



## Jane Arnold-Round

*Senior Clinical Consultant*

### EXPERIENCE:

- Sr. Regulatory Consultant, Emergo UK (formerly Mediqol Limited) – 2004 to Present
- Medical Device Product Specialist, BSI Product Services – 2000 to 2004
- Registration Officer, AstraZeneca Pharmaceuticals – 1999 to 2000
- Regulatory Affairs Specialist, Sulzer Vascutek Ltd. – 1994 to 1998
- Design Engineer, Medtronic – 1991 to 1993
- Researcher, Dept. Cardiac Surgery, Glasgow Royal Infirmary – 1990 to 1991

### AREAS of EXPERTISE:

#### *Devices:*

- Cardiovascular
- Tissue sealant
- Animal tissue-engineered

#### *Disciplines:*

- CE Marking strategies
- Design dossier preparation and review
- Biocompatibility and sterilization issues
- Global Regulatory Affairs
- ISO 9001:2000, ISO 13485

### TRAINING:

- ISO 9000 Auditor/Lead Auditor Course – BSI
- MDA Workshop for Notified Bodies – MDA (MHRA)
- Premarket Notification 510(K) Reviewers Training - FDA CDRH
- ISO 9000: 2000 Transition course for BSI Assessors - BSI
- CMDCAS assessor course - Health Canada
- EN ISO 10993: Biological Evaluation of Medical Devices - Medwise International
- MHRA Clinical Data Workshop - MHRA

### EDUCATION:

- B.Eng. Mechanical Engineering - 1989
- MSc – Bioengineering - 1990

### AFFILIATIONS

- Active member of BSI CH 149/01 Medical Devices utilizing tissues – 2004 to present