July 2022 Update

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NCBIO This Month

- Legislature releases state budget
- Senate committee advances PDUFA, MDUFA bill
- WTO adopts TRIPS waiver
- NCBiotech leads Build Back Better grant
- BIO 2022 wraps up
- Register for July 14 Lab Space Forum

... and more

NCBIO Legislative Reception

A great turnout for the June 22 NCBIO Legislative Reception

Life Science Caucus Co-Chair Sen. Mike Woodard
with Rachel Fones, Susan Thompson and Laura Marquis of IQVIA

NCBIO held its 2022 Legislative Reception on Wednesday, June 22, at the North Carolina Museum of History in Raleigh. The event was well attended by NCBIO members who were joined by a number of state senators. The House was still in session during the event, unfortunately. Thank you to our premier sponsors for their support of the event: Amgen, IQVIA, Lilly, Pfizer and We Work for Health NC.

Thanks to our sponsors: BIO, Biogen, Bristol Myers Squibb, FUJIFILM Diosynth Biotechnologies, Mallinckrodt Pharmaceuticals and Seqirus.
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STATE UPDATES

Medicaid expansion doesn't make legislature's budget

Republican leaders of the North Carolina House and Senate unveiled their $27.9 billion budget proposal Tuesday, just days before the General Assembly is set to adjourn for the year.
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The budget does not include an expansion of Medicaid that has been a longtime priority of Democrats and a proposal that Republicans have become more receptive to in recent months. In past years, lack of funding for Medicaid expansion has been a key obstacle to securing the governor?s support for budget legislation.
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The budget includes the following:

- Teachers will receive a 4.2% average increase in FY 22-23 and will receive a 9.1% total increase over the biennium.
- School employees will receive the greater of 4% or an increase to $15/hour.
- State agency employees will receive a 3.5% pay increase.
- State retirees will receive an additional 1.0% one-time retiree supplement (total of 4% over biennium).
- Economic development: $876 million to supplement major projects.
- School safety grants: $32 million for safety equipment, students in crisis and training.
- Mental health programs: $14.8 million.
- Water and sewer: $600 million additional and $2.5 billion over the biennium..

The budget bill also creates a $1 billion allocation for a newly created State Inflation Reserve. That fund would go toward ?costs associated with inflation and other measures necessary to stabilize? the state?s economy. No new tax cuts are included in the budget.
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NCBIO?s legislative priorities had mixed results.

- The NC Biotechnology Center?s requested funding of $500,000 recurring and $1 million nonrecurring is in the budget.
- No additional dollars were included in the budget for the One North Carolina Small Business Fund that matches SBIR/STTR awards, so the fund will have just $2 million for the 2022-23 fiscal year.Â
- A communication provision in the biosimilars substitution law that had expired is reinstated in the budget, and communication will now be required upon any interchangeable biologic substitution within five days.Â

The budget is expected to pass the General Assembly by the end of the week and go to Gov. Roy Cooper for his consideration. It is unclear whether he will sign or veto the budget.
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More at Raleigh News & Observer >>

NCBIO joins biotech round table with Rep. Deborah Ross

NCBIO joined a small group discussion June 27 requested by Rep. Deborah Ross and organizaed by the Incubate coalition. Ross wanted to hear about tax, IP and regulatory issues affecting the life sciences industry from local executives and advocacy groups.

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Incubate advocates for the patient, corporate, and investment communities by educating policymakers on the role of venture capital in bringing promising, innovative treatments to patients in need.

Gene therapy and rare diseases topic of Life Sciences Caucus

The General Assembly's Life Science Caucus met Tuesday, June 28, to learn about the promise of gene therapies as potential treatments for rare diseases.
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Nearly two dozen legislators and staff member heard from Priya Kishnani, M.D., and Vandana Shashi, M.D., of the Duke Undiagnosed Diseases Network and Marianne Hamilton Lopez, M.D., of the Duke Margolis Center for Health Policy along with Charlene Cowell, executive director of Bleeding Disorders of North Carolina. Caucus Co-Chairs Sen. Paul Newton, Sen. Mike Woodard and Rep. Donna White were in attendance.
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Hamilton Lopez told legislators that gene therapies will often differ from traditional treatment in that the therapies may only be administered once as opposed to conventional treatments that are given as multiple or continual doses of medication. Gene therapies are currently much more expensive than conventional therapies, which makes them a challenge for our current system to pay. The upfront cost of these breakthrough therapies must be weighed against the impressive benefits they offer compared to conventional therapies.

NATIONAL UPDATES

Senate Committee advances PDUFA, MDUFA reauthorization

The Senate Committee on Health, Education, Labor and Pensions passed its user fee reauthorization bill, the Food and Drug Administration Safety and Landmark Advancements Act (S.4348), out of committee by a vote of 13 to 9.Â
Â
Chairwoman Patty Murray (D-WA) and Ranking Member Richard Burr (R-NC) were able to defeat an extreme importation amendment offered by Senator Bernie Sanders (I-VT) by a vote of 15 to 7. The Sanders amendment would have

- allowed importation with no requirement for the HHS secretary to affirm safety or cost savings;
- allowed personal importation, including through online foreign pharmacies;
- allowed importation from Canada and the United Kingdom initially with potential later expansion to other countries; and
- included biologics and certain complex products.

Murray and Burr were only able to defeat the Sanders amendment by including some

Murray and Burr were only able to defeat the Sanders amendment by including some moderated importation provisions in their base text. The importation language in the user fee legislation that passed the HELP Committee

- maintains the safety and cost savings requirements from the HHS secretary in the current statute with an additional certification regarding secretarial oversight,
- codifies key provisions of the 2020 Trump final rule,
- allows personal importation with FDA rule making and safety guardrails,
- permits importation from Canada only and
- maintains exclusions (biologics, infusions, etc.).

The House has already passed its version of the bill and technically the Senate bill is ready to go to the floor for a vote, but given the short time frame, the Senate is already working with the House to conference the bill and work on an agreed upon version. The agreement will likely include language addressing clinical trial diversity (which is something patient advocates are seeking) and trial modernization.Â

More @ AdvaMed >>

BIO reacts as WTO approves TRIPS waiver

The World Trade Organization agreed to ?a waiver of certain requirements concerning compulsory licensing for COVID-19 vaccines.?
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Developing countries that want access to patented COVID vaccine technology no longer need to contact the patent holder before issuing a compulsory license, said Hans Sauer, deputy general counsel and vice president of IP for the Biotechnology Innovation Organization.
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?In 2021 alone, companies produced more than 11 billion doses of COVID vaccines, enough to give two shots to every adult on the planet,? said Michelle McMurry-Heath, M.D., Ph.D., president & CEO of BIO, in May. ?We anticipate that number jumping to 18.6 billion by the end of this year.?
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Originally proposed in October 2020 by India and South Africa, the TRIPS waiver was designed to support the global fight against the pandemic by opening up the technology behind COVID-19 vaccines so that developing countries could manufacture vaccines domestically to ensure they have adequate supplies.
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A total of 632 million doses of COVID-19 vaccines have been administered throughout the African Region, with 64 percent coming from the COVAX Facility, according to the World Health Organization. This equates to 56 doses per 100 persons and accounts for 40% of the doses required to achieve 70% of individuals completely vaccinated in all nations.
Â
The problem is that the vaccines aren?t getting into arms. Twenty-seven African countries out of 46 have administered fewer than 50% of doses received, says WHO. More tragically is that doses are getting ditched or destroyed all over the world ? from the EU, which has thrown away around 50 million?plus expired doses, to the Serum Institute of India, which may need to destroy 200 million doses in August/September due to oversupply.
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What the TRIPS waiver does do is give China and India access to the IP behind the new mRNA vaccines, said Nick Shipley, BIO executive vice president and chief advocacy officer.
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?The mRNA technology is a real seismic leap, there?s just no other way to put it. That?s why everyone wants it.?
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More @ BIO >>

Hudson's legislation to ensure access to cancer detection tools gains momentum in Congress

The Medicare Multi-Cancer Early Detection Screening Coverage Act (H.R. 1946) has achieved a significant milestone, earning the support of a bipartisan majority of members in the U.S. House of Representatives with 219 co-sponsors.
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This bipartisan and bicameral bill, which Rep. Richard Hudson (NC-08) introduced with Reps. Jodey Arrington (TX-19), Terri Sewell (AL-07) and Raul Ruiz (CA-36), will allow for multi-cancer early detection tests to be covered by Medicare in a timely manner upon approval by the Food and Drug Administration and once a clinical benefit is shown. The legislation enjoys the support of nearly half of the U.S. Senate, as well as more than 400 organizations across the country.
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The Medicare Multi-Cancer Early Detection Screening Coverage Act responds to a misalignment between advances in science and Medicare coverage by allowing for Medicare coverage of multi-cancer screening. It would significantly reduce delays for Medicare beneficiaries, while allowing the Centers for Medicare and Medicaid Services to use its evidence-based process to determine coverage. Accordingly, these new multi-cancer screening tools will complement existing screenings and dramatically improve our nation?s

screening tools will complement existing screenings and dramatically improve our nation?s cancer early detection capabilities.Â
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The legislation would accomplish the following:

- Create the authority for CMS to cover blood-based multi-cancer early detection tests and future test methods (like urine or hair tests), once approved by the FDA. Congress has acted before to create coverage for other cancer screenings including mammography and colorectal screenings.
- Maintain CMS? authority to use an evidence-based process to determine coverage parameters for these new tests.
- State that these new tools will complement, not replace, existing screenings and coverage, and cost sharing will not be affected.

More from Rep. Richard Hudson >>

ARPA-H launches

President Biden selected Adam Russell to be deputy director of the Advanced Research Projects Agency for Health and nominated Arati Prabhakar for director of the Office of Science and Technology Policy. The administration is waiting to select the ARPA-H director until after Congress completes the ARPA-H authorization bill.
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Meanwhile, on June 22, the House passed H.R. 5585, the ARPA-H Act by 336 to 85 with strong bipartisan support. Energy and Commerce Health Subcommittee Chair Anna Eshoo (D-CA) teamed up with Ranking Member Brett Guthrie (R-KY) to introduce a successful floor amendment that removed Senate confirmation for the director position, precisely as the White House wanted. In the Senate, similar authorization legislation is tucked inside the PREVENT Pandemics Act, which Senate HELP Committee Chair Patty Murray (D-WA) and Ranking Sen. Richard Burr (R-NC) have championed and passed out of their committee two months ago.Â

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USPTO extends Cancer Immunotherapy Pilot Program until September 30, seeks public input

To accelerate innovation in the health and medical fields, the United States Patent and Trademark Office has published a Federal Register Notice announcing a further extension of its Cancer Immunotherapy Pilot Program. Petitions requesting participation in the pilot program that are compliant with the program’s requirements and are filed on or before September 30 will be accepted.

Though all parameters will remain the same as in the original pilot through the September 30, 2022, extension, the USPTO is in the process of deciding whether to expand the scope of the pilot program, including beyond immunotherapy.

More @ USTPO >>

NCBIO Updates

NCBIO Member News

To be included in member news, send information about your organization to David Etchison.
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AskBio founder and CEO Sheila Mikhail testified at an FTC Merger Guidelines Listening Forum on June 21. Her testimony can be found at 38:40 in this video. More >>
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BD will acquire Parata Systems, an provider of pharmacy automation solutions, for $1.525 billion. More >>
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BioAgilytix Labs named Euan Menzies as its chairman and CEO. Jim Datin is retiring from his executive management role but will continue to serve as a nonexecutive member of the Board of Directors. More >>
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BioAgilytix Labs appointed Nathan Speicher as chief financial officer. Speicher is responsible for the strategy, planning and execution of the enterprise's finance and accounting operations. More >>
Â
BioAgilytix Labs appointed Christie Knittel Mabry as chief people officer. Mabry joins the executive leadership team and will lead people strategy across the business. More >>
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Biogen and Alectos Therapeutics have entered into a license and collaboration agreement to develop and commercialize a novel preclinical selective GBA2 inhibitor, AL01811, which has first-in-class potential as an oral disease modifying treatment for patients with Parkinson?s

disease. More >>
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Biogen and Happify Health are collaborating to provide a digital solution for patient education and engagement, powered by artificial intelligence, to support people living with multiple sclerosis. More >>
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Biogen received a patent from the European Patent Office that expires in Feb. 2028 related to TECFIDERA (dimethyl fumarate). The patent, EP 2 653 873, is directed to treating multiple sclerosis. More >>
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Boston Analytical has opened a new location in Morrisville offering sampling and testing services to support environmental monitoring, monitoring of critical utilities including water systems and compressed gases. More >>
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G1 Therapeutics announced that the last patient has been randomized in the Phase 3 clinical trial of trilaciclib for patients with metastatic colorectal cancer receiving chemotherapy. More >>
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G1 Therapeutics appointed Jacks Lee to its Board of Directors. Lee currently serves as senior vice president ? manufacturing & supply of Merck & Co., Inc. More >>
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Liquidia appointed Rajeev Saggar, M.D., to the position of chief medical officer overseeing all aspects of research, clinical development, medical affairs and regulatory affairs for the company. More >>
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The **North Carolina Biotechnology Center** awarded 18 grants and loans totaling $1,755,181 to universities, bioscience companies and nonprofit organizations in the third quarter of its fiscal year. More >>
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Novex Innovations President Jerry Barker and COO Doug Drabble jointly received the Entrepreneurial Excellence Award at Triad BioNight organized by **NCBiotech**.
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Novozymes and AgroFresh are forming a research and commercialization partnership towards developing biological solutions that can improve post-harvest food quality and minimize waste by fighting fungal pathogens. More >>
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Opus Genetics appointed Ben Yerxa, Ph.D., as chief executive officer. He previously served as acting CEO of Opus, in addition to former roles as CEO of the Foundation Fighting Blindness and the Retinal Degeneration Fund. More >>
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Qmera Pharmaceuticals has named Tom Compton as chief business officer. He willÂ promote analytical chemistry and sample analysis services for both pharmaceutical and biotech companies in RTP.Â
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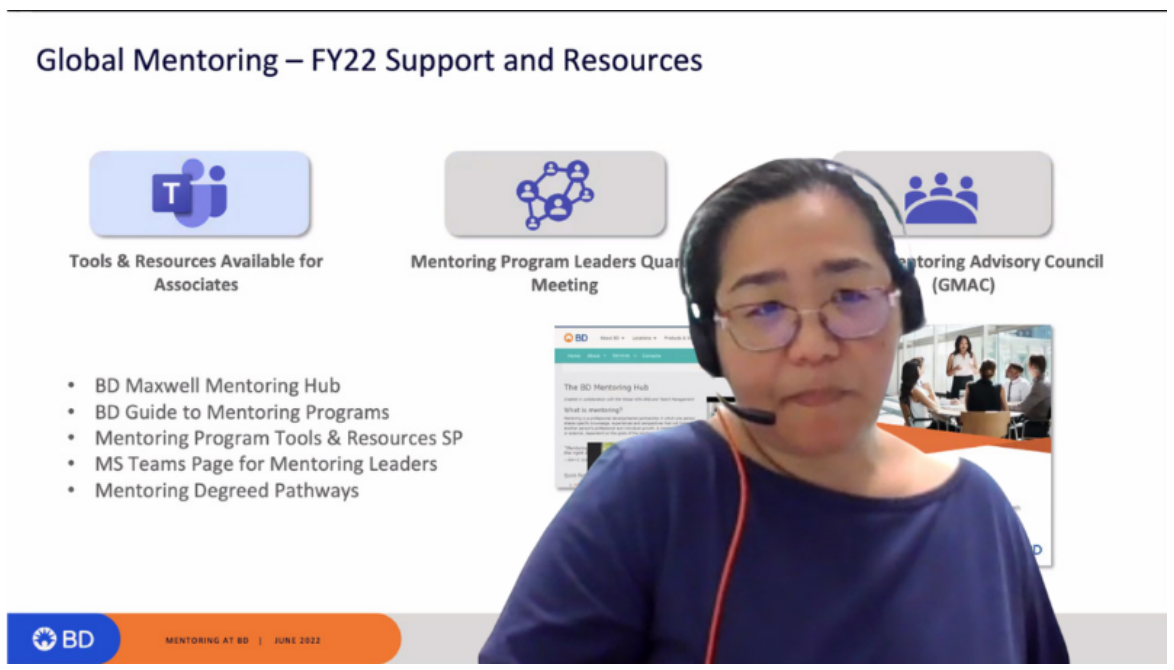
The **PPD** clinical research business of **Thermo Fisher Scientific** has been named Clinical Research Company of the Year at the 2022 PharmaTimes Clinical Researcher of the Year International competition held recently in London. More >>



NCBIO DEI Virtual Forum focuses on mentoring

NCBIO hosted its quarterly Diversity, Equity and Inclusion Forum Tuesday, June 28, focusing on mentoring programs. The program was virtual. Â
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BD Staff Engineer Melody Kuroda kicked off the discussion. She is a WIN+STEM associate resource group leader for BD's RTP location. BD?s WIN mentorship program has received national recognition. Kuroda talked about the program and her passion to attract, develop, and advance women in the medical device industry.Â
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Following the presentation, attendees broke out into discussion groups talking about mentoring frameworks and best practices. These groups were led by

- Drew Duncan, director of human resources, Biogen, and
- Ashley Jefferson, associate director, early career and talent outreach, Beam Therapeutics.

NCBiotech spearheading Build Back Better Regional Challenge grant

A coalition of partners from across North Carolina, led by the North Carolina Biotechnology Center, recently submitted a federal Economic Development Administration Build Back Better Regional Challenge grant Phase 2 proposal that marks a milestone in our state's economic evolution.

The seven projects outlined in this proposal provide a roadmap to the next big inflection point in North Carolina's life sciences manufacturing evolution.

North Carolina needs to fill an additional 12,000 life sciences manufacturing jobs in the coming years. And the only way to do that is to expand the pipeline of qualified talent. Diversifying the life sciences workforce is North Carolina's only hope for meeting this rapidly growing demand for specialized talent. And it's the right thing to do. Consider the fact that, 38% of North Carolina's life sciences companies operate in Durham County, where Black Americans hold just 20% of the life sciences jobs, yet constitute 36% of the population.

The NCBiotech BBBRC proposal takes a cluster-based approach to deploying seven individual but integrated projects across the spectrum from innovation to workforce and community development, to job creation, with a focus on distressed communities and historically excluded populations.

More @ WRAL TechWire >>

NCBIO Membership Director Natacha Janvier with NC Commerce Secretary Machelle Sanders at BIO 2022 in San Diego June 13-16.

What you might have missed at BIO 2022

After two years of meeting virtually due to the pandemic, the Biotechnology Innovation Organization went back to holding the BIO International Convention in-person in San Diego June 13?16.
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NC Commerce Secretary Machelle Sanders attended the conference and participated as a panelist in the session, "Building a Strong Biomanufacturing Workforce in the United States: A Conversation with State Economic Development Experts."
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The BIO International Convention is the world?s largest gathering of leaders in the biotechnology and life sciences industries, bringing together thousands of biotechnology and pharmaceutical executives for a chance to meet one another and foster new opportunities and promising partnerships. Here are some of the highlights.

- Seven-time Grand Slam singles champion, four-time Olympic gold medalist and entrepreneur Venus Williams discussed her groundbreaking career, business success and health journey in a conversation with Emmy-nominated sports reporter Erin Andrews in the keynote address of the BIO International Convention.
- One of the key lessons of the COVID-19 pandemic has been the need to strengthen government support for biotechnology, with direct funding but also through public-private partnerships and improvements in regulation, according to a super session that provided the perspective of six different countries, each represented by high-level

officials.

- The FDA?s Accelerated Approval Pathway must be preserved against current threats as it has been a lifeline for patients with rare diseases, life-threatening conditions, different types of cancer, or HIV/AIDS, a panel of experts at the BIO International Convention agreed. A report, ?Calculating the Value and Impact of Accelerated Approvals,? showed that, if new restrictions are placed on the FDA?s Accelerated Approval pathway, as many as two-thirds of the treatments that use this pathway would never reach patients.
- Life sciences and the biotechnology industry are key to the economic health of the world, America, and individual states. Helping biotech grow requires new talents and physical space as well as partnerships between government, the private sector, investors, and communities, panelists said.
- Improvements proposed to the next iteration of the Prescription Drug User Fee Act include an opportunity for developers of candidate drugs to hold more meetings with the FDA, an increase in staff that will build expertise at the FDA, a new rare disease program, and provisions to support diversity in clinical trials, according to a panel of experts. Potential problems with PDUFA VII include changes to the FDA?s Accelerated Approval pathway, a panel of state economic development experts said.
- Accelerated Approval, growing misinformation and declining life expectancy, and the need for more resources on the food side of the agency were among the topics FDA CommissionerÂ Robert M. Califf, M.D., discussed.
- Over the last 25 years, licensing of academic patents from universities and nonprofits has made a major contribution to US GDP, industrial gross production, and job creation, highlighting the importance of fundamental and applied research to the US economy as well as the necessity for public-private collaborations.

Awards honor leaders in Piedmont Triad biosciences

Some of the Piedmont Triad region?s most successful individuals and organizations working in the biosciences have been honored with Excellence Awards.
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The awards were given at Triad BioNight, a celebration of the region?s life sciences community organized by the Piedmont Triad Office of the North Carolina Biotechnology Center. Close to 400 people attended the networking and awards event June 23 at the Qubein Arena and Conference Center at High Point University in High Point.
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The recipients were chosen by a 12-member independent awards committee after nominations were solicited from the Triad region?s bioscience community.

- Jerry Barker and Doug Drabble of **Novex Innovations** in Winston-Salem jointly received the Entrepreneurial Excellence Award.
- Nancy V. Johnston of the North Carolina Biotechnology Center received the Biotechnology Community Leadership Excellence Award.
- The Joint School of Nanoscience and Nanoengineering?s Institute for Research Technologies received the Biotechnology Support/Service Excellence Award.
- The Wake Forest Institute for Regenerative Medicine?s NASA Vascular Team at the Wake Forest University School of Medicine received the Research and Development Excellence Award.
- Terry G. Howerton of Atkins Academic & Technology High School in Winston-Salem received the Academic Development Excellence Award.

More @ NCBiotech >>

BIO launches website to cover growing industry

BIO has unveiled Bio.News, a news site with easy-to-read and easy-to-share news articles by independent journalists, editors, and content creators, as well as smart analysis by BIO experts.

Covid-19 opened the world’s eyes to the wonders of biotechnology. But the biotech industry faces, at best, unfairly negative coverage and, at worst, misinformation and disinformation about science, which fueled vaccine hesitancy and led to many unnecessary deaths. Bio.News will provide more coverage about the wondrous things the industry is doing to cure disease, solve climate change and feed and fuel the world in more sustainable ways.

Events

NCBIO Lab Space Forum, July 14, 11:30 a.m. ? 1:30 p.m.

Our panelists will discuss the booming lab space market. Hear from them as they talk about their investments in North Carolina during the pandemic and plans following the pandemic. They will highlight new space available, take a look at the demand for specialized space and discuss how the real estate community is responding. Speakers includeÂ

- **Greg Capps**, managing director, North Carolina, Longfellow Real Estate Partners,

- **Joel Gates**, senior director of operations, Azzur Group, and
- **Marlene Spritzer**, vice president, Lee & Associates (moderator).

Thank you to our sponsors Alexandria Real Estate Equities, American Laboratory Trading, Azzur Group, Lee & Associates and Longfellow Real Estate Partners.

REGISTER NOW

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.
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- Success Stories: Talent Recruitment and Retention highlights Aperio Clinical Outcomes, Novozymes and StrideBio
- Financial Trends and Outlook with GSK, Incubate Coalition, JPMorgan and Solas Bioventures
- Health Equity and Disparity features Biogen, BIO, ECU's Center for Health Disparities, the Global Liver Institute and mdgroup

You will not want to miss this year?s programming and networking opportunities. Thank you to our current sponsors.

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- Silver: AdvaMed, The Conafay GroupÂ , Marsh McLennan Agency
- Bronze: Novozymes, PHC Corporation

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NCBIO calendar

- Hands-On cGMP Biomanufacturing Operations hosted by BTEC (7/12/2022 to 7/15/2022)
- Hands-On Essentials of Automation for Biomanufacturing hosted by BTEC (7/13/2022 to 7/14/2022)
- Office Hours: A Pioneering Mentoring Initiative hosted by Boehringer Ingelheim (7/14/2022)
- NCBIO Lab Space Luncheon and Forum (7/14/2022)
- Academy and Networking Reception hosted by Boehringer Ingelheim (7/14/2022)
- Analytical Methods for Gene Therapy Vector Characterization and Testing hosted by BTEC (7/18/2022 to 7/21/2022)
- Self Care - Transform Stress for Optimal Performance hosted by WIB-RTP (7/19/2022)
- Automation, Process Control, and Real-time Monitoring of Yeast Culture hosted by BTEC (7/26/2022 to 7/29/2022)
- Fermentation Engineering hosted by BTEC (8/2/2022 to 8/4/2022)
- Biopharmaceutical Lyophilization and Spray Drying hosted by BTEC (8/2/2022 to 8/5/2022)
- Hands-On cGMP Biomanufacturing of Vectors for Gene Therapy hosted by BTEC (8/8/2022 to 8/11/2022)

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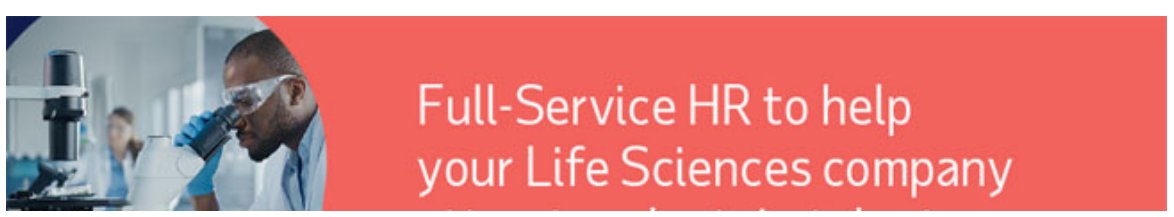

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Developing innovative, breakthrough products is the mission and focus of your life sciences organization. Great products are created by great employees, and if you're struggling to attract and keep top performers, your company may not reach its potential.

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