



August 2023 Update
Serving the NC Life Sciences Industry

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NCBIO This Month



Lab Space Forum draws crowd

The full house attending the NCBIO Lab Space Forum held July 13 at the NC Biotechnology Center got a look into the present and future of real estate in Research Triangle Park.Â

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Carolyn Coia, vice president, real estate for the Research Triangle Foundation, reviewed the history of RTP and moderated a panel that discussed the current state of space in the Park, changing demands and future plans for the area, which include a greater focus on housing and amenities. The panelists were

- **Ashley Ingram**, vice president at Jones Lang LaSalle;
- **Chase Kerley**, managing director of life sciences for Crescent Communities;
- **Alvaro Quintana**, associate principal and project designer with Flad Architects; and
- **Nathan Swiggett**, project director for McDonald York Building Company.

The forum was sponsored by [Clancy & Theys Construction Company](#), [CSC Leasing](#),Â [Facility Logix](#),Â [Medical Moving Solutions](#)Â and [PSC Biotech](#).Â



NCBIO Sustaining Members



NCBIO Supporting Members





STATE UPDATES

North Carolina ranks No. 1 for business

For the second year in a row, North Carolina was ranked No. 1 for business in CNBC's annual America's Top States for Business rankings.Â

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North Carolina's top strengths are workforce, economy, education and technology and innovation, according to CNBC. The state is weakest in the area of life, health and inclusion.

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CNBC noted that holding the top spot in the ranking consecutively is rare and that North Carolina has "amassed a trophy case full of economic development wins." [More at CNBC >>](#)

State budget negotiations drag on

Despite early hopes that the budget process would conclude by the end of the fiscal year on June 30, North Carolina is once again mired in lengthy negotiations over its biennial state budget.Â

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Top budget writers said that a budget deal will likely not be reached until mid-August. The House and Senate are still trying to agree on issues such as tax cuts, spending priorities and gaming expansion. The General Assembly is on break until Aug. 7.

Cooper sets Medicaid expansion date, pressuring legislators to act

Gov. Roy Cooper announced that the state will expand Medicaid on Oct. 1, even though lawmakers have not yet approved the funding.

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The Biden administration has agreed to the state's plan, which gives lawmakers until Sept. 1 to fund the proposal. If lawmakers miss the deadline, Medicaid expansion would be delayed until Dec. 1. More than 600,000 people are expected to be eligible for Medicaid expansion in North Carolina.

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Republican lawmakers have shown no signs of budging on their position of tying Medicaid expansion to the state budget.

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Cooper's announcement comes after 9,000 people who would have been eligible for health coverage under expansion were dropped from Medicaid.

Woodard to run for Durham mayor

Sen. Mike Woodard, co-chair of the General Assembly's Life Sciences Caucus, filed to run for mayor of Durham. The election will be held in November following October's primary election.

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Woodard does not need to give up his current Senate seat to run for the position and has said he will continue to serve in the legislature during his mayoral campaign. Woodard has served 11 years in the legislature and could file for re-election if he does not win the mayoral race. His Senate term runs through the end of 2024. [More at Associated Press >>](#)

Community colleges choose new leaders

The State Board of Community Colleges met July 21 and elected new board members. It was the first in-person meeting with Jeff Cox, Ed.D., the new president for the NC Community College System, at the helm.

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Thomas Looney, a retired senior executive at IBM and Lenovo, was unanimously elected as the new board chair. Looney said he hoped to strengthen partnerships between business and industry and make it a priority for North Carolina's community colleges to no longer be known as the state's best kept secret.

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The board also unanimously elected Grant Campbell, M.D., as the new vice chair. Campbell was appointed to the board in June 2022 after having stepped in to fill the unexpired term of former member Lee Barnes. The chair and vice chair serve for two years.Â

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Ann Whitford, Chaz Beasley and Ray Russell, Ph.D., were all reappointed to the board. Tony

Ann Whitford, Chaz Deasley and Ray Russell, Ph.D., were all reappointed to the board. Tony Pile, the student government representative, was also sworn in.

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Board members Wade Bryan "Bobby" Irwin Jr. and Burr Sullivan's terms expired at the end of June. Irwin and Sullivan will remain on the board until their seats are filled.

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The Board voted to hire Brian Merritt, Ph.D., as the system's new chief academic officer with a proposed start date of Sept. 1. Merritt currently serves as the president of McDowell Technical Community College.

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In addition, Phillip Price has been selected as the system's new vice president and chief financial officer. Price was the executive vice president and CFO at Central Carolina Community College in Sanford.

Â [More at EdNC >>](#)



NATIONAL UPDATES

If there are any topics or issues that are affecting your business or you want to know more about, please contact [Laura Gunter](#).

FTC increases scrutiny of PBMs

The Federal Trade Commission voted July 20 to disavow its previous guidance opposing transparency requirements for pharmacy benefit managers.

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The FTC is currently investigating PBMs and their role in rising drug prices. The agency's decision to disavow its previous guidance is a sign that the agency is taking a more critical look at PBMs and their practices.

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PBMs are companies that run drug benefit programs for health insurers. They negotiate discounts with drugmakers and decide which medicines insurance plans will cover. PBMs have been accused of using their market power to drive up drug prices.

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The FTC's investigation into PBMs is part of a broader effort by lawmakers and regulators to address the cost of prescription drugs. Lawmakers on both sides of the aisle are considering legislation that would regulate PBMs.

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The pharmaceutical industry has accused PBMs of preferring to cover higher-cost drugs so they can get higher rebates. PBMs deny these accusations.

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The FTC's decision to disavow its previous guidance should help lawmakers and regulators to better understand how PBMs operate.

Senate Finance Committee advances bill to require more PBM transparency

The Senate Finance Committee has approved a package of legislation July 26 that would bring more transparency to the practices of pharmacy benefit managers.

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The bill would require PBMs to report drug price data to Part D plans and to the Department of Health and Human Services annually and would ban a practice known as spread pricing, in which PBMs charge plans more for a drug than they reimburse pharmacies for dispensing it.

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The bill was approved on a bipartisan vote of 26-1, with Sen. Ron Johnson (R-Wis.) as the lone "no" vote. The Congressional Budget Office estimated the bill would reduce net government spending by \$1.7 billion from fiscal 2023 through fiscal 2033.

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The bill would also require payments to PBMs to be for a "bona fide service fee" that is not linked to a drug list price. Rebates, discounts and price concessions that result in a lower net cost for covered Part D drugs would still be allowed. The legislation also directs the HHS

inspector general to study the impact on patient out-of-pocket costs and Medicare Part D spending when insurers, PBMs and pharmacies own each other.

PAHPA legislation moves forward in Senate and House

Versions of legislation reauthorizing the Pandemic All Hazards and Preparedness Act were approved by a House committee on July 19 and a Senate committee on July 20.

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PAHPA establishes measures to prepare for future pandemics and “allows us to be ready for other kinds of biothreats and public health emergencies,” according to Phyllis Arthur, SVP of Infectious Disease and Emerging Science at the Biotechnology Innovation Organization.

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The legislation passed by the committees now awaits action by the full House and Senate to be followed by reconciliation of the two versions and final congressional approval. The current PAHPA’s five-year term expires Sept. 30, and it must be reauthorized by that date.

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In a July 20 executive session, the Senate Health, Education, Labor and Pensions Committee gave bipartisan approval to a proposal for PAHPA reauthorization. The version that ultimately passed the Senate committee did not include a proposed “reasonable pricing” clause, which would have controlled the prices of innovations developed through PAHPA and was opposed by BIO. [More at BIO >>](#)

Senate committee wants HHS funding well above House levels

The Senate Appropriations Committee has approved a \$224.4 billion spending bill that includes funding for the Department of Health and Human Services well above that approved by House appropriators.

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The Senate bill would give HHS \$117 billion in fiscal 2024, in line with 2023 levels. This is significantly higher than the \$103.3 billion that House GOP appropriators have proposed.

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The Senate bill would boost funding for the National Institutes of Health by \$943 million and provide \$1.5 billion for biomedical research agency ARPA-H. Republicans had proposed cutting NIH funding by \$3.8 billion and eliminating funding for two HHS programs: the Teen Pregnancy Prevention Program and the Ending HIV Epidemic Initiative. The Senate bill would retain funding for the former and boost it for the latter.

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The Senate bill also includes \$2 billion in additional emergency funding for HHS. This is well within the bounds of the debt limit deal negotiated by President Joe Biden and House Speaker Kevin McCarthy in May.

Why the Farm Bill matters to biotech

As Congress prepares the 2023 Farm Bill, there is an opportunity to boost biotechnology in agriculture.

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Renewed approximately every five years, generally with bipartisan support, the Farm Bill sets the course for agriculture policy and can greatly affect the use of biotech for plants, animals, biomanufacturing and energy.

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The current bill expires Sept. 30, and Congress is working now on the new Farm Bill. Those efforts could be delayed, however, by intense House scrutiny of all federal spending.

BIO supports a Farm Bill that builds the bioeconomy and encourages innovation by providing incentives and reducing unnecessary regulatory burdens.

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Specific recommendations from BIO include the following:

- Stronger BioPreferred incentives to promote federal use of biobased products by clearly defining these products in the North American Industry Classification System.
- Better regulation of biostimulants, biological substances that make plants more resilient and productive. The Biostimulant Act, proposed earlier this year, would improve regulation by defining biostimulants.
- Energy programs: Sustainable aviation fuel can dramatically reduce emissions from airline travel and should be incentivized. Incentives for biorefineries and biomass R&D are essential, too.Â
- Greenhouse gas reductions, thanks to biotech, should be better measured and incentivized.
- Better coordination among agencies so the U.S. Department of Agriculture, FDA and EPA can reduce regulatory obstacles and speed decision-making.
- Streamlined regulation of biotech to allow faster approval of innovations, such as gene editing, to make plants and animals healthier and more productive.

Farm Bill passage probably awaits a politicized battle over the federal budget. If it’s not passed by September, the current Farm Bill could be extended and renewed in 2024. [More at BIO >>](#)

Congress adjourns until September

Congress wrapped up a few final items of interest before adjourning until September. The Senate returns to session Sept. 5, and the House returns Sept. 11.

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The Senate Subcommittee on Intellectual Property held an oversight hearing on the U.S. Patent and Trademark Office featuring testimony from PTO Director Kathi Vidal. Members focused on the Patent Trial and Appeal Board and particularly the USPTO's Advance Notice of Proposed Rulemaking for Potential PTAB Reforms. Â Chairman Sen. Chris Coons (D-DE) and Ranking Member Sen. Thom Tillis (R-NC) both spoke about their legislation, the PREVAIL Act, which would codify needed reforms to the PTAB policies and procedures.

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In the House, Ranking Members Frank Pallone (D-NJ), Richie Neal (D-MA) and Bobby Scott (D-VA) introduced the Lowering Drug Costs for American Families Act, which would expand the Inflation Reduction Act into the private market and increase the number of drugs subject to negotiation from 20 to 50 starting in 2029.Â

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The House Energy & Commerce Committee Chair Cathy McMorris-Rodgers (R-WA) released a [discussion draft](#) on policies to address drug shortages.Â

July D.C. Fly-In with We Work for Health



NCBIO President Laura Gunter and representatives of We Work for Health were in D.C. July 13-14 and met with Sen. Ted Budd and members of Sen. Thom Tillis' staff, along with Reps. Richard Hudson, Jeff Jackson, Patrick McHenry, Greg Murphy, Wiley Nickel and Deborah Ross.

NCBIO Updates

NCBIO Member News

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





Pfizer Rocky Mount plant hit by tornado

Pfizer's manufacturing facility in Rocky Mount was damaged by a violent tornado that swept through the town on July 19.Â

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All 3,200 local Pfizer employees at the manufacturing site were safe and accounted for, Pfizer said. Crews worked around-the-clock to restore power, assess the structural integrity of the building and move finished medicines to nearby sites for storage, the company said. There does not appear to be any major damage to the medicine production areas, Pfizer said.

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Most of the damage was caused to the warehouse facility, which stores raw materials, packaging supplies and finished medicines awaiting release by quality assurance. Pfizer said it is working diligently to move product to other nearby sites for storage and to identify sources to replace damaged raw materials and supplies. The company is also exploring alternative manufacturing locations for production at its U.S. and international sites and across the company's partner network.Â

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Pfizer Chairman and CEO Albert Bourla, Ph.D., said that the company would continue to pay all employees during the closure of the plant and that Pfizer was [committed to rebuilding in Rocky Mount](#).

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Pfizer also announced a donation to the American Red Cross North Carolina Chapter and United Way Tar River Region to support the relief and recovery needs. Additionally, the Pfizer Foundation will match employee donations to these organizations. [More >>](#)

Amgen named Paul Lewus its North Carolina vice president of site operations replacing Bob Kenyon, who retired in June.

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Biocair has partnered with TrakCel and integrated their systems with OCELLOS to improve customer service, automation and visibility in the cell and gene therapy supply chain. [More >>](#)

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Biogen Inc. and Reata Pharmaceuticals, Inc. have entered into a definitive agreement under which Biogen has agreed to acquire Reata for \$172.50 per share in cash, reflecting an enterprise value of approximately \$7.3 billion. [More >>](#)

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Chiesi USA, Inc. announced that Jon Zwinski, CEO and general manager, has been appointed to the American Society of Health-System Pharmacists Foundation Board of Directors. [More >>](#)

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IQVIA received, along with the National Basketball Association and partners, a UNIVANTS of Healthcare Excellence award for its work in supporting the league with the 2020 NBA Bubble, an occupational health program implemented during the COVID-19 pandemic. [More >>](#)

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Eisai Co., Ltd. and **Biogen Inc.** announced that the FDA approved the supplemental Biologics License Application supporting the traditional approval of LEQEMBI (lecanemab-irmb) to treat Alzheimer's disease. [More >>](#)

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Kriya Therapeutics, Inc. announced the addition of over \$150 million in capital committed as part of its Series C financing, bringing the total Series C round to over \$430 million. [More >>](#)

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Eli Lilly and Company announced an agreement to acquire Versanis, a private clinical-stage biopharmaceutical company focused on the development of new medicines for the treatment of cardiometabolic diseases. [More >>](#)

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Eli Lilly and Company announced an agreement to acquire Sigilon, a biopharmaceutical company that seeks to develop functional cures for patients with a broad range of acute and chronic diseases. [More >>](#)

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Novartis announced the expansion of Beacon of Hope, its ten-year commitment to cocreate programs that address health and education inequities and create greater diversity, equity, inclusion and trust across the research and development ecosystem. [More >>](#)

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SAS was recognized by Forbes magazine as one of America's best employers for women. Women currently represent more than one-third of its global workforce, including management and executive positions, the company said. [More >>](#)

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Thermo Fisher Scientific Inc. has agreed to acquire CorEvitas, LLC, a provider of regulatory-grade, real-world evidence for approved medical treatments and therapies, from Audax Private Equity for \$912.5 million in cash. [More >>](#)

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Thermo Fisher Scientific Inc. has introduced Diomni Enterprise Software to help streamline routine diagnostics testing for standardization and faster time-to-results to address challenges with error-prone, manual molecular testing workflows. [More >>](#)

NCBIO members take the stage at AgBio

NCBIO members were front and center at [AgBio 2023](#) held July 19 in Danville, Virginia, and co-sponsored by NCBIO and Virginia BIO. A crowd of about 100 spent the day networking across state lines and hearing from experts on topics such as financing, policy, bio-controls and bio-stimulants.

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Introductory remarks came from the Virginia Department of Agriculture and the NC Department of Agriculture. Weston McCorkle, agricultural programs specialist for the NCDA, brought greetings from NC Agriculture Commissioner Steve Troxler and lauded the advances in biotech that are having real impact on the agricultural economies in both North Carolina and Virginia.Â

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Special thanks go to NCBIO member sponsors [Avantor](#), [CSC Leasing](#) and [DPR Construction](#).Â



Brooke Bissinger (center), marketing product manager, AgBiome



Novozymes' Kristi Woods on the biostimulants panel



Paul Ulanich with NCBiotech (left), Jess Hawthorne with CSC Leasing (right) and Karen LeVert with Pappas Capital (2nd from right) on the Financing Focus panel



Help inform the future of our workforce

The quality of our current and future workforce is increasingly seen as the most important factor in our region’s economic growth and vitality. To address this and improve the employment pipeline, NCBIO is partnering with regional workforce and economic development groups to better understand skills gaps and employer needs.

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We are seeking business owners and HR professionals to participate in the 2023 iteration of the Regional Skills Analysis, which covers both the greater Triangle and Cape Fear regions of North Carolina. The study was previously conducted in both 2020 and 2017. The survey is being conducted by RTI International, an independent nonprofit research institute.

The survey will take approximately 20 minutes to complete. As a thank you for your participation, there are weekly prize drawings for gift cards to local favorites. You will also be entered to win a grand prize of \$1,000 to the Umstead Hotel and Spa.

TAKE THE SURVEY

Events

Raleigh BIO Impact event canceled

The BIO Impact Ag & Environment Conference will **not** occur September 19-20, 2023.

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Instead, BIO reports that it is working with its agriculture and environment members and industry stakeholders to meaningfully integrate key issues into its broader portfolio of events. These companies all face economic and policy issues that are not unique to one sector and can be better served by acting in coordination.

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If you have thoughts, comments or suggestions on how BIO can better engage agriculture and environment members at BIO International Convention and other events, please share them [here](#).

Save the date: Sept. 12 DEI Virtual Forum: Rising and Failing of Employee-Led Groups

Save Sept. 12 at noon for the NCBIO DEI Virtual Forum Rising and Failing of Employee-Led groups.

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Find out more about business resource groups, employee resource groups and affinity groups during this NCBIO virtual forum. Groups can cover a diverse range of DEI areas including neurodiversity, generational issues and disabilities in the workplace.

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Panel members are:

- Josh Jones, director, sales & business development, Frankel Staffing (moderator)
- Ellen King, micro lab group leader / DE&I manager, Novozymes
- Jamie Ousterout, vice president, client success, The Diversity Movement

NCBIO will send out an advisory for registration and additional information about the forum.



Register for NCBIO Annual Meeting

Register now for this year’s Annual Meeting on Oct. 4. There is a \$50 registration fee per attendee.

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The program features a keynote presentation by **Emily Chee**, U.S. general manager,

Novartis Gene Therapies, and three panel sessions.Â

- **Federal Update** featuring ACRO, AdvaMed, BIO, IQVIA and PhRMA
- **Navigating Regulatory Hurdles in Pharma and Food** with Azzur Group, Duke University School of Medicine, Novozymes, Pairwise and Syneos Health
- **The Customer's Journey** moderated by Care4Carolina and features patients impacted by spinal muscular atrophy, sickle cell, cardiovascular disease and diabetes

See the complete list of speakers [here](#). You will have a number of opportunities to connect with attendees during the day. We hope you will join us on Oct. 4.

REGISTER NOW

Thank you to our 2023 Annual Meeting sponsors.

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NCBIO calendar

- Hands-On cGMP Biomanufacturing Operations hosted by BTEC (7/31/2023 to 8/3/2023)
- Introduction to Design of Experiments (DoE) for Bioprocess Analysis and Optimization hosted by BTEC (8/1/2023 to 8/3/2023)
- NCBIO Legislative Luncheon and Forum (8/1/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (8/2/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (8/9/2023)
- Hands-On cGMP Biomanufacturing of Vectors for Gene Therapy hosted by BTEC (8/14/2023 to 8/17/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (8/16/2023)
- DEI for Marketers and Communicators Summit hosted by The Diversity Movement (8/30/2023)
- Automation, Process Control, and Real-time Monitoring of Yeast Culture hosted by BTEC (9/12/2023 to 9/14/2023)
- PAT for Real-time Culture Monitoring and Closed-Loop Process Control

- hosted by BTEC (9/12/2023 to 9/14/2023)
- NCBIO DEI Virtual Forum: Rising and Failing of Employee-Led Groups (9/12/2023)
 - BioPharm America (9/13/2023 to 9/14/2023)
 - Tecnosalud International (9/13/2023 to 9/14/2023)

BIO Business Solutions



Let a BIO expert help

Did you know BIO hosts office hours on topics like R&D tax credits, grant writing, and regulatory inspections for NCBIO members? Schedule time with a subject matter expert and discuss matters that impact your research and business.

LEARN MORE




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