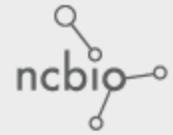




connections newsletter



**August 2018
UPDATE**

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NCBIO This Month

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NCBIO - Media

Find the latest news from NCBIO on the website ncbioscience.net, on [LinkedIn](#) and on Twitter at @ncbio.

NCBIO Links

[CED](#)

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[NC Biotech Center](#)

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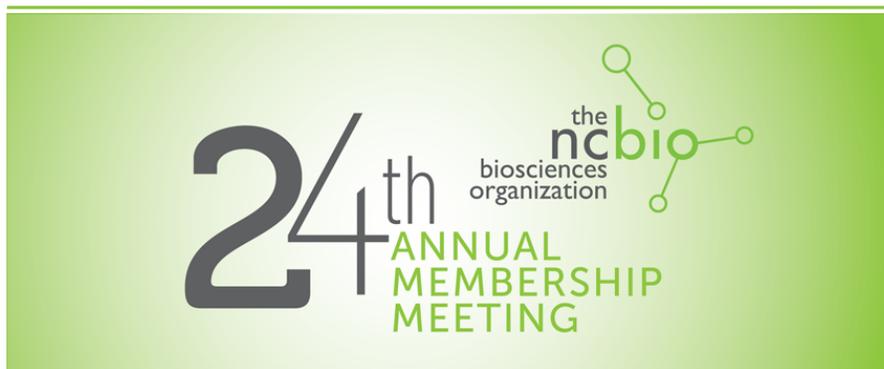
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Big Data and Precision Medicine – Topics for NCBIO’s Annual Membership Meeting, October 4



OCTOBER 4, 2018

NCBIO Sustaining Members

Biogen



Lilly

Precision Innovation will highlight this year's NCBio Annual Meeting – featuring three keynote speakers and two panels focusing on the new wave in life sciences. Join more than 200 NCBio members and leaders for our Annual Meeting on October 4. To register for the event, please visit the [event page](#) or contact [Amber Niebauer](#). The program kicks off at 8:00 a.m. and ends with a networking lunch from 1:00 to 2:00 p.m. Keynote speakers include:

- **Richard Staub**, President, R&D Solutions, Global Business Unit, [IQVIA](#) (formerly QuintilesIMS), will provide a *State of the Industry*.
- **Paul Ruddick**, Gene Therapy Commercial Development Lead, Hemophilia, Pfizer Rare Disease, [Pfizer](#), will speak with members on the *Future of the BioPharma Industry*. Paul will give attention to gene and cell therapies.
- **Anna Abram**, Deputy Commissioner for Policy, Planning, Legislation and Analysis, [U.S. Food & Drug Administration](#), will provide updates from FDA on *Policies and Perspectives*. Many NCBio members know Ms. Abram for her previous work as a Senior Health Policy Advisor to Senator Richard Burr.

The program also includes two interactive panel discussions.

- **Ashok Krishnamurthy**, Deputy Director, RENCi; Director, Biomedical Informatics Team, NCTraCS, will moderate the discussion on *How Big Data is Empowering Innovation*. Panelists for this session include representatives with Duke Clinical Research Institute, Foundation Medicine and Novozymes.
- **Sara Imhof**, Senior Director, Precision Health, NCBIotech, will moderate the panel *Precision-based Innovation* featuring representatives with Baebies, the Duke Center for Applied Genomics & Precision Medicine, Locus Biosciences, and the University of North Carolina's Nutrition Research Institute.

To register, visit the [event page](#) or contact [Amber Niebauer](#). If you are interested in sponsoring the event, contact [Laura Gunter](#). Thank you to all our sponsors:

- Platinum: [BIO](#), [Bioventus](#), [Cook Medical](#), and [VWR](#)
- Gold: [BDO](#), [Duke Energy](#), [FUJIFILM Diosynth Biotechnologies](#), [Merz](#), and [Novo Nordisk](#)
- Silver: [ALT](#), [Office Depot](#), [The Conafay Group](#), and [UCB](#)
- Bronze: [Business Wire](#), [G1 Therapeutics](#), [Grifols](#), [Nikon](#), [Novozymes](#), and [Royal Hill Consulting](#)

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US House Votes to Repeal Medical Device Tax

The US House has voted 238 to 132 to repeal the medical device tax ([H.R. 184, the Protect Medical Innovation Act of 2017](#)). Nine of the 13 North Carolina Congressional delegation voted in favor of repeal. The vote was largely along party lines, with Democrats opposing the measure. Republicans, except for Congressman Walter Jones, voted in favor of repeal. The tax imposes a 2.3 percent levy on revenues from the sale of medical devices. Even companies that are not profitable must pay the tax. The measure now goes to the Senate.

NCBio President Sam Taylor stated, "This measure is important to the medical device companies in North Carolina. The overwhelming, bipartisan support for full repeal of the medical device tax sends a strong message that lawmakers recognize this tax is not good health nor good fiscal policy. We know a significant majority of the Senate feels the same way, and we look forward working closely with Senator Richard Burr and Senator Thom Tillis to quickly take up this measure and ensure the medical technology industry continues to bring innovation to patient care across the country and around the world."

AdvaMed President and CEO Scott Whitaker stated, "The vote is a win for American innovation, American jobs, and most of all for American patients, who benefit from the



Novartis



Pfizer



We Work For Health



NCBio Supporting Members

Cook Medical



GSK



Merck



life-changing innovations our industry produces every day. We commend Rep. Erik Paulsen (R-Minn.) and a number of leaders from both sides of the aisle for their commitment to permanently repealing this onerous tax and for working to ensure our member companies have the long-term certainty they need to invest in R&D, hiring and other capital improvements to create the next-generation of treatments and cures.”

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Plan Ahead if Looking for New Lab Space



[Doug Edgeton, Andy Schwab, Neill Sherron, Justin Parker and Matthew Cooke](#)

Lab space is in demand and rents are going up according to panelists at the July NC BIO Luncheon and Forum on Lab Space in North Carolina. Matthew Cooke of Davis Moore told the audience, “The more time you have the better because there are often multiple groups competing for the same space.” He also noted that rents are going up in the RTP area even without decisions from Apple and Amazon on locating in the area.

Andy Schwab of First Flight Venture Center said, “There is a gap in the market, with a need for smaller space in the 1000-3000 sq. ft. range and with leases for less than five years for emerging companies.” Justin Parker with Wexford Science and Technology noted that BioLabs NC is helping fill part of that gap. He also discussed the important role of universities in North Carolina and their efforts in creating early stage companies.

Neill Sherron with Longfellow Real Estate Partners said, “Space in the Research Triangle is 2/3 of the cost in the Boston Cambridge area.” He also noted that the RTP market has a very low vacancy rate. Doug Edgeton, CEO of the North Carolina Biotechnology Center, moderated that panel and thanked developers for the investments they have made in North Carolina.

Thanks to our sponsors for this event; [Davis Moore](#), [Longfellow Real Estate Partners](#) and [Wexford Science and Technology](#).

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SBIR Road Tour in North Carolina

Proposal preparation, one-on-one meetings with federal program SBIR managers, and funding overviews were just a few of the topics discussed during the SBIR Road Tour in North Carolina during a two-day event June 21-22.

The event was hosted by First Flight Venture Center in partnership with the NC Biotechnology Center (NCBiotech), the Small Business Technology Development Center (SBTDC), LaunchBio, NC IDEA, the Council for Entrepreneurial Development and

NCBIO. Representatives of federal agencies with SBIR/STTR funding gave overviews of agency grant requirements during a session at the NC Biotechnology Center on June 22.

NCBIO was a sponsor of the luncheon. President Sam Taylor told participants about the reinstatement of state funding for SBIR matching grants in the 2017-18 State Budget. He noted that Rep. Nelson Dollar (R-Wake) was instrumental in helping secure the funding. He added, "We are pleased that companies in North Carolina had the opportunity to meet with SBIR funders and find out more about the process and ways to secure funding."

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New Senior Vice President at NC Biotechnology Center



The North Carolina Biotechnology Center has named Mary Beth Thomas, Ph.D., to the position of senior vice president, science and business development. Thomas has been serving as vice president of the Center's Emerging Sector Development program, leading focused initiatives in expanding North Carolina's life science commercialization opportunities in biodefense/biosecurity and precision health.

Thomas succeeds Ken Tindall, Ph.D., in the senior vice president role, following Tindall's retirement after 18 years at the Center. NCBIO thanks Tindall for his years of service to the life science industry in the state. [More](#)

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Three NC Companies to Present at MedTech Conference



Three North Carolina companies joined the prestigious list of participants in the 2018 [MedTech Innovator](#) Accelerator and Showcase programs. The Los Angeles-based non-profit is a global competition and accelerator for medical device, digital health and diagnostic companies. [RFPI](#) and [Physcient](#) are participating in MedTech's four-

month Showcase program for mid-stage companies. [Pneumonics](#) is competing in the Accelerator program. [More](#)

The program will culminate September 24-26 in Philadelphia, where all 50 companies will present in Showcase panels and exclusive partnering at the [MedTech Conference](#), powered by [AdvaMed](#). NCBIO members can save on registration for the event. Contact [Brenda Summers](#) to get your 10% discount registration code.

Along with industry leaders, the international conference attracts business development professionals, investors, policy-makers, members of the media, legal experts, consultants, distributors, and other important stakeholders. The conference also features world-class plenary speakers, networking, and business development opportunities. [Click to learn more.](#)

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Precision Medicine World Conference at Duke

[PMWC 2018 Duke](#) at the Washington Duke Inn September 24-25 will focus on success factors of varied technologies in precision medicine, how these innovations have and will continue to impact medicine, the challenges we still need to overcome to bring them to the clinic, the evidence necessary to encourage wider adoption by health care providers, elements needed to satisfy payors and regulators, and last but not least, why engagement with the community is critical for ultimate success and the approach we should take to achieve it.

NCBIO members can get a discount. Contact [Amber Niebauer](#) to get the code. PMWC 2018 Duke includes the following sessions and panel discussions:

- **Efforts to Accelerate Precision Medicine** with Lauren Silvis (Chief of Staff, FDA) and Patrick Conway (BCBSNC)
- The recent insights from the **All of Us Research Program** with Stephanie Devaney (NIH)
- Recent Advancements and new applications in **AI and Machine Learning** with Larry Carin (Duke), Guido Lanza (Numerate) and Michael Pencina (Duke)
- Why we can't ignore the **Microbiome** anymore with Jeff Gordon (Washington University), Lawrence David (Duke) and Rita Colwell (Johns Hopkins)
- New **Emerging Technologies in Precision Medicine** and their clinical impact with Mickey Kertesz (Karius Dx), Bob Langer (MIT) and Dawn Barry (Luna DNA)
- Where we stand with understanding **Resilience** with Stephen Friend (Sage Bionetworks) and Cathleen Colon-Emeric (Duke)
- Why we need **Diversity in Precision Medicine** with Hannah Valentine (NIH)
- A panel discussion around the **Investment Perspective in Precision Medicine** with Mike Pellini (Section 32) and Art Pappas (Pappas Capital)

[Click](#) to get a complete list of speakers and sessions.

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SEBIO – Atlanta in November

Mark your calendar for [SEBIO](#), the life sciences and medical technology conference connecting emerging companies with potential investors and corporate partners. Celebrating its 20th anniversary, the Southeast BIO Investor & Partnering Forum returns to Atlanta on November 13-14 with a new format, new networking opportunities, and new investment prospects. [More](#)

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NCBIO Board Approves New Members for the Organization



Previously Admitted Members and New Members:

Tim LaCroix (Aranz Medical), Julie Hampton (BDO), Brian Axe (NovaQuest Capital Management), Matthew Wasik (Sterile Lab Services), Gary Muddyman (Conversis), Mike Mann and Ryan Rapp (Pairwise Plants)

The NCBIO Board of Directors welcomed ten new members at the July Board meeting. They are:

- [**BDO USA, LLP**](#) is a full-service accounting and consulting firm, that delivers assurance, tax, and financial advisory services to clients throughout the country and around the globe.
- [**Conversis**](#) is a leading ISO certified supplier of translation and localization services, specialized in energy, technology, retail, marketing and medical.
- [**DPR Construction**](#) is a national technical builder that specializes in highly complex and sustainable projects.
- [**Flad Architects**](#) is specializing in the planning and design of innovative facilities for healthcare, higher education, and science and technology clients. Serving clients globally, Flad is a recognized leader in resolving the complex needs of knowledge-based organizations.
- [**NIIMBL**](#) is a public-private consortium dedicated to advancing biopharmaceuticals manufacturing innovation.
- [**NovaQuest Capital Management**](#) is an investment platform to provide strategic capital to life sciences and healthcare companies.
- [**Pairwise Plants**](#) is an agricultural company focused on using gene editing and leveraging natural diversity in agricultural crops in a new way to address global food challenges.
- [**Redbud Labs, Inc**](#) is a microfluidic chip manufacturer; pioneering a new category of consumable components with MXR, the world's first fully modular microfluidic mixer.
- [**R&S Chemicals, Inc.**](#) is a research, development, and manufacturing company (CRO) that specializes in contract projects in Chemical & Pharmaceutical Industries and in Academic Institutions. Offering Custom Synthesis in Organic Synthesis, Process Chemistry, Medicinal Chemistry & Drug Discovery and Chemical Research.
- [**Sterile Lab Services, LLC**](#) offers decontamination services for eradicating spores, pathogens, and bacteria.

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At the National Level

We Work for Health Fly-In



[We Work for Health Delegation from NC with Congressman David Rouzer.](#)

NCBIO and other organizations participated in the two-day We Work for Health Fly-In. Laura Gunter represented NCBIO in visits with members of the North Carolina Congressional delegation, including both Senator Burr and Tillis' offices. Medicare Part B

and D, importation of drugs, Medicare affordability and access, and the economic impact of the industry were just a few of the issues participants discussed with the delegation.

Jobs Act Passes U.S. House

The Biotechnology Innovation Organization ([BIO](#)) applauded the passage by the House of Representatives of the JOBS and Investor Confidence Act of 2018 (S. 488), or JOBS Act 3.0, in a widely bipartisan vote of 406-4. This legislation, which includes the Fostering Innovation Act (H.R. 1645), would significantly improve the ability of emerging biotech companies to invest their capital in the drug discovery process. [More](#)

PhRMA and BIO Submit Comments on HHS Plan on Drug Prices

[PhRMA](#) submitted comprehensive comments to the Department of Health and Human Services (HHS) request for information (RFI), *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*. While some of the changes in the RFI could make improvements to the system, others would be a step backward for patients. [More](#)

[BIO](#) also presented a statement to HHS. "First and foremost, this is an extraordinary time for biotechnology. The therapies in development and coming to the market are unlike any we have seen in the history of medicine....BIO and our members recognize that too many patients – even those with insurance – cannot afford the life-saving cures and treatments that biopharmaceutical companies are developing. We stand with the Trump Administration in our shared commitment to addressing this serious problem. To accomplish this, we must harness – not abandon – the free market that has delivered amazing innovations for patients and made America first in the world in biomedical innovation." [More](#)

FDA Commissioner on Biosimilars Action Plan, Advanced Manufacturing

In a statement released in July regarding a plan for biosimilars, FDA Commissioner Scott Gottlieb stated, "Our ability to build a market for safe, effective biosimilar products is key for patients and our nation's health care system. It's a key to promoting access and reducing health care costs. And it's a key to advancing public health. But I'm worried that the market for these products still isn't established. The ability for these products to penetrate clinical practice, and gain acceptance, is still not firm." [More](#)

In a recent blog, FDA Commissioner Scott Gottlieb said, "There's new technology that can improve drug quality, address shortages of medicines, lower drug costs, and bring pharmaceutical manufacturing back to the United States. At the FDA, we're focused on propelling these innovations, collectively referred to as advanced manufacturing." [More](#)

For other recent FDA information, [click](#).

Early Bird Rate for BIO Investor Forum – October 17-18

NCBIO members sign up for the Early Bird Rate by August 15th for the [BIO Investor Forum](#), October 17-18 in San Francisco. As a member of NCBIO, you get an added discount on registration for the BIO Investor Forum. **Registration is not required at this point.** Simply complete the [form](#), and you will be sent your discount code prior to registration opening in early-August.

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Member News

To be included in Member News, send information about your organization to Brenda Summers bsummers@ncbioscience.net

[AbbVie](#) and Calibr, a nonprofit drug discovery division of Scripps Research, announced a collaboration to develop T-cell therapies aimed primarily at cancer, including solid tumors. This collaboration broadens AbbVie's oncology research to access advanced precision medicine technology to expand the development of potentially life-changing treatments for patients with cancer. [More](#)

[Acurian Inc.](#) and Synexus have launched SynexusPlus, an integrated site solution for enrolling patients in clinical studies. Synexus and Acurian are part of Accelerated Enrollment Solutions (AES), a business unit of [PPD](#).

[AgBiome LLC](#) has secured \$65 million in Series C financing that will help the company bring novel crop protection products and solutions to the market. The investment group includes: The University of Texas Investment Management Company (UTIMCO), Fidelity Management and Research Company, Polaris Partners, ARCH Venture Partners, Innotech Advisers, Pontifax Global Food and Agriculture Technology Fund, and Monsanto Growth Ventures. "This is a watershed moment for AgBiome, and for agriculture. The support from UTIMCO, Fidelity, Polaris, Arch and other investors allows us to realize our vision to be the leading innovator in agriculture" says Scott Uknes, Co-CEO and Board member of AgBiome. [More](#)

[Baebies](#) recently celebrated a major milestone in newborn screening: **3 MILLION tests shipped**. This translates to 3 million chances at a healthy start. Find out more with Baebies' FDA authorized high throughput newborn screening platform [SEEKER](#) and [FINDER](#), a near patient pediatric diagnostic analyzer currently under development.

[BioCryst Pharmaceuticals](#) provided an update on the company's strategic and financial outlook as a standalone company following the recent termination of its merger agreement with Idera Pharmaceuticals, Inc. Jon P. Stonehouse, President and Chief Executive Officer of BioCryst, said, "We are moving forward executing our standalone strategy with a great deal of confidence in our programs, our pipeline and our ability to drive value for our stockholders. We have been, and will continue to be, focused on advancing our early- and late-stage programs toward commercial launch and getting new and valuable medicines into the hands of physicians as they treat serious conditions." [More](#)

[Eisai](#) and [Biogen](#) announced positive, topline results of the final analysis for BAN2401, an anti-amyloid beta protofibril antibody, in 856 patients with early Alzheimer's disease. The study achieved statistical significance on key predefined endpoints evaluating efficacy at 18 months on slowing progression in Alzheimer's Disease Composite Score (ADCOMS) and on reduction of amyloid accumulated in the brain as measured using amyloid-PET (positron emission tomography). [More](#)

[G1 Therapeutics, Inc.](#) announced appointments for two newly created executive leadership roles to support the company's continued growth. John Demaree joins the company as Chief Commercial Officer and Stillman Hanson has been named General Counsel. "We are excited to welcome John and Stillman to G1 and look forward to their contributions as we build out our commercial capabilities and expand our business development, legal and regulatory efforts," said Mark Velleca, M.D., Ph.D., Chief Executive Officer. [More](#)

[GSK](#) announced that Dermavant Sciences, a subsidiary of [Roivant Sciences](#), has agreed to purchase the rights to tapinarof, an investigational therapeutic aryl hydrocarbon receptor modulating agent (TAMA) for the treatment of psoriasis and atopic dermatitis and back-up programmes for a total consideration of £250 million, including an initial payment of £150 million and a potential future milestone payment of £100 million. [More](#)

[Liquidia Technologies, Inc.](#), a late-stage clinical biopharmaceutical company focused on the development and commercialization of human therapeutics using its proprietary PRINT® technology to transform the lives of patients, announced that it has filed a registration statement on Form S-1 with the U.S. Securities and Exchange Commission (the "SEC") relating to a proposed initial public offering of its common stock. The number of shares to be offered and the price range for the proposed offering have not yet been determined. Liquidia has applied to list its common stock on the Nasdaq Capital Market under the ticker symbol "LQDA." [More](#)

[Mayne Pharma Group Limited](#) announced the launch of clonidine extended-release (ER) tablets, 0.1mg in the United States. Mayne Pharma's CEO Scott Richards said, "The launch of clonidine ER tablets is our sixth generic product launch this calendar year. This product was developed internally and will be manufactured in Greenville, N.C., leveraging our potent handling and modified-release drug delivery capabilities." [More](#)

[Merz North America](#) announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for XEOMIN® (incobotulinumtoxinA) for the treatment of chronic sialorrhea, or excessive drooling, in adult patients. XEOMIN is the first and only neurotoxin with this approved indication in the U.S. "Until now, there has not been an FDA approved treatment for this debilitating condition," said Kevin O'Brien, Vice President and U.S. Head of Neurosciences, Merz North America. [More](#)

[Novozymes'](#) President of the Americas, Adam Monroe, spoke at the High-Level Political

Forum in New York on a panel called "Optimising resource use to nourish a growing world". One exciting idea surrounding is that business should bring solutions to the table. [More](#)

[Pharmaceutical Product Development, LLC](#) (PPD) has introduced a new patient enrollment model that significantly reduces the time and cost of conducting clinical trials for pharmaceutical and biotechnology customers. [PatientAdvantage](#) uses data-driven feasibility to identify eligible patients in the population first, then delivers qualified patients to high-performing investigative sites for enrollment – an approach that inverts the steps of the industry’s long-practiced trial-delivery method. [More](#)

[TransEnterix, Inc.](#) announced that the company has been added to the Russell 2000® Index at the conclusion of the Russell US Indexes annual reconstitution. "We are excited to be joining the Russell 2000 Index, which puts us alongside many of the largest public companies in the U.S." said Todd M. Pope, TransEnterix CEO. "We have worked diligently to create value for our shareholders, and we believe our inclusion represents a great opportunity to continue to do so by increasing our visibility and exposure to investors." [More](#)

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NCBIO Member Benefits – New Discounts from NCBIO Member Companies



[BIO Business Solutions](#)® provides NCBIO members with numerous discount prices. With more than \$350 million in annual sales, BIO Business Solutions® aggregates the purchasing power of over 3,000 life science companies from North America. Find out more about [NCBIO discounts](#).

Is there a fee to enroll in BIO Business Solutions®?

Members of NCBIO are eligible to participate **for no charge** as a benefit of membership.

How significant are the savings through BIO Business Solutions®?

Very significant! Here is a real-life example... A life science company in North Carolina, with 20 full time employees, taking advantage of just two of the BIO Business Solutions® offerings, saved \$61,025 in just one year. Had they not enrolled with BIO Business Solutions®, that year’s spending on the same products and services would have been \$119,745, a savings of 51%!

What kind of companies participate in BIO Business Solutions®?

Life science companies of all types and sizes participate in BIO Business Solutions®. We now have over 3,700 companies participating, and the number keeps growing.

HOW DO I GET STARTED?

Easy! Just let us know which programs you are interested in, and we can get you started- see bio.org/bbs/northcarolina for information. Or contact BIO at bbsinfo@bio.org or **(888) 246-1728**.

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Calendar

To view full calendar, [click](#).

[LaunchBio's "Larger Than Life Science" Monthly Networking Event](#)

Thursday Aug 2, 2018

... [read more](#)

[NIIMBL Technology Workshop – Cell Therapy Manufacturing Innovation](#)

Monday Aug 6, 2018

... [read more](#)

[LaunchBio's "Larger Than Life Science" Monthly Networking Event](#)

Thursday Sep 6, 2018

... [read more](#)

[Microrite Mold Workshop](#)

Monday Sep 17, 2018 - Tuesday Sep 18, 2018

... [read more](#)

[The MedTech Conference](#)

Monday Sep 24, 2018 - Wednesday Sep 26, 2018

... [read more](#)

[Precision Medicine World Conference](#)

Monday Sep 24, 2018 - Tuesday Sep 25, 2018

... [read more](#)

[Clinical Trial Supply Southeast 2018](#)

Tuesday Oct 2, 2018 - Wednesday Oct 3, 2018

... [read more](#)

[NCBIO Annual Membership Meeting 2018](#)

Thursday Oct 4, 2018

... [read more](#)

[LaunchBio's "Larger Than Life Science" Monthly Networking Event](#)

Thursday Oct 4, 2018

... [read more](#)

[Clinical Trial Supply East Coast 2018](#)

Tuesday Oct 16, 2018 - Wednesday Oct 17, 2018

... [read more](#)

[BIO Investor Forum](#)

Wednesday Oct 17, 2018 - Thursday Oct 18, 2018

... [read more](#)

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