Global Medical Safety
Post-Doctoral Global Medical Safety (GMS) Fellowship

2018-2020
A Message from the Head of Global Medical Organization

“At Janssen Pharmaceutical Companies of Johnson & Johnson, our employees are driven by a desire to do work that matters, and we are deeply dedicated to patients and all those who use our products.

Ensuring the ongoing safety of our products is a demonstration of how we live the values outlined in our organization’s Credo. Patients are waiting, and we are passionate about the science and medicine that enable us to truly understand the safety of our products and to serve patients!

Through the Global Medical Safety Post-Doctoral Fellowship Program, I hope that we can nurture and train the next generation of pharmacovigilance leaders who will serve and make a significant impact to patients.”

Samarth Parikh, PharmD,
Senior Scientist, Pharmacovigilance Evaluation and Reporting Fellowship Program Director
Global Medical Safety

A Message from the Director of the Fellowship Program

“The Global Medical Safety Post-Doctoral fellowship program provides a unique opportunity for PharmD graduates to enter the pharmaceutical industry directly after graduating from pharmacy school and to explore the growing field of pharmacovigilance. During this two-year program, fellows obtain hands-on training as well as continuous guidance and mentorship to provide an exceptional learning experience. This program aids greatly in helping the fellows achieve their professional goals and objectives. As a former fellow, I feel very fortunate to have had an opportunity to be a part of this program. I find it very rewarding to be able to contribute to the development of future PharmD professionals, help them achieve their goals, and set a strong foundation for their future career development within the pharmaceutical industry.”

Aran Maree, M.D.,
Chief Medical Officer
Janssen Pharmaceutical Companies of Johnson & Johnson
About Us

About Janssen Pharmaceutical Companies of Johnson & Johnson
Today, Johnson & Johnson has more than 265 operating companies in more than 60 countries with approximately 125,000 employees worldwide. With a relentless drive for innovation, Janssen Pharmaceutical Companies has become a leader in the pharmaceutical market. The company’s comprehensive and world-renowned line of products reaches over a billion people every day throughout the world.

Global Medical Safety
Global Medical Safety is dedicated to protecting patients. The division serves as a strategic asset by championing excellence in safety science and risk management and delivering scientific value throughout a product’s lifecycle.

As part of Janssen Research & Development, we are a global organization and are represented by working facilities in Horsham, Pennsylvania, USA; Spring House, Pennsylvania, USA; Titusville, New Jersey, USA; Raritan, New Jersey, USA; Toronto, Canada; Shanghai, China; Beerse, Belgium; High Wycombe, United Kingdom; and other safety offices throughout the world.

Global Medical Safety Responsibilities
- Monitor and assess the safety profile of marketed drugs and drugs in development by collecting safety data and evaluating safety signals
- Submit single case reports for adverse events and aggregate reports to the appropriate regulatory agencies throughout the world
- Facilitate effective communication through appropriate labeling to health professionals globally on the use of Janssen Pharmaceutical Companies’ products
- Respond to inquiries from US and international regulatory authorities on issues regarding drug safety
- Analyze adverse events that have been reported to the company and write aggregate reports involving medical assessments of the safety of Janssen Pharmaceutical Companies’ products
- Work as part of a multidisciplinary team to ensure that the safety profiles of all marketed products are communicated clearly and accurately
Fellowship Overview

This is a 2-year fellowship position available in GMS either at the Horsham, Pennsylvania campus, approximately 20 miles from Philadelphia and 40 miles from Princeton, New Jersey or the Raritan, New Jersey campus.

For the 2018-20 Janssen GMS fellowship recruitment, 1 fellowship position is available in the Pharmacovigilance Evaluation and Reporting Group. The Fellow will provide support for drugs in a diverse range of therapeutic areas including immunology, oncology, cardiovascular, metabolism, infectious disease, and neuroscience.

Salary and Benefits
Fellow will be a full-time Janssen Pharmaceutical Companies employee for a term of two years. Fellows are offered a competitive stipend and are eligible to participate in Johnson & Johnson’s benefits program; choices which includes medical, dental, life, accidental coverage, 401K, and pension plan. Fellow may also be given talent development opportunities by attending selected professional meetings and conventions.
Pharmacovigilance Evaluation and Reporting Fellow – Responsibilities

Responsibilities

- Evaluate adverse events and other safety concerns for marketed drugs throughout a product’s lifecycle
- Review adverse drug events, epidemiological studies, single case reports, and literature
- Apply medical insight and drug knowledge for possible drug association
- Respond to requests of health authorities globally through preparation of:
  - Ad Hoc Reports and other documents addressing specific safety issues
  - Documents supporting labeling changes and updates
- Prepare aggregate regulatory reports, such as Periodic Benefit Risk Evaluation Reports and Addendum to Clinical Overviews
- Develop an understanding of the overall post-marketing drug safety process, including safety surveillance and signal detection
- Improve verbal communication skills through professional presentations and team meetings
- Interact with members in regulatory, clinical, and surveillance functional groups along with other pharmacists and fellows across the Janssen Pharmaceutical Companies’ network
The Global Medical Safety Fellowship offers a two-year comprehensive experience within pharmaceutical industry, providing valuable opportunities to learn and develop essential skillsets necessary to be successful in an industry setting. Pharmacovigilance is an integral component of pharmaceutical companies, and the experiences offered through the GMS fellowship provide vital knowledge that can be applied not only to future careers within drug safety, but also to careers in other areas of the pharmaceutical industry. Through this fellowship program, I have applied and developed my analytical skills, project management skills, oral and written communication skills through constant support and encouragement of my mentors. I will also have an opportunity to gain experience in other areas of industry through rotations in various divisions, expanding the knowledge base and experiences I will be able to apply to my future career in industry. Through the variety of projects and interdisciplinary work that is offered, this fellowship provides an excellent foundation on which pharmacy graduates can begin a successful career in the pharmaceutical industry.

Cori Parker, PharmD
University of Georgia College of Pharmacy
PharmD candidates must graduate from an ACPE-accredited Doctor of Pharmacy Program

- Exceptional written and oral communication skills
- Strong academic performance, leadership, and interpersonal skills
- Please send the following application materials by **December 8, 2017** (electronically preferred):
  - A letter of intent
  - Curriculum vitae
  - Two writing samples representative of your ability to communicate medical information succinctly and appropriately and one PowerPoint presentation slide deck that shows communication and medical interpretation skills
- The following must be received by **December 11, 2017**:
  - Unofficial academic transcript
  - Three letters of recommendation
- The following must be received by **December 22, 2017**:
  - Official academic transcript (certified paper copy)

Samarth Parikh, PharmD
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Frequently Asked Questions

Who should I contact to ask questions regarding the fellowship program?

- Questions about the fellowship program can be directed to our current fellow:
  Cori Parker
  (cparke33@its.jnj.com)

Can I still apply if I do not attend ASHP Midyear?

- Although interviewing at ASHP Midyear is preferred, the application process does not require attendance and participation at the ASHP Midyear Clinical Meeting.

What is the timeline for the fellowship selection process?

- Prior to the ASHP Midyear Clinical Meeting, candidates can contact Cori Parker (cparke33@its.jnj.com) and Samarth Parikh (sparikh8@its.jnj.com) to schedule an interview. All candidates are required to register with PPS to attend the interview. You can register for PPS at: www.careerpharm.com/basicppsinfo.aspx
- During the ASHP Midyear Clinical Meeting, interviews will take place at the Janssen booth.
- After the ASHP Midyear Clinical Meeting, candidates are encouraged to submit their full application as soon as possible. Selected applicants will be contacted for an interview.
- The selection process will be finalized by the end of December.

Does the program provide additional career development opportunities?

- In addition to your core area of Pharmacovigilance Evaluation and Reporting, you will have the opportunity to gain experiences in other groups within Global Medical Safety. There are also opportunities to interact with pharmacists, fellows, and other Janssen Pharmaceutical Companies’ colleagues in various functional areas such as regulatory affairs, medical affairs, and clinical development.

What are my options after completion of the fellowship?

- This fellowship program offers many opportunities. Drug safety is a burgeoning area within the pharmaceutical industry and the work is tremendously rewarding. The program provides you with the opportunity to use your scientific and clinical knowledge to ensure that product risks are identified and communicated. In addition to that, you will gain an understanding of the overall post-marketing safety process by having hands-on experience in data and clinical analysis across multiple therapeutic areas. Whether your career goal is to become a pharmacovigilance scientist or to work in other areas such as regulatory or medical affairs, having drug safety training is an extremely valuable experience. Our program alumni have successfully obtained employment in a diverse spectrum of pharmaceutical industry positions as well as the FDA.