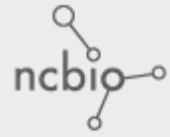




connections newsletter



**April 2017
UPDATE**

**Serving the NC Life
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NCBIO This Month

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Legislative Life Science Caucus Meets

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](#)

NCBIO Sustaining Members





Sen. Angela Bryant, Rep. Susan Martin, Sen. Tamara Barringer
and back row Rep. Ed Hanes

The North Carolina General Assembly's new Legislative Life Science Caucus held its first meeting on March 16th. NCBIO President Sam Taylor gave caucus members an overview of the industry in the State and outlined the NCBIO Legislative Agenda. Doug Edgeton, President and CEO of the North Carolina Biotechnology Center, discussed the economic impact of the life science industry in the State and gave an overview of the Center's work.

Edgeton announced that the Center's biennial economic impact study had found that North Carolina "is the fastest growing of the top life science states," now boasting 650 companies, directly employing 63,000 and generating an economic impact of \$86B. Edgeton also stated that, based on current trends, the Biotechnology Center's goal in the next eight years would be to bring total life science employment in the state to 100,000 employees with \$100B in economic impact.

The Caucus is being led by four co-chairs, two from each chamber and party in the Assembly: Representatives Susan Martin (R-Wilson) and Ed Hanes (D-Forsyth) from the State House, and Senators Tamara Barringer (R-Wake) and Angela Bryant (D-Nash) from the Senate.

In addition to the Co-Chairs, other members of the legislature have joined the Caucus. They are: Senators John Alexander (R-Wake), Dan Blue (D-Wake), Jay Chaudhuri (D-Wake), Ben Clark (D-Hoke), Cathy Dunn (R-Davidson), Rick Horner (R-Wilson), Brent Jackson (R-Sampson), Paul Newton (R-Cabarrus), Norman Sanderson (R-Pamlico), Terry Van Duyn (D-Buncombe), as well as Representatives Gale Adcock (D-Wake), Nelson Dollar (R-Wake), Yvonne Holley (D-Wake), Grier Martin (D-Wake), Rodney Moore (D-Mecklenburg), Greg Murphy (R-Pitt), and Larry Yarborough (R-Person). More legislators are expected to join the Caucus.

NCBIO members located in the districts of these Assembly members should be sure to thank them for their participation in the caucus. For assistance, contact [Marielle Roth](#) or call (919) 281-8960.

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NCBIO Legislative Reception April 5th



2017 Life Sciences
Legislative Reception



NCBIO Supporting Members

Cook Medical



Merck



Join more than 220 legislators and NCBIO members at the 2017 Annual Legislative Reception on April 5th. The reception is at the NC History Museum from 5:30-7:30 PM. For more information or to register, contact [Amber Niebauer](#).

Thanks to [AbbVie](#), [Amgen](#), [Astellas](#), [Bayer](#), [Biogen](#), [Johnson & Johnson](#), [Lilly](#), [Novozymes](#), [PhRMA](#), and [Syngenta](#) for helping make this event possible.

("The North Carolina Museum of History does not sponsor or endorse this event.")

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Former Biogen Executive Gets Committee Approval for State Position



Machel Sanders, former NCBIO Board Member and former Vice President and General Manager of Biogen's RTP site, has received approval from a Legislative Committee to serve as Governor Roy Cooper's Secretary of Administration. She must still be approved by another committee and the State Senate.

Sanders was appointed by Cooper in January, and legislation passed by the General Assembly in December now requires Senate approval of the Governor's Cabinet appointees.

The Department of Administration oversees operations such as building constructions, purchasing and contracting for good and services, maintaining facilities, managing state vehicles, acquiring and disposing of real property, and operating auxiliary services such as courier mail delivery and the sale of state and federal surplus property. In addition to its role as a service provider to other state agencies, the department provides staff support to several councils and commissions which advocate for the special needs of North Carolina's citizens. [More](#)

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Apprenticeship Training the Topic at March BMF Meeting



Forty-five percent of all jobs over the next decade will be in “**middle skill**” occupations, which require more than a high school diploma but less than a bachelor’s degree according to Dr. Pamela Howze with the NC Department of Commerce. Dr. Howze was the keynote speaker for the March BMF meeting.

Dr. Howze noted that some life science companies have been reluctant to adopt apprenticeship programs with high school students because companies use contract agencies for temp workers, and have concerns about insurance liability and safety. She said many companies are in need of information technology workers and are using apprenticeships because there are currently 12,000 unfilled IT positions in North Carolina. For industries in the State using the apprenticeship program, the average starting salary for an individual completing the program is \$50,000.

Trevis McCullough, Jr., a Wake Tech student and apprentice at GSK, talked with members about his experience with the program and how it was preparing him for a career in engineering.

For more information, contact [Dr. Howze](#) or BMF Program Manager [John Wagner](#).

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Hold May 16 for NC Bio Life Science Forum on Medical Devices

Are you interested in medical devices and FDA approvals? Join us on May 16 as we discuss Navigating FDA Approvals, Funding and Next Steps. The event is from 11:30 am – 1:30 pm at the North Carolina Biotechnology Center.

Panelists include:

- **Patrick Daly**, President and Chief Executive Officer, Cohera Medical
- **Rich West**, Chief Executive Officer and Founder, Baebies
- **Tim Willis**, Chief Executive Officer and Founder, MED1 Ventures

Thanks to [PricewaterhouseCoopers](#) and [TechnoSoft Innovations](#) for sponsoring the Forum. If you are interested in sponsoring the event, contact [Laura Gunter](#). For more information on the Forum program or to register, contact [Amber Niebauer](#).

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Global Health Drug Development Workshop, April 4th

Join the Triangle Global Health Consortium and the Global Health Innovation Alliance Accelerator on April 4th for a workshop exploring the concerns facing start-up companies, spin-offs from universities, institutes, the US government and traditional

pharmaceutical companies as they partner to develop and distribute new medicines and vaccines.

Developing and distributing medicines and vaccines for a global market involves expanded challenges and issues for the parties involved. Done well, these developments are smooth alliances between multi-functional organizations funded by both public and private organizations. Optimally, the resulting products benefit not just traditional markets but also those in less developed countries and regions.

[Register](#) and find out more.

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Johnson & Johnson Innovation Event, April 12th

On April 12, hear from Johnson & Johnson Innovation (JJI) leaders as they provide an overview of JJI goals and mission, highlighting how JJI interacts with the entrepreneurial community through JLABS, JJDC, and other JJI initiatives. The event is at the NC Biotechnology Center with registration at 10:30 am, presentations at 11 am, and networking lunch at 12:30 pm.

Participating representatives are:

- **Ibraheem Badejo**, Sr Director, New Ventures, Johnson & Johnson Innovation
- **Dana Deardorff**, Sr Director, New Ventures, Johnson & Johnson Innovation
- **Stefanie Dhanda**, Sr Director, Consumer Scientific Innovation, Johnson & Johnson Innovation
- **Nicola La Monica**, Sr Director, Infectious Disease and Vaccines Scientific Innovation, Johnson & Johnson Innovation
- **Kuldeep Neote**, Sr Director, New Ventures, Johnson & Johnson Innovation
- **Bob Radinsky**, VP, Oncology Scientific Innovation, Janssen R&D
- **Eric Schaeffer**, Sr Director, Neuroscience External Innovation, Janssen R&D

The event is free. To register and find out more, [click here](#).

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BRITE Career Fair April 12th

The Biomufacturing Research Institute & Technology Enterprise (BRITE) will be partnering with Career Services & Outreach to host its first [BRITE CAREER EXPO](#). North Carolina Central University has been ranked as one of the top HBCU's in the country as a result of its signature programs, including its degree in pharmaceutical sciences. Therefore, BRITE is proud to sponsor this recruitment event for organizations seeking to hire pharmaceutical sciences majors for internships and employment opportunities. If you are interested in recruiting at the event or finding out more information, contact [Natacha Janvier-Derilus](#), [Cassandra Brown](#) or [William Smith](#).

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Safety Summit on Crisis Management and Business Continuity – April 25th

Join management and individuals involved in risk mitigation, disaster recovery, safety and crisis management planning at the 3rd NC Safety Summit.

The keynote speaker is **Adam Kerop**, CFPS, Director, Pfizer's Business Resilience, Fire & Life Safety/Loss Prevention. Registration starts at 7:30 am and program at 8:30 am. Breakfast and lunch provided. The event is at the Pfizer Biotech Facility, 3316 Hawkins Ave., Sanford.

Find out [more](#). Register by sending an email to 2017_Safety_Summit@Pfizer.com with your name, title and name of company.

[Pfizer](#) and [Duke Energy](#) are sponsoring the summit. NC BIO's Biotech Manufacturers Forum is supporting this event.

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[Clinical Trial Supply Southeast Conference 2017](#)



The third annual Clinical Trial Supply Southeast will be May 3-4 in Cary. The conference offers industry peers in the Southeast area the opportunity to discuss and discover potential solutions to the biggest challenges with clinical supply processes.

Secure your place today by quoting reference **MK-ACEL** and [registering](#). [Email](#) for more information.

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[Ag Biotech Entrepreneurial Showcase – May 10-11](#)

Vern Hawkins, president of Syngenta Crop Protection, is the keynote for the Showcase event May 10-11. This is the fifth year that NC Biotech is convening ag biotech investment firms, global ag biotech companies and other key industry stakeholders for information sharing, networking, and partnering. The event is at the [Cotton Room](#) in Durham. [More](#) on the event and to register.

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[Precision Medicine World Conference](#)

The first East Coast Precision Medicine World Conference will be at Duke University on May 24-25. Coming from Silicon Valley, the 12th Annual Event will focus on biomedical technologies that are spurring exciting capabilities and initiatives to enable the translation of precision medicine into improvements in health care. Precision medicine is already leaving its mark in oncology and is expanding rapidly into other therapeutic areas. These technological and medical advances, as well as their applications to improve health care, are reflected in the content-rich two-day agenda of the [PMWC 2017 Duke conference](#) which is a cross-section through the world of precision medicine with its goal of increasing tailored approaches to the treatment of diseases and improvement of health.

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[At the National Level](#)

Dr. Scott Gottlieb Nominated as FDA Commissioner

"[AdvaMed](#) congratulates Dr. Gottlieb on his nomination as FDA Commissioner. His medical credentials, combined with years of service in leadership roles at both CMS and

FDA make him a strong choice to lead this key agency. Our industry applauds Dr. Gottlieb's commitment to innovation in medical technology and his recognition of its important role in providing the best care possible for patients," stated AdvaMed President and CEO Scott Whitaker. [More](#)

[PhRMA](#) President and CEO Steve Ubl also commented on the nomination. "PhRMA congratulates Dr. Gottlieb on his nomination to serve as Commissioner of the U.S. Food and Drug Administration. His extensive experience as a physician and breadth of health care knowledge will help ensure the FDA continues to play a vital role in protecting public health and innovation in the Agency's review and approval of new medicines for patients in need." [More](#)

Fostering Innovation Act Introduced in Congress

[BIO](#) applauds Reps. Kyrsten Sinema (D-AZ) and Trey Hollingsworth (R-IN) for introducing the Fostering Innovation Act. The legislation would reduce compliance costs for growing businesses that benefitted from the JOBS Act. [More](#)

FDA User Fees

PhRMA President and CEO Stephen J. Ubl issued the following statement in support of the U.S. Food and Drug Administration's (FDA) user fee programs the Prescription Drug User Fee Act (PDUFA) VI, Biosimilar User Fee Act (BsUFA) II and the Generic Drug User Fee Act (GDUFA) II:

"User fees are an important mechanism to support the critical work of the U.S. Food and Drug Administration in the human drug review process. Moving the Prescription Drug, Biosimilar and Generic Drug User Fee Acts forward in a timely manner is important to support FDA's mission of protecting public health and promoting innovation, to enhance the competitive market for treatments and to get medicines to patients in need.

"For over two decades, PDUFA has helped bring innovative medicines to patients by providing greater consistency, certainty and predictability in the science-based U.S. drug review process. The PDUFA VI agreement, along with the BsUFA II and the GDUFA II are needed to ensure the best and brightest minds at FDA are able to keep pace with the rapid advance of medicine." [More](#)

Reauthorization of the Medical Device User Fee Act is under consideration by the US Senate HELP Committee. "We look forward to engaging with members of Congress moving forward with reauthorization legislation," said Scott Whitaker, President and CEO of AdvaMed. "We support this new MDUFA package because we believe it is good for patients, good for innovation and good for the agency.

Some of the key benefits in the new user fee agreement include:

- Significant improvements for total review time goals, which will lower the total time goal for 510(k)s and PMAs to historical norms;
- Greater accountability, including two independent analyses of FDA's management of the review process – one at the beginning and one at the end of the MDUFA IV timeline;
- Further process enhancements to increase the consistency and timeliness of the review process; and
- Greater patient engagement provisions. [More](#)

BIO 2017 – Register by April 27th And Save \$200

There's no better place to connect with biotech's top people and most innovative technologies than at BIO 2017. The ideas shared here go beyond professional development. Experience powerful business partnering, benefit from invaluable education sessions and network with 16,000+ of the industry's brightest.

[Find out more and register.](#)

MDMA 2017 Annual Meeting, April 26-28, Washington, DC

Plan to attend the [Medical Device Manufacturers Association's](#) (MDMA's) 2017 Annual Meeting in the Nation's Capital, April 26-28. MDMA's Annual Meeting will cover key issues impacting the United States' leadership position in med tech innovation, and how to shape the regulatory and legislative agendas. This year's meeting will provide the latest on regulatory, reimbursement, compliance and international trends, as well interactive sessions with top policy makers from FDA, CMS and more. To check out speakers, registration and other information, [click](#). NCPIO members can receive a

\$100 discount.

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Member News

[AgBiome](#) announced that the [Zio™](#) fungicide has been approved by the EPA. This new biological fungicide will be marketed by SePRO and was developed by AgBiome, Inc. [More](#)

[BASF](#) announced that it has reached a global licensing agreement with the Broad Institute of MIT and Harvard for the use of CRISPR-Cas9 genome-editing technology to improve products in agricultural and industrial microbiology applications. [More](#)

[FUJIFILM Diosynth Biotechnologies](#), a leading global biologics Contract Development and Manufacturing Organization (CDMO), has announced the expansion of its Monoclonal Antibody development and manufacturing services with the introduction of its Saturn mAb Platform. The Saturn mAb Platform™ is the result of the application of years of experience developing and optimizing monoclonal antibodies processes with efficient cGMP production and batch disposition. [More](#)

[Metabolon, Inc.](#) announced that it is expanding its efforts to apply metabolomics to large population health studies taking place around the world. To support this, the Company has grown its team to include Alex Forrest-Hay as Vice President of Population Health and his staff to exclusively focus on these initiatives. [More](#)

[Novan, Inc.](#) announced that Paula Brown Stafford has been appointed to the newly created position of Chief Development Officer, in which she will be responsible for the tactical execution of clinical trials and the establishment of statistics and data management functions at the Company. She will team with Dr. Joyce Rico, Chief Medical Officer, as Novan prepares for upcoming interactions with the FDA, including the planned pre-submission meeting regarding a potential new drug application for SB204. [More](#)

Pharmaceutical Product Development, LLC ([PPD](#)) has launched a clinical research associates (CRAs) apprenticeship program targeted to military veterans and military service members with medical backgrounds who are transitioning to the civilian workforce. PPD's initiative, the first [CRA apprenticeship program](#) registered with the U.S. Department of Labor, will begin in North Carolina, Texas and California in the first quarter of this year.

[RTI International](#) celebrated the completion of the framing of its largest building on its Research Triangle Park campus with a beam signing by RTI executives and board members. Nearly 1,000 RTI staff members also signed the beam in advance. The 190,000 square-foot, six-story office building at the center of the main campus is expected to be completed in early 2018 and will provide workspace for about 670 RTI staff members. [More](#)

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

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Member Benefits



[BIO Business Solutions®](#) offers NCBI members special discounts. Find out more about [NCBIO discounts](#).

Check out the latest from [VWR](#). The best lab deal in the business just got ever better!

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- No hazardous material handling fees
- Generous rebates sent directly back to you on annual contract spend growth
- Sophisticated VWR inventory and planning software at no charge
- Additional after-hours support from the dedicated BIO-VWR hotline
- Long-term agreement stability from a proven partner

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Calendar

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Tuesday Apr 4, 2017

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[NCBIO Legislative Reception 2017](#)

Wednesday Apr 5, 2017

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[Meet with Johnson & Johnson Innovation](#)

Wednesday Apr 12, 2017

... [read more](#)

[Applied Principles & Techniques of Depth Flow Filtration](#)

Tuesday Apr 25, 2017 - Friday Apr 28, 2017

... [read more](#)

[3rd Annual NC Safety Summit](#)

Tuesday Apr 25, 2017

... [read more](#)

[Clinical Trial Supply Southeast Conference 2017](#)

Wednesday May 3, 2017 - Thursday May 4, 2017

... [read more](#)

[Ag Biotech Entrepreneurial Showcase 2017](#)

Wednesday May 10, 2017 - Thursday May 11, 2017

... [read more](#)

[NCBIO Medical Device Forum](#)

Tuesday May 16, 2017

... [read more](#)

[Chromatography Column Packing: Foundation & Applications](#)

Tuesday May 23, 2017 - Thursday May 25, 2017

... [read more](#)

[Precision Medicine World Conference \(PMWC\)](#)

Wednesday May 24, 2017 - Thursday May 25, 2017

... [read more](#)

[Foundations of Bioseparations & Biopharmaceutical Formulation](#)

Tuesday Jun 6, 2017 - Thursday Jun 8, 2017

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