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.
Introduction

GSK

UNC Eshelman School of Pharmacy

Fellowships

- US Medical Affairs
- Global Regulatory Affairs
- Pharmacokinetics/Pharmacodynamics

UNC GSK Fellowship Alumni

Application and Eligibility
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)
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.

Our strategy
Bring quality, needed healthcare products to as many people as possible, with our scientific and technical know-how and talented people.
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 know-how and talented people.

Pharmaceuticals

Our Pharmaceuticals business has a broad portfolio of innovative and established medicines in respiratory, HIV, immunoinflammation 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.

In 2019

£33.8bn total sales

£3.8bn Innovation sales from pharmaceutical and vaccine products launched in the last five years

$3.8bn R&D investment

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

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.

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.

Antibody with cytotoxic drug attached

Herpes zoster virus of shingles

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
We are using our science, technology, portfolio and resources to support development of products for prevention and treatment of 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
Patient focus
Transparency
Respect
Integrity

Our expectations
Courage
Accountability
Development
Teamwork

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

UNC PARTNERSHIP

The UNC Eshelman School of Pharmacy anchors one corner of North Carolina's famed Research Triangle Park (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
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 hands-on pharmaceutical 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

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.
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
**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

"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

**Program Director**

Antoinette Burgess, PharmD  
Head of Medical Stakeholder Engagement and Communication, US Medical Affairs, GSK

**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
- 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
- Gain an understanding of early and late phase clinical development and gain expertise in the requirements of regulatory submissions
- Obtain valuable foundational knowledge by partaking in the Regulatory Affairs Certification (RAC) course and examination
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.

“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 overview**

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

**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
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 state-of-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

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

“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
**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  

**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

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**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
Alexis Williams
Global Medical Information Leader, Medical Affairs, GSK
Medical Affairs Fellow 2018-2020

Katy Moore
Global Head, Clinical Pharmacology, Viiv Research & Development
Pharmacokinetics & Pharmacodynamics Clinical Pharmacology fellow 1993-1995

Patrick Wire
Senior Director, Therapeutic Group, Global Regulatory Affairs, GSK
Clinical Research & Drug Development; Pharmacokinetics fellow 1993-1995

Melissa Ellis
Director, SERM, Central Safety Department, GSK
Clinical Research & Drug Development fellow 1994-1996

Rob Kustra
Director, SERM, Central Safety Department, GSK
Clinical Research & Drug Development fellow 1995-1997

Lakshmi Vasist
Director, Clinical Pharmacology, GSK
Pharmacokinetics & Pharmacodynamics fellow 2004-2006

Justin Koteff
Director, Scientific Communications, Strategy & Medical Information, Viiv
Clinical Research & Drug Development fellow 2009-2011

Bryant Tran
Scientific Director, US Medical Affairs, GSK
Clinical Research & Drug Development fellow 2009-2011

Elizabeth Blair
Director, Clinical Development, Scientific Medical Office, Viiv
Clinical Research & Drug Development fellow 2012-2014

Elizaveta Budko
Manager, Therapeutic Group, Global Regulatory Affairs, GSK
Global Regulatory Affairs fellow 2014-2016

Brittany Dustman
Associate Director, Oncology Therapeutic Group, Global Regulatory Affairs, GSK
Global Regulatory Affairs fellow 2016-2018

Shiv Patel
Associate Director, Oncology Therapeutic Group, Global Regulatory Affairs, GSK
Global Regulatory Affairs fellow 2016-2018

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](http://pharmacydpetfellowships.web.unc.edu) for application instructions and deadlines. Early applications are highly encouraged.