Novartis
Pharmaceutical Industry Fellowship Program 2020

Pharmaceutical Industry Fellowship Program 2020
Leadership | Tradition | Motivation
Development | Dedication

NOVARTIS
Message to Prospective Fellows

When I started my career as a Post-Doctoral fellow at Novartis, I was seeking a fulfilling career in an untraditional pharmacy setting. The Rutgers Pharmaceutical Industry Fellowship exposed me to unique opportunities, provided me with lifelong mentors, an incredible network of colleagues and allowed me to build the foundation for my career in the pharmaceutical industry. Through the years I have remained a strong advocate for the Rutgers Pharmaceutical Industry Fellowship as a key vehicle for accelerated professional development.

I can attest that the broad background possessed by a Pharm.D. graduate is highly valued in our industry – and certainly here at Novartis. Established in 1990, the Novartis Fellowship is one of the longest standing programs within the Rutgers family of fellowships with over 150 fellows completing the program, signifying its strength and longevity. Each year, we set out to find the “best and the brightest” among the nation's pharmacy doctoral programs.

Novartis fellows consistently demonstrate the drive, self-motivation, and eagerness to learn and succeed within the various disciplines we offer, including early clinical development/translational medicine, clinical development, regulatory affairs, medical affairs, and commercial strategy/brand marketing.

I am enthusiastic about your interest in Novartis and wish you the best of luck during the challenging interview and application process.

Rob Kowalski, Pharm.D.
Global Head Regulatory Affairs
US Head Development
Novartis
Fellow 1993–1995

Rob Kowalski was one of the first fellows in the original Sandoz fellowship program from 1993-1995. Rob attended the University of Wisconsin-Madison where he received both a Bachelor of Science in Pharmaceutical Sciences and a Doctorate in Pharmacy.

“The broad background possessed by a Pharm.D. graduate is highly valued in our industry – and certainly here at Novartis.”
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Our mission is to discover new ways to improve and extend people’s lives.

Our vision is to be a trusted leader in changing the practice of medicine.
Novartis Fellowship Program

Our Program

The first year of the fellowship is typically dedicated to one of the departments described in this brochure. In the second year, fellows have the option to remain in the same department or transfer to another group elsewhere within Novartis.

Specific fellowship opportunities within departments vary depending on the interests of prospective candidates as well as the needs of Novartis. In order to maximize their overall experience and to build a solid skill set, fellows may be presented with the opportunity to participate in special projects of interest. Fellows may also attend seminars and workshops designed to build professional skills such as time and project management, negotiation, and developing and delivering presentations.

Opportunities to take internal training classes are also available. Fellows may be eligible to attend medical and professional conferences where they may present posters, participate in scientific sessions for continuing education credit, and network with colleagues.

Novartis fellows have the opportunity to participate in a three-month rotation either within or outside of Novartis. A broad range of opportunities are available, including clinical rotations at a university affiliated hospital, the Ernest Mario School of Pharmacy, government agencies such as the US Food and Drug Administration or the National Institutes of Health, or other external vendors. Such rotations are structured to allow fellows to broaden their experience.
Objectives
During the two-year program at Novartis, the fellow will:

- Gain a comprehensive overview of key areas within the pharmaceutical industry through practical insights and experiences
- Expand clinical knowledge through participation in both industrial and academic programs
- Promote the role and value of a clinically trained pharmacist within the pharmaceutical industry
- Actively participate in specific areas of industry and academia through direct involvement in various projects and assignments
- Become highly marketable for employment opportunities within the pharmaceutical industry

Our name, derived from the Latin novae artes, means “new skills” and reflects our commitment to bringing new healthcare products to patients and physicians worldwide.

Watch videos to learn more about the program, culture and why Novartis is for you:

- Choosing Novartis for Your Fellowship
- Experiencing a High Energy Culture
- Building Your Professional Network
Who We Are

Our Purpose
We reimagine medicine to improve and extend people’s lives. We use innovative science and technology to address some of society’s most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible. We also aim to reward those who invest their money, time and ideas in our company.

Our People
The greatest strength of Novartis is our people, whose diversity, energy and creativity are crucial to our success.

<table>
<thead>
<tr>
<th>HEADCOUNT</th>
<th>NATIONALITIES</th>
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<p>| ANNUAL TRAINING        | WOMEN         |</p>
<table>
<thead>
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<th>HOURS PER EMPLOYEE</th>
<th>IN MANAGEMENT</th>
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<td>22.6</td>
<td>42%</td>
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Our Culture
Curious  
Inspired  
Unbossed  

Our Values
Innovation  
Quality  
Collaboration  
Performance  
Courage  
Integrity
Our Products and Reach
We develop and produce innovative medicines to address patient needs in disease areas where our experience and knowledge have the potential to produce transformative treatments.

We also offer about 1000 generic medicines and biosimilars covering major therapeutic areas. They can bring substantial savings to patients and healthcare systems, and help improve access to healthcare.

Novartis has adopted a single set of ethical principles that should be applied in daily decision-making by all Novartis associates.
Novartis Company Profile

Novartis provides healthcare solutions that address the evolving needs of patients and societies worldwide. Our current portfolio includes more than 50 key marketed products, many of which are leaders in their respective therapeutics areas, including: Cardiology, Dermatology, Immunology, Neuroscience, Oncology, Ophthalmology, and Respiratory.

Novartis Pharmaceuticals Corporation is headquartered in East Hanover, New Jersey, which is approximately 40 miles west of New York City. Novartis Pharmaceuticals Corporation represents the United States pharmaceutical business headquarters of the worldwide Swiss firm Novartis AG, which was formed in January 1997 following the merger of Ciba-Geigy Ltd. and Sandoz Ltd.

Sandoz is strategically positioned to reach one billion patients with a broad portfolio of complex generics, value-added medicines and biosimilars. We offer a broad line of generic medicines – the foundation of global healthcare systems, but we’re also discovering new ways to improve and extend people’s lives though our innovative off-patent medicines [505(b)(2)], and global leadership in biosimilars.

In constant currencies.

200 + Projects in clinical development

9.1 bn Research and development spend (USD)

24 m Patients reached through access programs

17 m People reached through health education programs

1 In constant currencies and for continuing operations.
**Major Prescription Products†**

**Cardio-Renal-Metabolic**
- Entresto™ (sacubitril and valsartan)
- Galvus® (vildagliptin)*

**Global Health**
- Coartem® (artemether and lumefantrine)
- Comtan® (entacapone)
- Diovan®/Diovan HCT® (valsartan/valsartan and hydrochlorothiazide)
- Exforge®/Exforge HCT® (amlodipine and valsartan/amlodipine, valsartan, hydrochlorothiazide)

**Immunology, Hepatology & Dermatology**
- Cosentyx™ (secukinumab)
- Egaten (triclabendazole)
- Ilaris® (canakinumab)
- Myfortic® (mycophenolic acid)
- Neoral® (cyclosporine)
- Simulect® (basiliximab)
- Zortress® (everolimus)

**Neuroscience**
- Aimovig™ (erenumab)
- Exelon®/Exelon® Patch (rivastigmine)
- Gilenya® (fingolimod)
- Mayzent (siponimod)
- Zolgensma (onasemnogene abeparvovec-xioi)

**Oncology**
- Afinitor® (everolimus)
- Arzerra® (ofatumumab)
- Exjade® (deferasirox)
- Farydak® (panobinostat)
- Femara® (letrozole)
- Gleevac® (imatinib mesylate)
- Kisqali® (ribociclib)
- Kymriah™ (tisagenlecleucel)
- Mekinist® (trametinib)
- Piqray® (alpelisib)
- Promacta® (eltrombopag)
- Rydapt® (midostaurin)
- Sandostatin® (octreotide acetate)
- Tafinlar® (dabrafenib)
- Tasigna® (nilotinib)
- Zometa® (zoledronic acid)
- Zykadia™ (ceritinib)

**Ophthalmology**
- Beovu® (brolucizumab-dbll)
- Illevro® (nepafenac)
- Lucentis® (ranibizumab)
- Nevanac® (nepafenac)
- Pazeo® (olopatadine)
- Simbrinza® (brinzolamide/brimonidine tartrate)
- Travatan Z® (travoprost)
- Xiidra® (lifitegrast)

**Respiratory**
- Arcapta™
- Neohaler™ (indacaterol)
- Xolair® (omalizumab)
- Arcapta™
- Neohaler™ (indacaterol)
- Xolair® (omalizumab)

*Product not approved in the US.
†For statement of complete indications, please consult full prescribing information at [www.pharma.us.novartis.com](http://www.pharma.us.novartis.com).
2019–2020 Novartis Fellowship Program Leadership

Directors

**Angela Browne**
Global Program Regulatory Director
Regulatory Affairs
Respiratory
*Pharm.D.*, Purdue University
*B.S. Pharmacy*, Purdue University
Fellow 1999–2001

**Kudsia Hafeez**
Global Program Executive Director
Cardio-Renal-Metabolic
*Pharm.D.*, Purdue University
Fellow 2001–2003

Fellowship Coordinator

**Ginny Manfredi**
Senior Administrative Assistant
Regulatory Affairs
Respiratory
Novartis Fellowship Program Leadership Team

The Novartis Fellowship Program Leadership Team is comprised of past fellows that work in partnership with preceptors to champion the fellowship experience. The Novartis group leaders are additional mentors that provide support, guidance and background for the fellows to maximize their experience at Novartis.

**Group Leaders**

**Charlene Hall**
Global Head, Cell & Gene Technical Services  
Technical Operations  
Cell & Gene Therapy  
*Pharm.D.*, University of Michigan  
Fellow 2000–2002

**Daniel Carreon**
Lead Clinical Trial Leader  
Translational Clinical Oncology – Clinical Operations  
Novartis Institute for Biomedical Research  
*Pharm.D.*, Western University of Health Sciences  
Fellow 2010-2012

**Jennifer Slade**
Global Franchise Head, Solid Tumors  
Scientific Engagement & Communications  
Medical Affairs, Oncology  
*Pharm.D.*, Purdue University  
Fellow 2000–2002
Group Leaders

Christy Siegel
VP, Respiratory Franchise Head
Novartis Pharmaceuticals Corporation
Pharm.D., Ernest Mario School of Pharmacy, Rutgers University
Fellow 2000–2001

Nina Gutman Katz
Global Program Regulatory Director
Regulatory Affairs
Oncology
Pharm.D., Ernest Mario School of Pharmacy, Rutgers University
Fellow 2007–2009

Lincy Thomas George
Global Therapeutic Area Lead
Regulatory Affairs
Oncology
Pharm.D., Ernest Mario School of Pharmacy, Rutgers University
M.B.A., Gabelli School of Business, Fordham University
Fellow 2003–2005
2019-2020 Novartis Fellowship Program

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Global Development

Group Leader

Charlene Hall
Global Head, Cell & Gene Technical Services
Technical Operations
Cell & Gene Therapy
Pharm.D., University of Michigan
Fellow 2000–2002

Overview

Global Development roles oversee the development of new medicines discovered by our researchers and partners. These roles drive breakthrough innovations to improve and extend the lives of patients.

“A Pharm.D. has the unique skill set to drive drug development from the lab to the patient.”
Global Development Overview

Global Clinical Development & Trial Management

Global Development and Trial Management fellows serve as key members of their trial teams, providing operational input to the study worldwide. In this role, fellows will:

• Support the conduct of global Phase II and III clinical trials with study startup, execution, and close-out activities.

• Collaborate with the Global Trial Director to coordinate activities with the Global Clinical Trials Teams to ensure goals are met for study timeline, budget, operational procedures, and quality standards.

• Assist the Global Trial Director with the development of study documents such as protocols, case report forms, and clinical study reports.

• Interact regularly with all members of the global clinical development teams and with other Novartis line functions (such as Drug Regulatory Affairs, Biostatistics, Data Management, Programming, Medical Writing, and Drug Supply Management) as a participant in the Global Clinical Trial Team.
Global Development Overview

Quantitative Safety & Epidemiology (Not recruiting)

Quantitative Safety & Epidemiology provides high quality scientific contributions to safety management teams to support decision making in all phases of the drug life-cycle by evaluating safety data and benefit-risk.

In this global role, the Pharmacoepidemiologist fellow will:

• Learn how to evaluate, understand, interpret, and communicate patient safety data from diverse sources but with focus on real world data and literature reviews.
• Plan, discuss and execute simple non-interventional studies.
• Prepare analyses used in product submissions, in response to Health Authority questions, in labeling updates and in regulatory documents such as Periodic Safety Update Reports (PSURs) and Risk Management Plans (RMPs).

Global Program Management (Not recruiting)

Global Program Management drive the planning and execution of drug development programs and provides the information the enterprise needs to make the right portfolio decisions. GPM associates enable the cross-functional Global Program Teams (GPTs) to deliver the pipeline with optimal strategies, realistic plans, and seamless execution.

GPM fellow will:

• Be assigned a GPT where they will support the team to develop and maintain accurate plans and documentations, ensure smooth day-to-day operations, and help to resolve program issues.
• Trained in the enterprise project management system and will participate in planning projects, identifying alternative development scenarios, integrating line function activities, challenging schedules, and monitoring implementations.
• Have the opportunity to experience drug development first-hand through the lens of a single program. They will have extensive matrix interactions across a wide range of disciplines with the line function members of the GPT and their colleagues.
Second Year Fellows

Joseph Fink
Global Development & Trial Management
Cardio Renal Metabolic
Pharm.D., Drake University
M.B.A., Drake University

Lauren Holmes
Global Development & Trial Management
Respiratory
Pharm.D., Drake University
M.B.A., Drake University
M.P.H., Des Moines University
B.S., Biochemistry & Biology, University of Northern Iowa

“From day one, Novartis fellows can start to gather more responsibilities and work towards being an independent leader and valuable contributor on their respective teams.”
First Year Fellows

**Tori Morgan**
Global Development & Trial Management  
Oncology  
*Pharm.D.*, Purdue University

**Katelyn Schad**
Global Development & Trial Management  
Neuroscience  
*Pharm.D.*, Saint Louis College of Pharmacy

**Daniel Dudman**
Quantitative Safety & Epidemiology  
*Pharm.D.*, Butler University  
*M.S.*, Butler University

**Jordan Haines**
Global Program Management  
Oncology  
*Pharm.D.*, MCPHS University  
*B.S.*, Biology, University of Hartford
Early Clinical Development

Group Leader

Daniel Carreon
Lead Clinical Trial Leader
Translational Clinical Oncology – Clinical Operations
Novartis Institute for Biomedical Research
Pharm.D., Western University of Health Sciences
Fellow 2010-2012

Overview

Translational Medicine (TM) and Pharmacokinetic (PK) Sciences (PKS) are part of the Novartis Institutes for BioMedical Research (NIBR), the research arm of Novartis, and support all phases of development; from discovery through post-marketing.

Fellowship opportunities are being offered in TCO (Translational Clinical Oncology) as well as PKS.

“Innovation, creativity and collaboration run deep within every line function at Novartis.”
Early Clinical Development Overview

**Translational Medicine:** Scientists and clinicians within TM Clinical Sciences & Innovation (TM CS&I) and Translational Clinical Oncology (TCO) are primarily responsible for designing and conducting early phase clinical trials that explore the safety, tolerability and initial assessment of efficacy in healthy volunteers and patients.

- **NIBR TCO:** Fellows will be trained as a Clinical Trial Leader, coordinating all aspects of a clinical trial, which may include: leading a clinical trial team, developing clinical study protocol(s), designing case report forms (CRFs) and informed consent documents, selecting and initiating clinical sites, reviewing safety data, conducting dose escalation meetings, reporting and interpreting study results as well as managing study timelines, drug supply, and study vendors.

- All NIBR Fellows may contribute to program-level activities, including the development of regulatory documents such as the Investigator’s Brochure, briefing documents, annual safety reports, regulatory submissions, study abstracts, posters and meeting presentations as opportunities arise.

- Fellows may have the opportunity to support or conduct one or more: first-in-human, proof-of-concept, dose-range finding, PK drug-interaction and/or mechanistic profiling studies for novel therapeutics.

**Clinical Pharmacology/PK Sciences**  
(Not recruiting)

PKS scientists work across the development spectrum and are engaged in the analysis, interpretation and reporting of pharmacokinetic (PK), pharmacodynamic (PD), toxicokinetic (TK) and immunogenicity data generated during discovery through late phase development.

- **NIBR PKS:** Fellows will be trained as a PK Scientist designing studies and analyzing PK/PD data generated across research and full development. Fellows will support project teams and will gain proficiency with key modeling and analysis software platforms, e.g. Phoenix, as well as expertise in clinical pharmacology and PK/TK study design. PKS Fellows will also gain expertise in global regulations guiding clinical pharmacology and biopharmaceutical development.
Second Year Fellow

Victoria Nesbitt
Translational Clinical Oncology
Pharm.D., Duquesne University
B.S., Pharmaceutical Sciences, Duquesne

First Year Fellows

Naomey Sarkis
Translational Clinical Oncology
Pharm.D., Philadelphia College of Pharmacy
B.S., Pharmaceutical and Healthcare Studies
Philadelphia College of Pharmacy

Jennifer Han
PK Sciences
Pharm.D., University at Buffalo School of Pharmacy
M.S., University at Buffalo School of Pharmaceutical Sciences,
B.S., Nutrition Science, University of Georgia

“Being able to work with and learn from team members from multiple functional areas while striving towards a shared vision of helping patients is a truly rewarding experience.”
“Pharm.D. fellows are able to apply their vast scientific knowledge in clinical development to meet unmet medical needs.”
Commercial

Group Leader

Christy Siegel
VP, Respiratory Franchise Head
Novartis Pharmaceuticals Corporation
Pharm.D., Ernest Mario School of Pharmacy, Rutgers University
Fellow 2000-2001

Overview

The fellow works in cross-functional disease areas or brand teams that drive US Pharma strategy and growth. The primary objective is to deliver commercially meaningful brands to the US, providing recommendations to maximize US market opportunities including shaping Phase II and Phase III development programs, optimizing product profiles for successful launch and delivering on brand strategies to drive growth of Novartis promoted products.

“Novartis offers a dynamic commercial experience with opportunities to work on product launches and learn from seasoned employees.”
Commercial Fellowship Overview

• Drive development of pipeline products through deliverables including situation analysis, options assessment, patient journey, target product profile, forecast and launch readiness plans.

• Participate in evaluation of business development and licensing opportunities, including scientific/clinical and commercial assessments and participate in due diligence of select opportunities.

• Develop, implement, and execute brand strategy, marketing mix and operational plans that optimize sales, market share and revenue growth for the short and long term.

• Engage with marketing training, field force operations, and field training to enable our brands to achieve their strategic objectives to help patients with access.
Second Year Fellows

Kurtis Lee
Marketing
Oncology
Pharm.D., University of Michigan
B.S. Biological Sciences, University of California, Irvine

Andrew Van Deusen
Commercial
New Products, Business Development & Licensing
Pharm.D., University of Charleston School of Pharmacy
B.S. Pharmaceutical Sciences, Ohio State University

First Year Fellow

Jacob Tebbe
Commercial Launch Excellence
U.S. General Medicine
Pharm.D., Purdue University

“Mentorship, support, and professional growth. These are words I would use to describe the Novartis Fellowship Program.”
Medical Affairs

Group Leader

Jennifer Slade
Global Franchise Head, Solid Tumors
Scientific Engagement & Communications
Medical Affairs, Oncology
Pharm.D., Purdue University
Fellow 2000-2002

Overview

As part of the Medical Affairs umbrella of disciplines, Scientific Communications, Medical Information, and Field Medical work together to provide an integrated medical communication platform for Novartis. Fellowship opportunities in Medical Affairs can include positions in the Novartis divisions of Pharmaceuticals and Oncology in both the US and Global functions.

Individual Fellowship Role Descriptions

Scientific Communications is responsible for developing and disseminating scientific information on Novartis products through publications, medical education, and medical expert management.

- In this role, the fellow will have the opportunity to develop and execute the global publication plan, medical education curriculum, and driving congress strategy. The fellow will be responsible for the accuracy and quality of scientific content of manuscripts, abstracts, posters and presentations of clinical data. In addition, the fellow will develop internal medical communications and training.

MSL Strategy focuses on developing and executing filed medical strategic and tactical plans.

- In this role, the fellow will support global MSLs by creating MSL resources (e.g. slide decks, FAQs), scientific communication platform, internal communications and will lead global MSL team discussions to gather external HCP feedback. The fellow will also be responsible for the medical training curriculum for defined product(s) and related disease states.

Field Medical (MSL) is responsible for establishing and maintaining relationships with healthcare professionals by engaging in scientific discussions regarding Novartis products, therapeutic areas of interest, and sponsored research.

- In US Field Medical, the fellow will have the opportunity to develop internal medical resources and conduct field medical training for the US field medical team. During the second year of the program, the fellow will be assigned a territory to engage healthcare professionals in the field. medical training curriculum for defined product(s) and related disease states.
Medical Information is responsible for using scientific information to develop medical literature and drug information databases to research, evaluate, and develop evidence-based medical content for sub countries and regions to manage healthcare professional and customer interactions. The fellow will also be responsible for congress planning including HCP engagement, medical booth staffing and congress debriefs.

- In this role, the fellow will have the opportunity to develop high quality (relevant, rigorous, balanced) medical information documents for healthcare customers in response to unsolicited inquiries about Novartis products.

Regulatory Advertising & Promotion (A&P) is responsible for ensuring company communications promoting its products are consistent with laws and regulations which govern the promotion of prescription drugs in the US, as well as company policies and procedures related to these activities.

- In this role, the fellow will learn about the principles which inform US prescription drug promotional rules. In addition, the fellow will meet with multi-disciplinary teams who review proposed promotional materials, and will have the opportunity to provide regulatory guidance and inform business strategy on proposed promotional materials. The fellow will also review scientific, non-promotional materials for use by medical affairs associates.

- In this unique role, the fellow will complete one year in Medical Information & Communications and one year in Regulatory A&P.
Sandoz Medical Affairs Fellowship
(Not recruiting)

The various roles within Medical Affairs, Field Medical and Medical Services & Operations work collaboratively together to provide an educational communication platform for HCPs. This two-year fellowship within Sandoz Medical Affairs will provide the fellow an opportunity to learn the fundamental role of Medical Science Liaison and various areas under Medical Services & Operations team.

Medical Services & Operations
- Responsible for supporting key Medical Services such as Medical Information, Medical Education, Medical Communications as well as project management/operational needs for Medical Affairs
- Help develop medical information standard response letters to frequently asked questions and shadow the real-time medical information process
- Support the needs assessments and knowledge gaps for HCPs in several therapeutic areas and the process for reviewing and approving independent medical education grants
- Participate in medical reviews for promotional and non-promotional material, and launch planning
- Gain exposure to investigator-initiated trials (IITs) and engage with global stakeholders to assess areas where we can enhance alignment and communications regarding US IITs

Field Medical
Field Medical is responsible for interactions with healthcare practitioners providing scientific and clinical education regarding biosimilars and other Sandoz products.

- Develop relationships with HCPs (academic and non-academic physicians, nurse practitioners, registered nurses and physician assistants) to ensure that there is access to current medical and scientific information
- Shadow both with MSL team and Medical Account Management and Strategic Alliance team, with attendance at national and regional meetings, participation in national and regional teleconferences
- Development of KOL engagement strategy
- Support compendium and guideline submissions
Second Year Fellows

Asia Cook
Global Medical Information, U.S. Oncology Medical Information & Medical Science Liaison, Oncology
Pharm.D., Florida A & M University College of Pharmacy & Pharmaceutical Sciences
B.S., Biology, Albany State University

Francesca Francois
Medical Affairs
Global Scientific Oncology Communications
Pharm.D., Florida A & M University College of Pharmacy & Pharmaceutical Sciences,
M.P.H., Epidemiology, Florida International University
B.S., Health Education & Behavior, University of Florida

Akshay Patel
Regulatory Advertising & Promotion
Pharm.D., Ernest Mario School of Pharmacy,
Rutgers University

Alan Ross
U.S. Field Medical
Respiratory
Pharm.D., University of Tennessee College of Pharmacy
M.B.A., University of Memphis
B.S., Biochemistry, Middle Tennessee State University

Michael Severo
Scientific Communications
U.S. Oncology Medical, Scientific Affairs
Pharm.D., Philadelphia College of Pharmacy
B.S., Pharmaceutical & Healthcare Studies, Philadelphia
First Year Fellows

Cole Cecchini
U.S. Medical Information
U.S. CDMA
*Pharm.D.*, Temple University
*B.S.*, Biology, University of Alabama

Christopher Oh
Medical Affairs
Policy, Medical & External Engagement
Sandoz
*Pharm.D.*, University of Illinois, Chicago
*B.A.*, Biology, Northwestern University

Yasha Patel
U.S. Oncology Medical Information & Global Oncology
Medical Science Liaison Strategy
*Pharm.D.*, Ernest Mario School of Pharmacy, Rutgers University
*B.A.*, Cell Biology & Neuroscience, Rutgers University

“The industry is a place of hope, innovation, and growth, the products we work with save and improve the quality of people’s lives to make a difference to society.”
Regulatory Affairs

Group Leaders

**Nina Gutman Katz**
Global Program Regulatory Director
Regulatory Affairs
Oncology
*Pharm.D.*, Ernest Mario School of Pharmacy,
Rutgers University
Fellow 2007–2009

**Lincy Thomas George**
Global Therapeutic Area Lead
Regulatory Affairs
Oncology
*Pharm.D.*, Ernest Mario School of Pharmacy,
Rutgers University
*M.B.A.*, Gabelli School of Business, Fordham University
Fellow 2003–2005

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Overview

Three distinct Regulatory Affairs fellowship opportunities are offered: Regulatory Affairs Strategy, Regulatory Affairs Global Labeling, and Regulatory Affairs Chemistry, Manufacturing and Controls (CMC). In these roles, fellows will liaise with global cross-functional teams to provide strategic inputs to support product development, original registration and life cycle maintenance activities.

“The program at Novartis focuses on building a solid foundation with the goal of making a smooth transition to a successful career at Novartis after the fellowship.”
Regulatory Affairs Strategy

• Serve as the primary liaison with Health Authorities worldwide (e.g., the US Food and Drug Administration) for regulatory activities and submissions
• Provide strategic input and tactical support to expedite the development, submission and regulatory approval of new products
• Submit and maintain regulatory applications (e.g., Investigational New Drugs [INDs], New Drug Applications [NDAs], Biologics License Applications [BLAs], Clinical Trial Applications [CTAs], Marketing Authorization Applications [MAAs], 505(b)(2) NDAs, Abbreviated NDAs [ANDAs], and 351(k) biosimilar applications)

Regulatory Affairs Global Labeling

• Lead global, cross-functional teams in defining and setting labeling strategy for development programs and marketed products
• Create and maintain regulatory compliant, competitive, and up-to-date labeling documents
• Guide and support Country Organizations worldwide in the local implementation of labeling, including preparation of responses to labeling-related questions from Health Authorities

Regulatory CMC

• Serve as a liaison between Novartis and Health Authorities worldwide (e.g. the US FDA) for regulatory activities and submissions on CMC topics
• Develop CMC regulatory strategies specific to the manufacturing, testing and packaging for global products covering a variety of dosage forms in small molecule, biologic, cell and gene therapy, and/or biosimilar products, on a rotating basis
• Lead planning and preparation of global CMC regulatory documents for submissions covering different stages of product development and life cycle management (INDs, NDAs, BLAs, CTAs, MAAs, and post-approval change submissions)
Sandoz Regulatory Affairs Fellowship

The Sandoz Regulatory Affairs fellowship is designed to provide the fellow with an opportunity to develop core competencies and obtain knowledge and skills necessary to become proficient and confident in the practice of Regulatory Affairs in both the small molecule generic space (one year) as well as the biosimilar space (one year).

Overview

- Serve as the primary liaison between Sandoz and Health Authorities worldwide (e.g. the US Food and Drug Administration) for regulatory activities and submissions
- Provide strategic input and tactical support to expedite the submission and regulatory approval of generic drugs and biosimilar medicines
- Review, organize, and interpret Chemistry, Manufacturing, and Controls (CMC) information and data for regulatory submissions
- Submit and maintain 505(b)(2) New Drug Applications (NDAs), abbreviated NDAs (ANDAs), and 351(k) biosimilar applications
- Provide strategic input on product labeling
- Review global advertising and promotional materials

Sandoz contributes to society’s ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine.
“The program at Novartis focuses on building a solid foundation with the goal of making a smooth transition to a successful career at Novartis after the fellowship.”
Second Year Fellows

**Ryan Conway**
Regulatory Affairs  
Neuroscience  
*Pharm.D.*, Ernest Mario School of Pharmacy, Rutgers University

**Carolyn Zhu**
Regulatory Affairs  
Oncology  
*Pharm.D.*, Ernest Mario School of Pharmacy, Rutgers University

“The fellowship has given me the opportunity to participate in strategic regulatory and cross-functional discussions, both at a US and global level.”
First Year Fellows

**Brianna Devitt**
Regulatory Affairs
Oncology
*Pharm.D.*, Ernest Mario School of Pharmacy, Rutgers University

**Joanna McCormack**
Regulatory Affairs
Respiratory
*Pharm.D.*, MCPHS University

**June Wie**
Regulatory Affairs
Global Health
*Pharm.D.*, Philadelphia College of Pharmacy
*B.S.*, Pharmaceutical and Healthcare Studies, Philadelphia College of Pharmacy

**Boning Zhao**
Regulatory Affairs
Cardio Renal Metabolic
*Pharm.D.*, Ernest Mario School of Pharmacy, Rutgers University

**George Shyu**
Regulatory Affairs
CMC
*Pharm.D.*, University of Connecticut School of Pharmacy
*B.S.*, Animal Biotechnology, Rutgers University
At Novartis, we are reimagining medicine.
Novartis Fellowship Program Alumni

1990–1992
Mark Ammann
John Gladish
1991–1993
Irene Laurora
Bruce Robbins
1992–1994
Joseph Cordaro
1993–1995
Tracy Acker
Robert Kowalski
Sheri Thornberg
1994–1996
Veronica Valvano
Benedetto
Beth Keibler
Taunia Markvicka
1995–1997
Michele Pongowski
Ball
John Messina
1996–1998
Latifa Alladina
Branka Kowalski
Patricia Ledford
James Rawls
1997–1999
Soma Gupta
Sausanne Khalilieh
Lisa Kutney
Henry Owunna
Maria Pryor
Katenka Svendsen
Schumm
1998–2000
Kelley Piper Bradley
Kimberly Chappell
Lisa Malaty Ghaly
Lisa Pitt
Angela Sansone
Jane Chong Shen
Sheri Dranzo Siegel
1999–2001
Angela Browne
Kay Chitale
Shamita Gupta
Fonda Chen Liu
John Martin
Mendy McGuire
Scott Moren
Maria Moricz
Deepa Patel
Asli (Guven) Santos
Michelle Stolpman
Tsai
2000–2002
Bryan Campbell
Bonnie Lieberman
Ariel Mihic
Lillian Ng
Monil Shah
Jennifer (Stolk) Slade
Charlene (So) Hall
Susan Trieu
Andrea Viegas
2001–2003
Kevin Carl
Kimberly Dickerson
Kudsia Haefeez
Angela Liu
Ayanna (Abadie) Osso
Ram Palanki
Gar Park
Rick Satitpunwaycha
2002–2004
Telly Chi
Joseph A. Chiodo III
Darin Curtiss
Vanessa Foti Trainor
Celena Kwong
Laura B. Munir
Dat Nguyen
Alan Slade
Stephanie Tallon
Theresa Valdez
2003–2005
Payman Darouian
Harinder Dhillon
Michael Lu
Melissa (Pao) Mitchener
Stephen Mitchener
Todd Phillips
Lincy Thomas George
Lotus Yung
2004–2006
Ira Do
Aaron Huang
Michelle Libner
Erika Massenburg
Felice Peng
Emily Scalise
Bijal Sheth
Lucio Volino
2005–2007
Amena Ali
Chyrin (Buu) Chung
Andy Hwang
Glendolyn Johnson
Amy (Patel) Shah
2006–2008
Melina Cioffi
Kathy Dong
Vanessa Kan
Suzanne Maahs
Melody M. Lee
Dale Nepert
Leslie Servidio
Chris Sung
Stephanie Whalen
2007–2009
Jonelle Chapman
Nina Gutman Katz
Shilpa Kurpad
John Noh
Kanan Solanki
Myah Tran
Bryan Zembrowski

There is an extensive network of past fellows from Novartis working at the company and across the pharmaceutical industry.
2008–2010
Shazia Ali
Lyh Ping Lam
Vickie Laurent
Samuel Lee
Christopher Morrison
Dalal Nesheiwat
Hannah Mosca

2009–2011
Mercy Mathew
Abraham
Katherine Carter
Brian Manning
Kimberly Mazzarisi Colligan
Bijal Pandhi
Puja (Patel) Geist
Arshdeep Pooni
Jessica Wang

2010–2012
Narin Ahmed
Daniel Carreon
Dannis Chang
Breanne Donohue
Farah N. Hossain
Nickie Gallaher
Drea Pangilinan
Manisha Patel
Jiten Rana
Therese Swan
Alex Wang

2011–2013
Robert Boothroyd
Phillip Koo
Doris Lo
TanTan (Liza) Ng
Demetre Stamatis
Allison Upalawanna

2012–2014
Madhuri Dhawan
Director, Oncology
Search & Evaluation
BMS
Beth Drimalla
Director, Strategic Market Access
Novartis

Melissa Kuhn
Clinical Scientist
Product Development
Oncology
Genentech

Jeremy Lim
Senior Clinical Scientist, Early Clinical Development
Genentech

Melissa Neighbors
Regulatory Affair Professional, Independent Consultant

Joanne Nguyen
Medical Science Liaison
Cardiovascular
Boehringer Ingelheim

Michelle Pernice
Senior Director, Head of Regulatory Affairs
Dynavax

Lincoln Rogers
Assistant Scientific Director, Oncology
AbbVie

Marilyn Tsourounis
Director
Oncology
Regulatory Affairs
AstraZeneca

2013–2015
Jenna Konkel
Director, Field Medical, Migraine
Novartis
Lisa Krueger
Manager, Global Regulatory Affairs
AbbVie

Brigette Nezami
US Oncology
Scientific Communications
Novartis

Tuong Vi Nguyen
Clinical Research Scientist
Celgene

Hetal Pansuria
Director of Regulatory Affairs, Pacira Pharmaceuticals

Jennifer Poon
Associate Director, Global Regulatory Affairs
Ascentage Pharma

Maryam Shirmohamadali
Oncology Global Clinical Operations
Genentech

Matt Temer
Clinical Trial Manager
Gilead Sciences

Iris Wang
Associate Director, Precision Medicine
Medical Affairs
Novartis

2014–2016
Geetha Pudussery
Associate Director, Clinical Development
Ovid Therapeutics
Viraj Degaonkar
Clinical Scientist Associate
Genentech
Ashley Brower
Global Program Regulatory Manager
Novartis
Naomi Kozlowski
US Lead Regulatory Affairs
Amgen
Anisha Baghat
Associate Director, Medical Affairs
Intercept Pharmaceuticals
Julia Hautmann
MSL Respiratory
Sanofi Genzyme
Priya Ramachandran
Director, Field Medical, Oncology
Pfizer
<table>
<thead>
<tr>
<th>Year</th>
<th>Name</th>
<th>Role</th>
<th>Company</th>
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<tbody>
<tr>
<td>2015-2017</td>
<td>Kate Bender</td>
<td>Manager, Global Scientific Communications</td>
<td>Novartis</td>
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<tr>
<td></td>
<td>Alexandra Hendzel</td>
<td>Senior Regulatory Manager</td>
<td>Novartis</td>
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<tr>
<td></td>
<td>Rashaad Joseph</td>
<td>Associate Director, Global Scientific Communications</td>
<td>Novartis</td>
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<td></td>
<td>Ramya Mathew</td>
<td>Associate Director, Global MSL Strategy and Medical Information</td>
<td>Novartis</td>
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<td></td>
<td>Rubin Modi</td>
<td>Senior Manager, Global Regulatory Affairs</td>
<td>Celgene</td>
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<td></td>
<td>Zachary Post</td>
<td>Associate Director, MSL, Immunology/Dermatology</td>
<td>Novartis</td>
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<td></td>
<td>Dean Wetty</td>
<td>Early Development Regulatory Manager</td>
<td>NIBR</td>
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<td>2016-2018</td>
<td>Jake Myhill</td>
<td>Manager, Global Program Regulatory</td>
<td>Novartis</td>
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<td>Yekatsiaryna</td>
<td>Kastsetskaya Manager, Global Program Regulatory</td>
<td>Novartis</td>
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<td>Amanda Bright</td>
<td>Manager, Global Program Regulatory</td>
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<td>Mona Fassihi</td>
<td>Manager, Global Program Regulatory</td>
<td>Novartis</td>
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<td>Nehali Parikh</td>
<td>Manager, Global Program Regulatory</td>
<td>Novartis</td>
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<td>Pamela Gorczyca</td>
<td>Associate Director, Global Oncology Scientific Communications</td>
<td>Novartis</td>
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<tr>
<td>2017-2019</td>
<td>Gunjan Patel</td>
<td>Associate Director, Global Scientific Communications</td>
<td>Novartis</td>
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<tr>
<td></td>
<td>Galina Perel</td>
<td>Medical Science Liaison</td>
<td>Teva Pharmaceuticals</td>
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<td></td>
<td>Joe Britt</td>
<td>Medical Science Liaison, Neuroscience BestMSLs</td>
<td>Novartis</td>
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<tr>
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<td>Natalia Ceacovscaia</td>
<td>Associate Director, Early Clinical Development, Oncology</td>
<td>AstraZeneca</td>
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<td>Clarice Lee</td>
<td>Director, Clinical Development</td>
<td>Neurogene Inc.</td>
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<td></td>
<td>Sapna Chhagan</td>
<td>Clinical Trial Lead, Translational Clinical Oncology</td>
<td>Novartis</td>
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<td></td>
<td>Sharon Cross</td>
<td>Clinical Trial Manager, Oncology</td>
<td>H3 Biomedicine</td>
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<td>Austin Ferrara</td>
<td>Manager, Global Program Regulatory</td>
<td>Novartis</td>
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<td>Nate Fons</td>
<td>Manager, Global Program Regulatory</td>
<td>Novartis</td>
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<td></td>
<td>Meghan Kelly</td>
<td>Medical Science Liaison, Rheumatology</td>
<td>Novartis</td>
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<td></td>
<td>Heena Mavani</td>
<td>Medical Science Liaison, Oncology</td>
<td>Janssen</td>
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<tr>
<td></td>
<td>Shivani Shah</td>
<td>Manager, Global Program Regulatory</td>
<td>Novartis</td>
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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 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.
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:

**F** of Leading Companies — Partners include several of the top 21 global pharmaceutical and biopharmaceutical companies.

**O** utstanding Alumni Track Record — Over 1000 alumni hold prominent positions at many leading companies.

**S** trong Network — Over 200 fellows each year develop valuable, lasting connections with each other, alumni, preceptors and faculty.

**T** he Pathway to Industry — Since 1984, the Rutgers program has been nationally recognized, trusted, and proven as the pathway to industry for pharmacists.

**E** nhanced Career Path — Increasingly challenging assignments build depth of experience and enhance the potential for an accelerated career path.

**R** igorous 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 only be submitted electronically, and applicants are strongly encouraged to submit the above documents by December 1st.

Please address your Letter of Intent and 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