

Eugene B. Johnston, CQE, CQA
Head, North Carolina Office

Effective July 1, 2007 **Eugene B. Johnston**, will join the Biologics Consulting Group, Inc. (BCG) as the Head, North Carolina Office.

Mr. Johnston has over 30 years of experience in FDA-regulated industries in Quality Assurance, Quality Control and validation. He was most recently the Vice President, Quality Assurance and Regulatory Affairs at Biolex, a biopharmaceutical company involved in the development and production of therapeutic proteins using the Lemna Expression System (LEX™) which is based on the aquatic plant, Lemna. Mr. Johnston was responsible for establishing the Quality Assurance, Quality Control and Regulatory Affairs functions and Biolex and established the Quality Systems programs for preclinical and clinical manufacturing operations. In his role at Biolex, Mr. Johnston worked with cross-functional teams to establish GMP manufacturing capability for Biolex' plant based protein manufacturing platform to supply the needs of several Phase 1 and Phase 2 Clinical trails. He was also responsible for the regulatory operations which provided the support for the filing of several clinical trail applications. Mr. Johnston joined Biolex from Xanthon where he served as Vice President of Quality Systems.

Mr. Johnston was head of quality at Biogen's Research Triangle Park manufacturing facility where he was responsible for overseeing all Quality Assurance and Quality Control activities for the start-up and licensing of the Avonex® manufacturing facility. In his position at Biogen, Mr. Johnston established and managed the Quality Assurance and Quality Control functions, supported plant start-up and validation activities and led the PAI preparation efforts which resulted in FDA and EMEA approval within 33 months from the beginning construction. Prior to Biogen, Mr. Johnston was Director, Quality Assurance for Pharmacia's Parenteral Products operations where he was responsible for Quality Control and Quality Assurance for Pharmacia's operation for the manufacture of commercial and clinical LVP and SVP products. His background also includes managerial positions with Becton Dickinson. Mr. Johnston received his B.S. in Biology for the University of Dayton and is an ASQ Certified Quality Engineer and Certified Quality Auditor.

At Biologics Consulting Group, Gene will use his experience and knowledge to assist clients in:

- Development of Quality Systems and Quality Management Programs
- Investigations
- Problem solving
- Validation Master Plans
- Validation program development
- Facility start-up planning and design review
- PAI preparation
- GMP and due diligence audits
- Pre-IND Meeting Preparation
- IND support and review
- CMC development for preclinical and clinical stage companies