Securing and Sharing the Mission Worldwide:
Serving in the first USFDA Office in India

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Disclaimer

The points and views expressed in this presentation reflect the opinions of the presenter and do not necessarily represent the official position of the U.S. Food and Drug Administration.
Challenges of Globalization

Global Drug Manufacturing Supply Chain

Imported Finished Drug

Ingredients

Manufacture of Finished Drug

Ingredients

Active (API)

Ingredients
US Imports in 2009:
- 10-15% of food consumed
- 30% of drugs by value
- 80% of API used in US
- 50% of medical devices
- Expected annual growth 5-15%
Objectives of FDA’s Global Presence

1. Inspect firms that supply product to the United States
2. Interact and train industry on our requirements
3. Interact with our counterpart regulator in country and collaborate on quality and safety issues: build regulatory capacity
4. Interact and communicate with other US Government agencies at the embassy
So why is India Important?

- India supplies 40% of US Generic Drugs
- It supplies 2 out of 3 vaccines for the developing world
- It’s the largest supplier of HIV drugs in the world
- It supplies spices, seafood, rice, dietary supplements and cashew nuts to the US
Top 10 Countries for U.S. Drugs and Biologics Import
Fiscal Year: 2014

India Ranks 2 in Imported Lines
Becoming familiar with India
Food and Drug Regulation in India

Understanding the Regulatory Competent Authority
Government of India Regulators

Foods

Ministry of Health & Family Welfare
- Food Safety & Standards Authority (FSSAI)

Ministry of Food Processing & Industry (MOFPI)

Ministry of Commerce & Industry
- Export Inspection Council
- APEDA, MPEDA
- Spices Board

Drugs & Medical Devices

Ministry of Health & Family Welfare
- Central Drug Standard Control Office (CDSCO)
  - Drugs Controller General of India (DCGI)
  - Indian Council of Medical Research (ICMR)

Ministry of Chemicals & Fertilizers
- Department of Pharmaceuticals

Ministry of Science & Technology (MOST)
- Department of Biotechnology

State & Union Drug Administrations
**Central Drug Authority**

- Statutory enforcement & control
- Licensing of manufacturing (drugs & APIs)
- Monitoring, proficiency, & accreditation of drug testing labs
- Drug recalls

**FUTURE: Ministry of Health and Family Welfare CDSCO proposal**

**Central Drug Standards Control Office**

**State FDAs**

**Central Drug Authority**

**Drugs Controller General**

**Drugs Consultative Committee**

**Drugs Technical Advisory Board**

**Regulatory Affairs & Enforcement**

**New Drugs & Clinical Trials**

**Biological & biotechnology drugs**

**Pharmacovigilance**

**Medical Devices & Diagnostics**

**Imports**

**Quality control**
Centralizing Regulatory Authorities

- **Human Drugs**
- **Devices**
- **Vet Drugs**
- **Foods**

Towards Centralization
Drug Regulation in India

Role of Laboratories?
Drug regulation:
The Drugs and Cosmetics Act, 1940 (23 of 1940) and The Drugs and Cosmetics Rules, 1945, Ministry of Health and Family Welfare, Government of India
How did we begin?

- Dr. Beverly Corey opened the India Office in November 2008 in New Delhi and Mumbai
- 11 US direct Hires and 3 Indian Nationals arrive in July 2009
- Introduce ourselves to the Embassy
- The Ministry of Health in India
- The Industry at conferences
- We begin to inspect firms and gather information on exporters to the US
Beverly Corey: 1st Acting Country Director
Staff in the India Office
Objectives of FDA’s India Office

(1) Inspect firms that supply product to the United States
(2) Interact and train industry on our requirements
(3) Interact with our counterpart regulator in country and collaborate on quality and safety issues: build regulatory capacity
(4) Interact and communicate with other US Government agencies at the embassy
What is the advantage of being there?

- Timely Information about products and firms
- Parity of FDA inspections - Foreign and domestic
- Flexibility to conduct inspections - depth and quality
- Conducting joint International inspections
- Improved communication with industry and regulators - accompanied inspections with Indian regulator
Inspect Firms

- About 1/3 of FDA Inspections in India were conducted by the FDA India Office Staff in 2013
- The inventory of firms was confirmed by the India Office
- USFDA GUDFA regulations and registrations confirmed that there are 600+ Indian pharmaceutical sites
- The uncertainty regarding food manufacturing sites is considerably reduced
What is the Impact?

• Several Indian firms received warning letters for the first time
• Recalls based on quality issues increased
• Import Alerts for several package foods
• Indian industry has responded by investing in corrective and preventive actions
• Improved communication with Centers and ORA field staff and international regulators
Collaborate with Indian Regulators and Industry
Interactions with the Indian Regulator:

- Frequent meetings on collaboration to build capacity

- In 2014, USFDA signed a “Statement of Intent” to collaborate on pharmaceuticals with India’s Ministry of Health

- In 2015, USFDA signed a “Statement of Intent” with India’s Ministry of Commerce to cover foods

- The relationship is moving in the direction of improving trust and collaboration on food and medical products
Our Activities in the Pharmaceutical Area:

1) Train the trainer program on Good Clinical Practice
   Dr. David Lepay

2) Pharmacovigilance:
   New Bio-statistical methods to detect Adverse events
   Dr. Ram Tiwari

3) Designation of Orphan Drugs Workshop
   Dr. Mathew Thomas and James Reese
Our Activities in the Pharmaceutical Area:

4) Nine Workshops on Rapid Testing methods
   Dr. Lucinda Bushe, Dr. John Kauffman & Mr. Nick Westheimer

5) Four Workshops on “How to submit a generic application and aspects of Quality by Design”
   Dr. Lane Christensen and Dr. Vilayat Sayeed

6) Four Workshops on Data Integrity and Preventive controls for good manufacturing practice
   Thomas Arista, Alicia Muzacio, Abi D’Sa, Farhana Khan
Our Other Activities included:

7) Workshops on quality systems on medical devices and CDRH Inspection process

8) Several Workshops on Food Safety for Low acid Can Foods & steam sterilized products

9) Several Workshops on quality systems for spices, HACCP requirements

10) Several Workshops on quality systems for seafood HACCP
Interactions with other USG Agencies and International Offices

• Health and Human Service and its components (HHS)
  – Clinical trials (NIH)
• Drug Enforcement Agency (DEA)
  – Drugs of abuse
• Customs and Bordered Protection (CBP)
  – Counterfeit issues
• US Department of Agriculture (USDA)
  – Imports and Exports from and into India (Milk, Rice, Almonds, Spices)
• USDA Animal and Plant Health Inspection Service (APHIS)
  – Mangoes, Lychees
• Department of Commerce
  – Counterfeits and API imports from China and India
So what did we discover?

• Indian industry is extremely cost conscious and so will cut corners
• Some of these short cuts lead to quality issues
• Most data integrity issues are related to poor product and process design; lack of monitoring and supervision; and poor documentation practices
Data integrity

Generally in two areas:

**Laboratory Testing:**
1) Impurity testing
2) Dissolution testing

**Environmental Monitoring:**
Microbiological
Particulates
Areas of collaboration?

- **Good Manufacturing Practices**
  - Data Integrity
  - Quality Standards
  - Automation and Affordability
  - Clinical and Bioequivalence monitoring

- **Control of Counterfeits**
Current FDA India Office Priorities

Conduct high priority inspections and at short notice

Capacity Building and Outreach Activities

- Conduct Workshops (across all commodities and program areas) on
- Inviting Competent Authority inspectors to observe FDA drug, BIMO, and foods inspections
- Meeting with Key Stakeholders (industry and partners) to discuss FDA’s expectations for the manufacture and testing for safe and effective medicines
- Engaging academia to develop sustainable training programs for regulators and stakeholders
Priorities for the India Office

- Science-based approaches for enforcement
- Developing technical collaborations and competency in the use of rapid testing methods to detect spurious, substandard, falsely-labeled, fraudulent or counterfeit medicines (SSFFC)
- Collaborations to enhance FDA’s ability to build spectral libraries of critical drugs to assess the quality of finished pharmaceuticals entering the supply chain
Vision for the Future

• U.S. and India collaborations will increase in the generic and the bio-tech areas
• Indian manufacturer will continue to be a major supplier for the U.S. and world markets for quality generic drugs
• Indian vaccines and bio-tech products are likely to be imported into the U.S.
• Collaborations and the Bioequivalence and clinical trial space are to be expected to increase
• India will continue to dominate in the bio equivalence area for generic drugs
What will enhance the relationship?

• India having one standard for quality of medicines and food for its domestic and international supply chain

• Asia (India and China as major players) becoming major partners for development of medicines and training of international drug regulators

• India developing a quality and safety culture that continues to provide affordable medicines for the world

• India regulatory counterpart and industry joining international regulators forums (ICH, PICS) to address quality safety and efficacy issues for medical products
A Vision for the India Office

• Within FDA develop a seamless hiring process with the right kind of incentives
• Entrust Centers and ORA with a prominent international roles to share and train international regulators and inspectors: Move toward one quality standard for medicines and foods
• Move toward consensus standards for quality and risk management
• Develop a regional approach to collaborate within Asia with India and China as Regional Centers
• The public health impact could be enhanced if we plant seeds to include and cultivate India and China as our future trusted partners
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Namasthe!

“Declare the past, Diagnose the present, Foretell the future.”

— Hippocrates