

## Richard Love

*Senior Consultant*

### EXPERIENCE:

- **Project Director, Quality and Regulatory, Experien Group - 2006 to 2008**
- **Vice President, Quality Assurance and Regulatory Affairs, CardioMend - 2001 to 2006**
- **Operations Manager, Ramus Medical Technologies, 1997 to 2001**
- **Operations/Administration Manager, Autogenics - 1991 to 1997**

### AREAS OF EXPERTISE:

#### *Devices:*

- Cardiovascular
- Tissue sealant
- Animal tissue-engineered

#### *Disciplines:*

- Quality Management System implementation: ISO 9001, ISO 13485, FDA QSR
- Risk Management: ISO 14971
- Quality Management System and Supplier Auditing and Gap Analyses
- CE Marking strategies
- Design dossier preparation and review
- Sterilization issues
- Global Regulatory Affairs

### TRAINING AND PROFESSIONAL DEVELOPMENT:

- 2007 ISO 9001:2000 Lead Auditor Training, BSI Course, with emphasis on ISO 13485:2003
- 2007 Risk Management, changes per ISO 14971:2007 BSI
- 2008 Risk Analysis Techniques for Medical Devices RAPS
- 2008 What has changed for EO Sterilization?, AAMI, A comparison of the 1994 and 2007 versions of ANSI/AAMI/ISO 11135
- 2008 Changes to the European Medical Devices Directive, Emergo Group, changes made by Directive 2007/47/EC to MDD 93/42/EEC
- 2008 Information for Manufacturers Process CMDCAS, BSI

### EDUCATION:

- B.A. Philosophy, 1988