

SOO MIN YOU
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STATEMENT

Soomin is a dynamic professional with an engineering background and more than 6 years of experience in the biopharmaceutical industry. She has 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 Mailman School of Public Health, New York, NY Expected May 2026
Master of Science in Biostatistics

Cornell University, Ithaca, NY May 2017
Bachelor of Science in Chemical Engineering

WORK EXPERIENCE

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

- Executed validation of 15 harvest and XX 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 it 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 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

INTERSHIP EXPERIENCE

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.

TEACHING EXPERIENCE

Samsung Biologics, Songdo, Republic of Korea

May. 2022 –Jan. 2023

Qualified Trainer for Validator

- Provided comprehensive training on thermal data collection equipment to 30 internal employees and developed troubleshooting guides.

Samsung Biologics, Songdo, Republic of Korea

Aug. 2018 –Aug. 2020

Internal Instructor

- Conducted classroom training on validation protocols for 50 operators, providing in-depth knowledge of purpose, scope, procedure, and testing methods in compliance with data integrity and GMP.

SKILLS / CERTIFICATIONS.

Statistical Programming: Excel, R**Other tools:** Visio, Wolfram Mathematica**Language:**

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

Others

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