. You'll have tons of opportunities once you get in there. You'll use your science in all kinds of different ways. So get the basic training here at BRITE, and then you'll be really well-prepared to move wherever you want after you start working at these companies.

We're also working with the community colleges. We have four articulation agreements in place. It's a lot easier for those students to move from their as-

sociate degree program into the BRITE Pharmaceutical Sciences program for a four-year degree.

We've had around 10 graduate students in BRITE each year. Almost 100% of them go into the industry after they graduate. We're going to try to increase the number of students in our graduate program also.

**RENN** One of the things that has been interesting to me over the last couple of years is how little everybody understands about the biopharma business. They seem to think that everybody that works in the business has a Ph.D. They don't see anything that interests them, but when you start talking to them about all the possible opportunities, their eyes brighten up.

And oddly enough, I think things like COVID-19 help us, because there's so much emphasis on the medical industry to show how important the industry is.

**MEESON** We all have people within our organizations who have quite transferable skills. It's not all high degrees of chemical and biological and DNA manipulation. There are a lot of practical and mechanical aspects to the work that we do. At [Fujifilm Diosynth Biotechnologies], we promote [the biotechnology industry] at the high school level. And I think we'll probably work with some of your institutions directly or indirectly to make sure we do that, because that's a generic thing across the industry that I think we all need to follow.

**HARPHAM** On the community college side, we work to link those middle school or high school students with the community colleges and the STEM-related careers. We make that connection to help fuel that pipeline for future staffing.

**LAWLESS** The other audience to reach besides the students are their parents. Students will learn things while they're playing on their phones. They know electronics really well. The same with

parents. But we need to educate parents on what biotech is and that manufacturing in particular offers a pretty good career. In general, not many parents out there know about biotech, and they have a negative feeling about manufacturing: It's dirty and oily and steamy. So not only do you educate the middle schoolers, high schoolers but also the parents.

**RICK LAWLESS**

AveXis

**ARE THERE THINGS THAT THE INDUSTRY CAN DO TO HELP MAKE MANUFACTURING CAREERS MORE VISIBLE TO STUDENTS?**

**VAN NOORT** The biggest thing you can do to help the N.C. system in our four-year universities is remain strong partners with them, to remain and stay in their advisory boards, support them in their efforts to recruit students and support them in ways that enable them to do that outreach that you need. This can be done in lots of different ways, but I think that putting the power of the industry's needs behind what we are doing is going to make us a lot more successful. We're coming into some difficult times now, and we don't want to lose ground. We need the support that we can get for these

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## LIFE SCIENCES ROUND TABLE

very good programs already in place. It's going to be critical.

**HOW IS COVID-19 IMPACTING YOU TODAY, AND WHAT CAN WE EXPECT IN THE FUTURE AS WE RESPOND?**

**NAVARRO** We have a lot of people taking labs, and what some of the faculty [members] are doing is trying to identify some videos that the students can watch, but it may be that you have to develop video content in the future for these e-learning classes where students can have a virtual lab experience. It's not hands on, but at least they'll be able to have an idea of what the instruments look like and how they function, but it's going to be a challenge. Limited access to high-speed internet could limit or exclude those in rural areas or those with limited financial resources from e-learning opportunities.

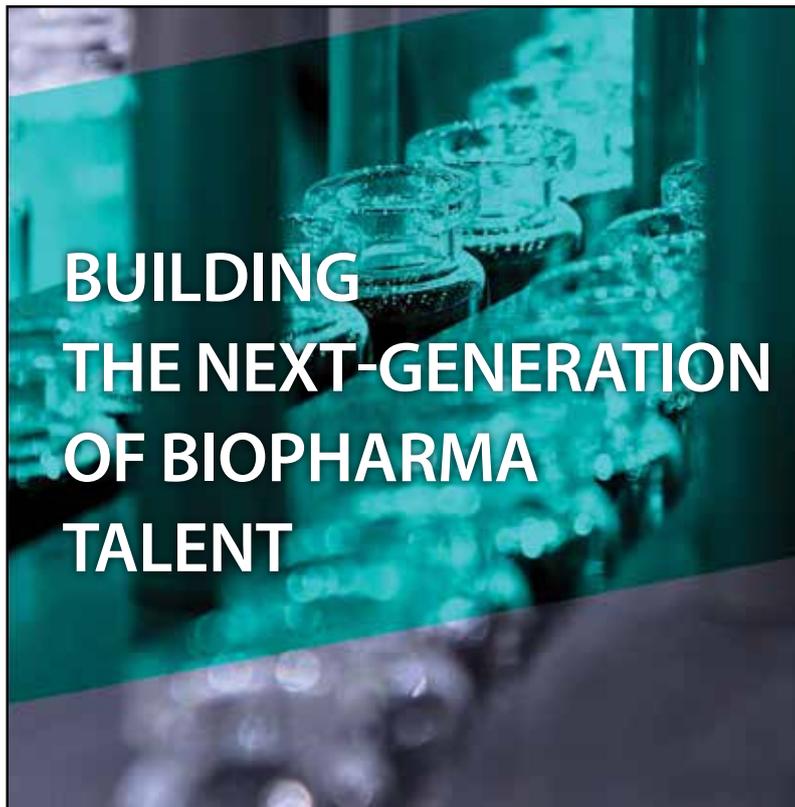


**HERNÁN NAVARRO**  
Biomanufacturing Research  
Institute and Technology  
Enterprise

**VAN NOORT** This is going to force us into rethinking a lot about how we do business. This is going to change how every single biomanufacturing industry member out there works with technology and how we educate students to meet those changes, and I believe that will be the No. 1 result that we'd see out of this that's going to be a positive.

**HARPHAM** We continue to provide top-tier training, and part of that is [through] virtual reality. We also are looking at enhanced implemented e-learning as supplemental support. With the virtual reality training, we've simulated multiple scenarios; it involves going into a facility and mapping out everything within a specific location where there's a mixing chamber, or it could be a fill line, for example.

It allows the individuals to train in a setting that could be hazardous or dangerous or not accessible at times, given



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these pharmaceutical companies are operating 24/7. So having that availability for someone to put on a headset and go through motions and have issues arrive and then go in and solve the issue is key. And we'll continue to explore those scenarios with companies across the state.

#### WHAT RESOURCES DO YOU NEED FROM THE STATE TO PROVIDE UP-TO-DATE TRAINING TO MEET THIS GROWING DEMAND?

**NAVARRO** From the N.C. Central side, there are certain things that we would like to add to our training, but they're very expensive.

For example, automation. We really don't have it in our budget to be able to set that up. It would be nice to have some extra funding for that, even if it's a one-time or if it's over a few years, to build in these new programs. And we're trying to move a lot of our courses online.



**MARTIN MEESON**  
FUJIFILM Diosynth  
Biotechnologies

**BALCHUNAS** Funding sounds so generic, but it is a critical piece of the

puzzle. I think from BTEC's perspective, I don't think we've ever reached what I would call capacity in terms of throughput. But if the industry demand is as big as it says it is, at some point we will hit a ceiling or wall in terms of capacity, and that wall could be limitations in space or limitations in instructional expertise. Whether that's space, whether that's faculty. I don't know which one it's going to be first. I think we could hit capacity at some point if the demand keeps growing.

Several people mentioned online learning, and I think that's going to be one of the most fascinating things for me to watch from NIIMBL's perspective. I'm listening to educators all over the country deal with the exact same issue right now: How do you teach technical hands-on labs online? I think two years from now, there's going to be a lot of innovation in the whole world of online learning, and I think this is going to be a catalyst. ■



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