



INSTITUTE OF MEDICINE

OF THE NATIONAL ACADEMIES

STRENGTHENING CORE ELEMENTS OF REGULATORY SYSTEMS IN DEVELOPING COUNTRIES

MARCH 2-3, 2011

MEETING AGENDA

Keck Building
500 Fifth Street NW
Washington, DC 20001

Day 1 Goals:

- 1) Introduce the National Academies' study process
- 2) Discuss bias and conflict-of-interest
- 3) Fully understand this study's statement of task
- 4) Learn about the capacity and priorities of the FDA

DAY ONE: WEDNESDAY, MARCH 2, 2011 The Keck Building, Room 109

SESSION 1 - CLOSED IOM COMMITTEE PROCESS AND CHARGE TO COMMITTEE

Objectives: To review the National Academies' study process that includes a bias and conflict-of-interest discussion; to discuss the role of the committee in addressing the statement of task; and to ensure the committee understands their statement of task.

SESSION 2- OPEN QUESTIONS ON STATEMENT OF TASK

11:10 – 11:30	Project Timeline and Statement of Task Sponsor Representative Introductions Jim Riviere , Committee Chair
11:30 – 12:15	Questions to Sponsor Mary Lou Valdez , Associate Commissioner for International Programs, FDA Kate Bond , Associate Director for Technical Cooperation/Capacity-Building, FDA
12:15	Lunch

SESSION 3- OPEN THE FDA PERSPECTIVE
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Objective: To learn about the FDA's current capacity and its international work.

12:45	Welcome the Public and Introduce Commissioner Hamburg Jim Riviere , Committee Chair
12:45 – 1:05	Keynote Address: Why is this study important to the FDA? Margaret Hamburg , Commissioner, FDA
1:05 – 1:25	Questions

- 1:25 – 2:30 What is the capacity of the FDA Centers? What are the key issues they face in international work?
Deb Autor, Director, Office of Compliance, FDA Center for Drug Evaluation and Research
Karen Midthun, Director, FDA Center for Biologics Evaluation and Research
Lillian Gill, Senior Associate Director, FDA Center for Devices and Radiological Health
Don Kraemer, Acting Deputy Director for Operations, FDA Center for Food Safety and Applied Nutrition
- 2:30 – 2:50 How is the FDA already working to build regulatory systems abroad?
Mac Lumpkin, FDA Deputy Commissioners for International Programs
- 2:50 – 3:20 Panel discussion with presenters
Jane Henney, Moderator
- 3:20 – 3:35 Break

SESSION 4 - OPEN CORE ELEMENTS OF REGULATORY SYSTEMS

Objective: To identify the core elements of regulatory systems in developing countries and what gaps exist in these systems.

- 3:35 – 4:00 Core Elements of Medical Device Regulatory Systems in Developing Countries
Michael Gropp, Vice President, Global Regulatory Strategy, Medtronic
Greg Kalbaugh, Director and Counsel, US Chamber of Commerce, US-India Business Council
- 4:00 – 4:25 Core Elements of Food Regulatory Systems in Developing Countries
Ernesto Enriquez, Ministry of Health, Mexico
Paul B. Young, Director, Chemical Analysis Operations, Waters Corporation
- 4:25 – 4:55 Core Elements of Drug and Biologics Regulatory Systems in Developing Countries
Jose Luis Di Fabio, Area Manager, PAHO
Ekopimo Okon Ibia, Director and US Regulatory Policy Lead, Global Regulatory Strategy, Policy, and Safety, Merck & Co., Inc.
- 4:55 – 5:45 What are the gaps in the systems? A panel discussion with presenters
Martha Brumfield, Moderator
- 5:45 **Adjourn**

DAY TWO: THURSDAY, MARCH 3, 2011
The Keck Building, Room 110

Day 2 Goals:

- 1) Learn about existing recommendations and the obstacles to implementing them
- 2) Make a strategy for how to tackle the statement of task
- 3) Discuss how to structure the final report
- 4) Begin considering possible recommendation topics

SESSION 5 - CLOSED
REACTIONS TO PRESENTATIONS AND PLANNING TRAVEL

Objective: To discuss the presentations and plan the travel meetings.

SESSION 6 - OPEN
EXISTING RECOMMENDATIONS AND OBSTACLES TO IMPLEMENTATION

Objective: To learn what recommendations have already been made to strengthen regulatory systems and what obstacles exist to implementing these recommendations.

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| 10:10 – 10:30 | The Global Harmonization Task Force
Michael Gropp , Vice President, Global Regulatory Strategy, Medtronic |
| 10:30 – 10:50 | Promoting the Quality of Medicines
Patrick Lukulay , Director, Promoting the Quality of Medicines Program, US Pharmacopeia |
| 10:50 – 11:10 | Capacity Building and the Partnership Training Institute Network
Paul B. Young , Director, Chemical Analysis Operations, Waters Corporation |
| 11:10 – 11:30 | The Global Food Safety Initiative
Mike Robach , Vice President Corporate Food Safety and Regulatory Affairs, Cargill |
| 11:30 – 11:50 | The International Medical Products Anti-Counterfeiting Taskforce
Howard Zucker , Senior Advisor, Division of Global Health & Human Rights, Massachusetts General Hospital |
| 11:50 – 12:30 | Lunch |
| 12:30 – 1:15 | What prevents implementing recommendations? A panel discussion with presenters
Tom Bollyky , Moderator |

SESSION 7 – CLOSED
DISCUSSION AND STRATEGY FOR THE WAY FORWARD

Objective: To review the previous session, begin discussing recommendations, and give feedback on the meeting.