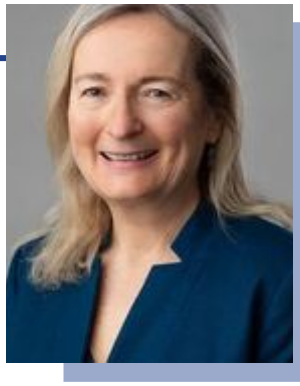
International Alliance for Biological Standardization

7th IABS Statistics Workshop

Accelerating Drug Development: How QbD, Regulatory Partnerships, and Pandemic Learning Can Further Expedite Meeting Patient Needs



Julia O'Neill

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Julia O'Neill leads CMC Modeling and Statistics for Moderna as a member of the Technical Development Leadership Team. She is a Fellow of the American Society for Quality. Since 2005 she has consulted supporting approval of multiple accelerated products including gene therapy, microbiome, and regenerative medicine.

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 development of specifications; development, qualification and validation of analytical methods; process development and qualification; control strategy authoring; design and implementation of Continued Process Verification programs; and expert Design of Experiments support for a wide range of development programs in vaccines, biologics, gene therapies, small molecules, and other products derived from biological materials. She is a Six Sigma Master Black Belt who built and directed multiple teams which have successfully resolved complex investigations, driven sustained improvements, and represented solutions to regulators. Her mentoring has provided encouragement for five colleagues to complete graduate degrees in statistics.

She has over 30 years of experience bridging statistics and chemical engineering in the pharmaceutical and chemical industries. Her education synthesizes statistics and engineering, with an MS in Statistics from the University of Wisconsin, and a BS in Chemical Engineering from the University of Maine.