

GSK Pharmaceutical Industry

Fellowship Program

Cover image

We aim to achieve industry-leading growth by investing effectively in our business, developing our people, and striving for innovation.

We commit to scientific and technical excellence by developing new products that meet the needs of patients, payers, and consumers.

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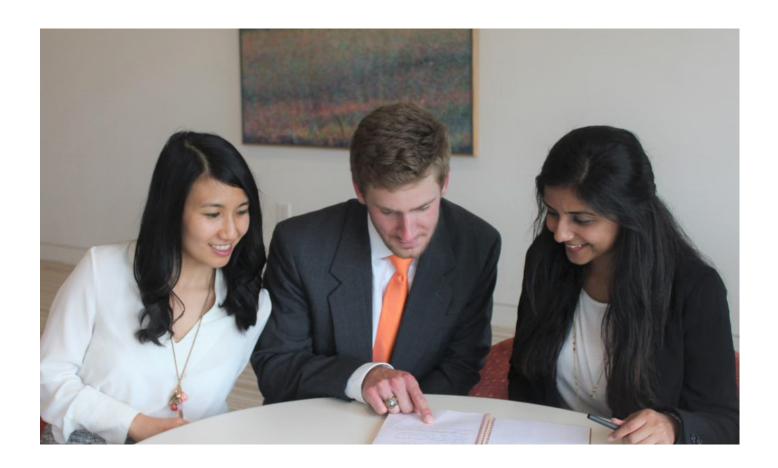
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Introduction

The fellowship programs, in partnership with UNC Eshelman School of Pharmacy and GSK, aim to develop pharmaceutical industry professionals to become successful leaders and innovators

The fellowship programs are two years in length, thus enabling fellows to develop a strong scientific foundation in areas of interest and apply practical knowledge in the setting of pharmaceutical drug development. There is an emphasis on ensuring direct contribution to the advancement of the pharmaceutical sciences as related to the field of study.

GSK has a rich history of collaborations with a variety of leading academic institutions through sponsorship of joint fellowship programs.



Fellowships offered by GSK in partnership with UNC Eshelman School of Pharmacy include:

US Medical Affairs
(PharmD or PhD)

Global Regulatory Affairs

(PharmD, PhD, or MD)

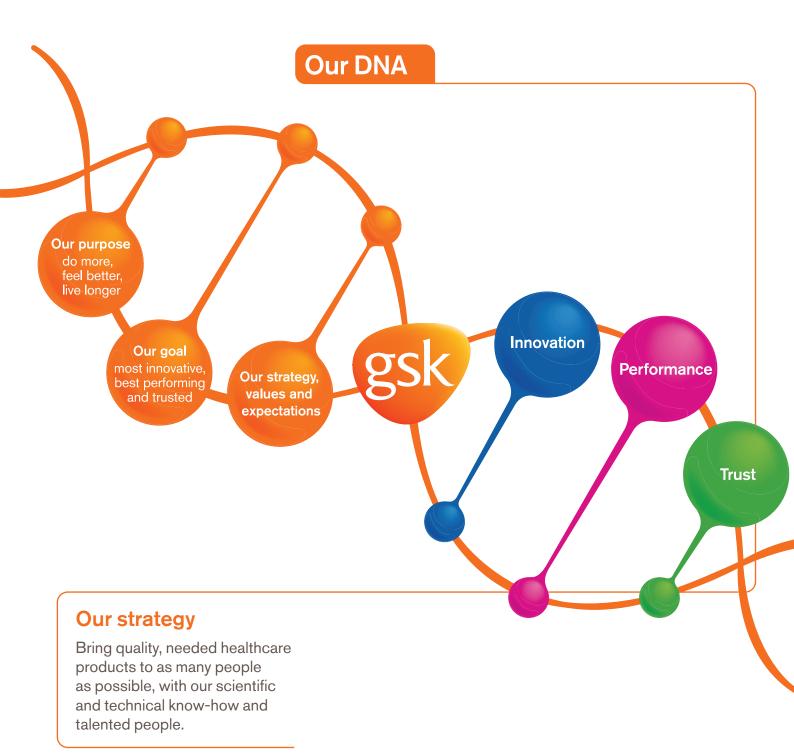
Pharmacokinetics/ Pharmacodynamic (PharmD, PhD, or MD)

GSK

We are one of the largest global pharmaceutical companies

Today there are millions of people without access to basic healthcare, thousands of diseases without adequate treatments and millions of people who suffer from everyday ailments. We want to change this. That's why we are harnessing our scientific and technical know-how, our talented people, our partnerships, and our global reach to develop and manufacture healthcare products for people who need them.

Our mission is to improve the quality of human life by enabling people to do more, feel better, and live longer.



GSK at a glance

Who we are

A science-led global healthcare company with a special purpose to help people do more, feel better, live longer.

We have three global businesses that discover, develop and manufacture innovative pharmaceutical medicines, vaccines and consumer healthcare products.

Our goal is to become one of the world's most innovative, best performing and trusted healthcare companies.



What we do

We aim to bring differentiated, high-quality and needed healthcare products to as many people as possible, with our three global businesses, scientific and technical knowhow and talented people.

In 2019

£33.8bn

total sales

£3.8bn

Innovation sales from pharmaceutical and vaccine products launched in the last five years

f4.6bn

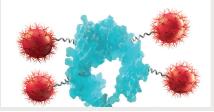
R&D investment

50

medicines(35) and vaccines(15) in the pipeline, including treatments for HIV, respiratory disease and oncology (as of July 2020)

Pharmaceuticals

Our Pharmaceuticals business has a broad portfolio of innovative and established medicines in respiratory, HIV, immuno-inflammation and oncology. We are strengthening our R&D pipeline through a focus on immunology, human genetics and advanced technologies to help us deliver transformational new medicines for patients.



Antibody with cytotoxic drug attached

Vaccines

We are the world's largest vaccines company*, delivering vaccines that help protect people at all stages of life. Our R&D focuses on developing vaccines against infectious diseases that combine high medical need and strong market potential.



Herpes zoster virus of shingles

Consumer Healthcare

Our world-leading Consumer Healthcare business combines science and consumer insights to create innovative everyday healthcare brands that consumers trust and experts recommend for oral health, pain relief, cold, flu and allergy, digestive health and vitamins, minerals and supplements.



Nociceptors, the sensors of the pain pathway

How we do it

Everyone at GSK is focused on our three long-term priorities.

Innovation

We invest in scientific and technical excellence to develop and launch a pipeline of new products that meet the needs of patients, payers and consumers.

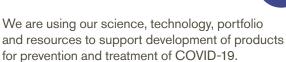
Performance

We deliver growth by investing effectively in our business, developing our people and executing competitively.

Trust

We are a responsible company – using our science and technology to address health needs, we are focused on making our products affordable and available, and being a modern employer.

Our global response in the fight against COVID-19



Our primary aim is to support the development of multiple adjuvanted COVID-19 vaccines, and we plan to produce 1 billion vaccine adjuvant doses in 2021. We are combining our expertise and scale with scientific partners from around the world including North America, China and Europe. Our adjuvant technology can boost the body's immune response, so less vaccine is needed for the same result and more people can be protected.

Shingles

Our shingles vaccine, which reached sales of £1.8bn in 2019, is now the most successful biopharma launch of the last 10 years.

HIV

1.7 million children living with HIV have limited treatment options. In 2019 we filed for approval of a new formulation of our innovative dolutegravir medicine to simplify, optimise and extend its use in babies and children living with HIV.

Our Culture

Our values and expectations are at the heart of everything we do – so that together we can deliver extraordinary impact for patients and consumers and make GSK a brilliant place to work.

Our values

Our expectations



| Why | we do it

To help millions of people around the world to do more, feel better, live longer.



UNC PARTNERSHIP

The UNC Eshelman School of Pharmacy, ranked as the #1 pharmacy school in the nation by the US News and World Report 2020, is a nationally recognized leader in progressive pharmaceutical care practice, education, and research. We are committed to building a diverse talent pipeline. Our global inclusion and diversity councils are driving our agenda.



CHAPEL HILL, NC

The Eshelman School of Pharmacy is part of the University of North Carolina at Chapel Hill, a major research university with a large academic medical center. The School of Pharmacy has specialized research centers pursuing advancements in drug delivery, nanotechnology cancer treatment, pharmacogenomics, and medication optimization.

The Chapel Hill campus is close to the RTP business region, and several large health systems. It offers a rich blend of culture, entertainment, recreation, fine dining, and some of the best college basketball action in the country.

RESEARCH TRIANGLE PARK (RTP), NC

UNC anchors one corner of North Carolina's famed RTP which hosts an abundance of pharmaceutical, biotechnology, and healthcare companies. This environment offers opportunities for collaboration in research, education, and patient care with partners in academia, industry, and healthcare.

RTP is the largest GSK commercial site that operates in the US and houses critical roles in pharmaceuticals, corporate, and manufacturing functions, as well as Research and Development (R&D) and ViiV Healthcare.

US Medical Affairs fellows gain pharmaceutical industry experience during the second year of the fellowship program at RTP. Global Regulatory Affairs fellows spend 2 years with their sponsor company.



"Year after year, I am in awe of our fellows' initiative and innovation and the unique hands-on learning opportunities afforded to them by the University and GSK."

Jo Ellen Rodgers, PharmD, BCPS, FCCP



Global Regulatory Affairs (GRA) fellows may be based out of UP or Waltham, based on business need, throughout the 2-year duration of the fellowship program.

UPPER PROVIDENCE (UP) / COLLEGEVILLE, PA

The Upper Providence GSK site, which is the US R&D Hub, is named for its location in Upper Providence Township, Montgomery County, Pennsylvania. It is approximately 30 miles northwest of Center City Philadelphia and approximately 35 miles from Philadelphia International Airport.

Pharmacokinetics/ Pharmacodynamics (PK/PD) fellows relocate to UP after their first year at UNC. At UP, GRA and PK/PD fellows gain handson pharmaeutical industry experience in a highly dynamic work environment.



WALTHAM, MA

The Waltham location, previously known as Tesaro, was acquired by GSK in 2019 to strengthen the oncology pipeline and has become a pivotal R&D location. It is located approximately 15 miles northwest of downtown Boston.

"Each year, for more than three decades, we have an incredible group of fellows, who make a significant contribution to the legacy of our program. These fellows are a reflection of UNC and GSK's strong long-standing commitment to train and develop the newest generation of pharmaceutical industry professionals."

Robert Dupuis, PharmD, FCCP



US Medical Affairs fellowship

The US Medical Affairs fellowship at GSK provides the practical training and experience needed to successfully obtain a position in the pharmaceutical industry, academia, clinical practice, or Contract Research Organizations

Fellows will work in a cross-functional matrix team which consists of the US Medical Affairs Lead, therapy area scientific/medical directors, global medical affairs, global clinical safety and pharmacovigilance, regulatory affairs, legal, health outcomes, research and development, and commercial.



Fellowship objectives

- Work closely with US Medical Affairs Leads and Accountable Medical Leads to execute tactics that support the overall medical strategy
- Understand principles of clinical research, apply clinical trial design strategies, and collect and analyze data
- Conduct strategic reviews of the medical literature and the competitive environment to identify data and educational gaps to enhance patient care
- Contribute to US scientific engagement between GSK and external communities to advance the understanding of disease treatment and management
- Participate in the medical review of promotional materials and communicate scientific information to internal and field based colleagues
- Support launch preparations for new medicines and/or new indications or label extensions

Program structure

Year one

At UNC Eshelman School of Pharmacy, fellows will have the opportunity to

- Review the principles of clinical research, such as Good Clinical Practice (GCP) and gain an understanding of the wellbeing of study subjects, data collection, analysis, and safety reporting
- Apply clinical design strategies, evaluate research designs and study reports, and utilize biostatistical tests
- Develop protocols, recruit and monitor subjects, collect and analyze data, and prepare an academic manuscript

Year two

At GSK within US Medical Affairs, fellows will have the opportunity to

- Understand the decision-making process that healthcare providers and payers follow for drug utilization
- Contribute to the development and execution of US Medical Affairs plans and integrate the voice of the customer including, providers, payers, patients, into a medical affairs strategy
- Gain clinical knowledge and product expertise in a therapeutic area

Program Director



Antoinette Burgess, PharmD Head of Medical Stakeholder Engagement and Communication, US Medical Affairs, GSK "The partnership between UNC and GSK provides a unique development opportunity. Fellows gain practical experience with the drug development and clinical trial process in an academic university setting and then apply those learnings within a pharmaceutical industry setting in US Medical Affairs. Our Fellows make a significant contribution as they develop on their journey with us and it helps to shape their overall professional careers."

Antoinette Burgess, PharmD

Preceptors



Tania Vila, PharmD Scientific Director, US Medical Affairs, GSK



Charlene Prazma, PhD Senior Scientific Director, US Medical Affairs, GSK

Fellows



Justin Veeder, PharmD Second Year Fellow UNC Eshelman School of Pharmacy



Catharine Nguyen, PharmD Second Year Fellow Temple University School of Pharmacy



Veronica Nguyen, PharmD First Year Fellow St. John's University



Darrian Proco, PharmD First Year Fellow UNC Eshelman School of Pharmacy

Global Regulatory Affairs fellowship

The Global Regulatory Affairs (GRA) fellowship provides practical training and experience in regulatory affairs to help fellows gain expertise in regulatory requirements and strategy pertinent to drug development

Fellows will develop an in-depth understanding of regulatory affairs and the drug development process from pre-clinical to post-marketing stages. Fellows will establish a strong foundation of experience and knowledge to lead a successful career within the pharmaceutical industry, Food and Drug Administration (FDA), or Contract Research Organizations (CROs).



Fellowship objectives

- Apply principles of pharmaceutical product development and develop regulatory strategy by using and interpreting regulations and guidelines
- Provide support to the life-cycle management activities pre- and post-approval, for drug and biologic products and gain an understanding of the principles of agency review processes
- Gain an understanding of early and late phase clinical development and gain expertise in the requirements of regulatory submissions
- Understand the various facets that exist within GRA including labeling, advertising and promotion, regulatory intelligence and strategy, chemistry manufacturing and controls (CMC), and non-clinical regulatory
- Obtain valuable foundational knowledge by partaking in the Regulatory Affairs Certification (RAC) course and examination

Program overview

Global Regulatory Affairs (GRA) fellows may be based out of Upper Providence or Waltham, based on business need, throughout the 2-year duration of the fellowship program.

GSK will recruit at least 2 qualified post-doctoral Regulatory Affairs fellow candidates to support either:

- Therapeutic Groups (Regulatory Strategy), including Oncology
- Chemistry, Manufacturing & Controls (CMC)

Candidates should identify which position is of interest.

During the fellowship, the fellow will work with regulatory leaders to gain hands-on experience and have the opportunity to

- Develop valuable regulatory strategic skills across all phases of drug development and function as an effective project team member
- Prepare regulatory interaction documents and submission packages and interact with regulatory agencies to guide product development
- Develop and maintain awareness of the regulatory landscape to inform drug development
- Participate in departmental initiatives for process improvements and/or regulatory knowledge management

Sponsor



Mark DeSiato Vice President, Therapeutic Group Regulatory Head, GSK

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"Fellows are given the opportunity to utilize the knowledge and leadership skills they have obtained from our partnership with UNC and gain hands on experience in the pharmaceutical industry at GSK. The program also assists in identifying and developing emerging talent to potentially support the future GSK business. On behalf of GRA, we very much look forward to working with the fellows over the coming years!"

Mark DeSiato

Program Director



Kevin Fitzgerald, BSPharm Senior Director, Delivery Team Lead & Regulatory Expert, Regulatory Transformation RPS, GSK

Program Preceptor



Shiv Patel, PharmD, RAC Associate Director, Oncology Therapeutic Group, Global Regulatory Affairs, GSK

Fellows



Riddhi Virparia, PharmD, RAC Second Year Fellow Oncology Therapeutic Group Rutgers University



Eric Mui, PharmD, RAC Second Year Fellow Chemistry, Manufacturing & Controls (CMC) University of Wisconsin, Madison



Deanna Rubin, PharmD First Year Fellow Oncology Therapeutic Group UNC Eshelman School of Pharmacy



Lauren Xu, PharmD, MS First Year Fellow Chemistry, Manufacturing & Controls (CMC) University of Pittsburgh

Pharmacokinetics/ Pharmacodynamics fellowship

The Pharmacokinetics/
Pharmacodynamics (PK/PD)
fellowship provides practical
training and experience
needed to successfully
obtain a position as a
Clinical Pharmacologist in
the pharmaceutical industry,
academia, or in a clinical
setting

The fellowship emphasizes coursework and hands-on experience focused on the application of population and physiologically-based PK/PD modeling and simulation techniques to guide drug development. Fellows will work on cross-functional teams and contribute to drug development from a clinical pharmacology perspective.



Fellowship objectives

- Understand the nature and relevance of clinical data evaluations relative to drug development
- Design and implement studies to examine drug absorption, drug disposition, pharmacodynamic endpoints and drug interactions in healthy human volunteers or diseased patient populations
- Understand foundational concepts related to population PK/PD and physiologically-based PK modeling and simulation techniques
- Understand important considerations in clinical trial design and the conduct of clinical investigations in specific patient populations (e.g., pediatrics)
- Perform PK/PD and statistical data analysis using relevant software packages
- Prepare a manuscript, seminar and other scholarly vehicles for communication of scientific results

Program structure

Year one

At UNC Eshelman School of Pharmacy, fellows will have the opportunity to

- Engage in didactic and scholarly training via coursework in population and physiologically-based PK/PD modeling and simulation techniques
- Coordinate and support clinical pharmacology, drug pharmacokinetic and metabolism studies and mathematical modeling with UNC Division of Pharmacotherapy and Experimental Therapeutics (DPET) faculty
- Design, conduct and carry out data analysis of clinical pharmacology studies in the academic setting as part of the learning experience

Year two

Fellows relocate to Upper Providence.

At GSK within Clinical Pharmacology Modelling and Simulation (CPMS), fellows will have the opportunity to

- Interact with multi-disciplinary teams to apply stateof-the-art quantitative methodologies to aid the development of compounds in the GSK portfolio; such as population PK/PD analyses, exposure-response, disease progression modeling and clinical trial simulations
- Provide expertise to the design and analysis of first-time-in-human, proof-of-concept, drug-drug interaction or other clinical pharmacology studies
- Contribute to modeling and simulation efforts for quantitative decision making to enhance study design, support candidate selection, provide dose rationale, and/or benchmark against competitor compounds

Sponsor



Rajendra Singh, PhD
Director, Clinical Pharmacology
Modeling and Simulation, GSK

Program Director



Daniel Gonzalez, PharmD, PhD Assistant Professor, Division of Pharmacotherapy and Experimental Therapeutics, UNC

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"An academic setting like UNC DPET within Eshelman School of Pharmacy, is a phenomenal learning environment for the fellow to become acquainted with the complex techniques that will aid him/her succeed at GSK. While at GSK the fellow will be able to seamlessly transition into the work utilizing GSK's state of the art capabilities in modeling and simulation projects"

Daniel Gonzalez, PharmD, PhD

Fellows



Fernando Carreño, PhD Second Year Fellow Federal University of Rio Grande do Sul



Eleni Karatza, PhD First Year Fellow National and Kapodistrian University of Athens



UNC GSK Fellowship Alumni

Employed at GSK

Keith Pappa

Head of Clinical Sciences, Chief Scientific and Medical Office, ViiV

Clinical Research & Drug Development fellow 1985-1986

Karol LaCroix

Team Leader, SERM, Central Safety Department, GSK

Clinical Research & Drug Development fellow 1986-1987

Linda Clayton

Director, SERM, Central Safety Department, GSK

Clinical Research & Drug Development fellow 1989-1990

Lynn Henson

Senior Director, SERM, Central Safety Department, GSK

Clinical Research & Drug Development fellow 1990-1992

Amy Meadowcroft

Director, Clinical Development, Medicine Delivery, GSK

Clinical Research & Drug Development fellow 1996-1998

Sarah Roberts

Manager, Global Regulatory Affairs, Labeling, GSK

Clinical Research & Drug Development fellow 1998-2000

Susan Ford

Director, Clinical Pharmacology, GSK

Pharmacokinetics & Pharmacodynamics fellow 2000-2002

Michael Lim

Director, EPCS, Global Oncology Franchise, GSK

Drug Development fellow 2001-2003

Purav Bhatt

Manager, Clinical Development, Medicine Delivery, GSK

Clinical Research & Drug Development fellow 2012-2014

Christine Trezza

Director, Medical Governance & Operations, Global Medical Affairs, ViiV

Clinical Research & Drug Development fellow 2013-2015

Michael Bogart

Manager, US Value Evidence Outcomes, GSK

Pharmaceutical Outcomes Research fellow 2013-2015

Jennifer Kim Cremer

Manager, Clinical Development, Respiratory & Specialty, GSK

Clinical Research & Drug Development fellow 2014-2016

Kristina Vishnevetskaya

Manager, Oncology Therapeutic Group, Global Regulatory Affairs, GSK

Global Regulatory Affairs fellow 2017-2019

Hitesh Patel

Medical Information Scientist, Medical Affairs, GSK

Medical Affairs fellow 2017-2019

Kwadwo Yeboah

Manager, Oncology Therapeutic Group, Global Regulatory Affairs, GSK

Global Regulatory Affairs Fellow 2018-2020

Lauren Hothem

MSL, Medical Affairs, GSK

Medical Affairs Fellow 2018-2020



EMPLOYED AT UNC

Denise Rhoney

Associate Dean for Curricular Innovation, PACE, UNC Eshelman School of Pharmacy

Clinical Research & Drug Development fellow 1993-1995

Craig R. Lee

Associate Professor of Pharmacy, DPET, UNC Eshelman School of Pharmacy

Clinical Research & Drug Development fellow 2000-2002





Katy Moore

Global Head, Clinical Pharmacology, ViiV Research & Development

Pharmacokinetics & Pharmacodynamics Clinical Pharmacology fellow 1993-1995

Lakshmi Vasist

Director, Clinical Pharmacology, GSK

Pharmacokinetics & Pharmacodynamics fellow 2004-2006

Elizaveta Budko

Manager, Therapeutic Group, Global Regulatory Affairs, GSK

Global Regulatory Affairs fellow 2014-2016

Alexis Williams

Global Medical Information Leader, Medical Affairs, GSK

Medical Affairs Fellow 2018-2020

Patrick Wire

Senior Director, Therapeutic Group, Global Regulatory Affairs, GSK

Clinical Research & Drug Development; Pharmacokinetics fellow 1993-1995

Justin Koteff

Director, Scientific Communications, Strategy & Medical Information, ViiV

Clinical Research & Drug Development fellow 2009-2011

Brittany Dustman

Associate Director, Oncology Therapeutic Group, Global Regulatory Affairs, GSK

Global Regulatory Affairs fellow 2016-2018

Melissa Ellis

Director, SERM, Central Safety Department, GSK

Clinical Research & Drug Development fellow 1994-1996

Bryant Tran

Scientific Director, US Medical Affairs, GSK

Clinical Research & Drug Development fellow 2009-2011

Shiv Patel

Associate Director, Oncology Therapeutic Group, Global Regulatory Affairs, GSK

Global Regulatory Affairs fellow 2016-2018

Rob Kustra

Director, SERM, Central Safety Department, GSK

Clinical Research & Drug Development fellow 1995-1997

Elizabeth Blair

Director, Clinical Development, Scientific Medical Office, ViiV

Clinical Research & Drug Development fellow 2012-2014

Prani Paka

Scientific Director, Global Medical Affairs Oncology, GSK

Medical Affairs fellow 2016-2018







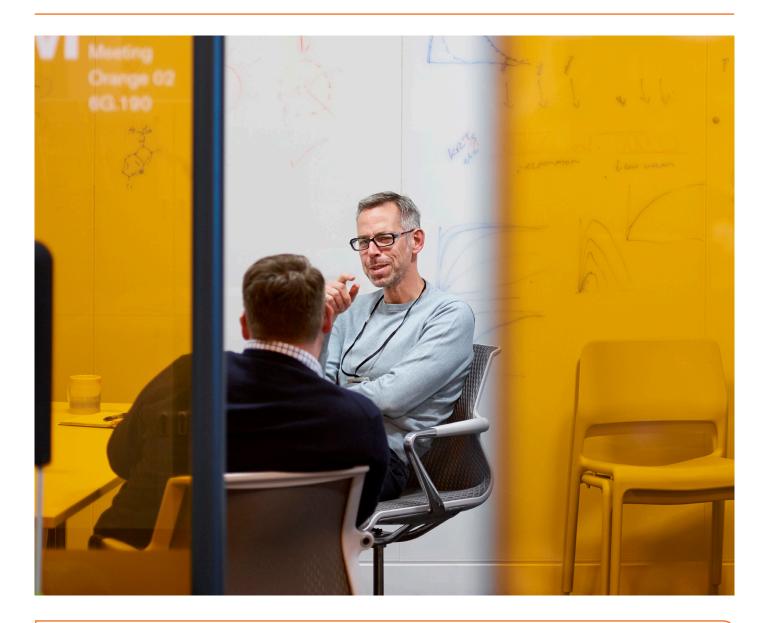


Application and Eligibility

The UNC Eshelman School of Pharmacy and GSK Pharmaceutical Industry Fellowships commence in July 2021.

Applicants must submit an online application including a letter of interest, CV, unofficial transcripts, and 3 letters of recommendation.

Interviews will be arranged virtually for selected candidates.



US Medical Affairs, Global Regulatory Affairs and PK/PD



Visit http://pharmacydpetfellowships.web.unc.edu for application instructions and deadlines.

Early applications are highly encouraged





GSK

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Waltham 1000 Winter St Waltham MA 02451

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