Basic Concepts of Clinical Design Part II

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Dr. Gleason, co-founder of Foresight Regulatory Strategies Inc., has greater than 40 years' experience in basic research and management of clinical trials for medical devices. He has extensive experience in design control, product development requirements and regulatory submissions for both the U.S. and international markets.

Previously, Dr. Gleason was Vice President, Quality Assurance and Regulatory Affairs with global regulatory responsibility for rigid gas permeable contact lens materials and care products for Polymer Technology (affiliate of Bausch & Lomb) and soft lens material registrations for Bausch & Lomb Contact Lens Division, Rochester, NY. As Vice President, Quality Assurance and Regulatory Affairs, Dr. Gleason had oversight responsibility for successful submissions of IDE's, PMA's, 510(k)'s, PMA supplements, ISO 9001/46001 certification (CE mark) and international product registrations in over 60 countries. He has participated in both ANSI and ISO committees for the development of medical device standards.