

Professional Experience

Biostatistician

(2015 - Present)

Biostudy Solutions, LLC, Wilmington, NC

- Perform statistical analyses for In Vitro projects
- Pharmacokinetic and statistical consultation for ANDA and NDA 505(b)(2) projects.
- Perform pharmacokinetic and statistical analyses for ANDA and NDA 505(b)(2) projects.
- Create pilot and pivotal designs for studies with PK endpoints.
- Review statistical sections in clinical study protocols for accuracy and FDA compliance.
- Create and review statistical analysis plans.
- Assist in creating and updating Standard Operating Procedures.
- Prepare and write statistical sections in Integrated Reports for ANDA and NDA submissions.
- Assist clients with responses to FDA deficiency letters.
- Fulfill all requirements of Statistical Analyst for Biostudy Solutions, LLC

Statistical Analyst

(2015)

Biostudy Solutions, LLC, Wilmington, NC.

- Perform SAS Programming to create tables, listing and figures.
- Review statistical sections in clinical study protocols for accuracy and FDA compliance.
- Creating clinical endpoint and pharmacokinetic study designs for phase 1 generic drug studies
- Assist in design and analyses of studies with Clinical and/or Pharmacodynamic endpoints

Programmer/Analyst

(2013)

Pharpoint Research, Wilmington, NC.

- Provide statistical programming support in the project specific programming of statistical tables, listings, and figures.
- Aid in ensuring the efficiency, quality, and integrity of statistical listings and tables.

Education

University of North Carolina at Wilmington

Bachelor of Science in Mathematics and Statistics 2013