



U.S. Food and Drug Administration

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13th CDER Forum for International Drug Regulatory Authorities
Focus on the Review Process
Holiday Inn--College Park, Maryland
October 17– 21, 2011

Monday October 17		
Clinical Trials and Data Integrity		
NOTE: This is a more advanced course from the basic CDER Forum		
TIME	PRESENTATION	PRESENTER
9:00 – 9:35 am	Overview and Introduction of Participants	Justina A. Molzon, M.S. Pharm., J.D. Associate Director for International Programs Center for Drug Evaluation and Research
9:35 – 9:55 am	Welcoming Comments <ul style="list-style-type: none"> • FDA's Pathway to Global Product Safety and Quality 	Deborah Autor, J.D. Deputy Commissioner for Global Regulatory Operations and Policy Office of the Commissioner
9:55 – 10:15 am	Office of Scientific Investigations <ul style="list-style-type: none"> • Introduction and Overview <ul style="list-style-type: none"> ○ FDA/CDER's mission and organization ○ Explanation of bioresearch monitoring and how it fits into the FDA and relates to the program ○ Quality by Design in Clinical Trials 	Leslie Ball, M.D. Acting Director, Office of Scientific Investigations Office of Compliance
10:15 – 10:25 am	<ul style="list-style-type: none"> • FDA-European Medicines Agency Good Clinical Practice Initiative <ul style="list-style-type: none"> ○ Implications for inspections, information sharing on applications, sharing information on best practices/guidances 	Cynthia Kleppinger, M.D. Senior Medical Officer, Outreach and Collaboration Office of Scientific Investigations
10:25 – 10:35 am	<ul style="list-style-type: none"> • International Collaborations <ul style="list-style-type: none"> ○ Potential, progress and pitfalls 	Mathew Thomas, M.D. Acting Team Leader, Outreach and Collaboration Office of Scientific Investigations
10:35 – 11:15 am	<ul style="list-style-type: none"> • Start-up of a Clinical Trial in a Foreign Country <ul style="list-style-type: none"> ○ Site selection and set up ○ CRO selection and challenges ○ Implementation issues in foreign countries 	Karen Reese, M.S., CCRA Branch Chief, Monitoring Operations Office of Clinical Site Oversight DAIDS, NIAID, NIH, DHHS
11:15 – 11:30 am	BREAK	
11:30 – 12:15 pm	<ul style="list-style-type: none"> • Application-related Inspection and Assessment of Data Reliability <ul style="list-style-type: none"> ○ How FDA approaches applications with data integrity problems at more than one site (including inspections of sponsors/CROs, and how OSI interacts with the CDER review divisions) 	Tejashri Purohit-Sheth, M.D. Acting Director, Division of Good Clinical Practice Compliance Office of Scientific Investigations

12:15 – 12:45 pm	<ul style="list-style-type: none"> ● Assessment of Data Integrity in New Drug Applications <ul style="list-style-type: none"> ○ Case studies on how FDA approaches applications with data integrity problems 	Jean Mulinde, M.D. Acting Branch Chief, Good Clinical Practice Assessment Branch Office of Scientific Investigations
12:45 – 1:00 pm	<ul style="list-style-type: none"> ● FDA Acceptance of Foreign Data (312.120) 	Jean Mulinde, M.D. Acting Branch Chief, Good Clinical Practice Assessment Branch Office of Scientific Investigations
1:00 – 2:00 pm	LUNCH	
2:00 – 2:45 pm	<ul style="list-style-type: none"> ● Good Clinical Practice Enforcement <ul style="list-style-type: none"> ○ Roles and responsibilities ○ FDA enforcement options ○ Overview of a Warning Letter 	Connie Lewin, M.D., M.P.H. Branch Chief, Good Clinical Practice Enforcement Branch Office of Scientific Investigations
2:45 – 3:15 pm	<ul style="list-style-type: none"> ● Overview of Clinical Monitoring <ul style="list-style-type: none"> ○ FDA perspective ○ Developing a monitoring plan ● Common data quality concerns with clinical monitoring and best practices to prevent their occurrence 	Ann Meeker-O'Connell, M.S. Acting Associate Director, Risk Science, Intelligence and Prioritization Office of Scientific Investigations
3:15 – 3:30 pm	BREAK	
3:30 – 3:55 pm	<ul style="list-style-type: none"> ● CDER Risk Model for Selection of Clinical Trial Inspections <ul style="list-style-type: none"> ○ Analytical Approaches to Clinical Trial Oversight 	Paul Okwesili, M.Eng. Operations Research Analyst Informatics and Infrastructure Office of Scientific Investigations
3:55 – 4:40 pm	<ul style="list-style-type: none"> ● Bioequivalence/ Good Laboratory Practice <ul style="list-style-type: none"> ○ Bioequivalence <ul style="list-style-type: none"> ○ FDA's BE inspection program - scope and basis ○ Points to consider - clinical and bioanalytical study conduct ○ Examples of inspectional findings ○ Impact of inspections ○ Good Laboratory Practice <ul style="list-style-type: none"> ○ FDA's GLP inspection program - scope and basis ○ GLP approach ○ Case studies and areas of concern ○ Impact of inspections 	Sam H. Haidar, Ph.D., R.Ph. Branch Chief Bioequivalence Investigations Branch Division of Bioequivalence and GLP Compliance Office of Scientific Investigations Zhou Chen, Ph.D. Pharmacologist Good Laboratory Practice Branch Office of Scientific Investigations
4:40 – 5:00 pm	<ul style="list-style-type: none"> ● FDA Resources for Future Use 	Cynthia Kleppinger, M.D. Senior Medical Officer, Outreach and Collaboration Office of Scientific Investigations

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Tuesday		
October 18, 2011		
The CDER Review Process—Overview		
TIME	PRESENTATION	PRESENTER
9:00 -9:15 am	Overview of the day	Justina Molzon, M.S. Pharm., J.D. Associate Director for International Programs/CDER
9:15- 9:45am	FDA's Transparency Initiative and Drugs@FDA	Mary Kremzner, Pharm. D. Deputy Director Division of Drug Information Office of Communications
9:45 -10:45 am	Drug Development in the 21 st Century: The Role of OND	Beth Duvall-Miller, B.S., Chemistry Team Leader, Regulatory Affairs Office of New Drugs
10:45 -11:00 am	BREAK	
11:00 - noon	Clinical Pharmacology Initiatives at the FDA	Gil Burckart Associate Director for Regulatory Policy Office of Clinical Pharmacology
12:15-12:45 pm	Group Photograph	Heather Lilly Technical Information Specialist Division of Training and Development
12:45 - 1:45 pm	LUNCH ON YOUR OWN	
1:45 pm –2:45 pm	Quality (CMC) Review: New Molecular Entities Generic Drugs	Swapan K De, Ph.D. CMC-Lead Office of New Drug Quality Assessment. Susan Rosencrance, Ph.D. Chemistry Reviewer Office of Generic Drugs
2:45 -3:45 pm	FDA Quality Initiatives for Pharmaceutical Development and Manufacturing	Debasis Ghosh Office of New Drug Quality Assessment
3:45 – 4:00 pm	BREAK	
4:00 – 5:00 pm	The Scientific Path Forward in Pediatric Product Development	Jean Temeck, M.D. Director of International Program International Team Lead Office of Pediatric Therapeutics

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Wednesday		
October 19, 2011		
The CDER Review Process—Focus on Etravirine (NDA 22-187)		
TIME	PRESENTATION	PRESENTER
9:00 -11:00 am	Determination of Bioequivalence Office of Generic Drugs	Jennifer Miller, Ph. D. Reviewer, Division of Bioequivalence Office of Generic Drugs Kuldeep Dhariwal, Ph.D. Team Leader, Division of Bioequivalence Office of Generic Drugs
11:00-11:15 am	BREAK	
11:15- 12:15 pm	Statistics at the FDA: How We Contribute to the Review of New Drug Applications	Fraser Smith Statistics Reviewer Division of Biometrics IV Office of Biostatistics
12:15 - 1:30 pm	LUNCH ON YOUR OWN	
1:30—1:45 pm	Opening Remarks	Debra Birnkrant, M.D. Director Division of Antiviral Products Office of New Drugs
1:45 pm –2:30 pm	Overview of Regulatory Principles Atazanavir Case Study Kaletra Case Study	Yodit Belew Division of Antiviral Products Office of New Drugs Alan Shaprio Regina Alivisatos
2:30 - 3:30 pm	HIV Drug-Drug Interactions Including Pharmacoenhancers	Vikram Arya, Ph.D., FCP Senior Clinical Pharmacology Reviewer Division of Clinical Pharmacology Office of Clinical Pharmacology
3:30 -3:45 pm	BREAK	
3:45 – 4:30 pm	Regulatory Issues in HIV Prevention: Oral Pre-Exposure Prophylaxis Vaginal Microbicides	Peter Miele Charu Mullick, M.D. Division of Antiviral Products Office of New Drugs
4:30 – 5:00 pm	EMA Review and WHO Article 58 procedure	Efthymios Manolis Scientific Administrator Scientific Advice Human Medicines Special Areas EMA

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Thursday		
October 20, 2011		
The CDER Review Process—Special Topics		
TIME	PRESENTATION	PRESENTER
9:00 -10:00 am	Post-market Drug Safety: Management of Remaining Areas of Uncertainty	Mwango Kashoki, M.D., M.P.H. Associate Director for Safety Office of New Drugs
10:00 -10:15 am	BREAK	
10:15 -11:30 am	FDA Review of Tools to Measure Treatment Efficacy	Ann Marie Trentacosti, M.D. Study Endpoints and Labeling Development Staff Office of New Drugs
11:30am-12:30 pm	Labeling: Review of U.S. Format and Content Requirements	Ann Marie Trentacosti, M.D. Study Endpoints Team, Study Endpoints and Labeling Development Staff Office of New Drugs
12:30 - 1:30 pm	LUNCH ON YOUR OWN	
1:30 - 2:30 pm	Integrity and Security of the Supply Chain	Karen Rothschild, Esq. Regulatory Counsel Drug Integrity and Security Program Office of Compliance
2:30 - 3:30 pm	Data Submission, Tools and Standards	Gary Gensinger Deputy Director Office of Business Process Support
3:30 - 3:45 pm	BREAK	
3:45 - 5:00 pm	Promoting Efficient Reviews and Information Exchange-The Influence of ICH and the CTD/eCTD	Justina Molzon. M.S. Pharm., J.D. Associate Director for International Programs/CDER

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Friday		
October 21, 2011		
Pharmacovigilance		
TIME	PRESENTATION	PRESENTER
9:00 am – 9:30 am	Overview: Office of Surveillance & Epidemiology	Gerald Dal Pan, M.D., M.H.S. Acting Office Director, OSE
9:30 am–11:00 am	Pharmacoepidemiology in CDER Overview: Division of Epidemiology	Tarek Hammad, M.D., Ph.D., M.Sc., M.S Associate Director of Epidemiology Division of Epidemiology (DEPI), OSE
11:00 am – 11:15 am	BREAK	
11:15 am – 12:15pm	Risk Management in the US Overview: Division Risk Management Review Process: Case example	Reema Jain, Pharm.D., M.P.H. Safety Evaluator Division of Risk Management (DRISK)
12:15 pm - 1:15 pm	LUNCH ON YOUR OWN	
1:15 pm – 2:30 pm	Pharmacovigilance (PV) in CDER Overview: Division of PV Case examples: 1) Lopinavir/Ritonavir Oral Solution Toxicity in Neonates 2) Proton-Pump Inhibitors and Hypomagnesemia	Tracy Salaam, Pharm. D. Safety Evaluator Debra Boxwell, Pharm.D. Safety Evaluator Teresa Rubio, Pharm.D. Safety Evaluator
2:30 pm – 2:45 pm	BREAK	
2:45 pm – 4:00 pm	Medication Errors: FDA Perspective Overview: Division Medication Error Prevention and Analysis Post-Marketing Surveillance Proprietary Name Review	Jibril Abdus-Samad, Pharm.D. Safety Evaluator Division of Medication Errors Prevention and Analysis (DMEPA)
4:00 pm- 5:00 pm	Closing and Evaluation	Justina Molzon, M.S.Pharm., J.D. Associate Director for International Programs