

**Keith H. Wells, Ph.D.**  
Head, Massachusetts Office



Keith H. Wells, Ph.D. joined Biologics Consulting Group, LLC (BCG) as Senior Consultant, Process Development and Manufacturing in October of 2000 and became Head of the Massachusetts Office in November of 2004. Dr. Wells is a Virologist (Ph.D., State University of New York Health Science Center at Syracuse) who brings to the firm over ten years of experience in the biopharmaceutical industry, principally in the areas of process development, process validation and manufacturing.

Most recently, as Senior Director of Vaccine manufacturing and Process Development for OraVax, Incorporated, he was responsible for directing all aspects of the process development and manufacturing of the entire company product portfolio including a family of novel live virus vaccines, recombinant vaccines, a bacterial toxoid and an immune globulin product. In addition, Dr. Wells authored the Chemistry, Manufacturing and Control section for two of the company's recent regulatory submissions and served as Project Manager for one of the company's live virus vaccine products.

Prior to his most recent experience, Dr. Wells was the Director of Vaccine Production and Product Development for another vaccine manufacturer. In that capacity he was responsible for directing all aspects of the process development and manufacturing of vaccine products in a multiuse, biological safety level 3 (BL3) facility. There he led a team of professional and technical staff with diverse backgrounds engaged in the production of IND vaccine products covering a wide range of infectious disease agents including viruses, bacteria and rickettsia, as well as bacterial toxins.

Dr. Wells also held positions of increasing responsibility in several areas of vaccine process development and manufacturing at a major pharmaceutical company. There he was responsible for troubleshooting and improving existing vaccine manufacturing processes, as well as developing, validating and transferring new processes to manufacturing. He was instrumental in the development and transfer of the manufacturing processes for two of the company's most



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recent vaccine products and was a key contributor to the company's successful efforts to license those products.

Dr. Wells is a member of the editorial board for Biotechnology Letters and has served on several National Institutes of Health contracts awards committees.

Dr. Wells' technical expertise in process development, validation and manufacturing, along with his extensive experience with managing complex scientific programs and business relationships such as joint ventures and contract manufacturing agreements from both a contractor and sponsor perspective, will significantly contribute to the expertise at BCG.