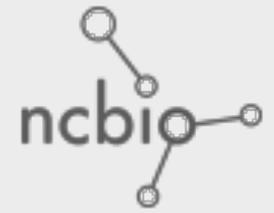




# connections newsletter



**APRIL 2019  
UPDATE**

**Serving the NC Life  
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## NCBIO This Month

- NCBIO Legislative Reception Showcases Industry
- Report Evaluates State's Life Science Landscape
- Cell and Gene Therapy Companies Growing in North Carolina
- Biotech Manufacturers Forum Focuses on Workforce Needs
- Review of 2019 Life Science Conference



- [At the National Level](#)
- [Member News](#)
- [Member Benefits](#)
- [Calendar](#)

## NCBIO - Media

Find the latest news from NCBIO on the website [ncbioscience.net](http://ncbioscience.net), on [LinkedIn](#) and on Twitter at [@ncbio](#).

## NCBIO Links

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Biotechnology Workforce](#)

## NCBIO Legislative Reception Showcases Industry



NCBIO members talked with lawmakers about the impact of the industry on the State's economy as well as projected growth for the next three to five years. More than 200 people turned out, making it one of the largest annual events that NCBIO has hosted for legislators. Participants had a chance to see a slide show presentation of companies across the State and view posters of companies.

## NCBIO Sustaining Members

[Biogen](#)



Life Science Co-Chairs: Rep. Donna White, Sen. Mike Woodard and Rep. Robert Reives

"We were pleased that so many new legislators attended to find out more about the industry," stated NCBIO President Sam Taylor. "We will be providing them additional information through the Legislative Life Science Caucus meetings and other activities."



Life Caucus Science Co-Chair Sen. Paul Newton talks with Mark Spitzer and Tony Almeida

The four new Co-Chairs for the Caucus talked with a number of members during the event. The Co-Chairs are Sen. Paul Newton (R-Cabarrus & Union), Rep. Donna McDowell White (R-Johnston), Sen. Mike Woodard (D-Durham, Granville & Person) and Rep. Robert Reives (D-Chatham & Durham).

Thank you to [Astellas](#), [BIO](#), [Biogen](#), [Bristol Myers Squibb](#), [Grifols](#), [IQVIA](#), [Lilly](#), [PhRMA](#), and [Syngenta](#) for sponsoring this Legislative Reception.

**The North Carolina Museum of History did not sponsor or endorse this event.**

[Back to top.](#)

## Report Evaluates State's Life Science Landscape

"North Carolina has established one of the nation's leading life science industry clusters, characterized by steady, long-term growth and establishment of a diverse blend of industry, technology, and market strengths and niches," states the executive summary



We Work For Health



## NCBIO Supporting Members

Cook Medical



Merck



of the newly published [2018 Evidence and Opportunity: Impact of Life Sciences in North Carolina](#).

The report for the North Carolina Biotechnology Center is produced by TEconomy Partners to track and evaluate the State's life science landscape. Findings include:

- Total jobs supported by the sector grew 33 percent from 2008 to 2018
- Total economic impact of the sector grew 82 percent in that same time, from \$45.8 billion to \$83.3 billion
- Nearly \$2.2 billion in state and local government revenues in 2018, up from \$1.4 billion in 2008

North Carolina stands as a global leader in the highly specialized world of biomanufacturing, thanks in large part to the 2003 launch of the NCBioImpact initiative in workforce development. At that time there were 17 companies in biomanufacturing, employing 4,754 people.

Those numbers jumped 93 percent by 2018, TEconomy says, with at least 25 biomanufacturers employing 9,163 people directly. Those workers are creating a wide range of high-value products including biopharmaceuticals, animal health products, food ingredients, and industrial products such as enzymes.

Find out [more information](#) about the sector.

[Back to top.](#)

## Cell and Gene Therapy Companies Growing in North Carolina



[Bill Monteith of Collectis](#)

[Collectis](#), is the latest cell therapy company to announce plans for a facility in North Carolina. Collectis, a biopharmaceutical company focused on developing immunotherapies based on gene-edited allogeneic CAR T-cells (UCART), announced that it has entered into a lease agreement to build an 82,000 square foot commercial-scale manufacturing facility named IMPACT (Innovative Manufacturing Plant for Allogeneic Cellular Therapies) in Raleigh for clinical and commercial production of Collectis' leading allogeneic UCART products. [More](#)

Collectis is planning to create up to 200 jobs as it locates its U.S. commercial-scale manufacturing facility in Wake County, Governor Roy Cooper announced at a news conference.

"North Carolina is proud to be a national leader in life sciences," said Governor Cooper. "The groundbreaking work that Collectis will produce in North Carolina will continue to strengthen our role in biopharmaceuticals, as well as have a major impact in the battle against cancer. We are particularly proud that North Carolina was the company's top pick for its manufacturing facility." [More](#)

"We are delighted that Collectis chose to enter North America through North Carolina," said Bill Bullock, NCBiotech senior vice president of economic development and

statewide operations. "It stands as a vital affirmation for our state's fast-growing ecosystem of gene therapy manufacturing and development excellence. In today's highly competitive global environment for this elegantly specialized field, success begets success. This announcement reflects that."

Bullock noted in remarks at the Collectis news conference that a significant cluster of high-profile companies, including Locus Biosciences, Precision BioSciences, Pfizer, AveXis, bluebird bio, and now Collectis, "are transforming leading-edge gene-editing technology into a new age of gene and cell therapies." [More](#)



Governor Cooper, state, local and company officials at bluebird bio dedication

Last month AveXis announced expansion plans for its new facility in Durham, and bluebird bio held a dedication ceremony for its cell and gene therapy plant last week. CEO Nick Leschly called the facility "a crucial step toward our mission of bringing a new generation of treatments to people living with severe genetic diseases and cancer."

The 125,000-square-foot facility will produce lentiviral vector for the company's investigational gene and cell therapies, including treatments for multiple myeloma, transfusion-dependent  $\beta$ -thalassemia and sickle cell disease. bluebird purchased the facility in November 2017 and has been refitting it with production suites, quality control testing laboratories and warehousing space. [More](#)

[Back to top.](#)

## **Biotech Manufacturers Forum Focuses on Workforce Needs**





Bill Bullock, Laura Rowley and John Balchunas

The growth in North Carolina's biomanufacturing sector and the need for more employees and training were the topics for the March BMF meeting. John Balchunas of the National Institute for Innovation in Manufacturing of Biopharmaceuticals (NIIMBL) talked about assessments under way by the organization. Bill Bullock and Laura Rowley with the North Carolina Biotechnology Center discussed growth by the industry and the *Window on the Workplace Survey* being conducted by the Center and NC BIO. Contact [John Wagner](#) or [Brenda Summers](#) for more information about the BMF.

[Back to top.](#)

## Review of 2019 Life Science Conference

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"The Journey to Becoming a Public Company," panel at the CED Life Science Conference in late February featured Terry-Ann Burrell, Managing Director, J.P. Morgan, as moderator and representatives of homegrown companies: Neal Fowler, CEO of Liquidia, and Mark Velleca, M.D., Ph.D. CEO of G1 Therapeutics. Fowler and Velleca discussed the ups and downs of growing a company.

Moise Khayrallah, Ph.D. received the Life Science Leadership Award at the closing luncheon of the conference. Dr. Khayrallah is a serial entrepreneur with over 30 years invested in pharmaceutical drug development and biotechnology companies. Emergo Therapeutics is Dr. Khayrallah's latest venture, his fifth startup in 12 years. Emergo focuses on the development of drugs which are meant to improve the function of the immune system where infectious disease is present. In addition, Dr. Khayrallah is Chairman of the Board and Co-Founder of QuatroBio, LLC, as well as Chairman of the Board of TARGET PharmaSolutions. [More](#)

Venture investors shared advice for entrepreneurs. [More](#) The author of *Bad Blood*, John Carreyrou, shared his advice to life science companies, encouraging them not to exaggerate claims about products. [More](#)

[Back to top.](#)

## At the National Level

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### Medical Device Repeal Legislation Introduced in US Senate

Scott Whitaker, President and CEO of the Advanced Medical Technology Association (AdvaMed), issued the following statement on introduction of bipartisan legislation (S. 692) – the Protect Medical Innovation Act – in the U.S. Senate to permanently repeal the medical device excise tax:

"Unless Congress acts quickly, America's medical technology companies face a \$20 billion tax hike at the end of 2019 when the device excise tax returns. If not stopped, this tax will put future patient innovations and good-paying U.S. jobs at risk." [More](#)

Mark Leahey, President and CEO of the Medical Device Manufacturers Association

(MDMA), noted, "When the medical device tax was in place, billions of dollars were sent to the I.R.S. instead of being invested in the next generation of cures and therapies for patients. We simply cannot allow this to happen again, and today's introduction of the 'Protect Medical Innovation Act' shows that a broad, bipartisan coalition in the Senate agrees." [More](#)

### **AdvaMed Fly-In Update**

NCBIO President Sam Taylor was in Washington February 26 and 27 to participate in AdvaMed's annual Congressional Fly-In. The chief topic for this year's event was repeal of the medical device tax.

While participating in the Fly-In, Taylor met with the offices of Senators Richard Burr and Thom Tillis, and Representatives G.K. Butterfield (D-1st), George Holding (R-2nd), David Price (D-4th), Richard Hudson (R-8th), Patrick McHenry (R-10th), and Mark Meadows (R-11th) to discuss the negative impacts of the tax and to request their co-sponsorship of legislation to repeal the medical device excise tax.

Bills to repeal the tax have been introduced in Senate and will be introduced in the House soon. In the House, 153 representatives have sign-on to co-sponsor the bill. As of this writing, North Carolina Representatives George Holding, Richard Hudson, Mark Meadows, David Rouzer and Mark Walker have said they will co-sponsor. In the Senate, 26 senators have co-sponsored the legislation, including North Carolina Senator Thom Tillis. NCBIO is continuing to contact member of our Congressional delegation to secure more co-sponsors for the legislation.

### **Gottlieb to Leave FDA – Former UNC-CH Research to Serve as Acting Commissioner**

FDA Commissioner Dr. Scott Gottlieb announced he will leave the agency in early April. Gottlieb has been head of the agency since 2017.

Scott Whitaker, President and CEO of AdvaMed, stated, "We want to thank Dr. Gottlieb for his service to the American public and his commitment to ensuring patients have access to the latest treatments, diagnostics and cures. During his tenure as FDA commissioner, Dr. Gottlieb has been a tireless advocate for improved patient care and for promoting innovative solutions to our most pressing health challenges, including greater use of medtech to combat the opioid crises. We wish him well in his future endeavors."

Health and Human Services Director Alex Azar announced that former UNC-CH Researcher, Dr. Ned Sharpless, who is currently director of the National Cancer Institute (NCI), will become the acting director when Gottlieb leaves. "Sharpless joined the NCI in October 2017 after serving as director of the University of North Carolina's Lineberger Comprehensive Cancer Center. He also founded or co-founded two Research Triangle-based biotechnology startup companies, Sapere Bio (formerly Healthspan Diagnostics) and G1 Therapeutics (formerly G-Zero Therapeutics)." [More](#)

### **Federal Budget Proposed by President Trump Could Impact Drug Pricing**

The Trump administration unveiled its [Fiscal Year 2020 budget](#). While spending is ultimately determined by Congress, the budget document outlines the spending and policy priorities the President and his allies are expected to push in the coming months. When it comes to the important issue of prescription drug costs, the budget outlines some good ideas and some troubling ones.

As BIO's President and CEO Jim Greenwood said in the wake of the budget's release:

"We applaud the President's efforts to lower patients' out of pocket costs for prescription drugs, and to rein in abuses and increase accountability within the 340B drug discount program. That said, we have serious concerns that elements of this proposal threaten to harm some of the nation's most vulnerable patients, including seniors and low-income families."

**The details:** While many of the ideas announced were included in [last year's drug pricing blueprint](#), here's how the budget would impact the drug cost ecosystem:

- **Medicare Part D:** Proposes a three-part plan that would eliminate cost-sharing on generic drugs and biosimilars for low-income beneficiaries; exclude manufacturer discounts when calculating beneficiary out-of-pocket costs in the coverage gap; and establish a beneficiary out-of-pocket maximum in the catastrophic phase.
- **Medicare Part B:** Proposes consolidating Part B drugs into Part D "when

savings can be gained”, creating inflation limit for reimbursement of Part B drugs, and reduces reimbursement (from ASP +6% to ASP -33%) when a drugmaker enters a “pay-for-delay” arrangement or takes other “anti-competitive action.”

- [Medicaid](#): Allows up to five states to test a closed formulary that would allow these states to negotiate drug prices directly with manufacturers.
- [340B program](#): Allows the Health Resources and Services Administration to create clear, enforceable standards for the 340B program and requires covered entities to report on the use of savings under the program; and requires a minimum level of charity care for 340B hospitals to receive a payment adjustment for uncompensated care.
- [FDA](#): Would prevent first-to-file generic applicants who have been awarded at 180-day exclusivity period from blocking subsequent generics from entering the market beyond the exclusivity period; and provides agency with more authority to deny citizen petitions.

**Go deeper:** BIO prepared a [more thorough overview](#) of the drug pricing proposals outlined in the president’s FY 2020 budget, including estimated savings to the federal government.

[Back to top.](#)

## Member News

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To be included in Member News, send information about your organization to [Brenda Summers](#)

[AgBiome](#) has been named to the Thrive Top 50 report for the second straight year. SVG Ventures announced its 2019 THRIVE Top 50 Report, an annual ranking of 50 leading global AgTech companies exemplifying the best in agriculture and food-focused innovation. [More](#)

[Aerie Pharmaceuticals](#) announces U.S. FDA approval of Rocklatan™ (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% for the reduction of Intraocular Pressure in patients with Open-Angle Glaucoma or Ocular Hypertension. [More](#)

[BD](#) (Becton, Dickinson and Company) announced the U.S. Food and Drug Administration has granted premarket approval for the Venovo™ venous stent, the first stent indicated to treat iliofemoral venous occlusive disease, which is obstructed or narrowed blood flow specific to the iliac and femoral veins located near the groin. [More](#)

[Biogen](#) has entered into a share purchase agreement with [FUJIFILM Corporation](#) (Fujifilm) under which Fujifilm will acquire the shares of Biogen’s subsidiary, which holds Biogen’s biologics manufacturing operations in Hillerød, Denmark. [More](#) Biogen has entered into an agreement to acquire Nightstar Therapeutics, a clinical-stage gene therapy company based in London, United Kingdom, which is focused on adeno-associated virus (AAV) treatments for inherited retinal disorders. [More](#)

[Chiesi USA, Inc.](#) has moved into its new headquarters in Cary. Chiesi will occupy the top two floors of Regency Woods II, a six-story development by The Spectrum Companies located off U.S. 64. “We’re excited to unite the Chiesi USA family under one roof in this extraordinary new building,” said Ken McBean, President and CEO of Chiesi USA. [More](#)

[Falcon Therapeutics](#) has been awarded a nearly \$1,500,000 Phase II Small Business Technology Transfer (SBTT) grant to progress its cell therapy for Glioblastoma (GBM). The treatment is used to potentially eradicate this common brain tumor, one of the deadliest and most difficult cancers to treat. [More](#)



[Forsyth Technical Community College](#) (FTCC), Davidson County Community College (DCCC) and Guilford Technical Community College (GTCC), hosted a group of six students from the Universidad Nacional de Villa Maria (UNVM) in Argentina to learn more about STEM education through community colleges in North Carolina. The visit was made possible through a \$25,000 grant from the *100,000 Strong in the Americas Innovation Fund* awarded to Forsyth Tech.

[ImmunoReagents Inc.](#) hosted a visit from Linda McMahon, Administrator of the Small Business Administration, on February 21. North Carolina Lt. Gov. Dan Forest and SBA North Carolina Director Lynn Douthett joined McMahon for the tour. [More](#)

[IQVIA](#) announced the launch of a patented technology platform that advances real-world research and protects genomic data privacy. E360 Genomics, a scalable, privacy-preserving genotypic-phenotypic database solution, provides an efficient way to conduct genomic research with genomic and clinical databases. [More](#)

[Liquidia Technologies, Inc.](#) announced the pricing of an underwritten public offering of 3,000,000 shares of its common stock at a public offering price of \$11.50, for total gross proceeds of \$34.5 million, before deducting underwriting discounts and commissions and expenses payable by Liquidia. [More](#)

[Pairwise](#) has entered into licensing agreements with Massachusetts General Hospital (MGH) and the Broad Institute of MIT and Harvard (Broad Institute) for their latest CRISPR genome editing technologies. These advancements in CRISPR will expand the technology's applications in crop editing and further enable research to bring new foods to market and increase the sustainability of modern agriculture. [More](#)

[Pharmaceutical Product Development, LLC](#) (PPD) has been named to *Training* magazine's 2019 *Training Top 125* list recognizing excellence in employee learning and development. This marks the eighth consecutive year PPD has been named to the magazine's list of top 125 businesses. *Training* magazine also honored Amy Chapman, a principal learning specialist with PPD, as a Top 5 Emerging Training Leader. [More](#)

[Syngenta](#) researchers recently published a paper in *Nature Biotechnology*, an international science journal, detailing their discovery of a genome-editing technique called haploid induction editing (HI-Edit™) technology, which ultimately reduces the time it takes to develop commercial crop varieties. [More](#) Syngenta Ventures announced new leadership for its global team. Corey Huck, head of Biologicals & Syngenta Ventures, now heads up the global Ventures team. Colin Steen, Syngenta Ventures Managing Director, will lead the daily operations of the team. [More](#)

[Thermo Fisher Scientific Inc.](#) announced that it is investing \$150 million in its Pharma Services business to provide additional capacity for sterile liquid and lyophilized product development and commercial manufacturing. Included in the site expansion projects are Monza and Ferentino, Italy, and Greenville, North Carolina. In response to customer requests, each of the sites will be equipped with aseptic filling lines and isolator technology. Construction is expected to be completed within the next 24 months. [More](#)

[vTv Therapeutics Inc.](#) announced that it has entered into a definitive agreement with certain institutional investors for the purchase and sale in a registered direct offering (the "Registered Direct Offering") of 3,636,364 shares of the Company's Class A common stock (the "Common Stock") at a price of \$1.65 per share for aggregate gross proceeds of approximately \$6.0 million. The offering is expected to close on or about March 20, 2019, subject to the satisfaction of customary closing conditions. [More](#)

## NCBIO Member Benefits – New Discounts from NCBIO Member Companies

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### NCBIO Member Benefits

4,000 companies saved nearly \$400 million in 2018 through BIO Business Solutions®. As an NCBIO member, you are eligible! This is a benefit of your NCBIO membership. Review the cost-savings offered by clicking [here](#) and choose the programs you're interested in. Email [biobusinesssolutions@bio.org](mailto:biobusinesssolutions@bio.org) with your choices and they will get you started. For all the latest news, promos, and event information, follow [BIO Business Solutions® on LinkedIn!](#)

Acquired by Avantor in 2017 as a wholly-owned subsidiary, [VWR](#) serves as a leading global provider of product and service solutions to laboratory and production customers. The combined company is a trusted end-to-end partner to customers and suppliers from discovery to delivery. It offers a diverse portfolio that includes over four million products and enables customer success through innovation, cGMP manufacturing and a comprehensive service offering.

For more than 15 years, VWR and BIO, have combined their core strengths to offer solutions that advance scientific innovation in the life sciences. The BIO-VWR program includes special pricing agreements with major manufacturers, plus many other member-only benefits. Enrollment is as simple as completing a one-page enrollment form/agreement.

Benefits include:

- Buying power of a large, national purchasing agreement
- Hot list of more than 8,000 items, with savings of up to 75% from list
- Hot list flexibility—pricing for high volume items commonly ordered can be added to the hot list to match your company's local pricing
- Discounts across the entire VWR product offering
- Special pricing on capital equipment items with list price of over \$1,100
- And much more.

Find out about VWR discounts by contacting Jason W. Kempton, Region Director - Pharma, Biotech, and Industrial, 843-743-6648, [Jason\\_Kempton@vwr.com](mailto:Jason_Kempton@vwr.com). Also find out more about other [NCBIO discounts](#).

[Back to top.](#)

## Calendar

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To view full calendar, [click](#).

### [Durham Tech Cell and Tissue Culture Techniques](#)

Monday Apr 1, 2019

... [read more](#)

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### [Durham Tech Molecular Biology Techniques](#)

Tuesday Apr 2, 2019

... [read more](#)

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### **[SBTDC Becoming an Investor Ready Entrepreneur](#)**

Wednesday Apr 3, 2019

... [read more](#)

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### **[Durham Tech Cell and Tissue Culture Techniques](#)**

Wednesday Apr 3, 2019

... [read more](#)

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### **[LaunchBio's Larger than Life Science - Transformers](#)**

Thursday Apr 4, 2019

... [read more](#)

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### **[Durham Tech Molecular Biology Techniques](#)**

Thursday Apr 4, 2019

... [read more](#)

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### **[Durham Tech Cell and Tissue Culture Techniques](#)**

Monday Apr 8, 2019

... [read more](#)

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### **[ASAP: Winning the Race in IIoT and Smart Manufacturing using Partnerships](#)**

Tuesday Apr 9, 2019

... [read more](#)

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### **[Durham Tech Molecular Biology Techniques](#)**

Tuesday Apr 9, 2019

... [read more](#)

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### **[Durham Tech Cell and Tissue Culture Techniques](#)**

Wednesday Apr 10, 2019

... [read more](#)

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### **[BPD Cell and Gene Therapy Symposium & Vendor Show](#)**

Thursday Apr 11, 2019

... [read more](#)

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### **[2019 SciTech Lecture Series: Gut Microbiome - A Goldmine of Therapeutics and Biomarkers of Aging-Related Metabolic Disorders](#)**

Thursday Apr 11, 2019

... [read more](#)

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### **[Durham Tech Molecular Biology Techniques](#)**

Thursday Apr 11, 2019

... [read more](#)

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### **[NCBioNetwork Fundamentals of Validation](#)**

Friday Apr 12, 2019

... [read more](#)

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### **[Durham Tech Cell and Tissue Culture Techniques](#)**

Monday Apr 15, 2019

... [read more](#)

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### **[Durham Tech Molecular Biology Techniques](#)**

Tuesday Apr 16, 2019

... [read more](#)

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### **[Story for Startups](#)**

Wednesday Apr 17, 2019

... [read more](#)

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### **[NCBiotech Ag Tech Professional Forum April 2019: Climate Change - In the Heat of the Night](#)**

Wednesday Apr 17, 2019

... [read more](#)

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### **[Durham Tech Cell and Tissue Culture Techniques](#)**

Wednesday Apr 17, 2019

... [read more](#)

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### **[SBIR/STTR Education Seminar: Winning SBIR/STTR Grants](#)**

Thursday Apr 25, 2019

... [read more](#)

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