



## Stuart R. Goldman

*Senior Consultant, Regulatory Affairs & Quality Assurance*

### EXPERIENCE:

- Staff Quality Assurance Engineer & Supervisor, CarboMedics, Inc. (A Sorin Group Company)

### AREAS OF EXPERTISE:

Including, but not limited to

#### *Products:*

- Dental
- Orthopedic
- Electrosurgical
- Radiology
- OB/GYN
- General & Plastic Surgery
- General Hospital & Personal Use

#### *Disciplines:*

- Quality Management Systems (ISO 13485/9001 & 21 CFR Part 820)
- Quality Management System Audits
- MDD 93/42/EEC
- Medical Device Classification & Regulatory Requirements (US & EU)
- USA FDA Submissions (513g, 510k, & Pre-IDE)
- FDA Warning Letter Responses
- EU Submissions (Technical Files & Design Dossiers)
- Materials Characterization & Device Testing
- High-Risk Devices (e.g., dental and orthopedic implants and cardiovascular, etc.)

### EDUCATION:

- BS, Materials Engineering, North Carolina State University, Raleigh, NC USA

### TRAINING AND CERTIFICATIONS:

- American Society for Quality – Certified Quality Manager, Auditor & Biomedical Auditor
- RABQSA International – Certified Quality Management System Auditor