



NAME: Tamy Kim, Pharm.D.

JOB TITLE: Associate Director of Regulatory Affairs, Office of Oncology and Hematology Products, Center for Drug Evaluation and Research

AGENCY: Food and Drug Administration (FDA)

**EDUCATION/DEGREES/CERTIFICATES/INSTITUTIONS:**

Dr. Tamy Kim attended Pennsylvania State University and then received her Doctor of Pharmacy Degree from the University of the Sciences in Philadelphia, PA in 2004. After obtaining her degree, Dr. Kim completed a Drug Information Specialty Residency at Purdue University in 2005. Dr. Kim also obtained a Certificate in Public Health from Georgetown University in 2010.

**CURRENT JOB DESCRIPTION:**

Dr. Kim is the Associate Director of Regulatory Affairs in the Office of Oncology and Hematology Products (OHOP) at the Food and Drug Administration (FDA) in Silver Spring, Maryland. As the Associate Director of Regulatory Affairs, her responsibilities include developing and implementing policies related to the drug development and review process. Dr. Kim is most involved in developing and implementing regulatory policies and process that affect OHOP, in particular policies for Accelerated Approval, Breakthrough Therapies, Special Protocol Assessments, Expedited Reviews, and PDUFA (Prescription Drug User Fee Act). Development and implementation of these policies require application of complex regulatory expertise and communication and collaboration with other offices within the FDA. As the Associate Director of Regulatory Affairs, Dr. Kim provides expertise to complex regulatory issues within the Oncology and Hematology Divisions; she oversees formal communications to pharmaceutical firms, and represents OHOP at meetings requiring regulatory expertise and guidance.

**QUALIFYING SKILLS FOR CURRENT POSITION:**

Dr. Kim joined the FDA in 2006 as a Regulatory Health Project Manager in the Division of Neurology Products. As a Regulatory Health Project Manager she was responsible for the management and coordination of review of Investigational New Drug Applications (INDs), New Drug Applications (NDAs), and Biologics License Applications (BLAs). Dr. Kim managed drugs in the following therapeutic areas: antiepileptics, multiple sclerosis, myasthenia gravis, and stroke. During her residency, she served as a drug information resident at Methodist Hospital handling drug information questions in all therapeutic areas. Also as a part of her residency, Dr. Kim was a drug information resident at a large pharmaceutical company focusing primarily on drug information questions for endocrine and neurology products.

Prior to joining FDA, Dr. Kim worked as a Medical Information Manager at another large pharmaceutical company where she was responsible for the review of medical information letters, providing responses to healthcare professional inquiries, and

reviewing promotional materials related to oncology products. She also worked as a retail pharmacist part-time from 2004 until 2009.

**MOST REWARDING PROFESSIONAL EXPERIENCE:**

Dr. Kim has had many rewarding professional experiences in her previous and current positions. She especially enjoys being involved in the FDA's drug regulation and approval process and having an impact on the public health.

*by CDR Melina N. Griffis*