



June 2023 Update

Serving the NC Life Sciences Industry

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NCBIO This Month

- General Assembly budget negotiations begin
- Congress rips into pharmacy benefit managers
- ARPA-H seeks partnerships, launches first program
- Medical Device Forum panel explores challenges
- Multiple NCBIO members receive TBJ Life Sciences Awards

NCBIO Sustaining Members



NCBIO Board adopts Strategic Plan

On May 16, the NCBIO Board of Directors adopted a new strategic plan for the organization by unanimous vote.

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The plan was developed by the Board's Strategic Planning Committee working with the guidance of Thinc Strategy and NCBIO staff beginning in the summer of 2022.

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Among the key findings of the planning process are that the organization

- has a diverse membership in terms of the size, type and in-state presence;
- has a strong reputation for advocating for the industry;
- is known primarily for state-level advocacy work;
- is less known for its extensive workforce-development efforts;
- is seen as a force bringing industry together in the state; and
- offers good value for the benefits delivered.

The approved plan identified four key focus areas for NCBIO:

- Advocacy leadership
- Workforce development
- Industry connections
- Member services

We'll bring you more on the Strategic Plan, our updated mission and expanded focus in the coming months with a full rollout expected by the time of the Annual Meeting in October.

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NCBIO Supporting Members





STATE UPDATES

Legislature enters home stretch as chambers negotiate budget

The General Assembly has entered into what is potentially the home stretch of its legislative session.

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The Senate passed and released their version of the budget the week of May 17, and the House voted unanimously to reject the version of its budget bill that was returned from the Senate.

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Some of the top items that will be discussed in the conference committee include tax cuts, teacher raises, and salary changes. In both the House and Senate's version of the budget, the personal income tax rate is reduced to 4.5% in 2024 and 3.99% by 2026. The Senate wants the rate to reach as low as 2.49% after 2029. In other differences, the Senate proposed an average teacher raise of 4.5%, while the House proposed a 10.2% raise.

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The Senate budget provides almost \$70 million to expand community college courses in high-demand career fields, including nursing and other health-related programs and \$10 million in reserves to help local governments develop new mega sites and prepare them for business.

The Senate budget also proposed additional deregulation of medical services through certificates of need. This provision caught the House by surprise, given the extensive negotiation over CON laws in the recently passed Medicaid expansion compromise and is sure to be a bone of contention between the chambers during the conference committee.

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One of the Senate's most expensive new items is the allocation of \$1.425 billion to NC Innovation. NC Innovation is a newly formed nonprofit that, among other things, purports to advance and commercialize applied research at our state's research universities. The House allocated only \$50 million to NC Innovation in their proposal.

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This is what typically happens in the process of creating a state budget, and top budget writers in both chambers are forming a conference committee to negotiate the differences between the two versions of the spending plan, which will likely take a minimum of three weeks.

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Legislative leaders say they hope a final budget proposal will be presented and passed by the end of the fiscal year, June 30. During this time, committees will continue to meet and bills will continue to be considered by both chambers.

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NCBIO is following a number of budget items, including funding for the One NC Small Business Fund, which received an additional recurring \$2 million in the House budget, and the N.C. Biotechnology Center, which received an increase in the House budget but nothing in the Senate's. The budget also contains \$600 million per year in wastewater grants for municipalities to upgrade public water systems.

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While budget appropriators complete their work, we are also following several dozen bills of interest through the legislative process.

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Among the bills under consideration we are following are House Bill 246, which clarifies that manufacturer financial assistance for patients is included in his or her deductible calculation, even for individuals with high-deductible plans. Other legislation we are tracking includes consumer privacy, increased wastewater capacity, medical equipment right-to-repair proposals and breast-cancer-screening coverage.Â



NATIONAL UPDATES

If there are any topics or issues that are affecting your business or you want to know more about, please contact [Laura Gunter](#).

Debt ceiling deal spares COVID research, treatments; leaves IRA drug negotiations unchanged

The debt ceiling deal struck by President Joe Biden and House Speaker Kevin McCarthy retains the \$5 billion in the federal budget for research into improved COVID-19 treatments.

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The House passed the deal (H.R. 3746) on May 31 314-117. Thirteen of fourteen North CarolinaÂ representatives voted for the bill with Rep. Dan Bishop being the dissenting vote and Rep. Deborah Ross missing the vote due to illness.

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The debt limit package, if signed into law, would claw back about \$30 billion in federal funding appropriated during the pandemic. However, reports say more than \$800 million to monitor and strengthen pharmaceutical supply chains and roughly \$2 billion for CDC activities such as genomic surveillance of the virus are excluded from the claw backs.

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The debt limit package doesn't touch the Inflation Reduction Act's drug price negotiation provisions despite the Biden administration's push to expand them in its fiscal 2024 budget proposal.

CMS says it will cover Alzheimer's drugs receiving traditional FDA approval

The Centers for Medicare and Medicaid Services announced on May 31 that it was committed to covering a new class of drugs for Alzheimer's disease once the drugs receive traditional FDA approval.

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CMS decided in 2022 to not fully cover new Alzheimer's drugs that had been approved via the FDA's accelerated-approval pathway. The FDA granted accelerated approval for two drugs that slow the progression of Alzheimer's by targeting certain plaques in the brain: Biogen's Aduhelm and Eisai's Leqembi. CMS said in a release that traditional approval for Leqembi could come within weeks.

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"If the FDA grants traditional approval, CMS is prepared to ensure anyone with Medicare Part B who meets the criteria is covered," CMS Administrator Chiquita Brooks-LaSureBrooks-LaSure said in a statement.

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Once those drugs get traditional approval, Medicare will cover them but only if the prescribing physician and team participate in a registry that collects evidence on the drug's outcomes for new areas of research.

E&C Health Subcommittee advances bills to bring transparency to PBMs and 340B

The House Energy & Commerce Health Subcommittee forwarded 17 bipartisan bills to the full committee on May 17. The approved legislation included a package to increase transparency on pricing, strengthen critical public health programs and secure access to care for low-income Americans.Â

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The subcommittee also discussed a comprehensive package to reauthorize and expand public health programs and increase transparency for hospitals, health plans and pharmacy benefit managers. In addition, the subcommittee advanced legislation to ensure Medicaid enrollees have access to breakthrough gene therapies and to reauthorize Animal Drug User Fee Amendments.

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The PBM Accountability Act targets business practices of PBMs that drive up prices for patients. It passed the subcommittee 27-0. The subcommittee also approved H.R. 1613, the Drug Price Transparency in Medicaid Act of 2023. H.R. 1613 is an amendment to Title XIX of the Social Security Act to improve transparency and prevent the use of spread pricing and related practices in the Medicaid program.

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The subcommittee also approved H.R. 3290, an amendment to Title III of the Public Health Service Act designed to ensure transparency and oversight of the 340B drug discount program.

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These bills now go to the full House Energy & Commerce Committee. If passed by the committee, they move to the full House for a vote.

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Comments about PBM abuses included the following:

- Rep. Stephanie Murphy (D-FL) said the Inflation Reduction Act price controls go too far and PBMs are the real problem. She said about 50 drugs have been pulled from

- development thanks to overreach by the IRA.
- Ranking Member Anna Eshoo (D-CA) said PBM abuses are “hurting people across the country. There isn’t any merit to this. ?. Not any value added,”
 - Witness Benjamin N. Rome, M.D., of Harvard Medical School said PBMs need to be regulated. Patients should not have to shop around for medicine; prices need to be reasonable from the start.
 - Witness Frederick Isasi, executive director of Families USA, said that large employers are not getting information from PBMs about money flow or the insurer’s rebates. Transparency is needed so the client (large employer) knows where the money flows, he said. PBMs should not be able to negotiate one price and then use a different price (the list price) for cost-sharing agreements with consumers, he said

[More at BIO](#)

Appeals court maintains Obamacare coverage of HIV preventive medicines while case proceeds

A federal appeals panel on May 15 maintained Obamacare's rules for free preventive care while legal challenges move forward.Â

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The panel at the 5th U.S. Circuit Court of Appeals issued an administrative stay of a lower Texas court's March decision that tossed out requirements that insurance companies cover the HIV prevention drugs and a range of preventive services nationwide at no cost to patients.

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The Justice Department and the conservative employers challenging the law appealed the case to the 5th Circuit which is expected to hear arguments on the case in the coming months.

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Many major insurers have already pledged to maintain preventive care at no cost to patients for the time being no matter what courts decide, but experts fear that patients could eventually be hit with out-of-pocket charges as the 5th Circuit and Supreme Court have ruled several times to eliminate pieces of the Affordable Care Act.

ARPA-H opens request for information on FDA collaboration and public-private partnerships

ARPA-H is seeking unique and creative ideas on how to best collaborate with the Food and Drug Administration to encourage and incentivize public-private partnerships in the health ecosystem, to accelerate better health outcomes for everyone.

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This Request for Information seeks novel insights, ideas, incentives, approaches, and models at the development stage and during pre-submission, submission, and post-submission interactions to help promote and accelerate innovation to yield better health outcomes while prioritizing patient safety.

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This effort aims to identify and understand innovative strategies that are possible under the current regulatory and statutory paradigm. The purpose is NOT to propose any changes to FDA regulatory authority or statutes. Respondents shall propose specific practices that the U.S. government might adopt to speed approvals and support emerging health innovations.

[More at ARPA-H](#)

ARPA-H announces first program launch

ARPA-H has launched its first program, Novel Innovations for Tissue Regeneration in Osteoarthritis, or NITRO.

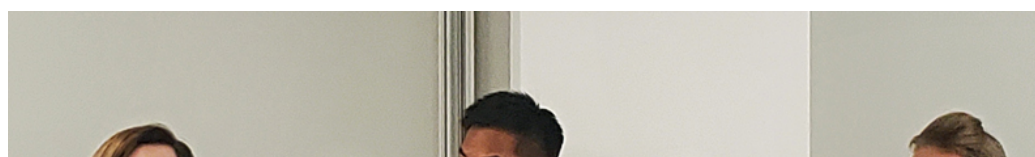
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NITRO will explore technologies focused on injectable bone regeneration, injectable cartilage regeneration and replacement joints built from human cells. These minimally invasive technologies could reverse the damage caused by osteoarthritis, which is the third leading cause of disability in the U.S. and for which existing treatments are largely heavily invasive (i.e. surgery).

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ARPA-H will issue a Broad Agency Announcement to solicit proposals for this program. Abstracts will be due on June 23, and full proposals will be due on July 28. A Proposer's Day is scheduled for June 15.

[More at NCPIO](#)





Laura Gunter (left) at the Larger Than Life Science, Onward NC: State of the NC Biotech Community LaunchBio event on May 14.

NCBIO Updates

Medical Device Forum panel discusses regulatory, supply chain challenges



“Navigating Regulatory and Supply Chain Challenges Today and Tomorrow” was the topic of the May 16 NCBIO Medical Device Luncheon and Forum held at the N.C Biotechnology Center.

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The discussion was moderated by Eric Hill, senior director, scientific and technical services for Boston Analytical, and included panelists

- **Stefanie Johns**, Ph.D., director, regulatory affairs, Kymanox;
- **Sean McCarthy**, senior director, clinical and regulatory affairs, YourBio Health;
- **Edgard Ngaboyamahina**, Ph.D., sustainability subject matter expert, RTI Innovation Advisors; and
- **Adam Zerda**, Ph.D., senior director, international affairs, Becton, Dickinson and Company.

The event was sponsored by [Clancy & Theys Construction Company](#), [Hughes Pittman & Gupton](#), [Mercury Business Services](#), [UniClean Cleanroom Services](#) and [YourBio Health](#). To start off, the panelists gave an overview of what was currently happening and most relevant to them in their working environment.

[More at NCBIO](#)

Clancy & Theys Construction Company



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Uniclean Cleanroom Services

YourBio Health





DEI forum discusses ups, downs of DEI journey

NCBIO hosted a virtual forum on The Ups and Downs of the DEI Journey on May 31, 2023. Participants heard from

- Ashley Jefferson, director, early career and talent outreach, Beam Therapeutics (moderator)
- Pan Patel, head of diversity and inclusion for clinical trials, IQVIA
- Anu Rania, director, business partner, TechOps IT, Purdue Pharma
- Susie Silver, senior consultant, LGBTQ+SME, facilitator and impact leader, The Diversity Movement

Panelists discussed diversity, equity and inclusion training; DEI in clinical trials; the business benefits of DEI and more. Forum attendees broke out into discussion groups that were not recorded. You can watch the forum recording and our other DEI programming on the [NCBIO YouTube channel](#).

NCBIO Member News

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

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Eisai Co., Ltd. and **Biogen Inc.** announced that Eisai has submitted a Marketing Authorization Application for lecanemab for the treatment of early Alzheimer's disease to the UK Medicines and Healthcare products Regulatory Agency in Great Britain. [More >>](#)

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Eisai Co., Ltd. and **Biogen Inc.** announced that Health Canada has accepted a New Drug Submission for lecanemab for the treatment of early Alzheimer's disease (mild cognitive impairment due to Alzheimer's disease and mild AD dementia) with confirmed amyloid pathology in the brain. [More >>](#)

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G1 Therapeutics, Inc. has appointed Monica Thomas as its general counsel and chief compliance officer. Thomas replaces Stillman Hanson who departed the company in May. [More >>](#)

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IngateyGen, LLC, a company is working to use gene-editing technology to produce low allergy peanut varieties, has moved from Elizabeth City to the First Flight Venture Center in RTP. [More >>](#)

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Pairwise launched its inaugural product, Conscious Greens, the first food introduced in the U.S. that was developed with CRISPR technology. Conscious Greens Purple Power Baby Greens Blend is a mix of colorful superfood leafy greens with a unique, fresh flavor and up to double the nutrition of romaine lettuce. [More >>](#)

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Pfizer and **Thermo Fisher Scientific Inc.** have entered into a collaboration agreement to help increase local access to next-generation-sequencing-based testing for lung and breast cancer patients in more than 30 countries across Latin America, Africa, the Middle East and Asia where advanced genomic testing has previously been limited or unavailable. [More >>](#)

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Smith Anderson has achieved Mansfield Certified Plus status for its actions to diversify leadership, recruit, hire and retain attorneys from underrepresented groups in the legal profession and for ensuring diverse lawyers are considered for new business efforts. [More >>](#)

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The following NCBIO members received 2023 Life Sciences Awards from the Triangle Business Journal

- **CSL Seairus**. [Company of the Year \(Public\)](#)

- **Baebies**, [Company of the Year \(Private\)](#)
- **Oerth Bio**, [Best Ag Bio](#)
- Susan Acker-Walsh, **Creo Inc.**, [Best Consultant \(Individual\)](#)

Events



Katie Couric, Robert Califf, M.D. will take stage at BIO23

Katie Couric, award-winning journalist, New York Times best-selling author, and longtime cancer advocate takes the Main Stage on Tuesday, June 6, where she will be interviewed by Rachel King, BIO CEO. Their discussion centers on Couric's tireless pursuit to stand up for science and patients.

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FDA Commissioner Robert Califf, M.D., will be the keynote speaker on Day 3 of the 2023 BIO International Convention in Boston. Califf will join BIO CEO Rachel King in a wide-ranging interview on Wednesday, June 7, at the BIO International Convention in Boston.

REGISTER NOW

Azzur's Science of Socializing coming back to RTP June 27

Azzur Group is hosting a Science of Socializing event at the Raleigh Beer Garden on Tuesday, June 27, to celebrate the grand opening of their newest facility - Azzur Cleanrooms on Demand Raleigh. Grab a drink and something to eat, catch up with colleagues, and mingle with other industry professionals.

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Food and beverages are on Azzur, and they hope to see you there!

LEARN MORE



Online workshop: How to craft a competitive SBIR/STTR proposal June 20, 22

Are you seeking funding to launch an innovative medtech product? National Institutes of Health provides nondilutive federal funding through the SBIR/STTR programs. The NIH SBIR/STTR programs award more than \$1.21 billion in R&D funding annually to qualified small businesses developing game-changing technologies ? a valuable source of funding for medtech companies to demonstrate proof-of-concept and advance product development.Â

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Join AdvaMed and BBCetc on June 20 and 22 for an expert-led workshop that walks you through how to craft a competitive SBIR/STTR proposal that meets the unique requirements of the NIH. This workshop is ideal for companies targeting the September 5 submission

deadline.

LEARN MORE

NCBIO Lab Space Luncheon and Forum July 13

The panel will look at the market dynamics, provide an overview of what space looks like (shell space, build to suit or turnkey), who is driving it and what does it mean for a company.

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We will talk about the evolution of RTP and what the next iteration may look like.

- Carolyn Coia, vice president, real estate, Research Triangle Foundation
- Chase Kerley, managing director, Crescent Communities
- Alvaro Quintana, associate principal and designer, Flad Architects
- Representatives with Jones Lang LaSalle and McDonald York Building Company

Thank you to our sponsors, Clancy & Theys Construction Company, CSC Leasing, Facility Logix, Medical Moving Solutions and PSC Biotech.

REGISTER NOW



Innovations in Ag: A Regional Perspective July 19, Danville Va.

NCBIO is excited to announce that we are partnering with Virginia Bio and the Institute for Advanced Learning and Research for an ag biotech event on July 19 in Virginia. This program will look at innovations in ag from a regional perspective. We hope you will join NCBIO members and others in Virginia for this event.

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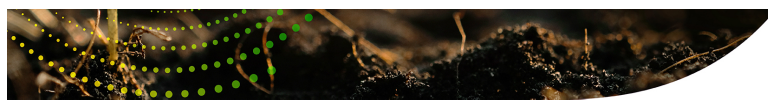
Topics to be covered include

- regulatory environment,
- financing,
- controlled environment agriculture,
- bio controls and
- bio stimulants.

If you are interested in sponsoring the joint event, please contact NCBIO Events Director [Amber Niebauer](#) for more information.

REGISTER NOW





September 19-20
Raleigh, NC

Register forÂ BIO Raleigh ag, environment event

The [BIO Impact Ag & Environment Conference](#) will be held, Sept. 19-20, in Raleigh This premier event brings together biotech innovators, investors, and policy makers focused on strengthening the bioeconomy to meet societal challenges.

REGISTER NOW



NCBIO Annual Meeting Oct. 4

Save the date for this year's Annual Meeting on Oct. 4. Registration will open on June 21. Members who register before July 20 will receive a 20% discount off the \$50 registration fee (implemented due to rising costs).

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The program features a keynote presentation by Emily Chee, U.S. general manager, Novartis Gene Therapies, and three panel sessions.Â

- **Federal Update** featuring ACRO, AdvaMed, BIO, IQVIA and PhRMA
- **Navigating Regulatory Hurdles in Pharma and Food** with Azzur Group, Duke University School of Medicine, Novozymes, Pairwise and Syneos Health
- **The Customer's Journey** moderated by Care4Carolina and features patients impacted by spinal muscular atrophy, sickle cell, cardiovascular disease and diabetes

See the complete list of speakers [here](#). You will have a number of opportunities to connect with attendees during the day. We hope you will join us on Oct. 4. Save the date now and more information will be sent in the coming weeks.

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Thank you to our 2023 Annual Meeting sponsors.





NCBio calendar

- Boil, Brews and Band hosted by First Flight Venture Center (6/1/2023)
- BIO 2023 International Convention (6/5/2023 to 6/8/2023)
- North Carolina Reception at BIO hosted by NCBiotech (6/6/2023)
- Export Coffee Talk, Doing Business in the Middle East: Business Culture Tips for the United Arab Emirates and Saudi Arabia hosted by EDPNC (6/8/2023)
- Analytical Methods for Gene Therapy Vector Characterization and Testing hosted by BTEC (6/13/2023 to 6/15/2023)
- Population Health Summer Institute hosted by Duke University (6/15/2023 to 6/30/2023)
- NIH SBIR/STTR Proposal Workshop (Part 1 and 2) hosted by AdvaMed (6/20/2023)
- NIH SBIR/STTR Proposal Workshop (Part 3 and 4) hosted by AdvaMed (6/22/2023)
- Application Tips & Resources to Help Secure SBIR & STTR Funding hosted by NCATS (6/26/2023)
- Hands-On Essentials of Automation for Biomanufacturing hosted by BTEC (6/27/2023 to 6/28/2023)
- Downstream Biopharmaceutical Processes: Fundamentals and Design hosted by BTEC (6/27/2023 to 6/29/2023)
- The Science of Socializing hosted by Azzur Group (6/27/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (6/28/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (7/5/2023)
- Microbial Contamination Control in Bioprocessing Operations hosted by BTEC (7/10/2023 to 7/12/2023)
- Hands-On cGMP Biomanufacturing Operations hosted by BTEC (7/11/2023 to 7/14/2023)
- Deep Tech Innovation Workshop hosted by Hangar6 (7/12/2023)
- NCBio Lab Space Luncheon and Forum (7/13/2023)



Marsh McLennan offers workplace trends report

While predicting and responding to employee benefits trends and employee expectations can be difficult, Marsh McLennan Agency can help its new 2023 report, Benefits Trends: The Evolving Workplace.

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Tomorrow's workforce is looking for more than a benefits plan. Employees are placing a higher premium on finding their purpose at work and challenging their employers to empathize with their disengagement and burnout. Employers can work to address these struggles with well-being benefits while also tackling the rising health benefits costs.

GET THE REPORT

BIO Business Solutions





Take every opportunity to save

Why BIO's Cost Savings program? It's a unique opportunity to save on the services your life science company already uses. You're also in good company with thousands of life science businesses already on board.

LEARN MORE




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