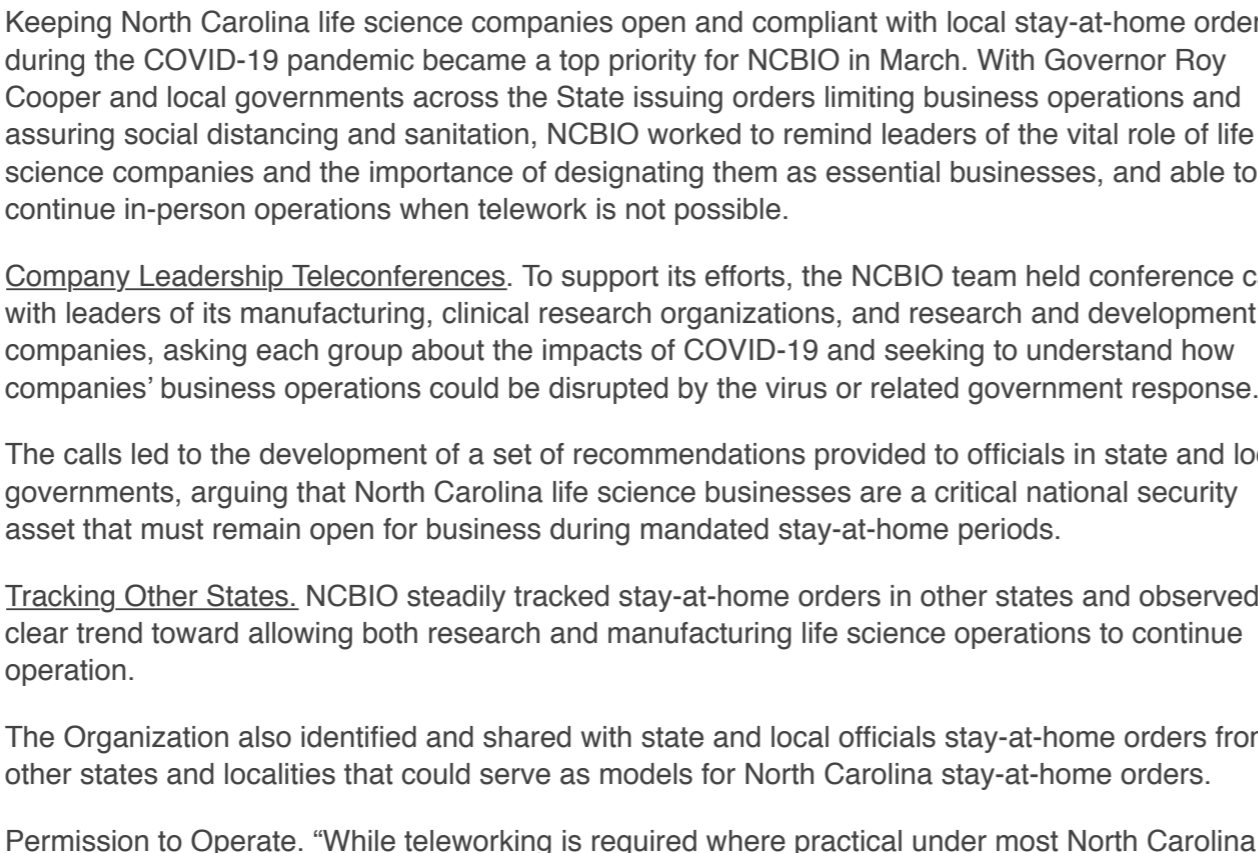


## NCBIO This Month

- NCBIO Monitoring Issues and Serving Members during Coronavirus Outbreak
- Legislative Life Caucus Tours Pfizer Facility
- NCBIO Legislative Reception Now June 3
- Leadership Development Focus of BMF Meeting

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

## NCBIO Monitoring Issues and Serving Members during Coronavirus Outbreak



Keeping North Carolina life science companies open and compliant with local stay-at-home orders during the COVID-19 pandemic became a top priority for NCBIO in March. With Governor Roy Cooper and local governments across the State issuing orders limiting business operations and assuring social distancing and sanitation, NCBIO worked to remind leaders of the vital role of life science companies and the importance of designating them as essential businesses, and able to continue in-person operations when telework is not possible.

**Company Leadership Teleconferences.** To support its efforts, the NCBIO team held conference calls with leaders of its manufacturing, clinical research organizations, and research and development companies, asking each group about the impacts of COVID-19 and seeking to understand how companies' business operations could be disrupted by the virus or related government response.

The calls led to the development of a set of recommendations provided to officials in state and local governments, arguing that North Carolina life science businesses are a critical national security asset that must remain open for business during mandated stay-at-home periods.

**Tracking Other States.** NCBIO steadily tracked stay-at-home orders in other states and observed a clear trend toward allowing both research and manufacturing life science operations to continue operation.

The organization also identified and shared with state and local officials stay-at-home orders from other states and localities that could serve as models for North Carolina stay-at-home orders.

**Permission to Operate.** "While teleworking is required where practical under most North Carolina stay-at-home orders, I am pleased that we know of no location in North Carolina where life science research and manufacturing businesses are required to cease on-premises operations," said NCBIO President Sam Taylor.

NCBIO is working particularly closely with Durham County to understand and assist our members in compliance with the County's stay-at-home orders. "We are grateful that Durham County's staff has been very transparent and helpful," said Taylor. The County has by far the most life science companies in the State.

**Value of Life Science.** "Life science manufacturing is essential to our nation's health care and food supply infrastructure," Taylor noted. "In addition, life science companies are working on research that will provide new therapies for people, along with ensuring that drugs, vaccines, and other products are available for the continued health of our citizens."

A number of our companies are providing testing and researching products for COVID-19. Having to deal with numerous government agencies is often confusing and challenging for companies, especially small research firms."

**COVID-19 Resources.** NCBIO has a COVID-19 resource [web page](#) for members that includes resources and ways to provide supplies and volunteer services. The North Carolina Biotechnology Center (NCBiotech) also has [information resources](#) available.

Please feel free to contact NCBIO assistant [Casey Nelson](#) about issues of concern to you, and she will send it to the appropriate staff member.

**National Partners.** At the national level, BIO has a dedicated [web site](#) explaining the industry's role in fighting the coronavirus.

BIO has also launched a [Coronavirus Hub](#) that connects entities that have relevant supplies, capacities, and resources to companies, researchers, or healthcare providers that need them.

**Federal COVID-19 Legislation.** BIO is reviewing the stimulus packages that have passed Congress and will continue updating information on its website. The third stimulus package provides a major small business loan program to help small companies keep the lights on and their employees working. The loans can ultimately be forgiven -- and thus become grants -- if companies meet relevant requirements.

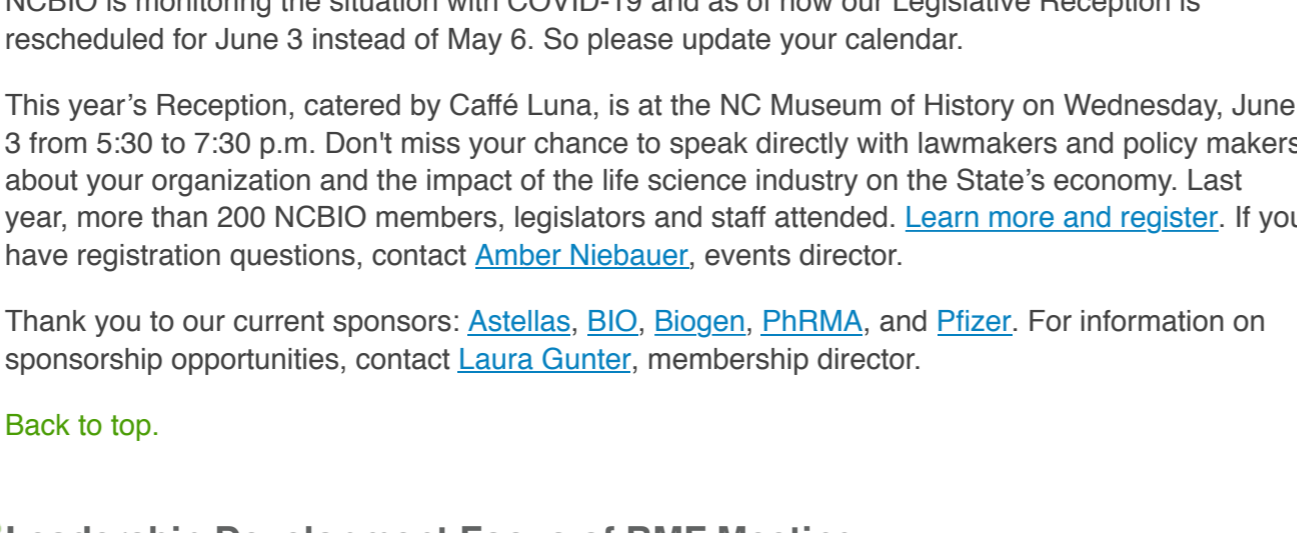
The bill also includes various tax relief mechanisms that will help ease the burden on our smaller companies in particular.

**New Drug Shortage Reporting Requirements.** In addition to its stimulus provisions, the bill contains new requirements to address drug shortages disclosure and risk planning. [A summary of these provisions is available here.](#)

BIO and PhRMA have teamed up to declare a [shared set of principles](#) to guide our industry during this crisis as we work together toward vaccines and cures.

[Back to top.](#)

## Legislative Life Science Caucus Tours Pfizer Facility



Melissa Bishop-Murphy (Pfizer), Sam Taylor (NCBIO), Rep. Terence Everitt, Rep. Joe Sam Queen, Rep. John Sauls, Rep. Robert Reeves, Sen. Paul Newton, Tony Mulcahy (Pfizer) and Allison Grams (Pfizer)

Members of the Life Science Caucus traveled to Sanford to visit the Pfizer vaccine and gene therapy facilities. Co-Chair Representative Robert Reeves (D-Chatham & Durham), who represents part of the area, noted the importance of continuing the growth in the industry, saying "results of our work are more than talking about policy, it's about jobs and families."

Co-Chairman Senator Paul Newton (R-Cabarrus) talked about the importance of reducing the franchise tax, so that companies can continue to grow and thrive. Dr. Robert Popovian of Pfizer discussed taxes, fees, Pharmacy Benefit Managers (PBMs) and other impacts on drug pricing.

Other lawmakers attending were Representative Terence Everitt (D-Wake), Representative Joe Sam Queen (D-Haywood, Jackson & Swain) and Representative John Sauls (F-Harnett & Lee).

Lawmakers got a first-hand look at vaccine manufacturing and received explanations of the process for manufacturing new gene therapies. "It is important for caucus members to have an understanding of gene therapies since our state has attracted so many of these new companies in recent years," said NCBIO President Sam Taylor. "We are excited to see the investment in new equipment and more training and new equipment for our education and training institutions so we can meet the needs for companies and continue to attract new industry."

[Back to top.](#)

## NCBIO Legislative Reception Now June 3



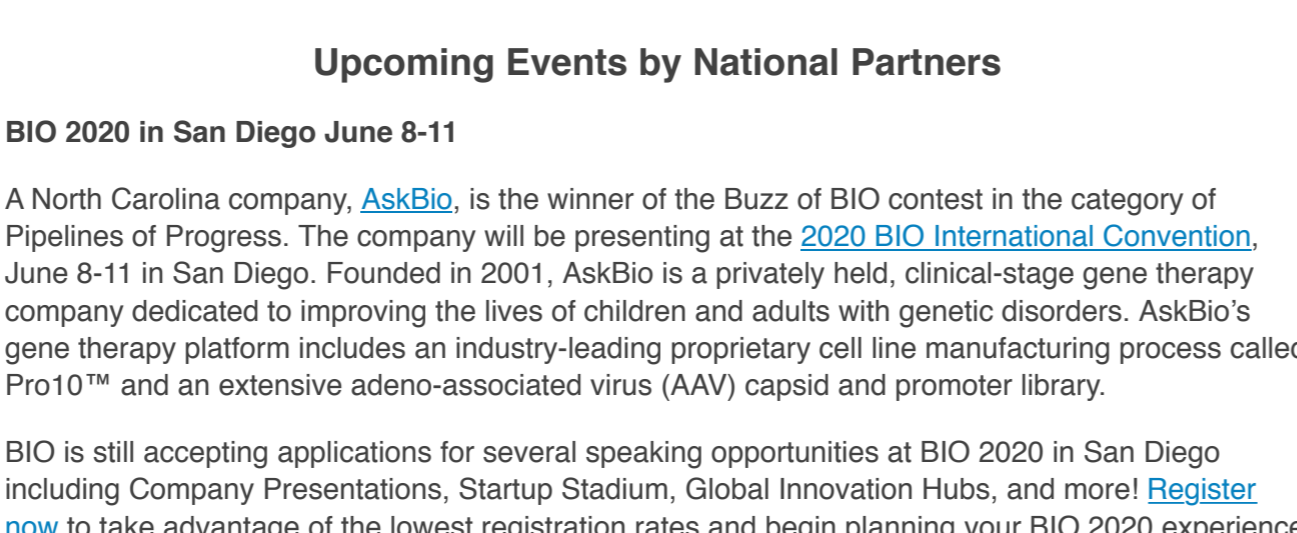
NCBIO is monitoring the situation with COVID-19 and as of now our Legislative Reception is rescheduled for June 3 instead of May 6. So please update your calendar.

This year's Reception, catered by Caffè Luna, is at the NC Museum of History on Wednesday, June 3 from 5:30 to 7:30 p.m. Don't miss your chance to speak directly with lawmakers and policy makers about your organization and the impact of the life science industry on the State's economy. Last year, more than 200 NCBIO members, legislators and staff attended. [Learn more and register.](#) If you have registration questions, contact [Amber Niebauer](#), events director.

Thank you to our current sponsors: [Astellas](#), [BIO](#), [Biogen](#), [PhRMA](#), and [Pfizer](#). For information on sponsorship opportunities, contact [Laura Gunter](#), membership director.

[Back to top.](#)

## Leadership Development Focus of BMF Meeting



Vinay Khanna, Darren Alfano and Jonathan Kegerise

Three NCBIO Biotech Manufacturers Forum (BMF) members shared leadership development strategies their sites use in growing and developing leaders. Darren Alfano says Novozymes has a "Lead the Way" process focusing on five core leadership skills: clarity direction and purpose, empower and follow up, assess and improve performance, coach and develop, and build collaborative teams. He noted that "high technical competency does not always equal great leadership" so having a solid plan to put the right people in the right positions is essential.

Jonathan Kegerise of Seqirus talked about the need to "build out a development tool kit and communicate frequently." He emphasized the importance of giving "your managers and leaders direction and support" so you attract, engage and retain employees.

Vinay Khanna with Merck Durham discussed the site's framework of a high-performance learning organization. The leadership strategy has three prongs; people skills, business skills and technical skills. He notes, "the system tracks progress and has process for providing coaching and feedback".

For more information about the NCBIO BMF, contact [John Wagner](#).

[Back to top.](#)

## At the National Level

### SEC Regulatory Changes Provide Small Biotech Companies Relief from Burdensome Requirements

The Securities and Exchange Commission (SEC) has adopted regulatory changes to provide small public companies with a temporary exemption from Sarbanes-Oxley 404(b) compliance. 404(b) requires public companies to report on the internal controls they have in place over their financial reporting. While well-intended, this regulatory requirement has proven to reduce market capitalizations, increase audit fees, force companies to exit public markets, and reduce R&D investments in pre-revenue startups that result in fewer inventions.

"Biotech companies across the country conduct their research without the certainty of a return on their investment, so they highly value resource efficiency," said Jim Greenwood, BIO's President and CEO. "Cost burdens like 404(b) can slow a company's progress in the lab and lengthen the amount of time it takes to deliver treatments for patients in need. I applaud the SEC for adopting a commonsense approach to ensuring less capital is going into unnecessary compliance and instead into lifesaving science."

Under the amendment, small public companies with public float of less than \$700 million that have annual revenues of less than \$100 million would be exempt from the 404(b) requirements. This regulatory obligation has been a longstanding burden for small biotechnology companies because of its extraordinary expense, their pre-revenue status, and the fact that it is of little use to their investors.

A similar proposal to the one adopted was championed by Senators Kyrsten Sinema and Thom Tillis of North Carolina and Representatives Trey Hollingsworth and Ben McAdams. Together, they have sponsored the Fostering Innovation Act (S. 452, H.R. 3986), a bipartisan bill that would provide for a 5-year extension of 404(b) exemption for qualifying public companies included in the 2012 JOBS Act.

### Share Your Experience with the FDA

BIO wants you to participate in BIO's survey tool on interactions with the Food & Drug Administration (FDA) during drug development.

BIO's real-time survey tool, [FDA/Sponsor Interactions During Drug Development](#), allows regulatory personnel at biopharmaceutical companies to quickly and easily provide feedback on their interactions with FDA during each phase of development for current, ongoing drug development programs.

All participants will receive exclusive access to reports, analysis, and webinars throughout the survey process. The survey will help BIO help you—by giving information to use when BIO advises the FDA on sponsor satisfaction levels, and help BIO make recommendations to FDA on how to improve responsiveness and communication with biopharmaceutical companies during all phases of the drug development process.

### Upcoming Events by National Partners

#### BIO 2020 in San Diego June 8-11

A North Carolina company, [AskBio](#), is the winner of the Buzz of BIO contest in the category of Pipelines of Progress. The company will be presenting at the [2020 BIO International Conference](#), June 8-11 in San Diego. Founded in 2001, AskBio is a privately held, clinical-stage gene therapy company dedicated to improving the lives of children and adults with genetic disorders. AskBio's gene therapy platform includes an industry-leading proprietary cell line manufacturing process called Pro10™ and an extensive adeno-associated virus (AAV) capsid and promoter library.

BIO is still accepting applications for several speaking opportunities at BIO 2020 in San Diego including Company Presentations, Startup Stadium, Global Innovation Hubs, and more! [Register now](#) to take advantage of the lowest registration rates and begin planning your BIO 2020 experience in San Diego, June 8-11.

BIO is partnering with OnPeak as the official, exclusive housing provider for the BIO International Convention in San Diego. OnPeak has several hotels near the San Diego Convention Center and your hotel reservations, personal data, and privacy are protected and secure. [Book housing.](#)

#### BIO IMPACT Ag & Environment Conference September 21-24

North Carolina is hosting the BIO IMPACT Ag & Environment Conference. The event will be held in Raleigh on September 21-24. This conference (formerly known as BIO World Congress) is centered on overcoming today's global challenges – and set forth towards a more sustainable future – by embracing the key role biotechnology plays in protecting our planet's resources, driving a strong economy and improving people's lives.

Join 1,000 leaders from all over the world for three days of education, networking and BIO One-on-One Partnering™. Learn more about the conference at [bio.org/impact](#).

Submissions for Company and Technical Presentations and Start-up Stadium will be reviewed on an ongoing basis. [Visit bioevents.hubb.me to submit your proposal!](#)

[Back to top.](#)

## Member News

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

**Astellis BioPharmaceutical, Inc.** (AskBio), announced the appointment of Tim Kelly, Ph.D., as President of Manufacturing. He will oversee all manufacturing functions at AskBio and its Viragen affiliate for the production of clinical- and commercial-scale AAV vectors. Prior to joining AskBio, Dr. Kelly was the President and Chief Executive Officer at KBI Biopharma. [More](#) AskBio has entered into a research collaboration and licensing agreement with the University of North Carolina at Chapel Hill (UNC) for the development and commercialization of gene therapy for Angelman syndrome. [More](#)

**BioDelivery Sciences International, Inc.** has appointed Jeffrey A. Bailey to its Board of Directors. Mr. Bailey brings more than 30 years of leadership experience building and leading high-quality pharmaceutical businesses across a diverse variety of important disciplines relevant to the continued growth and evolution of BDSI. [More](#)

**Biogen Inc.** announced that the Biogen Foundation has committed \$10 million to support global response efforts and communities around the world impacted by the COVID-19 pandemic. The funds will be used to address immediate critical needs, with the majority of donations going to support non-profit organizations in the U.S., including Massachusetts and North Carolina, in Italy and in other impacted countries worldwide. [More](#) Biogen Inc. and Sangamo Therapeutics, Inc. have executed a global licensing collaboration agreement to develop and commercialize ST-501 for tauopathies including Alzheimer's disease, ST-502 for synucleinopathies including Parkinson's disease, a third undisclosed neuromuscular disease target, and up to nine additional undisclosed neurological disease targets. [More](#)

**Chiesi U.S.A. Inc.** contributed more than \$980,000 in 2019 through its Chiesi in the Community corporate social responsibility (CSR) program, marking an increase of \$132,000 from donations in 2018. As an employee-led program, more than 150 Chiesi employees supported 121 unique charitable organizations with 2,400 hours of time throughout 2019. [More](#) Chiesi U.S.A. Inc. has been named as a Top Employer in the United States for the fifth consecutive year. The recognition is certified by the Top Employers Institute, a leading authority on identifying and measuring employment best practices worldwide. [More](#)

**CureDuchenne**, the leading global nonprofit focused on funding and finding a cure for the Duchenne muscular dystrophy, is rolling out a comprehensive suite of online resources for the Duchenne community. [More](#) CureDuchenne has announced a new partnership with Dyme Therapeutics, an innovative organization whose FORCE™ Platform is working to bring transformational therapies for serious muscle diseases, including Duchenne. [More](#)

**Eva Garland Consulting** is creating and maintaining a single point of reference list of funding opportunities that have been released to support researchers' efforts to combat the COVID-19 pandemic. Click here to view the updated list: [COVID-19 Response Funding Opportunities](#)

**FUJIFILM Diosynth Biotechnologies (FDB)**, announced that Steve Bagshaw, CEO of FDB, is retiring. Martin Meeson has been appointed by the FDB Executive Committee to succeed Steve Bagshaw as chief executive officer. Presently Meeson serves as president & chief operating officer of FUJIFILM Diosynth Biotechnologies, U.S.A., Inc. [More](#) FUJIFILM Diosynth Biotechnologies also announced the appointment of Christine Vannais as Chief Operating Officer (COO) of its North Carolina site, effective April 1, 2020. In this role, Vannais will be leading all aspects of FDB's North Carolina Operations. [More](#)

**G1 Therapeutics, Inc.** announced the appointments of Jack Bailey to its Board of Directors and Soma Gupta as its Chief Commercial Officer (CCO). "We are pleased to welcome Jack and Soma, and their breadth of commercial experience, as we work toward the approval of Iriliciclib in small cell lung cancer," said Mark Welleska, B.D., Ph.D., Chief Executive Officer. "We are on track to submit an NDA for Iriliciclib next quarter and are excited about its potential to improve outcomes for cancer patients treated with chemotherapy." [More](#)

**Grifols** announced that it has entered into a formal collaboration with BARDA, FDA, and other federal public health agencies to collect plasma from convalescent COVID-19 patients, process this specific plasma into a hyperimmune globulin and support the necessary preclinical and clinical studies to determine if anti-SARS-CoV-2 hyperimmune globulin therapy can successfully be used to treat COVID-19 disease. [More](#)

**Heat Biologics, Inc.** reported that it is collaborating with the University of Miami to develop a proprietary UM COVID-19 point-of-care diagnostic test. The new, patient-friendly test will require a simple pharyngeal throat swab to deliver on-the-spot results on a paper strip in under 30 minutes. [More](#)

Ron Lattanzio, CEO of **Luperto Dynamics**, believe esthered there should be better quality control with nuclear medicine injections, such as those administered for PET/CT scans. [More](#)

**Medicago** announced that the company has successfully produced a Virus-Like Particle (VLP) of the coronavirus just 20 days after obtaining the SARS-CoV-2 (virus causing the COVID-19 disease) under. Production of the VLP is the first step in developing a vaccine for COVID-19 which will now undergo preclinical testing for safety and efficacy. [More](#)

**PPD, Inc.** has been named by IDG's CIO as a 2020 CIO 100 Awarded honoree for developing a data-visualization platform enabling PPD to more quickly visualize targeted patient populations and investigator sites conducting clinical trials for pharmaceutical and biotech customers, helping speed the development of life-changing medicines. [More](#)

**Seqirus** announced that the FDA has approved the first quadrivalent adjuvanted influenza vaccine, FLUAD® Quadrivalent (Influenza Vaccine, Adjuvanted), to help protect adults 65 years and older against seasonal influenza. "Adults 65 years and older are at high risk for influenza-related complications each season and it is important to have influenza vaccines to help protect this vulnerable population," said Anjana Narain, Executive Vice President and General Manager at Seqirus.

[Back to top.](#)

## BIO 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! 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 [gave@bio.org](mailto:gave@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!](#)

BIO Business Solutions and its partners are offering a number of special benefits for those who are working from home. [Click here.](#)



**BREX**, the corporate credit card that members can secure through BIO Business Solutions, has a number of blogs that can inform members about funding, investors and fundamentals for startups. [Click here](#) to access blogs.

## ABOUT BIO BUSINESS SOLUTIONS

BIO Business Solutions is the largest cost savings purchasing program for the biotech industry, operated by the Biotechnology Innovation Organization (BIO). BIO leverages the purchasing power of the industry to negotiate with top suppliers to secure exceptional savings, favorable terms, and superior service for members. BIO Members can participate for no charge as a benefit of their membership and to save on items they need to run a successful biotechnology enterprise.

[Back to top.](#)

## Calendar

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

### NCBiotech Ag Tech Professional Forum

Thursday May 14, 2020  
... [read more](#)

### Southeast MedTech Forum

Tuesday May 19, 2020 - Wednesday May 20, 2020  
... [read more](#)

### BTEC Short Courses: Fermentation Engineering

Tuesday Jun 2, 2020 - Thursday Jun 4, 2020  
... [read more](#)

### LaunchBio: Larger than Life Science

Thursday Jun 4, 2020  
... [read more](#)

### BIO International Conference 2020

Monday Jun 8, 2020 - Thursday Jun 11, 2020  
... [read more](#)

### BTEC Short Courses: Hands-On cGMP Biomanufacturing of Vectors of Gene Therapy

Monday Jun 8, 2020 - Thursday Jun 11, 2020  
... [read more](#)

### Duke University's Population Health Summer Institute

Monday Jun 8, 2020 - Thursday Jun 11, 2020  
... [read more](#)

### Duke University's Population Health Summer Institute

Monday Jun 15, 2020 - Thursday Jun 18, 2020  
... [read more](#)

### BTEC Short Courses: Downstream Biopharmaceutical Processes-Fundamentals and Design

Tuesday Jun 16, 2020 - Thursday Jun 18, 2020  
... [read more](#)