



The U.S. Food and Drug Administration and Research Capacity Building

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A Global Agency with a strong domestic mission

- In 2007, the United States Imported over \$2 trillion worth of products, from over 825,000 manufacturers, through over 300 ports of entry .
- In the 21st century , while U.S. borders may be boundaries to FDA 's jurisdiction, they are not barriers. *Imports come from developed and developing countries alike.*
- FDA efforts can help to strengthen foreign regulatory systems through standards and guidelines that are based on objective data and scientific principles and processes.

FDA's New Global Presence

- China: Beijing, Guangzhou, and Shanghai. A total of 8 FDA experts, including 4 inspectors.
- Europe: U.S. Mission in Brussels, European Medicines Agency in London, and European Food Safety Agency in Parma. (1 expert in each)
- Latin America: San José, Costa Rica, Mexico City, and, most likely, Santiago, Chile. A total of 8 FDA experts.
- India: New Delhi and Mumbai, starting with 9 FDA experts with a total of 12 expected, including 5 inspectors.
- Middle East: currently established in Rockville (5 experts) while FDA continues to engage USDOS to establish an overseas presence.
- In complement, FDA's Office of Regulatory Affairs is developing a dedicated foreign cadre of inspectors.

FDA's New International Offices

- Better accomplish FDA's mission by helping to assure the safety, efficacy, quality, and availability of FDA-regulated products from abroad.
- Obtain more robust information to enable FDA officials to make better decisions about FDA-regulated products that are being developed for the US market, being reviewed for marketing authorization in the USA, being presented for entry into the USA, and that are currently on the US market.
- Where common interest exists, sustain an effective program of capacity-building initiatives to increase the ability of local authorities to ensure the quality and safety of medical products and foodstuffs produced in country - both for local consumption and export.

FDA's New International Offices (cont.)

- Collecting better information about the clinical trial data from these regions that support marketing applications in the USA and about the manufacture of FDA-regulated products destined for the USA.
- Serve as a regional focal point for in-country stakeholders to increase understanding of our standards and expectations regarding FDA-regulated products.

International Capacity Building/Collaboration

- Active engagement in Global Harmonization programs and expert consultations, i.e., Codex Committees and Task Forces, FAO and WHO Expert and Joint Committees.
- Active engagement in networks/fora such as the WHO Developing Country Vaccine Regulators Networks, WHO/AFRO African Vaccine Regulatory Forum, APEC Food Defense Assessments, and the Pan American Network for Drug Regulatory Harmonization.
- FDA's Initiative for the Approval and Tentatively Approved Antiretrovirals in association with the President's Emergency Plan for AIDS Relief.

Capacity Building/Collaboration (cont.)

- Range of Seminars/Workshops held abroad in such areas as Good Clinical Practices, Good Manufacturing Practices, Good Laboratory Practices, and Acceptance of Data in Clinical Trials.
- U.S. Fora for International Authorities hosted by FDA Centers (CDER, CFSAN, and CBER) to increase understanding of FDA's scientific processes, rules and regulations.
- Development of web-based training materials in foreign languages, i.e., Spanish, Chinese, and French through FDA/ORA University.
- Efforts to expand consumer education in foreign countries to create a domestic demand for more stringent product safety standards.