

**Calley A. Herzog**  
Consultant

Calley A. Herzog joined Biologics Consulting Group, Inc., as a Consultant on February 16, 2009.

Calley comes to BCG with over 8 years experience in various technical engineering roles, including 3 years experience as a Biomedical reviewer at FDA in the Office of Device Evaluation, Division of General, Restorative and Neurological Devices, General Surgery Devices Branch. At FDA, Calley was involved in the review process for 510(k)s, IDEs and as lead reviewer for PMAs. Calley's combination of industry and FDA experience positions her to provide clients with a specialized understanding of regulatory processes and the challenges they may encounter when interacting with the agency.

Calley holds a B.S. in Biomedical and Electrical Engineering from Vanderbilt University.

As a Consultant at Biologics Consulting Group, Inc. Calley will utilize her technical and regulatory expertise to assist clients in the following areas:

- Review, prepare and submit regulatory submissions;
- Technical support for review of bench testing, software documentation, risk analysis and device technical specifications for regulatory submissions;
- Review and prepare quality system documentation;
- Project management services for all types of regulatory projects.