Novartis

# Biopharmaceutical Industry Fellowship Program 2023 - 2024

## Novartis & Massachusetts College of Pharmacy and Health Sciences (MCPHS) University

NOVARTIS

# Table of Contents

# A Message from Fiona Marshall

There has never been a more promising time to be in drug discovery than today. Empowered by unprecedented tools and technologies, we have the potential to understand diseases at a deeper level than ever before and address their underlying causes with innovative new medicines. Every day, Novartis scientists and clinical researchers pursue this mission, working to make breakthrough discoveries and translate science into life-changing and life-saving medicines for patients.

Collaboration is at the heart of our approach. Our associates work together openly and closely across disciplines and geographies, collaborating with teams that span the breadth of our research-to-development-to-commercial continuum. We forge partnerships with leading academic institutions and researchers, biotech and technology companies, and beyond because we believe that innovation happens everywhere. And we collaborate with patients, whose insights, needs, and experiences guide our efforts to deliver medicines that can bring meaningful benefit to their lives.

If you believe in the promise of collaborative drug discovery, have the ambition to address pressing global health challenges, and aspire to learn how to create transformative medicines from industry-leading scientists and clinicians, then the Novartis & MCPHS Biopharmaceutical Industry Fellowship is the ideal opportunity for you. We appreciate your interest in Novartis and wish you the best during the application process.

Sincerely,
Fiona Marshal, Ph.D.
President, BioMedical Research

# Novartis & MCPHS Fellowship Overview

## Our Mission

The Novartis & MCPHS fellowship provides PharmD graduates with the unique opportunity to gain practical experience in early phase clinical trials. As integral members of the development team, Novartis fellows will utilize their clinical skills to contribute to the design and conduct of early phase trials.

Throughout the two-year fellowship program, Novartis fellows will be exposed to a multitude of early clinical research concepts. Fellowships positions are available in **Biomarker Development (BMD), Clinical Operations – General Medicine, Clinical Operations – Translational Clinical Oncology (TCO), Drug Development Quality Assurance (QA), and Regulatory Affairs (RA)**. As part of the drug development process, Novartis fellows will learn to excel in a dynamic, cross-functional, global team environment.

## Our Philosophy

The fellowship program is designed to foster individual learning and growth. Novartis fellows are encouraged to identify and develop special projects based on their interests, and have the opportunity to attend at least one national scientific meeting annually. Additionally, Novartis offers a variety of seminars and courses designed to build scientific and professional skills.

The Novartis fellow will have industry and faculty preceptors who will foster their professional growth by encouraging them to reach their full potential through dedicated mentorship.

# Novartis Research Overview and Pipeline

Novartis' global pharmaceutical research organization is headquartered in Cambridge, Massachusetts. As the growth engine of Novartis, we collaborate across scientific and organizational boundaries, with a focus on powerful new technologies that have the potential to be therapeutic breakthroughs for patients.

The Novartis global clinical pipeline includes more than **150** projects and over **500** clinical trials. Within Novartis' Cambridge campus, we have more than **5,600** dedicated scientists and physicians, working across **6** global campuses.

To learn more about our pipeline, click here.

## Our Culture

We strive to unleash the power of our people, and we cultivate a company culture that is inspired, curious, and unbossed.

## Our Values & Behaviors

Our 4 core values and behaviors underpin our company culture and summarize how we create an impact on our business and on each other, and they enable us to recognize and reward the time, expertise and ideas that contribute to our success. They provide the foundation for how we do things at Novartis.

To learn more about what Novartis has to offer, click here.

# Novartis Values

## Inspired

Our purpose answers the desire many people have for meaning and fulfilment in their work, so we want to make sure our people see the huge contribution that their work makes, to empower them to be their best selves every day and achieve their personal and professional goals.

## Curious

We believe curiosity fuels discovery. To develop innovative medicines and breakthrough healthcare solutions, we need curious minds with a constant desire to learn and a passion to discover new and better ways of doing things.

## Unbossed

Our people are most creative and productive when they are empowered to shape their work environment and pursue their ideas. We are focusing on encouraging leaders to remove obstacles and to empower their teams to reach their full potential. We are also equipping them with tools to be more self-aware and to set clear goals.

## Integrity

Be honest. Have courage. Do what is right.

# 2023-2024 Current Fellows

Front row: Ashley Huskey (BMD), Stephanie Chang (RA), Reina Marie Sanz (RA), Sandy Rodriguez (TCO)

Back row: Mathew Costello (QA), Joseph Sidoti (CS&I), Rana Said (BMD), Zamir Latif (CS&I), Seth Rice (TCO)

Not pictured: Jonathan Trolander (CS&I)

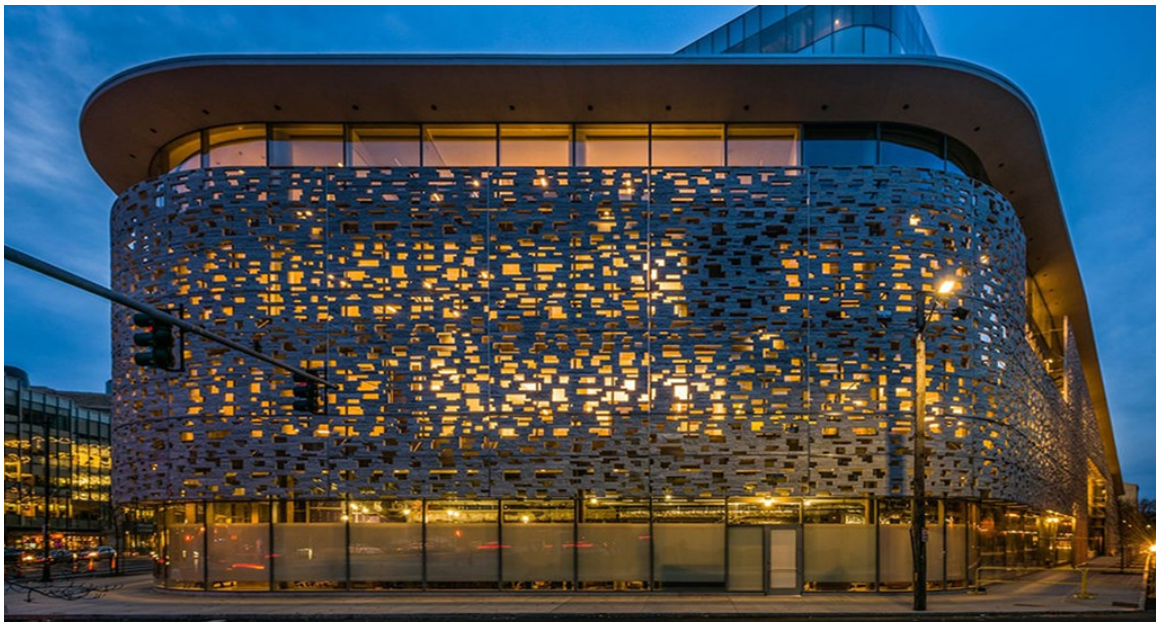
# Biomarker Development (BMD)

The BMD department in Translational Medicine delivers integrated biomarker plans using diverse expertise and knowledge in genetics, genomics, imaging, protein and cellular biology, human tissue research, vendor scientific monitoring, statistics, bioinformatics, digital endpoints, patient centric sampling and study coordination.

Biomarker solutions are critical in clinical development to: define the stage/subtype of the disease; predict the effect of medication; select a group of patients who would benefit most from a given therapy; and identify opportunities for development of companion diagnostics. Our scientists identify and use a wide range of biomarkers to investigate a disease, profile a compound's mechanism of action, potency and likely side effects, select patients who may respond to therapy based on their genetic profile; and develop parallel/ expanded indications for the compound.

**Our fellow will learn to:**

- Represent BMD on clinical trial teams, work with Biomarker Experts and Clinical Trial Leaders to develop biomarker plans for implementation in clinical studies
- Gain familiarity with innovative biomarker technologies used in clinical research
- Develop relevant study documentation, including clinical protocol biomarker sections, lab manuals, informed consent forms, and biomarker study budgets
- Work with internal and external stakeholders to resolve issues related to biomarker samples in ongoing clinical trials
- Acquire knowledge of potential ethical issues related to biomarker sample collection and analysis, and devise solutions that satisfy both ethical concerns and study objectives
- Lead and contribute to process improvement projects, technology evaluations, and other initiatives across Novartis' research sites



# BMD Fellows and Preceptors

**Ashley Huskey, PharmD**
1st Year Fellow, BMD
University of Colorado

**Rana Said, PharmD**
2nd Year Fellow, BMD
Rutgers University

**Dmitri Mikhailov, PhD**
Head of Biomarker Coordination
BMD Fellowship Director and Preceptor

**Dana Lee, PharmD, RPh**
Principal Scientist I
BMD Fellowship Preceptor

"This program fosters the skills necessary for professional and personal growth by working in an environment with a strong mentorship culture, hands-on learning, and by functioning as a contributing member of multi-disciplinary clinical trial teams."

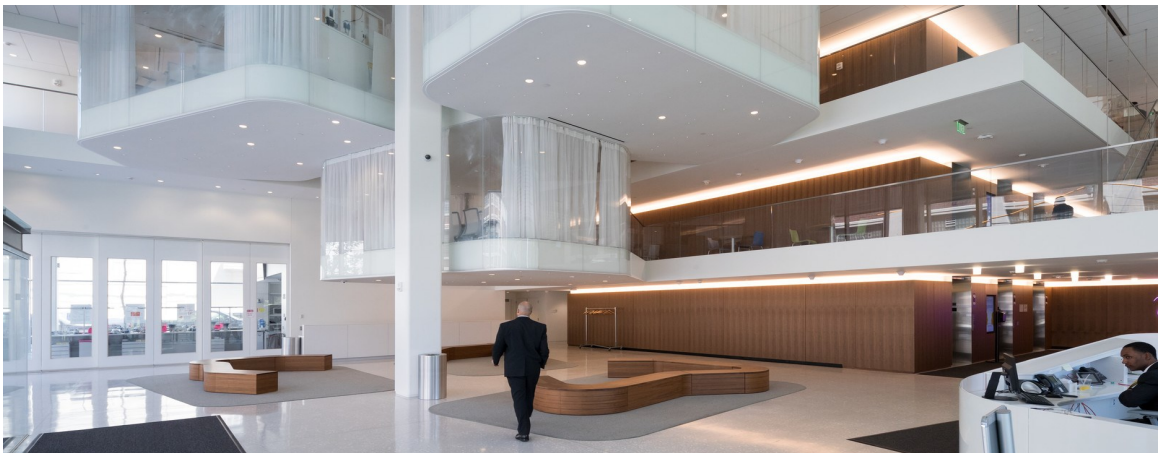
–Dmitri Mikhailov

# Clinical Operations – General Medicine

The Clinical Sciences & Innovation (CS&I) department in Translational Medicine is a dynamic group of clinical scientists responsible for the conduct and evaluation of Phase I and Phase IIa clinical studies. These studies are designed to profile safety, tolerability, pharmacokinetics and pharmacodynamics, and to provide early proof of efficacy of novel compounds in humans. Globally, CS&I performs early clinical research in diabetes, cardiovascular and metabolic conditions, ophthalmology, musculoskeletal disorders, neuroscience, respiratory, autoimmunity, dermatology, transplantation and tropical diseases. Over 100 clinical sciences experts in multiple CS&I locations worldwide strive to support a smooth transition from discovery research to clinical practice-driven by a strong focus on clinical & data sciences, clinical innovation, patient centricity and strategic planning. Our fellows will train to become Clinical Scientists through assistance in delegated tasks to support the Clinical Trial Team in the conduct of clinical studies within Translational Medicine.

**Our fellows will learn to:**

- Execute clinical trials in compliance with Novartis processes and current regulatory guidelines
- Support study start-up activities through initial feasibility, development of operational plans and trial budgets
- Develop and maintain essential trial documents such as Study Protocols, Informed Consent Forms, Pharmacy Manuals, Data Review Plans, and Clinical Trial Quality Risk Management Plans
- Liaise with Novartis Country Organizations, Investigator sites, Clinical Research Associates (CRAs), Contract Research Organizations (CROs), vendors, and other suppliers to ensure study deliverables are met
- Manage study and site performance via tracking of screening and enrollment activities, data entry, and protocol deviations
- In collaboration with the Medical Expert and Clinical Trial Team, coordinate the ongoing medical review of the clinical trial data and coordinate the data analysis and interpretation for first interpretable results
- Assist in the compilation of the clinical study report
- Maintenance of knowledge and training of ICH-GCP, current regulations and procedures
- Learn to work cross-culturally with colleagues and study sites around the world



# Clinical Operations – General Medicine Fellows and Preceptors

**Joseph Sidoti, PharmD**
1st Year Fellow, CS&I
Ohio Northern University

**Zamir Latif PharmD**
1st Year Fellow, CS&I
Purdue University

**Jonathan Trolander, PharmD**
2nd Year Fellow, CS&I
University of Rhode Island

**Megan Barton, BS**
Clinical Sciences Therapeutic Area Head, Global Health
CS&I Fellowship Director

**Katy Hayes, MPH**
Senior Clinical Scientist
CS&I Fellowship Preceptor

**Lee Anne Filosa, PharmD**
Senior Clinical Scientist
CS&I Fellowship Preceptor

"Starting from the moment I interviewed at Midyear, I felt that Novartis and the CS&I team had a supportive culture that would be a positive learning environment for me as I started my career. Six years later, I still feel this way. Novartis has been the ideal place for me to develop in my role."

–Lee Anne Filosa

# Clinical Operations – Translational Clinical Oncology (TCO)

Novartis' Translational Clinical Oncology accelerates innovative hematology/oncology compounds from target discovery to commercialization. TCO aims to advance patient outcomes in early trials by selecting patients based on the molecular mechanism of drugs and diseases.

The TCO function is responsible for: developing the strategy and executing first-in-human and proof-of-concept clinical trials for hematology/oncology therapeutics using adaptive design; developing and executing biomarker and imaging strategies in clinical trials; providing robust research support to hematology/oncology compounds to increase clinical trial success and maximize patient benefit through patient stratification, indication expansion, and combination therapy; managing of global clinical trials using patient selection and targeted therapies; and ensuring a smooth hand-off to full development to advance medicines to market.

**Our fellow will learn to:**

- Lead and participate in the clinical trial team to impact study design, conduct, and analysis
- Lead and coordinate the development of clinical trial protocols, amendments and related documents; drive and/or contribute to the development of trial-related documents and processes
- Develop effective working relationships with investigators. Support protocol training meetings and support CPOs in regulatory submission preparation and the conduct of regional meetings.
- Support the global multidisciplinary CTT to ensure all trial deliverables are met according to timelines, budget, quality standards and operational procedures: attend CTT meetings, assist in report study progress and issues.
- Prepare dose escalation meetings with investigators. Coordinate the real time availability of quality clinical trial data, including safety, efficacy, pharmacokinetic, imaging and biomarker data, to provide consolidated information for dose escalation meetings with investigators.
- Contribute to the design of data capture tools and statistical analysis plans
- Create and obtain essential regulatory trial documents
- Orchestrate selection and oversight of clinical trial sites and external vendors
- Participate in the ongoing review and cleaning of the clinical trial data, support final analysis and interpretation including the development of clinical trial reports, publications and internal/external presentations.
- Contribute to development of clinical section of regulatory documents like Investigator's Brochure, safety updates, IND/NDA submission documents, responses to Health Authorities questions

# TCO Fellows and Preceptors

**Sandy Rodriguez, PharmD**
1st Year Fellow, TCO
Chapman University

**Seth Rice, PharmD**
2nd Year Fellow, TCO
University of Michigan

**Craig Talluto, PhD**
Senior Clinical Operations Group Head
TCO Fellowship Director

**Rowshan Chowdhury, PharmD**
Clinical Trial Leader II
TCO Fellowship Associate Director
& Preceptor

**Sarah DiDominick, PharmD**
Clinical Scientist
TCO Fellowship Preceptor

"The name Novartis is derived from *novae artes*, meaning "new arts" or "new skills". I knew that I wanted to launch a career where innovation and creativity are highly valued, and believed Novartis to be a leader in these areas. Being here has only further solidified that belief."

–Rowshan Chowdhury

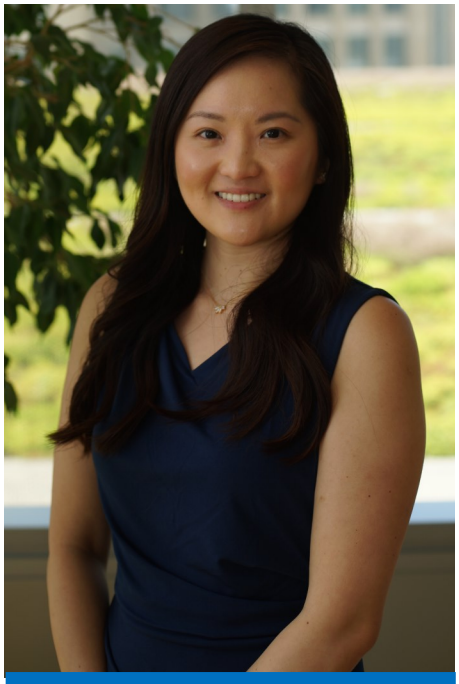
# Regulatory Affairs (RA)

The Regulatory Affairs Early Development (RA ED) department at Novartis is responsible for providing global strategic regulatory guidance to advance a diverse portfolio of compounds through the early phases of clinical research from first-in-human (FIH) Phase I trials through proof-of-concept (PoC) Phase IIa studies. RA ED supports programs across Oncology, Hematology, Non-Malignant Hematology and a wide range of General Medicine disease areas, including Autoimmunity/ Transplantation/Inflammation, Cardiovascular and Metabolism, Musculoskeletal, Neuroscience, Respiratory, and Tropical Diseases. Over the course of the two-year fellowship, the fellow will gain exposure to and assist in developing the global regulatory strategy for programs in a multitude of these disease areas which will lay the foundation to perform as a strong regulatory professional.

**Our fellow will learn to:**

- Support major global regulatory submissions to enable the conduct of FIH and PoC clinical studies, including Investigational New Drug applications (INDs) and Clinical Trial Applications (CTAs)
- Outline early- and late-stage development regulatory strategy for projects (small molecules, biologics, cell and gene therapies, and radioligand therapies) based on alignment and input from cross-functional drug development teams as well as interpretation of relevant health authority guidance documents and regulatory precedence
- Support and lead preparatory activities for meetings with global health authorities including pre-IND, End of Phase I/II, pre-submission, and scientific advice meetings
- Work with teams to prepare global regulatory maintenance submissions including IND Annual Reports, Development Safety Update Reports (DSURs), as well as protocol and information amendments
- Conduct regulatory intelligence research to inform the development strategy for a particular drug, disease, or therapeutic area
- Utilize the procedures, systems, and databases to comply with requirements for electronic record -keeping

# RA Fellows and Preceptors



**Stephanie Chang, PharmD, MPH**
1st Year Fellow, RA
Northeastern University

**Reina Marie Sanz, PharmD**
2nd Year Fellow, RA
University of the Pacific

"In RA Early Development, we are afforded the unique opportunity to be the bridge between discovery research in the lab, early translational development, as well as late stage development. This allows us to have a significant impact on the overall strategy and development of novel therapeutics at Novartis."

–RA Fellowship Department

**Monica Pham, PharmD**
Senior Global Program
Regulatory Manager
RA Co-Director and
Fellowship Preceptor

**Nathan Fons, PharmD**
Senior Global Program
Regulatory Manager
RA Fellowship Preceptor

**Emily Harris, PharmD, MS**
Senior Global Program
Regulatory Manager
RA Co-Director and
Fellowship Preceptor

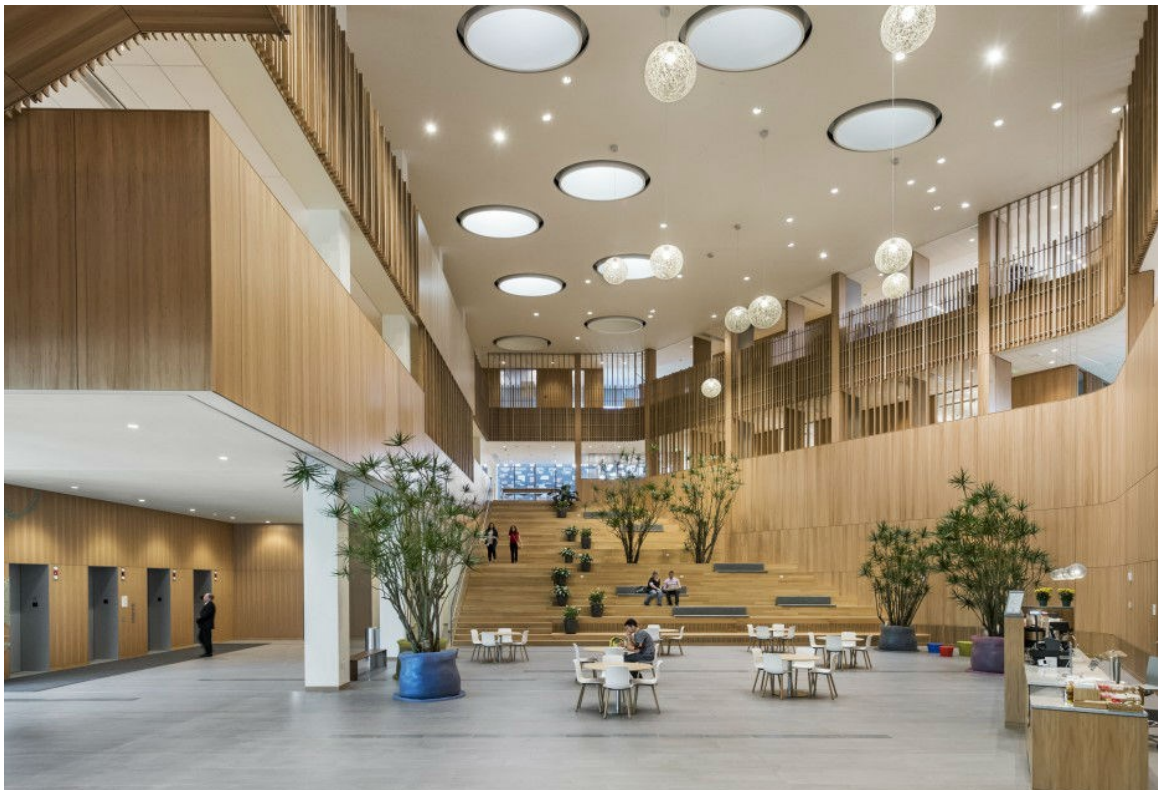
**Anna Liljeblad, PharmD**
Global Program
Regulatory Manager
RA Fellowship Preceptor

# Drug Development Quality Assurance

Novartis Quality provides guidance and support to highlight risks and build a quality mindset with scientists and clinical research teams to maintain compliance with ethical and regulatory requirements. The fellow will learn to apply Good Clinical Practice Guidelines (GCP) and International Conference of Harmonization (ICH) standards while working with associates in Quality and Operations to provide services that are specific to drug discovery and early development with the opportunity to explore later development stages.

**Our fellow will:**

- Explore the quality continuum from bench to bedside (i.e. drug discovery to marketed product)
- Investigate quality issues, determine root causes, and develop appropriate corrective and preventive action plans (CAPAs)
- Support and execute Quality projects
- Support preparation of compliance data and provide status updates
- Review and comment on standard operating procedures (SOPs) and draft regulatory requirements associated with clinical trials
- Participate and support quality actions in preparation for submission and inspection readiness
- Attend and participate in a clinical site monitoring visit and/or audit
- Deliver ICH/GCP Training



# QA Fellow and Preceptors

**Mathew Costello, PharmD**
2nd Year Fellow, QA
Northeast Ohio Medical University

**Laurie J. Hafer, PhD**
Head of Novartis Clinical Quality
QA Fellowship Director

**Gabrielle Kyne, MS**
**Biotechnology and Regulatory Affairs**
Director Clinical Quality
QA Fellowship Preceptor

"Novartis' research is the innovation engine, collaborating across scientific and organizational boundaries to bring therapies to patients with unmet medical needs. Early clinical trials are a crucial step in the process between drug discovery and clinical application, and Clinical Quality oversight of these trials ensures safe and compliant execution. Novartis Quality Assurance provides the MCPHS Fellow the opportunity to engage with researchers, biomarker development scientists, and clinical scientists in a fast moving, innovative environment"

–Gabrielle Kyne

# MCPHS Biopharmaceutical Industry Fellowship

**MCPHS Overview**

MCPHS University is a private institution with a history of specializing in health sciences, and offers programs that embody scholarship, professional service and community outreach. MCPHS University provides an academic environment to guide and support Fellows toward a successful career in the biopharmaceutical industry.

**Educational Mission:**

Fellowship programs at MCPHS University are established to provide high-quality, post-graduate opportunities for motivated individuals seeking advanced exposure to academics and immersion in the biopharmaceutical industry. The individual Fellowship programs strive to ensure quality, strength and continued development each year. Fellows will gain experience in the areas of teaching and research by participating in various courses and research with faculty preceptors.

Throughout the Fellowship program, MCPHS University faculty and company program leaders mentor Fellows according to their scholarly and professional interests.

**As an adjunct instructor at MCPHS University, Fellows have the opportunity to:**

- Develop, coordinate, and teach courses
- Co-precept students on advanced experiential rotations
- Create and publish scholarly research and/or review articles
- Present data at scientific and clinical meetings
- Participate in professional development seminars with other Fellows

**Amee Mistry, PharmD**
Professor of Pharmacy Practice,
Director, Biopharmaceutical
Industry Fellowship Program
MCPHS University

Dr. Amee Mistry is a Professor of Pharmacy Practice and has been with MCPHS University since 2006. Dr. Mistry earned her PharmD at the Albany College of Pharmacy and completed a PGY1 Community Practice Residency with Walgreens and MCPHS University. In 2015, Dr. Mistry took over as Director of the MCPHS Biopharmaceutical Industry Fellowship program. She works directly with leaders in the area to continue to foster growth and development of the post graduate program, and to assist the fellows in attaining positions within the pharmaceutical industry.

In addition, she is advisor for the student IPhO chapter at MCPHS, co-advisor for APhA-ASP, a national trainer for the APhA Pharmacy-Based Immunization training program, and is actively involved with the Massachusetts Pharmacists Association.

# MCPHS Faculty Preceptors

## Biomarker Development (BMD)

**Robert Campbell, PhD**
Associate Professor of
Pharmacy Practice
MCPHS University

## Clinical Operations – General Medicine

**Valerie Coppenrath, PharmD, BCPS**
Associate Professor
of Pharmacy Practice
MCPHS University

**Dinesh Yogartnam, PharmD, BCPS**
Associate Professor
of Pharmacy Practice
MCPHS University

## Clinical Operations – Translational Clinical Oncology (TCO)

**Christy Harris, PharmD, BCPS, BCOP**
Associate Professor
of Pharmacy Practice
MCPHS University

**Loriel Solodokin, PharmD**
Associate Professor of
Pharmacy Practice
MCPHS University

## Drug Development Quality Assurance

**Michael Bear, PharmD**
Associate Professor of
Pharmacy Practice, MCPHS
University

## Regulatory Affairs (RA)

**Phung C. On, PharmD, BCPS**
Associate Professor of
Pharmacy Practice
MCPHS University

# Application Requirements 2023-2024

## Eligibility

The MCPHS Biopharmaceutical Industry fellows will be selected on a nationally competitive basis. Applicants must have a Doctor of Pharmacy degree from an ACPE accredited college of pharmacy at the commencement of the program.

- Candidates must have strong written and verbal communication skills and a strong interest in pursuing a career within the biopharmaceutical industry.
- All candidates must have authorization to work in the United States throughout the duration of the one or two year fellowship. No visa sponsorship will be provided (i.e., TN, H-1B, STEM OPT, etc.).

## Application Procedure

The MCPHS application portal (SMApply) will open on **Monday, October 2nd, 2023**. Applicants must upload the following application materials to the online portal (https://mcphs.smapply.io) no later than **Friday, November 17th, 2023**:

- Letter of intent
- Curriculum vitae
- Unofficial college transcript
- Contact information of three references. References will receive an electronic recommendation form to complete separately.

Three recommendation evaluation forms must be submitted no later than **Monday, November 27th, 2023** via the online portal. This is NOT a letter of recommendation but an online form that the recommender will receive for completion from SMApply.

## Rolling Application Review & Interviews

All submitted applications will be reviewed on a rolling basis. Interviews will also be offered on a rolling basis and opportunities are limited. Priority will be given to those applicants who apply early, well in advance of the deadline.

Rolling interviews will start mid-October with pre-screens and a mixture of interview rounds which will conclude in December at the end of the ASHP Midyear Clinical Meeting. Candidates will be notified if selected for an interview.

# Application Requirements 2023-2024 (continued)

## ASHP Midyear & Onsite Interviews

The fellowship program will be conducting **in-person interviews** at the ASHP Midyear Clinical Meeting in Anaheim, CA. Applicants are strongly encouraged to attend. Candidates attending in-person will not be able to interview without registering for both ASHP and PPS. Please refer to the ASHP & PPS website for registration details.

Top candidates may be invited for interviews at the sponsoring company's location.

## Offer Dates

Recognizing that the choice of a Post-Doctoral Industry Fellowship is an important decision, MCPHS in conjunction with the Academic Industry Fellowship Alliance (AIFA), has agreed to extend offers for Fellowships no earlier than **Wednesday, December 13th, 2023**. We see this respect for candidate choice as a common aspect of each of our Program's cultures. We hope that other academic and non-academic Fellowship Programs will respect this timeline to allow for best program fit for candidates

## Onboarding

Final candidates will be required to go through additional screening / onboarding as required by MCPHS.

## Questions

Please email pharmd.fellowships@novartis.com