



**John R. Godshalk, MSE, MBA**  
Senior Consultant

John R. Godshalk, MSE, MBA joined the Biologics Consulting Group, LLC, as a Senior Consultant in December 2005.

John served as a Senior Review Biochemical Engineer and Lead cGMP inspector in the Division of Manufacturing and Product Quality at the Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA) for 3½ years. Prior to joining FDA he worked as a management consultant after obtaining his MBA.

During his tenure at DMPQ, John gained experience with products that include drugs, drug/device combination products, viral and bacterial vaccines, recombinant therapeutic and fractionation products, *in vitro* diagnostic test kits, and 510K medical devices. His inspection experience includes leading inspections of active pharmaceutical ingredient manufacturers, aseptic filling and finishing facilities, and contract manufacturers. He has performed numerous pre-approval and pre-licensing inspections for biological and biotechnology products. In addition, he has evaluated industry responses both for technical and regulatory merit during FDA regulatory compliance actions, and has assessed these responses and offered alternative solutions to resolve technical issues and regulatory concerns.

John gained extensive experience in evaluating pharmaceutical product facility design, assessment of validation approaches, and evaluation/development of regulatory strategy through both review work and representing CBER at numerous Type C meetings (i.e., facility, validation, and regulatory strategy related) with industry. John has provided advice to industry on regulatory strategies, best practices, and development of streamlined and leveraged validation approaches that meet FDA licensing requirements.

John has developed and given training programs for the FDA and regulated industry on pharmaceutical water, processing and instrumentation, lyophilization, cleaning methods and validation, and facilities for gene therapy. He contributed to formulation of FDA policy as a member of the committee writing the Guidance Document for the *Facilities and Controls for Cellular and Gene Therapy Product Manufacturing Operations*.

John has served as chair in the review of the Chemistry Manufacturing and Controls (CMC) sections of Biologics License Applications and Supplements for both novel and licensed biological products at CBER. He has trained CBER staff on the scientific and regulatory review and evaluation of these applications and supplements.

Prior to joining FDA, John used his business experience and MBA as a consultant in the areas of business planning, marketing, information technology and strategic planning, financial modeling and analysis, budgeting, business process engineering, project management, and management consulting.

At the Biologics Consulting Group, John will utilize his depth of experience in cGMP, regulatory affairs and management consulting to assist clients in the following areas:

- cGMP evaluation of pharmaceutical facilities, processes, and support infrastructure
- Evaluation of IND manufacturing facilities for compliance with appropriate requirements
- Pre-submission review and support
- Regulatory strategy development
- Evaluation of API production, sterilization, equipment cleaning, personnel monitoring, aseptic processing, lyophilization, quality systems, and finishing operations
- Evaluation, development and assistance with Type C (facility) meeting information for the FDA
- Third party audits of suppliers and contract manufacturing facilities
- Evaluation and development of Contract Manufacturing Agreements
- Internal training programs on cGMP issues
- Business and management consulting in the areas of: business and strategic planning, strategic marketing, financial modeling and analysis, IT planning/analysis, business process engineering, and project management

John received his B.S. in chemical engineering from N.C. State University, his M.S.E. in biochemical engineering from Johns Hopkins University, and his M.B.A. in marketing and finance from the University of Maryland.