October 21, 2012

The Southeastern Advanced Nanobiomaterial Manufacturing Institute

In response to the Request for Information on the National Network for Manufacturing Innovation (NNMI)

Submitting Organizations and Points of Contact

Ginger Rothrock, Ph.D.
Program Manager for Emerging Technologies
RTI International
919-541-6025
grothrock@rti.org

John W. Hardin, Ph.D.
Executive Director
Office of Science & Technology (OST)
North Carolina Department of Commerce
919-715-0516
jhardin@nccommerce.com

Griffith A. Kundahl
Executive Director
Center of Innovation for Nanobiotechnology
(720) 219-3896
griff@nanobiotech.org

Derek Schorzman, Ph.D.
Liquidia Technologies

With input from the following organizations:

Xanofi	North Carolina Biotechnology Center	Virginia Biotechnology Association
Syngenta	The University of North Carolina	North Carolina State University
Novozymes	Milliken & Company	Semiconductor Research Corporation
GlaxoSmithKline	Forsyth & Wake Technical Community College	The Joint School of Nanoscience and Nanoengineering
SAS		

Nanobiomanufacturing as a critical national need

Nanotechnology is viewed by the United States and throughout the world as a critical driver of future economic growth and an advanced technology capable of solving some of humanity's most vexing challenges. Realizing this potential requires progress on many fronts of manufacturing science and engineering. Ultimately, it will take reliable tools and processes for assembling the basic building blocks of nanotechnology products, cost-effectively producing these products in large quantities, and integrating them into systems spanning nanoscale to large-scale dimensions. Developing these core competencies in the United States will lead to a new, more sophisticated manufacturing sector.

Advances in nanobiomaterials have the potential to revolutionize the pharmaceutical industry, by dramatically improving prevention, diagnosis and treatment. Nanobiotechnology refers to highly specific medical intervention at the molecular scale for preventing, curing and treating disease. At this sub-micron size scale biological molecules and structures operate inside living cells. Recent advances in nanobiotechnology have led to ultrasensitive assays for identifying and treating diseases at earlier stages than conventional diagnostic tools, new ways of delivering powerful therapeutics to the point of disease within the body without unintended side effects, and the development of entire new classes of pharmaceuticals based upon nanostructures for broad classes of disease such as cardiovascular disease and cancer. Nanobiomaterial technologies have tremendous potential for *transformational results* – disruptive changes over and above current methods and strategies for healthcare, with wide-ranging implications.

Government funds for nanotechnology research have created some of the most sophisticated nanoscience laboratories in the world. Yet, research in nanotechnology to date has been largely focused on the discoveries of novel physical and chemical properties of various metallic, inorganic, or carbon-based materials, with a notable absence of capabilities and funds focused on manufacturing nanomaterials and their incorporation into products. Further, because of the historic, heavy emphasis on inorganic nanomaterials, the gap for manufacturing organic nanomaterials relevant to biotic systems is appreciably larger.

Delivering the many anticipated nanobiotechnology products of the future will require entirely new tools and procedures, scale-up plants, and a work force with a new set of skills. These include cost-effective and quantity-relevant methods for synthesizing and processing particles, tubes, fibers, and quantum dots; positioning, imaging, and measurement at nanoscale resolution; and modeling of manufacturing processes from nanoscale to macroscale. Several of these manufacturing processes are currently being realized in diverse but restricted scale forms, and they will need to be refined continuously to fully realize the promise of future nanotechnology products. The challenge is to build on these achievements and expand them to produce a wider range of structures, providing systems of larger scale, greater complexity, and increasingly higher performance. Key challenges in nanobiomaterial manufacturing processes are summarized below.

1. Scale-up of manufacturing processes from small lot sizes to mass production poses the first key challenge for manufacturing nano-scale products and materials. Process engineers need approaches that use mass production techniques and integrated assembly to reduce costs and accelerate the entry of nanomaterials into commercial applications. Unit operations that comprise these production methods must be scaled successfully and reproducibly from laboratory processes into production rates, while preserving the inherent nanoscale properties in the finished materials. While chemical processes typically deal with an immense number of structures with relatively simple assembly processes, and

electronic processes typically deal with a much smaller number of structures but highly complex assembly processes, nanobiomanufacturing will be called upon to deal with both a large number of structures and a highly complex hierarchical assembly, requiring significant engineering innovations.

2. Integrating bottom-up and top-down nanoscale processes into new manufacturing paradigms is the second key challenge. Today's first-generation nanoproducts are frequently manufactured with traditional manufacturing techniques, which can be prohibitively expensive and/or have limited throughput for many applications. For example, using photolithographic or direct-write methods to produce isolated particles on a "10's of wafers per hour" level would result in milligram quantities of product per day. Even highly touted tip-based nanomanufacturing processes has an inherently low rate of production in terms of mass throughput, producing 1×10^{-21} grams of product per batch in 2007. (Productive Nanosystems: A Technology Roadmap" 2007 Battelle Memorial Institute and Foresight Nanotech Institute). Current macroscopic assembly processes such as crystallization and mixing do not readily lend themselves to the fabrication of hierarchical systems of nanostructures.

3. Advanced analytical tools for probing and metrology that extend beyond optical resolution pose the third challenge to manufacturing processes. Nanomanufacturing processes must have effective control systems with accurate, timely measurements and rapid data assessment and response parameters. Advancements in high-volume, cost-effective production depend on the development of next-generation instrumentation for accurate and rapid characterization of nanomaterials. Optical methods currently used in metrology can be accurate, fast, and integrated in-line for process control, but have reached their detection and resolution limits for probing nanoscale structures. Integrating the process control components at the nanoscale will require a long-term commitment to R&D in diverse science and technology fields.

4. Uncertainty surrounding the Environmental Health & Safety (EHS) aspects of nanotechnology pose a realistic concern for industrial hygiene and occupational safety in the nanomanufacturing environment, in addition to consumer exposure to nanomaterials. Recent reports by NSET and the National Academies reflect the need to incorporate responsible processes for predicting and monitoring the risks inherent in human exposure across the product lifecycle. Understanding the potential for hazard, and establishing standard measurement practices to maximize data quality in the nanomanufacturing environment is of the highest priority to ensure commercial success with nanobiotechnology.

Specifically for nanobiomaterials, the ability to manipulate size, shape, chemistry and modulus of nanomaterials can have wide-ranging impact on how we diagnose and treat disease. New abilities to tune these features can provide researchers with a more thorough understanding of "how" and "why" cellular and organ systems react, allowing scientists to build highly efficient tools that can safely operate inside the body. New technologies that have the power to control size, shape, and other functionalities are currently being developed and have shown remarkable promise, but significant investment in *scaling-up* and producing engineered nano-structures in a *c*GMP environment is necessary to bring innovations to commercial reality. The technology has the potential to create new US-based industries, lower the cost of health-care, and positively impact human life.

Existing Efforts. Research activities in nanotechnology are an international effort. The U.S. has adopted a multidisciplinary approach and passed a bill in 2003, the NANO ACT, to encourage the "creation of partnerships, raise awareness, and implement strategic policies to resolve obstacles and promote nanotechnology." This Act along with other funding through the National Nanotechnology Initiative (NNI), to date, accounts for over $20 billion in federal investment in nanotechnology. In the US alone, there are currently more than 150 institutes and centers dedicated to nanotechnology R&D across the country, as well as focused efforts within multiple agencies. While there are multiple opportunities to investigate basic research on materials synthesis and characterization, including nanocomposites, atomic-layer deposition for nanoelectronics patterning, templating polymeric and biomolecular systems, directed assembly of 2D and 3D structures and modeling/simulation, there are few opportunities to translate these processes to commercial production. In the U.S., the NNI has been instrumental in focusing world attention on nanoscience and has provided world leadership in establishing the necessary interdisciplinary research. A major opportunity exists to leverage the past eleven years of NNI research platforms and to establish programs to translate this knowledge into viable products through the advancement of atomically precise technologies

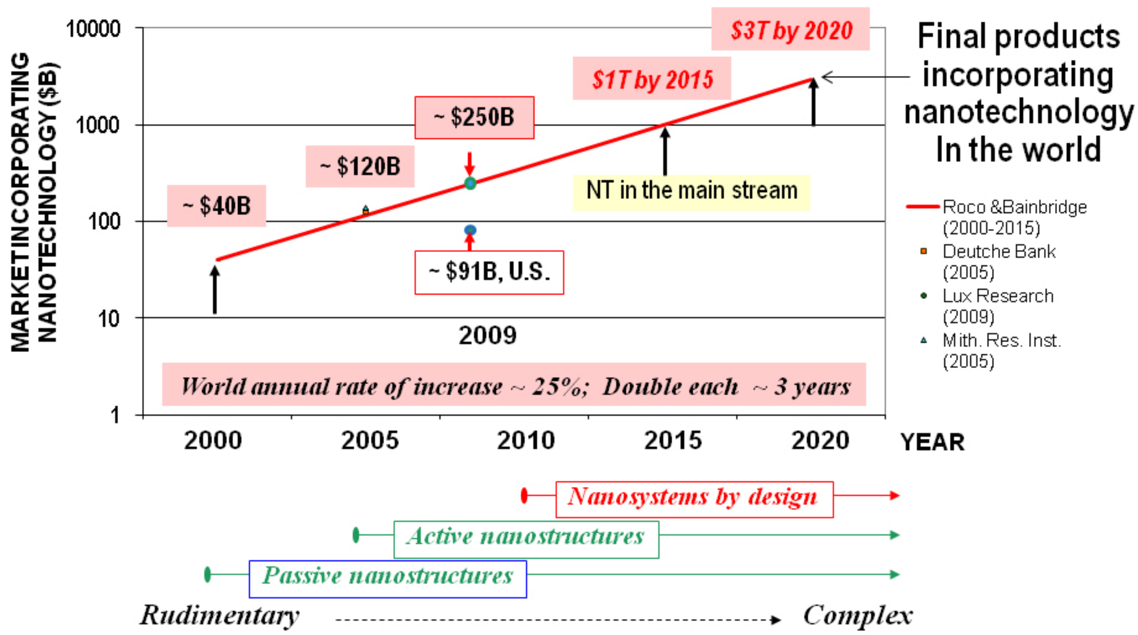
Based on the level of funding already given, there is no doubt that nanotechnology development is a national priority. The most recent report of the Interagency Working Group on Manufacturing R&D emphasizes that manufacturing R&D must go hand in hand with scientific discovery to ensure that US manufacturers can quickly transform innovations into products and processes. Nanomanufacturing is the means through which the Nation will realize the benefits of nanotechnology. These benefits are being realized through enhanced performance of products in a wide range of industries that include aerospace, automotive, communications, energy, environmental remediation, information, medical, pharmaceutical, and power. At the same time, realizing the promise of nanotechnology through the development of practical manufacturing methods will likely lead to industries and products yet to be imagined.

Market overview

.Nanobiotechnology represents a significant, thriving market, with pharmaceuticals representing the largest life science sector. The total market size in 2021 was recently forecasted to be US$136 billion, with a 60/40 split between nanocrystals and nanocarriers respectively; although developing new targeted delivery mechanisms may allow more value to be created for companies and entrepreneurs (Nanotechnology for Drug Delivery: Global Market for Nanocarriers, Cientifica, 2012). The market for “nano-enabled” pharmaceutical packaging is also growing 16.5% per year and will be worth $8.1bn by 2014 according to new research by iRAP.

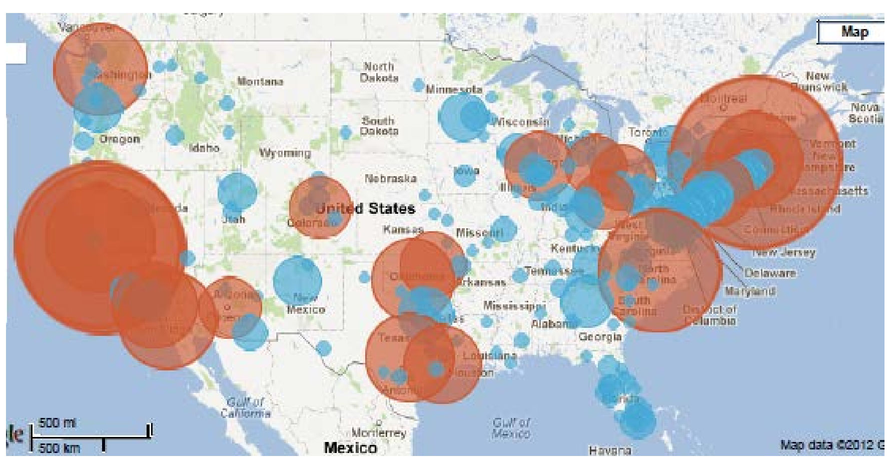
A recent federal government report marking the ten-year anniversary of the National Nanotechnology Initiative stated that, “the value of products incorporating nanotechnology as the key component reached about $200 billion in value worldwide in 2008, of which about $80 billion was in the United States (these products relied on relatively simple nanostructures). The estimation made in 2000 for a product value of $1 trillion by 2015, of which $800 billion would be in the United States, still appears to hold [see chart on next page]. **The market is doubling every three years as a result of successive introduction of new products**.” (M. Roco, "The Long View of Nanotechnology Development: The National Nanotechnology Initiative at Ten Years," 2011.)

Globally, there are many other countries that are poised to take advantage of the anticipated growth of this sector. The clusters around the world that are able to strategically organize, look to the future, and leverage their existing strengths and assets are the clusters that will garner the largest share of this emerging and huge global market.



North Carolina and its neighboring states as a leader

The largest US hubs of nanotech research and development include Boston, San Francisco, Houston/Austin and Research Triangle Park, although clusters of nanotechnology and nanobiotechnology are developing nation-wide, as evidenced by work from The Project on Emerging Nanotechnologies (PEN):



North Carolina, a state which successfully realized rapid job growth in the biotech sector over the past three decades through strategic and innovative economic development programs, is now very well-positioned to achieve the same success in the development of nanotechnology and other advanced technology workforce training and education. Partnering with neighboring communities along the I-85 corridor, including Richmond, VA through Greenville, SC, enables the generation of a cluster of large and small companies, institutions, innovation-led economic development groups to address the immediate manufacturing needs of the nanobiotech community. These areas are already home to over 100 companies and 50 research labs that focus on nanotechnology-based advanced materials and advanced manufacturing. This Southeast initiative builds upon the states' eminent positions in biotech, nanotech and manufacturing to focus on fast-prototyping capabilities, an emerging supply of advanced materials, and innovative manufacturing platforms for use in nano-enabled healthcare products. In a broader sense, the combination of the region's well-established life sciences cluster, acclaimed workforce education and development infrastructure, the individual states' collaborative multi-stakeholder ecosystem (including bottom-up and top-down support), and the rapidly emerging and massive global market for nanotechnology-enabled products, demonstrate high potential for success and sustainability of this manufacturing initiative.

A recent report from the Southern Growth Policies Board (Connecting the Dots: Creating a Southern Nanotechnology Network) identifies the following as summary of their key findings:

- Between 15-20 percent of all U.S. nanotechnology research activity occurs in the Southern Growth region with every Southern Growth state publishing nanotechnology articles, producing nanotechnology dissertations and winning nanotechnology grants.
- The Southern Growth region contains national and global leaders in nanotechnology research such as universities in Georgia, North Carolina and Virginia and at Oak Ridge National Laboratory (ORNL) in Tennessee.
- The region's industry segments largely reflect the U.S. distribution, with the Southern Growth region being slightly stronger in materials and biology.
- Nanotechnology companies cite the abundance of talent and overall quality of life as major assets of the region and lack of venture capital and national recognition as weaknesses.

Similarly, PEN has compiled more detailed data demonstrating how and where nanotechnology is being developed and commercialized in the United States. In general, NC ranked in the top 10 for: nanotech companies, academic institutions, and organizations with an 8th overall ranking for nanotech state, and Raleigh as the 3rd-highest nano metro area, in PEN's most recent analysis.

North Carolina's economic efforts in Nanobiotechnology: Given the significant federal investment that was being made in nanotechnology, N.C. looked to take advantage of its history in technology development and innovation. In the spring of 2005, the Governor's Task Force on Nanotechnology and N.C.'s Economy developed a roadmap as a call to action (A Roadmap for Nanotechnology in North Carolina's 21st Century Economy, 2006.) for N.C.'s political and policy leaders, industry, research institutions, educators, and the public to:

- Increase the state's ability to innovate;
- Increase the levels of collaboration between companies and R&D centers;
- Develop a well-educated and trained workforce;
- Provide a supportive public and political policy environment; and
- Diversify the state's technology cluster portfolio to include nanotechnology.

In 2009, the Center of Innovation for Nanobiotechnology (COIN) was launched as to further many of the goals of the N.C. Nanotechnology Roadmap as they pertain to life sciences. The cumulative efforts of the multi-agency taskforce, the COI program, NCBC, and COIN demonstrate strong regional support and a strategic effort by multiple stakeholders in a thriving ecosystem.

The Proposed Institute

The Southeast region is ideally suited to host one of these federally funded Institutes of Manufacturing Innovation with a focus on micro and nano materials for therapeutics, medical devices, and environmental health science applications to enhance the performance and effectiveness of healthcare products

Nanotechnology research is still in its infancy, and it may be at least five years or more before the first generation of truly *engineered* nanoproducts and nanodevices become commercially available. The pharmaceutical industry continues to evaluate the potential of new technologies to alleviate the burden of rising research costs, improve the speed and efficiency of the discovery process, and create high-value new generation therapeutics. While nanotechnology is widely seen as having huge potential, the pharmaceutical industry remains cautious to the idea it will be the universal remedy to their problems. This may be a primary reason why companies have been slow to invest resources in this area (Lux Research). Pharmaceutical companies have generally taken a "watch and see approach", and relatively few have established dedicated laboratories to explore the capabilities of nanotechnology in the market. Instead, companies continue to evaluate the potential of this technology through alliances with academic researchers and leading institutes, without addressing the "800 pound gorilla" of manufacturing scale-up.

The proposed mission of the institute is to address historical challenges associated with transitioning emerging technologies from small, lab-scale processes to high volume manufacturing, by providing facilities, equipment and knowledge to achieve pilot-scale manufacturing of nanobiomaterials and aiding in the development and assessment of subsequent nano-enabled products. The institute will focus on nanobiomanufacturing innovation, with input from technology end-users. The institute will be inclusive and favorable to small and medium sized companies, have a component of workforce development and become self-sustainable.

The Proposed Institute Focus

Institute members would select manufacturing platforms and resulting nanomaterials for development and production within the institute, and would have exclusive access to the materials for further assessment in downstream products. Technology "users" would then assess multiple platforms simultaneously at a fixed cost, allowing technology "contributors" to reach meaningful scales with less risk, at an exceedingly fast pace due to pre-negotiation and agreement to licensing, IP, and other provisions defined by the institute. Membership within the institute would consist of paying members, or technology "users", and members that are technology "contributors". Members include large companies with commercial products, small and medium-sized enterprises (SMEs), academic institutions and non-profit organizations. Large organizations with a vision toward U.S, manufacturing and global competitiveness, as well as SMEs with unique new nano-manufacturing platforms, are strongly encouraged to participate.

The proposed structure for institute operation includes an advisory board consisting of representatives from the member organizations who will select: (1) existing and emerging nano-manufacturing technologies, and (2) specific nanobiomaterials to create a “menu” of nanobiomaterials available through a foundry model.

Through this institute, we seek to establish a **Nanoparticle Foundry** much in the way that the Department of Energy through Lawrence Berkeley National Laboratory established the Molecular Foundry. The establishment of the Nanoparticle Foundry would address a key bottle neck for the generation of ideas and would play an important role in establishing our Nation’s preeminence in nanomanufacturing which is crucial to establishing and growing jobs in the US. There is a need for “qualified” nano- and micro-materials with control in particle size, shape and chemical composition and that are available at a scale useful for a broad range of scientific studies. The need for such “qualified” materials is different than the need being fulfilled by the nano-standards being developed by NIST which are mainly useful for very high end technology needs, like the calibration of measurement instrumentation. Rather, “qualified” materials are materials that are almost of the same quality as the standards being developed by NIST but meet additional specifications to allow for utility across differentiated industries, including larger quantities at lower costs than that associated with NIST calibration standards. Additionally, a set of well characterized materials (environmental and health) that represent the types of nanomaterials that are incorporated into products is needed to address many of the unknowns that could cause public distrust. While EH&S research has always been a focal point for the NNI, we need to ensure that the nanomaterials used for this research are the same classes of materials used for consumer products and are tested in a relevant context.

The technologies proposed will generate a host of novel organic nanomaterials, a unique capability that is crucial for evaluating life science applications. Through the technology providers of nanomanufacturing processes, one can allow researchers to have access to materials in meaningful volumes useful for many real world studies that NIST calibration standards are not suitable for. For example, important studies are needed and could be accomplished if “qualified nano-standards” were available such as aerosol standards (for inhalation studies, particulate distribution studies in cities and buildings, etc); environmental standards (for ground water fate studies, etc) and organic materials for *in vivo* biodistribution studies. The successful implementation of mass production methods for the fabrication of “smart” particles and fibers customized for specific uses, through the establishment of a Particle Foundry, will be an important technological breakthrough that will emerge to be a new tool for advancing our understanding and treatment of diseases. The institute will support the development of reference materials, test methods, and other standards that provide broad support for industry production of safe nanotechnology-based products.

Pilot-scale manufacturing equipment will be installed and operated within the institute by a combination of full-time staff, visiting scientists, consultants, contractors, and/or students, as required for each platform. Member organizations will then be given exclusive access to quantities of the nanobiomaterials for integration and prototyping in their desired product lines within the bounds of the membership agreement. Based on initial results, further modifications to the materials based on product design will be accessible, resulting in a nanomanufacturing process and nanomaterial product with a clear path to large-scale commercialization outside of the institute.

Candidate manufacturing platforms selected for implementation will include those that produce unique advanced materials of interest to the biomedical device, therapeutics, and health science sector, including: particles, nanofibers and wires, nano-textured films and coatings, membranes, and many more. Candidate nano-enabled product areas may include: engineered drug delivery and targeting, calibration standards, diagnostic devices, sensors, medical imaging, environmental safety testing, nanoparticle pharmacodynamics/pharmacokinetic studies, nanoparticle toxicology analyses, coatings and components for biomedical devices and tissue engineering, and others.

There are number of technology innovations that are and can be driven through government funding to a scale that will stimulate the industry:

- nano-engineered drugs can be designed to improve the therapeutic potential of approved or shelved products;
- nano-engineered drugs may improve dosing regimens, reduce drug dosage and potentially reduce the cost of treatment in the longer-term;
- nano-engineered drugs may open up new opportunities to target disease;
- nano-enabled delivery systems have the potential to deliver approved and new products in a targeted manner and thus reduce off-target effects;
- nano-enabled delivery systems have the potential to deliver a wide-range of "difficult-to-deliver" products such as large macromolecules (e.g. peptides & proteins) or toxic small molecules (e.g. chemotherapy agents);
- new nanomaterials may have potential applications in medical devices and implants;
- nanomaterials and nanosensors have potential applications in medical imaging, diagnostics and point-of-care helping to detect disease earlier

The Institute governance will build upon the foundation of the established, proven organizational models of programs including NIST MEP, Flexible Display Center in Phoenix, AZ and the Center for Advanced Microelectronics Manufacturing (CAMM) in Binghamton, NY. These groups have successfully developed structures amenable to industry participation and such structures will serve as a baseline for the Nanobio Institute. RTI International, with expertise relevant to such organizational models, is an efficient, nonprofit organization employing experts in essential roles of program management, manufacturing and industrial engineering, outreach, communications, administration and contracting/financial management. The newly established Institute will capitalize on and benefit by direct access to this professional expertise, ensuring a rapid start-up with an experienced and trained staff, facilities, and procedures.

Initial Partners and Structure

The Southeast is a dynamic cluster of academia, industry, technology and commercialization experts, manufacturing organizations, educational institutes and SMEs. The Nanobio Institute will build upon the region's reputation as a center of manufacturing innovation, and capitalize on the current strengths in biotechnology, nanotechnology, and information technology. The Proposed Institute has a strong SME engagement focus which will be facilitated by the state MEP Centers, established economic development organizations including the Department of Commerce, Virginia, North Carolina and South Carolina Biotechnology Centers, and COIN, the Center of Innovation for Nanobiotechnology, and non-profit institutions such as RTI International. Workforce development will be coordinated through a network of educational organizations which have a strong record of advanced technology training. Large and small industry will direct and support the development of advanced technology products relevant for NIH, DoD and commercial applications. The region has world-leading academic institutions and medical centers, including UNC Chapel Hill, Duke, NC State University, Virginia Commonwealth University, and others to provide a pipeline of new, innovative nanobiomanufacturing approaches. In fact, over half of the SMEs involved in the initial RFI are university start-ups. To partner with the technology providers are a host of large, multi-national pharmaceutical, medical device, agricultural and support firms that include GlaxoSmithKline, Merck, Wyeth, Novozymes, Abbott Laboratories, Boehringer

Ingelheim, BASF, Syngenta and Johnson&Johnson, to name a few. This institute will serve to enable the innovation ecosystem requiring expertise, entrepreneurship and commercialization capabilities from universities, SMEs, and large industry necessary to drive the development of advanced nanobiomaterial products.

Partners, advisors and beneficiaries of this project represent a broad group of academia, industry, economic development and research and development organizations, including but not limited to the list below. A large majority of these groups have given input with regards to the nanobiotechnology focus and strategic mission of the proposed Institute:

Government and Economic Development:

- Center Of Innovation for Nanobiotechnology (COIN)
- National Nanotechnology Coordination Office
- The Office of the Governor of the State of North Carolina
- The N.C. Department Commerce Office of Science and Technology
- The North Carolina Biotechnology Center
- The Virginia BioTechnology Association (VaBIO)

Academia:

- Forsyth Technical Community College
- Wake Technical Community College
- The Joint School of Nanoscience and Nanoengineering
- North Carolina State University, The Nonwovens Institute
- The University of North Carolina at Chapel Hill
- Virginia Commonwealth University

Industry:

- Liquidia Technologies
- Novozymes
- Xanofi
- GlaxoSmithKline
- SAS
- PPD
- IBM Life Sciences
- Lab21
- Milliken & Company
- Wyeth
- Syngenta
- AdvanceTEC

Non-Profit and For-Profit Industry Support:

- RTI International
- NSF National Nanotechnology Applications and Career Knowledge Network (NACK) at Penn State
- Research Triangle Park Partnership
- Semiconductor Research Corporation (SRC)
- The Virginia Partnership for Nanotechnology Education and Workforce Development

The Institute will aim to provide technology users with up to 6 nanobiomanufacturing technologies ("cores") at various stages of development; 3-4 technologies will be permanent installations and 2-3 technologies will rotate to ensure the Institute technology remains current. An Open Innovation process will be used to select the technologies for installation and rotation. As SMEs represent the largest segment of nanotechnology providers, we anticipate that at least 4 of the 6 nanobiomanufacturing cores will be SME-driven. These will be supported by nano-specific, technology-agnostic analytical capabilities and EHS support. The institute will utilize economic development partners to engage large businesses in the development of specialized supply chains to bring nanobiomaterials of interest to the desired commercial applications.

Background intellectual property and that generated by the Institute must be managed in a manner that is favorable to small and large businesses alike. The Institute will ensure that the IP generated and needed for the Institute research purposes is available for its members. Freedom to Operate (FTO) is extremely important and will be addressed from an early stage. RTI International will manage access to the IP and maintain confidentiality for project teams. A separate, independent firm will serve as licensing broker to ensure the self-sustainment of the Institute. Government agencies will retain government purpose depending on the funding source and contract terms. Members will agree to disclose any background IP in their control that is needed by a member to practice. Use of background IP will be on a royalty free, non-exclusive, non-assignable basis when needed to perform under the Institute agreement. Ownership of background IP will remain with the licensor. Institute Members are required to respect the proprietary data rights and prevent the disclosure of data identified as proprietary to unauthorized persons. The Institute will strive to enable the open exchange of manufacturing information and best practices. Provided the material is not subject to non-disclosure obligations, the results of research to be disseminated will be submitted to the members at least 30 days in advance to gain approval and identify potential proprietary information.

We anticipate three broad classes of IP generated or utilized:
Collective IP: IP generated and owned by the Institute and applied for the good of the Institute.
Individual IP: IP generated and owned by an individual member or user of the Institute
Shared IP: IP generated and owned by two or more members of the Institute or members and the Institute itself.

Sustainability and Impact

The business plan for the Nanobiomaterial manufacturing Institute focuses on providing advanced material technologies that meet critical, immediate needs in the pharmaceutical and agricultural commercial markets as well as the defense sector. The Institute builds on a foundation of existing relationships between the universities, SMEs, large biotech/pharma/agtech companies and economic development groups already co-located within the region. These relationships can be expanded, increased, and strengthened tremendously through the access to the broad array of nanobiomaterial technologies offered by the proposed Institute in a cluster-type model. Through key Institute partners such as RTI International, the Institute has direct access to business practices, professional contracting and financial staff able to handle large government contracting vehicles and complex intellectual property agreements. Projected revenue will be generated through Insititute membership fees, test nanomaterials produced through the particle foundry, industry funded development projects and royalties from licensing agreements. The Institute will benefit from cost sharing capabilities of its partners that include facilities, manufacturing and analytical equipment, and labor, which will augment the investments made by state and local governments. This infrastructure will enable the government's investment to be maximized in the R&D areas of nanomanufacturing including scale-up, process control, online nano-specific analytical tools and nanoEHS, in addition to technology transfer and workforce development efforts. The Institute will be staffed with full-time scientific and engineering personnel working side-by-side with member-provided staff to create a collaborative, open-access environment.

Using toolkits developed for monitoring economic impact, the Institute will track progress towards short and long-term goals, to include: industry engagements, intellectual property generated, workforce trained (including students, faculty and industrial employees), job creation, licenses granted, new products introduced, new companies formed and venture capital investment gained to estimate the value creation. As the Institute grows with new member companies and technology users, we anticipate the needs of the membership will shift as technology gaps close, technologies "graduate" to full commercial utility and new technologies are introduced. The business model will be designed to be flexible, with regular updates driven at the member Board level.

Education, Training and Workforce Development

This aspect focuses on the development of an educational model for workforce training in advanced technologies by leveraging existing assets in the southeast, a recognized global leader in biotechnology with an established and proven infrastructure in many industry-critical areas, including workforce development. Established some 30 years ago, the North Carolina Biotechnology Center (NCBC), the first of its kind in the world, coordinates the state's efforts in attracting and supporting the biotechnology industry with, among other things, a strong network of educational programs that provide a world-class workforce. NCBC also has the benefit of a centralized and coordinated statewide system of 58 community colleges. We aim to leverage existing assets from nationally established programs that have developed education materials, courses, curricula, strategies, and methods, specifically in the area of nanotech and similarly emerging technology fields, such as NSF's National Nanotechnology Applications and Career Knowledge Network (NACK), Nano-Link and others

Rapidly emerging and transformative technologies based upon advanced materials are dramatically changing traditional processes in biotech and in other industries, demanding a workforce with new skillsets. Although pockets of educational programs in advanced technologies have surfaced in NC, SC and VA there is no database available locally or regionally that defines workforce needs so that effective programs can be designed, nor is there a plan that defines or connects educational efforts across states so that a job-ready workforce can exist.

Focus areas

Activities to be undertaken include: (1) Program Development and Improvement, (2) Curriculum and Educational Materials Development, (3) Professional Development of Educators, (4) Manufacturing and Entrepreneurial Skills Development for Students, (5) Professional Internships and (6) Conferences and Workshops. Preliminary research points to the development of an educational model that emulates the region's successful history of workforce training in biomanufacturing. The model would consist of a multi-tiered network of stackable industry-approved credentials that would span both university and community college programs and would provide hands-on training to secondary and postsecondary faculty, college and community college students, transitional workers, including returning veterans, and incumbent workers. Community college short courses and certificates offered through Continuing Education provide both an affordable and flexible means of workforce training and offer a quick, effective and low barrier-to-entry platform. Developed with the support of industry, taught by industry professionals, and provided at an exceptional value to the workforce trainee, these courses can provide a multitude of benefits, reaching all levels of educational need in a coordinated manner across a regional network. Moreover, these hands-on training credentials can be designed to meet the accreditation needs of degree programs at community colleges and universities. As NC successfully did with biomanufacturing, a coordinated effort to define and support advanced technologies at the local, state and regional level must be undertaken.

Data related to job creation, location of jobs, and the skillsets related to those jobs need to be collected, analyzed and disseminated. Educational programs at the secondary, post-secondary and graduate levels need to be aligned in a cost-effective, rapidly responsive manner. In order to accomplish this feat, industry must play a vital role in design and implementation of workforce training programs. One aspect of the project will determine real workforce needs as defined by industry and quantify those needs as of today, and anticipated needs a year from now, five years from now, etc. The key will be the active engagement of current employers and future employers. This data will then be disseminated broadly, within the state, through COIN's database of 5000+ nanotechnology and advanced technology stakeholders, and also nationally through NACK's database and through the 15,000+ stakeholder database of the NanoBusiness Commercialization Association. The results will also be broadcast through portals available through the National Nanotechnology Coordination Office housed at the National Science Foundation in Arlington, Virginia