

# Positioning North Carolina as an Epicenter for Regulatory Science

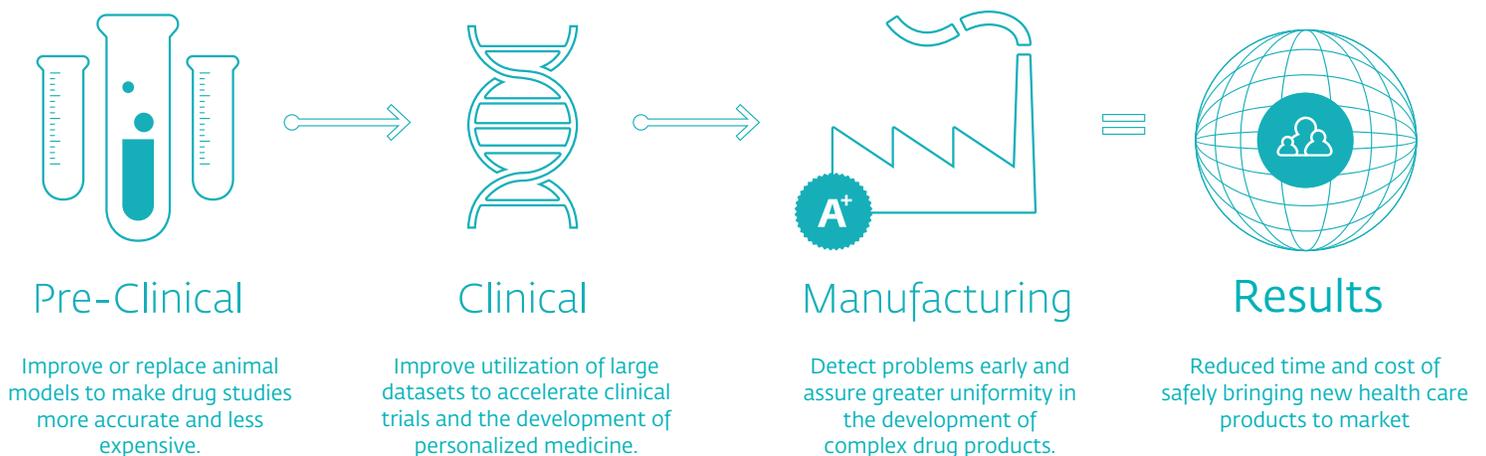
NC STATE UNIVERSITY | Institute for EMERGING ISSUES

John has a chronic illness. Several months ago, his medications made him feel worn out and sick, preventing him from participating in his daily responsibilities at home, work and in the community. After several modifications to his treatment he feels better, but not optimal. He has read about a new drug in development that shows promising results among people with similar genetic traits, but it is still years away from reaching a pharmacist's shelf.

## What is Regulatory Science?

John's quality of life depends on rapid advances in health innovations that bring important changes to the way health and life science products are developed, evaluated, manufactured and used. The field of regulatory science addresses the development of new tools, standards and approaches to assess the safety, efficacy, quality and performance of these products. These advancements can be used to reduce the time and cost of safely bringing new health care products to market, which is an attractive incentive for investors. Regulatory science also has significant potential to advance personalized medicine and improve patient outcomes.

### Ways Regulatory Science Can Innovate Health and Life Science Products



## Why Regulatory Science Now?

As a result of the innovation opportunities regulatory science can offer, the Institute for Emerging Issues (IEI), as part of its multi-year work on healthcare innovation that began in 2010, established the Business Committee on Regulatory Science (BCRS). The committee's main focus centered around determining how best to position North Carolina as an epicenter for Regulatory Science research, technology and workforce development. Partners in the BCRS effort included NCBio, The Hamner-UNC Institute for Drug Safety Sciences and the Burroughs Wellcome Fund. BCRS members, representing life science business leaders and academic and non-profit research institutions, met twice between December 2013 and March 2014.

## Regulatory Science in the United States

In 2011, the U.S. Food and Drug Administration (FDA) developed a strategic plan for regulatory science to modernize toxicology, stimulate innovation in clinical evaluations and personalized medicine, support new approaches to product manufacturing and quality, ensure FDA readiness to evaluate innovative emerging technologies and harness diverse data through Information Sciences. The FDA offered various funding opportunities in 2011 and 2012, including awards for Centers of Excellence in Regulatory Science and Innovation (CERSI). As a result, regulatory science hubs have emerged in California, Maryland and Arkansas, allowing these states to become front-runners in securing research funding and attracting talent. While not involved in the earliest of efforts, North Carolina is a strong contender to become a leader in regulatory science.

## Regulatory Science in North Carolina

Regulatory science has a direct effect on North Carolina life science companies. The state is third in the nation, behind only California and Massachusetts, in the size of its life science sector. The trade publication Genetic Engineering & Biotechnology News (GEN) listed the Research Triangle area as the nation's number eight biopharmaceutical cluster for 2014. More than 58,000 North Carolinians have bioscience jobs, earning an average of \$78,000 a year. In total, the industry supports 237,665 in direct and indirect jobs. Those workers earn a total of \$14.8 billion a year, and the industry generates \$59 billion in economic activity across the state. A large number of those jobs are in pharmaceutical, biotechnology and contract research organizations (CROs). The state also has the largest concentration of clinical research organizations in the world and more than 110 CROs call North Carolina home. Together, these companies employ 12,000 workers and comprise a \$24 billion industry. The entities, both big and small, help drug, diagnostic and medical device companies worldwide develop and test new products.



More than 58,000 North Carolinians have bioscience jobs, earning an average \$78,000 a year.



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North Carolina is 3rd in the nation behind only California and Massachusetts, in the size of its life-science sector.

BCRS looked at what was happening in other states as well as how North Carolina could build on its assets and raise its visibility in the area of regulatory science. In December 2013, the Committee heard from academic leaders about programs underway in North Carolina and talked with industry leaders about the opportunities for research, collaboration and partnership. The group concluded that cutting-edge regulatory science presents an opportunity for pre-clinical, clinical and manufacturing clusters in areas across North Carolina. They offer new development and testing services that substantially accelerate the development and testing of health products, as well as yield more effective manufacturing practices. Regulatory science offers these clusters important opportunities to stay competitive in the global health products market. North Carolina will need to identify its areas of deep expertise and potential collaborations if it is to match and surpass the efforts already underway in other states.

## Examples of North Carolina Assets Currently Supporting Regulatory Science:

North Carolina's academic and research institutions provide strong undergraduate, graduate and postdoctoral programs that create the life science industry workforce. These institutions also support clinical trial development and evaluation, generating a strong interplay for translating product development.

### **Duke University**

- School of Medicine
- Duke Clinical Research Institute

### **East Carolina University**

- Molecular Biology and Biotechnology, Department of Biology
- Brody School of Medicine

### **The Hamner Institutes for Health Sciences**

### **North Carolina Central University**

- Biomanufacturing Research Institute and Technology Enterprise (BRITE)

### **North Carolina State University**

- Golden LEAF Biomanufacturing Training & Education Center (BTEC)
- Department of Statistics

### **UNC-Chapel Hill**

- School of Medicine
- Eshelman School of Pharmacy
- Gillings School of Global Public Health
- A \$1.2 million funding project supported by FDA is under way at UNC-CH to study and improve the safety of synthetic heparin drug products.

### **UNC-Charlotte**

- Bioinformatics Services Division, College of Computing and Informatics

### **Wake Forest University**

- Wake Forest Baptist Medical Center
- Wake Forest Institute of Regenerative Medicine

## Findings and Recommendations

### 1. Inventory Assets

The programs highlighted during the BCRS, as well as other similar programs across the state, serve as a foundation for a regulatory science effort in North Carolina. However, there is no comprehensive listing of the many additional regulatory science-related assets in the university and nonprofit sectors. More information is needed on what is located in North Carolina and in other states.

#### ***The BCRS recommends that:***

- NC BIO develop a list of best practices from other states that may be useful in North Carolina (e.g., Arkansas' and Maryland's CERSIs).
- NC BIO, the NC Biotechnology Center and the UNC General Administration create an inventory of North Carolina's regulatory science-related academic and research assets. A first step is to work with REACH NC, which provides a database and other information on university and research institution capacities. While REACH NC currently provides information on life sciences, specific terms and/or definitions related to regulatory science should be developed as searchable terms in the database.
- BCRS members encourage North Carolina's academic and research institutions to utilize the asset inventory to identify opportunities for collaboration in cutting edge areas of regulatory science research.

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## 2. Collaborations

The BCRS identified opportunities for broader collaboration and information sharing, particularly regarding funding opportunities for regulatory science research projects.

*The BCRS recommends that:*

- The NC Biotechnology Center establish a regulatory science intellectual exchange group to support information sharing and other interactions among businesses and academic institutions. This group should:
  - Invite presentations from FDA officials and existing FDA-sponsored Centers of Excellence in Regulatory Science and Innovation (CERSI) in other states. Identifying areas of focus at FDA and in other states could indicate if there is a niche that would align with North Carolina's assets and could serve as the foundation for building a regulatory science program in North Carolina.
  - Monitor the potential for developing more formalized structures among institutions to apply for grants and other funding opportunities.
  - Determine ways to integrate industry into regulatory science-related academic and other non-profit programs.
  - Monitor FDA Broad Agency Announcements and Requests for Proposals for funding opportunities (e.g., recent announcements include: (1) Modernize toxicology, (2) Ensure FDA readiness to evaluate innovative emerging technologies and (3) Stimulate innovation in clinical evaluations and personalized medicine).
  - Develop a process for keeping the BCRS members informed about activities of the group.
- The NC Biotechnology Center integrate regulatory science into its life science brand for North Carolina.
- NC BIO create a forum for CROs to exchange ideas on policies, education, best practices and other areas of interest, especially in the realm of regulatory science.

## 3. Professional Education and Workforce Development

North Carolina has a strong history of establishing training for industry in the life science field. For example, the NCBioImpact training program is a collaboration of institutions across the University of North Carolina and North Carolina Community College systems to provide a continuum of education for students, incumbent workers and people who seek to change careers to enter the life science industry. NCBioImpact includes the NC State University Biomanufacturing Training and Education Center (BTEC). BTEC provides biomanufacturing training for the FDA, as well as training on influenza vaccine manufacturing for the Biomedical Advanced Research and Development Authority (BARDA) and World Health Organization (WHO).

The BCRS found that companies engaged in regulatory science-related activities need better access to workers with regulatory science-related training and education. However, it is unclear what type of professional education is needed and whether the needs of pre-clinical, clinical and manufacturing companies are aligned or divergent.

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**The BCRS recommends that:**

- NC BIO and the NC Biotechnology Center work with life science businesses and academic institutions to explore the potential for North Carolina universities and community colleges to:
  - Offer regulatory science curricula, including the potential to identify regulatory science as an academic discipline
  - Explore the possibility of creating a regulatory science credential for professional education programs and a Professional Master's in Regulatory Science
  - Create a collaborative platform to share information regarding regulatory science training needs and industry internships in regulatory science
- BTEC explore options with industry for providing a hands-on manufacturing-related regulatory science professional education programs for incumbent workers.

## What did we learn?

States successful in establishing clusters of academic and commercial regulatory science assets will be positioned to capitalize on the FDA's new emphasis on this important domain and to benefit economically from the commercialization and application of new regulatory science technologies. For North Carolina to develop its potential as a hub for regulatory science research, development and services, more work must be done to deepen connections among the state's life sciences clusters, research institutions and life science companies. We must also increase opportunities for dialogue with federal regulatory agencies regarding policy implementation, education and research funding. Academic, nonprofit and industry leaders working together to advance regulatory science in North Carolina can make an important contribution to the future growth of the state's life science cluster, as well as world health.

For questions/comments on this report, please contact Sarah Langer, health policy manager at the Institute for Emerging Issues, at [sarah\\_langer@ncsu.edu](mailto:sarah_langer@ncsu.edu).

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December 2013-March 2014

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