

Passion for Innovation.
Compassion for Patients.™

Post-Doctoral Pharmaceutical Industry Fellowships

- Two-Year Global Clinical Safety - Oncology
- Two-Year Global Regulatory Affairs - Oncology



ST. JOHN'S
UNIVERSITY



Daiichi-Sankyo

Today, we innovate by creating new medicines, as well as new methods of drug discovery and delivery. We strive to constantly develop, deepen and broaden our pipeline to address unmet medical needs.



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Welcome

Thank you for your interest in the St. John’s University / Daiichi Sankyo Post-Doctoral Fellowship Program. Daiichi Sankyo and St. John’s University strive to increase the visibility of the pharmacy profession and its role in shaping the pharmaceutical industry.

During the course of this Fellowship, Fellows become involved in both pharmaceutical industry and academia by being immersed in an international company through projects and as members of multi-disciplinary teams. Fellows also complete educational and research activities at St. John’s University. Daiichi Sankyo is a(n):

- Innovative company that has a plethora of novel products in its pipeline
- International industry leader
- Dedicated entity in promoting health and well-being across multiple disease states

We wish you the best of luck, welcome your interest, and urge you to consider applying to these Fellowship Programs.

Daiichi Sankyo, Inc. is the U.S. subsidiary of Daiichi Sankyo Co., Ltd., a global pharmaceutical company.

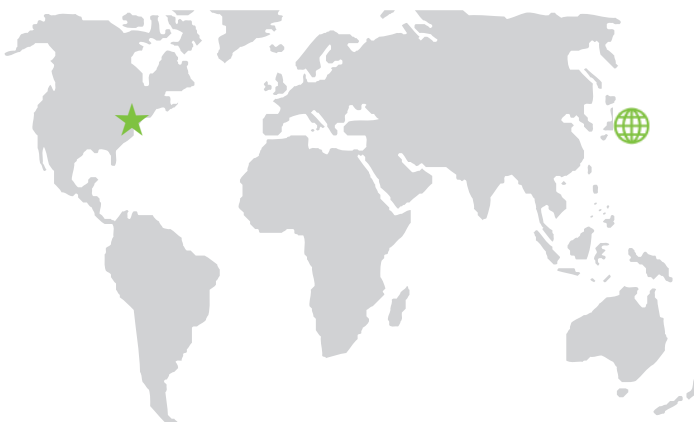
The company was formed in 2006 from the integration of two leading pharmaceutical companies, Sankyo Pharma, Inc. and Daiichi Pharmaceutical Corporation. Our team of nearly 1,400 U.S. employees is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients. The company has a 100-year history of innovation and discovery, and is focused on the development of cardiovascular and oncology therapies. Currently, Daiichi Sankyo, Inc. concentrates in the therapy areas of oncology, cardiovascular/metabolics, and internal medicine.

Our Company's values are the guiding principles that direct our decision-making. They speak to what is important to us as an organization and as individuals, along with what our patients, customers, and employees can expect from us.

A Rich Legacy



As the U.S. subsidiary of a global pharmaceutical innovator, Daiichi Sankyo, Inc. draws on a rich heritage of innovation, integrity and accountability. Our foundation and success has been built on therapies primarily focused in cardiology, including hypertension, thrombotic disorders, stroke risk reduction, dyslipidemia, diabetes and acute coronary syndrome.



HEADQUARTERS

★ **U.S.** Daiichi Sankyo, Inc.
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Basking Ridge, NJ 07920
Phone: +1 908 992 6400

🌐 **Global** Daiichi Sankyo Co., Ltd.
3-5-1, Nihonbashi Honcho,
Chuo-ku, Tokyo, 103-8426 Japan

REVENUE FY17

🌐 **Global**

\$8,661
million

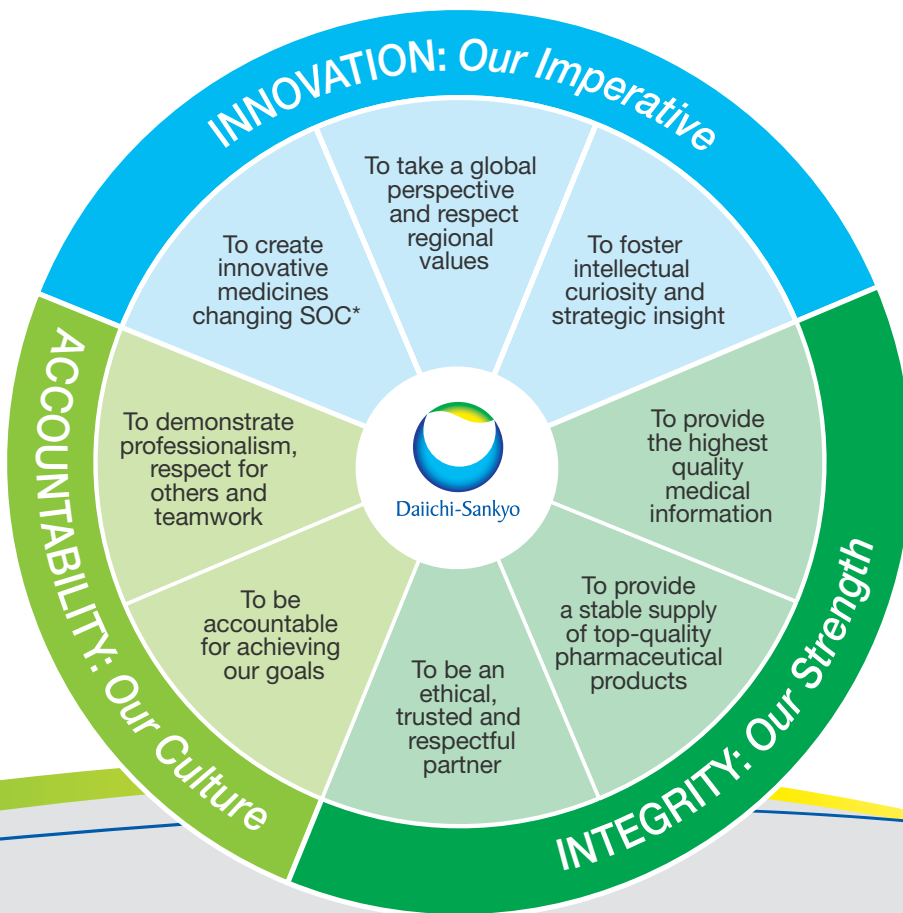
★ **U.S.**

\$1.625
billion

Values & Commitments



Daiichi-Sankyo



**SOC (Standard of Care): Universally applied best treatment practice in today's medical science*

Looking Ahead

Daiichi Sankyo has begun to transition from a maturing primary care product portfolio to a differentiated specialty portfolio that will include areas such as cardiovascular, pain management, IV iron therapy and oncology. We have already established a foothold in these areas through our partnerships marketing medicines for opioid-induced constipation and metastatic melanoma.

Our growing pain franchise seeks to offer patients a variety of treatment options that we hope will alleviate short- or long-term pain as well as provide relief from opioid-related side effects.

Our pipeline is rich with potential medications for oncology including treatments for cancers such as acute myeloid leukemia (AML), solid tumors and tenosynovial giant cell tumor (TGCT).



Daiichi Sankyo Cancer Enterprise

The mission of Daiichi Sankyo Cancer Enterprise is to leverage our world-class, innovative science and push beyond traditional thinking in order to create meaningful treatments for patients with cancer. We are dedicated to transforming science into value for patients, and this sense of obligation informs everything we do.



Care. Compassion. Science. It's Our Obligation.

World Class Science Organization

The Daiichi Sankyo Cancer Enterprise is committed to becoming a leading world-class science organization. Our team's exceptional scientific attitude results in outstanding medicinal chemistry, antibody engineering and discovery biology.

Dynamic and Sustainable R&D Organization

Our portfolio is powered by our research engines including two laboratories for biologic/immuno-oncology and small molecules in Japan, and Plexxikon Inc., our small molecule structure-guided R&D center in Berkeley, CA.

7 New Molecular Entities by 2025

Anchored by three pillars including our investigational Antibody Drug Conjugate Franchise, Acute Myeloid Leukemia Franchise and Breakthrough Science Franchise, we aim to deliver seven distinct new molecular entities over eight years during 2018 to 2025.

Enhanced Capabilities Through Collaboration

To complement and expand our premier cadre of internal scientists, we are collaborating with leading academic and business partners to leverage cutting-edge science in new treatment modalities, disease biology, diagnostics and pipeline prioritization.





About the Fellowships

The St. John's University / Daiichi Sankyo Fellowship Program is unique in that Fellows can rotate through various departments, depending on their interests.

Moreover, the individualized attention given to Fellows fosters their ability to become influential leaders in pharmaceutical industry. The St. John's University / Daiichi Sankyo Fellowship Program was created in 2011 to help accelerate the learning and stimulate the professional development of Fellows in the pharmaceutical industry. Fellows collaborate with and are integral members of multi-disciplinary teams.

The Program provides a broad understanding of the global drug development process and assists each Fellow's understanding of the key roles that Regulatory Affairs and Clinical Safety have in the drug development process, including the opportunity to gain "hands-on" experience concerning the requirements to identify, develop and market new medications. Additionally, the Fellow will enhance his/her knowledge through educational and research activities at St. John's University, College of Pharmacy and Health Sciences.

Fellowship Program History

Daiichi Sankyo is dedicated to providing its Fellows the most rewarding professional experience possible.

Every year the Fellowship Preceptors gauge where the company will have the most exciting and challenging work projects. Depending on Daiichi Sankyo, Inc.'s business needs for the year, the Fellowship Program is altered accordingly. Past Fellows have focused in Regulatory Affairs, Clinical Development, and Clinical Safety, and this year we are proud to offer Fellowship positions in Regulatory Affairs and Clinical Safety, focusing on the field of oncology. This type of flexibility within the St. John's University / Daiichi Sankyo Fellowship Program creates an opportunity for diversity and provides a unique and rewarding experience to each Fellow every year.

Global Regulatory Affairs - Oncology

Fellowship Program Structure

This Fellowship is designed to focus in the area of Global Regulatory Affairs - Oncology. Below is a summary of activities and outcomes by program year.

YEAR ONE

- Spend at least one full year within the Regulatory Affairs (RA) department
- Develop an understanding of the drug development process and regulatory requirements to file and maintain Investigational New Drug Applications (IND), New Drug Applications (NDA) for Oncology drugs and Biologics License Applications (BLA).
- Participate in the development of global regulatory strategies and health authority interactions
- Prepare regulatory interaction documents and submission packages
- Acquire a working knowledge of international and country-specific requirements to support the conduct of global clinical studies
- Acquire a working knowledge of the regulatory requirements to support global drug approvals
- Develop the necessary skill set to provide cross-functional project teams with rational and scientifically-driven regulatory strategic guidance across different phases of development
- Interact with other regulatory functions such as Regulatory-CMC (Chemistry, Manufacturing, and Controls), Regulatory Operations, and Labeling
- Attend national scientific conferences and FDA meetings
- Collaborate cross-functionally with global colleagues and scientists, representing diverse backgrounds, knowledge, and expertise

YEAR TWO

- Option to remain in RA or rotate (3-6 months) through various departments at Daiichi Sankyo, dependent on Fellow's level of interest and/or projects with a high priority level within the organization.

Rotations may include but are not limited to the following functional areas:

- Clinical Development
- Quantitative Clinical Pharmacology
- Clinical Safety and Pharmacovigilance
- FDA

Global Clinical Safety - Oncology

Fellowship Program Structure

This Fellowship is designed to focus in the area of Global Clinical Safety - Oncology. Below is a summary of activities and outcomes by program year.

YEAR ONE

- Spend at least one full year within the Clinical Safety (CS) department

Signal Identification & Evaluation

- Learn and apply signal identification and evaluation techniques
- Assist Clinical Safety physicians in assessing new signals and maintain a current signal tracking log
- Analyze safety data from multiple sources to deliver comprehensive conclusions.
- Gather competitive intelligence on safety information on other medications in class
- Collaborate with Epidemiology department within Clinical Safety to evaluate real-world data in support of benefit-risk assessment"
- Serve as a project manager for multidisciplinary Safety Management Team (SMT) discussions on emerging safety issues

Risk Management & Safety Communication

- Collaborate cross-functionally with global colleagues and scientists, representing diverse backgrounds, knowledge, and expertise

- Participate in developing Risk Management Plans (RMP) and Risk Evaluation and Mitigation Strategies (REMS)
- Identify gaps in safety surveillance plans/RMPs and escalate appropriately
- Participate in creating appropriate risk minimization activities for assigned products with CS physician
- Participate in creating strategies for communicating important safety information internally and externally with CS physician
- Support CS physician in developing key documents such as protocols, Investigator's Brochure, Core Data Sheet, and informed consent forms, as well as safety documents for regulatory submissions
- Demonstrate familiarity with the Guideline on Good Pharmacovigilance Practices and FDA Guidance related to clinical safety
- Prepare and present poster/abstracts/scientific papers as well as attend national scientific conferences, FDA meetings, and key opinion leader meetings

YEAR TWO

- Rotate (3-6 months) through various departments at Daiichi Sankyo, dependent on Fellow's level of interest and/or projects with a high priority level within the organization.

Rotations may include but not be limited to:

- Quantitative Clinical Pharmacology
- Clinical Development
- Pharmacoepidemiology
- Regulatory Affairs
- Project Management
- FDA

“The St. John’s / Daiichi Sankyo Fellowship...”



...is full of opportunities to gain real-world and leadership experience.

As a fellow, I have been involved in numerous important projects within the field of Oncology that have helped me develop my skills within the industry. Also, individual preceptors are dedicated in providing you with experiences that will further your personal and professional growth. Fellows will have an opportunity to interact with different cross-functional teams and explore other areas of interest during their second year. My experience at Daiichi Sankyo has been tremendously rewarding and I look forward to the remainder of this journey.”

Ben Kim, Pharm.D.

University of Michigan
First-Year Clinical Safety Fellow
2018–2020



...offers a broad range of experiences within a functional area which would not be available in most other companies.

Daiichi Sankyo is the quintessential mid-size pharmaceutical company which offers an assortment of unique benefits. Fellows have the range to rotate and/or assist with projects in every level within a functional area and have access to a large enough drug pipeline to learn from multiple therapeutic areas. Each fellow has their own individualized experience that is aligned with their interests and they have many opportunities to make their impression on industry leaders. The program also includes an academic component where the Fellow can gain teaching experience. I believe without a doubt in my mind that the experiences I gain as a Fellow will prepare me for successful career in industry.”

Mark Lee, Pharm.D., M.S.

University of Maryland
First-Year Quantitative Clinical Pharmacology Fellow
2018–2020



...fully integrates the Fellow into an established team of industry professionals.

Colleagues both within and outside of the function provide consistent opportunities to contribute meaningfully to key projects from both pre-marketing and post-marketing perspectives. A flexible program, Fellows are afforded the option of rotating into a different department during the 2nd year, providing a diverse and well-rounded experience. Additionally, the academic component with St. John's University allows for teaching experience and interaction with PharmD students. I am confident that this program will provide the professional and personal development necessary to succeed in the pharmaceutical industry long-term."

Hoang Pham, Pharm.D.

Northeastern University
Second Year Clinical Safety Fellow
2017–2019



...provides a solid foundation of hands on experience that enables the Fellows to learn at an accelerated pace.

All of your interactions with colleagues provides valuable insight on current trends in the industry and allows exposure into a broad array of expertise. Daiichi Sankyo provides a platform for the Fellows to be involved in a multitude of projects that prepares the individual to further their career in any discipline that they desire to obtain growth during their enrollment. This exposure coupled with the St. John's University resources provides a well-rounded program for the Fellow. This program is at the cutting edge of industry and is unparalleled in its variety of teachings and unlimited exposure to leaders within specific disciplines. I have no doubt that as a Fellow of this program I will be successful in all endeavors in the pharmaceutical industry."

Allison Allen, Pharm.D.

Temple University
Second-Year Regulatory Affairs Fellow
2017–2019

THE FELLOWSHIP TEAM





PAST FELLOWS



**Neil Dhopeswarkar,
Pharm.D.**

- Ph.D. Candidate in Pharmacoepidemiology
- University of Pennsylvania
- Fellow 2016–2018



**Derek E. Mires,
Pharm.D.**

- Associate Director, Global Oncology R&D
- Daiichi Sankyo, Inc.
- Fellow 2013–2015



**Michele Vigliotti,
Pharm.D.**

- Manager, Global Oncology R&D
- Daiichi Sankyo, Inc.
- Fellow 2016–2018



**Mike DeMarco,
Pharm.D., M.B.A.**

- Engagement Manager
- PwC
- Fellow 2012–2014



**Nicole Liaw,
Pharm.D.**

- Manager, Regulatory Affairs Strategy
- Daiichi Sankyo, Inc.
- Fellow 2015–2017



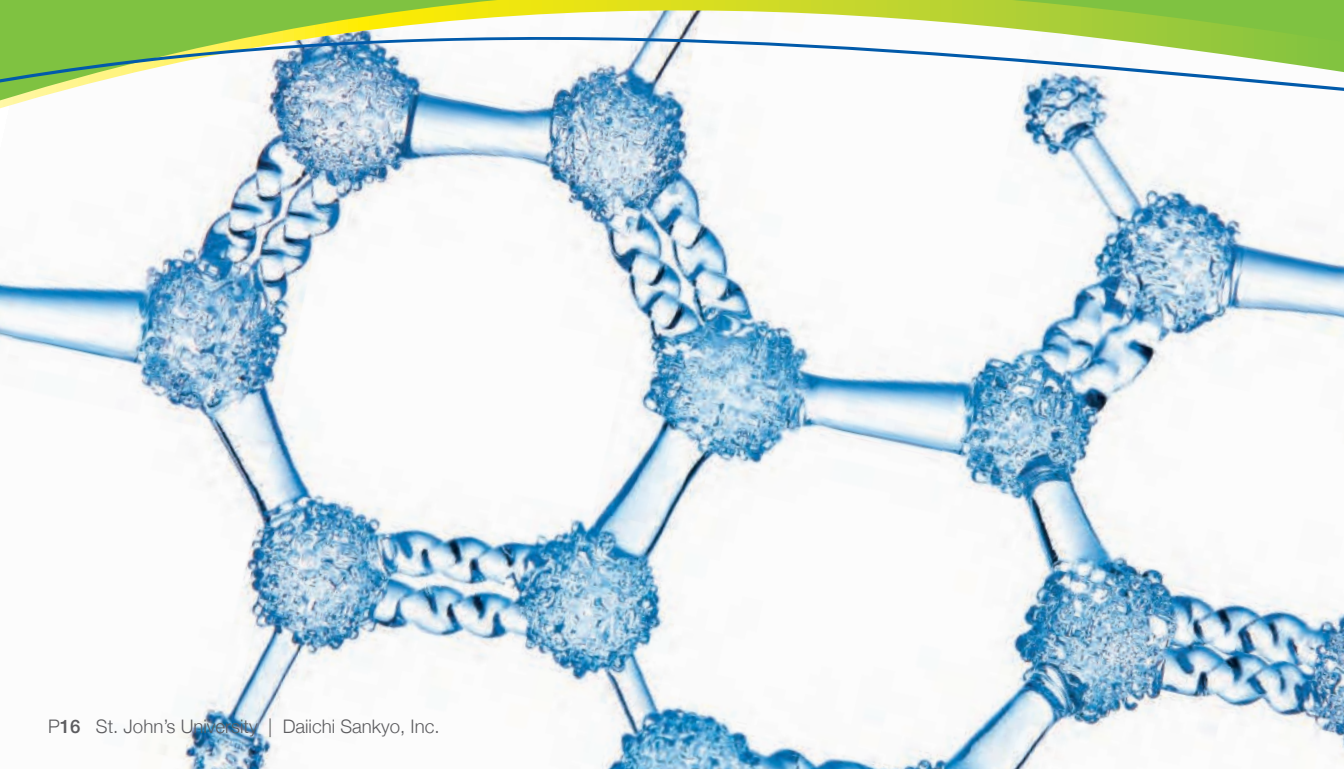
**Neda Aghajani Memar,
Pharm.D.**

- Associate Director, Regulatory Affairs
- Ovid Therapeutics
- Inaugural Fellow 2011–2013



**Elan Lutinger,
Pharm.D., M.B.A.**

- Senior Global Trial Manager
- Novartis
- Fellow 2014–2016



2019-2021 PRECEPTOR TESTIMONIALS



“The mission of Daiichi Sankyo’s Cancer Enterprise is to lead in science and transform evidence into value for cancer patients in need. This fellowship program will provide

invaluable hands-on experience in Regulatory Affairs in one of the most sought after therapeutic areas. Fellows will gain expertise in regulatory requirements and strategy pertinent to drug development. The fellow is a key member of the core matrix team and shares responsibility for developing and facilitating timely submission of documents to regulatory agencies around the globe. By the end of the fellowship in RA, the fellow should have an in-depth understanding of Global Regulatory Affairs and the drug development process from pre-clinical to post-marketing stages.”

Global Regulatory Affairs Preceptor: Sandra Smith, B.Sc. (Pharmacy), M.B.A.

Executive Director, Head AML Franchise/Small Molecules Regulatory Affairs

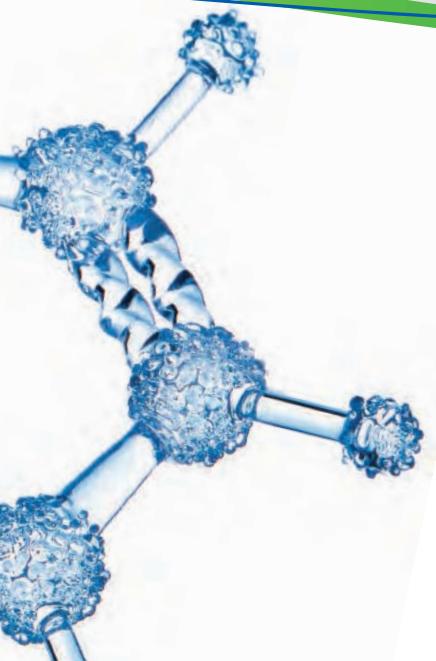


“Developing drugs that are safe and with optimal Benefit – Risk Balance is mission critical. Clinical Safety and Pharmacovigilance

is a discipline relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problems. Our program will provide the Fellow with an opportunity to learn methods of safety evaluation for drugs across therapeutic areas, and contribute to developing tools (e.g., RMPs and REMS) used to manage newly identified risks. Our Fellows participate actively in multi-disciplinary teams, gain a strong foundation of all aspects of drug development, and have opportunities to show-case their work.”

Global Clinical Safety Preceptor: Youngsook Choi, M.D.

Executive Director, Clinical Safety and Pharmacovigilance



St. John's University

COLLEGE OF PHARMACY AND HEALTH SCIENCES

St. John's University's primary campus is located on a residential 105-acre campus in Queens, New York and was founded in 1870 by the Congregation of Mission (Vincentian) Community. Recognized for its outstanding academic programs, rich student life, vibrant diversity and Big East vitality, the university boasts a population of over 20,000 students and 140,000 alumni across a number of campuses both in the United States and internationally.

The nationally recognized College of Pharmacy and Health Sciences prepares students for rewarding careers as practitioners, researchers and leaders in health care institutions, government and industry. Founded in 1929, the College offers numerous healthcare-related programs at the undergraduate and graduate levels including the Doctor of Pharmacy degree, Master of Science degrees in Pharmacy Administration and Public Health, and the Doctor of Philosophy in Pharmaceutical Sciences degree.

St. John's College of Pharmacy and Health Sciences is committed to shaping compassionate health care professionals to serve humanity through excellence in health care and biomedical research. Faculty, students and alumni of the College are actively involved in basic science as well as clinical research, and provide effective pharmaceutical care to a diverse patient population. The College continually works in partnership with numerous healthcare organizations throughout the New York metropolitan area to ensure the promotion, practice and delivery of the highest-quality health care services and research. Building on a dedication to greatness, its metropolitan location and its strategic alliances with leading healthcare institutions, the empowers effective leaders, good citizens and moral and ethical individuals. With its enhanced commitment to global education St. John's University also provides students with the opportunity to gain experience from an ever increasing global perspective.

Benefits of the Fellowship

Fellows are full time employees of St. John's University. In addition to being an excellent training and learning opportunity, the Fellowship provides a competitive stipend and benefits package, including individual comprehensive health insurance through St. John's University.

Upon successful completion of the Fellowship Program, a certificate of completion will be awarded by St. John's University College of Pharmacy and Health Sciences and Daiichi Sankyo, Inc.

St. John's University Component

Each Fellow will have opportunities at the University to participate in activities to promote professional development including:

- Formal and informal educational opportunities
- Completion of a formal teaching excellence program
- Active participation in the College's Fellows/residents seminar series
- Tuition remittance for graduate degrees
- Collaborative research projects with St. John's faculty
- Enrollment in Graduate degree programs available at the University to further his or her educational development (Master's or PhD degrees)
- On-campus teaching opportunities within the Doctor of Pharmacy Program
- Completion of an individual research project
- Precepting Pharm.D. students



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Application Process

& Eligibility Requirements

To be eligible, candidates must be graduates of an Accreditation Council for Pharmacy Education (ACPE) accredited Doctor of Pharmacy Program before July 1 of the Fellowship term and have a strong interest in a career in the pharmaceutical industry. Participation in the American Society of Health-Systems Pharmacist (ASHP) Midyear Clinical Meeting Personnel Placement Service (PPS) is strongly encouraged.

Interested Candidates Should Send:

REQUIRED ITEM

- Curriculum Vitae
- Letter of intent
- College transcript
- Three letters of recommendation

DEADLINE

December 14, 2018
December 14, 2018
December 14, 2018
December 14, 2018

Please send all correspondence to:

MAIL HARD COPIES TO:

Joseph M. Brocavich, Pharm.D.
Senior Associate Dean for Pharmacy
Associate Clinical Professor
College of Pharmacy and Health Sciences
St. John's University
8000 Utopia Parkway
Queens, New York 11439

MAIL ELECTRONIC COPIES TO:

Send emails to both:

- Joseph M. Brocavich, Pharm.D.
brocavij@stjohns.edu
- Daiichi Sankyo
DSIFellowship@dsi.com

More Information

For any additional information or questions:

ST. JOHN'S UNIVERSITY

Visit: www.stjohns.edu/academics/schools-and-colleges/college-pharmacy-and-health-sciences/residency-and-fellowship-programs

DAIICHI SANKYO, INC.

Email: DSIFellowship@dsi.com





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