



## **Melissa Schneider**

### **OVERVIEW**

As a Compliance Specialist with Compliance Insight, Inc., Melissa has worked with companies regionally and worldwide in the Pharmaceutical, Medical Device, Dietary Supplement, Biotechnology and Food industries in the field of Quality Assurance. Her consulting realm includes FDA and EU regulations. Melissa's strengths are in training, auditing and quality systems.

### **EXPERIENCE**

- ◆ Eight years as global trainer of multiple quality topics in FDA and EU regulated areas.
- ◆ Developed and implemented quality compliance system for new Good Tissue Practice compliant cellular therapy division at an academic research site for processing sterile human use cellular therapy products
- ◆ Assisted in developing and implementing quality systems for research site including sterile injectable pharmaceutical products, sterile combinations products, and sterile medical device products.
- ◆ Assistant Manager of Quality Assurance in a global pharmaceutical company assuring compliance of global supply unit and Medical Device Division
- ◆ Developed and helped implement Quality Systems for a new API plant in China
- ◆ Participant in multiple inspections by Regulatory agencies, including FDA, EU and DEA
- ◆ Responsible for performing Root Cause Analysis and investigation of issues
- ◆ Maintained compliance with US and foreign regulations
- ◆ Reviewed and approved SOPs, Material Specifications, Stability Protocols, Packaging and Labeling, Master Production Records, Batch Records, Validation Reports, Specifications, and Safety Policies
- ◆ Audited raw material suppliers and contract laboratories
- ◆ Coordinated efforts on recalls and provided progress reports to the FDA
- ◆ Conducted departmental meetings to facilitate transfer of newly developed products into mass production
- ◆ Prepared annual reports, adverse drug reaction reports, supplemental applications, and deficiency responses
- ◆ Assisted in validation remediation project, including developing protocols and reviewing quality documentation.
- ◆ Assisted in planning and executing company wide yearly GMP training.
- ◆ Solely responsible for new supplier, raw material evaluations

5850 Boymel Drive, Suite 1 • Fairfield, OH 45014  
Phone: 513-860-3512 • Fax: 513-860-3406  
[www.Compliance-Insight.com](http://www.Compliance-Insight.com)



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**EDUCATION/TRAINING**

Bachelor of Fine Arts, Graphic Design	Bowling Green State University	1990
Quality Auditing	Center For Professional Advancement	1996
Annual Product Reviews	Center For Professional Advancement	1997
GMP Institute Conference	GMP Institute	1998
Beyond the Barr Decision II	University of Rhode Island	1999
Training for GMP	GMP Institute	2000
Take the Mystery out of Your Steam System	Steam Economies	2000
FDA Issues in Biotech Startups	BioStart training	2007
ISGT Cellular Therapies Conference	ISGT	2008
Walking the Line in Academic Research	CCHMC	2009

**PROFESSIONAL AFFILIATIONS**

- ◆ Parenteral Drug Association (PDA)
- ◆ International Society for Pharmaceutical Engineering (ISPE)