



September 2022 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

- NC wins \$25 million Build Back Better award
- Legislative Luncheon draws a crowd
- Inflation Reduction Act to cost jobs, new treatments
- Congress considers new patent legislation
- TDM offers new diversity leader certificate
- Register for the Oct. 12 NCBIO Annual Meeting

... and more

NC coalition wins Phase 2 Build Back Better Regional Challenge Award

A statewide coalition of public and private partner organizations and institutions, led by the North Carolina Biotechnology Center, has received a Phase 2 award totaling nearly \$25 million from the U.S. Economic Development Administration's Build Back Better Regional Challenge.

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The NCBiotech-led consortium is one of only 21 projects chosen from 60 applicants nationwide. The Phase 2 award will further strengthen North Carolina's life sciences manufacturing cluster by expanding, connecting and promoting training and career opportunities to underserved and distressed communities, including historically excluded populations. The funding will be used for

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Workforce Diversification ? Establish six training hubs at North Carolina's Historically Black Colleges and Universities and at the University of North Carolina at Pembroke. The training hubs will deliver hands-on short courses on manufacturing biopharmaceuticals to an inclusive and diverse population. Led by BRITE at NCCU.

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Expand Training Access and Faculty Recruitment ?

Bolster the number of trained life sciences manufacturing workers by enrolling citizens from across the state in BioWork and other life sciences training programs expanded through this funding. Project led by the North Carolina Community College System.

Community Engagement ? Launch ambassador and apprenticeship programs to increase awareness of and access to life sciences manufacturing training and job opportunities. Led by NCBiotech.

NCBIO Sustaining Members

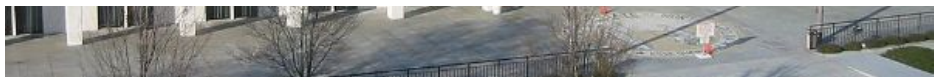


NCBIO Supporting Members



[More >>](#)





STATE UPDATES



Milestone Strategy's Joe Lanier and NCBIO President Laura Gunter moderate a panel comprising the chairs of the NC Life Sciences Caucus Sen. Mike Woodard, Rep. Donna White, Rep. Robert Reives and Sen. Paul Newton on Aug. 31.

At Legislative Luncheon, legislators encourage NCBIO members to make industry needs known

The co-chairs of the NC Life Sciences Caucus talked about workforce issues, transportation, infrastructure and economic development and asked NCBIO members to communicate the wants and needs of the life sciences industry to legislators at the NCBIO Legislative Luncheon and Forum held Wednesday, Aug. 31, at the NC Biotechnology Center.

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The event was sponsored by [G1 Therapeutics](#), [Mycovia Pharmaceuticals](#), [Nexsen Pruet](#), [North Carolina Research Campus](#) and [Ultragenyx](#).Â

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NCBIO members heard from Sen. Paul Newton, Sen. Mike Woodard, Rep. Donna White and Rep. Robert Reives. Moderator Joe Lanier, principal of Milestone Strategies, kicked off the discussion by asking the lawmakers how North Carolina's life sciences industry could build on successes like recurring funding for the One North Carolina Small Business Program.Â

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"The complexity of your business is a barrier to your success," Newton said. "We need your help being able to communicate succinctly, accurately whatever that issue is. You know it like the back of your hand, but we're dealing with colleagues who have never encountered the kind of issues that you face. So help us " Jerry Maguire moment " help us help you up by taking that complex issue and distilling it down in a way people will understand and be motivated to help you."Â

[MORE >>](#)



The NC House of Representatives has established a Select Committee on Advancing Women in STEM to study issues related to developing future generations of women leaders in science, technology, engineering and math. NCBIO President Laura Gunter (center) joined a presentation to the committee, along with Rep. Erin Pare, chair of the committee; Rep. Donna White, co-chair of the committee and the Life Sciences Caucus; Shirley Paddock, chair of the Women in BIO-RTP chapter and SVP at Syneos Health; and Sheila Mikhail, CEO of AskBio.



NATIONAL UPDATES

From NCBIO President Laura Gunter

As we approach the end of the fiscal year, several things remain to finalize by Sep. 30, including the renegotiation of the FDA user fees covering drugs, medical devices and biologics. Â

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We anticipate a very clean version of the fees moving or becoming part of a continuing resolution that will take us past the upcoming elections. If not, the FDA may begin layoffs, which could translate into significant delays to the industry. SBIR reauthorization also remains on the table. Â

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NCBIO has contacted the NC delegation on these issues and has taken part in Council of State Biosciences Associations letters. If you have particular stories or are willing to make calls or send emails, please [contact me](#). Please also see the [BIO SBIR reauthorization webinar](#) below for more information.

Part D drug price ?negotiation? comes at cost of jobs, investment, cures

When the U.S. Senate passed the Inflation Reduction Act on Aug. 7 that implemented government price fixing for Medicare Part D drugs, NCBIO penned the following [editorial](#) from Laura Gunter. The House passed the bill on Aug. 12, and President Biden signed it into law Aug. 16.

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This past weekend, the U.S. Senate passed the Inflation Reduction Act. Included in the law is a provision that gives Medicare Part D the ability to ?negotiate? the price of medicines for the first time. Negotiate is in quotation marks because lawmakers are being ironic; no one can legitimately call the new price-setting policy a negotiation.Â

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What the new law would do is allow bureaucrats at the Centers for Medicare Services to arbitrarily set prices for certain medicines. If the manufacturer of the medicine doesn?t like the price offered, that?s fine. The government will instead hit the manufacturer with a 95% tax on the profits earned by the medicine.Â

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Such an absurd policy will have a dramatic chilling effect on investment to create new treatments and cures. While American taxpayers may provide hundreds of millions of dollars for research through government agencies like the National Institutes of Health or the Department of Defense, the hard truth is that it takes hundreds of BILLIONS of dollars invested in life sciences companies to turn discoveries into treatments. Â

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A new analysis of 110 currently approved therapies shows that only 6 of them would have made it to market if this new policy had been in effect during their development. Companies would not have had the necessary funds to invest in research and development. This legislation represents a \$300 billion dollar blow to a sector that has saved millions of lives and is working tirelessly to end the global COVID-19 pandemic.Â

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NCBIO does support the Part D out-of-pocket-spending cap for patients included in the bill. We also recognize that some senators tried to protect the small, innovative companies that will be disproportionately affected when investment funds dry up and that there was an unsuccessful attempt to reform to the pharmacy benefit manager rebate system that is driving up out-of-pocket costs for everyone at the pharmacy counter. Â

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A recent analysis of the legislation passed by the Senate determined that it will likely lead to the loss of over 590,000 jobs across the country. In North Carolina, the toll would be a direct biopharma job loss of almost 6,600 jobs, along with nearly 37,000 jobs supported by the life sciences industry.Â

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There is very little win in this bill for North Carolina. Government price setting destroys

innovation and jobs by removing the incentive to invest in the industry and cures of tomorrow. It is now up to the House of Representatives to intervene and stop this ill-conceived scheme before it starts.Â

[More @ BIO >>](#)

CBO scores H.R. 2884,H.R. 2891 bills affecting generics, biosimilars

The Congressional Budget Office published its review ofÂ H.R. 2884, the [Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act](#), and H.R. 2891, the [Preserve Access to Affordable Generics and Biosimilars Act](#).

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Affordable Prescriptions for Patients Through Improvements to Patent Litigation Act

CBO estimates the bill would reduce the deficit by \$223 million over the first ten years. H.R. 2884 would limit to 20 the number of patents that could be included in infringement claims under the Biologics Price Competition and Innovation Act of 2009, the report says.Â

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Preserve Access to Affordable Generics and Biosimilars Act Â

This bill would limit settlement of patent litigation. CBO estimates it would reduce the deficit by \$258 million over the first ten yearsand that the bill would accelerate the availability of lower-priced generic or biosimilar drugs that would be affected by such agreements.

Tillis introduces legislation to expand patent eligibility

U.S. Senator Thom Tillis (R-NC) introduced the [Patent Eligibility Restoration Act of 2022](#), legislation that his office said will restore patent eligibility to important inventions across many fields, while also resolving legitimate concerns over the patenting of mere ideas, the mere discovery of what already exists in nature, and social and cultural content that everyone agrees is beyond the scope of the patent system.

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This bill affirms the basic principle that the patent system is central to promoting technology-based innovation, Tillis said.

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?I have long said that clear, strong, and predictable patent rights are imperative to enable investments in the broad array of innovative technologies that are critical to the economic and global competitiveness of the United States, and to its national security,? Senator Tillis said.

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?Unfortunately, our current Supreme Court?s patent eligibility jurisprudence is undermining American innovation and allowing foreign adversaries like China to overtake us in key technology innovations.?

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Due to a series of Supreme Court decisions, patent eligibility law in the United States has become confused, constricted, and unclear in recent years, Tillis said. This has led to inconsistent case decisions, uncertainty in innovation and investment communities, and unpredictable business outcomes.

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Tillis said there is now widespread bipartisan agreement in Congress and across all recent administrations that reforms are necessary to restore the United States to a position of global strength and leadership in key areas of technology and innovation, such as medical diagnostics, biotechnology, personalized medicine, artificial intelligence, 5G and blockchain.Â

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Tillis also introduced S.4704, the [Patent Examination and Quality Improvement Act of 2022](#). This legislation would evaluate prior and current initiatives and pilot programs relating to the quality of patents. It would evaluate the need for greater clarity in terms of what constitutes patent quality, the setting of patent quality metrics, and how the quality of work product performed by patent examiners is measured within the office.

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The bill would evaluate the need for recording examiner interviews via audio files or automated transcriptions, how the assignment of patent applications to examiners is undertaken, and the creation of a group that looks at real-world circumstances and uses that information to perform targeted review of certain patent applications.





NCBIO President Laura Gunter participated in a health care roundtable discussing drug development and workforce needs hosted by Rep. David Rouzer (R-NC 7), center, along with Randy Marchbanks, senior vice president, operations strategy at PPD, part of Thermo Fisher, right.

NCBIO Updates

Second class of Sam Taylor life sciences scholarship recipients named

The second class of recipients of the Samuel M. Taylor Memorial Life Sciences Scholarship in the NC Community Colleges Foundation has been named. This year, five scholarships have been awarded.Â

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The 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.Â

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The five 2022 scholarship recipients areÂ

- Gregory Ackerson of Winterville, who is studying biotechnology at Pitt Community College;Â
- Stephanie Alston of Wake Forest who is studying clinical trials research at Durham Tech. This is her second year as a Taylor scholarship recipient;Â
- Gage Lindley of Siler City, who is studying biotechnology at Central Carolina Community College; andÂ
- Keshia Sauls of Clayton, who is studying bioprocess technology at Johnston Community College.Â
- Ayonna Sawyer of Cofield, who is studying medical laboratory technology at College of the Albemarle

?We are so gratified by all the organizations and individuals who have stepped up to honor Sam?s legacy and extend our sincere thanks to them,? said NCBIO President Laura Gunter. ?He knew that an educated and qualified workforce is needed to drive the discovery and innovation for which the industry is known. He especially wanted our state?s citizens to have the educational opportunities and resources they need to have outstanding careers in the life sciences.?Â

[More >>](#)

NCBiotech Awards \$3.3 Million in Grants, Loans in Latest Quarter

The North Carolina Biotechnology Center awarded 32 grants and loans totaling \$3,304,543 to universities, bioscience companies and nonprofit organizations in the fourth quarter of its fiscal year.

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The awards, made in April, May and June, 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.

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Eight bioscience companies received Small Business Research Loans totaling \$1,850,000 to advance their research, product development, commercial viability and funding efforts. Nineteen bioscience companies that previously received loans from the Biotech Center raised over \$81 million in follow-on funding from other sources in the fourth quarter, according to research by the Biotech Center?s Life Science Intelligence staff.

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Eight universities received grants totaling just over \$1.1 million to advance bioscience research.

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[More >>](#)

NCBIO Member News

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

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Seven NCBIO members are recipients of the Triangle Business Journal's 2022 Best Place to

Seven NCPIO members are recipients of the Triangle Business Journal's 2022 Best Place to Work Awards.

- [AskBio](#) (Large companies)
- [DPR Construction](#) (Large companies)
- [Smith Anderson](#) (Large companies)
- [Wyrick Robbins](#) (Large companies)
- [G1 Therapeutics](#) (Medium companies)
- [Longfellow Real Estate Partners](#) (Medium companies)
- [McDonald York Building Co.](#) (Medium companies)

BD and Accelerate Diagnostics announced a worldwide commercial collaboration agreement where BD will offer Accelerate's rapid testing solution for antibiotic resistance and susceptibility offering results in hours, versus one to two days with some traditional laboratory methods. [More >>](#)

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BD announced a collaboration agreement with Labcorp creating a framework to develop, manufacture, market and commercialize flow-cytometry-based companion diagnostics intended to match patients with life-changing treatments for cancer and other diseases. [More >>](#)

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BioAgilytix Labs appointed Linda Robbie as chief operating officer. For the past three years,Â Robbie served as vice president and general manager of Boston operations, responsible for leading all bioanalytical services at BioAgilytix?s Boston laboratory. [More >>](#)

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BioCryst Pharmaceuticals announced that the FDA has granted orphan drug designation for BCX9250 for the treatment of fibrodysplasia ossificans progressiva, the irregular formation of bone outside the normal skeleton. [More >>](#)

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Chiesi USA sponsored the ASHP Foundation Pharmacy Leadership Scholars program in providing \$50,000 worth of research grants. Five early-stage pharmacist researchers were given \$10,000 grants, which supports meaningful research that advances diversity, equity, inclusion and access in health care. [More >>](#)

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Chimerix has signed a multiyear contract with the Biomedical Advanced Research and Development Authority to deliver up to 1.7 million treatment courses of tablet and suspension formulations of TEMBEXA, its smallpox treatment, to the U.S. government. [More >>](#)

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Enzyvant is among the National Organization for Rare Disorders 2022 Industry Innovation Awards recipients for the development and FDA approval of RETHYMIC, a one-time regenerative tissue-based therapy for pediatric congenital athymia. [More >>](#)

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G1 Therapeutics will host a virtual R&D Day, ?Innovations in Oncology: The Science of Trilaciclib,? on Thursday, Sept. 15, 2022, from 9 to 11 a.m. ET. [More >>](#)

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Kymanox named Fran DeGrazio to the newly formed Kymanox Executive Advisors team, a group of highly distinguished industry executives that has led some of the top companies in the biopharma industry. [More >>](#)

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Novo Nordisk published its [inaugural diversity and inclusion report](#) that lays out its commitments ? and progress ? for employees, patients and external audiences. [More >>](#)

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Seqirus will become CSL Seqirus as CSL announced that all its business units will be united as one family under the CSL global brand. [More >>](#)

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TARGAN (formerly Applied LifeSciences & Systems) has secured \$35 million of Series C equity financingÂ co-led by Mountain Group Partners and NovaQuest Capital Management. [More >>](#)

Events





Critical Conversations about DEI in the Workplace hosted by NCBIO

Certified diversity executive, entrepreneur, investor and author Donald Thompson will discuss "Critical Conversations about DEI in the Workplace" with NCBIO members.Â

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With two decades of experience growing and leading firms, Thompson is a thought leader on goal achievement, influencing company culture and driving exponential growth. As an entrepreneur, he has led multiple companies that have attained successful exits with strong returns for shareholders and employees. As CEO of The Diversity Movement and a certified diversity executive, he is a champion of DEI initiatives. Through his work, Thompson actively raises both awareness of and commitment to diversity, equity and inclusion in order to create a more inclusive society and improve business outcomes along the way.Â

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Thompson says, "I believe it's my responsibility to take my experiences and use them to create positive change in the business environment when I can and while I can." Find out about ways to create positive change during this NCBIO DEI virtual forum. Following Thompson's presentation, members can participate in breakout groups to share suggestions and best practices.

REGISTER NOW



NCBiotech invites you to Informing Innovation 2022 Sept. 8

Join the NC Biotechnology Center on Thursday, Sept. 8, for Life Science Intelligence's Informing Innovation 2022 event to learn more about strategies, resources and trends in scientific and business content. Get up to speed with life science information resources, search strategies, industry tools and more.

LEARN MORE



BIO Webinar: Reauthorization of SBIR/STTR Program funding Sept. 13

With the recent news around the pending renewal of SBIR/STTR programs, BIO will be co-hosting a unique webinar with the Council of State Biosciences Associations AdvaMed's Accel division, and State Medical Technology Alliance.Â

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In 2016, the SBIR/STTR Program was reauthorized through Sept. 30, 2022. With the looming deadline, a critical source of funding for small businesses may soon not be available, and time-sensitive R&D will be postponed.

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This free webinar will provide ways for the biotech community and our members to advocate for the reauthorization of SBIR/STTR programs.

REGISTER NOW

BIO Webinar: Understanding the prescription drug provisions of the Inflation Reduction Act Sept. 21

On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, which includes a number of significant prescription drug-related provisions, including a new drug price negotiation program in Medicare, inflation rebates in Medicare Part B and Part D, and a redesign of the Medicare Part D benefit, with a new patient out-of-pocket cap of \$2,000.

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Join BIO leadership as well as experts from the Hogan Lovells Life Sciences & Health Care team for overviews with Q&A on these newly enacted provisions.

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The first hour of the webinar will cover the new drug price negotiation program and inflation rebates in Medicare. The second hour will focus on the Medicare Part D benefit redesign and new out-of-pocket cap, as well as other important provisions that will reduce patient cost sharing.

REGISTER NOW



MDMA exec forum to offer expert insights into medtech strategies

We are proud to partner with the Medical Device Manufacturers Association to support their upcoming 2022 virtual Executive Forum on Sept. 23. MDMA is the leading voice for innovative and entrepreneurial medical devices companies, and this year's Executive Forum will deliver key insights on regulatory, reimbursement and other issues affecting our industry.

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ContactÂ [Natacha Janvier](#) for a registration discount code.

LEARN MORE

The Diversity Movement offers new certificate for DEI leaders

Our partner The Diversity Movement is offering a new certificate program, the Diversity Leader's Intensive on Oct. 3-6. This intensive goes beyond the "what?" and "why?" of diversity, equity, and inclusion training to focus on the "how-to?" and skills you need to build and sustain DEI at your organization. Led by The Diversity Movement's experts, you'll walk away from this 4-day intensive with practical information to put into practice right away, a certificate of competency, and amazing relationships that you develop with other cohort members.

LEARN MORE

Register now for NCBIO Annual Meeting Oct. 12

Join us in person for our Annual Meeting on Wednesday, Oct. 12, at the NC Biotechnology Center in Research Triangle Park. The Annual Meeting program features multiple networking opportunities, a keynote address and three panels.

- Success Stories: Talent Recruitment and Retention highlights Aperio Clinical Outcomes, Novozymes and StrideBio
- Financial Trends and Outlook with GSK, Incubate Coalition, JPMorgan, Pappas Capital and Solas Bioventures
- Health Equity and Disparity features Biogen, ECU's Center for Health Disparities, the Global Liver Institute and mdgroup
- Decisions to Locate and Expand in NC with Amgen, Fujifilm and Lilly

You will want to join this year's program and networking opportunities. Thank you.

You will not want to miss this year's programming and networking opportunities. I thank you to our current sponsors.

- Platinum: [Avantor delivered by VWR](#); [Bioventus](#), [Cook Medical](#), [Kymanox](#)
- Gold: [American Laboratory Trading](#), [Azzur Group](#), [FUJIFILM Diosynth Biotechnologies](#), [Grifols](#), [Novo Nordisk](#), [PSC Biotech](#)
- Silver: [AdvaMed](#), [Alexandria Real Estate Equities](#), [The Conafay Group](#), [Frontier Scientific Solutions](#), [Marsh McLennan Agency](#), [Mispro Biotech Services](#), [Smith Anderson](#), [Unifirst](#)
- Bronze: [Amgen](#), [Nikon](#), [Novozymes](#), [PHC Corporation](#), [UCB](#), [UMotif](#)

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Uniting top medtech executives

The MedTech Conference 2022 is the industry's leading event for the world's top medtech executives. Powered by AdvaMed, the premier medtech association, the conference brings together the industry's top professionals and prominent companies for three days of

- valuable networking with industry executives, start-ups, government officials, academics and more;
- access to cutting-edge innovation and technology from early-stage companies;
- trusted networking, deal-making, discovery, and knowledge building;
- 100-plus cross-cutting educational programming sessions; and
- business development opportunities with exclusive one-on-one meetings with industry stakeholders and investors.

[LEARN MORE](#)

2022 BIO Impact Ag & Environment Conference Canceled

BIO has decided to cancel the [2022 BIO Impact Ag & Environment Conference](#) and shift its focus to planning a world-class event for Raleigh in September 2023.

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BIO is constantly evaluating how best to serve its members and advance the interests of the agriculture and environment biotech sector. This cancellation shows how committed BIO is to ensure it safely hosts an event that is successful and reflects the priority we place on agricultural technology and environmental sustainability issues.

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Details about the 2023 conference will be available soon at www.bio.org/impact.

NCBIO calendar

- [Informing Innovation hosted by NCBiotech \(9/8/2022\)](#)
- [Strategies for Biotech/Medtech Startups: Successfully Navigating the USPTO and FDA hosted by Biocom California \(9/8/2022\)](#)
- [Does Gender make a Difference in the Entrepreneurial World hosted by First Flight Venture Center \(9/8/2022\)](#)
- [Reauthorization of SBIR/STTR Program Funding Webinar hosted by AdvaMed and CSBA \(9/13/2022\)](#)
- [Compensation Confidential hosted by LaunchBio \(9/14/2022\)](#)
- [cGMP Boot Camp hosted by Azzur Group \(9/20/2022\)](#)
- [Aseptic cGMP Boot Camp hosted by Azzur Group \(9/21/2022\)](#)
- [Critical Conversations about DEI in the Workplace hosted by NCBIO \(9/21/2022\)](#)
- [Understanding the Prescription Drug Provisions of the Inflation Reduction Act hosted by BIO \(9/21/2022\)](#)
- [NC Ag Tech Forum: One Health-Improving Rural and Urban Resilience hosted by NCBiotech \(9/21/2022\)](#)
- [Biotech Connect hosted by Elemental Machines \(9/22/2022\)](#)
- [Investigation Boot Camp hosted by Azzur Group \(9/22/2022\)](#)
- [Summit for Women in Tech hosted by NC TECH \(9/22/2022 to 9/23/2022\)](#)
- [Medical Technology Executive Forum hosted by MDMA \(9/23/2022\)](#)
- [Virtual Open House hosted by The Diversity Movement \(9/28/2022\)](#)

- [Virtual Open House hosted by The Diversity Movement \(9/20/2022\)](#)
- [USDA Role in International Initiatives to Advance Sustainable Productivity & Climate hosted by BIO \(9/28/2022\)](#)
- [The Diversity Leader's Intensive hosted by The Diversity Movement \(10/3/2022 to 10/6/2022\)](#)
- [Hands-On Single-Use Processing for Biopharmaceuticals hosted by BTEC \(10/11/2022 to 10/13/2022\)](#)
- [NCBIO Annual Meeting 2022 \(10/12/2022\)](#)

BIO Business Solutions

Nikon BioImaging Lab and Centers here to help



Life science professionals need access to data that can sometimes only be obtained on cutting-edge lab equipment. However, due to capital and expert staff requirements this may not be feasible. Nikon Instruments, BIO's preferred partner for microscopic-based imagery, is here to help with their BioImaging Lab and Centers.Â

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Equipped with full-service imaging, assay development, and expert microscopists ready to assist, Nikon's contract imaging services are meant to enhance and support your important research.Â

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Click below to learn more about Nikon's imaging services and contact save@bio.org for information on Nikon's exclusive BIO & state association member benefits.

LEARN MORE



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



detchison@ncbioscience.net
919.281.8960
ncbioscience.net

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