

## **Holly Scott**

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### **Senior Consultant**

Holly McNair Scott, a former FDA Field Investigator, will be joining Biologics Consulting Group, Inc., as a Senior Consultant for Biologics and Dietary Supplement inspections, investigations, and audits, on September 1, 2009.

Holly comes to BCG with over 18 years of multi-office experience with the Food and Drug Administration, including 4 years as a Consumer Safety Officer with the Center for Biologics Evaluation and Research, and 14 years as a Field Investigator with the Office of Regulatory Affairs Florida District Office (Miami and Orlando), specializing in the inspections of Blood, Plasma, and Human Tissue establishments, and Dietary Supplement Manufacturers. In addition, Holly brings many years of experience as a Clinical Investigator, IRB, Sponsor/Investigator, and Drug GMP Inspector. In 2002, Holly was awarded her FDA Level II Certification in Blood Banks and Plasma Centers, recognizing her expertise in the area of Biologics Inspections.

In addition, Holly was the Dietary Supplement Monitor for the Florida District, overseeing the inspections of Dietary Supplement Manufacturers and distributors. Holly conducted numerous investigations and inspections of these firms which resulted in FDA regulatory actions such as warning letters, seizures and injunctions. She had oversight for procedure development in this area, and authored the Districts Internet Surveillance/Undercover Buy Program which the district continues to utilize. Holly's expertise in this area includes enforcement of the new FDA Dietary Supplement Regulations.

Holly routinely acted as an acting Supervisory Investigator for the Florida District, overseeing the completion of workplan assignments, and liaising with multiple FDA Centers in order to accomplish Agency goals. Holly's expertise in the area of investigative interviewing, earned her higher profile FDA cases such as investigations into the importation of unlicensed flu vaccines, and fraudulently labeled human tissue, whilst working with FDA's Office of Criminal Investigations to generate enforcement action.

Holly has received numerous recognition awards for her work at FDA, including investigations into contaminated Human Tissue, her exemplary performance in the investigation of potentially deadly contaminated mouthwash, her team effort in the removal of Botulinum toxin-contaminated canned Chile Sauce from the marketplace, for her initiation and implementation of the Districts Internet Surveillance and Undercover Buy Program, and for her outstanding efforts in evaluation of safety issues related to Gamma Butyrolactone products, and support of those enforcement actions.

She holds a B.A Degree in Biology Education, from the University of Central Florida.

As a Senior Consultant for audits and FDA-style inspections of Human Tissue Operations, Biologics, and Dietary Supplements at The Biologics Consulting Group, Holly will utilize her broad technical and regulatory expertise to assist clients in the following areas:

- Providing in-house training on how to prepare for, and pass an FDA inspection;

- Perform a mock FDA inspection, assessment of current client compliance status, and hold a follow-up discussion of potential problem areas;
- Short and long term regulatory strategy for compliance with FDA regulations, and ongoing, periodic assessment of operations;
- Assisting clients with development of procedures that are compliant with FDA regulations;
- Provide clients with guidance on the preparation of product recall documents;
- Representing clients in interactions with FDA;
- Assisting clients in preparing for FDA regulatory meetings;
- Assisting clients in the review of FDA correspondence;
- Assisting clients with the preparation of FDA-483 and warning letter responses;
- Providing clients with a comprehensive "FDA style" review of validation and testing processes;
- Providing in-house training on FDA Regulatory issues and new policy developments;
- Assist clients with in-house investigations into quality issues;