

## Curriculum Vitae

**Calley A. Herzog**  
**cherzog@bcg-usa.com**

Consultant  
Biologics Consulting Group, Inc.  
Westminster, CO

### **EDUCATION**

**B.E.** *Biomedical and Electrical Engineering*, Vanderbilt University, Nashville, TN (2000)

### **EXPERIENCE**

#### **Biologics Consulting Group, Inc., Consultant**

(Feb. 2009 - present)

- Responsible for project management and consulting services for client projects including 510(k)s, PMAs, IDEs, preIDEs, Master Files, RFDs.
- Specializing in overcoming communication barriers with FDA, guiding clients through the process of premarket clearance or approval and preparing, organizing and submitting all required documentation for FDA submissions, registrations and user fees.

#### **M Squared Associates, Regulatory Consultant II**

(Nov. 2007 – Feb. 2009)

- Responsible for project management and consulting services for client projects including 510(k)s, PMAs, IDEs, preIDEs, Master Files, RFDs.
- Acted as independent consultant as well as on a project team with other consultants.
- Specialized in overcoming communication barriers with FDA and guiding clients through the process of premarket clearance or approval.
- **Special Training** – Passed Lead Auditor Training Course for ISO 13485. Current status is auditor in training.

#### **Seagate Technology, LLC, Quality and Reliability Engineer / DMT Lead**

Longmont, CO (2001-2003, 2006-2007)

#### **Validation Engineering/Product Assurance**

- Responsible for coordinating and managing test activity to insure the quality and reliability of hard drives.
- Developed and managed test plans for reliability and design verification testing for new products.
- Prepared accurate and informative status updates to upper management.
- Responsible for coordinating failure analysis and corrective action implementation on a daily basis.
- Acted as Design Maturity Test Engineer for Seagate's best selling product.



Calley A. Herzog

### **Project Management**

- Responsible for coordination of subprojects and management of workload and prioritization of seven other DMT engineers to assure timely completion of master projects.
- Act as a representative and contact person for all DMT/Product Assurance issues related to desktop products.

**CDRH, FDA**, Office of Device Evaluation, Division of General, Restorative and Neurological Devices General Surgery Devices Branch, *Biomedical Engineer*  
(2003-2005)

### **Biomedical Engineering**

- Responsible for review of technical data, statistical analysis and device specifications to assure medical device safety and effectiveness prior to market release.
- Reviewed medical device submissions for pre-market notification (510(k)), review of clinical protocol and device design for investigational device exemptions (IDE) and review of safety and effectiveness clinical data and device documentation for pre-market approval applications (PMA).
- Specialized in medical lasers, intense pulsed light systems, electrosurgical devices and bone growth stimulators.
- Provided consulting reviews for peers regarding electrical standards testing and software design documentation.

### **Project Management**

- Acted as Lead reviewer for a PMA team of expert reviewers.
- Participated in working group to update, standardize and publish the documentation requirements for submissions containing software related medical devices in an effort to educate both reviewers and industry. \

### **Special Recognition**

- Received outstanding achievement cash awards on several occasions.
- Volunteered to coordinate the contributions of 75 people and organize fundraising activities for an annual national charity campaign.

### **PROFESSIONAL SOCIETIES**

- RAPS (Regulatory Affairs Professional Society)