



iJOBS Career Panel Series: Clinical and Regulatory Affairs

Tuesday September 8, 2015

4:30-6:00pm

Center for Advanced Biotechnology and Medicine, Room 010

679 Hoes Lane West

Piscataway, NJ 08854

Regulatory Affairs –

Dialogs with health agencies such as the FDA. Works with clinical, marketing and basic science (toxicology and pharmacology) to get a drug approved.

Decides strategy such as in which countries trials will be done and what is needed for the clinical trials to be completed. You can act an international liaison between all the countries doing trials.

Write the introduction and questions for the clinical trial applications.

Advice is to do an online course such as RAPS or workshop to learn regulatory rules
<http://www.raps.org/education-training/online-learning/certificate-programs/>

Join the Drug Information Association so you can get tuned into what is going on in the field.

Medical Director –

Compound development team strategizes to bring science and medicine together and write clinical trials. Having an MD/PhD allows you to see patients, run clinical trials and do research in industry. You can be involved in the manufacturing side of regulatory affairs if you have a good chemistry background.

Other positions within this area include medical writer, R&D, statistician

General advice –

Learn stats and pharmokinetics/pharmacodynamics (PK/PD)

Most of the openings are in oncology right now so get experience before applying.

You can do a postdoc in a company which to make sure it is a good fit from both sides.

It is easier to start at the bench and then move to a different role within a company if you are interested in learning clinical or regulatory affairs. You can make a lateral move.

Show that you have a leadership role in your lab as a grad student or postdoc to help you get a job

Demonstrate that you have the ability to dissect a problem, and can articulate the solution by writing and speaking. It is not what you did in your PhD but how you think.

Practice interviewing at national meeting and be ready to ask them questions about the company and job.

Make sure you are happy and find your way through the many forks in the road.

You must be a team player

Imran Khan MD PhD

Medical Director

Janssen, Pharmaceutical Companies of Johnson and Johnson

ikhan19@its.jnj.com



Dr. Imran Khan MD PhD is a hematologist/oncologist working in Janssen Pharmaceuticals of Johnson & Johnson since August 2012. Dr. Khan did his MD PhD with a focus on nitric oxide binding to hemoglobin and myoglobin for his PhD dissertation at the Albert Einstein College of Medicine. He subsequently pursued training in diagnostic radiology in Boston and thereafter completed an internal medicine residency in New York. He subsequently completed a Hematology/Oncology fellowship at the Rutgers Cancer Institute of NJ and received the Motolinsky Outstanding fellow Award in Hematology. Thereafter Dr. Khan joined Janssen Pharmaceuticals. Dr. Khan's focus has been hematological malignancies and he is currently a Medical Director at Janssen. He is also a Clinical Assistant Professor at Rutgers Cancer Institute of NJ, Robert Wood Johnson Medical School and the Rutgers Graduate School of Biomedical Sciences. Dr. Khan maintains clinical privileges at Rutgers Cancer Institute of NJ, Robert Wood Johnson University Hospital and Princeton University Hospital.

Melissa Tice, PhD

Distinguished Scientist Global Regulatory Affairs Group

Merck & Co.

melissa_tice@merck.com



Dr. Tice is a Distinguished Scientist in Global Regulatory Affairs Group at Merck & Co. As the Regulatory Affairs liaison for KEYTRUDA (pembrolizuma) for the Melanoma indication for KEYTRUDA, she has been involved in obtaining the first Oncology "Breakthrough therapy" granted by the US FDA for KEYTRUDA

(pembrolizumab), a humanized monoclonal antibody that blocks the interaction between Programmed death receptor (PD-1) and its ligands (PD-L1 and PD-L2) and obtaining regulatory approval for this immunotherapy agent in the treatment of metastatic melanoma in the US, EU and other countries around the world. Dr. Tice has been involved in development of other Merck novel biologic and biosimilar products that address a variety of therapeutic areas.. Prior to joining Merck, Dr. Tice led the Gene Therapy and Biotechnology Group in Worldwide Regulatory Affairs at Schering-Plough Research Institute where she supported such programs as p53 adenovirus, interferon (INTRON A), anti-TNF (REMICADE) and other therapeutic monoclonal antibodies. Prior to regulatory affairs, Dr. Tice was a Senior Principal Scientist in CNS/CV Pharmacology Department at Schering-Plough Research Institute investigating novel molecular targets for the treatment of Alzheimer's disease and Schizophrenia. Dr. Tice received her undergraduate degree in Chemistry from Douglass College, Rutgers University in New Brunswick, NJ, a doctorate in Biological Chemistry from the University of Pennsylvania in Philadelphia, PA. and her postdoctoral training in the fields of molecular biology and receptor pharmacology at the centers of NINCDS and NIAAA at the National Institutes of Health in Bethesda, MD. Dr. Tice has over 25 years of experience in the pharmaceutical industry.