



Stephen D. Litwin, M.D.
Senior Clinical Consultant, Biologics Consulting Group, Inc

Stephen D. Litwin, M.D.
Senior Clinical Consultant

Stephen D. Litwin M.D., joined the Biologics Consulting Group, LLC on October 1, 2003 as a Senior Clinical Consultant.

Dr. Litwin joined BCG in 2003 after a long and active career in academia, and government.

After full training in Internal Medicine, he developed an independent research program as a faculty member and teacher in several Medical Institutions including Cornell Medical School where he served as a Full Professor. He held research and administrative positions from 1982 to 1991 when he joined the FDA in 1991 as a Senior Medical Reviewer in the Center for Biologic Evaluation and Research, Office of Therapeutics, (Oncology & Gene, Cell and Tissue therapies Divisions).

In 2003, he retired from FDA after serving for 12 years He has had intensive FDA regulatory, hands-on review experience for numerous INDs, IDEs and BLAs licensure of IL-2 (for Melanoma), GM-CSF , Bexxar (NH Lymphoma), CD34+ selection devices, erythropoietic agents, IL-3 & related lymphokines, monoclonal antibodies and others. His major current consultant activities are in Clinical Oncology, and Cell and Gene therapies relating to:

- clinical regulatory issues in Oncology & Cell therapy
- critical review of FDA packages, INDs/ BLAs/NDAs
- assistance in formulating drug development plans
- assistance in responding to FDA questions and comments
- preparing various regulatory application documents, Position Papers, due diligence reviews, etcetera