Butler University

PHARMACEUTICAL FELLOWSHIP PROGRAM

REGENERON

Lilly

FDA U.S. FOOD & DRUG ADMINISTRATION

BUTLER UNIVERSITY

Table of Contents

- A message from John B. Hertig, PharmD, MS, CPPS, FASHP Chair and Associate Professor
- About Butler University
- About the FDA
- About Eli Lilly & Regeneron

How To Apply

- Eligibility and Application Procedure
- Fellowship Benefits
- Frequently Asked Questions
- Fellowship Alumni

REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION

A message from John B. Hertig

Dear Prospective Medication Safety Fellow,

Thank you for your interest in the Butler University Fellowship Program.The purpose of this fellowship program is to develop the next generation of pharmacy leaders. Through the cooperation of three prominent partners representing academia, the pharmaceutical industry, and the United States Food and Drug Administration (USFDA), fellows will actively participate in various aspects of pharmaceutical innovation, contemporary practice, and global patient safety. By design, fellows have the opportunity to seek specialized areas of training including, but not limited to patient education, medical advising, promotional review, product launch, literature review, new product research, supply chain security (substandard and falsified medications), and evidence-based policy. Ultimately, this program is for those who want to be active leaders in defining the future of healthcare, making it safe and accessible for all.

Sincerely,

John B. Hertig, PharmD, MS, CPPS, FASHP
Chair and Associate Professor
Department of Pharmacy Practice
Butler University College of Pharmacy and Health Sciences
Indianapolis, IN, USA

REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION

About Butler

Located in Indianapolis, Indiana, Butler University is a nationally recognized university with six academic colleges. In 2020, Butler was ranked the top regional university in the Midwest and Most Innovative School among Midwest Regional universities by U.S. News & World Report. At the Butler University College of Pharmacy and Health Sciences, you will find a community of health professionals committed to excellence. Our programs prepare students and post-graduate learners to become leaders in their chosen fields. Butler University College of Pharmacy and Health Sciences has a variety of post-graduate residencies and fellowships, each designed to strengthen not only the professionals' specialty expertise, but also enhance teaching abilities in the classroom through faculty direction and mentorship.

About the U.S. FDA

Office of Medication Error Prevention and Risk Management (OMEPRM) includes Division of Medication Error Prevention and Analysis (DMEPA) and Division of Risk Management (DRISK). DMEPA looks to minimize medication errors in the U.S. healthcare system. As part of the FDA pre-approval process for new drug products, we review proposed proprietary drug names, container labels and other labeling, packaging, product design, and human factors protocols and study results to prevent medication errors. We also monitor and analyze medication error reports for marketed products to determine if regulatory actions such as labeling revisions or product redesign are needed to address reported errors. DRISK reviews all proposed REMS, REMS modifications, and REMS assessments for all products with approved REMS for conformance with current FDA standards.

REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION

About Eli Lilly

For more than 140 years, Lilly has worked tirelessly to develop and deliver trusted medicines that meet real needs. Their growing portfolio of medicines includes treatments in the areas of bone muscle joint, cancer, cardiovascular, diabetes, endocrine, immunology, neurodegeneration, neuroscience, and pain. Lilly's Global Patient Safety organization, consisting of more than 300 physicians, pharmacists, nurses, and other healthcare professionals are dedicated to the collection, monitoring, evaluation, and reporting of safety information through the science of pharmacovigilance.

About Regeneron

Regeneron is a leading biotechnology company that invents life-transforming medicines for people with serious diseases. Founded and led for over 30 years by physician-scientists, our unique ability to repeatedly and consistently translate science into medicine has led to eight FDA-approved medicines and numerous product candidates in development, all of which were homegrown in our laboratories. Our medicines and pipeline are designed to help patients with eye disease, allergic and inflammatory diseases, cancer, cardiovascular and metabolic diseases, infectious diseases, pain, and rare diseases.

REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION

Global Patient Safety and Pharmacovigilance

Actively Recruiting:
One Fellow for 2023–2025

Program Timeline

Academia	Eli Lilly	FDA
4 Months	*1 Year*	*8 Months*

Year 1 — **Year 2**

ACADEMIA

The fellow will gain experience in academia by being given the opportunity to publish original research, deliver presentations, and teach. The fellow will also have an opportunity to complete a teaching certificate and leadership program.

Location: Indianapolis, IN

INDUSTRY

The fellow will have opportunities to work cross-functionally on pre-and post-marketed compounds to assess and evaluate adverse events in the context of biological plausibility, indication for use, concomitant medications, and comorbid conditions to determine if the adverse events are drug-related. Fellows will actively participate in various aspects of pharmaceutical innovation, use optimization, and global safety

Location: Indianapolis, IN

FDA

The fellow will participate in intra- and inter-center projects in pre- and post-market arenas. The fellow will focus on research opportunities to address medication error issues related to drug packaging, nomenclature, labels and labeling. The fellow will utilize adverse drug event reporting date, medical literature, and more to assess safety related issues.

Silver Spring, MD

Eli Lilly Second Year Fellow:

"This fellowship has provided me with diverse experiences in academia, industry, and the FDA allowing for a holistic view of patient safety and equipped me with a unique platform to further patient safety on a global scale. The unique structure of this fellowship has allowed me to work with amazing mentors who have supported me and encouraged me along the way."

-Karolina Cieslak, PharmD

Eli Lilly First Year Fellow:

"This fellowship program has helped me gain insight into the various roles within global drug safety. I have had the opportunity to work alongside leaders in this functional area to provide me with unique learning experiences. This fellowship has allowed me to continue to build up my fundamental skills that will support me in my future career."

-Lauren Reinhard, PharmD

REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION

Medication Error Pharmacovigilance and Risk Management

Actively Recruiting:
One Fellow for 2023–2025

Program Timeline

Year 1			Year 2
Academia *4 Months*	**Regeneron** *1 Year*	**FDA** *8 Months*	

ACADEMIA

The fellow will gain experience in academia by being given the opportunity to publish original research, deliver presentations and teach. The fellow will also have an opportunity to complete a teaching certificate and leadership program.

Location: Indianapolis, IN

INDUSTRY

The fellow at Regeneron will be a part of a leading biotech company in evaluating safety and mitigating risk. The opportunity to work on numerous medications in the pipeline ranging from eye disease to metabolic disease will provide exposure to multiple therapeutic areas. The range of experiences will also allow the fellow to work cross-functionally as a team to promote medication safety.

Location: Tarrytown, NY

FDA

The fellow will participate in intra- and inter-center projects in pre- and post-market arenas. The fellow will focus on research opportunities to address medication error issues related to drug packaging, nomenclature, labels and labeling. The fellow will utilize adverse drug event reporting date, medical literature, and more to assess safety related issues.

Silver Spring, MD

Regeneron Second Year Fellow:

"The mentorship and breadth of experiences I have received have expanded my knowledge in risk management to help identify medication errors and improve the lives of patients on a global scale. This fellowship provides the ideal balance between structure and flexibility, while catering to each individual fellow's interests. The program directors are truly invested in equipping me with the tools needed for my career development."

-Vraj Patel, PharmD

Regeneron First Year Fellow:

"The fellowship program at Butler University is so unique given the variety of experiences it has to offer. I'm hopeful that the academic, industry, and FDA portion will offer different outlooks on medication safety that will provide an environment for professional growth and offer a solid foundation for a career in pharmacovigilance and risk management."

-Zarnab Jillani, PharmD

REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION

Application Process

Eligibility

To be considered for the Butler University Fellowship Program, you must meet the following requirements:

- Graduate of an Accredited Council for Pharmacy Education (ACPE)—accredited Doctor of Pharmacy program prior to the start of the fellowship term.
- Have a strong interest in pursuing a career in the pharmaceutical industry
- Eligible to work in the United States

Application Procedure

The Butler University Fellowship portal will open on **October 5, 2022**. Applicants must upload the following application materials to the online portal no later than **November 4, 2022**:

- Letter of Intent
- Curriculum Vitae
- Official college transcripts. Unofficial college transcripts can be used as a placeholder.
- Two letters of recommendation emailed to **rxfellowships@butler.edu**

All application materials will be reviewed on a rolling basis.

Interviews

The fellowship program will conduct virtual interviews on a rolling basis starting early November and will conclude interviews at the end of November. Candidates will be notified if selected for an interview.

Fellowship benefits:

- Competitive stipend
- Reimbursement for relocation during fellowship and professional travel expenses
- Enrollment in Indiana Pharmacy Teaching Certificate (IPTeC) Program
- Vacation and University Holidays
- Optional Butler University benefits package (health, Rx, vision, and dental)

REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION

FAQ

Do I need previous industry experience in order to be considered for the fellowship program?

- No, previous industry experience is not required.

Do I have to be a registered pharmacist to qualify for this fellowship?

- No, but licensure is strongly encouraged. To qualify for this fellowship, you must be a graduate of an ACPE-accredited PharmD program at the commencement of the fellowship.

Can I apply for more than one fellowship at Butler University?

- Yes, we welcome applicants to apply to explore all of the opportunities available at Butler University.

What is the timeline for the fellowship selection process?

- The Butler University application portal will open up on Wednesday, October 5, 2022. Applicants must upload their letter of intent, CV, official transcripts, and two letters of recommendation. Letters of recommendation must be emailed to **rxfellowships@butler.edu**.
- The application materials listed above must be received by Friday, November 4, 2022; however, applications will be accepted and reviewed prior to the due date. Due to the competitive nature of the selection process, applicants are encouraged to submit their application materials as soon as possible.

To whom do I make out the letter of recommendation?

- Please address all letters of recommendation to the fellowship program director:

  John B. Hertig, PharmD, MS, CPPS, FASHP
  Chair and Associate Professor
  Department of Pharmacy Practice
  Butler University College of Pharmacy and Health Sciences
  Indianapolis, IN, USA

For any other questions, please contact rxfellowships@butler.edu

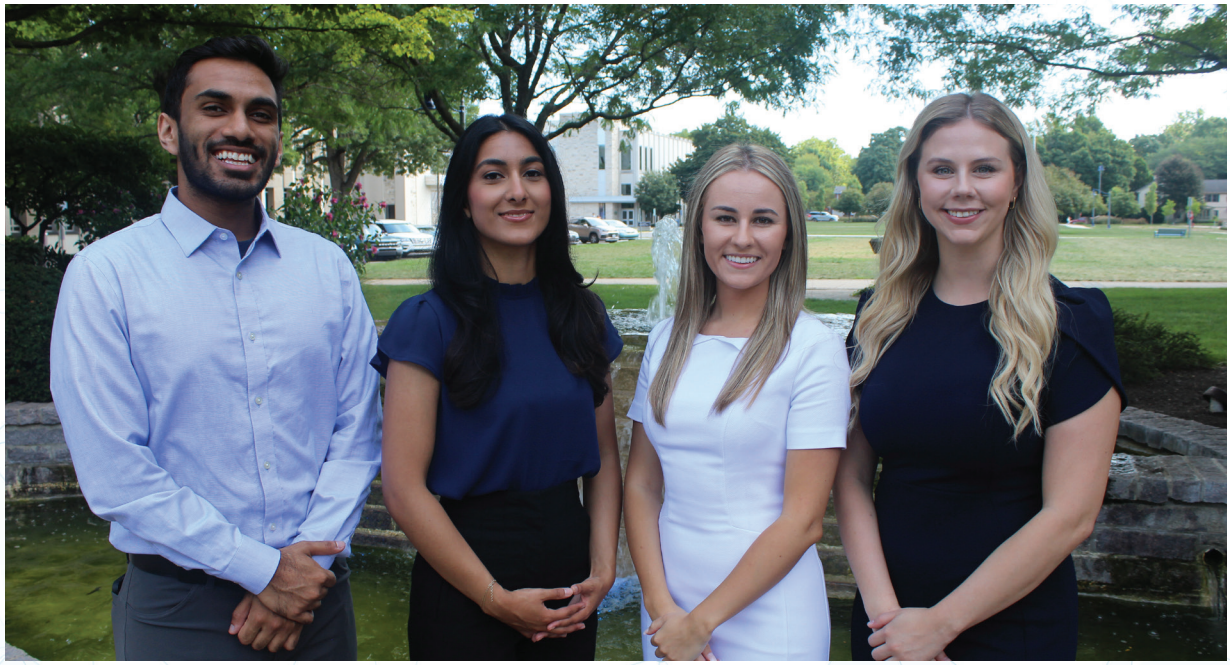
REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION

Fellowship Alumni

Irene Lin, PharmD
2020–2022
Senior Safety Data Scientist at Abbvie
University of Minnesota College of Pharmacy

Morgan Nicolas, PharmD
2020–2022
Manager, Trial Capabilities at Eli Lilly
The Ohio State University



Thank you for considering the Butler University Pharmaceutical Fellowship Program

Click here to apply today!

REGENERON | BUTLER UNIVERSITY

Lilly | FDA U.S. FOOD & DRUG ADMINISTRATION