



AUGUST 2020 UPDATE

Serving the NC Life Sciences Industry

http://ncbioscience.net 919-281-8960

home I about I calendar I news I member benefits I forums I advocacy I contact

NCBIO This Month

- · Legislators Enact Measures to Support Life Science Growth
- · Demand for Lab Space in NC Continues to Grow
- · Best Practices and Challenges Returning to Workplaces
- · NCBIO Annual Meeting Going Virtual Sept. 29 Oct. 2
- · NCBioImpact Training During COVID-19
- · Report Shows Life Science Industry Remains Strong in RTP

- · At the National Level
- · Member News
- · Member Benefits
- · Calendar

P ── Legislators Enact Measures to Support Life Science Growth



The North Carolina General Assembly has taken a break from lawmaking until September 2, when it will return to Raleigh to address any additional federal funding that is allocated to the State by Congress in August. Before leaving Raleigh, lawmakers took final action on a variety of matters of interest to the life science community.

NCBIO - Media

Find the latest news from NCBIO on the website ncbioscience.net, on LinkedIn and on Twitter at

NCBIO Links

CED

@ncbio.

NCBIO

NC Biotech Center

BRITE

BTEC

BioNetwork

NCBioImpact

North Carolina Pharmaceutical Services Network

NCABR

National Center for Biotechnology Workforce

NCBIO Sustaining Members

Biogen

Life science companies seeking new employees will benefit from enactment of House Bill 1023, an omnibus appropriations measure that includes \$500,000 for the North Carolina Biotechnology Center (Center). The Center is authorized by the legislation to provide grants and educational job placement services to match workers displaced or unemployed due to COVID-19 with essential job openings at life science companies that are currently working on treatments, therapies, vaccines or equipment in response to COVID-19.

The waning hours of the 2020 regular session also saw final approval of two other life science-related measures. The first, <u>S361</u>, modifies state insurance laws to establish guardrails for step therapy protocols sometimes used by insurers to limit access to expensive pharmaceutical treatments.

Senate Bill 315, the second measure of interest, clarifies that nitrogen offset credits generated by water quality improvements in the lower Neuse River Basin can, pending further study by the Department of Environmental Quality, be used on a one-for-one basis by treatment facilities on inland segments of the River. Biomanufacturing waste streams often contain significant amounts of nitrogen. Nitrogen offset credits can be purchased by system operators to compensate for nitrogen discharges that cannot be cost-efficiently removed by wastewater treatment systems.

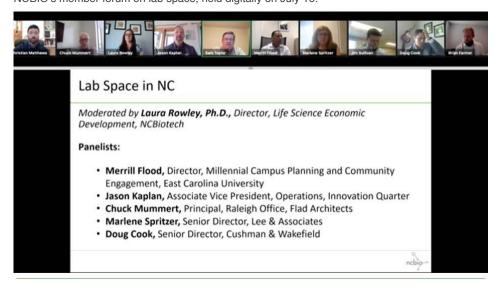
Several bills pending at the time our last newsletter was published failed to receive action in the closing days of the session. These include legislation providing additional funding for life science programs at North Carolina Central University (H1221), funding to support an agricultural biotechnology accelerator in the Research Triangle Region (H1099), and a measure that would have required pharmaceutical benefit managers to recognize manufacturer rebates as creditable against patient deductibles (S432).

Earlier in this year's session, the Assembly enacted legislation appropriating \$85M for research, testing and other COVID-related activities at North Carolina universities (H1043) and \$2M for the State's participation in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) (H472).

Back to top.

[⊸]Demand for Lab Space in NC Continues to Grow

COVID-19 has impacted the demand for lab space in North Carolina, but the state is continuing to see growth because its quality of life and lower costs, especially as compared to Boston and the West Coast. The positive assessment was one conclusion offered by panelists participating in NCBIO's member forum on lab space, held digitally on July 16.



Merrill Flood, Director of Planning and Community Engagement, East Carolina University Millennial Campus expects an increased need for lab space by pharmaceutical companies in the Greenville area as life science businesses on-shore activities imperiled by the COVID-19 pandemic. He provided an overview of projects under way on the East Carolina University campus, including the university's new Life Science and Biotechnology Building.

COVID-19 resulted in the iQ Healthtech Labs in Winston-Salem allowing Wake Forest Baptist Health to use its expertise to provide innovation and collaboration with non-traditional partners in mask making according to Jason Kaplan, Associate Vice President of Operations, Innovation Quarter. He





Pfizer



We Work For Health



NCBIO Supporting Members

Cook Medical



Merck







says labs have made adjustments on accessing space and using social distancing.

Chuck Mummert, Principal, Raleigh Office, Flad Architects outlined some new office design strategies for returning to work during COVID-19 along with use of such things as health kiosk/sanitation stations. He expects companies will be looking at changes in lab space modules as employees determine how to share space and equipment.

In looking for new lab space, Marlene Spritzer, Senior Director, Lee & Associates, urged companies to allow sufficient time to plan, confirm flexible terms, analyze all options and understand costs. She says demand for lab space is increasing in the RTP area.

Doug Cook, Senior Director, Cushman & Wakefield, said interest by outside investors is on the uptick in RTP. He also sees more interest in on-shoring because of supply chain issues during the pandemic.

The forum was moderated by Dr. Laura Rowley, Director, Life Science Economic Development,



Lab Space in North Carolina

July 16, 2020

















Thanks to CSC Leasing, Evans General Contractors, Humboldt and Lee & Associates for sponsoring this Forum.

Back to top.

Best Practices and Challenges Returning to Workplaces



Jeffrey Gagnon, Executive Managing Director, and Kay Barrett, Leader of Space Planning and Occupancy, Cushman & Wakefield, led a discussion on best practices for bringing employees back to work following the COVID-19 shutdowns for the NCBIO Biotech Manufacturers Virtual Forum on June 30. They shared some of the company's experiences with businesses in other parts of the

world that are ahead of us in the recovery.

Gagnon reviewed "<u>The Safe Six: Workplace Readiness Essentials</u>," which include preparing the building, preparing the workforce, controlling access, creating a social distancing plan, reducing touch points & increasing cleaning and communicating with confidence. He said, "Companies should think not only about who should come back, but also who is ready and able to come back."

Barrett discussed the importance of evaluating and controlling access and communicating information to employees prior to the return to workplace. She talked about the importance of reducing touchpoints and developing social distance plans. Managing the transition will be important.

Gagnon noted that studies show that "team collaboration is better than ever" with 75% agreeing or strongly agreeing they are collaborating effectively with colleagues and also 75% agreeing they feel productive when they need to focus. There are challenges such as Generation Z feels less connected to company culture working from home and also have inadequate home workspace. Millennials and Generation X report caregiver responsibilities.

Contact <u>John Wagner</u> or <u>Brenda Summers</u> if you have questions about the Biotech Manufacturers Forum.

Back to top.

PONCBIO Annual Meeting Going Virtual September 29 – October 2



The <u>26th Annual Meeting</u> is going virtual. Join other NCBIO members and guests on **Tuesday**, **September 29 - Friday**, **October 2** from **noon to 1:30 p.m.** Each day, we will host a program session including:

- Local Election Outlook with Democratic and Republican campaign consultants
 discussing the issues that are driving political debate and campaign promises,
 including an examination of the allure of drug price control and healthcare costs as
 a political issue.
- National Policy Outlook and Ramifications looks at policy in 2021 what does this mean for our companies?
- Value of Life Sciences: The Future of Health for Our People features a fireside chat interspersed with TED talks from local life science companies.
- Biotechnology's Promise: Feeding, Fueling and Healing the World wraps up
 the week's program of election, policy and promising technologies, and discusses
 the impact of all on our member companies in terms of job growth and innovation.

Thank you to our current sponsors for supporting the Annual Meeting.

- Platinum: BIO, Bioventus, Cook Medical, and VWR, Part of Avantor
- Gold: FUJIFILM Disoynth and Grifols
- Silver: AdvaMed, Business Wire, G1 Therapeutics, GSK, Novozymes, The Conafay Group and UCB

If you are interested in sponsoring the Annual Meeting, please contact <u>Laura Gunter</u>, membership director.

MCBioImpact Training During COVID-19

Partners in the NCBioImpact training program have pivoted to offer online courses during this pandemic period when access to training facilities and companies is limited.

<u>BioNetwork</u>, the life science training initiative of the NC Community College System, has pivoted to <u>online and hybrid courses</u> with 10 colleges offering some form of this training. New courses have also been developed. BioNetwork now has a CGMP overview course, an FDA Audit Preparation training, a Disinfection, Sterilization and Containment course and more. <u>BioWork</u> is continuing at various institutions as an online course.

The North Carolina Pharmaceutical Services Network in Greenville resumed in-person training with COVID condition guidelines in place.

BTEC at NC State University has an online course called <u>Fundamentals of Biomanufacturing</u> that has become quite popular over the last several months. Faculty are working on putting together a number of other online courses for professionals, and NCBIO will post in upcoming newsletters and on web site when they are ready. <u>BRITE at NC Central University</u> is in the planning stages of professional online courses.

Back to top.

⁻ Report Shows Life Science Industry Remains Strong in RTP



COVID-19 has impacted the industry sectors in the Triangle Region in varying degrees according to the latest skills analysis by RTI for the Raleigh Chamber, Wake County Economic Development, Capital Area Workforce Development, and the City of Raleigh. NCBIO sent emails to members encouraging participation in the analysis.

The life sciences, technology and manufacturing were leaders in planning to grow the workforce in the next three years according to the survey. Information was released during the Wake County Economic Development Summit series. You can find out more from a blog recapping the presentation written by Mike Hogan, research economist with RTI International. A recording of the entire presentation is available.

Back to top.

At the National Level

National Report Focuses on Need to Maintain US Biopharma Competitiveness

A report from the Information Technology & Innovation Foundation outlines the important of the US maintaining its leadership in the biopharma industry. Key points are:

The biopharmaceutical industry makes important contributions to the U.S. economy,

- including employing over 500,000 workers making 1.4 times the U.S. earnings average.
- The United States leads the world on most indices of R&D investment and innovation. From 2004 to 2018, U.S.-headquartered firms produced almost twice as many new drugs as did firms in Europe, and 3 to 4 times as many as Japan.
- Despite U.S. strengths in biopharmaceutical R&D and innovation, manufacturing has dropped. From 2009 to 2018, real value-added output in pharmaceutical and medicines manufacturing fell by nearly one-third.

Click to read the report.

National Public Health Campaign Designed to Mobilize Support of Vaccines

The <u>Public Goods Project</u> (PGP), a public health nonprofit responsible for some of the nation's most successful health campaigns, announced the launch of <u>STRONGER</u>, a first-of-its-kind national advocacy campaign against misinformation and for vaccines. While previous campaigns have focused on educating the public, STRONGER focuses on actively mobilizing the vast majority of Americans who know vaccines are safe and effective. <u>More</u> BIO is part of this campaign. <u>More</u>

Fund to Tackle Superbugs

More than 20 leading biopharmaceutical companies announced the creation of an estimated \$1 billion fund to help support the pipeline for new antibiotic treatments. The <u>AMR Action Fund</u> was launched as the threat of antimicrobial resistance, or AMR, continues to grow and claim more lives. <u>More</u>

BIO Offering Online Courses

Expand your drug manufacturing knowledge in just two weeks and gain unmatched industry insights with BIO Online Learning. Complete the Drug Manufacturing online course bundle to sharpen your skills on the manufacturing processes behind small molecule drugs and biologics - including therapeutic antibodies, cell therapies, and gene therapies. More

BIO Impact Virtual Ag & Environment Conference September 21-22

For 2020, the <u>BIO IMPACT Ag & Environment Conference</u> is now a comprehensive two-day digital education and business partnering event. This virtual gathering, hosted by the Biotechnology Innovation Organization, will bring together the global agriculture and environment biotech community.

Join BIO **September 21-22** for access to 1,000+ global thought-leaders, critical education, networking and business partnering to drive your business development through 2020. Learn more about the conference at bio.org/bioimpact.

NCBIO members get an exclusive 25% discount on the premiere BIO IMPACT Digital registration package. Contact Amber Niebauer to receive the discount form and gain access to a discounted rate of only \$300. You must opt-in by **August 14** to receive your unique discount code. Codes are non-transferable.

The Virtual MedTech Conference October 5-7



The <u>Virtual MedTech Conference</u> will feature a mix of live and on-demand content, available to all registrants right from their homes or offices. Expect the same high-quality education, world-class speakers and valuable business development in a dynamic and immersive virtual format. In addition, you have the unique opportunity to experience more of the conference with on demand content and partnering from Sept. 8 to Oct. 23, and livestreamed sessions taking place from October 5-9.

The Virtual MedTech Conference will offer MedTech Connect, the conference's networking platform for scheduling one-on-one meetings, enhanced this year so that meetings can take place virtually. MedTech Connect allows you to maximize your participation during The Virtual MedTech Conference by helping you find key stakeholders to request meetings with. Once meetings are accepted, the

system allows you to self-schedule virtual meetings using your preferred method, for example a video meeting platform or teleconference system. All meetings will take place during the week of October 5–9.

Register now through the partnership registration. NCBIO members get a 10% discount. Contact Amber Niebauer to get the code.

Back to top.

Member News

To be included in Member News, send information about your organization to Brenda Summers.

AgBiome announced a recent patent directed toward the Connate product line granted in the United States, further strengthening AgBiome's IP Protection around novel product offerings. More AgBiome also has announced the submission of Theia fungicide, its next product, to the EPA for review. Pending EPA registration, Theia will be the second biological fungicide that AgBiome has brought to market in the last three years. More

<u>Alexandria Real Estate Equities, Inc.</u> announced the winner of its inaugural \$100,000 AgTech Innovation Prize. The prize was awarded to TerMir Inc., a North Carolina—based agtech company pioneering an innovative and environmentally safe treatment for citrus greening disease—one of the most devastating citrus diseases in the world. <u>More</u>

<u>Baebies</u> was recently awarded a Phase IIB SBIR grant from the National Institutes of Health (NIH) for a project to develop a coagulation test panel utilizing very small volumes of blood with a rapid turn-around time. <u>More</u>

BD (Becton, Dickinson and Company) announced that the FDA granted Emergency Use Authorization (EUA) for a rapid, point-of-care, SARS-CoV-2 diagnostic test for use with its broadly available BD Veritor Plus System. More

Biogen and Eisai Co., Ltd. announced that Biogen has completed the submission of a Biologics License Application (BLA) to the FDA for the approval of aducanumab, an investigational treatment for Alzheimer's disease. If approved, aducanumab would become the first therapy to reduce the clinical decline of Alzheimer's disease and would also be the first therapy to demonstrate that removing amyloid beta resulted in better clinical outcomes. More

<u>Bioventus</u> is launching its SIGNAFUSE Bioactive Bone Graft in a new strip format. The strips consist of 55% bioglass by weight and have been shown to induce higher levels of osteoblast differentiation compared to other synthetic bone graft strips. <u>More</u>

Bluebird bio, Inc. has amended its existing co-promotion/co-development agreement with Bristol Myers Squibb (BMS) to enable the companies to focus their efforts on efficient commercialization of idecabtagene vicleucel (ide-cel; bb2121) in the U.S., the companies' lead investigational B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, currently in review with the FDA. Under the terms of the amended agreement, BMS will buy out its obligations to pay bluebird bio future ex-U.S. milestone and royalty payments for ide-cel and bb21217, the companies' second BCMA-directed CAR T immunotherapy, for a one-time upfront payment of \$200 million. More

<u>CSL Behring</u> announced that the first patient has been enrolled in its <u>Phase 2 study</u> to assess the safety and efficacy of CSL312 (garadacimab, Factor XIIa antagonist monoclonal antibody) to treat patients suffering from severe respiratory distress, a leading cause of death in patients with COVID-19 related pneumonia. <u>More</u>

<u>Cushman & Wakefield</u> has released <u>The Life Sciences: COVID-19 Report</u>, which explores the life science industry's unique position in the COVID-19 landscape. <u>More</u>

G1 Therapeutics, Inc. and Boehringer Ingelheim have entered into a co-promotion agreement for trilaciclib in the United States and Puerto Rico. Under the terms of the three-year agreement, G1 and Boehringer Ingelheim will collaborate on the commercialization of trilaciclib for its first potential indication in small cell lung cancer (SCLC), with the Boehringer Ingelheim oncology commercial team. More

GSK and Medicago announced a collaboration to develop and evaluate a COVID-19 candidate vaccine combining Medicago's recombinant Coronavirus Virus-Like Particles (CoVLP) with GSK's pandemic adjuvant system. CoVLPs mimic the structure of the virus responsible for COVID-19 disease, allowing them to be recognized by the immune system. More

<u>IQVIA</u> has announced its collaboration with <u>AstraZenica</u> to accelerate development of a potential new vaccine for COVID-19. This joint initiative is part of the U.S. government's recently announced Operation Warp Speed project. <u>More</u>

<u>Liquidia Technologies, Inc.</u> has closed on its previously announced underwritten public offering of 9,375,000 shares of its common stock at a public offering price of \$8.00, for total gross proceeds of \$75 million, before deducting underwriting discounts and commissions and expenses payable by Liquidia. <u>More</u>

<u>Pfizer Inc.</u> and BioNTech SE report that two of the companies' four investigational vaccine candidates from their BNT162 mRNA-based vaccine program (BNT162b1 and BNT162b2) being developed to help protect against SARS-CoV-2 (the virus that causes COVID-19), received Fast Track designation from the FDA. BNT162b1 and BNT162b2 are the two most advanced vaccine candidates in the BNT162 program currently being evaluated in ongoing Phase 1/2 clinical studies in the United States and Germany. <u>More</u>

PPD, Inc. has expanded its laboratory test portfolio by adding five new molecular, serology and functional assays designed expressly for COVID-19 vaccine and therapy development programs. These assays have been developed by PPD® Laboratories' bioanalytical, biomarker and vaccines sciences labs to run on multiple assay platforms and are compatible with high-throughput liquid handling so they can support large numbers of specimens, attributes that will be critical to the success of COVID-19 trials. More

Syneos Health® has signed a new three-year agreement with Pfizer Inc. to deliver global product development solutions to support Pfizer's portfolio. Under the terms of the agreement, Pfizer has the right to extend the term for up to an additional two years. Financial details of the agreement were not disclosed. More

Back to top.

POBIO Business Solutions



In 2019, BIO saved 4,300 companies nearly \$430 million through BIO Business Solutions® with volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more.

NCBIO members, you are eligible for BIO Business Solutions® volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more. 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 Bob Dearth or call 781-716-7555 with your choices and they will get you started. For all the latest news, promos, and event information, follow BIO Business Solutions® on LinkedIn!!



Boost Operational, Compliance, and Quality Efficiency and Streamline Auditing and Inspections

BIO's newest partner PSC Biotech provides discounts on electronic quality and inspection management software solutions that enable life science companies to efficiently deliver their products to regulated industries through: Adaptive Compliance Engine (ACE), ACE Essentials and AuditUtopia. Also, PSC Biotech provides customized solutions for computer systems validation (implementation, data migration, training, and development of custom features).

- 45 Day Free Trial of ACE and AuditUtopia.
- 15% Discount on ACETM, ACE Essentials, and AuditUtopia.
- 10% Discount on Computer System Validation (CSV) and Computer System Assurance (CSA) Services.
- BIO negotiated Master Services Agreement.

With questions or to schedule a demo, contact <u>Bob Dearth</u> or call 781-716-7555.

LEARN MORE

Back to top.



To view full calendar, click.

Learning and Adapting during COVID-19: Data for Cross-National Decision-Making

Thursday Jul 30, 2020

... read more

Café con NC

Wednesday Aug 5, 2020

... read more

The Art of Tech Transfer

Wednesday Aug 5, 2020

... read more

Mentor Monday with Amanda Elam, Founder of Galaxy Diagnostics

Monday Aug 17, 2020

... read more

The Art of Tech Transfer

Tuesday Aug 18, 2020

... read more

LaunchBio: Larger than Life Science

Thursday Sep 3, 2020

... read more

SBIR Road Tour Prep Course

Monday Sep 7, 2020

... read more

Three I's & Biosecurity Conference

Monday Sep 14, 2020 - Wednesday Sep 16, 2020

... read more

SBIR Road Tour - Durham

Monday Sep 14, 2020

... read more

NCBiotech Ag Tech Professional Forum

Wednesday Sep 16, 2020

... read more

IntraHealth International SwitchPoint 2020

Thursday Sep 17, 2020 - Friday Sep 18, 2020

... read more

MIRA: Machine-Learning & Informatics Research in Aging

Friday Sep 18, 2020

... read more

2020 BIO IMPACT Ag & Environment Conference

Monday Sep 21, 2020 - Tuesday Sep 22, 2020

... read more

BTEC Short Courses: Introduction to Design of Experiments (DoE) for Bioprocess Analysis and Optimization

Tuesday Sep 22, 2020 - Thursday Sep 24, 2020

... read more

NCBIO Annual Meeting 2020

Tuesday Sep 29, 2020 - Friday Oct 2, 2020

... read more

North Carolina Biosciences Organization © Copyright 2020

 $email: bsummers@ncbioscience.net phone: 919-281-8960 \ web: http://ncbioscience.net\\$

