REGULATORY PHARMACEUTICAL FELLOWSHIP

Government | Industry | Academia

2019-2021

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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.

- Available fellowships for 2019 – 2021:
  - 2 Drug Information
  - 2 Medication Safety
  - 1 Drug Advertising & Promotion
Lindsay E. Wagner, PharmD, BCPS
Lieutenant Commander, U.S. Public Health Service

Team Leader
Division of Drug Information
Food and Drug Administration

Drug Information Track Preceptor
Past Fellow: 2009 - 2011 Cycle

LCDR Wagner received her PharmD degree from the Albany College of Pharmacy and Health Sciences in 2009 and completed the Regulatory Pharmaceutical Fellowship in drug information in 2011. Following the fellowship, she accepted a position with the Division of Drug Information (DDI) as a civilian Consumer Safety Officer. In 2012, she joined the U.S. Public Health Service Commissioned Corps. In 2014, she joined DDI’s Senior Management Team as a Team Leader and in 2015 received a promotion to the rank of Lieutenant Commander.

In her current role as Team Leader, LCDR Wagner supervises teams of pharmacists and other experts to ensure timely, complete, and accurate responses to inquiries from around the globe on issues related to drug products. She provides leadership for many programs including FDA’s drug-related content on Facebook, the network of drug information pharmacists known as the Global Alliance of Drug Information Specialists on LinkedIn, CDER’s Expanded Access program in DDI including emergency request procedures, and policies and procedures important to MedWatch and adverse event reporting. LCDR Wagner involves her fellows in DDI’s written communication efforts, including writing campaign responses and social media posts. In addition to training fellows, LCDR Wagner trains and mentors student pharmacists, fellow officers, and post-graduate fellows in other scientific disciplines.
Indianapolis, IN
6 Months

College of Pharmacy

Titusville, NJ
12 months

Medical Information

Silver Spring, MD
6 months

Division of Drug Information

Indianapolis, IN
12 months

Global Medical Information

DRUG INFORMATION TRACK TIMELINE

Regulatory Pharmaceutical Fellowship
**Drug Info 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. 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, pharmacy student precepting, and other initiatives to better the overall customer experience.

**FDA**

The 6-month FDA rotation will provide an opportunity for fellows to refine their drug information skills in a regulatory setting. Fellows will respond to dozens of drug information inquiries from patients, health care professionals, and regulated industry received daily. Fellows will create and disseminate content on Twitter and LinkedIn and respond to questions on Facebook as part of FDA’s Social Media team. Fellows will work on video, podcast, and listserv content as well. Fellows will serve as liaisons to specific Review Divisions and assist with a number of high-profile initiatives including the Generic Drug User Fee Amendments, Expanded Access, and writing campaign responses.
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 twenty 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 40 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* and *Currents in Pharmacy Teaching and Learning*.

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" and chair of the professional program curriculum committee. 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.
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 20 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 and oncology products at Lilly and led development of launch portfolios of medical information responses for a new co-marketed molecule for type 2 diabetes and for a new compound for metastatic breast cancer. 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.
Samina Ali, PharmD

**Associate Director**
**Medical Information**
Janssen Scientific Affairs, LLC

Samina earned her BS and PharmD degrees from Rutgers University College of Pharmacy and completed an ASHP-accredited Hospital Pharmacy Practice Residency at the Mount Sinai Medical Center in New York City. With over 18-years experience at Janssen, Samina has led and supported Medical Information activities for multiple Janssen products in oncology, virology, GI, women’s health and urology. 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.

Payal Desai, PharmD

**Associate Director**
**Medical Information**
Janssen Scientific Affairs, LLC

Payal Desai earned a PharmD degree from the University of Sciences in Philadelphia. Dr. Desai worked in community practice before transitioning to a career in pharmaceutical industry. Over 20 years, Dr. Desai served at several pharmaceutical companies. In her current role at Janssen, she is the Associate Director of Medical Information, where she is responsible for the successful launch of cardiovascular products. She provides strategic medical support, develops internal education plans, and participates in several cross-functional teams. Payal was recognized with a 1-year rotation within the Medical Information Leadership team. She has mentored several Post-doc Fellows and pharmacy students throughout her career.
CURRENT DRUG INFO FELLOWS

Megan Cuomo, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY1
Current Fellow: 2018 – 2020 Cycle

Megan is a 2018 graduate of the University of North Carolina Eshelman School of Pharmacy in Chapel Hill, North Carolina. Megan is currently completing the academic portion of the fellowship where she assists with the “Principles of Drug Information and Literature Evaluation” course at Purdue University College of Pharmacy. Additionally, she assists with formulary management, answers drug information requests, and precepts students in the Drug Information Center at IU Methodist Hospital in Indianapolis, Indiana. In January 2019, Megan will begin her rotation in Medical Information at Janssen Scientific Affairs, LLC. In January 2020, she will start her rotation in the Division of Drug Information at the FDA.

Kaitlin Montagano, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY1
Current Fellow: 2018 – 2020 Cycle

Kaitlin graduated from Manchester University College of Pharmacy, Natural and Health Sciences in 2018. Kaitlin is currently completing the academic portion of the fellowship with Purdue University where she assists with the “Principles of Drug Information and Literature Evaluation” course and serves on the professional program curriculum committee. Additionally, Kaitlin practices as a Drug Information Specialist in the IU Health Drug Information Center responding to drug information requests, assisting with formulary management, and precepting advanced pharmacy practice (APPE) students. In January 2019, Kaitlin will begin her rotation at the FDA’s Division of Drug Information. Kaitlin’s industry rotation will begin at Astellas Pharma US, Inc. in July 2019.
Kiersten Walters, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY2
Current Fellow: 2017 – 2019 Cycle

Kiersten is a 2017 graduate of Purdue University College of Pharmacy. Kiersten is currently completing the industry portion of the fellowship at Eli Lilly & Company as her final rotation of the fellowship. In this role, she serves as a Medical Information Associate in the Global Medical Information department, working with both the Oncology and BioMeds teams. She assists with creating standard response documents, responding to escalated medical information requests, and developing training materials. Kiersten has also had the opportunity to support the launch of new products in multiple therapeutic areas, serve as a committee member for the Lilly pharmacist forum, and assist in pharmacy student rotation activities.

Jacqueline Wasynczuk, PharmD

Regulatory Pharmaceutical Fellow
Drug Information Track, PGY2
Current Fellow: 2017 – 2019 Cycle

Jackie is a 2017 graduate of Butler University College of Pharmacy and Health Sciences in Indianapolis, IN. Jackie is currently completing the industry portion of the fellowship. In this role, she serves on the medical information and knowledge integration teams for Cardiovascular and Metabolism at Janssen Scientific Affairs, LLC. Jackie assists in the development and delivery of drug information to healthcare professionals, payors, and consumers as well as review of promotional and non-promotional items for medical accuracy. She has also supported the launch of new indications for branded medications, mentored pharmacy students, and has had the opportunity to participate in networking and professional development events. In January 2019, Jackie will begin her rotation at the FDA in the Division of Drug Information.
Past Drug Info Fellow Testimonies

Sandra R. Bai, PharmD
Pharmacist, Division of Drug Information
U.S. Food and Drug Administration
Past Fellow: 2016 – 2018

“This fellowship is a smaller program with unique practice settings that allows for a lot of personal mentorship, professional development, and hands-on experience. Through this fellowship, I was able to present research at local and national conferences, publish articles in medical journals, and serve as a preceptor to pharmacy students. These opportunities provided the skills and network to feel prepared for a career in academia, industry, or government post-fellowship.”

Megan N. Freeland, PharmD
Founder
Stock-Rose Creative, LLC
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.”

Jay R. Fajiculay, PharmD
Designated Federal Officer
Division of Advisory Committee and Consultant Management
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.”
PAST DRUG INFO FELLOW TESTIMONIES

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

"This fellowship was one of the best decisions I have made. I utilized skills learned from my time as a fellow, to progress in my career and moving on to new roles, including public speaking, interpersonal communication, drug information knowledge, flexibility, and confidence."

Andrea M. TenBarge, PharmD
Consultant, Medical Digital Strategy and Capabilities
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 and fellows. It was through my experiences with the fellowship program that led me to where I am today!”

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.”
PAST DRUG INFO FELLOWS

2010-2012: Kimberly (Wu) Chiu, PharmD
Clinical Outcome Assessments Staff
Office of New Drugs
U.S. Food and Drug Administration

2009-2011: Lindsay E. (Davison) Wagner, PharmD, BCPS
Team Leader
Division of Drug Information
U. S. Food and Drug Administration

2007-2009: Jean Cunningham, PharmD
Clinical Content Specialist
Truven Health Analytics

2005-2007: Sanjeev K. Bhanot, PharmD
Associate Director, Medical Affairs
Merz Pharma Canada, Ltd.

2003-2005: Tanya Nelson, PharmD
Senior Medical Science Liaison
Janssen Scientific Affairs, LLC

2001-2003: John Ng, PharmD
Consumer Safety Officer
Division of Clinical Compliance Evaluation
Office of Scientific Investigations
U.S. Food and Drug Administration
Regulatory Pharmaceutical Fellowship
The 5-month rotation at Purdue University College of Pharmacy and Butler University College of Pharmacy and Health Sciences will provide the fellow with exposure to academia and the various medication safety initiatives. 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.

The fellow will spend 7 months of their tenure working in the Office of Surveillance and Epidemiology (OSE) or the Division of Drug Information (DDI) 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.

The fellow will have a 12-month rotation at Eli Lilly and Company or AbbVie 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 events to determine if they are drug-related. The fellow will be involved in safety signal detection and evaluation as well as participating in the development of regulatory documents to gain a foundational understanding of pharmacovigilance responsibilities within industry.
Alissa L. Russ, PhD
Assistant Professor
Purdue University
College of Pharmacy

Alissa Russ is an Assistant Professor of Pharmacy Practice and Affiliate Investigator with Regenstrief Institute, Inc. Dr. Russ integrates health services research with engineering methods to improve the design of health IT for healthcare professionals and patients. She has expertise in human factors engineering, usability evaluation, and health IT and teaches “Patient Safety and Informatics”, a required course for third-year pharmacy students. Dr. Russ has led federally-funded research to evaluate the design of medication alerts. Some of her other research studies include investigating medication safety incidents, understanding healthcare professionals’ decision-making, and enhancing technologies to aid medication reconciliation. Dr. Russ has given over 20 invited presentations and her research has received special recognition from the International Medical Informatics Association.

John B. Hertig, PharmD, MS, CPPS
Associate Professor
Butler University
College of Pharmacy and Health Sciences

John Hertig is an Associate Professor specializing in management, entrepreneurship, and patient safety. He received his Bachelor of Science in Pharmaceutical Sciences and Doctor of Pharmacy degrees from Purdue University. He completed a PGY1 pharmacy practice and PGY2 health-system pharmacy administration residency at The Ohio State University while obtaining a Masters in Health-System Pharmacy Administration. Dr. Hertig has lectured and published on a variety of leadership, administration, patient safety, and health policy topics, and is a member of the Editorial Advisory Board for The Joint Commission Journal on Quality and Patient Safety. He holds various national and international appointments, including advisory roles with the FDA and the Patient Safety Workgroup of the International Pharmaceutical Federation. Dr. Hertig is a member of the Board of Directors for the Alliance for Safe Online Pharmacies – Global, where he leads efforts to reduce the patient safety impact of illegal and counterfeit online drug distribution worldwide. He has served as President of the Indiana Society of Health-System Pharmacists and is a past Chair of the Legislative and Regulatory Council for the Indiana Pharmacist Alliance. Dr. Hertig received the Glen J. Sperandio Award, honoring the Indiana Health-System Pharmacist of the year, the “Excellence in Innovation” Award, and the Medication Safety Pharmacist of the Year award in Indiana.
Jennifer B. Mouser, PharmD

Safety Surveillance Director
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. Currently, she is the director of the safety surveillance team which is comprised of scientists who are responsible for the portfolio of investigational and approved drugs as well as scientists who are responsible for monitoring the safety of device delivery systems.
Adrienne M. Rothstein, PharmD

Director, Safety Data Sciences
Pharmacovigilance and Patient Safety
AbbVie

Adrienne received her BS in Pharmacy from St. John’s University and her PharmD from the University of Cincinnati. After graduation, she pursued a pharmacy practice residency at Stanford University Hospital. After completion of her training, she worked in drug information and pharmacovigilance at Elan Pharmaceuticals. Adrienne then worked at the FDA in the Office of Surveillance and Epidemiology, Division of Pharmacovigilance and Office of New Drugs, Division of Reproductive, Urology and Bone Products. Currently she is the director of a team that is responsible for safety surveillance of investigational and approved oncology products. Adrienne also contributes to a variety of regulatory submissions for investigational oncology products.

Melissa Truffa, RPh

Head, Safety Data Sciences
Pharmacovigilance and Patient Safety
AbbVie

Melissa is currently the Head of the Safety Data Science team that is responsible for safety surveillance and signal management for investigational and marketed products. Melissa’s prior experience includes 15 years of experience with various positions in the Office of Surveillance and Epidemiology, Division of Pharmacovigilance and the Office of New Drugs, Division of Antiviral Products. Prior to her position with FDA, Melissa was a clinical pharmacist at the University of Virginia Medical Center in hematology/oncology and pediatrics. Melissa earned her BS in Pharmacy from the University of Pittsburgh, School of Pharmacy, and a certificate of pharmacoepidemiology from the University of Pennsylvania/FDA educational program and a certificate of Public Health from the Georgetown University/FDA educational program.
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.
Danya Faruqi, PharmD

Regulatory Pharmaceutical Fellow
Medication Safety Track, PGY1
2018 – 2020 Cycle

Danya received her Doctorate of Pharmacy degree from Midwestern University Chicago College of Pharmacy. She is currently at Purdue University College of Pharmacy’s Center for Medication Safety Advancement (CMSA). While at CMSA, Danya will participate in a number of research projects and legislative initiatives including developing a longitudinal research project from the ground up. Danya will help facilitate the Medication Safety and Introduction to the Pharmaceutical Industry courses at Purdue University College of Pharmacy in West Lafayette, Indiana.

Kathryn Marwitz, PharmD, MPH

Regulatory Pharmaceutical Fellow
Medication Safety Track, PGY2
2017 – 2019 Cycle

Kathryn earned her Doctorate of Pharmacy degree from Drake University in Des Moines, Iowa and Master of Public Health degree from Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland. Kathryn is in her second year of the fellowship program working at Eli Lilly and Company, located in Indianapolis, Indiana in the Global Patient Safety department. At Lilly, Kathryn routinely monitors and analyzes adverse event data from a variety of sources. She leads product team meetings to discuss these data and the need for any potential safety updates. In addition, she is assisting with authoring regulatory documents. Kathryn will be transitioning to the FDA in November 2018 to work at the Office of Surveillance and Epidemiology (OSE).
Past Med Safety Fellow Testimonies

Katelyn Brown, PharmD
Sr. Research Scientist - Clinical
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.”

Kaitlyn Dana, PharmD
Project Planning Manager
Pfizer
Past Fellow: 2016-2018 Cycle

“The Regulatory Pharmaceutical Fellowship in Medication Safety has given me a true appreciation for the importance of medication safety across three unique institutions. There are endless ways to inspire medication safety, regardless of the organization, and in doing so directly impact public health. This program has enhanced my learning agility by challenging me to adapt to a new culture and position every eight months while continuously applying and building upon the previous experiences. The fellowship has specifically increased my confidence in pharmacovigilance and project management activities through working alongside experts. Aside from the skills and knowledge gained, I walked away with an extensive network of newfound colleagues (and friends) that have encouraged both my professional and personal growth. This fellowship established the foundation for the rest of my pharmaceutical career and for that I am grateful. As I transition in my career, medication safety will always be at the heart of my decision making thanks to this outstanding experience.”
DRUG ADVERTISING AND PROMOTION TRACK TIMELINE

01 Indianapolis, IN 9 Months
Regulatory Advertising & Promotion
Lilly
Jul. 2019 – Mar. 2020

02 Silver Spring, MD 9 Months
Office of Prescription Drug Promotion
FDA
Apr. 2020 – Dec. 2020

03 Indianapolis, IN 6 Months
College of Pharmacy
Purdue University

July 2019

June 2021
This 6-month rotation will provide the fellow with exposure to upper level academia and the different functions and responsibilities of academic administrators. The fellow will gain significant teaching experience through provision of didactic education including coordination of a core PharmD management and marketing course and experiential training of students.

This 9-month rotation will provide experience in the government promotional review process and provide overviews 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 other functions in the Office of Prescription Drug Promotion (OPDP). 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.

This 9-month rotation will provide an opportunity to develop an understanding of FDA regulations and guidance, industry codes, and Federal and State laws as it relates to prescription drug advertising and promotional materials and activities. The fellow will also have the opportunity to work directly with internal business partners such as marketing, legal, medical affairs, and other commercial and corporate representatives to ensure that a broad range of promotional materials are in compliance with applicable regulations and internal policies.
Mike Sauers, Director in Eli Lilly’s Global Regulatory Affairs, US Advertising, Promotion, and Policy group, advises on promotional compliance across the range of Lilly’s Oncology, Diabetes, and Biomedicines US marketed products. Prior to joining Lilly in 2017, Mike served for 10 years in the Food and Drug Administration’s (FDA) Office of Prescription Drug Promotion (OPDP). Mike held multiple posts within OPDP, most recently as the Supervisor of the Advertising and Promotion Policy Staff leading OPDP’s guidance, regulatory, and policy development, as well as the social science research, legal, and project management teams. Mike’s previous experience includes work as a Presidential Management Fellow in the HHS Office of the Secretary and as a Healthcare Representative for Pfizer, Inc. Mike received his Bachelor’s Degree in Neuroscience from the University of Delaware and a Master’s of Public Policy from Georgetown University.

Drum Ad Promo Preceptors – Purdue and Eli Lilly

Steve Abel, PharmD, FASHP

Associate Provost for Engagement
Professor, Pharmacy Practice
Purdue University

Prior to his appointment as associate provost for engagement in 2016 he served as associate vice president for engagement, associate vice provost for faculty affairs and held various positions within the Purdue University College of Pharmacy. These included assistant/associate dean for clinical programs, Head, Department of Pharmacy Practice and Bucke Professor of Pharmacy Practice. Steve received his B.S. (Pharmacy) and PharmD degrees from Purdue University and completed residency at Mayo Medical Center. He completed an Academic Leadership Fellowship through the Committee on Institutional Cooperation in 2007-2008, and an inaugural Purdue University provost fellowship focused on faculty affairs in 2009-2010. Steve is passionate about student education, faculty/leadership development, mentorship and community engagement. His research focuses on the development, implementation and evaluation of progressive pharmacy services, student enhancement of pharmacy practice, patient safety and interprofessional collaborative strategies. Steve developed the only fully immersive USP 797 compliant virtual cleanroom used for student education. The virtual cleanroom is commercially marketed through his company, Penguin Innovations.

Mike Sauers

Director, Global Regulatory Affairs
US Advertising, Promotion, and Policy
Eli Lilly and Company
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 ophthalmology and transplant 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, medical imaging, hematology, and urologic products. Before joining OPDP, Carrie was a community pharmacist.

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.
Nikki earned her pharmacy degree from Purdue University in 2017. Nikki was an Assistant Clinical Professor at Purdue University College of Pharmacy where she co-coordinated the Health Policy Applications course for P3 students and provided support for the Employers’ Forum of Indiana policy efforts. She is currently completing the industry portion of the fellowship at Johnson & Johnson, where she is a regulatory compliance lead. She will complete the fellowship at the FDA Office of Prescription Drug Promotion through July 2019.

2015-2017: John Riehl, PharmD
Regulatory Affairs, Advertising and Promotion Manager
Allergan

2013-2015: Sam Davis, PharmD
Content Medical Information Specialist – Promotional Review
Med Communications, Inc.

2011-2013: Ankur Kalola, PharmD
Regulatory Review Officer
Office of Prescription Drug Promotion
U.S. Food and Drug Administration

2009-2011: Nital Patel, PharmD, MBA
Senior Medical Science Director
Relypsy

2007-2009: Sheetal Patel, PharmD
Head, Regulatory Advertising and Promotion
Johnson & Johnson Health Care Compliance & Privacy

2005-2007: Samuel Skariah, PharmD
Lieutenant Commander, U.S. Public Health Service
Team Leader, Office of Prescription Drug Promotion
U.S. Food and Drug Administration

2003-2005: Amit Patel, PharmD
Director, Material Approval Process
Alcon, a Novartis Division
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
APPLICATION PROCESS

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

Preliminary interviews will take place at the American Society of Health-System Pharmacists Midyear Clinical Meeting Sunday, December 2 – Tuesday, December 4, 2018 via the Personnel Placement Service (PPS). A preliminary interview is encouraged but not required.

**All interested applicants must submit the following:**
1. Letter of intent for one of the three tracks
   - Specify sub-track/sponsor of interest
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 EDT** on **Wednesday, November 28, 2018.**

**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 FDA in Silver Spring, MD on Friday, January 4, 2019. For more information, please visit our website at: [www.fda.gov/RegPharmFellowship](http://www.fda.gov/RegPharmFellowship).
REGULATORY PHARMACEUTICAL FELLOWSHIP

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