Background and Meeting Objectives:
The last several decades have seen a rapid globalization of commerce, including within the medical product and technology sectors. Investigational studies are increasingly being conducted outside the countries that have a history as hubs for biomedical research, often in countries with limited regulatory capacity. Moreover, biopharmaceutical companies seeking global markets face requirements for regulatory submissions for the same product in numerous international jurisdictions that could introduce scientific requirements that are discordant with standards in their home markets. Discordant data requirements could result in additional clinical trials and animal studies, exposing more patients to experimental drugs and increasing the use of laboratory animals. There is a need for globally harmonized, science-based standards for the development and evaluation of safety, quality, and efficacy of medical products – both to enhance the efficiency and clarity of the drug development and evaluation process, and ultimately to promote and enhance product quality and the public’s health. There is also need for harmonization of standards for ongoing safety and quality surveillance of marketed biomedical products.

This public workshop will address needs for international harmonization of regulatory standards to support the development, evaluation and surveillance of biomedical products. Specifically, the discussions at the workshop will help identify principles, potential approaches, and strategies to advance the development or evolution of more harmonized regulatory standards.

The workshop objectives are to:

• Provide an overview of the current global regulatory landscape. Identify:
  o Current organized efforts to promote and evolve harmonized standards, and examples of areas where standards are viewed as adequately harmonized.
  o Areas of need for development or evolution of harmonized standards.

• Identify the characteristics of a well-harmonized regulation.

• Discuss principles to guide the establishment or evolution of harmonized regulations.

• Discuss options and approaches that could facilitate or underlie systemic organizational efforts to develop and/or evolve harmonized standards.
  o Discuss potential structures, methodologies, goals, and outcomes.
Day One: February 13, 2013

8:30 a.m. Opening Remarks

STEVEN GALSON, Workshop Co-Chair
Vice President for Global Regulatory Affairs
Amgen Inc.

TOM BOLLYKY, Workshop Co-Chair
Senior Fellow for Global Health, Economics, and Development
Council on Foreign Relations

8:50 a.m. Plenary Keynotes: Needs from the Perspective of Stakeholders

Keynote Address: Industry

PETER HONIG
VP and Head, Global Regulatory Affairs
AstraZeneca

Keynote Address: Regulator

HUBERT G. M. LEUFKENS
Chairman, Dutch Medicines Evaluation Board;
Member, Committee on Human Medicinal Products, European Medicines Agency

SESSION I: PRINCIPLES AND DEFINITIONAL CONSIDERATIONS

Session Objectives:

- Discuss potential goals for initiatives, including differences arising from terminology.
- Consider potential variations in approach depending on which terminology is adopted and how the desired outcome is defined.

9:35 a.m. Background and Session Objectives

ANDREAS SEITTER, Session Chair
Senior Health Specialist
Pharmaceuticals, Health, Nutrition, and Population
World Bank
9:40 a.m. **Series of Presentations**

*History and Importance of Terminology, the Terminology Landscape, and Options for Regulators*

MIKE WARD  
Manager, International Programs  
Health Canada

*Standards-Setting in the Context of Regulatory Harmonization*

CAROLYN COMPTON  
President and CEO  
Critical Path Institute

10:20 a.m. **Discussion with Speakers and Audience**

10:40 a.m. **BREAK**

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SESSION II: OVERVIEW OF CURRENT GLOBAL REGULATORY LANDSCAPE

Session Objectives:
- Provide an overview of the current global regulatory landscape.
- Identify current organized efforts to promote and evolve harmonized standards.
- Highlight examples of areas where standards are viewed as adequately harmonized and/or harmonization processes are viewed as well-working.

11:00 a.m. Background and Session Objectives

HANS HOGERZEIL, *Session Chair*  
Professor of Global Health  
University of Groningen, The Netherlands

11:05 a.m. **Series of Presentations**

*International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)*

TOSHIYOSHI TOMINAGA  
Professor  
Osaka City University Hospital
Latin America

JAMES FITZGERALD
Senior Advisor, Essential Medicines and Biologicals
Pan American Health Organization

APEC Regulatory Harmonization Steering Committee (RHSC)

MIKE WARD
Manager, International Programs
Health Canada

East African Community (EAC) Medicines Registration Harmonization Project

MARGARETH NDOMONDO-SIGONDA
Pharmaceutical Coordinator
New Partnership for Africa’s Development
African Union

12:05 p.m. Discussion with Speakers and Audience

Discussion Topics/Questions
• Description and characterization of existing international standards-setting bodies
• Description and examination of regional harmonization efforts
• Identification and discussion of particular standards that have been developed

12:30 p.m. LUNCH
SESSION III: AREAS OF NEED FOR HARMONIZED STANDARDS AND BARRIERS TO PROGRESS IN ADDRESSING THE GAPS

Session Objectives:

- Discuss gaps in the current structures, approaches, and international standards leading to unnecessary discordance among regulatory requirements.
  - Identify top-priority areas where harmonized standards need to be developed or evolved.
  - Consider regulatory requirements and harmonization needs across the full spectrum of medical product development, evaluation, and monitoring/surveillance.
- Discuss how gaps are identified and priorities are set within harmonization efforts.
- Having considered the gaps and areas of need, identify the key barriers that stand in the way of addressing the identified needs.
- Discuss approaches that have been tried and have failed to address the needs.

1:15 p.m. Background and Session Objectives

STEVEN GALSON, Session Chair
Vice President for Global Regulatory Affairs
Amgen Inc.

1:20 p.m. Stakeholder Presentations: Gaps in Current Structures and High-Priority Areas of Need

Overview: Gaps from the Regulator’s Perspective

DOUGLAS THROCKMORTON
Deputy Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Overview: Gaps from the Perspective of NGOs/Foundations/Product Development Partnerships

VINCENT AHONKHAI
Deputy Director, Regulatory Affairs
Bill and Melinda Gates Foundation

2:00 p.m. Overview of Charge to Breakout Groups

STEVEN GALSON, Session Chair
Vice President for Global Regulatory Affairs
Amgen Inc.
Breakout Groups Convene Concurrently

General Discussion Topics/Objectives:
- Identify the key barriers that stand in the way of addressing the identified needs. What are the issues that are the most pressing?
- Discuss approaches that have been tried and have failed to address the needs.
- Deliberate on potential options to address those high-priority needs for consideration at the workshop.

1. Qualification of Innovative Development Methods/Drug Development Tools
   [STAY IN LECTURE ROOM]
   - Richard Meibach, Novartis Pharmaceuticals (moderator)
   - Martha Brumfield, Critical Path Institute (rapporteur)

2. Clinical Development [BOARD ROOM]
   - Judith Kramer, Duke University (moderator)
   - Leslie Ball, U.S. Food and Drug Administration (rapporteur)

3. Evaluation & Evidentiary Requirements [ROOM 125]
   - Tim Franson, FaegreBD Consulting (moderator)
   - Lawrence Liberti, Centre for Innovation in Regulatory Science (rapporteur)

4. Postmarket Safety Surveillance [MEMBERS ROOM]
   - Amrit Ray, Johnson & Johnson (moderator)
   - Andy Stergachis, University of Washington (rapporteur)

5. Manufacturing Standards and Process [ROOM 114]
   - Moheb Nasr, GlaxoSmithKline (moderator)
   - Diane Zezza, Novartis Pharmaceuticals (rapporteur)

Breakout Groups Conclude

Reports from Breakout Groups

Day 1 Reflections

Adjourn day 1
SESSION IV: CHARACTERISTICS OF HARMONIZED REGULATIONS AND REGULATORY STRUCTURES

Session Objectives:
- Consider examples of standards-setting and regulatory harmonization from other sectors and their application to biomedical research and medical product regulation.
- Identify the characteristics of a “well-harmonized regulation” or well-working process.
- Discuss principles to guide the establishment or evolution of harmonized regulations or other desired process and outcomes.

8:35 a.m. Background and Session Objectives

JAMES FITZGERALD, Session Chair
Senior Advisor, Essential Medicines and Biologicals
Pan American Health Organization

8:40 a.m. Series of Presentations

Radiation Safety Standards
CINDY FLANNERY
Senior Health Physicist
U.S. Nuclear Regulatory Commission

Reflections on the Experiences of the World Health Organization
LEMBIT RAGO
Coordinator for Quality and Safety of Medicines
World Health Organization
Reflections on the Experiences of the European Medicines Agency
JOHN PURVES
Independent Consultant

9:10 a.m. Discussion with Speakers and Audience

9:40 a.m. BREAK

SESSION V: FINDING SOLUTIONS TO THE CHALLENGES OF REGULATORY HARMONIZATION: OPTIONS AND SYSTEMIC APPROACHES

Session Objectives:

- Discuss options and approaches that could facilitate or underlie systemic organizational efforts to develop and/or evolve harmonized standards.
- Discuss potential structures, methodologies, goals, and outcomes.
- Examine these issues with respect both to development and implementation of desired standards and/or processes.

10:00 a.m. Background and Session Objectives

MICHAEL J. BRENNAN, Session Chair
Senior Advisor, Global Affairs
Aeras

10:05 a.m. Reaction Panel: Potential Solutions from Stakeholder Perspectives

VINCENT AHONKhai
Deputy Director, Regulatory Affairs
Bill and Melinda Gates Foundation

RAYMOND CHUA
Group Director, Health Products Regulation Group
Singapore Health Sciences Authority

HIITI B. SILLO
Director General
Tanzania Food & Drugs Authority

MARY LOU VALDEZ
Associate Commissioner for International Programs
U.S. Food and Drug Administration

DAVID WOOD
Coordinator of Quality, Safety and Standards: Immunization, Vaccines and Biologicals
World Health Organization
10:55 a.m. **Discussion with Speakers and Audience**

**Discussion Topics/Questions:**
- What process or systemic approach holds most promise for supporting development of harmonized standards or processes?
- What are the needed structures to support implementation of harmonized standards or processes within various systems (e.g., training, capacity-building, networks, other needs)?
  - How can novel harmonization/convergence strategies, policies, and processes be implemented to facilitate the efficient global introduction of quality products?
- How can we promote and expand on current harmonization/convergence strategies to alleviate regulatory roadblocks?

11:30 a.m. **BREAK FOR LUNCH**

**SESSION VI: CONCLUDING STAKEHOLDER DISCUSSION: TACTICS AND STRATEGIES FOR A WAY FORWARD**

**Session Objectives:**
- Discuss key themes from the workshop.
- Based on workshop presentations and discussions, identify tactics and strategies (both short- and long-term for addressing the needs for developing and evolving more harmonized regulations and regulatory structures.

12:30 p.m. **Closing Discussion with Panelists and Audience: Led by Workshop Co-Chair(s)**

STEVEN GALSON, *Workshop Co-Chair*
Vice President for Global Regulatory Affairs
Amgen Inc.

TOM BOLLYKY, *Workshop Co-Chair*
Senior Fellow for Global Health, Economics, and Development
Council on Foreign Relations

12:35 p.m. **Panel 1: Presentation of Key Themes/Suggested Paths**

HANS HOGERZEIL, *Chair of Session I*
Director for Essential Medicines (former)
World Health Organization

ANDREAS SEITER, *Chair of Session II*
Senior Health Specialist
Pharmaceuticals, Health, Nutrition, and Population
World Bank
STEVEN GALSON, Chair of Session III  
Vice President for Global Regulatory Affairs  
Amgen Inc.

JAMES FITZGERALD, Chair of Session IV  
Senior Advisor, Essential Medicines and Biologicals  
Pan American Health Organization

MICHAEL J. BRENnan, Chair of Session V  
Senior Advisor, Global Affairs  
Aeras

1:00 p.m. Discussion with Speakers and Audience

1:30 p.m. Panel 2: Reflecting on Tactics and Strategies for a Way Forward

DEBORAH AUTOR  
Deputy Commissioner for Global Regulatory Operations and Policy  
U.S. Food and Drug Administration

HANS-GEORG EICHLER  
Senior Medical Officer  
European Medicines Agency

ALAN MORRISON  
Vice President for International Regulatory Affairs and Safety  
Amgen Inc.

2:00 p.m. Discussion with Speakers and Audience

2:45 p.m. ADJOURN