March 2023 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

- Legislative reception and Life Sciences Caucus
- Biden State of Union pledges insulin price cap, more
- CMS unveils three proposed drug-pricing models
- CEO Roundtable explores Inflation Reduction Act
- Policy committee reviews NCBIO priorities

NCBIO reaches quarter-million-dollar goal for Taylor scholarships

With a recent significant gift from Amgen, NCBIO has surpassed its goal of raising $250,000 to create a scholarship fund at the NC Community College Foundation for students pursuing degrees and certifications in the life sciences.
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The Samuel M. Taylor Memorial Life Sciences Scholarships are for students enrolled in agricultural biotechnology, biopharmaceutical technology, biotechnology, bioprocess technology, clinical trials research associate, facility maintenance technology and medical laboratory technology programs in the state's community colleges. The awards honor Sam Taylor, long-time president of NCBIO, the NC Biosciences Organization, who died in 2021 of pancreatic cancer.
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"Sam Taylor was a key architect of North Carolina's world-class biotech ecosystem, which was central to Amgen selecting the Triangle for our new manufacturing site," said Vice President of Amgen North Carolina Bob Kenyon. "We are humbled to be a small part of his enduring legacy of leadership and partnership."
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In addition to Amgen, leadership gifts have come from **Alexandria Real Estate Equities**, **Biogen** and **Hatteras Venture Partners**.Â
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Grifols, **Novo Nordisk**, **Frankel Staffing Partners**, **FUJIFILM Diosynth Biotechnologies** and **Smith Anderson** have also made significant contributions to the scholarship fund.

More at NCBIO

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STATE UPDATES

Nearly 250 NCBIO member representatives and North Carolina law makers came together Wednesday, March 1, at the NCBIO Legislative Reception held at the NC Museum of History in Raleigh.
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NCBIO greatly appreciates the support of our member sponsors who made this event possible.

GO TO PHOTO GALLERY

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Event sponsors

Doug Edgeton, president of the NC Biotechnology Center; Life Sciences Caucus co-chairs Sen. Mike Woodard, Rep. Donna White and Sen. Paul Newton; and NCBIO President Laura Gunter

Life Sciences Caucus hears report on life sciences growth in NC

The General Assembly's Life Sciences Caucus convened for the first time this year on Wednesday, Feb. 8, at the NC General Assembly. Caucus Co-chairs Sen. Paul Newton, Sen. Mike Woodard and Rep. Donna White hosted the gathering, whileÂ Rep. Robert Reives was unable to attend.
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Legislators heard from Doug Edgeton, president of the NC Biotechnology Center, who introduced Ryan Helwig, principal and project director at Teconomy Partners.Â
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Hedwig shared data from 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

NCBIO Policy Committee meets to review agenda

With Congress and the NC General Assembly back in session, the NCBIO Policy Committee convened for its first meeting on Friday, Feb. 24, to review NCBIO's legislative agenda for 2023.
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Joe Lanier, principal of Milestone Strategies, gave the committee an overview of what to expect from this long session of the General Assembly. NCBIO President Laura Gunter then gave an overview of the organization's legislative priorities for the year, which include the following:

- The One NC Small Business Fund provides matching funds to NC companies that receive federal SBIR/STTR awards. In the last legislative session, the One NC fund was provided with recurring funds in the state budget, which are available year. NCBIO supports increased funding for the fund and favors allowing companies to receive matching fund for multiple SBIR/STTR awards.
- NCBIO will advocate for continued funding and support for the NC Biotechnology Center.
- Workforce development will continue to be a key focus with NCBIO supporting increased funding for community-college-based training programs and increased salaries for the highly qualified faculty needed to staff these programs.
- State infrastructure support, especially wastewater capacity and management, is becoming an area of increased focus for NCBIO. There is a lot of work to be done in this area. Initially, NCBIO is meeting with legislative branch, the executive branch and the Department of Environmental Quality to review immediate needs and long-term needs to begin to work toward possible solutions. One area is supporting the DEQ in filling the many staff vacancies it has, particularly among the engineers needed for the planning and permitting process.
- NCBIO is working for the repeal or reduction of the franchise tax, a tax applied for the privilege of doing business in the state. The tax is solely based on net worth as the state has eliminated the calculations based on the value of real and tangible personal property or the taxpayer’s total actual

investment in tangible personal property. CBIO favors doing away with the tax altogether or at least reducing its effect on prerevenue companies.Â

Will Morgan of Manning, Fulton & Skinner gave an overview of the national priorities laid out by the Pharmaceutical Research and Manufacturers of America, which NCBIO supports.Â

NATIONAL UPDATES

Biden calls for universal insulin price cap in State of the Union

President Joe Biden called for expanding a new cap on insulin prices to all Americans as part of his 2023 State of the Union address.
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During the speech, Biden touted his administration's efforts to make health care more affordable, which included imposing a $35-per-month limit on insulin that took effect in January.
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But that price cap, which was passed as part of last year's Inflation Reduction Act, only applied to those beneficiaries covered by Medicare. Biden is now expected to renew his push for the policy to be applied to anyone with an insulin prescription.
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Insulin manufacturer Eli Lilly said Feb. 28 it will cut the list price of its most commonly prescribed insulin product Humulin by 70 percent in the fourth quarter of 2023. Lilly will also cut the list price of its nonbranded insulin lispro injection to $25 a vial effective May 1. The company will also launch Rezvoglar, an injected basal insulin interchangeable biosimilar to Sanofi's Lantus, for $92 for a five pack of pens on April 1.
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Democrats had originally planned to pass a universal insulin price cap last year as part of the Inflation Reduction Act, which was passed along party lines last August. But the policy was scaled back after Republicans successfully challenged its inclusion. Democrats since then have vowed to continue to push for its passage, arguing that it's broadly popular and crucial to ensuring that people can afford essential medicines.
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Still, Biden's fresh support for expanding the price cap is unlikely to result in much concrete progress. Republicans remain opposed to the measure, and are unlikely to even allow a vote on it in the House now that they control the chamber.
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During his speech, Biden also highlighted a handful of other health care accomplishments, including granting Medicare the right to negotiate drug prices and cap certain out-of-pocket pharmacy costs. He celebrated the three latest states to expand their Medicaid programs, while urging Congress to pass legislation that would close coverage gaps in the eleven holdout states that have yet to expand Medicaid.
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The president also called for continuing to lower health insurance costs, pointing to expanded Obamacare subsidies that the administration estimates lowered customers' premiums by an average of $800 per year and pushed the nation's uninsured rate to an all-time low.

More at Politico

CMS unveils three planned drug pricing models

CMS plans to develop and test three new payment models that aim to boost access to expensive cell and gene therapies, increase access and adherence to widely used generic drugs and incentivize completion of clinical trials for drugs approved under FDA's accelerated approval pathway.
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The effort, part of the agency's response to President Joe Biden's October executive order directing CMS to explore payment models that may further drive down prescription drug costs, will likely take years to propose, finalize, implement and test.
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Accelerated approval model: CMS is considering implementing a mandatory model to adjust payment for accelerated approval drugs to Medicare Part B fee-for-service providers to incentivize timely confirmatory trial completion.
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The goal of the model is to "reduce Medicare spending on drugs that have no confirmed clinical benefit," according to CMS. It is unclear exactly how the agency plans to adjust payments for accelerated approval drugs under the model, but Fowler said CMS "will certainly be talking to MedPAC" about its recommendations.
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Generic drug model: CMS is weighing allowing Medicare Part D sponsors to offer a list of approximately 150 generic drugs for common chronic conditions, such as hypertension, with a maximum copayment of $2 for a one-month supply.
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Cell and gene therapy model: The agency wants to test whether a partnership among CMS, drug manufacturers and state Medicaid agencies on an outcomes-based agreement can help Medicaid beneficiaries gain access to pricey cell and gene therapies. The goal is to create an alternative financing approach that helps mitigate the cost of expensive one-time therapies on state Medicaid agencies and high cost-sharing.
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What's next: HHS Secretary Xavier Becerra also directed the Center for Medicare & Medicaid Innovation to evaluate potential models to accelerate adoption of biosimilars, increase price transparency for prescription drugs and whether alternative payment approaches ? such as bundled payments ? for cell and gene therapies instead of traditional fee-for-service billing improves care and reduces overall Medicare spending.

House GOP oversight panel launches PBM investigation

The House Oversight and Accountability Committee opened an investigation on Wednesday into the business practices of pharmaceutical middlemen, known as pharmacy benefit managers, to examine their effect on patients ? the latest in a series of actions targeting the industry.
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Rep. James Comer (R-Ky.), who leads the panel, argued in a statement that PBMs increase drug prices and harm patients. PBMs negotiate discounts, known as rebates, on drugs with manufacturers and decide which medicines insurers cover.
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Comer is focused on the largest PBMs ? CVS Caremark, Express Scripts, and OptumRx ? that control roughly 80 percent of the prescription drug market. They also own, or are owned by, insurance companies and all have their own affiliated pharmacies.
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These three companies engage in "anti-competitive tactics," Comer said in a statement, and he's seeking "documents, communications and information related to their practices that are distorting the pharmaceutical market and limiting high quality care for patients."
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The investigation is the latest in a series of actions targeting PBMs, including the introduction of bipartisan bills critical of the industry, a Federal Trade Commission study and an intense lobbying effort by PBM opponents, such as independent pharmacies and drugmakers. There has also been an increasing level of state

pharmacies and drugmakers. There has also been an increasing level of state actions against PBMs, ratcheting up the pressure on federal lawmakers.
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The Senate Judiciary Committee advanced a package of patent-centric proposals last month aimed at boosting generic and biosimilar competition into the drug market (see below). The Pharmaceutical Care Management Association, which represents the PBMs, is now lobbying for full passage. They've also begun a seven-figure ad campaign touting the benefits of PBMs, and opposing a bipartisan Senate PBM bill from Sen. Maria Cantwell (D-Wash.) and Sen. Chuck Grassley (R-Iowa).

Judiciary Committee again advances drug patent reform bill package

As it did during the last Congress, the Senate Judiciary Committee on Thursday advanced five bipartisan bills that aim to boost generic and biosimilar competition in the pharmaceutical marketplace by voice vote.
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The package aims to boost coordination between the FDA and the U.S. Patent and Trademark Office, directs the Federal Trade Commission to study the role of pharmacy benefit managers in the supply chain, limits pay-for-delay agreements and deters use of citizen petitions that aim to delay competition.
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Lastly, the Affordable Prescriptions for Patients Act aims to facilitate competition by addressing "product hopping" and placing limits on the number of patents biologic manufacturers can assert.
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The bills have a good chance of moving through the full Senate, according to legislative staff, but it is unclear whether the legislation will move in the House, where Republicans have a narrow majority.
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That piece of legislation has drawn complaints from the brand drug industry, which argues the product hopping provision would "upend the biopharmaceutical innovation ecosystem" and create an "FTC enforcement cloud over almost any post-approval innovation."
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Sen. Mazie Hirono (D-Hawaii) seconded aspects of the pharmaceutical industry's concern about the bill, saying it may have unintended consequences. However, she said changes have been made to the legislation over time to "balance competing interests," and ultimately voted to advance it out of committee.
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Sen. Mike Lee (R-Utah) echoed another line of opposition from the pharmaceutical industry, noting the FTC already has the authority necessary to intervene when there is anticompetitive behavior in the marketplace.

MEDCAC advisers endorse CED suggestions

CMS' Medicare Evidence Development and Coverage Advisory Committee endorsed on Tuesday 17 proposed revisions to the agency's coverage with evidence development process. The goal is to ensure that studies produce evidence that can demonstrate whether a medical product is reasonable and necessary.
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The process has drawn fire in recent months after it was used to limit broad Medicare coverage of Alzheimer's drugs that target amyloid plaques in the brain. Tamara Syrek Jensen, director of CMS' coverage and analysis group, said the next steps include potentially proposing draft updates to the coverage with evidence-development criteria.

Federal judge says state drug importation efforts don't currently threaten pharma

A federal judge on Feb. 6 dismissed a bid to block a Trump-era regulation that aims to allow states to establish programs to import prescription drugs from Canada if HHS determines there will not be a risk to public health and if consumers will save money.
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The Pharmaceutical Research and Manufacturers of America and two other groups sued HHS in November 2020, arguing that the effort endangers the safety

of the drug supply chain, is unlikely to reduce costs and places “burdens” on the companies.

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But Timothy Kelly, a federal district court judge in Washington, D.C., wrote in the decision that the alleged harms lack “a substantial probability of materializing” and dismissed the lawsuit for a lack of standing.

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“No organization, nor any of their members, faces a concrete risk of harm from the inchoate importation program, as is required when suing,” Kelly wrote.

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PhRMA has not said whether it plans to appeal.

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The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 empowered the federal health department with the legal authority to permit importation of prescription drugs from Canada, but several HHS secretaries in Republican and Democrat administrations have declined to certify that allowing importation is safe and cost effective.

NCBIO Updates

DEI forum discusses leadership buy-in, engagement

Company leaders from **Amgen** and **Novo Nordisk** led an online discussion about support for DEI programs and activities Wednesday, Feb. 8.

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

Following the presentations, attendees reflected on their comments during breakout sessions.

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You can view the presentations on the NCBIO YouTube channel. The breakout sessions were not recorded.

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Our next DEI event is April 25. Click here for more information or to register.

CEO Roundtable explores Inflation Reduction Act

Attorneys from global law firm Akin Gump were on hand for the Feb. 23 NCBIO CEO Roundtable discussion, “Preparing for Price Setting under the Inflation

CEO Roundtable discussion, "Preparing for Price Setting under the Inflation Reduction Act," held at the NC Biotechnology Center.Â

The Akin Gump representatives there to share their expertise in health care and public policy making wereÂ Anna Abram, senior adviser; Louis Agnello, counsel; craig Bleifer, partner; and Kelly Cleary, partner.Â
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NCBIO members can request a copy of the presentation.

Novo Nordisk marks 100 year anniversary, 30 years in NC

This year, Novo Nordisk is celebrating its 100th anniversary along with 30 years of manufacturing operations in Johnston County.
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For 100 years, Novo Nordisk's purpose has been to drive change to defeat diabetes and other serious chronic diseases such as obesity, and rare blood and endocrine disorders. The company supports NC State, East Carolina University, NC Central and community colleges in Johnston, Durham and Pitt Counties to help educate and train individuals for careers in bio manufacturing.

More at Novo Nordisk

NCBiotech awards $2.3 million in grants, loans in latest quarter

The North Carolina Biotechnology Center awarded 19 grants and loans totaling more than $2.3 million to universities, bioscience companies and nonprofit organizations in the second quarter of its fiscal year.
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The awards, made in October, November and December 2022, will support life sciences research, technology commercialization and entrepreneurship throughout North Carolina. The funding will also help universities and companies attract follow-on funding from other sources.
Four bioscience companies received Small Business Research Loans totaling $850,000 to advance their research, product development and commercial viability.

- Two bioscience companies with technical proof-of-concept for products received Strategic Growth Loans totaling $1 million. The loans, matched by equal or greater funding from angel investors or venture capital firms, will help the companies commercialize their products.
- Three universities received four grants totaling $349,294 during the second quarter to advance bioscience research. The awards were given through two programs: FLASH Grants, which support creative ideas that show early indications of commercial potential, and Translational Research Grants, which fund projects that explore potential commercial applications or initiate the early commercial development of university-held life sciences

inventions.Â
- The North Carolina Central University Foundation received a $100,000 Presidential Initiative Award to address workforce equity in biomanufacturing.Â
- Four universities and one nonprofit organization received Biotechnology Event Sponsorships totaling $13,363 for biotechnology meetings and events.

More at NCBiotech

NCBIO Membership Director Natacha Janvier moderates a panel discussion on the skills needed for a successful career in the life sciences at the BioGrow: Training and Education across North Carolina event Feb. 9 at NC Biotech.

NCBIO Member News

To be included in member news, send information about your organization to David Etchison.
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Biocair reports a 30% increase in sales volume year on year at the end of 2022 while doubling its headcount to over 560 globally during the last two years. More >>
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BioAgilytix announced a new partnership with Microba Life Sciences to combine Microba's precise measurement of the human gut microbiome with BioAgilytix's full spectrum of advanced bioanalytical solutions. More >>
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Biogen Inc. and **Sage Therapeutics, Inc.** announced the FDA has accepted the filing of a New Drug Application for zuranolone in the treatment of major depressive disorder and postpartum depression. More >>
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Chiesi Group announced that the FDA has approved Lamzede (velmanase alfa-tycv) for the treatment of noncentral nervous system manifestations of alpha-mannosidosis in adult and pediatric patients. AM is an ultrarare, progressive lysosomal storage disorder caused by deficiency in the enzyme α-mannosidase. More >>
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Eisai Co., Ltd. and **Biogen Inc.** announced that the Biologics License Application for lecanemab, an investigational anti-amyloid beta protofibril antibody, has been designated for priority review by the National Medical Products Administration in China. More >>
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InGateyGen received $200,000 from NCBiotech to expand its technical and human resources for scaling up production of gene-edited peanut lines. Using CRISPR gene knockout technology, the company is developing an allergen-free peanut with undetectable allergen Ara h1-3 protein. More >>
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InSoma Bio received $500,000 from **NCBiotech** to scale up GMP production, finalize preclinical data and solidify the reimbursement and regulatory strategies for follow-on trials for its biopolymer Fractomer, which helps plastic surgeons perform breast reconstruction procedures for patients undergoing mastectomy. More >>
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The **PPD** clinical research business of **Thermo Fisher Scientific** was recognized

as an ISG Provider Lens Leader for its clinical development digital transformation services, patient engagement digital transformation services, and pharmacovigilance and regulatory affairs by Information Services Group for the third consecutive year. More >>

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The **PPD** clinical research business of **Thermo Fisher Scientific** has been awarded a five-year contract to provide regulatory affairs support and related services for the Blueprint MedTech program, a new multi-institute/center initiative at the National Institutes of Health supporting development of translational neurological devices. More >>

NCBIO Membership Director Natacha Janvier at the ISPE-CaSA 30th Annual Life Sciences Technology Show on Tuesday, Feb. 28, in Raleigh.

Events

Winning More SBIR/STTR Awards in North Carolina

First Flight Venture Center, the North Carolina Department of Commerce's Board of Science, Technology & Innovation, the NC Defense Technology Transition Office and four NC community colleges to host a series of SBIR/STTR Educational Events.Â

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Each event is specifically designed to be a combination of talks and 1:1s, with less of an emphasis upon the "big picture" SBIR/STTR, and more of an operational emphasis on answering the question, "What don't I know that you can tell me today that will make a difference in my ability to win an SBIR/STTR award?"

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Attendees will learn:

- why SBIRs and STTRs should be on your list of ways to find funding;
- how the government agencies are different when it comes to SBIRs and STTRs;
- how to prepare your company to be eligible to bid on these opportunities and
- how to break down the process for a SBIR and form a strategy.

The training events will be held in the following locations and dates from 9:30 a.m. - 4 p.m.

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Wednesday, March 8: Fayetteville

Fayetteville Technical Community College ? Horticulture Education Campus
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Thursday, March 9: Wilmington
Cape Fear Community College
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Wednesday, March 22: Winston-Salem
Forsyth Technical Community College at Innovation Quarter
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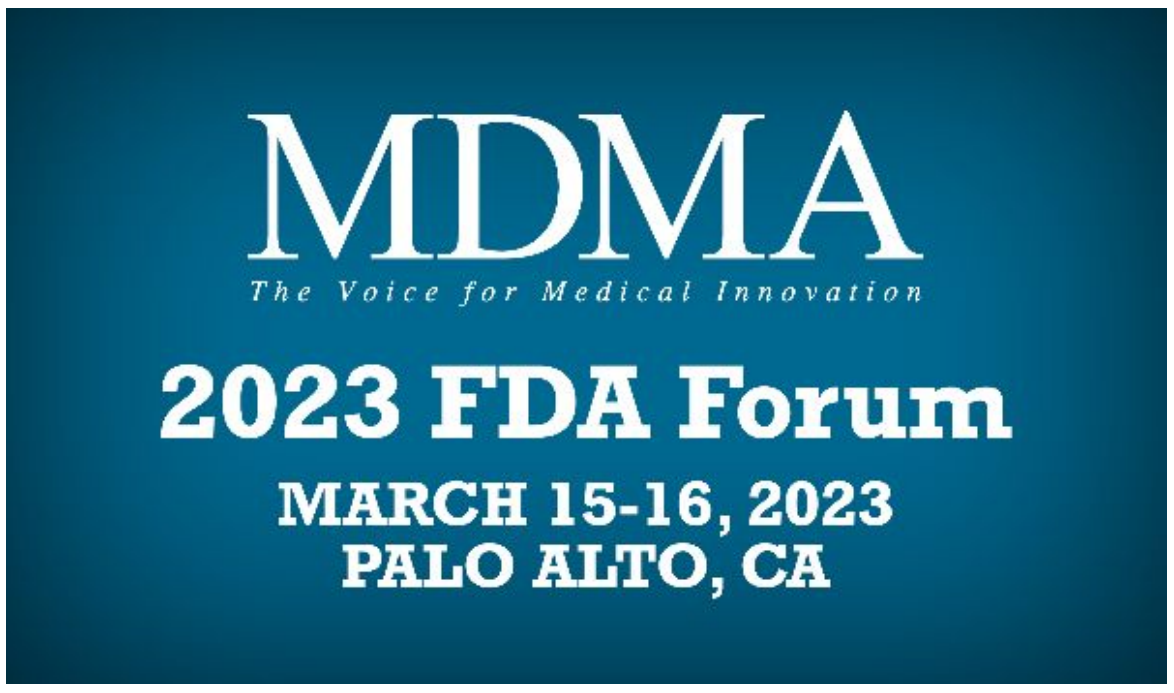
Thursday, March 23: Boone
Caldwell Community College ? Watauga Campus

LEARN MORE



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

Register for the NCBIO Emerging company and Technology Forum: Funding Process and Options March 22

Join us for a conversation on the Funding Process and Options for companies. We will begin the conversation with a summary of 2022 and the 2023 outlook in North Carolina, and hear from experts across multiple markets.

- Mike Carnes, senior director, investments, NC Biotechnology Center
- Allen Thomas, regional administrator, southeast region, U.S. Small Business Association

Business Association
- Representative with NIH SEED (invited)
- Johanna Grossman, Ph.D., regional head, health care & life sciences, capital markets, New York Stock Exchange
- Moderator TBD

Thank you to our sponsor, Nikon. If you are interested in sponsorship, please contact NCBIO Membership Director Natacha Janvier.

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

- Emerging Leaders Thermal Validation Course hosted by ISPE-CaSA (3/1/2023)
- 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)
- Winning More SBIRs/STTRs Awards in North Carolina (Fayetteville) hosted by FFVC (3/8/2023)
- From Curriculum to Workforce: How to Bring Regenerative Medicine to Your Students (3/8/2023)
- Winning More SBIRs/STTRs Awards in North Carolina (Wilmington) hosted by FFVC (3/9/2023)
- 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)
- March Madness Open House hosted by First Flight Venture Center (3/16/2023)
- Larger than Life Science: Building the C-Suite hosted by LaunchBio (3/21/2023)
- Winning More SBIRs/STTRs Awards in North Carolina (Winston-Salem) hosted by FFVC (3/22/2023)
- NCBIO Emerging Company and Technology Forum: Funding Process and Options (3/22/2023)
- Winning More SBIRs/STTRs Awards in North Carolina (Boone) hosted by FFVC (3/23/2023)
- Venture Connect hosted by CED (3/29/2023 to 3/30/2023)

BIO Business Solutions

NCBIO and BIO Business Solutions helps life science companies save on a wide range of business-critical products and services from lab and cleanroom products to office and everyday business services.
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Whether you are a start-up, mid-sized biotech company, or an established life science company, you will find opportunities to save and work with BIO's endorsed suppliers. Access savings and expertise today.

LEARN MORE

NCBIO
P.O. Box 14354
Research Triangle Park
North Carolina 27709

detchison@ncbioscience.net
919.281.8960
ncbioscience.net