CURRICULUM VITAE

Brianna Costales

2018

CONTACT INFORMATION

Tel: (909) 725-3569
Email: b.costales@ufl.edu

EDUCATION

2017 – Present	Doctor of Philosophy (PhD) Pharmaceutical Sciences Dept. of Pharmaceutical Outcomes and Policy University of Florida, Gainesville, FL
2009 – 2013	Bachelor of Science (BS) Health Science California State University, Fullerton, CA
2008 – 2009	Cypress College, Cypress, CA
2008	Crafton Hills Community College, Yucaipa, CA

Honors and Awards

2017 – Present	Grinter Fellowship, UF College of Pharmacy
2017 – Present	Graduate Student Assistantship, UF College of Pharmacy
2013	Eta Sigma Gamma Distinguished Service Award
2013	Community Engagement Medal, Center for Internships & Community Engagement, CSUF
2012 – 2013	Eta Sigma Gamma Honors Society, Delta Rho Chapter

RESEARCH EXPERIENCE

Academic Research

2014 American Public Health Association, Trade and Health Forum

- Retrospective literature review specific to international trade and public health
- Supervisor: Dr. Joshua Yang, Chair of the Trade and Health Forum

2012-2013 Fibromyalgia and Chronic Pain Center, California State University, Fullerton

- Research Assistant – responsibilities involved physical testing administration, data collection, and data entry.

- Cherry, B. J., Zettel-Watson, L., Chang, J., Shimizu, R., Rutledge, D. N., & Jones, C. J. (2012). Positive associations between physical and cognitive performance measures in fibromyalgia. *Archives of Physical Medicine & Rehabilitation, 93,* 63-71.
- Cherry, B. J., Zettel-Watson, L., Shimizu, R., Roberson, I., Rutledge, D. N., & Jones, C. J. (2012). Cognitive performance in individuals with and without fibromyalgia. *Journal of Gerontology, Series B: Psychological Sciences and Social Sciences, 69*(2), 199-208.

Professional Research

2015-2017 Phase I Clinical Trials

- A Randomized, Open-Label, Parallel Design, Multiple-Dose, Comparative Bioequivalence Study of XXX Extended-Release Injectable Suspension Versus XXX Extended-Release Injectable Suspension in Schizophrenia Patients Already Stabilized on XXX
- Interventional, randomised, double-blind, parallel-group, active-control, multiple-dose study investigating the effect of XXX on cardiac repolarisation in men and women with schizophrenia or schizoaffective disorder
- A Phase 1 Study of XXX and Oral XXX Coadministered with XXX in Adults with Schizophrenia
- A Multicenter, Randomized, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of XXX Using Poly (DL-lactice-co-glycolide) Polymer of Two Different Molecular Weights (Low and High Molecular Weights as Tests Treatments) Compared to Intermediate Molecular Weight (Reference Treatment) Polymer in Subjects with Schizophrenia
- A randomized, double-blind, placebo-controlled, parallel-group study to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of multiple oral doses of XXX in healthy elderly subjects
- A Phase 1, Double Blind, Sponsor Open, Randomized, Placebo-Controlled, Single Ascending Dose Study to Investigate the Safety, Tolerability, Pharmacokinetics and Pharmacodynamics of XXX in Subjects with Idiopathic Parkinson's Disease
- A Phase 1, Placebo-controlled, Single Ascending-dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Adults with Schizophrenia
- Phase 1 Combined Single and Multiple Rising Dose Study of the Safety and Pharmacokinetics of XXX Combination
- A Phase 1 Study to Evaluate the Effects of XXX on the Pharmacokinetics of XXX, A CYP3A Substrate, in Patients with Stable Schizophrenia
- A Randomized, Double-Blind, Placebo- And Active-Controlled, Multi-Center Study to Assess the Antipsychotic Efficacy of XXX After 6 Weeks of Treatment in Patients with Schizophrenia
- A Double Blind, Randomized, Placebo Controlled, Parallel Group Study to Simultaneously Qualify a Biomarker Algorithm for Prognosis of Risk of Developing Mild Cognitive Impairment due to Alzheimer's Disease (MCI due to AD) and to Test the Safety and Efficacy of XXX to Delay the Onset of MCI due to AD in Cognitively Normal Subjects
- A Phase 1, Randomized, Open-label, Study Evaluating the Pharmacokinetics of Various Dosing Regimens of XXX in Subjects with Stable Schizophrenia
- A Phase 1 Study of an XXX Initiation Regimen in Adults with Schizophrenia
- A Phase 1 Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX Following Administration to the Deltoid or Gluteal Muscle in Adults with Schizophrenia or Schizoaffective Disorder

2015-2017 Phase II-IV and Observational Clinical Trials

- A Phase 1b/2a, Double-Blind, Placebo-Controlled, Multiple Ascending Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of XXX in Subjects with Schizophrenia
- A Phase 2, Double-Blind, Placebo-Controlled Study of XXX, a Neurogenic Compound among Out-Patients with Major Depressive Disorder
- A Phase 3 Open Label Study to Evaluate the Long-term Safety and Tolerability of XXX in Adults with Relapsing Remitting Multiple Sclerosis
- A Phase 3, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX in Migraine Prevention
- A Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy, Safety, and Tolerability of Multiple Subcutaneous Injections of Depot XXX Over 24 Weeks in Treatment-Seeking Subjects with Opioid Use Disorder
- An Open-Label, Long-Term Safety and Tolerability Study of Depot XXX in Treatment-Seeking Subjects with Opioid Use Disorder
- A 12-week, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexibly-dosed, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of XXX in Adults with Moderate to Severe Binge Eating Disorder
- Prospective Cohort Study to Describe Patient-reported Outcomes in Subjects with Migraine Eligible for Prophylaxis
- XXX for Cannabis Use Disorder in Schizophrenia (Dartmouth College and NIDA)
- Psychometric Testing and Validation of a Novel PRO Measure for Assessing Subjective experience of Cognitive Impairment of Schizophrenia
- Validity of an online neurocognitive test battery, the XXX, in normal healthy adults

PROFESSIONAL EXPERIENCE

Aug 2017 – Present **College of Pharmacy, University of Florida, Gainesville, FL**
GRADUATE ASSISTANT/TEACHING ASSISTANT

- Graduate assistant responsibilities include assisting department faculty in the Pharmaceutical Sciences and PharmD programs.

Jul 2015 – Jul 2017 **Collaborative Neuroscience Network, LLC.**
Garden Grove, Torrance, and Long Beach, CA
QUALITY ASSURANCE COORDINATOR

- Planned, scheduled, and conducted internal quality assurance audits of the processes, procedures, and controls employed in the design, conduct, and analysis of phase I-IV clinical trials
- Reviewed internal documentation for compliance to SOPs, ICH, GCP, and other regulatory requirements
- Reviewed essential documents such as CRFs and Informed Consent Forms for adequacy and compliance with GCP and FDA regulations
- Assisted with preparation of investigator site files for sponsor, regulatory agency, and FDA inspection
- Documented audit observations, prepared audit reports, and made recommendations for appropriate corrective actions
- Familiarity with DSM-IV-TR, DSM-5, various clinical safety and efficacy assessments, and patient-reported outcome measurements
- Delegated study duties included source file maintenance and drug accountability

Jul 2014 – Jul 2015 **Hartley Medical Center Pharmacy, Long Beach, CA**
COMPLIANCE OFFICER

- Ensured compliance with state pharmacy boards, FDA, DEA, HIPAA, and OSHA regulations
- Kept abreast of laws relative to sterile and non-sterile pharmaceutical compounding
- Monitored pharmacy and controlled substances legislation for over 40 states
- Maintained data submissions and reporting to state prescription drug monitoring programs
- Drafted SOPs, HIPAA policies, and regulatory documents
- Audited prescriptions, compounding documents, and patient records
- Facilitated state permits and pharmacist-in-charge licensure renewals
- Worked directly with the president, management, pharmacy staff, and QA team

Oct 2013 – Nov 2014 **VCA All-Care Animal Referral Center, Fountain Valley, CA**
DOCTOR'S ASSISTANT

- Primarily supported Emergency, Critical Care, and Internal Medicine veterinary specialists
- Coordinated with front office, ICU/CCU, radiology, pharmacies, and laboratories
- Documented patient histories, doctor's SOAPs, and created discharge paperwork
- Expedited in-house prescriptions, refill authorizations, and outside pharmacy orders
- Gained knowledge of drug conversions, common drug names, and medical terminology

Oct 2012 – Oct 2013 **SDS Clinical Trials, Orange, CA**
CLINICAL RESEARCH ASSISTANT

- Assistant to the Director of Regulatory Affairs, CEO, study coordinators, and investigators
- Extensive maintenance of regulatory files, patient charts, and informed consent forms
- Drafted IRB pre-study, continuing review, and closeout reports
- Proofread, updated, and maintained current source documents
- Assisted with drug accountability of investigational products including temperature logs and shipments
- Supported recruitment specialists with prescreening referrals and verifying statuses

Jul 2009 – Oct 2013 **Neoderma (formally Wellskin Center), Anaheim and Torrance, CA**
FRONT AND BACK OFFICE ASSISTANT

- Receptionist and medical assistance for laser tattoo removal and various laser and aesthetic procedures
- Early exposure to a clinical setting, patient confidentiality/HIPAA, and pharmaceutical compounding
- Worked approximately 30 hours a week while maintaining a full-time school schedule

Aug 2009 – May 2011 **California State University, Fullerton, CA**
College of Health and Human Development
STUDENT ASSISTANT

- Administrative assistance for the faculty of the Department of Child and Adolescent Studies and the Department of Human Services

RELEVANT SOFTWARE KNOWLEDGE

- SAS Enterprise
- IBM SPSS statistics
- Minitab statistics software
- Electronic data capture systems (BioClinica, Oracle, Rave Medidata, ClinTrak, etc.)
- Microsoft Access, Excel, PowerPoint, and Word