Post-Doctoral Pharmaceutical Industry Fellowships

• Two-Year Clinical Development Program
• Two-Year Clinical Safety Program
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.
Welcome

Thank you for your interest in the Daiichi Sankyo Post-Doctoral Fellowship Program. Daiichi Sankyo and St. John’s University strive to increase the visibility of the Pharm.D. 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 this Fellowship Program.
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 2,500 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 hypertension, thrombosis, dyslipidemia, diabetes, and oncology. Its clinical development and regulatory activities are located in Edison, New Jersey in its Daiichi Sankyo Pharma Development division.

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.

**Innovation – our imperative**

Pharmaceutical innovation and therapeutic advances have had a dramatic impact on the lives of millions of people the world over. Innovation is our passion as well as a fundamental requirement in our ongoing pursuit to create innovative, world-class drugs. We encourage each employee to share in the spirit of innovation.

**Integrity – our strength**

We are distinguished by integrity. We strive to do things right as well as do the right things to improve the health and well-being of patients worldwide.

**Accountability – our culture**

Accountability is the cornerstone of our culture. It is at the intersection of research and patient need that we find our greatest challenges and our most extraordinary opportunities. We demonstrate our compassion for people and we honor our commitments to all those who depend on us to provide innovative therapies to patients around the globe.
About the Fellowships

The Fellowship Program at Daiichi Sankyo 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 Fellowship Program at St. John’s University/Daiichi Sankyo 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 Clinical Development 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 Pharma Development’s business needs for the year, the Fellowship Program is altered accordingly. Past Fellows have focused in Regulatory Affairs and Clinical Development, and this year we are proud to offer fellowship positions in Clinical Development and Clinical Safety. This type of flexibility within the Daiichi Sankyo Pharma Development Fellowship Program creates an opportunity for diversity and provides a unique and rewarding experience to each Fellow every year.
Clinical Development Program Structure

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

YEAR ONE

- At least one full year spent within the Clinical Development department at DSPD which is based in the Edison, New Jersey Office
- Learn strategies and processes for clinical trial start-up, execution and completion
- Acquire working knowledge of protocol development, case report form design, trial governance and management, medical monitoring, subject recruitment and retention, monitoring of investigational sites, data management, statistical analysis and clinical study report preparation
- Learn strategies for effective oversight and management of contract research organizations and other vendors, thereby ensuring that trials are conducted in accordance with Daiichi Sankyo Pharma Development Standard Operating Procedures (SOPs) and Good Clinical Practice (GCP) standards as well as federal and other national regulations
- Support the clinical operations team with trial implementation and management (e.g., planning investigator meetings, managing drug supply, management of investigational sites) to ensure high quality deliverables
- Present progress reports from ongoing clinical trials
- Participate on a cross-functional clinical trial team to assist with execution of the trial
- Attend national scientific conferences, medical meetings and key opinion leader meetings
- Prepare and present poster/abstracts/scientific papers
- Collaborate cross-functionally with global colleagues and scientists, representing diverse backgrounds, knowledge and expertise on a variety of issues and topics

YEAR TWO

- Rotate (3-6 months) through various departments at DSPD, 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:
  - Translational Medicine and Clinical Pharmacology
  - Clinical Pharmacovigilance and Drug Safety
  - Clinical Development (several therapeutic areas)
  - Project Management
  - Regulatory Affairs

Daiichi Sankyo Oncology

Daiichi Sankyo is bringing new vision to the fight against cancer. We are focusing on the discovery and development of novel oncology agents with the goal of delivering first-in-class and best-in-class treatments that address unmet clinical needs. The oncology pipeline of Daiichi Sankyo continues to grow and currently includes both small molecules and monoclonal antibodies with novel targets in both solid and hematological cancers.
“Our Fellows are seen as valuable members of the clinical trial team. Fellows actively participate in global projects to foster skills in clinical strategy, decision making, and project management. By working on trials across multiple phases of development, the Fellows gain a comprehensive understanding of the development process. Our Program also encourages Fellows to work with or rotate to other departments of interest to provide a well-rounded, professional experience.”

Clinical Development Preceptor: David Jacobs, M.D., M.B.A.
Senior Director, Clinical Development - Frontier

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Clinical Development Preceptor: Catherine Copigneaux, Pharm.D.
Director, Clinical Development - Oncology

“The Clinical Development Fellowship Program provides our Fellows with the opportunity to collaborate with Medical Monitors, Clinical Operations, Biostatisticians and other professionals on a global clinical trial team. We teach the fundamental concepts of protocol design and clinical trial management and help the Fellows develop skills in problem solving and decision making. The Fellows acquire in-depth knowledge of the disease being treated and practical experience managing a clinical trial in Phase II or III of development, thereby gaining a strong foundation for a career in drug development.”

Clinical Development Preceptor: Jim Hanyok, Pharm.D.
Senior Director, Clinical Development - Cardiovascular

“Our Industry Fellowship Program provides our Fellows with in-depth and well-rounded professional experiences based upon our company’s hands-on approach towards working and managing. In today’s complex and ever-evolving healthcare environment, we consider our Fellows an integral part of our team and teach the concept of sound drug development strategies and decision-making abilities that support global product drug development.”

Program Director/Regulatory Affairs Preceptor: Doreen Morgan, Pharm.D., M.S.
Executive Director, Regulatory Affairs
Clinical Safety Program Structure

This Fellowship is designed to focus in the area of Clinical Safety. 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 at DSPD which is based in the Edison, New Jersey Office

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
- Review and assess epidemiology literature
- Serve as a project manager for multidisciplinary Safety Management Team (SMT) discussions on emerging safety issues

Risk Management & Safety Communication

- 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, medical meetings, FDA Advisory Committee meeting, and key opinion leader meetings
- Collaborate cross-functionally with global colleagues and scientists, representing diverse backgrounds, knowledge, and expertise on a variety of issues and topics
YEARN TWO

- Rotate (3-6 months) through various departments at Daiichi Sankyo Pharma Development, 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:

  - Translational Medicine and Clinical Pharmacology
  - Clinical Development
  - Pharmacoepidemiology
  - Regulatory Affairs
  - Project Management

“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.”

Clinical Safety Preceptor: Youngsook Choi, M.D.
Executive Director, Clinical Safety 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 five metropolitan campuses.

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

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 Pharma Development.
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
- Collaborative research projects with St. John’s faculty
- Development of continuing education courses
- Active participation in the College’s fellows/residents seminar series
- 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
CURRENT FELLOW PERSPECTIVES

“Clinical development is a field of pharmaceutical industry that is ever-growing and expanding. As a Fellow in the St. John’s University/Daiichi Sankyo Program, I am at the forefront of innovation in a company that strives to promulgate global clinical trials, which will benefit patients’ lives. I am a valuable member of many multi-disciplinary teams, and glean scientific knowledge and valuable experience from every project that I work on. At St. John’s University, the teaching certificate portion has allowed me to become a better presenter and leader. Both components, at Daiichi Sankyo and at St. John’s University, will allow me to have a productive and influential career in pharmaceutical industry.”

Elan Lutinger, Pharm.D.
Long Island University | Second Year Clinical Development Fellow: 2014-2016

“The St. John’s University/Daiichi Sankyo Fellowship provides many opportunities for professional and personal development. I am surrounded by experienced and supportive mentors who value hands-on experience and the clinical and scientific training of pharmacists. The Program also offers a unique flexible second year in order to gain a greater understanding of the industry. Further complementing the Fellowship, the St. John’s academic component incorporates a research project and teaching experience. In all, the combination of Daiichi Sankyo and St. John’s University will definitely prepare me for a successful career in the pharmaceutical industry.”

Nicole Liaw, Pharm.D.
Northeastern University | First Year Regulatory Affairs Fellow: 2015-2017
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, but not required.

Interested Candidates Should Send:

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<td>Curriculum Vitae</td>
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<td>Letter of intent</td>
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<td>Three letters of recommendation</td>
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Please send all correspondence (electronic and hardcopy) to:
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Senior Associate Dean for Pharmacy
Associate Clinical Professor
College of Pharmacy and Health Sciences
St. John’s University
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Queens, New York 11439
Email: brocavij@stjohns.edu

Past Fellows

Neda Aghajani Memar, Pharm.D.
- Senior Manager, Regulatory Affairs
- Novartis
- Inaugural Fellow: 2011–2013

Mike DeMarco, Pharm.D.
- Manager, Regulatory Affairs Liaison
- Daiichi Sankyo, Inc.
- Fellow 2012–2014

Derek E. Mires, Pharm.D.
- Manager, Clinical Development
- Daiichi Sankyo, Inc.
- Fellow 2013–2015