

**SCOTT R. BURGER, MD**

**SPEAKER BIOSKETCH**

Scott R. Burger, MD, is the founder and principal of Advanced Cell and Gene Therapy, a consulting firm specializing in cell and gene therapy product development, providing expertise on GMP manufacturing, regulatory, and strategic aspects of these products. With over 30 years of experience, Dr. Burger has consulted for over 200 companies in North America, Europe, Asia, and Australia, advising on a wide range of CGT products for immunotherapy and regenerative medicine at all stages of development. Dr. Burger has served as an expert witness in cases involving CGT intellectual property, commercialization, FDA regulatory affairs, and GMP compliance.

Dr. Burger has consulted on over 100 regulatory submissions for CGT products, has been an invited speaker at internal FDA workshops, and has had numerous productive interactions with FDA Office of Therapeutic Products and its predecessors, OTAT and OCTGT. Additionally, he has served on the USP Cell, Gene and Tissue Therapies Expert Committee, the ISCT executive committee, advisory board and committees on gene therapy, regulatory affairs, commercialization, and product/process development. A graduate of the University of Pennsylvania School of Medicine, Dr. Burger completed training in clinical pathology and transfusion medicine at Washington University in St. Louis. He has authored over 200 scientific publications and presentations and received numerous honors and awards.

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