Chaewon Jeong

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PROFILE

Versatile Master of Biostatistics student with over 5 years of experience in clinical bioanalysis. Detail-oriented professional committed to ensuring accuracy and integrity in both data analysis and assay management. Successfully managed two global clinical trials, achieving FDA and EMA approvals through rigorous regulatory compliance and proactive risk mitigation.
Technical Skills: R, SAS, Python (2+ years); ELISA, MSD (5+ years); cell-based binding assay, LC-MS (1 year)

EDUCATION

DUKE UNIVERSITY, School of Medicine, Durham, NC
Master of Biostatistics, GPA: 4.00/4.00 Expected May 2026
Relevant Coursework: Statistical Theory I&II: Distributions & Inference, Applied Biostatistics I&II, Practice of Biostatistics I&II, Statistical Programming I&II: R & Python

SEOUL NATIONAL UNIVERSITY, College of Agriculture and Life Science, Seoul, Korea
Bachelor of Science, Applied Life Chemistry, GPA 3.91/4.3, Ranked 1/36, *Summa Cum Laude* Feb. 2019
Thesis: Expression and purification of Cas1 protein derived from *Burkholederia glumae*
Relevant Coursework: Organic Chemistry, Biochemistry, Molecular Biology, Biophysical Chemistry

EXPERIENCE

DUKE UNIVERSITY, Durham, NC
Research Assistant, Department of Biostatistics & Bioinformatics May 2025-Present
- Apply statistical methodologies to integrate small-scale clinical trial data with real-world databases to evaluate the efficacy of interventions in esophageal cancer patients

Biostatistics Research Intern, Biostatistics Core Training Internship Program (BCTIP) Jan 2025-Present
- Conduct statistical analyses for 4 projects within the Duke Department of Pharmacy, adhering to predefined SAP
- Author statistical analysis reports and review statistical method and result sections of manuscripts

SAMSUNG BIOEPIS, Incheon, Korea
Bioanalytical Project Manager, Clinical Bioanalysis Group, Quality Evaluation Team Jun. 2022-Mar. 2024
- Supervised bioanalytical method development, validation, and sample analysis following ICH M10 guidance to support pharmacokinetics, pharmacodynamics, and immunogenicity analyses
- Provide strategic input and scientific expertise to cross-functional teams on all bioanalysis issues, ensuring data transfer within 25 working days and managing the logistics and analysis of over 12,000 clinical samples
- Managed budgets and deliverables for concurrent projects totaling over $30 million, ensuring timely execution to meet critical milestones and business objectives
- Prepared comprehensive bioanalytical method sections for Common Technical Documents (CTDs), contributing to the regulatory approval of a denosumab biosimilar
- Evaluated the adoption of advanced equipment and automated assay platforms to enhance analytical efficiency

Associate Bioanalytical Project Manager, Clinical Bioanalysis Group, Quality Evaluation Team Jan. 2020-Jun. 2022
- Coordinated method transfer, validation, and sample analysis with bioanalytical vendors to ensure on-schedule completion in compliance with FDA, EMA, and ICH scientific and quality standards
- Prepared responses to regulatory review questions, contributing to the approval of the first biosimilar to Lucentis

Method Specialist, Clinical Bioanalysis Group, Quality Evaluation Team Jan. 2019-Jan. 2020
- Developed and validated ligand binding assays to characterize the pharmacokinetics, pharmacodynamics, and immunogenicity of biosimilar therapeutics, troubleshooting as needed to optimize method performance
- Managed the laboratory information management system (LIMS) operations within GxP-regulated environments

SEOUL NATIONAL UNIVERSITY, Department of Applied Biology and Chemistry
Undergraduate Research Intern Dec. 2016-Feb. 2017
- Optimized methods for expressing and purifying CRISPR-Cas proteins
- Conducted isothermal titration calorimetry experiments to determine protein interaction molar ratios