Biopharmaceutical Industry
PharmD Fellowships

Unique Fellowships, Endless Opportunities
Dear Prospective Biogen Fellow,

Thank you for your interest in the Biogen Post-PharmD Fellowship Programs. The evolving and growing world of biopharmaceutical industry has opened up a tremendous amount of opportunity for pharmacists looking for an alternative and diverse career path. Since the start of this fellowship, Biogen, in collaboration with MCPHS University, has trained and promoted the role of the Doctor of Pharmacy within the company, academia, and the industry as a whole. Fellows completing this program not only grow professionally in terms of skills and expertise, but have also made a substantial impact on programs integral to the success of Biogen.

Biogen is one of the oldest independent biotechnology companies in the world focused on developing and delivering therapies for neurodegenerative and autoimmune disorders. We provide a culture of innovation, inclusiveness, and empowerment. This environment allows for personal and professional growth, all while creating an atmosphere of learning and new opportunities for our employees. Our passion and focus is not only on improving the lives of patients, but also extends to supporting the local community, nurturing science education for students of every age, and maximizing our environmental sustainability.

We are at an exciting time at Biogen and we are committed to pursuing science that truly matters. Best of luck as you explore the different opportunities available to you, and I strongly encourage you to consider the Biogen fellowship.

Sincerely,

Al Sandrock, MD, PhD
Executive Vice President, Chief Medical Officer,
Head, Development and Worldwide Medical

“Our commitment is to educate our fellows on the complex, rapidly evolving world of biopharmaceutical drug development and to provide them with the necessary tools to help them shape their own careers.”

Carmen Bozic, MD
Senior Vice President
Global Development

“Led by world-class research and development, Biogen uses novel science and leading-edge technologies to discover, develop, commercialize, and manufacture transformative therapies for patients with few or no treatment options.”

Ralph Kern, MD
Senior Vice President
Worldwide Medical

For more than 35 years, Biogen has been helping to improve the lives of people living with serious medical conditions. Since our founding in 1978, we’ve produced therapies for diseases that affect hundreds of thousands of people around the world.

The company was founded in Zurich, Switzerland, by scientists who were the first to clone and express interferon, the monoclonal antibody that led to the development of our first multiple sclerosis (MS) therapy, AVONEX®. A pioneer in the biotechnology industry and one of the first biotech companies, Biogen now has the world’s leading portfolio of MS therapies and in 2014 introduced new treatments for hemophilia A and B, bringing the first innovation to patients in almost two decades. We are further applying our expertise to solve some of the most challenging and complex diseases in neuroscience, including Alzheimer’s disease, spinal muscular atrophy (SMA), Parkinson’s disease, and amyotrophic lateral sclerosis (ALS). The pace of discovery and innovation in neuroscience is accelerating rapidly, bringing the promise of incredible advances to patients. As we help lead this transformative period in neuroscience, Biogen is driving a deeper understanding of disease biology and working to develop potentially life-changing treatments for the people suffering from these conditions. Biogen is a truly global organization, with more than 7000 employees worldwide. In addition to our headquarters in Cambridge, Massachusetts, we have offices in the United States, Canada, Australia, Japan, and throughout Europe. We also have a direct commercial presence in 30 countries and distribution agreements in more than 60 additional countries. Working to solve difficult challenges is the foundation of both our research and our corporate responsibility. The same passion that drives our science is reflected in our corporate citizenship, environmental sustainability, and commitment to diversity.
MCPHS University Faculty Preceptors

**Lynn Squillace, JD, MPH**  
Director of Regulatory Sciences & Health Policy  
Assistant Professor

**Michael Steinberg, BA, BS, PharmD, BCOP**  
Professor of Pharmacy Practice

**Kristine Willett, PharmD, FASHP**  
Associate Professor of Pharmacy Practice

**Catherine Taglieri, BSP, PharmD, RPh**  
Assistant Professor of Pharmacy Practice

**Stefanie Nigro, PharmD, BCACP, BC-ADM**  
Assistant Professor

**William McCloskey, BA, BS, PharmD, RPh**  
Professor and Vice-Chair, Pharmacy Practice

**Brian Rittenhouse, MS, PhD**  
Pharmaceutical Business and Administrative Sciences

**About MCPHS University**

MCPHS University provides an academic environment to guide and support fellows toward a successful career in the biopharmaceutical industry. As a private institution with a history of specializing in the health sciences, MCPHS University offers programs that embody scholarship, professional service, and community outreach. Through MCPHS University, the fellow will have the opportunity to gain teaching and research experience in an academic setting. Throughout the program, MCPHS University faculty and company program leaders mentor fellows according to each fellow’s scholarly and professional interests.

As an adjunct assistant professor at MCPHS University, each fellow may have the opportunity to:
- develop, coordinate, and teach pharmacy courses.
- co-precept students on advanced experiential rotations.
- create and publish scholarly research and review articles.
- present data at scientific and clinical meetings.
- participate in professional development seminars.
About the Fellowships

Biogen, in collaboration with MCPHS University, offers 7 unique fellowship programs to promote the role of Doctor of Pharmacy (PharmD) within the biopharmaceutical industry:

- Regulatory Sciences/Safety and Benefit-Risk Management (Reg/SABR)
- Safety and Benefit-Risk Management (SABR)
- Regulatory Sciences–Advertising and Promotion (Reg–AP)
- Regulatory Sciences–Trial Master File/Clinical Trial Application (Reg–TMF/CTA)
- Global Medical Writing (GMW)
- Worldwide Medical (WWM)
- Real-World Outcomes, Innovative Partnerships, and Insights (RI2)

Fellows will gain extensive experience through a variety of practical activities in both industry and academic settings, which will enhance the potential for accelerated career development.

Eligibility

- Applicants must hold a Doctor of Pharmacy degree from an ACPE-accredited college of pharmacy by the commencement of the program.
- Candidates must have excellent written and oral (ie, verbal) communication skills and a strong interest in pursuing a career within the biopharmaceutical industry.
- The Biogen fellows will be selected on a nationally competitive basis.
- All fellowships last 2 years with a start date of July 1st.

Application Procedure

- Candidates are encouraged to request a preliminary interview at the American Society of Health-System Pharmacists (ASHP) midyear meeting through the Personal Placement Service (PPS) website.
- Interested candidates must submit their application materials online at http://www.mcphs.edu/BiopharmaceuticalFellowships, by December 20th.
  - Please submit a letter of intent, curriculum vitae, three references with contact information, and unofficial college transcript(s).
- Please submit 3 letters of recommendation to the program’s email address, which can be found in the table on the next page.

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**Regulatory Sciences**
Regulatory Sciences is a well-integrated global department that provides worldwide strategic regulatory guidance and operational support for Biogen’s development and commercial programs. The fellow will acquire a better understanding of the dynamics of the drug development process throughout the life cycle of our products, from early development through approval and commercialization. During the rotation in Regulatory Sciences, the fellow will have the opportunity to gain experience in the different functions of the regulatory department, which are as follows:

- Advertising and Promotion (AP)
- Operations
- Labeling
- Clinical Trial Applications (CTA)

**Safety and Benefit-Risk Management (SABR)**
Biogen is responsible for the continuous assessment of the benefit-risk relationship of all of its products—starting in the early stages of development and continuing through the postmarketing phase. Members of the SABR department are continuously working to gain a better understanding of the safety profile of marketed products and those in development, in order to provide the medical community and patients with the data necessary to make an informed decision regarding disease management. During the rotation in SABR, the fellow will have an opportunity to rotate through 3 general areas:

- Global Case Management
- Pharmacovigilance (PV) Scientists
- Epidemiology

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**Elective Options**
The fellow will have the opportunity to spend up to 4 months in another department within Biogen. Departments may include, but are not limited to:

- Clinical Drug Supply Chain
- Global Clinical Operations
- Global Commercial Strategy
- Health Economics and Outcomes Research
- Marketing

Also, the fellow will have the opportunity to precept PharmD students.

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**Program Directors**

- Mehdi Chakir, PharmD
  Director, SABR

- Stacie Knight
  Director, Regulatory Sciences

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**Second-Year Fellows**

- Colin Gillis, PharmD
  Northeastern University Bouvé College of Health Sciences

- Bhumi Patel, PharmD
  University of the Sciences Philadelphia College of Pharmacy

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**First-Year Fellows**

- Kathy Lu, PharmD
  University of the Sciences Philadelphia College of Pharmacy

- Tina Chhabra, PharmD
  Virginia Commonwealth University School of Pharmacy

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“The Biogen fellowship programs have been a source of incredibly talented and inspiring individuals who have contributed to the recognition of the programs throughout the company.”

Mehdi Chakir, PharmD
Director, SABR

“The Biogen fellowship programs have an unparalleled opportunity to see drug development from multiple positions. Fellows build a diverse experience base that lets them stand apart.”

Colin Gillis, PharmD
Northeastern University Bouvé College of Health Sciences

“This program is a unique opportunity for fellows to gain extensive practical experience in an invigorating environment and foster the skills necessary for success in the biopharmaceutical industry.”

Bhumi Patel, PharmD
University of the Sciences Philadelphia College of Pharmacy

“The partnership between MCPHS and Biogen provides a challenging yet nurturing environment for fellows to be fully immersed in high-profile projects, driving personal and professional growth through guidance from an impressive network of experienced individuals within the biopharmaceutical industry.”

Kathy Lu, PharmD
University of the Sciences Philadelphia College of Pharmacy

“The Regulatory Sciences and Safety & Benefit-Risk Management fellowship provides a unique platform that facilitates exposure to multiple facets of industry allowing for involvement in dynamic and valuable projects that foster professional and personal growth.”

Tina Chhabra, PharmD
Virginia Commonwealth University School of Pharmacy

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**Regulatory Sciences/Safety and Benefit-Risk Management Fellowship**

**2-YEAR PROGRAM**

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About Safety and Benefit-Risk Management

Biogen is responsible for the continuous assessment of the benefit-risk relationship of all of its products—starting in the early stages of development and continuing through the postmarketing phase. Members of the Safety and Benefit-Risk Management department are continuously working to gain a better understanding of the safety profile of marketed products and those in development in order to provide the medical community and patients with the data necessary to make an informed decision regarding disease management.

This 2-year Safety and Benefit-Risk fellowship is designed to provide an in-depth and hands-on experience. Through this program, the fellow will gain exposure to the following three general areas:

Safety Operations: During this rotation, the fellow will become knowledgeable about the adverse event reporting process including initial review and triage, adverse event report assessment, and distribution rules. The fellow will also enhance his or her understanding of clinical trial safety, ICSR reporting, global pharmacovigilance regulations and guidelines, safety data exchange agreements, and vendor oversight.

Epidemiology: During this rotation, the fellow will work closely with epidemiologists to provide REMS support, understand and evaluate real-world data, and prepare epidemiology-based product summaries.

Pharmacovigilance (PV) Scientists: During this rotation, the fellow will engage in safety surveillance activities and prepare and review signal evaluations, periodic safety update reports, and risk management plans utilizing the training and skills gained through previous rotations.

Program Director

“The success of our program is a tribute to highly motivated fellows, coupled with an exceptionally supportive environment throughout the company.”

Mehdi Chakir, PharmD
Director, SABR

Elective Options

- Regulatory Sciences
- Global Medical Writing
- Clinical Drug Supply Chain
- Global Clinical Operations
- Global Commercial Strategy
- Health Economics and Outcomes Research
Elective Options

The fellow will have the opportunity to spend up to 3 months in another department within Biogen. Departments may include, but are not limited to:

- Worldwide Medical
- Global Commercial Strategy
- Health Economics and Outcomes Research
- Safety and Benefit-Risk Management
- Regulatory Sciences

Also, the fellow will have the opportunity to precept PharmD students.
About Regulatory Sciences—TMF/CTA

This fellowship will primarily focus on the Trial Master File (TMF) and Clinical Trial Application (CTA). Over the course of 2 years, the fellow will be a member of cross-functional teams and work with key individuals that have a comprehensive knowledge of regulatory requirements for the planning, conduct, and reporting of clinical trials. Maintenance of the accurate and appropriate documentation is needed for managing the conduct of clinical trials and enables evaluation by audit or inspection for Good Clinical Practices (GCP) compliance. The fellow will also have the opportunity to complete collaborative initiatives within Regulatory Sciences.

The TMF is considered the autobiography of a study and is our evidence that the integrity of the trial data, study analysis, and study conclusions are credible, and that patient rights and safety have been protected. During the first year of the fellowship, the fellow will obtain a functional working knowledge within the TMF group as a support system for the TMF Study Owners, Manager, and Process Owner. The team provides comprehensive collaborative opportunities with TMF partners such as Global Clinical Operations, Safety and Benefit Risk Management, and Records Management. This provides the foundation for the second year of the fellowship.

During the second year, the fellow will gain direct experience within the CTA team, which is responsible for managing international clinical trial applications with health authorities. In doing so, the team is responsible for the oversight of Clinical Research Organizations (CRO) and the collaboration with Biogen to ensure timely execution of the application submissions. As an integral member of the cross-functional study team which provides regulatory strategy for the studies, the fellow will support the CTA lead with startup, maintenance, and close-out activities for various studies. The team provides regulatory training and education to increase the fellow’s exposure to multiple aspects of Regulatory Sciences.

Program Directors

“With an emphasis on effective leadership and open communication, the fellowship provides a strong network and numerous collaborative opportunities within regulatory functions. As a core member of the TMF/CTA team, fellows will be exposed to a broad insight of regulatory processes on a global level and develop a thorough understanding of clinical regulatory documents.”

Vinita Leslie, MA
Director, Regulatory Sciences

“The second year of the TMF/CTA Regulatory fellowship offers in-depth learning and experience in execution of clinical trial applications around the world. The fellow will be an integral part of the study management team and will provide the regulatory guidance needed to initiate and maintain regulatory approvals in a rapidly changing global environment.”

Mugdha Sitole, PharmD
Manager, Regulatory Sciences

First-Year Fellow

“I feel incredibly grateful to work in an environment where the culture is collaborative, not competitive. The TMF & CTA team at Biogen provides a great opportunity for professional and personal growth, as well as multiple teaching opportunities with MCPHS. As valued members of this multidisciplinary team, fellows gain increased exposure to the world of industry and regulatory sciences, and acquire an in-depth knowledge of the submission and compliance process on a global scale.”

April Nguyen, PharmD
University of the Pacific Thomas J. Long School of Pharmacy & Health Sciences
Global Medical Writing Fellowship

2-YEAR PROGRAM

GLOBAL MEDICAL WRITING

24 months

About Global Medical Writing

Biogen’s Global Medical Writing fellowship will focus on development of clinical and regulatory documents. In the course of 2 years, the fellow will work with cross-functional teams to develop an understanding of the drug development process, including regulatory documentation requirements for the planning, conduct, and reporting of clinical trials, as well as the submission, approval, and maintenance of marketing authorization for products.

Study-level documents: During the first year of the fellowship, the fellow will obtain a functional working knowledge of study-level documents such as clinical study protocols and reports required for the conduct and reporting of clinical trials. The fellow will become familiar with the components and structure of clinical protocols as well as the interpretation and reporting of data in clinical study reports, the flow of data within drug development, and its meaning to stakeholders.

The fellow will work closely with other areas within the Global Medical Writing department and with other functions in Global Development, such as Regulatory Sciences, Global Clinical Operations, Safety and Benefit Risk Management, Biostatistics and Clinical Data Sciences, and Quality and Compliance. Working closely with this cross-functional team provides comprehensive training and education as well as broad exposure to career opportunities in Global Development. Understanding how study-level documents are structured and written will provide the fellow with the foundation to understand how these documents support the overall drug development process at the program level.

Program-level documents: During the second year of the fellowship, the fellow will gain direct experience with writing program-level documents that are required for approval and maintenance of marketing authorization for products. These documents include global clinical and regulatory documents. This will allow the fellow to gain hands-on experience in the production of a wider variety of documents and an understanding of their place within the drug development process.

Program Directors

“Medical Writing offers a great vantage point to be involved in a wide range of activities that support drug development.”

Mark Fielding, PhD
Director, Medical Writing

“The medical writing fellowship program offers a unique opportunity to gain knowledge on clinical development through the preparation of clinical and regulatory documents.”

Begona Ruiz Perez, PhD
Associate Director, Medical Writing

First-Year Fellows

“This fellowship gives you the necessary fundamentals and experience in order to thrive and become successful in the pharmaceutical industry.”

Joseph Naggar, PharmD
MCPHS University– Boston

“The Global Medical Writing Fellowship is a distinctive and challenging opportunity to integrate clinical knowledge into the industry environment. Fellows work in close collaboration with multiple departments involved in clinical development, and develop a thorough understanding of the different regulatory requirements on a global scale. This program provides a platform for professional growth within Biogen and MCPHS University thanks to remarkable preceptors and colleagues.”

Jihae Lim, PharmD
Temple University School of Pharmacy
About Worldwide Medical

Biogen's Worldwide Medical (WWM) departmental mission is to inform real-world medical practice and to optimize patient outcomes by generating, assimilating, and delivering clear, timely, clinically relevant information that addresses unmet medical needs. We do this by providing support to Research and Development, Corporate Development, and Global Commercial Operations, and by being responsible for clinical development and research, medical publications, biostatistics, medical education, and many other services. Worldwide Medical is also responsible for providing healthcare professionals, regulatory agencies, and professional groups with the medical and scientific information they need to understand our company's products.

During the first year of the fellowship program, the fellow will have the opportunity to explore the different functional areas within Worldwide Medical. If desired, the fellow will have the opportunity to select a rotation outside of Worldwide Medical for greater experience and understanding of the biopharmaceutical industry.

For the second year of the fellowship, the fellow will pick an area of concentration to prepare them for a career within the pharmaceutical industry. The area of concentration must be within Worldwide Medical.
About RI²

Biogen’s Real-World Outcomes, Innovative Partnerships, and Insights (RI²) team establishes and fosters ongoing professional relationships with key managed-market decision makers and policymakers to provide comprehensive medical education, collaborative research opportunities, and comparative effectiveness health outcomes solutions that seek to improve patient care within a cost-conscious and evolving healthcare environment.

During the first year of the fellowship, the fellow will obtain a working functional knowledge within the core groups with which RI² partners. The fellow will also have an opportunity to choose a rotation outside of the core curriculum to enhance his or her experience and understanding of the biopharmaceutical industry.

The second year of the fellowship is dedicated to gaining an advanced experience within the RI² team. The fellow will complete various research initiatives, present at congresses, partake in field medical market access interactions, and consistently work to be a trusted partner within the team.

Elective Options

The fellow will have the opportunity to spend up to 3 months in another department within Biogen. Departments may include, but are not limited to:

- Health and Economics Outcomes Research
- Value Based Medicine
- Pricing and Channel Distribution
- Patient Services
- US Medical Director’s Office
- Government Policy and Advocacy
- Global Market Access
- Worldwide Medical

Program Directors

“The Real-World Outcomes, Innovative Partnerships, and Insights Fellowship provides fellows an opportunity to learn key principles of pharmacoeconomics and outcomes research as well as the application of such research within the industry setting.”

Mehul Jhaveri, PharmD, MPH
Director, US Real-World Outcomes, Innovative Partnerships, and Insights

“Our Real-World Outcomes, Innovative Partnerships, and Insights Fellowship offering provides a unique breadth of evidence generation strategy for Payer stakeholders across all brand and pipeline products to transform patient lives. Future fellows will be well equipped for leadership in an evolving healthcare market.”

Eric Hall, BS, PhD
Director, US Real-World Outcomes, Innovative Partnerships, and Insights

Second-Year Fellow

“The Real-World Outcomes, Innovative Partnerships, and Insights Fellowship program offers a premier opportunity to engage in meaningful discussions with US Payers. Additionally, the experienced mentorship and targeted rotational curriculum in both the Commercial and Medical books of business prime the individual for success within the biopharmaceutical industry.”

Kun Yang, PharmD
University of Maryland School of Pharmacy

First-Year Fellow

“The Real-World Outcomes, Innovative Partnerships, and Insights Fellowship provides a great opportunity to work with both internal teams and key external stakeholders by leveraging the scientific innovation of our products in order to better inform value-based decisions. Furthermore, this program grants fellows the opportunity to become fully immersed across both the medical and commercial sectors in order to garner the requisite experience essential for a successful career in the biopharmaceutical industry.”

Jaanai Babb, PharmD
Rutgers University Ernest Mario School of Pharmacy
Frequently Asked Questions

What is the timeline for the fellowship selection process?
• Initial interviews for the fellowship are conducted at the ASHP Midyear Clinical Meeting. All candidates will need to register with Personnel Placement Service (PPS) in order to interview.
• To request an interview, select the fellowship program(s) of interest through the PPS portal and provide your contact information and a copy of your CV.
• Applicants may submit their application materials before or after the ASHP Midyear Clinical Meeting. All application materials must be received by December 20th; however, applications will be accepted and reviewed prior to the due date. Due to the competitive nature of the selection process, applicants are encouraged to submit their application materials as soon as possible.
• The selection process will be complete in late January.

Do I need previous industry experience in order to be considered for the fellowship program?
• No, previous industry experience is not required, but it is beneficial.

Do I have to be a registered pharmacist to qualify for this fellowship?
• No, but licensure is strongly encouraged. To qualify for this fellowship, you must be a graduate of an ACPE-accredited PharmD program at the commencement of the fellowship.

Will I be able to defer my student loans?
• Yes, provided that the student loan company accepts fellowship deferment. Candidates should contact their lender(s) for more information regarding eligibility and terms of deferment.

Can I apply for more than 1 fellowship at Biogen?
• Yes, we welcome potential applicants to explore all of the opportunities available at Biogen.

Is a cover letter required to request an interview at PPS?
• No, a cover letter is not needed for the initial interview request, but a letter of intent is required in the formal application.

Are there any other elective options available that are not listed?
• All elective options are subject to availability. Additional options may be available depending on interest.
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<td>Richard Lem, PharmD</td>
<td>Jonathan Kendter, PharmD</td>
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<td>Rutgers University</td>
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<td>Ernest Mario School of Pharmacy</td>
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<tr>
<td>Assistant Director, Regulatory Affairs</td>
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<td>Advertising and Promotion</td>
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*Fellowship Alumni (Cont’d)*