

Pharmaceutical Industry and Education Fellowship Program



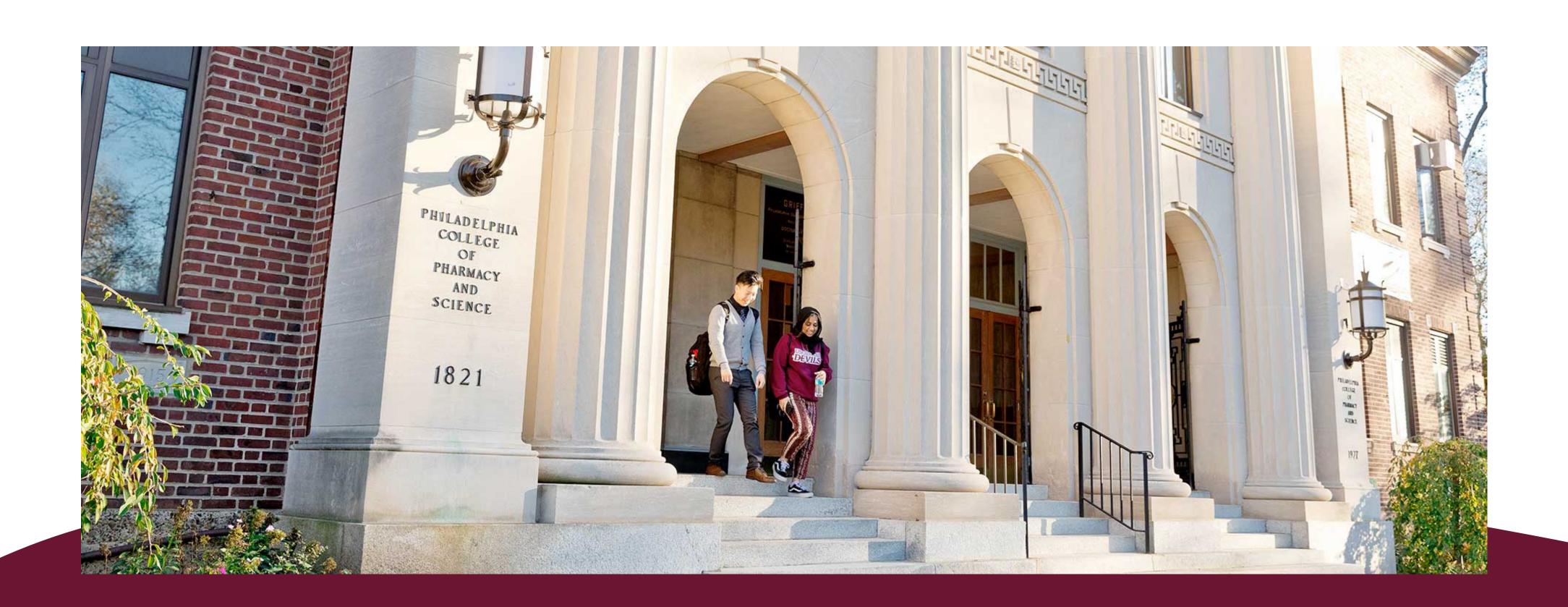
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Fellowship Overview

Founded in 2007, the Pharmaceutical Industry and Education Fellowship Program at University of the Sciences (USciences) provides pharmacists with hands-on experiential training in a collaborative, team-based corporate environment. The academic component of the fellowship provides opportunities to apply new skills and enhance professional growth in pursuit of a career in the pharmaceutical industry.

Throughout the Program, Fellows Are Expected To:

- Develop and cultivate core skills and competencies in analytical reasoning, critical and strategic thinking, problem solving, communication, influencing, and teamwork
- Develop professional responsibility and enhance leadership presence
- Enhance interpersonal communication through scientific engagement with healthcare providers, strategic business partners, and patients
- Strengthen verbal and written scientific communication skills
- Demonstrate working knowledge of all applicable laws, regulations, and guidance documents pertaining to specific functional roles
- Utilize and apply critical thinking and clinical knowledge to all projects and assignments

Academic Overview

Academic Component

- Appointment to clinical instructor in Pharmacy Practice in Philadelphia College of Pharmacy at USciences
- Completion of the Teaching and Learning Curriculum (TLC), which involves developing an ACPE-accredited Continuing Education presentation and engaging in small group teaching

Professional Growth and Service

- Participate in professional development workshops, student organizations, project leadership, and mentoring activities
- Attend meetings and conferences to enhance knowledge, support fellowship recruitment, staff the medical information booth, and engage in professional networking

Scholarly Activity (Optional)

- Enroll, tuition-free, in the online MBA in Pharmaceutical and Healthcare Business offered through the university
- Participate in professional development workshops, student organizations, project leadership, and student mentorship
- Collaborate with faculty on an IRB-approved research project



Fellowship Industry Partners











CSL Behring Biotherapies for Life[™]

RECRUITING: 2 FELLOWS

MEDICAL INFORMATION / MEDICAL AFFAIRS FELLOWSHIP

King of Prussia, PA

- CSL Behring is a fast-paced, innovative, biopharmaceutical company focused on developing & delivering life-changing therapies for patients with devastating & rare diseases.
- This one-year fellowship in Medical Information and Medical Affairs provides indepth training to advance skills in medical communications, scientific writing, scientific education, and medical content review.



Michael McDaniel, PharmD

Medical Information/Medical Affairs Fellow

University of Maryland School of Pharmacy '20



Rahima Hussien, PharmD

Medical Information/Medical Affairs Fellow
University of Missouri-Kansas City "19



Medical Information

- Enhance skills in literature retrieval and analysis
- Improve scientific writing skills by developing medical inquiry response documents and handling escalated requests
- Utilize critical thinking and clinical knowledge to develop fair and balanced communications of product information
- Support product launch and sales training material development
- Build relationships with internal and external business partners

Medical Affairs

- Enhance interpersonal communications through cross-functional team collaboration
- Engage and collaborate with subject matter experts across Medical Affairs
- Gain exposure to scientific writing through scientific abstract and poster development
- Review medical content for accuracy as part of the medical review team



RECRUITING: 2 FELLOWS

MULTIDISCIPLINARY FELLOWSHIP

GLOBAL MEDICAL AFFAIRS, GLOBAL REGULATORY AFFAIRS, CLINICAL DEVELOPMENT

Plainsboro, NJ

- Genmab US, Inc. is an international biotechnology company specializing in the creation and development of differentiated antibody therapeutics for the treatment of cancer.
- This 2-year multidisciplinary program offers an opportunity for fellows to gain experience across Global Medical Affairs, Global Regulatory Affairs, and Clinical Development.
- Our goal is to cultivate future leaders in the biotechnology industry and sharpen the skills needed for a successful career.



Rachel No, PharmD

Global Medical Affairs Fellow

University of Michigan College of Pharmacy '20

Click here to view the Genmab brochure!



Global Medical Affairs

- Create and maintain a database of Global Medical Information responses, including consistently evaluating opportunities to innovate the content format
- Develop a global strategic publication plan collaborating closely with key stakeholders including Medical Strategy, Statistics, Medical Research Team, and Senior Leaders
- Understand the congress planning process from identifying key sessions to developing summaries following conclusion of the meeting while collaborating with large cross-matrix team

Global Regulatory Affairs

- Develop understanding of global regulations and guidances related to drug development
- Support cross-functional product teams by offering expertise and strategic guidance on regulatory requirements for global drug development and market registrations
- File and maintain Investigational New Drug Applications (INDAs), New Drug Applications (NDAs), Marketing Authorization Applications (MAAs) and Clinical Trial Applications (CTAs)
- Acquire a working knowledge of international and country-specific requirements to support the conduct of global clinical studies

Clinical Development

- Gain knowledge in Translational Medicine and Pharmacokinetics concepts, and clinical regulations, including International Conference on Harmonization guidelines and Good Clinical Practice requirements
- Achieve proficiency in understanding clinical research protocol(s)
- Develop technical writing skills by creating a mock abbreviated protocol
- Support study execution by understanding the process of investigator calls, evaluating escalation of clinical questions and clinical data querying





RECRUITING: 1 FELLOW

GLOBAL REGULATORY AFFAIRS FELLOWSHIP

Princeton, NJ

- Kyowa Kirin Co., Ltd. is a Japan-based global specialty
 pharmaceutical company known for their state-of-the-art antibody
 technologies for the treatment of oncology, nephrology, central
 nervous system and immunology.
- This is a newly added program to the USciences Fellowship Program.
- This 2-year Global Regulatory Affairs fellowship offers an opportunity for fellows to gain experience across Global Medical Affairs, Global Regulatory Affairs, and Clinical Development and encompasses aspects of Regulatory Strategy, Regulatory Intelligence and Regulatory Chemistry Manufacturing and Controls



Global Regulatory Affairs

- Develop broad understanding of regulatory drug development process from early stage to post-marketing
- Develop a strong global regulatory strategy skillset while actively contributing to regulatory planning, strategy, and filings to support company assets
- Develop the ability to assess development programs from a regulatory perspective
- Proactively identify regulatory issues impacting program progress and development and advise management on resolutions
- Obtain knowledge of country-specific regulatory processes, with focus on FDA and EMA regulations and requirements
- Interpret local and global regulations and apply interpretative analyses of key regulatory guidance documents as they relate to ongoing projects and submissions
- Engage and collaborate cross-functionally with a variety of departments within the company as a partner in the drug development process



RECRUITING: 1 FELLOW

MEDICAL INFORMATION - PAYER & HEALTH-SYSTEMS

HEMATOLOGY/ONCOLOGY

Horsham, PA

- Janssen, part of the Johnson & Johnson family of Companies, aims to transform individual lives and fundamentally change the way diseases are managed, interpreted, and prevented.
- The fellowship is two years in Medical Information at Janssen Scientific Affairs in Solid Tumor Oncology, Hematology/Oncology, or Immunology with an additional external rotation.
- For 2021, we will be recruiting for Hematology/Oncology only.
- The fellow will hone skills in critiquing and communicating complex scientific information to a variety of audiences, including consumers, health-care professionals and health-care policy decision makers.



Mohsan Iftikhar, PharmD

Second Year Fellow, Hematology, Oncology
Albany College of Pharmacy and Health

Sciences '19



Andrew Knapp, PharmD

First Year Fellow, Solid Tumor Oncology
University of Kansas School of Pharmacy '20



Phuong Nguyen, PharmD

First Year Fellow, Immunology
University of Minnesota College of Pharmacy '20



Medical Information

- Develop in-depth knowledge of the therapeutic area
- Enhance skills in scientific literature retrieval, analysis, and communication
- Improve scientific writing skills by authoring scientific response letters and escalated medical information requests from clinicians, payers and other population-based healthcare decision-makers
- Utilize critical thinking and clinical knowledge to develop fair and balanced communications of product information to clinicians and compendia
- Participate in the creation and maintenance of formulary dossiers
- Support product launch and sales training material development
- Develop training materials focused on payer, health system, and clinical decision resource topics for internal-use only
- Provide medical review for promotional materials as well as reactive/proactive scientific material
- Support development of Voice-of-Customer (VOC) reports, including analysis of inquiries received by Janssen Medical Information Communication Channel and identification of trends/key insights
- Support therapeutic area value assessment framework reviews



Pharmacy Benefit Manager

- Develop an understanding of the various roles a pharmacist plays at a managed care organization and basic operations of a managed care organization
- Support Formulary Management Pharmacists and Clinical Marketing Intelligence teams to update and maintain formulary decision making resources (e.g. drug monographs, drug class reviews, prior authorization criteria, cost savings analyses)
- Opportunity to present clinical topics to pharmacy team during specialty subcommittee meetings
- Develop an understanding of the strategy for monitoring pipeline drugs for a managed care organization



RECRUITING: 1 FELLOW

THE BIOLOGICS PRODUCT DEVELOPMENT & INVESTIGATIONAL DRUG TRIAL DESIGN AND MANAGEMENT FELLOWSHIP

RESEARCH AND DEVELOPMENT

Malvern, PA

- This fellowship program provides fellows with an opportunity to work on new modalities and technologies to create new drug products and processes within Janssen Biologics Drug Product Development (DPD).
- The fellow will have an opportunity to work with an investigational drug throughout the drug development process, both near molecule conception through every phase of development.
- This experience includes understanding and executing science-driven benchtop experiments and support of robust, institutionally-reviewed investigational drug trials involving real patients.
- The fellow will learn how to solve open-ended scientific and investigational drug trial problems creatively and independently.
- The fellow will seek to show the value pharmacists can provide to the drug development process through developing more and drawing upon a rich knowledge base of biotherapeutics and science.



Joe Weidman, PharmD, BSPS

The Biologics Product Development &
Investigational Drug Trial Design and
Management Fellow
University of Pittsburgh '20



Biologics Product Development (18-months)

- Provide support in the areas of drug product design, dosage preparation, administration and instructional training
- Support the collaboration with DPD Formulation Scientists, Global Trial Mangers, Study Responsible Physicians, Study Managers and Pharmacists to ensure that drug preparation and administration can be flawlessly executed at investigational sites for Phase 1 to Phase 3 clinical studies
- Support the creation of workflows for drug product in-use stability and compatibility studies
- Support the creation of Investigational Product Preparation and Administration Procedures and associated training materials for use at investigational study sites
- Support the creation, execution and reporting of In-Use Drug Studies
- Support studies to develop optimal formulation for drug products
- Support studies to evaluate the manufacturing process of drug product formulations
- Assist in technology transfer of drug product and process to fill/finish sites
- Author/review technical reports documenting results and conclusions from formulation and process development studies
- ullet Provide effective communication with other fellows and team members on supported $_{15}$ projects



Investigational Drug Trial Execution (6-months)

- External service selection and set-up, including ensuring that scope of work and specifications are consistent with protocol requirements, budget, and timelines
- Tracking of project deliverables & timelines using functional planning tools
- Transparent communication across all members of the cross-functional team
- Creation and update of study-specific documents such as Monitoring Guidelines, Informed Consent Form(s), IMP related documentation, and safety related documents
- Support of risk identification and mitigation strategy creation and roll-out
- Support of study training creation and roll-out (at central, local, and site level)
- Coordinate and participate in internal and external study specific meetings, as necessary, and document outcomes, actions, and decisions. Follow-up to resolution when required
- Support quality oversight and inspection readiness activities
- Work with internal partners to assist in management of activities such as country and site feasibility
- Other activities as delegated by the investigational drug trial management team



RECRUITING: 2 FELLOWS

MEDICAL INFORMATION / MEDICAL AFFAIRS FELLOWSHIP

Ft. Washington, PA

- The McNeil Consumer Healthcare Division of Johnson & Johnson Consumer, Inc. develops and markets a broad range of well-known and trusted OTC products in the United States.
- The consumer-based, one-year fellowship provides an opportunity to obtain experiential training in both Medical Information and Medical Affairs.
- A variety of projects and shadowing experiences are available for fellows interested in gaining additional exposure to the Regulatory Affairs functional area as well.



Jaroslav Homola, PharmD Medical Information/ Medical Affairs Fellow Medical Information/ Medical Affairs Fellow Northeastern University '19



Krishna Patel, PharmD University of the Sciences '20



Medical Information

- Participate on innovative teams that aid in new consumer product development
- Collect, review, interpret, and disseminate medical information pertinent to J&J's OTC product lines
- Develop core skills related to scientific exchange, medical materials development, customer communications, and medical content review
- Build relationships with internal and external business partners
- Improve scientific writing skills by authoring medical information response documents and escalated medical information requests
- Utilize critical thinking and clinical knowledge to develop fair and balanced communications of product information
- Improve verbal communication skills through delivery of scientific presentations and journal club presentations
- Participate in promotional review committee to ensure that data included are appropriately medically supported in promotional materials



Medical Affairs

- Participate on multifunctional medical team that includes: Regulatory Affairs, Medical & Drug information, Global Medical Safety, Research & Development and Clinical Operations
- Participate in analysis and interpretation of clinical study data
- Learn how to identify and address potential medical issues and ensure implementation of risk-management strategies
- Participate in the development of medical strategies for company products
- Assist in the development of medical content for congresses, symposia, and advisory boards
- Provide medical support (medical training and education) to Marketing and Sales

Other Opportunities

- Ability to work one on one with Regulatory professionals on a variety of Regulatory projects
- Ability to network with pharmacists through a variety of resource groups within the J&J organization including but not limited to a Pharmacist's Network and a PharmD Annual Summit

Application Process

Step 1: Request First-Round Interviews

Request a first-round interview through PPS or email pharmafellows@usciences.edu starting **Wednesday**, **October 21**, **2020**. You must submit your Curriculum Vitae (CV) and Letter of Intent (LOI). Applications are reviewed on a rolling basis, so apply early!

Step 2: Virtual First-Round Interviews

Current fellows will contact candidates to schedule virtual first-round interviews during the ASHP Midyear Clinical Meeting on **December 6 - 8, 2020.**

Step 3: Formal Application

To be eligible for a fellowship position, candidates must submit a formal application through the <u>USciences Application Portal</u> by <u>Wednesday</u>, <u>December 2</u>, <u>2020 at 11:59 PM (EST)</u>. Search for the respective fellowship program and submit your application along with a CV, LOI, a writing sample, three references (names and contact information), and unofficial college transcript(s).*

*NOTE: Applicants who are interested in the Janssen Biologics Product Development & Investigational Drug Trial Design and Management Fellowship do not submit the formal application on the USciences Application Portal. They will receive additional information about the formal application process after the first-round interview at ASHP Midyear.

Step 4: Final-Round Interviews and Next Steps

Candidates will be contacted by current fellows for virtual final-round interviews and next steps.

Connect with us!



Pharmafellows@usciences.edu



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USciences Pharmacy Fellowship Website