Celebrating 20 years

MCPHS
BIOPHARMACEUTICAL INDUSTRY
FELLOWSHIP PROGRAM

LAUNCH YOUR CAREER IN THE HEART OF BIOTECH

2024–2025

THE HISTORY OF MCPHS

Massachusetts College of Pharmacy and Health Sciences (MCPHS) is the oldest institution of higher education in the city of Boston and has the second-oldest pharmacy program in the United States. Since its founding in 1823, MCPHS has been on the cutting edge of innovation in healthcare education. We are committed to training professionals for the future of the exciting, ever-expanding healthcare industry and helping them achieve their career goals. The addition of the Worcester, MA, and Manchester, NH, campuses has supported our commitment. Through their proactive efforts, our students, alumni, and faculty have had an impact on countless disciplines across the healthcare world and beyond.

FELLOWSHIP OVERVIEW

Founded in 2003, the fellowship program is designed to provide Doctor of Pharmacy (PharmD) graduates with in-depth, specialized training within the biopharmaceutical industry. Since the program's inception, and with its industry-leading partners, the program has continued to offer innovative and challenging positions. Each position affords significant experience in a corporate setting, enabling fellows to hone their business and clinical skills. The program also aims to foster professional development; provide intensive, hands-on training; and expose fellows to a variety of industry and academia-based opportunities.

LEARN MORE AT:
WWW.MCPHS.EDU/PHARMDFELLOW

FROM THE DESK OF THE DIRECTOR

Thank you for your interest in the MCPHS Biopharmaceutical Industry Fellowship Program! I am extremely excited and look forward to welcoming the next cohort of talented fellows. Our wonderful tight-knit industry network encompasses eleven of the top companies that are advancing healthcare and improving patient lives. Each year we look to recruit highly talented one-year or two-year fellows to work within a wide variety of functional areas. The majority of our fellows are in the greater Boston or Cambridge area—the heart of biotechnology in Massachusetts and the Northeast.

Since the program's inception in 2003, we have consistently grown to offer as many opportunities as possible to PharmDs seeking career paths to industry. We have a vast alumni network, of over 300 industry professionals; many of them have remained within the greater Boston area, but you will also find them working throughout the United States. They serve as wonderful mentors and are a key resource to our fellows.

Through their industry experience, quarterly professional development sessions, teaching on one of the three MCPHS campuses, volunteering in the community, attending various networking events, and so much more, our fellows are highly trained and sought after within the pharmaceutical industry.

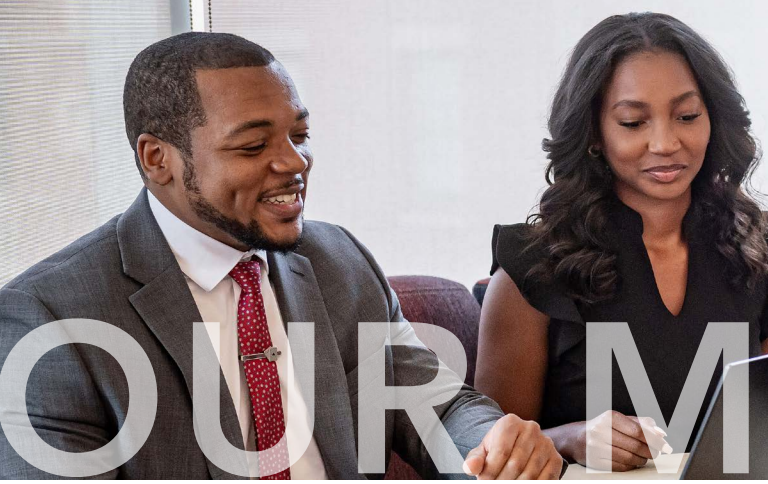
I wish each one of you good luck as you explore your options within the MCPHS Biopharmaceutical Industry Fellowship Program! We hope you find what you are looking for and will be able to join us!

AMEE MISTRY **PharmD, RPh**

Professor of Pharmacy Practice

Director, Biopharmaceutical Industry Fellowship Program, MCPHS

"The MCPHS fellowship program is the gateway for PharmDs to experience and explore the biopharmaceutical industry's diverse working environments through structured training. This program is both challenging and exciting yet offers various opportunities that PharmDs would not have exposure to in a traditional setting. Graduates of our program are highly desirable due to their technical expertise, their interpersonal skills, and their understanding of how the business of drug discovery, development, and commercialization is carried out on both a domestic and a global scale."



OUR MISSION

To develop strong biopharmaceutical industry leaders through significant hands-on experience in their respective functional areas as well as provide unique teaching and scholarship opportunities under the mentorship of MCPHS faculty.

ACADEMIC COMPONENTS

MCPHS 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 health sciences, MCPHS offers programs that embody scholarship, professional service, and community outreach. Through MCPHS, fellows be expected to participate in teaching and scholarly research.. MCPHS faculty will be paired with fellows to mentor them and help them achieve their teaching and scholarly goals.

ISSION

As a postdoctoral fellow at MCPHS, each fellow may have the opportunity to

- develop, coordinate, and teach within required or elective pharmacy courses;
- co-precept students on advanced pharmacy practice experiential rotations (APPEs);
- assist in the publication of scholarly research and review articles;
- present posters and data at scientific and clinical meetings; and
- participate in professional development seminars.

FELLOWSHIP PROGRAM OPPORTUNITIES

BIOMARKER DEVELOPMENT

Responsible for developing integrated biomarker plans using diverse expertise and knowledge in genetics, genomics, imaging, protein and cellular biology, statistics, and bioinformatics.

- Gain familiarity with innovative biomarker technologies used in clinical research.
- Build professional experience coordinating with internal and external stakeholders to manage biomarker samples and evaluations in ongoing clinical trials.
- Lead and contribute to process improvement projects, technology evaluations, and other initiatives across organization.

CLINICAL DEVELOPMENT/OPERATIONS

Responsible for designing and executing clinical development plans.

- Lead study team from trial initiation to completion.
- Plan and manage operational plans including risk-mitigation strategies, trial budgets, study timelines, and quality standards.
- Develop trial documents in collaboration with study team.
- Work with study team to conduct ongoing reviews of clinical trial data.
- Contribute scientific input for development of study reports, data tools, and statistical plans.
- Provide operational expertise and leadership to ensure feasibility and execution of clinical trials.
- Identify and select vendors and perform ongoing vendor management.

Note: Therapeutics Development Fellowship at Biogen comprises Clinical Development, Global Clinical Operations, and Analytics and Data Sciences. Analytics and Data Sciences is responsible for integrating innovative approaches to accessing and analyzing data in drug development.

CLINICAL DOCUMENTATION (REGULATORY MEDICAL WRITING)

Responsible for producing clinical documents required by the U.S. Food and Drug Administration and other government agencies worldwide to report the outcomes of clinical studies and support drug approval.

- Collaborate with cross-functional teams to produce high-quality clinical documents that meet regulatory requirements. Documents include protocols, investigator brochures, clinical summary modules, and clinical study reports.
- Meet content, format, and navigational requirements by leading cross-functional teams through the writing, review, and approval process.
- Facilitate the assembly, compilation, and completion of documents needed to initiate clinical studies.

CLINICAL RESEARCH PHARMACY

Responsible for enhancing patient safety through the implementation of patient-focused tools that improve the use of investigational products (IPs) at clinical sites and at home.

- Develop strategies to promote and monitor patient adherence to investigational therapies.
- Author, review, and approve clinical study documents relating to IP handling.
- Participate in the development of tools that will enhance clinical trial data integrity and maintain regulatory compliance.

BHUMI PATEL PharmD, MBA(c)

Regulatory Affairs/Safety and Benefit-Risk Management Fellow, MCPHS/Biogen, 2015–2017

Current Position: Regulatory Global Labeling Lead, Pfizer Oncology

"Each day in the fellowship brought new opportunities, which allowed me to grow both personally and professionally. I gained a deep knowledge of the biopharmaceutical industry through mentorship and a stellar program designed to enable me with the foundation and skill set I needed for a successful career."

AHMAD KHAN PharmD

Medical Affairs/Medical Science Liaison (Multiple Sclerosis) Fellow, MCPHS/Sanofi Genzyme, 2015–2017

Current Position: Regional Medical Director, Horizon

"Looking back on my fellowship, I am able to reflect on the tremendous amount of hands-on experience I gained within U.S. medical affairs. By rotating through multiple core functional areas, I strengthened my knowledge of the biopharmaceutical industry and effectively collaborated with numerous in-house and field-based colleagues. My mentors were heavily invested in my personal and professional development, challenging me with new opportunities. Along with extensive exposure to the industry, my role as an assistant adjunct faculty member allowed me to facilitate various lab sessions and teach didactic lectures, which truly gave me a unique clinical experience that I've carried forward throughout my professional career. The strong bonds I cultivated amongst my cofellows grew my network with highly intelligent and motivated professionals."

CLINICAL SUPPLY CHAIN

Responsible for leading the development and execution of supply strategies for investigational products (IPs), from first in human trials to commercialization.

- Collaborate with a cross-functional team to direct the development, production, and distribution of IP materials.
- Optimize supply strategies to manage the dynamic changes that occur during clinical development.
- Provide feedback and review of key study documents that influence clinical trial design, product strategies, and site-facing resources.
- Forecast and manage IP inventory to ensure supply continuity.
- Ensure study document accuracy while remaining in alignment with regulatory and quality requirements.
- Coordinate development of IP labels and finished goods packaging that promote ease of use by sites and study participants.
- Monitor study risks related to clinical supply to identify and mitigate potential issues.

DRUG SAFETY AND PHARMACOVIGILANCE

Accountable for analyzing the safety profile of company products over the entirety of each product's life cycle.

- Evaluate and communicate the risks associated with each product so that the company, healthcare professionals, and patients are able to make informed healthcare decisions.
- Detect, assess, and report adverse events from clinical trials and postmarketing safety surveillance.

- Collaborate with other functional areas to provide safety information that will shape investigative and postmarketing activities.
- Identify safety signals and determine the necessity of updating product labeling.
- Provide ongoing safety updates to health authorities through periodic aggregate safety reports and ad hoc requests.
- Develop risk-management plans to describe how the company will monitor and minimize risks associated with each product.

GLOBAL COMMERCIAL STRATEGY

Responsible for the development and execution of global commercial strategies and supporting marketing materials necessary for realization of brand goals.

- Create and refine product and disease value messaging to drive brand success throughout various stages of product life cycle.
- Increase brand awareness through coordinated marketing opportunities at global conferences and disease awareness campaigns.
- Lead the cross-functional core team in the development and execution of brand strategy.
- Identify marketing opportunities and areas of unmet need through execution of global market research initiatives.
- Gather and analyze competitive intelligence insights to support the brand within the context of the evolving market landscape.
- Engage with patient advocacy organizations to better understand the needs of patient communities.
- Provide commercial assessments for new and existing therapies that may complement the company's current portfolio.

HAYK KRIKORIAN PharmD

Global Pharmacovigilance & Epidemiology Fellow, MCPHS / Sanofi Genzyme, 2017–2019

Current Position: Senior Safety Scientist, Cerevel Therapeutics

"In my experience as an MCPHS PharmD fellow at Sanofi Genzyme, I was incorporated into post-marketing safety teams and worked on meaningful projects from day 1. My 2-year fellowship in Global Pharmacovigilance provided me with a solid foundational experience allowing me to jumpstart my career in biotech. In addition to gaining valuable hands-on experience, fellows are surrounded by a network of peers fostering connections for years to come."

ABENA BOAHENE PharmD

Clinical Supply Strategy and Management Fellow, MCPHS/Pfizer Inc., 2017–2019

Current Position: Medical Science Liaison, Hematology/Gene Therapy, Vertex Pharmaceuticals

"I couldn't have asked for a better springboard from which to launch my career in industry. The commitment of my industry preceptors to the success of the fellows opened the doors to multiple leadership, learning, and networking opportunities for me. Additionally, the collaboration with MCPHS University—in the form of mentorship from academic preceptors, the teaching certificate program, and the MCPHS Fellowship Network—provided yet another opportunity for me to develop a different but equally important skill set. These really set me up for success and enabled me to smoothly transition to a different functional area at the end of my fellowship—a true testament to the well-rounded experience I gained through this program."

GLOBAL MEDICAL INFORMATION

Responsible for responding to unsolicited requests for medical and clinical information about marketed products and products in development as well as disease/diagnosis-related questions received from healthcare professionals, patients/consumers, and public and private payers.

- Develop a strong understanding of the therapeutic area and develop product expertise including but not limited to general product information, efficacy, safety information, adverse effects, drug interactions and concomitant use, pharmacokinetics and pharmacodynamics, dosing and administration, use in special populations, and pharmacoeconomics.
- Develop the skills to evaluate scientific data and literature effectively.
- Develop medical information response documents to respond to medical inquiries.
- Attend and staff medical information booths at medical congresses.
- Collaborate with cross-functional teams and departments, including legal, regulatory, scientific communications, global medical affairs, medical science liaisons, pharmacovigilance, medical/clinical review, marketing, and other departments, to develop and obtain approval of global medical information resources.

MEDICAL AND VALUES-BASED OUTCOMES

Responsible for fostering ongoing professional relationships with key population-based healthcare decision makers to provide comprehensive medical education and collaborative research opportunities to ensure proper coverage and access to pharmaceuticals for patients. Also responsible for seeking to improve patient care in an evolving and increasingly cost-conscious healthcare environment.

- Create and communicate medical value propositions to population-based healthcare decision makers.
- Conduct real-world or health-economic research initiatives in partnership with both internal colleagues and external stakeholders.
- Present at congresses and partake in field rides with the medical outcomes science liaison team.
- Consistently work to be a trusted partner within the team.

MEDICAL AFFAIRS

Responsible for acting as an internal medical and scientific expert to train, educate, and ensure material accuracy and integrity by generating data, providing medical education, and communicating insights to address unmet medical needs.

- Work with cross-functional teams on the development and approval of core clinical material (e.g., field slide sets, abstracts, manuscripts, posters).
- Build scientific relationships and collaborate with key opinion leaders, payers, and midlevel practitioners via advisory boards, investigator meetings, and field visits in order to further develop the medical strategy.
- Educate the medical team and sales forces on the drug and disease state and provide them with scientifically accurate, balanced information to communicate to stakeholders.

- Aid in the implementation of an appropriate publication strategy, provide ideas for generating manuscripts of scientific interest and commercial value, and write and review manuscripts and abstracts with appropriate clinical messages.

QUALITY ASSURANCE

Responsible for providing quality oversight of issues that impact patients across the quality system in both an operational and a strategic capacity. Quality Assurance serves at the interface of current standards such as good manufacturing practice and good clinical practice from early phase through postapproval surveillance studies.

- Conduct reviews of internal and external processes for ensuring compliance with regulatory standards and requirements, protecting the company's reputation, and ultimately promoting continuous improvement.
- Support the process and documentation for the preparation of investigational products at clinical sites.
- Manage investigations and complaints for product-related issues to identify root causes and appropriate resolutions.
- Promote a robust quality culture across the entire organization.

ABIMBOLA COLE PharmD, MPH

Global Pharmacovigilance Fellow,
MCPHS/Takeda, 2017–2019

Current Position: Scientific Director, Safety Evaluation & Risk Management (SERM), GSK

"Pursuing a fellowship after completing my PharmD degree was one of the best choices I made. My fellowship experience gave me a strong foundation in industry and provided me with numerous opportunities that allowed me to grow both professionally and as an individual. Through interactions and participation with various interdisciplinary teams at Takeda, and professional development provided by MCPHS University, I finished the fellowship with skills and experiences that surpassed what is expected of one in the industry for just two years."

REGULATORY AFFAIRS

Responsible for providing regulatory strategy and guidance for global developmental and commercial programs.

- Collaborate with and lead cross-functional teams to develop appropriate regulatory strategies from preclinical to postmarketing stages.
- Facilitate and compile submissions to health authorities, such as investigational new drug applications/clinical trial applications, new drug applications/biologics license applications/ marketing authorizations, annual reports, orphan drug designation applications, and amendments.
- Support and/or lead interactions between the company and health authorities.
- Support, create, and/or coordinate the development of study documents and product labeling.
- Review and approve advertising and promotional material (advertising/promotion regulatory fellowship).

U.S. MARKETING

Responsible for acting as the medical point person on marketing plans, training efforts, and strategy execution while applying clinical insights within the marketing function.

- Contribute to market landscaping related to new technologies and assist in shaping the medical marketing strategy.
- Lead innovative marketing projects intended to drive business forward and educate patients and healthcare providers on proper use of technology.
- Translate pertinent clinical study results into marketing and educational tools.

U.S. MEDICAL MANAGED CARE

Gain advanced experience in U.S. payer access and the evolving payer models, including pharmacy benefit managers, health maintenance organizations, Medicare, Medicaid, and other healthcare decision makers.

- Establish and foster ongoing professional relationships with key managed-market decision/policy makers to provide comprehensive medical education and health outcomes solutions.
- Support the Medical Managed Care team during field customer engagements and provide insights to internal stakeholders on key evidence gaps relevant to specific accounts.
- Work with cross-functional colleagues on health-economic data communication and identify opportunities for cross-functional collaborations.
- Identify and facilitate health-outcomes research or educational opportunities and contribute to the design and execution of patient outcomes and medical economics strategy.

MCPHS FELLOWSHIP NETWORK (MFN)

The MCPHS Biopharmaceutical Fellowship emphasizes not only personal and professional development but the creation of lasting connections. The MCPHS Fellowship Network, or MFN, brings together program directors, industry preceptors, current fellows, and program alumni to forge bonds that extend far beyond the one- or two-year fellowship appointment. The dedicated and diverse group of alumni take an active role in mentoring current fellows—a testament to the strength of the network. The MFN has created a launch pad for successful careers in the industry for pharmacists of all backgrounds while affording numerous opportunities for lifelong friendships to be made along the way.

CONNECT WITH US

FELLOWSHIP BLOG

The fellowship blog features articles by the MFN. It serves as a resource to learn about the fellowship program and raises awareness about the importance of involving pharmacists in the biopharmaceutical industry. It is also the easiest way to get up-to-date information about fellowship events, recruitment, and more. Scan the QR code to link to the fellowship blog or visit **www.mcphsfellowship.com**.

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agios

ALEXION
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SAREPTA
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