REGULATORY PHARMACEUTICAL FELLOWSHIP

Government | Industry | Academia

2017-2019

Jointly sponsored by:

FDA | Purdue University | Lilly | Janssen | Johnson & Johnson
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Fellowship Objectives

- Train selected candidates via a two-year, knowledge-based program on medical and regulatory aspects of drug information, medication safety, or advertising and promotion.

- Maintain and enhance a scientific link among the Food and Drug Administration (FDA), academia, and the pharmaceutical industry.

- Offer opportunities for fellows to understand the complex participating roles of the FDA and the pharmaceutical industry in the delivery of drug information and the regulatory oversight of prescription drug marketing and safety practices.

- Provide participants the opportunity to experience careers in the areas of government, academia, and industry.

- Qualify program graduates to pursue careers in each unique practice area.

- The 2017 – 2019 program cycle will be recruiting for the following fellowship tracks: Drug Information, Medication Safety, & Drug Advertising and Promotion.
Lindsay graduated from the Albany College of Pharmacy and Health Sciences in 2009 and completed the Regulatory Pharmaceutical Fellowship drug information track from 2009 – 2011 at Purdue University, Janssen Pharmaceuticals, and the FDA.

Lindsay joined the Division of Drug Information (DDI) as a civilian Consumer Safety Officer (CSO). In 2012 Lindsay became a Commissioned Corps officer in the U.S. Public Health Service. In 2014 she accepted a Team Leader position and joined DDI’s Senior Management Team.

In her role as Team Leader, she leads a team of pharmacists and other experts and oversees a variety of programs. Lindsay trains and mentors her team to respond to drug information requests via phone and email from consumers, industry, and other healthcare professionals; edits and reviews written communications for web and social media platforms including Facebook and LinkedIn; serves as a steward of Gallup’s Strengths-based management program; precepts student pharmacists and the drug information track fellows; and advocates for process improvements through developing new Standard Operating Procedure’s and other training programs.
Drug Information Track Timeline

Drug Information Track #1

01 Indianapolis, IN
College of Pharmacy
Jul. 2017- Dec. 2017

02 Titusville, NJ
Medical Information
Jan. 2018- Dec. 2018

03 Silver Spring, MD
Division of Drug Information

Drug Information Track #2

01 Indianapolis, IN
College of Pharmacy
Jul. 2017- Dec. 2017

02 Silver Spring, MD
Division of Drug Information

03 Indianapolis, IN
Global Medical Information

July 2017

June 2019

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**Drug Information Track Overview**

**Purdue**

The 6-month portion will expose the fellow to academia and the responsibilities of institutional-based drug information centers. The program offers experience with the provision of drug information at IU Health and Purdue’s Center for Medication Safety Advancement (CMSA). Fellows will conduct a research project suitable for presentation at a national meeting and publication in a peer-reviewed pharmacy journal and participate in the Indiana Pharmacy Teaching Certificate Program. The fellow gains significant experience in academia, providing didactic and experiential training to student pharmacists.

**Janssen**

The 12-month rotation provides the opportunity for the fellow to gain experience as a member of a medical information team in a pharmaceutical industry setting. The program allows the fellow to develop skills related to development and delivery of drug information to healthcare professionals, payors, consumers, and business partners through a variety of methods. The fellow will have the option to participate in collaborative inter- and intra-departmental projects, mentor pharmacy students, and network with other pharmacists within the organization and through a pharmacist-focused resource group.

**Eli Lilly**

The 12-month rotation in medical information will be focused within the Oncology Medical Affairs team to answer questions from healthcare professionals for newly launched products or new indications for existing products. The fellow will be trained in the development of medical information deliverables supporting the call center, field-medical personnel, medical websites, and other delivery channels. In addition, the fellow will have opportunities to contribute to other departmental projects, market research, and other initiatives to better the overall customer experience.

**FDA**

The 6-month FDA rotation will provide an opportunity for the fellow to respond to drug information requests and provide support for various FDA initiatives. The fellow will follow a Drug Safety Communication from conception to publication and improve the risk assessment process through increasing voluntary reporting of serious spontaneous adverse events. The fellow will be a member of the Division’s Social Media team, which has hundreds of thousands of followers and subscribers across Twitter, Facebook, listservs, videos, and podcasts. The fellow will also engage with DDI’s Global Alliance of Drug Information Specialists on LinkedIn, promoting partnerships among pharmacists.
Samina earned her BS and PharmD degrees from Rutgers University College of Pharmacy. Prior to joining Janssen Scientific Affairs, she completed an ASHP-accredited Hospital Pharmacy Practice Residency at the Mount Sinai Medical Center in New York City and practiced in the retail pharmacy setting with Pathmark Stores in New Jersey. While at Janssen, she continued to provide part-time support for Pathmark for almost 8 years.

Throughout her 15 plus-year career at Janssen, Samina has led and supported Medical Information activities for multiple Janssen products in oncology, virology, GI, women’s health and urology, and contributed to a variety of intradepartmental projects focusing on safety, technology and professional development. Samina supported the launch of Janssen’s first oral diabetes products and is currently responsible for the strategy and review of scientific responses, development of Academy of Managed Care Pharmacy (AMCP)-formatted formulary dossiers and review of promotional and sales training materials for these products. In addition, Samina participated in a one-year rotational leadership program within the Medical Information Leadership Team. She also coaches her team members on key Medical Information-related activities and mentors pharmacy students and fellows affiliated with Rutgers University and the Philadelphia College of Pharmacy.
Kathy Mybeck, PharmD

Consultant,
Global Medical Information

Eli Lilly and Company

Kathy earned her PharmD degree from Purdue University. Prior to joining Eli Lilly and Company, she completed an ASHP-accredited Drug Information Residency with Purdue University and Eli Lilly and Company as well as a Drug Information Externship at Hoffmann-La Roche in Nutley, New Jersey.

Throughout her 18 plus-year career at Eli Lilly and Company, Kathy has held various roles within Medical Information and Regulatory Affairs. Kathy provided global medical information support for endocrine products at Lilly and led development of a launch portfolio of medical information responses for a new co-marketed molecule for type 2 diabetes. In addition, she facilitated medical information launch strategies for oncology pipeline products and mentored new medical information personnel. Kathy also served as an Implementation Lead for the Regulatory Transformation initiative by partnering with the Labeling department on process and system updates. She then became one of the Managers for the Global Labeling Department managing staff and day-to-day operations within the function including creation and maintenance of global product information and US labeling. Kathy continues to coach her team members on medical information-related activities and precept PharmD students from a variety of schools. Kathy was a coordinator for the Purdue/Lilly Drug Information Residency and helped author a publication regarding withdrawal of prescription drugs from worldwide pharmaceutical markets.
Amy H. Sheehan, PharmD

Associate Professor, Pharmacy Practice
Purdue University
College of Pharmacy

Amy graduated from the University of Cincinnati where she received her BS and PharmD degrees. After graduation, she pursued post-doctoral training through a Drug Information Practice and Pharmacotherapy Residency with the National Institutes of Health. For the past seventeen years, Amy has been working with Purdue University College of Pharmacy Department of Pharmacy Practice and the Indiana University (IU) 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. Amy serves on the Indiana Pharmacy Teaching Certificate (IPTeC) Program Executive Committee and is currently a member of the Editorial Board for the *Annals of Pharmacotherapy*.

Amy is responsible for didactic instruction of the principles of drug information, including literature evaluation and interpretation of biomedical statistics, within the professional degree program at Purdue University. She serves as course coordinator for PHRM 848, "Principles of Drug Information and Literature Evaluation" and CLPH 45300, "Advanced Literature Evaluation". Amy’s practice site is the IU Health Center for Medication Management located at Methodist Hospital in Indianapolis, where she contributes to the provision of comprehensive drug information services for all IU Health-affiliated hospitals throughout the state of Indiana. Amy serves as a preceptor for experiential rotations for student pharmacists, pharmacy residents, and pharmacy fellows.
Current Drug Info Fellow

Sandra R. Bai, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY1
Current Fellow: 2016 – 2018 Cycle

Sandra is a 2016 graduate of Butler University College of Pharmacy and Health Sciences in Indianapolis, IN. Sandra is currently completing the academic portion of the fellowship. In this role, she serves as a Drug Information Specialist in the IU Health Drug Information Center. She assists with formulary management, drug information requests, and precepting students. Sandra also assists with the “Principles of Drug Information and Literature Evaluation” course at Purdue University College of Pharmacy. In January 2017, she will begin her rotation at Janssen Scientific Affairs, LLC.

Past Drug Info Fellows

Megan N. Brown, PharmD

Health Communications Specialist, Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention (CDC)
Past Fellow: 2015-2017 Cycle

“My favorite aspect of the regulatory pharmaceutical fellowship was that it prepared me to be a strong communicator in a variety of settings—academia, health system, pharmaceutical industry, and public health. I believe that this level of preparation is unique to this particular fellowship program and is its greatest strength. My experience in the fellowship motivated me to pursue a public health communications role, where I am able to communicate health information to health care professionals, the general public, and other audiences on a national scale.”
Past Drug Info Fellows

Jay R. Fajiculay, PharmD
Designated Federal Officer, Division of Advisory Committees and Consultants Management (DACCM)
CDER, U.S. Food and Drug Administration
Past Fellow: 2014 – 2016 Cycle

“Completing the fellowship has been one of the best career decisions I have ever made. The support and guidance from the preceptors provided an enhanced environment of learning that I will take with me forever. Throughout the fellowship, I had the opportunity to incorporate my interests in digital and technology-based learning across various practice settings. From presenting at local and international conferences, to developing digital applications that are now used in the global arena, the fellowship has prepared me to succeed in beginning my new career.”

Bhavini T. Parikh, PharmD
Senior Manager, Medical Information
AstraZeneca
Past Fellow: 2013 – 2015 Cycle

"Completing this fellowship was one of the best decisions I have ever made for my career. The unique program allowed me to step outside of my comfort zone, which in turn led to a great deal of professional development. I made lifelong friends and mentors along the way, and was able to explore various career fields. Upon graduating from the program, these experiences allowed me to feel prepared to start my career in any field of my choice."

Andrea M. TenBarge, PharmD
Associate Consultant, Medical Channels & Visual Media
Eli Lilly and Company
Past Fellow: 2012 – 2014 Cycle

“Choosing to complete the Regulatory Pharmaceutical Fellowship program has been one of the best decisions I have made in my career. Through my fellowship experiences, I discovered my love for innovative digital strategy and was able to land a very unique position which combined my love for medicine with my love for digital and visual media while still being able to continue my love of teaching by precepting fourth year pharmacy students. It was through my experiences with the fellowship program that led me to where I am today!”
Past Drug Info Fellows

Genevieve L. Ness, PharmD
Director, Christy Houston Foundation Drug Information Center
Assistant Professor, Pharmaceutical, Social and Administrative Sciences
Belmont University College of Pharmacy
Past Fellow: 2011-2013 Cycle

“The skills I obtained during the fellowship serve as the foundation of my career as a faculty member and a director of a drug information center. Bringing the three diverse perspectives to the classroom illustrates to my students the versatility of drug information skills and provides them with insight into diverse career paths. As a drug information center director, I use these skills to seek partnerships with other universities and pharmaceutical companies in addition to managing the output of drug information question responses.”

Kimberly W. Chiu, PharmD
Consumer Safety Officer, Division of Drug Information
Food and Drug Administration
Past Fellow: 2010 - 2012

“The Regulatory Pharmaceutical Fellowship’s unique format is a great opportunity for professional and personal growth. Professionally I developed a unique skill set which prepared me for challenging positions in a variety of settings. Personally I grew under the strong mentorship of the program's preceptors.”

Jean E. Cunningham, PharmD, BCPS
Senior Clinical Content Specialist
Truven Health Analytics
Past Fellow: 2007 - 2009

“The fellowship offered me the opportunity to build and refine my literature evaluation, drug information, and professional presentation skills (to name just a few). I was able to experience or contribute to hospital formulary management, advisory committee meetings, and promotional drug advertising standards. After completing the fellowship, I was able to secure a faculty position in drug information and continued some of the research and publication efforts I started during the fellowship. When I decided I wanted to find a position beyond academia, the fellowship experiences definitely helped me move into the drug information publishing industry. Hands down, this is one of the best investments I have made in my career.”
MEDICATION SAFETY TRACK TIMELINE

MEDICATION SAFETY

July 2017

01 Indianapolis, IN
Center for Medication Safety Advancement
Jul. 2017 – Feb. 2018

02 Indianapolis, IN
Surveillance and Global Patient Safety

03 Silver Spring, MD
Office of Surveillance and Epidemiology

June 2019

Regulatory Pharmaceutical Fellowship
**Purdue**

The 8-month rotation at Purdue University College of Pharmacy’s Center for Medication Safety Advancement (CMSA) will provide the fellow with exposure to academia and the various medication safety initiatives undertaken by CMSA. The fellow will actively participate in practice-based research to foster the discovery and delivery of information and practices to enhance medication safety. There will be numerous opportunities to publish original research and deliver presentations. Additionally, the fellow will have the opportunity to educate students, both didactically and through preceptorship.

**Lilly**

The fellow will spend an 8-month rotation at Eli Lilly and Company working on the Surveillance team within Global Patient Safety. During this time, the fellow will have opportunities to work cross-functionally between pre- and post-marketed compounds to detect and evaluate adverse effects and other problems to determine if they are drug-related. The fellow will be involved in routine surveillance work as well as participating in the development of regulatory documents to gain a foundational understanding of pharmacovigilance responsibilities within industry.

**FDA**

The fellow will spend the last 8 months of their tenure working in the Office of Surveillance and Epidemiology (OSE) at the FDA. During this time, the fellow will have the opportunity to participate in intra- and inter-center projects in both the pre- and post-market arenas. Additionally, the fellow will utilize adverse drug event reporting data, medical literature, and established knowledge of marketed drug products to assess postmarked safety-related issues and conduct active surveillance work.
John Hertig, PharmD, MS
Associate Director, CMSA
Courtesy Clinical Assistant Professor of Pharmacy Practice
Purdue University College of Pharmacy

Dr. Hertig received his Bachelors of Science in Pharmaceutical Sciences and Doctor of Pharmacy Degree from Purdue University. Following graduation he completed a combined PGY1/PGY2 Masters in Health-System Pharmacy Administration residency at The Ohio State University Medical Center in Columbus, OH. As part of this program, he received a Masters degree in Health-System Pharmacy Administration from the Ohio State University. In his current role he assists in setting and managing the mission and vision of the organization, leads strategic initiatives, forms partnerships, educates, and acts as a catalyst to help improve the lives of patients.

Kyle Hultgren, PharmD
Director, CMSA
Courtesy Clinical Assistant Professor of Pharmacy Practice
Purdue University College of Pharmacy

Dr. Hultgren is Managing Director of CMSA where he pursues the development of innovative safe medication use practices as well as engaging methods to educate healthcare practitioners and student pharmacists. Dr. Hultgren is a co-author of a certification program in partnership with Purdue University and the Veterans Health Administration on Lean Healthcare and Systems Redesign that has been provided to over 8,000 professionals in health systems nationwide. His current work includes predictive analytics for adverse drug events and utilizing simulation methodologies for training medical professionals on safe medication use practices. He also serves as Chairman of the Rx-SafeNet Practice Based Research Network Advisory Board for community pharmacy based medication safety research in Indiana.
Jennifer B. Mouser, PharmD
Manager, Safety Surveillance
Global Patient Safety
Eli Lilly and Company

Jennifer received her PharmD from Butler University. Following graduation, she worked as a retail pharmacist before accepting a safety surveillance position at Eli Lilly in Global Patient Safety. Jennifer served for several years as a safety surveillance scientist identifying and evaluating safety trends and potential safety risks for investigational and approved medications while also continuing to contribute to pharmacy practice as a part-time retail pharmacist. She now serves as the manager of the safety surveillance team comprised of scientists who are responsible for investigational and approved medications in a variety of therapeutic areas, including diabetes, cardiovascular, men's health, osteoporosis, and autoimmune disorders.

William P. Brookfield, MS
Consultant, Safety Surveillance
Global Patient Safety
Eli Lilly and Company

Bill obtained his pharmacy and pharmacology degrees from Butler University. Following graduation, he began his career in hospital pharmacy and served as a clinical pharmacist, an assistant director of pharmacy and a director of pharmacy over the span of 20 years. In hospital pharmacy, Bill spent time working with two outpatient clinics in diabetes and pulmonology and served as a clinical pharmacist for a family practice residency program. He precepted numerous pharmacy students in administrative and clinical hospital rotations. Bill remains actively involved in student and resident programs at Lilly. He precepts 16 to 18 PharmD students annually at Lilly. He also serves as a pharmacology professor at the University of Indianapolis in their physical therapy program and lectures in continuing education seminars for practicing physical therapists.
Irene Z. Chan, PharmD, BCPS
Commander, U.S. Public Health Service
Deputy Director, Division of Medication Error Prevention and Analysis (DMEPA)
Office of Surveillance and Epidemiology
Food and Drug Administration

CDR Chan received her B.S. and Doctorate degrees in Pharmacy from Rutgers University Ernest Mario School of Pharmacy. Upon graduation, she was called to active duty and assigned to Gallup Indian Medical Center where she completed a PGY1 Pharmacy Practice Residency. She continued with the Indian Health Service for over five years in both inpatient and outpatient pharmacy settings. In 2009, she transferred to FDA. In her current role she leverages her knowledge of regulatory science, human factors, and risk management to provide oversight of safety recommendations regarding drug nomenclature, labels, labeling, packaging, and product design.

S. Christopher Jones, PharmD, MPH
Commander, U.S. Public Health Service
Deputy Director, Division of Pharmacovigilance II (DPV)
Office of Surveillance and Epidemiology
Food and Drug Administration

CDR Jones earned his PharmD in 2001 from Virginia Commonwealth University (VCU). He also holds an undergraduate degree in chemistry from VCU and a Master of Public Health degree from Johns Hopkins. During pharmacy school, he joined the US Navy under a scholarship program. After graduation he was commissioned and stationed at Naval Medical Center Portsmouth. He practiced in outpatient, inpatient, and clinic settings. Following his military service, he transitioned to the U.S. Public Health Service at FDA in Silver Spring MD. Today, he is responsible for the post-marketing surveillance of adverse drug events in the Division of Pharmacovigilance II. He is involved in a variety of pharmacovigilance projects and has interests in drug safety and epidemiology.
Kaitlyn N. Dana, PharmD
Regulatory Pharmaceutical Fellow
Medication Safety Track, PGY1
Current Fellow: 2016 – 2018 Cycle

Kaitlyn received her Bachelors of Science in Pharmacy Studies and Doctor of Pharmacy degree from the University of Connecticut School of Pharmacy in Storrs, Connecticut. Kaitlyn is currently at Purdue University College of Pharmacy’s Center for Medication Safety Advancement (CMSA). During her time at CMSA, she will partner on a variety of research projects, legislative initiatives, and publications working towards promoting medication safety at the local and national level. Kaitlyn will also help facilitate the Medication Safety course and Introduction to the Pharmaceutical Industry elective at Purdue University College of Pharmacy in West Lafayette, Indiana.

Past Medication Safety Fellows

Katelyn Brown, PharmD
Consultant, Diabetes Real World Outcomes
Eli Lilly and Company
Past Fellow: 2013-2015 Cycle

“"The Purdue/Lilly/FDA fellowship broadened my horizons to opportunities available to those with a PharmD. My program directors took a vested interest in my development which motivated and helped me obtain my goals by the end of the fellowship. Upon completion of the fellowship, I had developed expertise in project management, medication safety, and leadership which have significantly contributed to the success in my current position.""
Drug Advertising & Promotion Track Timeline

August 2017

01 Indianapolis, IN
4 Months

Purdue University
College of Pharmacy
Aug. 2017 - Nov. 2017

02 Titusville, NJ
12 Months

Johnson & Johnson
Regulatory Advertising & Promotion
Dec. 2017 - Nov. 2018

03 Silver Spring, MD
8 Months

FDA
Office of Prescription Drug Promotion

July 2019
Regulatory Pharmaceutical Fellowship
During this 8 month rotation, the fellow will gain experience in the government promotional review process and become familiar with sections of the Federal Food, Drug, and Cosmetic Act and relevant FDA Guidance documents. The fellow will assist in the review of promotional materials, evaluate draft product labeling (package inserts), research and evaluate industry complaints, and work with the trade name review group or the patient-related outcome claim evaluation team. The fellow will be mentored by a senior member of OPDP and will work collaboratively to develop departmental projects tailored to the fellow’s interests.

**Purdue**

This 4 month Purdue rotation will provide the fellow with exposure to academia and the different functions and responsibilities of institutional-based pharmacy administration. The fellow will have experiences in formulary management, medication safety, and drug-use policy. The fellow will gain significant experience in academia providing didactic and experiential training of students.

**Janssen**

This 12 month rotation will provide an opportunity to develop an understanding of FDA regulations, industry codes, Healthcare Compliance policies, and Federal and State laws as it relates to prescription drugs and biologics advertising and promotion activities. The fellow will also have an opportunity to work directly with internal business partners such as marketing, sales training, medical affairs, field based commercials and medical representatives, and Law department to ensure compliance with promotional activities.

**ADVERTISING & PROMOTION TRACK**

**FDA**
Sheetal Patel is Head, Regulatory Advertising and Promotion, within Pharmaceutical Group Health Care Compliance organization. In this role, Sheetal provides regulatory guidance of promotional and marketing activities to ensure compliance with federal laws and regulations.

Previously, she held the position of Lieutenant Commander, Senior Regulatory Review Officer, at the Food and Drug Administration, Office of Prescription Drug Promotion. Sheetal received her Doctorate of Pharmacy from the Philadelphia College of Pharmacy, University of the Sciences and completed a post-doctoral fellowship in Regulatory Advertising and Promotion with Johnson & Johnson, Food and Drug Administration, and Purdue University.

Jia currently serves as the Associate Director – Regulatory Lead with the Regulatory, Advertising and Promotion department supporting Cardiovascular Metabolism franchise. She is responsible for providing guidance regarding promotional regulatory and marketing compliance considerations in the R&D and commercial arenas, including anticipated launch strategies and marketing campaigns for the cardiovascular franchise.

Jia is a licensed New Jersey pharmacist with a B.S. and Doctor of Pharmacy from the Ernest Mario School of Pharmacy at Rutgers University. She has been with J&J for 8 years, with 5 years in Medical Information and 3 years with Regulatory, Advertising and Promotion. Jia is a Certified Compliance and Ethics Professional and holds the Seton Hall Law School Health Care Compliance Certification.
Samuel Skariah, PharmD  
Commander, U.S. Public Health Service  
Team Leader, Office of Prescription Drug Promotion  
Food and Drug Administration  
Past Fellow 2005 - 2007 Cycle

Sam graduated from the University of Illinois at Chicago College of Pharmacy where he received his PharmD. He then went on to complete this same track of the regulatory fellowship that was in conjunction with Purdue University, Eli Lilly and Company, and the FDA. He is a Commander in the United States Public Health Service and has served as Team Leader within FDA’s Office of Prescription Drug Promotion (OPDP) since 2013. Previous to that role, he served as an FDA-OPDP reviewer for various therapeutic areas including metabolic and endocrine, oncology, pulmonary, gastroenterology, and analgesia/addiction products.

Carrie Newcomer, PharmD

Regulatory Review Officer, Office of Prescription Drug Promotion  
Food and Drug Administration

Carrie graduated from the University of Pittsburgh School of Pharmacy where she received her PharmD. She has been a regulatory review officer for the Office of Prescription Drug Promotion (OPDP) since 2005, and currently reviews promotional materials for transplant and ophthalmology products. She also coordinates the new reviewer training program and the FDA Pharmacy Student Experiential Program for OPDP.

During her time at OPDP, Carrie has been responsible for working in various therapeutic areas including reproductive and urologic products. Before joining OPDP, Carrie was a community pharmacist.
Dr. Zillich graduated with a BS and PharmD from Purdue University. Then, he completed four years of post-graduate training prior to his first academic appointment as an Assistant Professor of Pharmacy Practice at Purdue University College of Pharmacy. From 1999 through 2001, he completed a general practice (PGY1) residency and a specialty residency in ambulatory care (PGY2) at the University of Kentucky Medical Center. From 2001 through 2003, he completed a health outcomes research fellowship at the University of Iowa Colleges of Pharmac and Medicine under the direction of Barry Carter. Currently, Dr. Zillich holds an academic appointment as the William S. Bucke Professor and Head, Department of Pharmacy Practice at Purdue University College of Pharmacy and a Research Scientist appointment at the Veterans Affairs Health Services Research and Development Center for Health Information and Communication.

At Purdue, Dr. Sachdev serves as core course director/teaches in a Health Policy Applications course in which students conduct live debates on eighteen salient healthcare policy topics, teaches in Public Health and Marketing & Management courses, and serves as the preceptor for a legislative policy clerkship at the Indiana State House. The Employers’ Forum of Indiana is a unique healthcare coalition consisting of self-insured employers, health plans, hospitals, physician groups, pharmacy benefit managers, pharmacies, and other interested parties who work collaboratively on initiatives to improve the value of health care provided in Indiana. Dr. Sachdev has served on the American Society of Health-System Pharmacists (ASHP) executive committee for five years and currently serves as their Chair of the Council on Public Policy and as member of AJHP’s editorial advisory board. Locally, she serves as Co-Chair of the Legislative and Regulatory Task Force for the Indiana Pharmacists Alliance (IPA), Indiana’s state pharmacy association, and as Board Member-at-Large for the Indiana Society of Health-System Pharmacists.
CURRENT & PAST ADVERTISING AND PROMOTION FELLOWS

John Riehl, PharmD

Regulatory Pharmaceutical Fellow
Advertising and Promotion Track, PGY2
Current Fellow: 2015 – 2017 Cycle

John is a 2015 graduate of Jefferson College of Pharmacy – Thomas Jefferson University. John is currently completing the FDA portion of the fellowship, serving as a Regulatory Reviewer within the Office of Prescription Drug Promotion. He assists with providing written advisory comments to pharmaceutical sponsors, drafting enforcement letters on violative promotional material, and reviewing draft labeling to ensure compliance with FDA regulations.

Sam Davis, PharmD

Senior Medical Information Specialist
Med Communications
Past Fellow: 2013-2015 Cycle

“I am so grateful and honored that I was able to participate in the two year regulatory advertising and promotion fellowship. It is a one-of-a-kind fellowship experience that combines academia, industry, and government rotations. The fellowship was truly an amazing experience that prepared me to embrace a number of opportunities and helped to lay a foundation for success in pharmaceutical industry.”

Ankur Kalola, PharmD

Regulatory Review Officer, Office of Prescription Drug Promotion
Food and Drug Administration
Past Fellow: 2011-2013 Cycle

After earning his pharmacy degree from Rutgers University in New Jersey in 2011, Ankur completed a two year fellowship focused in Promotional Regulatory Affairs. During his fellowship, he worked with Janssen Pharmaceuticals, the Food and Drug Administration, and Purdue University. He now currently works for the Office of Prescription Drug Promotion within the FDA as a regulatory review officer. He is responsible for focusing on advertising and promotion related to various therapeutic areas including metabolic and endocrine products.
PAST ADVERTISING AND PROMOTION FELLOWS

Nital Patel, PharmD, MBA
Medical Science Director
Relyspa, Inc.
Past fellow: 2009-2011 Cycle

Nital Patel graduated from Drake University with both her PharmD and MBA. Following completion of the regulatory pharmaceutical fellowship, Nital worked as Medical Science Liaison at both Sanofi and Questcor pharmaceuticals. Currently, Nital is a Medical Science Director at Relyspa Inc, A Vifor Company, leading strategic development and tactical execution of plans to develop the medical brand and engage scientific thought leaders.

Amit Patel, PharmD
Head, Material Approval Process
Alcon, a Novartis Company
Past fellow: 2003-2005 Cycle

"This is a very unique fellowship program which provides a great opportunity to build your understanding of the FDA regulations pertaining to advertising and promotion of pharmaceutical products. The opportunity to gain experience at the FDA is very valuable, and prepares you to manage regulatory issues from both the FDA and Pharmaceutical company perspective. Overall, I have enjoyed my experience as a fellow and a preceptor during this program."

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FELLOWSHIP BENEFITS

- Competitive stipend
- Reimbursement for relocation and professional travel expenses
- Enrollment in the Indiana Pharmacy Teaching Certificate Program
- Purdue University benefits package (i.e. health insurance, prescription coverage, vision plan, dental)
- Vacation and University holidays

1 year membership in the Regulatory Affairs Professionals Society
The fellow must be a graduate from an ACPE-accredited college of pharmacy, or otherwise eligible for licensure as a pharmacist, prior to the start of the fellowship term.

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

All interested applicants must submit the following:
1. Letter of intent for one of the three tracks
2. Contact information for three references
3. Curriculum Vitae
4. Official transcripts (electronic copies OK)

All application materials should be submitted electronically to the email contacts below no later than 11:59 pm EST on Wednesday, December 14, 2016.

Drug Information Track: DrugInformationFellowship@gmail.com
Medication Safety Track: MedicationSafetyFellowship@gmail.com
Drug Advertising and Promotion Track: DrugMarketingFellowship@gmail.com

On-site interviews will take place at the FDA in Silver Spring, MD on Friday, January 6, 2017. For more information, please visit our website at: http://www.fda.gov/RegPharmFellowship.
REGULATORY PHARMACEUTICAL FELLOWSHIP

2017 – 2019 Cycle

Government | Industry | Academia

Jointly sponsored by:

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