Butler University

PHARMACEUTICAL FELLOWSHIP PROGRAM













Table of Contents

- A message from John B. Hertig, PharmD, MS, CPPS, FASHP, FFIP Chair and Associate Professor
- About Butler University
- About the FDA
- About Eli Lilly & Regeneron
- About Recordati Rare Diseases, Inc.
- Two Year Programs
 - > Global Patient Safety and Pharmacovigilance
 - > Medication Error, Pharmacovigilance, and Risk Management
- One Year Program
 - > Medical Information and Medical Affairs

How To Apply

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













A message from John B. Hertig

Dear Prospective 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, FFIP

Chair and Associate Professor Department of Pharmacy Practice Butler University College of Pharmacy and Health Sciences Indianapolis, IN, USA













Located in Indianapolis,
Indiana, Butler University is a
nationally recognized university
with six academic colleges. In
2023, 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.



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.











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 12 FDA-approved or authorized 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.

About Recordati Rare Diseases, Inc.



Recordati Rare Diseases, Inc. (RRD) is a biopharmaceutical company committed to providing often overlooked orphan therapies to the underserved rare disease communities of North America. RRD is a part of the rare disease business within the Recordati Group, a public international pharmaceutical company committed to the research and development of new specialties with a focus on treatments for rare

diseases. RRD focuses on inborn errors of metabolism, rare endocrine disorders, and rare oncologic/hematologic conditions.











Two Year Programs

Global Patient Safety and Pharmacovigilance





Actively Recruiting: One Fellow for 2024–2026

Program Timeline

Academia 4 Months Eli Lilly 1 Year FDA 8 Months

Year 2

CADEMIA

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



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.



inter-center projects in pre- and postmarket 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.

The fellow will participate in intra- and

Silver Spring, MD



Eli Lilly Second 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



Eli Lilly First Year Fellow:

"This fellowship program with Butler University lays the foundation for an exceptional career in pharmacovigilance and patient safety. It has not only allowed me to explore various patient safety roles within the pharmaceutical industry, but has also given me the

unique opportunity to educate future pharmacists about how they can be patient safety advocates. I am confident that through this program I will develop the skills needed to have an impactful career in this realm."

-Hanna Owens, PharmD











Medication Error Pharmacovigilance and Risk Management





Actively Recruiting: One Fellow for 2024-2026

Program Timeline

Academia 4 Months

Regeneron 1 Year

FDA 8 Months

Year 1 Year 2

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

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



The fellow will participate in intra- and market arenas. The fellow will focus packaging, nomenclature, labels and labeling. The fellow will utilize adverse related issues.

Silver Spring, MD



Regeneron Second 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 First Year Fellow:

The fellowship program at Butler has afforded me the opportunity to gain a holistic understanding of pharmacovigilance and risk management across a wide variety of practice settings. The mentors I have encountered through this program have been

deeply invested in equipping me with the skills and knowledge needed to be an effective advocate for patient safety. I am excited to grow further both personally and professionally within this role, and am confident in the support I will receive as I embark on my future career.

-Rachel Matthews, PharmD











One Year Program

Medical Information and Medical Affairs

Inaugural Fellowship starting July 2024

Actively Recruiting: One Fellow for 2024-2025



Program Timeline

Butler University Longitudinal Experience

Recordati Rare Diseases, Inc. 12 Months

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 DURATION: longitudinal throughout the year

*Travel and housing expenses will be covered by fellow's travel budget during required time in Indianapolis.

The fellow will serve as an integral part of the Medical **Information and Medical Affairs** team, collaborating crossfunctionally to create product and disease-specific assets aligned with the current medical strategy. This experience will equip them with the essential skills and knowledge required to advance healthcare through data-driven approaches and cross-functional collaboration.

LOCATION: Bridgewater, NJ DURATION: 12 months

PROGRAM HIGHLIGHTS:

- · Enhance medical writing skills by response documents
- Develop expertise in literature retrieval and analysis
- Ensure medical accuracy of promotional materials
- Engage at scientific congresses to provide support for the Medical Affairs booth
- Contribute to comprehensive initiatives within the entire Medical Affairs organization

REGENERON









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 4**, **2023**. Applicants must upload the following application materials to the online portal no later than **November 3**, **2023**:

- Letter of Intent
- Curriculum Vitae
- Official college transcripts. Unofficial college transcripts can be used as a placeholder.
- $\bullet \ \ Two \ letters \ of \ recommendation \ emailed \ to \ {\bf rxfellowships@butler.edu}$

All application materials will be reviewed on a rolling basis.

Interviews

The fellowship program will conduct virtual interviews on a rolling basis 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)











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 4, 2023. 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 3, 2023; 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, FFIP 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











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



Karolina Cieslak, PharmD 2021–2023 Associate Director, Risk Management at Eli Lilly University of Illinois Chicago College of Pharmacy



Vraj Patel, PharmD 2021–2023 Medication Safety Evaluator at the FDA UNC Eshelman College of Pharmacy

Thank you for considering the Butler University
Pharmaceutical Fellowship Program

Click here to apply today!









