

Boehringer Ingelheim Pharmaceuticals, Inc.

2024-2026 Postdoctoral Fellowship Program

















About Boehringer Ingelheim

The pharmaceutical company Boehringer Ingelheim Pharmaceuticals was founded in 1885 by Albert Boehringer (1861-1939) in Ingelheim, Germany. From its humble beginnings in 1885, when it employed just 28 people in Nieder-Ingelheim, it has grown to become the largest private pharmaceutical enterprise.

Boehringer Ingelheim was established in the United States in 1971. Our U.S. headquarters are based in Ridgefield, Connecticut, with 10 additional locations throughout the United States.

People with Purpose

At Boehringer Ingelheim, we recognize that our strength and competitive advantage are, in part, the result of our commitment to sustaining an organization that encourages diversity in all aspects of the business, whether that be in the diversity of the background of our employees, of thoughts and ideas, or in the diversity of our partners and suppliers.

The commitment, competence, and creative power of our people, sustained for well over a century, have made Boehringer Ingelheim a first-class, fast-growing pharmaceutical corporation. This is reflected in the energy and innovation of approximately 52,000 employees worldwide.

We offer our employees demanding and challenging tasks, and the appropriate opportunities for development and career advancement at national and international levels.

Boehringer Ingelheim Worldwide



Value through Innovation

As a privately-held pharmaceutical company, Boehringer Ingelheim is focused on science that leads to more health for our patients and their families. The discovery and development of innovative medicines is fundamental to our continued growth and success. Our blueprint for innovation is tailored to accelerate the delivery of breakthrough medicines to the patients we serve by integrating research pre-clinical and early clinical development, translational medicine, and external partnering functions. This fusion of expertise combined with a dynamic research approach and an increased emphasis on external collaborations means we can effectively incubate the most creative ideas and be among the pioneers in emerging fields of medicine.

The cornerstone of our research into new medicines is focused on those disease areas where we have built significant expertise over time. We are concentrating our research efforts and investment in these key therapeutic areas:

Our Areas of Research & Development:

- · Cardio-Renal-Metabolic disease
- Central Nervous System disease
- Immunology and Respiratory diseases
- Oncology and Cancer Immunology
- Retinal Health

A Culture of Responsibility & Commitment

At Boehringer Ingelheim, we recognize that we are part of a global community, and our family of employees feels strongly about partnering with organizations to improve it.

The ethical principles that have guided Boehringer Ingelheim for more than 130 years have created a culture of corporate social responsibility and commitment.

Through the Boehringer Ingelheim Cares Foundation, we offer programs that strengthen our communities, including:

- Patient Assistance Program
- Global Product Donation Program
- Financial Contributions Program
- Employee Skills-Based Volunteer Program

Our mission is to help patients, serve our customers, and produce innovative research and scientific advancements to impact the millions of people who rely on us. Simply put, we are committed to doing the right thing—for our patients, our customers, our communities, our employees, and everyone we serve.



Executive Sponsor Message to Prospective Fellows





Lennart Jungersten MD, PhD Senior Vice President Medicine and Regulatory Affairs

"The fellowship is a unique way to acquire a deeper understanding of various aspects of the pharmaceutical industry with valuable hands-on experiences. Boehringer Ingelheim is a family-owned global company allowing Fellows the chance to gain exposure to diverse markets and cultures. As the Sponsor of the fellowship program, I am proud of all the professionals who work hard to provide our Fellows with comprehensive training and mentorship throughout the program. Our Fellows are equipped with the necessary skills and knowledge to make meaningful contributions and help provide solutions to patients in need early in their careers. Graduates from the Boehringer Ingelheim Fellowship Program have a track record of successful careers and have access to various opportunities for further professional growth and development within the organization."













Medical Affairs and Scientific Communications Fellowship Program

Boehringer Ingelheim is proud to offer a 2-year, rotation-based, Fellowship program within Clinical Development and Medical Affairs (CDMA). This design provides pharmacists with broad U.S. Medical Affairs exposure. The program will allow Fellows to develop the competencies necessary to engage in comprehensive Medical activities within CDMA. Fellows will be based at Boehringer Ingelheim's U.S. headquarters in Ridgefield, CT and will complete 9-months each in Medical Affairs and Scientific Communications (MASC). Additionally, Fellows will complete 6 months of elective rotational experiences in one or more areas outside of CDMA through which they will gain an understanding of the broad range of opportunities available within the pharmaceutical industry.

Medical Strategy

As part of their experience, Fellows will:

- Actively participate in therapeutic area development, execution, and strategic alignment of U.S. Medical and brand tactics
- Develop cross-functional project management skills by partnering with internal and external stakeholders to support U.S. Medical Information and Publication teams
- Gain experience in planning and executing advisory board meetings and engaging Key External Experts (KEEs)
- Develop educational materials, train internal Medical team members, and disseminate data from scientific manuscripts, congresses, etc.
- Collaborate cross-functionally with internal and external colleagues to plan and implement educational programs at national conferences
- Participate in the medical review of promotional and non-promotional materials as part of a multidisciplinary team

Scientific Communications

As part of their experience, Fellows will:

- Provide complete, accurate, balanced and referenced responses to medical information inquiries from healthcare professionals and patients
- Maintain a comprehensive product response database as well as contribute to the development of managed care formulary dossiers
- Conduct tailored product trainings that meet the needs of diverse audiences (e.g., Call Center personnel, field-based representatives)
- Participate in the medical review of promotional and non-promotional materials as part of a multidisciplinary team (e.g., Grant Review Committees, Human Pharma Review Committees)
- Contribute to the strategy and development of publications for major journal manuscripts, Congress posters and presentations
- Collaborate with Medical Strategy for the review of Investigator-Initiated Studies (IIS) and Independent Medical Education proposals





Medical Affairs and Scientific Communications Fellowship Program

Rotational Experiences

The Fellow will have an opportunity to participate in rotational experiences with other departments.

Potential electives include, but are not limited to:

- Field-Based Medicine
- Health Economics and Outcomes Research
- Market Research
- Marketing/Commercial
- Medical Education
- Patient Advocacy
- Publications
- Regulatory Affairs
- Trade Relations

Other rotations can be arranged based on availability and interest of the Fellow.

Fellows will also gain numerous development opportunities by:

- Leading and executing a longitudinal research project to improve medical processes and presenting the outcomes at a national medical conference
- Enhancing leadership and management skills by precepting Advanced Pharmacy Practice Experience students
- Gaining an understanding of corporate structure, regulatory considerations and the drug development process
- Networking across Boehringer Ingelheim to learn about various opportunities in the pharmaceutical industry and participating in skills-based volunteerism



*Elective rotations based on availability













Clinical Development & Operations (CD&O) Fellowship Program

Boehringer Ingelheim's Clinical Development & Operations Fellowship is a 2-year program designed to provide pharmacists with an understanding of the clinical development of investigational medicinal products and in particular how Clinical Trials are conducted. The Fellow will be based in Study Management and Conduct and will work closely with an experienced Clinical Trial Manager (CTM) and/or Clinical Trial Leader (CTL). The Fellow will gain an understanding of the history of drug development, the U.S. Code of Federal Regulations, ICH/CGP guidelines and have the opportunity to:

- Work collaboratively as part of a local or global clinical trial team
- Develop and maintain relationships with internal and external partners, including investigational sites
- Identify and correct operational issues and provide periodic study updates to management
- Actively support Trial Preparation, Trial Conduct, Trial Closeout, and Reporting (e.g. investigational site selection, maintain study oversight, project management of trial, Investigator Meeting preparation and presentation)
- May assist in study vendor budget review, contract finalization, invoice approval and budget reconciliation.
- Responsible for timely, complete and compliant archiving of all relevant global documents for the Trial Master File (TMF) and Clinical Trial Report (CTR) Appendices.

Rotational Experiences

The Fellow will have an opportunity to participate in multiple rotations with other Boehringer Ingelheim departments, including but not limited to:

- Business Operations
- Site Planning and Optimization
- Site Management & Monitoring
- Clinical Contracting & Vendor Management

Other rotations can be arranged based on availability and interest of the fellow.













Clinical Pharmacology Fellowship Program

Boehringer Ingelheim is proud to offer a 2-year fellowship program within Translational Medicine & Clinical Pharmacology. Fellows will initially work under the guidance of a Clinical Pharmacology Lead (CPhL) to provide required clinical pharmacology inputs on drug development projects. The successful candidate will have a strong grasp of clinical pharmacology principles and quantitative pharmacology skills with hands-on experience in the implementation of common software tools (e.g., Phoenix) for pharmacology analyses.

As part of their experience, Fellows will:

- Develop a sound understanding and application of global regulatory guidance (e.g., FDA, EMA, PMDA)
 that are essential in designing drug development strategy
- Design the clinical pharmacology aspects of the clinical trial protocol (trials in healthy volunteers/patients) as well as analyze and interpret Clinical PK/PD results (e.g., food effect study, drugdrug interaction study, formulation bridging study, single rising dose study)
- Create clinical pharmacology sections of documents such as clinical trial protocols, clinical trial reports, investigator brochure, and response to authority requests
- Undertake a review of literature to find solutions to scientific challenges and to design clinical trial/project strategies
- Present internally as well as externally (for instance, presentation at professional clinical pharmacology meetings) and coauthor scientific manuscripts depending on project needs













Regulatory Affairs Fellowship Program

Boehringer Ingelheim is proud to offer five 2-year fellowship positions within Regulatory Affairs. The 2-year Regulatory Affairs program will allow the Fellows to obtain in-depth and hands-on experience in Product Strategy, Labeling, Chemistry, Manufacturing, and Controls (CMC), Policy & Intelligence, or Advertising and Promotion. The Fellows will be essential contributors to the various regulatory activities within, and interactions on behalf of, Boehringer Ingelheim. Upon completion of the program, the Fellows will have gained the technical and strategic capabilities to begin a career in the dynamic field of Regulatory Affairs.

The Product Strategy Fellow will:

- Participate in Regulatory Affairs sub-teams to assist the U.S. Regional Regulatory Lead and Global Regulatory Lead in providing strategic input to cross-functional product teams to aid in the successful development, registration, and commercialization of products in all phases of development
- Gain exposure to the strategy for interactions with health authorities, including preparation for FDA meetings and responses to information requests
- Develop proficiency in the critical evaluation of evolving regulatory trends in order to assess impact on drug development activities and development strategies
- Gain an understanding of the applicable FDA regulations and guidance related to the development of prescription drug labeling, as well as advertising and promotional labeling materials
- Coordinate submissions to FDA as appropriate including but not limited to investigational new drug applications, annual reports, general FDA correspondence and amendments
- Lead and execute a longitudinal research project or major submission within Regulatory Affairs

The Labeling Fellow will:

- Chair meetings of the Product Label Review Teams (PLRT) for each assigned marketed product and provide functional support for discussions
- Bring PLRT proposals to Product Labeling Committee (PLC) for discussion, review, and approval
- Coordinate preparation of regulatory labeling documents needed for regulatory submissions
- Assist with FDA interactions, such as labeling negotiations, on assigned projects/products
- Interact with Global Labeling (GL) before major US labeling changes to ensure consistency with company core labeling
- Support late-stage development labeling for NCEs/NBEs and labeling supplements initiated by BI





Regulatory Affairs Fellowship Program

The Chemistry, Manufacturing, and Controls (CMC) Fellow will:

- Gain exposure to the regulatory aspects of CMC during the lifecycle of BI assets, and execute regulatory activities required of an NDA Holder for compliance to FDA for U.S. products in BIPI's commercial portfolio
- Effect timely and appropriate regulatory change management of CMC changes, including those of increasing complexity and/or business impact, in accordance with the Corporate Change Management Procedures
- Review, and approve regulatory documents for submission, construct in eCTD format, and file supplemental NDA (sNDA) submissions for CMC changes
- Manage the preparation, content finalization, and submission of the NDA Annual Report
- Review the reports for potential CMC impact to safety of the product
- Contribute to assessment of potential quality defects, technical product complaints and/or patient complaints
- Liaise with FDA in written communication and participate in FDA meetings on regulatory issues
- Act as US Agent for BI's Type II DMFs incorporated into marketed and established products
- Ensure CPD-3 database accurately reflects the approved/dispatched CMC information

The Policy & Intelligence Fellow will:

- Lead requests for global country-level regulatory information from various partners
- Collaborate with partners to support any compliance and process initiatives
- Own the review and refinement of regulatory FDA guidance and recommendations by developing written comments reflecting BI's priorities for submission to health authorities
- Serve as Regulatory intelligence lead on highly sophisticated cross-functional teams
- Provide regular communications and briefings to global and regional policy management on relevant global regulatory policy issues
- Provide strategic regulatory advice to RA colleagues on drug development and device projects, registration, and marketed products in preparation for HA meetings
- Prepare and coordinate internal customer feedback on proposed laws, regulations and guidances, to ensure consideration of BI's positions by trade organizations





Regulatory Affairs Fellowship Program

The Advertising and Promotion (AdPromo) Fellow will:

- Gain knowledge and understanding of drug development, including phases of clinical studies, general requirements for drug marketing approval and basic statistics.
- Serve as the Regulatory Affairs representative on the Human Pharma Review Committee (HPRC) team, working cross-functionally with Medical, Legal and Marketing stakeholders.
- Build a foundational understanding of compliance with the Food Drug and Cosmetic Act (FDCA), FDA Guidances, and the current Regulatory landscape.
- Review promotional claims and materials for Boehringer Ingelheim prescription drugs for compliance with FDCA and for consistency with product labeling.
- Review scientific exchange communications, disease awareness campaigns, and other unbranded materials that require HPRC approval.
- Actively contribute in HPRC, providing regulatory guidance on promotional communications and risk mitigation strategies across therapeutic areas.
- Upon completion of the fellowship, become proficient in Regulatory Affairs Advertising and Promotion Compliance through hands-on training and responsibilities across therapeutic areas.

First Year Fellows





Nicholas Ferri, PharmD Medical Affairs and Scientific Communications Albany College of Pharmacy



Shaina Shah, PharmD, MBA Medical Affairs and Scientific Communications University of Toledo



Genesis Gil Torres, PharmD Clinical Development & Operations Albany College of Pharmacy



Brittany Lomax, PharmD Clinical Development & Operations Florida A&M University



Noah Frazier, PharmD Clinical Pharmacology Virginia Commonwealth University



Cheuk Fung Chan, PharmD Clinical Pharmacology University of the Pacific



David Arnold, **PharmD** Regulatory Affairs University of New Mexico

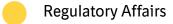


Ngoctran (Nina) Tran, PharmD, MS Regulatory Affairs University of Southern California













Asim Ali, **PharmD** Regulatory Affairs D'Youville University

Second Year Fellows





Ayush Sood, PharmD

Medical Affairs & Scientific Communications
Philadelphia College of Pharmacy



Eduardo Legaspi, PharmD Medical Affairs & Scientific Communications University of Michigan



Xiaofan Tian, PharmD
Clinical Pharmacology
Rutgers University



Roy Walton, PharmD Regulatory Affairs University of Connecticut

- Medical Affairs & Scientific Communications
- Clinical Development & Operations
- Clinical Pharmacology
- Regulatory Affairs

2024 – 2026 Fellowship Preceptors





Asha Philip, PharmD Sr. Associate Director, CDMA Scientific Communications, Medical Information



Joseph Abrajano, PhD Sr. Associate Director, CDMA Scientific Communications, Grants & Research



Harjeet Caberwal, PharmD Director, CDMA Cardiometabolic



Nicole Silengo, PharmD Associate Director, CDMA Scientific Communications, Medical Information



Martina Amelsberg, MD Associate Director, CDMA Scientific Communications, Medical Information



Nicole Meade, PhD Director, CDMA CNS



Addison Eads, PharmD Associate Director, CDMA Scientific Communications, Medical Information



Jacob Runyan, MSc, MBA Director, Scientific Communications



Roland Larkin, PhD, MBA Director, CDMA CNS



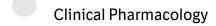
Carolyn Shuart, PharmD Sr. Associate Director, CDMA Scientific Communications, Medical Information

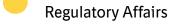


Rachel Spino, PharmD
Associate Director, CDMA
Scientific Communications,
Medical Information









2024 – 2026 Fellowship Preceptors





Silvana Giustino, RN, BSN Director, Study Management and Conduct



Beth Joseph, MPHDirector, Study Management and Conduct



Dawn Dinallo, MSDirector, Study Management and Conduct



Teffany Davenport, MSDirector, Study Management and Conduct



Fenglei Huang, PhD Senior Director, Translational Medicine and Clinical Pharmacology



Ash Sharma, PhD Executive Director, Translational Medicine and Clinical Pharmacology

- Medical Affairs & Scientific Communications
- Clinical Development & Operations
- Clinical Pharmacology
- Regulatory Affairs

2024 – 2026 Fellowship Preceptors





Andrew Gee, PhD Director, Marketed Products



Tara Ruszcyk, PharmD Senior Associate Director, Advertising & Promotion Compliance



William Gallo, PharmD Associate Director, Advertising & Promotion Compliance



Amy Patel, PharmD Senior Associate Director, Labeling Content



Dawn ColletteDirector,
Cardiometabolic and Respiratory



Maureen Oakes, PharmD Executive Director, U.S. Regulatory Lead, Cardiometabolic and Respiratory

- Medical Affairs & Scientific Communications
- Clinical Development & Operations
- Clinical Pharmacology
- Regulatory Affairs

Fellowship Alumni



Sindoor Patel, PharmD, RPh Manager, Clinical Trial Manager Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT

2021-2023

HeeJae Choi, PharmD, RPh Trial Clinical Pharmacologist Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT

Emily Coffer, PharmD Manager, Clinical Trial Manager Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT

Addison Eads, PharmD
Associate Director
Scientific Communications, Medical Information
Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, CT

Catherine Stirbis, PharmD

My Tran, PharmD Product Labeling Operations Associate - Contractor Magnit Global INC. Ridgefield, CT

2020-2022

Rachel Vatman, PharmD Clinical Scientist, Study Management and Conduct Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT

Addison Nguyen, PharmD Associate Director, US Regulatory Affairs, CMR Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT

2020-2022

Jayed Momin, PharmD, RPh Senior Manager, US Medical Affairs Bayer Pharmaceuticals Whippany, NJ

2020 - 2021

Rachel Spino, PharmD
Associate Director, CDMA
Scientific Communications and Medical Information
Boehringer Ingelheim Pharmaceuticals, Inc.
Ridgefield, CT

Yue Xiang, PharmD
Oncology Clinical Pharmacology Reviewer
U.S. Food and Drug Administration,
White Oak, Maryland

2019 - 2021

Shom Ganguly, PharmD Medical Science Liaison, Immunology Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT

Ling Ding, PharmD Medical Information & Review Manager Takeda Pharmaceuticals Lexington, MA

2018 - 2020

Samuel Fu, PharmD, MS Manager, Early Pipeline Scientific Communication Seagen Inc. Bothell, Washington

Nicole Silengo, PharmD, RPh Associate Director, CDMA Scientific Communications and Medical Information Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT



2017 - 2018

Allison Cui, PharmD Associate Director, Medical Science Liaison Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT

2016 - 2017

Neha Kapur, PharmD Associate Medical Director, Neurology Lundbeck Deerfield, IL

2015 - 2016

Joy Lee, PharmD Director, Medical Affairs Strategy Myovant Sciences Brisbane, CA

2014 - 2015

Michele Miller, PharmD Director, Medical Information Mirati Therapeutics San Diego, CA

2013 - 2014

Meghal Khokhani, PharmD Medical Science Liaison, Immunology AbbVie Inc. North Chicago, IL

2012 - 2013

Brian Calamari, PharmD Principal National Medical Outcomes Science Liaison AbbVie Inc. North Chicago, IL

Former Fellow Testimonials





"I am truly grateful for my fellowship experience in Medical Affairs and Scientific Communications with Boehringer Ingelheim. I was provided ample resources and support from my preceptors which helped refine my skillset as a healthcare professional in the industry setting. Every individual I had the pleasure of working with was invested in my learning, development, and success. I had the ability to work autonomously on impactful projects and initiatives that were both a business need and of my personal interests. I am happy to be an alumni of this program to support and mentor the incoming fellowship class."

Nicole Silengo, PharmD 2018-2020 Fellow



"The Medical Information Fellowship at Boehringer Ingelheim was an invaluable opportunity that allowed me to develop into a capable industry professional. As a fellow, I gained valuable experience working with various cross-functional teams to support the Cardiovascular therapeutic area. Additionally, my preceptors encouraged and supported me in pursuing my interests in the areas of Business Development & Licensing, Field-Based Medicine, and Pipeline Marketing through a number of rotational and shadowing experiences. Following completion of my fellowship, I am overjoyed to be able to continue my professional career at Boehringer Ingelheim. I look forward to implementing and leveraging the skills I developed during my fellowship as I progress through my career to bring value to the organization."

Allison Cui, PharmD 2017-2018 Fellow



Application Requirements:

Doctor of Pharmacy degree from an ACPE-accredited school or college of pharmacy earned prior to the start date at Boehringer Ingelheim.

- Please submit an interview request with your curriculum vitae and letter of intent via PPS or <u>Boehringer Ingelheim</u> <u>Careers Portal</u> and searching for the post-doctoral fellowship of interest.
- Must be legally authorized to work in the United States without restriction.

Please address your Letter of Intent & Letters of Recommendation to one of the following:

- Asha Philip, PharmD (Medical Affairs & Scientific Communications)
- Beth Joseph, MPH (Clinical Development & Operations)
- Dawn Dinallo, MS (Clinical Development & Operations)
- Ash Sharma, PhD (Clinical Pharmacology)
- Maureen Oakes, PharmD (Regulatory Affairs)

Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Road Ridgefield, CT 06877

Contact:

MEDPharmDFellowships.RDG@boehringer-ingelheim.com



Application Materials	Start Date
Application via BI Careers Portal	September 1st, 2023
Three letters of recommendations	Required only for candidates that advance to final round of interviews

For more information, visit:

<u>Boehringer Ingelheim Careers Portal</u>

Use search terms "post-doctoral fellow"