



February 2023 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

- General Assembly back in session
- COVID emergency to end
- FDA stays course on orphan drugs
- Novo Nordisk gives \$6 million to Durham Tech
- Register for NCBIO DEI Forum, Legislative Reception

Record year of life sciences growth wins accolades for NC

Life sciences and related companies from around the world announced new or expanded facilities in 2022 that will bring more than \$2.1 billion in investment and over 2,700 new jobs to North Carolina.

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The investments, along with new or expanded facilities in other sectors, gave North Carolina its best year to date for the number of new jobs created across all industries. Over 28,300 new jobs were announced during the year, according to Gov. Roy Cooper's office.

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The record year earned North Carolina several national accolades, including:

- The 2022 State of the Year Award from Business Facilities, a national magazine for corporate site selectors and economic development professionals. It's the second time in the last three years the publication has given North Carolina the top honor among the 50 states;
- Top State for Business from CNBC, the national cable business news channel;
- Top Business Climate from Site Selection Magazine, a publication covering global corporate real estate strategy and economic development; and
- No. 4 biotech hub ranking for the Research Triangle, according to Fierce Biotech, an online news site covering the biotechnology sector.

Thirty-two life sciences and related companies announced 33 projects in North Carolina that will create construction jobs and then life sciences jobs.

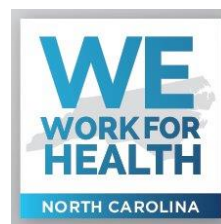
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"North Carolina enjoyed another banner year for life sciences company recruitments and expansions, confirming that the state offers major competitive advantages for this sector," said Doug Edgeton, president and chief executive officer of the North Carolina Biotechnology Center.

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Â [More at NCBiotech](#)

NCBIO Sustaining Members



NCBIO Supporting Members



GRAIL





STATE UPDATES

Life Sciences Caucus meets Feb. 8 to hear report on life sciences growth in NC

The General Assembly's Life Sciences Caucus will convene for the first time this year on Wednesday, Feb. 8, at 7:30 a.m. in the NCGA Member Cafeteria. Caucus Co-chairs Sen. Paul Newton, Sen. Mike Woodard, Rep. Donna White and Rep. Robert Reives will host the event, and legislators will hear from Doug Edgeton, president of the NC Biotechnology Center, and Ryan Helwig, principal and project director at Teconomy Partners.Â

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Legislators will hear about the latest TEconomy report, 2022 Evidence and Opportunity, that documents continuing growth of the state's life sciences industry and how it has generated a \$100 million increase in state and local tax revenues since 2020. TEconomy does similar economic reports for multiple states and for BIO. They are uniquely qualified to put NC's successes into perspective and to discuss those opportunities and barriers to continued success.Â

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If you would like to attend, please let [Laura Gunter](#) know.

Legislature reconvenes, House makes committee assignments

The General Assembly reconvened on Wednesday, Jan. 25. Both chambers officially began their work for the 2023 long session. Chamber leaders do not expect any roll call votes until late this week at the earliest, and the pace of the session will not pick up for several weeks.

House committees announced

Speaker Tim Moore (R-Cleveland) announced House committee assignments in advance of bill introductions. There are 44 House committees (the Senate has 18), including several newly created panels: Disaster Recovery and Homeland Security, Oversight Reform, State Personnel and Unemployment Insurance.Â

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While most House committees have multiple chairs, the leadership burden is concentrated in the most powerful committees. The Appropriations Committee has ten appointed chairs, while the Finance Committee has seven. Both Appropriations and Finance have members designated as senior chairs, who will lead the committees and manage budget negotiations with the Senate.Â

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In addition, four Democrats were appointed as committee chairs:

- Rep. Shelly Willingham (D-Nash) as chair of Alcoholic Beverage Control Committee
- Rep. Tricia Cotham (D-Mecklenburg) as chair of Education K-12 Committee
- Rep. Michael Wray (D-Northampton) as senior chair of Finance Committee
- Rep. Garland Pierce (D-Hoke) as chair of the Committee on Families, Children and Aging

These appointments are important for House Republicans as they are one vote short of a supermajority and will likely lean on these moderate Democrats for veto override votes on various issues. The complete list of House committees and their members can be found [here](#).

Opening day bills filed

A number of high profile bills were introduced in the opening hours of the new legislative session, including Democratic bills in both chambers on abortion rights.Â

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Bills of note filed on opening day include:

- [Senate Bill 2](#) NC Compassionate Care Act: This bill creating a legal

- [Senate Bill 5](#) NC Compassionate Care Act: This bill creating a legal structure for the use of medicinal marijuana has been refiled by Sen. Bill Rabon (R), Sen. Mike Lee (R) and Sen. Paul Lowe (D).
- [Senate Bill 16](#) Preserving Competition in Health Care Act: This legislation sets up a review process for the sale or mergers of hospitals, which would be led by the attorney general. Public hearings would be required, and the attorney general would look at whether the terms of the deal are “reasonable” with “fair market value” paid. The attorney general would also be tasked with considering “whether the proposed transaction may have a significant effect on the cost, availability, accessibility or quality of health care services for any affected community.” This bill has bipartisan support with Sen. Jim Burgin (R), Sen. Kevin Corbin (R) and Sen. Julie Mayfield (D) as the bill sponsors with the public support of Attorney General Josh Stein (D).



NATIONAL UPDATES

COVID emergency’s end will mean higher costs, barriers to those seeking care

From Politico

The White House’s announcement that it will end the Covid-19 public health emergency and a separate COVID national emergency on May 11 will mean new costs and more hassles for Americans seeking health care.

- It will also affect those receiving government nutrition assistance and could make it easier for immigrants to request asylum.
- Many will have to pay for COVID-19 vaccines, tests and treatments. People without health insurance will have to pay out of pocket, while those with private plans could see more costs depending on the terms of their insurance.Â
- Employers will no longer be able to offer telehealth access as a premium, tax-free benefit separate from other health plans.
- Medicare coverage requirements that were waived during the emergency will now resume.
- Medicaid and CHIP coverage will change in some ways, as state and federal agencies made changes, such as boosting provider payments, increasing beneficiary access to medicines and expanding some covered services, to their programs because of the emergency.
- Hospitals will lose the 20 percent increase in Medicare payments they’ve received for treating COVID patients.
- The White House said the end of the emergency would also end Title 42, a health policy used at the start of the pandemic to shut down the southern border by denying immigrants the opportunity to request asylum.
- The FDA will continue to have the power to authorize vaccines, tests and drugs on an emergency basis.

[More >>](#)

What to expect from the Republican House of Representatives

From Politico

With a historic days-long speaker’s race and adoption of a rules package behind them, House Republicans are turning to their next task: Balancing their slim majority with policy and political landmines.

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1. Prepare for a months-long fight over raising the debt ceiling. The White House and House Republicans are waiting to see who will blink first. The White House is warning that it won't negotiate on the debt ceiling.

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But House Republicans want to negotiate spending concessions in exchange for increasing the debt limit. As part of negotiations that ultimately landed him the gavel, McCarthy agreed that the House won't take up a debt ceiling increase unless Congress either cuts \$130 billion in spending during the next fiscal year or tackles broader fiscal reforms.

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2. Republicans are about to fight themselves on defense spending. The House GOP's push for steep spending cuts could put one of its signature achievements ? larger defense budgets ? in the crosshairs.

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Defense hawks are warning they won't support reducing the Pentagon budget, but not all Republicans are on the same page on whether defense spending should be exempted from the \$130 billion in cuts. Even McCarthy, who made a deal with conservatives to pursue discretionary spending cuts, has signaled the Pentagon should get the same scrutiny as other parts of the budget.

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Complicating matters, GOP defense leaders want another big increase in Pentagon spending, which would amplify proposed cuts to non-defense programs under the arrangement to return to fiscal 2022 levels.

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3. Abortion legislation is unlikely to pass Congress. House and Senate Republicans will likely introduce legislation to enact nationwide abortion restrictions. But don't expect a bill to make it through Congress and to President Joe Biden's desk.

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4. Expect investigations to be at the center of the House GOP's agenda.

Republicans are set to kick off a long list of high-profile investigations that will span multiple committees and spark headline-grabbing showdowns with the Biden administration.

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The newest investigation is being sparked by Biden's team finding classified documents at both his Wilmington, Del., residence and at a Biden think tank.

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The Oversight Committee, chaired by Rep. James Comer (R-Ky.), is also expected to focus on three main areas: An investigation into Hunter Biden and the Biden family; the border; and the origins of the coronavirus.

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The border and the Department of Homeland Security are expected to be a target for two other panels: Homeland Security and the Judiciary Committee.

Republicans view DHS Secretary Alejandro Mayorkas as their most likely impeachment target, though with the party's thin margins and early skepticism from centrists, that could be a heavy lift.

FDA approach to orphan drugs staying same

From Politico

The FDA intends to continue to tie orphan-drug exclusivity to indications approved by the agency instead of an entire disease area.

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The decision follows a ruling by the Court of Appeals for the Eleventh Circuit that the orphan-drug exclusivity for the FDA's approval of Catalyst Pharmaceuticals' drug in November 2018 for the treatment of Lambert-Eaton myasthenic syndrome, a rare autoimmune disease, in adults blocks the agency from approving other firms' drugs for other LEMS indications.

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The agency argues its interpretation of the orphan drug exclusivity law "best advances" the balance of incentivizing rare disease drug development and ensuring patients ? especially children ? have access to orphan drugs.

Medical device makers renew lobbying amid White House review of ethylene oxide proposal

From Politico

The medical device industry is ramping up efforts to influence an EPA proposal

under White House review to limit emissions of a carcinogenic gas used to sterilize their products that companies worry might lead to shortages and disrupt the U.S.’s ability to sterilize millions of essential medical devices.

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In August, the EPA found that the chemical ethylene oxide ? used on roughly half of the more than 20 billion medical devices sold in the U.S. that require sterilization annually ? is contributing to elevated cancer risks in 23 communities close to sterilizing facilities.

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AdvaMed, the largest trade lobby for medical device manufacturers, sent a letter to President Joe Biden warning that if even a small number of the approximately 100 sterilizing facilities decide to close rather than comply with the new regulations, the supply chain for medical devices will be at risk.

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The long-awaited proposed rule, now expected to be published in April, has also drawn the attention of the FDA. In August, top medical device regulator Jeff Shuren said he shares the EPA’s concern about the release of unsafe levels of ethylene oxide, but warned there are no adequate sterilizing alternatives to the gas for many medical devices.

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The FDA is working with device makers to reduce the amount of ethylene oxide used to sterilize their products and encouraging the development of new sterilization methods to ultimately replace ethylene oxide.

NCBIO Updates



Shaylah Nunn Jones, Novo Nordisk’s government and public affairs lead, announces \$6 million gift at press conference January 11. Image Durham Tech

Novo Nordisk to support Durham Tech’s life sciences programs and new training center with \$6 million gift

Novo Nordisk announced a \$6 million gift to Durham Technical Community College to support the College’s life sciences program and a new 35,000-square-foot Life Sciences Training Center.Â

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“Today’s announcement is about a company’s investment in the people of this region. It’s not just big news for Durham Tech and the high-quality education and training it will enable us to provide, it’s life-changing news for the thousands of local residents who will benefit and go on to great jobs in a growing and important industry,” said J. B. Buxton, president of Durham Tech. “This marks the largest donation in our college’s history, and we are proud to partner with Novo Nordisk and their commitment to creating economic opportunity for the people of Durham and our greater Triangle region.” Â

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Novo Nordisk, with three manufacturing facilities across Durham and Clayton, is celebrating its 30 years in the Triangle. This donation is part of Novo Nordisk’s decades-long effort to support the growth of the local biotechnology sector. With nearly 1,800 employees across the region, ensuring a strong, resilient workforce for the future is a top priority for Novo Nordisk, as the company has plans to continue expanding its biomanufacturing operations.Â

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“Novo Nordisk is committed to ensuring that both individuals planning their future careers and those seeking a transition understand and have access to the promise that a career in life sciences can bring,” said Shaylah Nunn Jones, Novo Nordisk’s government and public affairs

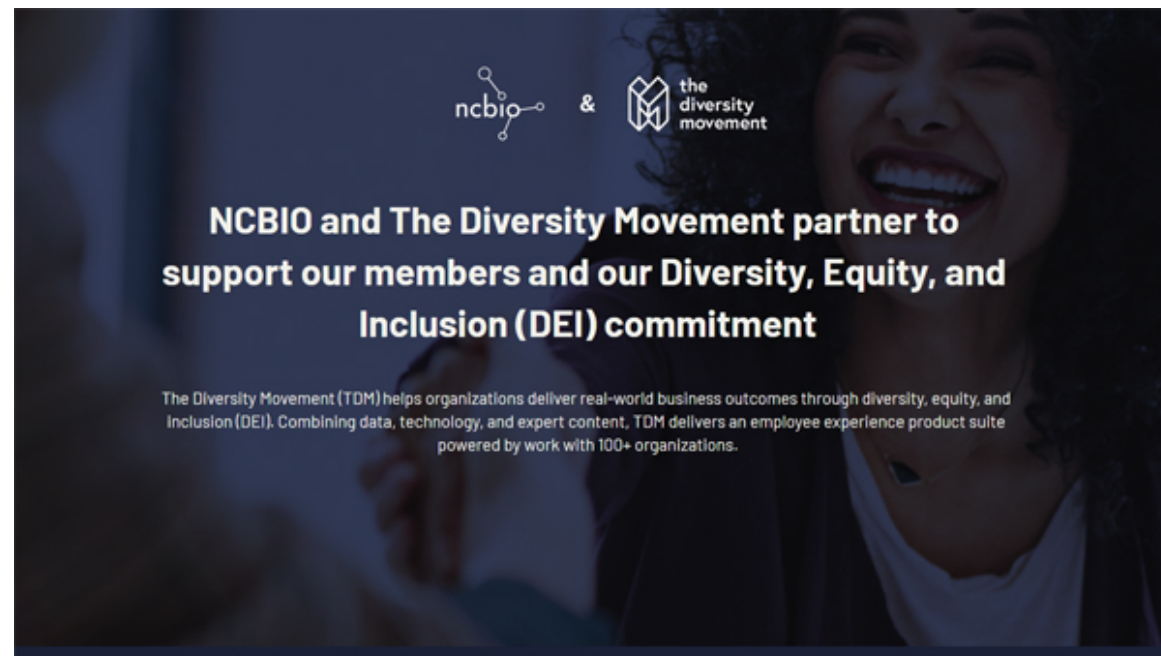
sciences can bring,” said Snayian Nunn Jones, Novo Nordisk’s government and public affairs lead. “Through this partnership with Durham Tech, we will provide apprenticeships, internships, scholarship programs, and the latest biotech equipment to train the future workforce, and that is exciting. We are proud of our region’s dynamic biotech industry and are thrilled to help expand and diversify our talent pipeline.”

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With the support of Novo Nordisk, Durham Tech will be able to

- establish a Biotechnology Associate of Applied Science degree program (for current college students),
- create onsite training for biotechnology career transition programs to upskill or reskill existing employees and other related workforce training partnerships and
- ensure students are prepared on biotechnology equipment. Provide outreach and awareness for area middle and high school students.

[More at Durham Tech >>](#)



The Diversity Movement creates DEI portal for NCBIO members

The Diversity Movement, NCBIO’s partner in providing diversity, equity and inclusion services and programming to our members, has created a dedicated webpage of resources for NCBIO members.

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Materials that were previously available on the [NCBIO DEI webpage](#) can now be found at <https://landing.thediversitymovement.com/ncbio/>. There are many free resources to explore, including

- free DEI educational resources,
- digital learning courses and certifications,
- microlearning content and
- consulting services.

NCBIO members receive a discount on all TDM programming and services.

VISIT THE DIVERSITY MOVEMENT

NCBIO Policy Committee reconvenes for legislative session

With the start of the new session of the General Assembly, NCBIO will be convening its Policy Committee. The committee is open to all interested member companies. A first call will take place on Feb 24. If you need more information, please email [Turquoise Burke](#) or call 919-281-8960.

NCBIO Member News

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

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Asklepios BioPharmaceutical, Inc. has signed a multiyear research collaboration and option agreement with ReCode Therapeutics to work together to develop a novel platform for full gene insertion by single-vector delivery of gene editing and DNA cargoes. [More >>](#)

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Eisai Co., Ltd. and **Biogen Inc.** announced that under the Accelerated Approval Pathway the FDA has approved lecanemab-irmb, a humanized immunoglobulin gamma 1 monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta for the treatment of Alzheimer’s disease. [More >>](#)

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Eisai Co., Ltd. and **Biogen Inc.** announced that an application for manufacturing and marketing approval for lecanemab , an anti-amyloid- β protofibril antibody, in Japan has been designated for priority review by the Japanese Ministry of Health, Labour and Welfare. [More >>](#)

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Eli Lilly and Company plans to invest an additional \$450 million and create at least 100 new jobs to expand its manufacturing capacity at the company's Research Triangle Park facility. [More >>](#)

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IQVIA announced the first life sciences industry collaboration with Alibaba Cloud in China to provide solutions hosted in Mainland China leveraging Salesforce on Alibaba Cloud. [More >>](#)

^

Novan, Inc. has submitted a new drug application to the FDA seeking marketing approval for berdazimer gel, 10.3% (SB206) for the topical treatment of molluscum contagiosum. [More >>](#)

^

Novo Nordisk announced a \$6 million gift to Durham Technical Community College to support the College's life sciences program and a new 35,000-square-foot Life Sciences Training Center. [More >>](#)

^

Opus Genetics has acquired the rights to two preclinical-stage AAV-based gene therapy product candidates for inherited retinal diseases from Iveric Bio. [More >>](#)

^

Pfizer Inc. will acquire Abzena's manufacturing facility in Sanford. The state-of-the-art facility will have extensive capabilities for producing biologics drug substance and will provide additional manufacturing capacity allowing Pfizer to help accelerate its pipeline. [More >>](#)

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Pathalys Pharma announced it has raised \$150 million through a combination of secured product financing and equity to support the two phase 3 clinical trials, registration efforts and precommercialization activities for upacalcet. [More >>](#)

Events

NCBIO Virtual DEI Forum: Top-Down Leadership Buy-In and Engagement Feb. 8

Join us online from noon to 1 p.m. Wednesday, Feb. 8, to hear from company leaders from Amgen and Novo Nordisk about support for DEI programs and activities.

- **Renee Romaine**, program manager, DEI&B and culture at Novo Nordisk, will highlight findings from a recent report.^
- **Mari Beth Tandy**, executive director and quality site head at Amgen, will discuss their efforts at the new manufacturing facility in Holly Springs.

Following the presentations, attendees will have a chance to reflect on their comments during breakout sessions.

REGISTER NOW



MDMA FDA Forum March 15-16

NCBIO has partnered with the Medical Device Manufacturers Association to support its upcoming FDA Forum being held in Palo Alto, California, March 15-16. NCBIO members are eligible for discounted pricing. Contact [Amber Niebauer](#) for the discount registration code.

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MDMA's 2023 FDA Forum will feature senior officials from FDA and industry and focus on the key regulatory issues impacting the medical device industry.

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Designed specifically for medical device regulatory professionals and executive decision makers, MDMA's FDA Forum promises to deliver key regulatory insights and preview trends that will affect your regulatory and business strategies.

Topics will include

- CDRH Update
- Navigating 510(k), De Novo, PMA Programs
- Digital Health
- MDUFA V Implementation
- Post COVID Transition
- Best Practices for Presubmission meetings
- Emerging Issues (Biocompatibility, Human Factors, Cyber Security & More)

Registration fees

- MDMA Members - \$695
- State Member - \$795 with discount code
- Nonmembers - \$895

LEARN MORE



Join NCBIO members and legislators for an evening reception highlighting the state's life sciences industry. You will have the opportunity to discuss workforce training, life science program funding, innovation and tax policy and other topics of interest with legislators and policy makers.

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If you are interested in sponsoring this event, please contact NCBIO Membership Director [Natacha Janvier](#).

Premier sponsors



Event sponsors





REGISTER NOW



Register and reserve your housing today.

Registration and housing for the 2023 BIO International Convention in Boston is now open. This June we will come together to stand up for innovation and stand up for science. It's time to inspire, honor, and recognize the true value of the breakthrough work biotech performs for society.

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For additional information, visit the [registration page](#) to review package options and the [housing page](#) to see preferred hotel listings and housing guidelines.

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We encourage you to act quickly to take advantage of great savings and hotel room availability. See you in Boston!

REGISTER NOW

NCBio calendar

- [Supply Chain Challenges & Solutions hosted by NCWTA Triangle Chapter \(2/2/2023\)](#)
- [Outlook for Tech hosted by NC TECH \(2/3/2023\)](#)
- [CEO & Investor Conference hosted by BIO \(2/6/2023 to 2/9/2023\)](#)
- [Virtual Internship, Co-op, and Early Talent Career Fair - Employers Must Register by Jan. 10 \(2/7/2023\)](#)
- [NCBio Virtual DEI Forum: Top-Down Leadership Buy-In and Engagement \(2/8/2023\)](#)
- [How to WIN SBIR/STTR Grants hosted by FFVC \(2/9/2023\)](#)
- [BPD BioGrow hosted by NCBiotech \(2/9/2023\)](#)
- [Supplying mRNA COVID-19 Vaccine at Unprecedented Pace and Scale hosted by NCSU \(2/10/2023\)](#)
- [Career & Internship Expo hosted by High Point University \(2/14/2023\)](#)
- [One Health: Improving Rural and Urban Resilience hosted by NCBiotech \(2/15/2023\)](#)
- [ISPE-CaSA 2023 Life Sciences Technology Show \(2/28/2023\)](#)
- [NCBio Legislative Reception 2023 \(3/1/2023\)](#)
- [Applied Cleaning Validation Practices: A STERIS Master Class hosted by BTEC \(3/2/2023 to 3/3/2023\)](#)
- [Biopharmaceutical Lyophilization and Spray Drying hosted by BTEC \(3/13/2023 to 3/16/2023\)](#)
- [Annual Occupational Safety and Health Winter Institute hosted by UNC \(3/13/2023 to 3/17/2023\)](#)
- [FDA Forum hosted by MDMA \(3/15/2023 to 3/16/2023\)](#)

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