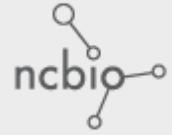




connections newsletter



**September 2017
UPDATE**

**Serving the NC Life
Sciences Industry**

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NCBIO This Month

- NCBIO Legislative Luncheon & Forum – September 7
- NCBIO Annual Meeting – October 5
- President Trump Signs FDARA
- Spotlight High Point
- Food Processing Center to Open in 2018 at NC Research Campus
- NCBiotech Awards \$3.6 Million in Loans, Grants in Latest Quarter
- NC Film Premiere: Food Evolution
- Informing Innovation 2017 – November 16
- New 2017 NC Ag Biotech Economic Growth Report
- Annual ACS CAN Research Breakfast - September 29



- At the National Level
- Member News
- Member Benefits
- Calendar

NCBIO Legislative Luncheon & Forum – September 7



NCBIO - Media

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

NCBIO Links

[CED](#)

[NCBIO](#)

[NC Biotech Center](#)

[BRITE](#)

[BTEC](#)

[BioNetwork](#)

[NCBioImpact](#)

[North Carolina
Pharmaceutical Services
Network](#)

NCBIO Sustaining Members



GSK

House Senior Appropriations Chairman, Representative Nelson Dollar (R-Wake) will be one of the speakers for the Annual NCBio Legislative Luncheon and Forum. Co-Chairs of the Legislative Life Science Caucus will also talk during the event at the Archie K Davis Conference Center, RTP Headquarters, 12 Davis Drive, Durham. (at I-40, exit 280) *(Please note this is a different location from most of our events.)*

Rep. Dollar has been a strong supporter of life science funding and was an important ally for the North Carolina Biotechnology Center funding, the additional \$500,000 for BTEC (NC State University) training funds and for supporting the Office of Science, Technology and Innovation. Co-Chairs of the Caucus, Senator Tamar Barringer (R-Wake), Representative Susan Martin (R-Wilson) and Representative Ed Hanes (D-Forsyth) will discuss the Caucus work during the session. They have been very supportive of funding for the life science industry and held more meetings than anticipated because interest was so high in getting more information. (The other Co-Chair, Senator Angela Bryant, is invited to speak.)

For more information, contact Laura Gunter lgunter@ncbioscience.net. Thanks to our sponsors for this event: [Jenkins Wilson Taylor and Hunt](#), [Liquidia](#), and [PhRMA](#)



Lilly



Pfizer



We Work For Health



NCBio Annual Meeting – October 5



NCBio Supporting Members

Cook Medical



Merck



Don't forget to secure your seat at NCBio's Annual Meeting on October 5th from 8:00 a.m. to 3:00 p.m. Approximately 250 members and guests will come together for networking and information sharing. To register for the event, view a complete list of speakers, or receive information on hotel accommodations (*discounted room block available until 9/13*), check the [event webpage](#) or contact [Amber Niebauer](#).

We have a great lineup of keynote speakers and topics including: Jeff George, former Chief Executive Officer of Sandoz and Alcon, Novartis Group, speaking on leadership and transition; David Hollinrake, North America Region Director and President, Syngenta Seeds, talking about the ag biotech industry; and Morten Nielsen, Senior Vice President, Diabetes API US, Novo Nordisk, discussing the company's relocation and expansion in North Carolina.

Attendees will participate in a fireside chat with panelists from Cook Medical and Grifols as they discuss federal and government affairs from the company's perspective and will also be engaged in a robust discussion with leaders from Piper Jaffray and Silicon Valley Bank as they provide a spotlight on the markets.

Following the networking lunch, members will get an overview of the EY **2017 Beyond Borders: Staying the Course** report. EY has monitored the biotechnology industry for the past 31 years and reports on financial metrics, deal analysis, investment in the industry, and future global trends. Join a live discussion of this year's edition of Beyond Borders. **Ellen Licking**, Senior Analyst, Global Life Science Industry, EY, will present the report. There is a separate registration for this part of the program. [Click here](#).

Thank you to all the event sponsors for their support.

Platinum: [Bioventus](#), [Cook Medical](#), [Novo Nordisk](#) and [VWR](#)

Gold: [Bayer](#), [BioNetwork](#), [Fujifilm Diosynth](#), [Grifols](#), [Merz](#) and [The Conafay Group](#)

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Bronze: [BD](#), [Business Wire](#), [EY](#), [G1 Therapeutics](#), [Nikon](#), [Novartis](#), [Novozymes](#), [PhRMA](#), [PPD](#), and [Royal Hill Consulting](#)

President Trump Signs FDARA

President Trump has signed the FDA Reauthorization Act of 2017, which included the PDUFA, MDUFA and other user fees.

BIO CEO and President Jim Greenwood stated, "President Trump's signature on this landmark legislation is the culmination of a years-long collaborative process in which patients, industry, FDA, legislators and other stakeholders worked tirelessly to identify ways in which FDA's human drug review programs can be improved to deliver better health care for every American and enhance the incorporation of the patient voice in drug development and review." [More](#)

Steve Ubl, President and CEO of PhRMA stated, "In today's new era of medicine, where breakthrough science is transforming patient care, the signing of FDARA is a major victory for the patients in need of innovative, lifesaving treatments. By reauthorizing PDUFA and the other user fees, the administration is leading the way toward greater efficiency at the U.S. Food and Drug Administration (FDA) and increasing competition in the biopharmaceutical market." [More](#)

The proposal was also supported by AdvaMed. CEO Scott Whitaker said, "The robust FDA performance goals, process improvements, increased accountability and additional resources provided for under the new user fee agreement represent a victory for the agency, innovation and, most importantly, patients. The bill also includes pro-innovation provisions to improve the FDA inspections process and streamline device accessory classification."

[Back to top.](#)

Spotlight High Point

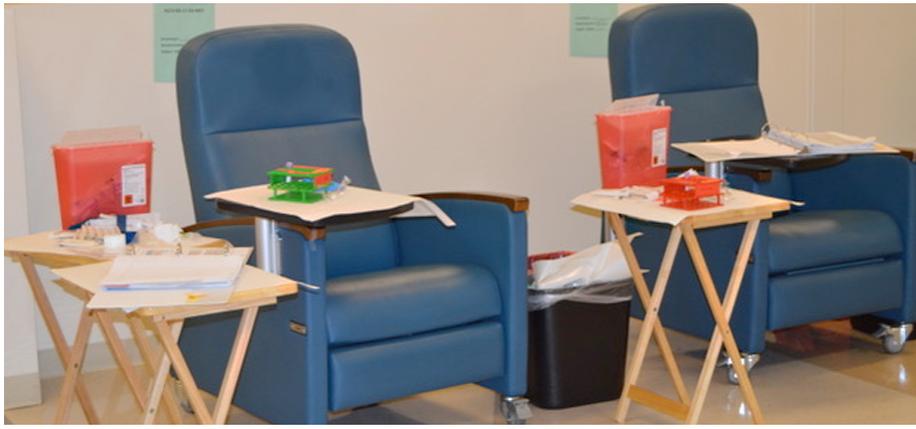
NCBIO staff is visiting life science companies in various regions of the state to find out more about the scope of the industry. Laura Gunter and Brenda Summers were in High Point earlier in the month to visit with vTv Therapeutics™ and Hight Point Clinical Trials Center.



[Rudy Howard and Nura Strong of vTv](#)

[vTv Therapeutics](#)™ recently announced that the U.S. Patent and Trademark Office has issued a patent with claims protecting methods of treatment using azeliragon, the oral antagonist of the Receptor for Advanced Glycation Endproducts (RAGE) for treatment of mild Alzheimer's disease. vTv, a clinical-stage biopharmaceutical company engaged in the discovery and development of orally administered small molecule drug candidates, is currently the only company developing a treatment for Alzheimer's disease by targeting the RAGE receptor. vTv is focusing on a pipeline of drug candidates for the treatment of diabetes as well as inflammatory disorders and the prevention of muscle

weakness. The company also has Bioanalytical testing facilities that provide a range of services.



[High Point Clinical Trials Center](#) has operated for more than a decade. The facility has two fully independent research units that can be configured for various study needs. The Center works with CROs, virtual companies and pharmaceutical companies to perform Phase 1 through Phase 3 studies on site. The organization has research physicians to oversee the work and has participated in more than 500 clinical trials in a variety of therapeutic areas. The facility has two specimen preparation labs. The company has a mobile outreach unit that participates in community events. Physician Investigators are also involved in the community and have participated in other volunteer medical initiatives both domestically and overseas. These activities not only provide healthcare services to the medically underserved but they serve as an educational opportunity where patients learn about clinical trial research and evolving new therapies. [More](#)

[Back to top.](#)

Food Processing Center to Open in 2018 at NC Research Campus

The North Carolina Food Processing Innovation Center (FPIC) is moving forward with the recent passage of the North Carolina state budget, which included \$4.4M in funding. The new center, set to open in 2018, also will receive \$700,000 in recurring funds for operational support. An initiative of North Carolina State University, the North Carolina Department of Agriculture and Consumer Services, and the [North Carolina Research Campus](#) (NCRC), the FPIC is poised to revolutionize food processing and manufacturing in North Carolina.

The 10,000-square-foot facility will be housed in the NCRC Core Laboratory Building and will be the only of its kind in the country. While there are other university-based food innovation centers nationwide, the FPIC will be the only one that is cGMP certified, which means that an FDA-regulated system of controls will ensure a high level of quality at every step. [More](#)

[Back to top.](#)

NCBiotech Awards \$3.6 Million in Loans, Grants in Latest Quarter

The North Carolina Biotechnology Center awarded 47 loans and grants totaling \$3.6 million to universities, bioscience companies and other entities in the fourth quarter of its 2016-2017 fiscal year ending June 30. [More](#)

Eighteen bioscience companies previously funded by NCBiotech loans raised more than \$128 million in follow-on funding from other sources during the fourth quarter of 2016-17. [More](#)

[Back to top.](#)

[NC Film Premiere: Food Evolution](#)



The North Carolina Biotechnology Center, in collaboration with [GMO Answers](#), will host the North Carolina film premiere of "[Food Evolution](#)." Traveling from Hawaiian papaya groves to banana farms in Uganda to the cornfields of Iowa, "Food Evolution," narrated by renowned astrophysicist and science communicator Neil deGrasse Tyson, wrestles with the emotions and the science driving one of the most heated arguments of our time. The Premiere is October 5th, 5:00 pm to 9:00 pm at The Carolina Theatre, Durham. To register and find out more, [click](#).

[Back to top.](#)

[Informing Innovation 2017 – November](#)

Learn how to address the challenges of accessing information in your organization at **Informing Innovation 2017**, hosted by [Life Science Intelligence](#) at the North Carolina Biotechnology Center on November 16th. Learn how to better navigate the landscape of scientific literature and business information resources, and gain greater perspective on managing subscriptions and accessing content. Connect with content providers to learn more about tools and resources essential to discovery. [For more information.](#)

[Back to top.](#)

[New 2017 NC Ag Biotech Economic Growth Report](#)

More than 100 agbiotech companies are now located across North Carolina, employing more than 9300 people according to a new report. [Click](#) to find out more.

[Back to top.](#)

[Annual ACS CAN Research Breakfast - September 29](#)

The American Cancer Society Cancer Action Network (ACS CAN), the advocacy affiliate of the American Cancer Society will host its Annual North Carolina Research Breakfast, September 29th, 7:30 am - 9:00 am, Wake Forest Baptist Medical Center Comprehensive Cancer Center, Winston-Salem. This event brings together more than a hundred leaders from the business, education, government and research communities. The 2017 event will highlight the accomplishments and innovative strides of North Carolina cancer researchers. Government elected officials will be invited to participate to raise their awareness of importance of state and federal cancer research funding in our state.

To purchase tickets or become a patron level sponsor, contact Ray Riordan at 919-334-7203; Ray.Riordan@cancer.org, or www.acscan.org/ncbreakfast Contributions or Gifts to the American Cancer Society Cancer Action Network, Inc. are not tax deductible.

[Back to top.](#)

At the National Level

New Report on Steps for Greater Transparency in Health Care

The Network for Excellence in Health Innovation (NEHI) released a [new report](#) that outlines steps for greater transparency in health care. The report states that helping consumers make well-informed decisions can lead to higher quality of care, greater patient satisfaction and better use of the nation's health care resources. [More](#)

Industry Leaders and More at MedTech Conference September 25-27

FDA Commissioner Scott Gottlieb, M.D. is one of the keynote speakers for [The MedTech Conference](#) powered by AdvaMed. The [agenda](#) is filling up with expert industry speakers and leaders. The event in San Jose, CA will have opportunities for business development, networking with industry leaders and policy makers and a look at new innovative technologies. Find out more [information](#) and [register](#).

MDMA Executive Forum – September 15

The [10th Annual Medical Technology Executive Forum](#) will be at the Crowne Plaza Cabana in Palo Alto, CA, September 15th. Hear from some of the top industry experts and government officials who will address investment options, FDA reforms, reimbursement strategies, and much more. [Register](#).

BIO Investor Forum – NCBio Members Get Discount

The 16th annual BIO Investor Forum will host more than 175 healthcare [venture capital and public market investors](#) and more than 600 business development executives from [leading global pharmaceutical and biotechnology companies](#). **NCBio members receive \$400 in conference registration savings** using code **BIOBIF24** and benefit from the BIO Member rate! BIO Member companies should contact bblake@bio.org to take advantage of additional savings. [Learn more and register now.](#)

[Back to top.](#)

Member News

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

[Baebies, Inc.](#) announced the first assays on the FINDER launch panel, currently under development. The panel includes tests for total serum bilirubin, albumin, direct bilirubin, and glucose-6-phosphate dehydrogenase (G6PD) on a single cartridge, making it the first comprehensive, rapid and near-patient testing solution for hyperbilirubinemia. [More](#)

NCBio members [BASF](#), [EY](#) and [Liquidia Technologies](#) were named by *Triangle Business Journal* as 2017 Best Places to Work. [More](#)

[G1 Therapeutics](#) reports second quarter financial results. "The second quarter of 2017 proved to be transformational for G1, as we made further progress with our oncology drug development programs and raised \$107.1 million in net proceeds in our successful initial public offering," said Mark Velleca, M.D., Ph.D., Chief Executive Officer of G1. [More](#)

[Novartis](#) announced that the US Food and Drug Administration (FDA) has approved Kymriah(TM)(tisagenlecleucel) suspension for intravenous infusion, formerly CTL019, the first chimeric antigen receptor T cell (CAR-T) therapy, for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. [More](#)

[Novan, Inc.](#) announced that Paula Brown Stafford has been appointed to the company's Board of Directors, effective immediately. Ms. Stafford joined Novan in March of this year and will continue as the Chief Development Officer. The company also announced the addition of Tomoko Maeda-Chubachi, M.D., Ph.D. as Vice President of Medical Dermatology, effective September 1. [More](#)

[Pfizer Inc.](#) has selected Lee County for a new expansion of its manufacturing facilities as the company prepares to produce new gene therapy medicines. Governor Roy Cooper announced the company plans to invest \$100 million in its Sanford facilities, creating 40 jobs and building upon a technology first developed at the University of North Carolina at Chapel Hill. [More](#)

Pharmaceutical Product Development, LLC ([PPD](#)) announced that Susan Atkinson, Ph.D., Senior Vice President of Global Biometrics for PPD, has been named to the 2017 PharmaVOICE 100 list of the most inspiring people in the life sciences industry. [More](#)

[Seqirus](#), a global leader in the prevention of influenza, announced that the accelerated development of cell-based manufacturing technology at its state-of-the-art manufacturing facility in Holly Springs, has delivered a four-fold increase in seasonal influenza vaccine output in just two years, strengthening the United States' capacity to respond to pandemic threats. [More](#)

[TransEnterix, Inc.](#) announced that it has installed a Senhance Surgical Robot at the Institute for Surgical Advancement at Florida Hospital Orlando. "The selection of a U.S. innovation center is a critical milestone in the global expansion of Senhance," said Todd M. Pope, President and CEO at TransEnterix. "We are pleased to partner with a leading institution such as Florida Hospital Orlando and the clinicians at the Institute for Surgical Advancement. Together, we will continue to usher in an expansion in the use of robotics to advance minimally invasive surgery." [More](#)

[Back to top.](#)

Member Benefits



[BIO Business Solutions](#)® provides NCBio members with numerous discount prices. BIO Business Solutions® aggregates the purchasing power of over 3,000 biotech companies from North America. Find out more about [NCBio discounts](#).

 VWR We Enable Science	Lab Supplies	 Office DEPOT	Office Supplies
 Nikon	Research Grade Microscope Systems	 CHUBB	Business Insurance (Clinical Trials, Product, Property & Casualty)
 ALT AMERICAN LABORATORY TRADING	Refurbished Lab Equip. & Asset Management	 ups	Shipping Services
 Aircas Healthcare an Air Liquide company	Packaged & Bulk Gases	 AON Empower Results*	Executive Liability Insurance
 illumina	Gene Sequencing Solutions	 BusinessWire A Berkshire Hathaway Company	News Distribution Services
 CleanHarbors	Environmental Services	 ShareVault Share documents. Simply, securely.	Secure Document Sharing & Virtual Data Room
 UniFirst U1st Uniforms • Services • Solutions UniClean Cleanroom Services	Workwear and Cleanroom Services	 humboldt relax. and get moving.	Moving & Storage

[Back to top.](#)

Calendar

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

[Introduction to Design of Experiments \(DoE\) for Bioprocess Analysis & Optimization](#)

Tuesday Sep 5, 2017 - Thursday Sep 7, 2017

... [read more](#)

[Legislative Luncheon & Forum](#)

Thursday Sep 7, 2017

... [read more](#)

Categories: *Legislative Forum*

- [Register Now](#)

[MDMA's 10th Annual Medical Technology Executive Forum](#)

Friday Sep 15, 2017

... [read more](#)

[Manufacturing Conference 2017](#)

Tuesday Sep 19, 2017 - Wednesday Sep 20, 2017

... [read more](#)

[Healthcare and Tech Giants Team Up GlaxoSmithKline + Google -> Galvani](#)

Tuesday Sep 19, 2017

... [read more](#)

[The MedTech Conference](#)

Monday Sep 25, 2017 - Wednesday Sep 27, 2017

... [read more](#)

[Triangle Global Health 2017 Annual Conference](#)

Thursday Sep 28, 2017

... [read more](#)

[Hands-On Single-Use Processing for Biopharmaceuticals](#)

Tuesday Oct 3, 2017 - Thursday Oct 5, 2017

... [read more](#)

[NCBIO Annual Meeting 2017](#)

Thursday Oct 5, 2017

... [read more](#)

Categories: Annual Meeting

- [Register Now](#)

[Applied Principles & Techniques of Depth Flow Filtration \(DFF\) & Tangential Flow Filtration \(TFF\) for BioPharm Downstream Purification](#)

Tuesday Oct 17, 2017 - Friday Oct 20, 2017

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[BIO Investor Forum](#)

Tuesday Oct 17, 2017 - Wednesday Oct 18, 2017

... [read more](#)

[MEDICA](#)

Monday Nov 13, 2017 - Thursday Nov 16, 2017

... [read more](#)

[19th Annual Southeast BIO Investor & Partnering Forum](#)

Tuesday Nov 14, 2017 - Thursday Nov 16, 2017

... [read more](#)

[Informing Innovation 2017](#)

Thursday Nov 16, 2017

... [read more](#)

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