SOO MIN YOU

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EDUCATION

Columbia University Mailman School of Public Health, New York, NY

Master of Science in Biostatistics Expected

Cornell University, Ithaca, NY

Bachelor of Science in Chemical Engineering

May 2026 May 2017

WORK EXPERIENCE

Samsung Biologics, Songdo, Republic of Korea

Senior Scientist, Quality Assurance

Apr. 2021 - May 2024

- Executed validation of 15 harvest and 25 cleaning systems for drug substance manufacturing in Plant 4, a facility aimed at strengthening company market position.
- Contributed to enhancing the company's competitiveness and enabling to offer end-to-end services for mRNA vaccine productions, particularly during the pandemic, by reducing the qualification time with a comprehensive validation plan
- Provided guidance on validation plans and operation requirements and performed gap assessments of current practices in Manufacturing Science and Technology (MSAT) lab and Good Manufacturing Practice (GMP) requirements.
- Calculated and implemented cleaning limit for drug substances and drug products by assessing their toxicity levels, degradation results, total organic carbon recovery to minimize cross contamination and to ensure quality and safety
- Reviewed and approved 50 deviation and 10 change control records to capture policy violations and to improve process controls and efficiency
- Identified and resolved risks in process using Failure Modes and Effects Analysis tools

Scientist, Validation

Jul. 2017 - Apr. 2021

- Verified computerized system validation such as Manufacturing Control System (MCS) and Building Management System (BMS) as validation subject matter expert.
- Successfully implemented automated backup servers for manufacturing equipment to ensure data security and compliance with 21 CFR Part 11 and Annex 11 requirements.
- Introduced new interface servers to streamline manufacturing equipment interface and centralized account management, improving efficiency and eliminating the need for local accounts.
- Performed Technological Transfer of new products to facility: participated in assessment of allowable Total Organic Carbon (TOC) residue for each newly introduced product

University of Science and Technology (UST), Korea Railroad Research Institute

Jun. 2015 - Aug. 2015

Associate Intern

- Conducted data collection, analysis, and interpretation to support ongoing research projects.
- Prepared and maintained detailed laboratory records, including experiment logs and technical reports.

LABORATORY EXPERIENCE

Chemical Engineering Laboratory, Sungkyunkwan University

Jun. 2013 - Jul. 2013

Laboratory Intern

• Assisted in research on hydrogen production methods, including photocatalytic water splitting using semiconductors to generate hydrogen and oxygen, for development of alternative energies.

Biochemistry Laboratory, Yonsei University

Laboratory Intern

Jul. 2012 - Aug.2012

- Assisted in laboratory experiments to produce and analyze genetically modified mouse for gene targeting.
- Conducted DNA extraction, mini prep, and midi prep, using analytical laboratory equipment and centrifuges.

PROJECTS

Global Violence, https://projecthyee.github.io/globalviolence/

Group Project for P8105 Data Science I

Dec. 2024

• Explored factors driving serious assault, sexual violence, and intentional homicide worldwide from 2015 to 2023 using R and built a website with a screencast.

SKILLS / CERTIFICATIONS

Statistical Programming: Excel |R Studio with Github

Other tools: Visio | Wolfram Mathematica

Languages: Fluent in Korean and English | Conversational in French: DELF/DALF B1 (May 2020) **Certifications:** Green Mountain Quality Assurance LLC. Data Integrity 2019 Training Certificate |

ECA - Cleaning Validation Training Certificate