

Catherine E. Patterson, Ph.D.

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Professional Experience

SPECIALTIES & CONTINUING INTERESTS

Human Disease and its Treatments (Efficacy and Safety) – Investigation of medical literature, legal files and worldwide regulatory documents for medical conditions, drug products and medical devices - Provide expertise, writing, and presentations to clarify the scientific aspects of broad client needs - Adverse event and labeling analyses often utilize a variety of global resources, including but not limited to, PubMed, Embase, FAERS, and MAUDE - FDA interactions related to 510(k), PMA, pre-IND, IND, NDA, ANDA and 505(b)(2) submissions: responses to FDA, questions posed to FDA and FDA meetings

Scientific Writing – Persuasive use in FDA submission preparations, white papers, clinical study protocols, medical descriptions and labeling as well as that required in litigation or specific client requests – Additional experience with peer-reviewed publications, invited reviews, grant writing and editing others work product

Immune Cell Responses – Studied T and B cells by analyzing cytotoxicity assays, ELISAs and flow profiles as well as microscopic imaging to visualize immune cell and virus-infected neuron interactions in tissues and primary cultures of brain slices or cultured cells. Included measles virus and BSL3 experience with West Nile virus.

Current **Chief Scientific Officer** - Biotech Research Group (BRG), Tampa, Florida

Previous **Director of Scientific Research** - Pharmaceutical Development Group (PDG), Tampa, Florida

- Drug and Device product submissions to FDA, activities include medical and regulatory research, brainstorming, scientific writing, client and FDA meetings
- Perform pharmacovigilance and device safety review activities
- Provided scientific research guidance and legal support – including to Expert Dr. Cheryl D. Blume
- Experience includes a variety of drug and device classes, their indications, mechanisms of action and side effects: antiepileptics, osteoporosis treatments, diabetes medications, certain cancer treatments, women's urogenital devices (mesh and Essure), topical pain treatments, depression medications, diarrhea treatments, antibiotics and hormone therapy for men and women, contrast agents
- Interest in congenital malformations, in utero exposure to drugs and the regulatory ramifications

Past **Research Assistant Professor** - University of South Florida, College of Medicine, Tampa, Florida
Themes – Immune Cell and Allergy Dependence on Cannabinoid Signaling

Assistant Professor - Case Western Reserve University, School of Medicine, Cleveland, Ohio
Themes – Virus-Host Interactions; Molecular Virology; Virus Infection of the CNS

Postdoctoral Fellow - Fox Chase Cancer Center, Philadelphia, Pennsylvania

Doctoral Candidate - Princeton University, Princeton, New Jersey

Associate Scientist - DuPont and DuPont Merck Pharmaceutical Company, Wilmington, Delaware

Academic Background

Postdoctoral Fellow

Fox Chase Cancer Center, Philadelphia, Pennsylvania

Ph.D. in Molecular Biology

Princeton University, Princeton, New Jersey

B.S. in Molecular & Cell Biology

The Pennsylvania State University, University Park, Pennsylvania

Formal Teaching Experience – Undergraduate, Graduate and Medical School Students