



REGULATORY PHARMACEUTICAL FELLOWSHIP

Government
Industry
Academia
2020-2022

Jointly sponsored by:



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FELLOWSHIP OVERVIEW

PROGRAM DESCRIPTION

The purpose of the Regulatory Pharmaceutical Fellowship program is to train selected candidates in one of three tracks focused on the medical and regulatory aspects of drug information dissemination, drug advertising and promotion, or medication safety. The program serves to maintain and enhance a scientific link among FDA, academia, and the pharmaceutical industry. The fellowship provides participants the unique opportunity to experience careers in the areas of government, academia, and industry, qualifying graduates to pursue career opportunities in each respective area.

FELLOWSHIP BENEFITS

- Competitive stipend
- Reimbursement for relocation during fellowship and professional travel expenses
- Enrollment in the Indiana Pharmacy Teaching Certificate (IPTeC) Program
- Vacation and University holidays
- Optional Purdue University benefits package (health, Rx, vision, and dental)
- 1-year membership in the Regulatory Affairs Professionals Society (RAPS) and a copy of Fundamentals of Regulatory Affairs

2020 – 2022 Recruitment

Drug Information – 3 positions

Medication Safety – 2 positions



ELIGIBILITY REQUIREMENTS

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. All applicants must be U.S. citizens to complete the program. Candidates who do not meet this requirement should not apply.

Preliminary interviews will be conducted during PPS at the American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting annually. Save the date for on-site interviews on January 3, 2020.

APPLICATION PROCESS

All interested applicants must submit the following:

1. Letter of intent for one of the two tracks – specify track & sponsor of interest
2. Contact information for three references – including email and phone number
3. Curriculum Vitae
4. Official transcripts (electronic copies accepted)

All application materials should be submitted electronically to the email contacts below no later than **11:59 pm EST on Wednesday, December 4, 2019.**

On-site interviews will take place at FDA in Silver Spring, MD on Friday, January 3, 2020. For more information, visit our website at: www.fda.gov/RegPharmFellowship

Submit to:
Drug Information Track
DrugInformationFellowship@gmail.com
Medication Safety Track
MedicationSafetyFellowship@gmail.com

Additional fellowship opportunities are available with our partners. Visit FDA's ORISE website at: <https://orise.orau.gov/fda/> or Purdue's website at: www.phpr.purdue.edu/residencies/current

DRUG INFORMATION

PROGRAM OVERVIEW

INDUSTRY

This experience provides the opportunity for the fellow to gain training as a member of a medical information team in the pharmaceutical industry. The fellow will develop skills related to development and delivery of drug information to healthcare professionals, payors, consumers, and business partners through a variety of methods.

See locations below.

FDA

The FDA experience provides an opportunity for fellows to refine their drug information skills in a regulatory setting. Fellows respond to drug information inquiries from patients, health care professionals, and regulated industry; create and disseminate content; and assist with a number of high-profile initiatives.

Silver Spring, MD

ACADEMIA

The Purdue University experience exposes the fellow to academia and an institutional-based drug information center at Indiana University Health. Fellows will conduct a research project for presentation at a national meeting and publication in a peer-reviewed pharmacy journal. Significant teaching experience in an out of the classroom is provided.

West Lafayette & Indianapolis, IN

FELLOWSHIP SCHEDULE: 3 TRACKS, 1 FELLOW EACH

TRACK 1

PURDUE
UNIVERSITY

FDA

Lilly

COLLEGE OF
PHARMACY

DIVISION OF DRUG
INFORMATION

GLOBAL MEDICAL INFORMATION
Indianapolis, IN

6 months:
07/2020 – 12/2020

6 months:
12/2020 – 06/2021

12 months:
07/2021 – 06/2022

TRACK 2

PURDUE
UNIVERSITY

janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

FDA

COLLEGE OF
PHARMACY

MEDICAL INFORMATION
Titusville, NJ

DIVISION OF DRUG
INFORMATION

6 months:
07/2020 – 12/2020

12 months:
12/2020 – 12/2021

6 months:
01/2022 – 06/2022

TRACK 3

 **astellas**

FDA

PURDUE
UNIVERSITY

MEDICAL INFORMATION
Northbrook, IL

DIVISION OF DRUG
INFORMATION

COLLEGE OF
PHARMACY

12 months:
07/2020 – 06/2021

6 months:
07/2021 – 01/2022

6 months:
01/2022 – 06/2022



Megan Cuomo, PharmD
 Industry Sponsor: Janssen
 Scientific Affairs, LLC
 Second Year Fellow:
 2018-2020 Cycle



CURRENT FELLOWS

Kaitlin Montagano, PharmD
 Industry Sponsor:
 Astellas Pharma US, Inc.
 Second Year Fellow:
 2018-2020 Cycle



Minh Tran, PharmD
 Industry Sponsor: Janssen
 Scientific Affairs, LLC
 First Year Fellow:
 2019-2021 Cycle



Dylan Vo, PharmD
 Industry Sponsor:
 Eli Lilly and Company
 First Year Fellow:
 2019-2021 Cycle

PAST FELLOWS

- 2017-2019: Kiersten Rybakov, PharmD**
 Associate Consultant, Global Medical Information
 Eli Lilly and Company
- 2017-2019 Jacqueline Wasynczuk, PharmD**
 Assistant Professor, Department of Pharmacy Practice
 Thomas Jefferson University
- 2016-2018: Sandra Bai, PharmD**
 Pharmacist, Division of Drug Information
 Food and Drug Administration
- 2015-2016: Megan N. Freeland, PharmD**
 Owner, Healthcare Digital Marketing Consultant
 StockRose Creative, LLC
- 2014-2016: Jay R. Fajiculay, PharmD**
 Designated Federal Officer, Division of Advisory Committees and
 Consultant Management
 Food and Drug Administration
- 2013-2015: Bhavani T. Parikh, PharmD**
 Leader, Global Medical Affairs
 AstraZeneca
- 2012-2014: Andrea M. TenBarge, PharmD**
 Consultant, Medical Digital Strategy and Capabilities
 Eli Lilly and Company
- 2011-2013: Genevieve Lynn (Ness) Engle, PharmD**
 Director, Christy Houston Foundation Drug Information Center
 Assistant Professor of Pharmaceutical, Social and Administrative
 Sciences, Belmont University College of Pharmacy
- 2010-2012: Kimberly (Wu) Chiu, PharmD**
 Science Policy Analyst
 Division of Clinical Outcome Assessment
 Office of New Drugs- Immediate Office
 Food and Drug Administration



- 2009-2011: Lindsay E. Wagner, PharmD, BCPS**
 Lieutenant Commander, U.S Public Health Service
 Branch Chief, Division of Drug Information
 Food and Drug Administration
- 2007-2009: Jean Cunningham, PharmD**
 Senior Clinical Content Specialist, Value-Based Care
 IBM Watson Health
- 2005-2007: Sanjeev K. Bhanot, PharmD**
 Director of 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
 Food and Drug Administration

DRUG INFORMATION

PROGRAM PRECEPTORS



Amy H. Sheehan, PharmD | Purdue University
amheck@Indiana.edu

For the past twenty years, Amy has worked with Purdue University College of Pharmacy and the Indiana University (IU) Health Center for Medication Management, where she contributes to the provision of comprehensive drug information services for all IU Health-affiliated hospitals. 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. She serves as course coordinator for a drug information and advance literature evaluation class, and is chair of the professional program curriculum committee.



Lindsay Wagner, PharmD, BCPS | LCDR, USPHS | FDA
Past Fellow 2009 - 2011 Cycle
Lindsay.Wagner@fda.hhs.gov

LCDR Wagner received her PharmD degree from the Albany College of Pharmacy and Health Sciences. She has been with the FDA in the Division of Drug Information since graduating from the fellowship. In her current role as Branch Chief, she supervises other pharmacists to help the public get the accurate, science-based information they need about human drugs. Lindsay provides leadership for many additional programs, including Expanded Access and social media, and precepts students.



Sandra Bai, PharmD | FDA
Past Fellow 2016 - 2018 Cycle
Sandra.Bai@fda.hhs.gov

Sandra earned her PharmD degree from Butler University College of Pharmacy. Following graduation, she completed the two year Regulatory Pharmaceutical Fellowship in Drug Information with rotations at Purdue University, Janssen Scientific Affairs, LLC, and FDA. Following the fellowship, she accepted a position with the Division of Drug Information (DDI) at FDA. In her current role at DDI, Sandra provides timely, complete, and accurate responses to inquiries from consumers, health care professionals, and industry. Sandra is also a member of DDI's Social Media team and leads the Drug Info Rounds video program.



Raj Patel, PharmD | FDA
Raj.Patel@fda.hhs.gov

Raj earned his PharmD degree from the University of Sciences in Philadelphia. In his current role at FDA, he is the Social Media Lead for FDA's Center for Drug Evaluation and Research. He oversees the development and release of all information distributed via social media and provides expert advice and counsel on social media activities to engage stakeholders. Raj leads a team of pharmacists who provide drug information through social media to consumers, health care professionals, and industry. He is also a member of the DDI podcast team and helps produce three podcast series.



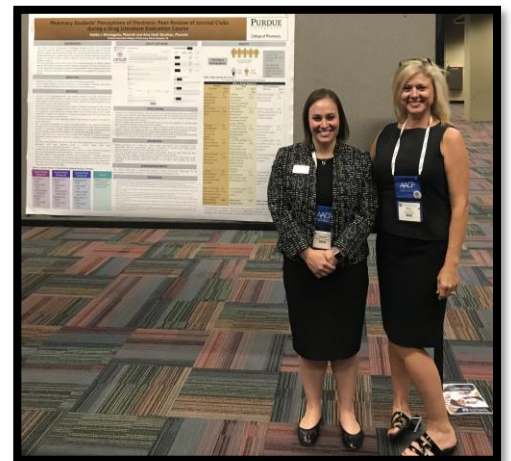
Why Drug Information?

"The three rotations provided in this fellowship build on each other, allowing me to continue to refine my drug information and teaching skills over the course of the two years. I am also thankful for the excellent professional connections and mentors that I have gained from this program."

-Megan Cuomo
Second Year Drug Information Fellow

"This fellowship program is unique in its provision of in-depth exposure to drug information practice within academia, government, and the pharmaceutical industry. Over a year in, the breadth of opportunities I have experienced has far surpassed the high expectations I had when I chose this program. I could not be more thankful to have had this opportunity."

-Kaitlin J. Montagano
Second Year Drug Information Fellow



DRUG INFORMATION

PROGRAM PRECEPTORS

Kathy Mybeck, PharmD | Eli Lilly and Company

Mybeck_Kathy@lilly.com

Throughout her 20 plus-year career at Eli Lilly and Company, Kathy has held various roles within Medical Information and Regulatory Affairs. Kathy has provided global medical information support and led development of launch portfolio medical information responses and strategies for endocrine and oncology products at Lilly. Kathy also served as an Implementation Lead for the Regulatory Transformation initiative by partnering with the Labeling department on process and system updates. Kathy continues to coach her team members on medical information-related activities and precept PharmD students from a variety of schools.



Lilly

Samina Ali, PharmD | Janssen Scientific Affairs, LLC

sali2@its.jnj.com



Janssen
PHARMACEUTICAL COMPANIES
of Johnson & Johnson

Samina earned her BS and PharmD degrees from Rutgers University College of Pharmacy and completed a Pharmacy Practice Residency at Mount Sinai Medical Center in New York City. 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 | Janssen Scientific Affairs, LLC

pdesai1@its.jnj.com

Payal Desai earned a PharmD degree from the University of Sciences in Philadelphia. 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.



Janssen
PHARMACEUTICAL COMPANIES
of Johnson & Johnson

Jeanette Jiang, PharmD | Astellas

jeanette.jiang@astellas.com



astellas

Jeanette has oversight of products in the cardiovascular, infectious disease, immunology, and urology therapeutic area. She leads the Medical Affairs planning and execution of scientific conferences, facilitate the development of key medical messages, organize and prepare the scientific content for the education and training of Medical Affairs colleagues. Throughout her career, Jeanette has served as a preceptor to students and residents from a variety of universities. She also has served on a subcommittee for phactMI™, which is a collaboration of Medical Information (MI) departments at pharmaceutical companies that are dedicated to supporting healthcare professionals.

Derek Varga, PharmD | Astellas

derek.varga@astellas.com

Derek Varga leads the Subject Matter Experts of the Urology, Infectious disease, Cardiovascular, Immunology, and Transplant therapeutic areas in Medical Information. Derek also precepts students for the University of Illinois at Chicago and other college of pharmacies at Astellas. Derek is an alumnus of Drake University and of the Scott & White Memorial Hospital Primary Care residency. Prior to Astellas Derek was a shared faculty member with St. Louis College of Pharmacy with a practice site in Primary Care at the John Cochran VA in St. Louis.



astellas



Why Drug Information?

"I chose this fellowship because of the unique opportunity to practice drug information in various settings and the illustrious history of prior fellows. I have learned so much during my first few months and am excited to continue to develop my drug information skills at my next rotation site."

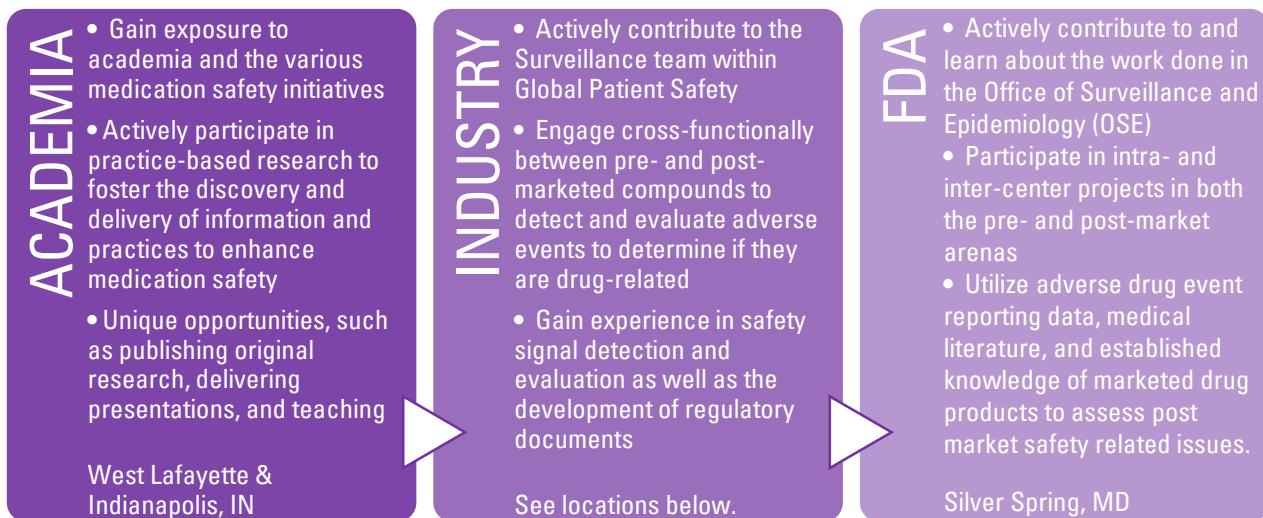
-Dylan Vo
First Year Drug Information Fellow

"This fellowship has opened so many doors for me as a recent graduate. The individuals I have met and the opportunities that I've been given as a fellow far exceed my expectations. I cannot express my gratitude enough for my preceptors and co-fellows alike. There is no doubt in my mind that I will be prepared for whatever career opportunities I embark on in the future."

-Minh Tran
First Year Drug Information Fellow

MEDICATION SAFETY

PROGRAM OBJECTIVES



FELLOWSHIP SCHEDULE: 2 TRACKS, 1 FELLOW EACH

TRACK 1



COLLEGES OF PHARMACY	GLOBAL PATIENT SAFETY Indianapolis, IN	OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
5 months: 07/2020 – 11/2020	12 months: 12/2020 – 11/2021	7 months: 12/2021 – 06/2022

TRACK 2



COLLEGES OF PHARMACY	GLOBAL PATIENT SAFETY North Chicago, IL	OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY
5 months: 07/2020 – 11/2020	12 months: 12/2020 – 11/2021	7 months: 12/2021 – 06/2022



Danya Faruqi, PharmD

Industry Sponsor:
Eli Lilly and Company
Second Year Fellow:
2018-2020 Cycle



Jonell Nwabueze, PharmD

Industry Sponsor:
Eli Lilly and Company
First Year Fellow:
2019-2021 Cycle



Charlotte Moureaud, PharmD

Industry Sponsor:
Abbvie
First Year Fellow:
2019-2021 Cycle

CURRENT FELLOWS

PAST FELLOWS

2017-2019: Kathryn Marwitz, PharmD, MPH

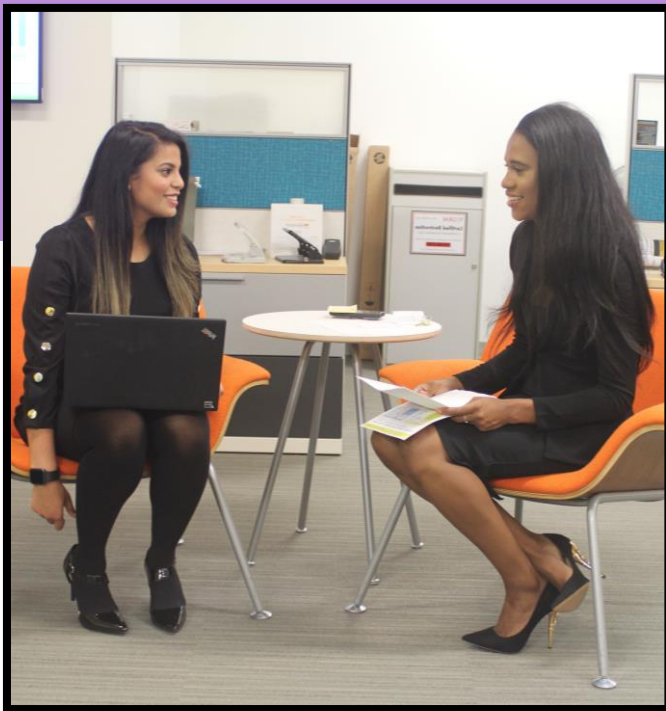
Assistant Professor of Pharmaceutical Sciences
(Social and Administrative Sciences)
Manchester University College of Pharmacy, Natural & Health Sciences

2016-2018: Kaitlyn Dana, PharmD

Project Planning Manager
Pfizer, Groton, CT

2013-2015: Katelyn Brown, PharmD

Diabetes Real World Outcomes Consultant
Eli Lilly and Company; Indianapolis, IN



Why Medication Safety?

"Let's say you have the best drug on the market, cures the disease 100% of the time, favorable dosing, and is even affordable. There's one thing that will stop you from approving your drug. No matter how effective your miracle compound is, you have to answer one question: is your drug safe?"

The drug development process will continue to evolve, but the foundational piece, medication safety, will stand the test of time. Here's a good question: What job do you want for the rest of your life? Here's an even better question: Will you have the skillset and training to enter a different role if you change your mind?

From the academic component at a top university, to a built-in high-level industry experience, followed by unparalleled training at the FDA, this fellowship provides an abundance of exclusive experiences. After taking a look at the diverse current roles of our past fellows, I knew I would have the opportunity to work in many different sectors post-fellowship. I chose medication safety aware that no matter what project I work on, or the stage in development a product is in: one thing will remain constant and non-negotiable: the safety of that compound. This fellowship gives me the tools to create an impenetrable foundation with transferable skills that will carry me throughout my career. I chose this fellowship after deciding the foundation of my career is also non-negotiable."

- Jonell Nwabueze
First Year Medication Safety Fellow

MEDICATION SAFETY



Why Medication Safety?

“Medication safety has been a passion of mine for quite some time.

This fellowship will allow me to expand my knowledge and expertise in several different settings, impacting patient lives on a global scale.”

-Charlotte Moureaud
First Year Medication Safety Fellow

PROGRAM PRECEPTORS



FDA

Irene Z. Chan, PharmD, BCPS | CAPT, USPHS | FDA

Irene.Chan2@fda.hhs.gov

CAPT 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.

Christopher Jones, PharmD, MPH | CAPT, USPHS | FDA

Steven.Jones@fda.hhs.gov

CAPT Jones earned his PharmD in 2001 from Virginia Commonwealth University (VCU). He holds an undergraduate degree in chemistry from VCU & a Master of Public Health degree from Johns Hopkins. CDR Jones joined the US Navy under a scholarship program. After graduation he was commissioned & 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 the FDA. Today, he is responsible for the post-marketing surveillance of adverse drug events in the Division of Pharmacovigilance II. His interest includes drug safety and epidemiology



FDA

Adrienne M. Rothstein, PharmD | Abbvie

Adrienne.Rothstein@abbvie.com

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. She then worked in drug information & pharmacovigilance at Elan Pharmaceuticals. Adrienne later worked at the FDA in OSE, Division of Pharmacovigilance and OND, Division of Reproductive, Urology and Bone Products. Today, she is the director of a team that is responsible for safety surveillance of investigational and approved oncology products and she contributes to a variety of regulatory submissions for investigational oncology products.



abbvie

Alexandra Terry, PharmD, BCPS | AbbVie

Alexandra.Terry@abbvie.com

Alexandra received her PharmD from University of Illinois at Chicago and BS in biochemistry from Northern Illinois University. She completed the Eli Lilly Visiting Scientist Fellowship in regulatory affairs. Following her fellowship, she completed a PGY1 Pharmacy Practice Residency at OSF Saint Francis Medical Center. Alexandra joined AbbVie after the completion of her postgraduate training. Her current role involves development of surveillance strategy, signal evaluation, and authoring global safety reports. She supports a variety of products in the oncology and general medicine therapeutic areas for both investigational and approved products.



abbvie

Rachel Booze, PharmD | Eli Lilly and Company

Rachel received her PharmD from Purdue University. Following graduation, she completed the Eli Lilly and Company Visiting Scientist Fellowship in the Global Labeling Department before accepting a safety surveillance position in Global Patient Safety. As a Clinical Surveillance Scientist, Rachel is responsible for signal detection, safety data evaluation, and risk assessment in support of Lilly's products in development as well as for marketed medicines and devices globally. She supports a variety of products in the diabetes therapeutic area.



Lilly

MEDICATION SAFETY

PROGRAM PRECEPTORS



John B. Hertig, PharmD, MS, CPPS, FASHP | Butler University
jhertig@butler.edu

John B. Hertig is an Associate Professor and Vice-Chair of Pharmacy Practice at Butler University where he specializes 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 & PGY2 health-system pharmacy administration residency at The Ohio State University Medical Center while obtaining his Master's degree. Among various national and international appointments, he serves as Vice President of the Americas for the International Pharmaceutical Federation's Hospital Section, and as a Director for the Alliance for Safe Online Pharmacies.



Alissa Russ, PhD | Purdue University
aruss@purdue.edu

Dr. Alissa L. Russ is Assistant Professor of Pharmacy Practice, Purdue University and Affiliate Investigator with Regenstrief Institute, Inc. in Indianapolis, IN. She teaches "Patient Safety and Informatics" to third-year pharmacy students. Dr. Russ integrates health services research with human factors engineering methods to improve the design of health information technologies (IT) for healthcare professionals and patients. Dr. Russ leads federally-funded research to evaluate the design of medication alerts, including drug-allergy, drug-drug interaction, and drug-disease alerts. Dr. Russ has given over thirty invited presentations and her research has received special recognition from the International Medical Informatics Association.



Dan Degnan, PharmD, MS, CPPS, FASHP | Purdue University
ddegnan@purdue.edu

Dan Degnan currently serves as the Associate Director for the Professional Program Laboratory and is a Clinical Assistant Professor of Pharmacy Practice (Courtesy) at the Purdue University College of Pharmacy. He has an appointment at the Regenstrief Center for Healthcare Engineering at Purdue as a Clinical Research Associate with expertise and research interests in the area of medication safety technology, advanced pharmacy automation, pharmacy operations and high reliability in healthcare. Prior to his role at Purdue, Dr. Degnan served as the Medication Safety Officer at Community Health Network in Indianapolis for almost 10 years. He has held leadership positions in national organizations for both pharmacy and healthcare quality.



Kyle Hultgren, PharmD | Purdue University
khultgre@purdue.edu

Kyle Hultgren is the director of the Purdue University College of Pharmacy's Center for Medication Safety Advancement. Dr. Hultgren's current research includes extensive work on dashboards and measurement systems for the evaluation and improvement of medication use systems as well as large adverse event data set analysis. He holds multiple copyrights on mobile computer simulation technology and two patents on medical devices designed to improve patient safety. Dr. Hultgren lectures nationally and internationally on safe medication use practices and teaches regularly in the Doctor of Pharmacy curriculum where he is the 2016 Dr. Aziz Teaching Award recipient.



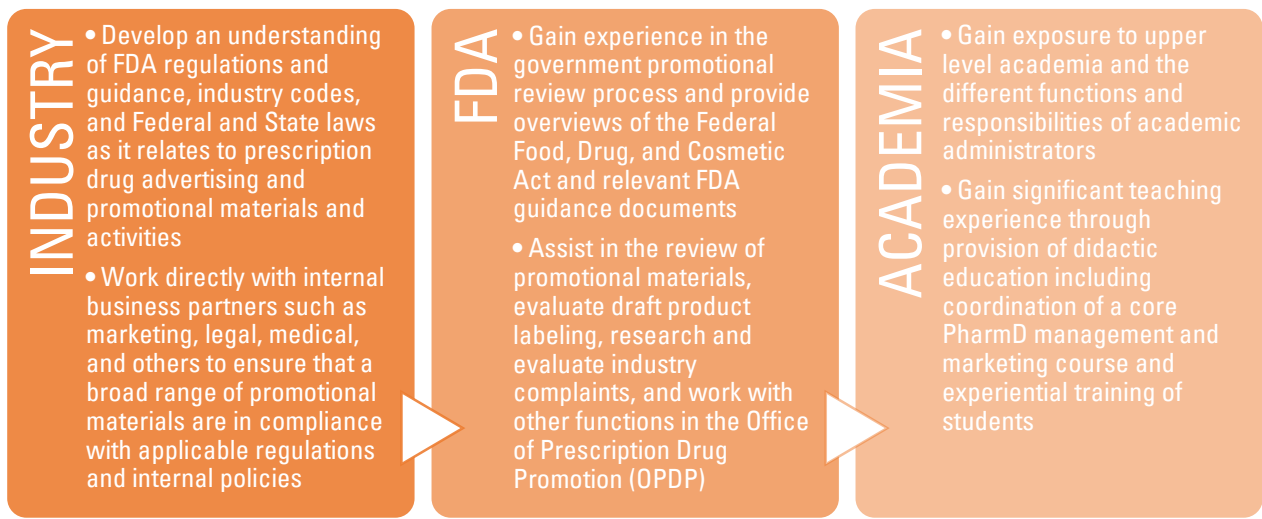
Fellow Spotlight

Danya completed her academic rotation with Purdue University and is currently at Eli Lilly and Company where she is working as a Clinical Surveillance Scientist within Global Patient Safety. Over the past 11 months, she has worked on completing deliverables for drugs in a variety of therapeutic areas including diabetes, psych, and oncology. For her final rotation, Danya will be rotating through the FDA within the Division of Pharmacovigilance and the Division of Medication Error Prevention and Analysis. Danya loves to travel and trying new foods. Being a Midwest girl, she is excited to explore the east coast one bite at a time!

-Danya Faruqi
Second Year Medication Safety Fellow

ADVERTISING AND PROMOTION

PROGRAM OBJECTIVES



FELLOWSHIP SCHEDULE: 1 TRACK, 1 FELLOW

INDUSTRY ADVERTISING & PROMOTION	OFFICE OF PRESCRIPTION DRUG PROMOTION	COLLEGE OF PHARMACY
9 months	9 months	6 months

PAST FELLOWS

2017-2019: Nikki Pedersen, PharmD
Senior Regulatory Affairs Specialist, Ad/Promo
Abbott Laboratories

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

2013-2015: Sam Davis, PharmD
Consultant, Global Regulatory Affairs
US Advertising & Promotion
Eli Lilly & Company, Lilly USA, LLC

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, East Team Lead
Relypsa

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

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

2003-2005: Amit Patel, PharmD
Sr. Director, Regulatory Affairs Advertising and Promotion
ACADIA Pharmaceuticals Inc.

CURRENT FELLOW

Jennifer Chen, PharmD

Industry Sponsor:
Eli Lilly and Company
First Year Fellow:
2019-2021 Cycle



PROGRAM PRECEPTORS

Mike Sauers | Eli Lilly and Company

sauers_michael_a@lilly.com



Mike Sauers, Director in Eli Lilly's Global Regulatory Affairs, US Advertising and Promotion 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 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.

Sam Skariah, PharmD | CDR, USPHS | FDA

Past Fellow 2005 - 2007 Cycle
sam.skariah@fda.hhs.gov



CDR Skariah 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.

Carrie Newcomer, PharmD | FDA

carrie.newcomer@fda.hhs.gov

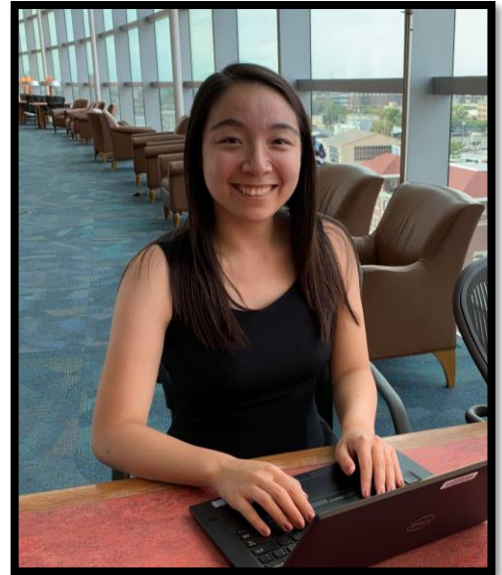


Carrie graduated from the University of Pittsburgh School of Pharmacy where she received her PharmD. She has been a regulatory review officer for the Office of Prescription Drug Promotion (OPDP) since 2005, and currently reviews promotional materials for ophthalmology and transplant products. She also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

Steven Abel, PharmD, FASHP | Purdue University

abels@purdue.edu

Prior to his appointment as associate provost for engagement in 2016, Steve served as associate vice president for engagement, associate vice provost for faculty affairs and held various positions within the Purdue University College of Pharmacy. He has 18 years of prior practice experience, primarily in a health-system setting. Steve received his B.S. (Pharmacy) and PharmD degrees from Purdue University and completed residency at Mayo Medical Center. Steve is passionate about student education, faculty/leadership development, mentorship and community engagement. Steve developed the only fully immersive USP 797 compliant virtual cleanroom used for student education, commercially marketed through his company, Penguin Innovations.



Why Advertising and Promotion?

"I love how Regulatory Advertising and Promotion is a field in which I can utilize my pharmacy knowledge to analyze clinical trials, as well as exercise my interpersonal skills to lead discussions among cross-functional groups. I became especially interested in this fellowship due to the unparalleled and invaluable opportunities it provides to gain significant work experience in both FDA and pharmaceutical industry. I am also highly anticipating the academia portion because I am excited to not only give back to the Purdue University College of Pharmacy, but also learn about mentorship and teaching, which is knowledge that will surely be applicable to any future career path. Throughout this fellowship, I am humbled I will have the privilege to work with preceptors who are not only invested in my personal and professional growth, but are also highly respected and experienced professionals in their respective fields. I am truly looking forward to making an impact on patient care by ensuring both patients and healthcare providers are appropriately educated about their medications through drug advertising and promotional materials."

-Jennifer Chen

First Year Advertising and Promotion Fellow

REGULATORY PHARMACEUTICAL FELLOWSHIP

Government
Industry
Academia

2020-2022

To reach our current fellows and ask questions, write to:

Drug Information Track:

DrugInformationFellowship@gmail.com

Medication Safety Track:

MedicationSafetyFellowship@gmail.com

Advertising and Promotion Track:

DrugMarketingFellowship@gmail.com

Jointly sponsored by:

