



Novel medicines.
Innovative technologies.
Rewarding work.
Profound impact.

Global Regulatory Affairs Fellowship

SJU SAINT JOSEPH'S
UNIVERSITY
Philadelphia College of Pharmacy

KYOWA KIRIN

Changing medicine, *changing lives*



Kyowa Kirin is a specialty pharmaceutical company focused on creating innovative medicines with the latest biotechnology. For more than 30 years, we have pursued scientific discoveries that address unmet clinical needs. We work in an unbroken chain—from research and discovery, through development and commercialization—in order to surmount the challenges of innovating in new frontiers.

Our commitment to advancing breakthroughs has produced a portfolio of specialty medicines with novel mechanisms of action. Since 2018, the company has received approval from the U.S. Food and Drug Administration (FDA) for three first-in-class treatments. These medicines add to Kyowa Kirin's rich history of innovation, delivering treatments for Oncology, Immunology/Allergy, Nephrology and Neurology.

Grounded by our expertise in antibody engineering, we continue to investigate new molecules with the potential to change medicine and lives.

Values that drive *achievement*



Commitment to Life



Innovation



Integrity



Teamwork/Wa*

*Wa = The Japanese principle of seeking the harmony of the team over personal interests.

Global Regulatory Affairs Strategy *Fellowship Program Description:*

Not 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 post marketing 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, NDS, MAAs, orphan, etc. for submission to US, 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

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)

Application Requirements:

Candidates should submit an application through jobs.sju.edu with the following:

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

Eligibility:

- Fellowship candidates must be a U.S. citizen or permanent resident
- 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



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.

KYOWA KIRIN-NORTH AMERICA LOCATIONS

Commercial

135 Route 202/206, Suite 6
Bedminster, NJ 07921
Phone: 908-234-1096

Clinical Development

212 Carnegie Center Drive,
Suite 400
Princeton, NJ 08540
Phone: 609-919-1100

Research & Discovery

9420 Athena Circle
La Jolla, CA 92037
Phone: 858-952-7000



Kyowa Kirin, Inc. - U.S.



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