# NCLifeSci Connections Newsletter

**August 2024 Update**

**Serving the NC Life Sciences Industry**

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## Trials of tenancy discussed at Lab Space Forum


**Moderator Matt Goodrich of Davis Moore with panelists Hortense Dodo of IngateyGen, Life Edit Therapeutics' Chase Brett and Locus Biosciences' Paul Garofolo**

A panel of biotech tenants came together at the NCLifeSci Lab Space Forum held Tuesday, July 23, at the NC Biotechnology Center to discuss the intricacies of growing a life sciences company in rented Research Triangle Park office and lab space.
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The conversation, which ranged from startup challenges to balky climate controls, offered valuable insights for both established and emerging companies.Â
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**Matt Goodrich**, corporate real estate adviser at Davis Moore, moderated a panel comprisingÂ

- **Chase Brett**, associate director, facilities and engineering for Life Edit Therapeutics;Â
- **Hortense Dodo**, president of IngateyGen; andÂ
- **Paul Garofolo**, co-founder and chief executive officer of Locus Biosciences.Â

The forum was sponsored by Clean Harbors, Flagship Lab Services and Longfellow Real Estate Partners.Â
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Securing and designing lab space is a significant challenge. Panelists emphasized the importance of understanding a company's growth plans before signing a lease and the need for careful space planning, especially for smaller companies. Construction delays, supply chain disruptions, and the intricacies of multi-tenant building infrastructure adds to the complexity.

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# STATE UPDATES

## North Carolina second in CNBC best-for-business rankings

After back-to-back years as CNBC's best state for business, North Carolina is No. 2 in the 2024 rankings behind perennial favorite Virginia.
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So what changed? In previous years, the most important category in the study was workforce, North Carolina ranked No. 1. CNBC this year made infrastructure the top category, where North Carolina was 20th.
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North Carolina remains only the second state named to the top spot back-to-back since CNBC started the rankings in 2007. Virginia, which last won in 2021, has received the top honors six times.Â
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Just three points separated Virginia and North Carolina. The top two states were followed by Texas and Georgia in third and fourth place. More at CNBC

## House returns to override vetoes, Senate yet to do same

On July 31, the House reconvened and successfully overrode a series of bills that were vetoed by Gov. Roy Cooper.
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Voting largely along party lines, the chamber overrode HB 155 which allows the NC DMV to issue title certificates for all-terrain and utility vehicles; HB 556 which deals with changes in the law regarding tenancy, notaries and small claims court; and HB 690, which blocks state agencies from taking payments in central bank digital currency.
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Notice of the overrides were sent to the Senate, which has not yet returned to hold votes.

# 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.**

## CMS price "negotiations" are done, results still under wraps

The first Medicare drug price negotiations formally came to a close Aug. 1 ? but under a strict confidentiality agreement between drug makers and CMS, the final prices are still to be revealed.
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The pharmaceutical industry also took another loss in court July 31 as a federal judge backed the Biden administration against Novo Nordisk, a decision notable because the company argued that CMS overstepped by combining several insulin products as a single drug for price talks. Novo Nordisk said it plans to appeal.
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The judge in the case wrote that the company failed to show it had standing, agreeing with HHS that Novo Nordisk’s challenge seeking to enjoin the program as a whole was overbroad. He also denied the company's request for summary judgment on grounds that Â that the Inflation Reduction Act’s Medicare drug price negotiation program also violates the Fifth Amendment’s due process clause, the First Amendment by compelling speech and the

Administrative Procedure Act.
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The judge had previously ruled against the Bristol Myers Squibb and Janssen Pharmaceutical in similar suits.
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Lawsuits brought by Merck and the U.S. Chamber of Commerce still await decisions at the district court level. Other drug makers are currently appealing their cases.
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Vice President Kamala Harris is signaling that she wants to extend an out-of-pocket cap on drug costs to the private market if she is elected in November. Under the Inflation Reduction Act, a $2,000 annual cap will take effect next year for older adults on Medicare.

## Congress adjourns for August recess, funding bills languish

House members left Washington early for August recess after Republicans abandoned their push to pass all the annual spending bills before the break. The Senate adjourned a week later on Aug. 2.
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The House passed a interior-environment funding bill late July 24, with conservatives considering rejecting the legislation as their amendments continued to fail. Five of them ultimately did, with one Democrat defecting to vote in favor, in a 210-205 vote. Of the dozens of bills that make up the federal appropriations process, five have been passed by the House so far.
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On July 9,Â House appropriators advanced a bill out of committee that directs $3.5 billion in taxpayer funds to the FDA by a 29-26 vote.
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The fiscal 2025 bill, approved by the House Appropriations Committee, also includes $3.25 billion for the agency from user fees.
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Those totals are a small dip from current funding levels of $3.52 billion in discretionary funding and $3.2 billion in user fees. The Biden administration asked for $7.2 billion in total funding in its budget request ? a higher amount than the total $6.75 billion in the House bill.
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Before adjourning the Senate on Aug. 2, senators held a joint hearing on the assassination attempt on former President Donald Trump, which featured testimony from FBI and Secret Service officials. The chamber also held votes on child-privacy legislation before finishing up.

## New bipartisan House bill cracks down on PBMs after hearing

Reps. Jake Auchincloss (D-Massachusetts) and Diana Harshbarger (R-Tennessee) introduced a new PBM bill titled the Pharmacists Fight Back Act. This legislation addresses spread pricing, increases transparency among PBMs and restricts the ability of PBMs to create network exclusions.
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The legislators said that Pharmacists Fight Back Act reins in large PBMs responsible for hundreds of millions of dollars in overcharges via spread pricing in Medicaid-managed care plans. The bill implements a transparent pharmacy reimbursement model using market-based pricing benchmarked to the national average drug acquisition cost. It also removes the ability of PBMs to restrict patient choice via network exclusions, and protects community pharmacists by prohibiting PBMs from steering patients to PBM-affiliated pharmacies.Â
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The legislation comes on the heels of a hearing by the House Oversight and Accountability Committee and a report from the FTC that states, "PBMs inflate prescription drug costs and interfere with patient care for their own financial benefit."
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Key takeaways from the FTC report include:

- PBMs have gained significant power over prescription drug access and prices through increased concentration and vertical integration.
- Increased concentration and vertical integration may have enabled PBMs to lessen competition, disadvantage rivals and inflate drug cost.
- PBM and brand drug manufacturer rebate contracts may impair or block less expensive competing products, including generic and biosimilar drugs.

The chief executives of the three largest PBMs, responsible for processing 80% of U.S. prescriptions testified before the committee.
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Committee Chair James Comer (R-Kentucky) said PBMs should not own pharmacies or be owned by insurers. Rep. Buddy Carter (R-Georgia) noted PBMs help their own pharmacies, harming independents, and called their practices “despicable.” More at BIO

## FTC targets PBMs with lawsuit over high drug costs

The Federal Trade Commission is gearing up to sue major health care companies for allegedly manipulating the drug market to maximize profits.
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The lawsuit targets pharmacy benefit managers owned by UnitedHealth Group, CVS and Cigna. The FTC claims these companies prioritize high-cost brand-name drugs, including insulin, over cheaper alternatives, thereby driving up costs for patients and insurers.
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A core issue is the rebate system where drug companies pay PBMs to include their medications on covered drug lists. This practice, critics argue, inflates drug prices.
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The case highlights the complex interplay between drug manufacturers, PBMs, and insurers, with each party accusing the others of anti-competitive practices. The outcome of the lawsuit could significantly affect the pharmaceutical industry and drug prices for consumers.

## FDA launches Rare Disease Innovation Hub to expedite treatments

The Food and Drug Administration announced July 17 the creation of a Rare Disease Innovation Hub to “expedite development and approval of safe and effective drugs and biologics” for rare diseases.
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What it will do, according to the FDA:

- Serve as a single point of connection and engagement with the rare disease community, including patient and caregiver groups, trade organizations, and scientific/ academic organizations.
- Enhance intercenter collaboration to address common scientific, clinical and policy issues related to rare disease product development.
- “Advance regulatory science with dedicated workstreams for consideration of novel endpoints, biomarker development and assays, innovative trial design, real world evidence, and statistical methods.

An estimated 10,000+ rare diseases affect more than 30 million people ? approximately one out of every 10 people ? in the U.S., and about half of these people are children. Many rare conditions are life threatening, and most do not have approved treatments.

More at BIO

## Â House committee tells FDA to suspend lab developed test ruleÂ

The House Appropriations Committee directed the FDA to suspend the implementation of its final rule on laboratory developed tests.
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The committee said that the final rule carries the risk of greatly altering the United States’ laboratory testing infrastructure and reducing patient access to information that informs their health-care decision making.
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The Appropriations Committee voted to provide the FDA with $3.5 billion in direct appropriations and recommended that the agency suspend work on the final rule and partner with Congress to modernize the regulation of LDTs.
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The FDA had previously taken an enforcement-discretion approach with LDTs, but the new rule implemented in April would have regulated them as medical devices, subjecting them to a stricter review process. More at MedTechDive

## FDA announces FY 2025 user fee rates

The FDA has published its user fee rates for fiscal year 2025 across its prescription drug, generic drug, biosimilar, medical device and over-the-counter monograph drug programs.
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The rates are calculated by factoring in its resources against the number of applications it expects to receive over the next fiscal cycle based on historical trends.
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**PDUFA.** FDA estimates the base revenue for FY 2025 for the Prescription Drug User Fee Amendment at $1,358,764,346 before factoring in inflation and other factors. The new estimate is more than an 8% increase compared to its FY 2024 estimate of $1,256,844,387.
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**MDUFA.** FDA estimates the base revenue for FY 2025 for the Medical Device User Fee Amendment at $350,746,400 before factoring in inflation and other factors. The new estimate is more than a 4% increase compared to its FY 2024 estimate of $335,750,000.
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See the full list of fees at Regulatory Focus.

## BIO opposes proposed rule on challenging patents

A U.S. Patent and Trademark Office proposal to make it easier to challenge patents would cause extensive harm to the patent system, BIO said.

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USPTO’s Notice of Proposed Rulemaking regarding Terminal Disclaimer Practice to Obviate Nonstatutory Double Patenting is intended to make it cheaper and easier to strike down whole families of patents to prevent them “from potentially deterring competition.”Â
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“BIO believes that the proposed rule "is unsupported by the factual record, lacks legal authority, lacks a policy justification, is inconsistent with statutory and case law, and would cause extensive harm to the patent system,” says BIO’s comments.
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BIO’s specific objections include:

- The proposed rule is based on the assumption that many innovative products are protected by “too many” patents, but for drugs the average number of patents for products registered with the Food and Drug Administration is 3-5.
- USPTO has no legal right to make such overarching changes to patent protections.The proposed rule “would undermine the value of U.S. patents, and discourage innovators from seeking U.S. patents on improvement inventions and follow-on technologies."
- It would raise the cost of patent examinations.Â

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# NCLifeSci Updates

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**NCLifeSci President Laura Gunter recognized and thanked board members Tom Fagley, the previous treasurer, and Scott Sewell, who is retiring, for their outstanding service to the organization.**

## Board of Directors welcomes new members, hears from NCInnovation, increases some dues

The NCLifeSci Board of Directors met Thrusday, Aug. 1, at the NC Biotechnology Center to welcome new members and hear a presentation from NCInnovation, an initiative of the NC General Assembly that aims to bridge the "valley of death" between government funding and private investment for new tech generated by North Carolina's public universities.
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The Executive Committee of the board approved dues increases for some membership levels in the organization. Member companies with three or fewer employees will now pay $300 a year. Affiliate members and out-of-state members (those without an in-state presence) will pay $2,000 a year.
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The board approved new members:

- Aer Therapeutics, Inc.Â
- Botany AI Inc. dba Ummino
- Dickson
- Jurata Thin Film, Inc.Â
- Medical Leverage
- NuRevelation, LLC
- Quanticision Diagnostics Inc.
- Solve Therapeutics, Inc.Â
- Surplus Solutions LLC
- Torque Bio, Inc.Â
- Zageno

Bennet Waters, president and CEO of NCInnovation, gave an overview of the organization's state funding model and its efforts to leverage homegrown innovation for economic growth in North Carolina.

- NCInnovation has established regional innovation hubs and partnerships to accelerate the commercialization of applied research generated by the state's R2 and other universities, which do not include R1 universities UNC-Chapel Hill or NC State.
- The organizations providing nondilutive grants to bridge the "valley of death" funding gap for early-stage companies.
- NCInnovation is funded by the proceeds of an endowment created from state reserve monies. The endowment's principal remains under the control of the legislature.
- Focusing on retaining talent and companies in North Carolina rather than losing them to other states is a key reason for the creation of NCInnovation.

NCLifeSci President Laura Gunter recognized and thanked board members Tom Fagley and Scott Sewell for their outstanding service to the organization. Fagley served a lengthy tenure as the organization's treasurer, and Sewell is retiring from Cook Medical and the board at the end of August after many years of service to both.


**Two of NCLifeSci's newest members were represented by Josh Pankratz of Surplus Solutions, LLC and Curtis Heinsohn with New England Biolabs (previously admitted).**

## NCLifeSci Member News

**Eisai** and **Biogen** announced that LEQEMBI (generic name: lecanemab) has been approved in Israel and in Hong Kong as a treatment of Alzheimer’s disease in patients with early AD. More >>
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**Frankel Staffing** will be closing Aug. 31 as owners Rod Frankel and Lee Frankel enter retirement and semiretirement, respectively.
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**G1 Therapeutics** announced that the company has been added to the broad-market Russell 3000 and small-cap Russell 2000 Indexes as of July 1.
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**Galaxy Diagnostics** launched two tests that give therapists powerful new tools to identify potentially deadly but usually treatable insect-borne bacterial infections in people and animals. More >>
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**GRAIL** completed its spin-off from Illumina and began trading on the Nasdaq under the symbol “GRAL.” More >>
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**GRAIL** enrolled the first participant in the REACH/Galleri-Medicare study at Community Health Network, an integrated health care system in central Indiana with more than 200 sites of care. More >>
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**Humacyte** has been granted the FDA’s Regenerative Medicine Advanced Therapy designation for patients with advanced peripheral artery disease. More >>
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**IQVIA** announced that a leading, independent research firm, Everest Group, has recognized IQVIA as a Leader in its Life Sciences Regulatory and Medical Affairs Operations PEAK Matrix Assessment 2024 survey, which measures both market impact and delivery effectiveness. More >>
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**Lilly** announced that the FDA approved Kisunla (donanemab-azbt, 350 mg/20 mL once-monthly injection for IV infusion), the company's Alzheimer's treatment for adults with early symptomatic Alzheimer's disease. More >>
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**Thermo Fisher Scientific** has introduced a new pre-transplant risk assessment assay that helps assess risk of early acute rejection in kidney transplant recipients. More >>

## Events

### NCLifeSci calendar

- Preparing for Pandemics: Local Leadership for Global Impact hosted by NC Global Health Alliance and RTI International (8/7/2024)
- MedTech Conference 101 Webinar hosted by AdvaMed (8/7/2024)
- Challenges of Administrative Burden and Prior Authorization hosted by NCMGMA, NCMSE (8/13/2024)

NCMGMA-NCMSF (8/13/2024)
- Maximizing Opportunities: How to Best Prepare for International Trade Shows hosted by NCBiotech (8/20/2024)
- CEAg World Conference and Expo (8/26/2024 to 8/28/2024)
- U.S. Data Privacy for Health Summit (9/10/2024)
- International Life Science & Biotech Conference (9/11/2024 to 9/12/2024)

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## NCMS Webinar: Insurance Barriers to Care Aug. 13

Patients across North Carolina continue to struggle to access the care they rely on to manage symptoms and control their illness. Meanwhile, health insurers are increasingly adopting protocols that reduce access to care for patients and increase administrative burdens on providers.
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To help raise awareness of the widespread impact of burdensome health insurer practices and encourage providers to take action on behalf of their patients, the North Carolina Medical Society is holding an educational webinar on Tuesday, Aug. 13, from 12 ? 1 p.m.

**REGISTER NOW**

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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 Sept. 10 at the NC Biotechnology Center.
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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.
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NCLifeSci members receive a 20% discount on their registration. Contact Amber Niebauer for the discount code.Â

**LEARN MORE**

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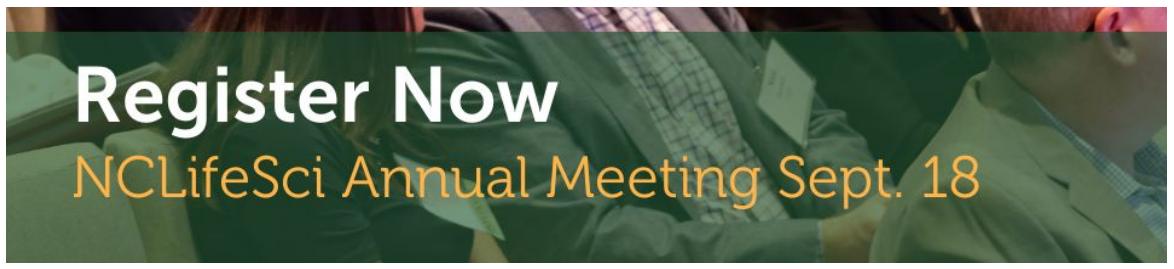


There are only a few spots left for members who want to attend the NCLifeSci Annual Meeting and 30th anniversary celebration on Wednesday, Sept. 18, at the NC Biotechnology Center. The 2024 Annual Meeting will feature a keynote presentation and three panel sessions.

- Keynote by Edgardo Hernandez, executive vice president and president, manufacturing operations, Eli Lilly and Company.
- Federal Update / Patient Advocacy panel featuring the Arthritis Foundation, the Biotechnology Innovation Organization, Edwards Lifesciences, 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, the Chordoma Foundation, the Foundation Fighting Blindness and Jurata Thin Film.

Thank you to our Annual Meeting sponsors for making this event possible.

**Podcast** - Maynard Nexsen
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**Bronze** - BIO,Â Marsh McLennan Agency, Mispro, NIIMBL, Novonesi, Surplus Solutions and TeamLogic IT
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There is a $50 registration fee for the meeting. If registration is full, you will be able to add your name to a waiting list should a spot open up.

**REGISTER NOW**

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## Life Sciences Economic Development Summit 2024 and Celebrating Life Sciences Success in North Carolina

Mark your calendars for the NC Biotechnology Center's Life Sciences Economic Development Summit and 40th anniversary celebration, "Celebrating Life Sciences Success in North Carolina," an educational program and celebration of the state's innovative, highly collaborative life sciences ecosystem.

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## Medtech Conference Oct. 15-17 in Toronto

The MedTech Conference in Toronto, Oct. 15-17, will help you look ahead and create new possibilities. Featuring world-class speakers, a cross-cutting educational program, invaluable networking and next-level technology, this forum for transformational ideas is a can’t-miss event for the industry’s prominent and most promising companies.
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Contact Amber Niebauer for a discount registration code.

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## SCIX Science and Technology Career Fair Oct. 22-23

Job hunting, hiring or just looking to expand your professional development skills? Attend the free Science & Technology Expo and Career Fair at SciX in Raleigh, Oct. 22-23. The SciX Conference offers this valuable opportunity for networking and career advancement within the spectroscopy and analytical chemistry community.
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Attend the free Science & Technology Expo and Career Fair at SciX in Raleigh Oct. 22-23 and connect with world-class talents who specialize in groundbreaking analytical instrumentation and data science techniques for clinical, biopharmaceutical, nanotech and industrial applications This career fair will take place on Tuesday and Wednesday during the conference in the exhibit hall.Â
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Oct. 22: 9:30 a.m. - 5 p.m.
Oct. 23: 9:30 a.m. - 4 p.m.
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The employer package includes

- All access to Expo
- 6' skirted table and chair
- Lunch ticket for each day of Career Fair
- Digital, social media, and print brand recognition

**LEARN MORE**

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## Join NCLifeSci for kickoff reception at JPM Jan. 12

We’re kicking off JPM Healthcare Week 2025 in style on Sunday, Jan. 12, from 4 to 7 p.m. at the Marker San Francisco. Hosted by AZBio, Biocom California, BioNJ, Bio Utah, Colorado

Bioscience Association, Georgia Bio, Life Sciences Pennsylvania, MichBio, **NCLifeSci**, New York Bio, Oregon Bio, Virginia Bio and more, the State Bio Friends Reception kicks off the largest annual gathering of health care innovators and investors in the world.
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This is a private reception by invitation only, and tickets are limited. If you are interested in attending, please contact Alex Caruso to be added to the list of possible attendees.Â

**NCLifeSci JPM Kickoff Reception Sponsors**

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## Business Solutions from NCLifeSci


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Read our recent newsletter on how life science companies ship biologics, specialty pharmaceuticals, and standard packages.

**LEARN MORE**

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