American Society for Quality (www.asq.org) – Washington D.C. and Maryland Metro, Section 509 (www.asq509.org)

Biomed/Biotech Special Interest Group Meeting

"Medication Errors 101!" (~45 min)

Presented by

Linda Y. Kim-Jung, PharmD (linda.kim-jung@fda.hhs.gov)

Consumer Safety Officer
Medical Review and Pharmacovigilance Team, Division of Surveillance
Office of Surveillance and Compliance (OS&C)
Center for Veterinary Medicine (CVM), FDA

"Steps to a Quality CBER Submission" (~90 min)

Presented by

Ms. Susan Yu (susan.yu@fda.hhs.gov)

Lead Regulatory Quality Manager
Division of Manufacturing and Product Quality (DMPQ)
Office of Compliance and Biologics Quality (OCBQ)
Center for Biologics Evaluation and Review (CBER), FDA

June 11, 2009 (Thursday) Evening

6:00 PM – Networking and Pizza and soft drink with a door prize

6:15 – 9:00 PM – Program

9:00 – 9:15 PM – Door-prize drawing and networking

Open and free to the public

Location:

Kelly's Deli Conference Center, 7519 Standish Place, Rockville, MD 20855

Driving directions:

From **I-270** (N or S bound):

Take Exit 9A and exit from the first right exit.
Turn left (east) onto Shady Grove Dr.
Turn right (south) onto Rockville Pike (**Route 355**).
Turn left (east) onto East Gude Dr.
Turn left (north) immediately onto Crabb's Branch Dr.
Turn left (west) immediately onto Standish Place.
(The first building on your right side is 7519 Standish Place; open parking)

The conference room is on the first floor with its entrance opposite to the left side of building main entrance.

For headcount purpose, please register by *Thursday noon, June 11, 2009.*

Registration Website: http://www.asq509.org/ht/d/DoSurvey/i/35817

For registration problems or further information contact **Dr. George Chang**, Co-Chair of Biomed/Biotech SIG, at gchang2008@yahoo.com or call **240-793-8425**.

A. Presentation Summary:

Medication Errors 101. This presentation will include a general introduction about the sources of drug risks followed by a summary of the current medication error prevention initiatives in FDA. The focus of the talk will be in regards to the trade-name confusion and error-prone label/labeling issues. Lastly, about how medication error prevention and analysis ties into the overall efforts of promoting drug safety will be discussed.

Steps to a Quality CBER Submission. The speaker will provide an overview of the steps to consider when preparing a submission for CBER from a facility and current good manufacturing practice reviewer's viewpoint. The speaker will provide an overview of the CBER review process and products; identify resources that can be used when preparing a submission; discuss statutes and regulations that must be followed; review steps that may be used to help an efficient CBER review and inspection; review submission pitfalls; and provide comments from reviewers about problems encountered in submissions and during inspection.

B. Speakers' Bios:

Linda Y. Kim-Jung, PharmD., **Consumer Safety Officer**, Medical Review and Pharmacovigilance Team, Division of Surveillance, Center for Veterinary Medicine (CVM), FDA.

Prior to join CVM in early 2009, Dr. Kim-Jung was a Team Leader and a Safety Evaluator at the Division of Medication Error Prevention and Analysis (DMEPA), CDER, FDA for 6 years. In DMEPA, she was responsible for both premarket medication error review and post-market surveillance of proprietary name confusions and product label/labeling errors.

Before joining the Federal Government, Dr. Kim-Jung was a Drug Safety Specialist at the Human Genome Sciences, Inc. where she was responsible for monitoring serious adverse events for drugs in clinical trials. In her earlier part of career, she was a safety reviewer at the US Pharmacopeia for the Medication Error Reporting Program and Drug Product Problem Reporting program. She is also a practicing pharmacist and has worked at various pharmacy settings including Walter Reed Army Medical Center and community pharmacies. Dr. Kim-Jung earned my pharmacy degree from the Philadelphia College of Pharmacy and Sciences.

Susan S. Yu, BS, Lead Regulatory Quality Manager, Division of Manufacturing and Product Quality (DMPQ), Office of Compliance and Biologics Quality (OCBQ), Center for Biologics Evaluation and Review (CBER), FDA

Ms. Susan Yu has been in this position since January 2008. Her position includes implementing a quality management program within DMPQ, reviewing all policy, guidance, and procedures relevant to DMPQ, and help plan and facilitate CBER training programs. She has been the lead inspector for pre-license and pre-approval inspections for vaccine, in-vitro diagnostic, recombinant, plasma fractionated and novel products. She has performed scientific, administrative and regulatory review of biological submissions, including biological license applications, supplements, annual reports, post marketing commitments, new drug applications, investigational new drugs, and 510(k)s.

Susan was previously with the Office of Blood Research and Review, CBER, as a Regulatory Health Information Specialist. Prior to joining FDA, she was a Medical Technologist serving as a quality assurance specialist and Contracting Officer's Technical Representative for the Navy HIV Testing Program, and was a Medical Technologist in the clinical laboratory at Walter Reed Army Medical Center. She received a B.Sc. degree in Medical Technology from Edinboro University of Pennsylvania. Susan has passed the training requirements for certification as a Quality Management Systems Auditor/ Lead Auditor by the RABQSA International Management System Auditor Certification Program.