Regulatory Pharmaceutical Fellowship

FDA / Industry / Academia

Jointly Sponsored By:

2012 – 2014 Information Package

Introduction

The Regulatory Pharmaceutical Fellowship specializing in drug information is a two-year, learning based program designed to train the selected candidate on the medical and regulatory aspects of drug information dissemination. The program serves to maintain and enhance a scientific link among the Food and Drug Administration (FDA), academia, and the pharmaceutical industry. The program also provides an opportunity for the fellow to develop an understanding of the processes and practices of the FDA and industry in the delivery of drug information and the regulatory oversight of drug information practices. The fellowship provides opportunities in the area of academia, government, and pharmaceutical industry. Graduates of the program will be qualified to pursue career opportunities in all three arenas.

The two-year fellowship consists of a 9-month rotation with FDA's Center for Drug Evaluation and Research (Silver Spring, MD); a 6-month rotation with Purdue University College of Pharmacy (Indianapolis, IN); and a 9-month rotation either at Eli Lilly & Company (Indianapolis, IN) or Janssen Scientific Affairs, LLC (Raritan, NJ), The program has two tracks: one drug information track (recruits annually) and one drug advertising and promotion track (recruits biennially).

For 2012-2014, the program has one position available in Drug Information.

Fellowship Schedule

PURDUE UNIVERSITY → Lilly → FDA

Jul 2012 – Dec 2012 | Jan 2013 – Sept 2013 | Oct 2013 – Jun 2014

Drug Information Track

FELLOWSHIP

Drug Information

Purdue University, Indiana University Health, Wishard Health Services
Indianapolis, IN

The 6-month academic drug information portion of the Regulatory Affairs Fellowship will provide the fellow with exposure to academia and the different functions and responsibilities of institutional-based drug information centers. The program with Purdue University College of Pharmacy offers experience with the provision of drug information including formulary management, adverse drug event reporting, medication safety, and drug-use policy in conjunction with Indiana University Health and Wishard Health Services. In addition, the fellow gains significant experience in academia, providing didactic and experiential training to Purdue University student pharmacists.

Eli Lilly & Company
Indianapolis, IN

The 9-month rotation at Lilly will provide an opportunity for the fellow to develop skills in the practice of medical information in industry. The fellow will complete projects related to the delivery of medical information to providers, patients, and payers. The program offers experience with Health 2.0 (the intersection between healthcare and technology) and Lilly's strategy and use of e-channels to communicate medical information to customers. The fellow gains knowledge and understanding of the Health 2.0 space, Lilly's thoughts and strategies as it relates to scientific and medical opportunities, and the importance of networking and collaboration.

Food and Drug Administration
Silver Spring, MD

The 9-month rotation at FDA will provide an opportunity for the fellow to respond to drug information requests, mentor pharmacy students, and provide support for various FDA initiatives to health care professionals, consumers and industry. The program allows the fellow to work with Review Divisions to draft Drug Safety Communications for clinically significant drug safety alerts, and improve the risk assessment process through increasing voluntary reporting of serious spontaneous adverse events. The fellow will be a member of Division of Drug Information's Social Media team, which utilizes tools such as Twitter, listservs, blogs, audio and video podcasts to disseminate the latest drug information to the public.

FELLOWSHIP

Drug Information

Current Fellow: 2011 - 2013
Genevieve Lynn Ness, PharmD

Regulatory Pharmaceutical Fellow in Drug Information

Genevieve graduated from the University of the Sciences in Philadelphia, Pennsylvania where she received her PharmD degree in May 2011. Genevieve is currently completing the academia portion of the fellowship. She has gained experience at Indiana University's Center for Medication Management where she has had the opportunity to answer various drug information questions and prepare monographs to be presented at the hospital's monthly P&T committee meeting. Genevieve will be assisting with the "Principles of Drug Information and Literature Evaluation" course this fall and begin her Eli Lilly rotation in January.

Current Fellow: 2010 - 2012
Kimberly Wu, PharmD

Regulatory Pharmaceutical Fellow in Drug Information

Kimberly graduated from the University of Maryland School of Pharmacy in 2010 where she received her PharmD. Kimberly began her fellowship with exposure to academia (teaching and precepting students) as well as the different functions and responsibilities of institutional-based drug information centers. Kimberly is currently at Eli Lilly and Company in Global Medical Information supporting endocrine products as well as the Global Information Disclosure team. She will begin her rotation at the FDA 's Division of Drug Information in October 2011.

FELLOWSHIP

Drug Information

Past Fellow: 2009 - 2011
Lindsay E. Davison, PharmD

Consumer Safety Officer – Division of Drug Information
FDA Center for Drug Evaluation and Research

Lindsay graduated with her PharmD degree from the Albany College of Pharmacy and Health Sciences in Albany, New York in 2009. During the Fellowship Lindsay taught in the Drug Information and Literature Evaluation course at Purdue University, serving as Co-Coordinator in her second year. She was part of the Cardiovascular team in Internal Medicine at Janssen Scientific Affairs, LLC and co-authored the book chapter *Pharmaceutical Industry and Regulatory Affairs* in *Drug Information: A Guide for Pharmacists* with previous fellow Jean Cunningham. After completing the Fellowship at FDA, Lindsay accepted a fulltime position as a Consumer Safety Officer. She has also been accepted as a Lieutenant in the U.S. Public Health Service and is awaiting her call to active duty.

Past Fellow: 2007 - 2009
Jean E. Cunningham, PharmD, BCPS

Assistant Professor of Pharmacy Practice
The University Of Findlay College Of Pharmacy

Jean graduated from the University of Toledo in Toledo, Ohio in 2007 where she received her PharmD degree. After completing the two-year Regulatory Pharmaceutical Fellowship specializing in Drug Information Jean was dedicated to a role in academia and accepted a position in at the University of Findlay in Findlay, Ohio. Jean teaches in a variety of practice areas including Drug Information, Self-Care/Nonprescription Drugs, Introduction to Pharmacy Practice and Communication. Jean now serves as the director of the Medication Therapy Management Consultation Center (MTMCC) at The University of Findlay College of Pharmacy.

FELLOWSHIP

Drug Information

Past Fellow: 2005 - 2007
Sanjeev K. Bhanot, PharmD

Manager, Medical Science Liaisons
Merz Pharma Canada, Ltd.

Sanjeev (Sonny) graduated from the University of the Sciences in Philadelphia, Pennsylvania in 2005 where he received his PharmD degree. After completing the two-year Regulatory Pharmaceutical Fellowship in Drug Information, Sonny began his career working with the Medical Affairs Company as a Clinical Specialist. Recently Sonny has been promoted to a new role as a manager for Medical Science Liaisons.

Past Fellow: 2003 - 2005
Tanya Nelson, PharmD

Manager, Medical Information – Internal Medicine
Janssen Scientific Affairs, LLC

Tanya graduated from Florida A&M University in Tallahassee, Florida in 2002 where she received her PharmD degree. Tanya joined J&J in 2006 shortly after completing the Regulatory Pharmaceutical Fellowship specializing in Drug Information and a prior PGY-1 Residency in Miami, Florida. Tanya's responsibilities include creating accurate and fair-balanced medical information materials, providing medical review of materials for training, promotion, and scientific exchange, and collaborating with internal business partners and external customers on ad hoc projects. Previously, Tanya supported the launch of DORIBAX™, ACIPHEX®, and NUCYNTA™.

FELLOWSHIP

Drug Information

Preceptor: Purdue University
Amy Heck Sheehan, PharmD

Associate Professor of Pharmacy Practice
Purdue University College of Pharmacy

Amy graduated with from the University of Cincinnati where she received her PharmD. After graduation, she pursued post-doctoral training through a Drug Information Practice and Pharmacotherapy Residency with the National Institutes of Health. For the past twelve years, Amy has been working with Purdue University Department of Pharmacy Practice and the Indiana University Health Center for Medication Management. She has published over 25 peer-reviewed articles in the pharmacy literature and authored book chapters for therapeutics and drug information textbooks. She currently serves as a member of the Editorial Board for the *Annals of Pharmacotherapy.*

Amy coordinates two courses for the Department of Pharmacy Practice. These include CLPH 86700 “Principles of Drug Information and Literature Evaluation” and CLPH 45300 “Advanced Literature Evaluation”. She also serves as Co-Coordinator for the Purdue University & Clarian Health PGY2 Drug Information Residency.

Amy’s practice site is the Indiana University Center for Medication Management where she is involved with the provision of comprehensive drug information services for a multi-hospital network.

FELLOWSHIP

Drug Information

Preceptor: Eli Lilly and Company
Jennifer L. Riggins, PharmD

Director, Global Information Disclosure
Global Medical Communications
Eli Lilly and Company

Jennifer graduated from Butler University where she received her PharmD. Following graduation, she joined Eli Lilly and Company and quickly became a leader in the globalization and development of the Global Medical Information and Global Medical Communications departments. Throughout her career, Jennifer has contributed to strategy development and implementation, business process development, tools and technology, people development, and external outreach. Jennifer currently serves as Director of Global Information Disclosure - the organization responsible for developing information disclosure capabilities, including e-capabilities, and establishing governance mechanisms for information disclosure and communication of medical information to external customers and stakeholders.

Jennifer has been actively involved in student, resident, and fellow programs at Lilly. She served as the Program Director for the Purdue University/Eli Lilly and Company Drug Information Residency program for 15 years.

Jennifer is an active volunteer of the Drug Information Association (DIA). Jennifer currently serves as the Chair of the Advisory Council of North America, co-chair of the Member and Volunteer Engagement committee and as a member of the DIA Board of Directors and the Board Finance committee.

FELLOWSHIP

Drug Information

Preceptor: Food and Drug Administration
Catherine Y. Chew, PharmD

Senior Supervisory Health Promotion Officer
FDA Center for Drug Research and Evaluation
Division of Drug Information

Catherine graduated from the University of Maryland at Baltimore where she received her PharmD. Prior to joining the FDA, Catherine worked at Johns Hopkins Hospital in the Pediatric Pharmacy of the Children's Center.

Catherine is a team leader in FDA's Division of Drug Information, which responds to inquiries from industry, healthcare professionals, and consumers from within the US and internationally. As the administrator of the FDA Drug Info listserv and Twitter, and as a writer and voice/face for audio and video podcasts, Catherine proactively disseminates the latest drug information from FDA. She serves on DDI's Social Media team, lectures at various pharmacy conferences and universities, and precepts fellows, students and residents,

Catherine is also a Commander in the US Public Health Service. As a PHS officer, she recruits for PHS, serves as a point of contact for pharmacy schools, administers immunizations and has been on multiple deployments.

Fellowship

FELLOWSHIP BENEFITS

- Competitive stipend
- Reimbursement for relocation and professional travel expenses
- Enrollment in Indiana Pharmacy Resident Teaching Certificate (IPTeC) Program
- Purdue University benefits package
  - Health insurance
  - Prescription coverage
  - Vision plan
  - Dental (optional)
- Vacation and University holidays

Fellowship

APPLICATION PROCESS

The fellow must be a graduate from an ACPE-accredited college of pharmacy, or otherwise eligible for licensure, prior to the start of the fellowship term.

Preliminary interviews are conducted during the American Society of Health-System Pharmacists Midyear Clinical Meeting annually. Participation in PPS is not required for application.

All interested applicants should submit the following:
1.Letter of intent
2.Curriculum Vitae
3. Official transcripts
4. Three references with contact information
(references will be contacted by telephone or email; letters not required)

All application materials should be submitted electronically to DrugInformationFellowship@gmail.com
no later than **midnight on Friday, December 16, 2011**.

On-site interviews will take place at FDA in Silver Spring, Maryland on Friday, January 13, 2012.

Travel will be coordinated by the fellowship co-sponsors.

Please visit our website at: http://www.fda.gov/RegFellowshipDI