Post-Doctoral Pharmaceutical Industry Fellowship

Two-Year Regulatory Affairs 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-Doctorate Fellowship program. Daiichi Sankyo, in collaboration with St. John’s University, strives 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 becoming immersed in an international company through projects and as members of multi-disciplinary teams, while also completing 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 Fellowship

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 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 role that Regulatory Affairs has in the drug development process, including the opportunity to gain “hands-on” experience concerning the requirements to identify, approve 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 the fellowship position in Regulatory Affairs. 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.
Program Structure

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

YEAR ONE

• At least one full year spent within the Regulatory Affairs department at DSPD which is based in the Edison, New Jersey office

• Work with preceptors and other regulatory functional leaders in Regulatory Affairs (CMC, FDA liaison, Regulatory Operations, Labeling Group) to develop skills and understanding of the regulations (federal/local) required to file and maintain INDs, NDAs primarily in the U.S.

• Acquire a working knowledge of global/international requirements (ICH Guidances, local/regional regulations i.e. EMA, PMDA, etc) to support the conduct of clinical studies (pre and post marketing) with a global focus

• Participate on an International Project Team (IPT) to support global studies for registration

• Develop the necessary skill set to provide project teams with rational and scientifically driven regulatory strategic guidance for all phases of drug development

• Participate via project teams on large multi-national Phase 3 registration trials and Life Cycle Management programs

• Attend national scientific conferences, medical meetings, FDA Advisory Committee meeting, 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
FELLOW PERSPECTIVES

“The St. John’s University/Daiichi Sankyo Clinical Development Fellowship provides a comprehensive and unique experience in the pharmaceutical industry. As a valued member of the clinical development team, I contribute to the design and management of global clinical trials in various phases of the product life-cycle. Collaborating with key company leaders, I am able to shape and support the cardiovascular development strategy. Under the St. John’s component, I am cultivating my communication and presentation skills through the completion of a teaching certificate. The strong mentorship at Daiichi Sankyo and St. John’s University is preparing me to lead a successful career in the pharmaceutical industry.”

Derek E. Mires, Pharm.D.

“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 multidisciplinary 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 | First Year Clinical Development Fellow | Current Fellow: 2014–2016
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
“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

“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

“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
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 Pharmacists (ASHP) Midyear Clinical Meeting Personnel Placement Service (PPS) is strongly encouraged, but not required.

Interested Candidates Should Send:

**REQUIRED ITEM**                                **DEADLINE**
Curriculum Vitae                                     December 17, 2014
Letter of intent                                     December 17, 2014
College transcript                                   December 22, 2014
Three letters of recommendation                     December 22, 2014

Please send all correspondence (electronic and hardcopy) 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
Email: brocavij@stjohns.edu

Past Fellows

Neda Aghajani Memar, Pharm.D.
- Manager, Regulatory Affairs Liaison
- Daiichi Sankyo, Inc.
- Inaugural Fellow: 2011–2013

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