Empowering Our People to Shine

PharmD Fellowships

TAKEDA PHARMACEUTICALS & PURDUE UNIVERSITY

Purdue University

Empowering Our People to Shine
ABOUT TAKEDA
Founded in 1781 and headquartered in Osaka, Japan, Takeda is a global, R&D-driven bio-pharmaceutical company committed to bringing better health and a brighter future to patients by translating science into life-changing medicines. Takeda focuses its research efforts on gastroenterology, neuroscience and oncology, plus vaccines.

For more information see www.takeda.com or www.takedavaccines.com

MISSION
Takeda is committed to strive towards better health for people worldwide through leading innovation in medicine.

Takeda – Purdue Fellowship Programs
Takeda Pharmaceuticals and Purdue University are offering three fellowship programs that are two-years in duration:

- Global Regulatory Affairs Drugs & Biologics Fellowship
- Global Regulatory Affairs Vaccines Fellowship
- Early Clinical Trial Operations Fellowship

The majority of the fellow’s time will be spent at Takeda in Cambridge, MA. The fellow will be an employee of Purdue University in West Lafayette, IN.

The Takeda – Purdue Fellowships will provide Doctor of Pharmacy (PharmD) graduates with the opportunity to gain specialized, hands-on training and experience in Global Regulatory Affairs and Clinical Operations. The fellowship is designed to prepare and develop the PharmD graduate for a career in regulatory strategy and drug development. In addition to bolstering a scientific link between Takeda and Purdue University, the fellowship aims to enhance the regulatory strategy and clinical operations activities at Takeda, with a goal to eventually serve and improve the drug development process across the industry.

The fellowship candidate should be passionate about a career in the pharmaceutical industry, be motivated to learn and contribute in a collaborative environment, possess excellent oral and written communication skills and demonstrate strong leadership qualities and the ability to influence in a matrixed environment.
For over 125 years, Purdue has trained the world’s elite pharmacy leaders through acclaimed curricula, preeminent faculty and active industry partnerships.

As an Adjunct Clinical Assistant Professor at Purdue, the fellow may have the opportunity to:

- Develop, coordinate and provide lectures for didactic pharmacy courses
- Co-precept pharmacy students on advanced experiential rotations
- Participate in professional development seminars with other fellows and residents from Purdue and/or Takeda-affiliated programs
- Create and lead university outreach activities to promote the fellowship program
- Lead future Takeda – Purdue fellowship recruitment activities
- Obtain an Indiana Pharmacy Teaching Certificate (IPTeC)
- Lead research project(s) and present poster(s) at professional conferences
- Publish articles in scholarly journals

**Purdue University College of Pharmacy**

The opportunities provided by the Takeda – Purdue partnership allow us to further advance our mission of preparing the next generation of leaders in pharmacy and the pharmaceutical sciences. This program enables fellows to gain transformational experiences for career development. We at Purdue are grateful for Takeda’s commitment to a program that truly represent the highest level of excellence.

*Eric L. Barker, PhD*
Dean and Professor
Purdue University College of Pharmacy

The Purdue/Takeda Fellowship offers a unique opportunity for the fellow to gain insight and contribute significantly to the teaching, research and engagement arms of world class academic and industry enterprises.

*Alan J. Zillich, PharmD, FCCP*
William S. Bucke Professor and Head of the Department of Pharmacy Practice

As a top 10 pharmacy program, Purdue University College of Pharmacy has a strong reputation for training elite pharmacy leaders. The fellow will have the opportunity to contribute to the didactic instruction and experiential learning of student pharmacists, as well as interact with world-class pharmacy faculty and researchers.

*Amy Heck Sheehan, PharmD*
Associate Professor of Pharmacy Practice
Purdue University College of Pharmacy
Global Regulatory Affairs Drugs & Biologics Fellowship

Global Regulatory Affairs (GRA) Overview
At Takeda, the fellow will receive mentorship and individual guidance from the Global Regulatory Affairs Strategy team and will collaborate with cross-functional project teams, as well as Global Health Authorities. Additionally, the fellow will acquire a better understanding of the global drug development process through participation in various activities in the United States, the European Union, Japan and emerging markets.

Global Regulatory Affairs (GRA) at Takeda
- Serves as the primary liaison between Takeda and Global Health Authorities
- Provides regulatory intelligence necessary to generate and present information to meet the needs of key stakeholders including Global Health Authorities, patients, purchasers and prescribers
- Provides regulatory strategic input required to expedite drug development, filing and global regulatory approval of new drug or biologic products
- Collaborates with cross-functional teams to provide regulatory strategy to optimally design and implement successful drug development strategies
- Leads the development, submission and maintenance of Investigational New Drugs (INDs), New Drug Applications (NDAs), Clinical Trial Applications (CTAs) and Marketing Authorization Applications (MAAs)
- Ensures compliance with global regulations and supports the interpretation of global health authority requirements

GRA Drugs & Biologics Fellowship Details
ELIGIBILITY
The fellow will be selected on a nationally competitive basis. To be eligible, candidates must be graduates of an Accreditation Council for Pharmacy Education (ACPE) accredited Doctor of Pharmacy Program before the fellowship begins in July.

Participation in the American Society of Health-Systems Pharmacist (ASHP) Midyear Clinical Meeting Personnel Placement Services (PPS) is strongly encouraged, but not required. The candidate must be eligible to work in the United States, as Purdue and Takeda will not provide sponsorship to foreign students.

BENEFITS
The fellow will receive a competitive stipend and benefits package, including comprehensive health and dental insurance. The fellowship will sponsor attendance at one or more professional meetings, conferences or workshops.

CERTIFICATE OF COMPLETION
Purdue University and Takeda will award a professional certificate upon successful completion of the fellowship.

APPLICATION REQUIREMENTS:
- Curriculum Vitae
- Letter of Intent
- Official college of pharmacy transcript
- Three letters of recommendation

PLEASE SEND ALL CORRESPONDENCE TO:
Yijia Luo, PharmD, RPh, RAC
Takeda Pharmaceuticals International Co.
40 Landsdowne Street
Cambridge, MA 02139, USA
Email: GRAFellowship@takeda.com
Our Regulatory Affairs team provides creative regulatory strategies that enable Takeda to provide meaningful medicines to patients. We are committed to developing and maintaining the highest level of regulatory expertise. As a pharmacist with 20 years of experience in regulatory affairs, I know that pharmacists are well positioned to excel in this exciting and rewarding profession.

Tom Harris, RPh
Senior Vice President, Head of Global Regulatory Affairs

Regulatory Affairs touches every part of the Takeda organization throughout the development of new medicines. As a member of a Global Regulatory Team, the fellow will assist in creating a global regulatory strategy for a compound and participate in the compound’s development.

Jonathon Parker, RPh, MS, PhD
Vice President, Global Regulatory Affairs
Head, Global Regulatory Affairs Development – Neuroscience
Head, Global Regulatory Intelligence and Policy
Executive Sponsor, Takeda – Purdue GRA Fellowship

It was an honor to be the inaugural fellow of this program. I am grateful for the opportunity it provided to transition to a full-time role at Takeda and be part of the fellowship program again. In the ever-changing and complex field of regulatory strategy, this fellowship provides an ideal combination of focused training with dedicated mentorship and real-world experience to a candidate interested in pursuing a career in Global Regulatory Affairs.

Yijia Luo, PharmD, RPh, RAC
Manager, Global Regulatory Affairs Development – Neuroscience
Fellowship Coordinator, Takeda – Purdue Fellowships

As the inaugural fellow in Boston, I am grateful for the opportunity to join cross-functional teams and participate in global regulatory strategy and drug development. My dedicated mentors at Takeda and Purdue continuously support and guide me as I develop professionally as a fellow and future regulatory strategist. I believe this fellowship will serve as a strong foundation upon which I may build a successful and rewarding career in the pharmaceutical industry and academia.

Monica N. Pham, PharmD, RPh
2017-2019 Fellow, Global Regulatory Affairs Development – Neuroscience
Texas A&M College of Pharmacy

As a pharmacist, I am uniquely positioned to deliver a fresh outlook on drug development by understanding the interplay between regulatory policy and science. Through daily hands-on experience, constant communication with incredible mentors both at Takeda and Purdue, and program flexibility I am confident this fellowship will be a platform to a successful career in global regulatory strategy and drug development.

Justin G. Moots, PharmD
2018-2020 Fellow, Global Regulatory Affairs Development – Gastroenterology
Virginia Commonwealth University

CURRENT FELLOWS

PAST FELLOWS

2016-2018
Lance Kruger, PharmD, RPh
Manager, Global Regulatory Affairs – Labeling
Takeda Pharmaceuticals

2015-2017
Yijia Luo, PharmD, RPh, RAC
Manager, Global Regulatory Affairs Development – Neuroscience
Takeda Pharmaceuticals
Global Regulatory Affairs Vaccines Fellowship

Global Regulatory Affairs Vaccines Overview
At Takeda Vaccines, the fellow will receive mentorship and individual guidance from the Regulatory Affairs Vaccines (RAV) strategy team and will collaborate with cross-functional vaccine development project teams. Additionally, the fellow will acquire a better understanding of the global vaccine development process through participation in various activities in the United States, the European Union, Latin America and Asia Pacific Markets.

Global Regulatory Affairs Vaccines at Takeda
• Collaborates with RAV team to develop innovative regulatory strategies for challenging infectious diseases
• Provides regulatory guidance and strategy as a member of cross-functional development teams
• Leads the development, submission and maintenance of Investigational New Drug Applications (INDs), Biologics License Applications (BLAs) and Marketing Authorization Applications (MAAs)
• Ensures compliance with global regulations and supports the interpretation of worldwide health authority requirements
• Serves as the primary liaison between Takeda and Global Health Authorities

GRA Vaccines Fellowship Details

ELIGIBILITY
The fellow will be selected on a nationally competitive basis. To be eligible, candidates must be graduates of an Accreditation Council for Pharmacy Education (ACPE) accredited Doctor of Pharmacy Program before the fellowship begins in July.

Participation in the American Society of Health-Systems Pharmacist (ASHP) Midyear Clinical Meeting Personnel Placement Services (PPS) is strongly encouraged, but not required. The candidate must be eligible to work in the United States, as Purdue and Takeda will not provide sponsorship to foreign students.

BENEFITS
The fellow will receive a competitive stipend and benefits package, including comprehensive health and dental insurance. Attendance at one or more professional meetings, conferences or workshops will be sponsored by the fellowship.

CERTIFICATE OF COMPLETION
Purdue University and Takeda will award a professional certificate upon successful completion of the fellowship.

APPLICATION REQUIREMENTS:
• Curriculum Vitae
• Letter of Intent
• Official college of pharmacy transcript
• Three letters of recommendation

PLEASE SEND ALL CORRESPONDENCE TO:
Matthew Curtis
Takeda Pharmaceuticals International Co.
40 Landsdowne Street
Cambridge, MA 02139, USA
Email: VBURAFellowship@takeda.com

Takeda Sponsors

The fight against global infectious disease requires significant collaboration. Takeda is forging partnerships and collaborating across R&D, clinical science, operations and commercial functions to achieve its mission of making important vaccines available to those who need them, and Regulatory Affairs’ contribution is pivotal in this endeavor.

John Boslego, MD
Senior Vice President and Head of Global Vaccines Development

We are excited to be part of the Purdue Fellowship program. Vaccine Regulatory Affairs works very closely with all our business partners to contribute to our mission: to develop and deliver innovative vaccines that tackle the toughest problems in public health and improve the lives of people around the world.

Sue Fekete, MS
Senior Director, Regulatory Affairs Vaccines
Fellowship Director, Takeda – Purdue GRA Vaccines Fellowship
Early Clinical Trial Operations Fellowship

Early Clinical Trial Operations (ECO) Overview
The ECO function at Takeda is responsible for operational strategy, planning and oversight of early development clinical programs. The fellow will receive mentorship and individual guidance from the ECO team and collaborate on cross-functional teams.

Early Clinical Trial Operations (ECO) at Takeda
- Provides operational expertise and strategic input to the development of Clinical Development Plans supporting the overall clinical strategy through to Proof Of Concept
- Develops operational strategy on programs in close collaboration with strategic partners and serves as the liaison between partners and Takeda
- Leads clinical program budget planning and accountable for external spend related to clinical program execution
- Ensures that budgets, enrollment and gaiting are accurate by working closely with strategic partners and internal departments
- Provides sponsor’s oversight of strategic partners, program level direction and support to ensure the effective execution of clinical studies
- Reviews and provides expert clinical operations input into clinical documents related to the drug development process, such as Investigator’s Brochures, INDs, IMPDs, study synopsis and protocols, clinical study reports, NDAs, MAAs and other safety documents

ECO Fellowship Details

ELIGIBILITY
The fellow will be selected on a nationally competitive basis. To be eligible, candidates must be graduates of an Accreditation Council for Pharmacy Education (ACPE) accredited Doctor of Pharmacy Program before the fellowship begins in July.

PARTICIPATION
- Provides operational expertise and strategic input to the development of Clinical Development Plans supporting the overall clinical strategy through to Proof Of Concept
- Develops operational strategy on programs in close collaboration with strategic partners and serves as the liaison between partners and Takeda
- Leads clinical program budget planning and accountable for external spend related to clinical program execution
- Ensures that budgets, enrollment and gaiting are accurate by working closely with strategic partners and internal departments
- Provides sponsor’s oversight of strategic partners, program level direction and support to ensure the effective execution of clinical studies
- Reviews and provides expert clinical operations input into clinical documents related to the drug development process, such as Investigator’s Brochures, INDs, IMPDs, study synopsis and protocols, clinical study reports, NDAs, MAAs and other safety documents

APPLICATION REQUIREMENTS:
- Curriculum Vitae
- Letter of Intent
- Official college of pharmacy transcript
- Three letters of recommendation

PLEASE SEND ALL CORRESPONDENCE TO:
Rhett Behrje, MS
Takeda Pharmaceuticals International Co.
40 Landsdowne Street
Cambridge, MA 02139, USA
Email: ecofellowship@takeda.com

TAKEDA SPONSORS

Our Early Clinical Operations team translates our cutting edge science into innovative clinical trials. As a member of ECO, the fellow will assist in the planning and oversight of multiple early phase clinical trials (Phase 1-2a) in various indications and will contribute to advance therapies closer to patients.

David Rogovitz, PharmD, MSc.
Senior Director, Early Clinical Operations
Fellowship Director, Takeda – Purdue ECO Fellowship

Within the Translational Research and Early Clinical operations group, a fellow will participate in the translation strategy of drug candidates in gastroenterology, neuroscience and rare disease indications as these assets transition from the “bench” and preclinical models into the clinic via first in human health volunteers and patient proof of concept clinical trials. As an early program clinical operational lead, a fellow will contribute in program team meetings and help the early Clinical Operational Program Lead to manage the clinical strategy and execution, while working closely with a mentor and other team members.

Rhett Behrje, MS
Associate Director, Early Clinical Operations
Fellowship Coordinator, Takeda – Purdue ECO Fellowship