



connections newsletter



**SEPTEMBER 2019
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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[NCBioImpact](#)

[North Carolina Pharmaceutical Services Network](#)

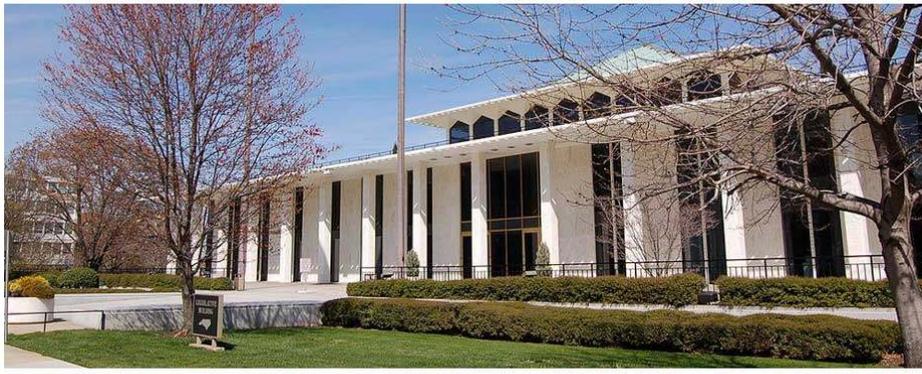
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NCBIO Sustaining Members

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[Legislators Consider New Proposals as Budget Impasse Lingers](#)



While Governor Cooper and the General Assembly remain at odds over state appropriations legislation vetoed by Cooper, the State House has been working on bills with potential benefits for the life science industry.

House leaders added a variety of new provisions to an [omnibus health care](#) package introduced in the Senate (S361). The House changes include guardrails for step therapy and a provision that would require insurers to cover oral cancer drugs on the same basis as parenteral cancer treatments. An attempt to add drug transparency provisions to the legislation failed on a vote of 57 to 51 after Speaker Tim Moore ruled the provision out of order.

The House also has adopted new legislation increasing state regulation of pharmacy benefit managers. The proposal was added to [a Senate bill](#) already in the House.

The Senate now must decide whether to accept the House changes or go to conference committee to reconcile differences between the two Chambers.

The fate of the vetoed annual appropriations bill is still uncertain. The bill includes a variety of life-science related appropriations, including:

- \$1M in non-recurring funding in both years of the 2019-21 biennium for the State's SBIR/STTR matching grant program, commonly known as the One North Carolina Small Business Program.
- \$500,000 in additional recurring funding for the North Carolina Biotechnology Center, and \$500,000 in non-recurring funding for the 2019-20 fiscal year.
- \$2M for each year of the biennium for North Carolina's participation in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL).

Legislators have also received word that the 2018-19 fiscal year ended with a larger than expected surplus. The Assembly had anticipated the year would end with an extra \$643M in the state's coffers. The actual surplus was nearly \$897M. Legislators must now decide how to handle the additional revenue. NCBIO is working to determine whether any of the additional funds might be applied to life science priorities.

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NCBIO Annual Meeting October 3 – RSVP Now



Just one month until NCBI's 25th [Annual Meeting](#) on October 3 from 8:00 a.m. to 3:00 p.m. at the NCBI Biotech Center. More than 150 life science leaders are already registered to attend. Attendees will hear from a great line up of speakers and discussion topics - two panels and two keynotes. Additionally, there will be ample networking opportunities. A dessert reception following lunch will celebrate our 25 years of service to the life science community.

We will have two keynote presentations.

- New Innovations: Personalized Health and Cancer Treatment by **Marty Murphy, DMedSc, Ph.D., FASCO**, Founding Chief Executive Officer, CEO Roundtable on Cancer and Project Data Sphere
- Financial market and economic outlook by J.P. Morgan's Co-Heads of Healthcare Banking, **Peter Meath** and **Lauren Ruane**

The Access and Availability panel will be moderated by **Dr. Marianne Lopez**, Research Director, Value-Based Payment Reform, Duke-Margolis Center for Health Policy. The group will discuss how to assure patient access to novel and established therapies while controlling cost. Panelists include leaders from Novartis, the International Myeloma Foundation, George Washington University, and Wake Forest Baptist Health.

The Ag and Human Microbiome panel discussion will be moderated by **John Ryals, Ph.D.**, former President and Chief Executive Officer, and Chair Emeritus, Board of Directors, Metabolon. Panelists include representatives from Premex, DHRMI, and AgBiome. They will take us from acknowledging the microbiome – animal, human, and plant - to understanding how to manipulate it for nutritional and therapeutic purposes.

During the reception, we will highlight accomplishments over the years with brief remarks and a slideshow. We will also recognize current and former board members at this time for their dedication to the life sciences.

To learn more about sessions and speakers or to register, [click here](#). If you need assistance with registration, contact [Amber Niebauer](#). We anticipate more than 200 members to register so don't miss your opportunity!

Thank you to our current sponsors:

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

Gold: [BDO](#), [FUJIFILM Diosynth Biotechnologies](#), [Grifols](#), and [Novo Nordisk](#)

Silver: [AdvaMed](#), [Charter Medical](#), [Office Depot](#), [The Conafay Group](#), [UCB](#)

Bronze: [Business Wire](#), [G1 Therapeutics](#), [GSK](#), [Mispro Biotech Services](#), [Nikon](#), and [Novozymes](#)

If you are interested in sponsoring the Annual Meeting, please contact [Laura Gunter](#).

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Plant Expansions and Dedications

Pfizer will invest an additional half billion dollar for the construction of its state-of-the-art gene therapy manufacturing facility in Sanford. This facility is anticipated to support Pfizer's continuing investment in gene therapy research and development, similar to Pfizer's Chapel Hill and Kit Creek research and development sites. This facility would expand the company's presence in North Carolina, where there are currently more than 3,600 Pfizer colleagues, including 650 in Sanford. The expanded facility is projected to add approximately 300 new jobs.

"At Pfizer, our purpose is breakthroughs that change patients' lives," said Angela Hwang, Group President, Pfizer Biopharmaceuticals Group. "We're excited to build this new state-of-the-art facility in Sanford because it will have the potential to help us develop novel methods to deliver transformative treatments to patients."

"This investment will further strengthen Pfizer's leadership in gene therapy manufacturing technology," said Mike McDermott, President, Pfizer Global Supply. "The expansion of the Sanford site is expected to create hundreds of highly skilled jobs, which would increase Sanford's high-tech manufacturing environment and is part of our overall plan to invest approximately \$5 billion in U.S.-based capital projects over the next several years."



Tony Mulcahy, Angela Hwang, Governor Cooper and Mike McDermott

Governor Roy Cooper, who attended the announcement, noted that North Carolina has made strategic decisions to invest in life sciences research and biomanufacturing. “This is one of the areas we are seeing positive job developments,” Cooper said. He noted that companies are looking for a talented workforce and the State is committed to growing the sector.

In addition to its gene therapy operations, colleagues at Pfizer’s Sanford facility also manufacture components for the company’s vaccine portfolio, including Prevnar 13 and several vaccines currently in Pfizer’s research pipeline. [More](#)

Thermo Fisher Scientific dedicated its newly installed training center to advance the onboarding and training of employees who will work on the company’s manufacturing line providing industry-leading resources and technologies. The facility is equipped with virtual reality and augmented reality capabilities, which mimic a real-world operating environment and equipment, and reduce the amount of training time by 50%, resulting in cost savings. The new training center is part of Thermo Fisher’s \$55M investment in its [Greenville facility](#).



ThermoFisher Senior Vice President & President, Pharma Services, Michel Lagarde unveils a plaque dedicating the virtual reality training center. Marc Casper (center) President & CEO, ThermoFisher Scientific and Nick Bushur (left), Vice President & General Manager observe.

Also, during the event, Thermo Fisher Scientific presented a check for \$5,000 along with 1,200 backpacks filled with science materials to the Pitt County Education Foundation. The backpacks will be provided to all middle schools in Pitt County to support students interested in STEM careers.

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BioWork Certification Program Update Almost Finished



Vernon Shoaf opens BioWork train-the-trainer session

BioNetwork leaders and trainers are finalizing course plans for the updated BioWork certification program, which teaches the foundational skills to begin a career as a process technician. A train-the-trainer program was held in mid-August for community college programs that will be offering the BioWork course. Johnston County Community College has piloted the updated program twice and Wake Tech Community College once. Other colleges will be adding the updated certification in January.

In another effort, BioNetwork has completed the first phase of the re-write of the new Process Technician exam. A company survey focusing on manufacturing associates was sent out this week. This survey is needed to validate the knowledge and skills that will be on the exam. [Click](#) to find out more and participate.

For more information about the two initiatives, visit ncbionetwork.org/BioWork or contact [Vernon Shoaf](#), Senior Director, BioNetwork Learning Solutions Center.

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NIIMBL and FDA Sign Agreement to Support Innovation in Biopharma Manufacturing

The National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) announced that the University of Delaware, on behalf of NIIMBL, has entered into a Collaborative Research and Development Agreement (CRADA) with the Food and Drug Administration (FDA). The FDA and NIIMBL will have the ability to collaborate in a pre-competitive environment to strengthen research, innovation, training, and collaboration in the biopharmaceutical manufacturing industry. NC BIO, NC Biotech Center, BTEC, BRITE, BioNetwork, UNCW, and other North Carolina academic institutions are participating in NIIMBL. [More](#)

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NC Biotechnology Center (NCBiotech) Awards \$2 Million to Boost Bioscience Community

NCBiotech awarded 22 grants and loans totaling \$2,050,778 to universities, bioscience companies and other organizations in the fourth quarter of its fiscal year. The awards, made from April 1 to June 30, will support life science research and technology commercialization throughout North Carolina. The funding will also help universities and companies attract follow-on funding from other sources. [More](#)

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Invest in Cures Forum

[Invest in Cures](#) is a full-day forum that explores how disease foundations are accelerating the commercialization of early-stage technologies and therapies. The program combines main stage

sessions and panel discussions with intimate gatherings and high-level networking. Invest in Cures welcomes researchers, clinicians and investment professionals from leading nonprofit organizations to discuss innovative approaches to supporting and funding translational research and drug development.

There are two events during Invest in Cures. The first is a ***Disease Foundation Forum*** at the NC Biotechnology Center, September 25, 3:00 – 6:00 PM. This event is hosted by LaunchBio, and NC BIO, CED, BioLabs and the NC Biotechnology Center are presenting partners.

The second - UNC's Catalyst for Rare Diseases and the Rare Disease InfoHub are presenting a ***Rare Disease Forum*** on Thursday, September 26, for stakeholders to discuss the status and potential changes required to overcome the research, clinical, regulatory and economic barriers to effective treatment of rare diseases.

[Click to register](#) for one or both events.

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Looking for a Mentoring Program?

Starting a company can be difficult, a great mentor can make all the difference. The Council for Entrepreneurial Development (CED), offers a unique service that approaches mentorship from a team perspective. Venture Mentoring Service (VMS) has helped over 200 entrepreneurial companies make better business decisions through free consulting from top executives in the community. Discover more about CED's Venture Mentoring Service and the vast knowledge base available [here](#).

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Disability Summit at Biogen October 24

“Working Beyond Barriers: Leveraging Inclusion to Drive Behavior and Culture and Change Disability Summit,” is the focus of an event at Biogen's 5000 Davis Drive campus, October 24. The session is in partnership with Disability: In North Carolina. Having a diverse and inclusive culture is critical to performance and organizational growth. Join other leaders to share best practices for organizations at various levels and create a successful blueprint to engage with hiring managers to increase employment for people with disabilities.

Keynote speaker is John Register, Paralympic Athlete and Military Veteran. Event highlights include:

- ERG/BRG Best Practices Panel
- Sourcing Top Talent including People with Disabilities
- Facilitated Round Tables
- Key Take-A-Ways
- Establish an Active Consortium

For more information contact, accessability@biogen.com, and [click](#) to register.

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Informing Innovation 2019 – September 19



[Life Science Intelligence](#) at the North Carolina Biotechnology Center (NCBiotech) is hosting Informing Innovation on September 19. You can get up to speed in life science market research techniques; learn the landscape of scientific literature, patent and business information resources; and receive sources and strategies for finding the data you need to innovate.

Hear from a keynote panel on *Information Needs through the Funding Process*, moderated by Dr. Vivian Doelling, Ph.D., Vice President of Emerging Company Development at NCBiotech. Panelists are:

- Joe Nixon, Vice President of Business Development at Locus Biosciences Inc.
- Eva Garland, Ph.D., CEO of Eva Garland Consulting LLC
- Mike Carnes, Technology Commercialization Counselor at SBTDC

You will also be able to connect with content providers to learn more about the industry tools and resources that are essential to discovery. [Find out more](#) and [register](#).

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At the National Level

Senator Thom Tillis Receives Award for Support of Medicare Part D



Senator Thom Tillis receives award

NCBIO joined Meals on Wheels of Wake County, NAMI-NC, and the American Cancer Society Cancer Action Network, to present Senator Thom Tillis with the Partnership to Fight Chronic Disease's **2019 Champion for Healthy Seniors Award**. Senator Tillis' protection of Medicare Part D and his support of what Part D does for some of the sickest patients including those with chronic conditions was the impetus for the award. Senator Tillis had a short tour of the Meals on Wheels operations, followed by a thirty-minute discussion with the group and the award presentation. NCBIO reminded the Senator of the importance of innovation and North Carolina's role in both innovation and manufacturing. Senator Tillis also discussed the importance of IP as the lifeblood of the industry. He continues to be a strong advocate for the industry and for keeping the patient at the forefront of legislative action.

Efforts Continue to Repeal Medical Device Tax

NCBIO is continuing work with AdvaMed, MDMA and other groups to repeal the Medical Device Tax

before the current suspension of the tax expires at the end of the year. The groups plan to send a letter to U.S. House and Senate leadership urging action on the tax. As the letter states, "At a time when the federal government is working to promote investment in U.S. industries of the future, it is inconsistent that a tax of this magnitude is placed on the medical device industry. We must do all we can to encourage and promote research, development, investment and innovation, and we remain dedicated to working with Congress to finally repeal the medical device tax this year." For more information, contact [Sam Taylor](#).

Upcoming National Events: NCBio Members Can Get Discounts

[MDMA's 12th Annual Medical Technology Executive Forum](#) is being held on September 13th at the Crowne Plaza Cabana in Palo Alto, CA. NCBio members can get a \$100 discount. MDMA's Medical Technology Executive Forum will bring together 150 CEOs and senior executives to discuss the critical issues that affect product commercialization and the common challenges faced by med-tech companies today. Contact NCBio Events Director [Amber Niebauer](#) for your \$100 discount code off nonmember registration. For additional information, contact Sheri DeVinney at sdevinney@medicaldevices.org or call 202-354-7171.

[The MedTech Conference](#) by AdvaMed is September 23-25 in Boston. The event features world-class plenary speakers, cross-cutting programming, valuable networking and business development opportunities. NCBio members can save 10% on [registration](#). Contact NCBio Events Director [Amber Niebauer](#) for the discount code.

The [Bio Investor Forum](#) is October 22-23 in San Francisco. It is an international biotech investor conference focused on investment trends and opportunities in life sciences, with unbiased emphasis on venture-stage growth and emerging public companies as well as those poised to join the growth "watch list" in 2020. Find out more about [registration](#).

Nine New Members Joined NCBio



Representatives of new NCBio members - Joe Bastine (Aerotek), Sue Meecham (NALA Systems), Christopher Crean (Xyzagen), Vanessa Procter (Sage Therapeutics), Stephen Williams (Aerotek), Phil Ball (Allergan) and David Liverett (EASi)

The NCBio Board of Directors approved membership for nine new members at the August meeting. The new members are:

[Aerotek](#) is a staffing agency that specializes in clinical and scientific, engineering, industrial and accounting recruiting and staffing services.

[Allergan](#) is a global pharmaceutical leader with over 17,000 employees, focused on developing, manufacturing, and commercializing branded pharmaceutical, device, biologic, surgical & regenerative medicines for patients worldwide.

[EASi](#) is a global services company specializing in engineering and sciences with an experienced team of consultants that deliver services across a range of industries, including energy and utilities, transportation, heavy equipment, consumer and industrial products, medical devices, pharmaceutical and biotechnology, as well as academic and health care research.

[Isolere Bio](#) is developing innovative, non-chromatographic protein purification solutions by combining affinity with stimulus-responsive phase separation.

[NALA Systems](#) is dedicated to bringing new reverse osmosis membranes to market to challenge the performance, efficiency, and durability of the current commercial products and expand the window of treatable water while reducing required pretreatment.

[Phelps Dunbar](#) provides creative legal solutions to life science clients throughout the south and nationwide. The lawyers at Phelps Dunbar work together across many legal disciplines, including admiralty, business, insurance and reinsurance, litigation and labor and employment, to ensure that clients meet their goals and objectives, whether it is a Fortune 500 corporation or a small, local company.

[Porzio Life Sciences](#) (PorzioLS) strives to improve the efficiency of life science departments, including sample compliance, legal, regulatory, governmental affairs and marketing and sales. They help pharmaceutical, medical device and biotechnology companies, wholesale distributors, labelers, sales and sales support companies master the continually changing regulatory environment that impacts their business.

TriPharm is a state-of-the-art contract manufacturer (CDMO) that offers a wide variety of fill finish services to pharma and biotech clients.

[Xyzagen](#) is a boutique, client focused, contract research and consulting organization with a focus on 505(b)(1) and 505(b)(2) early drug discovery, nonclinical pharmacology & pharmacokinetics, clinical pharmacology/PK and regulatory IND/NDA strategy, and submission writing and consulting.

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Member News

To be included in Member News, send information about your organization to [Brenda Summers](#)

[Asklepios BioPharmaceutical, Inc.](#) (AskBio) and Selecta Biosciences, Inc. announced a strategic partnership to jointly develop, manufacture and commercialize targeted therapeutics for life-changing, next-generation adeno-associated virus (AAV) gene therapies in areas of high medical need. This partnership will leverage the unique proprietary technology platforms of both companies with a human proof of concept trial to validate the potential for re-dosing in patients with genetic diseases. [More](#) AskBio acquired Synpromics, the leader in gene control synthetic promoter technology, bioinformatics and intelligent data-driven design that enables more precise cell targeting and gene expression. [More](#)

[Eva Garland Consulting, LLC](#) (EGC) continues to secure its reputation as one of the most rapidly growing companies in the U.S. by capturing the 928th spot on this year's Inc. 5000 list. Since 1982, the Inc. 5000 list has honored the fastest growing privately held companies in America. EGC is being recognized on the list for the second year in a row as a result of the company's strong performance over the three-year period of 2015-2018. [More](#)

[G1 Therapeutics, Inc.](#) announced the appointment of Mark Avagliano as Chief Business Officer. [More](#)

[Glycan Therapeutics](#) received SBIR Phase-II support (\$2.4 million) in July from NIH-NHLBI for development of a new carbohydrate-based anticoagulant drug. The funding supports scale-up of a 100% synthetic heparin molecule for early phase clinical trials and IND enabling studies. Synthetic heparin is a single molecular entity amenable for straightforward quality control and regulatory process, eliminating the risk of adulteration. Glycan is changing the century old practice of sourcing heparin from animal species and near complete reliance on imports. The synthetic heparin drug will be manufactured under tight regulatory control and completely sourced domestically.

[GSK](#) announced that Jack Bailey, President U.S. Pharmaceuticals, has decided to step down from his role at the end of the year. Bailey will be succeeded by Maya Martinez-Davis, currently Regional President, Latin America Region at EMD Serono, the biopharmaceutical business of Merck KGaA, Darmstadt, Germany. [More](#)

[Heat Biologics, Inc.](#), a clinical-stage biopharmaceutical company specialized in the development of therapeutics designed to activate a patient's immune system against cancer, announced that the U.S. Food & Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application to initiate a Phase 1 clinical trial of HS-130, in combination with HS-110, for patients with advanced solid tumors refractory to standard of care. [More](#)

[IQVIA](#) announced its launch of the IQVIA Patient Portal, a global web-based solution built on a leading health cloud platform. This innovative tool enables increases in clinical trial patient recruitment, engagement and retention by ensuring transparency and collaboration before, during, and after a clinical study. [More](#)

Two [Jenkins Wilson Taylor and Hunt](#) attorneys are included in the 2020 edition of *The Best Lawyers*

in America for Patent Law. Jeff Wilson and Arles Taylor were listed for their work in Patent Law. [More](#)

[Metabolon](#) and three national research groups are teaming together to discover the frailty biomarkers that may shed light on why some people become frail, determine the severity of frailty and what can be done to help avoid the condition. The Canadian Frailty Network, the Canadian Longitudinal Study of Aging (CLSA), the McMaster Institute for Research on Aging (MIRA), and Metabolon, Inc. have announced a collaborative partnership to develop a \$4M research program. [More](#)

[Novo Nordisk](#) has purchased an existing tableting facility in Durham. Novo Nordisk will utilize this additional manufacturing and packaging site to continue its mission to defeat diabetes, specifically, creating U.S. to U.S. supply of future oral diabetes tablets.

[PPD](#) and NeoGenomics announced the grand opening of a NeoGenomics oncology-focused clinical trials testing lab in the same building as the PPD Laboratories central lab in Singapore. [More](#)

The FDA announced its approval of pretomanid, a new drug developed to treat Extensively Drug-Resistant Tuberculosis (XDR-TB) and treatment intolerant/non-responsive Multidrug-Resistant (MDR) TB. [RTI International](#) (RTI) scientist Dr. Doris Rouse and her team have collaborated closely with TB Alliance on the development of pretomanid for almost 20 years. [More](#)

[Syneos Health](#) announced that [CEO Alistair Macdonald](#) has been named to PharmaVOICE magazine's annual list of the 100 most inspiring leaders in the life sciences industry. [More](#)

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BIO Business Solutions



Last year BIO saved 4,200 companies nearly \$460 million through BIO Business Solutions with volume-based discounts and favorable contract terms on lab supplies, waste removal, microscopes, shipping, gases, and more.

NCBIO members, you are eligible! This is a benefit of your NCBIO membership. Review the cost-savings offered by clicking [here](#) and choose the programs you're interested in. Email biobusinesssolutions@bio.org with your choices and they will get you started. For all the latest news, promos, and event information, follow [BIO Business Solutions on LinkedIn!](#)

CHUBB

Chubb is now offering BIO members insurance protection for small & emerging life sciences companies. BIO's endorsed provider, Chubb, has enhanced their coverage for startup and early stage organizations with the creation of Chubb's Business Owner's Policy, Chubb BOP, for small businesses up to \$30 million in revenue. What type of life sciences organizations benefit from BOP?

- Biotechnology, pharmaceutical, and medical device manufacturers and distributors
- Life science research and development companies
- Dietary supplement and nutraceutical manufacturers and distributors

What are some of the common needs that Chubb will cover?

- Research and development property is included within the automatic blanket limit of insurance up to \$500,000
- Change in controlled environment up to \$250,000
- Condemnation of undamaged stock up to \$250,000

- Contamination not otherwise insured up to \$250,000
- Personal property off-premises up to \$75,000
- Scientific animals up to \$100,000

More Info On Bio-Chubb Offering

Chubb is the marketing name used to refer to subsidiaries of Chubb Limited (NYSE: CB) providing insurance and related services. For a list of these subsidiaries, please visit Chubb's website, www.chubb.com. Chubb provides commercial and personal property and casualty insurance, personal accident and supplemental health insurance, reinsurance and life insurance to a diverse group of clients. Chubb®, the Chubb® logo and Chubb. Insured.SM are trademarks of Chubb. All products may not be available in all states. Surplus lines insurance sold only through licensed surplus lines producers.

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Calendar

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

[LaunchBio: Larger than Life Science](#)

Thursday Sep 5, 2019

... [read more](#)

[GSK and UNC: Jointly venturing to find a cure for HIV/AIDS](#)

Thursday Sep 5, 2019

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[NCSU International Symposium: Precision Systems and Data Analysis in Animal Agriculture](#)

Monday Sep 9, 2019 - Tuesday Sep 10, 2019

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[MDMA 2019 Medical Technology Executive Forum](#)

Friday Sep 13, 2019

... [read more](#)

[NCBiotech Ag Tech Professional Forum September 2019](#)

Wednesday Sep 18, 2019

... [read more](#)

[NCRAF Seminar: Transitioning to a Career in Pharma Regulatory Affairs](#)

Thursday Sep 19, 2019

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[Informing Innovation 2019](#)

Thursday Sep 19, 2019

... [read more](#)

[MedTech Conference 2019](#)

Monday Sep 23, 2019 - Wednesday Sep 25, 2019

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[NCBIO Annual Meeting 2019](#)

Thursday Oct 3, 2019

... [read more](#)

[LaunchBio: Larger than Life Science](#)

Thursday Oct 3, 2019

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

Tuesday Oct 8, 2019 - Thursday Oct 10, 2019

... [read more](#)

[BTEC Hands-On cGMP Biomanufacturing Operations](#)

Tuesday Oct 15, 2019 - Friday Oct 18, 2019

... [read more](#)

[Triangle Global Health Annual Conference](#)

Wednesday Oct 16, 2019

... [read more](#)

[Clinical Trial Supply East Coast 2019](#)

Wednesday Oct 16, 2019 - Thursday Oct 17, 2019

... [read more](#)

[NCRAF Seminar](#)

Thursday Oct 17, 2019

... [read more](#)

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