

Jeffrey C. Baker, PhD

Deputy Director of the Office of Biotechnology Products in the Center for Drug Evaluation and Research at the FDA (retired in April 2021)

Senior Fellow in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)



Dr. Baker holds a bachelor's degree in biochemistry and molecular biology from Northwestern University, doctorate in biochemistry from the University of North Texas, and pursued post-doctoral studies at the University of California, Berkeley. He joined Eli Lilly & Co in 1988 and led the development and launch of several first in class biologics, supported post-launch manufacturing process development activities. Dr. Baker received the Lilly President's Award twice, once for work associated with the development and launch of Humalog, the first insulin analog, and once for work associated with the development and launch of drotrecogen alfa, the first recombinant protein therapeutic manufactured from human cells. Dr. Baker left Lilly to be Sr. Director of Manufacturing Science and Technology at MedImmune, a subsidiary of AstraZeneca and, in 2011, was appointed Deputy Director of the Office of Biotechnology Products in the Center for Drug Evaluation and Research at the FDA. Dr. Baker has received six CDER awards or citations for leadership and program development and in 2018 received an FDA Honors Award for contributions to "modernizing the U.S. regulatory system for biotechnology products through sustained creative leadership and collaboration." In 2019 Dr. Baker was detailed to the Advanced Manufacturing National Program Office at NIST where he worked with private and inter-Agency biopharmaceutical manufacturing stakeholders to advance biopharma elements of the National Strategic Plan for Manufacturing in the United States. He was recalled to FDA 2020 where he participated in responses to the global pandemic and Advanced Manufacturing programs in the Office of the Commissioner. He retired from the Agency in April of 2021. He remains active in the biotech community as a Senior Fellow in the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL), participating in conferences, and working with several universities as a both a lecturer and advisor on program development.