Rebecca Sheets PhD

Board member

USA

Rebecca Sheets is the principal consultant for Grimalkin Partners and an Adjunct Professor at Catholic University of America, teaching core courses for a M.S. in Biotechnology Program in the Biology Department in the School of Arts and Sciences. She also serves on the boards of the International Alliance for Biological Standardization and Math Dojo STL.

Dr. Sheets published a book by Elsevier's Academic Press imprint entitled, "Fundamentals of Biologicals Regulation: Vaccines & Biotechnology Medicines" (Click here to read).

In 2013, Rebecca Sheets retired from the U.S. Public Health Service in which she served as the Vaccine Scientific and Regulatory Specialist at the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. In this role, she formulated regulatory strategy for the Division of AIDS on pre-clinical development translating research concepts into HIV vaccine candidates suitable for human clinical trials. She also served as a subject matter expert on vaccine cell substrates and vaccine pre-clinical safety assessment, including toxicology. Further, she served the Vaccine Research Center in a similar capacity until 2012.

Rebecca Sheets obtained her B.S. degree in Biology from the California Institute of Technology; M.S. degree in Cellular, Viral, and Molecular Biology from the University of Utah School of Medicine, and Ph.D. in Pathology from the University of Southern California School of Medicine.

Dr. Sheets served for 9 years (1993-2002) as a Scientific Reviewer in the Viral Vaccines Branch of the Division of Vaccines and Related Products Applications, Office of Vaccines Research and Review, CBER/FDA. In 1994, to foster her commitment to public health, she became a Commissioned Officer in the U.S. Public Health Service (Scientist Category), in which she was promoted to the rank of Captain (CAPT) before retiring in 2013. She transferred to NIH from FDA in 2002.

Both at FDA and at NIH, she has striven to advance policy regarding vaccine cell substrates. Because of her virology background, a strong focus of this effort has been regarding the adventitious agent tests. From 2006-2014, she served as Co-chair of the World Health Organization's Study Group on Cell Substrates and as Chair of the Adventitious Agents Sub-committee. This Study Group was tasked with providing technical advice to revise the WHO's guidance on the subject, which was adopted by their Expert Committee on Biological Standardization (ECBS) in Oct. 2010. In 2013, she was involved in Implementation Workshops for this guidance. In addition, a separate Risk Assessment document was also adopted by the ECBS in Oct. 2014. Dr. Sheets has served WHO in developing or updating and revising several additional guidelines including those for HIV vaccines, HPV vaccines (adopted by ECBS), clinical evaluation of vaccines (adopted by ECBS), DNA vaccines (adopted by ECBS), and mRNA vaccines (in preparation).

CAPT (ret.) Sheets strives to implement the NIH policy and US mandates that researchers reduce, refine, or replace (3 R's) animals used for product safety testing. In this spirit, she completed research projects to determine how to achieve this goal with animals used in adventitious agent testing.

In addition, she has considered means to streamline or more rationally assure preclinical safety of vaccine candidates than the standard toxicology ("drug-screening") studies currently required. She is currently organizing a 3 R's conference to be held in Oct. 2018.

In addition to the recently published book, Dr. Sheets has published two book chapters, edited a book in a series, and published in peer-reviewed journal over 40 articles, including reviews, meeting reports, and primary data papers. She has also been responsible for drafting several government documents that have been promulgated via the web or in print. Considering her expertise, she has been a frequent lecturer, speaker, chair, moderator, or discussant at international conferences on topics ranging from cell substrates and adventitious agents, vaccine adjuvants, and risk assessments, to Good "X" Practices, human challenge trials, and vaccine toxicology.