

SOO MIN YOU
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STATEMENT

- Dynamic professional with an engineering background and experiences in the biopharmaceutical industry. Currently pursuing a master's degree in Biostatistics at Columbia University's Mailman School of Public Health.
- Proven track record in ensuring compliance and quality control in regulated environments with a keen interest in leveraging biostatistics to enhance data-driven decision making in the biopharmaceuticals sector.

EDUCATION

Columbia University, New York, United States of America Expected May 2026
Master of Science in Biostatistics

Cornell University, Ithaca, United States of America May 2017
Bachelor of Science in Chemical Engineering

WORK EXPERIENCE

Samsung Biologics, Songdo, Republic of Korea Apr. 2021 – May 2024
Senior Scientist, Quality Assurance

- Successfully completed the initial qualification and release of new facilities (e.g. mRNA facility and Plant 5 drug substances facility)
- 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 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
- Supported establishment of data integrity practice in the facility

Samsung Biologics, Songdo, Republic of Korea Jul. 2017 – Apr. 2021
Scientist, Validation

- Worked as validation subject matter expert to verify computerized system validation such as Manufacturing Control System (MCS) and Building Management System (BMS).
- Successfully implemented backup servers for manufacturing equipment and introduction of software that ensures data security to meet the requirements of 21 CFR Part 11 and Annex 11 requirements.
- Performed Technological Transfer of new products to facility: participated in assessment of allowable Total Organic Carbon (TOC) residue for each newly introduced product

PROJECT EXPERIENCE

"Risk Assessment and remediation actions for MSAT Laboratory" Feb. 2023 – May 2023
Participated as Quality Assurance, Samsung Biologics

- Provided guidance on validation plans and operation requirements and performed gap assessments of current practices in MSAT lab and GMP requirements.

"Introduction of mRNA manufacturing facility in SBL Plant 3" Nov. 2021 – Aug. 2022
Participated as Quality Assurance, Samsung Biologics

- Developed and executed a comprehensive validation plan for the facility as the main Validation Quality member, overseeing protocol generation, execution, and report approval.
- Contributed to enhancing the company's competitiveness and enabling it to offer end-to-end services for mRNA vaccine productions, particularly during the pandemic, by reducing construction and qualification time for the new facility.

"Continuous Improvement for Data Integrity (DI)" Apr. 2020 – Mar. 2021
Participated as Validation Subject Matter Expert, Samsung Biologics

- Contributed toward the implementation of data integrity practices in the manufacturing facility, ensuring compliance with 21 CFR Part 11 and Annex 11 requirements.
- Implemented automated backup servers and infrastructures, ensuring data preservation and loss-prevention, with a focus on maintaining metadata during data transfers.

- Introduced new interface servers to streamline manufacturing equipment interface and centralized account management, improving efficiency and eliminating the need for local accounts.
- Successfully reduced manual backup time and resolved account lockout issues, resulting in increased productivity.

Chemical Engineering laboratory, Sungkyunkwan University

Jun. 2013 – Jul. 2013

Laboratory Intern

- Supported laboratory experiments focused on alternative energies, specifically solar and hydrogen energy.
- Assisted in research on hydrogen production methods, including photocatalytic water splitting using semiconductors to generate hydrogen and oxygen.
- Collected experiment results and data, and contributed toward data organization.

Biochemistry Laboratory, Yonsei University

Jul. 2012 – Aug. 2012

Laboratory Intern

- 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.

SKILLS / EXTRACURRICULAR ACTIVITIES

Language

- Fluent in English
- Conversational in French: DELF/DALF B1 (May. 2020)

Programs

- Proficient in Microsoft Office (Word, Excel, PowerPoint and Visio)
- Capable of using R, RStudio
- Capable of using Wolfram Mathematica

Others

- Green Mountain Quality Assurance LLC. Data Integrity 2019 Training Certificate
- ECA – Cleaning Validation Training Certificate