

ASEAN-US
Technical Assistance & Training Facility



SUMMARY AND PARTICIPANT EVALUATION

**ASEAN Member Country Drug Regulators/CDER Forum Study
Tour, Washington, DC (April 16-23, 2007)**



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SUBMITTED BY
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ASEAN-US Facility

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The ASEAN-US Technical Assistance and Training Facility sponsored six ASEAN Member Country drug regulatory authorities to participate in intensive technical training and meetings in the Washington, DC area in April 2007. The group attended the week-long Center for Drug Evaluation and Research (CDER) Forum for International Drug Regulatory authorities, and held constructive consultations with the U.S. Food and Drug Administration (USFDA), a U.S. Government interagency group, and U.S. industry representatives. The study tour was held under the context of the Work Program of the ASEAN-US Trade and Investment Framework Arrangement (TIFA), in which the USTR has committed to support ASEAN's own efforts to harmonize pharmaceutical regulations, particularly as regards licensing and registration. More broadly, the visit also met objectives under the ASEAN-US Enhanced Partnership in which ASEAN and the U.S. have agreed to cooperate in the areas of standards and conformance.

The six study tour participants were drawn from ASEAN's Consulting Committee on Standards and Quality Pharmaceutical Product Working Group (PPWG), which has a mandate to harmonize pharmaceutical technical regulations/requirements across ASEAN Member Countries, and the Implementation Working Group (IWG) for the ASEAN Common Technical Dossier (ACTD), which is ensuring implementation of a common registration format that would ease trade in the region without compromising drug quality, safety and efficacy. The participants represented regulatory authorities in Indonesia, the Philippines, Singapore and Vietnam.

The CDER Forum, held April 16-20, allowed for exchange of information among drug regulators from various countries and provided an overview of specific US drug regulatory processes. The Forum also provided training on issues of direct relevance to implementation of the ASEAN Common Technical Dossier, including bioequivalence, product quality, safety and efficacy, good manufacturing practices and post-market surveillance. Participants rated the forum very high, praising its interactive format and coverage of issues and recommending that colleagues attend future CDER Forums.

Monday, April 23rd was reserved for ASEAN-US dialogue. Participants spent the morning with the U.S. FDA learning about its use of International Conference on Harmonization (ICH) Guidelines and discussing possible areas for cooperation between ASEAN regulatory authorities and the FDA. The FDA welcomed future cooperation, affirmed the benefits of harmonization, and introduced its key staff for follow up. The FDA agreed to provide FDA alumni trainer contact information to respond to specific needs if requested by ASEAN. Moreover, FDA representatives cited, the ICH's Global Cooperation Group (GCG), as a ready forum from which ASEAN could seek capacity building assistance. The ICH has already proposed to work with regional harmonization groups, including ASEAN. The FDA suggested that ASEAN submit specific training requests to the GCG and offered cost-effective training solutions, including video-conference training or aligning training with the next ICH meeting scheduled for October in Japan. ASEAN representatives agreed to report back to the PPWG for next steps. As the IWG has already canvassed ASEAN Member Countries for specific training needs, ASEAN is poised to submit a formal request quickly.

The ASEAN Member Country representatives outlined their current PPWG and IWG work program for representatives of USTR, the US Department of State, Department of Commerce and the US Patent and Trademark Office at the interagency session. USTR reiterated its support for the PPWG's harmonization efforts under the TIFA work program and asked if the PPWG would be open to US dialogue. ASEAN Member Country discussed two mechanisms for dialogue, the ASEAN Pharmaceutical Research-based Association (APRA) composed primarily of multinational corporations and the ASEAN Pharmaceutical Club for the generics industry. Members of USTR and the US Patent and Trademark Office raised intellectual property rights as an area for possible future cooperation, specifically combating counterfeit medicines and data protection. ASEAN Member Country Representatives affirmed the importance of such issues and it was pointed out that the ASEAN Working Group on Technical Cooperation in Pharmaceuticals (under the Health Ministries) has a work plan to combat counterfeit drugs. The coordinating country for that program is Indonesia.

An afternoon session with Pharmaceutical Research and Manufacturers Association (PhRMA) produced a constructive dialogue between industry representatives and ASEAN drug regulators. Industry representatives posed tough technical questions regarding ASEAN's implementation of the ACTD. Recognizing the challenge to regulators, they were impressed to hear about progress and would like to continue the dialogue and provide assistance if possible. Industry participants praised ASEAN for setting an example in harmonization, and encouraged them to remain a leader in their field. The ASEAN representatives agreed that the dialogue with the private sector was useful and thanked them for the opportunity. Indeed the need for more and regular communication with the private sector, regulators and negotiators emerged as a theme in both the wrap-up session and participant evaluations.

A summary of participant evaluations, the full agenda, and the ASEAN presentation to its meeting partners is attached.

Evaluation Summary

CDER Forum/ASEAN Drug Regulators Study Tour

ASEAN-US Technical Assistance & Training Facility Workshop

April 16-23, 2007

Washington, DC

Your answers to this questionnaire will help us to improve our training programs. Thank you for taking the time to fill it out.

Personal Data

Countries of representation: Indonesia, Philippines,
Vietnam, Singapore

Gender: 2 Male 4 Female

Conference & Meetings

On a scale of 1 to 6, please rate how informative each session was for you. A rating of 6 indicates that you found the session highly informative; a rating of 1 that you did not find it informative.

Presentation and Presenter	Average
FDA CDER Forum <i>US FDA</i>	6
FDA-ASEAN Drug Regulators <i>Justine Molzon/Juliet Ho</i>	5
USTR-Interagency Meeting <i>David Katz</i>	4
PhRMA <i>Mark Paxton</i>	5

Subject Matter

1. What part of the CDER Forum did you like the most?
 - Post-market program and related regulatory services
 - OTC regulations and generics
 - Interactive format, lots of opportunities for questions
 - Depth and scope of presentations

2. What part of the CDER Forum did you like the least?

- None (x2)
- Not sure

3. What other topics would you like to see included?

- More harmonization issues on pharmaceuticals
- Food supplements
- Office of Ombudsmen, vaccines and biotropicals, cell and tissue therapies, gene therapy → another CDER Forum may be needed.

4. Did this course use a good mix of lecture and interactive discussion?

- Yes (x4)

5. Would you recommend that ASEAN representatives attend the CDER Forum in the future? Why/why not?

- Yes, because the forum is quite informative
- Yes, the forum is very useful
- Yes, relevant information

6. What part of the FDA, interagency and PhRMA meetings did you like the most/find the most useful?

- FDA (x2)
- Meeting with FDA and discussion on future training
- FDA dialogue

7. What part of the FDA, interagency and PhRMA meetings did you like the least

- Interagency
- None
- Interagency meeting – expectations different on both sides

8. What sorts of follow-up activities with the FDA, private sector representatives and other US government agencies would you find useful?

- Effective network with FDA and better communication mechanism with private sector representatives.
- All of these.
- Perhaps a capacity work plan needs to be developed.
- Training forum on key regulatory issues would be useful, especially if held offsite in the region.

Thank you for filling out this questionnaire. Additional comments on any aspect of this course are welcome.

Agenda

ASEAN Drug Regulators/CDER Forum Study Tour

April 16 - 23, 2007

Washington, D.C. USA

APRIL 16 - 20, 2007
US Food and Drug Administration
Center for Drug Evaluation and Research
International Drug Regulators Forum

APRIL 16 **Overview of Process and Structure**

8:30 - 9:00 a.m.	<i>Registration</i>	
9:00 - 9:15	Welcome and Introduction	Justina A. Molzon, M.S. Pharm., J.D. Associate Director International Programs CDER, FDA
9:15 - 9:45	FDA in the International Community Introduction of Countries Attending Forum	Justina A. Molzon, M.S. Pharm., J.D. Associate Director International Programs CDER, FDA Beverly Corey, DVM Director International Relations Staff Office of International Programs Office of the Commissioner, FDA
9:45 - 10:45	CDER's Center Director	Steven K. Galson Director CDER, FDA
10:45 - 11:00	<i>Break</i>	
11:00 - 12:00 p.m.	Drug Review and Related Activities in the United States	Mary E. Kremzner, Pharm.D. Deputy Director Division of Drug Information Office of Training and Communications CDER, FDA
12:00 - 1:30	<i>Lunch</i>	
1:30 - 2:00	Good Review Practices	Howard D. Chazin, M.D., M.B.A Medical Officer Guidance and Policy Team Office of New Drugs CDER, FDA
2:00 - 3:00	Drug Review Process Overview	Ramzi Dagher Lead Medical Officer Division of Drug Oncology Products Office of Oncology Drug Products Office of New Drugs, CDER, FDA

Agenda

ASEAN Drug Regulators/CDER Forum Study Tour

April 16 - 23, 2007

Washington, D.C. USA

3:00 - 3:15	Good Guidance Practices	Nancy Derr Writer/Editor/Policy Analyst Office of Regulatory Policy CDER, FDA
3:15 - 3:30	ICH and the Common Technical Document	Justina A. Molzon, M.S. Pharm., J.D. Associate Director International Programs CDER, FDA
3:30 - 3:45	<i>Break</i>	
3:45 - 4:30	Advisory Committees	Igor Cerny, Pharm.D. Director Advisors and Consultants Staff Office of Executive Programs CDER, FDA
4:30 - 5:00	Training Reviewers	Janice Newcomb Director Division of Training and Development Office of Training and Communications CDER, FDA

APRIL 17	Review of New Molecular Entities	
9:00 - 9:15	Welcome	Justina A. Molzon, M.S. Pharm., J.D. Associate Director, International Programs, CDER, FDA
9:15 - 10:15	Overview of the Office of New Drugs	Grace Carmouze Lead Project Management Officer, Immediate Office, Office of New Drugs, CDER, FDA
10:15 - 10:30	<i>Break</i>	
10:30 - 11:30	Labeling Overview	Jeanne Delasko Label Initiatives Specialist Office of New Drugs, CDER, FDA
11:30 - 1:00 p.m.	<i>Lunch</i>	
1:00 - 1:15	Photo	
1:15 - 3:15	Panel of Discipline Roles and Review Templates	Discipline Panel <ul style="list-style-type: none">• Medical Officer Lesley-Anne Furlong, MD Medical Officer, Division of Reproductive and Urologic Drug Products, Office of Drug Evaluation 3, CDER, FDA• Project Manager Leah Christl, Ph.D.,

Agenda

ASEAN Drug Regulators/CDER Forum Study Tour

April 16 - 23, 2007

Washington, D.C. USA

		Regulatory Project Manager and Acting Chief, Project Management Staff, Office of Nonprescription Products, Office of New Drugs, CDER, FDA
	<ul style="list-style-type: none">• Chemist	Norman Schmuff Branch Chief, Branch IV Division of Pre-Marketing Assessment II, Office of New Drug Quality Assessment, Office of Pharmaceutical Science, CDER, FDA
	<ul style="list-style-type: none">• Pharmacologist	Angelica Dorantes Division of Clinical Pharmacology I Office of Clinical Pharmacology, Office of Translational Sciences, CDER, FDA
	<ul style="list-style-type: none">• Statistician	Daphne Ty Lin, Ph. D. Deputy Director Division Of Biometrics III Office Of Biostatistics Office of Pharmacoepidemiology and Statistical Science, CDER, FDA
	<ul style="list-style-type: none">• Drug Safety	Denise Toyer, Pharm.D., R.PH Deputy Director, Division of Medication Errors and Technical Support, Office of Drug Safety, CDER, FDA
	<ul style="list-style-type: none">• Biologics	Steve Kozlowski, M.D. Director, Office of Biotechnology Products, Office of Pharmaceutical Science, CDER
	<ul style="list-style-type: none">• Pharmacologist Toxicologist	Amy L. Ellis, Ph.D. Division of Anti-Infective and Ophthalmology Products Office of Antimicrobial Products Office of New Drugs, CDER, FDA
3:15 - 3:30	<i>Break</i>	
3:30 - 4:15	Specialty Reviews - Biologics	Glen Jones Associate Director For Regulatory Affairs, Office Of Oncology Drug Products, Office Of New Drugs, CDER, FDA
4:15 - 4:45	Specialty Reviews - Pediatrics	Jean Temeck, M.D., Medical Team Leader. Pediatric and Maternal Health Staff, Immediate Office, Office of New Drugs, CDER, FDA

Agenda

ASEAN Drug Regulators/CDER Forum Study Tour

April 16 - 23, 2007

Washington, D.C. USA

APRIL 18		
Review of OTC and Generics		
9:00 - 9:05 a.m.	Welcome	Justina A. Molzon, M.S. Pharm., J.D. Associate Director International Programs CDER, FDA
9:05 - 9:45	Regulation of Over-The-Counter Drugs	Leah Christl, Ph.D., Regulatory Project Manager and Acting Chief, Project Management Staff, Office of Nonprescription Products, Office of New Drugs, CDER, FDA
9:45 - 10:45	Overview of the Generic Drug Process	Ted Sherwood Management Analyst Office of Pharmaceutical Science CDER, FDA
10:45 - 11:00	<i>Break</i>	
10:45 - 11:45	Chemistry	Ubrani Venkataram Chemist Division of Chemistry II Office of Generic Drugs Office of Pharmaceutical Sciences CDER, FDA
11:45 - 1:15 p.m.	<i>Lunch</i>	
1:15 - 2:30	BioEquivalence	Shirley K. Lu, Ph.D. Division of Bioequivalence Office of Generic Drugs, CDER, FDA Barbara M. Davit, J.D., Ph.D. Deputy Director, Division of Bioequivalence Office of Generic Drugs
2:30 - 3:15	Ethics	Vincent R. Tolino Director, Ethics and Integrity Staff, Office of Management Programs, Office of Management, Office of the Commissioner, FDA
3:15 - 3:30	<i>Break</i>	
3:30 - 4:15	The Role of CDER's Office of Business Process Support	Gary M. Gensinger, MBA Director Regulatory Review Support Staff Office of Business Process Support CDER, FDA

Agenda

ASEAN Drug Regulators/CDER Forum Study Tour

April 16 - 23, 2007

Washington, D.C. USA

APRIL 19	Good Manufacturing Practice and Good Clinical Practice	
9:00 - 9:15	Welcome	Justina A. Molzon, M.S. Pharm., J.D. Associate Director International Programs CDER, FDA
9:15 - 9:30	Compliance Overview	Deborah M. Autor, Esq. Director Office of Compliance, CDER, FDA
9:30 - 10:30	New Drugs and Labeling Compliance	
	<ul style="list-style-type: none">• Overview	Kathleen R. Anderson, Pharm. D. Deputy Director Division of New Drugs and Labeling Compliance Office of Compliance, CDER, FDA
	<ul style="list-style-type: none">• Internet and Health Fraud	Linda Silvers, D.V.M., M.P.H. Team Leader, Division of New Drugs and Labeling Compliance Office of Compliance, CDER, FDA
	<ul style="list-style-type: none">• New Drugs and Labeling	Sakineh Walther, R.N. Consumer Safety Officer, Division of New Drugs and Labeling Compliance Office of Compliance, CDER, FDA
	<ul style="list-style-type: none">• Over-the-Counter Drugs	Robert Heller Team Leader, Division of New Drugs and Labeling Compliance Office of Compliance, CDER, FDA
	<ul style="list-style-type: none">• Imports Exports	Ada Irizarry Team Leader, Division of New Drugs and Labeling Compliance Office of Compliance, CDER, FDA
	<ul style="list-style-type: none">• Compounding	Robert Kang, Pharm. D. Regulatory Operations Officer, Division of New Drugs and Labeling Compliance Office of Compliance, CDER, FDA
10:30 - 10:45	<i>Break</i>	
10:45 - 11:45	Drug Manufacturing and Product Quality	Grace E. McNally Acting Deputy Division Director, Drug Manufacturing and Product Quality, Office of Compliance, CDER, FDA
11:45 - 1:00 p.m.	<i>Lunch</i>	
1:00 - 2:00	Scientific Investigations	Constance Lewin, MD, MPH Branch Chief, Good Clinical Practice Branch 1,

Agenda

ASEAN Drug Regulators/CDER Forum Study Tour

April 16 - 23, 2007

Washington, D.C. USA

		Division of Scientific Investigations, Office of Compliance, CDER, FDA
2:00 - 2:45	Inspectional Process and Good Laboratory Practices	Ruark Lanham Investigator / Program Expert Division of Field Investigations Office of Regional Operations Office of Regulatory Affairs, FDA
2:45 - 3:00	<i>Break</i>	
3:00 - 4:00	Compliance Risk Management and Surveillance	John W. Gardner, MD, DrPH Director, Div. Compliance Risk Management & Surveillance Office of Compliance, CDER, FDA

APRIL 20	Postmarketing	
9:00 - 9:15	Welcome	Justina A. Molzon, M.S. Pharm., J.D. Associate Director International Programs CDER, FDA
9:15 - 10:30	Overview of Drug Safety	Gerald Dal Pan, M.D. Director Office of Surveillance and Epidemiology, CDER, FDA
10:30 - 11:00	Medication Errors	Denise Toyer Division of Medication Errors and Technical Support Office of Drug Safety, CDER, FDA
11:00 - 12:00	Drug Marketing, Advertising, and Communications	Barbara Chong, Pharm.D., BCPS Team Leader Division of Drug Marketing, Advertising, and Communications Office of Medical Policy, CDER, FDA
12:00 - 12:30	WEB Developments at CDER	Monica Unger, M.L.S. Web Project Manager Division of Information Services Office of Training and Communications, CDER, FDA

Agenda

ASEAN Drug Regulators/CDER Forum Study Tour

April 16 - 23, 2007

Washington, D.C. USA

APRIL 23, 2007

ASEAN-US Technical Assistance & Training Facility
ASEAN-US Dialogue

APRIL 23

ASEAN-US Dialogue

Session 1	9:00 – 11:00	US Food and Drug Administration (Rockville, MD) <i>Julia Ho, Associate Director for Asia and the Pacific, Office of International Programs</i> <i>CAPT Justina Molzon, M.S., Pharm, J.D., Associate Director for International Programs, Center for Drug Evaluation and Research (CDER)</i> <i>Barry W. Poole, RPh., Director, Division of Drug Information, Office of Training and Communication, Center for Drug Evaluation and Research (CDER), FDA</i> <ul style="list-style-type: none">• ASEAN activities on pharmaceutical, current work and future directions• Presentation of the US FDA on its use International Conference on Harmonization (ICH) Guidelines• Possible areas for cooperation between ASEAN Regulatory Authorities and USFDA to facilitate the implementation of ASEAN-US Trade and Investment Arrangement Work Program with respect to pharmaceutical registration.
Session 2	11:30 – 12:30	Interagency Session, Office of the United States Trade Representative <i>David Katz, Director, Southeast Asian Affairs, USTR</i> <ul style="list-style-type: none">• ASEAN presentation: PPWG overview• ASEAN- US cooperation on trade and investment• The TIFA, TIFA Work Program, and ASEAN-US Enhanced Partnership• Other possible future areas of cooperation (data protection, anti-counterfeiting, and others)
	1:00 – 2:00	Lunch with PhRMA
Session 3	2:00 – 4:00	PhRMA, US Industry Association & US-ASEAN Business Council <i>Mark Paxton, Associate VP, International Regulatory Affairs</i> <ul style="list-style-type: none">• Overview of ASEAN PPWG Work Program• ASEAN -Industry Q&A Session
Session 4	4:00-5:00	The ASEAN-US Facility and ADVANCE – How USAID works with ASEAN <i>Nathan Associates Representatives</i>
Session 5	5:00-5:30	Wrap Up & Evaluations