



October 2022 Update

Serving the NC Life Sciences Industry

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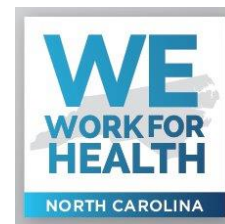
919.281.8960

NCBIO This Month

- NCBIO Annual Meeting less than two weeks away
- NC hospitals offer Medicaid expansion compromise
- Policy riders purged from UFA reauthorization
- Biden nominates ARPA-H director
- Critical conversations in DEI
- Save with PSC Biotech and United Van Lines

... and more

NCBIO Sustaining Members



NCBIO Annual Meeting Oct. 12

The NCBIO Annual Meeting on Wednesday, Oct. 12, at the NC Biotechnology Center in Research Triangle Park will feature multiple networking opportunities and four panel discussions.

- **Success Stories: Talent Recruitment and Retention** highlights FUJIFILM Diosynth, Lilly, Novozymes and StrideBio
- **Financial Trends and Outlook** with GSK, Incubate Coalition, JPMorgan, Pappas Capital and Solas Bioventures
- **Health Equity and Disparity** features BIO, Biogen, ECU's Center for Health Disparities, the Global Liver Institute and mdgroup
- **Decisions to Locate and Expand in NC** with Amgen, Economic Development Partnership of NC, FUJIFILM and Lilly

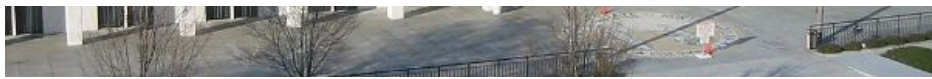
Thank you to all of our sponsors who are making this event possible.

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- Gold: [American Laboratory Trading](#), [Azzur Group](#), [FUJIFILM Diosynth Biotechnologies](#), [Grifols](#), [Novo Nordisk](#), [PSC Biotech](#)
- Silver: [AdvaMed](#), [Alexandria Real Estate Equities](#), [The Conafay Group](#), [Frontier Scientific Solutions](#), [Marsh McLennan Agency](#), [Mispro Biotech Services](#), [Smith Anderson](#), [Unifirst](#)
- Bronze: [Amgen](#), [BioCryst](#), [Nikon](#), [Novozymes](#), [PHC Corporation](#), [UCB](#), [UMotif](#)

We look forward to seeing everyone there!

NCBIO Supporting Members





STATE UPDATES

All's quiet in Raleigh, now's the time to share your thoughts

It is about as quiet as it gets in Raleigh right now as all eyes turn to the November election. The General Assembly was in session briefly this past month to handle a few administrative matters and will be back in session on Oct. 18.

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This brief pause is an ideal time for you to tell us about ideas, issue, comments or concerns you have that our lawmakers may be able to assist you with. The chairs of the Life Sciences Caucus (Sen. Paul Newton, Sen. Mike Woodard, Rep. Donna White and Rep. Robert Reives) have all expressed their eagerness to work with our members to remove barriers and help our industry succeed in North Carolina. If you have thoughts you would like to share, don't hesitate to [contact me](#).

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Laura Gunter
NCBIO President

NC hospitals offer compromise on Medicaid expansion, CON reform

THE ASSOCIATED PRESS

North Carolina's hospitals and hospital systems unveiled an offer on Sept. 16 that could shake up stalled negotiations to pass legislation that would expand Medicaid to cover hundreds of thousands of low-income adults in the state.

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The North Carolina Healthcare Association said the offer sent to Republican legislative leaders and Democratic Gov. Roy Cooper also contained reforms to some state laws that require regulatory approval before certain medical buildings can be constructed or services offered in a region.

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Senate leader Phil Berger this summer accused the association of refusing to compromise on "certificate of need" rules. Changes to these rules were contained in the Senate version of an expansion measure approved in June. Berger said they were needed to increase the supply of medical services that would be needed to treat the growing Medicaid population.

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The association said its proposal would have hospitals paying a majority of the state's share to cover another 600,000 people at a cost of over \$550 million annually. The state's hospitals also would participate in a federally funded program that would enhance their Medicaid reimbursement rates for providing care, providing new revenues.

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The proposal would do away with certificate of need laws for psychiatric inpatient beds and beds to treat people with chemical dependency. It also, within five years, would scale back regulations for operating rooms within ambulatory surgical centers, which the association says would result in a loss of revenue for them.

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The General Assembly is scheduled to return to Raleigh in October.

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[More at Associated Press >>](#)



NATIONAL UPDATES

Congress expected to provide three more years of SBIR, STTR funding

The House of Representatives is expected to pass a stopgap funding bill today that will fund the government through Dec. 16. This continuing resolution will also fund the Small Business Innovation Research, Small Business Technology Transfer and several related pilot programs for three years, through Sept. 30, 2025.

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The Senate passed the continuing resolution (S. 4900) 72-25 on Sept. 29. The House vote is expected to be closer as Republican leaders are urging their members to vote "no." The SBIR/STTR programs expire Sept. 30.

Completely clean FDA-industry user fee deal attached to a must-pass government spending bill

ENDPOINTS

As the fiscal year comes an end, FDA-related policy riders approved in both House and Senate committees, at least for now, appear dead. The Senate has passed and the House is expected to pass a short-term government spending bill to keep federal agencies open until Dec. 16.

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But the absence of riders (both sides previously announced a "practically clean" deal last week) in this continuing resolution doesn't mean Democrats are done fighting to add these accelerated approvals and other regulatory reforms for cosmetics, nutritional products and diagnostic tests.

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As part of the agreement for a clean CR and user fee deal, Democrats are looking to only authorize certain measures that are tangential to the actual industry-FDA agreements until Dec. 16.

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Those partial reauthorizations set up a likely battle in mid-December over programs like the Best Pharmaceuticals for Children Program, which allows the NIH to fund studies of off-patent drugs in children, the orphan drug grants that defray the cost of developing rare disease drugs, and certain reporting requirements on pending generic drug applications.

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But outside of these delayed items (and it's still unclear who's opposed to reauthorizing some or all of these measures), Democrats entirely caved to their Republican peers after much discussion and voting on several different reforms, some of which the FDA even seemed almost ready to endorse. The shift came in late July, after Sen. Richard Burr, retiring minority leader on the Senate HELP committee, took a stand on a completely clean user fee bill.

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NCBIO stays in close contact with the NC delegation on this issues and has taken part in Council of State Biosciences Associations letters. If you have particular stories or are willing to make calls or send emails, please [contact Laura Gunter](#).

[More at Endpoints >>](#)

Biden launches national biotechnology and biomanufacturing initiative

ASSOCIATED PRESS

President Joe Biden is launching a new initiative to encourage biotech production and research in the U.S., the latest move by the White House to boost domestic industry.

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Biden signed an executive order implementing the initiative and, his administration will host a summit and announce new investments from several federal agencies, according to a White House fact sheet.

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The initiative will seek to boost biomanufacturing in pharmaceuticals but also in other industries such as agriculture, plastics and energy.

[More at AP >>](#)

Biden appoints Renee Wegrzyn as inaugural ARPA-H director

NATURE

President Joe Biden has selected Renee Wegrzyn, a biologist and former government scientist, as the inaugural director of the Advanced Research Projects Agency for Health, an agency created by his administration to find innovative solutions to biomedical problems. Although researchers applaud Biden's choice, they say that Wegrzyn will have her work cut out, because many details about the agency are still in limbo, including how it should be structured and what health issues it should prioritize.

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Wegrzyn spent more than five years working as a programme manager at DARPA, where her portfolio included projects that used synthetic biology to counter infectious disease and

bolster biosecurity. At the agency, Wegrzyn led its Safe Genes program, a four-year, \$65-million initiative aimed at safeguarding against the potential dangers of the gene-editing technique CRISPR.

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Since leaving DARPA in 2020, Wegrzyn has served as a vice-president at Ginkgo Bioworks, a bio-engineering company in Boston, Massachusetts. Ginkgo has not yet announced when Wegrzyn will step down.

[More at Nature >>](#)

FDA's cell and gene therapy office to add 100 new positions

ENDPOINTS

Housed within the FDA's Center for Biologics Evaluation and Research, the once-tiny Office of Tissues and Advanced Therapies, which regulates all cell and gene therapy products, faces a workload that now includes more than 3,000 active INDs.

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OTAT employs about 300 people, but thanks to the upcoming PDUFA VII reauthorization, it will look at adding about 100 more employees over the next four to five years. In terms of vacancies currently, OTAT Director Wilson Bryan said the office is looking to fill 40 to 50 positions, and many of those are to fill departures by FDAers who can make much larger salaries in industry.

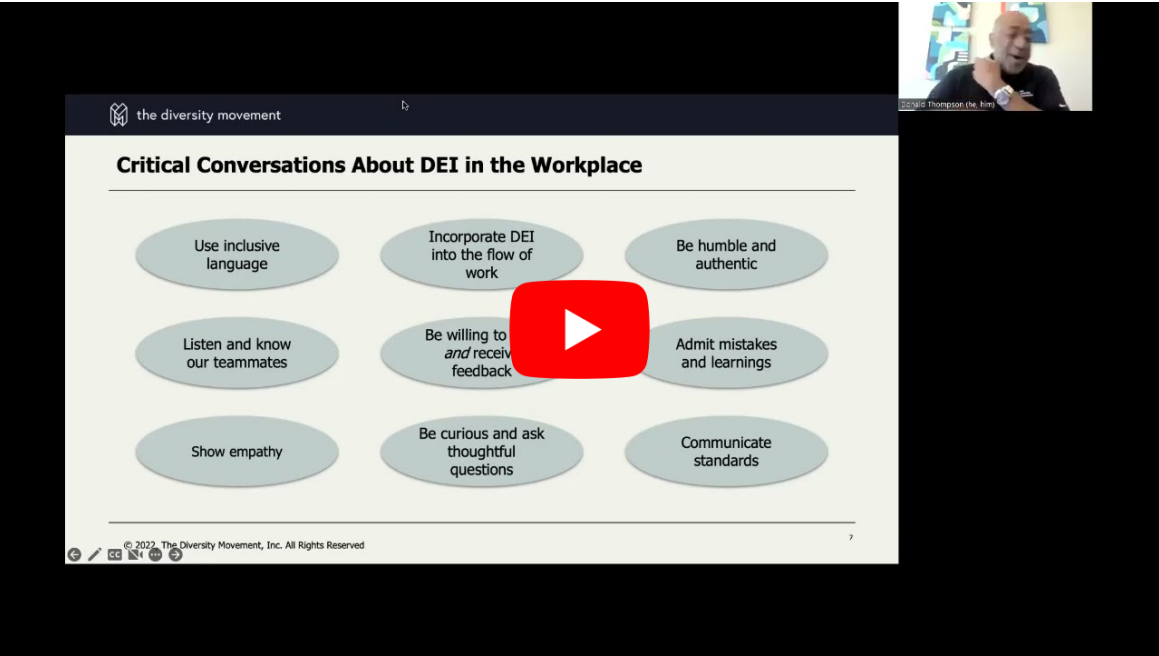
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In February 2021, OTAT underwent a major reorganization where its branch focused on gene therapy CMC split into two, and its cell therapy branch also split into two branches, as well. He said the focus now is to be sure new folks coming on board get the proper training and attention they need, and to be sure that OTAT is being consistent with sponsors across the office.

[More at Endpoints >>](#)

NCBIO Updates

Diversity Movement founder discusses critical workplace conversations



Donald Thompson, founder and CEO of The Diversity Movement, spoke to NCBI members about "Critical Conversations in the Workplace" in a Sept. 14 online forum. The [event recording](#) is available on NCBI's YouTube channel and is part NCBI's Roadmap to Diversity series.

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"The points of view and perspectives that people have are driven by their experiences for sure, but they're also driven by the moment or season they are in in their life," Thompson said. "In order to have critical conversations with people, we have to start with empathy. We have to start with really understanding, as best we can in the business context, what people have going on. What people are going through at the moment changes how they receive information."

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Empathy is key to setting the temperature of dialogue and finding the common ground needed to move a discussion forward, he said. He gave a number of personal anecdote, addressing topics such as including personal pronouns.

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"Why do I need to have my pronouns on my email? Why do I need to have them on my own business cards?," he said. "My team sat down with me and said, 'Donald, you're not putting your pronouns on your resume for you. As a leader, you're creating space for others to be their authentic self at the moment of their readiness.'"

[More at YouTube >>](#)

NCPIO Member News

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

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The following NCPIO members are among the 50 companies named the fastest growing in the Triangle region by the Triangle Business Journal:

- **BioAgilytix**
- **Kymanox**
- **Locus Biosciences**

[More >>](#)

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The following NCPIO members had leaders recognizedÂ as part of the Triangle Business Journals 2022 CEO of the Year & C-suite Awards:

- **Bioventus:** [General Counsel Anthony D'Adamio](#)
- **Humacyte:** [CEO Laura Niklason](#)
- **Merz Aesthetics:** [CSO Samantha Kerr](#)

BD will expand its footprint in Johnston County by adding a manufacturing site in addition to its existing distribution center with a planned investment of \$25 million to \$30 million. The new site will employ 22 people initially with average annual wages of more than \$83,000. [More >>](#)

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Biogen announced that the European Medicines Agency has accepted the marketing authorization application for B1B800, a biosimilar candidate referencing RoACTEMRA 1 (tocilizumab), an anti-interleukin-6 receptor monoclonal antibody. [More >>](#)

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Chiesi USA announced a partnership with North Carolina Central University's Biomanufacturing Research Institute and Technology Enterprise and awarded grants to researchers focused on DE&I-related programs. [More >>](#)

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Chimerix announced the closing of its sale of TEMBEXA to Emergent BioSolutions Inc. for \$238 million. TEMBEXA is FDA approved for the treatment of smallpox. [More >>](#)

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Eisai and **Biogen** announced positive topline results from Eisai's large global Phase 3 confirmatory Clarity AD clinical trial of 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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Locus Biosciences has treated the first patient in a study evaluating its lead product candidate, LBP-EC01, a precision medicine targeting recurrent urinary tract infections caused by E. coli bacteria. [More >>](#)

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Novo Nordisk and Microsoft have entered a new strategic collaboration to combine Microsoft's computational services, cloud and artificial intelligence with Novo Nordisk's drug discovery, development and data science capabilities. [More >>](#)

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RTI International received a \$4 million federal grant to support the Build Back Better Regional Challenge and will partner with the Ohio-based State Science and Technology Institute to coordinate and lead a community of practice that will build long-term connections between the challenge's 60 finalist coalitions. [More >>](#)

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Thermo Fisher Scientific's PPD unit has been awarded a 10-year indefinite-delivery, indefinite-quantity contract by the National Cancer InstituteÂ to support NCI's Cancer Trials Support Unit. [More >>](#)

Events

The Diversity Movement offers new certificate for DEI leaders

Our partner The Diversity Movement is offering a new certificate program, the Diversity Leader's Intensive on Oct. 3-6. This intensive goes beyond the "what?" and "why?" of diversity, equity, and inclusion training to focus on the "how-to?" and skills you need to build and sustain DEI at your organization. Led by The Diversity Movement's experts, you'll walk away from this 4-day intensive with practical information to put into practice right away, a certificate of competency, and amazing relationships that you develop with other cohort members.

LEARN MORE





Uniting top medtech executives

The MedTech Conference 2022 is the industry’s leading event for the world’s top medtech executives. Powered by AdvaMed, the premier medtech association, the conference brings together the industry’s top professionals and prominent companies for three days of

- valuable networking with industry executives, start-ups, government officials, academics and more;
- access to cutting-edge innovation and technology from early-stage companies;
- trusted networking, deal-making, discovery, and knowledge building;
- 100-plus cross-cutting educational programming sessions; and
- business development opportunities with exclusive one-on-one meetings with industry stakeholders and investors.

NCBIO members receive a 10% discount. Contact NCBIO Membership Director [Natacha Janvier](#) for the code. A group coming from North Carolina could generate additional discounts so please contact us with your interest in attending.

LEARN MORE



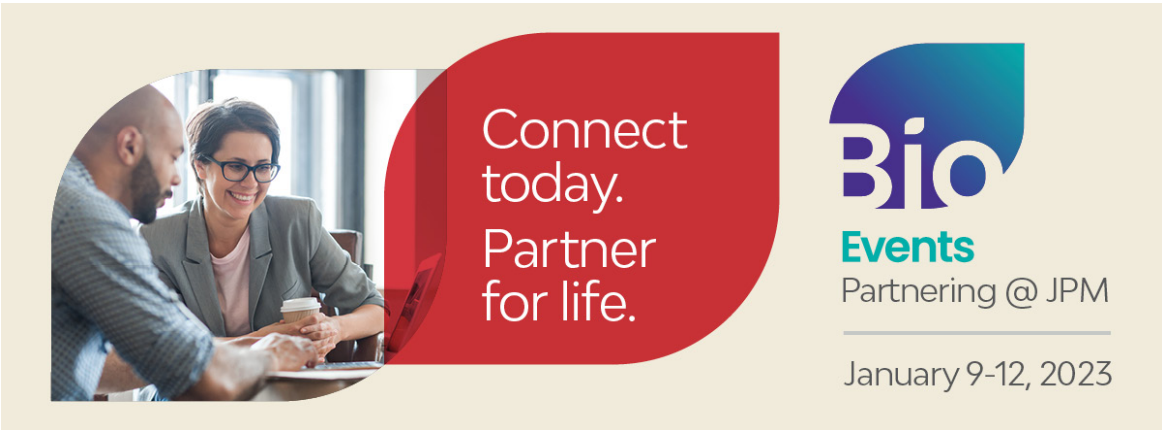
Sikich to host hockey night for NCBIO members at PNC Arena

Join [Sikich](#), a global company specializing in technology-enabled professional services, and Coupa, for the Nov. 10 Carolina Hurricanes game against the Edmonton Oilers. Enjoy networking, food, drinks and fun as you watch the Carolina Hurricanes go against the Edmonton Oilers in a private luxury suite.

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With fantastic views of the action, you’ll network with like-minded peers in the life sciences industry. Reserve your seat by Nov. 3. Seats are limited!

REGISTER NOW



BIO One-on-One Partnering with on-site meeting space at JPM Week Jan. 9-12

Join BIO as its One-on-One Partnering returns to San Francisco for 2023 J.P. Morgan

Healthcare Conference week. Use the system to easily identify potential partners and investors, and manage your JPM week meetings all in one place, both in-person and virtually. Even better, benefit from BIO-provided meeting space at the San Francisco Marriott Marquis, available on a first-come-first-served basis for meetings scheduled through the system.Â

LEARN MORE

NCBio calendar

- [The Diversity Leader?s Intensive hosted by The Diversity Movement \(10/3/2022 to 10/6/2022\)](#)
- [Trending Technologies: What Lies Ahead for Nucleic Acid Technology hosted by LaunchBio \(10/6/2022\)](#)
- [NC World Trade Association Triangle Chapter Meeting with Dr. Michael Walden \(10/6/2022\)](#)
- [Science of Socializing hosted by Azzur Group \(10/6/2022\)](#)
- [Hands-On Single-Use Processing for Biopharmaceuticals hosted by BTEC \(10/11/2022 to 10/13/2022\)](#)
- [NCBio Annual Meeting 2022 \(10/12/2022\)](#)
- [cGMP Boot Camp hosted by Azzur Group \(10/18/2022\)](#)
- [Aseptic cGMP Boot Camp hosted by Azzur Group \(10/19/2022\)](#)
- [Investigation Boot Camp hosted by Azzur Group \(10/20/2022\)](#)
- [Small Business Resources and Funding to Advance Translational Science Innovation hosted by NCATS \(10/20/2022\)](#)
- [Funding Fundamentals: Creating a Network of Trusted Partners hosted by LaunchBio \(10/20/2022\)](#)
- [Upstream Production Process Development for Biopharmaceuticals hosted by BTEC \(10/24/2022 to 11/4/2022\)](#)
- [The MedTech Conference powered by AdvaMed \(10/24/2022 to 10/26/2022\)](#)
- [Applied Principles and Techniques of Depth Flow Filtration \(DFF\) and Tangential Flow Filtration \(TFF\) for BioPharm Downstream Purification hosted by BTEC \(10/25/2022 to 10/28/2022\)](#)
- [Patient & Health Advocacy Summit hosted by BIO \(10/27/2022 to 10/28/2022\)](#)
- [A Night at the Arena hosted by Sikich \(11/10/2022\)](#)
- [cGMP Boot Camp hosted by Azzur Group \(11/15/2022\)](#)

BIO Business Solutions



Big savings on electronic quality and audit solutions from PSC

PSC Biotech provides NCBio members with exclusive cost savings on electronic quality and audit management system solutions and professional consulting services. NCBio members will receive discounts on software solutions, quality management, auditing and all professional services, including commissioning, qualification, and validation; computer system validation; quality assurance; regulatory affairs; technical writing; calibration; and project management support. NCBio members can take advantage of the following special offers:

- 10% discount on all professional consulting services for regulatory affairs; technical writing; audit; commissioning, qualification and validation; computer system validation and IT; calibration; engineering; and project management support.
- 35% discount on the initialization fee and user licenses for [PSC Software](#) (Adaptive Compliance Engine, ACE Essentials and AuditUtopia). Subscriptions include the hosting, cloud storage, technical support, and upgrades to future versions of software.
- 21-day free trial of [ACE](#), [ACE Essentials](#) and [AuditUtopia or ACE Inspection](#).

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United Van Lines offers moving, relocation benefits for NCBio members



- Access to more than 300 agent locations across the country, including Humboldt Storage and Moving
- Local, long-distance, and international moving solutions
- Laboratory, office, and employee relocations
- Regulatory compliant, climate-controlled specimen relocation for laboratory moves and more!

Is your life sciences company downsizing or relocating? The last few years resulted in the need for less and/or more collaborative spaces for many companies. If this is the case for you, look no further than United Van Lines, America's #1 Mover.

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Whether you are moving across the country or just across state lines, United Van Lines offers innovative moving solutions designed for moves of any complexity. Even your employees can take advantage of reduced moving rates if they are relocating - what a perk!Â

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As BIO's preferred moving and storage company, United Van Lines provides life sciences companies with discounts on climate-controlled moving, employee relocation and more.

LEARN MORE



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