January 2024 Update

Serving the NC Life Sciences Industry

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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.
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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.Â

Gunter joins state BIOs at NYSE to ring in Biotech Month

The NC Life Sciences Organization joined fellow life science trade organizations from across the country to ring the closing bell at the New York Stock Exchange Wednesday, Jan. 3, and kick off Biotech Month.
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NCLifeSci President Laura Gunter was among the 16 leaders in attendance at the event, which was held jointly by NewYorkBIO and NYSE to celebrate the link between investment and innovation to best serve patients nationwide.

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STATE UPDATES

2024 Election updates: filing period closes

North Carolina's candidate filing period ended on Dec. 15, bringing additional clarity to the 2024 election.
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Congresswoman Kathy Manning (NC-6) and Congressman Wiley Nickel (NC-13) will not seek re-election. Both of their districts were redrawn by the General Assembly this year and now lean Republican.
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Two General Assembly members that have been leaders in health care policy have announced that they are retiring. Sen. Joyce Krawiec (R-Forsyth) and Rep. Kristin Baker (R-Cabarrus) will not seek re-election for another term, nor is Senate Majority Whip Jim Perry (R-Beaufort, Craven, Lenoir). Rep. Marvin Lucas (D-Cumberland) also announced his retirement along with Rep. Kelly Alexander (D-Mecklenburg) and Rep. Rosa Gill (D-Wake).
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Following the re-drawing of the NC House and Senate maps, four state senators found themselves in a “double-bunked” district, meaning two members were redrawn into the same district.
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Sen. Natasha Marcus (D-Mecklenburg) and Sen. Vicki Sawyer (R-Iredell) are in the same district in northern Mecklenburg County and southern Iredell County. Marcus said she would not contend against Sawyer and announced her run for NC insurance commissioner instead. As the only candidate in the Democratic primary, she will likely face incumbent Mike Causey (R) in the general election.
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In Wake County, Sen. Jay Chaudhuri (D-Wake) and Sen. Lisa Grafstein (D-Wake) are double-bunked in the northern part of the county. Grafstein said that she will be moving to southern Wake County and running for NC Senate in District 13.
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NC Sen. Mary Willis Bode (D-Wake) also decided not to run for re-election, with NC Rep. Terence Everitt (D-Wake) subsequently announcing his plan to switch chambers and run for that seat. NC Senate District 18 is a nearly even partisan split, so it is likely to be an especially close and very expensive race in the Triangle media market.
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NC House Rep. John Bradford (R-Mecklenburg) previously announced he was running for State Treasurer but is now running for Congress in NC-8. Congressman Dan Bishop (NC-8) currently holds the seat, but he is running for NC attorney general.Â
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NC House Rep. Grey Mills (R-Iredell) filed to run in NC-10, the seat currently held by Congressman Patrick McHenry, who will be retiring at the end of his term. Rep. Mills will face former U.S. Army Green Beret Pat Harrigan in the Republican primary. Harrigan originally filed for Congress in NC-14 but switched to NC-10 after McHenry announced his retirement.

UNC-P, NCCU to offer free bioprocessing training

UNC Pembroke and North Carolina Central University are teaming up to offer a free two-week bioprocessing training program to equip NC residents with skills for high-demand jobs in biopharmaceutical manufacturing.
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Starting Jan 22, this hands-on course will prepare up to 12 participants for entry-level positions in the industry, focusing particularly on economically challenged counties in North Carolina.
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This initiative is part of the Accelerate NC ? Life Sciences Manufacturing program funded by a $25 million grant to promote workforce equity and economic development across the state.
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NCCU partnered with UNCP to launch this first program within the HBCU/HAIU Coalition. More universities in the coalition are expected to follow suit in 2024.
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To participate, applicants must be 18 or older with a high school diploma or GED and complete five online modules. The program covers both upstream and downstream bioprocessing and leads to several industry-recognized certifications, including an advanced

certificate in biopharmaceutical manufacturing. More at UNCP >>

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.

Congress returns to face tight deadlines

Congress returns from the holidays on Jan. 9 to tackle a busy January agenda, including passing two major health care spending bills and potentially attaching significant health initiatives.
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Lawmakers face a tight deadline of Jan. 19 to pass the Agriculture-FDA spending bill before a partial government shutdown looms. They have until Feb. 2 to pass the Labor-HHS spending bill and fund the rest of the government, including major domestic programs and the Pentagon.
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Further complicating matters, there is no agreement on a top-line spending number yet. House Speaker Mike Johnson has vowed to avoid "short-term" stopgap measures to fund the government, and while a full-year patch has been discussed, lawmakers from both parties are increasingly opposed to such an approach.
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The spending bills could be one of the last major vehicles for legislation before an election year, making them especially important for lawmakers and advocates. The Jan. 19 vehicle, which includes several expiring health program extenders, is being eyed for potential health transparency legislation.
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The House and Senate have different approaches to reducing health care costs. For example, the two chambers' HELP and Finance committees have differing views on PBMs, and the Senate has not yet adopted the House's "site-neutral" policies, which aim to equalize payments for services provided at hospital outpatient facilities and independent doctors' offices.

Congress fails to act on R&D tax amortization in 2023

A 2017 tax rule that went into effect in 2022 requiring the amortization of research and development expenses has created significant challenges for many life sciences startups and small businesses.
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Previously, grant money received by these companies and spent on R&D could be deducted immediately in full, but the new rule forces them to spread the deduction over five years for domestic R&D and 15 years for overseas R&D.
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The new rule sparked a bipartisan effort to repeal the amortization requirement. Sen. Thom Tillis (R-NC) and Sen. Ted Budd (R-NC) are among the cosponsors of the American Innovation and Jobs Act, which would restore full expensing for R&D costs. In the House, 197 representatives, including six NC Democrats (Don Davis, Valerie Foushee, Jeff Jackson, Kathy Manning, Wiley Nickel and Deborah Ross) and two NC Republicans (Chuck Edwards and Greg Murphy) have co-sponsored a similar bill.
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However, Congress failed to address the R&D deduction before adjourning in December, but there is some possibility that it could be included in spending bills that Congress will consider in January and February.Â
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NCLifeSci will be supporting an impending BIOaction Campaign led by BIO to amplify our collective position on this issue and drive grassroots engagement. We will be sharing more details soon on how you can make your voice heard.
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In the meantime, it is helpful for members of Congress to hear from their local constituent companies with the estimated number of jobs affected, types of research and innovation threatened, overall local economic impact (such as postponing expansion plans, hiring freezes, etc.), so please put some of these figures together. Reach out to Laura Gunter to share or get the contact information for members of North Carolina's delegation.

Busy year ahead for FDA

The FDA faces a packed agenda in 2024 with leadership changes, inspection improvements, potential tobacco regulations, and a decision on phenylephrine in cold medicines.
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Congress adjourned without passing a year-end spending bill, leaving FDA appropriations and other health care items unresolved.
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Principal Deputy Commissioner Janet Woodcock is retiring, affecting drug oversight and daily operations. Chief Scientist NamandjÃ© Bumpus is slated to take over for Woodcock.

The agency will reorganize and strengthen its field-based oversight program with a workforce reorganization and rebranding. This follows scrutiny over the Abbott formula crisis and foreign drug inspections.

A ban on menthol cigarettes and flavored cigars inches closer to finalization, targeting March and April releases respectively. Maximum nicotine levels in cigarettes are also under consideration.

The FDA may order the removal of phenylephrine from over-the-counter products based on expert advice. The removal process could take months with lawsuits and retail changes already happening.
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As 2023 drew to close, the FDA issued a slew of regulatory guidance documents covering the following and more (links to PDFs):

- digital health technologies
- real-word data from trial registries
- master protocols for drug and biologicals development
- COVID-19 monoclonal antibody development

A longtime priority of FDA Commissioner Robert Califf ? improving clinical trials ? got a boost this week with the release of a final rule updating rules of the road aimed at protecting people who participate in clinical research.

Biden Administration claims march-in right, Chamber rallies opposition

The Biden administration has determined it has the authority under the 1980 Bayh-Dole Act to seize patents of certain medications developed with public funds that it deems excessively expensive, although the administration is emphasizing a cautious approach.
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A new framework outlining factors for using march-in rights will be released, with public input encouraged, the administration said. The Biden administration aims to solidify health care as a core campaign platform, with potential drug-price proposals coming soon. Recent legislation capping insulin prices and allowing Medicare drug price negotiation likely will be further expanded.
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The pharmaceutical industry argues that it is illegal for the government to seize patents and doing so would disincentivize the development of new drugs.
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Fearing a broader impact on tech and clean energy, the business community is gearing up to fight the Biden administration's potential seizure of patents. On Dec. 21, the U.S. Chamber of Commerce convenened over 100 companies, trade groups and individuals, including BIO and PhRMA, to strategize a resistance. Industry fears the policy could extend beyond pharmaceuticals, endangering patents in emerging technologies like clean energy.
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The Bayh-Dole Coalition has requested a comment period extension, send a joint letter to the administration and filed freedom-of-information requests for details on the policy's development. More at BIO

Biden administration attacks IRA drug-pricing lawsuit in court

The Biden administration fired back at the pharmaceutical industry in a recent court filing, addressing legal challenges to its Medicare drug price negotiation authority.Â
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The administration argues the U.S. Chamber of Commerce and other plaintiffs suing over the program's excise tax should have targeted the Treasury Department, not Health and Human Services. They also claim a lawsuit challenging an unimposed tax is premature.

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The Justice Department counters industry claims that the program violates the nondelegation doctrine by highlighting historical precedents and arguing that Congress provided clear guidelines for the program's implementation. Nondelegation holds that Congress cannot transfer its legislative authority to another government branch without providing guidance.

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The Court's upcoming rulings on administrative state challenges could impact how they view the Medicare program case. The administration predicts the Court will uphold delegation in this case.

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Court briefs in the case continue through January. This is one of several industry lawsuits aiming to block the program, which carries high stakes for both sides.

Pharma pushes back against tougher merger rules

The pharmaceutical industry is bracing for a potential clash with the Biden administration over stricter merger and acquisition regulations.Â

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The Federal Trade Commission and the Justice Department's tougher stance has drawn concern from companies like Merck, AbbVie, and Amgen, who argue that mergers are crucial for innovation in the high-risk, high-cost world of drug development.

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The Partnership for the U.S. Life Science Ecosystem is lobbying against tougher regulations, arguing they stifle innovation. Drug companies claim acquisitions are essential to bring new treatments to market due to high failure rates and costs. Some industry leaders report that the government's stance is already having a chilling effect that has led to a decline in mergers and acquisitions due to the uncertain regulatory landscape.

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Broader antitrust enforcement under FTC Chair Lina Khan encompasses health care and biotech sectors. In the pharmaceutical sector, the FTC has focused on bundled discounts for products, which it argues could cement market dominance. The agency has also taken an aggressive stance against hospital mergers and, in an ongoing legal battle, challenged genetic-sequencing firm Illumina’s takeover of cancer-test developer Grail.

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The agencies are crafting final guidelines, setting the stage for potential legal challenges from companies.

Nineteen Democrats sign letter against TRIPS waiver

Nineteen House Democrats signed a letter to U.S. Trade Representative Katherine Tai opposing an expansion of the TRIPS waiver to COVID-19 therapeutics or diagnostics. The signatories include North Carolina Representatives Ted Davis, Wiley Nickel and Deborah Ross.

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This letter follows the very successful briefing the New Democrats held on the waiver at which Christoph Bausch, COO of BIO member company SAb Biotherapeutics, made an outstanding presentation which was attended by several of the signatories.

EPA planning for final rule on ethylene oxide

The Environmental Protection Agency plans to sign a final rule targeting ethylene oxide emissions from commercial sterilizers, Reg. 2060-AU37, in March.

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Another rule that will limit ethylene oxide emissions from a number of chemical manufacturing facilities, Reg. 2060-AV71, is under a court-ordered deadline to be finished by March 29. Also in March, EPA plans to propose a rule governing EtO emissions from hospital sterilizers, Reg. 2060-AV95. That’s a month later than was projected under the spring agenda.

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The FDA is holding a Medical Device Sterilization Town Hall with a focus on ethylene oxide on Jan. 10 at 2 p.m.

BIO urges action on agricultural exports

BIO and 34 other organizations wrote the President’s Export Council last week urging action on agricultural trade, and the council conveyed those concerns in writing to President Joe Biden.

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The letter to the PEC, the principal national advisory committee on international trade, listed recommendations to expand market opportunities, reduce trade barriers, and address sustainability.

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Recommendations include

- Enforce existing trade agreements?by strengthening the World Trade Organization dispute resolution process and enforcing all free trade agreements.

- Lead on international sustainability and climate efforts?by supporting climate-smart agricultural practices that include biotech solutions.
- Increase collaboration to diversify the agriculture supply chain for inputs like fertilizers.
- Establish a robust agricultural trade agenda to remove tariffs and other barriers and open up more markets for American goods.

The letter mentioned the U.S.-Mexico-Canada Agreement, which Mexico has violated with its plan to ban U.S. biotech corn. A panel is expected to rule in that dispute in mid-2024.

COVID-related tariff exclusions extended five months

The Biden administration extended most tariff exclusions for Chinese medical and non-medical products until May 31, 2025. This temporary reprieve aims to avoid disruptions while providing time for adjustments and aligning with an ongoing review of all China tariffs.

- 77 medical products (masks, gloves, gowns, etc.) and 352 non-medical products excluded from tariffs for another 5 months.
- Extension allows for smoother transition and aligns with a broader review of China tariffs expected to continue in 2024.
- Biden administration has gradually reduced excluded medical products since 2020. Industry groups criticize USTR's last-minute renewals and lack of transparency.

This delay allows businesses and consumers to adapt while the government determines the long-term future of China tariffs.

NCLifeSci Updates

BIO’s John Murphy: Real numbers tell real value of new drugs

Meaningful discussion of drug costs and benefits requires accounting for rebates, BIO Chief Policy Officer John Murphy explained in RealClearHealth.

“Typically, manufacturers give enormous discounts to middlemen” ? pharmacy benefit managers ? to obtain insurance coverage for their drugs, Murphy says. These discounts, often given as rebates, must be considered in weighing the true cost of a drug.
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Huge savings: “In 2022, drug manufacturers offered $223 billion in rebates and discounts off the nominal’ list’ prices of brand-name medicines ? nearly half the official total spending on prescription drugs,” Murphy notes.
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The reality: As an example, the Institute for Clinical and Economic Review estimated the new anti-obesity drug Wegovy would cost $13,000 a year, but it really costs about $6,500.
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The bottom line: “With potentially millions of Americans’ health on the line, it’s critical that we all share the same basic set of facts,” Murphy writes. “Yes, innovation is expensive?but it’s often worth it. Let’s stop blaming the innovators.” Read more at Real Clear Health >>

NCLifeSci Member News

Atsena Therapeutics announced positive 12-month safety and efficacy data from the ongoing Phase I/II trial of ATSN-101, the company’s investigational gene therapy for the treatment of GUCY2D-associated Leber congenital amaurosis. More >>
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Biocair announced its partnership with Aramex Ireland to expand its presence in the Irish market to provide specialist and bulk logistics solutions for the pharmaceutical, medical and biotechnology sectors. More >>
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Biogen announced that the European Medicines Agency recommended marketing authorization for SKYCLARYS (omaveloxolone) for the treatment of Friedreich’s ataxia. If approved by the European Commission, SKYCLARYS will be the first treatment authorized within the EU for this rare, genetic, progressive neuromuscular disease. More >>
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Biogen and **Sage Therapeutics** announced ZURZUVAE (zuranolone) 50 mg CIV is now available by prescription for the treatment of postpartum depression for adults in the United States, with product already at specialty pharmacies and delivered to patients. More >>
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Chimerix promoted Michelle LaSpaluto, vice president of corporate financial planning and investor relations, to chief financial officer effective Dec. 1, 2023. More >>
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Eisai and **Biogen launched** humanized antisoluble aggregated amyloid-beta monoclonal antibody LEQEMBI Intravenous Infusion (200 mg, 500mg, lecanemab) in Japan on Dec. 20, following its inclusion in the price listing on the Japan National Health Insurance Drug Price List. More >>
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Kymanox announced the rollout of its Product Design, Development and Commercialization Group to foster seamless collaboration among specialized teams with a primary goal of supporting the swift and successful commercialization of high impact combination products (e.g., biologic in a drug delivery device) for its clients. More >>
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The **PPD** clinical research business of **Thermo Fisher Scientific** has been selected by the BARDA to implement the first BARDA-supported Phase II platform clinical trial to investigate multiple therapeutic options for the treatment of acute respiratory distress syndrome. More >>
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ProKidney appointed Nikhil Pereira-Kamath, its vice president of business development & innovative solutions, to chief business officer. More >>
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Thermo Fisher Scientific launched CorEvidence, a proprietary cloud-based data lake platform optimizing pharmacovigilance case processing and safety data management processes that enhances CorEvitas clinical research registries offered by Thermo Fisher's **PPD** clinical research business. More >>

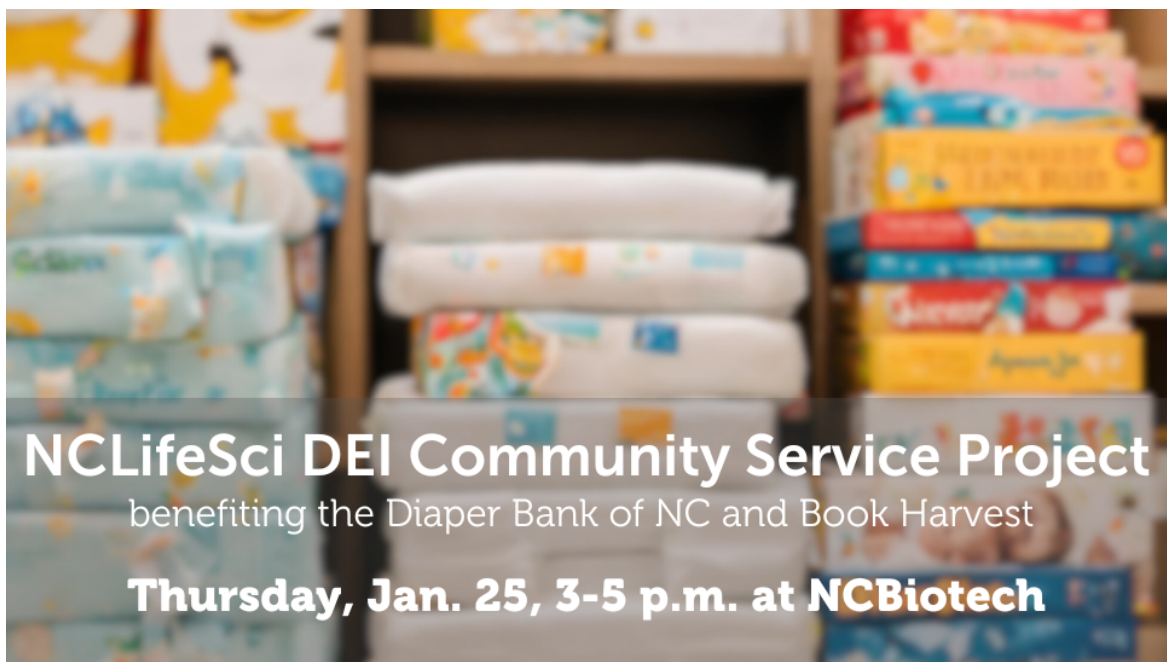
Events

Signals from JPM Week for 2024 Business Development Planning: Jan. 18 webinar

Announcements around and during JPM Week each January often create waves throughout the biotechnology ecosystem. Join this webinar to learn what experienced dealmakers and market analysts found most relevant and influential from JPM Week to consider when planning your own capital formation and partnering priorities for 2024. Developments affecting M&A trends, the IPO window, licensing trends and investor sentiment will all be discussed.

This webinar will also preview the program for the BIO CEO & Investor Conference Feb. 26-27 and explain how BIO's One-on-One Partnering during the event can help you make progress against your 2024 priorities.

REGISTER NOW



NCLifeSci DEI Community Service Project

Join NCLifeSci for an afternoon of networking and help support those in need in our communities. We will be participating in two service projects: Diaper Bank of NC and Book Harvest. Please bring your supply or book donation with you to the event. See below for more information regarding each organization and what they accept. We will have collection bins on site.
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Diaper Bank of NC

- Supply donation: Donate diapers, formula, period products, adult incontinence supplies and more at the event.
- Monetary donation: Your tax-deductible donation can be made online.

Book Harvest

- Book Donation: Bring your new or gently used children's books for readers 0 to 18 to the event. They love donations of board books; picture books; Spanish and bilingual books; books that portray all children and honor diverse backgrounds, languages,

abilities and perspectives; and stories by and about people of color.
- Monetary Donation: Your tax-deductible donation can be made online.Â

REGISTER NOW

Wilmington putting the TECH in BioTECH and Life Sciences in 2024, Jan. 25

The Network for Entrepreneurs in Wilmington invites you to join them at Ironclad Brewery in downtown Wilmington to learn more about the city's growing life sciences sector. Speakers at the event will include Kymanox CEO Stephen Perry and NCLifeSci president Laura Gunter.
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Wilmington has a growing life sciences sector with technology that is seeking capital and resources for pharmaceutical startups. Local leaders continue to deepen the city's relationship with the Triangle to attract resources to help Wilmington startups.

In the last year, both OpiAID and Boreas Monitoring Solutions are Wilmington success stories that represent the city's ecosystem and its evolution into an innovation economy.

So what is next for the city? With the life sciences is one of the top three industries in North Carolina, how will Wilmington grow this sector? Join NEW leaders on Thursday, Jan. 25, at Wilmington's Ironclad Brewery to find out.
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Speakers include

- Rob Cooley , CEO of Nuream
- Chris Lamb, CEO of Device Solutions
- Laura Gunter , President of NC Life Sciences Organization
- Moderator, Stephen Perry, CEO of Kymanox

REGISTER NOW

Find your next partner at BIO CEO & Investor Conference Feb. 26-27

Don't miss one of the largest investor conferences in our industry where institutional investors, industry analysts, and senior executives are shaping the future investment landscape of biotechnology.
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Join BIO in February to:

- Find and request meetings with potential partners using the BIO One-on-One

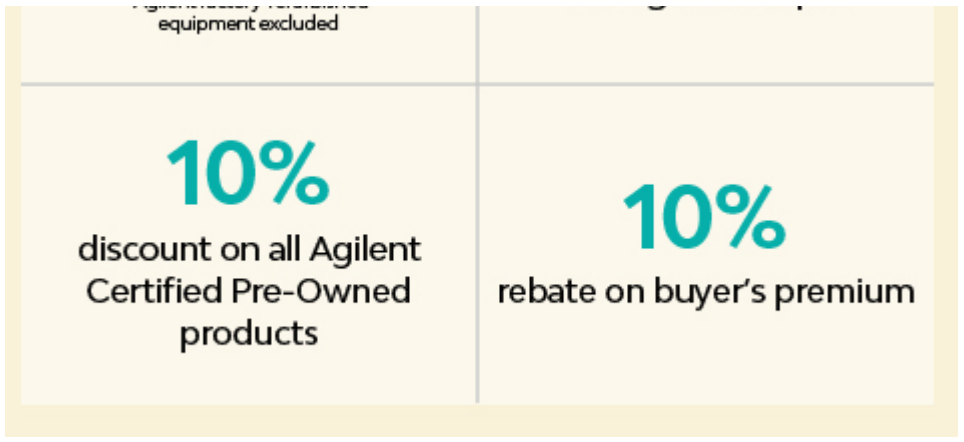
Partnering? system
- Discover the latest innovations in biotech during Company Presentations
- Hear from thought-leaders during sessions on therapeutic advancements, market outlook, and policy priorities

LEARN MORE

NCLifeSci calendar

- 42nd Annual Healthcare Conference hosted by J.P. Morgan (invitation only) (1/8/2024 to 1/11/2024)
- Partnering at JPM Week hosted by BIO (1/8/2024 to 1/12/2024)
- How to File an EEI through ACE hosted by EDPNC (1/9/2024)
- Non-Dilutive Funding Summit hosted by FreeMind Group (1/10/2024)
- Life Sciences Networking and RTP Facility Tour hosted by Azzur Group (1/10/2024)
- 4th Annual Mid-Atlantic Synthetic Biology Symposium (1/11/2024 to 1/12/2024)
- Introduction To Aseptic Processing Course hosted by Azzur Group (1/15/2024 to 1/19/2024)
- Overview of U.S. Food & Drug Administration Regulatory Requirements for Exports hosted by U.S. Dept. of Commerce (1/17/2024)
- Global Regulatory Requirements for U.S. Medical Device Exporters hosted by U.S. Dept. of Commerce (1/24/2024)
- Biotechnology Career Symposium hosted by Humacyte (1/25/2024)
- NCLifeSci DEI Community Service Project (1/25/2024)
- Life Sciences Marketing: Crisis Management in 10 Steps hosted by NCBiotech (1/30/2024)
- BPD BioGrow: Training and Education Across North Carolina hosted by NCBiotech (2/1/2024)
- Outlook for Tech hosted by NC TECH (2/2/2024 to 2/3/2024)
- Navigating Global Market Access for U.S. Medical Device & Diagnostic Companies hosted by U.S. Dept. of Commerce (2/7/2024)

BIO Business Solutions



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American Laboratory Tradin is a full-service provider of premium refurbished lab equipment and surplus strategy services for the life sciences. With more than 6,000 instruments in stock ranging from small benchtop accessories to robust triple quad mass spectrometers ? all items are carefully refurbished and delivered with a one-year warranty. ALT also purchases, consigns, trades, or auctions your surplus equipment to monetize your assets and maximize your ROI.

LEARN MORE

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