An Overview of FDA India Office Activities
and
Recent Initiatives of FDA

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New Challenges in Global Regulatory Perspectives
An Overview

• Why is FDA in India?
• What have we been up to?
• What are some of the new initiatives and guidance documents?
• What have we observed in our inspections?
• How can you make contact with us?
• Questions?
Challenges of Globalization

Globalization has fundamentally changed the environment for regulating food and medical products and created unique regulatory challenges for FDA:

- More foreign facilities supplying the U.S.;
- Increasing volume of imported products;
- More outsourcing of manufacturing and clinical trials;
- Greater complexity in supply chains;
- Growing complexity of products and manufacturing methods;
- Imports coming from countries with less well developed regulatory systems; and
- Greater opportunities for economic fraud.
Number of Foreign Sites Making FDA-Regulated Drugs Has More Than Doubled Since 2001

- **CY01**: 1,282
- **CY02**: 1,507
- **CY03**: 1,780
- **CY04**: 2,046
- **CY05**: 2,323
- **CY06**: 2,595
- **CY07**: 2,820

Note: Number of foreign facilities inspections are scaled in fiscal year. Number of foreign facilities are scaled in calendar year. Numbers approximate due to data limitations.
21st Century Reality

• Our borders are still *boundaries*, but not *barriers*
  – Not barriers to disease, information flow, product acquisition, or the challenges of globalization

• Borders can no longer be the first line of defense

• We can no longer “inspect” out bad products at the border

• Borders must be places where we “audit” that indeed quality has been built in at the point of manufacture

We must:

• Engage more effectively abroad in order to be more effective at home
FDA’s Statutory Mission

...participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements.
FDA’s Foreign Posts
Indian Office Staffing Plans

New Delhi Office:

Country Director
Deputy Director
1 Senior Technical Expert (medicines)
2 Senior Technical Experts (foods)
2 Senior Technical Experts (medical devices)

Mumbai Office:

5 Consumer Safety Officers/Inspectors
Key India Office Tasks

• Further strengthen a strong regulator-to-regulator relationship
• Learn more about the industries that wish to export to the USA and help them understand U.S. expectations for each exported product
• More easily inspect manufacturing and processing facilities
• Help verify that products exported to the USA and the way they are manufactured meet U.S. health and safety requirements
• *When requested*, collaborate with counterpart food and medical product agencies to improve product safety.
India Office Technical Cooperation Activities

- CDRH training-of-trainers (TOT) for India’s evolving and growing devices inspectorate
- Multi-phase TOT training for DCGI in GCP inspections supporting the local oversight clinical trials
- Enabling DCGI attendance at International Regulators Forum (part of the ICH global cooperation group)
- Delivering 1-day training for industry on FDA Regulation of Medical Devices
- Enabling DCGI staff to travel to the 2009 GMP Inspectors Summit in the US
- Delivering more than a dozen presentations to industry-associations (devices, drugs and FDA’s India Office)
- FOODS
  - Delivered two-day LACF and Thermal Processing course for industry
  - Process Control class to Food Technology Students at Univ. of Delhi
FDA India Office – Activities

Meetings with the Ministry for Health and Family Welfare, Secretary and Joint Secretary, DCGI & Pharmexil

Meetings with Industry at conferences held by DIA, IDMA, IPA, BDMA, ASSOCHAM, CII and at symposiums held by the Government of India

We have done Pre-Approval Drug and Bioequivalence Inspections
Our Collaboration in GCP/Clinical Trial Inspections
Joint Workshops
with
Government of India
Ministry of Health and Family Welfare,
Directorate General of Health Services
Central Drugs Standard Control Organization (C.D.S.C.O.)

At the request of...
Government of India FDA initiated this outreach for Regulatory Officials of the Government of India
Building Global Capacity for Regulatory Review and Inspection of Clinical Trials

- International capacity-building in GCP/GCP inspection is developed as a three- to four-phase “train-the-trainers” program.

- Program to extend over a period of approximately three years.

- At each phase, objectives and agenda are agreed upon between U.S. FDA’s OIP, FDA faculty, and the host national regulatory authority.

- And between phases, specific activities and milestones are established and completed by the host authority.
Rationale

- India has experienced significant growth in clinical research.
- Growth in studies sponsored by industry and not-for-profit organizations.
- Growth in studies destined for U.S. FDA to support marketing applications.
- Opportunity to leverage FDA inspectional resources through GCP inspections conducted by GOI officials.
THE PLAN

Joint Train-the-Trainer Workshops

Phase I: Basic Workshop on Good Clinical Practice (GCP)/Clinical Research Inspection, September 2-5, 2008, FDA Bhavan, New Delhi.

Phase II: Advanced Workshop on Good Clinical Practice (GCP)/Clinical Research Inspection, June 8-12, 2009, Office of the Deputy Drugs Controller (India), C.D.S.C.O. West Zone, Mumbai.

Phase III: Implementation Workshop (proposed 2010 – in planning stage) – Conducted by GOI and observed by U.S. FDA Experts
Phase I GCP Training – Identification & Building of Skills
FDA Bhavan, September 2-5, 2008, New Delhi

Focus areas:
- Comprehensive lectures on Good Clinical Practice,
- Mechanics of inspection,
- Setting-up a GCP inspection program,
- Investigative interviewing,
- Structure and review of a clinical research protocol,
- Analysis of informed consent documentation,
- Assessment of quality and integrity in a clinical data audit,
- On-site orientation to a clinical research site.
Phase II (Mock Inspections)

Conducted by teams at four clinical research sites, with each team:

- Reviewing the study protocol in depth
- Developing an inspection plan
- Conducting a mock inspection
- Presenting findings and recommendations to the respective clinical investigator
- Developing oral and written reports for classroom discussion
Outcome of Phase II

Close –out Meeting of GCP-II

- 24 Future Trainers were Certified by DCGI
- Planning for Implementation
  - Establishing procedures and infrastructure for GCP inspections in India
  - Performance of additional training inspections
  - 2010 Implementation Workshop(s) to refine procedures, train new trainers, and provide outreach to regulated research community in India
Recent Initiatives of FDA
Changes in Senior Political Leadership

- FDA’s new commissioner Dr. Margaret Hamburg, took office in May, 2009.
  - emphasized a commitment to “swift, aggressive, and effective enforcement of FDA laws and regulations”. See [http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm176119.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm176119.htm)
The Commissioner’s Enforcement Priorities:

• Set post-inspection deadlines
• Take responsible steps to speed the warning letter process
• Work more closely with FDA’s regulatory partners internationally
• Prioritize follow-up on warning letters and other enforcement actions
• Be prepared to take immediate action in response to public health risks
• Develop and implement a formal warning letter “close-out” process.”
New Priorities at the FDA

– The need for increased transparency
– The need to increase and maintain credibility with the public
– To improve the US food safety system; Move the agency agenda from mitigating public health harm to an objective to prevent harm by keeping unsafe food from entering commerce in the first place.
– The Office of the Commissioner-level “Office of Foods” was established in August 2009
FDA’s Transparency Initiative

• FDA launched a web-based resource called *FDA Basics*

*FDA Basics* resource at
http://www.fda.gov/AboutFDA/Basics

• The resource includes:
  – Questions and answers about the agency and the products that the agency regulates
  – Short videos that explain various agency activities
  – Conversations with agency personnel about the work of their Office
New FDA Guidance for Industry
Guidance for Industry
Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

Webpage:
http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm179018.htm
The label of a dietary supplement should also include language indicating that the purpose of the domestic address or phone number is to report serious adverse events associated with use of the dietary supplement.
Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

- Information that must be included on the label of a dietary supplement to enable consumers to report serious adverse events associated with the use of the dietary supplement
Residual Solvents in Drug Products Marketed in the United States
Guidance for Industry
Residual Solvents in Drug Products Marketed in the United States

Webpage:
New Guidance on Q8 (R2) Pharmaceutical Development
Guidance for Industry
Q8 (R2) Pharmaceutical Development

Webpage:

November 2009 ICH revision 2
Current Good Manufacturing Practices

1. Do the CGMPs require a firm to retain the equipment status identification labels with the batch record or other file? Assuming each major piece of equipment has a unique "Cleaning and Use Log" that is adequately retained, is it acceptable to discard these 'quick reference' equipment labels?

2. Can containers, closures, and packaging materials be sampled for receipt examination in the warehouse?

3. A firm has multiple media fill failures. They conducted their media fills using TSB (trypsic soy broth) prepared by filtration through 0.2 micron sterilizing filter. Investigation did not show any obvious causes. What could be the source of contamination?
Current Good Manufacturing Practices

Webpage:
Our GMP Inspections
Focus of these Inspections in India:

- Management Responsibilities
- Focus on Application Integrity (Records, Manufacturing Systems, Laboratory test results)
- Monitor Impurities in API and inactive ingredients
- Perform Stability studies and investigate OOS incidents
- Ensure that supply chains are secure
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FDA India Office Contact

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Thank you

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