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Dear Prospective Fellow,

On behalf of Amgen Global Regulatory Affairs and Safety (GRAAS) and Global Value Access & Policy (GVA&P), 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 a successful career 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 by your engagement as a pharmacist, a fellow, and a future industry professional.

Sincerely,

Steven Galson, MD, MPH, Senior Vice President, Amgen Global Regulatory Affairs and Safety
Mark Taisey, Vice President, Amgen Global Regulatory Affairs
Claes Hornstrand, Vice President, Amgen Global Value, Access, and Policy
At Amgen, we believe in a “biology first” approach. We use cutting-edge science and technology to study the subtest biological mechanisms in search of therapies that will improve the lives of those who suffer from disease. Amgen believes that the cure for disease can be found inside each and every one of us. So, to help people we must focus on people.

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.
INNOVATIVE RESEARCH

Understanding the fundamental biological mechanisms of human life 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 encourages 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. As advances in human genetics continue to shed new light on the molecular roots of disease, the Amgen subsidiary deCODE Genetics, a global leader in human genetics, along with our collaboration with Utah-based Intermountain Healthcare and partnership with the Whole Genome Sequencing Project, provide the potential to greatly improve 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.

The Global Regulatory Affairs and Safety (GRAAS), which includes Global Regulatory Affairs (GRA) and Global Patient Safety, and Global Value Access & Policy (GVA&P) organizations at Amgen have a lean and nimble operating model, 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.
At Amgen, Global Regulatory Affairs (GRA) is responsible for the design of regulatory strategies for the advancement and approval of our products. GRA colleagues develop strategies that leverage innovative clinical trial designs and expedited approval pathways to efficiently deliver our products to patients. GRA Fellows are embedded in our 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.

GRA 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 GRA 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. 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

“I have found working with our fellows to be a rich and rewarding experience. Amgen benefits from the fresh perspective the fellows bring to our project teams. Our fellows gain practical knowledge and develop skill sets through mentorship by experienced regulatory professionals and a work environment that encourages continuous learning and innovation. Fellows are given opportunities to make an immediate impact on programs and over time assume responsibility for increasingly complex initiatives. This program has been mutually beneficial to both our fellows and to Amgen, and I greatly enjoy my role as preceptor.”

Stephanie Hansen, PharmD
2019 - 2021 GRA Fellow
University of Utah

Jackie Kline, PhD
Executive Director, GRA Oncology
2019 - 2021 GRA Preceptor
The Global Regulatory Affairs and Safety (GRAAS) 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 Global Regulatory Affairs, Regulatory Policy, Global Patient Safety, Global CMC, and Global Labeling. 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 and safety.

Competency areas the fellow may develop include: safety surveillance, risk management, benefit-risk assessment, regulatory strategy, review and approval of labeling and promotional materials, and 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.

- **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 Labeling**: Responsible for bringing Amgen teams and business partners together to efficiently develop accurate, consistent, competitive, and quality information for healthcare professionals and patients.

- **Global Patient Safety**: Responsible for continuous evaluation of the safety profile of our products to optimize the safe use of Amgen products through continuous benefit/risk assessment and communication.

“With growing complexities of the global regulatory landscape, opportunities such as the Amgen GRAAS Fellowship are of tremendous value in developing talent to become future leaders in the biotech industry. Working alongside industry leaders at Amgen, GRAAS Fellows are immersed into a variety of experiences to help grow their knowledge and develop skill sets which may include strategizing global regulatory filings, interacting with health authorities, and supporting evaluation and communication of the safety profile of Amgen’s products. This diversity of experience provides fellows with a broad view of regulatory and safety activities enabling a big picture perspective and development of strategic thinking skills. It is an honor and a pleasure to serve as a preceptor for this Fellowship in supporting talented fellows and watching them grow and flourish in their careers.”
The joint Global Regulatory Affairs (GRA) and Global Value Access & Policy (GVA&P) 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 GRA and GVA&P organizations, and in the second half, the fellow will have the opportunity to design a program that would enable a career in either GRA or GVA&P 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 GRA and GVA&P. 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, global payer leads, as well as regional leads in both functions. The fellowship spans across 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 GRA or GVA&P functions upon completion of this 2-year fellowship program.

“Providing opportunities for the next generation of leaders to do hands-on and in-depth training in drug development is one of the most important responsibilities current leaders have in an R&D intensive area such as biotechnology. Since patient access and sustainability in healthcare costs is an important part of health systems, we are extremely lucky to have forged the partnership with Rutgers to provide the combined regulatory and access fellowship here at Amgen. We think that future leaders who cross train in key areas like regulatory and access will be that much better prepared to deal with the new complexities in providing healthcare in the US, and globally. And also, the incredibly talented and outgoing fellows we have challenge us to think in new ways and make me appreciate how much a diverse workforce contributes to cutting edge science.”
RUTGERS FELLOWSHIP ALUMNI AT AMGEN

Alex Lo, Marketing, Manager
Charles Dahm, Senior Medical Science Liaison
Chris Wang, Regulatory Promotion and Material Compliance, Senior Manager
Grace Patterson, Regulatory Promotion and Material Compliance, Manager
Kelly Velasco, Global Scientific Communications, Senior Manager
Malay Naik, Marketing, Manager
Maya Shehayeb, Manager, Medical Writing
Naomi Kozlowski, Regulatory Promotion and Material Compliance, Manager
Samantha Kaufman, Medical Communications, Manager
Shivani Gandhi, Global Regulatory Affairs, Senior Manager
Soraya Hassanpour, Global Regulatory Affairs, Manager
Stephanie Lock, Global Regulatory Affairs, Manager
Vicki Loh, Global Scientific Communications, Director
Vivian Lee, Regulatory Promotion and Material Compliance, Manager
RUTGERS PHARMACEUTICAL FELLOWSHIP PROGRAM

PROGRAM HISTORY

In 1984, at Rutgers, The State University of New Jersey, the Ernest Mario School of Pharmacy and two pharmaceutical companies began a 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 21 companies within the pharmaceutical and biopharmaceutical industries and over 200 fellows annually.

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, and scholarly activity; and
• arrange specialized fellowship training opportunities within the pharmaceutical and biopharmaceutical industries.

Recently in 2018, our program has 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 and Dr. Michael Toscani, Research Professor and the Director for the Institute for Pharmaceutical Industry Fellowships.

2019 RPIF Program Certificate

More than 1000 post-doctoral fellows have completed the RPIF Program, most of whom are pursuing influential and rewarding careers in the pharmaceutical and biopharmaceutical industries throughout the US and abroad. The RPIF Program has preceptors/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 industries and the fellow’s functional area.

PROFESSIONAL DEVELOPMENT SERIES

All fellows gather at Rutgers once or twice 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’ presentation skills, emotional intelligence, promote connectivity and a sense of community among fellows from different companies and disciplines, develop new skill sets under the guidance of external trainers, and provide general knowledge about various aspects of drug development and issues facing the pharmaceutical and biopharmaceutical industries.

The fellows learn from each other through individual and group presentations and debates on topics and issues related to the pharmaceutical and biopharmaceutical industries. This dynamic forum 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, and conflict resolution skills; giving and receiving feedback; and business and dining etiquette). Other PDD guest speakers include senior industry executives, patient advocacy groups, and successful RPIF Program alumni who share their 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.

2019 FELLOWSHIP CERTIFICATE DINNER

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KEY PROGRAM FEATURES
The Rutgers Pharmaceutical Industry Fellowship Program FOSTERs the growth and development of future pharmaceutical and biopharmaceutical industry professionals through the following key program features:

- Family of Leading Companies—Partners include several of the top 21 global pharmaceutical and biopharmaceutical companies
- Outstanding Alumni Track Record—Over 1000 alumni hold prominent positions at many leading companies
- Strong Network—Over 200 fellows each year develop valuable, lasting connections with each other, alumni, preceptors and faculty
- The Pathway to Industry—Since 1984, the Rutgers program has been nationally recognized, trusted, and proven as the pathway to industry for pharmacists
- Enhanced Career Path—Increasingly challenging assignments build depth of experience and enhance the potential for an accelerated career path
- Rigorous Academic Component—Rutgers affiliation provides academic and professional development opportunities

Rutgers, The State University of New Jersey, with approximately 70,875 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 is part of Rutgers Biomedical and Health Sciences, the only state school of pharmacy in New Jersey, with approximately 1,300 students in its Doctor of Pharmacy program. The Rutgers Ernest Mario School of Pharmacy is located on the University’s main science and technology campus in Piscataway, New Jersey. Because of its close proximity to the nation’s leading pharmaceutical and biopharmaceutical companies, the Ernest Mario School of Pharmacy and the RPIF Program are uniquely capable of providing fellows with advanced training in the pharmaceutical and biopharmaceutical industries.

APPLICATION PROCESS AND ELIGIBILITY REQUIREMENTS
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. Participation in the ASHP Midyear Clinical Meeting/PPS is strongly encouraged. Interested individuals may submit their application materials (curriculum vitae, three letters of recommendation and a letter of intent) beginning November 23, 2019 and complete a program interest form online by visiting our website at: pharmafellows.rutgers.edu

All application materials must be submitted electronically, and applicants are strongly encouraged to submit the above documents by December 1st.

Please address your Letter of Intent & Letters of Recommendation 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
GROW BEYOND

For more information, please visit:

amgen.com
pharmafellows.rutgers.edu