

# Global Regulatory Affairs Fellowship





# Changing medicine, changing lives



We are a global specialty pharmaceutical company with a 70-year history of breakthrough life science innovation. We are proud of our Japanese heritage and long-term perspective that informs how we do business.

Our team is working to engineer the next generation of antibodies and cell and gene therapies, aiming to deliver life-changing value to patients, especially those with high unmet medical needs and those with rare diseases. A shared commitment to our values, to sustainable growth, and to making people smile unites our efforts across four regions worldwide.

# Values that drive achievement









**Commitment to Life** 

**Innovation** 

**Integrity** 

Teamwork/Wa\*

# Global Regulatory Affairs Strategy Fellowship Program Description:

Recruiting: 1 fellow / Location: Princeton, NJ / Duration: 2 years

Kyowa Kirin, in partnership with Philadelphia College of Pharmacy at Saint Joseph's University, is excited to continue to offer a two-year Global Regulatory Affairs Fellowship to obtain industry training with the primary focus on Regulatory Strategy. The academic component of the fellowship provides opportunities to apply new skills and enhance professional growth in pursuit of a career in the pharmaceutical industry.

# **Company Responsibilities:**

- Support development of global and regional regulatory strategies, as well as identify risks and their mitigation for assigned investigational and marketed products at all lifecycle stages while ensuring commercial objectives are met
- Participate in authoring of and/or review of regulatory documents which may include INDs / CTAs, NDAs / BLAs, NDSs, MAAs, etc. for submission to U.S., Canada, and/or other Rest of World regulatory agencies
- Support regulatory lead and project team activities for formal meetings with regulatory health authorities
- Gain knowledge of country specific regulatory processes, regulations, and requirements
- Demonstrate excellent interpersonal skills and the ability to manage and/or lead multiple tasks
- Engage and collaborate cross-functionally with a variety of departments within the company

### **Application Requirements:**

Candidates should submit an application through <u>SJU Workday</u> with the following:

- Curriculum vitae
- Writing sample
- Letter of intent
- List of references
- Unofficial college transcript(s)

# **Eligibility:**

- Fellowship candidates must be U.S. citizens or permanent residents
- Applicants must have a PharmD from an ACPE-accredited school prior to the start of the fellowship

Additional application requirements will be shared via Saint Joseph's University website during the recruitment season.

# Additional Activities at Saint Joseph's University:

- Complete a 12-month teaching certificate program, engage in small group teaching, and develop an ACPE-accredited CE presentation
- Participate in professional development workshops, student organizations, project leadership, and mentoring activities
- Attend meetings and conferences to enhance knowledge, support fellowship recruitment, and engage in professional networking
- Collaborate with faculty on an IRB-approved research project (optional)
- Enroll tuition-free in the online MBA in Pharmaceutical and Healthcare Business (optional)

"Throughout my time as a fellow here at Kyowa Kirin, I have been given extensive opportunities to develop my regulatory thinking. The team here really values your input and is committed to guiding you through your professional journey. What I love most about being a fellow at Kyowa Kirin is that our company philosophy of making patients smile is reflected in the heart of the work we do every day."



Rebecca Liu, PharmD,
2023–2025 Global Regulatory Affairs Fellow
Rutgers University
Ernest Mario School of Pharmacy'23







"I've found Kyowa Kirin to be a diverse, innovative, and inspiring company with a collaborative work environment of highly skilled professionals. Since the start of the program, I was given a variety of opportunities to learn from the regulatory team as well as showcase my knowledge gained through my education and experience. Our teamwork motto, 'One for all, all for one,' is greatly seen through interactions with welcoming, flexible, and supportive colleagues. Kyowa Kirin is an organization that enables individuals to pursue their career ambitions through involvement in various activities."

Daria Polyarskaya, PharmD, MHA, RPh Manager, Regulatory Affairs 2021–2023 Global Regulatory Affairs Fellow Rosalind Franklin University of Medicine and Science College of Pharmacy '21

# **Collaborating to** innovate

Within our walls and across our industry, collaboration is the way Kyowa Kirin does business. Our history of innovation is built on forming and fostering high-potential collaborations to accelerate delivery of new science and heighten our impact.

# Here's how we are partnering, today and in the future:

- Scientific collaborations
- Business development and licensing

- Advocacy and public affairs
- Access, reimbursement, patient support services – Kyowa Kirin Cares

# Join us in our mission

We're committed to working together to understand clinical needs and opportunities for innovation that result in real advances for patients. See what it's like to work <u>here</u>.

#### **KYOWA KIRIN - NORTH AMERICA LOCATIONS**

### Canada

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## **Research & Discovery**

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