

The Piedmont Triad is pleased to provide this information in response to the BioEconomy Challenge request for information. The input is based on North Carolina's success with building a life-science cluster.

The items listed below are not in order of importance and have been formatted as bullet points.

- Establish an FDA committee of academic and corporate leaders, including those from medical device, diagnostics and theranostics companies, to collaborate on the development and refining of predictive modeling programs for drug safety and efficacy. This could help reduce untoward side effects, costs and time from discovery to the marketplace.
- The FDA should:
 - (a) review list of FDA-approved indications for which INDs, clinical trials, and NDAs can be filed/conducted,
 - (b) review FDA-approved primary and secondary endpoint/outcome metrics. Researchers at prominent academic institutions are developing methodologies for measuring clinical trial results, but the FDA may not be coordinating with them.
- Establish an FDA subcommittee involving FDA clinicians/statisticians, academic researchers and life-science company chief medical officers to address unmet medical needs.
- To spur workforce development and economic growth, the federal government should establish a grant program to enable academic institutions to fund scientific/engineering internships at life science companies. This will broaden opportunities and stimulate interest in STEM education and provide win-win outcomes for students and life-science companies. The North Carolina Biotechnology Center's undergraduate and industrial (postdoctoral) fellowship programs are examples of successful models.
- With the assumption that life sciences companies prefer to hire locally, an obvious source for talent (i.e. laboratory technicians) is the community college system. The Associate of Applied Science degree programs at community colleges can be taken to the next level, particularly in nationally certified/credentialed programs, through federal reimbursement of tuition and related expenses directly to community colleges (subject to certain restrictions) for displaced workers receiving unemployment compensation who are seeking career changes into life sciences. This would help create jobs and provide a workforce-ready pool of talent.

- Encourage commercialization of new technologies through loan programs in the \$100,000 to \$250,000 range that don't require personal collateral such as the family home of an academic scientist or entrepreneur in loan guarantees, and simplify application forms.
- Advance the NIH initiative to establish a national translational research center/institute that can spur commercialization of basic university research discoveries via grants and other funding.
- Repeal that portion of the Patient Protection and Affordable Care Act which will institute a 2.3 percent federal tax on medical device company revenues in 2013.
- Support certification programs in development: Certification of specialized skill-sets affirms a knowledge and experience base for practitioners in a particular field, their employers, and the public at large. Working with partners at the national and state level, we aim to advance a process of adapting existing, or if necessary, creating the required certification for the biosciences technical workforce. (National Center for the Biotechnology Workforce, a NC BioNetwork Center, and the National Association of Manufacturers)