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GSK is proud to partner with University of North Carolina (UNC) Eshelman School of Pharmacy to offer 2-year fellowship programs, aiming to develop pharmaceutical industry professionals to become successful leaders and innovators.

**Introduction**

Our goal is to provide the opportunity for fellows to gain the skills, knowledge, and experience needed to pursue a career in the pharmaceutical industry, enabling them to become successful leaders and innovators. Fellows develop a strong scientific foundation in areas of interest by gaining practical experience in the pharmaceutical drug development setting and applying those learnings for the advancement of pharmaceutical sciences.

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:

- **Global Regulatory Affairs** (PharmD, PhD, or MD)
- **Pharmacokinetics/Pharmacodynamics** (PharmD, PhD, or MD)
- **US Medical Affairs** (PharmD or PhD)
- **Global Pharmacovigilance** (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.

We are one of the largest global pharmaceutical companies.

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

Our Purpose
We unite science, technology and talent to get ahead of disease together.

Our Culture
We are ambitious for patients, accountable for impact and we do the right thing.
GSK at a glance

Who we are
We are a global biopharma company with a purpose to unite science, technology and talent to get ahead of disease together.

Innovation
Finding new vaccines and medicines where they are needed. With better, faster and smarter R&D.
We’re combining the power of genetic and genomic insights into the causes of disease, with the speed and scale of artificial intelligence and machine learning.

Performance
New commitments to growth and a significant step-change in delivery over the next five years. Over £33bn sales by 2031.
Our bold ambitions mean more GSK vaccines and medicines than ever before:
• Including innovative new products
• Reaching people who need them.

Trust
Delivering our strategy responsibly: always considering the social, environmental and governance impacts of everything we do from lab to patient.
We’re taking action in six areas that matter most to us: pricing and access; global health and health security; diversity, equity and inclusion; environmental sustainability; product governance; and ethical standards.

In 2021
3 Major Approvals
7 Regulatory Submissions
20+ Business Development Deals

In 2021
£24bn Pharmaceuticals sales
767m Vaccine Doses Delivered
17bn Medicine Doses Delivered

In 2021
1st In the Access to Medicine Index
1st In Dow Jones Sustainability Index

What we do
We aim to positively impact the health of 2.5 billion people over the next 10 years. Our bold ambitions for patients are reflected in new commitments to growth and a step-change in performance.

How we do it
Everyone at GSK is focused on our three long-term priorities, underpinned by our ambition to build a more purpose and performance-driven culture, aligned to our values.

General Medicines
General medicines are usually prescribed in primary care or community settings by general healthcare practitioners. For us, this includes our inhaled medicines for asthma and COPD, antibiotics and medicines for skin diseases. Every day, these medicines improve health and make life better for millions of people all over the world.

Specialty Medicines
Specialty medicines are prescribed by specialist healthcare practitioners. For GSK this includes our cancer medicines that have life-changing potential for patients. We’re also developing medicines for immune-mediated conditions, including the first new medicine for the chronic autoimmune condition lupus in over 50 years.

Vaccines
Our vaccines portfolio is the broadest in the industry, helping protect people from meningitis, shingles, flu, polio, measles, and many more. Today, two million doses of our vaccines are administered daily, and 4 in 10 of the world’s children receive a GSK vaccine each year.

Shingles
Our Shingrix vaccine, which reached sales of £2 billion in 2020, is the most successful biopharma launch of the last 10 years.

HIV
Around 38 million people across the world live with HIV, including approximately 17 million children. Ensuring no child living with HIV is left behind: in June 2020 we received US FDA approval, followed by European EMA approval in January 2021, of the first-ever dispersible tablet formulation of dolutegravir, for children from four weeks of age.

Our Covid-19 response
Since the COVID-19 pandemic began, we have been seeking ways to use our scientific expertise and technology to make a difference. We are working with several scientific partners to develop a broad portfolio of potential solutions from prevention to treatment, with several investigational COVID-19 vaccines and antibody medicines in clinical studies.
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.

“Each year, for more than four 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
Professor, Division of Pharmacotherapy and Experimental Therapeutics
Director of Fellowship Programs

“Every year, it is my privilege to observe the development of our highly motivated fellows, as they engage in opportunities and activities afforded to them by the University and GSK that could transform treatment! I am proud to be a part of the process.”

Gauri Rao, PharmD, MS
Associate Professor, Division of Pharmacotherapy and Experimental Therapeutics
Associate Director of Fellowship Programs

UNC Partnership

The UNC 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.

DURHAM NORTH CAROLINA

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. Durham 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 ViV Healthcare.

US Medical Affairs and PK/PD fellows gain pharmaceutical industry experience during the second year of the fellowship program at Durham. Global Regulatory Affairs fellows spend 2 years with their sponsor company. Global Pharmacovigilance fellows spend time over both years at Durham.

UPPER PROVIDENCE (UP) / COLLEGEVILLE PENNSYLVANIA

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. At UP, GRA and PK/PD fellows gain hands-on pharmaceutical industry experience in a highly dynamic work environment.

WALTHAM MASSACHUSETTS

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.
US Medical Affairs Fellowship

Fellows have a unique opportunity to gain practical experience in the clinical drug development setting and apply those learnings within medical affairs at GSK. Fellows gain the practical training and experience to pursue a career in the pharmaceutical industry, academia, clinical practice or with a contract research organization.

Fellows collaborate cross-functionally with US Senior Medical Affairs Leads, Scientific Directors, Scientific Training Directors, Medical Capabilities Directors and Field Medical Liaisons in support of the overall medicine plan. Fellows make impactful contributions to the business as they learn and develop professionally during their fellowship journey.

Fellowship Objectives

- Understand the role of Medical Affairs in the pharmaceutical industry working closely with the US Senior Medical Affairs Lead and collaborating cross-functionally for a medicine in support of the overall medicine plan
- 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 1

At the 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 2

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, Medical Engagement and Capabilities

“Working through the program at UNC and GSK, fellows gain a strategic, comprehensive development opportunity. Fellows gain first-hand experience with the drug development and clinical trial process and the demands of working in a fast-paced, dynamic setting and then apply those learnings within a pharmaceutical industry setting in US Medical Affairs. Our Fellows make a significant contribution as they work on their journey with us and help to shape our overall professional careers.”

Preceptors

Kelly Pincus, PharmD
US Medical Affairs, Senior Director & Head Medical Communications & Scientific Training, Oncology

Jennifer Wolfe, PharmD
US Medical Affairs Lead, Niraparib, Oncology

George Clayton, PharmD
Director, Medical Capabilities and Learning Excellence

Fellows

Michael Mac, PharmD
Second Year Fellow UNC Eshelman School of Pharmacy

Preston Skersick, PharmD
Second Year Fellow Mercer University College of Pharmacy

Christopher Randhawa, PharmD
First Year Fellow Wilkes University College of Pharmacy

James Collins, PharmD
First Year Fellow UNC Eshelman School of Pharmacy

Ye a r  1

Program Director

Antoinette Burgess, PharmD
Head, Medical Engagement and Capabilities

Ye a r  2

Preceptors

Kelly Pincus, PharmD
US Medical Affairs, Senior Director & Head Medical Communications & Scientific Training, Oncology

Jennifer Wolfe, PharmD
US Medical Affairs Lead, Niraparib, Oncology

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First Year Fellow UNC Eshelman School of Pharmacy
Global Regulatory Affairs Fellowship

The Global Regulatory Affairs (GRA) fellowship provides practical training and experience 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 strategies. 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

• 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 of global regulatory affairs, including labeling, advertising and promotion, regulatory intelligence and strategy, chemistry manufacturing and controls (CMC), and non-clinical regulatory
• Participate in departmental initiatives for process improvements and/or regulatory knowledge management
• 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, or Chemistry, Manufacturing & Controls (CMC). Candidates should identify which position is of interest.

Therapeutic Groups (TG)
The TG fellow will have the opportunity to:

• Become an integrated member of the cross-functional team and provide regulatory strategic input for both early and late-stage clinical development programs
• Interact with health authorities globally through correspondences and preparation of submission packages to guide product development
• Develop and maintain awareness of the regulatory landscape to inform drug development

Chemistry, Manufacturing & Controls (CMC)
The CMC fellow will have the opportunity to:

• Liaise with health authorities to obtain scientific advice and respond to CMC questions
• Collaborate with a variety of functional areas, such as biopharmaceutical development and supply, manufacturing, device engineering, quality, and clinical to determine overall CMC regulatory strategy for biopharmaceuticals/cell gene therapy (CGT)
• Plan/prepare CMC Biopharmaceuticals regulatory documents for global submissions across all stages of product development and life cycle
• Support health authority engagements related to scientific advice and CMC questions

Sponsor

“GSK is proud to partner with UNC to offer fellows the opportunity to develop the expertise necessary to pursue a rewarding career within Regulatory. This fellowship represents a unique opportunity for talented and ambitious individuals to accelerate their careers. GRA is committed to providing fellows leadership support, mentoring and development opportunities to help ensure they thrive and flourish. We look forward to working with diverse and emerging talent to help them become tomorrow’s great leaders.”

Jonathan LaCalamita
Head, US Regulatory Advertising and Promotion Policy

Program Director

Kevin Fitzgerald, BSPharm
Senior Director, Specialty Therapeutic Group R&D Global Regulatory Affairs

CMC Fellows

Holly Maize, PharmD
Second Year Fellow Medical College of Wisconsin School of Pharmacy

Nhi Duong, PharmD
First Year Fellow California Northstate University College of Pharmacy

TG (Strategy) Fellows

Hayley Karpick, PharmD
Second Year Fellow Oncology Therapeutic Group Purdue University College of Pharmacy

Heejin (Jinny) Hur, PharmD
First Year Fellow Oncology Therapeutic Group University of Illinois Chicago College of Pharmacy

Sanni Rana, PharmD
First Year Fellow Specialty Therapeutic Group UNC Eshelman School of Pharmacy
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.

In addition, fellows will implement model-informed drug discovery and development (MID3) approaches to accelerate and de-risk drug development to bring novel therapies to patients faster.

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

At the 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

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

Brandon Swift, PhD
Senior Director, Clinical Pharmacology, Modeling and Simulation, Clinical Pharmacology and Experimental Medicine, R&D, GSK

Fellow

Victória Etges Helfer, PhD
First Year Fellow
Federal University of Rio Grande do Sul

Program Director

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

An academic setting like the UNC DPET within the Eshelman School of Pharmacy is a phenomenal learning environment for the fellow to become acquainted with the concepts and methodologies that will aid them at GSK. While at GSK, the fellow will contribute to drug development programs by utilizing state-of-the-art modeling and simulation techniques.
Global Pharmacovigilance Fellowship

The GSK Global Pharmacovigilance Fellowship provides practical training and experience in pharmacovigilance (PV) allowing the fellow to obtain the fundamental skills required to embark on a successful career in pharmacovigilance.

The fellowship will bridge the gap from student to industry professional by focusing on global patient safety and development of skills and qualities needed to excel in a corporate environment.

Fellowship Objectives

- Gain understanding of the role of global pharmacovigilance in the lifecycle of a pharmaceutical product including how pre-clinical, clinical, and post-marketing safety work translates to real-world use
- Develop fundamental pharmacovigilance skills to be well equipped to launch a successful career in pharmacovigilance and other disciplines within the pharmaceutical industry
- Evaluate and identify potential safety concerns, and develop associated communication to inform of the risk
- Exposure to contemporary PV technologies and methodologies such as emerging data sources, Artificial Intelligence (AI), and machine learning
- Develop leadership and critical thinking skills to hold a successful career in PV space
- Work cross-functionally within matrix teams representing the safety organization

Sponsor

Peggy Webster, MD, MBA
Head of Vaccine Safety

Executive Director

Lora Schlans, PharmD
Safety Evaluation/Risk Management (SERM)/Head Oncology/Hematology

Year 1

Time Allotment and Program Structure

- Fellow will spend three days a week at University of North Carolina Eshelman School of Pharmacy and two days a week at GSK for the first half of the first year and then two days a week at UNC Eshelman School of Pharmacy and three days a week at GSK for the second half of the year.
- UNC: Fellow will focus on coursework and professional development, participate in fellows forum, and will be paired with faculty conducting clinical research and focus on a project with a safety element.
- GSK: During the first half of the year the fellow will be exposed to various areas of pharmacovigilance with primary focus on pharmacovist roles within the department. During the second half of the year the fellow will gain exposure to pharmaceuticals, vaccines, PV innovation/research, and drug safety throughout the product lifecycle (pre-First Time In Human, clinical development, and post-marketing). This will allow the fellow to identify an area for which to focus during the second year of the fellowship.
- Fellow will be assigned a preceptor at GSK to mentor to oversee and facilitate learning opportunities in order to develop an understanding of pharmacovigilance practices, global regulations, and clinical development in order to apply these fundamentals in monitoring patient safety.
- Fellow will be placed in rotational opportunities among the Global Safety functions at GSK to gain exposure to multiple facets of PV activities.
- The fellow will complete two scholarly activities as agreed with preceptor. Examples include:
  - Journal article or other publication (preferably on GSK product)
  - Develop process improvement initiative and present to department
  - Present on current/updated standard operating procedures (SOP) of safety specific process
  - Attend and present at one US based professional meeting relating to the fellowship program

Year 2

Time Allotment and Program Structure

- Fellow will spend the majority of time at GSK working in an identified area of interest in Pharmacovigilance. This may be split into six month rotations if two primary areas of interest.
- Fellow may spend up to 10% of time on a special project (ie publications, certifications, research) in order to apply these fundamentals in global regulations, and clinical development.
- Fully integrate into ongoing program working with assigned team including a safety physician and scientist. The safety representative will assume primary mentor responsibilities for the fellow.
- The fellow will complete two scholarly activities as agreed with preceptor.
  - Journal article or other publication (preferably on GSK product)
  - Develop process improvement initiative and present to department
  - Present on current/updated SOP of safety specific processes
  - Attend and present at one US based professional meeting relating to the fellowship program

Co-Program Directors

Josh Ruane, PharmD
Vaccines SERM
Principal Scientist

Lan-Anh Brittany Do, PharmD
Vaccines SERM
Principal Scientist

Preceptors

Greg Powell, PharmD, M BA
Senior Director, Safety and Clinical Innovations

Abimbola Cole, PharmD, MPH
Oncology/Hematology SERM
Scientific Director
Keith Pappa  
Head of Clinical Sciences, Chief Scientific and Medical Office, ViiV Clinical Research & Drug Development fellow 1985-1986

Lynn Henson  
Senior Director, SERM, Central Safety Department, GSK Clinical Research & Drug Development fellow 1990-1992

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

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

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

Christine Trezza  
Director, Medical Governance & Operations, Global Medical Affairs, ViiV Clinical Research & Drug Development fellow 2013-2015

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

Jennifer Kim Cremer  

Prani Paka  
Scientific Director, Global Medical Affairs Oncology, GSK Medical Affairs fellow 2016-2018

Stephanie Kim  
Manager, Specialty Therapeutic Group, Global Regulatory Affairs, GSK Global Regulatory Affairs fellow 2021-2022

Lauren Xu  
Manager, CMC Global Regulatory Affairs, GSK Chemistry, Manufacturing, and Controls (CMC) fellow 2020-2022

Deanna Rubin  
Manager, Oncology Therapeutic Group, Global Regulatory Affairs, GSK Global Regulatory Affairs fellow 2020-2022

Lauren Hothem  
Director Medical Communications & Scientific Training, Medical Affairs fellow 2018-2020

Eric Mui  
Associate Director, CMC Regulatory Affairs, Development-GRA-Biopharm Development Projects Chemistry, Manufacturing, Controls (CMC) fellow 2019-2021

Fernando Carreño  
Manager, Quantitative Clinical Pharmacology Oncology - Clinical Pharmacology, Modeling and Simulation (CPMS) Department Pharmacokinetics/Pharmacodynamics fellow 2019-2021

Darian Proco  
Scientific Manager, Gepotidicin, Medical Affairs, GSK Medical Affairs fellow 2020-2022

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  
Professor of Pharmacy, DPET, UNC Eshelman School of Pharmacy Clinical Research & Drug Development fellow 2000-2002

UNC GSK Fellowship Alumni  
(Employed at GSK)
Application and Eligibility

The UNC Eshelman School of Pharmacy and GSK Pharmaceutical Industry Fellowships commence in July 2023. Applicants must submit an online application including a letter of interest, CV, unofficial transcript, and 3 letters of recommendation. Interviews will be arranged virtually for selected candidates.

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