



Joseph C. Fratantoni, MD
Senior Clinical Consultant

Joseph C. Fratantoni, MD, has joined Biologics Consulting Group, Inc., as a Senior Clinical Consultant. Dr. Fratantoni, a clinical and research hematologist by training, brings over 30 years of experience in biologics research, development and regulation, with 18 of those years at the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA).

Most recently, he was Vice President, Medical Affairs and Clinical Development, for MaxCyte, Inc, in Gaithersburg, MD. While there, he managed the clinical and regulatory aspects of development of a cell-loading technology for use with clinical cell and gene therapy. He contributed to research, managed collaborative clinical studies with academic centers developed regulatory strategies and made regulatory submissions. He had extensive experience in presenting and explaining the company's product and data to various groups of investors. Prior to MaxCyte, from 1996 to 1999, he was Vice President at the consulting group, C L McIntosh & Associates where he assisted members of industry with regulatory strategy and interaction with FDA dealing with a range of biologic products.

Dr Fratantoni went to CBER/FDA in 1978 as Chief of the Laboratory of Cellular Hematology and remained at CBER until 1996. From 1992, he was Director of the Division of Hematology. His areas of research and regulatory responsibility included:

- Platelets for transfusion, where he completely revised and simplified CBER's regulatory approach;
- Development of a regulatory approach for cell separators, which enabled approval of products collected by apheresis;
- Blood substitutes, a highly complex and contentious area where he worked with other agencies and with industry to set criteria for efficacy and safety;
- Inactivation of pathogens in plasma and cellular products, which included developing realistic criteria for approval;
- Clinical review of tissue plasminogen activator, the first "blockbuster" recombinant product, which required identification of an acceptable clinical endpoint.
- Chairmanship of reviews of the erythropoietins, including identification of important safety issues and management of complex orphan product issues.
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Prior to his time at FDA, Dr Fratantoni had several positions at NIH. He was a Research Associate in the laboratory of Dr. Elizabeth Neufeld and contributed to her early studies on mucopolysaccharide storage diseases, and was then a Staff Hematologist and the NIH Clinical Center. From 1974 to 1978, he was a Branch Chief at the NHLBI Blood Division where he initiated and monitored clinical trials on prevention of pulmonary embolism in surgery and on the etiology and course of Factor VIII inhibitors in hemophilia.

Dr Fratantoni has been clinically active throughout his career and holds the position of Clinical Professor of Medicine at the Uniformed Services University. He earned an M.D. from Cornell University Medical College, an A.M. in chemistry from Harvard University and a B.S. in chemistry from Fordham College.

As a Senior Clinical Consultant with Biologics Consulting Group, Inc., Dr. Fratantoni will utilize his clinical, research and regulatory experience in development of drugs and biologics to assist clients by:

- Providing advice on regulatory and development strategies of blood products, blood-related biopharmaceuticals and recombinant-based products.
- Assisting clients in planning and executing IND applications, from selection of product definition and choice of indications, through protocol design and production, to meetings with FDA and submission of the application.
- Helping clients in responding to FDA questions and comments that are received at meetings or in written evaluations of submissions
- Providing assistance in creation of the whole range of FDA submissions and offering critical review of drafts of FDA packages, including INDs/ BLAs/NDAs
- Working with clients to prepare for presentations to investors, including venture capital groups, investment bankers and private investment groups.