RUTGERS
Institute for Pharmaceutical
Industry Fellowships

AMGEN®

PHARMACEUTICAL INDUSTRY FELLOWSHIP PROGRAM 2024 - 2025

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WELCOME

Dear Prospective Fellow,

On behalf of Amgen Global Regulatory Affairs and Strategy (GRAAS) and Global Value & Access (GV&A), we would like to thank you for your interest in pursuing a fellowship at one of the world's leading independent biotechnology companies. Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics, and recognizes the special contributions pharmacists bring to this process.

Pharmacists are committed to applying science to dramatically improve the lives of patients, which is at the heart of everything that we do at Amgen. Here, pharmacists play a critical role throughout all parts of our organization.

Our values are the bedrock of our company, and excellence in all aspects of our performance is valued. Fellowships at Amgen are designed to prepare our fellows for successful careers in the pharmaceutical industry.

On behalf of everyone at Amgen, we wish you the most success in a career of serving patients. The entire industry benefits from your engagement as a pharmacist, a fellow, and a future industry professional.

Sincerely,
Mark Taisey, Senior Vice President, Amgen Global Regulatory Affairs and Strategy
Jackie Kline, Vice President, Amgen Global Regulatory Affairs, Oncology
Laura Bloss, Vice President, Amgen Global Regulatory Affairs, General Medicine
Gavin Lewis, Vice President, Amgen Global Value and Access

OUR MISSION: TO SERVE PATIENTS

ABOUT AMGEN

At Amgen, we believe in a “biology first” approach. We use cutting-edge science and technology to study the subtlest biological mechanisms in search of therapies that will improve the lives of those who suffer from serious diseases. Amgen believes that the cure for disease can be found inside each and every one of us.

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its biologics manufacturing expertise to strive for solutions that improve health outcomes and dramatically improve people’s lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world’s leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

CLICK TO LEARN MORE:

Amgen Fact Sheet | The Answers Within - Biology First | The Amgen Difference - Our People, Our Values | Amgen YouTube Homepage

TRANSFORMATIVE RESEARCH

Understanding the fundamental biological mechanisms of disease is a defining feature of Amgen's discovery research efforts and a major contributor to the development of Amgen's deep and broad pipeline of potential new medicines. Amgen's "biology first" approach permits its scientists to first explore the complex molecular pathways of disease before determining what type of medicine, or modality, is most likely to deliver optimal efficacy and safety. With the advances in human genetics, Amgen continues to shed new light on the molecular roots of disease. Amgen subsidiary deCODE Genetics, a global leader in human genetics, is a powerful differentiator, greatly improving how we identify and validate human disease targets.

AMGEN VALUES

Be Science-Based
Our success depends on superior scientific innovation, integrity and continuous improvement in all aspects of our business through the application of the scientific method. We see the scientific method as a multi-step process that includes designing the right experiment, collecting and analyzing data and rational decision making. It is not subjective or emotional, but rather a logical, open and rational process. Applying the scientific method in all parts of the organization is expected and highly valued.

Compete Intensely and Win
We compete against time, past performance and industry rivals to rapidly achieve high quality results. Winning requires taking risks. We cannot be lulled into complacency by previous achievements. Though we compete intensely, we maintain high ethical standards and demand integrity in our dealings with competitors, customers, partners and each other.

Create Value for Patients, Staff and Stockholders
We provide value by focusing on the needs of patients. Amgen creates a work environment that provides opportunities for staff members to reach their full potential. We strive to provide stockholders with superior long-term returns while balancing the needs of patients, staff and stockholders.

Be Ethical
We are relentless in applying the highest ethical standards to our products, services and communications.

Trust and Respect Each Other
Every job at Amgen is important and every Amgen staff member is important. We attract diverse, capable and committed people and provide an environment that fosters inclusion, respect, individual responsibility and values diversity. Trust is strengthened through personal initiative and by obtaining quality results rapidly.

Ensure Quality
Quality is a cornerstone of all of our activities. We seek the highest quality information, decisions and people. We produce high quality products and services. Quality is woven into the fabric of everything we do.

Work in Teams
Our teams work quickly to move scientific breakthroughs from the lab through the clinic to the marketplace and to support other aspects of our business. Diverse teams working together generate the best decisions for patients, staff and stockholders. Our team structure provides opportunities for Amgen staff to impact the direction of the organization, to gain broader perspective about other functions within Amgen and to reach their full potential.

Collaborate, Communicate and Be Accountable
Leaders at Amgen seek input and involve key stakeholders in important decisions. In gathering input, strong leaders will welcome diverse opinions, conflicting views and open dialogue for serious consideration. They will clearly communicate decisions and rationale openly and in a timely manner. Once a decision is made, the leader and members of the team will all be accountable for the results and for implementing the decision rapidly.

FELLOWSHIP OVERVIEW

Southern California has been Amgen's home since inception. Thousand Oaks is where Amgen is globally headquartered and is in close proximity to a number of top-notch academic research institutions. Amgen has a far-reaching global footprint, which continues to grow. Amgen is the first and only Southern California fellowship opportunity within the Rutgers Pharmaceutical Industry Fellowship (RPIF) Program.

Both the GRAAS and GV&A organizations at Amgen have lean and nimble operating models, which offers fellows the valuable opportunity to leverage their scientific background to make meaningful and strategic contributions early in their career.

Advanced Development Planning

In addition to program and project based development opportunities, fellows will have the opportunity to interact both formally and informally with management and senior management. These interactions will serve as early exposure to organizational and high-level strategic learning. Fellows will be encouraged to identify and solicit mentorship from senior leadership throughout their fellowship experience. Senior leadership support and mentorship facilitates the strong development of future leaders in the pharmaceutical industry.

PROGRAM LEADERSHIP AT AMGEN

Mark Taisey
Senior Vice President, GRAAS

Executive Sponsor - GRAAS

Jackie Kline, PhD
Vice President, GRA, Oncology

Executive Sponsor - GRA

Laura Bloss, PhD
Vice President, GRA, General Medicine

Executive Sponsor - GRA

Gavin Lewis, MS
Vice President, GV&A

Executive Sponsor - GV&A

Jennifer Steinbock, MA, RAC
Director, GRA, General Medicine

Fellowship Co-Director

Lyndsey Milburn, PharmD, MBA, RUCIF
Manager, US Regulatory Lead, General Medicine

Fellowship Co-Director

Rutgers University Certified Industry Fellow, 2022

Ariana Aun, PharmD, RAC
Senior Manager, US Regulatory Lead, Oncology

Fellowship Co-Director

US REGULATORY STRATEGY FELLOWSHIP

Amber Duche, PharmD, MBA
2022 - 2024 US Regulatory Strategy Fellow
Ferris State University

Sabine Puglia, PharmD
2023 - 2025 US Regulatory Strategy Fellow
University of Illinois at Chicago

PROGRAM OVERVIEW

This program is recruiting for 2024.

At Amgen, the Regulatory Therapeutic Area (TA) teams are responsible for the planning and execution of regulatory strategies for the advancement and approval of our innovative and biosimilar products. Our Regulatory TA professionals leverage innovative clinical trial designs and expedited approval pathways to efficiently deliver our products to patients. US Regulatory Strategy Fellows are embedded in regulatory project teams and directly contribute to the development of our products.

Amgen's product portfolio spans a broad range of therapeutic areas including oncology, hematology, cardiovascular, neuroscience, bone, inflammation, metabolic, and endocrine. Our fellows are given the opportunity to focus their experience on a single therapeutic area or to divide their time across multiple areas.

US Regulatory Strategy Fellows participate in a structured development program which is designed to prepare them for a rewarding career in regulatory affairs. Fellows are assigned to project teams and work with a designated preceptor and under the mentorship of experienced regulatory professionals. During their time in the program, they gain a deeper understanding of the practical considerations of drug development such as navigating a matrix team environment, addressing discordant feedback from multiple regulatory authorities, and negotiating with the FDA.

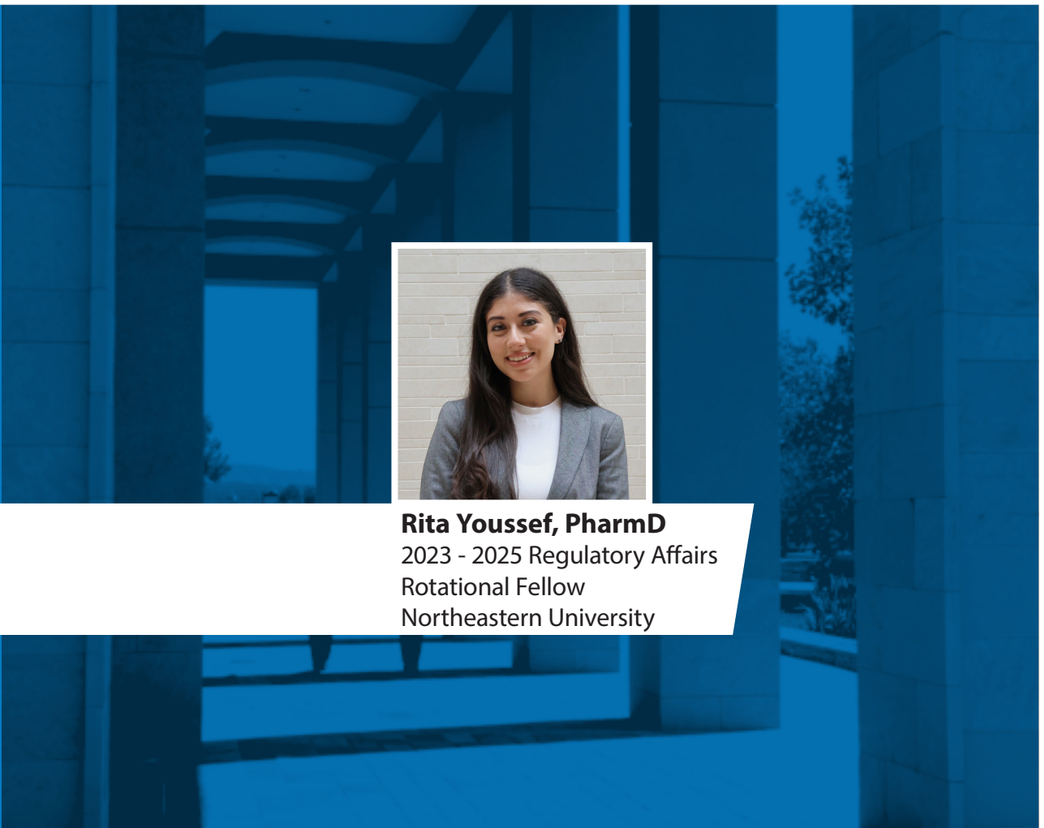
Amgen US Regulatory Strategy Fellows primarily focus on US regulatory affairs. In addition, they are exposed to European Union, Japan, and China regulatory considerations through regular participation in Global Regulatory Teams. Fellows also have the opportunity to learn about areas within regulatory such as labeling strategy and regulatory promotions. As contributing members of our teams, fellows participate in the following types of activities:

- Assessment of the regulatory landscape for a given disease area
- Routine regulatory submissions such as protocol amendments and clinical study reports
- Development and execution of regulatory submission plans for Investigational New Drug applications and requests for orphan drug designation
- Contribute to planning and execution of meetings with US FDA

Adam J. Rupert, MS, RAC
Executive Director, GRA General Medicine
2022 - 2025 Preceptor

"Over the years, the Amgen US Regulatory Strategy Fellowship has provided numerous Rutgers fellows the foundation and skills required to begin their regulatory affairs careers. At Amgen, fellows work closely with top level regulatory professionals and receive regular guidance and advice from mentors. Fellows have the opportunity to develop the regulatory strategy for complex and routine regulatory filings and health authority meeting interactions, while also working closely with US Regulatory Leads to gain additional awareness and understanding of the full scope of managing the US Regulatory role. Through these experiences, fellows learn how to thrive in a fast-paced environment, collaborate with cross-functional colleagues, and demonstrate leadership and ownership for the programs they work on. As a preceptor, I make it a priority of mine to work closely with the fellows to understand their goals and chart a course to ensure fellows have all of the support needed to seamlessly transition into a career in regulatory affairs."

REGULATORY AFFAIRS ROTATIONAL FELLOWSHIP



Rita Youssef, PharmD
2023 - 2025 Regulatory Affairs Rotational Fellow
Northeastern University

PROGRAM OVERVIEW

This program is NOT recruiting for 2024.

The Regulatory Affairs Rotational Fellow follows a rotational development plan in the first year with 3-month rotations across different functions based on the fellow's choice. Rotation opportunities include US/Global Regulatory Affairs, Regulatory Policy, Regulatory Promotion, Chemistry, Manufacturing, and Control (CMC) Regulatory and Device Regulatory. The fellow will gain hands-on experience in multiple functions within an accelerated time period, providing a unique opportunity to clarify his/her interests in the diverse field of regulatory affairs.

Competency areas the fellow may develop include: regulatory strategy, review and approval of labeling and promotional materials, and influencing regulatory policy.

In each rotation, the fellow will have the opportunity to work with staff globally and learn to navigate the complex matrix and team environment at a large pharmaceutical company. This rotational structure will prepare the fellow for a career in a function to be determined in the second half of the fellowship, tailored to personal interests, strengths and targeted areas for development.

Potential rotations include:

- **Global Regulatory Affairs**: Responsible for designing regulatory strategies and leveraging the expertise of cross-functional teams to execute regulatory strategies for the approval and advancement of our products worldwide

- **Regulatory Policy**: Responsible for engaging with trade associations and global health authorities, contributing to evolving global regulatory policies, improving processes to adhere to new broad-impact guidelines and maintaining GRAAS awareness of regulatory intelligence

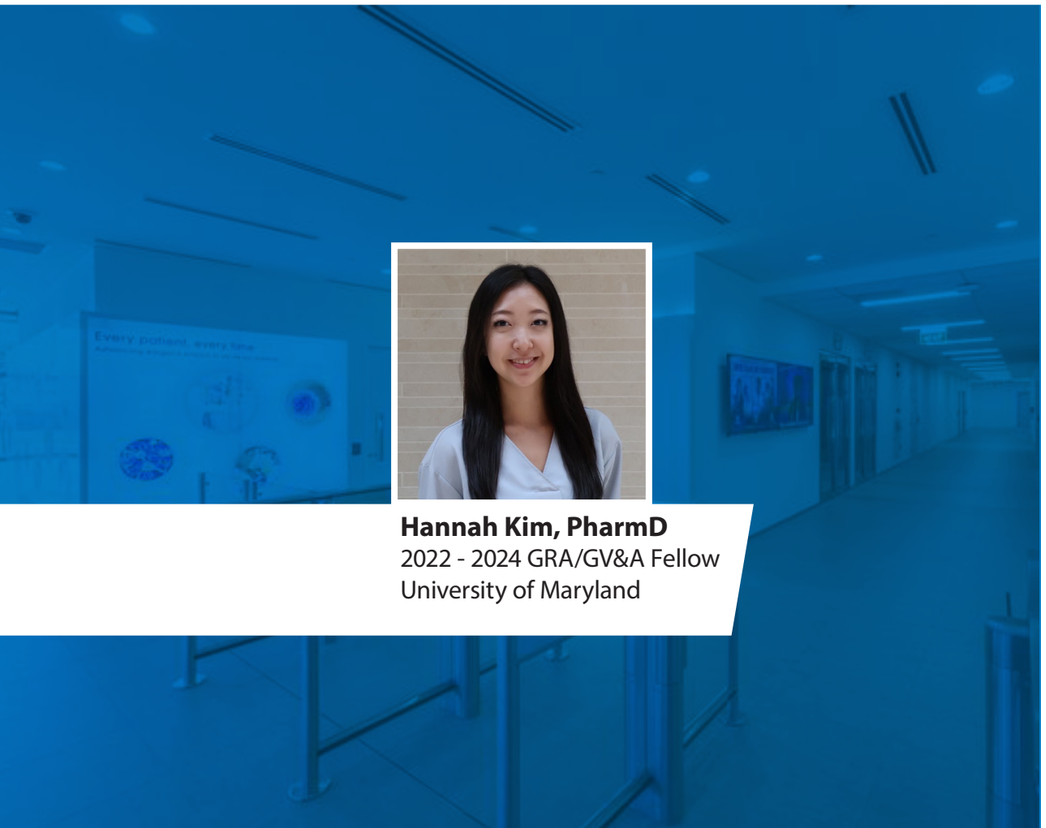
- **Regulatory Promotion**: Responsible for providing strategic regulatory guidance and reviewing/assessing risks associated with promotional materials and activities

- **Global CMC/Device Regulatory**: Responsible for developing CMC and device regulatory strategy and communicating technical specifications to regulatory authorities to drive registration and lifecycle management of our products

Mike Abernathy, MS, RAC
Executive Director, Global CMC Regulatory Affairs
2023 - 2025 Preceptor

"The Amgen Regulatory Affairs Rotational Fellowship is a unique opportunity for fellows to immerse themselves in a variety of challenging, diverse and complex regulatory environments to hone their skills as regulatory scientists, and as future leaders of our industry and profession. As an industry leader, Amgen provides a strong foundation for fellows to flourish and thrive, including state of the art technologies, a product portfolio that consists of a wide array of modalities and world class science and scientists. From the lens of a preceptor it is extremely rewarding to play a role in facilitating the fellow's advancement, watching them flourish and above all else it is a true honor to be able to give back and make a positive impact on their careers."

RA/GV&A FELLOWSHIP



Hannah Kim, PharmD
2022 - 2024 GRA/GV&A Fellow
University of Maryland

PROGRAM OVERVIEW

This program is recruiting for 2024.

The joint Regulatory Affairs (RA) and Global Value & Access (GV&A) Fellowship will follow a hybrid development plan, helping the fellow to prepare for a rewarding career in this dynamic, ever-changing environment within the pharmaceutical/biotech industry. The first half of the fellowship is intended to provide an opportunity for fellows to work in both the RA and GV&A organizations, and in the second half, the fellow will have the opprtunity to design a program that would enable a career in either RA or GV&A at the end of the 2-year fellowship. This fellowship provides a unique opportunity for the fellow to become an expert in the cross-section of RA and GV&A. This perspective will be highly valued by the organization throughout the development and commercialization of innovative products.

With a global scope, the fellow will work with a designated preceptor, global regulatory leads, access strategy leads, as well as affiliate leads in both functions and will work across several therapeutic areas. Although the fellowship focuses on strategy, the fellow will also gain the technical expertise necessary to succeed in a career in either the RA or GV&A functions upon completion of this 2-year fellowship program.

Eduardo Santos, MBA, MS
Executive Director, Global Value and Access
Preceptor 2023 - 2024

"Increasingly, healthcare systems around the globe are wrestling with the challenge of not only providing patient access to medicines but also containing rising healthcare costs. Here at Amgen, we have been fortunate to provide a combined fellowship that allows fellows to train not only in regulatory affairs but also in value, access and pricing. This dual perspective better equips future leaders to deal with the complexities of providing healthcare in the US and globally. The incredibly talented and outgoing fellows we have challenge us to think in new ways and to appreciate how much a diverse workforce contributes to cutting-edge science."





RUTGERS FELLOWSHIP ALUMNI AT AMGEN

Jocelyn Black-Paul, Regulatory Promotion & Material Compliance, Manager

Jeremy Borbon, Marketing, Senior Manager

Charles Dahm, Senior Regional Medical Science Liaison

Anastasiya Gusak, Safety, Senior Manager

Stephanie Hansen, Global Regulatory Affairs, Manager

Naomi Kozlowski, Regulatory Promotion & Material Compliance, Sr. Manager

Alex Lo, Marketing, Manager

Vicki Loh, Global Medical Communications, Director

Angelina Mandic, Global Regulatory Affairs, Manager

Lyndsey Milburn, Global Regulatory Affairs, Manager

Malay Naik, Marketing, Director

Grace Patterson, Regulatory Promotion & Material Compliance, Sr. Manager

Anusha Ponnuru, Global Regulatory Affairs, Manager

Maya Shehayeb, Global Publications, Senior Manager

Kelly Velasco, US Medical, Medical Director


RUTGERS
Ernest Mario School of Pharmacy

Soaring Ever Higher
Pharmaceutical Industry Fellowship Program

Rutgers Pharmaceutical Industry Fellowship Program

Ernest Mario School of Pharmacy
Rutgers, The State University of New Jersey

Program History

In 1984, at Rutgers, The State University of New Jersey, the Ernest Mario School of Pharmacy and two pharmaceutical companies began a first-of-its-kind collaborative pilot program to evaluate the potential contributions of clinically-trained pharmacists within a pharmaceutical industry practice setting. Following the successful pilot, the Rutgers Pharmaceutical Industry Fellowship (RPIF) Program grew significantly and expanded to include 27 companies within the pharmaceutical and biopharmaceutical industry and approximately 350 Fellows.

In 2002, Dr. Ernest Mario generously provided an endowment to establish the ***Institute for Pharmaceutical Industry Fellowships*** to enhance and promote the role of pharmacists in industry through the RPIF Program. The Institute staff members:

- provide leadership and administrative support
- promote quality, communication, scholarly activity, and professional development
- arrange specialized Fellowship training opportunities within the pharmaceutical and biopharmaceutical industry.

In 2018, our Program expanded to offer interdisciplinary Fellows' training by adding select physician Fellowship opportunities to our well-established program.

The RPIF Program has thrived under the leadership of the founder, Dr. Joseph A. Barone, Dean and Professor II of the Ernest Mario School of Pharmacy, Dr. Carolyn Seyss, the Director for the Institute for Pharmaceutical Industry Fellowships, and Dr. Michael Toscani as the Director Emeritus.

The RPIF Program Certificate is now associated with special credentials so our alumni can now proudly identify themselves as **RUCIF (Rutgers University Certified Industry Fellow)**. Well over 1,500 Post-Doctoral Fellows have completed the RPIF Program, most of whom are experiencing influential and rewarding careers in the pharmaceutical and biopharmaceutical industry throughout the US and abroad. The RPIF Program has Preceptors and Mentors from industry who share their knowledge and experiences with the Fellows through an intense but closely-guided training program. Assignments and projects are challenging, meaningful, and designed to enhance understanding of the pharmaceutical and biopharmaceutical industry and the Fellow's functional area(s). Our goal is to provide the environment for Fellows to build the foundations to fuel their careers as future leaders in the industry.

Connect with us on social media: @RutgersFellow

Joseph A. Barone, Pharm.D., F.C.C.P.
Dean and Professor II
Ernest Mario School of Pharmacy
Rutgers University

Carolyn Seyss, Pharm.D., RUCIF
Fellowship Director
Institute for Pharmaceutical Industry Fellowships
Ernest Mario School of Pharmacy

Michael Toscani, Pharm.D.
Research Professor,
Fellowship Director Emeritus
Institute for Pharmaceutical Industry Fellowships

RUTGERS
Institute for Pharmaceutical Industry Fellowships

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Ernest Mario School of Pharmacy

Soaring Ever Higher

Pharmaceutical Industry Fellowship Program

Key Program Features

The Rutgers Pharmaceutical Industry Fellowship Program **FOSTER**s the growth and development of future pharmaceutical and biopharmaceutical industry professionals and leaders through key program features:

F	**Family of Leading Companies** – Partners include several of the top global pharmaceutical and biopharmaceutical companies and offer large to small company environments.
O	**Outstanding Alumni Track Record** – Well over 1,500 alumni hold prominent positions at many leading companies, including VP and C-suite levels.
S	**Strong Network** — Fellows develop valuable, lasting connections with each other, alumni, Preceptors, and Rutgers EMSOP faculty.
T	**Trusted and Proven Since 1984** — the Rutgers Fellowship Program is nationally recognized, trusted, and proven as the key pathway to industry for pharmacists as future leaders.
E	**Enhanced Career Development** – Breadth of experiences informs career path choices, increasingly challenging assignments build depth of experience, and visibility creates opportunities - enhancing the potential for accelerated career paths.
R	**Rigorous Academic Component** – Rutgers affiliation provides academic and professional development opportunities.

Rutgers, The State University of New Jersey, with over 67,000 students in its three campuses, is one of the major state university systems in the United States. The New Jersey College of Pharmacy was founded in 1892 and was incorporated into the University in 1927. The Ernest Mario School of Pharmacy (EMSOP) is part of Rutgers Biomedical and Health Sciences (RBHS), the only state school of pharmacy in New Jersey, with approximately 1,350 students in its Doctor of Pharmacy degree program. The Rutgers EMSOP is located on the University's main science and technology campus in Piscataway, New Jersey. Because of its relationship with and close proximity to most of the nation's leading pharmaceutical and biopharmaceutical companies, the EMSOP and the RPIF Program are uniquely capable of providing Fellows with advanced training in the pharmaceutical and biopharmaceutical industry.

Connect with us on social media: @RutgersFellow

Professional Development Series

All Fellows gather once monthly as a group to participate in the Professional Development Day (PDD) series, an important component of their training that complements the hands-on experience provided at the partner companies. The PDDs are steered by a committee of Fellows and are designed to enhance the Fellows' leadership skills such as emotional intelligence, communication, critical decision making, and presentation skills. Fellows develop skill sets under the guidance of external trainers and accomplished RPIF alumni. PDDs also provide general knowledge about various aspects of drug development/commercialization and issues facing the pharmaceutical and biopharmaceutical industry, and promote connectivity and a sense of community among Fellows and alumni from different companies and disciplines.

The Fellows can learn from each other through individual and group presentations on topics and issues related to the pharmaceutical and biopharmaceutical industry. The dynamic forum of PDD provides an opportunity for open discussion and debate among Fellows, Rutgers faculty, and company Preceptors. In addition, outside experts provide training and professional development in a variety of areas (e.g., tools for corporate success, professional writing, presentations, meeting facilitation, negotiating, influencing, networking, conflict resolution, giving and receiving feedback, and business etiquette). Other PDD guest speakers include senior industry executives, including our successful RPIF Program alumni, who share their career paths, insights, and experiences. Importantly, PDDs provide an excellent opportunity for Fellows to interact with each other and develop lasting personal friendships and a strong professional network of Fellows, faculty, alumni, and other industry executives.

RUTGERS
Institute for Pharmaceutical Industry Fellowships

RUTGERS
Ernest Mario School of Pharmacy

Soaring Ever Higher
Pharmaceutical Industry Fellowship Program

Application Process and Eligibility Requirements:
Pharmacy Fellows for the Rutgers Pharmaceutical Industry Fellowship Program are selected on a nationally competitive basis. Candidates must have completed a Doctor of Pharmacy degree from an ACPE-accredited institution before July 1 of the fellowship term.

How to Apply:
The RPIF Program is highly competitive. Candidates will be selected for interviews on a rolling basis, so we strongly encourage you to submit your application as soon as possible.

Interested candidates may submit their application with short-answer questions and supporting materials (letter of intent, curriculum vitae, and 3 letters of recommendation) as soon as October 6, 2023 by visiting our website at: https://pharmafellows.rutgers.edu/how-to-apply/

All application materials **must be submitted electronically to the RPIF Website** per instructions on the site.

Your Letter of Intent & Letters of Recommendation should be addressed to:

Joseph A. Barone, Pharm.D., F.C.C.P.
Dean and Professor II
Ernest Mario School of Pharmacy
Rutgers, The State University of New Jersey
160 Frelinghuysen Road
Piscataway, NJ 08854-8020

Required Items	Submit by
Application with short-answer questions	October 13th
Letter of Intent (LOI)	October 13th
Curriculum Vitae (CV)	October 13th
Letters of Recommendation (LORs)	December 1st

Alliance of Industry Fellowship Associates Fellowship Offers
Recognizing that the choice of a Post-Doctoral Industry Fellowship is an important decision, AIFA exists to promote a common aspect of each of our program's cultures by supporting a consensus first offer date of December 13, 2023 for all fellowship candidates.

We hope that other academic and non-academic Fellowship Programs will respect this timeline to allow for best program fit for candidates.

AIFA
Alliance of Industry Fellowship Associates

Connect with us on social media: @RutgersFellow

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Institute for Pharmaceutical Industry Fellowships

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For more information, please visit:

amgen.com
pharmafellows.rutgers.edu