Rachael Anatol, Ph.D. Deputy Super Office Director, Office of Therapeutic Products (OTP), Center for Biologics Evaluation and Research (CBER), Federal Drug Administration

Rachael Anatol, Ph.D., is Deputy Super Office Director, Office of Therapeutic Products (OTP), Center for Biologics Evaluation and Research (CBER), FDA, and Acting Chief of the Policy and Special Projects Staff. OTP regulates cell and gene therapies, plasma protein therapeutics, xenotransplantation products, human tissues, devices, and combination products. Rachael, together with the Super Office Director, Nicole Verdun, is responsible for all regulatory, policy, and research work conducted in OTP.

Between December 2022 and December 2023, Rachael served as Senior Vice President for Science and Regulatory Affairs at the Biotechnology Innovation Organization (BIO). In this role, Rachael led all aspects of BIO's science and regulatory advocacy function, managed the BIO Board Regulatory Environment Committee, and advised executive and senior-level BIO staff on BIO's science and regulatory agenda. Prior to joining BIO in December 2022, Rachael spent 16 years at the Food and Drug Administration, where she took on roles of increasing responsibility in the CBER, culminating as Deputy Director of the Office of Tissues and Advanced Therapies (the predecessor office to OTP).

Rachael received her Ph.D. in molecular and cell biology from the University of Maryland, College Park, and completed her post-doctoral training at NIH's National Heart, Lung, and Blood Institute.