



## August 2022 Update

Serving the NC Life Sciences Industry

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## NCBIO This Month

- [Act to oppose government price setting for drugs!](#)
- Lab Space Forum covers options for expanding
- Legislature's short session ends
- Back to start on PDUFA
- NC delegation unified in attracting ARPA-H
- BIO releases new DEI report
- Register for Aug. 31 Legislative Forum and Oct. 12 Annual Meeting

... and more

## TAKE ACTION! Tell Congress to oppose government price setting and support innovation for patients

Lawmakers in Washington are finalizing a reconciliation bill that will devastate America's innovative biopharmaceutical industry ? dealing a \$300 billion dollar blow to the sector that has saved millions of lives and is working tirelessly to end the global COVID-19 pandemic.

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Efforts by Congress to impose government price setting in Medicare will result in fewer research and development dollars going toward groundbreaking treatments for patients with life-limiting and fatal conditions.

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Even worse, the proposed legislation will likely lead to the loss of over 590,000 jobs across the country ? dealing a crippling blow to our economy and to families everywhere. In North Carolina, this means a direct biopharma job loss of **almost 6,600 jobs** ? a disastrous toll to our economy.

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This policy will chill future investment in next-generation cures for patients in need. Tell Congress to oppose government price setting on American biopharmaceutical innovation.

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**Use the button below to contact your elected officials via email and tell them that government price setting harms innovation. Add your personal story, which will help get your representative's attention. It's also important to use your home address; being a constituent of the representative is powerful in the conversation.**

**ACT NOW!**

## NCBIO Sustaining Members



## NCBIO Supporting Members



GRAIL





## STATE UPDATES

### General Assembly brings short sessions to close

The NC General Assembly finished its work in early July and adjourned. Here's a look at what was and wasn't accomplished in this short session.

The biosimilars sunset provision was repealed, which reinstated a communication requirement for pharmacists to inform physicians when they substitute an interchangeable biosimilar for a prescribed biologic. In 2015, the General Assembly approved the use of biosimilars as substitutes for biologic treatments, and pharmacists were required to notify prescribing physicians if a substitution was made. That notification requirement came with a sunset provision that eventually nullified the communication requirement. NCBIO worked with a coalition of biologics and biosimilars manufacturers to encourage legislators to repeal the sunset provision, which reinstated the notification mandate. Pharmacists, providers and health plans were brought into the discussion to find common language all could support.

The NC Biotechnology Center received an additional \$500,000 recurring and \$1 million nonrecurring funds.

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The One NC Small Business Program, which provides matching dollars to companies who win SBIR and STTR grants, will have \$2 million in recurring funds for the 22-23 fiscal year.

Â This short session budget did not include any additional funding. In 2021 the legislature and governor enacted a two-year budget that included \$5 million in the first year for the One NC Small Business program, \$2 million of which was recurring and \$3 million was nonrecurring.

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There was no movement on the NC Qualified Business Venture Tax Credit this session. From 1989 to 2013, North Carolina's QBV program provided significant tax benefits for investments in certain types of businesses. Individual investors were entitled to a tax credit equal to 25% of the purchase price paid by the investor for the equity securities or subordinated debt of the Qualified Business. The maximum credit was \$50,000. NCBIO is working with a growing network of angel investors to advocate for the reauthorization for the Qualified Business Venture Tax Credit or a similar mechanisms for encouraging innovation across the state.



**NCBIO President Laura Gunter moderated a discussion July 27 on the role of science in policy making at the Sigma Xi Society's Science Policy Boot Camp. Life Science Caucus Co-chairs Sen. Paul Newton and Sen. Mike Woodard, along with Rep. Gale Adcock, comprised the panel.**







## NATIONAL UPDATES

### FDA user fee bill deadÂline falls apart? ThouÂsands of pink slips for FDA could be comÂing as Burr seeks to start anew

The batÂtle over what to inÂclude in this latÂest round of user fee legÂisÂlaÂtion ? the inÂdusÂtry money that pays for all bioÂpharÂma drug and biÂoÂlogÂic reÂviews at the FDA and has to be reauthoÂrized every five years ? is comÂing to a head as ConÂgress looks to meet an AuÂgust reÂcess deadÂline beÂfore the FDA has to send out thouÂsands of warnÂings to much-needed reviewÂers that they?ll be soon laid off.

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Not onÂly would the FDA be forced to send the pink slips, but all curÂrent PDUFA (and other UFAs, including medical devices and biologics) reviews would grind to a halt as the agency would no longer have the staff to meet its deadÂlines.

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SenÂate health comÂmitÂee rankÂing memÂber Sen. Richard Burr inÂtroÂduced a blank verÂsion of the user fee legÂisÂlaÂtion as an atÂtempt to start over withÂout any of the poliÂiÂcy ridÂers that made it out of the comÂmitÂee, like the acÂcelÂerÂatÂed apÂproval pathÂway changes that would alÂlow the FDA to reÂquire comÂpaÂnies to beÂgin postÂmarÂketÂing studÂies beÂfore grantÂiÂng the sped-up approvals.

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?UnÂforÂtuÂnateÂly, the user fee packÂage reÂportÂed out of comÂmitÂee would, if enÂactÂed, unÂderÂmine the very purÂpose of the user fee proÂgram,? Burr said in a stateÂment. ?The poliÂcies added to this bill enÂdanÂger the deÂvelÂopÂment of drugs for rare disÂeases, imÂperÂil inÂtelÂlecÂtuÂal propÂerÂty rights, threatÂen AmerÂiÂcans? acÂcess to breakÂthrough treatÂments and cures, and deÂter priÂvate secÂtor inÂnoÂvaÂtion. In efÂfect, this proÂposÂal would comÂproÂmise the FDA?s overÂall abilÂiÂty to keep pace with adÂvanceÂments in the inÂdusÂtry it regÂuÂlates.?

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[More @ Endpoints >>](#)

### BIO: New drug pricing deal could propel us "light years back into the dark ages of biomedical research"

Democratic lawmakers in the U.S. Senate advanced drug pricing legislation July 6 that would drastically alter the Medicare program. The drug pricing provisions would, among other things, empower the government to directly negotiate with pharmaceutical companies on the prices of select drugs.

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?The misguided legislation, which is largely similar to a proposal floated last year, includes risky medical price control tactics that will ultimately harm the very patients and seniors that lawmakers claim to be helping," said Michelle McMurry-Heath, M.D., Ph.D., president and CEO of the Biotechnology Innovation Organization.

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?As we?ve previously warned, ?negotiation? is simply a euphemism for a government takeover of a sector that, on its own, has been historically successful in saving millions of lives."

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The Incubate Coalition, an organization of venture capital firms representing the patient, corporate and investment communities, sent [a letter](#) to all Senate offices urging them to pursue reforms that protect R&D and more meaningfully reduce patient out-of-pocket costs.

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"As the voice for life science venture capital in the United States, Incubate appreciates the ongoing opportunity to work with you on health care policy. At a time when biopharmaceutical advancements are enabling us to cure disease, fight pandemics and even extend longevity, it is critical that policymakers enact legislation that not only supports the U.S.? robust ecosystem for research and development that makes life-changing medicines a reality but ensures that all Americans have equitable access to them.

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**That is why we are so disheartened to see the Senate considering a package that ignores those priorities and instead pursues political headlines at the cost of future therapies for patients."**

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Let Congress know that government price setting is a bad idea! [Click to email](#) your senators and representatives.

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[More @ BIO >>](#)

## North Carolina unified in attracting new ARPA-H headquarters to the state

Leaders from public and private universities, businesses, nonprofits, trade associations and state government have joined forces to bring the new Advanced Research Projects Agency for Health headquarters to North Carolina.

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ARPA-H recently received \$1 billion in inaugural funding from Congress to improve the U.S. government?s ability to speed biomedical and health research to prevent, detect and treat diseases like Alzheimer?s, diabetes and cancer.

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The ARPA-H in NC Coalition, facilitated by the North Carolina Biotechnology Center, is some 30 partners strong and growing. The Coalition is coordinating efforts locally and in Washington to demonstrate that, with this partnership, ARPA-H can have a rapid, effective start and accomplish its mission in the Tar Heel state. Each partner adds to the case that North Carolina has the expertise, record of entrepreneurial disruption, cross-sector collaboration and scientific innovations. North Carolina translates ideas from initial technology to discovery to development through manufacturing to prevent, treat and potentially cure a range of diseases.

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This statewide collaboration follows a recent bipartisan letter from members of North Carolina?s Congressional delegation led by Rep. David E. Price and both Sens. Richard Burr and Thom Tillis. The bipartisan members urge Xavier Becerra, secretary of the U.S. Department of Health and Human Services, to strongly consider North Carolina, with its unique assets, as the best location for launching ARPA-H?s success.Â

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[More @ NCBIO >>](#)

## EEOC updates COVID-19 testing guidance

On July 12, the Equal Employment Opportunity Commission updated its guidance and FAQ around COVID-19 testing and the Americans with Disabilities Act, the Rehabilitation Act and other EEO laws.

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While employers previously had broad latitude to screen workers for Covid-19, the new EEOC guidelines say employers must show testing procedures are both job related and consistent with business necessity. They'll also need to consider the trajectory of COVID-19 cases in their communities.

- Screening Employees: Before the update, an employer was legally permitted to require on-site COVID-19 viral screening testing. According to the new guidance, employers have to prove that testing employees is ?job related and consistent with business necessity.? Whether testing is a ?business necessity? can be based on several factors, including community transmission rates, employee vaccination status, and working conditions.
- Antibody Testing: Employers cannot require antibody tests before allowing employees to re-enter the workplace, as they do not reliably determine whether someone is currently infected or immune.Â
- Applicants: Employers may test applicants for COVID-19, after making a conditional job offer, so long as they are doing so consistently.Â
- Rescinding Job Offers: A job offer can only be rescinded if it is absolutely necessary that the employee start employment immediately and in-person. Current CDC guidelines should be evaluated prior to making this decision.Â

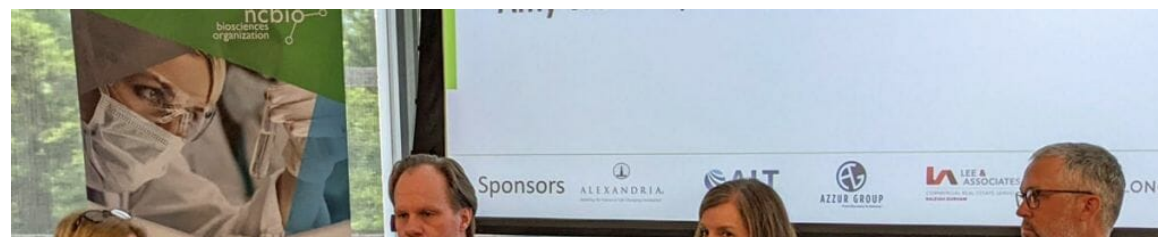
?[The new guidance] makes clear that, going forward, employers will need to assess whether current pandemic circumstances and individual workplace circumstances justify viral screening testing of employees to prevent workplace transmission of Covid-19,? the EEOC said in [the new guidelines](#).

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## NCBIO Updates

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### Lab Space Forum discusses tight supply, innovative solutions to lab space shortage





Strategies for meeting the booming demand for lab space in the Triangle and across North Carolina were shared and discussed by panelists from Azzur Group, Lee & Associates, Longfellow Real Estate Partners and Lincoln Harris at the NCBIO Lab Space Forum and Luncheon held Thursday, July 14, at the NC Biotechnology Center.Â

The event was sponsored by [Alexandria Real Estate Equities](#), [American Laboratory Trading](#), [Azzur Group](#), [Lee & Associates](#) and [Longfellow Real Estate Partners](#).Â

**Marlene Spritzer**, vice president of Lee & Associates, moderated a panel comprisingÂ

- **Greg Capps**, managing director, North Carolina, Longfellow Real Estate Partners;Â
- **Joel Gates**, senior director of operations, Azzur Group; and Â
- **Amy Watkins**, vice president, brokerage, Lincoln Harris.Â

[More >>](#)

## NCBIO welcomes news members

At the July 28 meeting of the NCBIO Board of Directors, the following companies were unanimously approved as new members of the organization:

- [Alacrity Medical Innovations](#) has helped medical innovators advance their vision on over 53 Class II and Class III devices since 2006.
- [Astellas Gene Therapies](#) is an Astellas Center of Excellence developing genetic medicines with the potential to deliver transformative value for patients.
- [Cell Culture Company](#) delivers whole cell pellets, cell lysates, custom monoclonal antibody and recombinant protein manufacturing services from development to commercialization.
- [Dovetail Consulting Group](#) is a boutique consulting firm providing compliance advisory services to pharmaceutical and biotech companies.Â
- [Frontier Scientific Solutions](#) is a new, more efficient, effective, and innovative supply chain solution for the life sciences and pharmaceuticals industry based in Wilmington.
- [NoviSystems](#) provides a bundled hardware/software solution for data fusion, self-service dashboards, NLP, and machine learning.
- [McDonald York Building Company](#) is one of the oldest and largest local, family-owned commercial general contracting companies in the Triangle and provides general contracting, construction management and design-build services.
- [Pathalys Pharma](#) is a private, late-stage clinical biopharmaceutical company committed to the development of multiple advanced therapeutics that address unmet needs in the management of late stage chronic kidney disease.
- [RS&H](#) offers award-winning architectural design services, engineering and consulting across a spectrum of industries.
- [Veloxis Pharmaceuticals](#) is a fully integrated specialty pharmaceutical company committed to improving the lives of transplant patients and focused on the global development and commercialization of medications used by transplant patients and by patients with serious related diseases.

## NCBIO Member News

*To be included in member news, send information about your organization to [David Etchison](#).*Â

**BioAgilytix** has secured the ISO 27001:2013 certification for its Information Security Management System, a seal of approval for the safety of its IT systems and processes. [More >>](#)Â

**Biogen** announced that the FDA has accepted a New Drug Application and granted priority review for tofersen, an investigational drug for superoxide dismutase 1 amyotrophic lateral sclerosis. [More >>](#)Â

**Chiesi** signed the U.S. Department of Health and Human Services Health Care Sector Climate Pledge, committing to reduce greenhouse gas emissions 50% byÂ 2030. [More >>](#)Â

**Eisai** and **Biogen** announced today that the FDA has accepted the Biologics License Application under the accelerated approval pathway for lecanemab, an investigational anti-



amyloid beta protofibril antibody for the treatment of mild cognitive impairment due to Alzheimer’s disease with confirmed presence of amyloid pathology in the brain. [More >>](#)

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**G1 Therapeutics** has appointed Norman E. “Ned” Sharpless, M.D., to its Board of Directors. Sharpless is an accomplished oncologist who has led academic institutions and government agencies, including most recently serving as Director of the National Cancer Institute. [More >>](#)

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**G1 Therapeutics** announced that the China National Medical Products Administration has conditionally approved COSELA (trilaciclib hydrochloride for injection), which was jointly developed for use in Greater China by Simcere and G1 Therapeutics. [More >>](#)

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**IQVIA** was named a Leader in the IDC MarketScape: Worldwide Life Science Sales and Marketing IT Outsourcing Services 2022 Vendor Assessment. [More >>](#)

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**Kymanox** named Izi Bruker, Ph.D., has been named as the first Fellow of Kymanox, an honor reserved for professionals who are at the very pinnacle in their field and who are regarded as one of the most advanced subject matter experts amongst peers. [More >>](#)

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**Mycovia** announced U.S. availability of VIVJOA (oteseconazole) capsules, an azole antifungal indicated to reduce the incidence of recurrent vulvovaginal candidiasis in females with a history of RVVC who are not of reproductive potential. [More >>](#)

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**NALA Membranes** successfully closed a \$1.5 million investment round to support commercialization of a new generation of chlorine resistant membranes for reverse osmosis applications. [More >>](#)

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**Womble Bond Dickinson** is opening an office in San Francisco through a combination with Cooper, White & Cooper LLP, a multipractice firm with more than a century of experience providing comprehensive representation to clients in the Bay Area and across the country. [More >>](#)

## BIO DEI report finds improvements in gender parity; more progress needed in racial and ethnicity representation

BIO [released its third annual report](#) that examines diversity, equity, and inclusion in the biotechnology industry. The report, “Measuring Diversity in the Biotech Industry: Tracking Progress in Small and Large Companies,” investigates the state of DEI in the biotechnology industry and includes representation data, current DEI approaches and initiatives, and data comparisons to previous reports.

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 At the responding companies, women now make up 49% of employees, compared to 47% in 2020 and 45% in 2019, but 34% of executive teams and 20% of CEOs. Employees of color make up 38% of all employees compared to 24% of executive teams and 28% of CEOs. The survey found meaningful growth in some companies – more than 4 in 10 increased representation of executives of color by more than 5%.

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 Other key findings:

- Most organizations (nearly 80%) indicate that attracting, recruiting, and promoting diverse talent are priorities of their DEI programs.
- Small and large organizations differ significantly in the establishment of their HR and DEI functions. While large organization respondents all have established HR functions (100%) and the vast majority also have DEI programming (86%), half of small organizations have HR staff (50%), and only a few have DEI programming (18%).
- Small organizations have opportunities to increase their commitment to DEI. Four out of 10 small companies have a stated goal to create an inclusive environment and 37% have a public commitment to diversity.
- Large companies set DEI commitments, but could improve accountability. Only 15% of large organizations consider workforce diversity in leadership evaluations, and DEI metrics impact performance evaluations and/or compensation for leaders in only 23% of large organizations.
- Large companies should focus on sustaining and growing existing DEI efforts. For example, only 32% of large employers require diverse pools of candidates for senior positions and only 28% have sponsorship programs.
- Small organizations should focus on prioritized DEI initiatives and setting up Employee Resource Groups. Fewer than one out of 10 small organizations have ERGs compared to almost 80% large organizations.

Get the BIO report and many other DEI resources at [ncbioscience.net/dei](https://ncbioscience.net/dei).

## Events

NCBIO Legislative Luncheon and Forum Aug. 31

Hear from the NC Legislative Life Sciences Caucus co-chairs in a session moderated by NCBIO President Laura Gunter and NCBIO Consultant Joe Lanier of Milestone Strategies. This is an outstanding opportunity to visit with Caucus leadership and discuss the state of our industry.

- Sen. Paul Newton
- Sen. Mike Woodard
- Rep. Donna White
- Rep. Robert Reives

The Caucus co-chairs will provide a wrap up of recent legislative activity with a focus on ongoing economic development initiatives. Additional topics may include discussion of regulatory issues, the One NC Small Business Fund, workforce development, science and technology education and more.

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This is your time to help educate and create champions for the life sciences industry. Please bring your questions to the forum and be prepared to interact with Caucus leadership. Thank you to [Ultragenyx](#) for sponsoring this forum. If you are interested in sponsorship, please contact Membership Director [Natacha Janvier](#) for more information.

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**At this time, registration is limited to active members. Courtesy members may register but will be notified of their status and added to a wait list.**

### REGISTER NOW

## Register now for NCBIO Annual Meeting Oct. 12

Join us in person for our Annual Meeting on Wednesday, Oct. 12, at the NC Biotechnology Center in Research Triangle Park. The Annual Meeting program features multiple networking opportunities, a keynote address and three panels.

- Success Stories: Talent Recruitment and Retention highlights Aperio Clinical Outcomes, Novozymes and StrideBio
- Financial Trends and Outlook with GSK, Incubate Coalition, JPMorgan, Pappas Capital and Solas Bioventures
- Health Equity and Disparity features Biogen, BIO, ECU's Center for Health Disparities, the Global Liver Institute and mdgroup

You will not want to miss this year's programming and networking opportunities. Thank you to our current sponsors.

- Platinum: [Avantor delivered by VWR](#); [Bioventus](#), [Cook Medical](#), [Kymanox](#)
- Gold: [American Laboratory Trading](#), [Azzur Group](#), [FUJIFILM Diosynth Biotechnologies](#), [Grifols](#), [Novo Nordisk](#), [PSC Biotech](#)
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- Bronze: [Nikon](#), [Novozymes](#), [PHC Corporation](#)

### LEARN MORE



## The Right Exposure. The Biggest Impact. Welcome to Start-Up Stadium.

By participating in BIO Impact's Start-up Stadium at the Ag & Environment Conference Sept. 19-21 in Omaha, you'll share your work with investors and get discounted registration fees and complimentary access to BIO One-on-One Partnering. Be sure and register before August 11 to take advantage of BIO's early bird rates! Â

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Who can participate? Companies that have:

- Raised less than \$10 million since inception
- Previous business pitch or competition experience
- Fewer than 20 full-time employees
- Not previously been named a BIO Start-Up Stadium winner

Participation in Startup Stadium offers countless benefits:Â

- Connect with capital: Engage with key members of the investment community, venture philanthropy groups, strategic partners and nondilutive capital at the world?s largest biotechnology event.
- Network strategically: Meet with state and regional affiliates, as well as early-stage companies at the beginning of their life cycle.
- Gain expert feedback: During BIO Impact, investor judges will attend start-up presentations and do live Q&As with start-up finalists.

**APPLY NOW**



# AZZUR GROUP

From Discovery To Delivery™

## Azzur Group offers training for working in cleanrooms

The Azzur Training Center offers training that spans GxP concepts but specializes in the aseptic manufacturing space that will allow you to start, scale and sustain your GxP organization. Upcoming courses offered in August at Azzur's Cary location are

- Aug. 16, cGMP Boot Camp
- Aug. 17, Aseptic cGMP Boot Camp
- Aug. 18, Investigation Boot Camp

**LEARN MORE**

## NCBio calendar

- Fermentation Engineering hosted by BTEC (8/2/2022 to 8/4/2022)
- Biopharmaceutical Lyophilization and Spray Drying hosted by BTEC (8/2/2022 to 8/5/2022)
- Hands-On cGMP Biomanufacturing of Vectors for Gene Therapy hosted by BTEC (8/8/2022 to 8/11/2022)
- Leadership Summit hosted by NC TECH (8/10/2022 to 8/11/2022)
- Summer Bash at Boxyard hosted by WIB-RTP (8/24/2022)
- How Data Science is Revolutionizing the Agriculture Industry hosted by LaunchBio (8/25/2022)
- NCBio Legislative Luncheon and Forum (8/31/2022)

## BIO Business Solutions and other opportunities

Improved UPS Healthcare shipping benefits for NCBio members





One driver/pickup  
for air & ground

Local healthcare  
expertise &  
resources

Healthcare risk  
mitigation products  
& specialty handling

UPS Healthcare brings reliability, scalability and security to life science companies every day. Its portfolio of end-to-end services is well-suited to meet today's complex logistics demands for the pharmaceutical, medical device, and laboratory diagnostic industries. Learn exactly how from [UPS Healthcare](#).

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Through NCBIO's partnership with UPS Healthcare, you get access to exclusive rates on a full suite of UPS services. And after recent renegotiations, the savings have gotten even better. While the same popular shipping services, like UPS Next Day Air, and UPS Worldwide Express, remain at reduced rates, the price band range to qualify for discounts is narrower. For example, a company that spends \$1,500 to \$4,999.99 weekly for UPS Next Day Air shipping now receives a 60% discount rather than a 50-55% discount under the previous arrangement.

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As an NCBIO member, be confident that your critical healthcare shipments will be delivered timely and with care by a quality-focused and patient-driven organization.

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NCBIO members save up to

- 74% on UPS Next Day Air,
- 59% on UPS 2nd Day Air and UPS 3 Day Select Services,
- 51% on UPS Ground Commercial Services, and
- 68% on UPS Worldwide International Services.


[LEARN MORE](#)

## BASF auction to offer research equipment, consumables

BASF is auctioning off lab equipment and consumables from its RTP site. The online bidding will run from Aug. 26 to 30. You can view the items available and register to bid [here](#).




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