FDA's Pharmaceutical Inspectorate

Association of Food and Drug Officials

June 2006

Susan M. Setterberg

Regional Director, Central Region

Food and Drug Administration

Pharmaceutical Inspectorate

- Where we started
  - Part of the Quality Drug Initiative
  - Summer 2002 initiated discussions
  - Dedicated investigators
  - Initiated training for Process Analytical Technology

Pharmaceutical Inspectorate

- Desired Goal
  - Establish a staff of highly trained individuals that focus a majority of their time on conducting human and animal drug quality inspections on high risk firms.

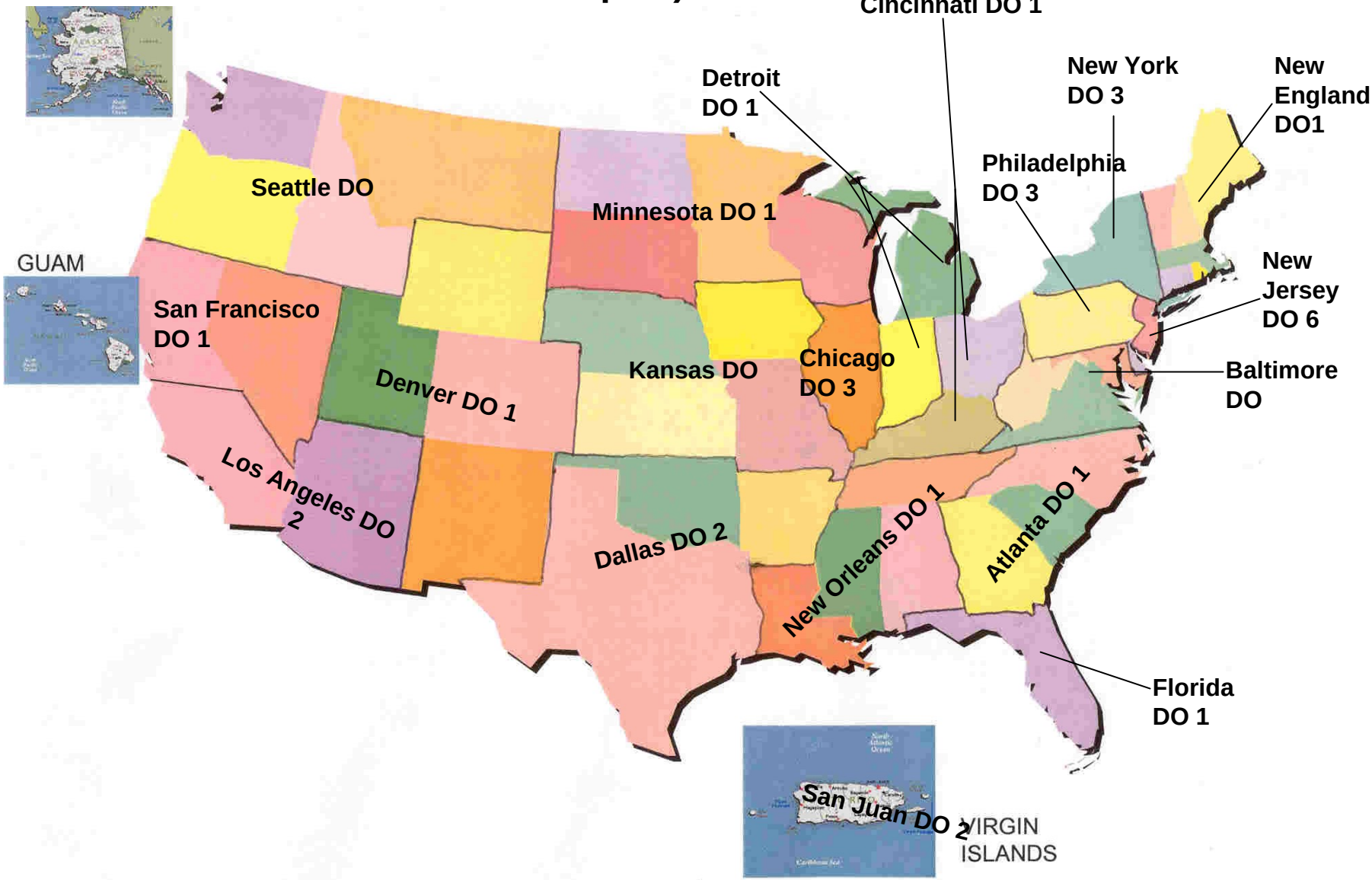
Pharmaceutical Inspectorate

- Desired Goal
  - Establish a close working relationship between all individuals in the field and centers

Pharmaceutical Inspectorate

- Process
  - Review of position descriptions for current field specialists
  - Examination of data for a year of accomplishments
  - Current workforce review
  - Reviewed the field training programs

Pharmaceutical Specialists by District in 2003 (CSO Drug and Commissioned Corp 05)



Pharmaceutical Inspectorate

- Findings
  - Current position descriptions appropriate
  - Most specialists predominantly focused in their specific programs
  - Number of Potential candidates good
  - Certification Program could be expanded

Pharmaceutical Inspectorate

- Training Development Steps
  - Used Existing Level I
  - Initiated Level II Certification for the drug program
  - Expanded the Field Certification Program to a new level

Pharmaceutical Inspectorate

- Certification Program Components
  - Curriculum Defined
  - Formal National Courses, Web based training, OJT, District Courses
  - Assessments
  - Certification Board
  - Course Advisory Group
  - Continuing Education

Pharmaceutical Inspectorate

- Curriculum – General Considerations
  - Set minimum expectations
  - Extensive review
  - Courses meet Continuing Education Standards
  - Lecturers to include experts in government, academia and industry

Pharmaceutical Inspectorate

- Competencies for the PI (modules)
  - Regulating Pharmaceutical Quality and Relationship to FDA's Mission
  - Risk Management
  - Advanced Quality Systems
  - Pharmaceutical Science
  - Current Regulatory Programs and Procedures
  - Technology
  - Investigational

Pharmaceutical Inspectorate

- Regulating Pharmaceutical Quality and Relationship to FDA's Mission
  - Philosophy
- Risk Management
  - Current concepts related to product quality
  - How to apply knowledge to inspections
  - GMP compliance
  - State of control
  - Impact of GMP violations

Pharmaceutical Inspectorate

- Advanced Quality Systems
  - Quality management techniques
  - Implementation of quality systems approaches to pharmaceutical production
- Pharmaceutical Science
  - Science underlying approaches to controlling product quality
  - Causes of variability

Pharmaceutical Inspectorate

- Current Regulatory Programs and Procedures
  - Integration of review and inspectional programs regarding product quality
  - Critical thinking
  - Inspectional discretion
  - Effective communication of complex issues

Pharmaceutical Inspectorate

- Technology
  - Science and technology advances in pharmaceutical manufacturing
  - How advances enhance quality of inspections
  - Impact on inspectional approach
  - Best practices
  - Future technological developments and impact on production

Pharmaceutical Inspectorate

- Investigational
  - Identifying new knowledge needed
  - Sources of information
  - Investigational technique differences across program areas

Pharmaceutical Inspectorate

- Objectives of Training

The PI participants

- are capable of making judgments about a firm’s risk management programs, product and process knowledge, process capability, and robustness of quality systems.

Pharmaceutical Inspectorate

- Objectives of Training

The PI participants

- will use risk assessment in conducting inspections and making recommendations.
- will establish a network with Center Product Specialists and Technical Experts.

Pharmaceutical Inspectorate

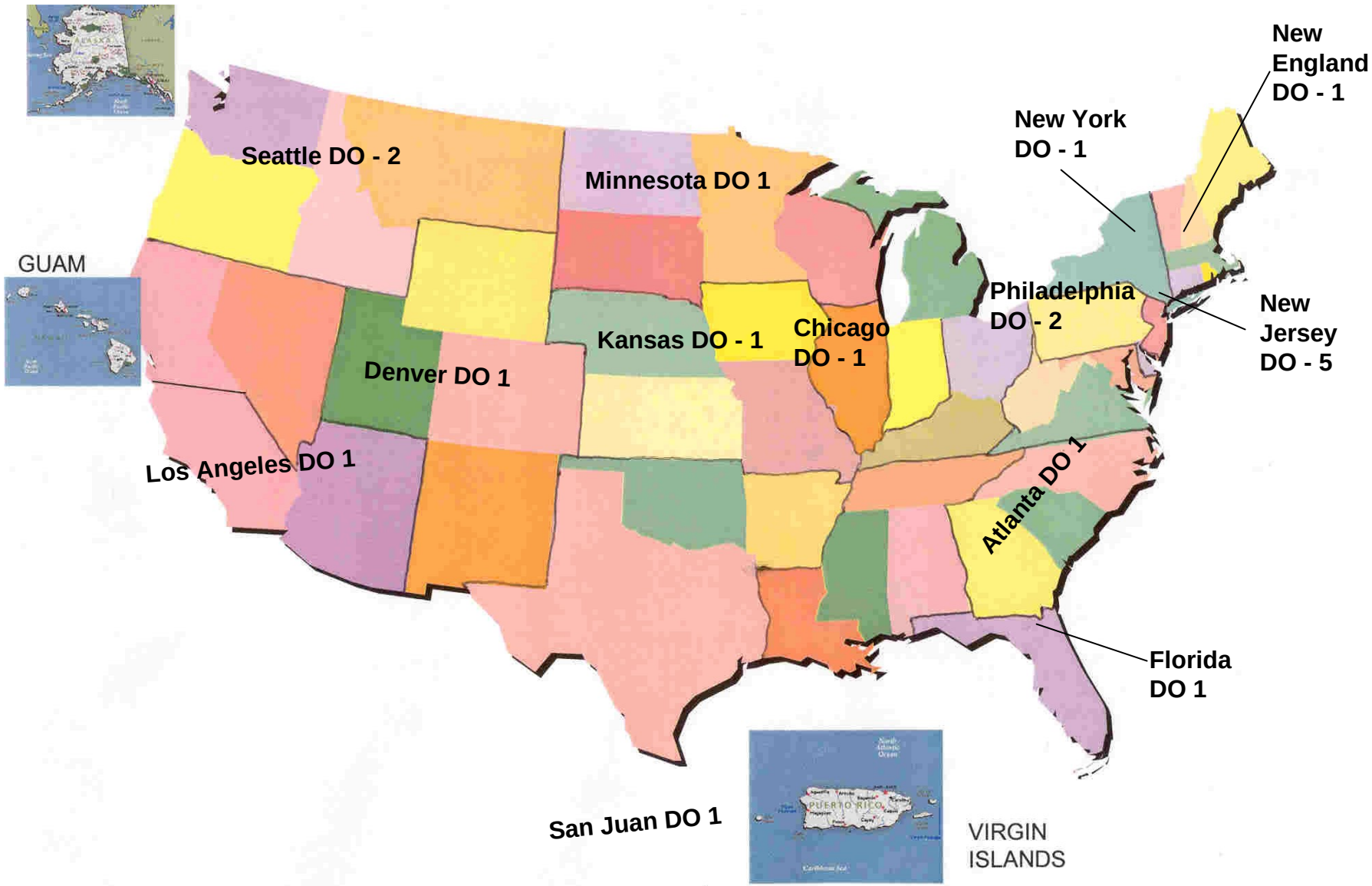
- Results of Program
  - Well trained workforce
  - Mechanism to train on new technologies
  - Closer interactions between Centers and ORA
  - Consistency
  - Roll out policy changes

Pharmaceutical Inspectorate

- Status of Program
  - Level II Certifications
  - Auditors
  - Curriculum completion and Details
  - Level III (PI) Candidates

Pharmaceutical Inspectorate Candidates and Graduates

April 2006



Pharmaceutical Inspectorate

- What's next
  - Updates for the PI
  - Second Class launch
  - Reach back to Level I and II training with concepts
  - Video Conferences for the Field and Centers
  - Compliance Officer course

Pharmaceutical Inspectorate

- What's Next
  - Quality Management System
    - PI Quality Task Force identified as an adjunct to the Council on Pharmaceutical Quality
    - Assure currency of existing procedures
    - Adopt new procedures for CSO/Center interactions
    - Communications
    - Continuous Education
    - Evaluation and Improvement

Pharmaceutical Inspectorate

http://www.fda.gov/cder/gmp/gmp2004_finalreport2004.htm
http://www.fda.gov/cder/gmp/gmp2004/pharma.inspect.htm
http://www.fda.gov/cder/gmp/21stcenturysummary.htm
http://www.fda.gov/cder/gmp/pharminspectorate.htm
http://www.fda.gov/cder/gmp/PI-q&a.htm
http://www.fda.gov/cder/gmp/index.htm

Pharmaceutical Inspectorate

Thank you!