Advancing Regulatory Science

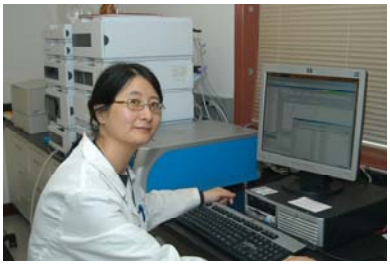
CBER Receives Accreditation for Laboratory Testing of Influenza Vaccines and Evaluation of Blood Donor Screening Kits.

Commissioner Margaret Hamburg, MD has identified several strategic FDA priorities that are critical to enabling the agency to enhance the health and well-being of Americans. One of those priorities is advancing regulatory science and innovation.

Regulatory science is the science of developing new tools, standards, and approaches to more efficiently develop products and to facilitate the evaluation of product safety, effectiveness, quality, and performance. Modernizing evaluation and approval processes will help ensure timely availability of innovative products for consumers and patients.

The recent accreditation of the CBER Laboratory Quality System (LQS) by an internationally recognized authority is one example of the center's ability to advance regulatory science and reliably evaluate influenza vaccines and blood donor screening tests.

The CBER Laboratory Quality System Program



The LQS program is the coordinated organizational structure, procedures, processes and resources CBER uses to evaluate and test regulated biological products. This includes testing performed in support of:

- lot release or surveillance
- licensing
- supplements and amendments to licenses
- official investigative actions
- development & characterization of official reference materials and physical standards
- other studies relevant to product testing

CBER documents policies, systems, programs, procedures, and instructions under the LQS in order to ensure the quality of its product testing results. The objectives for LQS are to:

- enhance testing quality and consistency
- ensure laboratory activities are aligned with mission of CBER
- enable CBER to facilitate international harmonization of regulation and trade

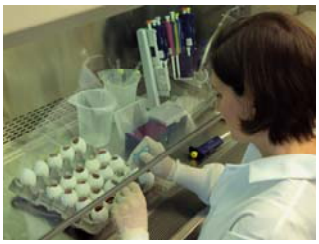
The development of LQS at CBER and its subsequent evaluation by a national accrediting authority, the American Association for Laboratory Accreditation (A2LA), was made possible through the leadership of:

- Quality Assurance Staff (Office of the Director)
- Office of Vaccines Research and Review
- Office of Blood Research and Review
- Office of Compliance and Biologics Quality

In October 2010, A2LA awarded the CBER LQS program accreditation to an international testing standard known as ISO/IEC 17025.

This accreditation identified specific LQS competence in laboratory testing in consistently producing valid results.

Specifically, CBER received accreditation in the fields of biological and chemical testing for:



- six *in vitro* methods used most frequently for evaluating the safety and effectiveness of influenza vaccines (including sterility)
- seven methods for evaluating blood donor screening kits that test for the presence of
    - AIDS virus
    - hepatitis B and C viruses
    - human T-lymphotrophic viruses I and II
    - *Trypanosoma cruzi* (the cause of Chagas disease)
    - West Nile virus.

The accreditation of the LQS program at CBER by the American Association for Laboratory Accreditation signifies that this program is an international leader in biological products regulation based on its expertise in these areas of regulatory science.