POST-DOCTORAL PHARMACEUTICAL INDUSTRY FELLOWSHIP

ST. JOHN’S UNIVERSITY AND AMERICAN REGENT
On behalf of American Regent and St. John’s University, we would like to thank prospective fellows for interest in our unique program.

OUR VALUES

At American Regent, we are committed to our core values. We continually deliver exceptional customer service to patients, healthcare providers, and manufacturers. Our growth efforts are directed towards the ever-changing world of healthcare. With specialization in the nephrology market, we are able to help treat patients with complicated histories and prevalent disease states such as diabetes and hypertension, the two leading causes of kidney disease. Our efforts to produce quality products reflect our dedication to the care and health of those we serve. Our partnerships with various organizations are able to give us direct insight into patient outcomes and provider satisfaction with our products.

MISSION

American Regent has been supplying quality injectable products to the medical community throughout the US and Canada since 1967. Specialization in the nephrology market and expertise in manufacturing capabilities have enabled us to satisfy essential needs and establish a strong presence with the healthcare system.
FELLOWSHIP OBJECTIVES

The two-year post-doctoral pharmaceutical industry fellowship is designed to provide the Doctor of Pharmacy graduate a profound and unique experience within a pharmaceutical corporation, American Regent. The fellow will have exposure to various departments within American Regent as well as research and teaching opportunities at St. John’s University College of Pharmacy and Health Sciences. It is the goal of the program to provide the fellow with the skills and tools necessary for a successful career in the pharmaceutical industry.

FELLOWSHIP DIRECTOR

“...unique exposure to the inner-workings of a pharmaceutical company in a professional environment conducive to learning. The program imparts knowledge and experience necessary to allow each fellow to become competent in providing accurate medical information to healthcare professionals, sales and clinical teams, and consumers. Additionally, each fellow rotates through a series of responsibilities that provide the backbone of training and supervised experience in pharmaceutical marketing. Though our Fellowship Program is relatively new, the fellows have helped us to develop the program into a comprehensive, worthwhile and wholly enjoyable experience.”

William C. Fridrich, R.Ph., M.S., M.B.A.
Director of Medical Affairs
Fellowship Director

Bill earned a Master of Science in Organizational Management in 2011, a Master of Business Administration in 2010, and a Bachelor of Science in Pharmacy in 1987. He initiated and is the Director of the American Regent/St. John’s University Fellowship Program, and is the lead preceptor for both the St. John’s University and Long Island University pharmacy student industry rotation programs. In his 9 years with the company, Bill and the Medical Affairs team have been an integral part of American Regent’s educational and medical information efforts, overseeing speakers programs, educational grant requests, medical information responses to healthcare professionals, sales training, and processing of product quality complaints. Prior to joining American Regent, Bill was the Director of Pharmacy at a national home infusion company, and practiced in both hospital and retail pharmacy disciplines.
FELLOWSHIP
OBJECTIVES

CLINICAL RESEARCH & DEVELOPMENT
NORRISTOWN, PENNSYLVANIA

- 20 miles outside of Philadelphia
- Minutes from the King of Prussia mall, the largest mall on the East coast

MEDICAL AFFAIRS & PHARMACEUTICAL MARKETING
SHIRLEY, NEW YORK

- 60 miles east of New York City
- Minutes from critically-acclaimed beaches & Long Island Wine Region

St. John’s University and American Regent
AT A GLANCE

- Founded in 1910 in Munich, Germany as Luitpold-Werk and entered the US Market in 1978
- President & CEO – Mary Jane Helenek, R.Ph., M.S., M.B.A.
- Manufactures over 100 different pharmaceutical products and devices including Venofer® and Injectafer®
- Headquarters located in Shirley, NY on Long Island with additional facilities located in Norristown, PA and Columbus, OH
- Employs over 850 personnel

PRESIDENT & CEO

“The American Regent Post-Doctoral Fellowship is geared for highly motivated professionals that want to obtain broad hands-on experience to the many facets of pharmaceutical marketing and medical affairs. No other fellowship program offers the opportunity to be an integral part of drug development through launch and life cycle management. Expect to be constantly challenged, make significant contributions and upon completion develop finely honed skills, enabling the fellow to effectively meet their career goals.”

Mary Jane Helenek, R.Ph., M.S., M.B.A.
President & CEO
Founded in 1910 in Munich, Germany as Luitpold-Werk and entered the US Market in 1978

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THE HISTORY OF AMERICAN REGENT

1967
A group of dedicated professionals launch our company under the name American Quinine, which provides quality, parenteral products to medical communities within the US and Canada.

1991
Sankyo, a Japanese pharmaceutical company, acquires Luitpold and its subsidiary, American Regent Laboratories, Inc.

MID 1980s
Luitpold Pharmaceuticals, Inc. acquires American Quinine and transforms the name to American Regent Laboratories, Inc.

1996
American Regent Laboratories introduces Dexferrum® (iron dextran injection, USP).

1991
Sankyo, a Japanese pharmaceutical company, acquires Luitpold and its subsidiary, American Regent Laboratories, Inc.

2000
Venofer® (iron sucrose injection, USP) is approved for the treatment of iron deficiency anemia in patients suffering from chronic kidney disease. Since its inception in the United States, Venofer® has emerged as a brand leader and is now the #1 prescribed IV iron in the US.

2005
Sankyo merges with Daiichi Pharmaceutical Company, Ltd. to become Daiichi-Sankyo Company, Ltd.

2002
The name American Regent Laboratories, Inc. was shortened to American Regent, Inc.

2009
Luitpold acquires PharmaForce, Inc. broadening its line of generic, multisource injectables.

2013
Injectafer® (ferric carboxymaltose injection) becomes the 1st high-dose, non-dextran IV iron indicated to treat a broad, adult patient population with iron deficiency anemia.

Post-Doctoral Pharmaceutical Industry Fellowship
“The fellowship program at American Regent provides a unique opportunity to be exposed to both medical affairs and pharmaceutical marketing. American Regent offers a warm environment where you have multiple mentors providing a support system to foster your training and learning experience in the company. Working in a smaller company you are able to be involved in different projects through various departments which expands the learning potential exponentially. The fellowship program is structured to ensure the fellow is able to build a strong skill set to be marketable in the competitive pharmaceutical world while also allowing for flexibility to explore interests in careers such as medical science liaison, pharmacovigilance, regulatory affairs, and clinical research.”

Kimberly Becker, B.S., Pharm.D.
First-Year Fellow
Medical Affairs & Pharmaceutical Marketing
MCPHS University, Worcester
Medical Affairs & Pharmaceutical Marketing Fellowship

Medical Affairs Overview

Pharmacists in the Department of Medical Affairs provide efficient and unbiased medical information concerning the company’s pharmaceutical products to healthcare professionals, consumers, and internal associates.

Upon completion of rotation within this department, the fellow should be able to:

- Address the medical needs of the company by utilizing strong analytical skills to evaluate medical literature
- Apply clinical expertise to interpret scientific data
- Identify and report adverse events
- Provide enhanced verbal communication
- Utilize comprehensive medical writing skills in response to medical inquiries from customers
- Utilize clinical knowledge in the development of healthcare-related publications, meetings, and digital media for an array of audiences, including healthcare professionals and consumers
- Critically analyze and evaluate evidence-based medicine
- Aid in the planning and implementation of Speakers Bureau programs and materials that adhere to PhRMA and FDA guidelines
- Collaborate and network with key opinion leaders (KOLs) from industry, managed care, and academia in the creation of marketing and educational programs
- Manage company expectations while effectively integrating key clinical messages into programs for healthcare professionals
- Provide scientific support at meetings
- Work directly with the Medical Science Liaisons:
  - Coordinate clinical information between sponsor companies and experts in the field
  - Develop and cultivate relationships with experts, training speakers and the sales force
  - Provide medical information support
  - Develop educational programs and materials
  - Interact with Medical Science Liaisons and Sales Team members at “Lunch and Learn” meetings
- Strengthen medical expertise, gain in-depth experience, and acquire abilities required in the pharmaceutical industry
- Review promotional and non-promotional materials
- Identify and address specific needs of our consumers, healthcare professionals, personnel and healthcare-related organizations by providing scientific responses regarding Luitpold Pharmaceuticals, Inc. and American Regent products
- Develop and present educational lectures on products and disease states to sales training groups and other company employees
- Research, review, and coordinate scientific and clinical materials that support corporate goals
Pharmaceutical Marketing Overview

Business opportunities for pharmacists in industry include various roles within Pharmaceutical Marketing. The Marketing department is responsible for strategic and tactical implementation of the advertising and promotion of the company’s products and brands. The fellow will work directly with the marketing team and serve a cross-functional role with sales representatives, managed markets team, and business development.

Upon completion of rotation within this department, the fellow should be able to:

• Manage a broad range of responsibilities comparable to those managed by current team members
• Understand medical marketing
• Develop programs that drive healthcare providers’ awareness of the brand, in an effort to optimize utilization
• Develop marketing strategy and tactics to optimize brands
• Collaborate with agencies and cross-functional teams to execute strategic and tactical plans through appropriate sales, marketing, and medical channels
• Trend, forecast, and create patient model evaluations based on past and present market data analyses
  – Gain an understanding of forecasting and patient evaluation model
• Develop competitive intelligence
• Develop sales promotional materials

Left to right: Ana Russell, Paul Cerza, Janice McCarron, Kimberly Becker, Jaclyn Viola, Dolly Chao, Alicia Shepard
PHARMACEUTICAL MARKETING PERSONNEL

“The Marketing department plays a vital role in the commercialization and success of pharmaceutical brands. At Luitpold, we offer a unique program whereby fellows can gain hands on experience in both Medical Affairs and Marketing. Everything we do in pharmaceutical marketing is rooted in science. This fellowship program gives the post-doctoral fellow a perfect opportunity to combine their clinical background with creativity and analytical skills to solve critical business issues. I am extremely impressed with the fellows that have rotated into this program. They have taken on key projects to drive business objectives, including supporting the advertising agency selection process, developing digital strategies, providing clinical trial overview presentations, strategic brand planning, market research initiatives and the creation of scientific educational programs. I look forward to working with these bright and highly motivated individuals.”

Dolly Chao, M.B.A.
Director of Marketing, Iron Franchise
Commercial Operations

“Our collaborative fellowship program with St. John’s University has enabled us to build and solidify relationships with professionals of the present and future. We are truly grateful to be able to work through our fellowship program with young professionals with whom we foster and encourage cognitive growth. The fellowship with St. John’s has demonstrated to be an excellent opportunity for both the preceptor and fellow to exchange ideas, develop business strategies and promote educational growth.”

Paul Cerza, Pharm.D., M.B.A.
Senior Manager of Commercial Planning
Commercial Operations

“The Medical Affairs and Pharmaceutical Marketing fellowship at American Regent has been a memorable and life changing experience. During my fellowship, I was challenged to think differently and creatively, and was able to utilize my clinical pharmacy knowledge in the dynamic setting of the pharmaceutical industry. I had the unique opportunity to work with the brand team by supporting strategic marketing decisions and leading tactical execution plans. The preceptors at American Regent use a hands-on mentorship approach which has contributed to both my personal and professional growth and development. Through different projects, I had the opportunity to collaborate with internal colleagues and work cross-functionally within the company. I am very grateful for the experiences this fellowship program has provided, which has led me to pursue a career within pharmaceutical brand management.”

Jaclyn Viola, Pharm.D., R.Ph.
Associate Product Manager, Iron Franchise
Commercial Operations

“The Marketing team consists of individuals with a diverse range of academic and professional backgrounds and I’ve had the pleasure of working with a number of fellowship graduates who later assumed permanent Marketing positions. These graduates add a clinical perspective to the marketing process that is grounded in a comprehensive medical and commercial experience that benefits the entire department.”

Alicia Shepard, M.B.A.
Brand Manager, Iron Franchise
Commercial Operations
MEDICAL AFFAIRS AND PHARMACEUTICAL MARKETING FELLOWSHIP STRUCTURE

YEAR ONE

- Medical Affairs
- Pharmaceutical Marketing

YEAR TWO

- Sales
- Clinical Research
- Market Research
- Regulatory Affairs
- Medical Science Liaison (MSL)
- Medical Affairs
- Marketing
- Quality Assurance
- Pharmacovigilance
- Rotate Areas of Interest

MEDICAL AFFAIRS PERSONNEL

Margaret Norris, R.Ph.
Senior Clinical Pharmacist, Medical Affairs

“The opportunity to interact with the individuals in our fellowship program has been an enlightening experience and has provided a way to share knowledge and instill the desire to further careers in the pharmaceutical industry. While working in the Medical Affairs Department the fellows develop a true sense of how their education can be applied to another facet of the pharmaceutical spectrum.”

Fran Gatto, B.S., Pharm.D., R.Ph.
Senior Clinical Pharmacist, Medical Affairs

“The partnership of American Regent and St. John’s University offers the Post-Doctoral Fellow a unique opportunity to continue their journey of professional learning in today’s healthcare industry. The fellow enters the program with a pharmacy degree and throughout their 2-years at American Regent, skills such as leadership and communication are cultivated to assist our patients, healthcare professionals, and colleagues. The fellow becomes a valued member of the healthcare team, rotates through several departments, and enhances their learning and professional growth which is essential for a career in the pharmaceutical industry.”

Mary Ann Rago, Pharm.D., M.B.A., R.Ph.
Senior Clinical Pharmacist, Medical Affairs

“Our two year post-doctoral fellowship provides the Pharm.D. graduate with a unique opportunity to gain experience within the pharmaceutical industry with a hands-on approach. The fellow becomes an integral part of our pharmaceutical marketing and medical affairs teams. Our clinical pharmacists mentor the fellows who learn how to develop clear and concise drug information responses as well as educational and promotional materials. The fellow will grow both personally and professionally in this role. Prior fellows contributed to the exciting launch of a new drug.”
Clinical Research & Development Fellowship

Clinical Research & Development Overview

Clinical research & development is one of the pivotal components within a pharmaceutical company for the approval of drug products as well as post-marketing, research and regulatory compliance. Upon completion of the rotation within this department, the fellow will have a keen insight in:

- Understanding the drug development process from pre-clinical through Phase IV
- Comprehending the importance of study design tailored to specific phases of clinical research
- Comprehending the importance of different considerations in designing and conducting clinical investigations in various indications/populations
- Understanding the process in the conduction of clinical research through practical experience in analyzing and presenting clinical data study results
- Understanding the regulatory aspects pertaining to clinical development and operations

Throughout the fellowship, the fellow may be able to participate in the following responsibilities:

- Advance the anemia franchise and other relevant business through clinical knowledge, medical insights, and innovations in clinical research
- Assist in the protocol design and conduct through scientific principles
- Support clinical research protocols by adherence to Good Clinical Practice (GCP) guidelines
- Develop case report forms to properly collect data for analysis in clinical trials
- Conduct study monitoring through onsite initiation of studies, routine monitoring and closeout site visits
- Participate in review, cleaning and analysis of clinical trial data
- Support various areas in clinical trial during the study startup, execution, and closeout
- Report clinical trial results (i.e., preparation of clinical study reports) and publications (i.e., preparation of abstracts and manuscripts)
- Coordinate with internal and external stakeholders to ensure feasibility and proper implementation of clinical trials
- Assist in development of program level activities, such as Investigators’ Brochures, safety updates, IND and NDA submissions documents, and responses to Health Authority questions
- Manage external vendors for clinical trials
- Assist in development of budget projections and timelines of clinical trials
- Assist in contracting with investigators, budget negotiations, and payment processes
- Interact with global partners and regulatory agencies

Clinical Research & Development team based in our Norristown, PA facility
The two-year post doctoral pharmaceutical industry fellowship program will provide the fellow a unique opportunity to better understand the inner workings of a multi-faceted Clinical Research and Development (CR&D) department. Due to the revolving nature of CR&D this program would allow the fellow to gain insight into the different stages of product development. The fellow would gain experience by actively participating in the product development process which could include, but not limited to, initial study conception and design, protocol development and procedures for protocol execution, quality control of the study data, analyses of the data captured and final preparation of documents for submissions to Regulatory Agencies. This program allows the fellow real world, hands on experience in CR&D.

Angelia D. Butcher
Senior Clinical Project Manager
Clinical Research and Development

The Luitpold clinical research fellowship offers the post doctoral fellow the unique opportunity to gain exposure and experience to all phases of clinical research. As a mid-size pharmaceutical company the clinical operations personnel become much more involved in all aspects of drug development compared to larger companies. The fellow will gain experience in all areas of clinical drug development from protocol design and development through completion of the clinical study report and publication. The fellow will gain hands on experience with clinical monitoring, investigator contract and budget negotiations, contracting with and managing contract research organizations, data review and cleaning and all other aspects of clinical research. The fellow will gain the experience and skills necessary to excel in the field of clinical drug development.

Todd A. Koch
Senior Clinical Project Manager
Clinical Research and Development

“Being a fellow and now an employee of Luitpold Pharmaceuticals, the fellowship here provides a great experience. As a fellow, I was able to work with preceptors and mentors that provide you with hands-on experience. I worked cross-functionally among different disciplines within the company and am now working in a department which requires all the necessary skills that I built upon. I strongly believe that this pathway is a great way to mold a Pharm.D. graduate into an exceptional professional.”

Andy He, Pharm.D. R.Ph.
Manager, Medical Affairs

This fellowship has become an integral part of American Regent. The fellow will experience firsthand what it takes to be part of a pharmaceutical company from the pre-approval stages all the way to the launch of a product. Being a mid-sized company, the fellows in our group are exposed to many different aspects of drug development including clinical development, pharmacovigilance and medical affairs. However, the fellow also has many opportunities to be part of other departments in our commercial operations group including marketing, sales, and sales support. In essence, they have the opportunity to gain experience in almost any area in which they have an interest. The fellow will be presented with many diverse project opportunities and will broaden their experience both professionally and personally on their way to becoming a competent and rounded professional in the pharmaceutical industry.”

Marc Tokars
Vice President of Clinical Operations
St. John’s University is located on a residential 105-acre campus in Queens, New York and was founded in 1870 by the 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 St. John’s University College of Pharmacy and Health Sciences prepares students for rewarding careers as practitioners, researchers, and leaders in government and industry. Founded in 1929, the College offers numerous healthcare-related programs at the undergraduate and graduate levels including the entry-level Doctor of Pharmacy degree, Master of Science degrees in Pharmaceutical Sciences and Pharmacy Administration, and the Doctor of Philosophy in Pharmaceutical Sciences degree.

St. John’s University 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 sciences as well as clinical research, and provide 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 College empowers effective leaders, good citizens, and moral and ethical individuals.
College of Pharmacy & Health Sciences Components
The fellow may apply for an affiliate faculty appointment at St. John’s University College of Pharmacy and Health Sciences and will precept entry-level Doctor of Pharmacy students who are assigned to American Regent for experiential training.
Additionally, each fellow will have opportunities at the University to participate in activities to promote professional development including:
• Formal and informal educational opportunities
• Collaborative research projects with St. John’s faculty
• Development of continuing education courses
• Resident and fellow seminar series with the College of Pharmacy and Health Sciences
• 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
• Individual research project(s)
• Opportunity to participate in a teaching certificate program

CERTIFICATE OF COMPLETION
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 American Regent.

ELIGIBILITY FOR FELLOWSHIP
Fellows are chosen from a nationally competitive selection process. To be eligible, candidates must graduate from an Accreditation Council for Pharmacy Education (ACPE) accredited Doctor of Pharmacy program and have a keen interest in pursuing a career in the pharmaceutical industry.

SALARY AND BENEFITS
The fellow will be a full-time St. John’s University employee. A competitive stipend will be given as well as options for comprehensive health, dental, and vision insurance. Travel to professional meetings, conventions, and other facilities of the company may be possible.
APPLICATION PROCESS

Application Process
Interested candidates should send:

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<th>REQUIRED ITEM</th>
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<td>Curriculum Vitae</td>
<td>December 17th</td>
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<td>Letter of intent</td>
<td>December 17th</td>
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<td>College transcript</td>
<td>December 17th</td>
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<tr>
<td>Three letters of recommendation</td>
<td>December 21st</td>
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Please send all correspondence (electronic and hard-copy) to:
Joseph Brocavich, Pharm.D.
Senior Associate Dean for Pharmacy Programs
Associate Clinical Professor
College of Pharmacy and Health Sciences
St. John’s University, 8000 Utopia Parkway
Queens, NY 11439
Email: brocavij@stjohns.edu

*All candidates must request and schedule an interview by contacting Dr. Brocavich.

For any questions regarding the fellowship program or application process, please contact fellowship@americanregent.com