



June 2024 Update
Serving the NC Life Sciences Industry

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Legislative Reception



NCLifeSci board member Bennett Love with BioKier, NCLifeSci President Laura Gunter, Sen. Mike Woodard and NCBiotech President Doug Edgeton.

NCLifeSci hosted its annual Legislative Reception for members of the NC General Assembly Tuesday, May 14, drawing more than 150 members and lawmakers to the NC Museum of History in Raleigh.

MORE PHOTOS



NCLifeSci Sustaining Members



NCLifeSci Supporting Members





STATE UPDATES

Death of speaker's father pauses legislature

The House and Senate held skeleton sessions last week after the death of Speaker Tim Moore's father on Monday. Most committee activity was canceled, and the lack of floor votes allowed members to attend the funeral,

This week, legislative business will return to normal. Floor votes are anticipated and committees will resume. A timeline for a state budget that would allow a vote by the end of June is still possible, but only if Republican legislative leadership reaches a spending agreement in the next two weeks.

State dials down budget surplus estimates

The Office of State Budget and Management released an updated Consensus General Revenue Forecast that significantly downgraded an earlier estimate of a \$1.4 billion surplus during the current biennium budget cycle.

The revised numbers indicate approximately \$225 million less in surplus revenue during this fiscal year and \$205 million less in FY 2024-25 revenue as compared to the April forecast.

However, the office still projects there will be \$196 million surplus this year and an \$800 million revenue surplus for FY 2024-25.

Final Call for One NC Small Business Program applications

The One North Carolina Small Business Program remains open until June 30 or until funds are exhausted. Submit your applications for SBIR/STTR matching funds as soon as possible.

- [Matching Funds Program](#) (PDF)
- [Incentive Funds Program](#) (PDF)

Republican runoff picks lieutenant governor, auditor candidates

In a May 14 runoff election, Republicans voters picked Hal Weatherman as the their nominee for lieutenant governor and Dave Boliek for state auditor. Three percent of registered voters (approximately 131,500 North Carolinians) voted in the election.

Weatherman will face Democrat Sen. Rachel Hunt (D-Mecklenburg) in November's election. Boliek will be up against Democrat Jessica Holmes and Libertarian Bob Drach.



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](#).

RIO survey reveals dependence on Chinese CDMOs

BIO survey reveals dependence on Chinese CDMOs

A BIO survey of 124 biopharma companies found that 79% have at least one contract or product with a China-based or China-owned CDMO/CMO, and they'll need up to eight years to switch manufacturing partners ? or millions of patients could be affected.

On May 15, the House Oversight and Accountability Committee overwhelmingly advanced the proposed BIOSECURE Act that would effectively prohibit the operations of Chinese “companies of concern” in the U.S. by prohibiting them ? and any businesses that use their products ? from receiving federal contracts, grants or loans.

The BIO survey indicates that companies will need as many as eight years if they are required to change manufacturing partners. The more advanced the research program, the longer it will take and already-approved medicines will take the longest. The most recent draft of the legislation sets 2032 as the deadline for decoupling.

Without a pathway to ensure continued access and thoughtfully decouple from China, millions of patients could be affected by the potential loss of access to approved medicines or stalled R&D.

The survey covered a broad cross-section of the industry: 124 unique biopharma and biotech companies?large, medium and small, as well as preclinical companies and companies with products in clinical development. More than two-thirds (68%) of these companies are small emerging companies with fewer than 250 employees. The vast majority (79%) have at least one contract or product with a China-based or China-owned CDMO/CMO.

Labs sue to block FDA regulation of laboratory-developed tests

The American Clinical Laboratory Association filed suite on May 29 against the FDA over new regulations that would impose stricter requirements on certain laboratory tests. The ACLA argues that the FDA doesn't have the legal authority to make these changes.

The FDA says the stricter rules are needed to ensure test accuracy, but the ACLA disagrees and points out that many older tests won't be subject to the new rules.

This lawsuit challenges a major policy change by the Biden administration. If successful, it could block the FDA's new rules.

Meanwhile, lawmakers are considering legislation, particularly the VALID Act, that would overhaul how lab tests are regulated altogether.

Agencies outline new plan for regulating biotech

The FDA, EPA and Department of Agriculture are overhauling regulations for biotech products, including drugs, medical devices and those created with new gene-editing technologies like CRISPR. This comes after an executive order by President Biden and public input calling for clearer and more streamlined regulations.

The new plan includes:

- A risk-based approach to regulating changes made to already approved products.
- Policies to ensure the safety of gene-edited products.
- A program to expedite development of future gene-editing therapies that use the same platform as a previously approved one.

The goal is to both modernize regulations and reduce unnecessary burdens for companies while still ensuring safety. The FDA is taking the lead on gene-editing and has already issued some guidance on this front. There is a [website](#) for stakeholders to follow updates on the evolving regulations.

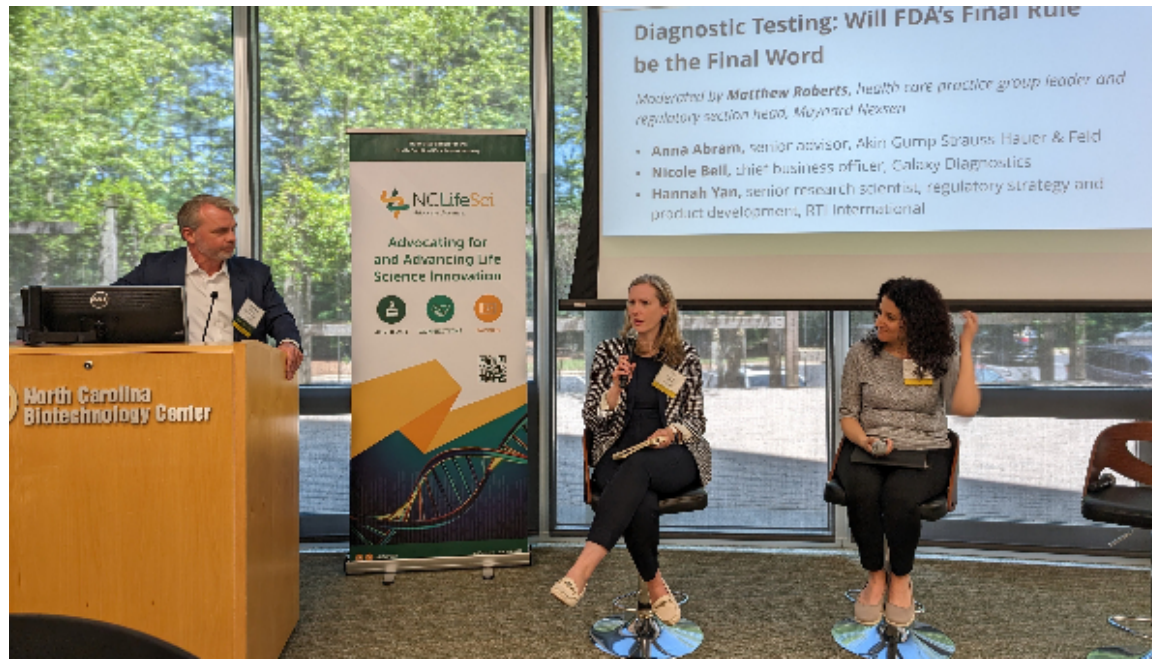
Farm Bill draft released by House committee

The House Agriculture Committee forwarded a draft of a five-year Farm Bill with numerous measures supporting biotech by a 33-21 bipartisan vote on May 24.

BIO is still analyzing the effects of amendments to [H.R. 8467](#). Overall, the draft supports innovative work in the lab, field and marketplace. It would

- Advance and enlarge the “virtuous circle” of biotechnology-driven innovation;
- Treat biotechnology as a national security imperative;
- Identify and break down barriers to accessing medicines, in animal health and pandemic preparedness provisions; and
- Support biotech's unique role in food security and climate impact.

NCLifeSci Updates



Medical Device Forum examines FDA lab test rule, VALID Act

Panelists discussed [the FDA rule](#) regulating laboratory-developed tests and the prospect of the VALID Act superseding the rule at the NCLifeSci Medical Device Forum and Luncheon held Tuesday, May 21, at the NC Biotechnology Center.

The forum was sponsored by the [Economic Development Partnership of North Carolina](#) and [Maynard Nexsen](#).

Matthew Roberts, health care practice group leader and regulatory section head, Maynard Nexsen, moderated the panel, which included

- Anna Abram, senior advisor, Akin Gump Strauss Hauer & Feld LLP;
- Nicole Bell, chief business officer, Galaxy Diagnostics; and
- Hannah Yan, senior research scientist, regulatory strategy and product development, RTI International.

The panelists discussed the need for regulation of diagnostics to ensure patient and political confidence in test results and reviewed the importance of clear and specific regulations, tailored regulation for small businesses and the need for case-by-case assessments while maintaining regulatory certainty so that innovation can thrive.

The panel reviewed the VALID Act, which has aimed to modernize FDA regulation of diagnostic tests but has faced opposition from stakeholders on concerns around regulatory burden. After the VALID Act's failed to pass Congress, the FDA felt it had no choice but to issue its final rule regulating laboratory-developed tests as lawmakers had failed to act.

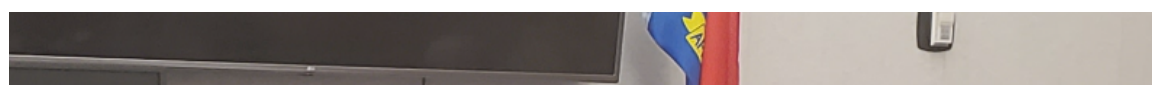


NCLifeSci editorial praising EPIC Act appears in Carolina Journal

The Carolina Journal published an op-ed by NCLifeSci president Laura Gunter that recognizes and thanks member of North Carolina's Congressional delegation for working to remove the nonsensical penalty the Inflation Reduction Act imposed on small-molecule drugs.

"Fortunately, North Carolina's own U.S. Reps. Greg Murphy, a Republican medical doctor representing NC-3; and Don Davis, a Democrat representing NC-1; as well as Rep. Brett Guthrie of Kentucky, recently introduced the bipartisan Ensuring Pathways to Innovative Cures (EPIC) Act. The bill will reverse this misguided policy and restore incentives for small-molecule drug development. Passing their bill would protect local jobs, boost North Carolina's economy, and help countless patients in need."

[Read more at The Carolina Journal](#)





NCLifeSci President Laura Gunter served on the Ecosystem Panel at the [2024 Federal and State Technology Bootcamp](#) at First Flight Venture Center May 16-17. NCLifeSci was a sponsor of the event.

NCLifeSci Member News

AES Clean Technology, has appointed Chris Miller as chief executive officer. Before joining AES, Miller was president of Exyte's BioPharma and Life Sciences Global Business Unit operating in 14 countries to deliver engineering, design, construction and fabrication services. [More >>](#)

Biogen and Human Immunology Biosciences announced that the companies have entered into a definitive agreement under which Biogen has agreed to acquire HI-Bio for \$1.15 billion upfront and up to \$650 million in potential milestone payments. [More >>](#)

Biogen announced that the European Commission has granted marketing authorization under exceptional circumstances and maintained orphan designation for QALSODY (tofersen) for the treatment of adults with amyotrophic lateral sclerosis associated with a mutation in the superoxide dismutase 1 gene. [More >>](#)

Chiesi Group and Gossamer Bio announced that they have entered into a global collaboration and license agreement to develop and commercialize serralutinib, a potential inhaled treatment of pulmonary hypertension. [More >>](#)

Eisai and **Biogen** announced that Eisai has initiated the rolling submission of a Biologics License Application to the FDA for lecanemab-irmb (U.S. brand name: LEQEMBI) subcutaneous autoinjector for weekly maintenance dosing after it was granted Fast Track designation by the FDA. [More >>](#)

Eisai and **Biogen** announced that the Ministry of Food and Drug Safety in South Korea has approved humanized antisoluble aggregated amyloid-beta monoclonal antibody "LEQEMBI®" (lecanemab) for treatment in adult patients with mild cognitive impairment due to Alzheimer's disease. [More >>](#)

G1 Therapeutics and Deimos Biosciences announced a global licensing agreement (excluding the Asia-Pacific region) for lerociclib for radioprotective uses. [More >>](#)

G1 Therapeutics announced the presentation of mature Phase 2 clinical trial results describing the positive impact of trilaciclib in combination with a TROP2 ADC (sacituzumab govitecan; SG) on overall survival and tolerability compared to SG alone based on historical data from the ASCENT trial. [More >>](#)

Pairwise has entered into an exclusive product licensing agreement with Bayer to further develop and sell Pairwise's leafy greens blend, edited with CRISPR for improved flavor and launched last year, at scale. [More >>](#)

PQE Group's U.S. subsidiary has been Certified by Great Place To Work for the third consecutive year, an award based entirely on what current employees say about their experience working there. [More >>](#)

Syneos Health announced that PM360 has named six Syneos employees as recipients of PM360's 10th Annual ELITE 100 Awards. [More >>](#)

Syneos Health announced that two of its employees have been recognized by the Healthcare Businesswomen's Association for advancing women's careers, fueling innovation and having a positive impact on society. [More >>](#)

Thermo Fisher Scientific introduced the Applied Biosystems Axiom BloodGenomiX Array and Software, a first-of-its-kind solution for more precise blood genotyping in clinical research that detects most extended and rare blood groups, tissue and platelet types in a single, high-

...the most common and the most popular, used in a variety of ways, including throughput assay. [More >>](#)

Womble Bond Dickinson elected Merrick Benn as the firm's next U.S. chair and CEO. Currently a member of the firm's Global Board, Benn will assume this new role on Jan. 1. [More >>](#)

A reorganized, restructured and reimagined BIO

John Crowley, president and CEO of the Biotechnology Innovation Organization, sent the following message to BIO members on May 23.

"Earlier this week we launched a Reorganized, Restructured and Reimagined BIO to better align our operations with our mission and strategic priorities. As I began as BIO's CEO on March 5, I stated that BIO would have Seven Core Strategic Priorities. These are:

- Advance & Enlarge the "Virtuous Circle" of Biotechnology Driven Innovation
- Identify and Breakdown Barriers to Access to Medicines
- Powerful Story Telling: Who we are & Who we serve?What we do?Why we do what we do?Where we work
- Extraordinary Focus on Patients, Caregivers & Families
- Biotechnology as a National Security Imperative
- Expand & Engage Our Membership & Stakeholders
- Food Security & Climate Impact: Biotech's Unique Role

Aligned around these priorities, I made organizational decisions which resulted in separating 30 employees from BIO. These are the most difficult decisions that any leader must make. All of these individuals are talented and dedicated professionals, and we are profoundly grateful for their contributions.

Our new plan refocuses BIO's activities, resources and critical priorities for success around Eight Centers of Excellence that reflect the seven priorities above. Each of the Centers now has a business unit head as indicated below who reports directly to me. These BIO leaders now constitute my Senior Executive Team (SET) here at BIO. These Centers of Excellence at BIO are:

- Health Care Policies & Programs (Phyllis Arthur, Head)
- Agricultural & Environmental Policies & Programs (Beth Ellikidis, Interim Head)
- Patient Advocacy (Michele Oshman, Head)
- Communications (Scott Frotman, Interim Head)
- Business Operations (Stephen Jasko, Head)
- Federal Government Affairs (Aiken Hackett, Head)
- State Governments & Associations (Patrick Plues, Head)
- Legal (Peter McHugh, Head)

I also conducted one media interview with Steve Usdin of BioCentury to provide greater context for external audiences about what we are doing and, more importantly, why. You can find that article linked [HERE](#).

To be an effective and highly credible advocate for patients, industry, economic growth, and national security, we must hold ourselves to the highest standards and be a best-in-class organization.

You have my commitment to that vision ahead."



The purple tomato hits stores just in time for summer

Close to two decades of research birthed a biotech tomato with enhanced nutrition that is hitting retail stores just in time for summer salads. The developer, Norfolk Healthy Produce,

announced on May 15 that the tomatoes will be available in select grocery stores in the Southeast and Mid-Atlantic, including North Carolina.

After a thumbs up from the U.S. Department of Agriculture in 2022, the purple tomato was approved by the Food and Drug Administration the following year. Some of the tomatoes are grown in Williamston, North Carolina, and Norfolk brought them to the NC Biotechnology for a tasting event in June of last year.

While it retains the traditional flavor and texture of a classic red tomato, the purple tomato has the added nutritive benefits of anthocyanin, a powerful antioxidant that gives blueberries their color. To bring this nutrient to the tomato, Norfolk introduced two genes from the snapdragon flower that resulted in a unique color and enhanced health benefits. [More at BIO >>](#)

Events

Explore neurodiversity at work with NCLifeSci June 13

Join NCLifeSci on Thursday, June 13, for an online discussion exploring "Our Differences for the Better - Neurodiversity at Work." After this session, which is part of NCLifeSci's ongoing DEI events, you will be able to

- define neurodiversity and discuss the business case for hiring neurodiverse talent;
- hear real life experiences from various perspectives, success stories and tips from a panel of experts; and
- get equipped with resources and tools to help build a more equitable and inclusive workforce.

This panel discussion features

- **Tanya Garcia** with Pfizer;
- **Nicole Griffin**, PGS DEI disability program manager, Pfizer;
- **Melanie Sanders**, certified diversity executive and senior consultant, The Diversity Movement (moderator); and
- **Lindsay Wrege**, owner and co-founder, 321 Coffee.

Coffee will be distributed to 20 selected participants in attendance thanks to 321 Coffee and our sponsors: [McDonald York Building Company](#), [mdgroup](#) and [Lindy Biosciences](#).

REGISTER NOW

You are cordially invited
to attend a celebration
in honor of

Senator
**MIKE
WOODARD**

for his work advancing STEM policies and serving
as co-chair of the Life Sciences Caucus

**Wednesday, June 12, 2024
6:00pm**
Museum of Life and Science
433 W Murray Ave, Durham NC 27704

To attend, please respond by June 7



Executive Education: Women in Leadership June 20-22

SKEMA Women in Leadership Program: Build your self-awareness, confidence, leadership capabilities and ability to influence others through the Women in Leadership program, designed for women who are taking on new leadership roles for the first time.

When: June 20-22

Where: SKEMA Business School (NC State Centennial Campus, Raleigh, NC)

Program Instructor: Ivonne Chinno- Klevans, Ph.D., professor of leadership & decision making at Kenan-Flagler Business School at UNC-Chapel Hill; SKEMA adjunct professor

Cost: \$3500 (\$250 discount for additional attendees)

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New horizons of bio innovation at ON Helix 2024 July 4

In the dynamic landscape of improving patient outcomes, New Horizons refers to the advances in diagnostics, technology, therapeutics and ecosystems that are enabling future innovation in patient treatments. Don't miss this opportunity to connect with the One Nucleus network to explore New Horizons for Bio Innovation held July 4 in Cambridge, United Kingdom.

ON Helix 2024 offers:

- High content mix of keynote talks, exciting companies to watch and panel discussions from key opinion leaders
- Networking with 250+ delegates on the day
- Option to arrange 1-2-1 meetings with delegates via the event app
- ON Helix Fringe events for informal in-person networking
- Exhibition Area for invaluable support from our network
- Delegate rates from only £325 +VAT (approx. \$440+VAT)
- Sponsorship opportunities from £1.5K + VAT (approx. \$1890+VAT)

NCLifeSci receive a 10% discount off registration. Contact [Amber Niebauer](#) for a discount registration code.

[LEARN MORE](#)

Avoid international sales mistakes with EDPNC June 19 online

Join the Economic Development Partnership of North Carolina for its next online Export Coffee Talk, "International Sales Mistakes and How to Avoid Them," on Wednesday, June 19, 10-11 a.m. Zach Selch, an international sales consultant with a proven track record of sales performance, will lead the discussion about common pitfalls. Selch and co-panelist Amy Bosco, also a seasoned international sales expert, will offer tactics and strategies to drive

explosive international sales growth.

Panelists:

- Zach Selch, international sales consultant and global sales mentor
- Amy Bosco, director of global business development, Beekley Medical and award-winning exporter and leader

Some questions that will be covered:

- What should companies think about before initiating international outreach?
- How do you land the sale?
- What are the best post trade show sales strategies?
- How can I identify the most profitable markets for growth?
- How can I find the right distribution partners?
- What are the best practices for driving long term engagement and accountability from my channel partners?

REGISTER NOW

NCLifeSci Lab Space Luncheon and Forum July 23

Save the date or register now for the NCLifeSci Lab Space Luncheon and Forum to be held Tuesday, July 23, at the NC Biotechnology Center from 11:30 a.m. to 2 p.m.

Details will be coming soon.

Thank you to [Flagship Lab Services](#) for sponsoring this event. If you are interested in sponsoring the Lab Space Forum, contact Membership Director [Natacha Janvier](#) for more details.

LEARN MORE



Talk & Tour

Solving Common Development & Manufacturing Challenges for Small/Mid-Size Biotech



REGISTER HERE



Date: Thursday, July 25th, 2024

Time: Registration - 12:30 p.m.
Event - 1:00-5:00 p.m.

Talk: NC Biotech Center
15 TW Alexander Dr. Durham, NC

Tour: Alcami Testing Lab & Manufacturing

Cost: \$25 PDA members
\$35 Non-members
\$10 Students

12:30 - 1:00 p.m.	Registration
1:00 - 1:30 p.m.	PDA SE & LLS Opening Remarks Presenter: Lexie Petsikas, Leukemia & Lymphoma Society
1:30 - 2:00 p.m.	Key Learnings in Sterile Fill Finish Manufacturing Presenter: Alex Drennan, Alcami
2:00 - 2:15 p.m.	A Look into a CDMO's Microbiology Capabilities Presenter: Jeremy Mainville, Alcami
2:15 - 2:45 p.m.	Laboratory Biologic Capabilities & Support for Clients Presenter: Elliott Franco, Ph.D., Alcami
3:00 - 5:00 p.m.	Alcami Biologic Lab & Parenteral Manufacturing Tours Transportation provided; refreshments served

Questions? info@pdase.org

All proceeds benefit



LEUKEMIA & LYMPHOMA SOCIETY



LIGHT THE NIGHT

*Tickets are tax deductible

Alcami to co-host Talk & Tour July 25 with Leukemia &

Lymphoma Society

Alcami Corporation is co-hosting a Talk & Tour event with the Parenteral Drug Association's Southeast Chapter on July 25 at the North Carolina Biotechnology Center from 12:30 ? 5 p.m. Alcamo personnel will share key learnings in sterile fill-finish manufacturing, CDMO microbiology capabilities and lab biologic capabilities, as well as project streamlining with a focus on oncology. The event includes tours of Alcamo's four cutting-edge sterile fill-finish suites in the heart of RTP (with transportation provided) plus a networking reception and heavy hors d'oeuvres.

Open to the public at a cost of \$25 for PDA members, \$35 for nonmembers and \$10 for students, all registration fees will be donated to the Leukemia & Lymphoma Society's Light the Night Fundraiser. Funds raised through Light the Night enable the LLS to fund treatments for all forms of blood cancers.

LEARN MORE

MyData-TRUST Data privacy summit Sept. 10 at NCBiotech

After more than five years in organizing Data Privacy for Life Science Summit in Europe, MyData-TRUST is bringing its concept to the U.S.! Join them for their first edition of the U.S. Data Privacy for Health 2024, taking place in Durham, Sept. 10, at the NC Biotechnology Center.

The perfect occasion to meet other data privacy officers, privacy experts, lawyers and clinical professionals ? all with the same goal: Share knowledge, discuss challenges and find solutions for their Global Data Privacy in the Life Sciences Industry.

NCLifeSci members receive a 20% discount on their registration. Contact [Amber Neibauer](#) for the discount code.

LEARN MORE



We look forward to gathering with NCLifeSci members for our 30th anniversary celebration at our Annual Meeting on Wednesday, Sept. 18. The 2024 Annual Meeting will feature a keynote presentation and three panel sessions.

- Keynote by Edgardo Hernandez, executive vice president and president, manufacturing operations, Eli Lilly and Company.
- Federal Update / Patient Advocacy panel featuring the Arthritis Foundation, Biotechnology Innovation Organization, Merck and the National Organization for Rare Disorders.
- Best Practices and Lessons Learned from AI panel with PPD, SAS and Womble Bond Dickinson.
- Past, Present and Future featuring Biogen, Brightseed Bio, the Chordoma Foundation, the Foundation Fighting Blindness and Jurata Thin Film.

There will also be ample networking opportunities. Register today for the early bird rate of \$40 using the button below.

Thank you to our current Annual Meeting sponsors.

Podcast - [Maynard Nexsen](#)

Platinum - [American Laboratory Trading](#), [Avantor](#), [Azzur Group](#) and [Kymanox](#)

Gold - [FUJIFILM Diosynth Biotechnologies](#), [Grifols](#), [Novartis](#), [PSC Biotech](#), [Smith](#)

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Bronze - [BIO](#), [Marsh McLennan Agency](#), [Mispro](#), [NIIMBL](#), [Novonosis](#) and [Surplus Solutions](#)

If you are interested in sponsoring the Annual Meeting, we have bronze sponsorships available. All other sponsor levels are sold out. Contact NCLifeSci Membership Director [Natacha Janvier](#) for more information.

REGISTER NOW

NCLifeSci calendar

- [Export Coffee Talk: Expanding Your Life Sciences Activities to Europe - Discover What the Paris Region Has to Offer](#) hosted by EDPNC (6/12/2024)
- [Our Differences for the Better - Neurodiversity at Work](#) hosted by NCLifeSci (6/13/2024)
- [Boil, Brews and Band](#) hosted by First Flight (6/20/2024)
- [Deep Tech Workshop Series with Windlift](#) hosted by First Flight Venture Center (6/25/2024)
- [Triad BioNight](#) hosted by NCBiotech (6/27/2024)
- [ON Helix: New Horizons for Bio Innovation](#) hosted by One Nucleus (7/4/2024)
- [Deep Tech Workshop Series with Plantd Materials](#) hosted by First Flight Venture Center (7/11/2024)

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and streamline



and streamline
your HR

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Did you know that life science companies earn 30% more time in their day by leveraging ADP's payroll and benefit support? Companies also net a four to five times return on their investment with ADP's R&D tax credit support.

Attending the BIO International Convention in San Diego? Stop by the BIO Pavilion (#3027) June 3-6 to learn more about the BIO-ADP program and how they can help.

[LEARN MORE](#)

NCLifeSci member seal available



New for 2024, NCLifeSci offers a seal our member organizations can display on their websites and wherever they feel it is appropriate and valuable to highlight their relationship with NCLifeSci. Members may use the seal for as long as their NCLifeSci membership is active.

The image above is adequate for many digital uses, including websites. If you would like receive the NCLifeSci membership seal in all available formats, please email [Communications Director David Etchison](mailto:DavidEtchison@NCLifeSci.org).



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📞

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📍

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