

Since 2005, Julia O'Neill has supported approval of multiple accelerated products including vaccine, gene therapy, microbiome, and regenerative medicines. From 2020 to 2023 she was a Distinguished Fellow on the Moderna Technical Development Leadership Team, where she built and led a new department, CMC Modeling and Statistics, while a member of the Spikevax vaccine technical development team. She was named a Fellow of the American Society for Quality in 2020 in recognition of her passion for connecting people and data across disciplines to accelerate delivery of life-changing medicines to patients at commercial quality scale. She is the 2023 recipient of the ASA Gerald J. Hahn Quality & Productivity Achievement Award, and an Associate Director of CASSS.

From 2005 to 2015 O'Neill worked at Merck (MSD) as Senior Scientific Fellow – Statistics in Regulatory & Analytical Sciences; and Director in Global Technical Operations, with a primary focus on vaccines and biologics. Her experience includes justification of specifications; stability and shelf-life analysis; development, qualification, and validation of analytical methods; process development and qualification; control strategy authoring; comparability assessment; design and implementation of Continued Process Verification programs; and expert Design of Experiments support. She delivered an invited full-day course on statistical applications in development and manufacturing for the FDA Staff College in 2016. She has over 30 years of experience bridging statistics and chemical engineering in the pharmaceutical and chemical industries.