Post-Doctoral Fellowships
UNC Eshelman School of Pharmacy
2023
Introduction

Robert E. Dupuis, PharmD, FCCP
Director, Clinical Fellowship Programs
re_dupuis@unc.edu

Julie Leemkuil
Fellowship Program Manager
julie_leemkuil@unc.edu

Division of Pharmacotherapy and Experimental Therapeutics
Presentation Overview

- Introduction
- Fellowship Structure
- Fellowship Opportunities
- Application Process
- Q&A
UNC Eshelman School of Pharmacy

• The UNC Eshelman School of Pharmacy is a nationally recognized leader in progressive pharmaceutical care practice, education, and research. It is currently ranked as the No. 1 pharmacy school in the nation by the US News and World Report.

• The UNC Fellowship program has a history of success for training fellows for over 40 years.
UNC Academic Fellowships

- Oncology
- T32 Clinical Pharmacology
Industry-Sponsored Fellowships

Clinical Research/Drug Development
- PPD
- UCB - Neurology (MD only)

Regulatory Affairs: Regulatory Strategy, Chemistry, Manufacturing and Controls (CMC)
- GSK

Medical Affairs
- GSK
- United Therapeutics

Market Access and Informatics
- AESARA

Pharmacokinetics/Pharmacodynamics/Pharmacometrics
- Genentech
- Janssen

Global Drug Safety/Pharmacovigilance
- United Therapeutics
- GSK
Two-Year Training Program

- First year*
  - Hands-on experience with clinical/translational research and regulatory processes with a faculty advisor
  - Coursework at Eshelman School of Pharmacy
  - Weekly Graduate Student/Fellow Seminar
  - Monthly Fellows Forum
  - UNC, Duke, and Research Triangle Park seminars, workshops, and symposia
  - Opportunity to complete a teaching certificate at UNC and/or mentor students
  - Writing and presentation of research opportunities
  - *Regulatory Affairs spends both years with sponsor

- Second year
  - Industry-sponsored company

- Opportunities for presentations at national and international professional meetings (poster, platform) and publications

- Fellowship alumni mentoring
Coursework

• Coursework is specific to each program:
  – Clinical Trial Design, Drug Development, PK/PD, Modeling/Simulation, Quantitative Methods in Clinical Research, Drug Metabolism, Genomics
  – Regulatory Affairs Certification
  – Leadership, Public Speaking, Teaching Certificate
  – MPS in Biomedical and Health Informatics program
  – Additional seminars offered through NC Tracs and other organizations

• Fellows Forum (monthly)
  – Discuss the latest topics in the drug development industry
  – Learn from leaders with various industry partners, network with alumni

• DPET Seminar (weekly)
  – Faculty, graduate students, fellows, guest speakers
FDA - Office of Clinical Pharmacology

- Fellows have the opportunity to complete a 2-month rotation
- During this time Fellows will have the opportunity to:
  - Conduct research to assist with FDA guidance development
  - Attend cross-functional review meetings of regulatory submissions
  - Have the opportunity to interact with sponsors conducting studies
  - Network with FDA employees in various divisions/offices
Objectives: To provide practical training/experience and develop competency in the scientific research process, including conceptualizing, planning, conducting, and reporting studies as well as presenting and reporting study findings
Clinical Research/Drug Development Fellows

Kayla Tunehag
PPD
Campbell University
ktunehag@unc.edu

Ashton Pearce
PPD
Campbell University
ashtonpearc@unc.edu

Grace Liu
PPD
UNC
hsuanhui@unc.edu
Clinical Research: First Year at UNC

- Preclinical/clinical drug development (Phase I-IV)
- Investigator-initiated clinical trials
- Protocol development
- Regulatory/IRB/grant submissions
- Data and biostatistical analysis
- Study coordination
- Abstract/poster/platform presentations
- Publications in scientific journals
- Coursework on study design and statistical analysis
- Optional opportunities for bench research
- PharmD student mentorship
Clinical Research: Second Year at PPD

• Global and cross-functional collaboration to bring investigational drugs to market
• Rotations tailored to fellows’ interests
  – Protocol development and coordination, study support (Phases I-IV)
  – Project management
  – Pharmacovigilance
  – Medical writing
  – Strategic development and feasibility
  – Pharmacokinetics
  – Regulatory Affairs
• Hands-on training for a variety of career paths
MEDICAL AFFAIRS

Objectives: To provide practical training/experience and develop competency in the scientific research process, including conceptualizing, planning, conducting, and reporting studies as well as presenting and reporting study findings
Medical Affairs Fellows

James Collins
GSK
University of North Carolina
jb_collins@unc.edu

Chris Ramdass
GSK
Wilkes University
cramdass@unc.edu

Sarah Kaspari
United Therapeutics
University of Michigan
kaspari@unc.edu

Eugene Lee
GSK
Northeastern University
leeeug@unc.edu

Lia Upchurch
GSK
Mercer University
mdupchur@unc.edu

Katie Paxton
United Therapeutics
University of South Carolina
kpaxton@unc.edu
Medical Affairs: First Year at UNC

- Preclinical/clinical drug development (Phase I-IV)
- Protocol development
- Investigator-initiated clinical trials
- Regulatory/IRB/grant submissions
- Data and biostatistical analysis
- Study coordination
- Abstract/poster/platform presentations
- Publications in scientific journals
- Coursework on study design and statistical analysis
- Optional opportunities for bench research
- PharmD student mentorship
- Begin transition to work at industry partner
Medical Affairs: Second Year

• Develop clinical proficiency within the assigned therapeutic area
• Launch preparations for new medications, new indications or label extensions
• Competitive intelligence and market analysis
• Medical review of promotional materials and medical content development/review for internal and field-based colleagues
• Provide medical support for congress meetings
• Preparation of regulatory documents e.g., NDA annual reports, label updates
• Support post-marketing studies
• Includes: global medical affairs, commercial, regulatory affairs, legal, health outcomes, clinical research, and global clinical safety and pharmacovigilance as they relate to the daily activities and special projects of US Medical Affairs
GLOBAL REGULATORY AFFAIRS (GRA)

Objectives: To provide practical training and experience to develop competency in key regulatory functions, to understand the regulatory requirements for drug development and the evolving regulatory environment
Global Regulatory Affairs (GRA)

Nhi Duong  
GSK - CMC  
California Northstate University College of Pharmacy  
dmynhi@unc.edu

Sanni Rana  
GSK  
University of North Carolina  
srana@live.unc.edu

Jessica Miller  
GSK - CMC  
University of North Carolina  
jm7@live.unc.edu

Bashir Idris  
GSK - GRA  
Virginia Commonwealth University  
idrisb@unc.edu

Faatimah Arshad  
GSK - GRA  
Texas Tech University  
faatimah@unc.edu
Global Regulatory Affairs (GRA)

Regulatory Strategy (Oncology Therapeutic Group)

Chemistry, Manufacturing, and Controls (CMC Biopharmaceuticals)

Timeline and Location: 24 months at Upper Providence, PA or Waltham, MA
GRA Fellowship

GSK opportunities:

• Life-cycle management activities pre- and post-approval for drugs/biologics
• Shadowing and project experience in various departments (labeling, ad/promo, CMC, strategy, non-clinical, etc.)
• Prepare and submit regulatory documents and submission packages
• Contribute to clinical studies for global infectious diseases, oncology and various disease states
• Interactions with and submissions to regulatory agencies

Specific coursework:

• Regulatory Affairs Certification (RAC) preparation course/exam
Pharmacokinetics/Pharmacodynamics and Pharmacometrics

**Objective:** to provide expertise in drug development, quantitative pharmacology, translational research, and pharmacometrics
PK/PD/PM Fellows

Miramar Kardouh
Certara
University of California, San Francisco
miramar.kardouh@unc.edu

Jeanne Kom
Allucent-Innovation
University of North Texas
HSC
eleung@unc.edu

Taek Lee
Certara
University of North Carolina
HSC
taek@live.unc.edu

Olagoke Sule
Genentech
University of North Texas
HSC
osule@unc.edu

Daniel Oliveira
Certara
University of California, San Francisco
dolive@unc.edu

Rui Zhong
BMS
University of Minnesota
ruizhong@unc.edu

Li Chen
Allucent
University of Michigan-Ann Arbor
chenliw@unc.edu

Sihong Zhang
Certara
University of Minnesota
sihongz@unc.edu

Taran Lundgren
Janssen
Emory University
talun@unc.edu
PK/PD/PM: First Year

• Design and implement PK and PD studies in healthy volunteers, patient populations, or in vitro/pre-clinical models
• Development of physiologically based models using software as PKsim, SimCyp, and Rstrip
• Non-compartmental analysis of trial data
• Graduate-level courses and advanced PK/PD training
• Biostatistical and pharmacometrics analyses
• Learn to use modelling and simulation software such as Phoenix WinNonlin, NONMEM, and ADAPT5
PK/PD/PM: Second Year

• Population or physiologically-based PK/PD modeling
  • Evaluation of competing models
• Exposure response
• Disease progression modeling and simulation
• Clinical trial simulations
• Clinical pharmacology studies (e.g., FTIH, PoC, DDI, food)
Global Product Safety/Pharmacovigilance Fellows

Samantha Matys
United Therapeutics
University of Florida
sammatys@email.unc.edu

Kristina Paramore
GSK
University of North Carolina
kristina_paramore@unc.edu

Suzan Gomes
United Therapeutics
University of North Carolina
suzan_gomes@unc.edu
GLOBAL PRODUCT SAFETY/PHARMACOVIGILANCE

Objectives: To develop an understanding of global risk management and drug safety throughout the entire lifecycle of a drug product, from pre-clinical development to clinical implementation and prescribing.
GPS/PV: First Year

• Time spent with both the company and UNC during first year
• Company will introduce fellow to PV practices, global regulations, and clinical development activities related to patient safety
• **GSK Fellow:** Partner with faculty member at UNC ESOP
  — Contribute to clinical research w/ emphasis on safety outcomes, including protocol development, data analysis, abstract/poster/manuscript submissions
• **United Therapeutics Fellow:** Partner with UNC Medical Center Medication Management & Optimization team
  — Rotation opportunities in medication safety, pharmacy analytics, formulary management, investigational drug services, and clinical research
  — Layered learning/mentorship with PGY2 resident and PharmD students
• Coursework on study design and statistical analysis
• PharmD student mentorship
• Optional Regulatory Affairs Certification
GPS/PV: Second Year

- Contribute to the safety evaluation and risk management of an asset
- Collaborate in matrix environment
- Signal detection analysis and risk characterization
- Evaluate, interpret, synthesize, and present safety data to key stakeholders
- Prepare safety regulatory documents for submission including
  - PBRER (Periodic Benefit Risk Evaluation Report)
  - DSUR (Developmental Safety Update Report)
  - DCSI (Development Core Safety Information)
- Develop manuscripts assessing the safety profile of investigational and marketed products
Objectives: To provide practical training, experience, and competency in health outcomes research/market access/informatics
Health Outcomes and Market Access

AESARA is a digital-forward market access agency, designing innovative solutions that enable transformative market access.

We provide actionable insights and deliver results that align with health outcomes and market access strategies for small biotech to large pharmaceutical companies.

Fellows are involved in developing creative solutions in health outcomes and market access directly impacting industry clients. Fellows receive one-on-one mentorship from individuals with years of industry and healthcare consulting experience.

Fellows gain a deep understanding of health outcome research methods, analytical skills, and communication skills.
Health Outcomes and Market Access

Fellows will have the opportunity to work with various faculty within the Division of Pharmaceutical Outcomes and Policy (DPOP) and the Practice Advancement and Clinical Education (PACE)

DPOP

Our research focuses on health outcomes and how to support medication-taking at the individual, practice, and system level.

Amanda Seyerle, PhD, MSPH
Assistant Professor-DPOP
Fellowship Co-Director

PACE

Faculty are engaged in research to advance the future of the profession while improving patient-centered, team-based care delivery.

Sachiko Ozawa, PhD, MHS
Associate Professor-PACE
Fellowship Co-Director

Research methods

- Budget Impact Analysis
- Cost of Illness Analysis
- Cost Benefit Analysis
- Cost Effectiveness Analysis
- Discrete Choice Experiments
- Electronic Health Record Analysis
- Focus Groups
- Key Informant Interviews
- Modeling & Simulations
- Survey Data Collection
- Systematic Reviews
Health Outcomes and Market Access

- **First year:** Split time evenly with AESARA (50%) and with PACE/DPOP faculty (50%)
- **Second year:** Majority (80%) of time to be spent working with AESARA, 20% to continue interactions with UNC faculty and complete on-going projects
  - Increased role in project management and client communication at AESARA
- **Exposure to the application of health outcomes research to biopharma**
  - Contact with a variety of biopharmaceutical companies, including the top 10 companies in Pharma
  - Exposure to health outcomes and market access strategies across multiple therapeutic areas
  - Healthcare economic information and pre-approval information exchange
  - Experience in US/Global reimbursement environment
  - Develop a working knowledge of economic model development
  - Strong health economics outcomes research foundation
  - Effectively work within a matrix environment
- **Applications due October 22, see UNC website for more details**
ACADEMIC

Objectives: To gain extensive training and experience in designing and conducting clinical studies, scientific and grant writing, presentation skills as well as teaching skills
UNC Academic Fellowships

Fellows spend two years at UNC, guided by a faculty mentor from DPET in his/her area of interest.

Projects are conducted in collaboration with different departments (e.g., UNC School of Medicine, School of Public Health, Duke Medical Center, etc.) in addition to investigators external to UNC.

Research Opportunities

• Lead research projects and serve as principal investigator (co-certified by faculty advisor), design in vitro, pre-clinical, and clinical studies.
• Gain experience securing funding for studies including grant writing and preparing for study initiation.
• Serve as study coordinator for clinical trials to gain experience with subject screening and recruitment as well as data collection and analysis.
• Create new applications for study approval, work with UNC IRB to modify and renew applications.
• Disseminate study findings through presentation (e.g., abstract/poster, platform) and peer-reviewed publication.
UNC Academic Fellowships

Teaching Opportunities
- Facilitate small/large group discussions in the PharmD curriculum and provide feedback on clinical decision making to students
- Contribute to educational assessment projects (e.g. OSCE)
- Develop patient cases and other educational materials (e.g. tests, quizzes)
- Deliver didactic lectures in specific therapeutic modules and electives
- Participate in UNC Teaching Certification for residents and fellows

Clinical Opportunities
- Serve as a clinical pharmacist for specialty clinics at UNC Medical Center

Presentations/Publications
- Present therapeutic topics at various local, national and global meetings
- Publish review articles, case reports, etc.
What Is Included?

• Competitive stipend
• Coverage of relocation expenses
• Health insurance + UNC benefits package
• Support for professional travel and career development
Application Process

• Application
  – Visit pharmacydpetfellowships.web.unc.edu for instructions
  – 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

• Timeline
  – Applications open: October 1, 2023
  – Appointments begin July 1, 2024
  – Offers sent no earlier than Dec 13, 2023
    • Academic Industry Fellowship Alliance (AIFA) Consensus Statement
Opportunities Post-Fellowship

[Logos of various companies and organizations]
Questions?