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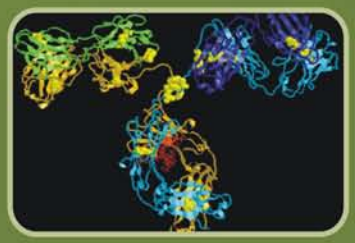
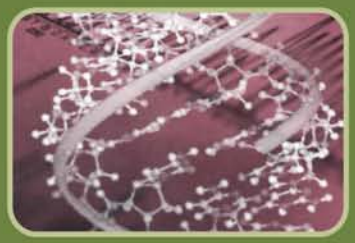
## Executive Summary

# Accelerating Innovation in 21st Century Biosciences: Identifying the Measurement, Standards, and Technological Challenges

October 19-22, 2008
Gaithersburg, Maryland






# Foreword

This report provides an overview of a landmark conference held at the National Institute of Standards and Technology in October 2008, "Accelerating Innovation in 21st Century Biosciences: Identifying the Measurement, Standards, and Technological Challenges." The ideas generated and catalogued during the conference provide an updated perspective on the importance of measurement science to technological innovation in essential sectors, including agriculture, energy, environment, biopharmaceutical manufacturing, and medicine.

The conference was co-hosted by the National Institute of Standards and Technology and the University of Maryland Biotechnology Institute. Numerous sponsors also contributed to the support of the conference (see back cover).

This Executive Summary reports on the expert input of bioscience professionals from all over the globe concerning the most urgent measurement and standards barriers to innovation in the biosciences. It provides a strategic framework for research throughout the measurements and standards community worldwide. The full Conference Report can be viewed at http://www.cstl.nist.gov/Biosciences.html

The members of the Steering and Organizing Committees for the Conference wish to thank the session chairs and moderators, speakers, and participants who contributed to its success.

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# EXECUTIVE SUMMARY

## Overview

The science of understanding how biological systems operate and interact with one another (the biosciences) is increasingly important to global prosperity and quality of life. As the world's population grows, so will the need for more efficient and sustainable ways to grow food, keep people healthy, produce energy, and manufacture biological drugs, therapeutics, and chemicals. These advances can only be realized by gaining a deeper understanding of how biological systems operate—an understanding that depends on advancing the state of the art in biosciences measurement.

Despite major breakthroughs and discoveries in recent years, our understanding of biological systems still faces many challenges. Biology is an informational science that depends on accurate measurements and standards. Whether quantifying the amount of protein in a cancer cell or the rate at which an organism converts sugar to alcohol, measurements are the foundation for improving our understanding of biological systems.

**Exhibit E.1 Conference Focus Areas**

**Agriculture** - increasing yield, quality, and safety in the world's food supply

**Bioenergy** - obtaining sustainable energy from biological sources

**Environment** - understanding our planet through linking molecules to ecosystems

**Biopharmaceutical Manufacturing** - obtaining higher quality products through better bioprocess measurements

**Medicine** - improving health through measurement of complex biological signatures

**Hot Topics** - unrecognized, overlooked, underestimated, and often ignored measurement needs in the biosciences, including

- Agriculture viability
- Antibiotic and antiviral drug resistance
- Environmental bioremediation
- Environmental bioterrorism monitoring
- Marine versus terrestrial sources of bioenergy
- Personalized medicine
- Stem cell therapy
- Synthetic biology

To identify measurement challenges in the biosciences, the National Institute of Standards and Technology (NIST) and the University of Maryland Biotechnology Institute (UMBI) co-hosted an international conference, *Accelerating Innovation in 21st Century Biosciences: Identifying the Measurement, Standards, and Technological Challenges*, on October 19-22, 2008, in Gaithersburg, Maryland.

Attended by leading bioscience professionals from all over the world, this landmark event was a first-time opportunity to discuss the global measurement and standards challenges to innovation in key bioscience areas (Exhibit E.1). Bioscience practitioners with diverse backgrounds met to share the views of international policymakers, create opportunities for networking and collaboration, and discuss opportunities and challenges. This report provides an overview of the conference and the important ideas generated by experts in the field.

## Priority Measurement and Standards Challenges

An important outcome of the conference is a prioritized list of challenges that can be used to guide future research at NIST and the measurement and standards community worldwide. These priorities are summarized in Exhibit E.2.

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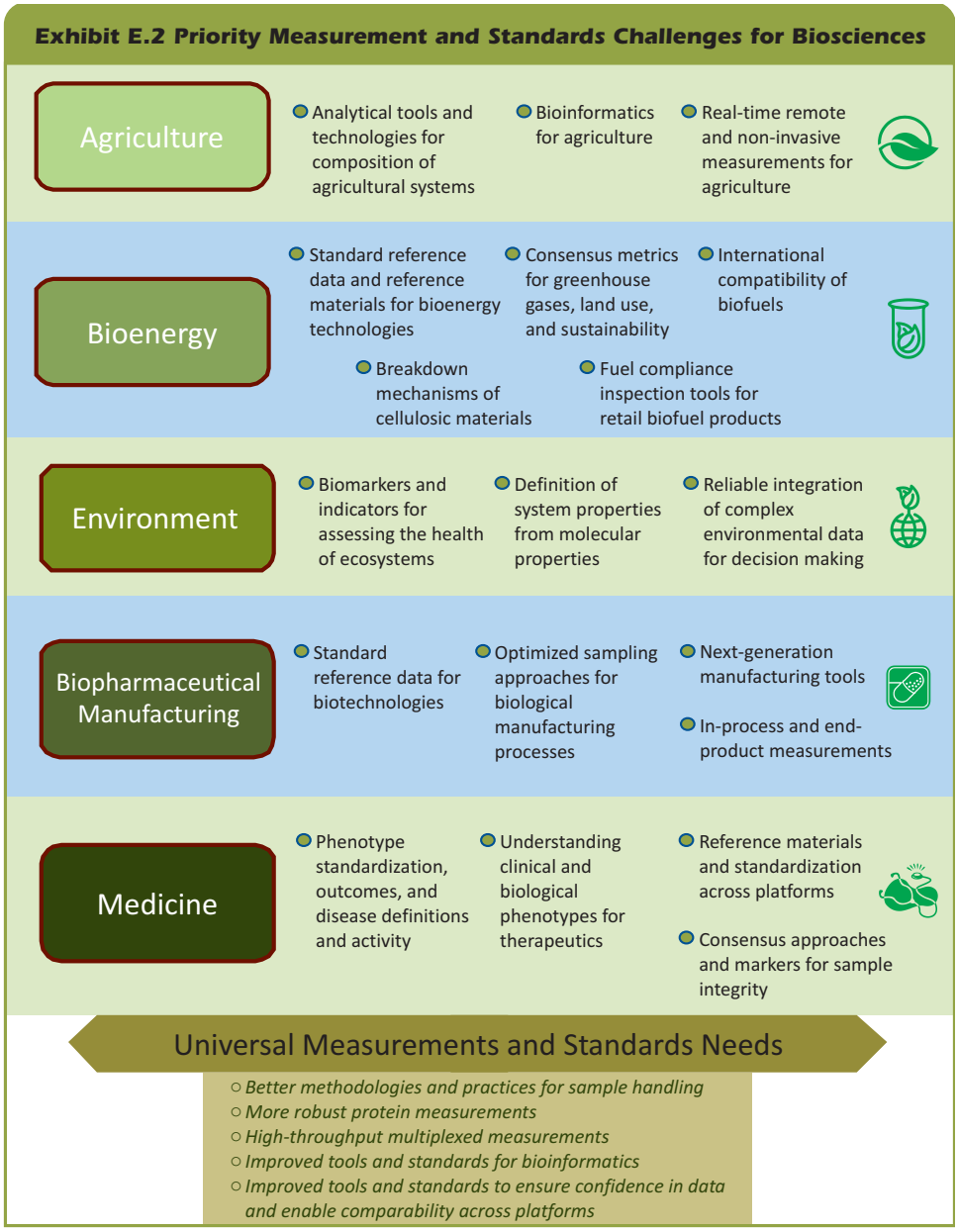
**Agriculture** - ***Standards and standardized methods*** *are a priority, as they assure confidence and consistency in biological measurements of plant/animal systems and their ecological and environmental interactions. As markets continue to expand globally, international standards will be important to assure worldwide product acceptance.* ***Improved measurement methods*** *are also needed to achieve greater accuracy, speed of measurements and analysis, and real-time, remote capability. Innovative technologies are needed to measure complex biological system parameters, such as water in plants, structures of microbiota, and reversible interactions in living systems. Assimilation and dissemination of data and accessible* ***bioinformatics systems*** *are critical and remain a significant challenge.* ***Sustainable agriculture*** *will require consensus on how to measure sustainability and life-cycle impacts. Ensuring that sustainable practices are attractive to farmers and livestock operators, and communicating the true cost of sustainability, are both key challenges.*

**Exhibit E.2 Priority Measurement and Standards Challenges for Biosciences**




**Bioenergy** - Improved ***characterization methods*** *for various forms of biomass in terms of composition, reliability, quality, and enzyme activity, are needed, particularly for next-generation biofuels. Methods are also needed to monitor the characteristics of biomass in production and harvesting; during conversion processes; and in storage, transport, and delivery. The* ***standardization and sustainability of biofuels*** *is a global challenge that requires nations to work together. Standards are needed to establish the performance and sustainability of biofuels regardless of feedstock. Ensuring consistent measurements and standards across the biofuels supply chain requires an extensive network of measurement methods. While some exist, many others need to be developed, particularly for biomass production. On the production side, characterizing the breakdown mechanisms of and measuring the parameters relevant to the* ***recalcitrance of cellulosic biomass*** *are key challenges to unlocking the energy potential of non-food biomass resources such as perennial grasses, wood energy crops, and agricultural residues.*

**Environment** - Priority challenges for obtaining ***system properties*** involve defining the critical attributes of ecosystems, determining the measures of system health, and identifying the indicators that provide early warning of changes in ecosystem health that are important to sustaining human well-being. Standardized, validated methods for the development and use of ***biomarkers*** are currently lacking and are critical to effective early warning systems. Issues such as natural variability, specificity of biomarkers, and variability across environmental conditions impede standardization and need to be addressed. The major challenge to incorporating ***broad perspective variables*** (e.g., resource and land use, air and water transport, climate change) will depend on the effective integration of diverse data at different scales, from the molecular to systems level. Effective early warning systems will require an array of measurement technologies ranging from DNA probes to satellites, geographic information systems (GIS), and others. A greater understanding of the links between external drivers and ***stressors affecting ecosystem health, environmental exposures, and system-level responses*** is needed as a foundation for an environmental early warning system. This knowledge is impeded by the growing magnitude and diversity of toxins, chemicals, hazardous compounds, pathogens, diseases, and other stressors released into water, air, land, and living systems. New measurements and standards, including sampling methods, are required for toxins, microbial contaminants, pathogens, and many other threats to a healthy environment.

**Biopharmaceutical Manufacturing** - ***Controlling and monitoring biological manufacturing processes*** that work with living cells is difficult due to a high degree of uncertainty, both in processing and obtaining desired product attributes. The ability to make measurements in complex matrices in a process environment and ***obtain samples online and in-process*** remains a significant challenge. Without understanding the mechanisms behind product variability, obtaining the desired attributes becomes an iterative process. Finding simpler ways to mimic complex systems (e.g., immune system assay), more accurate bioassays, and measuring *in vivo* changes could improve pathways to reliable product attributes. ***Tools for measuring system parameters*** such as structural properties, aggregation, oxidation, and others, will ultimately pave the way for predictive biotechnology and product development. The high cost of measurement remains a significant impediment in today's biomanufacturing environment.

**Medicine** - Developing ***sampling standards and protocols*** for the proper processing, handling, and treatment of cells, tissues, and other biological samples is a high priority. Without standard methods, the result is questionable sample integrity, poor reproducibility of results, and difficulty in performing credible analysis. Definitions and ***standards for phenotype data*** are also critical; these are needed to help identify, characterize, and predict disease pathways, activity, and disease and treatment outcomes. ***Standardization of data and assays across biological platforms*** is a priority, but is hindered by the diversity of platforms and a lack of interoperability and comparability among platforms. There is a need for clear ***definition of reference points***, and improved traceability of measurements to reference points. ***Information exchange*** and ensuring consistency of information continues to be a major challenge.

## Universal Ideas and Observations

The universal, crosscutting needs identified across all biosciences are:

- Better methodologies and practices for sample handling
- More robust protein measurements
- High-throughput multiplexed measurements
- Improved tools and standards for bioinformatics
- Improved tools and standards to ensure confidence in data and enable comparability across platforms

# EXECUTIVE SUMMARY

Observations that emerged from the conference include the following:

- Improvements in the biosciences are key to global economic security and quality of life in the future
- A much deeper understanding of complex biological systems is needed
- Highly sophisticated measurements are needed in order to study the relevant changes that occur in complex biomolecular networks
- Major measurement challenges exist that are stifling innovation in the biosciences
- Current technology is inadequate due to a very limited measurement infrastructure that allows scientists to have confidence in only a very small percentage of the biomeasurements being conducted
- New multiplex, multiparametric measurement technologies must be invented and developed
- These new measurement systems will rely heavily on the accuracy and comparability of the data obtained from current technologies as a basis upon which to build the new systems
- Standardization of current measurement technologies will be needed to enable next-generation systems
- Standardization of next-generation biomeasurement systems that bridge historical and new data will be needed as new methods emerge

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