



AgiOS Pharmaceuticals, Inc.

Biopharmaceutical Industry Fellowship Programs

Currently recruiting 2-year programs

- Clinical Development, Clinical Scientist
- Clinical Supply Chain
- Medical Safety and Risk Management

2027–2029



↓ Agios: Fueled By Connections to Transform Rare Diseases™

We are striving to redefine the future of rare disease treatment.

At Agios, we are fueled by connections: to one another, to our communities, and to rare disease patients. We believe meaningful progress begins with understanding, listening to the needs of patients and their families and learning from their experiences to develop medicines that have the potential to transform lives.

This community-first approach is embedded throughout Agios. It shapes how we advance our research, design clinical programs, develop educational and patient support resources, and foster a culture where employees are connected to and inspired by the communities we serve.

Agios is focused on making a meaningful difference for people living with rare diseases through the discovery, development, and delivery of innovative medicines. Our pioneering research in pyruvate kinase (PK) activation led to the development of mitapivat, the first and only approved therapy for PK deficiency and the first and only approved treatment for all subtypes of thalassemia, regardless of genotype or transfusion burden. Mitapivat is approved for adults with thalassemia in the European Union, Saudi Arabia, and United Arab Emirates under the brand name PYRUKYND®, as well as in the U.S. under the brand name AQVESME™. The medicine is also approved as PYRUKYND for adults with PK deficiency in both the U.S. and Europe.

In addition, our robust pipeline includes late-, mid-, and early-stage programs across several rare diseases, including sickle cell disease, immune thrombocytopenia, polycythemia vera, and phenylketonuria.



↓ Our Values Guide Our Actions and Decisions

Aim High

We're here to do great things in partnership with patients. We set the bar high for ourselves, and we keep working to raise it. At our core, we're guided by a deep respect for the science and a commitment always to act with the utmost integrity.

Come Together

We foster a caring and open community with our team. We grow supportive relationships with patients and caregivers. We build trusting connections with collaborators. Together, we make a bigger impact than we ever could alone.

Embrace Differences

Because opportunities and insights come from anywhere and anyone, we honor all voices and encourage honest dialogue. We learn equally from success and failure, bringing an open mind and a flexible approach to everything we do.

Bring Your Whole Self

We know we make the biggest impact when each of us can contribute and lead in our own way. So, we honor everything that makes you uniquely "you" – and we never, ever tolerate jerks. At the end of the day, we aim to solve serious problems and have fun doing it.

Blaze New Trails

We ask the tough questions that lead to groundbreaking scientific advances. We nurture a creative mindset and resourceful approach that spark life-changing innovations for patients. No matter where our journey takes us, we keep challenging ourselves and our colleagues to find new and better ways to realize the potential of our science.

For more information about the Agios pipeline, please scan the QR code.



↓ The Agios Fellowship Experience

At Agios, we strive to offer a balanced fellowship program that can help sharpen both technical and interpersonal skill sets, which we believe can help produce a well-rounded colleague at the end of the fellowship tenure.

Our fellows get started quickly in their functional areas with hands-on learning and the development of technical skill sets relevant to their role. Under the guidance of their preceptors, fellows will begin taking responsibility for tasks within their team to learn by doing. The program encourages fellows to leverage lessons learned, continuously building their abilities through firsthand experiences. We believe having the opportunity to interact directly with a new concept, then apply the insights gained to refine future approaches is key on the way to building confidence when doing something new. A new Agios fellow can expect to be collaborating with colleagues in their department, and cross-functionally on different project teams, shortly after on-boarding training has completed. Agios strives to have fellows who are comfortable interacting with teammates in various departments and are confident participating in day-to-day operations by the end of their first year.

The Agios fellowship program also emphasizes developing well-connected colleagues, supported by the Agios company culture. Our fellows can expect invitations to both of Agios' annual whole-team meetings, Agios Connect and the Agios Fall Gathering. Attendance at these events connects fellows with colleagues from other departments and offers opportunities to interact with members of the Agios leadership team.

Fellows are also given freedom to direct the initiatives of their fellowship program. Our fellows regularly interact with the Agios program directors to set the direction of different fellowship events and align strategies for major initiatives like Midyear recruitment. The Agios value of "Lead from Every Chair" is intentionally incorporated into the fellowship structure, as we are always looking for creative solutions and input on opportunities for improvement.



When joining a mid-sized company like Agios, fellows can expect to be well connected amongst their department and with larger cross-functional teams.

Agios' size enables regular department-wide meetings, allowing each group to align strategies to tackle complex issues and refine their approaches to day-to-day activities.

The company's size means fellows will take direct responsibility for the projects they manage but can also identify colleagues with experience and expertise if a creative solution is needed. Becoming well-integrated into the team is crucial for operating effectively while maintaining Agios' high standards of quality. We look forward to developing the next generation of pharmaceutical professionals who will bring creativity, resourcefulness, and positive team dynamics to their role post-fellowship.



↓ Clinical Development, Clinical Scientist

About Clinical Development, Clinical Scientist Fellowship

Clinical development is responsible for the architecture of clinical trial concepts, protocol development, study start up, study execution, data review and cleaning, clinical interpretation of data, publication contributions, and serves as a clinical resource for regulatory filings and queries from authorities and sites. Within clinical development, clinical scientists play a role on the clinical trial working group (CTWG). They work to help align and execute on study goals and strategy within the clinical trial working group; serve as a resource for investigators on patient eligibility, safety, and protocol questions; and partner cross-functionally with early or late-stage clinical development, medical, and commercial teams.

Clinical Development, Clinical Scientist Fellowship Goals and Objectives

The fellow will gain hands-on knowledge of US and Global clinical development at Agios. The fellow will gain experience in clinical trial-related activities within the cross-functional clinical trial working group and gain an extensive understanding of the responsibilities of a clinical scientist. The fellow will:

- Develop a strong clinical development knowledge base and be able to apply their skills practically
- Obtain well-rounded knowledge of country and region-specific clinical trial processes
- Cultivate strong communication and project management skills
- Collaborate cross-functionally with various departments within the company and with key external collaborators as a partner in the clinical development process



Clinical Scientist Program Design

The fellow will join our dynamic Clinical and Translational Development (CTD) function in the Research and Development organization at Agios and will be given a plethora of opportunities to learn the business of rare disease drug development. Fellows at Agios are given the opportunity to grow into integral team members through meaningful, hands-on experiences that evolve over time. As they take on increasing responsibility and gain exposure to a wide range of projects, they make a tangible impact across the organization. Within the Clinical and Translational Development (CTD) function, the Clinical Scientist team offers a dynamic environment where fellows can grow professionally, collaborate with a diverse and enthusiastic group of researchers, and take advantage of valuable learning and development opportunities.

Clinical Development: Year1

- Learn the purpose and goals of a clinical scientist across different phases of clinical development
- Gain an understanding of the structure and function of a clinical trial and the roles and responsibilities of a clinical scientist within study start up, execution, and closeout
- Collaborate with key team members and functions who are part of clinical trial working groups at Agios, such as Clinical Operations, Regulatory Affairs, Data Management, and Safety for assigned trial(s)
- Become familiar with clinical trials being run at Agios (Phase 1-3, Adult and Pediatric, and clinical pharmacology) and participate in the review and analysis of study data
- Independently review contracts, study documents, clinical data and protocol deviations for assigned trial(s)
- Perform initial review of key study documents
- Develop a working knowledge of GCP and ICH

Clinical Development: Year2

- Contribute to initial authoring and/or review of key study documents (Protocol, Informed Consent Form (ICF), Investigator Brochure (IB), Lab Manual, etc.)
- Respond to site queries and regulatory authority queries in conjunction with clinical scientist (CS)
- Contribute to clinical data review activities across an indication/molecule
- Assist in development of clinical data review standards and timelines with cross-functional teams
- Play a role in preparing for functional review of program milestones and data supporting milestones such as interim analyses, database locks, publications, clinical advisory boards and clinical study reports (CSR), etc. as needed for assigned trial(s)
- Serve as a clinical contributor for other relevant activities (analysis plans, filing, data monitoring committee, clinical advisory boards, etc.) as needed for assigned trial(s)

Clinical Development Team

Program Director

Erin Laflam, PharmD, RPh

Director, Clinical Science – Clinical and Translational Development



Erin is a clinical scientist within the Clinical & Translational Development team at Agios. Erin's main role at Agios is serving as the lead clinical scientist on our pipeline AG-181 program and our phase 3 pediatric pyruvate kinase deficiency studies. She has worked in the pharmaceutical industry for nearly 10 years, with experience mainly in hematology and oncology, with past roles in medical communications and medical affairs including publications and medical information. She has also served as a MCPHS Fellowship Director in the past and has seen first-hand the impact a Post-PharmD fellow can have on a team; she enjoys mentoring fellows and helping them find their niche. Prior to switching careers to the pharmaceutical industry, Erin was a pharmacy manager at CVS Health in the Boston area. Erin received her Doctorate of Pharmacy from the University of Rhode Island.

Program Preceptor

Pranita Chilakamarri, PharmD

Senior Manager, Clinical Science – Clinical and Translational Development



Pranita joined Agios in 2023 as a Clinical Scientist within the Clinical & Translational Development team. She currently works on the late-stage sickle cell disease studies, contributing to key study milestones, and previously supported the pediatric pyruvate kinase deficiency studies. Her prior experience includes clinical science work focused on cell therapies. Pranita received her PharmD from the University of Saint Joseph and pursued a post-graduate fellowship with Pfizer/MCPHS University.

Program Preceptor

Olivia Roginski, PharmD, RPh

Senior Manager, Clinical Science – Clinical and Translational Development



Olivia joined Agios in 2023 as a Clinical Scientist within the Clinical & Translational Development team. She is currently involved with data review activities for the late-stage adult thalassemia studies and also supports the pediatric thalassemia studies. Previously, Olivia was a Clinical Scientist at a Midwest-based medical device company. She received her PharmD degree from Purdue University and completed a two-year post-graduate Clinical Development fellowship at Novartis Institutes for BioMedical Research and MCPHS University.

↓ Clinical Supply Chain Program

About Clinical Supply Chain

The Clinical Supply Chain team at Agios develops the strategies for managing all aspects of drug supply for investigational studies and expanded access programs. Responsible for management of all clinical supply production and distribution activities, Agios' Clinical Supply team members collaborate across a multitude of departments in drug development and oversee activities between drug product manufacturing and dispensation to patients at the clinic. These activities include determination of drug demand forecasts, development of packaging and labeling supply plans, facilitation of manufacturing with external vendors, setting up global distribution strategies, and development of risk mitigation plans. As an integral part of clinical program and study teams, Clinical Supply members also contribute to clinical study protocols, provide guidance on patient centric packaging design, participate in the build of randomization and trial supply management (RTSM) systems, and develop the masking strategy for blinded studies. Supporting multiple quickly growing programs, the group utilizes industry expertise and explores cutting-edge technology to continuously improve the way Agios delivers medications to patients.

Clinical Supply Chain Fellowship Goals and Objectives

The fellow will gain hands-on knowledge of Clinical Supply Chain activities within the Technical Operations organization and gain an extensive understanding of the drug development process.

Objectives include:

- Develop end-to-end clinical supply chain knowledge and be able to apply their skills practically to drug supply management at the clinical study and program level
- Cultivate strong communication, leadership, and project management skills
- Collaborate cross-functionally with various departments within the company as a partner in the drug development process
- Recognize common supply challenges and act proactively to ensure study demand is met throughout the trial process
- Effectively coordinate activities and communication with vendors within an external manufacturing and logistics network



Clinical Supply Chain Fellowship Program Design

As an integrated member of the Clinical Supply Chain team at Agios, the fellow will be provided with a variety of opportunities for growth and development across Agios' pipeline. Working in a future-oriented and improvement-focused environment, the fellow will gain hands-on clinical supply chain experiences to further enhance their professional knowledge. Assuming increasing responsibility over the two years, the fellow will obtain a deep comprehension of clinical supply chain's role, responsibilities, and day-to-day tasks as part of a cross-functional team to support global drug development.

Through the afforded mentorship, leadership, and empowerment of the fellowship team at Agios, the fellow will have access to the following responsibilities:

Clinical Supply Chain: Year1

- Integrate into the Clinical Supply Chain/Technical Operations teams
- Learn how to interpret clinical study protocols to determine drug demand and supply strategies
- Support the Clinical Supply team in completing day-to-day drug supply management tasks
- Gain an understanding of and hands-on training in applicable clinical supply technology platforms
- Transition to full responsibility of clinical supply activities for an ongoing clinical trial
- Develop cross-functional leadership skills by coordinating and leading clinical supply plan meetings
- Gain exposure to the entire Supply Chain Organization, including Commercial Supply, Clinical/Commercial Supply Planning, and Logistics
- Lead weekly operational planning discussions between the Clinical Supply Chain and Quality Assurance teams

Clinical Supply Chain: Year2

- Take ownership of drug supply activities as a Clinical Supply lead for one or more global clinical trials
- Be responsible for drug demand forecasting, trial monitoring & resupply planning, study technology set-up, risk mitigation plans, and global distribution strategy and activities
- Schedule and facilitate packaging and labeling manufacturing with external vendors
- Collaborate regularly with Clinical Operations, Quality Assurance, and Regulatory Affairs to efficiently deliver clinical supplies while ensuring compliance to all applicable laws and regulations
- Contribute to program level supply planning to determine drug product manufacturing timing and allocate inventory amongst clinical studies
- Become proficient in using drug forecasting technology to create a drug demand model for applicable clinical studies
- Represent Clinical Supply Chain as an active member of clinical trial working groups and project teams

Clinical Supply Chain Team

Program Director

Zach Kogut, PharmD, MBA, RPh

Associate Director, Clinical Supply Chain



Zach joined Agios in 2021 after completing a 2-year fellowship in Global Clinical Supply. He currently serves as the supply chain program lead for cividoplenib, managing forecasting, packaging, and labeling operations for studies using the compounds. Zach also serves as a Business Relationship Manager, coordinating interactions between Agios and one of our supply chain vendors. Since joining Agios, he has managed blinding of clinical trials, aligned dosing strategies with drug manufacturing capabilities, and participated on commercial launch teams for pyruvate kinase deficiency and thalassemia indications. Zach is originally from La Grange, Kentucky and graduated from the University of Kentucky with a PharmD/MBA in 2019.

Program Preceptor

Marvilla Asencio Moreira, PharmD, RPh

Senior Manager, Clinical Supply Chain



Marvilla is a Clinical Supply Chain Protocol Lead supporting Phase 3 pediatric studies in pyruvate kinase deficiency and thalassemia, overseeing global drug supply strategy, planning, and execution to ensure uninterrupted clinical trial support. She also serves as the primary packaging lead for mitapivat 1 mg granule sachets (stick packs), driving packaging development and cross-functional coordination to support the successful delivery of clinical supplies for pediatric studies. Marvilla earned her PharmD from the University of Maryland School of Pharmacy in 2021 and completed a two-year Clinical Supply Chain Fellowship with MCPHS / Agios Pharmaceuticals in 2023.

Current Fellow

Michaela (Micha) Andrawes, PharmD, RPh, MSc

2nd Year Fellow, Clinical Supply Chain



Micha is a second-year Clinical Supply Chain Fellow at Agios and a graduate of the University of Southern California, where she earned her PharmD and Master of Science in Clinical and Experimental Therapeutics. Her experience as an EMT during the COVID-19 pandemic inspired her passion for helping bring innovative therapies to patients. At Agios, Micha is gaining hands-on experience across Clinical Supply Chain and Technical Operations while contributing to meaningful, patient-focused initiatives. Her fellowship experience has been transformative, providing opportunities to lead impactful projects, collaborate across functions, and learn from exceptional mentors. Through Agios' supportive, innovative, and patient-centered culture, she is developing the confidence, leadership skills, and professional foundation to succeed wherever her career takes her. Micha is deeply grateful for the mentorship, growth, and opportunities she continues to receive and is proud to be part of an organization that invests in both its patients and its people.

↓ Medical Safety & Risk Management

About Medical Safety and Risk Management (MSRM)

Medical Safety & Risk Management (MSRM) is responsible for managing the safety profile of products throughout their lifecycle through the continuous monitoring, assessment, and communication of safety information. As such, MSRM plays a key role in the identification, evaluation, and management of emerging safety signals in drug development and for maintaining this activity for products in the post-marketing setting. MSRM also ensures on-time reporting of high-quality individual case reports as well as the creation and timely submission of aggregate safety reports to fulfill global regulatory requirements. In addition, MSRM is an active participant in the creation of clear, consistent, and accurate product labeling, risk management plans, and other product-related information.

MSRM Fellowship Goals and Objectives

The goal of the Agios MSRM Fellowship Program is to give the fellow hands-on knowledge of US and global pharmacovigilance activities including a broad understanding of global pharmacovigilance regulations, pharmacovigilance operations, aggregate safety reporting, signal detection, and risk management across all stages of drug development, from early stage to post-marketing.

Objectives include:

- Developing a strong safety and risk management knowledge base and applying those skills practically in the areas of aggregate reports, signal detection and signal management
- Obtaining well-rounded knowledge of country-specific pharmacovigilance regulations
- Cultivating strong communication and project management skills
- Collaborating cross-functionally with various internal departments as a partner in the product development process



MSRM Program Design

As an integrated member of the MSRM team at Agios, the fellow will be provided with a vast array of invaluable opportunities across the Agios product portfolio. These opportunities will enable the fellow to gain real-life pharmacovigilance experience and will deeply enhance their professional knowledge. Over the two years, the fellow will take on projects of increasing scope and responsibility while obtaining a deep comprehension of safety's roles, responsibilities, and day-to-day tasks. Inherently, the fellow will familiarize themselves with the complexities and cross-functional nature of the drug development process.

With the mentorship of the fellowship team at Agios, the fellow will have access to the following career-enhancing activities and responsibilities:

MSRM: Year1

- Work with safety operations colleagues to gain a solid understanding of roles and responsibilities in individual case management and medical review of cases
- Understand global pharmacovigilance regulations and begin applying knowledge to ensure compliance
- Observe how safety interacts with other functions and actively participate in these interactions
- Participate in the authoring of aggregate safety reports for submission to regulatory agencies worldwide
- Gain a solid understanding of signal detection, signal evaluation, and signal management activities
- Become integrated in the cross-functional teams while working on different deliverables and as a safety governance coordinator

MSRM: Year2

- Gain exposure and hands-on experience on the core REMS pillars and principles including strategy, program design and implementation, and compliance and monitoring
- Partner closely with a Global Safety Lead and the cross-functional team to support the overall safety strategy, surveillance, and lifecycle management of an assigned development program
- Author/review safety sections of the protocol, informed consent form, and other study-specific documents
- Participate in generating responses to safety-related health authority queries
- Contribute to the creation and maintenance of Safety Risk Management Plans
- Contribute to the safety sections of the Investigator's Brochure and aggregate reports

MSRM Team

Program Director

Jennifer Brooke, PharmD, RPh

Vice President, Global Safety Sciences \ Medical Safety And Risk Management



Jennifer is the head of the global safety sciences team at Agios. In her current role Jennifer leads the signal management process and creation and assessment of regulatory required aggregate reports and risk management plans across the Agios product portfolio. Prior to Agios, Jennifer worked in pharmacovigilance at both CROs and pharma/biotech companies for >15 years in a variety of therapeutic areas with a focus on rare diseases and oncology. She also worked in medical information and as a retail pharmacist. Jennifer received her BS in Pharmacy from the University of Pittsburgh and her PharmD from the University of North Carolina.

Program Preceptor

Victoria Carr, PharmD, RPh

Associate Director, Global Safety Sciences \ Medical Safety and Risk Management



Victoria joined Agios in 2022 as a Global Safety Scientist where she supports the management of the safety profiles of Agios' products, both marketed and in clinical development. As an active member of the global safety sciences team, Victoria regularly participates in various activities across Agios' portfolio including signal detection, signal management, authoring aggregate reports and risk management plans, and updating safety-related documents. Victoria is an alumna of the MCPHS fellowship program and completed her PharmD fellowship at Biogen. Victoria received her BS in Neuroscience from Union College and her PharmD at MCPHS University-Worcester.

Current Fellow

Joshua D Sebastian, PharmD, RPh

2nd Year Fellow, Medical Safety and Risk Management



As a second year Medical Safety and Risk Management fellow, I've had the opportunity to build strong connections with individuals on the safety team and those in different functional areas. Through meetings with colleagues, I have received guidance that will further my experience and support me as I enhance my abilities within the functional area of safety. I am gaining insight into the role I look to step into as the Safety Governance Coordinator, while also starting my rotation with the Safety Operations team. My experiences have shown me the true passion the Agios team provides regarding the fellowship process, as they have set me up for success. I look forward to continuing my journey with such an inclusive and inspiring community. I am confident that my professional development will continue to build throughout my time at Agios and look forward to what the future holds.

↓ Medical Affairs Program

About Medical Affairs Fellowship

Medical Affairs at Agios develops the strategy for and manages external engagement with healthcare practitioners. This strategy and engagement require the development and delivery of educational content including reactive educational slide decks, symposia, abstracts, publications, and other scientific content. Supporting multiple growing development programs, the group strives to utilize industry expertise to deliver accurate and timely scientific information to enable clinicians to make the best and most informed decisions on behalf of their patients.

Medical Affairs Fellowship Goals and Objectives

The goal of the medical affairs program is to allow the fellow to gain hands-on knowledge of Medical Affairs activities within the organization and gain an extensive understanding of the drug development process.

Objectives include:

- Applying their clinical training and scientific background to learn about disease state and the clinical development of medications within the Agios pipeline, including but not limited to pyruvate kinase deficiency, thalassemia, and sickle cell disease
- Cultivating strong communication and project management skills
- Collaborating cross-functionally with various departments within the company as a partner in the product development process
- Effectively coordinating activities and communicating with vendors to support multiple functions' efforts to educate external health care practitioners
- Gaining a full understanding of Agios' portfolio and the specifics of the clinical data for each program



Medical Affairs Fellowship Program Design

As a fully integrated member of the Medical Affairs team at Agios, the fellow will have the opportunity to rotate through different functional groups to experience the breadth of roles and responsibilities available within Medical Affairs. The fellowship will culminate with a long-term project with the program medical director and scientific communications team, leveraging the skills developed throughout the program to support the ongoing strategic vision of the medical affairs program.

Medical Affairs: Year 1

- Develop and update medical information standard response summaries with new publications, congress data, press releases, clinical trial information, etc.
- Perform literature searches on a case-by-case basis as needed
- Provide accurate, complete, and timely responses to medical information queries and/or direct call center to the proper source for that information or create customized responses (literature searches) for US and ex-US requestors
- Develop in-depth knowledge on clinical data associated with clinical trials, publications, and studies in Global Drug Development (GDD) related to Agios programs
- Review promotional and non-promotional materials as a participant at Medical Legal Regulatory (MLR) Review
- Develop and implement new or updates to scientific platform and lexicon for Agios program with newly generated data, messaging, program milestones, etc.
- Support digital and traditional global scientific communications activities including development and execution of medical content for medical affairs microsite, reactive slide decks, congress materials, innovative new methods for sharing informational materials, etc.
- Collaborate with Global Scientific Communications Leads, cross functional internal stakeholders, and external experts/authors to create, review, and manage congress abstract/presentation as needed
- Gain deeper understanding for industry (global) scientific communications and publication processes/requirements/best practices

Medical Affairs: Year 2

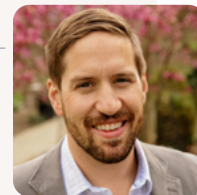
- Contribute to initial authoring and/or review of key study documents (Protocol, Informed Consent Form (ICF), Investigator Brochure (IB), Lab Manual, etc.)
- Respond to site queries and regulatory authority queries in conjunction with clinical scientists (CS)
- Contribute to clinical data review activities across an indication/molecule
- Assist in development of clinical data review standards and timelines with cross-functional teams
- Play a role in preparing for functional review of program milestones and data supporting milestones such as interim analyses, database locks, publications, clinical advisory boards and clinical study reports (CSR), etc. as needed for assigned trial(s)
- Serve as a clinical contributor for other relevant activities (analysis plans, filing, data monitoring committee, clinical advisory boards, etc.) as needed for assigned trial(s)

Medical Affairs Team

Program Director/Preceptor

Dan Bartos, PhD

Dan Bartos is a Medical Affairs leader with experience in hematology, rare disease, and field medical strategy. As Director of the MSL Field Team at Agios Pharmaceuticals, he leads a team of MSLs across the western US who support product launch execution, drives cross-functional collaboration, and is director of the Medical Affairs Fellowship Program. His background includes global clinical trial leadership, KOL engagement strategy, scientific exchange, medical education, and talent development, supported by a Ph.D. in Physiology from the University of Kentucky and extensive experience across academia (UC, Davis & CU Anschutz) and industry.

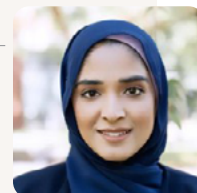


Current Fellow

Ayesha Farooqui, PharmD

2nd Year Fellow, Medical Affairs

As the inaugural Medical Affairs Fellow at Agios, I have had the unique opportunity to help shape a program rooted in purpose, collaboration, and scientific innovation. Throughout my fellowship, I have built a strong foundation in rare hematologic diseases while gaining experience across key Medical Affairs functions, including Medical Information, Scientific Communications, Field Medical, and Patient Advocacy. Agios has fostered my professional growth by tailoring learning opportunities and projects to align with my interests and career goals. I have been fortunate to contribute towards two product launches during my fellowship. What truly sets Agios apart is its culture. Collaboration is genuine, leadership is approachable, and every voice is valued. Most importantly, the patient-first mindset guides every discussion and decision, aligning closely with my own values and making this fellowship a meaningful and inspiring start to my career.



↓ Clinical GMP-Quality Assurance Program

About GMP Quality Assurance

GMP-Quality Assurance is a specific function within quality assurance responsible for manufacturing oversight, lot release and vendor oversight for the CMC (chemistry and manufacturing controls) quality aspects of pharmaceutical clinical development programs. The Fellow will work with the GMP-QA team in support of lot release of investigational products Phase 1 through Phase 3. This team collaborates with a diverse cross-functional team, including CMC, analytical development, quality systems-QA, quality control-QA, regulatory affairs and clinical supply chain to provide and ensure lots are released according to approved specifications to meet supply chain timelines. The fellow will gain hands-on knowledge of GMP-quality assurance activities within the Technical Operations organization and gain an extensive understanding of the drug development process.

Objectives include:

- Develop end-to-end quality oversight knowledge primarily in the clinical space
- Cultivate strong communication, leadership, and project management/organization skills
- Collaborate cross-functionally with various departments within the company as a partner in the drug development process
- Understand the requirements for supplying drug for Phase 1-3 studies, US only and global studies, blinded studies, Investigator Sponsored Trials (IST), and Expanded Access Programs (EAP)
- Recognize common quality challenges and act proactively to ensure product quality is met throughout the clinical trial process
- Effectively coordinate activities and communication with vendors within an external manufacturing network

GMP Quality Assurance Program Design

The GMP-QA Fellowship follows a rotational development plan with the first year focused on the clinical packaging and labeling (P&L) QA space, specific to release of finished goods in support of clinical trials. End of year 1 and year 2 may expand into quality oversight, clinical drug products and drug substances. The fellow will gain hands-on GMP-Quality Assurance experiences to further enhance their professional knowledge. Assuming increasing responsibility over the two years, the fellow will obtain a deep comprehension of GMP-QA's role, responsibilities, and day-to-day tasks as part of a cross-functional team to support global clinical and drug development.



Through the afforded mentorship, leadership, and empowerment of the fellowship team at Agios, the fellow will have access to the following responsibilities:

GMP-Quality Assurance: Year 1

- Integrate into the Quality Assurance/Technical Operations teams
- Observe how GMP-Quality Assurance team interacts with other functions within Agios and external vendors and actively participate in these interactions
- Gain an understanding of and hands-on training in applicable clinical supply and quality assurance technology platforms
- Work with CMO's (Contract Manufacturing Organizations) to provide quality oversight of all primary and secondary packaging as well as labeling activities of clinical supplies, including review of master batch records, packaging specifications and executed batch records
- Work with the quality manager to fully investigate any P&L manufacturing deviations
- Provide Agios sponsor lot release on all primary and secondary packaging as well as labeling activities of clinical supplies.
- Support QP (Qualified Person) release for EU (European Union) clinical trials
- Gain exposure to the entire Quality Assurance department
- Supporting internal and external qualification audits

GMP-Quality Assurance: Year 2

- Expand experience to provide quality oversight of all primary and secondary packaging, including review of master batch records, packaging specifications and executed batch records (may start in year 1)
- Expand experience to provide quality oversight of clinical drug products and/or drug substance manufacturing, including review of master batch records, executed batch records, product specifications, and part number generation
- Collaborate regularly with supply chain and CMC to efficiently deliver clinical supplies while ensuring compliance to all applicable laws and regulations
- Become proficient in clinical inventory system as well as electronic document management system (eDMS) and electronic quality management system (eQMS) in support of change controls, CAPAs and effectiveness checks

Clinical GMP-Quality Assurance Team

Program Director

Dennis Sullivan

Senior Director, GMP-Quality Assurance

Dennis started working at Agios in March 2020 as Sr. Manager in the GMP-QA team, supporting clinical drug product and drug substance manufacturing and lot release. Dennis was promoted to Associate Director in June 2021 and now leads the clinical GMP-QA team responsible for quality oversight of all clinical manufacturing including drug substance, drug product and packaging and labeling. Dennis has over 20 years' experience in the pharmaceutical industry.



Program Director

Omayra Olmo

Associate Director, GMP-Quality Assurance

Omayra joined Agios in August 2020 as a manager in GMP-QA clinical Packaging & labeling team. She was promoted to lead the clinical packaging and labeling team in October 2021. Omayra has over 25 years' experience in the pharmaceutical industry.



Program Preceptor

Ashley Jacobs, ASQ-CQA

Senior Manager, GMP-Quality Assurance

Ashley started working at Agios in September of 2021 as a Manager in the GMP-QA team, supporting the clinical packaging and labeling team. She is the GMP-QA rep for several studies, including AG-181, AG-236, and several of the mitapivat studies. She was promoted to Sr. Manager in November 2022. Ashley has over 17 years' experience in the pharmaceutical industry.



Current Fellow

Martina Sourial, BS, PharmD

2nd Year Fellow, Clinical GMP-Quality Assurance

As a second-year Clinical GMP-QA Fellow, I have found the experience to be both rewarding and enriching. I have developed a strong foundation in the pharmaceutical industry by contributing to key quality assurance activities that support clinical development. My role has allowed me to collaborate with cross-functional teams and external partners to ensure compliance with Good Manufacturing Practices and to support the timely release of clinical trial materials. The collaborative and supportive team environment has fostered meaningful professional relationships and continuous learning. I am grateful to be part of a program that emphasizes personal growth, mentorship, and development within a dynamic industry setting.



↓ HEOR Program

About Health Economics & Outcomes Research (HEOR) Fellowship

The Health Economics & Outcomes Research (HEOR) department at Agios is responsible for generating, interpreting, and communicating high quality evidence, supporting assets from early development through post marketing, to demonstrate value and help ensure optimal access to Agios' therapies. The HEOR team leads patient-centered research via the incorporation of clinical outcomes assessments within trials, evidence generation (real-world evidence, observational studies, systematic literature reviews, etc.), health economics (cost-effectiveness models, budget impact models), and value demonstration. These activities serve to highlight the unmet need and communicate value to key stakeholders including patients, health care providers, payers, and regulatory bodies. As an integral part of drug development and commercialization, the HEOR group continuously collaborates cross-functionally to ensure alignment of strategy across teams.

HEOR Fellowship Goals and Objectives

The goal of the Agios HEOR Fellowship Program is to equip the fellow with technical skills and provide opportunities for real-world application of HEOR in the pharmaceutical industry.

Objectives include:

- To provide training and experience in the areas of health economics, outcomes research, and market access
- To enhance the fellow's technical expertise in literature evaluation, epidemiology, research methodology, value communication, and biostatistics
- To provide experience contributing to research and development of investigational products with a focus on clinical outcomes assessments

HEOR Team

Program Director/Preceptor

Christina Chamberlain, PhD

Senior Director, HEOR

Christina leads the Agios HEOR team responsible for evidence generation and value demonstration of Agios' PK activator assets. She originally joined Agios in 2019 and later transitioned to Servier Pharmaceuticals as part of the oncology portfolio acquisition. Christina was a Global HEOR lead for Astellas Pharma's early-stage programs in ophthalmology and rare diseases before re-joining Agios in 2024. Christina also has experience in HEOR consultancy and received her PhD in Pharmaceutical Economics and Policy from the University of Southern California.



HEOR Program Design

As an integrated member of the HEOR team at Agios, the fellow will achieve a deeper understanding of the complexities surrounding cost and access of pharmaceuticals within the rare disease portfolio, including pyruvate kinase deficiency, thalassemia, and sickle cell disease. Over two years, the fellow will gain proficiency in the analytical methods required to evaluate pharmaceutical products and communicate their value to patients and other stakeholders within the healthcare system. Agios offers experienced leadership to guide the fellow in key areas of HEOR to become a well-rounded researcher and strategist. Activities and responsibilities over the two years may include and are not limited to the following:

HEOR: Year1

- Integrate into the HEOR and relevant cross-functional teams by collaborating regularly with Clinical Development, Medical Affairs, Market Access, Marketing, and Regulatory
- Learn to demonstrate value by contributing to development of value dossiers (AMCP dossier, Global value dossier)
- Develop skills in health economics by contributing to budget impact models, burden of illness models, and cost-effectiveness models
- Conduct HTA surveillance, systematic literature reviews, and other evidence generation activities

HEOR: Year2

- Gain experience in patient-centered research and improve understanding of clinical outcomes assessments and their role in drug development and commercialization
- Become proficient in generating real-world evidence (cohort studies, claims analyses, indirect treatment comparisons, etc.) using advanced outcomes research methodology



↓ Regulatory Affairs Program

Regulatory Affairs Fellowship

Through the Regulatory Affairs Fellowship, the fellow will obtain in-depth and hands-on experience in Regulatory Affairs, with the opportunity to complete rotations to gain exposure to various Regulatory Affairs functional areas, namely Clinical Strategy; Chemistry, Manufacturing, and Controls (CMC); and Regulatory Operations. Upon completion of the program, the fellow will have gained the foundational knowledge and key competencies to begin a career in the dynamic field of Regulatory Affairs.

Regulatory Affairs Clinical Strategy

Regulatory Affairs–Clinical Strategy (RA–CS) professionals are responsible for developing regulatory strategy and leading health authority interactions to support global drug development from pre-IND through registration and life cycle management. They manage the planning, coordination, and execution of high-quality regulatory submissions of original applications (i.e., New Drug Applications (NDAs)/Marketing Authorisation Applications (MAAs), Investigational New Drug Applications (INDs)/Clinical Trial Applications (CTAs)) and any subsequent major amendments, supplements, and variations. The RA–CS team interfaces with a diverse cross-functional team to ensure the regulatory strategy is aligned with the overall clinical development plan and corporate objectives.

Regulatory Affairs Clinical Strategy Fellowship Goals and Objectives

The goal of the RA–CS rotation is to provide the fellow with hands-on global experience in clinical strategy in order to develop a comprehensive understanding of this clinical strategy's role in the drug development process from early stage to post-marketing.

Objectives include:

- Develop a strong global regulatory strategy skillset while actively contributing to regulatory planning and submissions
- Obtain well-rounded knowledge of country-specific regulatory processes
- Cultivate strong communication, leadership, and project management skills by collaborating cross-functionally with numerous departments within the company, as well as with external vendors, as a partner in the drug development process



Regulatory Affairs CMC Fellowship Goals and Objectives

The goal of the RA-CMC rotation is to give the fellow hands-on knowledge of US and Global RA-CMC strategy and tactics, including an understanding of quality pharmaceutical development, CMC dossier planning and development, and health authority interactions.

Objectives include:

- Develop a strong understanding of US and global CMC regulatory guidance and industry practice
- Obtaining well-rounded knowledge of the process for planning, preparing, and submitting CMC dossiers
- Cultivate strong communication and project management skills by collaborating cross-functionally with numerous departments within the company as a partner in pharmaceutical development

Regulatory Affairs Operations

Regulatory Affairs – Operations is a specific function within Regulatory Affairs that is responsible for the coordination of essential documentation and resources required for the filing of global applications. Additionally, they provide tools, training, and overall support to submission stakeholders while proactively implementing efficient information management, scalable operational excellence, and innovative digital solutions. They partner with other functions (e.g., Clinical and Quality) to comply with the requirements from health authorities within regulatory information systems and provide a clear framework internally to maintain streamlined submission timelines.



Regulatory Affairs Operations

Goals and Objectives

The goal of the RA-Operations rotation is to provide the fellow with hands-on knowledge and experience with the planning and operational management of Regulatory submissions, including exposure to submission systems, processes, and industry standards and guidelines.

Objectives include:

- Develop an understanding of the Electronic Common Technical Document (eCTD) structure required for global health authority submissions as well as the systems and tools used to support the management of regulatory information/submission development
- Obtain exposure to and assist with the preparation of submission deliverables, while collaborating with external publishing vendors, for eCTD submissions to global health authorities
- Cultivate strong communication, project management skills, and a working knowledge of the regulations and processes that govern the content and maintenance of controlled documents required by the FDA, EMA, and ICH

Regulatory Affairs Fellowship

Program Design

The Regulatory Affairs Fellowship follows a rotational development plan in the first year, with approximately three-month rotations across different Regulatory focus areas, namely Clinical Strategy; Chemistry, Manufacturing, and Controls (CMC); and Regulatory Operations. The fellow will gain hands-on experience in multiple positions within an accelerated period, providing a unique opportunity to clarify their interests in the diverse field of Regulatory Affairs. In each rotation, the fellow will have the opportunity to integrate with working groups and learn to navigate the team environment at Agios. Following the completion of the rotational structure, fellows will select the Regulatory function in which they will focus for the second year of the fellowship, tailored to their personal interests, strengths, and targeted areas for development.

Regulatory Affairs Team

Program Director

Christina Bender, BS

Senior Director, Regulatory Affairs

Christina is the Head of Regulatory Strategy at Agios. She is accountable for leading a team of regulatory strategists responsible for developing the global regulatory strategy of assets in Agios' pipeline at various phases of development. She was also a preceptor for three MCPHS/ Agios regulatory fellow alumni. Prior to joining Agios in June 2016, Christina worked in Regulatory Affairs at Genentech and EMD Serono where she was the regulatory lead for multiple initial marketing application submissions across oncology (heme and solid tumors) and neurology, including the first authorized breakthrough therapy treatment in the United States. Christina received her Bachelor of Science Degree in Genetics from the University of California, Davis.



Program Preceptor

Maura Maloney, MS

Senior Director, Regulatory Affairs- Chemistry Manufacturing and Controls

Maura is a Senior Director of Regulatory Affairs at Agios. As the lead of the Regulatory-CMC function, Maura is responsible for strategy and tactics for Quality/CMC submissions for investigational stage, registration stage, and marketed products, including responses to queries and interactions with health authorities on CMC topics. Prior to Agios, Maura held roles in CMC of increasing responsibility at small-to-mid size pharmaceutical companies, including Formulation Development at Alkermes, Product Development at GTx, Inc. and Director of CMC at Amarin Pharma Inc., prior to focusing on Reg-CMC several years ago. Maura received her Bachelor of Arts degree in Biology from Boston University and her Master of Arts degree in Biology from Harvard University Extension School.



Activities and responsibilities over the two years may include and are not limited to the following:

Regulatory Affairs Rotation in Clinical Strategy, CMC, and Operations: **Year1**

- Rotate through the 3 Regulatory Affairs functions at Agios (Clinical Strategy, CMC, Regulatory Operations) to gain exposure to various Regulatory disciplines and guide selection of the area of focus for Year 2 of the fellowship
- Integrate into cross-functional teams (e.g., Technical Operations/CMC; Quality Assurance; Clinical Trial Working Group) to understand Regulatory Affairs' roles and responsibilities and gain familiarity with the complex cross-functional nature of the drug development process
- Support Regulatory leads in planning and executing Regulatory submissions to support Agios' clinical development programs
- Gain an understanding of Regulatory requirements, guidance documents, and resources for US and ex-US drug development, including timelines and processes for US IND submissions and ex-US CTAs
- Gain a complete understanding of Agios' portfolio, processes, and the applicable systems used for regulatory planning and health authority submissions

Deep Dive in Selected Regulatory Focus Area: **Year2**

- Increased responsibility and ownership for planning, preparation, and submission of Regulatory documents to global Health Authorities
- Observe how to develop regulatory strategy, including a deep dive into global regulatory requirements and research of Regulatory intelligence and precedent
- Assist with planning, preparing, and tracking responses to Health Authority queries
- Represent Regulatory Affairs on cross-functional team sub-teams; provide Regulatory recommendations and guidance to cross-functional teams
- Gain experience with planning and preparing for Health Authority meetings
- Cultivate communication and submission management/project management skills

Regulatory Affairs Team

Program Preceptor

Jamie Scialdone, MS

**Senior Director,
Regulatory Affairs – Operations**



Jamie is a Senior Director of Regulatory Affairs at Agios. As the head of the regulatory operations function, Jamie is responsible for submission management activities for global health authority applications, maintenance of regulatory information and systems, medical writing operations and oversight of the Agios review committee for promotional and non-promotional material. Prior to joining Agios, Jamie held roles in regulatory operations of increasing responsibility at other pharma/biotech companies, including Biogen where she worked for over 15 years. Jamie received her Master of Science degree in Regulatory Affairs from Northeastern University.



↓ A Unique Fellowship Program

Agios, in collaboration with MCPHS, offers a unique fellowship program to promote the role of the Doctor of Pharmacy (PharmD) within the biopharmaceutical industry. A fellow gains extensive experiences through various practical activities in both industry and academic settings, which could enhance the potential for accelerated career development. Agios is currently recruiting for the following 2027–2029 fellowship programs:

- **Clinical Development, Clinical Scientist**
- **Clinical Supply Chain**
- **Medical Safety and Risk Management**

About MCPHS

This fellowship program is designed to offer Doctor of Pharmacy graduates in-depth experience within a biopharmaceutical industry setting. In addition, PharmD graduates will have the opportunity to enhance their clinical and academic background in conjunction with MCPHS. Overall, this fellowship program will provide the training and experiences necessary to prepare the fellow for a career in the competitive pharmaceutical industry.

MCPHS University Component

As an adjunct instructor at MCPHS, the fellow may have the opportunity to:

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

Benefits and Compensation

The fellowship will provide a competitive stipend and benefits package, including comprehensive health insurance. In addition, the fellowship will offer an allowance for travel to one or more professional meetings, conferences, or workshops. The fellow may qualify for student loan deferment, allowing for the postponement of loan payments until the completion of the fellowship program. The lender of the student loan(s) will be able to provide specific information regarding eligibility and terms of deferment.



Certificate of Completion

MCPHS and Agios will award a professional certificate upon successful completion of the fellowship program.

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.).

For more information or questions, please contact our Agios Fellowship Co-Coordinators:

Zach Kogut, PharmD, MBA, RPh

Associate Director, Clinical Supply Chain

Zach.Kogut@agios.com

Jennifer Brooke, PharmD, RPh

Vice President, Global Safety Sciences |
Medical Safety Risk Management

Jennifer.Brooke@agios.com

↓ How to Apply

Application Procedure

The MCPHS application portal (SMAApply) will open up on **Monday, October 5, 2026**. Applicants must upload the following application materials to the online portal (<https://mcphs.smapply.io>) by **Monday, November 2, 2026**:

- **Letter of Intent:**
Addressed to the company specific program director/lead; found in each company brochure
- **Curriculum vitae**
- **Unofficial college transcript**
- **Contact information for three references:**
References will receive an electronic recommendation form to complete separately.

Three recommendation evaluation forms must be submitted no later than **Friday, November 20, 2026** via the online portal. This is NOT a letter of recommendation but an online form that the recommender will receive for completion from SMAApply.

Application Review and Interview Timeline

Following a review of submitted applications, pre-screens and preliminary interviews will begin in October. Additional interviews, including final rounds will take place in December during ASHP. Candidates will be notified if selected for an interview. The process is rigorous and competitive; therefore, candidates should submit their applications well in advance of posted deadlines as priority will be given to those who apply early.

ASHP Midyear & Onsite Interviews

The fellowship program will be conducting in-person interviews at the ASHP Midyear Clinical Meeting in Orlando, FL. Attendance is strongly encouraged, but not required. Please refer to the ASHP & PPS website for registration details. Top candidates may be invited for interviews at the sponsoring company's location.

AIFA First Offer Date

The choice of a Post-Doctoral Fellowship is an important decision. MCPHS, in conjunction with the Alliance of Industry Fellowship Associates (AIFA), has aligned to extend offers for Fellowships no earlier than Friday, December 11, 2026. We believe this is a positive reflection of the cultures our Programs offer, and that culture is a critical consideration in choice of Fellowship.

We hope that other academic and non-academic Fellowship Programs will NOT pressure candidates to accept offers prior to this aligned offer date.

Onboarding

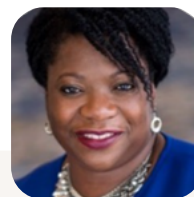
Final candidates will be required to go through additional screening / onboarding as required by MCPHS.

MCPHS Fellowship Leadership Team

Amee Mistry, PharmD, RPh

Director of the Postdoctoral Biopharmaceutical Industry Fellowship Program

Amee Mistry is Professor of Pharmacy Practice and has been with MCPHS University since 2006. Amee earned her PharmD at the Albany College of Pharmacy and completed a PGY1 Community Practice Residency with Walgreens and MCPHS University. In 2015, Amee 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 postgraduate 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.



Amee Mistry, PharmD, RPh | Samantha Nganju, MBA, Assistant Director

↓ Fellowship Alumni

Joseph Carey, PharmD, RPh

Agios Fellowship Alumni | Medical Safety and Risk Management

“My fellowship at Agios was an invaluable opportunity that helped shape the foundation of my career. The program provided hands-on experience in pharmacovigilance and safety risk management while offering countless opportunities to learn from talented and supportive colleagues. Through challenging projects, cross-functional collaboration, and dedicated mentorship, I strengthened both my technical expertise and professional confidence. Agios fostered an environment that encouraged continuous growth, curiosity, and meaningful contribution from day one. As a fellowship alumnus, I am deeply grateful for the experience and the lasting impact it has had on my professional journey.”



Josh Mottet, PharmD

Agios Fellowship Alumni | Clinical Supply Chain

“My fellowship experience at Agios was truly transformative, and I am incredibly grateful to have been part of such an exceptional program. From the interview process onward, Agios’ collaborative and patient-centered culture was evident and remained a defining part of my experience. Fellows are empowered to make meaningful contributions from day one, take ownership of impactful work, and gain valuable exposure across multiple functions. The program is intentionally designed to foster professional growth, cross-functional collaboration, and the skills needed to succeed beyond the fellowship. Throughout my time at Agios, I felt supported, encouraged to share my voice, and challenged to grow. The company’s commitment to innovation is matched by its dedication to developing future leaders, while keeping patients at the center of every decision. I would not be where I am in my career today without the mentorship, support, and opportunities provided by the incredible team at Agios. The experience shaped me both professionally and personally, and I will always be grateful for the foundation it provided.”



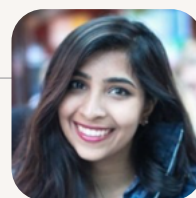
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Agios Fellowship Alumni
HEOR



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Clinical Supply Chain



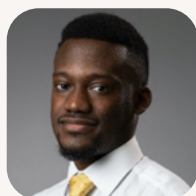
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India Gwynn
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